User Manual

EDANUSA

elite V8

Patient Monitor

Version 1.0

CE 0123

About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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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.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

Table of Contents

Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use

This monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters including 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.) and anesthetic gas (AG)of adults, pediatrics and neonates in hospital environments.

The arrhythmia detection and ST-segment analysis are not intended for neonatal patients.

This monitor is suitable for use in hospital environments including but not limited to OR, PACU, ICU and neonate intensive care room.

1.2 Safety Guidance

WARNING

1 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.

2 Medical technical equipment such as this monitor/monitoring system must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.

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

4 EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

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.

6 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.

WARNING

7 Route all cables away from patient's throat to avoid possible strangulation.

8 Devices connecting with monitor should be equipotential.

9 If the earth protection system is not stable, use the batteries for power supply.

10 Two batteries must be used when the monitor uses internal power supply.

11 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 60601-1-1. 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/EN60601-1-1. If in doubt, consult our technical service department or your local distributor.

12 The monitor is equipped with a wireless AP via network interface 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.

13 Only use patient cable and other accessories supplied by EDAN. Or else, the performance and electric shock protection can not be guaranteed, and the patient may be injured. Prior to use, check if the casing of a disposable or sterilized accessory is intact. Do not use it if its casing is damaged.

14 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 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 Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices. Be sure to perform the electromagnetic compatibility test, as described in the Wireless LAN System Installation, before installation and any time new medical equipment is added to the Wireless LAN coverage area.

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

17 If multiple instruments are connected to a patient, the sum of the leakage currents must not exceed the limits; or it may result in shock hazard.

18 During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off, and only the patient information and alarm settings can be saved. After reconnecting the power supply, the user should turn on the monitor for monitoring.

WARNING

19 Keep away from fire immediately when leakage or foul odor is detected.

20 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. Inappropriate disposals of waste may contaminate the environment. 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.

21 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.

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

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

24 This equipment is not intended for family usage.

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, 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 could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

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

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

8 Avoid liquid splash on the device. The temperature must be kept between 5°C and 40°C while working. And it should be kept between -20°C and 55°C during transportation and storage.

CAUTION

9 To ensure patient safety, use only parts and accessories manufactured or recommended by EDAN.

10 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.

11 Protect the device against mechanical damage resulting from gravitation, collision, powerful vibration and so on.

12 A drafty environment for monitor installation is required, and do not block up the ventilation grille at the back of the device.

13 Federal law restricts this device to sale by or on the order of a physician.

NOTE:

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

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

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

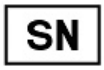
4 This monitor is not a device for treatment purposes.

5 The pictures and interfaces in this manual are for reference only.

6 Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.

1.3 Explanation of Symbols on the Monitor

	This symbol indicates that the equipment is IEC/EN60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.
	This symbol indicates that the instrument is IEC/EN 60601-1 Type BF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.
	Symbol for “Caution”

	Equipotential grounding
	Consult Instructions For Use
	Non-ionizing electromagnetic radiation
	Alternating Current
	Battery indicator
	Power Supply switch
	Serial number
	Network port
	USB (Universal Serial Bus) Connection
	Audio alarm is off
	NIBP measurement
	Trend graph
	Freeze
	Record

	Menu
	VGA output, External Monitor
	RS-232 port
	Nurse call port
	SD Card port
	Signal output port
	Signal output
	PAM connector
CE 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
EC REP	Authorised representative in the European community
	Date of manufacture
	Manufacturer
P/N	Part Number

	Recycle
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
	Locked position
	Gas inlet
	Gas outlet (evac)
	ISA equipped to measure CO_2 only.
	ISA equipped to measure multiple gases.

Chapter 2 Installation

NOTE:

1 The monitor settings must be specified by the authorized hospital personnel.

2 To ensure that the monitor works properly, please read the user manual and follow the steps before using the monitor.

2.1 Initial Inspection

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

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

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

2.2 Mounting the Monitor

Place the monitor on a flat, level surface, hang it on the bed rail, or mount it on a wall. For detailed information about how to install the wall mount for the monitor, please refer to the *Wall Mounting Bracket Assembly Instruction*.

WARNING

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

2 The safe load of the top splint is 20kg. Overweight may cause the device to rupture and even fall over.

2.3 Connecting the Power Cable

Before connecting the power cable, check if the fuse is well installed inside the connector. (Refer to the illustration *Rear View* in the section *3.1.1* and locate “AC power input”.) The specification of the fuse is T3.15AH250V.

Connection procedure of the AC power line is listed below:

1 Make sure the AC power supply complies with the following specifications: 100V-240V~, 50Hz/60Hz, 1.8A~0.75A.

2 Apply the power line provided with the monitor. Plug the power line to inlet interface of the monitor. Connect the other end of the power line to a grounded 3-phase power output.

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.

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 The interval between double pressing of POWER switch should be longer than 1 minute.

4 After continuous 360-hour runtime, 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 21 Recording* for details.

2.6 Setting Date and Time

To set the date and time:

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

NOTE:

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

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 of the main board.

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 Reference Card - for quick reminders during use.

Chapter 3 Basic Operation

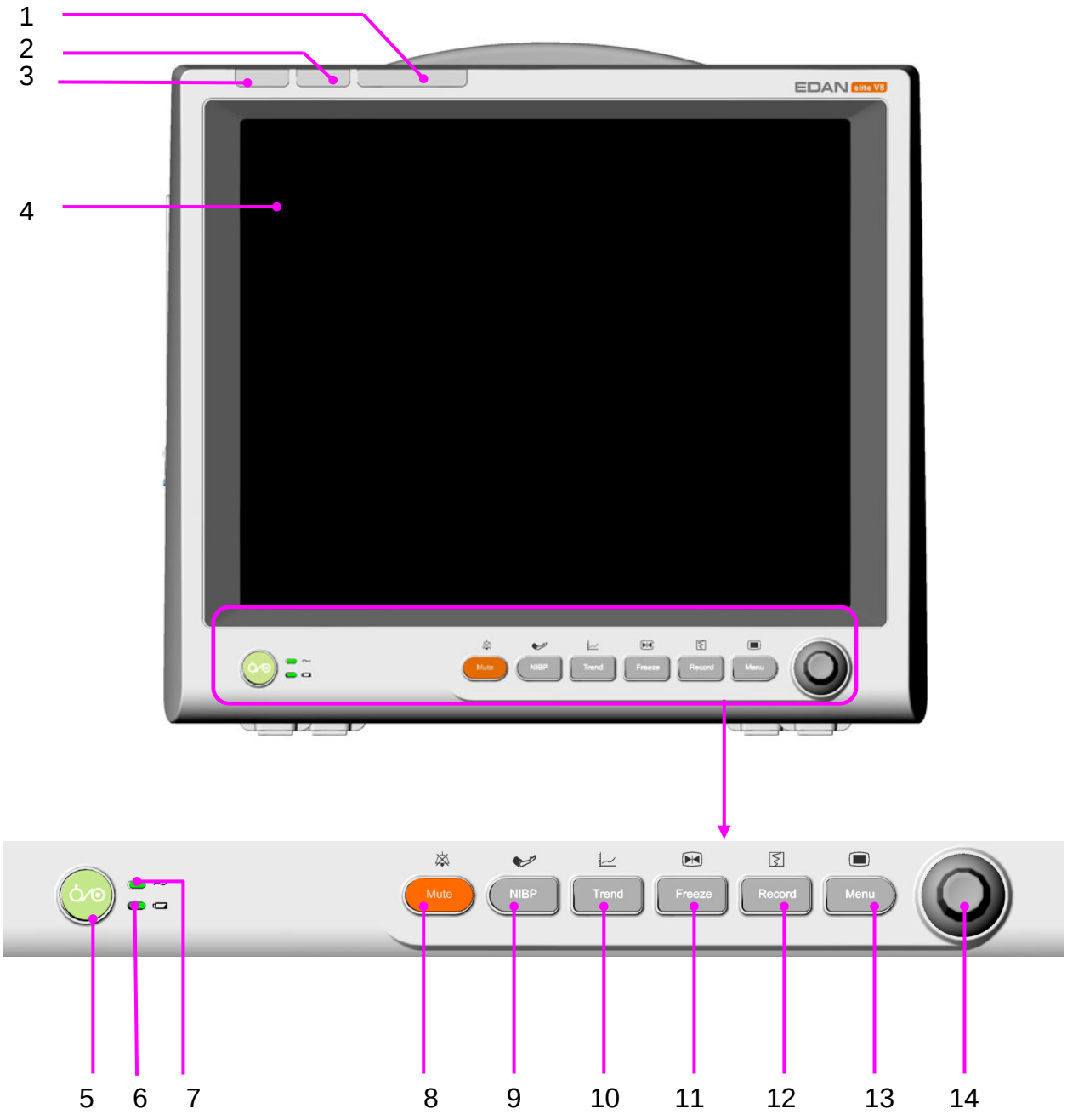
This user manual is based on the maximum configuration and therefore your monitor may not have all of the functions and options described in the manual. Also, illustrations in this manual serve as examples only and do not necessarily reflect the setup on your monitor. The content displayed on you monitor depends on the way it has been tailored for your hospital.

3.1 Overview

The elite V8 patient monitor offers a monitoring solution optimized for the surgical, cardiac, medical and intensive care environments. Combining patient surveillance and data management, it allows multi-measurement monitoring by linking separate modules with “plug-and-play” convenience. The monitor stores data in trend and event. Users can see tabular as well as graphical trends and document them on a recorder.

3.1.1 Main Unit

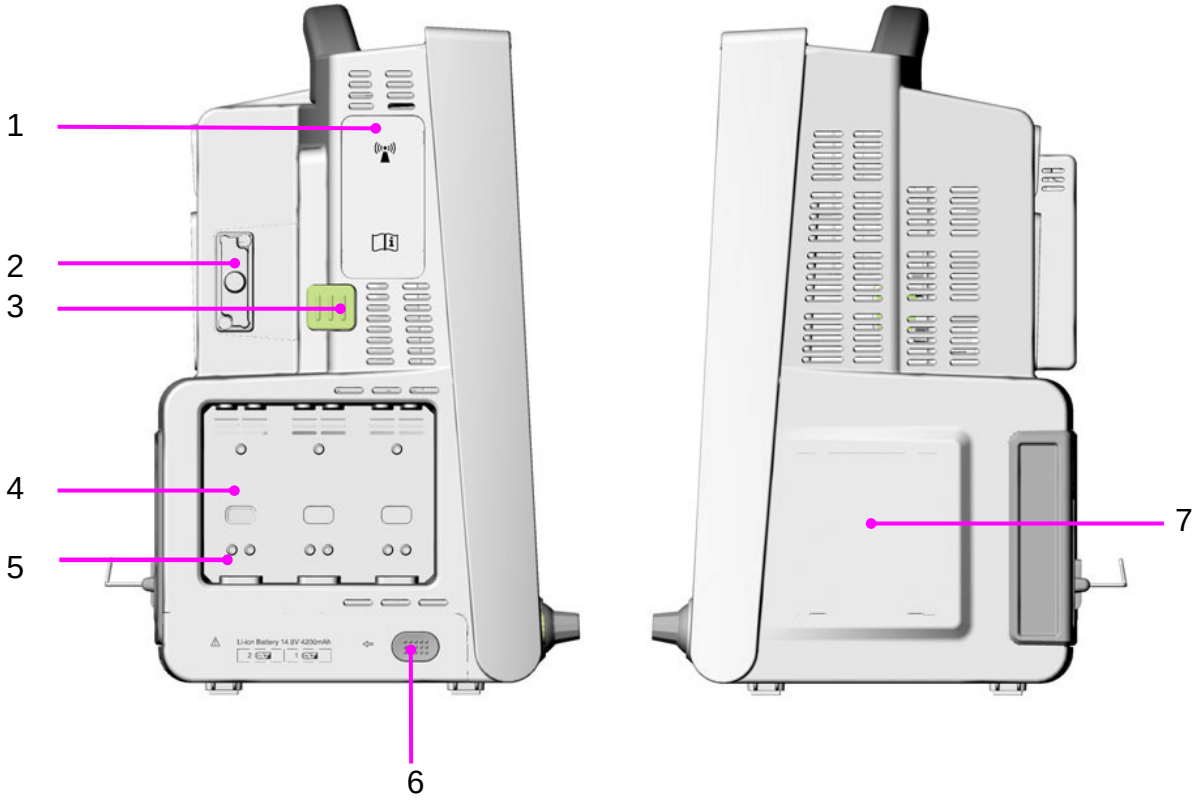
Front View



1	Alarm mute indicator	When the audible alarm is mute, the indicator is in red.
2	Physiological alarm indicator	When a physiological alarm occurs, the indicator lights on or flashes with different frequencies and colors reflecting the alarm level.

3	Technical alarm indicator	When a technical alarm occurs, the indicator lights on or flashes with different frequencies and colors reflecting the alarm level.
4	Display	17-inch TFT screen with resolution of 1280×1024
5	Power supply switch	Press it to turn the monitor on when the monitor is connected to the AC power supply, or press the key to turn the monitor off when the monitor is on.
6	Battery indicator	Refer to the section *Battery Indicator* for details.
7	AC power indicator	
8	Mute	Press it to suspend the output of all audible alarm signals.
9	Start/stop NIBP measurement	Press it to start or stop blood pressure measurement.
10	Trend	Press it to review the trend table.
11	Freeze/unfreeze	Press it to freeze or unfreeze waveforms.
12	Start/stop recording	Press it to start or stop recording.
13	Menu	If no menu is displayed on the screen, pressing it will enter the main menu. If there is a menu displayed on the screen, pressing it will close that menu.
14	Trim Knob	Users can rotate the trim knob clockwise or counter-clockwise to highlight the desired item, and press it to select the item.

Side View

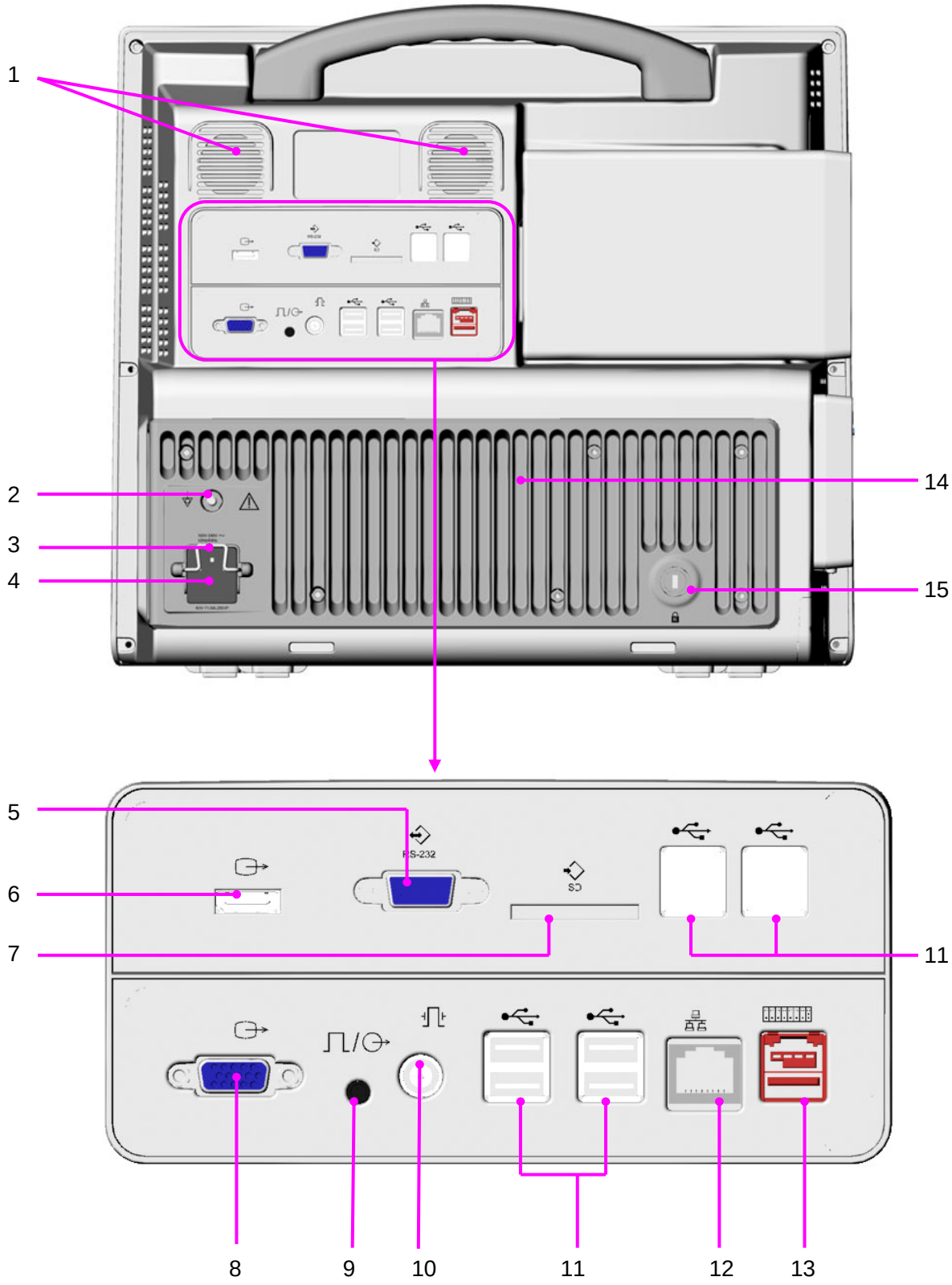


1	Compartment for optional device, supporting WIFI module and hard disk
2	XM module slot
3	XM module snap-fix
4	Plug-in module slots
5	Contact
6	Battery compartment latch
7	Compartment for recorder

NOTE:

To avoid bad contact caused by dust accumulation, clean the contacts regularly by wiping them with a cotton swab moistened with alcohol.

Rear View



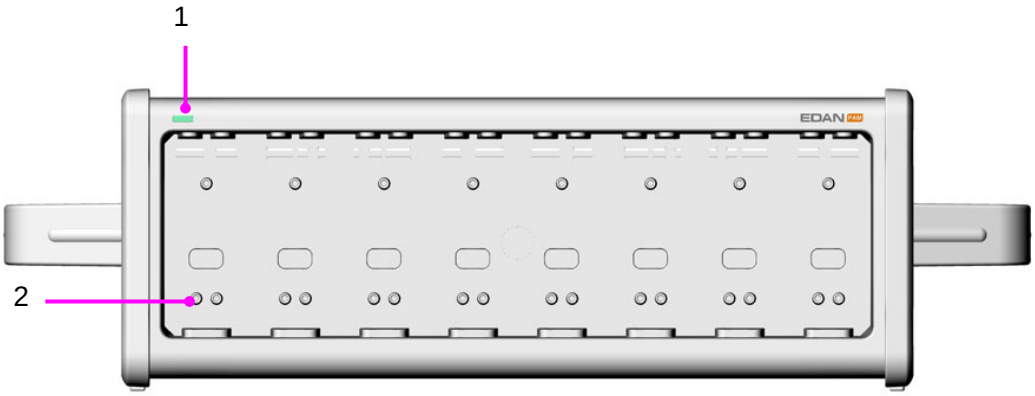
1	Speaker	For alarm tones, pulse tones and so forth.
2	Equipotential grounding terminal	If the monitor is used together with other devices, connect this terminal to eliminate potential ground differences between devices.
3	Power cable safety latch	Used to prevent the power cable from detaching.
4	AC power input	
5	RS232 interface	Connect it to communicate with other devices.
6	Extended video interface	It connects a secondary display, which extends the display capability of your monitor.
7	SD card slot	Used to mount an SD memory card.
8	VGA output	It enables the VGA video output. **NOTE:** If incomplete display occurs on the screen of an external display connecting to the monitor via the VGA output, adjust it with the button for automatic screen adapting of the external display, or refer to its user manual.
9	Nurse call port/analog output	If users select it as nurse call, 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. If users select it as analog output, the monitor outputs the waveform through the port. **NOTE:** The function of nurse call/ analog output is only available when the XM module is inserted in the monitor.

10	Defibrillator synchronization	The monitor outputs the defibrillator synchronization signal through the port. **NOTE:** The function of defibrillator synchronization is only available when the XM module is inserted in the monitor.
11	USB interfaces	They support USB1.0/2.0 output.
12	Network interface	It connects the monitor to the central monitoring system via standard network cable.
13	PAM connector	It connects the Parameter Amplifier Mainframe to the monitor.
14	Heat sink	
15	Anti-thief lock	

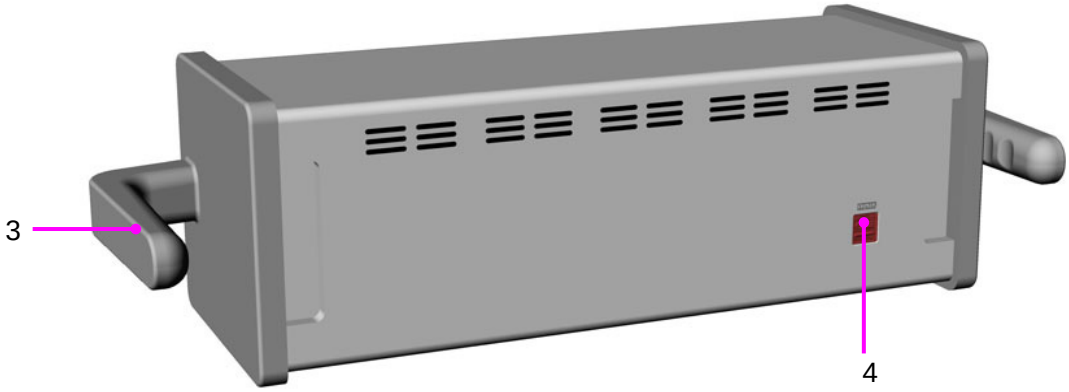
3.1.2 Parameter Amplifier Mainframe

Users can connect one Parameter Amplifier Mainframe (PAM) to the monitor via a particular link cable. The PAM provides 8 slots for mounting measurement modules. The number of modules mounted in the PAM varies with the number of slots needed by different modules.

Front View



Rear View



1 Indicator

- On: when the PAM works normally;
- Off: when the PAM is disconnected from the monitor, power supply malfunction occurs or the monitor is powered off.

2 Contact

3 Handle

4 PAM connector

NOTE:

To avoid bad contact caused by dust accumulation, clean the contacts regularly by wiping them with a cotton swab moistened with alcohol.

3.1.3 Measurement Modules

Users can use a maximum of 8 measurement modules with the PAM and additional 3 modules in the integrated module slots in the monitor. The number of modules mounted in the monitor varies with the number of slots needed by different modules.

The connector socket on the front of each module is of the same color as the corresponding connector plug on the transducer or patient cable.

Modules supported by this monitor are:

1 V-AG module (sidestream): Anesthetic gas module for sidestream.

2 V-CO_2 module (mainstream): Carbon dioxide module for mainstream.

3 V-AG module (mainstream): Anesthetic gas module for mainstream.

4 V-C.O. module: Cardiac output module.

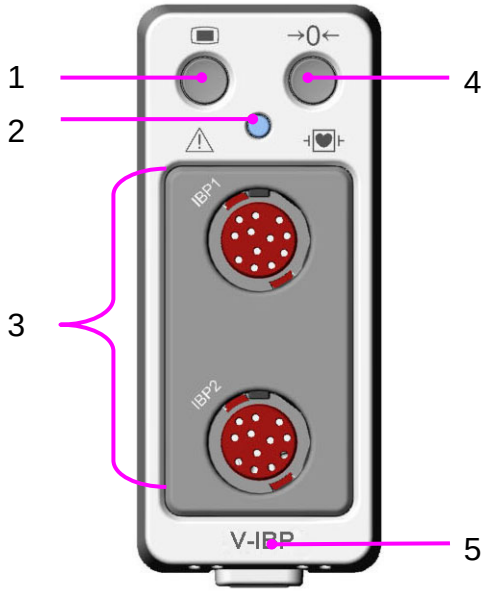
5 V-IBP module: Invasive blood pressure module.

6 V-CO_2 module (sidestream): Carbon dioxide module for sidestream.

7 V-SpO_2 module: Functional arterial oxygen saturation module.

Example Module

The structure of each plug-in module is similar: the module name is located at the bottom part; hard keys are in the upper part; measurement connectors are in the lower part. Take the V-IBP module for example:



1 Setup key: press to enter setup menu of the measurement module.

2 Indicator

- On: when the module works normally.
- Flash: when the module is being initialized or malfunctioning.
- Off: when the module is unconnected.

3 Connectors for transducer/sensor

4 Second module-specific key, such as the zero key for IBP.

5 Module name.

Plugging/ Unplugging Modules

Users can plug and unplug modules during monitoring.

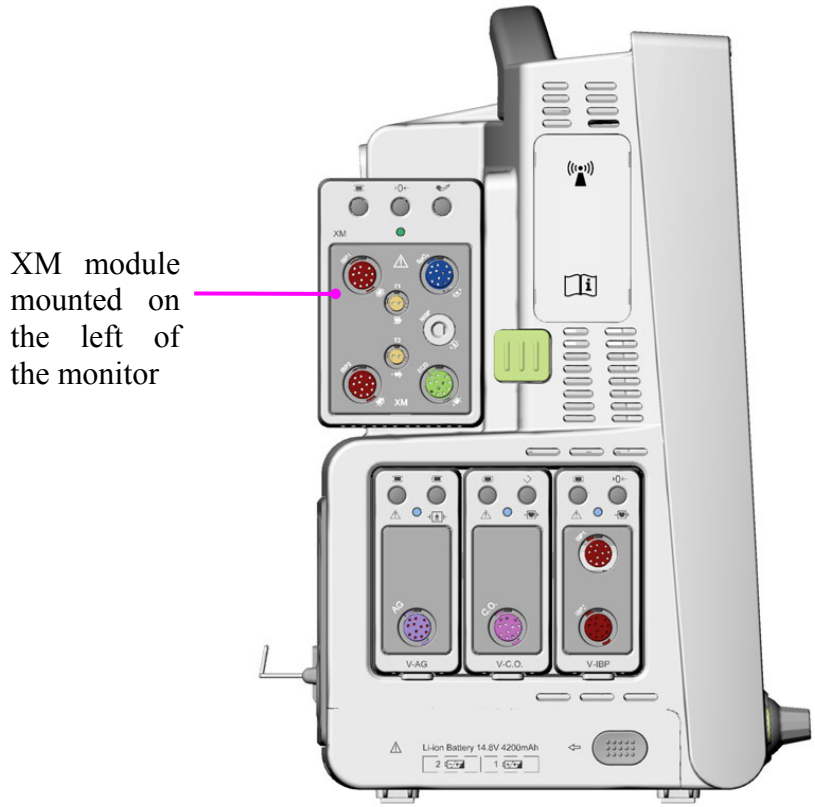
- To plug a module, insert the module until the lever on the module clicks into place.
- To unplug a module, press the lever upwards and pull the module out.

NOTE:

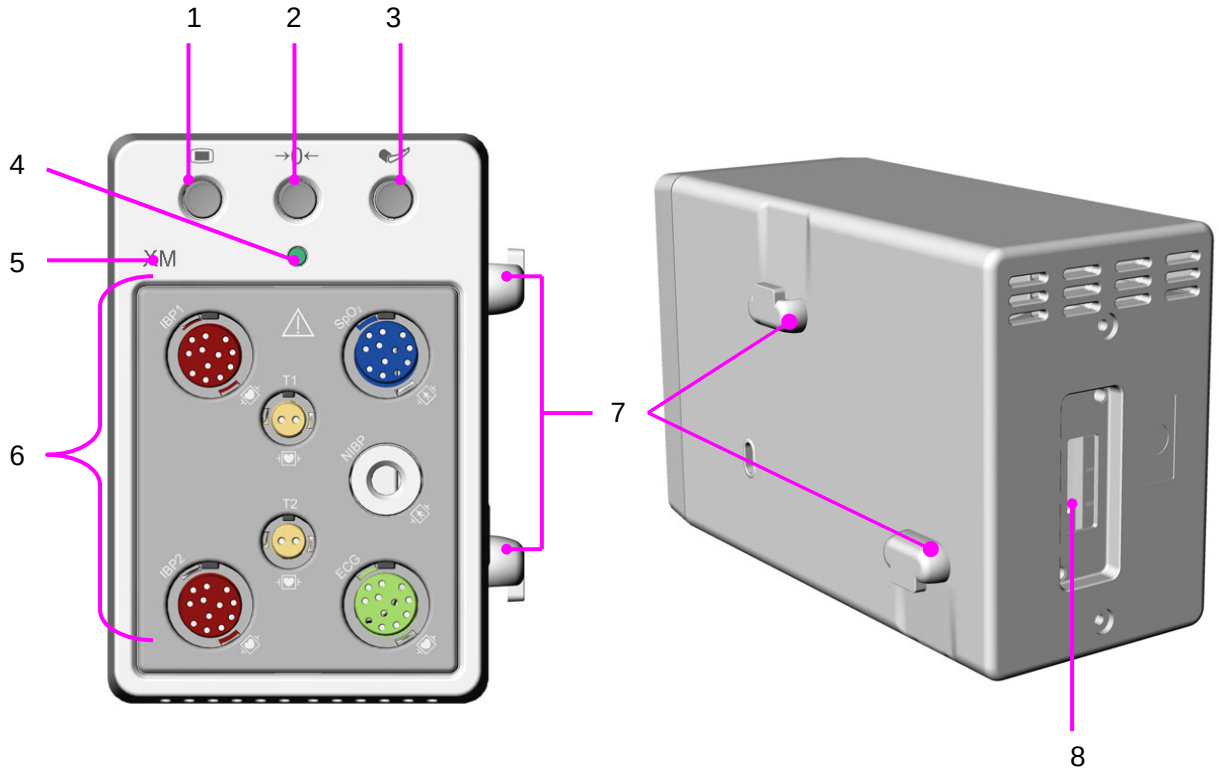
Make sure the indicator on the module is on after the module is plugged in the monitor. Otherwise, re-plug the module until the indicator is on.

