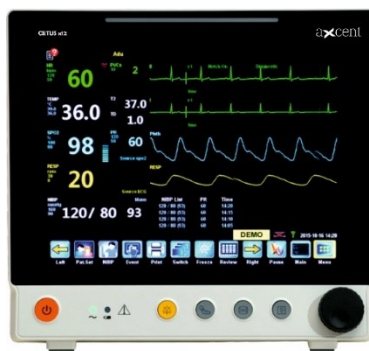


CETUS x12 / x15

MULTI-PARAMETER PATIENT MONITOR

INSTRUCTIONS FOR USE

[Version 1.4.1]



Notice

Thanks for purchasing aXcent medical Multi-parameter Patient Monitor.

Before operating, please read this Manual carefully to ensure proper use.

Please keep this Manual properly for future reference.

Product Name:	Multi-Parameter Patient Monitor
Model:	CETUSx12,CETUSx15.
Structure and Components:	The monitor consists of master unit, display, ECG cable, SpO2 probe, blood pressure cuff, and temperature probe.
Scope of Application:	Monitors patient ECG, respiration (RESP), blood oxygen saturation (SpO2), pulse rate (PR), noninvasive blood pressure (NIBP), and temperature (TEMP) as well as displays, reviews and stores the monitoring information.
Manufacturer:	aXcent medical GmbH Josef-Görres-Platz 2 56068 Koblenz Germany

Version: 1.4.1

Date of Issue: August, 2021

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Statement

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The content of this Manual is subject to change without prior notice.

Only if the following requirements are met, aXcent will be responsible for the safety, reliability and performance of the product, i.e.:

- Assembly, expansion, re-adjustment, improvement and repair should only be performed by qualified personnel approved by aXcent;
- All the replaced parts and supported accessories and consumables relate to the maintenance shall be originally from aXcent or others approved by aXcent;
- The electrical equipment complies with relevant standards and the requirements of this Manual;
- The product is operated in accordance with this Manual.

Warranty and Maintenance Services

The warranty period is 2 years for this product and 6 months for the main accessories. The main accessories include: blood oxygen probe and extension cable, ECG cable, blood pressure cuff and catheter, temperature probe, power cord, stent, and ground wire.

Consumables are disposable materials that should be replaced after each use or wearing parts that should be replaced periodically. The consumables are not covered by warranty.

The warranty period is counted from the purchasing date.

aXcent will be responsible for the safety, reliability and performance of the product if the following requirements are met:

- The product is used in accordance with the Operator's Manual.
- Product installation, repair and upgrade are carried out by personnel approved or authorized by aXcent.
- The storage, operating and electrical environment meets product specifications.
- The S/N label or manufacturer logo of the product is clearly visible, and it is identified and confirmed that the product is manufactured by aXcent.
- The damage is caused by non-human factors (human factors include accidentally dropping, sabotage, etc.).

The products that meet the warranty regulations can enjoy free service, and the products beyond the scope of the warranty will be charged for service. The freight (including customs fees) for transport of this product to aXcent for maintenance is assumed by the user. For the maintenance due to any reason other than the abovementioned causes, aXcent will charge for service, and the user needs to pay additional costs for maintenance and parts.

When the warranty expires, aXcent will continue to provide charged maintenance services.

If you do not pay or delay the payment of maintenance fees, aXcent will suspend the repair services until you pay up.

After-sales Service Unit

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Preface

Notice

This Operator's Manual is the necessary instructions for the safe use of this product. This Manual introduces the use, properties, method of operation, safety information and intended use of the Multi-parameter Patient Monitor in details. Before using the product, please carefully read and understand the contents of this Manual and abide by the method of operation stated in this Manual in order to ensure the safety of patients and operators.

This Operator's Manual is a major component of the product and should always be placed near the product for easy reference.

Object of Application

This Operator's Manual is intended for professional clinical staff or personnel with experience in the use of monitoring equipment. The readers should have knowledge and work experience in medical procedures, practices and terminology of patient monitoring.

Illustration

All the illustrations in this Operator's Manual are for reference only. The menus, settings and parameters of the illustrations may be different from the monitor.

Convention

- [Character]: Used to represent the string in the software or characters on the interface.
- →: This symbol is used to indicate operation step.

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Chapter 1. Safety

1.1 Safety Information



Danger

- A warning that alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in serious injury or death to the user or patient.



Warning

- Alerts you to potential hazard or unsafe operation. Failure to avoid such hazard or operation may result in minor or moderate personal injury or damage to the product or other properties, and possibly in a remote risk of more serious injury.



Caution

- In order to safely use the device continuously, it is required to comply with the instructions listed. The instructions listed in this Manual are not substitute for the medical procedure being performed.

Note

- Emphasize important considerations, and provide a description or explanation in order to make better use of the product.
- In order to safely use the device continuously, it is required to comply with the instructions listed. The instructions listed in this Manual are not substitute for the medical procedure being performed.

1.1.1 Danger

This product does not involve information of danger levels.

1.1.2 Warning



Warning

- This monitor is used for clinical patient monitoring, and only trained and qualified doctors and nurses are allowed to use this monitor.

- Before operating, the user must check if the device, cables and accessories are functioning properly and safely.
- The alarm volume, upper and lower alarm limit should be set according to the actual situation of the patient. Do not just rely on audio alarm system while monitoring the patient, because too low alarm volume or complete shutdown may result in alarm failure and endanger the patient safety. Please pay close attention to the actual clinical situation of the patient.
- This device can only be connected to a grounded electrical outlet; if the power outlet is not connected to the ground wire, do not use the outlet; instead, supply power to the device with rechargeable batteries.
- Do not open the enclosure in order to avoid an electric shock. Any repair and upgrade of the monitor must be done by service personnel trained and authorized by aXcent.
- When handling packaging materials, abide by local laws and regulations or hospital waste disposal regulations. Keep the packaging materials away from children.
- Do not use this instrument at a place with inflammables such as anesthetics to prevent explosion or fire.
- Please install the power lines and cables of accessories carefully to avoid patient entanglement or suffocation, cables tangled or electrical interference.
- The devices connected to the monitor should form an equipotential body (protective grounding effectively connected).
- When the monitor is used together with electrosurgical devices, the user (a doctor or a nurse) should ensure the safety of the patient and instrument.
- The physiological wave, physiological parameters and alarm information displayed on the monitor are only for the doctor's reference and should not be directly used as the basis for clinical treatment.
- This is not a therapeutic unit.
- For patients with pacemakers, the cardi tach ometer may count the pacemaker pulse in case of a cardiac arrest or arrhythmias. Never rely solely on the cardi tach ometer alarm. Closely monitor the patients with pacemakers. For the inhibition of the device on pacemakers, refer to this Operator's Manual.

1.1.3 Caution



Caution

- To avoid damage to the instrument and to ensure patient safety, please use the accessories specified in this Manual.
- Please install or carry the instrument properly to prevent damage due to falling, collision, strong vibration or other mechanical force.

- The electromagnetic fields may affect the performance of the instrument, so that using other devices in the vicinity of this instrument must comply with relevant EMC requirements. For example: mobile phone, X-ray or MRI equipment is likely to be a source of interference, since they will transmit high intensity electromagnetic radiation.
- Before powering on the device, make sure that the power used by the device complies with the supply voltage and frequency requirements on the equipment label or in the Operator's Manual.
- When the instrument and accessories are about to exceed the useful life, it must be treated in accordance with relevant local laws and regulations or the hospital's rules and regulations.

1.1.4 Note

Notes

- Install the device at a place easy for observation, operation and maintenance.
- Keep this Manual near the instrument for easy reference.
- The instrument should be used only by one patient at the same time.

1.2 Symbols

The symbols appearing on the instrument are as follows:

	Defibrillation-proof type CF applied part		Auxiliary output interface
	Defibrillation-proof type BF applied part		USB interface
	Caution: Refer to accompanying documents (Operator's Manual).		Network Interface
	Power on / off		Signal input and output interface
	AC power supply (AC)		Display Interface
	Battery operating indicator		Equipotential terminal
	Alarm silence		Serial Number
	NIBP		Production date
	Wave freezing		Manufacturer info
	Print		Waste Electrical and Electronic Equipment Directive
	Refer to the Operator's Manual		Manufacturer's declaration of product compliance with applicable EEC directives and the Notified Body reference number

Chapter 2. Monitor Overview

2.1 Introduction

2.1.1 Scope of Application

This monitor is suitable for bedside monitoring of adult, pediatric and neonate.

This monitor enables ECG, respiration (RESP), pulse rate (PR), blood oxygen saturation (SPO2), noninvasive blood pressure (NIBP), and temperature (TEMP) monitoring. It is equipped with a replaceable built-in battery to provide convenience for the patient movement in hospital.

2.1.2 Contraindications

None.

2.1.3 Composition and Structure

The monitor consists of master unit, display, ECG cable, SpO2 probe, blood oxygen cuff, temperature probe, and built-in lithium battery.

2.2 Master Unit

2.2.1 Front View

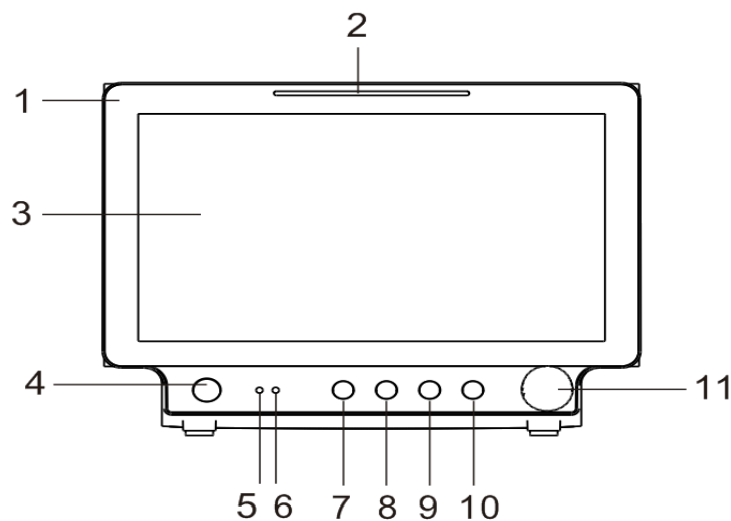


Fig. 2-1 Front View (CETUSx15)

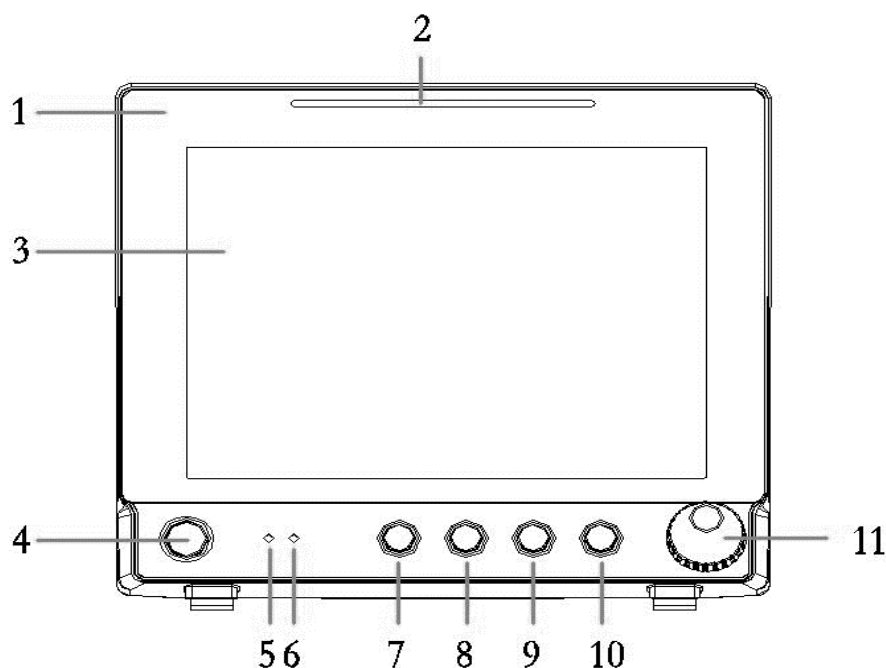


Fig. 2-2 Front View (CETUSx12)

1. Company logo
2. Alarm indicator

The alarm indicator indicates the levels of physiological alarms and technical alarms in different colors and flashing frequencies:

 - High: red, fast flashes
 - Medium: yellow, slow flashes
 - Low: yellow, lit without flashing.
3. Display
4. Power on / off button
 - Power on: When the monitor has been connected to AC power supply, press this key to turn on the monitor.
 - Power off: In power on state, press and hold this key for two seconds to turn off the monitor.
 - The key integrates indicator, which is lit when the monitor is turned on and off when the monitor is turned off.
5. AC power indicator
 - On: The monitor has been connected to AC power.
 - Off: The monitor has not been connected to AC power.
6. Battery indicator

- On: The battery is being charged or has been fully charged.
 - Off: The battery has not been installed, or the battery has been installed but the AC power is not connected and the monitor is not turned on.
 - Flashing: The monitor is being powered by the battery.
7. Silence key: Press this key to turn off/resume the alarm sound of the system.
 8. NIBP measurement start / stop key: press this key to start / stop the measurement of non-invasive blood pressure.
 9. Freeze key: Press this key to freeze / unfreeze the wave.
 10. Print key
 11. Shuttle

Shuttle can be used to perform the following operations:

- Rotate: Rotate clockwise or counterclockwise to move the focus.
- Press: Press the knob to perform an action, such as access to a menu or execute a command.

2.2.2 Side View

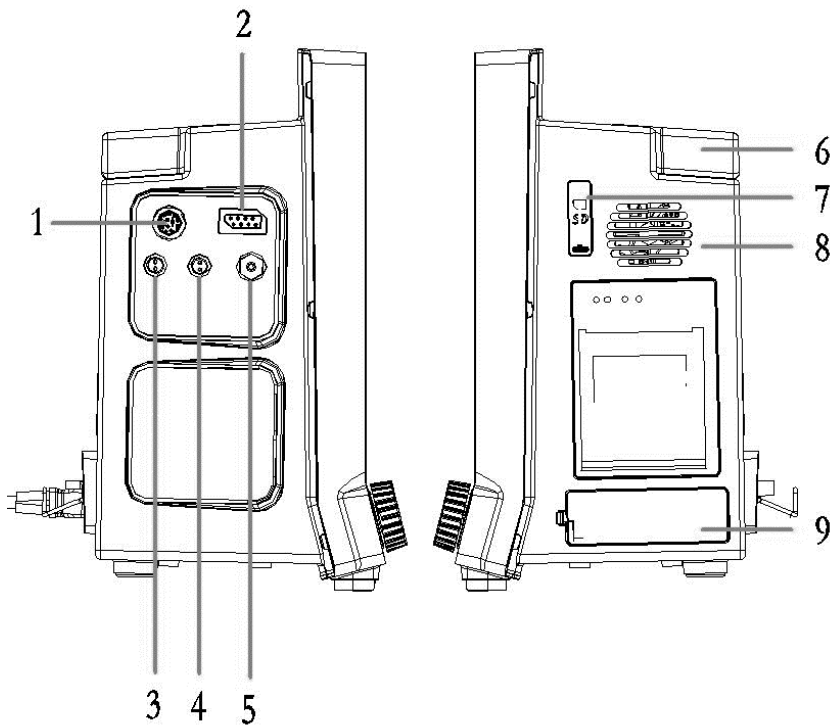


Fig. 2-3 Side View (All models)

- | | |
|---------|-------------------------|
| 1. ECG | —— ECG cable interface |
| 2. SpO2 | —— SpO2 cable interface |

- 3. T1 — Temperature probe interface
- 4. T2 — Temperature probe interface
- 5. NIBP — NIBP cuff interface
- 6. Movable handle
- 7. SD card slot (not available)
- 8. Fan outlet
- 9. Battery cover

2.2.3 Rear View

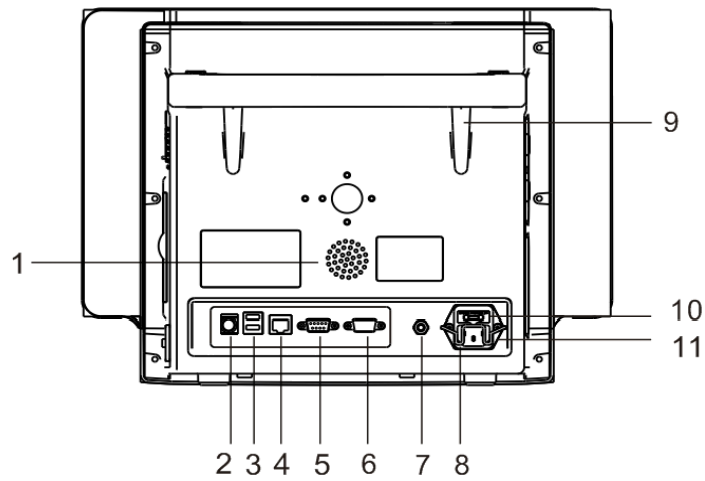


Fig. 2-4 Rear View (CETUSx15)

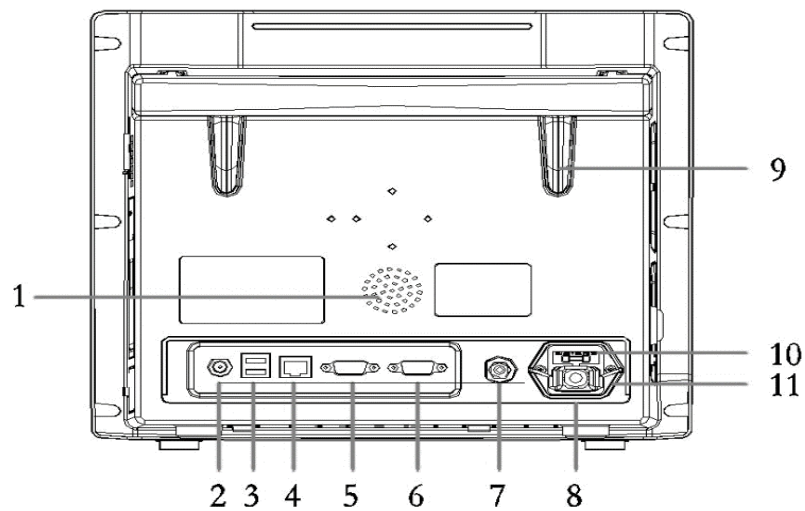


Fig. 2-5 Rear View (CETUSx12)

1. Speaker holes
2. Auxiliary output interface (nurse call, unrealized)
3. USB interfaces (2): Connect an external storage device to upgrade the monitor software.
4. Network interface
5. Signal input and output interface: standard DB9 interface, which can be connected to the PC to output data or connected with a compatible device.
6. Display interface: Connected to a standard color VGA/HDMI monitor for auxiliary display and monitoring. External monitor displays the same content as the monitor display.
7. Equipotential terminal: When other devices are used in conjunction with the monitor, you should connect the equipotential terminals of other devices and the monitor with wires to eliminate the ground potential difference between different devices and ensure safety.
8. Power cord retaining hook
9. Hook
10. Fuse
11. AC power socket

2.3 Screen Display

The monitor uses high-resolution color TFT LCD, which can clearly show the physiological parameters and waves and other information of patients and provide patient information, alarm information, clock, monitor status and other tips. The figure below is the standard interface (demo mode) of the monitor in the normal monitoring state.

The screen of the standard interface is divided into five areas: 1.Info area, 2.Parameter area, 3.Wave area, 4.Info tip area, 5.Smart hotkey area.



Fig. 2-6 Standard Interface (Demo Mode)

1. Introduction of info area (1)
The info area includes patient information, alarm status icon, physiological alarms and technical alarms from left to right.
2. Introduction of parameter area (2)
It consists of small parameter areas, which show the corresponding parameter measurement value and current upper and lower alarm limits of each parameter module. The parameters are shown in fixed positions, that is, from top to bottom and from left to right:
 - ECG parameter area
 - NIBP parameter area
 - SPO2 and PR parameter area
 - TEMP parameter area
 - RESP parameter area
3. Introduction of wave area (3)
It mainly displays the waves of physiological parameters, and upper left corner of each wave shows the wave name.
4. Introduction of info tip area (4)
Display the current time, freezing information, battery status, network status, etc.; in DEMO mode, it displays [DEMO].
5. Introduction of smart hotkey area (5)
The smart hotkey area shows the hotkeys, which are mainly used for some common operations; see 2.4 for details.

2.4 Smart Hotkeys

Smart hotkeys are some graphics hotkeys displayed at the bottom of the main screen of the monitor and enable you to use certain features conveniently. The smart hotkeys at the bottom of the main screen are divided into fixed smart hotkeys and removable smart hotkeys.

There are five fixed smart hotkeys, of which the names or features are:



[Pause]: Alarm pause



[Left]: Slide left to show more smart hotkeys



[Right]: Slide right to show more smart hotkeys



[Main]: Return to the main interface



[Menu]: Main menu

There are ten removable smart hotkeys:



[Pat.Set]: Patient info setting key



[NIBP]: NIBP measurement start / stop key



[Event]: Manual event



[Print]: Print key



[Switch]: Interface switch key



[Freeze]: Freeze key



[Ala.Set]: Alarm setting key



[Silence]: Silence key



[Review]: Review key



[Vol.Set]: Volume setting key

Chapter 3. Basic Operation

3.1 Installation

Note

- To ensure normal working of the monitor, read this chapter before use, and install as required.



Warning

- All analog and digital devices connected to the monitor must be certified by IEC standards (e.g., IEC 60950 Data Processing Equipment Standard and IEC 60601-1 Medical Equipment Standard). Furthermore, all configurations shall comply with valid version of IEC 60601-1 standard. The personnel connecting additional devices to the input / output signal ports are responsible for the compliance with IEC 60601-1 standard. If there is any question, please contact aXcent.
- If the patient cable interface and network interface are connected with multiple devices, the total electric leakage cannot exceed the allowable value.
- The copyright of the monitor software belongs to aXcent. Without permission, any organization or individual shall not interpolate, copy or exchange by any means or form.
- When the monitor is combined with other devices, it must comply with IEC60601-1, and shouldn't be connected with multi-socket wire board or extension cord.

3.1.1 Unpacking

Before unpacking, please check the box carefully. If any damage is found, please contact the carrier immediately. Unpack properly, take out the monitor and accessories carefully, and check the accessories according to the packing list. Check for any mechanical damage and if the items are complete. If there is any question, please contact our sales department or dealer.

Note

- Please keep the packing box and material for use in future transporting or storage.

3.1.2 Environmental Requirements

The storage, transport and use of the monitor must meet the following environmental requirements.

Working environment	Ambient temperature range	5°C~40°C
	Relative humidity range	<80%
	Atmospheric pressure range	70kPa~106kPa
Supply voltage requirement	Supply voltage	a.c.100V~240V, d.c.11.1V
	Power frequency	50Hz/60Hz
	Input power	40VA-60VA
	Fuse	FUSE T 1.6A
Transportation	Prevent severe shock, vibration, rain and snow splashing during transport.	
Storage	The packaged monitor should be stored in well-ventilated room with ambient temperature -20°C~+55°C, relative humidity lower than <93%, atmospheric pressure 50kPa~106kPa, and without corrosive gases.	

The operating environment of the monitor should avoid noise, vibration, dust, corrosive or flammable and explosive materials. In order to allow air flowing smoothly and achieve good heat dissipation, at least 2 inches (5cm) clearance should be kept around the device.

When the device is moved from one environment to another, the device may have condensation due to differences in temperature or humidity. In this case, wait until the condensation disappears before using the device.



Warning

- Please ensure that the device operates under stipulated environment, or else technical specifications declared in this Manual may not be met, and it may result in damage to equipment and other unforeseen consequences.

3.2 Connecting to AC Power

Connect to AC power in the following steps:

- Make sure that the AC power supply meets the following specifications: AC 100V ~ 240V, 50/60Hz.

- Use the power cord provided with the monitor. Plug the power cord into the power connector of the monitor and plug the other end of the power cord into the mains (low voltage power supply network facilities) power outlet with protective earthing.

Note

- Connect the power cord to the dedicated outlet in the hospital.

3.3 Turning on

3.3.1 Checking the Monitor

- Before turning on, check whether there is mechanical damage to the monitor, and whether the external cables and accessories are connected correctly.
- Plug the power cord into the AC power outlet. If using battery power, make sure the battery is fully charged.
- Check all the functions required for patient monitoring to make sure that the monitor works properly.



Warning

- If the monitor is damaged, or fails to work normally, do not use it for patient monitoring. Please contact the maintenance personnel or aXcent immediately.

3.3.2 Starting the Monitor

After checking the monitor, you'll be ready to start the monitor.

Press the power switch, the yellow and red warning lights flash once in turn, and the system enters the program reading interface; then the company's LOGO is shown; finally, the system makes a “tick” sound, the boot screen disappears, and the system enters the main interface.

If the yellow and red warning lights flash once in turn when the device is turned on and the monitor makes a “tick” sound, the warning system of the monitor can work normally.

Notes

- If any fatal error occurs during self-test, the system will alarm.
- Check all available monitoring functions to ensure that the monitor functions properly.

- If the monitor integrates a battery, charge the battery after each use to secure sufficient power.

3.3.3 Connecting the Sensor

Connect the required sensor to the monitor and the monitoring position on the patient.

Note

- For proper connections and related requirements for a variety of sensors, see Chapters 7-12.

3.3.4 Starting Monitoring

Start monitoring in the following steps:

- Check if the patient cable and the sensor are connected properly.
- Check if the settings of the monitor are correct, such as: patient category [Patient Cat.]
- For the details of parameter measurement or monitoring, see the appropriate section.

3.4 Turning off

Please turn off the monitor in the following steps:

- Disconnect the cables and sensors connected to the patient.
- Press and hold the power switch for two seconds to pop up the 5sec countdown window, and the monitor turns off in five seconds.



Caution

- If the monitor cannot be turned off properly or special cases occur, you can simply disconnect the power to force shutdown. However, forced shutdown may cause data loss, and is not recommended.

3.5 Basic Operation

3.5.1 Using the Shuttle

Shuttle can be used to perform the following operations:

- Rotate: Rotate clockwise or counterclockwise to move the focus.
- Press: Press the shuttle to perform an action, such as access to a menu or execute a command.

Shuttle is the main control key. On the interface or the menu, the green highlighted box that moves with the knob turning is called the cursor. By turning the shuttle, you can position the cursor in order to perform the desired operation.

3.5.2 Using Keys

The monitor has three types of keys:

- Soft keys: The position that the cursor can stay on the interface, allowing quick access to certain menus or performing certain actions, including:
 - ◆ Parameter hotkey: Select a parameter area and enter the appropriate parameter setup menu.
 - ◆ Wave hotkey: Select a wave area and enter the appropriate parameter setup menu.
 - ◆ Smart hotkey: The shortcut keys that the user can operate quickly at bottom of the screen; see “Smart Shortcuts” for details.
- Hard keys: The physical keys on the monitor, such as the alarm silence key on the front panel.
- Popup keys: Menu keys relevant to the tasks that automatically appear in the monitor screen when needed. For example: the confirmation key popped up when you need to confirm the change.

3.5.3 Using the Touch Screen

You can directly click on the touch screen to quickly and easily accomplish some operations.

3.5.4 Using Soft Keyboard

Click on the edit box, and the system will display the soft keyboard on the screen; you can turn the shuttle or use the touch screen to select characters one by one, and input data. Use the Back key to delete a single character; use the Enter key to confirm that you have finished entering and close the soft keyboard.

3.5.5 Using Menu

Select the  [Menu] key on the monitor interface via the shuttle or directly the touch screen to open the [Main Menu] as shown below. Through the main menu, you can complete most of the operations and settings.