3.1.4 XM Module

The XM module is integrated with functions of multiple measurement modules of ECG, RESP, SpO_2, TEMP, IBP and NIBP. Plug the XM module in the XM module slot on the left side of the monitor, and it is connected with the monitor as shown below:



Overview of XM Module



1 Setup key: press to enter the XM module setup menu.

2 Zero key: press to enter the zero IBP menu.

3 NIBP start/ stop key: press to start or stop NIBP measurement.

4 Indicator

- On: when the module works normally.
- Flash: when the module is being initialized or malfunctioning.
- Off: when the module is unconnected.

5 Module name

6 Connectors for transducer/sensor

7 Snap-fix

8 Connector to the monitor

Installing the XM Module

Mate the snap-fixes on the right side of the module with the slots on the rear of the monitor, and push the module forwards until the lever clicks in place, then fasten the module with the snap-fix on the left side of the monitor.

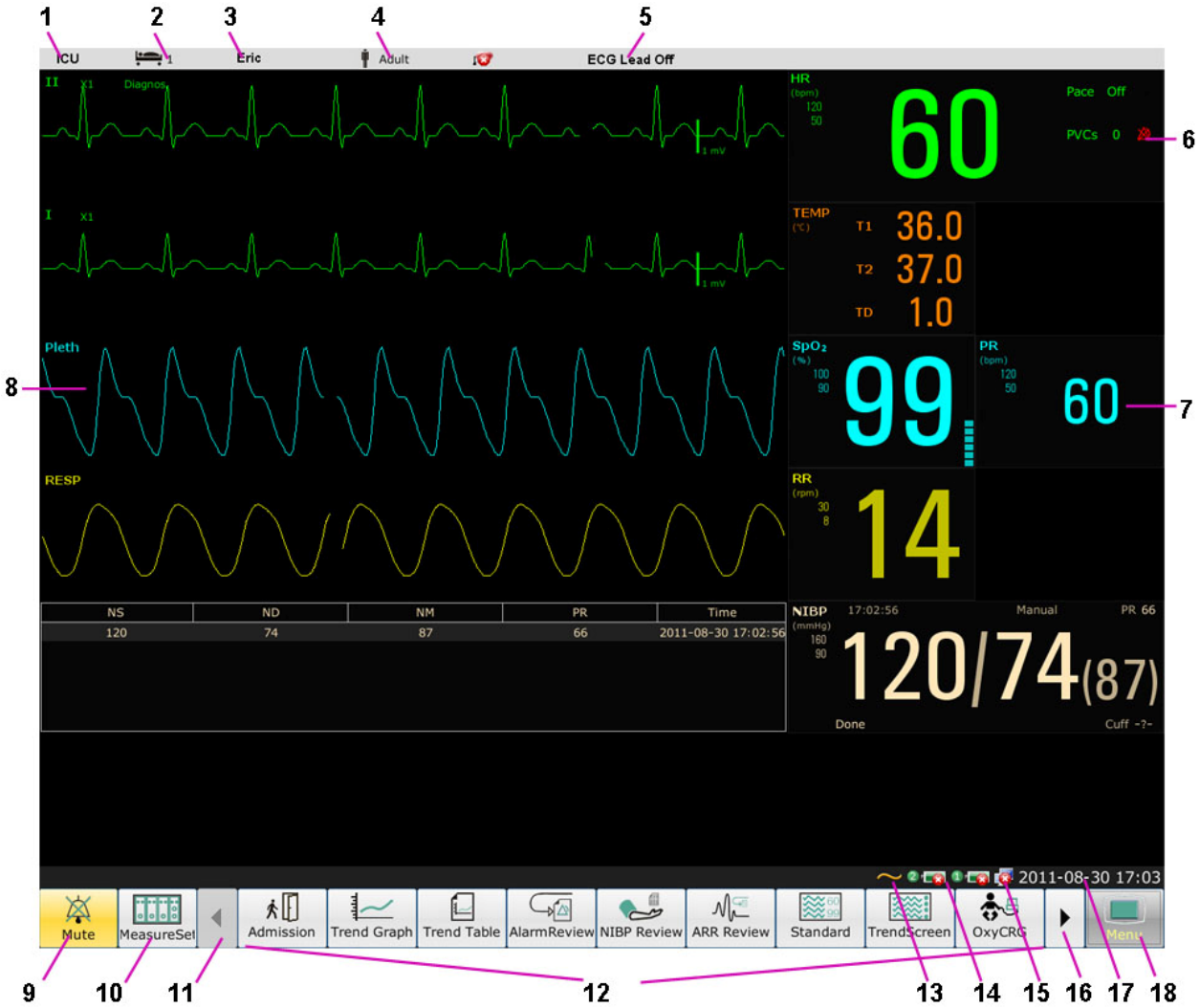
3.1.5 Configuration

The configuration of elite V8 is listed below:

Size (L×W×H)	Figure	Function Configuration
425 mm (L) × 245 mm (W) × 382 mm (H)	Square	ECG (3-lead, 5-lead, 12-lead), RESP, SpO_2, PR, NIBP, TEMP, IBP, CO_2, C.O., AG

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 numerics, 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.



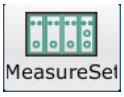
1	Department	10	Measurement setup key
2	Bed number	11	Scroll left to display more shortcut keys
3	Patient name	12	Shortcut key area
4	Patient type	13	Symbol for AC power supply
5	Alarm status area	14	Symbol for battery status
6	Symbol for alarm off	15	Symbol for networking
7	Measurement value	16	Scroll right to display more shortcut keys
8	Parameter waveform	17	Date and time
9	Mute key	18	Menu key

3.2.1 Using Keys

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 mute the audible alarm.



To display the measuring setup interface.

To display the main setup menu.

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.


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


Switch to the large font screen


Perform 12-lead record


Set the module switch

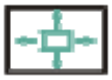

Admit a patient


Change the key volume


Review the trend graph


Adjust the screen brightness


Review the trend table


Calibrate the touch screen


Review the alarm event


Zero the IBP sensor


Access the NIBP review


Alarm setup


Access the ARR review


Change the beat volume


Switch to the trend screen


Enter standby mode

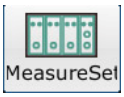

Select this item by the trim knob to enable the touch screen operation

3.2.1.3 Hardkeys

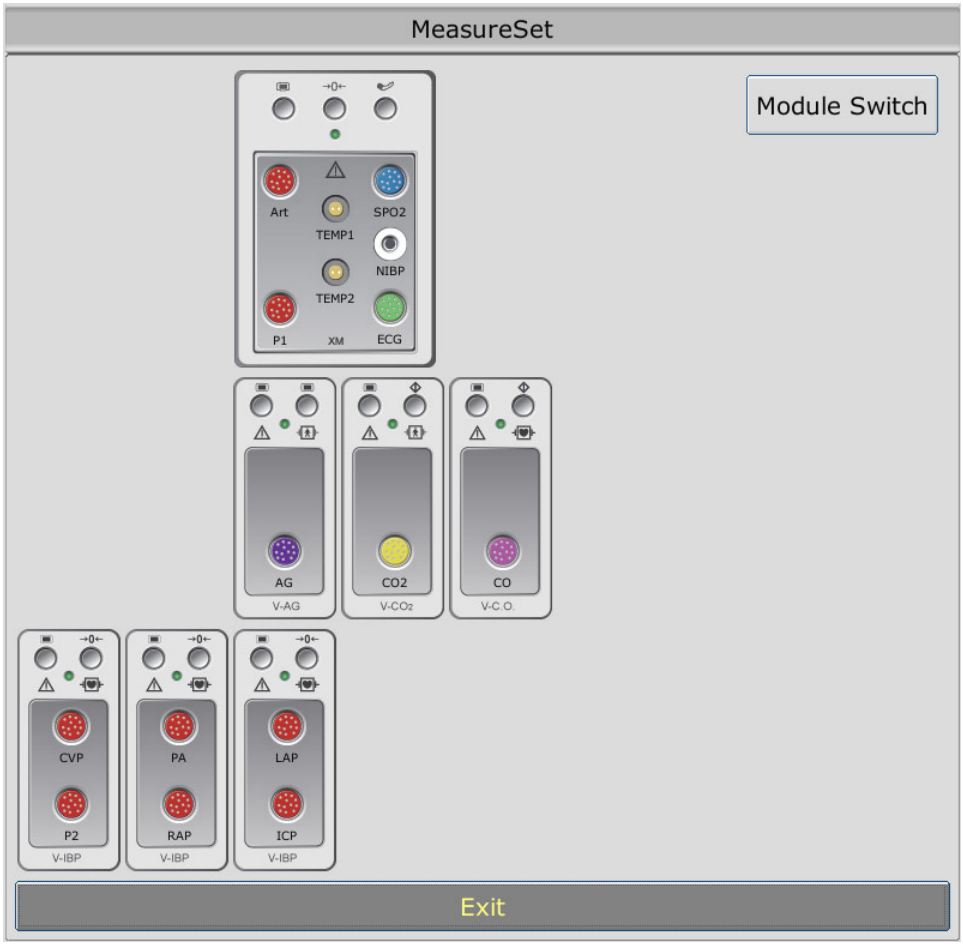
A hardkey is a physical key on a monitoring device, such as the recording key on the front panel. Refer to the illustration in *3.1.1 Main Unit* for more information.

3.3 Setting Parameters

3.3.1 Accessing the Parameter Menu

Select 

on the bottom of the screen to enter the **MeasureSet** menu as shown below. The display on your monitor may be configured to look slightly different depending on the modules mounted.



This menu displays the measurement modules which have been mounted in the XM module slot, three-slot module rack and PAM from top to bottom. Beside each measurement connector is the measurement label. The color in which a measurement connector appears matches the status of the measurement parameter.

 Colored: indicates the module is activated.

 Grey: indicates the module is deactivated.

 Colored with a “!” appearing: indicates a module conflict.

 For IBP connectors, with a circle-slash symbol appearing: indicates an IBP module conflict.

 Colored with an “X” appearing: indicates a module error.

3.3.2 Activating / Deactivating a Parameter Measurement

For different measurement parameters, approaches to parameter activation / deactivation may vary a little. Take the parameters ECG and NIBP in XM module for example:

- To activate / deactivate the ECG measurement, select the ECG connector in the XM module on the **MeasureSet** menu, and set the ECG measurement to on or off on the pop-up submenu.
- To activate / deactivated the NIBP measurement, select the NIBP connector in the XM module on the **MeasureSet** menu, and the NIBP measurement will directly be activated / deactivated.

3.3.3 Resolving Module Conflicts

This monitor supports a maximum of eight channels of IBP measurement. Both the XM module and each V-IBP module provide two channels of IBP measurement. A maximum of four V-IBP modules can be used simultaneously if the XM module is not used, while three if the XM module is used. If eight channels of IBP measurement are loaded, another IBP module’s plugging in will trigger an IBP module; the corresponding IBP connector will be changed into  on the **MeasureSet** menu as an indication. To remove the IBP conflict, unplug the conflicting module and re-plug it while less than eight channels of IBP are loaded.

For other modules, only one of the same type is available at a time; another one inserted will be in the conflicting status. For example, if a CO_2 module (module A) is loaded then another CO_2 module (module B) is inserted, a symbol “!” in red will appear on the corresponding connector on the **MeasureSet** menu to indicate a module conflict. To use module B, directly select the connector of module B on the **MeasureSet** menu, and module A is consequently switched to be in conflicting status.

3.3.4 Resolving IBP Label Conflicts

Each label must be unique and can only be assigned once. The measurement labels are stored in the measurement modules. If you try to use two measurement modules that have identical labels, this causes a label conflict in the monitor.

For example, an IBP module (module A) has already been loaded and the label Art is used for module A. Then another IBP module (module B) is inserted and the label Art is also used for

module B. In this case, a label conflict will be triggered. A prompt indicating IBP label conflict will appear on the left of the screen. Additionally, at the corresponding measurements area, two labels flicker to indicate a label conflict. The label inside the brackets is the conflicting one while the label outside the brackets is the default one assigned by the system. Via comparing the labels displayed on the **MeasureSet** menu with the label outside the brackets, you may identify the model with a label conflict and accordingly decide on the module to work.

The IBP module with a label conflict will not provide any measurement data; besides, the functions of setup, zeroing and calibrating are unavailable. To resolve the label conflict, you have to change the conflicting label into a non-conflicting one. Three resolutions are available:

Resolution 1:

1 Select the IBP channel with a label conflict on the screen and open the **Options** menu.

2 Choose another label among the options from the **Alias** pull-down list to resolve the label conflict.

Resolution 2:

1 Deactivate the parameter with label A which works properly or unplug the corresponding module.

2 The conflicting label A will consequently turn to be available.

Resolution 3:

1 Choose another label for label A which works properly.

2 The conflicting label A will consequently turn to be available.

3.4 Operating Mode

3.4.1 Demo Mode

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

1. Select the **Demo** key on the screen directly or.
2. Select **Menu** > **Common Function**, then choose **Demo Mode** from the popup interface and input password **3045**.

After entering **Demo Mode**, the monitor will perform as follows:

- Storing no data of new patient.
- Pausing to give all types of alarms.
- Pausing to transmit patient data to CMS and other network devices.
- Pausing to store the currently recorded data, and clearing the memory used to store recording and printing data.

- Real data: the parameter measurement value and real waveform displayed on the screen are from the predefined analog data, not true data of the patient being monitored.
- History data: the monitor will store the analog real-time data in Demo mode, including trend data, patient information, alarm event, waveform and setting.

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

WARNING

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

3.4.2 Standby Mode

Standby mode can be used when you want to temporarily interrupt monitoring. To enter standby mode, please press the shortcut key on the screen directly. To resume monitoring, select anything on the screen or press any key.

3.5 Changing Monitor Settings

3.5.1 Adjusting Screen Brightness

To change the screen brightness, please:

1. Press the **Brightness** 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.

Your monitor may be configured with lower brightness in standby mode and also for transport to conserve battery power.

3.5.2 Changing Date and Time

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

WARNING

A change in date and time will influence the storage of trend data.

3.6 Adjusting Volume

3.6.1 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, please:

1. Select the **Key Volume** key on the screen directly or.
2. Select **Menu** > **System Setup** > **Key Volume**, then select the appropriate setting for the key volume: **Five** is the loudest and **Zero** is the quietest.

3.6.2 Adjusting Alarm Volume

To change the alarm volume, please

1. Press the **Alarm Volume** key on the screen directly or.
2. Select **Menu** > **Alarm Setup** > **Alarm Volume**, and select the desired setting from the popup interface. For detailed information, please refer to Section *Controlling Alarm Volume*.

3.6.3 Adjusting Beat Volume

To change the beat volume, please press the **Beat Volume** key on the screen directly or refer to Section *Setting Beat Volume*.

3.7 Checking Your Monitor Version

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

3.8 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:

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

3.9 Setting Languages

To change the language, please:

1. Select **Menu** > **Maintenance** > **User Maintain**, then type the correct password **ABC** 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 valid, please restart the monitor.

3.10 Calibrating Screens

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

1. Select the **Touch Calib** shortcut key on the screen directly or select **Menu** > **Maintenance** > **User Maintain**, then input maintenance password **ABC**, then select **TouchScr Calibration** from the popup interface.

2. The symbol  appears on the screen.

3. Click on the central point of the symbol  .

4. After successful calibration, the message of **Screen Calibration Completed** appears on the screen. Then select **Exit** to finish the calibration.

3.11 Disabling the TouchScreen

The user can disable touchscreen operation by pressing and holding the **Menu** shortcut key for 3 seconds. A message of **Screen Locked** and the symbol  are displayed at the bottom of screen if the touchscreen is disabled. To enable the touchscreen operation, turn the knob to select the symbol  and press it**.**

NOTE:

When the touch screen is locked, **Menu** > **Display Setting** > **Wave Num.** is unavailable. Thus, users cannot change the number of displayed waves on the screen.

3.12 Using the Bar Code Scanner

To enter the barcode setup menu, please select **Menu** > **Maintenance** > **User Maintain**, after entering the required password **ABC**, select **Other Setup** > **BarCode Setup**. Then the user can set serial No, last Name, first Name and so on.

If **Auto Update** is set to **On**, the patient information is updated automatically by using a bar code scanner. If **Auto Update** is set to **Off**, the user needs to update the patient information manually.

Chapter 4 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.

4.1 Alarm Category

The monitor provides three types of alarm: physiological alarms, technical alarms and prompts.

4.1.1 Physiological alarms

If one or several physiological parameters of the currently monitored patient exceed the predefined alarm limit, for example: SpO_2 values exceed the alarm limit, the monitor will give an alarm, and this type of alarm is called physiological alarms. About the detailed alarm information, please refer to the Section *physiological alarm information*.

4.1.2 Technical Alarms

If one or several technical status of the device is in abnormal status, such as: lead off or low battery and so on, the monitor will give an alarm. And this type of alarm is called technical alarms. Technical alarms can't be disabled. About the detailed alarm information, please refer to Section *technical alarm information*.

4.1.3 Prompts

The monitor can give the character indication of monitoring process or other functions, such as: ARR relearning and so on. And this character is called prompts. About the detailed alarm information, please refer to Section *Prompts*.

4.2 Alarm Levels

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

1. High level alarms

   Indicating that the patient is in a life threatening situation and an emergency treatment is demanded.

2. Medium level alarms

   The patient's vital signs appear abnormally or the device system status is abnormal, indicating that prompt operator response is required.

3. Low level alarms

   The patient's vital signs appear abnormal or the device system status appears abnormally, indicating that operator awareness is required.

Alarm Sound

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

Alarm level	Prompt
High	Mode is "DO-DO-DO------DO-DO, DO-DO-DO------DO-DO", which is triggered once every 5 seconds. The alarm indicator flashes in red, with frequency of 1.4Hz～2.8Hz.
Medium	Mode is "DO-DO-DO", which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4Hz～0.8Hz.
Low	Mode is "DO-", which is triggered once every 30 seconds.

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

WARNING

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

4.3 Controlling Alarm

4.3.1 Setting Parameter Alarm

Alarm switch, alarm record and alarm level settings are available on the respective menu for each parameter alarm setup. And for most parameters, the methods to access their alarm setup menus are similar. Take HR for example, methods to set parameter alarm will be introduced below.

Setting Alarm Switch

Click on the ECG area on the screen, select **ECG Setup** > **Alarm Setup** > **HR Alarm Setup**, and then set the **Switch** to **On** or **Off** from the drop-down list.

Alarm Off symbol  is displayed on the parameter area if the parameter alarm is switched to off.

WARNING

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.

Setting Alarm Record

Click on the ECG area on the screen, select **ECG Setup** > **Alarm Setup** > **HR Alarm Setup**, and then set the **Record** to **On** or **Off** from the drop-down list.

Setting Alarm Level

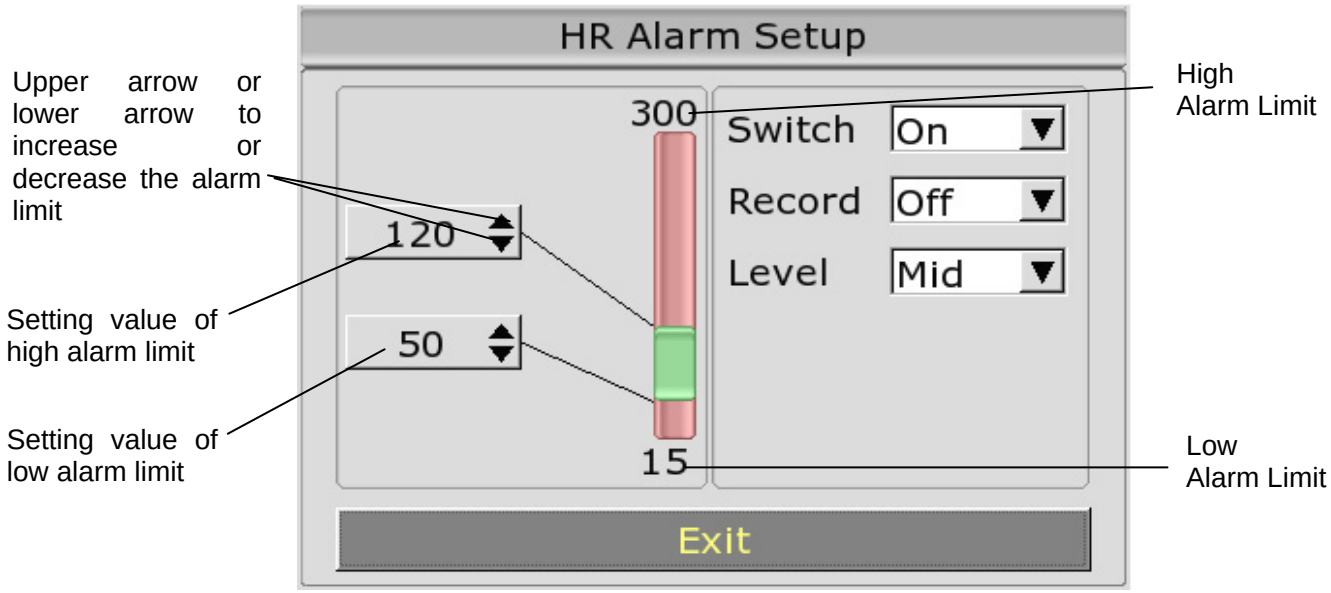
Click on the ECG area on the screen, select **ECG Setup** > **Alarm Setup** > **HR Alarm Setup**, and then set the **Level** to **High**, **Mid** or **Low** from the drop-down list.

Setting Alarm Limits

WARNING

1. Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.
2. Setting alarm limits to extreme values may cause the alarm system to become ineffective.

Click on the ECG area on the screen, select **ECG Setup** > **Alarm Setup** > **HR Alarm Setup**, and set the alarm limits on this interface as follows:



4.3.2 Temporary Alarm Mute

The monitor will give an audible alarm when there is an alarm during the audio alarm pause and the alarm indicator and screen flash indicating there is an alarm. The top of monitor displays the following:

1. Alarm pause symbol .
2. The remaining pause time is displayed in text and the word background is red.

The user can set the audio alarm pause to **60 s**, **120 s**, or **180 s** based on the requirement.

4.3.3 Alarm Mute

To mute the alarm, please select **Menu** > **Maintenance > User Maintain > Alarm Setup**, and set **Mute** to **On,** then press the key on the front panel for more than three seconds.

4.3.4 Controlling Alarm Volume

The monitor provides five levels of alarm volume: **1**, **2**, **3**, **4** and **5**. For adjusting the alarm volume, please refer to Section *Adjusting Alarm Volume*.

4.4 Latching Alarms

To set the alarm latch function, please select **Menu** > **Maintenance** > **User Maintain** > **Alarm Setup** and set **Alarm Latch** from the pull-down list. If it is set to **On**, when an alarm occurs, the monitor will display the alarm message of the parameter in the alarm status area. If the parameter resumes to normal, the alarm information of this parameter still displays in the alarm display area and the alarm time is also displayed. If many parameters appear to be latching alarms, the alarm messages are displayed in the physiological alarm message area in turn.

To deselect the alarm latch, please set **Alarm Latch** to **Off.** When **Alarm Latch** is set to **Off**, the latch function is invalid.

4.5 Disabling Sensor off Alarms

To set sensor off alarm, please select **Menu** > **Maintenance** > **User Maintain** and enter the required password **ABC**. 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, the user can press the Mute key on the front panel to disable the alarm signal. Then the alarm indicator stops flashing and the monitor is in temporary mute alarm status. If the user presses the Mute key again or the temporary mute time ends, the monitor resumes audible alarm. And the monitor will display prompt message of sensor off alarm.

4.6 Testing Alarms

When you switch the monitor on, a self test is started. You must check that the alarm indicator lights and that you hear a single tone. This indicates that the visible and audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

Chapter 5 Alarm Information

5.1 Physiological Alarm Information

Message	Cause	Alarm level
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
ASYSTOLE	No QRS is detected for 4 consecutive seconds	User-selectable
VFIB/VTAC	Ventricular tachycardia: The fibrillation wave lasts for 4 consecutive seconds; or the number of continuous Vent beats is larger than the upper limit of cluster Vent beats (≥5). The RR interval is less than 600ms.	User-selectable
VT>2	3≤ the number of cluster PVCs < 5	User-selectable
COUPLET	2 consecutive PVCs	User-selectable
BIGEMINY	Vent Bigeminy	User-selectable
TRIGEMINY	Vent Trigeminy	User-selectable
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 PVCs not belonging to the type of above mentioned PVCs.	User-selectable
TACHY	5 consecutive QRS complex, RR interval is less than 0.5s.	User-selectable
BRADY	5 consecutive QRS complex, RR interval is longer than 1.5s.	User-selectable
MISSED BEATS	When HR is less than 100 beats/min., no heart beat is tested during the period 1.75 times of the average RR interval; or When HR is higher than 100beat/min, no beat is tested within 1 second.	User-selectable
IRR	IRREGULAR RHYTHM: The patient has irregular heart rate, check patient's condition, electrodes, cables and leads.	User-selectable

Message	Cause	Alarm level
PNC	PACE NOT CAPTURE: After the pacemaker is paced, QRS complex can not be detected during 300ms.	User-selectable
PNP	PACER NOT PACED: After the QRS complex, no pace is detected during 1.75 times of RR interval.	User-selectable
VBRADY	VENTRICULAR BRADYCARDIA: The patient has irregular HR, and his average HR is less than 60bpm. Check his condition, electrodes, cables and leads.	User-selectable
VENT	VENTRICULAR RHYTHM: The patient has irregular heart rate, check patient's condition, electrodes, cables and leads.	User-selectable
RESP APNEA	RESP can not be measured within specific time interval.	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
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
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, so the monitor can't detect the pulse signal.	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
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
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 TEMP is above upper alarm limit.	User-selectable
TEMP Low	Measuring value of TEMP is below lower alarm limit.	User-selectable
SYS High	SYS measuring value is above upper alarm limit.	User-selectable

Message	Cause	Alarm level
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
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
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
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

Message	Cause	Alarm level
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
$EtCO_2$ 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
CO_2 APNEA	In a specific time interval, no RESP 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
EtO_2 High	EtO_2 measuring value is above upper alarm limit.	User-selectable
EtO_2 Low	EtO_2 measuring value is below lower alarm limit.	User-selectable
FiO_2 High	FiO_2 measuring value is above upper alarm limit.	User-selectable
FiO_2 Low	FiO_2 measuring value is below lower alarm limit.	User-selectable
EtN_2O High	EtN_2O measuring value is above upper alarm limit.	User-selectable
FiN_2O Low	FiN_2O measuring value is below lower alarm limit.	User-selectable
EtHAL High	EtHAL measuring value is above upper alarm limit.	User-selectable
EtHAL Low	EtHAL measuring value is below lower alarm limit.	User-selectable
FiHAL High	FiHAL measuring value is above upper alarm limit.	User-selectable
FiHAL Low	FiHAL measuring value is below lower alarm limit.	User-selectable
EtENF High	EtENF measuring value is above upper alarm limit.	User-selectable
EtENF Low	EtENF measuring value is below lower alarm limit.	User-selectable
FiENF High	FiENF measuring value is above upper alarm limit.	User-selectable
FiENF Low	FiENF measuring value is below lower alarm limit.	User-selectable
EtISO High	EtISO measuring value is above upper alarm limit.	User-selectable
EtISO Low	EtISO measuring value is below lower alarm limit.	User-selectable
FiISO High	FiISO measuring value is above upper alarm limit.	User-selectable
FiISO Low	FiISO measuring value is below lower alarm limit.	User-selectable
EtSEV High	EtSEV measuring value is above upper alarm limit.	User-selectable
EtSEV Low	EtSEV measuring value is below lower alarm limit.	User-selectable
FiSEV High	FiSEV measuring value is above upper alarm limit.	User-selectable

Message	Cause	Alarm level
FiSEV Low	FiSEV measuring value is below lower alarm limit.	User-selectable
EtDES High	EtDES measuring value is above upper alarm limit.	User-selectable
EtDES Low	EtDES measuring value is below lower alarm limit.	User-selectable
FiDES High	FiDES measuring value is above upper alarm limit.	User-selectable
FiDES Low	FiDES measuring value is below lower alarm limit.	User-selectable
AG FiO_2 Low	FiO_2 measurement value is too low.	High
AG APNEA	In a specific time interval, no RESP can be detected using AG module.	High
TB High	TB measuring value is above upper alarm.	User-selectable
TB Low	TB measuring value is below lower alarm.	User-selectable

5.2 Technical Alarm Information

NOTE:

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

Message	Cause	Alarm Level	Action Taken
ECG Lead Off	More than one ECG electrode falls off the skin or ECG cables fall off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG V Lead Off	ECG electrode V falls off the skin or ECG cables fall off.	Low	
ECG LL Lead Off	ECG electrode LL falls off the skin or ECG cables fall off the monitor.	Low	Make sure that all electrodes, leads and patient cables are

Message	Cause	Alarm Level	Action Taken
ECG LA Lead Off	ECG electrode LA falls off the skin or ECG cables fall off the monitor.	Low	properly connected.
ECG RA Lead Off	ECG electrode RA falls off the skin or ECG cables fall off the monitor.	Low	
ECG Signal Exceed	ECG measuring value is beyond measuring range.	High	Check lead connection and patient condition
ECG Signal Overflow	The amplitude of ECG signal is too wide.	Low	Please modify the ECG gain.
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.
ECG Noise	ECG measuring signal is greatly interrupted.	Low	Check lead connection and patient condition
ECG V1 Lead Off	ECG electrode V1 falls off the skin or ECG cables fall off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG V2 Lead Off	ECG electrode V2 falls off the skin or ECG cables fall off.	Low	
ECG V3 Lead Off	ECG electrode V3 falls off the skin or ECG cables fall off.	Low	
ECG V4 Lead Off	ECG electrode V4 falls off the skin or ECG cables fall off.	Low	
ECG V5 Lead Off	ECG electrode V5 falls off the skin or ECG cables fall off.	Low	Make sure that all electrodes, leads and patient cables are

Message	Cause	Alarm Level	Action Taken
ECG V6 Lead Off	ECG electrode V6 falls off the skin or ECG cables fall off.	Low	properly connected.
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.
SpO_2 Sensor Off	SpO_2 sensor may be disconnected from the patient or the monitor.	Low	Make sure the sensor is well connected to the patient's finger or other parts.
SpO_2 No Sensor	SpO_2 sensor was not connected well or connected to the monitor, or the connection is loose.	Low	Make sure the monitor and sensor is well connected, reconnect the sensor.
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 Low Perfusion	The pulse signal is too weak or the perfusion of the measurement site is too low	Low	Reconnect the SpO_2 sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO_2 Noisy Signal	There is interference with SpO_2 measurement signals and the waveform is abnormal.	Medium	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.	Medium	Reduce interference of the ambient light and avoid sensor's exposure to strong light.
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 Loose Cuff	Cuff is no properly wrapped or no cuff exists.	Low	Properly wrap the cuff.
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 Signal Saturated	Signal amplitude too strong	Low	Stop the patient from moving.
NIBP Init Pressure High	The initial pressure is too high during measuring	High	Measure again, if failure persists, stop measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm Level	Action Taken
NIBP Invalid Reset	The hardware pressure is too high	Low	Measure again, if failure persists, stop using measuring function of NIBP module and 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 Tube Leak	NIBP cuff or pump has a leakage.	Low	Check the NIBP cuff and pump for leakages.
NIBP Cuff Type Error	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
Air Pressure Error	Environment atmospheric pressure abnormal or system pressure abnormal.	Low	Check whether the airway is occluded or pressure sensor works properly in pressure meter mode. If the problem still exists, contact your service personnel.
NIBP Self Test Error	Sensor or other hardware errors.	High	Contact your service personnel.
NIBP Pneumatic Leak	NIBP cuff or pump has a leakage.	Low	Check the NIBP cuff and pump for leakages.
NIBP System Failure	Hardware abnormal	High	Contact your service personnel.
NIBP Cuff Leak	Cuff, pump or airway has a leakage.	Low	NIBP cuff isn't properly connected, or there is a leak in the airway.