Fig. 3-1 [Main Menu]

The style of other menus is basically similar to the [Main Menu], and generally consists of the following components:

- Menu title: a summary of the current menu.
- Close menu: Close the current menu, exit the current menu or close the current menu and return to the previous menu.
- Main display area: display options, buttons or prompt messages. The symbol ">>" indicates that selecting this option can enter the corresponding submenu.
- Confirmation key area: Some menus contain a confirmation key area to confirm the menu operations, including confirmation and cancel key.

3.6 Operating Mode

The monitor has 2 operating modes, of which the demo mode is protected by a password.

1. Monitoring mode (operating mode)

This is the daily operating mode of patient monitoring; you can change some settings in accordance with the patients, such as alarm limits. However, when the patient is discharged, the monitor will restore these settings to default according to pre-set configuration.

2. Demo mode

This mode is protected by a password (default: 8888) for demonstration purpose only.

■ Enter the demo mode:

- ◆ Select  [Menu] Smart Hotkey→[Main Menu];
- ◆ Select [Demo >>] → enter the password and confirm, and the monitor enters the demo mode.

■ Exit demo mode:

- ◆ Select  [Menu] Smart Hotkey→[Main Menu];
- ◆ Select [Exit Demo >>] and the monitor exits the demo mode.



Warning

- The demo mode is mainly used to show the machine performance and for user training. In actual clinical use, the demo function is prohibited in order to avoid mistaking the displayed waves and parameters as those of the patient, thus affecting patient monitoring, and delaying diagnosis and treatment.

3.7 Measurement Setup

This section only describes the general settings of measuring wave in monitor mode; for other specific settings of each parameter, please refer to the appropriate section.

Click the wave area of a parameter to enter the appropriate setup menu. The setup menu defines the specific wave setup of the parameter, such as wave gain and wave speed; you may set the waves of different parameters as needed.

3.8 Freezing Waves

In the patient monitoring process, you can freeze the wave on the screen, review and

carefully observe the patient's condition during this time. Freeze / unfreeze the wave as follows:

Select  [Freeze] hotkey to freeze the displayed wave of the monitor.

Click  [Freeze] hotkey again to release the freezing state.

3.9 Other Common Setup

The common setup of the monitor is the general setup that defines how the monitor works, for example: alarm volume setting. They may affect the setup of multiple measurements or display interfaces.

3.9.1 Defining the Monitor

When install the monitor or change the usage occasion, the monitor should be defined as follows:

- Select  [Menu] Smart Hotkey→[Main Menu];
- Select [User Maintenance >>]→ [User Maintenance] menu;
 - ◆ Select [Device Name]: Enter device name through the soft keyboard on the screen.
 - ◆ Select [Department]: Enter the sector and department using the device through the soft keyboard on the screen.
 - ◆ Select [Bed No.]: Enter the bed number through the soft keyboard on the screen.

3.9.2 Language Setup

Set the monitor language in the following steps:

- Select  [Menu] Smart Hotkey→[Main Menu];
- Select [User Maintenance >>]→ [User Maintenance] menu;
- Select [Language], and select the option as needed:
 - ◆ [English]: The interface language of the monitor is English.
 - ◆ [Spanish]: The interface language of the monitor is Spanish.
 - ◆ [PYCCKNN]: The interface language of the monitor is Russian.
 - ◆ [Francais]: The interface language of the monitor is French.

- ◆ [Turkce]: The interface language of the monitor is Turkish.
- ◆ [Chinese]: The interface language of the monitor is Chinese.
- ◆ [Portugues]: The interface language of the monitor is Portuguese.
- ◆ [Deutsch]: The interface language of the monitor is German.
- ◆ [Polskie]: The interface language of the monitor is Polish.
- ◆ [Romania]: The interface language of the monitor is Romanian.
- ◆ [Italia]: The interface language of the monitor is Italian.

3.9.3 Date and Time

Set the monitor time in the following steps:

- Select  [Menu] Smart Hotkey → [Main Menu];
- Select [User Maintenance >>] → enter [User Maintenance] menu;
- Select [Time Setup >>] → enter [Time Setup] menu;
- Select [Date Format], and set the date format in accordance with custom
 - ◆ [YYYY-MM-DD]: Year - Month - Day.
 - ◆ [MM-DD-YYYY]: Month - Day - Year.
 - ◆ [DD-MM-YYYY]: Day - Month - Year.
- [Date]: Set the year, month, and day.
- [Time]: Set the hour, minute and second.

3.9.4 Volume Control

1. Alarm volume

- Select  Vol.Set smart hotkey → [Volume Setup] menu;
- Select [Alarm Vol]: Set [Y]. Y is X~9, X is the minimum volume, and Y value plus / minus 1 when turning the shuttle once.

2. Key-pressing volume

- Select  Vol.Set smart hotkey → [Volume Setup] menu;
- Select [Key Volume]: [N]. N value ranges from 0 to 9, plus / minus 1 when turning the shuttle once, select 0 to turn off the key-pressing tone, and select 9 to set to the maximum volume.

3. QRS volume

- Select  Vol.Set smart hotkey → [Volume Setup] menu;

Select [QRS Volume]: [M]. M values ranges from 0 to 9, plus / minus 1 when turning the shuttle once, select 0 to turn off the key-pressing tone, and select 9 to set to the maximum volume.

3.9.5 Setting Parameter Unit

You can select a preferred unit through the following operations

- Select  [Menu] Smart Hotkey→[Main Menu];
- Select [User Maintenance >>]→ [User Maintenance] menu;
- Select [Unit Setup >>] → [Unit Setup] menu;
 - ◆ Select [Height], and select the unit [cm] / [inch] as needed.
 - ◆ Select [Weight Unit], and select the unit [kg] / [lb] as needed.
 - ◆ Select [Press.Unit], and select the unit [mmHg] / [kPa] as needed.
 - ◆ Select [Temp Unit], and select the unit [°C] / [°F] as needed.

Chapter 4. Patient Information Management

Connect the patient to the monitor, and the monitor will display and store the physiological data of the patient, so the patient can be monitored without admitting the patient. However, admitting the patient correctly is very important.

If the monitor has admitted the patient, it is recommended to operate the monitor to discharge the current patient before connecting to (not admitted) the next patient. Otherwise, the data of the previous patient will be stored in the data of the current patient.



Warning

- Whether the patient is admitted or not, the system will give a default value to [Patient Cat.] and [Paced], and the user must confirm that the default value is appropriate for the patient being monitored.
- For patients with pacemakers, [Paced] must be set to [Yes]. Otherwise, the pacing pulse will be treated as normal QRS wave group, and the system is unable to detect the alarm status of [ECG Signal weak].
- For patients without a pacemaker, [Paced] must be set to [No]. Otherwise, the system is unable to detect the arrhythmias (including PVCs count) related to ventricular premature beats, and fails to perform ST segment analysis.

4.1 Patient Setup Menu

You can manage the patients through the [Patient Setup] menu; to enter the [Patient Setup] menu, operate as follows:

Select  [Menu] Smart Hotkey → [Main Menu];

Select [Patient Setup >>] → [Patient Setup] menu, as shown in Fig. 4-1.

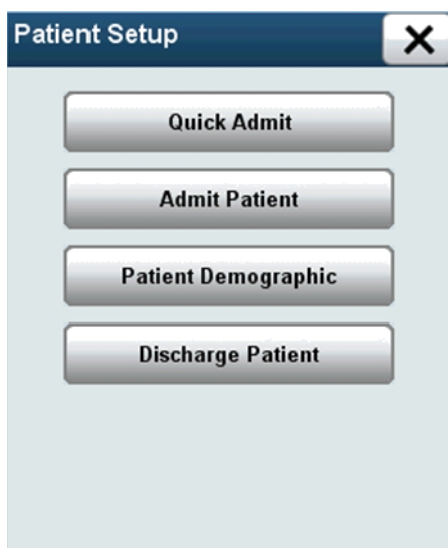


Fig. 4-1 Patient Info Setting

4.2 Admitting a Patient Quickly

Admit a patient quickly as follows:

In [Patient Setup] menu, select [Quick Admit] → [Warning] menu → [OK] → [Quick Admit] menu, which is shown below:

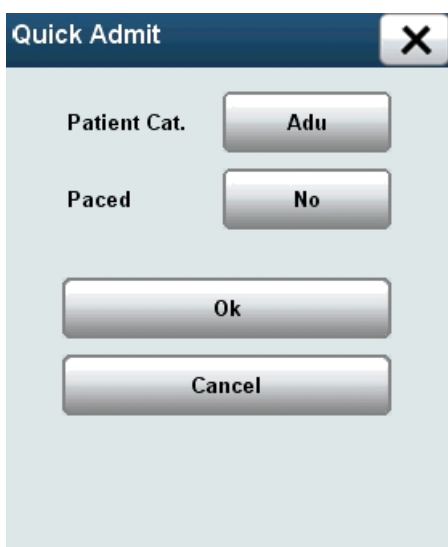


Fig. 4-2 Quick Admitting Menu

- Select [Patient Cat.], and set the patient category as needed:
 - ◆ [Adu]: Adults.
 - ◆ [Ped]: Pediatric.
 - ◆ [Neo]: Neonate.

- Select [Paced], and set whether the patient wears a pacemaker according to the patient condition:
 - ◆ [Yes]: The patient wears a cardiac pacemaker.
 - ◆ [No]: The patient does not wear a cardiac pacemaker.

After setting, select [OK] to save the current setup; select [Cancel] and do not save the current setup.

4.3 Admitting a Patient

To admit a patient, operate as follows:

In the [Patient Setup] menu, select [Admit Patient] → [Warning] → [OK] → [Patient Info] menu, which is shown below:

The screenshot shows a 'Patient Info' dialog box with the following fields and controls:

- SurName**: Text input field.
- Name**: Text input field.
- Case**: Text input field.
- Gender**: Button.
- Height (cm)**: Text input field.
- Patient Cat.**: Button with 'Adu'.
- Weight (kg)**: Text input field.
- Paced**: Button with 'No'.
- Blood Type**: Button.
- Admit date (yyyymm-dd)**: Three separate text input boxes separated by hyphens.
- Birthday (yyyymm-dd)**: Three separate text input boxes separated by hyphens.
- Ok**: Button at the bottom left.
- Cancel**: Button at the bottom right.

Fig. 4-3 Patient Info

1. Select [SurName], and enter patient's surname through the soft keyboard.
2. Select [Name], and enter patient name through the soft keyboard.
3. Select [Case], and enter the case number through the soft keyboard.

4. Select [Gender], and set the patient's gender according to the patient condition:
 - ◆ [Male]: Males.
 - ◆ [Female]: Females.
 - ◆ [Others]: Others.
5. Select [Patient Cat.], and set the patient category as needed:
 - ◆ [Adu]: Adults.
 - ◆ [Ped]: Pediatric.
 - ◆ [Neo]: Neonate.
6. Select [Paced], and set whether the patient wears a pacemaker according to the patient condition:
 - ◆ [Yes]: The patient wears a cardiac pacemaker.
 - ◆ [No]: The patient does not wear a cardiac pacemaker.
7. Select [High (cm)], and set the patient's height via the pop-up keyboard on the screen.
8. Select [Weight (kg)], and set the patient's weight via the pop-up keyboard on the screen.
9. Select [Blood Type], and set the patient's blood type:
 - ◆ [A]: Patient blood type is A.
 - ◆ [B]: Patient blood type is B.
 - ◆ [AB]: Patient blood type is AB.
 - ◆ [O]: Patient blood type is O.
 - ◆ [Others]: Other blood type of the patient.
10. Select [Admit date (yyyy-mm-dd)], and set the date of admitting the patient.
11. Select [Birthday (yyyy-mm-dd)], and set the birth date of the patient.

After setting, select [OK] to save the current setup; select [Cancel] and do not save the current setup.

4.4 Editing Patient Info

When the monitor has admitted a patient, but the patient information is incomplete, or needs to be changed:

Select the patient info area on the display to pop up [Patient Info] menu as shown in Fig. 4-3, and complement or change the patient info in the [Patient Info] menu; see 4.2 for specific

operation.

4.5 Discharging a Patient

To discharge a patient, operate as follows:

In the [Patient Setup] menu, select [Discharge Patient] → [Warning] → [OK] to finish the operation of discharging a patient.

After the patient is discharged, all the information of the patient stored by the monitor will be cleared. Therefore, discharge the patient only when needed.

Chapter 5. User Interface

The monitor has four working interfaces, which are “Normal Screen”, “Big Numerics”, “ECG 7-Lead Half-Screen”, “ECG 7-Lead Full-Screen” and “ECG 12-Lead Full-Screen”. The user can select the working interface according to needs, and get different screen information. Below describes the working interfaces.

5.1 Selecting User Interface

Select the user interface as follows:

- Select  [Switch] smart hotkey→[Screen Setup];
- Select [Screen Select], and select the user interface according to needs:
 - ◆ [Normal Screen]: Standard interface.
 - ◆ [Big Numerics]: Big font interface.
 - ◆ [ECG 7-Lead Half-Screen]: ECG 7-lead half-screen.
 - ◆ [ECG 7-Lead Full-Screen]: ECG 7-lead full screen
 - ◆ [ECG 12-Lead Full-Screen]: ECG 12-lead full screen(Optional)
 - ◆ [OxyCRG Screen]: OxyCRG interface
 - ◆ [DynaTrend Screen]: DynaTrend interface

5.2 Interface Introduction

5.2.1 Normal Screen

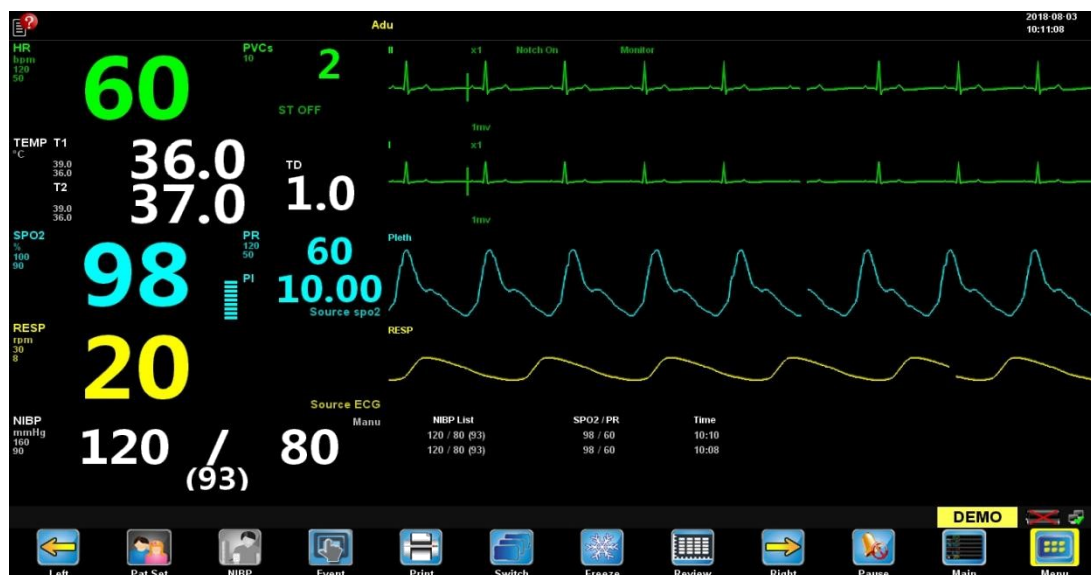


Fig. 5-1 Normal Screen

The normal screen provides the parameter wave being monitored and the parameters displayed in the parameter area. This is the basic working interface of the monitor. The interface displays all parameters, two ECG waves, one blood oxygen binding capacity scan wave, and one respiratory wave. You can remove unwanted parameter from the display.

5.2.2 Big Numerics

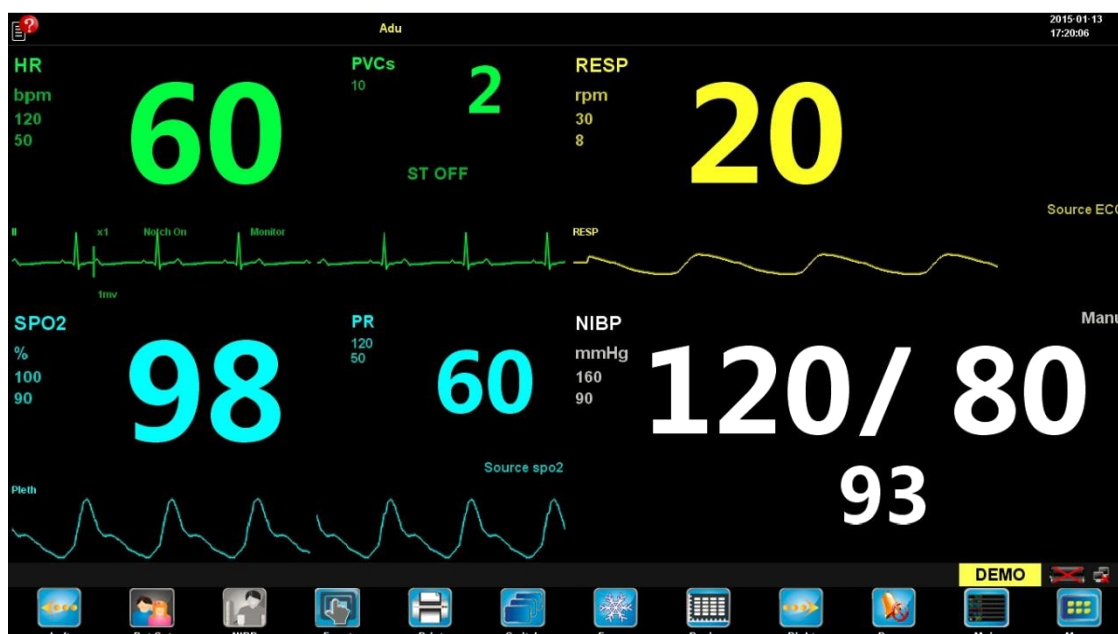


Fig. 5-2 Big Numerics Screen

Big Numerics screen allows observing other parameters except the body temperature, one ECG wave, one respiratory wave, and one blood oxygen binding capacity scan wave.

5.2.3 ECG 7-Lead Half-Screen

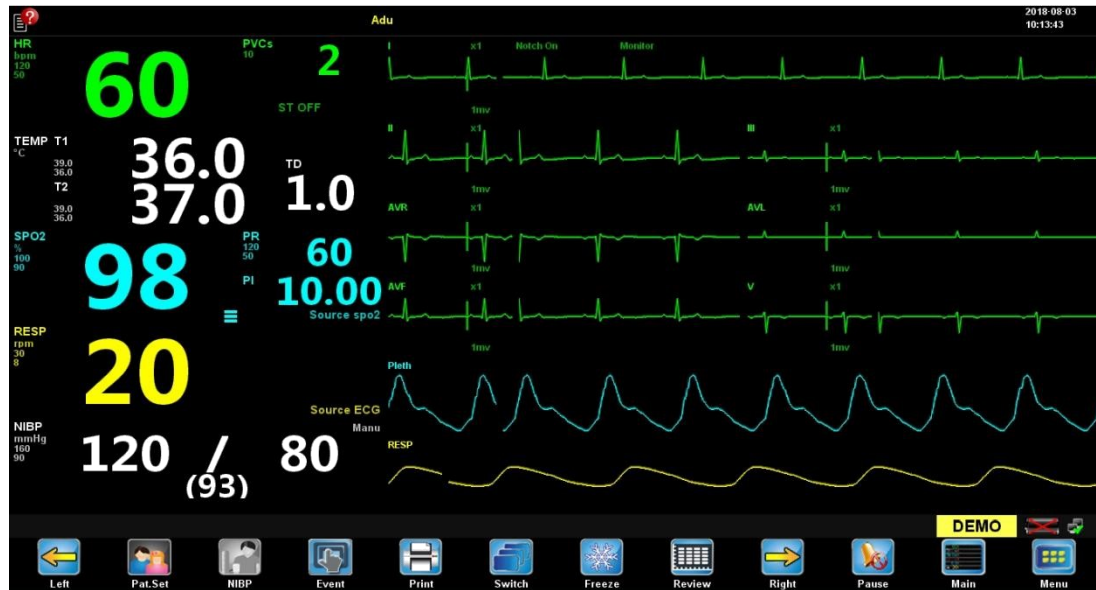


Fig. 5-3 ECG 7-Lead Half-Screen

ECG 7-Lead Half-Screen allows observing all parameters, seven ECG waves (I, II, III, AVR, AVL, AVF, V), one blood oxygen binding capacity scan wave, and one respiratory wave.

5.2.4 ECG 7-Lead Full-Screen

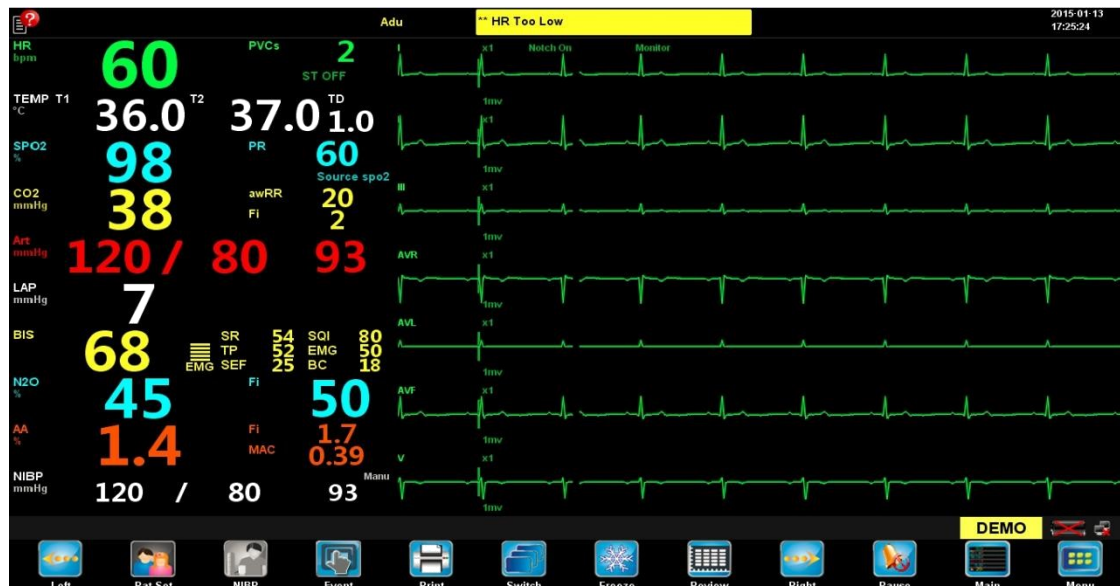


Fig. 5-4 ECG 7-Lead Full-Screen

This interface allows observing all parameters, and seven ECG waves (I, II, III, AVR, AVL, AVF, V) simultaneously.

5.2.5 ECG 12-Lead Full-Screen

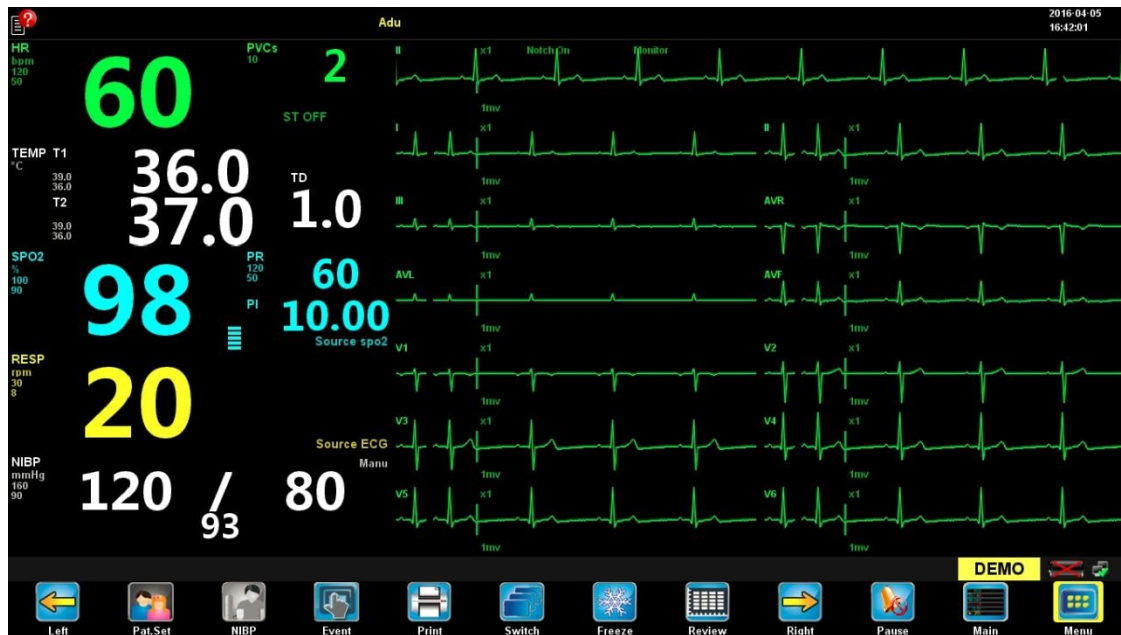


Fig. 5-5 ECG 12-Lead Full-Screen

This interface allows observing all parameters, and twelve ECG waves (I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5, V6) simultaneously.

5.2.6 OxyCRG Screen

The Respiratory Oxygenation graph screen is shown below

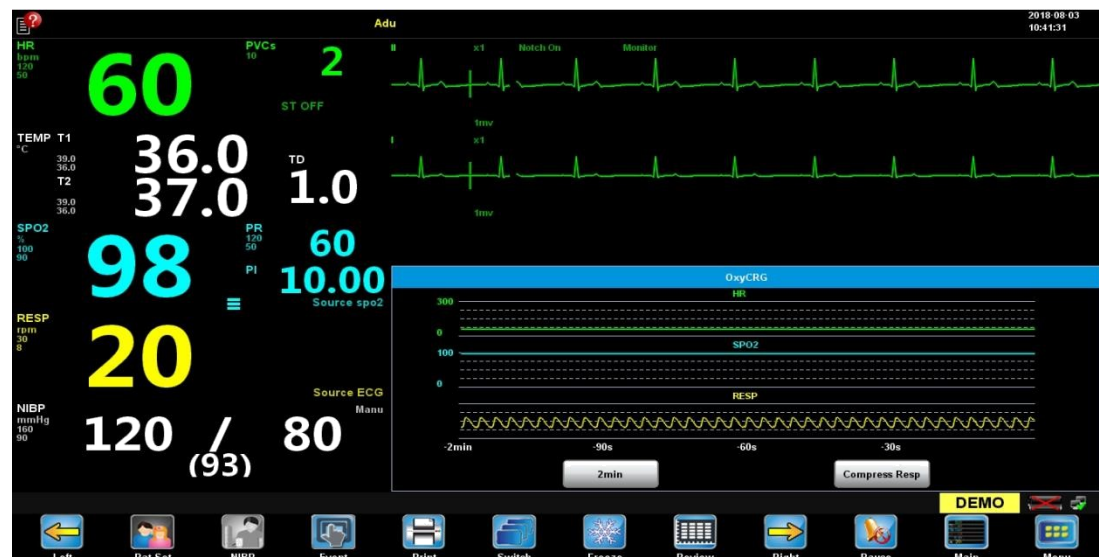


Fig. 5-6 OxyCRG Screen

The respiratory oxygenation diagram interface occupies the lower half of the waveform area and is composed of HR trend, SpO2 trend, and compressed respiratory wave or RR trend. There are 2 hot keys below: trend time length and compressed breath / RR trend.

1. Trend time length

You can select the length of time: 1 minute, 2 minutes, 4 minutes

2. Respiratory wave / RR trend

You can toggle the display of [Respiratory Wave] or [RR Trend]

5.2.7 DynaTrend Screen

The DynaTrend screen is shown below:

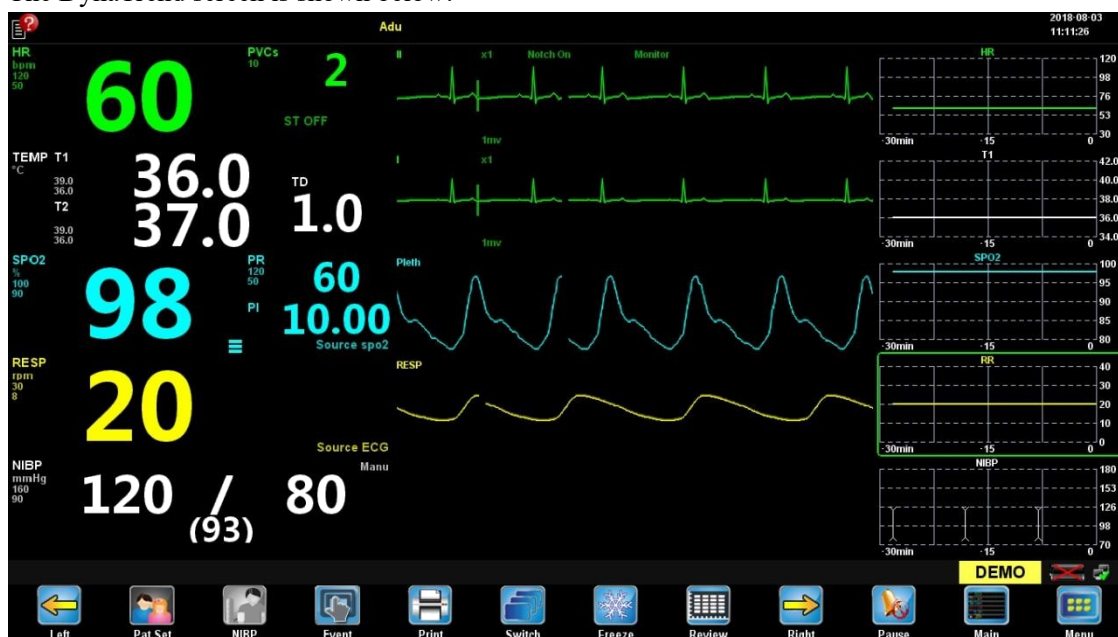


Fig. 5-7 DynaTrend Screen

Dynamic short trends are located on the right side of the waveform area, showing trends for a range of parameters over the most recent period. The top of each trend graph shows the trend of the parameter name, the right shows the scale, below shows the time.

The trend time, the right scale, the parameter name can be changed manually: select any parameter trend area, select **【Parameter】**, **【Trend Time】**, **【Standard】** and **【Reference】** in the **【Short Trend Setting】** menu. [Maximum value].

The respiratory oxygenation diagram interface occupies the lower half of the waveform area and is composed of HR trend, SpO2 trend, and compressed respiratory wave or RR trend. There are 2 hot keys below: trend time length and compressed breath / RR trend.

1. Trend time length

You can select the length of time: 1 minute, 2 minutes, and 4 minutes

2. Respiratory wave / RR trend

You can toggle the display of [Respiratory Wave] or [RR Trend]

Chapter 6. Alarm

Alarm means that the monitor prompts the medical staff through sound and light when the patient being monitored has abnormal changes in vital signs or the monitor has a failure and unable to monitor the patient successfully.



Warning

- In any single region (e.g. ICU), it has potential dangers if the same or similar devices use different alarm setups.

Note

- After setting, the alarm and other parameters of the monitor will not be lost when the system power is cut off, unless modified manually; connect the power again (external and internal) and turn on the monitor, it will resume normal working, and the alarm and other parameters remain unchanged.

6.1 Alarm Type

According to the nature of the alarm, the alarms of the monitor can be divided into physiological alarms, technical alarms and prompt messages.

■ Physiological alarms

A physiological alarm is usually triggered when a physiological parameter of the patient exceeds the alarm limit or the patient has physiological abnormalities. The information of physiological alarm is displayed in the physiological alarm area on top of the screen.

■ Technical alarms

Technical alarm is also known as a system error message, which is caused by improper operation or system failure resulting in system malfunction or monitoring result distorted. The information of technical alarm is displayed in the technical alarm area on top of the screen.

■ Prompt messages

Strictly speaking, the prompt messages are not alarms. The monitor also will display some information associated with system status in addition to the physiological alarms and

technical alarms, and generally such information do not involve the patient's vital signs. The prompt messages generally appear in the technical alarm area and parameters area.

6.2 Alarm Level

According to the severity of the alarm, the physiological alarms of the monitor can be divided into high level, medium level and low level.

■ High level alarms

The patient is in critical condition that is life-threatening, and should be immediately rescued;

Or the monitor has a serious mechanical failure or malfunction, causing it unable to detect the patient's critical state and endangering the patient's life.

■ Medium level alarms

The patient's physiological signs are abnormal, and appropriate measures or treatment should be taken immediately;

Or although it won't endanger the patient's life, the mechanical failure or misoperation of the monitor will affect the normal monitoring of key physiological parameters.

■ Low level alarms

The patient's physiological signs are abnormal, and appropriate measures or treatment may need to be taken;

Or certain monitoring function is invalid due to mechanical failure or misoperation, but it won't endanger the patient's life.

The levels of all technical alarms and some physiological alarms have been set in the monitor at the factory and cannot be modified by the user. The levels of some physiological alarms can be modified.

6.3 Alarm Mode

When an alarm occurs, the monitor uses the following audible or visual alarm to prompt the user:

■ Light alarm

- Audible alarm
- Alarm info
- Parameter flashing

Of which, the light alarm, audible alarm, and alarm info distinguish the alarm levels in a different manner respectively.

6.3.1 Light Alarm

When an alarm occurs, the alarm indicator will flash in different colors and frequencies to prompt the alarm level.

- High level alarm: Red, fast flashes
- Medium level alarm: Yellow, slow flashes
- Low level alarm: Yellow, lit without flashing

6.3.2 Audible Alarm

An audible alarm is that the monitor prompts the alarm levels with different sound characteristics when an alarm occurs.

- High level alarm: Beep - beep - beep -- beep - beep ---- beep - beep - beep -- beep - beep
- Medium level alarm: Beep - beep - beep
- Low level alarm: Beep

6.3.3 Alarm Info

Alarm info refers to that the physiological or technical alarm area of the monitor will display the corresponding alarm information when an alarm occurs. The system will distinguish the alarm levels with different background colors:

- High level alarm: Red
- Medium level alarm: Yellow
- Low level alarm: Yellow

The following flags in front of physiological alarms are used to distinguish the alarm levels:

- High level alarm: ***
- Medium level alarm: **
- Low level alarm: *

6.3.4 Parameter Flashing

When a physiological parameter of the patient alarms, the parameter values in the parameter area will flash once per second, and the upper limit and lower limit of the parameter will also flash at the same frequency, indicating that the parameter exceeds the upper limit or lower limit.

6.4 Alarm States

In addition to the above alarm modes, you can also set the monitor to the following four alarm states as needed, and display different alarm icons on the screen:

-  Alarm silence
-  Alarm sound off
-  Alarm pause
-  Alarm off

6.4.1 Silence

Select  [Silence] smart hotkey, and you can temporarily turn off the alarm sound of currently occurring physiological alarms of the monitor, but the alarm information is still retained. For technical alarms, clear the alarm state, display alarm prompt information only and the monitor enters alarm silence state, and the alarm state icon area displays the  icon.

When a new physiological alarm or technical alarm occurs, the alarm silence is automatically canceled.

6.4.2 Alarm sound off

The alarm sound can be turned off through the following operations:

- Select  [Menu] Smart Hotkey → [Main Menu];
- Select [User Maintenance >>] → [User Maintenance] menu;
- Select [Alarm Param >>] → [Ala.Para Setup] menu;
- Set [Min Alarm Vol] to [0];

- Select  [Vol.Set] smart hotkey → [Volume Setup] menu;
- Set [Alarm Volume] to [0].

When the alarm sound is turned off, the alarm state area on the screen shows the  icon.

If [Min Alarm Vol] is larger than 0, the system will cancel alarm sound off state.

6.4.3 Alarm Pause

Press the  [Pause] smart hotkey to temporarily stop the alarm of the monitor in the following steps:

- Alarm state icon area will display the  icon.
- The light alarm and audible alarm of the physiological alarms are suspended, and the alarm information is not displayed.
- The remaining time of alarm pause is displayed in the physiological alarm area.
- Alarm parameters and upper / lower limit stop flashing.
- The audible alarm and light alarm of technical alarms are suspended, but the alarm message is still displayed.

After the alarm pause is finished, the monitor will automatically cancel the alarm pause state.

During the alarm pause, you can also press  [Pause] smart hotkey to manually cancel the alarm pause.

You can set the alarm pause time as follows:

- Select  [Menu] Smart Hotkey → [Main Menu];
- Select [User Maintenance >>] → [User Maintenance] menu;
- Select [Alarm Param >>] → [Ala.Para Setup] menu;
- Select [Alarm Pause Time], and set the alarm pause time as needed:
 - ◆ [1min] / [2min] / [3min] / [4min] / [5min] / [10min] / [15min]: Set the alarm pause time to 1 min, 2 min, 3 min, 4 min, 5 min, 10 min or 15 min. By default, the alarm pause time is 2 minutes.
 - ◆ [Permanent]: Set the alarm pause time to permanent.

6.4.4 Alarm off

As shown in 6.4.3, if the [Alarm Pause Time] is set to [Permanent], press the  [Pause] smart hotkey, and the monitor will turn off the alarm. In this case, except the alarm prompt

characteristics maintained in alarm pause state:

- Alarm state icon area will display the  icon.
- The physiological alarm area displays [Alarm Pause].

You can press the  [Pause] smart hotkey again to manually cancel the alarm off.

If the monitor is in the alarm state of suspension or closure of senior technical alarm is triggered, the alarm and the alarm off pause are automatically canceled.



Warning

- When the alarm volume is set to 0 or the alarm pause time is set to permanent, the monitor does not sound an alarm when an alarm occurs. Therefore, the operator should use this feature carefully.

6.5 Alarm Setup

6.5.1 Setting the Alarm Sound

See 3.9.4 Volume Control for the method to set the alarm volume.

6.5.2 Setting the Alarm Delay Time

For over-limit alarm of continuous measurement parameter, you can set the alarm delay time.

If the alarm condition disappears during the delay period, the monitor won't alarm. In

[Ala.Param Setup] menu, select [Alarm Delay] time and [ST Alarm Delay] time.

The specific operation is as follows:

- Select  [Menu] Smart Hotkey→[Main Menu];
- Select [User Maintenance >>] → [User Maintenance] menu;
- Select [Alarm Param >>] → [Ala.Param Setup] menu;
- Select [Alarm Delay], and set the alarm delay time as needed:
 - ◆ [Off]: Turn off the alarm delay.
 - ◆ [1s] / [2s] / [3s] / [4s] / [5s] / [6s] / [7s] / [8s]: Alarm delay time is 1 sec, 2 sec, 3 sec, 4 sec, 5 sec, 6 sec, 7 sec or 8 sec. By default, the alarm delay time is 4 seconds.
- Select [ST Alarm Delay], and set the ST alarm delay time as needed
 - ◆ [Off]: ST alarm delay is off
 - ◆ [10s] / [20s] / [30s] / [45s] / [1min] / [2min] / [3min]: ST alarm delay time is 10

sec, 20 sec, 30 sec, 45 sec, 1 min, 2 min or 3 min. By default, the ST alarm delay time is 20 seconds.

The system sets physiological alarm delay time and also sets 1~2s delay time after technical alarm been triggered. Normally the delay time is limited to 5s.

6.5.3 Setting a Parameter Alarm

With SpO2 for example, select the SpO2 parameter area, select [Alarm Setup >>] in the popup [SpO2 Setup] menu to enter the SpO2 alarm setup interface.

1. Turn on / off alarm

- Select [Alarm Switch] and set the alarm switch as follows:

- ◆ [On]: Turn on SpO2 alarm; when the parameter alarm occurs, the monitor will prompt according to the set alarm level.
- ◆ [OFF]: Turn off SpO2 alarm;  icon is displayed in the parameter area, and the monitor won't prompt the parameter alarm.

2. Set the alarm level

- Select [Alarm Level], and set the alarm level as follows:

- ◆ [Low]: Set the alarm level to low.
- ◆ [Mid]: Set the alarm level to medium.
- ◆ [High]: Set the alarm level to high.

3. Set the alarm limit

In any cases, the alarm system only allows setting the values within the effective range of the system, and the upper alarm limit must be higher than the lower alarm limit.

- Select [Spo2 Low Limit] and set the lower limit of SpO2 alarm.

- Select [Spo2 High Limit] and set the upper limit of SpO2 alarm.

4. Restore default alarm setup

- Select [Default], and restore the alarm setup to the factory default.

Note

- When setting the upper and lower alarm limit, confirm the patient category to be adults or pediatric, and set its scope according to the clinical need. If the setting exceeds the alarm limit, the alarm system will fail easily.

- When the alarm limit is turned on, and the upper and lower alarm limits are manually set, the instrument will display the upper and lower alarm limits continuously, and the initial alarm preset value won't be provided additionally.

6.6 Latch Alarm

Physiological alarms can be set to [Latching] or [No latching].

- [Latching]: Even if the cause of physiological alarm is cleared, the system will still be "latched," that is, continue to display the alarm information corresponding to physiological alarm, the alarm sound also continues, but the alarm mode has the following changes:
 - ◆ Parameters and upper or lower alarm limit are no longer flashing.
 - ◆ Display the time that the latest alarm was triggered after the alarm message in the physiological alarm area.
- [No latching]: After the causes of physiological alarm are cleared, the system will no longer prompt the physiological alarm.

The default alarm of the system is non-latching alarm; you can set the alarm as latching or non-latching in the following steps:



- Select [Menu] Smart Hotkey→[Main Menu];
- Select [User Maintenance >>]→ [User Maintenance] menu;
- Select [Alarm Param >>] → [Ala.Param Setup] menu;
- Select [Latching Alarms], and set the alarm as needed:
 - ◆ [Latching]: Latching alarm.
 - ◆ [No latching]: Non-latching alarm.

6.7 Manual Event

In the patient monitoring process, some events may have an impact on the patient, resulting in changes of some monitoring waves or parameters. In order to assist in the analysis of these



effects, you can manually record these events through the [Event] smart hotkey, and then view it in the event review; refer to 13.4 Event Review for detailed operation.

Chapter 7. ECG

7.1 Overview

Electrocardiogram (ECG) is produced by the continuous electrical activity of the patient's heart, and displayed with waves and numerics on the monitor in order to accurately assess the physiological state of the patient at the time. The ECG cable should be connected properly, so as to obtain a correct measurement value and normal display. This monitor can simultaneously display up to 12-Lead ECG waveforms.

Patient cable consists of two parts:

- Wires connected to the monitor
- ECG device connected to the patient

Connect to the monitor with five lead ECG cable, and ECG can display two different waves by adjusting the two leads. You can use the shuttle to change the lead name on the left of the ECG wave on the screen and select the lead to be monitored.

The parameters displayed in the parameter area of the monitor include heart rate (HR), ST segment measurements and arrhythmia counts per minute.

All these parameters can be used as alarm parameters.

Note

- In the factory setup of this instrument, ECG waves display in the first two waves from the top in the wave area in the normal screen.

7.2 Safety Information



Warning

- To monitor ECG signal with this monitor, ECG cable and ECG electrodes specified in the Operator's Manual must be used.
- When you connect electrodes or patient cable, make sure that the patient is absolutely not connected with any other conductive parts or in contact with the ground. In particular, make sure that all the ECG electrodes, including the neutral electrodes, are attached to the patient and prevent them from contact with the conductive parts or ground.

- Periodically check the skin that the electrode is placed at; if there is any sign of allergy, replace the electrode or change the placement position.
- Electrosurgery (ESU) device interference, defibrillator discharge:
 - ✧ When the patient needs defibrillation, do not use non-defibrillator type ECG cables.
 - ✧ During defibrillation, the operating personnel shall not touch the patient, tables and instrument.
 - ✧ During defibrillation, the ECG cable connected with the patient's body may be damaged. Check if the function is normal again before using these cables.
 - ✧ Recover within 10 seconds after defibrillation and will not lose any stored data. During electrosurgery (ESU) or defibrillation, the measurement accuracy may be temporarily reduced. This does not affect the safety of the patient or the instrument.
 - ✧ Do not expose this equipment to X-ray or strong magnetic fields (MRI).

7.3 Monitoring Steps

7.3.1 Preparation

Before placing the electrode, prepare the patient's skin in the following steps:

- Skin preparation: Since the skin is a poor conductor, it is very important to treat the patient's skin for electrode placement appropriately to make good contact between the electrode and the skin. Select the flat position with less muscles for the electrode placement, and refer to the method below for treatment of the skin:
 - ◆ Remove the body hair at the position for electrode placement.
 - ◆ Gently rub the skin at the position for electrode placement to remove dead skin cells.
 - ◆ Wash the skin thoroughly with soap and water (do not use ether and pure alcohol, as this will increase the skin's impedance).
 - ◆ Dry the skin completely before placing the electrode.
- Install the spring clip or stud prior to the placement of the electrodes.
- Place the electrode on the patient.
-  Connect the ECG cable and ECG interface.

Warning

Check if the lead is normal before monitoring. When the ECG cable is unplugged, the screen will display [ECG Lead Off] prompt and trigger an audible and visual alarm.

7.3.2 Selecting Lead

- Select the ECG parameter area or wave area → [ECG Setup] menu;
- Select [Other Setup >>] → [ECG Other Setup] menu;
- Select [Lead Type], and select the ECG lead as needed:
 - ◆ [3-Lead]: 3-lead; ECG wave options: I, II, III.
 - ◆ [5-Lead]: 5-lead; ECG wave options: I, II, III, AVR, AVL, AVF, V.
 - ◆ [12-Lead](Optional): 12-lead; ECG wave options: I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5, V6.

7.3.3 Lead Name and Corresponding Color

The lead names in European standard and U.S. standard are shown in Table 7-1.

Table 7-1: Lead Name in European Standard and American Standard

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

7.3.4 Installing Electrodes

■ 3-lead

The electrode placement position of 3-lead is shown in Fig. 7-1:

- ◆ R electrode: placed below the clavicle, near the right shoulder.
- ◆ L electrode: placed below the clavicle, near the left shoulder.
- ◆ F electrode: placed on the left abdomen.

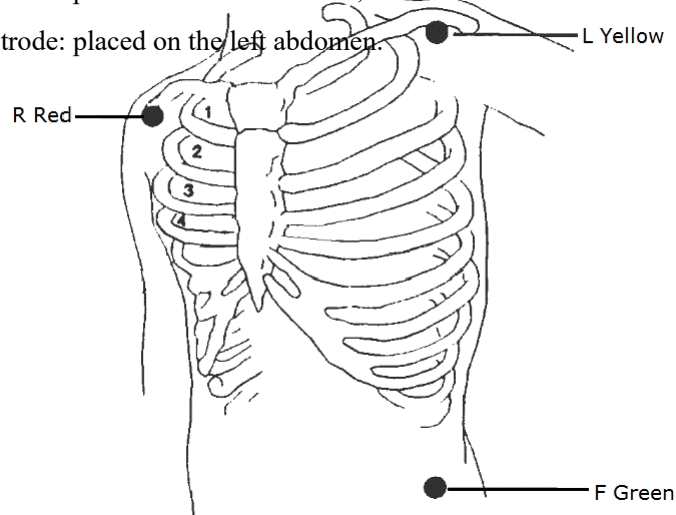


Fig. 7-1 3-lead Connection Method

■ 5-lead

The electrode placement position of 5-lead is shown in Fig. 7-2:

- ◆ R electrode: placed below the clavicle, near the right shoulder.
- ◆ L electrode: placed below the clavicle, near the left shoulder.
- ◆ N electrode: placed on the right abdomen.
- ◆ F electrode: placed on the left abdomen.
- ◆ C electrode: placed on the chest wall.

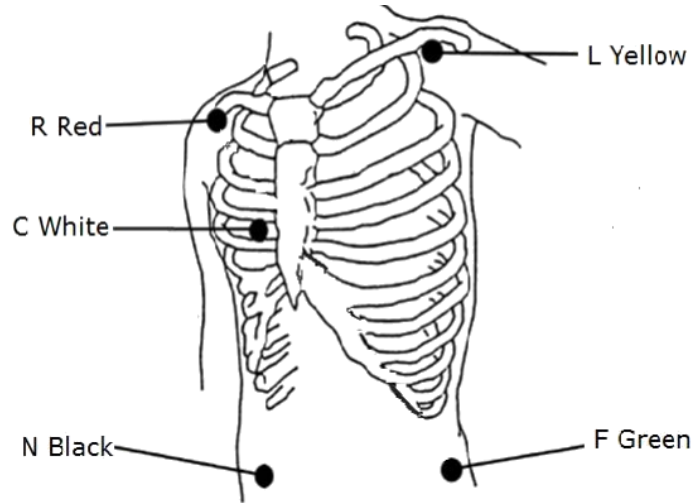


Fig. 7-2 European 5-lead Connection Method

- For 5-lead configuration, place the chest (V) lead electrode in one of these locations (see Fig. 7-3):
 - ◆ V1 is in the fourth intercostal on the right edge of the sternum.
 - ◆ V2 is in the fourth intercostal on the left edge of the sternum.
 - ◆ V3 is in the middle position of V2 and V4.
 - ◆ V4 is in the fifth intercostal of the left mid-clavicular line.
 - ◆ V5 is in the left anterior axillary line, at the same level of V4.
 - ◆ V6 is in the left axillary midline, at the same level of V4.
 - ◆ V3R-V7R is in the right chest wall, corresponding to the position of the left side.
 - ◆ VE is located on the xiphoid process. For the “V” lead placement on the back, place the “V” electrode in one of the following locations.
 - ◆ V7 is in the fifth intercostal of the left posterior axillary line on the back.
 - ◆ V7R is in the fifth intercostal of the right posterior axillary line on the back.

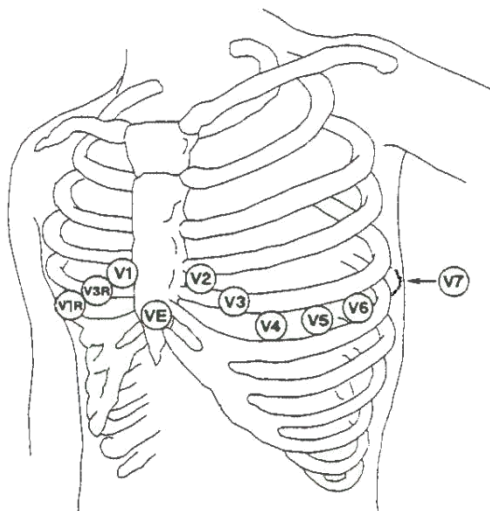


Fig. 7-3 Chest Lead Electrode Placement Position for 5-lead

■ 12-Lead

12-lead ECG are using 10 electrodes, which are placed on the patient's four limbs and chest. The limb electrodes should be placed on the soft skin and the chest electrodes placed according to the physician's preference. The electrode placement position of 12-lead is shown in Fig. 7-4:

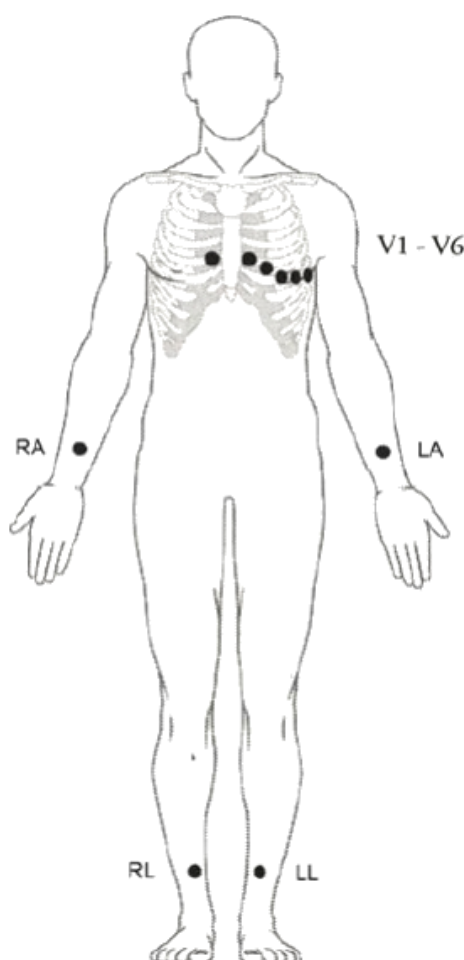


Fig. 7-4 Chest Lead Electrode Placement Position for 12-lead

Lead Placement for Surgical Patients

The surgical site should be taken into consideration when placing electrodes on a surgical patient. e.g. for open-chest surgery, the chest electrodes can be placed on the lateral chest or back. To reduce artifacts and interference from electrosurgical units, the limb electrodes can be placed close to the shoulders and lower abdomen and the chest electrodes on the left side of the mid-chest. Do not place the electrodes on the upper arm. Otherwise, the ECG waveform will be very small.

Notes

- To ensure patient safety, all leads must be connected to the patient.
- If the electrodes are attached correctly, but the ECG wave is not accurate, then replace the lead.
- Interference from ungrounded instrument near the patient and ESU interference may cause wave problems.

7.3.5 Checking the Pacemaking Status

Before ECG monitoring, it is very important to set the pacemaking state of the patient properly. If the patient has a pacemaker, set [Paced] to [Yes], and the icon  displays in the patient information area. When the system detects a pacing signal, the “|” symbol will be marked in the top of the ECG wave.

You can change the pacing state in the following method:

- Select the patient information area to pop up the [Patient Info] menu;
- Select [Yes] / [No] for [Paced] as needed, indicating that the patient with or without pacemaker

7.4 ECG Display

- ECG wave display

The monitor displays two ECG waves on the normal screen. Fig. 7-5 below is the monitoring interface of 5-lead, and is for reference purposes only. The graphics displayed on your monitor may be slightly different.

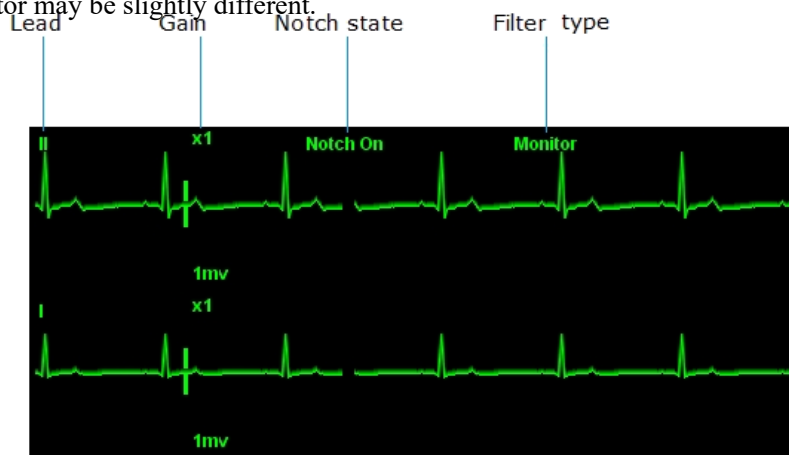


Fig. 7-5 ECG Wave on Normal Screen

In addition, when [Paced] is set to [Yes], and the patient wears a pacemaker, the “|” symbol will be marked in the top of the ECG wave.