Message	Cause	Alarm Level	Action Taken
NIBP Leak Test Error	Hardware abnormal	High	Check whether the airway is occluded or pressure sensor works properly in pressure meter mode. If the problem still exists, contact your service personnel.
NIBP Weak Signal	Cuff is too loose or patient pulse is too weak.	Low	Use other method to measure blood pressure.
NIBP Excessive Motion	Due to arm motion, signal noise is too large or pulse rate is not regular.	Low	Make sure that the patient under monitoring is motionless.
NIBP Range Exceeded	Maybe the patient blood pressure value is beyond the measurement range.	Low	Maybe the patient blood pressure value is beyond the measurement range.
NIBP Air Leak	The cuff pressure can't reach the set value within 60sec and 20sec in Neo mode.	Low	Check the connections and the wrapped cuff to see whether they are all prepared well.
NIBP Pressure Low	The module isn't able to detect the SYSTOLIC. Apply pressure again.	Low	Inflate again and retry thrice. Check whether the patient has an over high blood pressure or it is interfered by movement.
NIBP Pulse Abnormal	Abnormal oscillometric waveform	Low	Retry twice. Check for hyperkinesia or arrhythmia.
NIBP Pulse Signal Weak	Pulse is too low to measure.	Low	Check the patient's condition or the wrapped cuff.

Message	Cause	Alarm Level	Action Taken
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
Excessive T2	TEMP2 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
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.
YY Sensor Off (YY stands for the IBP label name)	IBP sensor falls off.	Low	Check the sensor connection and reconnect the sensor.
YY Comm Fail (YY stands for the label name)	IBP module failure or communication failure	High	Stop measuring function of IBP module, and notify biomedical engineer or Manufacturer's service staff.
CO 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.
CO TI No Sensor	C.O. TI sensor not connected	Low	Insert injective temperature sensor.

Message	Cause	Alarm Level	Action Taken
CO TB No Sensor	C.O. TB sensor not connected	Low	Insert TB sensor.
TEMP Out Of Range	TB measuring value is above measuring range.	High	Please check TB sensor.
CO Lack Param	C.O. measuring needs parameters	High	Please input patient's height and weight.
AA Out Of Range	The AA concentration exceeds the accuracy range of gas module.	High	Reduce AA concentration.
O_2 Sensor Error	The oxygen sensor of the sidestream gas module has a failure.	Medium	Stop measuring of AG module, and notify biomedical engineer or Manufacturer's service staff.
AG Comm Fail	AG module failure or communication failure.	High	Stop measuring function of AG module, and notify biomedical engineer or Manufacturer's service staff.
AG Zero Required	AG module requires zero.	Low	Please perform zeroing.
AG Self-Testing	AG module is self testing.	Low	Please wait the self testing finishing.
AG Replace O_2 Sensor	O_2 sensor needs to be replaced.	High	Please replace the O_2 sensor.
AG Check Adapter	AG module checks adapter.	Low	Please wait check finishing.
O_2 Cali Required	O_2 needs to be calibrated.	Low	Please calibrate O_2.
AG Software Error	AG module software abnormal	High	Please replace software revision.
AG Hardware Error	AG module has hardware failure.	High	Please check whether the hardware works properly.
AG Motor Error	AG module motor abnormal	High	Please check whether the motor works properly.

Message	Cause	Alarm Level	Action Taken
AG Uncalibrated	AG module uncalibrated	Low	Please calibrate the AG module.
AG Replace Adapter	AG module needs to change adapter	High	Please replace the adapter.
O_2 Out Of Range	O_2 is out of range.	High	Please make O_2 range resume normal.
AG TEMP Out Of Range	AG module temperature out of range	High	Please make the temperature resume normal.
AG Baro Press Out Of Range	AG module baro pressure out of pressure	High	Please make the baro pressure value resume normal.
AG AA Id Unreliable	AG module can't identify the AG agent.	Medium	Reduce gas agent type.
AG Span Calib In Progress	AG module is calibrating	Low	Please wait calibration finishing.
AG Calibration Fail	AG module calibration failure	Medium	Please check whether the module works properly.
Unable To Calibrate	AG module can't be calibrated	Medium	Please check whether the module works properly.
AG Zero In Progress	AG module is zeroing	Low	Please wait zeroing.
AG Occlusion	The sampling line is clogged.	Medium	Replace the sampling line.
AG Init Fail	AG module has a failure.	High	AG module works improperly.
AG Data Limit Error	AG module has a failure.	High	AG module works improperly.
AG Usa Error	AG module has a failure.	High	AG module works improperly.
AG Cal Fail	AG module fails to calibrate	High	AG module works improperly.
AG Zref Fail	AG module fails to zero	High	AG module works improperly.
AG Change Oxygen Sensor	Replace oxygen sensor of AG module	Low	Please wait changing finishing.

Message	Cause	Alarm Level	Action Taken
AG No Oxygen Sensor	The oxygen sensor falls off from the AG module.	High	Connect the sensor again.
AG Mixed Agents	AG module detects mixture gas agent.	Medium	Close the subsidiary gas agent.
CO_2 Occlude	Water trap of sidestream is occluded	Low	Make sure the gas exhaust works well
CO_2 Out Of Range	The CO_2 concentration exceeds the accuracy range of gas module.	High	Reduce CO_2 concentration.
CO_2 Sensor Faulty	CO_2 module failure	High	Stop measuring function of CO_2 module, notify biomedical engineer.
CO_2 Sensor Over Temp			
CO_2 Comm Fail	CO_2 module failure or communication failure	High	Check if the water tray has been fixed.
CO_2 Ram Error	CO_2 module failure	High	Stop using CO_2 alarm function, and notify biomedical engineer or Manufacturer's service staff.
CO_2 Rom Error	CO_2 module failure	High	
CO_2 Zero Required	Zero calibration failure	Low	Disconnect the sampling cannula or adapter from the airway; initiate the zeroing before making sure that no expired air is inside the sampling cannula and adapter.

Message	Cause	Alarm Level	Action Taken
CO_2 Check Adapter	The cannula is off or disconnected	Low	Check if the adapter is well connected or use another adapter.
AA Out Range	The concentration of anesthetic exceeds the accuracy range of gas module.	High	Reduce AA concentration.
O_2 Sensor Error	The oxygen sensor of the sidestream gas module has a failure.	Medium	Stop measuring of AG module, and notify biomedical engineer or Manufacturer's service staff.
Temp exceed limit	The TEMP value is beyond the range of +25°C ~ +45°C.	Med	Put the sensor into the sensor bracket, take it out and measure again.
No Temp Sensor	TEMP sensor is not connected to the TEMP module.	Low	Connect the sensor and the monitor well, and measure again.
Ambient temp too high	The Sensor temperature is higher than +40°C	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.
Ambient temp too low	The Sensor temperature is lower than +10°C	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.

Message	Cause	Alarm Level	Action Taken
Probe data error	Offline: NTC resistance >R 0 °C; Short: NTC resistance <R+100 °C.	Medium	Put the sensor into the sensor bracket, take it out and measure again. If the problem persists, stop using measuring function of TEMP module, and notify biomedical engineer or manufacturer's service staff.
Probe heater error	Single failure	Medium	Put the sensor into the sensor bracket, take it out and measure again. If the problem persists, stop using measuring function of TEMP module, or notify biomedical engineer or manufacturer's service staff.
Probe temp too high	The original temperature of sensor >+33 °C & ≤+40 °C.	Low	Put the sensor into the sensor bracket, measure again after the sensor temperature reaches normal value.
Temp Sensor Off	After the sensor temperature reaches Predict value, it descends to the value lower than Predict value.	Medium	Reconnect the sensor and make sure that the cable is properly connected.
Battery Low	Battery Low	High	Please change the battery or charging.
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper

Message	Cause	Alarm Level	Action Taken
Recorder setup needed	The user presses the **RECORD** button when the monitor is not installed with a recorder.	Low	Notify the manufacturer's service staff to install and set the recorder.

5.3 Prompts

Message	Cause
ECG Arr Learning	The QRS template building required for Arr. Analysis is in process.
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.
Manual Measuring	In manual measuring mode.
Continual Measuring	In continuous measuring mode.
Auto Measuring	In automatic measuring mode.
Measure Abort	Measurement over
Calibrating	During calibrating
Calibrate Abort	Calibration over
Leak Testing	During pneumatic test
Leak Test Ok	NIBP module has passed leak test.
Leak Test Abort	Pneumatic test over
Resetting	NIBP module in resetting
Please Start	NIBP module is in idle status
Done	NIBP measurement successfully done
Continual Measuring	NIBP module performs continual measuring
Stat Measuring	NIBP module performs STAT function
Please Switch To Maintain Mode	NIBP module is in normal mode, the user can't start leak test and pressure calibration. Please enter **User Maintain > NIBP Maintain** and switch to **Maintain Mode** to perform leak test or pressure calibration.
Please Switch To Normal Mode	NIBP module is in maintaining mode, the user can't start blood pressure measurement. Please enter **User Maintain > NIBP Maintain** and switch to **Normal Mode** to perform blood pressure measurement.

Message	**Cause**
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 Sensor Warm Up	The CO_2 module is in warm-up state
Excessive CO Temp	TB measuring value is beyond measuring range.
Excessive Temp, CO Measurement Fail.	C.O. measuring needs parameters
CO measure need param.	Measurement is unavailable due to absence of setting patient height and weight. Please enter **Menu** > **Patient Setup** > **Patient Info.**, and input the patient height and weight.
No Sensor, CO measurement fail	No Sensor, C.O. measurement fail
Measuring...	The C.O. module is performing measuring
Ready for new measurement	C.O. module is ready for new measurement
Invalid CO result	C.O. measurement result is invalid
CO Measurement Complete	C.O. Measurement is completed
CO Measurement Abort	C.O. Measurement is aborted
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 30s.
AG Standby	AG module is operating in the standby status.
No module detected	No module is mounted in the monitor.
No module activated	No module is activated.
Loading module…	The system is loading the inserted module.
IBP alias collision	The label offered by the IBP module is inconsistent with the label assigned by the monitor.
DC supply (Battery only)	Only one battery is in use.

5.4 Adjustable Range of Alarm Limits

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

	Patient Type	ALM HI	ALM LO
HR	ADU	300	15
	PED	350	15
	NEO	350	15

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

	ALM HI	ALM LO
ST	2.0	-2.0

PVCs alarm upper limits are listed as follows:

	ALM HI	ALM LO
PVCs	10	

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

	Patient Type	ALM HI	ALM LO
RESP	ADU	120	6
	PED	150	6
	NEO	150	6

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

	ALM HI	ALM LO
SpO_2	100	0

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

	ALM HI	ALM LO
PR	300	30

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

Patient Type		ALM HI	ALM LO
ADU	SYS	270	40
	DIA	215	10
	MAP	235	20
PED	SYS	200	40
	DIA	150	10
	MAP	165	20
NEO	SYS	135	40
	DIA	100	10
	MAP	110	20

TEMP alarm limits are listed as follows:

	ALM HI	ALM LO
T1	50°C (122 º F)	0°C (32 º F)
T2	50°C (122 º F)	0°C (32 º F)
TD	50°C (90 º F)	0°C (0 º F)

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

	ALM HI	ALM LO
Art	300	0
RAP	40	-10
LAP	40	-10
CVP	40	-10
PA	120	-6
ICP	40	-10
P1	300	-50
P2	300	-50

CO_2 alarm limits are listed as follows:

	ALM HI	ALM LO
$EtCO_2$	150 mmHg	0
$FiCO_2$	50 mmHg	3
AwRR	150 rpm	2 rpm

C.O. alarm limits are listed as follows:

	ALM HI	ALM LO
TB	43°C (109.4℉)	23°C(73.4℉)

AG alarm limits are listed as follows:

Patient Type		ALM HI	ALM LO
ADU	$FiCO_2$	25.0%	0.0%
	$EtCO_2$	25.0%	0.0%
	FiO_2	88.0%	18.0%
	EtO_2	90.0%	18.0%
	FiN_2O	100.0%	0.0%
	EtN_2O	100.0%	0.0%
	EtDes	18.0%	0%
	FiDes	18.0%	0%
	EtIso	5.0%	0%
	FiIso	5.0%	0%
	EtHal	5.0%	0%
	FiHal	5.0%	0%
	EtSev	8.0%	0%
	FiSev	8.0%	0%
	EtEnf	5.0%	0%
	FiEnf	5.0%	0%
	awRR	150 rpm	0 rpm
	Apnea Time	40s	20s

Patient Type		ALM HI	ALM LO
PED	$FiCO_2$	25.0%	0.0%
	$EtCO_2$	25.0%	0.0%
	FiO_2	88.0%	18.0%
	EtO_2	90.0%	18.0%
	FiN_2O	100.0%	0.0%
	EtN_2O	100.0%	0.0%
	EtDes	18.0%	0%
	FiDes	18.0%	0%
	EtIso	5.0%	0%
	FiIso	5.0%	0%
	EtHal	5.0%	0%
	FiHal	5.0%	0%
	EtSev	8.0%	0%
	FiSev	8.0%	0%
	EtEnf	5.0%	0%
	FiEnf	5.0%	0%
	awRR	150 rpm	0 rpm
	Apnea Time	40s	20s

Patient Type		ALM HI	ALM LO
NEO	$FiCO_2$	25.0%	0.0%
	$EtCO_2$	25.0%	0.0%
	FiO_2	88.0%	18.0%
	EtO_2	90.0%	18.0%
	FiN_2O	100.0%	0.0%
	EtN_2O	100.0%	0.0%
	EtDes	18.0%	0%
	FiDes	18.0%	0%
	EtIso	5.0%	0%
	FiIso	5.0%	0%
	EtHal	5.0%	0%
	FiHal	5.0%	0%
	EtSev	8.0%	0%
	FiSev	8.0%	0%
	EtEnf	5.0%	0%
	FiEnf	5.0%	0%
	awRR	150 rpm	0 rpm
	Apnea Time	40 s	20 s

Chapter 6 Managing Patients

6.1 Admitting a Patient

The monitor displays physiological data and stores it in the trends as soon as a patient is connected. This allows you 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:
   - **Serial No**: Enter the patient's medical record number (MRN), for example 12345678.
   - **Last name**: Enter the patient's last name (family name), for example Smith.
   - **First name**: Enter the patient's first name, for example Joseph.
   - **Gender**: Choose **Male** or **Female**.
   - **Type**: Choose the patient type, either **Adult**, **Pediat**, or **Neonat**.
   - **BloodType**: **N/A, A, B, AB** and **O**.
   - **Pace**: Choose **On** or **Off** (You must select **On** if your patient has a pacemaker).
   - **Date of Birth**: Enter the patient's date of birth.
   - **Date of Admission**: Enter the patient's date of admission.
   - **Height**: Enter the patient's height.
   - **Weight**: Enter the patient's weight.
   - **Doctor**: Enter any extra information about the patient or treatment.
5. Select **Exit**.

6.1.1 Patient Category and Paced Status

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.

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.

6.2 Quick Admit

If you do not have the time or information to fully admit a patient. Complete the rest of the patient information later. To quickly admit a patient, please:

1. Select **Menu** > **Patient Setup** > **Quick Admit**, then a message is displayed to ask the user to confirm to update patient.

2. Click on **No** to cancel this operation; click on **Yes** to continue and the **Patient Info** window is displayed, choose **Type** and **Pace** and set them to the correct mode**.**

3. Select **Exit.**

6.3 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.

6.4 Updating a Patient

You should always perform an update before starting monitoring for a new patient. When you select **Menu > Patient Setup > Quick Admit**, or **Menu > Patient Setup > New Patient**, a message of **Press 'Yes' to create new patient profile by clearing all current patient data...** is displayed.

- If the user selects **Yes,** the monitor will update the patient information.
- If the user selects **No,** the monitor won't update the patient information and returns to patient setup interface.

NOTE:

Discharging patient will clear the history data in the monitor associated with the patient.

6.5 Central Monitoring System

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

1. The monitor sends patient information, real-time monitoring or measurement data to the central monitoring system.
2. The real-time monitoring information is displayed on the central monitoring system as the same to the monitor, and the central monitoring system can perform some bilateral control. For example: changing patient information, receiving patient, discharging patient and so forth.

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

And the monitor supports HL 7 protocol.

NOTE:

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.

Chapter 7 User Interface

7.1 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.

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

7.2 Selecting Display Parameters

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

1. Select **Menu** > **System Setup** > **Module Switch**.
2. Select the required parameters from the popup interface.
3. Press **Exit** to exit the menu and the screen will adjust the parameters automatically.

7.3 Changing Waveform Position

The user can exchange the waveform positions of parameter A and parameter B, please refer to the following steps to do so:

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.

7.4 Changing Interface Layout

To change the interface layout, please refer to the following steps:

1. Select **Menu** > **Display Setting**.
2. Select one interface from the popup menu.
3. The user can implement one kind of function screen based on the requirements. If the user selects the **Large Font** option, there is no function screen to be selected.

7.5 Viewing Trend Screen

To view the short trend screen, the user can press the **Trend Screen** key on the screen directly or select **Menu** > **Display Setting > View Selection > TrendScreen**.

7.6 Viewing Oxygen Screen

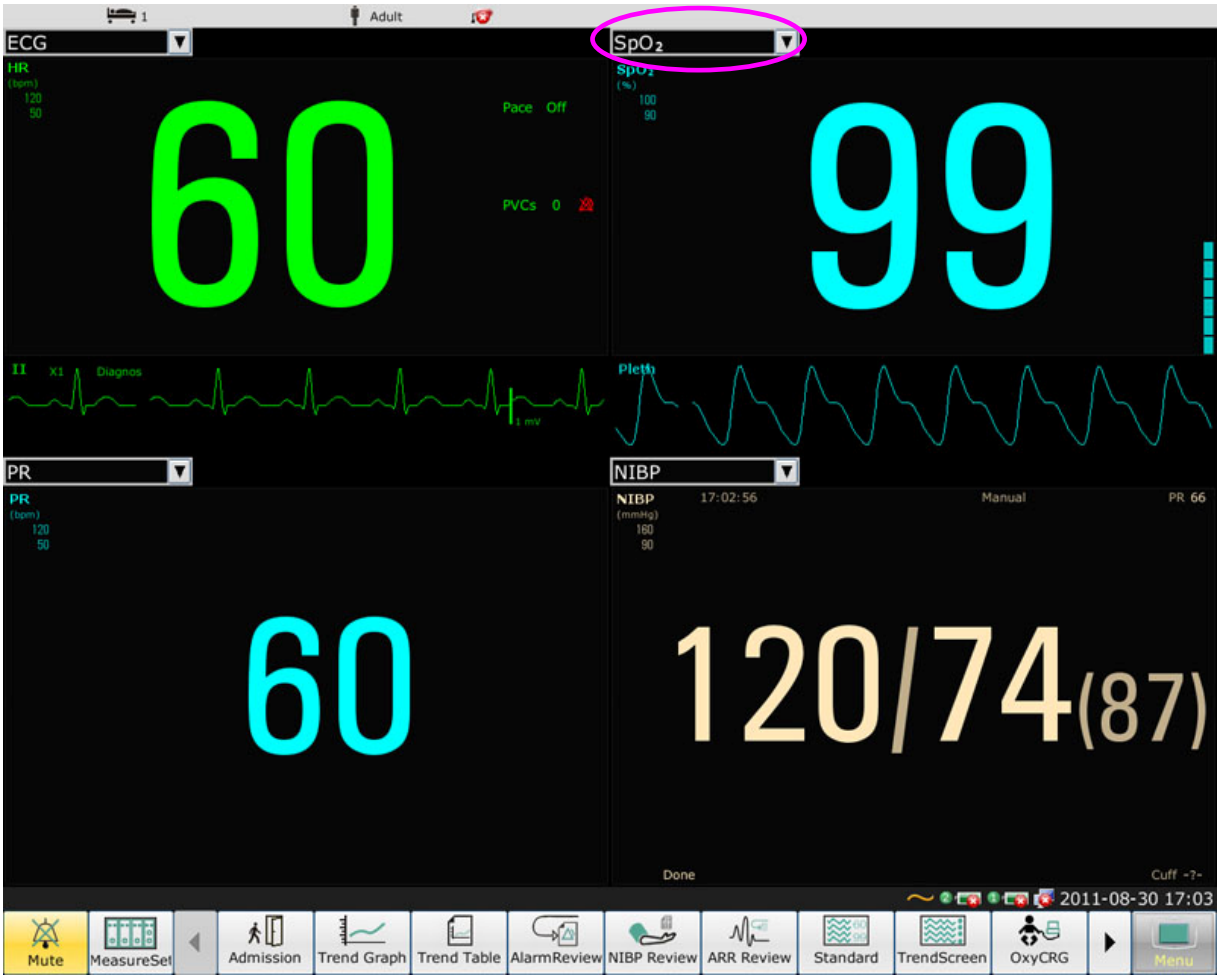
To view the oxygen screen, the user can press the **oxyCRG** key on the screen or select **Menu** > **Display Setting > View Selection > oxyCRG**. This interface is always used in NICU because the SpO_2, HR and Resp of the neonate are different from those of adults.

7.7 Viewing Large Font Screen

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

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

To view the large font interface of a specific parameter, please select the parameter from the pull-down list on the interface (the red circle shown in the following figure).



7.8 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 **ABC**. Then select **Color Select** to make color changes on parameter and color.

NOTE:
To make the color changes effective, please restart the monitor after changing the colors.

7.9 User Configuration

Users can save the current monitor's configuration, delete the saved user configuration and rename it.

To save the user configuration:

1. Select **Menu > Maintenance > User Maintain**, enter the required password **ABC** and then select **User Configure**.
2. Click on **Save**, enter a file name for the configuration and confirm it. A message will display after the operation.

To delete the user configuration:

1. Select **Menu > Maintenance > User Maintain**, enter the required password **ABC** and then select **User Configure**.
2. Select the configuration file needed to delete from the list, click on **Delete** and confirm the operation. A message will display after the operation.

To rename the user configuration:

1. Select **Menu > Maintenance > User Maintain**, enter the required password **ABC** and then select **User Configure**.
2. Select a configuration file needed to rename from the list and click on **Rename**.
3. Enter a name for the configuration file and confirm it.

7.10 USB Configuration

When installing several monitors with identical user configuration, it is not necessary to set each device separately. An USB drive can be used to transfer the configuration from monitor to monitor.

To export the current monitor's configuration:

1. Connect USB device to the monitor's USB port.
2. Select **Menu > Maintenance > User Maintain**, enter the required password **ABC** and then select **USB Configure**.
3. Select **Export** to export configuration. A status message will display after the operation.

To import the configuration on the USB drive to the monitor:

1. Connect the USB drive to the monitor's USB port.
2. Select **Menu** > **Maintenance** > **User Maintain,** enter the required password **ABC** and then select **USB Configure**.
3. Select **Import** and select a configuration file needed to import from the list; confirm the operation. A status message will display after the operation.

Besides, users can delete configuration files from the USB device via the monitor:

1. Connect USB device to the monitor's USB port.
2. Select **Menu** > **Maintenance** > **User Maintain**, enter the required password **ABC** and then select **USB Configure**.
3. Select **Delete** and select a configuration file needed to delete from the list; confirm the operation.

NOTE:

1 The U disk only supports two kinds of format: FAT and FAT 32.

2 The exported configuration files are saved into the folder named USERCONFIG, and the user can't modify files the in the folder.

3 Up to three configuration files can be saved and recognized.

4 To make monitors using the same user configuration display identically, the display setting in each monitor should be the same.

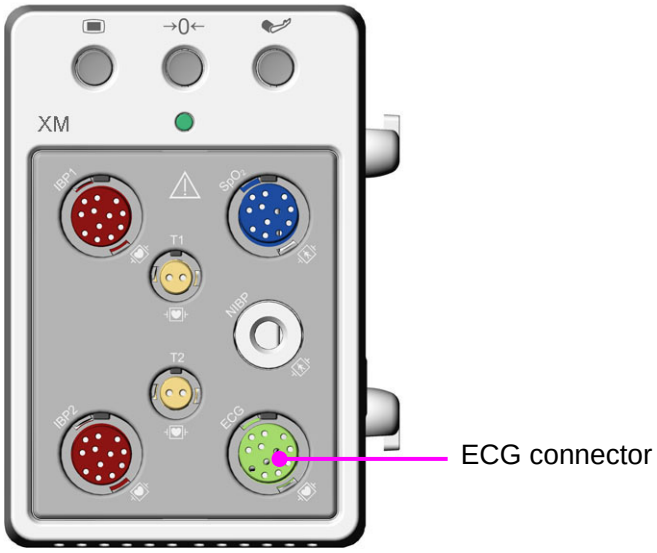
7.11 Default Configuration

To set default configuration, select **Menu** > **Default**. Users can choose a factory configuration (adult, pediatric or neonate) based on the patient category. Also, users can choose a user configuration saved in the monitor. For more information about user configuration, refer to *7.9 User Configuration* and *7.10 USB Configuration*.

Chapter 8 Monitoring ECG

8.1 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.



8.2 ECG Safety Information

WARNING

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

2 Only use the ECG leads supplied by the manufacturer when using the monitor for ECG monitoring.

3 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.

4 Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.

5 Place the electrode carefully and ensure a good contact.

6 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 audible alarm is activated.

7 When using the monitor with the defibrillator or other high-frequency equipment, please use defibrillator-proof ECG lead to avoid burn.

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

WARNING

9 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.

10 For patients with pacemakers, the pacing impulse analysis function must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected.

11 The electrodes should be made of the same metal materials.

12 ECG cables can be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again.

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 signal at the ECG output on the IntelliVue patient monitors is delayed by a maximum of 30 ms. Your biomedical engineer should verify that your ECG/Defibrillator combination does not exceed the recommended maximum delay of 60 ms.

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

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 3v/m) specifies that the electrical field density exceeding 1v/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.

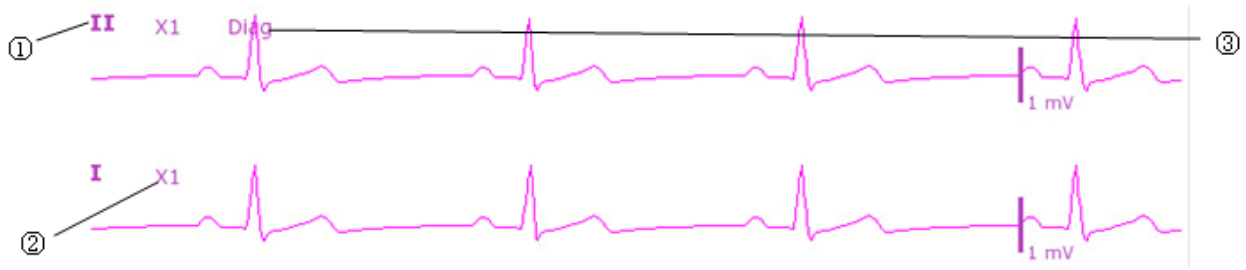
5 In the default settings of the monitor, the ECG waveforms are the first two waveforms from top in the waveform area.

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.

8.3 ECG Display

The figure below is for reference only.



The symbol "①"indicates lead name of display waveform: there are several options, such as Ⅰ, Ⅱ, Ⅲ, aVR, aVF, aVL, V. If you want to change the lead, please refer to section *Selecting Calculation Lead*.

The symbol "②" 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*.

The symbol "③" indicates Filter setting, there are three options: **Monitor**, **Surgery** and **Diagnos**. If you want to change it, please refer to section *Changing the ECG Filter Setting*.

8.3.1 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 Wave Setup** > **ECG Gain**, then select an appropriate factor from the pop-up box to adjust the ECG waveform.

X0.125 to make strength of ECG signal waveform of 1mV become 1.25mm;

X0.25 to make strength of ECG signal waveform of 1mV become 2.5mm;

X0.5 to make strength of ECG signal waveform of 1mV become 5mm;

X1 to make strength of ECG signal waveform of 1mV become 10mm;

X2 to make strength of ECG signal waveform of 1mV become 20mm;

X4 to make strength of ECG signal waveform of 1mV become 40mm;

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.

8.3.2 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.

– **Diagnos**: Use when diagnostic quality is required. The unfiltered ECG wave is displayed so that changes such as R-wave notching or discrete elevation or depression of the ST segments are visible.

8.4 Selecting Calculation Lead

On the **Normal** interface, the users can select either **3 LEADS** or **5 LEADS** for this item. 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.

8.5 Monitoring Procedure

8.5.1 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.

8.5.2 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.
4. Plug the patient cable into the ECG connector on XM module.

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.

8.5.3 Selecting Lead Type

To change the lead type, please:

1. Select the ECG parameter area, open the **ECG Setup** menu;
2. Set **Lead Type** to **3 Leads**, **5 Leads** or **12 Leads** based on the lead used.

8.5.4 Installing Electrodes

NOTE:

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

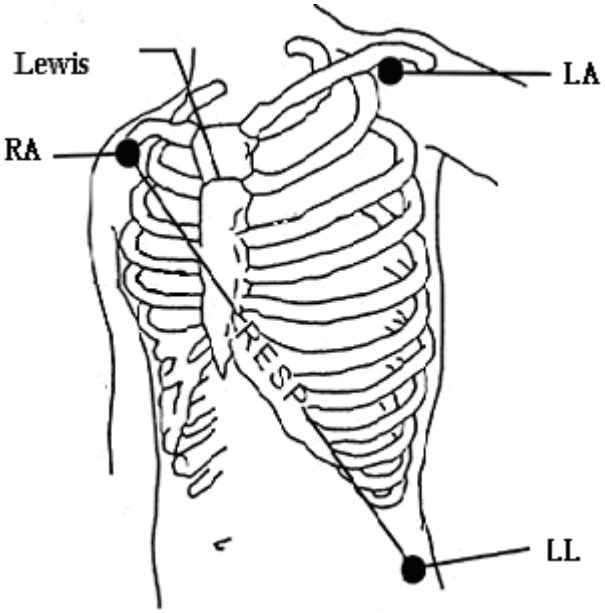
AHA (American Standard)		**IEC (Europe Standard)**	
Electrode Labels	Color	Electrode Labels	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green

AHA (American Standard)		IEC (Europe Standard)	
V4	Brown/Blue	C4	White/ Brown
V5	Brown/Orange	C5	White/ Black
V6	Brown/Purple	C6	White/ Purple

8.5.4.1 Electrode Placement for 3-lead

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.

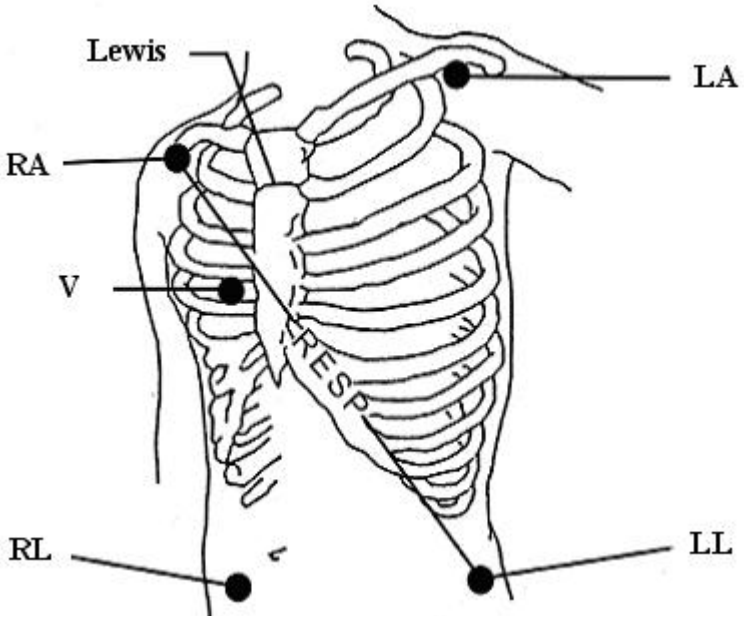


Electrode Placement for 3-lead

8.5.4.2 Electrode Placement for 5-lead

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.



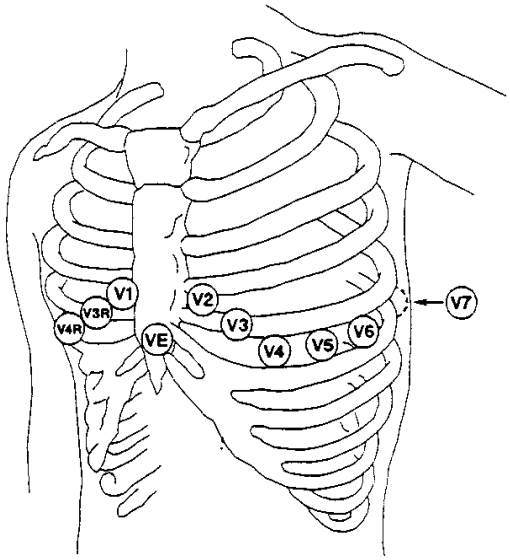
Electrode Placement for 5-lead

NOTE:

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

For 5-lead, 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.



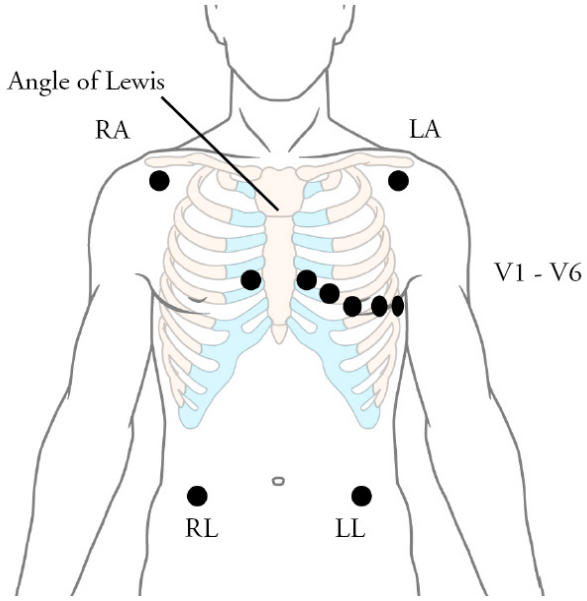
V-Electrode Placement for 5-lead

8.5.4.3 Electrode Placement for 12-lead

Take the American standard for example; the 12-lead electrodes should be placed as follows:

The limb electrodes are placed in the same position as the 3-lead placement.

- RL placement: on the right hypogastrium.
- 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.



Electrode Placement for 12-lead

8.5.4.4 Recommended ECG Lead 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

1 When using electrosurgical (ES) equipment, never place ECG electrodes near to the grounding plate of the ES device, as this can cause a lot of interference on the ECG signal.
2 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 the ECG cables which are defibrillator-proof.

NOTE:

1 If an ECG waveform is not accurate, while the electrodes are tightly attached, try to change the lead.

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

8.6 ECG Menu Setup

8.6.1 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 at least one ECG lead can be measured without a technical condition. The monitor will automatically switch to Pulse as the alarm source if:

–a valid ECG lead can no longer be measured and

–a pulse source is switched on and available.

The monitor then uses the pulse rate from the measurement currently active as system pulse. While Pulse is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the monitor automatically uses HR as alarm source.

8.6.2 Smart Lead Off

In **5 LEADS**, **12 LEADS** mode, if **CH1** and **CH2** can not be measured because of the lead off or other reasons, it can shift to other modes to collect an ECG waveform.

To change smart lead off setting, please select **ECG Setup** > **Smart Leadoff**, then a pop-up menu is displayed.

8.6.3 Setting Beat Volume

Beat volume is from HR or PR, depending on your HR alarm setting. Five selections are available: **0, 1, 2, 3, 4, 5**. **5** indicates the maximum volume. **0** indicates the minimum volume.

To change the beat volume, select **ECG Setup** > **Beat Volume**, then select an appropriate volume from the pop-up list.

8.6.4 ECG Display

It varies with **Lead Type**. When **Lead Type** is set to **3 Leads, Display** can be set to **Normal**, and it can display one ECG waveform on the main screen.

When **Lead Type** is set to **5 Leads, Display** can be set to **Normal**, **Full-Scr** and **Half-Scr**. Select **Normal** to display two ECG waveforms on the main screen; select **Full-Scr** to display seven ECG waveforms which occupy the area of seven waveforms on the main screen; Select **Half-Scr** to display seven ECG waveforms on the screen, occupying the area of four waveforms.

NOTE:

If **3 Leads** is selected in the **ECG Setup** menu, only **Normal** can be selected for **Display** in the sub-menu.

8.6.5 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.

NOTE:

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

2 If **Pace** is set to **On**, the system will not perform some types of ARR analysis.

WARNING

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. Keep pacemaker patients under close observation.

8.6.6 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 device can't be monitored during ECG calibration.

8.6.7 ECG Waveform Settings

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

8.6.8 12 Leads ECG

8.6.8.1 Activating 12-Lead ECG Monitoring

Select **Menu** > **Maintenance** > **User Maintain** > **Other SetUp** > **12 Leads Activate** 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 12-lead ECG monitoring function will be activated.

NOTE:

If the 12-lead ECG monitoring fails to be activated, users can reenter the password and try to activate this function again.

8.6.8.2 Monitoring Procedure

1 Select and place the 12-lead electrodes as introduced in the above-mentioned section.

2 Select **12 Leads** from the pull-down list of **Lead Type**, and also set **Display** to **12 Leads**.

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 **Diagnos** and can not be changed.

8.7 ST Segment Monitoring

The monitor performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics and snippets 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, please refer to the following figure.

NOTE:

1 ST-segment analysis is intended for adults only.

2 When **ST Analysis** is **On**, the monitor should be in **Diagnos** mode.

3 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.

8.7.1 Setting ST Analysis

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

8.7.2 ST Display

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

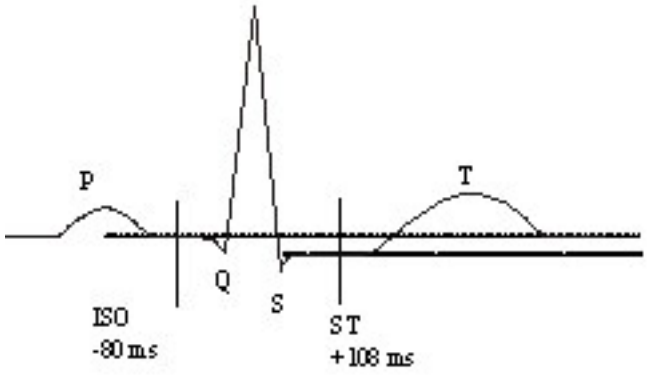
ST						
	I	0.08	aVR	-0.09	V	0.04
	II	0.10	aVL	0.03		
	III	0.02	aVF	0.06		

8.7.3 ST Analysis Alarm Setting

The user can select **ECG Setup** > **ST Analysis** > **Alarm Setup** to set the upper alarm limit and lower alarm limit. **ALM HI** can be set to 0.2 mV ~ 2.0 mV, and **ALM LO** can be set to –2.0 mV ~ 0.2 mV. **ALM HI** should be higher than **ALM LO**.

8.7.4 About ST Measurement Points

The ST value for each beat 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.

8.7.5 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.

8.8 Arr. Monitoring

8.8.1 Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of neonatal and adult patients in clinics, and detect the changes of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarming 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.

The monitor can support up to 16 different arrhythmia analyses.

ARR Types	Occurring Condition
ASYSTOLE	No QRS is detected for 4 seconds
VFIB/VTAC	Ventricular tachycardia: The fibrillation wave lasts for 4 consecutive seconds; or the number of continuous Vent beats is larger than the upper limit of cluster Vent beats (≥5). The RR interval is less than 600ms.
VT>2	3≤ the number of cluster PVCs < 5
COUPLET	2 consecutive PVCs
BIGEMINY	Vent Bigeminy
TRIGEMINY	Vent Trigeminy
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 PVCs not belonging to the type of above mentioned PVCs.
TACHY	5 consecutive QRS complex, RR interval is less than 0.5s.
BRADY	5 consecutive QRS complex, RR interval is longer than 1.5s.
MISSED BEATS	When HR is less than 100 beats/min., no heart beat is tested during the period 1.75 times of the average RR interval; or When HR is higher than 100beat/min, no beat is tested within 1 second.
IRR	The patient has irregular heart rate, check patient's condition, electrodes, cables and leads
PNC	After the pacemaker is paced, QRS complex can not be detected during 300ms.

ARR Types	Occurring Condition
PNP	After the QRS complex, no pace is detected during 1.75 times of RR interval.
VBRADY	The patient has irregular HR, and his average HR is less than 60bpm. Check his condition, electrodes, cables and leads.
VENT	The patient has irregular heart rate, check patient's condition, electrodes, cables and leads.

8.8.2 ARR Analysis Menu

8.8.2.1 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.

8.8.2.2 PVCs Alarm

Select **On** in the menu to enable prompt message when an alarm occurs; select **Off** to disable the alarm function, and there will be a symbol  beside **PVCs**.

WARNING

When the PVCs 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.

8.8.2.3 ARR Relearning

Pick this item to start a learning procedure, and **ECG ARR LEARNING** is displayed on the screen. The ECG ARR LEARNING will start automatically in the following status:

- Connecting leads;
- Starting ARR learning manually;
- Switching calculation leads.

8.8.2.4 ARR Alarm

The users can switch on or off all arrhythmia alarms by selecting **ECG Setup > ARR Analysis > ARR Alarm**. And some arrhythmia alarms can be individually switched on or off. They are: **ASYSTOLE**, **VFIB/VTAC**, **R-ON-T**, **VT>2**, **COUPLET**, **PVC**, **BIGEMINY**, **TRIGEMINY**, **TACHY**, **BRADY**, **MISSED BEATS, IRR, PNC, PNP, VBRADY** and **VENT**.

To switch individual alarm on or off, select **ECG Setup > ARR Analysis > ARR Alarm**. The user can set the individual ARR alarm from the popup interface.

Chapter 9 Monitoring RESP

9.1 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.

9.2 RESP Safety Information

WARNING

1 If you do not set the detection level for the respiration correctly in manual detection mode, it may not be possible for the monitor to detect apnea. If you set the detection level 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 The respiration measurement does not recognize obstructive and mixed apneas - it only indicates an alarm when a pre-adjusted time has elapsed since the last detected breath.

3 If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3V/m), field strengths above 1V/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.

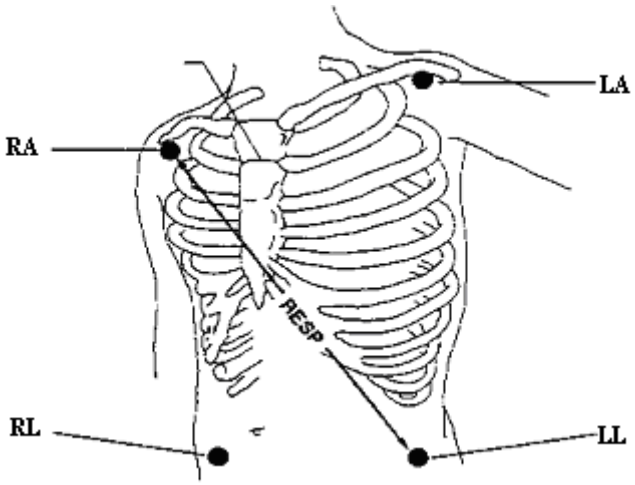
NOTE:

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

9.3 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-lead

9.4 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.

9.5 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 midaxillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave.

9.6 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.

9.7 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.

9.8 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.

9.9 Changing the Size of the Respiration Wave

Select the RESP waveform area to open the **Resp Wave Setup** menu:

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

9.10 Changing the Apnea Time

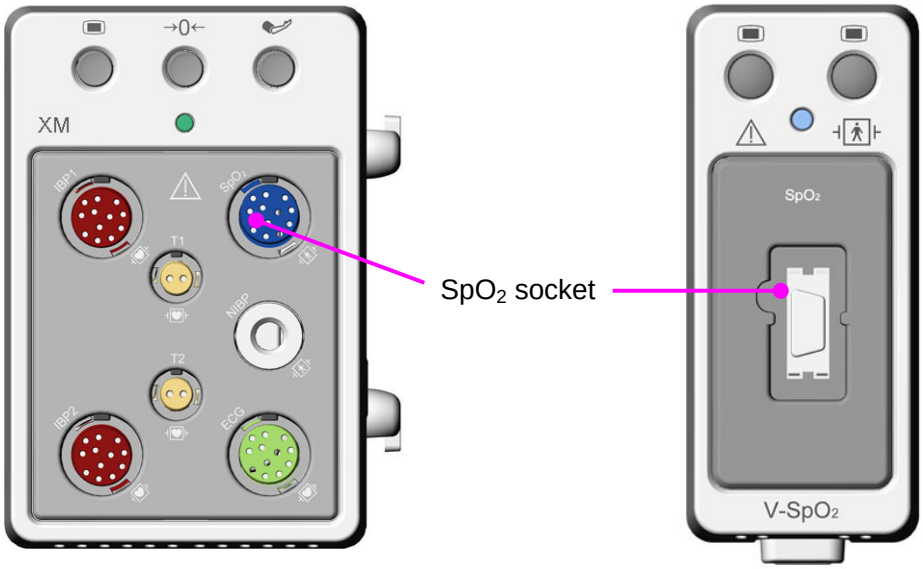
The apnea alarm is a high priority red alarm used to detect apneas. The apnea alarm delay time defines the time period between the point where the monitor cannot detect any respiration activity and the indication of the apnea alarm.

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

Chapter 10 Monitoring SpO_2

10.1 Overview

SpO_2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO_2 measuring unit. SpO_2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% of the hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the monitor will read 97%. The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.



10.2 SpO_2 Safety Information

WARNING

1 If the SpO_2 sensor can not work properly, please reconnect the sensor or change a new one.

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

3 Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. More frequent examinations may be required for different patients.

WARNING

4 Tissue damage may be caused by incorrect application or prolonged measurement duration using the sensor (more than 4 hours). Inspect the sensor periodically according to the sensor user manual.

5 Neonate SpO_2 sensor can only be used when required, no more than 20 min at a time.

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

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

NOTE:

1 Make sure the nail covers the light window. The wire should be on the backside of the hand.

2 SpO_2 waveform is not proportional to the pulse volume.

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

4 Don't use the functional tester to access the SpO_2 accuracy.

5 The device is calibrated to display functional oxygen saturation.

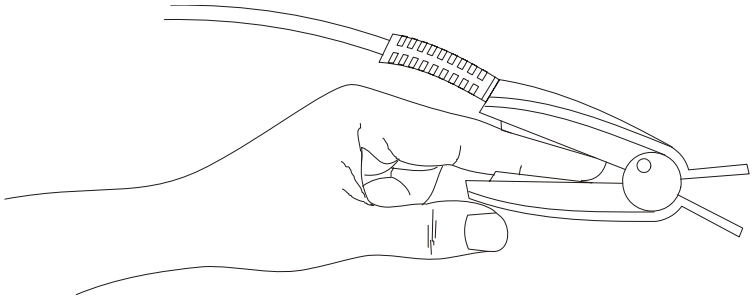
6 The materials with which the patient or any other person can come into contact conform with the standard of ISO10993.

10.3 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 finger.
3. Plug the connector of the sensor extension cable into the SpO_2 socket on XM module or V-SpO_2 module.



Mounting of the Sensor

WARNING

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

NOTE:

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

Interference can be caused by:

- High levels of ambient light or strobe lights or flashing lights (such as fire alarm lamps). (Hint: cover application site with opaque material.)
- High-frequency electrical noise, including electro-surgical apparatus and defibrillators
- Intravascular dye injections
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin
- Excessive patient movement and vibration
- Improper sensor application
- Low perfusion or high signal attenuation
- Venous pulsation
- Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line

10.4 Setting SpO_2 as Pulse Source

1. In the **PR Setup** menu, select **PR Source**;
2. Select **SpO_2** from the pop-up list.

10.5 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**.

10.6 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.

Chapter 11 Monitoring PR

11.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). You can display a pulse from any measured SpO_2 signal or any arterial pressure.

11.2 Setting PR Source

The monitor provides PR sources options, but currently only SpO_2 is supported. If the parameter as PR source is switched off, the monitor will switch based on priority. If all parameters producing SpO_2 are switched off, the PR parameter will be switched off.

11.3 Setting PR Volume

Six selections are available: **0, 1**, **2**, **3**, **4**, and **5**. **5** indicates the maximum volume. **0** indicates no sound. You can change **PR Volume** in the **PR Setup** menu.

11.4 Selecting the Active Alarm Source

In most cases, the HR and Pulse numerics are identical. In order to avoid simultaneous alarms on HR and Pulse, the monitor uses either ECG or Pulse as its active alarm source. To change the alarm source, select Alarm Source in the ECG/Pulse Alarms menu, then select

- **HR**: if you want HR to be the alarm source for HR/Pulse.
- **PR**: If you select Pulse as the active alarm source, the monitor will prompt you to confirm your choice. Be aware that if you select Pulse as the alarm source, ECG HR alarms are switched off.
- **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 at least one ECG lead can be measured without an technical alarm condition. The monitor will automatically switch to Pulse as the alarm source.

NOTE:

Pulse alarms are only generated when the active alarm source is set to **PR**, a pulse source is set as system pulse and pulse alarms are switched on.

Chapter 12 Monitoring NIBP

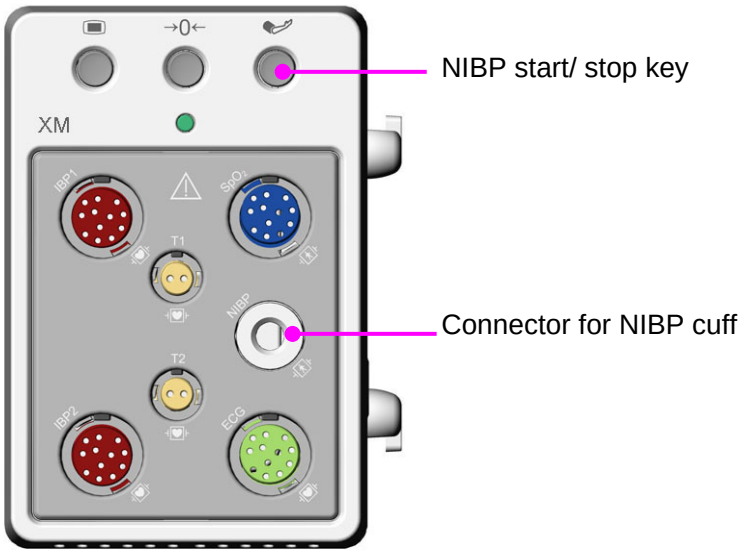
12.1 Overview

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients.

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

In adult and pediatric mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10-1992) in relation to mean error and standard deviation, when compared to auscultatory measurements in a representative patient population. For the auscultatory reference, the fifth Korotkoff sound was used to determine the diastolic pressure.

In neonatal mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10-1992) in relation to mean error and standard deviation, when compared to intra-arterial measurements in a representative patient population.



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

WARNING

3 Ensure that the correct setting is selected when performing measurements. It may be dangerous for the children to use an over pressure level.

4 The equipment is suitable for use in the presence of electrosurgery.

5 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.

6 Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, child or neonate.)

7 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

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

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 an alarm occurs or measurement fails, please discontinue the measurement.

3 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.

4 Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of patient.

12.3 Measurement Limitations

Measurements are impossible with heart 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.

12.4 Measurement Methods

There are three methods of measuring NIBP:

- Manual - measurement on demand.
- Auto - continually repeated measurements (between 1 and 480 minute adjustable interval).
- Sequence - the measurement will run consecutively in five minutes, then the monitor enters manual mode.

WARNING

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

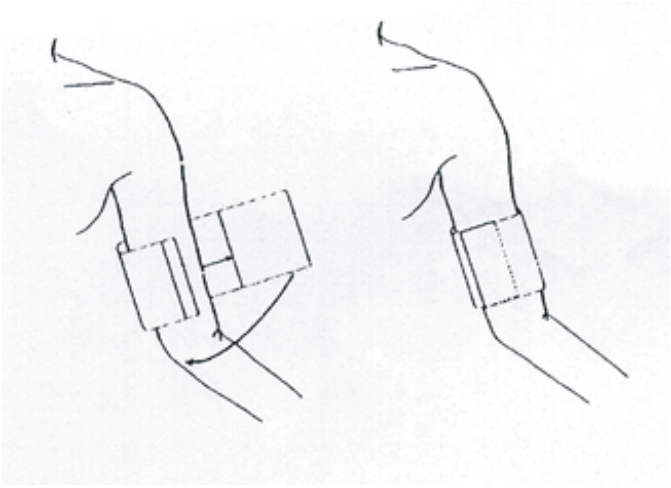
12.5 Measurement Procedures

1. Connect the air hose to the connector on XM module and switch on the monitor.
2. Apply the blood pressure cuff to the patient's arm or leg and follow the instructions below. Ensure that the cuff is completely deflated.

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

NOTE:

The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.



Cuff Usage

3. Connect the cuff to the air tubing.
4. Check whether the patient mode is appropriately selected. Access the **Patient Setup** menu from **Menu**. Turn the knob to select the required patient **Type** in the **Patient Info.** menu.
5. Select a measurement mode in the **NIBP Setup** menu. Refer to section ***Operation Prompts*** for details.
6. Press the button on the front panel to start a measurement.

NOTE:

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

12.5.1 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 to start a manual measurement.

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

2. Automatical Measurement

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Auto**, then press the  button on the front panel to start the automatical measurement according to the selected time interval.

3. Continuous measurement

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

4. Stopping continuous measurement

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

12.5.2 Correcting the Measurement if Limb is not at Heart Level

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

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

12.6 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.

12.7 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.

12.8 Calibrating NIBP

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

12.9 Leak Test

This item is used for leak test. Turn the knob to pick the **Leak Test** item in the **User Maintain > NIBP Maintain** menu to start the air leakage test. When the item is selected, it will change into **Stop**. If this item is selected again, the system will stop air leakage test. And the item returns to **Leak Test**.

WARNING

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

Procedure of Leak Test

- Connect the cuff securely with the socket for NIBP air hole.
- Wrap the cuff around the cylinder of an appropriate size.
- Access **User Maintain > NIBP Maintain**.
- Turn the knob to the **Leak Test** item and press the item. Then the prompt of **Leak Testing** will appear indicating that the system has started performing leak test.
- The system will automatically inflate the pneumatic system to about 180 mmHg.
- After 20 seconds, the system will automatically open the deflating valve, which marks the completion of a pneumatic measurement.
- If the prompt of **Leak Test OK** appears, it indicates that the airway is in good situation and no air leaks exist. However if the alarm information of **NIBP Cuff Leak** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the pneumatic test. If the failure prompt still appears, please contact the manufacturer for repair.

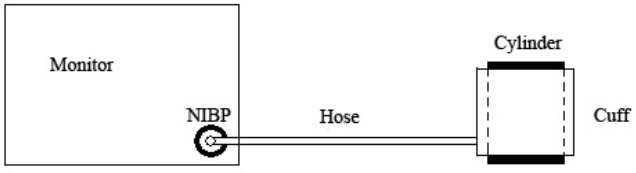


Diagram of NIBP Air Leakage Test

12.10 Setting Inflation Mode

To change the inflation mode, you can:

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

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

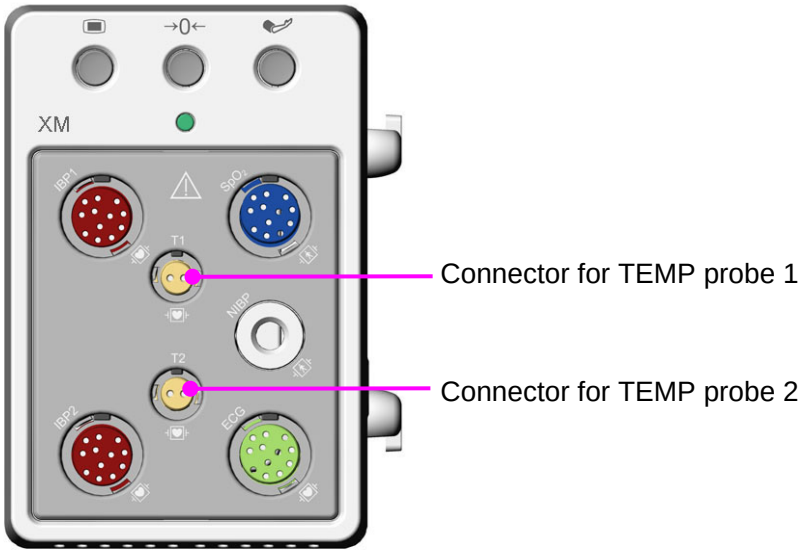
- If **Manual** is chosen, the preset value by users will be adopted as the inflation value when measuring blood pressure.
- If **AUTO** is chosen, the default value will be adopted as the inflation value when measuring blood pressure.