■ ECG parameter display

The ECG parameter area of the monitor in the normal screen is shown in Fig. 7-6:

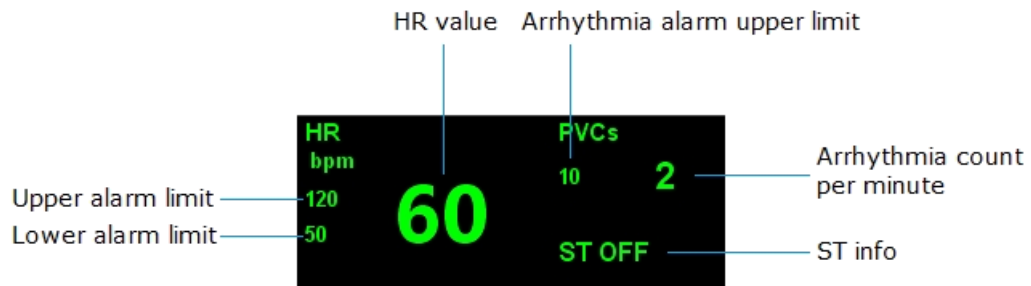


Fig. 7-6 ECG Parameter in Normal Screen

7.5 Alarm Setup

Select [Alarm Setup >>] → [Alarm Setup] interface to set ECG related alarms; see 6.5 Alarm Setup for the setting method.

7.6 ECG Setup

Click the ECG parameter area or wave ECG area to pop up the [ECG Setup] menu, which is as shown below. You can set the ECG through the [ECG Setup] menu.

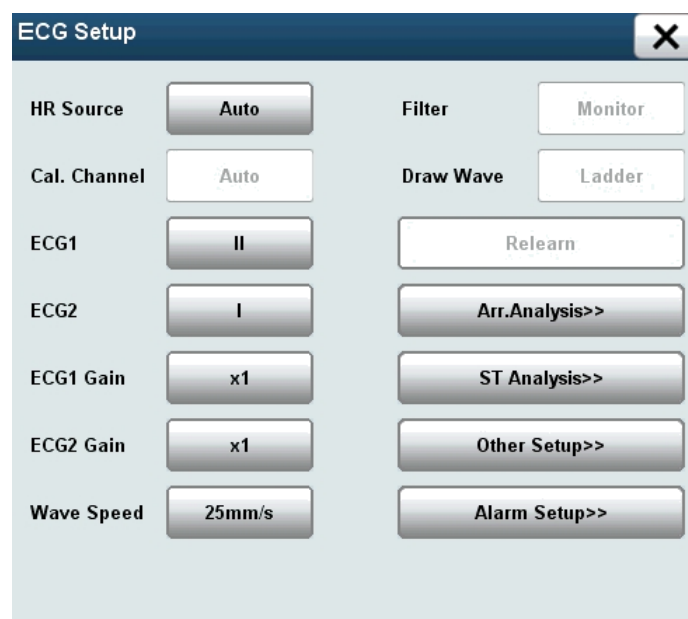


Fig. 7-7 [ECG Setup] Menu

- Select [HR Source], and set the heart rate source:
 - ◆ [Auto]: Automatically select HR source.
 - ◆ [ECG]: Select ECG monitoring as the HR source.
 - ◆ [SPO2]: Select SpO2 monitoring as the HR source.
- Select [Cal.Channel] and select heart rate calculation channel.

Select [ECG1] / [ECG2] to set the display wave channel. Select ECG1/ECG2, and set the names of upper ECG wave and lower ECG wave on the screen.

- ECG1/ECG2 should not be the source of the same wave.
- Select [ECG1 Gain] / [ECG2 Gain] and set the ECG wave gain. When the wave is shorter, increase the wave gain factor appropriately; when the wave is high or the peak cannot be displayed, reduce the wave gain appropriately.
- Select [Wave Speed], and set the wave speed.
- Select [Filter], and set the filter mode:
 - ◆ [Monitor]: Monitor mode
 - ◆ [Diagnostic]: Diagnostic mode
 - ◆ [Surgery]: Surgery mode
 - ◆ [Strong]: Strong filter mode
- Select [Draw Wave], and set the wave drawing method as below:
 - ◆ [Smooth]: Smooth
 - ◆ [Ladder]: Ladder; default.
- Select [Relearn] to learn arrhythmia. In the following cases, you need to start arrhythmia self-learning:
 - ◆ In ECG monitoring process, when the patient's ECG module has larger changes, arrhythmia self-learning should be started once.
 - ◆ ECG module changes could cause wrong arrhythmia alarm, ST measurement lost, and inaccurate heart rate.

Chapter 8. Resp

8.1 Overview

Thoracic electrical bioimpedance is a method used for measuring the respiration. When the patient is breathing, the thoracic impedance between two ECG electrodes changes due to thoracic activity. The monitor generates a respiratory wave on the screen by measuring the changing impedance value. The monitor calculates the respiration rate (RR) according to the wave cycle.

8.2 Safety Information

Note

- Respiration monitoring does not apply to patients with large range of activities, as this may lead to false alarms.



Warning

- Do not use anti-electric knife ECG cable for respiration monitoring.
- Respiration measurement cannot identify the apnea because it will alarm if the next respiration is not detected in the predetermined period after last respiration, and therefore it cannot be used for diagnostic purpose.

8.3 Placing Electrodes for Respiration Monitoring

Since the skin is a poor conductor, it is very important to treat the patient's skin for electrode placement appropriately to get better respiration signals. Refer to 7.3.1.

Respiration measurement uses standard ECG cable and electrode placement method. You can use different ECG cables (3-lead, 5-lead). Respiratory signal is measured between two ECG electrodes. If standard ECG electrode position is used, the two electrodes are R (right arm) and L (left arm) electrodes of I lead or R (right arm) and F (left leg) electrode of II lead.

Note

- For optimal respiration wave, R and L electrodes should be placed horizontally if I lead is selected for respiration measurement; R and F electrodes should be placed diagonally if II lead is selected for respiration measurement.

Fig. 8-1 below shows the placement of 5-lead electrodes

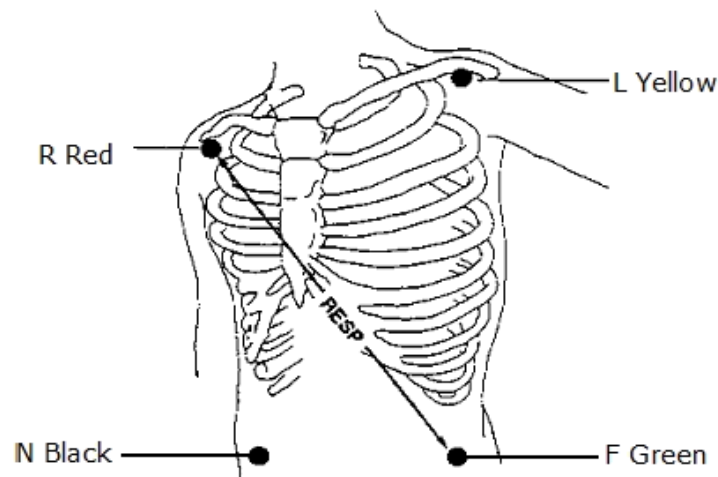


Fig. 8-1 5-lead Respiration Electrode Placement

8.3.1 Adjusting Position of Respiration Electrode

If you want to measure ECG and respiration simultaneously, you may need to adjust the position of the two electrodes for respiration measurement. Adjusting the standard position of ECG electrodes will lead to changes in the ECG wave, and may affect the ST and arrhythmia analysis.

8.3.2 Cardiomotility Superimposing

The effect of cardiomotility on the respiratory wave is called cardiomotility superimposing. When the respiration electrodes collect impedance changes caused by rhythmic blood flow, this will happen. Placing the respiration electrodes correctly will reduce this effect. The liver and ventricle should avoid the connection of respiration electrode, so that the heart or pulsating flow won't generate artifact.

8.4 Resp Display

Resp wave is as shown in Fig. 8-2:

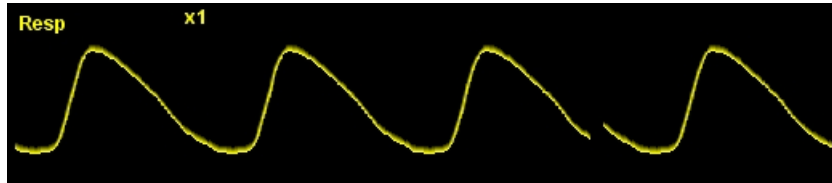


Fig. 8-2 Resp Wave

Resp parameters are displayed as shown in Fig. 8-3:



Fig. 8-3 Resp Parameter Area

8.5 Resp Setup

Click the ECG parameter zone or ECG wave area → [RESP Setup] menu, which is shown below. You can set Resp through [RESP Setup] menu.

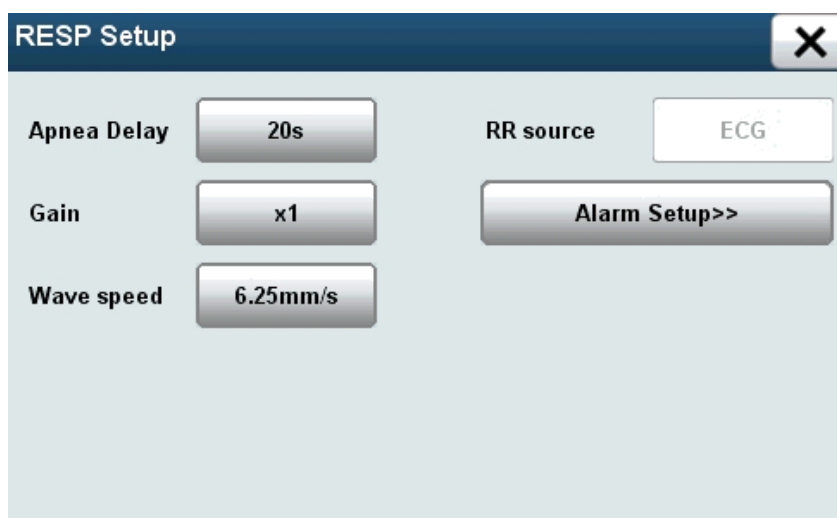


Fig. 8-4 [RESP Setup] Menu

8.5.1 Setting Apnea Time

Apnea alarm is a high level alarm for monitoring the apnea. In [RESP Setup] menu, set [Apnea Delay] to an appropriate value and set the apnea alarm time. When the apnea time of the patient is longer than the set time, the monitor will trigger an alarm. Default apnea alarm time is 20s.

8.5.2 Adjusting Wave Gain

In [RESP Setup] menu, select [Gain], and set the wave gain: the greater gain, the higher wave amplitude.

8.5.3 Setting Scanning Speed

In [RESP Setup] menu, select [Wave speed], and set the scanning speed: the faster scanning speed, the smoother wave.

8.6 Alarm Setup

Select [Alarm Setup >>] to enter the [Alarm Setup] interface, and set the RESP alarm; see 6.5 Alarm Setup for the setting method.

Chapter 9. PR

9.1 Overview

The mechanical activity of the heart causes arterial pulsation, and PR (pulse rate) value can be obtained by measuring this pulsation. PR value can be obtained through SpO2 measurement.

9.2 Display

The color of PR parameter area is same as SpO2 parameter color of PR source, as shown in Fig. 9-1:

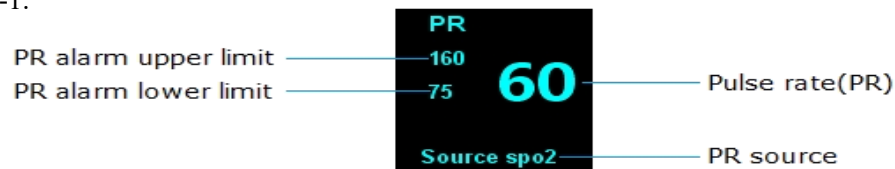


Fig. 9-1 PR Parameter Area

9.3 Setting PR Sound

Select SpO2 parameter area or Pleth wave area → [SpO2 Setup] menu;

Select [Pulse Vol.] to set [Pulse Vol.] to 0~9, and plus / minus 1 each time the shuttle is turned. Select 0 to turn off the key-pressing tone, and select 9 to set the maximum volume.

Note

- HR sound has higher priority than PR sound; when HR makes a sound, PR won't; when HR sound is 0, PR can make a sound.

9.4 Alarm Setup

Select PR parameter area → [SpO2 Setup] menu → [Alarm Setup >>] to enter the [Alarm Setup] interface, and set PR alarm switch, alarm level and upper/lower alarm limit. See 6.5 Alarm Setup for detailed setting method.

Chapter 10. SpO₂

10.1 Overview

Blood oxygen saturation (SpO₂) is the percentage of oxyhemoglobin (HbO₂) capacity bound by oxygen in the blood in the total hemoglobin (Hb) capacity that can be combined, that is, the concentration of oxygen in the blood.

The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

The principle for monitoring the pulse SpO₂ is to fix the probe fingerstall on the patient's finger, use the finger as a transparent container for hemoglobin, use 660nm wavelength red light and 880nm near-infrared light as the incident light, maximum output power is 300 mw, measure the light transmission intensity through the tissue bed, and calculate the concentration of hemoglobin and SpO₂.

The passing lights depend on a variety of factors, most of which are constant. However, one of these factors, the arterial blood flow, changes with time, as it is pulsating. By measuring the light absorbed during pulsating, it is possible to obtain the arterial blood SpO₂. Detection pulsation can give a "plethysmography" wave and pulse rate signal.

The main screen displays "SPO₂" value and "plethysmography" wave.

This monitor applies to measure SPO₂ of adults (>18 years), pediatric (30 Days to 18 years), neonate. Contact SPO₂ probe to Patient's finger or toe to get SPO₂ value and "plethysmography" wave

SPO₂ function of this monitor has been calibrated in factory.

10.2 Safety Information



Warning

- Please use SpO₂ sensor specified in this Manual, operate in accordance with the Manual, and observe all warnings and precautions.

- Before monitoring, check whether the sensor cable is normal. When SPO2 sensor cable is unplugged from the socket, the screen will display [SPO2Sensor OFF] error message and trigger an audible and visual alarm simultaneously.
- If the sensor or sensor packaging has signs of damage, do not use this SPO2 sensor; return it to the manufacturer.
- If there is carboxyhemoglobin, methemoglobin or dye diluted chemical, the SPO2 value will have deviation.
- When the patient has a tendency to hypoxia, use the oximeter to analyze blood samples in order to fully grasp the patient's condition.
- Do not put the sensor on limbs with arterial duct or intravenous tube.
- Do not intertwine electrosurgical equipment cable with the sensor cable.
- Avoid using the monitor and sensors while using the NMR equipment, in order to avoid severe burns to the patient as a result of induced currents.
- During long time continuous monitoring of a patient, check the position of SpO2 sensor once every 2 hours, and move properly when the skin changes or every four hours. Some patients may require more frequent inspection, such as patients with perfusion disorders or sensitive skin, because persistent and prolonged monitoring may increase unpredictable skin changes, such as allergies, redness, blistering or pressure necrosis.
- Carefully select SpO2 alarm upper limit. High oxygen level will cause crystal-like fibrous tissue disease to premature children.

Note

- Do not put the oxygen probe and blood pressure cuff on the same limb, because blood flow occlusion during blood pressure measurement will affect the SpO2 readings.
- This monitor cannot be used to verify the accuracy of SPO2 Probe and SPO2 machine.

10.3 Monitoring Steps

1. Select the appropriate SpO2 sensor according to the patient.
2. Turn on the monitor, and connect the SpO2 lead wire to the monitor.
3. Clean the measurement site, such as finger with nail polish.
4. Put the SpO2 sensor probe on the patient's body.
5. Select the appropriate alarm settings.
6. Start monitoring.

Note

- Turn on the monitor, plug in SPO2 probe and connect patient's finger, monitor displays SPO2 wave, 【SPO2 Pulse Search】 displayed in the technical alarm area until the monitor measured SPO2 value and pulse rate. 【SPO2 Search Timeout】 displayed in the technical alarm area until the monitor measured pulse rate. Check the sensor mounting position, whether the sensor is damaged or sensor type. Reconnect the sensor or use new sensor.

10.4 Display

003 SpO2 parameter area is shown in Fig. 10-1.

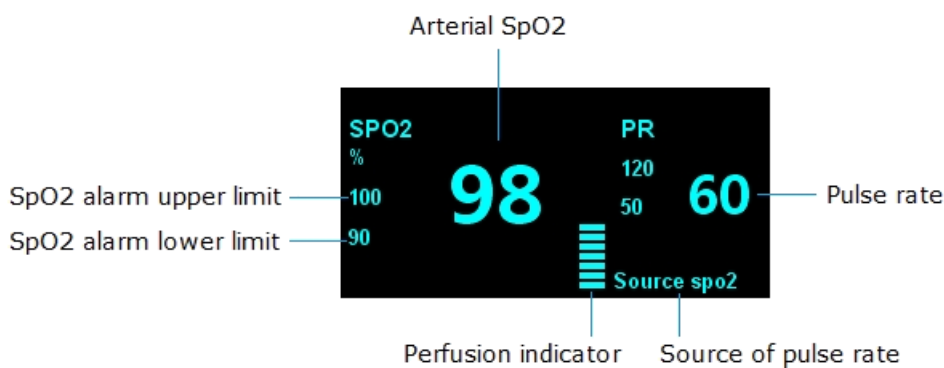


Fig. 10-1 003 SpO2 Parameter Area

0039 SpO2 parameter area is shown in Fig. 10-2.

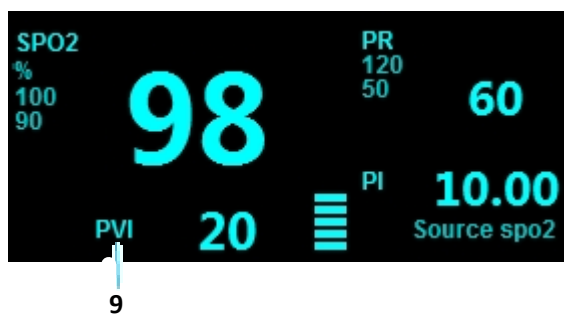


Fig. 10-2 0039 SPO2 Parameter

Masimo SpO2 parameter area is shown in Fig. 10-3.

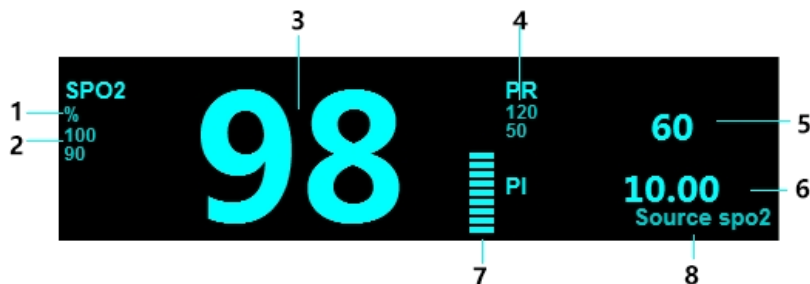
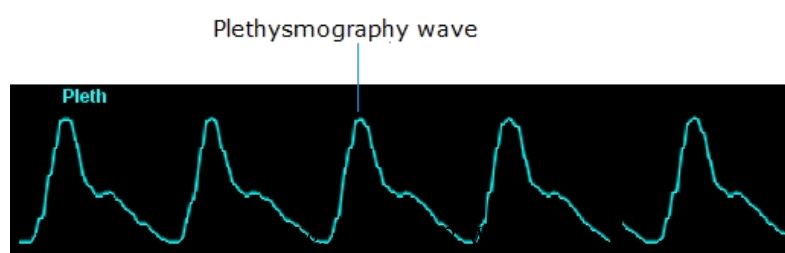


Fig. 10-3 Masimo SpO2 Parameter

1. SpO2 unit

2. Spo2 alarm range
3. SpO2 value
4. PR alarm range
5. PR value
6. PI value
7. PI indicator
8. Source of PR
9. Pleth Variability Index
10. SpO2 wave is shown in Fig. 10-3.



Parameters Description

Perfusion Index (PI): PI is a value that indicates arterial pulse signal strength as the percentage of pulsatile signal to non-pulsatile signal. The perfusion index allows clinicians to place sensors on optimal sites.

PVI is Pleth Variability Index

10.5 Setting SpO2

Select SpO2 parameter area or Pleth wave area → [SpO2 Setup] menu, which is shown below. You can set SpO2 through [SpO2 Setup] menu.



Fig. 10-3 [SpO2 Setup] Menu

10.5.1 Setting Wave Speed

- Select [Wave Speed] and set wave speed to [12.5mm/s] or [25mm/s]; the faster speed, the smoother wave.

10.5.2 Setting Wave Mode

- Select [Wave Mode], and set the wave drawing mode
 - ◆ [Scan]: Scan mode.
 - ◆ [Fill]: Fill mode.

10.5.3 Setting Average Time

SpO₂ values displayed on the monitor are the results averaged from the data collected over time. The shorter the average time, the faster the monitor responds when the patient's SpO₂ value changes, but the measurement accuracy is lower. Conversely, the longer the average time, the slower the monitor responds when the patient's SpO₂ value changes, but the measurement accuracy is higher. In monitoring critically ill patients, a smaller average time is conducive to timely analysis of the disease.

The setting method follows:

- Select [Avg.Time] to set the average time to [2s], [3s], [4s], [5s], [6s], [7s] or [8s].
- For Masimo SpO₂ module, select [Avg.Time] in the [SpO₂ Setup] menu and then toggle between [2-4 s], [4-6 s], [8 s], [10 s], [12 s], [14 s] and [16 s].

10.5.4 Setting SpO₂ Sensitivity

For Masimo SpO₂ module, you can set [Sensitivity] to [Normal] or [Max] in the [SpO₂ Setup] menu. When the [Sensitivity] is set to [Max], the patient monitor is more sensitive to minor signals. When monitoring critically ill patients whose pulsations are very weak, it is strongly recommended that the sensitivity is set to [Max]. When the patient tends to be in motion, noise or invalid signals may be caused. In this case, it is recommended that the sensitivity is set to [Normal] so that the interference caused by motion can be filtered and therefore the measurement stability can be ensured.

10.6 Measuring Influencing Factors

During operation, the following factors can affect the accuracy of SpO₂ measurement:

- High-frequency radio wave interference, such as interference generated by the host system or interference from electrosurgery instrument connected to the system.
- Intravenous dye.
- Too frequent movement of the patient.
- External light radiation.
- Sensor is improperly installed or improperly in contact with the patient.
- Sensor temperature (optimum temperature 28°C~42°C).
- The sensor is placed on limbs with blood pressure cuff, arterial duct or lumen tube.
- Concentration of non-functional hemoglobin such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- SpO2 too low.
- Poor perfusion of test site.
- Shock, anemia, hypothermia, and the application of vasoconstrictor drugs may reduce the arterial blood flow to a level that cannot be measured.
- The measurement also depends on the absorption of specific wavelengths of light by oxyhemoglobin and reduced hemoglobin. If there is any other substance that absorbs the same wavelength, the measurement may have false or low SPO2 values, such as: carbon hemoglobin, methemoglobin, methylene blue, and indigo carmine.
- SPO2 probe described in Annex is recommended.
- Operating environment limit: Operating temperature range: 5~40°C, Humidity range: <80% (non-condensing), Elevation range: -500m~5000m.

10.7 Alarm Setup

In [SpO2 Setup] menu, select [Alarm Setup >>] to enter [Alarm Setup] interface, and set SPO2 alarm switch, alarm level, upper and lower alarm limit. See 6.5 Alarm Setup for detailed setting method

10.8 Masimo Information



- Masimo Patents
Masimo Patent: www.masimo.com/patents.htm
- No Implied License
Possession or purchase of this device does not convey any express or implied license to use

the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

■ Masimo Spo2 product description

The Masimo module is intended to monitor the PR, SpO₂, PI of patients.

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor is connected to the pulse oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in three way

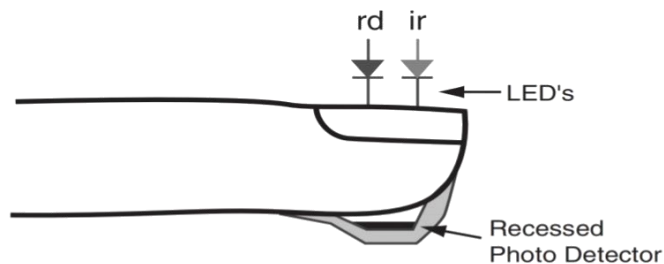
1. As a percent value for arterial oxygen saturation (SpO₂)
2. As a pulse rate (PR)
3. As a plethysmographic waveform

■ Masimo Spo2 Operating principals

Pulse oximetry is governed by the following principles

1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Pulse Oximeter uses a two-wavelength pulsatile system to distinguish between oxygenated and deoxygenated blood. Signal data is obtained by passing red(rd)(660 nm wavelength) and infrared (ir)(905 nm wavelength) light through a vascular bed (for example a fingertip, a hand, a foot) and measuring changes in light absorption during the pulsatile cycle. This information may be useful to clinicians. The radiant power of the light is rated at 0.79mW (max.). See figure below. utilizes a sensor with red and infrared light-emitting diodes (LEDs) that pass light through the site to a photodiode (photodetector).The photodetector receives the light, converts it into an electronic signal and sends it for calculate.



Once receives the signal from the sensor, it utilizes Masimo SET signal extraction technology for calculation of the patient's functional oxygen saturation and pulse rate.



Warning

- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse oximeter unless the setup was verified to be correct.
- Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the pulse oximeter if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below:
 - Avoid placing the device on surfaces with visible liquid spills.
 - Do not soak or immerse the device in liquids.
 - Do not attempt to sterilize the device.
 - Use cleaning solutions only as instructed in this operator's manual.
 - Do not attempt to clean the device while monitoring a patient.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.
- Inaccurate SpO₂ readings may be caused by:
 - Improper sensor application and placement
 - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO₂. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
 - Elevated levels of bilirubin
 - Elevated levels of dyshemoglobin
 - Vasospastic disease, such as Raynaud's, and peripheral vascular disease

- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Severe anemia
- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders
- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- The pulse oximeter is not an apnea monitor.
- The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter should not be used for arrhythmia analysis.
- SpO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.

CAUTION:

- Do not place the pulse oximeter where the controls can be changed by the patient.
- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.
- If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

- If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor and/or patient cable when a “Replace sensor” and/or “Replace patient cable”, or a persistent poor signal quality message (such as “Low SIQ”) is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.
- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.
- Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.



Notes

- A functional tester cannot be used to assess the accuracy of the pulse oximeter.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.

- When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

Chapter 11. NIBP

11.1 Overview

The monitor uses oscillometric method to measure noninvasive blood pressure (NIBP), and applies to adults, pediatric and neonate.

The oscillometric method for measuring blood pressure is to inflate a cuff with a certain amount of pressure until the arterial blood flow has been completely blocked. As pressure decreases, the arterial blood flow will be completely occluded, gradually opened, and completely opened. Then, the pulsation of the arterial vascular wall will generate a shock wave in the cuff. SBP, MBP, and DBP are obtained by measuring and analyzing cuff pressure oscillations when deflating.

- Produce first most clear signal - reflect SBP
- Oscillation amplitude reaches the peak - reflect MAP
- When the cuff pressure is suddenly lowered - reflect DBP

Measuring mode: manual, cycle, and continuous. Each mode shows systolic, mean and diastolic blood pressure.

- Manual mode

Using Manual mode start to measures by hand

- Automatic mode measures

Use manual mode to open automatic mode, then the measure will automatically turn to automatic mode after a certain time. During measurement. Any error will stop the current automatic measurement, but not affect next automatic measurement unless the time interval less than 30s. If the time interval less than 30s, should delay the next automatic measurement, keep the interval more than 30s.

The time interval can be chosen in automatic mode as follow: 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240, 480 minutes

- Continuous mode

Choose continuous mode, 5 seconds after completing a measurement start the next measurement, continue 5 minutes then stop. During measurement. Any error will stop the continuous measurement. If the first measurement time is over 4 minutes and 40 seconds but less than 5 minutes, the continuous mode will stop before 5 minutes, if the first measurement time is over 5 minutes, the continuous mode will stop after 5 minutes

11.2 Safety Information



Warning

- Do not carry out non-invasive blood pressure measurement on patients with sickle cell disease and skin damage or any expected damage.
- For patients with severe coagulation disorder, determine if the automatic blood pressure measurement is carried out according to the clinical evaluation, since the friction of body and cuff may produce hematoma.
- When measuring a child patient, ensure that the correct patient category (see Patient Info menu setting) is selected in order to ensure that maximum cuff pressure does not exceed the measuring range of the patient (pediatric mode: 240mmHg, Neonatal Mode: 150mmHg). Using the wrong patient mode may endanger the safety of patients because higher adult blood pressure level does not apply to children.
- Do not install a cuff on the limbs with intravenous infusion or duct, because it may lead to tissue damage around the duct when the cuff is inflated and makes the infusion slow down or be blocked.
- The inflatable tube connecting the blood pressure cuff and the monitor should be smooth without entanglement.
- For patients with severe thrombotic disorders, determine whether to carry out automatic blood pressure measurement according to the clinical situations, since the limb bundled with a cuff may produce hematoma.
- Measure blood pressure frequently will affect the distribution of blood flow, May endanger the safety of patients.
- Check the patient's physiological condition before measure blood pressure, in order to ensure that long time measure will not damage the circulation of patients
- Mastectomy patients, using NIBP cuff to measure blood pressure on the surgery side arm.

11.3 Measurement Limits

According to the patient's condition, the oscillometric method has some limitations. This measurement is to look for the regular pulse waves generated by arterial pressure. If the patient's condition makes this detection method difficult, the measured value becomes unreliable, and pressure measurement time increases. The user should be aware that the following conditions may interfere with measurement method, making the pressure measurement unreliable or extend the time. In this case, the patient's condition does not allow measurement.

■ Patient movement

If the patient is moving, shaking or cramping, the measurement will be unreliable or even impossible, as these may interfere with the detection of arterial pressure pulse, and extend the pressure measurement time.

■ Arrhythmia

If the patient shows arrhythmia which results in irregular heartbeat, the measurement will be unreliable and even cannot be done, and the pressure measurement time will be extended.

■ Use of an artificial heart-lung machine

If a patient is connected to an artificial heart-lung machine, the measurement will be impossible.

■ Pressure changes

If the arterial pressure pulse is being analyzed to obtain a measured value at a certain time and the blood pressure of the patient changes rapidly, the measurement will be unreliable or impossible.

■ Severe shock

If the patient is in severe shock or hypothermia, the pressure measurement will not be reliable, because the decrease of blood flow to the periphery would cause decrease in arterial pulsation.

■ Limit heart rate

If the heart rate is below 40bpm (beats / min) or above 240bpm (beats / min), the blood pressure measurement is impossible.

■ Obese patients

A thick layer of fat around a limb blocks the arterial oscillation so that it cannot reach the cuff. The accuracy is lower than normal.

■ Environmental Requirements

Measure blood pressure should meet the environment range as follow: ambient humidity < 80%, no condensing, ambient temperature 5 ~40°C altitude -500m~5000m. NIBP performance and measurement accuracy will be affected beyond the range.

11.4 Measurement Procedure

11.4.1 Preparing for Measurement

1. Turn on the monitor, and check if it works properly;
2. Verify the patient category, and make changes if improper;
3. Connect the blood pressure cuff extension tube to the monitor;
4. Select the cuff in accordance with the following method, make sure that the cuff is completely deflated, and then tie it to the upper arm or thigh of the patient.
 - ◆ Determine the limb circumference of the patient.
 - ◆ Select the appropriate cuff (marked with appropriate limb circumference). Cuff width should be 40% of the limb circumference or 2/3 of the upper arm length. The length of the inflated part of the cuff should be sufficient for 50%~80% around the limb.
 - ◆ Place the cuff on the upper arm or thigh of the patient, and ensure that the marking ϕ is located just above the appropriate artery. Make sure that the cuff does not wrap too tight around the limb, or it may cause distal discoloration or even ischemia.

11.4.2 Patient posture requirements during measurement

1. Sit comfortable or lie down relax;
2. No crossing legs
3. Back and elbow should be supported;
4. The center of NIBP cuff and the right atrium are at in the same level.
5. Remind patients, no talking during measurement and try to relax.

Note

- If there is any question of measurement value, please repeat measurement then get average value, if the average value is not correct, please change to mechanical blood pressure measurement equipment.

11.4.3 Starting / Stopping Measurement

Use the  buttons on the monitor panel or  [NIBP] smart hotkey on the display to start / stop the blood pressure measurement.

11.4.4 Correcting Measurement Results

The position of limb blood pressure measurement should be in the same horizontal position of the patient's heart. Otherwise, correct the measurement results with the following

correction method:

- If the cuff is above the heart level position, increase 0.75mmHg (0.10kPa) per centimeter of gap to the measured results.
- If the cuff is below the heart level position, subtract 0.75mmHg (0.10kPa) per centimeter of gap from the measured results.
- If the patient is obese or clothes are too thick, subtract 5mmHg ~ 10mmHg (0.65kPa ~ 1.3kPa) from the measured results.

11.5 NIBP Display

NIBP measurement has no waveform display, and only displays NIBP measurement results in the parameter area, as shown in Fig. 11-1. The figure below is for reference only. The graphics displayed on the monitor may be slightly different.

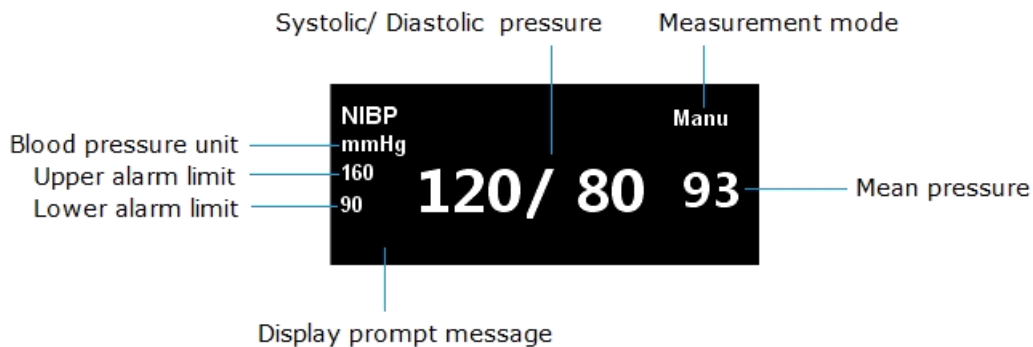


Fig. 11-1 NIBP Parameter Area

11.6 Setting Inflation Pressure

If necessary, you can manually set the initial cuff inflation pressure as follows:

- Select the NIBP parameter area → [NIBP Setup] menu;
- Select [Pre-Infl Press], and set the appropriate cuff pressure value.

11.7 NIBP Resetting

Select NIBP parameter area → [NIBP Setup] menu → Select [Reset], and restore the inflation pressure of the blood pressure pump to currently configured initial settings. When

the blood pressure pump is not working properly, but no warning is given, you can reset the blood pressure pump, and automatically restores the blood pressure pump.

11.8 NIBP Leakage Test

The purpose of leakage test is to detect if the sealing of the air passage is in good condition. If the leakage test passes, the NIBP parameter area displays [Leakage test Stopped]. If not passed, the NIBP parameter area displays [Cuff leak] message. NIBP leakage test shall be at least once every two years or when you think that the reading is not accurate.

Prepare the following materials before the test:

- Adult cuff: one
- Inflation tube: one
- Cylinder of appropriate size: one

Leakage test process

1. Connect the cuff to the NIBP pore of the monitor
2. Wrap the cuff on the cylinder of appropriate size.
3. Set the patient category to adults.
4. Select  [Menu] Smart Hotkey → [Main Menu];
5. Select [User Maintenance >>] → [User Maintenance] menu;
6. Select [Module Maintenance >>] → [Module Maintenance] menu;
7. Select [NIBP >>] → [NIBP Maintenance] menu, and select [Leak Test] for leakage test.
8. After 20s, the system will automatically open the bleeder valve, and the leak test finishes.
9. If the NIBP parameter area displays [Leakage test Stopped], the system does not leak. If it displays [Cuff leak], it indicates that the air passage leaks. At this time, the operator should check if the entire connection is loose, and test for leak once again when the connection is correct. If there is error prompt still, please contact the manufacturer for repair.

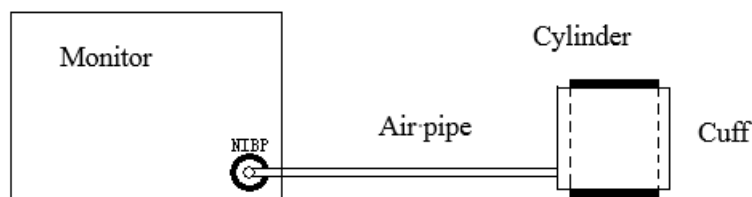


Fig. 11-2 NIBP Leakage Test Connection Diagram

11.9 NIBP Calibration

Users can not calibrate NIBP. If calibration is required, please contact your service representative. Cuff pressure sensor should be checked and calibrated at least once every two years by qualified professional service personnel.

11.10 Clean and disinfection method of NIBP cuff

If necessary, NIBP cuff and NIBP extension tube can be cleaned and disinfected together without being separated.

11.10.1 Cleaning Method:

1. Prepare enzyme cleaning agent, distilled water and 10% solvent, respectively in different spray bottle.
2. Sprinkle cleaning agent on NIBP cuff, connector and extension tube, keep 1 minutes for the dry stains.
3. Use a soft cloth to wipe smooth face. Use soft hair brush to brush visible stain and irregular surface

Note

- Please be especially careful to clean the air ball and control valve of whole air system. Do not allow any liquid entering into reversing valve and saturated valve
- Don't use a soft cotton ball and fiber to clean this accessory, because they will stick on the cuff and extension tube.

11.10.2 Disinfection Method

1. Sprinkle bleach solution (Formula: the proportion of water and bleaching powder to 1:10) then keep 5 minutes
2. Wipe off excess bleach solution and elute with distilled water again
3. Natural dry cuff

11.11 Alarm Setup

In [NIBP Setup] menu, select [Alarm Setup >>] to enter [Alarm Setup] interface, and set NIBP alarm switch, alarm level, upper and lower alarm limit. See 6.5 Alarm Setup for detailed setting method.

Chapter 12. Temp

12.1 Overview

This monitor has two temperature measurement channels; the temperature sensor will measure the body temperature and calculate the difference between the body temperature data.

12.2 Safety Information



Warning

- Before monitoring, check if the probe cable is normal. Unplug the temperature probe cable from the jack, the screen will display [TEMP1/TEMP2 Sensor Off] prompt and make an alarm sound.
- Calibrate the temperature measuring instrument at least once every two years (or according to hospital procedures). When calibration is required, please contact the manufacturer.

12.3 Measurement Steps

Please refer to the following steps:

1. Turn on the monitor and check if it works normally.
2. Select the appropriate temperature probe according to the patient category and measurement needs.
3. Insert the probe lead wire into the temperature probe interface.
4. Attach the probe to the patient properly.
5. Make sure that the alarm settings apply to the patient.

12.4 Measuring Requirements

The normal measuring range of body temperature is 5~50°C, and the accuracy is consistent in this range.

The environmental temperature range for body temperature measuring is 0~55°C, the minimum measuring time is 1s, and the measuring interval is 1s.



Warning

- Please measure the body temperature in the specified environmental temperature range, or else it may be dangerous.

12.5 Temp Display

The monitor can display the body temperature of two channels (T1 and T2) and the alarm limits, difference between the two temperature (TD) and temperature units. Select Temp parameter area and open the [Temp Setup] menu.

Temp display area is shown below:

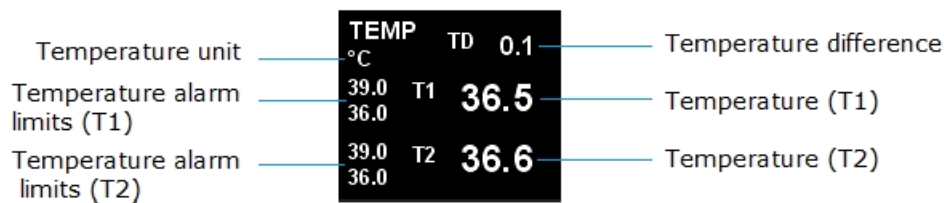


Fig. 12-1 TEMP Parameter Area

12.6 Selecting Resistance Type of Temp Probe

Select the appropriate [Temp Sensor] value according to the actual resistance of the temperature probe being used. The specific setting method follows:

- Select  [Menu] smart hotkey → [Main Menu];
- Select [Factory Maintenance] → Enter and confirm the password → [Factory Maintenance] menu;
- In [Factory Maintenance] menu, set [Temp Sensor] to
 - ◆ [10K], probe resistance is 10kΩ;
 - ◆ [2K], probe resistance is 2.25kΩ.



Warning

- If the temperature value displayed by the monitor has significant difference from the body temperature under normal condition, please check if the probe resistance of the monitor matches the resistance set in the monitor system; if not, please replace a probe with appropriate resistance or adjust the monitor and select the appropriate resistance.

12.7 Setting Temperature Unit

You can define your favorite temperature unit as follows:

- Select TEMP parameter area → [TEMP Setup] menu;
- In the [TEMP Setup] menu, set [Unit] to [°C] or [°F].

12.8 Alarm Setup

In [TEMP Setup] menu, select [Alarm Setup >>] to enter [Alarm Setup] interface, and set TEMP alarm switch, alarm level, upper and lower alarm limit. See 6.5 Alarm Setup for details of setting method.

12.9 Quick Temp (Optional)

12.9.1 Quick Temperature Display



Select **Switch** Enter **Screen Setup** menu, go to **Main** page and select **QTT** from main screen, as shown below Fig. 12-2.

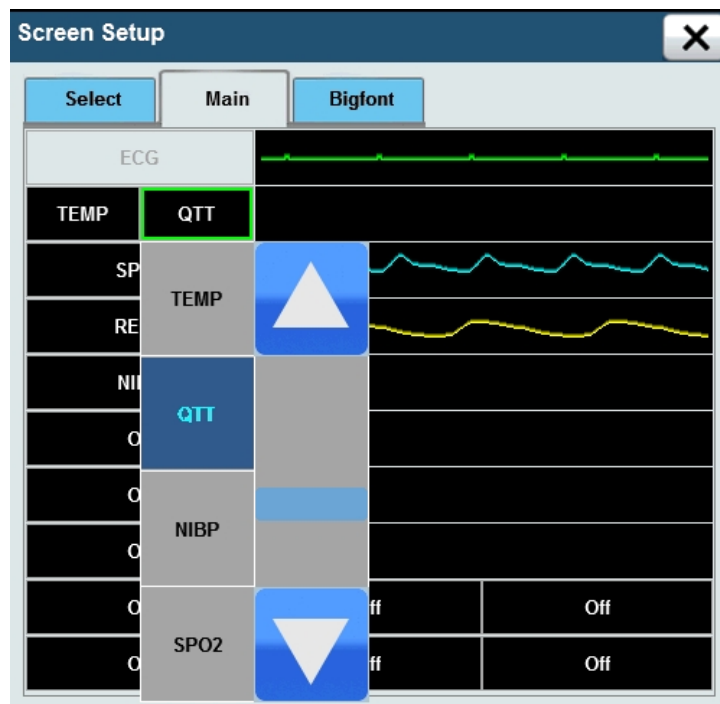


Fig. 13-2 Screen Setup Menu

QTT parameter will display in the main screen, when there is no measurement, the numeric area will show **【-?-】**, after measurement by using ear thermometer, this area will display measurement result same as ear thermometer shows. As shown below Fig. 12-3.



Fig. 12-3 QTT Parameter Area

Select QTT parameter area to enter **【QTT Setup】** menu for unit setup and alarm setup, as shown below Fig.12-4.

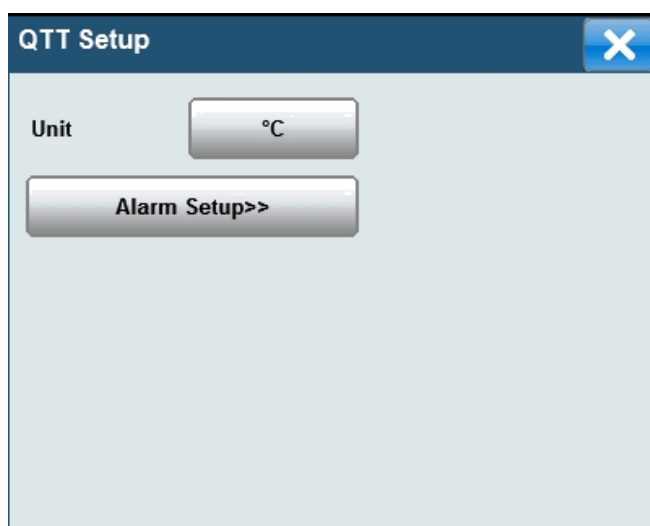


Fig. 12-4 QTT Setup

12.9.2. Accessories list

Cover cap x 1 pc, probe cover x 1 pack, pressure disk x 1 pc, battery x 1 pc (inside of ear thermometer). As shown below Fig. 12-5



Fig. 12-5 Infrared Ear Thermometer list

Notice: When clean the device with alcohol, please wait till alcohol complete dry before measurement.

Chapter 13. Review

The monitor provides up to 120 hours trend data review of all monitoring parameters, 1000 groups of NIBP measurement data and 200 alarm events. The user can select trend chart or trend table to view trend change; or view the latest wave.

13.1 Reviewing Trend Chart

Select  [Review] smart hotkey to enter [Review] menu, and select [Graphic] to enter the following window.

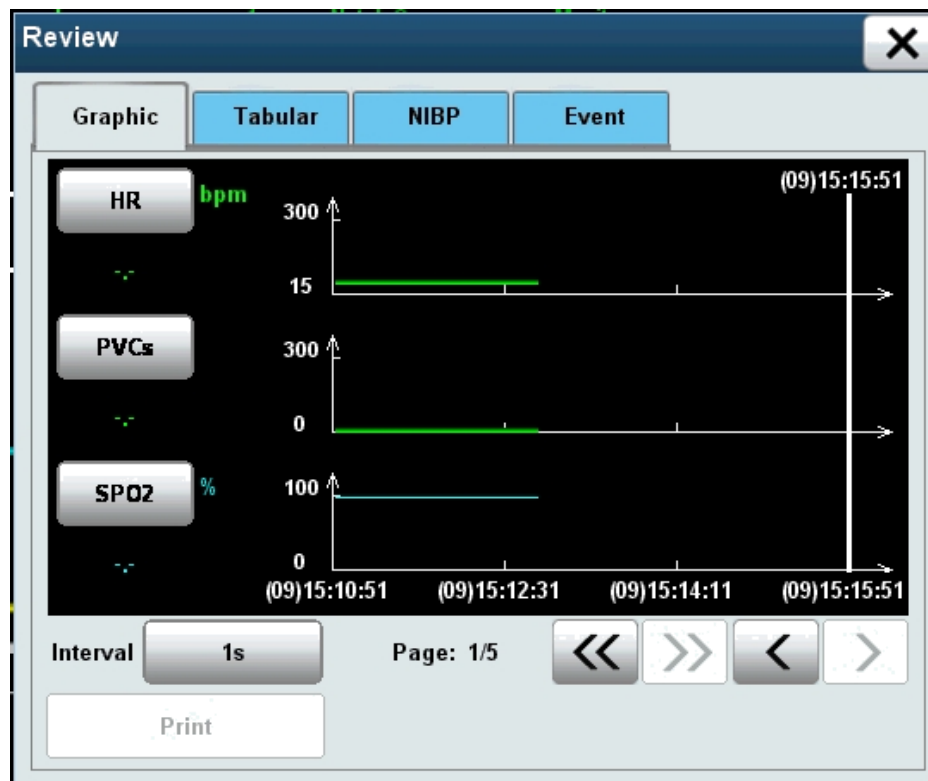


Fig. 13-1 Trend Chart

- In the trend chart, use the following method to select the parameter to be reviewed:
 - ◆ Select the parameter box, rotate the shuttle to select the parameters to be reviewed, click on the shuttle, and set the parameter box as the parameter to be reviewed.
- Select [Interval], and select the option as needed:
 - ◆ [1s]: observe the trend of the last hour at 1sec interval.

- ◆ [5s]: observe the trend of the last eight hours at 5sec interval.
 - ◆ [1min]: observe the trend of the last 120 hour at 1min interval.
 - ◆ [5min]: observe the trend of the last 120 hour at 5min interval.
 - ◆ [10min]: observe the trend of the last 120 hour at 10min interval.
 - ◆ [30min]: observe the trend of the last 120 hour at 30min interval.
 - ◆ [60min]: observe the trend of the last 120 hour at 60min interval.
- Browse the trend chart in the following method:
- ◆ Select  and  to move the trend cursor.
 - ◆ Select  and  to turn pages to left or right and move the trend chart.
 - ◆ The cursor top displays the current time corresponding to the current cursor position, and the left of the trend chart window displays the parameter values of the time, which will change automatically with the move of trend cursor.

13.2 Reviewing Trend Table

Select  [Review] smart hotkey to enter [Review] menu, select [Tabular] and enter the following window.

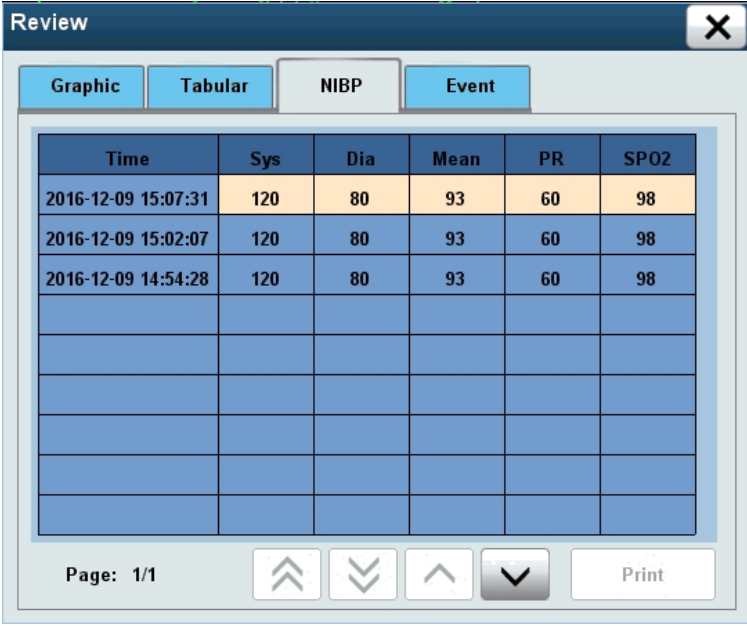


Fig. 13-2 Trend Table

- Select [Interval], and select the option as needed:
 - ◆ [1s]: observe the data of the last hour at 1sec interval.
 - ◆ [5s]: observe the data of the last eight hours at 5sec interval.
 - ◆ [1min]: observe the data of the last 120 hour at 1min interval.
 - ◆ [5min]: observe the data of the last 120 hour at 5min interval.
 - ◆ [10min]: observe the data of the last 120 hour at 10min interval.
 - ◆ [30min]: observe the data of the last 120 hour at 30min interval.
 - ◆ [60min]: observe the data of the last 120 hour at 60min interval.
- Browse the trend table in the following method:
 - ◆ Select  and  to turn pages to left or right and move the trend table to observe the target parameters.
 - ◆ Select  and  to move the trend table upward or downward progressively and observe more data.
 - ◆ Select  and  to turn pages up or down and move the trend table to observe more data.

13.3 NIBP Measurement Review

Select  [Review] smart hotkey to enter [Review] menu, and select [NIBP] to enter the following window



The screenshot shows a window titled "Review" with a close button (X) in the top right corner. Below the title bar are four tabs: "Graphic", "Tabular", "NIBP", and "Event". The "NIBP" tab is currently selected. The main area of the window contains a table with the following data:

Time	Sys	Dia	Mean	PR	SP02
2016-12-09 15:07:31	120	80	93	60	98
2016-12-09 15:02:07	120	80	93	60	98
2016-12-09 14:54:28	120	80	93	60	98

At the bottom of the window, there is a status bar that says "Page: 1/1". To the right of the status bar are four navigation buttons: a double up arrow, a double down arrow, a single up arrow, and a single down arrow. To the right of these buttons is a "Print" button.

Fig. 13-3 Measurement of NIBP Review

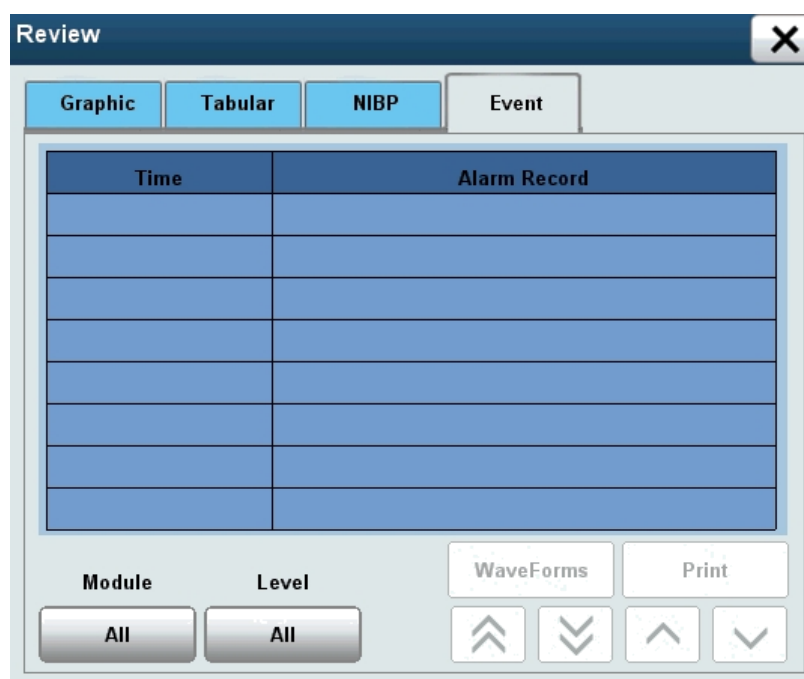
This window shows the measurement time of noninvasive blood pressure, systolic blood pressure [Sys], diastolic blood pressure [Dia], mean blood pressure [Mean] and pulse rate [PR]. The monitor can store 1000 sets of NIBP measurements in total.

■ NIBP viewing method is as follows:

- ◆ Select  and  to move the trend table upward or downward progressively and observe more data.
- ◆ Select  and  to turn pages up or down and move the trend table to observe more data.

13.4 Event Review

Select  [Review] smart hotkey to enter [Review] menu, and select [Event] to enter the following window.



13.4 Event Review

This window shows the time of alarm events and corresponding alarm information, and the time of manual events and corresponding manual tag events. This monitor allows reviewing 200 events in total, including the physiological alarm events, technical alarm events and manual events.