Chapter 13 Monitoring TEMP

13.1 Overview

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is inserted in the rectum.

Two TEMP probes can be used simultaneously to measure two TEMP values, and get the temperature difference. The standard configuration is axilla sensor for adult.



13.2 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 audible 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.

NOTE:

Disposable TEMP probe can only be used once for one patient.

13.3 TEMP Monitoring Setup

- If you are using disposable TEMP probes, you need to plug the TEMP cable into the connector for TEMP probe on XM module and then connect the probe to the cable. With a reusable TEMP probe you can plug the probe directly into the TEMP connector on XM module.

- Apply the TEMP probes securely to the patient.
- Switch on the monitor

It takes 5 minutes for the temperature measurement to stabilize.

13.4 Calculating Temp Difference

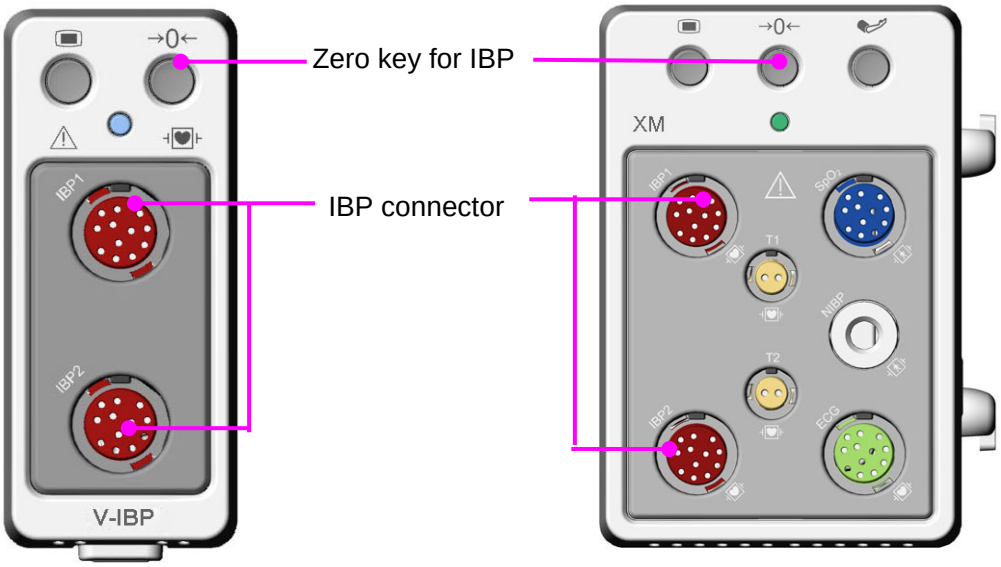
The monitor can calculate and display the difference between two temperature values by subtracting the second value from the first. The difference is labeled TD.

Chapter 14 Monitoring IBP

14.1 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 a maximum of eight channels, and displays waveforms and pressure of measured direct blood pressure (SYS, DIA and MAP).



14.2 IBP Safety Information

WARNING

1 The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.

2 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.

3 Disposable IBP transducer or domes should not be reused.

4 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.

NOTE:

1 Use only the pressure transducer listed in the IBP Accessories

2 Calibrate the instrument either whenever a new transducer is used, or as frequently as dictated by your Hospital Procedures Policy.

14.3 Monitoring Procedures

Preparatory steps for IBP measurement:

1. Plug the pressure cable into the IBP socket on XM module or V-IBP module and switch on the monitor.
2. Flushing through the system with normal saline solution. Ensure that the system is free of air bubbles.
3. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.
4. Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.
5. For the label name selection, please refer to Selecting a Pressure for Monitoring.
6. To zero the transducer, please refer to Zeroing the Pressure Transducer.

WARNING

If there are air bubbles in the pressure line or the transducer, you should flush the system with the solution to be infused.

14.3.1 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
CVP	Central venous pressure
ICP	Intracranial pressure
LAP	Left atrial pressure
RAP	Right atrial pressure
P1-P2	Alternative non-specific pressure labels

14.3.2 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.

14.3.3 Zeroing a Pressure Measurement

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**.
4. When you see the message **Zero Ok**, please close the stopcock to atmospheric pressure, and open the stopcock to the patient.

14.3.4 Troubleshooting the Pressure Zeroing (Taking Art for Example)

The status message lists the probable cause of an unsuccessful calibration.

Message	Corrective Action
Art ZERO FAIL	Make sure that the transducer is not attached to the patient
Art SENSOR OFF, FAIL	Make sure that transducer is not off, and then proceed zeroing
IN DEMO, FAIL	Make sure that the monitor is not in DEMO mode. Contact service technician if necessary
PRESSURE OVER 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.

14.3.5 IBP Pressure Calibration

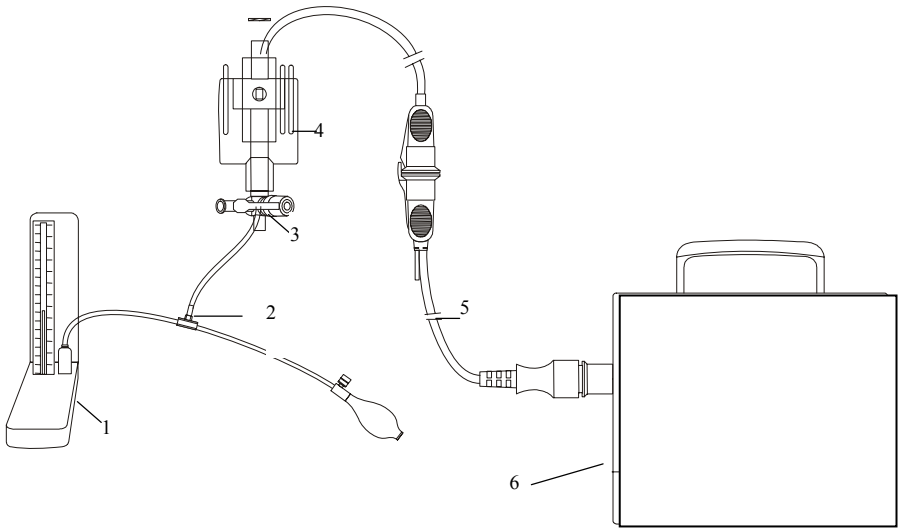
1. Mercury calibration should be performed by the biomedical engineering department either whenever a new transducer is used, or as frequently as dictated by your Hospital Procedures Policy.
2. The purpose of the calibration is to ensure that the system gives you accurate measurements.

3. Before starting a mercury calibration, a zero procedure must be performed.

If you need to perform this procedure yourself, you will need the following equipment: Standard sphygmomanometer, 3-way stopcock and Tubing (approximately 25 cm long).

The calibration procedure is listed below:

1. Close the stopcock that was open to atmospheric pressure for the zero calibration.
2. Attach the tubing to the sphygmomanometer.
3. Ensure that connection to patient is off.
4. Connect the 3-way connector to the 3-way stopcock that is not connected to the patient catheter.
5. Open the port of the 3-way stopcock to the sphygmomanometer.
6. Select the channel to be calibrated in the menu and select the pressure value to which the IBP is to be adjusted.
7. Inflate to make the mercury bar rise to the setup pressure value.
8. Adjust repeatedly until the value in the menu is equal to the pressure value shown by the mercury calibration.
9. Press the Start button, the device will begin calibrating.
10. Wait for the calibrated result. You should take corresponding measures based on the prompt information.
11. After calibration, disassemble the blood pressure tubing and the attached 3-way valve.



1: Hydrargyrum pressure meter; 2: 3-way connector; 3: 3-way stopcock; 4: Pressure transducer; 5: Pressure transducer interface cable; 6: Monitor

IBP Calibration

14.3.6 Troubleshooting the Pressure Calibration

The status line lists the probable reasons of an unsuccessful calibration.

Message	Corrective Action
Sensor Off, Fail!	Make sure that sensor is not off, then start the calibration. Contact service technician if necessary.
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 you have selected transducer value in IBP CAL, and then start the calibration. Contact service technician if necessary.
Pulsate Pressure Calibration Fail	Make sure that pressure value shown by hydrargyrum pressure meter is changeless. Contact service technician if necessary.

14.4 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**.

Chapter 15 Monitoring CO_2

15.1 Overview

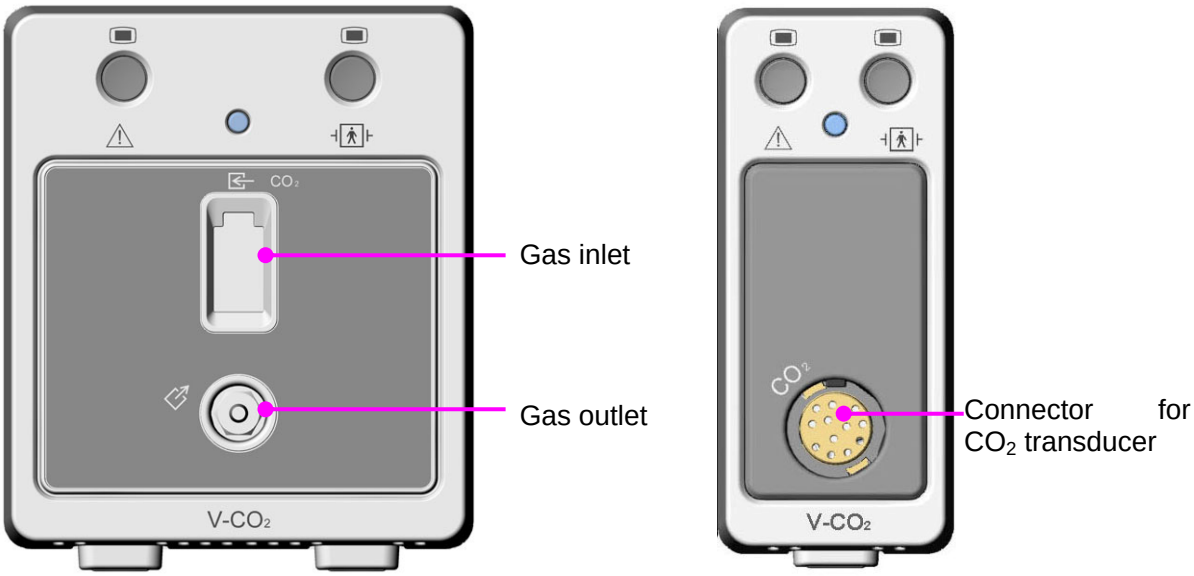
The monitor provides the SideStream and MainStream methods for CO_2 monitoring.

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 CO_2 sensor. You can measure SideStream CO_2 using the monitor's built-in CO_2 measurement.
- MainStream measurement uses a CO_2 sensor attached to an airway adapter directly inserted into the patient's breathing system.

Identifying CO_2 Modules

From left to right are: sidestream CO_2 module and mainstream CO_2 module.



15.2 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.

WARNING

4 The monitor will be damaged if any pipeline from the CO_2 module is disconnected, or the 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 In the presence of electromagnetic devices (i.e., electrocautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20V/m will not adversely affect module performance.

8 Do not place the sensor cables or tubing in any manner that may cause entanglement or strangulation.

9 Do not store the CO_2 Module at temperatures less than -40º F (-40º C) or greater than 158º F (70º C). Do not operate the CO_2 Module at temperatures less than 32ºF (0º C) or greater than 104º F (40º C).

NOTE:

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.

15.3 Monitoring Procedures

15.3.1 Zeroing the sensor

You must perform zeroing following the steps when using the new airway adapter.

1. Expose the sensor to room air and keep it away from all sources of CO_2 including the ventilator, the patient's breath and the operator's.
2. In the **CO_2 Setup** menu, please set the **Work Mode** to **Measure**.
3. In the **CO_2 Setup** menu, select **Zero Calibration**.
4. If the system briefly displays **Zero In Progress**, the process is successful. After the zeroing calibration is finished, you can start CO_2 Monitoring. If the system displays **Breath detected** or **Zero required**, zeroing has failed. Zero calibration must be performed again.

15.3.2 Sidestream CO_2 Module

NOTE:

1 You must perform a zero calibration as described in this procedure each time the ambient temperature changes more than 10°C (for example during transport).

2 Disconnect the cannula, airway adapter or sample line from the sensor when they are not in use.

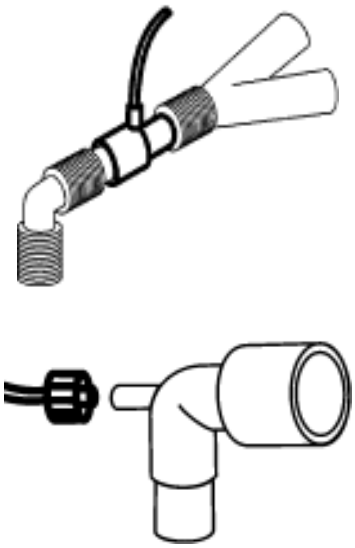
15.3.2.1 Measurement Steps

1 Plug the sensor cable into the CO_2 input connector on the sidestream CO_2 module. Allow the sensor two minutes for warm-up.

2 Connect the cannula, airway adapter, or sample line as required to the sensor. It will click into place when seated correctly.

3 To zero the sensor, please refer to zeroing the sensor.

4 For intubated patients, an airway adapter is required;



Air adapter

For non-intubated patients: Place the nasal cannula onto the patient.

Place the nasal cannula

NOTE:

1 Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.

2 Always disconnect the cannula, airway adapter or sample line from the sensor when the sensor is not in use.

15.3.2.2 Removing Exhaust Gases from the System

WARNING

Anesthetics: When using the sidestream CO_2 measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, to 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.

15.3.3 Mainstream CO_2 Module

NOTE:

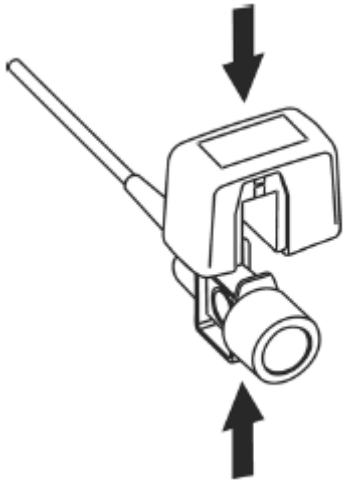
You must perform a zero calibration as described in this procedure each time you use a new airway adapter.

15.3.3.1 Measurement Steps

1 Attach the sensor connector to the CO_2 connector on the mainstream CO_2 module.

2 Wait two minutes, allowing the sensor to reach its operating temperature and a stable thermal condition.

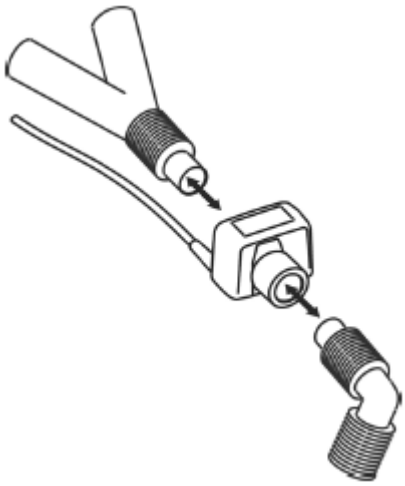
3 Choose the appropriate airway adapter and connect it to the sensor head. The airway adapter clicks into place when seated correctly.



Connecting Sensor

4 To zero the sensor, please refer to zeroing the sensor;

5 Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y-section.



Connecting Airway Adapter

WARNING

1 No routine user calibration required.

2 Accuracy is affected by temperature and barometric pressure.

NOTE:

1 Replace the airway adapter, if excessive moisture or secretions are observed in the tubing or if the CO_2 waveform changes unexpectedly without a change in patient status.

2 To avoid infection, use only sterilized, disinfected or disposable airway adapters.

3 Inspect the airway adapters prior to use. Do not use it if airway adapter appears damaged or broken. Observe airway adapter color coding for patient population.

4 Periodically check the flow sensor and tubing for excessive moisture or secretion buildup.

15.3.3.2 Removing Exhaust Gases from the System

WARNING

Anesthetics: when using the mainstream CO_2 measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, to avoid exposing medical staff to anesthetics.

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

15.4 Setting CO_2 Waveform Setup

Select the CO_2 waveform area to open the CO_2 waveform menu:

- Set **Mode** to **Curve** or **Filled** as your desire.
- Set **Sweep** to an appropriate value from the pop-up list. The bigger the value is, the quicker the speed is.

15.5 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. There are **Baro Press, O_2 Compens**, **Balance Gas** and **Anes Agent** in the **Other Setup** menu of the **CO2 Setup** menu and the user can select the desired item.

15.6 Changing Apnea Alarm

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

1. Select the **CO_2 Setup** menu to open it;
2. Select **Apnea Alm** from the menu;
3. 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.

15.7 Setting CO_2 Waveform

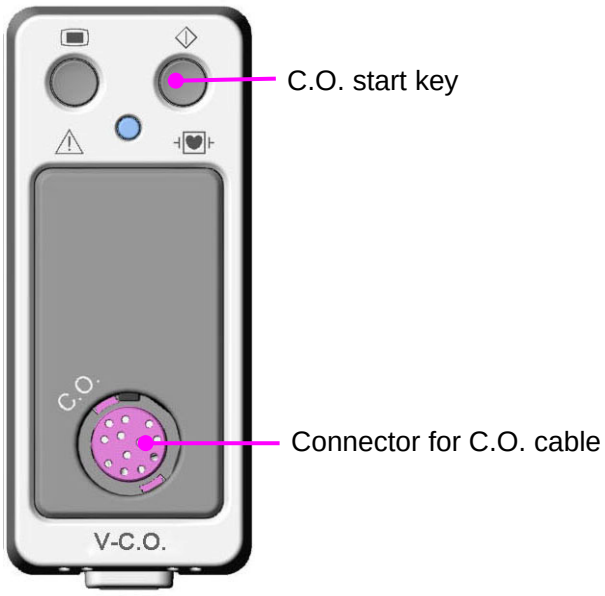
Open the menu **CO_2 Wave Setup** by clicking on the CO_2 waveform area:

- 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.

Chapter 16 Monitoring C.O.

16.1 Overview

The Cardiac Output (C.O.) measurement is performed by using Thermodilution method. The monitor can determine blood temperature, measure cardiac output, and perform hemodynamic calculations. You can have iced injecta using either the flow through system or individual syringes of injecta. You can perform up to 6 measurements before editing the average Cardiac Output. The prompt message on the screen will tell you when to inject.



16.2 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.

NOTE:

To replace the catheter thermistor, please enter the catheter computation coefficient into the **Constant** item according to the instruction.

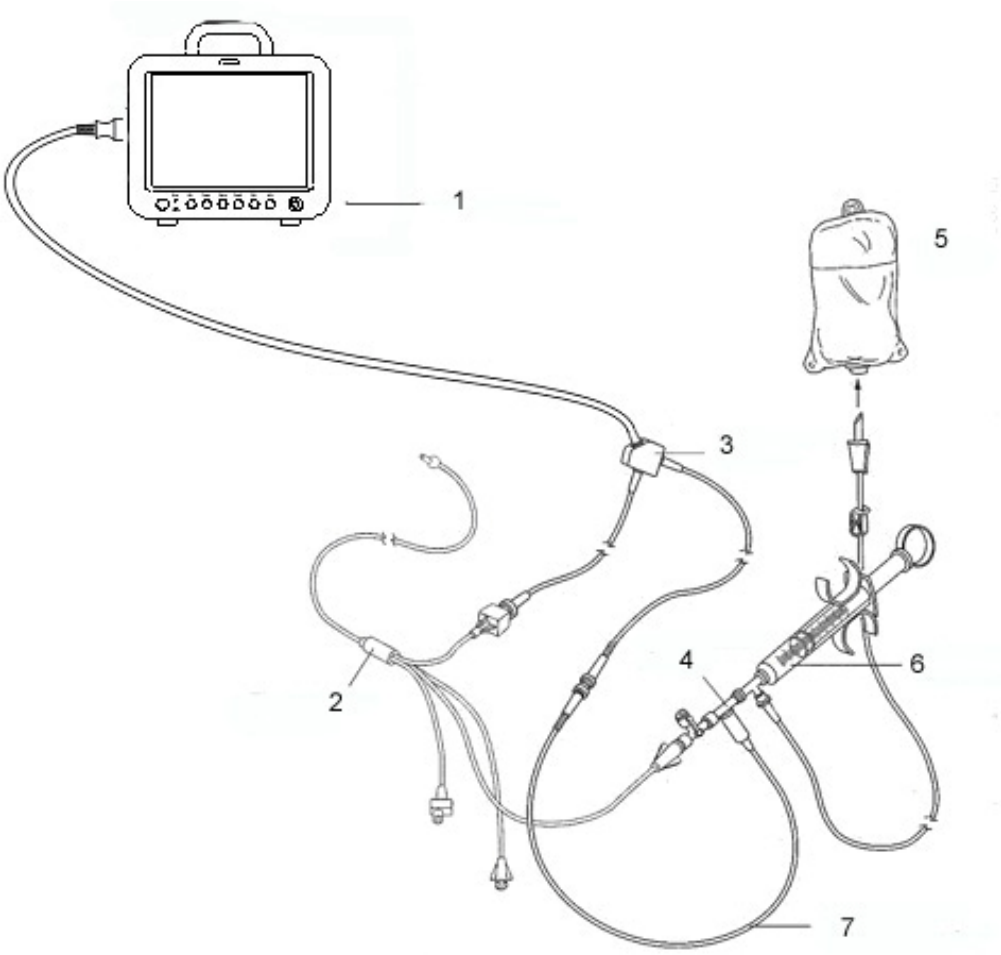
16.3 C.O. Monitoring Procedures

1. Plug the C.O. cable into the C.O. socket on V-C.O. module and turn on the monitor.
2. Attach the injectate probe connector and catheter thermistor connector to the appropriate parts of the cardiac output interface cable. And open the patient information window to confirm the patient's height and weight.

3. Pick the **CO Measure** item in the **CO Option** menu.

4. You can perform more than one measurement as required.

5. After the completion of the measurement, access the **CO Measure** window for **Review** to edit the measured data.



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

WARNING

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

NOTE:

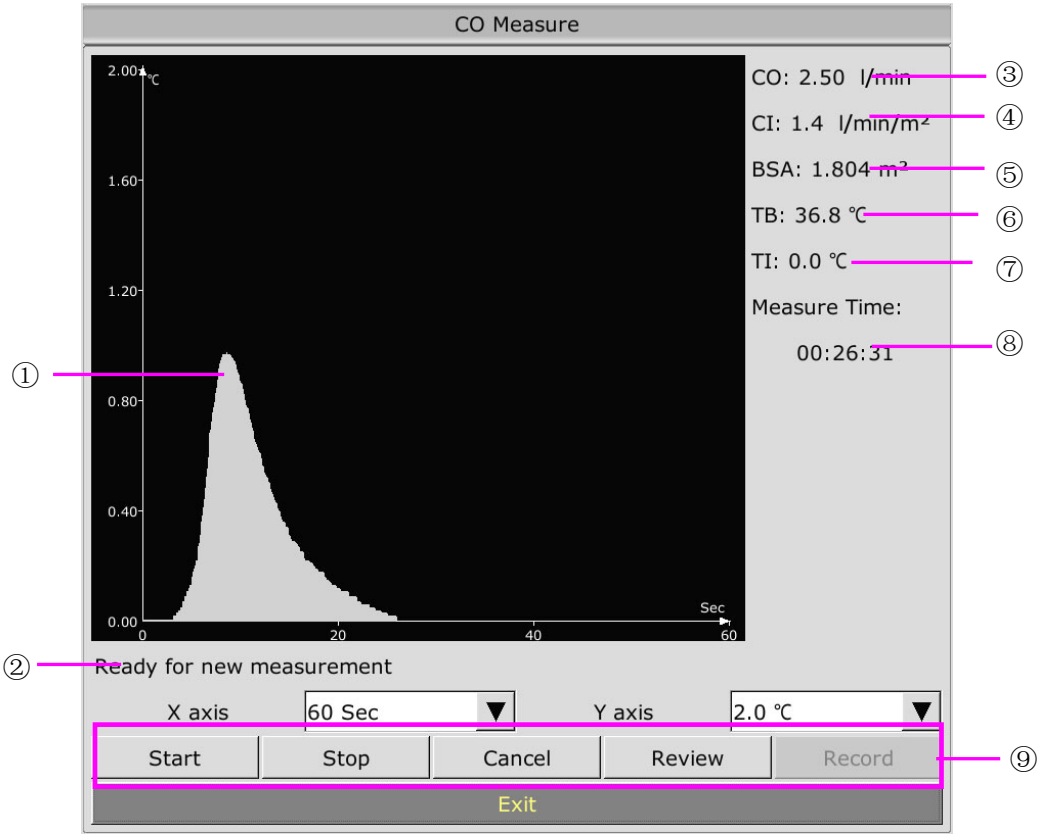
The blood temperature alarm will not function during C.O. measurement. It will resume automatically when the measurement is over.

16.4 C.O. Measurement Window

Select the **CO Option** menu to enter the **CO Measure** window and start C.O. measurement. If C.O. transducer is not connected, the monitor will display **No Sensor** on the screen.

NOTE:

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



C.O. Measure Window

①	Measurement curve
②	Prompt message area
③	Cardiac Output
④	Cardiac Index
⑤	Body Surface Area
⑥	Blood Temperature
⑦	Injectate Temperature
⑧	Start time of the measurement
⑨	Function keys

The functional keys on the CO 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.
Y axis	Change the scale Y (temperature) value. Three modes are available: 0~0.5°C, 0~1°C, 0~2.0°C. Adjust the scale by the temperature differences. A smaller scale results in a larger curve.
X axis	Change the Scale X (time) value. Two modes are available: 0~30s, 0~60s. If you start measurement in the 0~30s mode, it will be switched to 0~60s mode automatically if the measurement can not finish within 30 seconds. After the switch, no further adjustment can be made to the Scale X.
Review	Enter the **Review** window
Exit	Press the item to exit **CO Measure**.

16.5 Measurement Process

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 (③ and ④ 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 (⑧ 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 can not be performed until the time reduces to zero and a message **Ready for new measurement** appears.

NOTE:

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

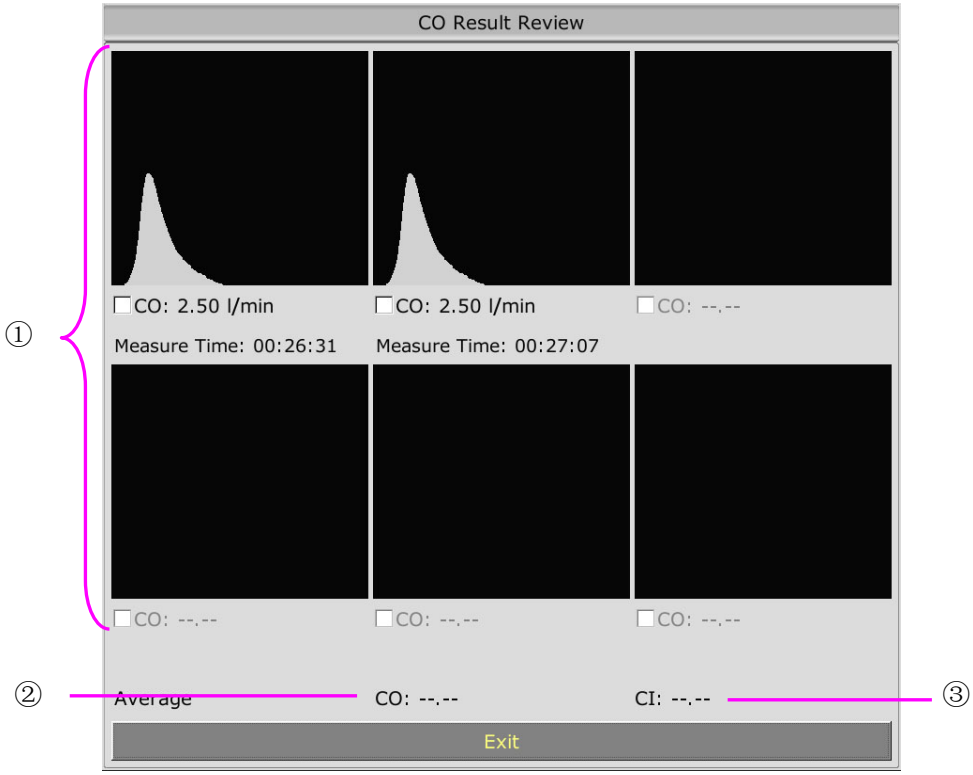
2 It is strongly recommended that you wait at least 1 minute (or longer depending on the patient's clinical condition) before starting the next measurement.

Repeat this procedure until you have completed the measurements you want.

You can perform a maximum of six measurement editing. If you perform additional measurements the earliest measurement each time will be deleted. If any of the curves in the editing window is not selected for calculation (excluded from the averaging calculations), the place will be taken by the new measurement.