- Select [Module], and select an option as needed:
 - ◆ [ECG]: View ECG-related alarm events.
 - ◆ [SPO2]: View SPO2 related alarm events.
 - ◆ [NIBP]: View NIBP related alarm events.
 - ◆ [RESP]: View RESP related alarm events.
 - ◆ [TEMP]: View TEMP related alarm events.
 - ◆ [Manual]: View manual events.
 - ◆ [All]: View all related events.
- Select [Level], and select an option as needed:
 - ◆ [High]: View high level alarm events.
 - ◆ [Mid]: View middle level alarm events.
 - ◆ [Low]: View low level alarm events and manual events.
- Select [Wave Forms] to view the waveform and relevant parameters when alarm occurs, as shown in Fig. 13.5 below:

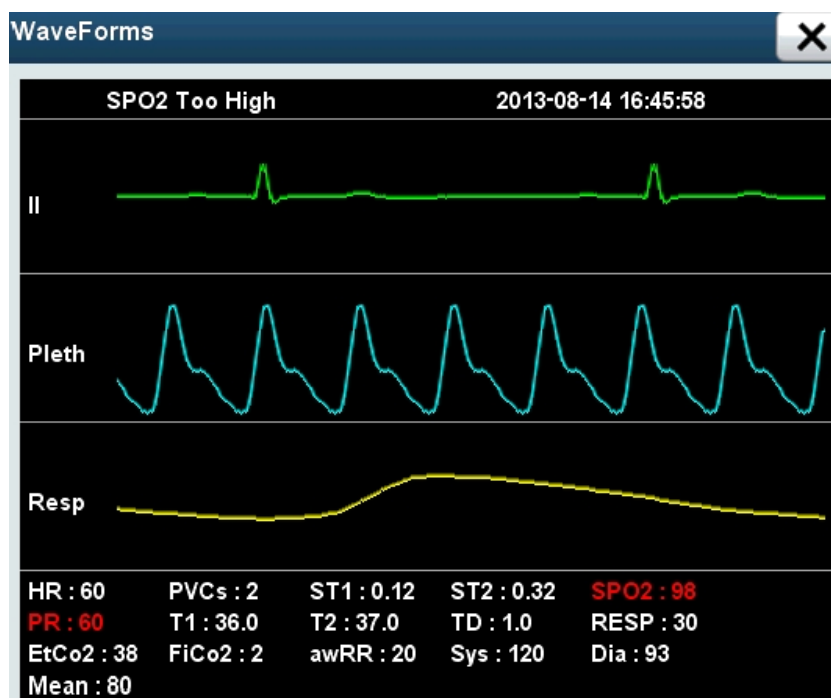


Fig. 13.5 Waveform Review

- Event viewing method is as follows:
 - ◆ Select  and  to move the trend table upward or downward progressively and observe more data.
 - ◆ Select  and  to turn pages up or down and move the trend table to observe

more data.

Chapter 14. CO2 (Optional)

14.1 Introduction

CO2 monitoring is a continuous, non-invasive technique for determining the concentration of CO2 in the patient's airway by measuring the absorption of infrared (IR) light of specific wavelengths. The CO2 has its own absorption characteristic and the amount of light passing the gas probe depends on the concentration of the measured CO2. When a specific band of IR light is passed through respiratory gas samples, some of IR light will be absorbed by the CO2 molecules. The amount of IR light transmitted after it has been passed through the respiratory gas sample is measured with a photodetector. From the amount of IR light measured, the concentration of CO2 is calculated.

There are two kinds of CO2 measuring module:

1. Mainstream(IRMA) measurement uses a CO2 sensor attached to an airway adapter directly inserted into the patient's breathing system.
2. Sidestream/Microstream (ISA) measurement samples expired patient gas at a constant sample flow from the patient's airway and analyzes it with a CO2 sensor built into the CO2 module.

The measurement provides:

1. A CO2 waveform.
2. End tidal CO2 value (EtCO2): the CO2 value measured at the end of the expiration phase.
3. Fraction of inspired CO2 (FiCO2): the smallest CO2 value measured during inspiration.
4. Airway respiration rate (awRR): the number of breaths per minute, calculated from the CO2 waveform.



Fig. 14.1 CO2 Parameter and waveform

Warning

ISA and IRMA can only be operated by professionals having received career training and possessed a good knowledge of the Manual.

Please specify the working temperature of environment to run ISA and IRMA module, ISA modules are not designed for (MRI) environment, during the MRI scan, ISA module must be on the outside of MRI.

ISA and IRMA CO2 module only as an auxiliary equipment of patient evaluation, it must be use with other vital signs and symptoms of evaluation equipment instrument.

ISA and IRMA module using in high frequency surgical equipment will be lead to the result of measure.

In using, don't stretch the Probe cable of ISA and IRMA.

14.2 Preparing to Measure CO₂

14.2.1 Using a Sidestream CO₂ Module

1. Connect the Interface cable of CO₂ module to the monitor interface with CO₂ mark.
2. Connect Nomoline sample line to the input interface of CO₂ module.

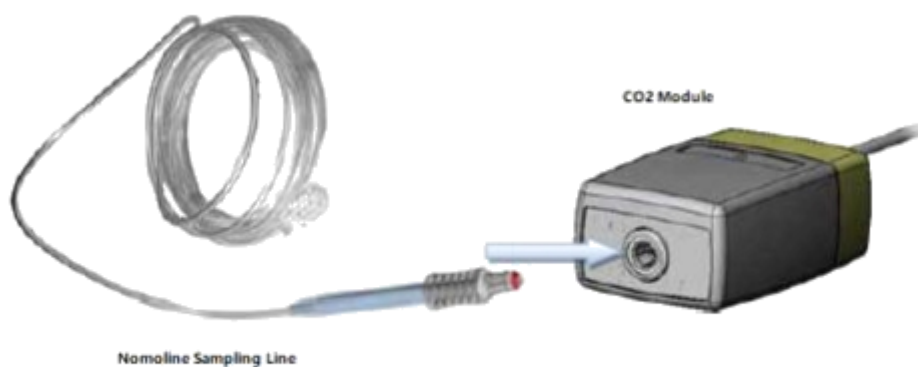


Fig. 14-2 Sidestream CO₂ Module and nomoline

3. Exit of Gas sample Connect to drain-off system, or the gas flow loop back to the patients.
4. Start Monitor, green LED of input interface CO₂ module can be normal work.
5. Access the [CO₂ Setup] menu to set [Operating Mode] to [Measure]. After about 10S, the module can be enter measure.

WARNING

- Nomoline sample line can't be reusing, and sample tube can be waste treatment after used according to the regulations of the local medical rule.
- Changed Nomoline sample tube every 2 weeks or it displayed "tube stoppage" (Red sampling line).
- Only can use MASIMO produced Nomoline sampling tube, otherwise it will lead to inaccurate measurements.
- Seriously rationalize sampling tube, to reduce the risk of twisting or bridle patients.
- Please confirm whether the current sampling tube is suitable for the patient, don't be confused baby and adult/child tube when connection.
- Check whether sample gas velocity in patients with given category is too high.
- When put ISA CO₂ module, should be firmly installed ISA module, avoid to put it in patients on the location.
- If the acquisition of gas samples for breathing air supply, use bacteria filter on the exhaust side all the time.

CAUTION:

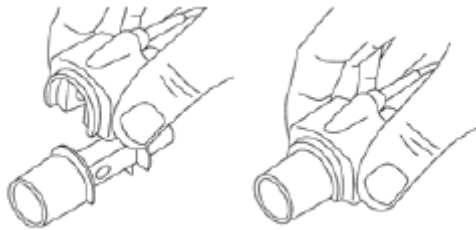
- Nomoline sampling tube connected to the front of breathing circuit, actions as follow:
- Connect sampling tube to the CO2 gas module.
- Check the port to green light (indicating system normal).
- Exhaling to the sampling tube, check monitor interface whether display effective carbon dioxide waveform and parameter values.
- Block sampling tube, wait for 10s, check whether display clogging alarm and air interface display red light.
- After connect ISA module, View ISA interface indicator to Judge normal operation.
- Under the right circumstances, checking the sampling tube was leakproofness of patients. Chart14-

1 ISA module index signal

Index signal	condition
Green light no flicker	System Normal
Green light flicker	Zeroing
Blue light no flicker	There is Anesthetic gases
Red light no flicker	Sensor Error
Red light flicker	Testing sampling tube

14.2.2 Using a Mainstream CO2 Module

1. Connect Interface cut cable of Mainstream CO2 module and monitor which mark CO2.
2. Install probe of the mainstream CO2 module to airway adapter, probe will get into place after right installed.



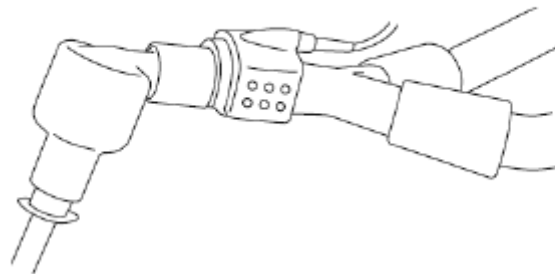
- Green LED light indicate IRMA Probe of Mainstream CO2 Module can be use normally.



- Connect 15MM (M) of IRMA airway adapter to Y connector of breathing circuit.



- Connect 15MM (F) of Mainstream CO2 module airway adapter to internal tube of patient.



- In the **【CO2 Setup】** menu, select **【Operating Mode】** and toggle **【Measure】**, after 10s, Module enter into Measuring condition.

WARNING

- Do not repeat use disposable IRMA airway adapter, or it will cause cross infection.
- The used disposable airway adapter should be dealt with according to the regulations of local medical waste
- Please confirm the current sampling tube is suitable for patient .do not confused baby and adult/child tube.
- The CO2 module probe should always make status LED facing up, unless use HME mainstream CO2 protection module probe.
- Avoid CO2 module probe in contact with baby's body directly when CO2 mainstream module probe connected to infant circuit.(no matter for any reason to make the CO2 sensor direct contact with any part of baby's body ,must be use insulating materials between CO2 and part of body).
- Don't put IRMA airway adapter between endotracheal tube and elbow, otherwise secreta of patient will jam the airway adapter and operation mistake.
- Replace adapter if airway adapter in water/water condensation
- Only using made in Masimo IRMA airway adapter.

CAUTION

- Before CO2 airway adapter connecting to breathing circuit, Verify CO2 readings and waveform on the monitor, after install CO2 sensor to airway adapter module, check patient's seal.
After access module, check LED lights of IRMA Probe indication, to check if module is working normally.

Chart 14-2 Probe index signal

index signal	condition
Green light no flicker	System Normal
Green light flicker	Zeroing
Red light no flicker	Sensor Error
Red light flicker	Testing sampling tube

14.3 CO2 Settings

Turn knob to move cursor to the area of CO2 parameters, Press button to enter setting **【CO2 setup】** menu.



Fig. 14-3 CO2 setup menu

【Apnea time】: The Monitor will alarm if the patient has stopped breathing for longer than the preset apnea time. Can Setup for: 20s, 25s, 30s, 35s, 40s, 45s, 50s, 55s, 60s

【Operating Mode】: CO2 module can setup to “Measure” or “Standby”.

Measure: CO2 module can be normal measurement and zeroing etc.

On standby: CO2 module do not work, not accept CO2 measurement, zeroing, calibrating etc.

【O2 Compen】: Can setup for low, medium, high, default value is low.

【N2O Compen】: Can setup for ON, OFF, default value is off.

【Unit】: Use for EtCO2 and FICO2 parameter display, can setup units for mmHg, Kpa, %, Default value is mmHg.

【Waveform speed】: Use for adjust speed of CO2 waveform, can setup for 6.25mm/s, 12.5mm/s, 25mm/s

【Waveform type】

Draw: The CO₂ wave is displayed as a curved line.

Fill: The CO₂ wave is displayed as a filled area.

【Scale】 Change the size of the CO₂ waveform by adjusting the wave.

14.4 Measurement limitations

The following factors may influence the accuracy of measurement:

- The quantitative influence of humidity or condensation.
- The quantitative influence of atmospheric.
- Gas or water steam of interference
- Other sources of interference.

14.5 Zeroing the Sensor

In order to ensure the CO₂ module measurement with high accuracy, should be zero according to the following suggestions:

For Mainstream IRMA Modules:

- New IRMA airway adapter installed on IRMA probe before Zeroing, Airway adapter don't need connected to patient circuit, wait for 10S makes probe preheating.
- Open **【CO₂ setup】** Menu, Select **【Zeroing】** button, IRMA module starting zeroing. During the process of zeroing, the green LED of the probe flashes for about 5s.



WARNING

- Incorrectly zero of the probe will cause the false results of the gas degrees.
- ISA sidestream module.
- ISA side stream module is automatically zeroed by sampling the gas from the breathing circuit to the ambient air. It performs automatic calibration every 24 hours. Each calibration takes less than 10 seconds. User can also manually zero when necessary, select the [AA Setup] menu, and press the [Zero] button.



Warning

- While ISA module calibration, ensure that the ISA module in a well-ventilated place. Before and during calibration, avoid breathing in the vicinity of ISA module.

14.6 Notice

If the ISA module is installed with an oxygen sensor, then the automatic zero procedure includes the oxygen sensor calibration of indoor air.

Calibration

All the required constants of IRMA mainstream modules are stored in each IRMA probe, so after replacing the probe of IRMA, no calibration is required.

Before shipment, a permanent calibration is performed to the ISA sidestream, with a stable design, no periodic calibration is required for the module.

A calibration to the CO₂ sidestream can be performed once a year on the request of the user or when the deviation is large. For more information, see the Maintenance section.

14.7 Cleaning

- 1. Regularly clean the ISA sidestream or the AG module of the IRMA mainstream, a high concentration of 70% ethanol or isopropanol with a damp cloth is recommended.
- 2. To prevent the cleaning liquid and dust into the ISA sidestream module, the module needs to be connected to the Nomoline sampling tube all the time while being cleaned.
- 3. For the AG module of the IRMA mainstream, it is required to remove the disposable IRMA airway adapter before cleaning the IRMA probe



Warning

- IRMA mainstream CO₂ module and Nomoline sampling tube is not sterile equipment, please Do Not autoclave the device, otherwise it will cause damage.
- Never disinfect the IRMA probe or the ISA sidestream module and do not put either of them into immersed liquid.
- Do not use the quantitative spray or spray equipment together with the sidestream module or the IRMA airway adapter. Otherwise it may clog the bacteria filter
- Do not apply a negative pressure to Nomoline(such as using a syringe) to remove the condensation

Chapter 15. IBP (Optional)

15.1 Overview

The monitor can monitor up to 4 invasive blood pressures and displays the systolic, diastolic and mean pressures and a waveform for each pressure.

15.2 Safety Information

Warning

- Use only pressure transducers specified in this manual. Never reuse disposable pressure transducers.
- When connecting and using accessories, applied parts should avoid from contacting metal parts of electric apparatus.
- To reduce the hazard of burns during high-frequency surgical procedure, ensure that the monitor's cables and transducers never come into contact with the high-frequency surgical units.

15.3 Starting Measurement

- Plug the pressure cable into the IBP connector.
- Prepare the flush solution.
- Flush the system to exhaust all air from the tubing. Ensure that the transducer and stopcocks are free of air bubbles.

Warning

- If air bubbles appear in the tubing system, flush the system with the infusion solution again. Air bubble may lead to wrong pressure reading.
- Connect the pressure line to the patient catheter.
- Position the transducer so that it is level with the heart, approximately at the level of the midaxillary line.
- Select the appropriate label.
- Zero the transducer. After a successful zeroing, turn off the stopcock to the atmosphere and turn on the stopcock to the patient.

Warning

- If measuring intracranial pressure (ICP) with a sitting patient, level the transducer with the top of the patient's ear. Incorrect leveling may give incorrect values.

15.4 IBP Display

The IBP measurement is displayed on the monitor as a waveform and numeric pressures. For different pressures, display may be different.

Blow image is for reference only, the real display on monitor may be slightly different.

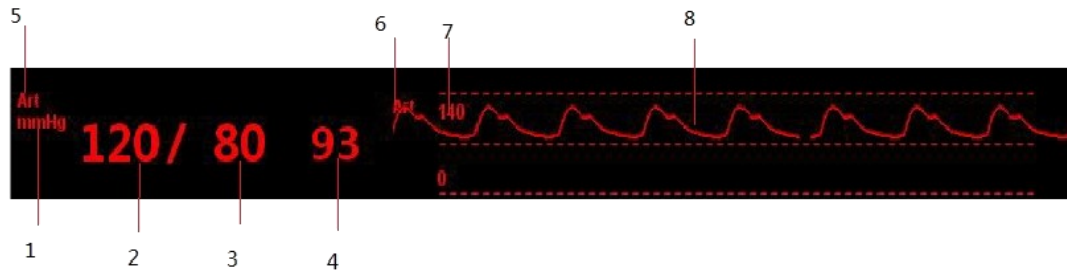


Fig .15.1 IBP Parameter Area and Waveform Area

1. Pressure unit
2. Systolic pressure
3. Diastolic pressure
4. Mean pressure
5. Pressure
6. Waveform name
7. Pressure range
8. Waveform area

For venous pressures, the parameter window shows the mean pressure only. If ICP and one or more of Art, AO, BAP, FAP pressures are measured simultaneously, the ICP parameter area will display numeric cerebral perfusion pressure (CPP), which is obtained by subtracting ICP from the mean pressure of one of the above-mentioned arterial pressures.

When multiple IBP signals are measured, IBP waveforms can be displayed overlappingly in a multi-channel waveform area. All the overlapped waveforms use the same upper, lower gridline, The left side of waveform display arterial pressure name and the gridline(except PA),Right side of waveform display venous pressure name and the gridline.

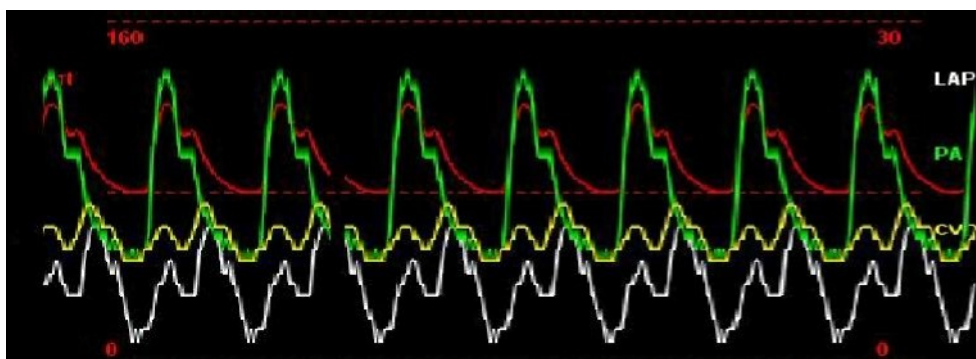


Fig.15.2 IBP Overlap waveform display

15.5 IBP Settings

Select any IBP parameter to enter the IBP setup menu:

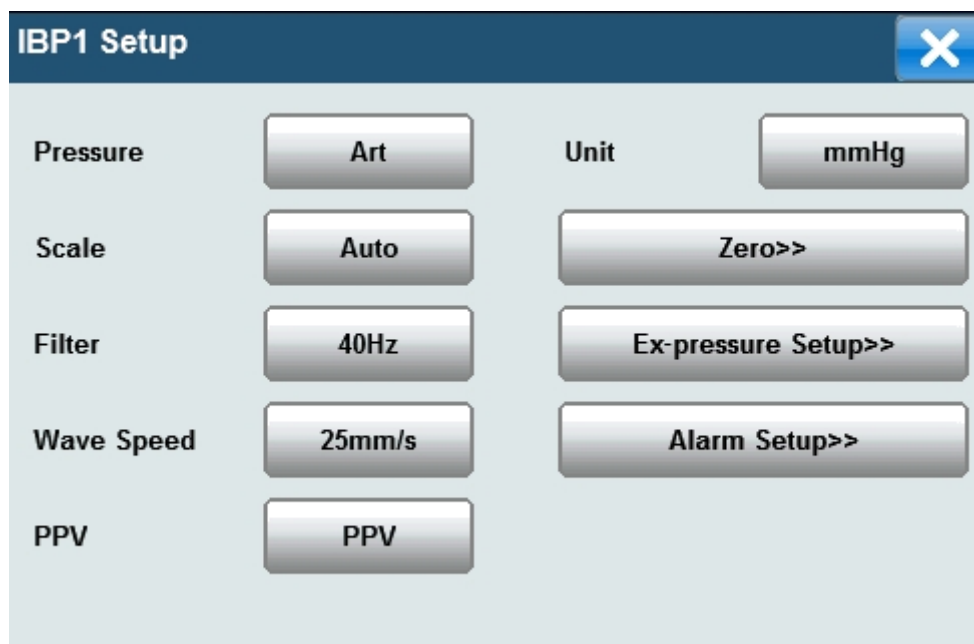


Fig. 15.3 IBP setup menu

1. Pressure

Select the pressure you want to change to enter the **【IBP setup】** menu, Select the **【pressure】** and choose what you want from the dropdown list.

Pressure name	Description	Pressure name	Description
Art	Arterial blood pressure	CVP	Central venous pressure
AO	Aortic pressure	LAP	Left atrial pressure
UAP	Umbilical arterial pressure	RAP	Right atrial pressure
BAP	Brachial arterial pressure	ICP	Intracranial pressure
FAP	Femoral arterial pressure	UVP	Umbilical venous pressure
PA	Pulmonary artery pressure	P1~P4	Expansion pressure

2. Scale range

When single IBP waveform displays, Scale range can setup to: Auto, -10~10, 0~20, 0~30, -10~40, 0~40, -50~50, 0~60, 0~80, -10~120, 0~140, 30~140, 60~140, 0~160, 0~200, 0~240, -50~300, 50~300 (Unit mmHg). User can choose scale range according to measuring site. Scale default setting is auto, monitor will adjust the IBP scale automatically according to the IBP measurement result.

When multiple IBP waveforms overlay display, the scale range consists of 2 parts: left scale range and right scale range. Left scale range is arterial pressure range (except PA), adjustable range of -50~300mmHg, and the right side scale range is venous pressure, can be adjusted in the range of -10~120mmHg.

3. Filter Mode

Can be set to 40HZ, 12HZ, Default is 40HZ.

4. Wave Speed

Wave Speed can be set to 12.5mm/s, 25mm/s/default is 25mm/s.

5. Pressure unit

Select any IBP parameter area, enter the **【IBP Setup】** you can change the pressure unit of all the IBP parameter area and waveform area. Pressure unit can be set to mmHg, KPa, default display is mmHg.

6. Zero Calibration

Zero Calibration should be done after connecting the sensor.

7. Pressure type setup

Set the pressure type of extension pressure P1~P4, Pressure type can be set to arterial pressure or venous pressure.

8. IBP waveform display mode

IBP waveform display mode: single or overlap, default is single display. IBP wave overlap display need to enter the **【screen setup】** choosing IBP overlap.

Chapter 16. AG (Optional)

16.1 Introduction

Anesthetic gas (AG) module is used to measure the gas N₂O, CO₂, O₂(Optional) and agent gas from patient respiratory gas, anesthetic gas concentration of respiratory gas. Patient's anesthesia depth and physiological function of disturbance have a close relationship. Monitoring anesthetic gas concentration play a great role in guiding the implement of anesthesia and improving anesthesia safety.

The theoretical basis of anesthesia module measurement is that different gases absorb certain wavelengths of infrared (IR) light. The process of anesthesia module analyzing patient respiratory gas is continuously measuring infrared absorption rate of airflow through the infrared spectrometer.

The measurement of degree of oxygen absorption is based on the features of the paramagnetic oxygen. The principle of paramagnetic oxygen measurement is according to the magnetization sensitivity of the magnetic field to distinguish between oxygen and other gases.

Oxygen will be attracted by magnetic field, because of oxygen with paramagnetic

The monitor supports two kinds of anesthesia modules:

1. IRMA mainstream module
2. ISA sidestream module

Anesthesia module provides the following exhale and inhale gas values:

1. CO₂: end-tidal carbon dioxide- EtCO₂ and Inhale carbon dioxide-FiCO₂
2. O₂ (Optional): Exhale oxygen-EtO₂ and inhale of oxygen-FiO₂
3. N₂O: end-tidal nitrous oxide and Inhale nitrous oxide-FiN₂O
4. Anesthetic Agent (AA): Aesthesia gases DES, ISO, ENF, SEV and HAL.
5. AWRR: breaths per minute
6. MAC: The minimum alveolar concentration of some kind of inhalation anesthetics that can make 50% of the patients at an atmospheric pressure do no dynamic response when cut in the skin. MAC value is a basic indicator of inhalation anesthesia depth.



WARNING

- Don't put any flammable anesthetic gas environment
- ISA and IRMA could only be used by the staff who have received vocational training, familiar with this manual operation
- Please run the ISA and IRMA module at specified working temperature ISA modules are not designed for MRI environment, During MRI scanning, ISA module must be outside
- ISA and IRMA CO₂ modules are just auxiliary equipment for patient evaluation, It should be used together with other vital signs evaluation equipment

- ISA and IRMA modules may be interfered by high frequency surgical equipment and measure incorrectly.
- In the process of application, please do not stretch the ISA and IRMA module probe cable

16.2 AG measurement equipment

16.2.1 Sidestream

1. Connect the AG module cable to the monitor with AG interface
2. Connect Nomoline sampling tube to the input interface of AG module



Fig.16-1 Input interface of sampling tube

3. Connect the sample gas exit to discharge system, or make the gas flow loop back
4. Start the monitor, it works when AG module input interface indicator is green
5. In the 【AG set】 menu set 【operation mode】 as 【measure】, after about 10 s, The module will start measuring

Warning

- Nomoline sampling tube cannot be reused, sample tube should be handled according to the regulations of the local medical waste treatment.
- Every two weeks or when it shows "tube stoppage" (sampling tube input interface began to appear red flashing) change Nomoline sampling tube.
- Only can use Nomoline sampling tube produced by MASIMO, otherwise it will lead to inaccurate measurements
- Seriously rationalize sampling tube, reduce the risk of twisting or bridle patients
- when connecting the sampling tube, please confirm whether the current sampling tube is suitable for the current patient, do not confuse baby and adult/child sampling tubes
- Check whether the sample gas velocity is too high for given patient type
- The ISA CO2 module should be firmly installed to avoid it falling on the patients.

If the collecting gas sample is breathing air supply, use bacteria filter on the exhaust side all the time

 Note

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

- Connect the sampling tube to the CO2 module gas entry interface.
- Check whether the green light of the interface is on stably (indicating system normal)
- Breathing into the sampling tube to check whether the monitor interface shows effective carbon dioxide waveform and parameter values.
- block sampling tube with your fingertips for 10 s to check whether appear clogging alarm and flash red light at the gas entrance
- Under proper circumstances, exam the leakproofness of loop execution connecting the sampling tubes.

Chart 16-1 ISA Module indicator

Indication signal	STATUS
Green light is not flashing	System OK
Green light flashing	zeroing
Blue light is not flashing	There's anesthetic gasses
Red light do not flashing	Sensor Error
Red light flashing	Check the sampling tube

16.2.2 Main stream

1. Connect mainstream AG module interface cable to the monitor with AG interface
2. Install mainstream AG module probe to airway adapter, after right insertion, the probe will be locked in place



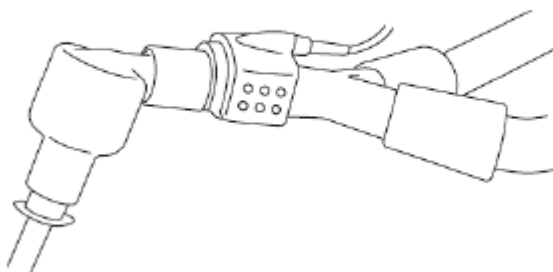
3. Green LED indicates IRMA probe mainstream AG module can be normal used.



4. Connect 15 mm male connector of IRMA airway adapter to the Y connector breathing circuit



5. Connect 15 mm female connector of Mainstream AG module airway adapter to the patients with endotracheal tube.



6. In the **【AG set】** menu set **【operation mode】**to **【measurement】**, after about 10 s, The module will start measuring .