16.6 Editing C.O.

Pick the **Review** button on the **CO Measure** menu to access the **Review** as shown below:



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

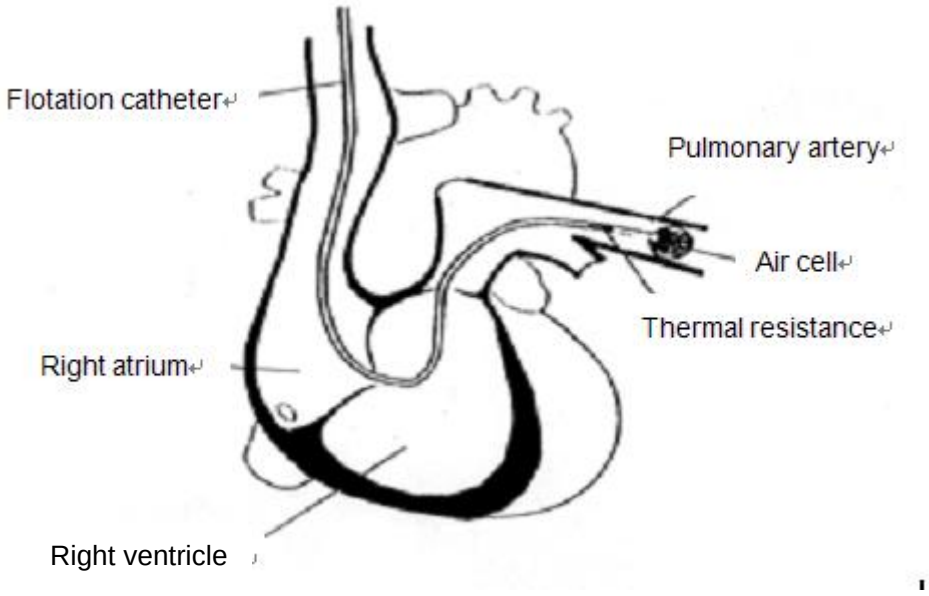
Values of selected measurements can be averaged and stored in the C.O. item in the HEMOD menu as the basis for Hemodynamic calculations.

16.7 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

16.8 Setting the Computation Constant

The computation constant is associated with catheter and injectate volume. When the catheter is changed, please adjust **Constant** in the **CO Settings** menu based on product description provided by the manufacturer.

16.9 Recording C.O. Measurements

C.O. measurement can be recorded by the recorder. To record the C.O. measurement, please select **Record** in the **CO Measure** menu.

16.10 Setting INJ. TEMP Source

To change the INJ Temp Source, please:

1 Select **Inj Temp Source** in the **CO Settings** menu;

2 Select **Auto** or **Manual** from the list;

- **Manual**: directly displaying the injectate temperature from INJ. TEMP.
- **Auto**: indicating the system obtains the injectate temperature through sampling.

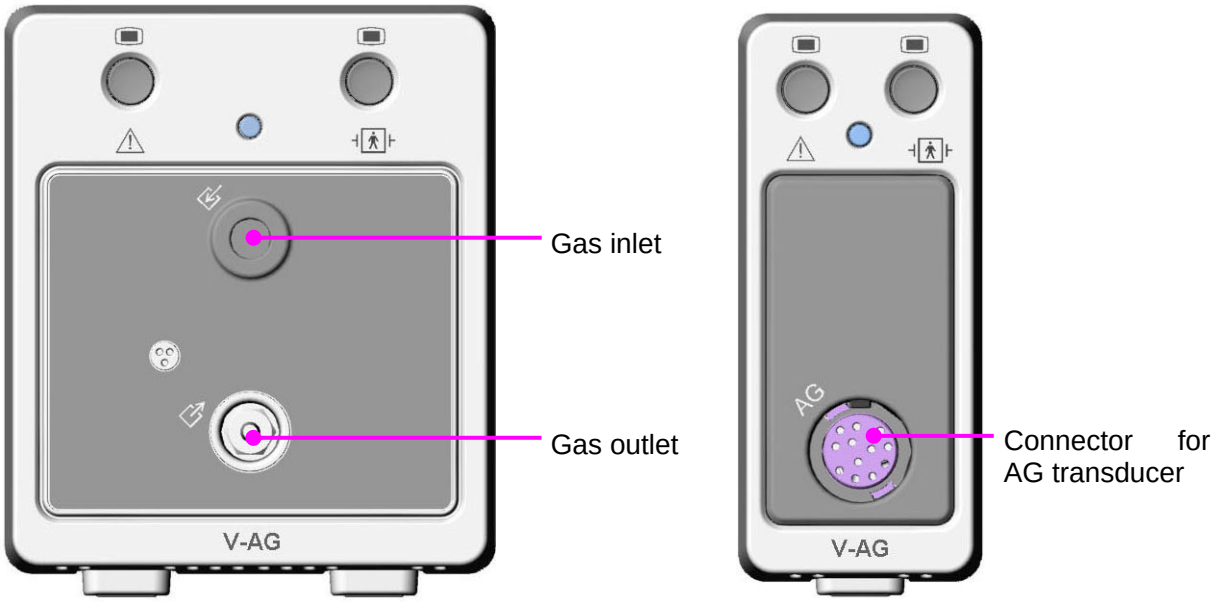
Chapter 17 Monitoring AG

17.1 Overview

The monitor uses ISA sidestreasm gas analyzer (hereinafter called ISA analyzer) and IRMA mainstream module (hereinafter called IRMA module) to monitor the anesthetic gas which can be used to measure the gases of adult, pediatric and neonatal patients during anesthesia, recovery and respiratory care. And the anesthetic gas includes Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), CO_2 and N_2O.

Identifying AG Module

From left to right are: sidestream AG module and mainstream AG module.



17.2 Safety Information

17.2.1 Safety Information for ISA Analyzer

WARNING

1 The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals only.

2 Use only Nomoline sampling lines manufactured by PHASEIN.

3 The ISA analyzer must not be used with flammable anesthetic agents.

4 Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.

5 Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination.

6 Do not lift the monitor by the sampling line as it could disconnect from the monitor, causing the monitor to fall on the patient.

WARNING

7 Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste; otherwise, it may cause environmental contamination.

8 Use only airway T-adapters with the sampling point in the center of the adapter.

9 Do only use sample lines intended for anesthetic agents if N2O and/or anesthetic agents are being used.

10 Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.

11 Do not use adult/pediatric type sampling line configurations with infants, as this may add dead space to the patient circuit.

12 Do not use infant type sampling line configurations with adults, as this may cause excessive flow resistance.

13 Do not use the ISA analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

14 Check that the gas sample flow is not too high for the present patient category.

15 Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.

16 The Nomoline sampling line and its interfaces are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.

17 Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.

18 ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

19 Replace the sampling line if the sampling line input connector starts flashing red, or a “Sample line clogged” message is displayed on the host.

20 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.

21 ISA analyzers are not designed for MRI environments.

22 During MRI scanning, the monitor must be placed outside the MRI suite.

23 Use of high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.

24 Use of high frequency electrosurgical equipment may enhance the risk of being burned; therefore, a static-free or conductive respiratory cannula is not recommended.

25 Do not use external ambient cooling of the ISA device.

WARNING

26 Do not apply negative pressure to remove condensed water from the Nomoline Family sampling line.

27 Too strong positive or negative pressure in the patient circuit might affect the sample flow.

28 Strong scavenging suction pressure might affect the sample flow.

29 Exhaust gases should be returned to the patient circuit or a scavenging system.

30 Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.

31 Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.

32 Do not sterilize or immerse Nomoline Family sampling lines in liquid.

33 Do not operate the ISA sidestream gas analyzer if the enclosure is damaged.

CAUTION

1 The ISA analyzers should be securely mounted in order to avoid the risk of damage to the ISA.

2 Do not apply tension to the ISA analyzer cable.

3 Do not operate the ISA analyzer outside the specified operating temperature environment.

4 The sidestream AG module configured with ISA OR+ analyzer is fragile and should be handled with care.

5 After plugging the module into the monitor, remember to connect the sampling line to the module to prevent dust ingress which may result in performance degradation.

17.2.2 Safety Information for IRMA Module

WARNING

1 The IRMA probe is intended for use by authorized and trained medical personnel only.

2 The IRMA probe must not be used with flammable anesthetic agents.

3 Disposable IRMA airway adapters shall not be reused. Used disposable airway adapters shall be disposed of in accordance with local regulations for medical wastes; otherwise, it may cause environmental contamination.

WARNING

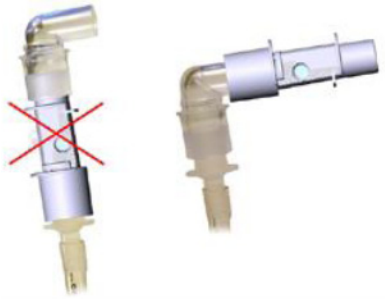
4 Do not use the IRMA Adult/Pediatric adapter with infants as the adapter adds 6 ml dead space to the patient circuit.

5 Do not use the IRMA airway adapter with adults as this may cause excessive flow resistance.

6 Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.

7 Use of high frequency electrosurgical equipment may enhance the risk of being burned; therefore, a static-free or conductive respiratory cannula is not recommended.

8 Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.



9 Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.

10 The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessment of clinical signs and symptoms.

11 Incorrect probe zeroing will result in false gas readings.

12 Incorrect agent selection by the user for IRMA AX (no automatic agent identification) will result in false agent readings.

13 Using IRMA AX (no automatic identification) with gas mixtures containing more than one agent will result in false agent readings.

14 Replace the adapter if rainout/condensation occurs inside the airway adapter.

15 Use only PHASEIN manufactured IRMA airway adapters.

CAUTION

1 Do not apply tension to the probe cable.

2 Do not operate the IRMA probe outside the specified operating temperature environment.

17.3 Monitoring Steps

17.3.1 Monitoring Steps for ISA Analyzer

17.3.1.1 Performing a Pre-use Check

Before connecting the Nomoline sampling line to the breathing circuit, do the following:

1. Connect the sampling line to the ISA gas inlet connector (LEGI).
2. Check that the LEGI shows a steady green light (indicating that the system is OK).
3. For ISA OR+ and ISA AX+ module with O_2 option fitted: Check that the O_2 reading on the monitor is correct (21%).
4. Breathe into the sampling line and check that valid CO_2 waveforms and values are displayed on the monitor.
5. Occlude the sampling line with a fingertip and wait for 10 seconds.
6. Check that an occlusion alarm is displayed and that the LEGI shows a flashing red light.
7. If applicable: Perform a tightness check of the patient circuit with the sampling line attached.

17.3.1.2 Leakage Check

1. Connect a new Nomoline sampling line with male luer lock to the ISA LEGI and check that the LEGI shows a steady green light.
2. Connect a short silicon tubing with an inner diameter of 3/32” (2.4 mm) to the Nomoline male luer.
3. Exhale a long breath into the silicon tubing until the CO_2 concentration is greater than 4.5 vol% or 34 mmHg.
4. Quickly connect the silicon tubing tightly to the exhaust port.
5. Wait 1 minute until the CO_2 concentration has stabilized. Note the value.
6. Wait 1 minute and check that the CO_2 concentration has not decreased more than 0.4 vol% or 3 mmHg. If it has decreased more there is a major leakage in the ISA unit or in the Nomoline. Do not operate the ISA if there is a major leakage in the unit.

17.3.1.3 System Setup for Analyzer

If your system is using the plug-in and measure ISA analyzer, please follow the setup instructions below:

1. Connect the ISA analyzer interface cable to the monitor.
2. Connect a Nomoline sampling line to the ISA analyzer input connector.
3. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit.
4. Power up the monitor.

5. A green LED indicates that the ISA analyzer is ready for use.
6. Perform a pre-use check as described in section Perform a pre-use Check.

17.3.1.4 Zeroing

The infrared module needs to establish a zero reference level for the CO_2, N_2O and anesthetic agent gas measurement. This zero calibration is here referred to as "zeroing".

ISA analyzer performs zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed every 24 hours, and takes less than 3 seconds for ISA CO_2 module and less than 10 seconds for ISA analyzer.

If the ISA analyzer is fitted with an oxygen sensor, the automatic zeroing will also include room air calibration of the oxygen sensor.

WARNING

Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the ISA analyzer is placed in a well ventilated place. Avoid breathing near the ISA analyzer before or during the zeroing procedure.

17.3.1.5 Cleaning

The ISA sidestream gas analyzers and Nomoline Adapter can be cleaned using a cloth moistened (not wet) with max 70% ethanol or isopropyl alcohol.

To prevent cleaning liquids and dust from entering the ISA gas analyzer through its LEGI connector, keep the Nomoline Family sampling line connected while cleaning the analyzer.

CAUTION

Never sterilize or immerse the ISA sidestream gas analyzer in liquid.

17.3.1.6 Maintenance

Once every year, or whenever gas readings are questionable, perform a leakage check according to section 17.3.1.2 and verify gas readings with a reference instrument or with calibration gas.

WARNING

The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any parts of the sampling line.

17.3.1.7 Replacement of Consumables

The Nomoline and Nomoline Airway Adapter Set are single-patient use products.

The Nomoline Adapter is a multiple-patient use product.

The T-adapter and Nomo Extension are single-patient use products.

All consumables mentioned above should be replaced according to good clinical practice or when an occlusion message appears. Occlusion occurs when the sample flow is too low. This is indicated by a flashing red LEGI together with a message on the monitor.

17.3.1.8 MAC Calculation

The MAC value is calculated and displayed by using end-tidal (Et) gas concentrations according to the following formula:

$$MAC = \frac{\%Et(AA1)}{X(AA1)} + \frac{\%Et(AA2)}{X(AA2)} + \frac{\%Et(N2O)}{100}$$

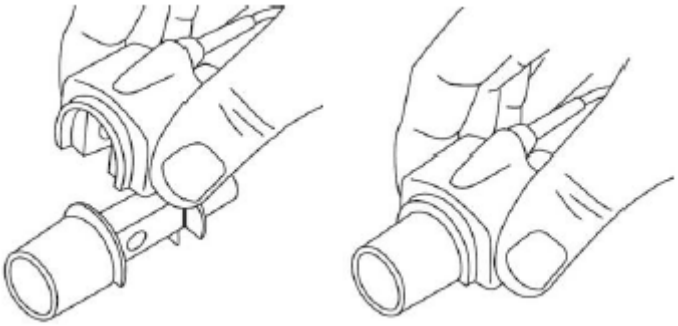
X (AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

NOTE:

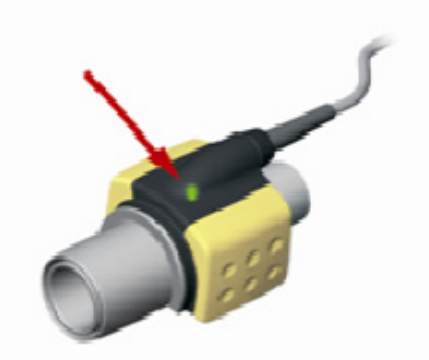
Altitude, patient age and other individual factors are not considered in the formula above.

17.3.2 Monitoring Steps for IRMA Module

1. Plug the IRMA connector into the IRMA input and switch the power on.
2. Snap the IRMA sensor head on the top of the IRMA airway adapter. It will click into place when properly seated.



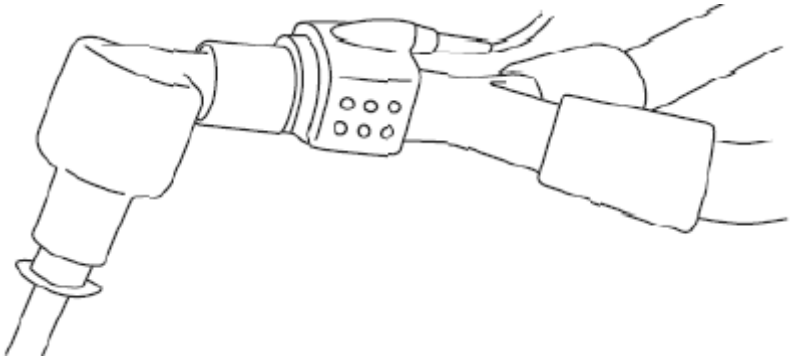
3. A green LED indicates that the IRMA probe is ready for use.



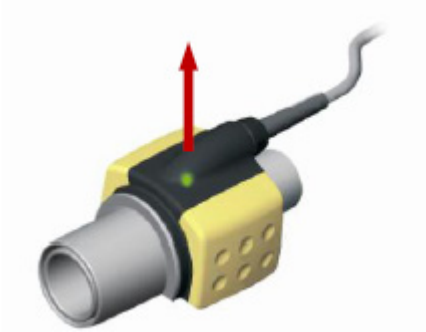
4. Connect IRMA /airway adapter 15mm male connector to the breathing circuit Y-piece.

5. Connect the IRMA /airway adapter 15mm female connector to the patient's endotracheal tube.

Alternatively, connect an HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IPMA probe. Placing an HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.



6. Unless the IRMA probe is protected with an HME always position the IRMA probe with the status LED pointing upwards.



17.3.2.1 Placement of IRMA Probe

When connecting IRMA probe to an infant patient circuit, it is important to avoid a direct contact between the IRMA probe and the infant's body. If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body, an insulation material shall be placed between the IRMA probe and the body.

WARNING

The IRMA probe is not intended to be in long term skin contact.

17.3.2.2 Performing a Pre-use Check

Prior to connecting the IRMA airway adapter to the breathing circuit, verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.

Perform the tightness check of the patient circuit with the IRMA probe snapped on the IRMA airway adapter.

17.3.2.3 Zeroing

WARNING

Incorrect probe zeroing will result in false gas readings.

In order to secure high precision of the IRMA probe measurements the following zeroing recommendations should be followed.

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the host instrument to transmit a zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the zeroing procedure. The presence of ambient air (21% O_2 and 0% CO_2) in the IRMA airway adapter is of crucial importance for a successful zeroing. If a "Zero Required" alarm should appear directly after a zeroing procedure, the procedure has to be repeated.

Always perform a pre-use check after zeroing the probe.

Zeroing for IRMA CO_2 probes:

Zeroing needs to be performed ONLY when an offset in gas values is observed, or when an unspecified accuracy message is displayed.

Allow 10 seconds for warm up of the IRMA CO_2 probe after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

Zeroing for IRMA AX+ probes:

Zeroing should be performed every time the IRMA airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy message is displayed.

Allow 30 seconds for warm up of the IRMA AX+ probes after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

17.3.2.4 Cleaning

The IRMA probe can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA airway adapter prior to cleaning the IRMA probe.

CAUTION

1 The IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.

2 Never sterilize or immerse the IRMA probe in liquid.

17.3.2.5 Maintenance

Gas readings should be verified at regular intervals with a reference instrument or by conducting the gas check. The suggested interval is once every year.

17.3.2.6 MAC Calculation

The MAC value is calculated and displayed by using end-tidal (ET) gas concentrations according to the following formula:

$MAC=\%ET(AA_1)/X(AA_1)+\%ET(AA_2)/X(AA_2)+\%ET(N_2O)/100$

X(AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

17.4 Setting Work Mode

There are two woke modes: **Measure** and **Standby**. To change the work mode, please refer to the following steps:

1 Select the **CO_2 (AG)**/ **O_2**/ **N_2O**/ **AA**/ **HAL**/ **ENF**/ **ISO**/ **SEV**/ **DES Setup** menu;

2 Select **Work Mode** on the interface and select **Measure** or **Standby** from the pull-down list.

17.5 Setting Apnea Alarm Time

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

1 Select the **CO_2 (AG) Setup** > **Apnea Alarm**;

2 Choose the apnea alarm time from the pull-down list.

17.6 Working Status of ISA analyzer

Working status of the ISA analyzer can be indicated by the indicator. For the detailed information, please refer to the following table.

Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check sampling line

17.7 Working Status of IRMA Module

The working status of the IRMA module can be transmitted by the IRMA probe. For the detailed information, please refer to the following table.

Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check adapter

17.8 N_2O and O_2 Compensations

The following models need O_2 compensation: IRMA AX+, IRMA CO_2, ISA AX+, ISA CO_2. The following models need N_2O compensation: IRMA CO_2 and ISA CO_2. For the compensation details, please refer to the following table.

O_2 Range	Set O_2 Range
0~30 vol%	21
30~70 vol%	50
70~100 vol%	85

N_2O Range	Set N_2O Range
0~30 vol%	0
30~70 vol%	50

17.9 Effects of Humidity

The partial pressure and the volume percentage of CO_2, N_2O, O_2 and anesthetic agents depend on the amount of water vapor in the measured gas. The O_2 measurement will be calibrated to show 20.8 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure. 20.8 vol% O_2 corresponds to the actual O_2 concentration in room air with 0.7 vol% H_2O concentration (at 1013 hPa this equals for example 25°C and 23% RH). The measurement of CO_2, N_2O, and anesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS).

When the breathing gas flows through the sampling line, the gas temperature will adapt to ambient before reaching the gas analyzer. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.

If CO_2 values at BTPS are required, the following equation can be used:

$$EtCO2(BTPS) = EtCO2 * \left(1 - \left(\frac{3.8}{Pamb}\right)\right)$$

where:

$EtCO_2$ = $EtCO_2$ value sent from ISA [vol %]

Pamb = Ambient pressure sent from ISA [kPa]

3.8 = Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa]

$EtCO_2(BTPS)$ = $EtCO_2$ gas concentration at BTPS [vol%]

O_2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H_2O.

Chapter 18 Freeze

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 12 minutes. 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.

18.1 Entering/Exiting Freeze Status

18.1.1 Entering Freeze Status

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

18.1.2 Exiting Freeze Status

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

- Select the **Exit** option in/from the **Freeze** menu;
- Press the  button on the control panel 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, 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 repeatedly over a short period of time may result in discontinuous waveforms on the screen.

18.2 Reviewing Frozen Waveform

By moving the waveform, you may review a waveform of 12 minutes before it is frozen. For a waveform of less than 12 minutes, the remaining part is displayed as a straight line. Use the rotary snob on the control panel to move the cursor to the **Review** option in the **Freeze** menu. Press the knob. By turning the knob left or right, frozen waveforms on the screen will move left or right correspondingly. There is an arrow indicating upward on the right side of the last waveform.

Chapter 19 Review

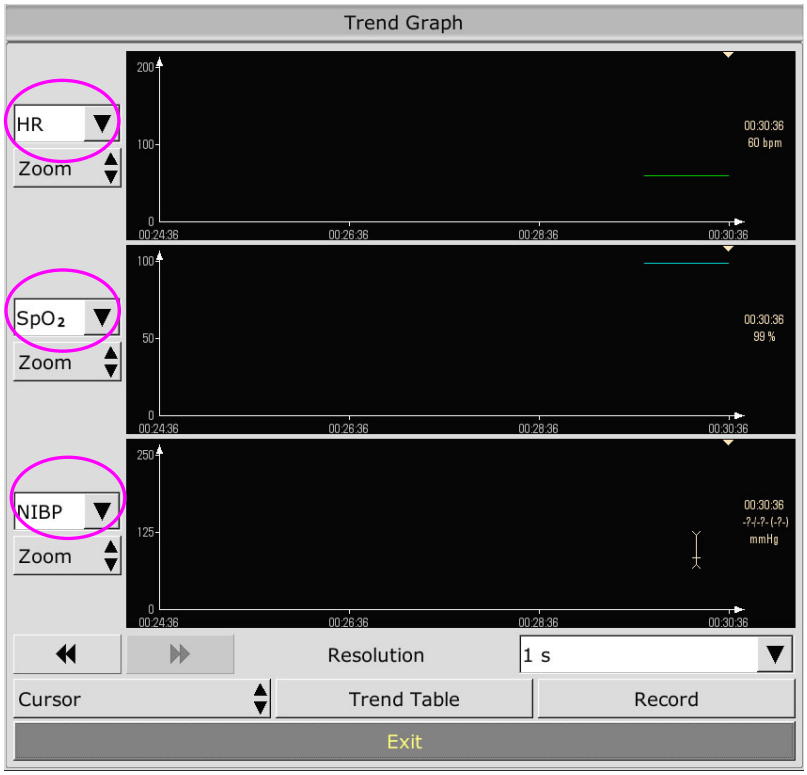
The monitor provides 150-hour trend data of all parameters, storage of 1200 NIBP measurement results and 200 alarm events. This chapter gives detailed instruction for review of all data.

19.1 Trend Graph Review

- The latest 1-hour trend is displayed every 1 or 5 seconds.
- The latest 150-hour trend is displayed every 1, 5 or 10 minutes.

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

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



19.1.1 Selecting Trend Graph of Specific Parameter

The monitor can review trend graph of different parameters. To change the existing trend graph, please select **Menu** > **Review** > **Trend Graph** and select a required parameter name from the popup list (as shown in red text in the above figure).

19.1.2 Setting Resolution

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

19.1.3 Scrolling Left and Right the Screen

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

19.1.4 Switching to the Trend Table

The user can switch to the trend table interface on the **Trend Graph** interface. To do so, please select **Menu** > **Review** > **Trend Graph** and select the **Trend Table** option from the popup interface.

19.1.5 Record

The monitor can make a tabular trend recording of the data in the current trend graph window. The report will use the current trend interval settings. For the detailed information about recording the trend graph, please refer to Chapter *Recording*.

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**, then the trend table is displayed.

19.2.1 Setting Resolution

The monitor can support seven kinds of interval. To set an appropriate resolution, please select **Menu** > **Review** > **Trend Table** and an interface is displayed. Choose **Resolution** on the interface to open the list and select an appropriate interval among **1 sec**, **5 sec**, **1 min**, **5 min**, **10 min**, **30 min** and **60 min**.

19.2.2 Scrolling the Screen

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

19.2.3 Switching to Trend Graph

The user can switch to the trend graph on the **Trend Table** interface. To do so, please select **Menu** > **Review** > **Trend Table** and select the **Trend Graph** option from the popup interface.

19.2.4 Recording

The monitor can make a tabular trend recording of the data in the current trend graph window. The report will use the current trend interval settings. For the detailed information about recording the trend table, please refer to Chapter *Recording*.

19.3 NIBP Review

To review the NIBP measurement data, select the **NIBP Review** key on the screen or select **Menu** > **Review** > **NIBP Review,** then the **NIBP Review** window is displayed.

19.3.1 Scrolling the Screen

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

19.3.2 Recording

The monitor can record the measurement data in the NIBP review window. For the detailed information about recording the NIBP review, please refer to Chapter *Recording*.

19.4 Alarm Review

The monitor can display up to 8 alarm events in the current screen.

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

19.4.1 Scrolling the Screen

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

19.4.2 Selecting Alarm Event of Specific Parameter

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

19.4.3 Setting Time Index

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

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

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

19.5 Arr Review

Select **ECG Setup** > **Arr Analysis**> **Arr Review** or **Menu > Review > Arr Review** to open the Arr review interface**.** The interface displays the latest arrhythmia events.

19.5.1 Scrolling the Screen

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

19.5.2 Arrhythmia Alarm Review

You may select an alarm event by the knob 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-scecond waveform.
- Select **Record** and output the arrhythmia waveform by the recorder.
- Select another name from the pull-down list of **Rename** for the arrhythmia event to change its name.
- Select **Delete** to remove a specific arrhythmia event.
- Select **Alarm List** or **Exit** to get back to the arrhythmia review interface.

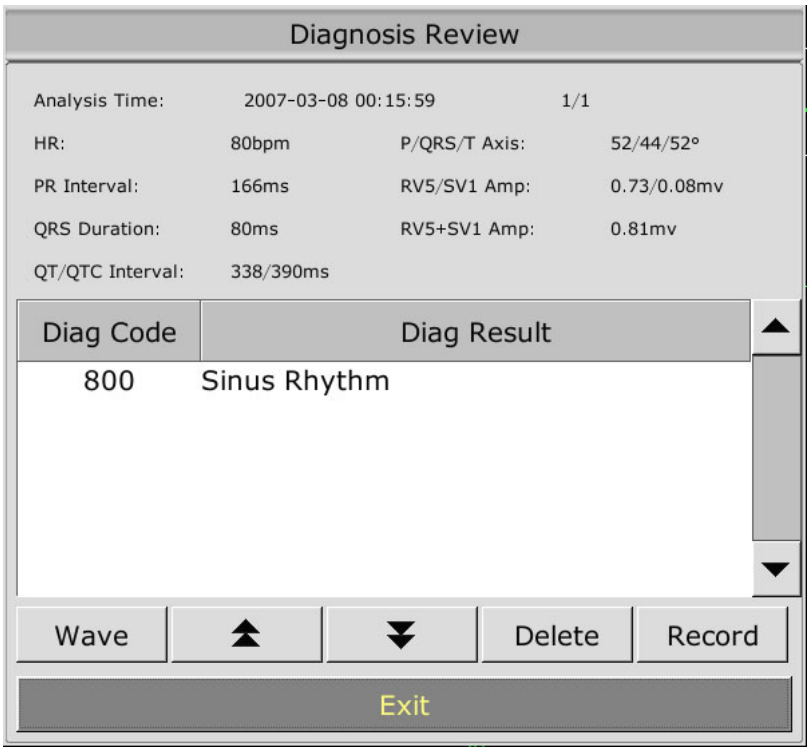
NOTE:

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.

19.6 12-lead Diagnosis Review

Select **Menu** > **Review** > **Analysis Review** to open the 12-lead analysis review interface.



19.6.1 Scrolling the Screen

All analysis results or waveforms can't be displayed on the current screen due to the screen limitation. The user can scroll up and down the screen manually to see the analysis results or waveforms that do not fit in the current view by selecting and pressing the symbol and displayed on the 12-lead analysis review interface.

19.6.2 Deleting Diagnosis Results

The user can delete the analysis results displayed on the current screen by selecting **Delete** on the interface.

19.6.3 Switching Between Waveforms and Results

The user can review the analysis waveforms on the analysis result interface by selecting the **Wave** option and review the analysis results on the analysis waveform interface by selecting the **Results** option.

19.6.4 Recording

The monitor can record the 12-lead diagnosis waveforms or results displayed on the current screen. To do so, press **Record** on the interface. For the detailed information about recording the diagnosis waveforms or results, please refer to Chapter *Recording*.

Chapter 20 Calculation and Titration Table

The monitor provides calculation 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 is not described in this Instructions for Use. To perform one calculation, select **Menu** > **Common Function** > **Drug Dose**.