WARNING

- IRMA adaptor cannot be reused, or will cause the cross infection
- Used adaptor should be handled according to the regulations of the local medical waste treatment.
- when connecting the sampling tube, please confirm whether the current sampling tube is suitable for the current patient, do not confuse baby and adult/child sampling tubes
- Unless you use HME mainstream CO₂ protection module probe, , CO₂ module probe should always be placed facing up

- When CO2 mainstream module probe connected to the infant circuit, must avoid the CO2 module probe directly contact with the baby's body. (No matter any reason, do not make the CO2 sensor direct contact with any part of the baby's body. there must be insulating materials between CO2 probe and the body).
- Don't put IRMA airway adapter between the endotracheal tube and elbow, otherwise may cause patient secretions blocking adapter window and lead to operation mistake.
- To prevent secretions and moisture gathered at the window and oxygen battery port, always put IRMA probe in the vertical position and make the LED upward.
- If there's water/water condensation in the airway adaptor, then replace the adaptor.
- Could only use IRMA airway adapter made by Masimo.

CAREFUL

- Verify the CO2 readings and waveforms on the monitor before connecting CO2 airway adapter to the breathing circuit. Check the patient's seal, after installing the CO2 sensor to the module on airway adaptor. After connecting to module, check the status of the LED lights on the view IRMA probe to judge whether the module is normally working.

After connecting to the module, check the status of the LED lights on IRMA probe to judge whether the module is normal working.

Chart 16-2 IRMA Module indicator

Indicator signal	Status
Green light is not flashing	System OK
Green light flashing	zeroing
Blue light is not flashing	There's anesthetic gas
Red light do not flashing	Sensor Error
Red light flashing	Check the sampling tube

16.3 AG Display



Fig.16-2 AG parameters and waveforms

AG module will display the measured waveforms and parameters on the monitor screen:

CO₂, O₂, N₂O, AA (Et and Fi number)

AWRR: CO₂, O₂, AA and N₂O

waveform: The monitor can also show up to 4 anesthetic gasses waveforms at the same time.

When AG module identify two anesthetic gasses, AA waveform shows the main anesthetic gas.

Parameters area only supports the breathing and suction value of main anesthetic gases whether O₂ waveform is displayed according to whether the module of O₂ is configured.

MAC: Minimum alveolar concentration

MAC is the standard of effect of inhalation anesthesia gas.

The value of MAC represents the concentration of alveolar anesthetic gas (one atmospheric pressure), which is also the concentration makes 50% of the population tested does not produce muscle motion response to standardized pain stimulus.

According to the following formula, can use the end gas concentration to calculate MAC value:

$$\text{MAC} = \frac{\% \text{Et}(\text{AA1})}{\text{X}(\text{AA1})} + \frac{\% \text{Et}(\text{AA2})}{\text{X}(\text{AA2})} + \frac{\% \text{Et}(\text{N}_2\text{O})}{100}$$

Et(AA1): The value of the end of primary breathing anesthetic gas

Et(AA2): The value of the end of second breathing anesthetic gas

Et(N₂O): The value of the end of primary breathing N₂O

X(AA1): The 1 MAC density corresponding to inhalation primary anesthetic gas

X(AA2): The 1 MAC density corresponding to second inhalation anesthetic gas

The 1 MAC density of every inhalation anesthetic gas:

Anesthetics	HAL	ISO	ENF	SEV	DES
X(AA)	0.75%	1.15%	1.7%	2.05%	6.0%

for example: Anesthesia module measures the gasses at the end of the patient breathe

DES=4%, HAL=0.5%, N₂O=50%, so the value of MAC:

$$\text{MAC} = \frac{4\%}{6.0\%} + \frac{0.5\%}{0.75\%} + \frac{50\%}{100} = 1.83$$



Attention

- None of the above formula considering altitude, patient age and other personal factors.
EtAA2 could only be used for IRMA AX+/OR+ probes.

16.4 AG Setup

16.4.1 AA Setup

Select the parameter area or waveform, the [AA Setup] menu will be popped out



Fig.16-3 AA Setup menu

[Apnea Delay] When the apnea time surpasses the setup time, the patient monitor will show the “CO2 apnea” advanced physiological alarm.

The setting option: 20s, 25s, 30s, 35s, 40s, 45s, 50s, 55s, 60s, the default setting is 20s.

[Operating model]: Set AG module operating mode, the operation mode can be set to “measure” or “standby”.

Measurement mode: AG modules can be normal measurement, zero and other operations.

Standby mode: If AG module does not work, the AG measurement, calibration or other operations are not allowed.

[O2 Compensation] As to the installed oxygen battery module, the module will automatically perform oxygen compensation. And for the non-installed oxygen battery module, manually compensation setup is required.

The O2 compensation can be set to high, medium and low. The default is low.

[Waveform Speed] AA waveform display for adjusting speed can be set to 6.25mm/s, 12.5mm/s, 25mm/s, the default is 12.5mm/s.

[Waveform Model] The display of waveform model.

Scanning lines: the line portrayal of AA waveform.

Fill: the display of filling the bottom of AA waveform.

[Waveform Scale]: Adjust the position of the ruler on the waveform and the corresponding waveform amplitude will change. It can be set to 3, 5, and 4.5,6,9,18.

16.4.2 O2 Setup

For the AG module which has installed oxygen battery, select the O2 parameter area or waveform area, the [O2 Setup] menu will be popped out.



Fig.16-4 O2 Setup menu

[Unit]: It can be set to mmHg, % or Kya, the default is %. N2O and AA unit are %.

[Waveform Scale]: Adjust the position of the ruler for waveform of O2 and the O2 waveform amplitude changes accordingly. It can be set to 20, 25, 35, 50, 100. The default is 25.

16.4.3 N2O Setup

Select the N2O parameter area or waveform area, the [N2O Setup] menu will be popped out.



Fig. 16-5 N2O Setup menu

[Waveform Scale]: Adjust the position of the ruler for waveform of N2O and the N2O waveform amplitude changes accordingly. It can be set to 20, 25, 35, 50, 100. The default is 25.

16.4.4 CO2 Setup

Select the CO2 parameter or waveform area, the [CO2 Setup] menu will be popped out.

CO2 Setup	
Apnea Delay	20s
Wave Mode	Scan
Operating Mode	Measure
Wave Scale	40
O2 Compens	Low
	Start Zero Cal.
Unit	mmHg
	Alarm Setup>>
Wave Speed	12.5mm/s

Fig. 16-6 CO2 Setup menu

[Unit]: The unit of CO2 can be set to mmHg, % or kPa, the default is%.

[Waveform Scale]: Adjust the position of the ruler for waveform of CO2 and the CO2 waveform amplitude changes accordingly. It can be set to 20, 40, 60, 80, the default is 40.

16.5 Measurement Accuracy Factors

The following factors may affect the accuracy of measurement:

- 1.The quantitative impact of humidity or condensation.
- 2.The quantitative impact of atmospheric pressure.
- 3.Interfering gases or water vapors.
- 4.The other sources of interference.

16.6 Zero

To ensure high measurement accuracy of the AG module, it should be zero in accordance with the following recommendations:

IRMA mainstream module

After every change of IRMA airway adapter, if there is a shift gas value or display an unspecified

gas precision message, then zero operation should be performed.

1. Start IRMA probe, wait for a period of time for the probe to be pre-heated (IRMA OR module 15s, IRMA AX+/OR+ module 30s, at least 1 minute after replacing IRMA OR module adapter)
2. Select the [AA Setup] menu, press the [Start] button to zero.

Warning

- Incorrectly zero of the probe will cause the false results of the degrees.

ISA sidestream module

ISA side stream module is automatically zeroed by sampling the gas from the breathing circuit to the ambient air. It performs automatic calibration every 24 hours. Each calibration takes less than 10 seconds. User can also manually zero when necessary, select the [AA Setup] menu, and press the [Zero] button.

Warning

While ISA module calibration, ensure that the ISA module in a well-ventilated place. Before and during calibration, avoid breathing in the vicinity of ISA module.

Notice

If the ISA module is installed with an oxygen sensor, then the automatic zero procedure includes the oxygen sensor calibration of indoor air.

16.7 Calibration

All the required constants of IRMA mainstream modules are stored in each IRMA probe, so after replacing the probe of IRMA, no calibration is required.

Before shipment, a permanent calibration is performed to the ISA sidestream, with a stable design, no periodic calibration is required for the module.

16.8 Cleaning

- 1.1. Regularly clean the ISA sidestream or the AG module of the IRMA mainstream, a high concentration of 70% ethanol or isopropanol with a damp cloth is recommended.

2.To prevent the cleaning liquid and dust into the ISA sidestream module, the module needs to be connected to the Nomoline sampling tube all the time while being cleaned.

3.For the AG module of the IRMA mainstream, it is required to remove the disposable IRMA airway adapter before cleaning the IRMA probe.

 Warning

- IRMA mainstream CO2 module and Nomoline sampling tube is not sterile equipment, please Do Not autoclave the device, otherwise it will cause damage.
- Never disinfect the IRMA probe or the ISA sidestream module and do not put either of them into immersed liquid.
- Do not use the quantitative spray or spray equipment together with the sidestream module or the IRMA airway adapter. Otherwise it may clog the bacteria filter.
- Do not apply a negative pressure to Nomoline (such as using a syringe) to remove the condensation.

Chapter 17. C.O. (Optional)

17.1 Overview

Cardiac output (C.O.) module is inserted into the plug-in slot of the monitor for C.O. measurement. C.O. measurement adopts the thermodilution method to invasively measure the cardiac output and other hemodynamic parameters in order to determine the flow rate of the blood circulation system.

As for the thermal dilution method, the cold solution is introduced into the blood circulation system, and measuring the resulting drop in temperature at a downstream site. In the window of the C.O. measurement, the temperature change is shown as a curve, and the monitor will calculate the C.O. value according to this curve. The C.O. value is inversely proportional to the area under this curve. Cardiac output is a continuous variable; therefore, to obtain a reliable C.O. average value, a series of measurements must be carried out. Generally, the average value of multiple thermal dilution measurements is used for therapy decision.

17.2 Safety Information

⚠ Warning:

- Never reuse the disposable accessories.
- Never touch the C.O. connecting cable when defibrillation is carried out during the C.O. monitoring period. Otherwise, electric injury, electric shock or other damages might be caused
- Do not soak or wet the connector.
- Do not soak the C.O. connecting cable in alcohol; otherwise, the connecting cable might be hardened or damaged.
- Never sterilize the C.O. connecting cable at high pressure.

17.3 C.O. Display

There is no waveform display of C.O. measurement on the main interface, only the value of C.O., TB (temperature of blood) and the prompt info can displayed in the parameter zone. See the interface in the following figure:



Fig. 17-1 C.O. parameter display

17.4 Measurement of C.O.

1. Insert the C.O. interface cable to the C.O. module.
2. As shown in the following figure, insert the thermistor connecting cable of the Swan-Ganz catheter into the thermistor connector, and connect the In-line Injectate sensor cable to the In-line Injectate.

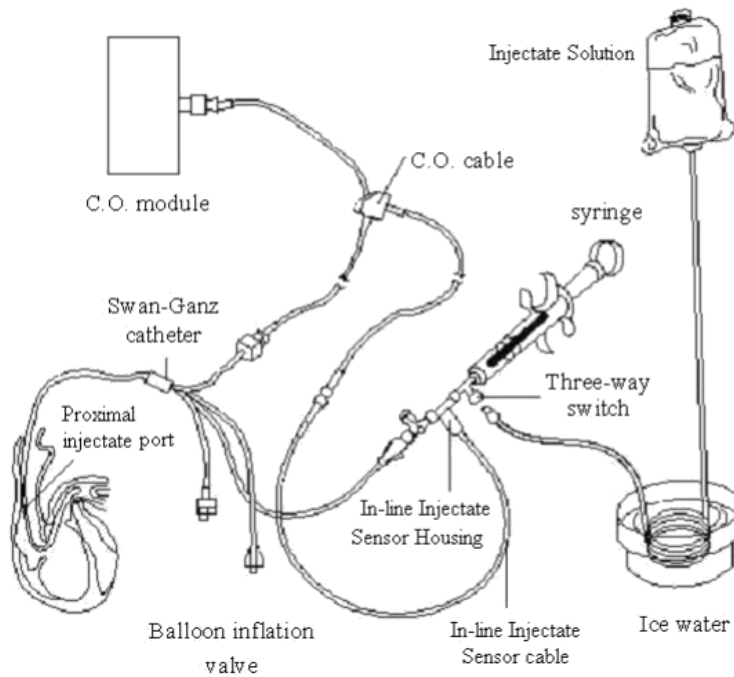


Fig. 17-2 C.O. accessories connection

3. Input patient height and weight in **【Patient Info】** menu.
4. Select the C.O. parameter zone to enter into the menu of **【C.O. Setup】**, and select the **【C.O. Screen】** from **【Switch】** smart key to enter into the measurement window.
5. If the **【Measure Mode】** in the **【Setup C.O.】** is set as single, when the words “Ready for New measurement” are displayed on the screen, select the **【Start】** to start the C.O. measurement. When there is prompt information “Inject now...” on the screen, please inject the solution to the right atrium port of the Swan-Ganz catheter. The optimal injection rate is 2.5ml/s. The cardiac output, cardiac index and corresponding curve will display in the measurement window in real time.
6. Select the **【C.O. Measure】** to open the C.O. measurement window as shown in the following figure, please pay attention that whether the TB cable is well connected and the value of C.O. setting is correspond with actual value before C.O. measurement.

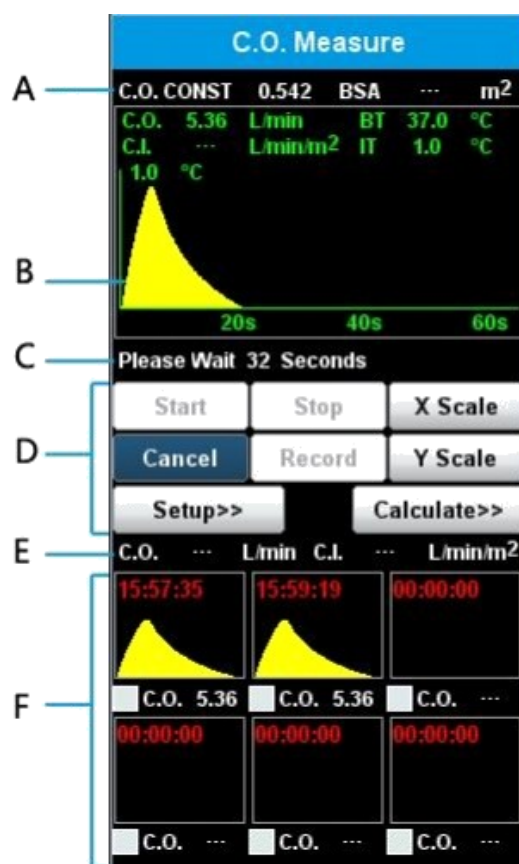


Fig 17-3 C.O. measurement window

Below the C.O. measurement window, the following function buttons are included:

【Start】 : Start a C.O. measurement.

【Delete】 : Selectively delete the measured values in the historical measurement window.

【Hemodynamic】: Open the menu of 【Hemodynamic】. See 17.5.2 of this chapter for the detailed content of the menu.

【C.O. ITEM】 : Open the C.O. item to browse the measurement results.

【Setup Scale】 : Open the menu of scale setting to adjust the scale range.

【Setup C.O.】 : Open the menu of 【Setup C.O.】. See 17.5 of this chapter for the detailed content of the menu.

【Record】 : Record the latest measurement curve and measurement result.

17.5 C.O. Setting

17.5.1 C.O. Setup

Select the 【Setup C.O.】 to set the items in the C.O. setting window in proper order.

- 【Measure Mode】 : Single mode or continuous mode is optional.
- 【TI Source】 : The temperature source of injectate can be input by the user or measured by the injectate temperature probe. The options include manual and auto. When 【Auto】 is set, the temperature of injectate can be obtained through the In-line Injectate sensor cable in real

time.

- **【Setup TI】** : When the **【TI Source】** is automatic, the TI is unadjustable;
- when the **【TI Source】** is manual, the TI is adjustable.
- **【Inj.Vol】** : 3cc, 5cc or 10cc is optional.
- **【Cath.Const】** : The set value of the constant can be obtained in the document attached to the Swan-Ganz catheter, which depends on the injectate volume, temperature and the catheter type. To change this value, please select the catheter constant in the window of **【Setup C.O.】**, and input the correct value.
- **【Weight】** : Set the correct patient's body weight, which is used to calculate the hemodynamic and other parameters.
- **【Height】** : Set the correct patient's height, which is used to calculate the hemodynamic and other parameters.
- **【TEMP Unit】** : °C or °F is optional.

17.5.2 Alarm-related Settings

- Select the **【Alm Switch】** in the menu of **【C.O. Setup】** to open or close the alarm.
- Select the **【Alm Level】** in the menu of **【C.O. Setup】**; The alarm is divided into low, med and high according to the severity of the alarm.
- Select the **【TB Hi Lmt】** in the menu of **【C.O. Setup】** to set the alarm upper limit of the blood temperature.
- Select the **【TB Lo Lmt】** in the menu of **【C.O. Setup】** to set the alarm lower limit of the blood temperature.

17.5.3 Hemodynamic

Select the **【C.O. Measure】** in the menu of **【C.O. Setup】**, and select the **【Hemodynamic】** in the menu bar below the C.O. measurement window to open the hemodynamic window.

Important hemodynamic parameter values are displayed in the hemodynamic window. These parameters consist of parameters for monitoring and parameters for calculation. Select the **【Calculation】** to switch the display of parameters for monitoring and parameters for calculation. Parameters for monitoring refer to the input values which can be obtained from the patient monitoring data and the values which are inputted manually. The parameters for monitoring, the identifications and

Parameter	Abbreviation	Unit
Cardiac output	C.O.	L/min
Heart rate	HR	bpm
Pulmonary artery wedge pressure	PAWP	mmHg
Mean artery pressure	MAP	mmHg
Mean pulmonary artery pressure	MPAP	mmHg
Central venous pressure	CVP	mmHg
End diastolic volume	EDV	mL
Height	Height	cm
Weight	Weight	kg

Parameters for calculation refer to the parameter values automatically calculated by the selection of **【Calculation】**. The parameters for calculation, the identifications and the corresponding measurement units are as shown in the following figure:

Parameter	Full Name	Unit
C.I.	Cardiac index	L/min/m ²
BSA	Body surface area	m ²
SV	Stroke volume	mL
SVI	Stroke index	mL/m ²
SVR	Systemic vascular resistance	dyn·s/cm ⁵
SVRI	Systemic vascular resistance index	dyn·s·m ² /cm ⁵
PVR	Pulmonary vascular resistance	dyn·s/cm ⁵
PVRI	Pulmonary vascular resistance index	dyn·s·m ² /cm ⁵
LCW	Left ventricular work	kg·m
LCWI	Left ventricular work index	kg·m/m ²
RCW	Right ventricular work	kg·m
RCWI	Right ventricular work index	kg·m/m ²
LVSW	Left ventricular stroke work	g·m
LVSWI	Left ventricular stroke work index	g·m/m ²
RVSW	Right ventricular stroke work	g·m
RVSWI	Right ventricular stroke work index	g·m/m ²
EF	Ejection fraction	%

The functions of the buttons below the display window of parameters for calculation are as follows:

【<<*/*】 and 【>>*/*】 : Display the historical input values and the calculation results.

【Range】 : Display the normal range or the unit.

【Record】 : Print the calculation results.

【Show Input】 : Switch the display of the input values and the calculation results.

17.6 Measurement Restrictions

C.O. measurement has its restrictions. It is inadvisable to carry out C.O. measurement when the patient is under one or more of the following circumstances:

- ◆ Patient with right heart valve disease
- ◆ Patient with blood coagulation disorder
- ◆ Patient with vessel disease
- ◆ Patient with thrombolytic therapy
- ◆ Patient with pulmonary hyperpiesia
- ◆ Patient with pacemaker
- ◆ Patient with systemic hypotension

17.7 Influencing Factors

Some factors influencing the cardiac output include:

- The temperature and volume of injectate solution
- The injection rate, the frequency and the interval
- The position of catheter relative to the lung
- The injection technique of the operator

Chapter 18. BIS (Optional)

18.1 Introduction

Bispectral Index (BIS) monitoring helps to monitor the level of consciousness of a patient under general anesthesia or sedation in the OR and ICU. The BIS sensor is placed on the patient's forehead to capture electroencephalographic (EEG) signals from which several numerics are derived, including a single BIS between 100 (wide awake) and zero (absence of brain electrical activity) that represents the patient's level of consciousness. This enables clinicians to customize the precise type and amount of anesthetic or sedative medication that each patient needs.

BIS module is produced by Aspect Medical Company. This module uses the electrical activity in the cerebral cortex EEG, combines bispectral index and spectral analysis method, given certain amount of bispectral index, combined with the quality of EEG analysis of comprehensive evaluation of factors such as the patient's current state of consciousness, to identify the anesthetic depth.

18.2 Safety Information

For patients with neurological disorders, patients taking psychoactive medication, and children below the age of 1 year, BIS values should be interpreted cautiously.

WARNING

- The conductive parts of sensors and connectors should not come into contact with other conductive parts, including earth.
- To reduce the hazard of burns in the high-frequency surgical neutral electrode connection, the BIS sensor should not be located between the surgical site and the electro-surgical unit return electrode.
- The BIS sensor must not be located between defibrillator pads when a defibrillator is used on a patient connected to the patient monitor. The BIS sensor must not be located between defibrillator pads when a defibrillator is used on a patient connected to the patient monitor.
- To avoid the risk of strangulation, BIS module sensor cable must be carefully placed and fixed.

18.3 BIS Display

The BIS module provides BIS, SQI, EMG, SR, SEF, TP, PC value and 2 channel EEG wave, as following:



Fig. 18-1 BIS parameter area

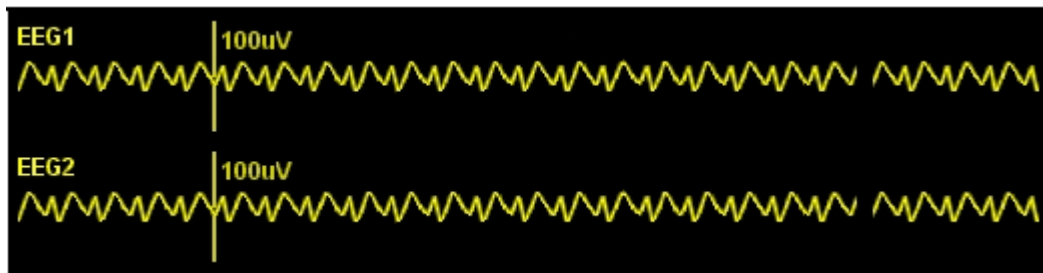


Fig. 18-2 EEG waveform

1. Bispectral Index (BIS)

The BIS numeric reflects the patient's level of consciousness. It ranges from 100 for wide awake to 0 in the absence of brain activity.

BIS numeric	BIS value description
100	The patient is widely awake.
70	The patient is underdosed but still unlikely to become aware.
60	The patient is under general anesthesia and loses consciousness.
40	The patient is overdosed and in deep hypnosis.
0	The EEG waveform is displayed as a flat line, and the patient has no electrical brain activity.

2. Electromyograph (EMG)

EMG bar graph reflects the electrical power of muscle activity and high frequency artifacts. The minimum possible EMG is about 25 dB.

- ◆ EMG < 55 dB: This is an acceptable ECG.
- ◆ EMG ≤ 30 dB: This is an optimal EMG.

3. Suppression Ratio (SR)

SR numeric is the percentage of time over the last 63-second period during which the EEG is considered to be in a suppressed state.

4. Spectral Edge Frequency (SEF)

The SEF is a frequency below which 95% of the total power is measured

5. Signal Quality Index (SQI)

The SQI numeric reflects signal quality and provides information about the reliability of the BIS, SEF, TP, and SR numerics during the last minute.

It ranges from 0-100%:

- ◆ SQI < 15%: the numerics cannot be derived.

- ◆ SQI 15 to 50%: the numerics cannot be reliably derived.
- ◆ SQI 50% to 100%: the numerics are reliable.

6. Total Power (TP)

TP numeric indicates the power in the frequency band 0.5-30Hz. The useful range is 30-100db.

18.4 Set up the BIS Measurement

1. Connect the BISx model to the BIS interface of the patient monitor.

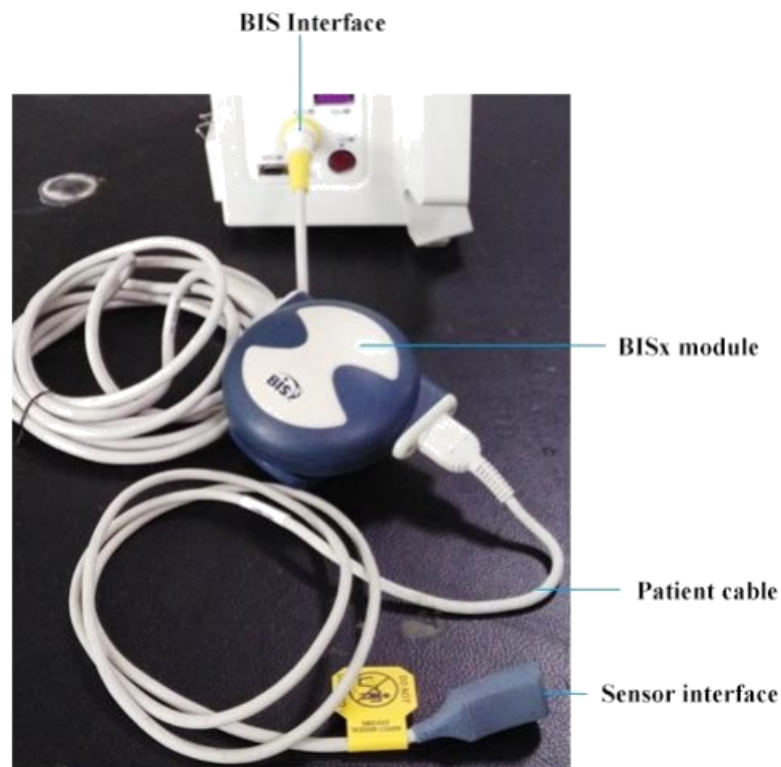


Fig. 18-3 BISx module connection

2. Use the attachment clip to secure the BISx model near, but not above the level of the patient's head.
3. Attach the BIS sensor to the patient following the instructions supplied with sensor.

⚠ NOTE

Make sure the patient's skin is dry. A wet sensor or a salt bridge could result in erroneous BIS and impedance values.

4. Connect the BIS sensor to the patient interface cable. As soon as a valid sensor is detected, the impedances of all electrodes are measured automatically and the impedance value for each electrode is displayed in the sensor check window.

⚠ CAUTION

Do not attach the BISx model to the patient's skin for long time. Otherwise, the BISx heats while on the patient and may cause discomfort.