NOTE:

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

20.1 Drug Calculation

20.1.1 Calculation Procedures

1. The drug calculation window is displayed by selecting **Menu** > **Common Function** > **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. Enter the patient's weight.
5. Enter the correct parameter value.
6. Confirm whether the calculation result is correct.

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 Size are invalid in the neonatal mode.

20.2 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 trend table will vary with the changes above. And the user can perform the following:

- Scroll up and down the screen by selecting and pressing the symbol  and  displayed on the trend graph.
- Record the data displayed in the current window by selecting **Record**.

Chapter 21 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	Recording key, press this key to start or stop recording task.
3	Paper outlet
4	Recorder Door

21.1 Performance of the Recorder

- Waveform record is printed at the rate of 12.5mm/s, 25 mm/s or 50 mm/s.
- 48mm wide printout paper.
- 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.

21.2 Recording Type

The monitor provides several types of stripe recording:

- Continuous real-time recording
- Time recording
- Alarm recording
- Trend graph, trend table recording
- Arrhythmia review recording
- Drug calculation titration recording
- NIBP review recording
- Alarm review recording
- Hemodynamic Calculation result recording
- 12-lead analysis recording

21.3 Starting and Stopping Recording

You can start and stop the recording in the following ways:

Continuous real-time recording	Press the **Record** button on the front panel to start the recording, and repress it to stop the recording.
Auto recording	Record three waveforms selected in **Recorder Setup** menu according to the setup time interval in **Recorder Setup** menu. It will automatically stop in 8 seconds.
Trend graph recording	Enter the **Menu > Review > Trend Graph** menu, and press the **Record** button to start recording.
Trend table recording	Enter the **Menu > Review > Trend Table** menu, and press the **Record** button to start recording.
NIBP review recording	Enter the **Menu > Review > NIBP Review** menu, then press the **Record** button to start recording.
12-lead diagnosis recording	Select **Record** on the diagnosis review interface to start the recording. To stop the recording, press the **Record** button on the front panel.
C.O. measurements recording	Select **Record** on the **CO Measure** interface to start the recording. To stop the recording, press the **Record** button on the front panel.

The recorder will stop recording in the following situations:

- The recording task is finished.
- No paper in the recorder.

- Malfunction stops the recorder from running properly.

NOTE:

You can press the button on the front panel to stop the currently recording process.

21.4 Recorder Operations and Status Messages

21.4.1 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 print head may be damaged.

21.4.2 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.

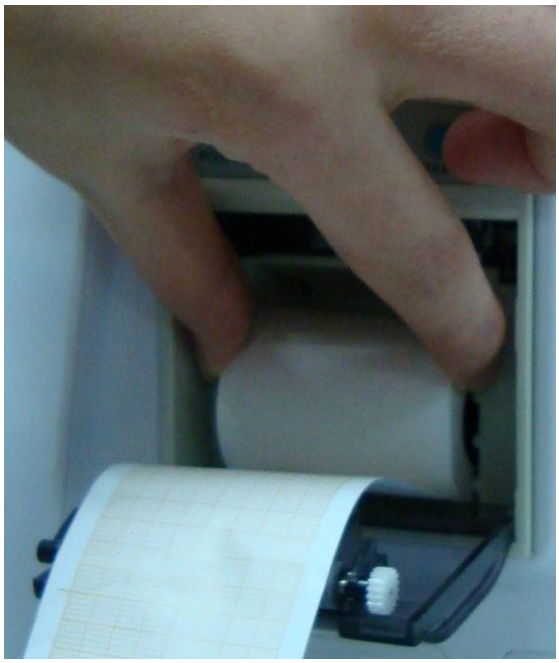
21.4.3 Paper Out

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

21.4.4 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 2cm 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.

21.4.5 Removing Paper Jam

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

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

NOTE:

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

Chapter 22 Other Functions

22.1 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.

22.2 Wireless Network

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

NOTE:

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

2 The obstacle may interfere with data transmission and even cause data loss.

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

Chapter 23 Using Battery

This monitor can run on battery power, which ensures its uninterrupted operation even when AC power supply is interrupted. The batteries recharge 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 batteries. If the monitor is powered by batteries, the monitor will switch off automatically before the batteries are completely depleted.

23.1 Battery Safety Information

WARNING

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

2 The service life of the batteries depends on the service frequency and time. The service life of the batteries is about three years if the batteries are well maintained and stored. The service life of the batteries may shorten if they are used inappropriately.

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

4 Do not unplug the batteries when monitoring.

5 Do not heat or throw the batteries into a fire.

6 Do not use, leave the batteries close to fire or other places where temperature may be above 60°C.

7 Do not immerse, throw, or wet the batteries in water/seawater.

8 Do not destroy the batteries: do not pierce the batteries with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the batteries.

9 Use the batteries only in the monitor. Do not solder the leading wire and the battery terminal directly.

10 If liquid leaking from the batteries gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately. If liquid leaks of the batteries splash onto your skin or clothes, wash well with fresh water immediately.

11 Keep away from fire immediately when leakage or foul odor is detected.

12 Stop using the batteries if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.

13 Do not use a battery with serious scar or deformation.

WARNING

14 Use the batteries with similar performance, which can extend the service life of the batteries. If one of the two batteries is malfunctioning, it is recommended to change both of the two batteries.

15 When the monitor is running on battery power, do not replace the batteries during monitoring patients; or the monitor will be powered off, which may result in patient injury.

23.2 Battery Power Indicator

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

23.3 Battery Status on the Main Screen

Battery status symbols show the status of each battery detected and the combined battery power remaining; also, they tell you which battery compartments they are in, either 1 or 2.


The battery is in compartment 1.


The battery is in compartment 2.


Remaining battery power: 100%.


Remaining battery power: 75%


Remaining battery power: 50%


Remaining battery power: 25%


Batteries are almost depleted and need to recharge immediately.


No battery is installed.

23.4 Checking Battery Performance

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

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

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

23.5 Replacing the Battery

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

1. To open the battery door, press the battery compartment latch and pull the battery door leftwards according to indication beside the button.
2. Remove the battery from the compartment.
3. Insert a new battery into the battery compartment.
4. Close the battery door.

NOTE:

The markers which respectively indicate compartment 1 and compartment 2 on the battery door are corresponding to the symbols 1 and 2 on the main screen.

23.6 Recycling the Battery

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

WARNING

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

23.7 Maintaining the Battery

To prolong the life of the batteries, there is current limitation for using batteries. Therefore, the monitor which runs on battery power may not be powered on under following circumstances:

1. Only one battery is installed.
2. One of the two installed batteries is damaged, or large capacity difference between the two installed batteries exists.
3. Batteries in the monitor are almost empty.

If above-mentioned circumstances are detected, recharge the batteries or use another two batteries with similar capacity.

Batteries should be conditioned regularly to maintain their useful life.

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

Discharge the battery completely once every month.

Chapter 24 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 makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Consult your hospital's Infection Control Officer or Epidemiologist for control infection.

24.1 General Points

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

- Always dilute according to the manufacturer's instructions or use lowest possible concentration.
- Do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Never use bleach.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).

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.

24.2 Cleaning

WARNING

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

24.2.1 Cleaning the Monitor

Regular cleaning of the monitor shell and the screen are strongly recommended. Use only non-caustic detergents such as soap and warm water (40°C /104 º F maximum) to clean the monitor shell. Do not use strong solvents such as acetone or trichloroethylene.

Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing. Do not permit any liquid to enter the monitor case and avoid pouring it on the monitor while cleaning. Do not allow water or cleaning solution to enter the measurement connectors. Wipe around, except connector sockets.

Examples of disinfectants that can be used on the instrument casing are listed below:

- Tenside;
- Diluted Ammonia Water < 3%;
- Alcohol;

24.2.2 Cleaning the Accessories

24.2.2.1 Cleaning the ECG Cables and Lead Wires

NOTE:

1. Use only recommended cleaning substances and disinfectants listed in this document. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
2. Keep the cable and lead wires free of dust and dirt.
3. Never immerse or soak the ECG cable.
4. Inspect the cables after cleaning.

CAUTION

Do not allow a cleaning or disinfecting agent to leave residues on any equipment surface. After allowing the appropriate time for the agent to work (as indicated by the manufacturer), wipe off residues with a cloth dampened with water.

Clean with a lint-free cloth, moistened with warm water (40°C /104º F) and substances listed below. Never use strong solvents such as acetone or trichloroethylene.

Approved Cleaning Substances

- Mild Soaps
- Tenside (as active cleaning agent)

Cables and lead wires can be cleaned with a warm, damp cloth and mild soap, or isopropyl alcohol wipes.

CAUTION

The decision to sterilize must be made per your institution’s requirements with an awareness of the effect on the integrity of the cable or leadwire.

24.2.2.2 Cleaning the Blood Pressure Cuff

Wipe cuffs with a solution of mild soap and water. If the cover requires more rigorous cleaning, remove the air bladder first. Allow the cover to thoroughly air dry before use.

Cuffs have been tested to withstand the following recommended disinfectants: cidex, sporicidin, microzid, isopropyl-alcohol 70%, ethanol 70% buraton liquid.

24.2.2.3 Cleaning the SpO_2 Sensor

These reusable sensors should be cleaned and disinfected, but never sterilized. The validated cleaning agents are listed below:

- Mild Detergent
- Salt Solution (1%)

24.2.2.4 Other Accessories

For cleaning other accessories, please contact the manufactures for details.

24.3 Disinfection

WARNING

Do not mix disinfecting solutions (such as bleach and ammonia), or it may produce hazardous gases.

To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

Recommended types of disinfecting agents are:

- Alcohol
- Aldehyde

CAUTION

Do not use Eto gas or formaldehyde to disinfect the monitor.

24.4 Sterilization

Do not sterilize the monitor or the accessories, unless this is necessary according to your hospital regulation.

Clean and disinfect the accessories before sterilizing using Ethylene Oxide (Eto) gas sterilization only. Don’t autoclave.

WARNING

Please sterilize and disinfect the accessories timely to prevent the cross infection between patients.

Chapter 25 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.

25.1 Inspecting

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

The following items should be checked:

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

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

25.2 Maintenance Task and Test Schedule

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 ECG synchronization of the monitor and defibrillator	At least once every two years, or as needed.

Maintenance and Test Schedule	**Frequency**
NIBP Leakage Inspection	At least once every two years, or as specified by local laws.
NIBP Pressure Calibration	At least once every two years, or as specified by local laws.
NIBP Calibration	At least once every two years, or as specified by local laws.
CO_2 Calibration and Performance Test	At least once every two years, or if you suspect the measurement values are incorrect.
AG Calibration	If you suspect the measurement values are incorrect and need to calibrate, please contact the manufacturer.

Chapter 26 Warranty and Service

26.1 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.

26.2 Contact information

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

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Chapter 27 Accessories

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

WARNING

1 Never reuse disposable transducers, sensors, accessories and their casing that are intended for single use; or only use them on a single patient. Reuse may compromise device functionality and system performance and cause a potential hazard.

2 Use only EDAN-approved accessories. Using non-EDAN-approved accessories may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by EDAN with patient monitors by other manufacturers.

3 Do not use a sterilized accessory if its casing is damaged.

NOTE:

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

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

27.1 Standard Accessories

Part Number	Accessories
01.57.471068-10	7-pin extension cable (EDAN)
02.01.210120	SpO_2 Finger Sensor, adult, 1m, resuable
01.57.471077-10	NIBP tube
01.57.040205	NIBP Cuff, Adult, 25cm-35cm, reusable
01.15.040225-10	2-pin adult skin temperature probe (10K/25°C)
01.57.471067-10	ECG trunk cable, 5-lead, Defibrillator-Proof, AHA, reusable
01.57.471167-10	ECG trunk cable, 5-lead, Defibrillator-Proof, IEC, reusable
01.57.471023	ECG limb wires, 5-lead, snap, AHA, 0.9m, reusable
01.57.040207	ECG limb wires, 5-lead, snap, IEC, 0.9m, reusable
11.57.471056	ECG Electrodes, adult, disposable, 30 pieces
11.13.01950	Power cable
01.13.36014	Power Cable(IEC Standard) 220V
11.13.36015	Power Cable(AHA Standard)
01.21.064143	Rechargeable Lithium-Ion battery (14.8V, 4.2Ah)
11.13.114214	SE-1 ground cable

27.2 Optional Accessories

The following table lists the optional configuration for the monitor.

27.2.1 ECG Accessories

Part Number	Accessories
01.57.471072-10	ECG trunk cable, 10-lead, Defibrillator-Proof, AHA, 2.6m, reusable
01.57.471168-10	ECG trunk cable, 10-lead, Defibrillator-Proof, IEC, 2.6m, reusable
01.57.109101	ECG limb wires, 10-lead, snap, AHA, 0.9m, reusable
01.57.040203	ECG limb wires, 10-lead, snap, IEC, 0.9m, reusable
01.57.471169-10	ECG limb wires, 10-lead, clip, AHA, 0.9m, reusable
01.57.471163-10	ECG limb wires, 10-lead, clip, IEC, 0.9m, reusable
01.57.471067-10	ECG trunk cable, 5-lead, Defibrillator-Proof, AHA, 2.6m, reusable
01.57.471167-10	ECG trunk cable, 5-lead, Defibrillator-Proof, IEC, 2.6m, reusable
01.57.471023	ECG limb wires, 5-lead, snap, AHA, 0.9m, reusable
01.57.040207	ECG limb wires, 5-lead, snap, IEC, 0.9m, reusable
01.57.040208	ECG limb wires, 5-lead, clip, IEC, 0.9m, reusable
01.57.471170-10	ECG limb cable, 5-lead, clip, AHA, reusable
01.57.471164-10	ECG trunk cable, 3-lead, Defibrillator-Proof, AHA, 2.6m, reusable
01.57.471171-10	ECG trunk cable, 3-lead, Defibrillator-Proof, IEC, 2.6m, reusable
01.57.471165-10	ECG limb cable, 3-lead, clip, AHA, 0.9m, reusable
01.57.471025	ECG limb cable, 3-lead, clip, IEC, 0.9m, reusable
11.57.471056	Adult Disposable Adhesive Electrodes, TYCO H99SG,30PCS/ package, CE
11.57.471060	Adult Disposable Adhesive Electrodes, TYCO Medi-Trace 200, 100PCS/ package, FDA
11.57.471057	Children/ Neonatal Disposable Adhesive Electrodes, TYCO H124SG, 50PCS/package,CE

27.2.2 SpO_2 Accessories

Part Number	Accessories
02.01.210120	EDAN SH1 Adult Reusable SpO_2 Sensor (DB9) (Only compatible with EDAN SpO_2 module and EDAN SpO_2 Extension cable), 1m (finger type, patient size>40kg)
12.01.110492	EDAN SH3 Neonate Warp SpO_2 Sensor (DB9) (Only compatible with EDAN SpO_2 module and EDAN SpO_2 Extension cable),1m
02.01.210123	EDAN SH4 Adult Silicone Soft-tip SpO_2 Sensor (DB9) (Immersion Disinfection) (Only compatible with EDAN SpO_2 module and EDAN SpO_2 Extension cable), 1m (finger type, patient size>50kg)
02.01.210121	EDAN SH5 pediatric Silicone Soft-tip SpO_2 Sensor (DB9) (Only compatible with EDAN SpO_2 module and EDAN SpO_2 Extension cable), 1m (finger type, patient size: 10kg to 50kg)
01.57.471068-10	EDAN SpO_2 Extension cable(7P, 2m, TPU)
01.57.040196	Adult Single-Patient SpO_2 sensor (patient size>30kg)
01.57.040197	Pediatrics Single-Patient SpO_2 sensor (patient size: 10kg to 50kg)
01.57.040198	Infant Single-Patient SpO_2 sensor (patient size: 3kg to 20kg)
01.57.040199	Neonate Single-Patient SpO_2 sensor (patient size<3kg)
11.15.30043	Nellcor Reusable Adult SpO_2 Sensor (DS-100A OxiMax)
11.15.40096	Nellcor Reusable Adult/Neonate SpO_2 Sensor (OXI-A/N OxiMax)
01.57.471069-10	Nellcor SpO_2 Extension cable (Compatible with Nellcor OXI-Max SpO2 module and Nellcor sensor)

27.2.3 NIBP Accessories

Part Number	Accessories
11.57.40020	Infant blood pressure cuff (10-19cm), CM1201
11.57.40018	Pediatrics blood pressure cuff (18-26cm), CM1202
11.57.40029	Adult blood pressure cuff (25-35cm), CM1203
01.57.040205	NIBP Cuff, Adult, 25cm-35cm, reusable
01.57.040211	NIBP Cuff, Child, 18cm-26cm, reusable
01.57.040212	NIBP Cuff, Infant, 10cm-19cm, reusable
11.57.40097	Neonatal Disposable Cuff 5102 (About 6-9cm)
11.57.40098	Neonatal Disposable Cuff 5104 (About 9-14cm)
01.57.471157	NIBP Cuff, neonatal #1, 3-6cm, disposable
01.57.471158	NIBP Cuff, neonatal #2, 4-8cm, disposable
01.57.471159	NIBP Cuff, neonatal #3, 6-11cm, disposable

Part Number	Accessories
01.57.471160	NIBP Cuff, neonatal #4, 7-13cm, disposable
01.57.471161	NIBP Cuff, neonatal #5, 8-15cm, disposable
01.57.471077-10	NIBP Tube (3m) with connector
01.59.473006-10	NIBP Tube for Neonatal Cuff (Only compatible with Neonatal Disposable cuff)

27.2.4 Temp Accessories

Part Number	Accessories
01.15.040226-10	2-pin adult skin temperature probe (2.252K/25°C)
01.15.040227-10	2-pin adult intracavitary temperature probe (2.252K/25°C)
01.15.040225-10	2-pin adult skin temperature probe (10K/25°C)
01.15.040228-10	2-pin adult intracavitary temperature probe（10K/25°C)

27.2.5 IBP Accessories

Part Number	Accessories
01.57.471070-10	Pressure transducer interface cable, BD
11.57.40121	Disposable pressure transducer kit (BD DT-4812)
01.57.471172-10	Pressure transducer interface cable, EDWARD
01.57.471173-10	Pressure transducer interface cable, HOSPIRA
01.57.471166-10	Pressure transducer interface cable, UTAH

27.2.6 CO2 Accessories

Part Number	Accessories
01.57.471085-10	CO_2 Module Extension cable
11.57.078139	Disposable CO_2 Nasal Cannula - Adult (Respironics 3468ADU-00)
11.57.078151	Adult/Pediatric Airway adapter kit with dehumidification tubing
11.57.078154	Disposable Sampling Line Kit with Dehumidification Tubing (Respironics 3475-00)
11.57.471019	Reuseable Adult/ Pediatric Airway Adapter (7007-01)
11.57.471020	Reuseable Neonate/ Infant Airway Adapter (7053-01)
11.59.078155	Disposable Adult Airway Adapter (6063-00)
11.59.078156	Disposable Neonatal(infant/ pediatric) Airway Adapter (6312-00)
11.57.078142	Adult Nasal CO_2 with O_2 delivery sampling cannula
11.57.078143	Pediatric Nasal CO_2 with O2 delivery sampling cannula

Part Number	Accessories
11.57.078144	Infant Nasal CO_2 with O_2 delivery sampling cannula
11.57.101019	Adult Nasal/ Oral CO_2 sampling cannula
11.57.101020	Pediatric Nasal/ Oral CO_2 sampling cannula
11.57.101021	Adult Nasal/ Oral CO_2 with O_2 delivery sampling cannula
01.12.031598	Adult/Pediatric Airway adapter kit
11.57.078140	Disposable CO_2 Nasal Cannula - Pediatric (Respironics 3468PED-00)
11.57.078141	Disposable CO_2 Nasal Cannula - Infant (Respironics 3468INF-00)
11.57.078152	Pediatric/ Infant Airway adapter kit with dehumidification tubing
11.57.078158	Pediatric mask/ mainstream 9960PED-00
11.57.078159	Adult standard mask/ mainstream 9960STD-00
11.57.078160	Adult large mask/ mainstream 9960STD-00
11.57.078161	Band/mainstream 8751-00
11.12.078162	bayonet socket

27.2.7 C.O. Accessories

Part Number	Accessories
01.57.471071-10	Cardiac output cable
11.13.40119	In-line Injection temperature probe (BD 684056-SP4042)
11.57.40120	In-line Injection temperature probe housing (BD 680006-SP5045)
11.57.100175	Control Syringe (Medex MA387)

27.2.8 AG Accessories

Part Number	Accessories
01.57.471086-10	GAS module extension cable
11.57.471043-10	Nomoline with Luer Lock connector, 25pieces/box, CAT.NO. 108210
11.57.471042-10	IRMA Airway Adapter, Adult/Pediatric, 25pieces/box, CAT.NO. 106220
01.57.471189	Nomoline Adapter
01.57.471190	Nomoline Airway Adapter Set
01.57.471191	Nomo Extension
01.57.471192	T-adapter

27.2.9 Other Accessories

Part Number	Accessories
22.08.208017	XM module
22.08.208020	V-CO_2 module (sidestream)
22.08.208021	V-CO_2 module (mainstream)
22.08.208022	V-AG module (sidestream)
22.08.208023	V-AG module (mainstream)
22.08.208029	V-C.O. module
22.08.208030	Parameter amplifier mainframe
22.08.208031	V-IBP module
22.08.208036	V-SpO_2 module (Nellcor)
01.57.78035	Recording paper
02.01.101207	ASUS wireless AP (WL-330g EAP)

A Product Specifications

A.1 Classification

Anti-electroshock type	Class I equipment and internal powered equipment
EMC type	Group I, Class A
Anti-electroshock degree	ECG (RESP), TEMP, IBP, C.O. CF SpO_2, NIBP, CO_2, AG BF
Ingress Protection	IPX1
Disinfection/sterilization method	Refer to Chapter Care and Cleaning for details.
Working system	Continuous operation equipment
Compliant with Safety Standards	IEC 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 60601-1-2:2001+A1, ISO 9919, ISO 21647, IEC/EN 60601-2-27, IEC/EN 60601-2-30, IEC/EN 60601-2-34, IEC/EN 60601-2-49, ANSI/AAMI SP10, IEC/EN 60601-2-25, AAMI/ANSI EC13, EN12470-4 EN1060-1 EN1060-3, EN1060-4

A.2 Physical Specifications

Product	**Dimension**	**Max Weight**	**Comments**
elite V8	425 mm (L) × 245 mm (W)× 382 mm (H)	<14 kg	Including batteries, XM module and recorder, without options
XM module	188 mm (L) × 81.5 mm (W)× 120 mm (H)	<1 kg	Without accessories
V-IBP module	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories
V-C.O. module	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories

Product	Dimension	Max Weight	Comments
V-CO_2 module (mainstream)	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories
V-CO_2 module (sidestream)	134 mm (L) × 84 mm (W)× 102 mm (H)	<0.65 kg	Without accessories
V-AG module (mainstream)	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories
V-AG module (sidestream)	134 mm (L) × 84 mm (W)× 102 mm (H)	<0.65 kg	Without accessories
V-SpO_2 module	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories
PAM	503 mm (L) × 170 mm (W)× 148 mm (H)	<2.5 kg	Without accessories

A.3 Environmental Specifications

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.

Main unit, PAM, XM module, V-SpO_2 module, V-IBP module, V-C.O. module, Recorder	
Temperature	
Working	+0°C ~ +40°C
Transport and Storage	-20°C ~ +55°C
Humidity	
Working	15% ~ 95% (non-condensing)
Transport and Storage	15% ~ 95% (non-condensing)
Altitude	
Working	860hPa ~ 1060hPa

Transport and Storage	700hPa ~ 1060hPa
Power Supply	100V-240V~, 50Hz/60Hz, 1.8A~0.75A. Pmax=180VA FUSE: T3.15AH250VP

V-CO_2 module (sidestream)	
Temperature	
Working	+5°C ~ +35°C
Transport and Storage	-20°C ~ +55°C
Humidity	
Working	10% ~ 90% (non-condensing)
Transport and Storage	10% ~ 90% (non-condensing)
Altitude	
Working	530hPa ~ 1066hPa
Transport and Storage	530hPa ~ 1066hPa

V-CO_2 module (mainstream)	
Temperature	
Working	+0°C ~ +40°C
Transport and Storage	-20°C ~ +55°C
Humidity	
Working	10% ~ 90% (non-condensing)
Transport and Storage	10% ~ 90% (non-condensing)
Altitude	
Working	530hPa ~ 1066hPa
Transport and Storage	530hPa ~ 1066hPa

V-AG module (sidestream)	
Temperature	
Working	+5°C ~ +40°C
Transport and Storage	-20°C ~ +55°C
Humidity	

Working	10% ~ 95% (non-condensing)
Transport and Storage	10% ~ 95% (non-condensing)
Altitude	
Working	525hPa ~ 1200hPa
Transport and Storage	500hPa ~ 1200hPa

V-AG module (mainstream)	
Temperature	
Working	+10°C ~ +40°C
Transport and Storage	-20°C ~ +55°C
Humidity	
Working	10% ~ 95% (non-condensing)
Transport and Storage	10% ~ 95% (non-condensing)
Altitude	
Working	525hPa ~ 1200hPa
Transport and Storage	500hPa ~ 1200hPa

A.4 Leakage Current

	Applied Part	**Normal Condition**	**Single Fault Condition**
Earth Leakage Current		<0.5 mA	<1 mA
Enclosure Leakage Current		<0.1 mA	<0.5 mA
Patient Leakage Current	CF	AC: <0.01 mA DC: <0.01 mA	AC: <0.05 mA DC: <0.05 mA
	BF	AC: <0.1 mA DC: <0.01 mA	AC: <0.5 mA DC: <0.05 mA
Patient Leakage Current (Mains on Applied Parts)	CF		<0.05 mA
	BF		<5 mA
Patient Auxiliary Current	CF	AC: <0.01 mA DC: <0.01 mA	AC: <0.05 mA DC: <0.05 mA
	BF	AC: <0.1 mA DC: <0.01 mA	AC: <0.5 mA DC: <0.05 mA

A.5 Display

Display	**Messages**
Display screen: 17 inch color TFT, touch screen is configurable Resolution: 1280 × 1024	A maximum of 12 waveforms One power LED One physiological alarm LED One technical alarm LED One alarm mute LED One charge LED

A.6 Battery

Number	2	
Capacity	4.2 Ah	
Nominal Voltage	14.8 V DC	
Operating Time	120 min	with 2 new, fully charged batteries, at 25°C, typical configuration (continuous SpO_2 measurement and NIBP automatic measurement mode at interval of 15 minutes, ECG/TEMP module connected, recording at interval of 10 minutes, brightness set to “1”)
	90 min	with 2 new, fully charged batteries, at 25°C, typical configuration (continuous SpO_2 measurement and NIBP automatic measurement mode at interval of 15 minutes, ECG/TEMP module connected, sidestream CO_2 and sidestream AG modules connected, recording at interval of 10 minutes, brightness set to “1”)
Charge Time	4.2 Ah 350 min (Monitor is on or in standby mode.)	

A.7 Recorder

Record Width	48 mm
Paper Speed	12.5mm/s, 25 mm/s, 50 mm/s
Trace	1/2/3 optional
Recording types	Continuous real-time recording 8 second real-time recording Parameter alarm recording Trend recording Titration table recording Frozen waveform recording

A.8 Review

Trend Review	
Short	1 hr, at 1 second resolution
Long	150 hrs, at 1 min. resolution
Review	1200 sets of NIBP measurement data

A.9 ECG

Lead Mode	3-Lead: I, II, III 5-Lead: I, II, III, aVR, aVL, aVF, V 12-Lead: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Lead naming style	AHA, IEC
Display Sensitivity	1.25mm/mV (×0.125), 2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2), 40mm/mV (×4), AUTO gain
Sweep	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s
Bandwidth (-3dB)	Diagnosis: 0.05Hz ~ 150Hz Monitor: 0.5Hz ~ 40Hz Surgery: 1Hz ~ 20Hz
CMRR (Common Mode Rejection Ratio)	Diagnosis: >95dB (the Notch filter is off) Monitor: >105dB (the Notch filter is on) Surgery: >105dB (the Notch filter is on)
Notch	In diagnosis, monitor and surgery modes: 50Hz/60Hz (Notch filter can be turned on or off manually)
Differential Input Impedance	>5MΩ
Input Signal Range	±8mV PP
Accuracy of Input Signal Reproduction	The total error and frequency response comply with ANSI/AAMI EC13:2002, Sect. 4.2.9.8.
Electrode Offset Potential Tolerance	±500mV

Auxiliary Current (Leads off detection)	Active electrode: <100nA Reference electrode: <900nA
Input Offset Current	≤0.1μA
Recovery time after Defibrillation	<5s
Leakage current of patient	<10μA
Scale signal	1mVPP, accuracy is ±5%
System noise	<30μVPP
Sampling frequency	1000Hz
Sampling channel switch time	<80μS
A/D precision	24 Bits
ESU Protection	Incision mode: 300W Congelation mode: 100W Restore time: ≤10s Meets the requirements of ANSI/AAMI EC13: 2002 Sect. 4.1.2.1 a)
Noise Suppression of Electrotome	Tested according to the test method in EC13: 2002 Sect.5.2.9.14, it complies with ANSI/AAMI EC13:2002 Sect.4.2.9.14.
Pace Pulse	
Pulse indicator	Pulse is marked if the requirements of ANSI/AAMI EC13:2002, Sect. 4.1.4.1 are met: Amplitude: ±2 mV ~ ±700 mV Width: 0.1 ms ~2 ms Ascending time: 10 μs ~ 100 μs

Pulse Rejection	Pulse is rejected if the requirements of ANSI/AAMI EC13-2002, Sect. 4.1.4.1 are met: Amplitude: ±2 mV ~ ±700 mV Width: 0.1 ms ~2 ms Ascending time: 10 μs ~100 μs
Minimum input slew rate (lead II)	>2.5V/S
Heart Rate	
HR Calculation	
Range	ADU: 15 bpm ~ 300 bpm PED/NEO: 15 bpm ~ 350 bpm
Accuracy	±1% or 1 bpm, whichever is greater
Resolution	1 bpm
Sensibility	≥300 μVPP
PVC	
Range	ADU: 0~300 PVCs/ min PED/NEO: 0~350 PVCs/ min
Resolution	1 PVCs/min
ST value	
Range	-2.0 mV ~ +2.0 mV
Accuracy	-0.8 mV ~ +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV
HR Averaging Method	

Method 1	Normally, 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 1200ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	ADU: 120 bpm ~ 300 bpm PED/NEO: 160 bpm ~ 350 bpm
Normal	ADU: 41 bpm ~ 119 bpm PED/NEO: 61 bpm ~159 bpm
Brady	ADU: 15 bpm ~ 40 bpm PED/NEO: 15 bpm ~ 60 bpm
Range of Ventricular Rhythm	
Ventricular Tachycardia	The interval of 5 consecutive ventricular beats is less than 600 ms
Ventricular Rhythm	The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms
Ventricular Bradycardia	The interval of 5 consecutive ventricular beats is more than 1000 ms
Startup time for Tachycardia	
Ventricular Tachycardia 1 mV 206bpm	Gain 1.0: 10 s Gain 0.5: 10 s Gain 2.0: 10 s
Ventricular Tachycardia 2 mV 195bpm	Gain 1.0: 10 s Gain 0.5: 10 s Gain 2.0: 10 s

<table>
<tr><td>Response time of Heart Rate Meter to Change in HR</td><td colspan="3">HR range: 80 bpm ~ 120 bpm
Range : 7s ~ 8s, average is 7.5s
HR range: 80bpm ~ 40bpm
Range : 7s ~ 8s, average is 7.5s</td></tr>
<tr><td>Tall T-wave Rejection</td><td colspan="3">Exceeds ANSI/AAMI EC13-2002 Sect. 4.1.2.1 c) minimum recommended 1.2mV T-Wave amplitude</td></tr>
<tr><td>Accuracy of Heart Rate Meter and Response to Irregular Rhythm</td><td colspan="3">Complied with ANSI/AAMI EC13-2002 Sect.4.1.2.1 e), the HR value after 20 seconds of stabilization is displayed as follows:
Ventricular bigeminy: 80bpm±1bpm
Slow alternating ventricular bigeminy: 60bpm±1bpm
Rapid alternating ventricular bigeminy: 120bpm±1bpm
Bidirectional systoles: 91bpm±1bpm</td></tr>
<tr><td rowspan="8">Arrhythmia analyses</td><td colspan="2">Non-Paced Patient</td><td>Paced Patient</td></tr>
<tr><td>ASYSTOLE</td><td>R on T</td><td>ASYSTOLE</td></tr>
<tr><td>VFIB/VTAC</td><td>PVC</td><td>TACHY</td></tr>
<tr><td>COUPLET</td><td>TACHY</td><td>BRADY</td></tr>
<tr><td>VT>2</td><td>BRADY</td><td>PNC</td></tr>
<tr><td>BIGEMINY</td><td>MISSED BEATS</td><td rowspan="3">PNP</td></tr>
<tr><td>TRIGEMINY</td><td>IRR</td></tr>
<tr><td>VENT</td><td>VBRADY</td></tr>
</table>

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.10 RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is lead II.
Respiration excitation waveform	Sinusoid, 62.8kHz(± 10%), <300μA
Measuring Sensitivity	200 to 4500 baseline impedance: 0.3Ω
Differential input impendence	> 2.5MΩ
Waveform bandwidth	0.2Hz ~ 2.5Hz (-3dB)
Baseline Impedance Range	200Ω ~ 2500Ω (no leads cables resistance)
	2200Ω ~ 4500Ω (leads cables 1KΩ resistance)
Noise	<0.1 Ω (3/ 5-lead monitoring)
	<0.2 Ω (12-lead monitoring)
Maximum dynamic range	Baseline impedance: 500Ω Variable impedance: 3Ω No clipping
RR Measuring Range:	
Adult	0 rpm ~120rpm
Neo/Ped	0 rpm ~150rpm
Resolution	1 rpm
Accuracy	±2 rpm
Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Apnea Alarm Time Setup	10s, 15s, 20s, 25s, 30s, 35s, 40s

A.11 NIBP

Technique	Oscillometry
Mode	Manual, Auto, Continuous
Measuring interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90/120/240/480 min
Continuous	5min, interval is 5s
Measuring type	SYS, DIA, MAP
Measuring Range	
Adult mode	SYS: 40 mmHg ~ 270 mmHg DIA: 10 mmHg ~ 215 mmHg MAP: 20 mmHg ~ 235 mmHg
Pediatric mode	SYS: 40 mmHg ~ 200 mmHg DIA: 10 mmHg ~ 150 mmHg MAP: 20 mmHg ~ 165 mmHg
Neonatal mode	SYS: 40 mmHg ~ 135 mmHg DIA: 10 mmHg ~ 100 mmHg MAP: 20 mmHg ~ 110 mmHg
Alarm Type	SYS, DIA, MAP
Cuff pressure measuring range	0 mmHg ~ 300 mmHg
Pressure resolution	1mmHg
Maximum mean error	±5mmHg
Maximum standard deviation	8mmHg
Maximum measuring period	
Adult/Pediatric	120s
Neonate	90s
Typical measuring period	30s ~ 45s (depend on HR/motion disturbance)
Overpressure protection (Dual overpressure protection)	
Adult	297±3mmHg
Pediatric	240±3mmHg
Neonatal	147±3mmHg
PR	
Measuring range	40 bpm ~240bpm

Accuracy	±3bpm or 3.5%, whichever is greater

A.12 SpO_2

Measuring Range	0 ~ 100 %	
Alarm Range	0 ~ 100 %	
Resolution	1 %	
Accuracy		
Adult /Pediatric	±2 % (70%~100% SpO_2)	
	Undefined (0~69% SpO_2)	
Neonate	±3 % (70%~100% SpO_2)	
	Undefined (0~69% SpO_2)	
Pulse Rate		
Measuring Range	25 bpm ~ 300 bpm	
Alarm Range	30 bpm ~ 300 bpm	
Resolution	1 bpm	
Accuracy	±2bpm	
Data update period	1s	
Wave length		
Red light	660±3 nm	
Infrared light	905±5 nm	
Emitted light energy	Less than 15 mW	
Nellcor module		
Measuring Range		1% ~ 100%
Alarm Range		1% ~ 100%
Resolution		1%
Data update period		1s

Accuracy	Sensor Type	Accuracy
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST	± 2 (70% ~ 100% SpO_2)
	OxiCliq A, OxiCliq P, OxiCliq N (Adult), OxiCliq N (Neonate), OxiCliq I	± 2.5 (70% ~ 100% SpO_2)
	D-YS (Infant to Adult), DS-100A, OXI-A/N, OXI-P/I	± 3(70% ~ 100% SpO_2)
	D-YS (including D-YSE ear clip), D-YS (including D-YSPD spotclip)	± 3.5(70% ~ 100% SpO_2)
* When the sensor is used on neonates as recommended, the specified accuracy range increases by ±1 compared with that used on adults.		
Pulse Rate		
Measuring Range		20bpm ~ 300bpm
Resolution		1bpm
Accuracy		± 3bpm (20bpm ~ 250bpm)
Sensor		Wave length: approximately 660 and 900nm
		Emitted light energy: <15mW

A.13 TEMP

Channel	2
Sensor type	YSI-10K and YSI-2.252K
Technique	Thermal resistance
Position	Skin, oral cavity, rectum
Measuring Range	0 °C ~ 50 °C(32 ºF ~ 122 ºF)
Resolution	0.1°C (0.1 ºF)
Accuracy (Without sensor)	±0.1°C or ±0.2 ºF
Refresh Time	Every 1s ~ 2s

A.14 IBP

Technique	Direct invasive measurement
Pressure measuring range	-50 to +300 mmHg
Resolution	1 mmHg
Accuracy (without sensor)	± 2 % or ±1 mmHg, whichever is greater
Pressure sensor	
Sensitivity	5 (μV/V/mmHg)
Impedance	300 to 3000 Ω
Frequency response	d.c. to 12.5 or 40 Hz
Zero	Range: ±200 mmHg
	Accuracy: ±1 mmHg
Measuring range	
Art	0 mmHg to +300 mmHg
PA	-6 to +120mmHg
CVP/RAP/LAP/ICP	-10 to +40 mmHg
P1/P2	-50 to +300 mmHg
Volume displacement of MSI	4.5×10^{-4} in^3 / 100 mmHg

A.15 CO_2

Applicable Patient Type	Adult, pediatric and neonatal patients	
Technique	Infra-red Absorption Technique	
Unit	mmHg, %, Kpa	
Measuring Range		
$EtCO_2$	0 mmHg ~ 150 mmHg	
$FiCO_2$	3 mmHg ~50 mmHg	
AwRR	0 rpm ~ 150 rpm (Mainstream) 2 rpm ~ 150 rpm (Sidestream)	
Resolution	$EtCO_2$	1mmHg
	$FiCO_2$	1mmHg
	AwRR	1 rpm

$EtCO_2$ Accuracy	± 2 mmHg, 0 to 40 mmHg
	± 5 % of reading, 41 to 70 mmHg
	± 8 % of reading, 71 to 100 mmHg
	± 10 % of reading, 101 to 150 mmHg
AwRR Accuracy	± 1 rpm
Sample Gas Flowrate	50 ±10 ml/min
O_2 Compensation	
Range	0 ~ 100%
Resolution	1%
Default	16%
Stability	
Short Term Drift	Drift over 4 hours < 0.8 mmHg
Long Term Drift	120 hours
Initialization time	It displays the value within 15s and meets the requirement for measurement accuracy within 2min. (Mainstream)
	It displays the value within 20s and meets the requirement for measurement accuracy within 2min. (Sidestream)
Response time	60ms (Mainstream) 3s (Sidestream)
Calibration	Not required.
Barometric pressure compensation	User setup
Alarm Type	$EtCO_2$, $FiCO_2$, AwRR
Apnea Alarm Delay	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.

Interfering Gas and Vapor Effects on $EtCO_2$ Measurement Values:

Gas or vapor	Gas level (%)	Quantitative effect/Comments
Nitrous oxide Halothane Enflurane Isoflurane Sevoflurane Xenon Helium Desflurane	60 4 5 5 5 80 50 15	Dry and Saturated Gas 0 – 40 mmHg: ± 1 mmHg additional error 41 – 70 mmHg: ± 2.5% additional error 71 – 100 mmHg: ± 4% additional error 101 – 150 mmHg: ± 5% additional error *Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present. Desflurane: The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38mmHg. Xenon: The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38mmHg.

Barometric Pressure on $EtCO_2$ Measurement Values:

Quantitative effect
Ambient Barometric, Operational 0 – 40 mmHg: ± 1 mmHg additional error 41 – 70 mmHg: ± 2.5% additional error 71 – 100 mmHg: ± 4% additional error 101 – 150 mmHg: ± 5% additional error *Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.

A.16 C.O.

Technique	Thermodilution Technique
Measuring range	
C.O.	0.1 L/min ~ 20L/min
TB	23°C ~ 43°C(73.4 º F ~109.4 º F)
TI	Auto: -1°C ~ 27°C(30.2 º F ~80.6 º F) Manual: 0°C ~ 27°C(32℉~80.6℉)
Resolution	
C.O.	0.1L/min
TB, TI	+0.1°C (+0.1 º F)
Alarm Range	23°C ~ 43°C (73.4℉~109.4℉)
Accuracy	
C.O.	±5% or ± 0.2 L/min
TB	±0.1°C
TI	±0.1°C
Output parameters	C.O.
	Hemodynamic Calculation

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.17 AG

A.17.1 Sidestream

Module Type	ISA AX+ Analyzer	Displaying the concentration of CO_2, N_2O, and two anaesthesia agent and identifying the anaesthesia agent automatically (portable module)
	ISA OR+ Analyzer	Displaying the concentration of CO_2, O_2, N_2O, and two anaesthesia agent and identifying the anaesthesia agent automatically (portable module)

Measurement Parameters	CO_2 , N_2O , O_2, Halothane (HAL), Isoflurane(ISO), Enflurane(ENF), Sevoflurane(SEV) , Desflurane(DES), awRR, MAC	
Measurement Principle	CO_2, N_2O, Anaesthesia Agent: infra-red absorption characteristic; O_2: Paramagnetic method	
Sampling Flow Rate	50 ml/min	
Work Mode	Measurement, Standby	
Warm-up Time	< 20s	
Typical Rise Time	$CO_2 \leq 200$ms $O_2 \leq 350$ms $N_2O \leq 350$ms $O_2 \leq 450$ms	
Primary Anaesthesia Agent Threshold	≤ 0.15 vol%	
Second Anaesthesia Agent Threshold	0.2 vol% + 10%	
Agent Identification Time	< 20 seconds (typically < 10 seconds)	
Response Time	< 3 seconds	
Standard Conditions		
GAS	Range	Accuracy
CO_2	0 to 15 vol% 15 to 25 vol%	±(0.2 vol% + 2% of reading) Unspecified
N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
HAL, ENF, ISO	0 to 8 vol % 8 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
SEV	0 to 10 vol % 10 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
DES	0 to 22 vol % 22 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
O_2	0 to 100 vol %	±(1 vol% + 2% of reading)
All Conditions		

Gas	Accuracy
CO_2	±(0.3kPa + 4% of reading)
N_2O	±(2kPa + 5% of reading)
Agents	±(0.2kPa + 10% of reading)
O_2	±(2kPa + 2 of reading)
Apnea Alarm Delay	20s~40s
Alarm	Providing alarms of $EtCO_2$, $FiCO_2$, EtO_2 , FiO_2 , EtN_2O , FiN_2O , EtAA , FiAA , awRR
Mechanical Robustness	Meets the shock and vibration requirements of SS-EN ISO 21647:2004 clause 21.101

Interfering gas and vapor effects:

Gas or Vapour	Gas Level	CO_2		Agents	N_2O
		ISA CO_2	ISA AX+		
N_2O [4]	60 vol%	– [2]	– [1]	– [1]	– [1]
HAL [4]	4 vol%	– [1]	– [1]	– [1]	– [1]
ENF, ISO, SEV [4]	5 vol%	+8% of reading [3]	– [1]	– [1]	– [1]
DES [4]	15 vol%	+12% of reading [3]	– [1]	– [1]	– [1]
Xe(Xenon) [4]	80 vol%	-10% of reading [3]		– [1]	– [1]
He(Helium) [4]	50 vol%	-6% of reading [3]		– [1]	– [1]
Metered Dose Inhaler Propellants [4]	Not for use with metered dose inhaler propellants				
C_2H_5OH(Ethanol) [4]	0.3 vol%	– [1]	– [1]	– [1]	– [1]
C_3H_7OH (Isopropanol) [4]	0.5 vol%	– [1]	– [1]	– [1]	– [1]
CH_3COCH_3 (Acetone) [4]	1 vol%	– [1]	– [1]	– [1]	– [1]
CH_4(Methane) [4]	3 vol%	– [1]	– [1]	– [1]	– [1]
CO(Carbon monoxide) [5]	1 vol%	– [1]	– [1]	– [1]	– [1]

NO(Nitrogen monoxide)	0.02 vol%	– [1]	– [1]	– [1]	– [1]
O_2 [5]	100 vol%	– [2]	– [2]	– [1]	– [1]

Note 1: Negligible interference, effect included in the specification "Accuracy, all conditions" above.

Note 2: Negligible interference with N_2O / O_2 concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06)*5.0 vol% =4.7 vol% CO_2.

Note 4: According to the EN ISO 21647 standard.

Note 5: In addition to the EN ISO 21647 standard.

A.17.2 Mainstream

Module Type	IRMA AX+	Displaying the concentration of CO_2, N_2O and two anaesthesia agent and indentifying two anaesthesia agent
Measurement Parameters	CO_2, N_2O, HAL, Isoflurane(ISO), Enflurane(ENF), Sevoflurane(SEV), Desflurane(DES), awRR, MAC	
Measurement Principle	CO_2, N_2O, anaesthesia agent: infra-red absorption characteristic	
Warm-up Time	Concentrations are reported and the automatic agent indentification is running within 10 seconds. Full accuracy within 20 seconds	
Rise Time	$CO_2 \leq 90$ms $N_2O \leq 300$ms HAL, ISO, ENF, SEV, DES ≤ 300ms	
Primary Agent Threshold	0.15 vol%	
Secondary Agent Threshold	0.2 vol% + 10% of total agent concentration	
Agent Identificaiton Time	< 20 seconds (typically < 10 seconds)	
Response Time	< 1 second	

Standard Conditions		
Gas	Range	Accuracy
CO_2	0 ~ 10 vol% 10 ~ 15vol% 15 ~ 25 vol%	±(0.2 vol% + 2% of reading) ±(0.3 vol% + 2% of reading) Unspecified
N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
HAL ISO ENF	0 to 8 vol% 8 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
SEV	0 to 10 vol% 10 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
DES	0 to 22 vol% 22 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
All Conditions		
GAS	Accuracy	
CO_2	±(0.3 vol% + 4 % of reading)	
N_2O	±(2 vol% + 4 % of reading)	
Agents	±(0.2 vol% + 10 % of reading)	
Apnea Alarm Delay	20s ~ 40s	
Alarm	Providing alarms of $EtCO_2$, $FiCO_2$, EtO_2 , FiO_2 , EtN_2O , FiN_2O , EtAA, FiAA, awRR	

Interfering gas and vapour effects:

Gas or vapour	Gas level	CO_2		Agents	N_2O
		IRMA CO_2	IRMA AX+		
N_2O[4)]	60 vol%	–[1&2)]	–[1&2)]	–[1)]	–[1)]
HAL[4)]	4 vol%	–[1)]	–[1)]	–[1)]	–[1)]
ENF, ISO, SEV[4)]	5 vol%	+8% of reading[3)]	–[1)]	–[1)]	–[1)]
DES[4)]	15 vol%	+12% of reading[3)]	–[1)]	–[1)]	–[1)]
Xe(Xenon)[4)]	80 vol%	-10% of reading[3)]		–[1)]	–[1)]

He(Helium) [4]	50 vol%	-6% of reading [3]		– [1]	– [1]
Metered dose inhaler propellants[4]	Not for use with metered dose inhaler propellants				
C_2H_5OH(Ethanol) [4]	0.3 vol%	– [1]	– [1]	– [1]	– [1]
C_3H_7OH (Isopropanol) [4]	0.5 vol%	– [1]	– [1]	– [1]	– [1]
CH_3COCH_3 (Acetone) [4]	1 vol%	– [1]	– [1]	– [1]	– [1]
CH_4(Methane) [4]	3 vol%	– [1]	– [1]	– [1]	– [1]
CO(Carbon monoxide) [5]	1 vol%	– [1]	– [1]	– [1]	– [1]
O_2[5]	100 vol%	– [1&2]	– [1&2]	– [1]	– [1]

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

Note 2: For probes not measuring N_2O and/or O_2 the concentrations shall be set from monitor. (IRMA CO_2 measures neither N_2O, nor O_2. IRMA AX+ does not measure O_2.)

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the measured CO_2 concentration will typically be (1-0.06)*5.0 vol% =4.7 vol% CO_2.

Note 4: According to the EN ISO 21647 standard.

Note 5: In addition to the EN ISO 21647 standard.

A.18 Wireless Network

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

A.19 Interfaces

A.19.1 Analog Output

Bandwidth (-3dB; reference frequency: 10Hz)	Diagnosis: 0.05Hz ~ 100Hz Monitor: 0.5Hz ~ 40Hz Surgery: 1Hz ~ 20Hz
Maximum Transmission Delay (Diagnosis Mode)	500ms
Sensitivity	1V/1mV ±10%
PACE Rejection/ Enhancement	Not applicable.
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	<500Ω
Interface Type	PJ-365 socket, 3.5mm audio plug

A.19.2 Defibrillator Synchronization

Output Impedance	<500Ω
Maximum Time Delay	35mS (R-wave peak to leading edge of pulse)
Waveform	Rectangular wave
Amplitude	High level: 3.5V ~ 5V, providing a maximum of 1mA output current; Low level: <0.5V, receiving a maximum of 5mA input current
Minimum Required R-wave Amplitude	0.3mV
Pulse Width	100mS±10%
Limited Current	15mA rating
Rising and Falling Time	<1mS
Interface Type	BNC-SR-2P connector

A.19.3 Nurse Call

Drive Mode	Voltage Output
Power Supply	≤12VDC, 200mA Max.
Contact Type	Normally open or contact (optional)
Interface Type	PJ-365 socket, 3.5mm audio plug

A.19.4 USB Interfaces

Number of USB Interfaces	Standard: 4; optional: 4
Drive Mode	HOST interface, USB1.0/2.0 protocol
Power Supply	5VDC, 500mA Max.
Interface Type	USB A-type port

A.19.5 VGA Interface

Number of VGA Interface	1
Horizontal Refreshing Rate	63.49KHZ
Video Signal	0.7 Vpp @ 75 Ohm, HSYNC/VSYNC signal TTL
Interface Type	DB-15 female receptacle

A.19.6 DVI Interface

*Auto drive is only applicable to DVI display. A HDMI-to-DVI tieline is required.

Clock Rate	108.0MHZ
DVI Video Signal	1280×1024@85HZ; 4:3;
Interface Type	HDMI A-type port

A.19.7 RS232 Interface

Level	RS232
Power Supply	+/-13.2V, 60mA Max.
Interface Type	DB-9 female receptacle

A.19.8 PAM Interface

*Only use link cable supplied by EDAN.

Level	RS422
Power Supply	≤24VDC, 2A Max.
Interface Type	POWER USB port

A.19.9 Network Interface

Bandwidth	10MHZ ~ 100MHZ
Interface Type	Standard RJ-45 network interface

B EMC Information

- Guidance and Manufacture's Declaration

B.1 Electromagnetic Emissions - for all EQUIPMENT and SYSTEMS

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

B.2 Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	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 ±1 kV for input /output signal	±2kV for power supply lines ±1 kV for input /output signal	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	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Patient Monitor requires continued operation during power mains interruptions, it is recommended that the Patient Monitor be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

B.3 Electromagnetic Immunity - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Patient Monitor should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{rms} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). 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 the Patient Monitor is used exceeds the applicable RF compliance level above, the Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Patient Monitor.

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

B.4 Recommended Separation Distances

Recommended separation distances between

portable and mobile RF communications equipment and the monitor

The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.36**	**0.37**	**0.74**
1	**1.16**	**1.17**	**2.33**
10	**3.69**	**3.69**	**7.38**
100	**11.67**	**11.67**	**23.33**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

C Default Settings

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

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

C.1 Patient Information Default Settings

Patient Information Settings	
Patient Type	Adult
Pace	Off

C.2 Alarm Default Settings

Alarm Settings	
Pause Time	120s
Mute	On
Sensor Off Alarm	On
Alarm Latch	Unlatch

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		
Lead Type	5 Leads		
Display	Normal		
Filter	Monitor		
Smart Lead Off	Off		
Heart Volume	2		
ST Analysis	ADU	PED	NEO
ST Analysis	Off		

Alarm Switch	Off		
Alarm Level	Medium		
Alarm Record	Off		
Alarm High Limit (ST-X)	0.2		
Alarm Low Limit (ST-X)	-0.2		
X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6.			
ARR Analysis			
ARR Analysis	On		
PVCs Alarm Level	Medium		
PVCs Alarm Switch	Off		
PVCs Alarm Record	Off		
ARR Alarm Settings	Alarm Switch	Alarm Level	Alarm Record
ASYSTOLE	On	High	Off
VFIB/VTAC	On	High	Off
R ON T	On	Medium	Off
VT > 2	On	Medium	Off
COUPLET	On	Medium	Off
PVC	On	Medium	Off
BIGEMINY	On	Medium	Off
TRIGEMINY	On	Medium	Off
TACHY	On	Medium	Off
BRADY	On	Medium	Off
MISSEDBEATS	On	Medium	Off
IRR	On	Medium	Off
PNC	On	Medium	Off
PNP	On	Medium	Off
VBRADY	On	Medium	Off
VENT	On	Medium	Off

C.4 RESP

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 Time	20s		
Calculation Type	Auto		
Resp Type	II		
Sweep	12.5mm/s		
Amplitude	1		

C.5 SpO_2

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	12.5mm/s		

C.6 PR

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

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
Inflation value	160	140	100
Unit	mmHg		
Interval	Manual		

C.8 TEMP

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

IBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Unit	mmHg		
Filter	12.5Hz		
	SYS, DIA, MAP	SYS, DIA, MAP	SYS, DIA, MAP
Alarm High Limit (ART, P1, P2)	160, 90, 110	160, 90, 110	160, 90, 110
Alarm Low Limit (ART, P1, P2)	90, 50, 70	90, 50, 70	90, 50, 70
Alarm High Limit (PA)	35, 16, 20	35, 16, 20	35, 16, 20
Alarm Low Limit (PA)	10, 0, 0	10, 0, 0	10, 0, 0
	MAP	MAP	MAP
Alarm High Limit (CVP, RAP, LAP, ICP)	10	10	10
Alarm Low Limit (CVP, RAP, LAP, ICP)	0	0	0

C.10 CO_2

CO2 Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Standby		
Unit	mmHg		
Apnea Time	20s		
O_2 Compensate	16%		
Anes Agent	0%		
Alarm High Limit ($EtCO_2$)	50	50	45
Alarm Low Limit ($EtCO_2$)	15	20	30
Alarm High Limit ($FiCO_2$)	4	4	4

Alarm High Limit (AWRR)	30	30	100
Alarm Low Limit (AWRR)	8	8	30
Sweep	12.5mm/s		
Amplitude	Low		

C.11 AG

AG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Measure		
Apnea Time	20s		
Unit	%		
O_2 Compensate	OFF		
Anes Agent	HAL		
Alarm High Limit (EtAA)	8.0	8.0	8.0
Alarm Low Limit (EtAA)	0.0	0.0	0.0
Alarm High Limit (FiAA)	6.0	6.0	6.0
Alarm Low Limit (FiAA)	0.0	0.0	0.0
Alarm High Limit (EtN_2O)	55	55	55
Alarm Low Limit (EtN_2O)	0	0	0
Alarm High Limit (FiN_2O)	53	53	53
Alarm Low Limit (FiN_2O)	0	0	0
Alarm High Limit (EtO_2)	90.0	90.0	90.0
Alarm Low Limit (EtO_2)	18.0	18.0	18.0
Alarm High Limit (FiO_2)	88.0	88.0	88.0
Alarm Low Limit (FiO_2)	18.0	18.0	18.0
Sweep	12.5mm/s		
Amplitude	2		

D Abbreviation

Abbr	English Full Name/Description
AC	Alternating current
Adu	Adult
AG	Anaesthesia gas
Art	Arterial
aVF	Left foot augmented lead
aVL	Left arm augmented lead
aVR	Right arm augmented lead
awRR	Airway respiration rate
BP	Blood pressure
BTPS	Body temperature and pressure, saturated
CI	Cardiac index
C.O.	Cardiac output
CISPR	International Special Committee on Radio Interference
CMS	Central monitoring system
CO_2	Carbon dioxide
COHb	Carboxyhemoglobin
CVP	Central venous pressure
DC	Direct current
Des	Desflurane
Dia	Diastolic
ECG	Electrocardiogram
EEC	European Economic Community
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
Enf	Enflurane
ESU	Electrosurgical unit
Et	End-tidal
$EtCO_2$	End-tidal carbon dioxide
EtN_2O	End-tidal nitrous oxide

Abbr	**English Full Name/Description**
Eto	Ethylene oxide
EtO_2	End-tidal oxygen
FCC	Federal Communication Commission
FDA	Food and Drug Administration
Fi	Fraction of inspired
$FiCO_2$	Fraction of inspired carbon dioxide
FiN_2O	Fraction of inspired nitrous oxide
FiO_2	Fraction of inspired oxygen
Hal	Halothane
Hb	Hemoglobin
Hb-CO	Carbon mono-xide hemoglobin
HR	Heart rate
IBP	Invasive blood pressure
ICP	Intracranial pressure
ICU	Intensive care unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
Iso	Isoflurane
LA	Left arm
LAP	Left atrial pressure
LCD	Liquid crystal display
LED	Light emitting diode
LL	Left leg
MAP	Mean arterial pressure
MDD	Medical Device Directive
MetHb	Methemoglobin
MRI	Magnetic resonance imaging
N/A	Not applied
N_2	Nitrogen
N_2O	Nitrous oxide

Abbr	**English Full Name/Description**
Neo	Neonate
NIBP	Non-invasive blood pressure
O_2	Oxygen
oxyCRG	Oxygen cardio-respirogram
PA	Pulmonary artery
PAWP	Pulmonary artery wedge pressure
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse rate
PVC	Premature ventricular complex
R	Right
RA	Right arm
RAP	Right atrial pressure
Resp	Respiration
RHb	Reduced hemoglobin
RL	Right leg
RR	Respiration Rate
Sev	Sevoflurane
SYS	Systolic pressure
TB	Blood Temperature
TD	Temperature difference
TEMP	Temperature
USB	Universal serial bus

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EDANUSA
www.edanusa.com

4901 Morena Blvd., Suite 505
San Deigo, CA 92117
Tel: 888.850.4597