18.5 BIS Setup menu

【BIS Setup】 menu is shown as below:

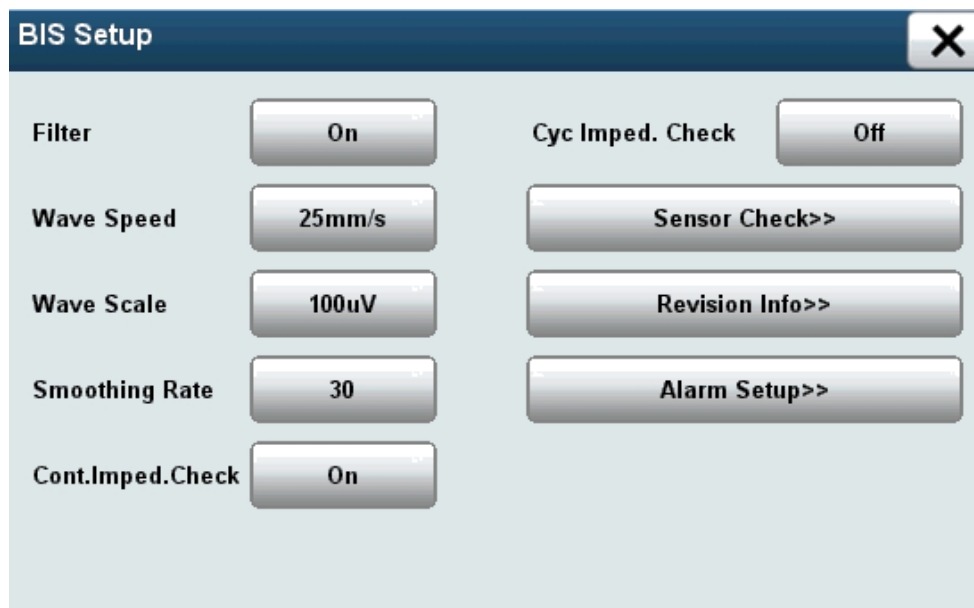


Fig.18-4 BIS Setup menu

18.5.1 Continuous Impedance Check

By default, this check is switched on. It checks:

- ◆ The combined impedance of the signal electrodes plus the reference electrode. This is done continuously and does not affect the EEG wave. As long as the impedances are within the valid range, there is no prompt message of this check or its results.
- ◆ The impedance of the ground electrode. This is done every ten minutes and takes approximately four seconds. It causes an artifact in the EEG wave, and the message [BIS Ground Checking] is displayed on the monitor during the check. If the ground electrode does not pass this check, another check is initiated. This continues until the ground electrode passes the check. If the continuous impedance check interferes with other measurements, it can be switched off. To do this:
- ◆ Enter 【BIS setting】, Select [Cont. Imped.Check] and then select[On] or [Off].

⚠ CAUTION

- Switching the continuous impedance check off will disable automatic prompt to the user of impedance value changes, which may lead to incorrect BIS values. Therefore, this

should only be done if the check interferes with or disturbs other measurements.

- When use semi-reusable sensor, continuous impedance monitoring cannot be turned off. If turn off the checking when sensor is connected, it will automatically open.

18.5.2 Cyclic Impedance Check

This measures the exact impedance of each individual electrode. It causes a disturbed EEG wave, and **【BIS Impedance Check】** is displayed on the monitor

■ The cyclic impedance check is automatically initiated when a sensor is connected. To manually start a cyclic impedance check manually, you can:

- ◆ Select [Cyc Imped. Check] in the [BIS Setup] menu and then select [On] or [Off].

The cyclic impedance check stops automatically if the impedances of all electrodes are within the valid range. To manually stop a cyclic impedance check, you can:

- ◆ Select [Cyc Imped. Check] in the [BIS Setup] menu and then select [On] or [Off].

If **【Cyc Imped. Check】** has stopped before ground electrode impedance check pass, it will automatically start the ground electrode impedance check, and cannot be disconnected.

18.5.3 BIS Sensor Check

To start sensor check, select [Sensor Check >>] in the [BIS Setup] menu.

The graphic in the BIS sensor check window automatically adapts to show the type of sensor you are using, show three or four electrodes as required. Each symbol in the graphic represents an electrode and illustrates the most recently-measured impedance status of the electrodes: 1 is the reference electrode; 2 the ground electrode; 3 and 4 are signal electrodes.

In addition, if it detects any electrode or combination electrode to skin impedance higher than the limit or the electrode fall off, it will generate alarm **【BIS impedance high】** or **【Lead off】**

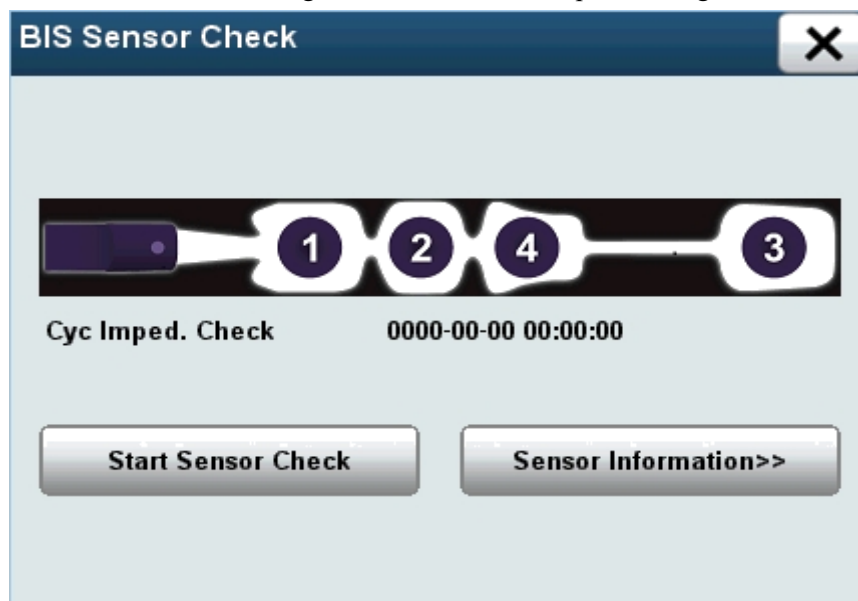


Fig. 18-5 BIS sensor check

Status	Action
Pass	No action necessary.
BIS impedance high	Check the sensor-to-skin contact. If necessary, clean and dry skin.
Failed	1. 1.Reconnect electrode, or check the sensor-to-skin contact. If necessary, clean and dry skin. 2. Check the sensor-to-skin contact. If necessary, clean and dry skin.

18.5.4 Filter

Low pass and high pass filters can filter out undesirable interference from the raw EEG waveform display. Notch filter can filter frequency lines interference. Filter settings will affect the EEG waveform and SEF and TP values, but does not affect the BIS, EMG, SR, SQI value.

To set up filter, Select **【Filter】** to **【On】** or **【Off】** in the **【BIS Setup】** menu,

18.5.5 BIS Smoothing Rate

The smoothing rate defines how the monitor averages the BIS value.

Enter the [BIS Setup] menu, select [Smoothing Rate] to change smoothing rate you need.

- ◆ 15 seconds: With this smoothing rate, the monitor provides increase responsiveness to changes in the patient's state.
- ◆ 30 seconds: The monitor provides a smoother BIS trend with decreased variability and sensitivity to artifact.

18.5.6 Wave scale

Change the scale only change the appearance of the waveform, it does not affect the signal analysis, nor does it impact report record or the print signal.

Enter the [BIS setup] menu, select [wave scale] to adjusted the scale. The optional scale value: 50uV, 100uV, 200uV 500uV. EEG waveform vertical line appear on the scale, and its height is equal to the amount of uV value.

18.5.7 Revision info

Showing display sensor, BIS module version info.

Chapter 19. NMT (Optional)

19.1 Overview

Monitoring the effect of neuromuscular blocking agents (NMBAs) can be accomplished in several ways.

The most frequently used method is clinical evaluation using a peripheral nerve stimulator.

Although the technique is simple, it lacks accuracy because of its subjective interpretation of the responses.

Accurate and objective information on the degree of neuromuscular paralysis can be obtained by measuring the force of contraction of a certain muscle (mechanomyography).

However, the equipment needed is rather bulky and difficult to use during routine surgery because of the elaborate set-up procedure and its sensitivity to movement.

A good alternative for force measurement of acceleration (acceleromyography). According to the second law of Newton: Force equals Mass times Acceleration ($F=Ma$), the acceleration of a muscle has a linear correlation with the contraction force of that muscle. It has been shown that there is a good correlation between the results of acceleromyography and mechanomyography.

19.2 Short Set-up

19.2.1 Checking Patients for Muscle Relaxation

In the set-up menu of the TOF-Watch, display of the stimulation strength can be switched from mA (default setting) to μC , according to local preferences. As a default setting, the stimulation current is set at 50 mA.

1. Place electrodes in position, attach the acceleration transducer to the thumb with adhesive tape.
2. Turn TOF-Watch on by pressing the  button (1) and holding it down for 1s.
3. Administer the induction agent.
4. When the patient is adequately sedated, press  (22) for automatic calibration (optional).
5. Hold down the  button (3) for repetitive TOF stimulation.

The TOF-Watch is now ready for the further monitoring of neuromuscular transmission.

During surgery muscle relaxation can be monitored continuously to assess the need for either repeated administration of a muscle relaxant or for the use of a reversal agent during recovery.

19.2.2 Checking Patient for Residual Curarization

The use of the automatic set-up of the TOF-Watch on patients already relaxed will result in incorrect selection of internal gain due to fading. The following procedure should be used:

- 1、 Place electrodes in position, attach the acceleration transducer to the thumb with adhesive tape.
- 2、 Turn TOF-Watch on by pressing the  button (1) and holding it down for 1s.
- 3、 The strength of the stimulation (mA or μ C) can be adjusted manually by pressing the mA(μ C) up (21) or down button (23).

- 4、 Press  (3).

Since no control twitch height has been established, only the TOF ratio yields information about the recovery of a patient and not a single twitch measurement.

19.2.3 Nerve Location for Loco-regional Anesthesia

The TOF-Watch can be used as an aid in nerve location for loco-regional anesthesia using a special stimulation cable. This cable contains one lead with a connector fitting to a surface electrode and one lead with a connected to a needle electrode.

Once this cable is inserted in the TOF-Watch, the instrument automatically reverts to the locoregional anesthesia mode. Since only a visual assessment of the response is needed, no responses are shown on the display.

- 1、 Connect special stimulation cable to the TOF-Watch
- 2、 Place the surface electrode in position
- 3、 Turn TOF-Watch on by pressing the  button (1) and holding it down for 1s.
- 4、 Start the repetitive 1Hz stimulation by pressing the  (24)button
- 5、 The strength of the stimulation (mA or μ C, shown on the display) can be adjusted manually by pressing the mA (μ C) up button (21) or down button (23).

The TOF-Watch is now ready for use in locating the nerve with the needle electrode.

19.3 Pre-Operative Set-up

19.3.1 Cable Connections (Objective Monitoring)

The TOF-Watch can be used for objective monitoring by using two cables:

A) Acceleration transducer cable and B) stimulation cable.

When surface electrodes are used, the instrument automatically uses stimulation pulses of 200 μ s (300 μ s) at 0-60 Ma (0-12/18 μ C). The pre-defined default current is set at 50 mA.

Attach the simulation cable to the surface electrodes placed on the ulnar nerve.

Attach the acceleration transducer with its largest flat side to the thumb by means of adhesive tape. Connect both cables to designated color-coded outlets on the TOF-Watch (reversal of the cables is not possible because of a mechanical barrier).

19.3.2 Cable Connections (Subjective Monitoring)

When the acceleration transducer is not connected to the TOF-Watch, the instrument can be used as a peripheral nerve stimulator.

When surface electrodes are used, the TOF-Watch automatically shows only the stimulation strength in mA (μ C) and stimulation mode.

The pre-defined default stimulation strength is set at 50 mA. Attach the simulation cable to the surface electrodes placed on the ulnar nerve (see above), and connect to the designated color-coded outlet on the TOF-Watch (insertion of the cable in the wrong outlet is not possible because of a mechanical barrier).

19.3.3 Cable Connections (Loco-regional Anesthesia)

When the special cable for a needle electrode is used, the TOF-Watch can be used for nerve location in loco-regional anesthesia.

The TOF-Watch will automatically revert to the loco-regional anesthesia mode, enabling stimulation with a pulse width of 40 μ s, and a current ranging between 0 and 6.0mA.

The total charge delivered varies between 0 and 0.24 μ C. In the set-up menu, display of the strength of the simulation can be switched from μ C (pre-installed) to mA.

The pre-defined default setting is 0 μ C. Patient responses are not shown on the display.

Attach the special cable to a needle electrode and a surface electrode, and connect to the designated color-coded outlet on the TOF-Watch (insertion of the cable in the wrong outlet is not possible because of a mechanical barrier).

19.3.4 Electrodes

When monitoring neuromuscular transmission, the TOF-Watch should always be used with round surface electrodes with snap connection. Small (pediatric) electrodes are advisable to obtain a sufficient current density. In order to ensure a steady quality of the test, be sure only to use CE marked electrodes.

19.3.5 Electrode Placement

Acceleromyography can take place by stimulating the facial nerve and monitoring the response of the orbicularis oculi muscle or by stimulating the posterior tibial nerve and monitoring the response of the flexor hallucis brevis muscle. However, stimulation of the ulnar nerve and acceleration measurements at the adductor pollicis is preferred for routine monitoring.

The electrodes are placed over the ulnar nerve on the volar side of the wrist. The distal electrode is positioned where the proximal bending line crosses the radial side of the flexor carpi ulnaris muscle. The proximal electrode can be placed either 2 to 3 cm proximal of the distal electrode or over the ulnar nerve at the elbow.

- Correct positioning of the electrodes is important. Small displacement may result in considerable changes in stimulation current requirements. Furthermore, the electrodes must be positioned in such a way to avoid direct stimulation of the muscle.
- Place the electrodes on each side of the expected position of the ulnar nerve. In this way, the effect of any minor misjudgment of the actual nerve position is minimized.
- It has been found that slight pressure on the electrodes may improve the stimulation considerably. Therefore, taping the electrodes to the skin may be advisable.



Fig. 19-1 Electrode and transducer placement

19.3.6 Position of the Transducer

The transducer should be placed with its largest flat side against the thumb.

The transducer cable must be fixed in such a way that no traction is applied to the transducer and that movement of the thumb is not obstructed in any way.

- Small sideways movements of the thumb may be noticed during stimulation. If this is the case, reposition the transducer in such a way that the movement is perpendicular.
- The more distal the transducer is placed on the thumb, the stronger the acceleration signal. This effect can be used to adjust the signal strength.

19.3.7 Arm Position

The arm, used for the acceleration measurement, should be kept immobile during the whole procedure. Movement of the arm to another position may change the twitch height considerably. Although the twitch height may still differ from the original value, the train-of-four ratio will not

be affected. At later stages of recovery the patient may perform voluntary movements of the hand, which in turn may disturb the measurements and recordings.

19.3.8 Connection to Stimulator

Always make sure that the TOF-Watch is switched off or that the display shows the stop symbol



(7) before touching the electrodes.

The proximal electrode is usually connected to the white (positive) clip on the stimulator cable.

The distal electrode should be connected to the black (negative) clip.

If both electrodes are near the wrist, the polarity is less critical. The stimulator pulses are

monophasic. Switching the electrode connection (exchanging  with ) may sometimes increase the stimulation considerably.

19.3.9 Skin Resistance

The skin resistance together with the electrode resistance from the total resistance in the stimulating circuit. The stimulator in the TOF-Watch is of the constant current type.

This means that the stimulation voltage automatically increases with the resistance.

As long as the voltage remains below the maximum value (=300V) the stimulator can deliver the selected pulse. For a maximal current of 60mA, the maximal resistance will be 5KOhm.

If the resistance is above this value, the “skin resistance too high” symbol  (12) will be displayed, and the stimulation stops. If the current is reduced, the corresponding voltage drops and stimulation can be resumed.

- Insufficient cleaning of the skin may be the cause of a too high skin resistance.

Note that there is not necessarily any relation between high skin resistance and problems of reaching supramaximal stimulation

19.3.10 Control Twitch Height

The patient should be anesthetized before operating the stimulator because nerve stimulation can be painful for a conscious patient.

Control twitch height is the twitch height when the patient is not relaxed. Control twitch height is set to 100% at calibration.

19.3.11 Calibration

The size of the transducer signal varies from patient to patient. In order to establish a control twitch height value of 100% for the 1Hz or 0.1 Hz modes, the transducer gain is set by pressing

the  button (22) for more than 1s.

- If the responses of a non-relaxed patient are too small for an accurate measurement, as can be seen in children or when using the orbicularis oculi muscle, then a gain calibration will optimize the sensitivity.

19.3.12 Sensitivity

It may be observed that the thumb makes very small movements although no response is shown on the display. This is not an error: the movement is below the threshold of 3% control twitch height at which the TOF-Watch starts to display the responses.

19.3.13 Stimulation Units

The TOF-Watch can show the strength of the electrical stimulation in both milli-amperes [Ma] and micro-coulomb [μ C]. For routine monitoring the default setting is in mA, for use in locoregional anesthesia the default setting is in μ C. It is possible to change between the two modes in the set-up menu.

19.4 NMT Display

The monitor displays NMT parameter on the normal screen. Fig. 7-4 below is the monitoring interface of NMT, and is for reference purposes only. The graphics displayed on your monitor may be slightly different.

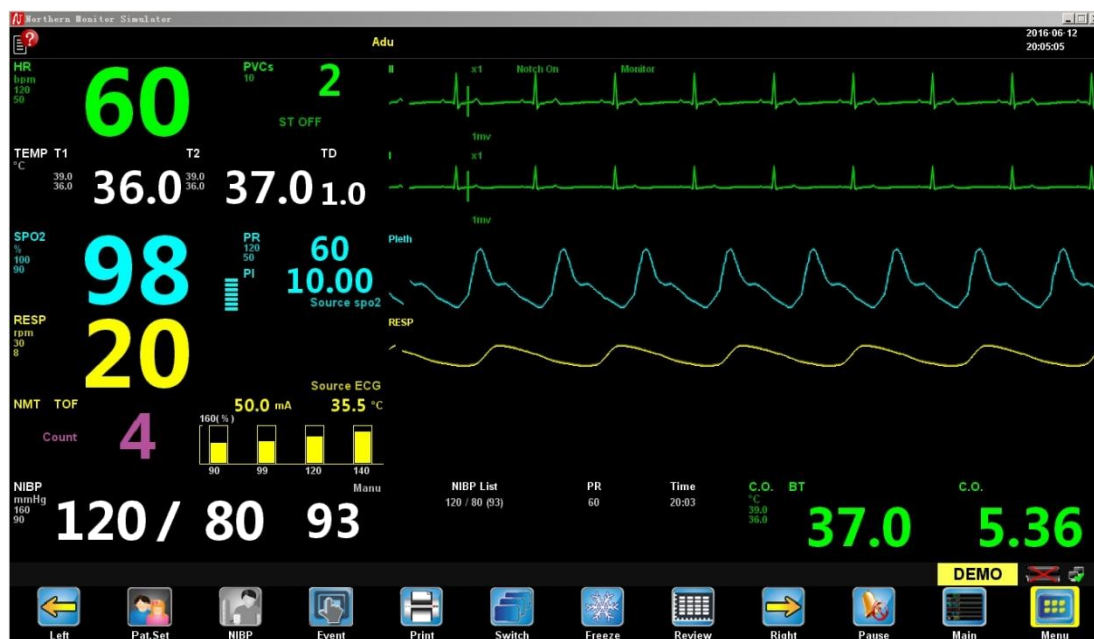


Fig. 19-2 NMT Parameter in Normal Screen

Chapter 20. Calculate

20.1 Overview

This monitor provides computing capabilities, the calculated values are not directly measured patient data, but the results from the monitor calculated according to the appropriate data you provide.

The following calculations can be performed on the monitor:

- Hemodynamic Calculation
- Dose Calculation
- Renal Function Calculation
- Oxygenation Calculation
- MEWS System

To calculate something, in the main menu, select [calculate], select a different calculation function to calculate.



Notes

- Calculation is independent of the other features of the monitor, the patient can not object computing monitor the guardianship. Calculating operation will not affect the care of patients who are



Warning

- Should be carefully calculated to verify the correctness of input parameters and results of suitability. The Company does not assume any responsibility for all the consequences of input and operational errors caused by

20.2 Dose Calculation

20.2.1 Calculating Step

1. in the menu, select [calculate] → [Dose Cal.].
2. Select the type [patient cat.] and [Drug Name]. In [Drug Name] drop-down list on the right, you can select the required drug name from the following 15 kinds of medicines. Among them, the name of the drug A, B, C, D, and E can be defined by the user.

Drug A, B, C, D, E

Aminophylline

Dobutamine

Dopamine

Epinephrine
 Heparin
 Isuprel
 Lidocaine
 Nipride
 Nitroglycerin
 Pitocin

3. After the completion of the previous operation, the system will automatically give a default value. These data cannot be calculated as a result, they must enter the known, the correct parameter values according to the doctor's instructions.

4. Enter the weight of the patient.

5. Enter the correct parameter values

6. Confirm the correctness of the calculation results

20.2.2 Unit of Measurement

Each drug fixed unit or unit series are calculated. In the same unit in the series, will hexadecimal parameter values with the input of the unit is automatically adjusted.

Units of various drugs as follows:

Drug A, B, C, aminophylline, dobutamine, dopamine, epinephrine, isoproterenol, lidocaine, nitroglycerin and sodium nitroprusside, using a series of units: g, mg, mcg.

Drug D, Heparin and oxytocin, the use of series unit: unit, KU, MU.

Drug E use Unit: mEq

When a custom of certain drugs, the operator should be the drug of choice in accordance with Series A, B, C, D, E.

20.2.3 Titration Table

After completion of the drug calculation, Drug calculation titration table] window, select ["] to open the titration table.

In the titration table, you can change:

[Reference]

[Interval]

[Dose type]

After you change the above options, the titration data in the table will change accordingly.

You can also:

Select  and  button to select and observe more data.

20.3 Oxygenation Calculation

20.3.1 Calculating Step

- 1, in the menu, select [calculate] → [Oxygenation Cal.].
 - 2, enter the correct values for each parameter.
 3. Select the [calculate] button, you can calculate the value of each output parameter.
- For beyond the reasonable range of output value, which is shown as a yellow background. Now all parameters will disappear behind the unit, parameter out of range, reasonable range will be displayed.
 - [---] indicates an invalid value

20.3.2 Input Parameter

Abbreviation	Unit	English full name
C.O.	L/min	Cardiac output
FiO ₂	%	Percentage fraction of inspired oxygen
PaO ₂	mmHg	Partial pressure of oxygen in the arteries
PaCO ₂	mmHg	Partial pressure of carbon dioxide in the arteries
SaO ₂	%	Arterial oxygen saturation
PvO ₂	mmHg	Partial pressure of oxygen in venous blood
SvO ₂	%	Venous oxygen saturation
Hb	g/L	Hemoglobin
CaO ₂	ml/L	Arterial oxygen content
CvO ₂	ml/L	Venous oxygen content
VO ₂	ml/min	Oxygen consumption
RQ		Respiratory quotient
ATMP	mmHg	Atmospheric pressure
Height	cm	Height
weight	Kg	weight

20.3.3 Output Parameter

Abbreviation	Unit	English full name
BSA	m ²	Body surface area
VO ₂ calc	ml/min	Oxygen consumption
C(a-v)O ₂	ml/L	Arteriovenous oxygen content difference
O ₂ ER	%	Oxygen extraction ratio
DO ₂	ml/min	Oxygen transport
PAO ₂	mmHg	Partial pressure of oxygen in the alveoli

AaDO ₂	mmHg	Alveolar-arterial oxygen difference
CcO ₂	ml/L	Capillary oxygen content
Qs/Qt	%	Venous admixture
C.O. calc	L/min	Calculated cardiac output

20.4 Ventilation Calculation

20.4.1 Calculating Step

- 1, in the menu, select [computing "] → [Ventilation Calculation].
 - 2, enter the correct values for each parameter.
 3. Select the [computing] button, you can calculate the value of each output parameter.
- For beyond the reasonable range of output value, which is shown as a yellow background. Now all parameters will disappear behind the unit, parameter out of range, reasonable range will be displayed.
 - [---] indicates an invalid value

20.4.2 Input Parameter

Abbreviation	Unit	English full name
FiO ₂	%	Percentage fraction of inspired oxygen
RR	Rpm	Respiration rate
PeCO ₂	mmHg	Partial pressure of mixed expiratory CO ₂
PaCO ₂	mmHg	Partial pressure of carbon dioxide in the arteries
PaO ₂	mmHg	Partial pressure of oxygen in the arteries
TV	ml	Tidal volume
RQ		Respiratory quotient
ATMP	mmHg	Atmospheric pressure

20.4.3 Output Parameter

Abbreviation	Unit	English full name
PAO ₂	mmHg	Partial pressure of oxygen in the alveoli
AaDO ₂	mmHg	Alveolar-arterial oxygen difference
Pa/FiO ₂	mmHg	Oxygenation ratio
a/AO ₂	%	Arterial to alveolar oxygen ratio
MV	L/min	Minute volume
V _d	ml	Volume of physiological dead space
V _d /V _t	%	physiological dead space in percent of tidal volume
VA	L/min	Alveolar volume

20.5 Hemodynamic Calculation

20.5.1 Calculating Step

1. In the menu, select [calculate] → [Hemodynamic Cal.].
 2. Enter the correct values for each parameter.
- If the patient is under guardianship is calculated, then HR, Art Mean, PA Mean CVP and the default value is the current real-time measurements; If you have just performed CO measurements, the default value CO is chosen more times the average CO measurements; height and weight from the patient information entered. When the monitor cannot be selected to provide these data, the display is blank, you need to manually enter.
 - If the patient is not on the guardianship of the calculation, you need to verify or modify all input values.
3. Select the [calculate] button, you can calculate the value of each output parameter.
- For beyond the reasonable range of output value, which is shown as a yellow background. Now all parameters will disappear behind the unit, parameter out of range, reasonable range will be displayed.
 - [---] indicates an invalid value

20.5.2 Input Parameter

Abbreviation	Unit	English full name
C.O.	L/min	Cardiac output
HR	bpm	Heart rate
PAWP	mmHg	Pulmonary artery wedge pressure
Art Mean	mmHg	artery mean pressure
PA Mean	mmHg	Pulmonary artery mean pressure
CVP	mmHg	Central venous pressure
EDA	ml	End-diastolic volume
Height	cm	Height
weight	Kg	weight

20.5.3 Output Parameter

Abbreviation	Unit	English full name
C.I.	L/min/m ²	Cardiac index
BSA	m ²	Body surface area
SV	ml	Stroke volume
SI	ml/m ²	Stroke index
SVR	DS/cm ⁵	Systemic vascular resistance
SVRI	DS/ m ² /cm ⁵	Systemic vascular resistance index

PVR	DS/cm ⁵	Pulmonary vascular resistance
PVRI	DS/ m ² /cm ⁵	Pulmonary vascular resistance index
LCW	Kg.m	Left Cardiac work
LCWI	Kg.m/m ²	Left Cardiac work index
LVSW	g.m	Left ventricular stroke work
LVSWI	g.m/ m ²	Left ventricular stroke work index
RCW	Kg.m	Right Cardiac work
RCWI	Kg.m/m ²	Right Cardiac work index
RVSW	g.m	Right ventricular stroke work
RVSWI	g.m/ m ²	Right ventricular stroke work index
EF	%	Ejection fraction

20.6 Renal Function Calculation

20.6.1 Calculating Step

- 1, in the menu, select [calculate] → [Renal Cal.].
 - 2, enter the correct values for each parameter.
 3. Select the [calculate] button, you can calculate the value of each output parameter.
- For beyond the reasonable range of output value, which is shown as a yellow background.
Now all parameters will disappear behind the unit, parameter out of range, reasonable range will be displayed.
 - [---] indicates an invalid value

20.6.2 Input Parameter

Abbreviation	Unit	English full name
URK	mmol/L	Urine potassium
URNa	mmol/L	Urinary sodium
Urine	ml/24h	Urine
Posm	mOsm/kgH ₂ O	Plasm osmolality
Uosm	mOsm/kgH ₂ O	Urine osmolality
SerNa	mmol/L	Serum sodium
Cr	μmol/L	creatinine
UCr	μmol/L	Urine creatinine
BUN	mmol/L	Blood urea nitrogen
Height	cm	Height
weight	Kg	weight

20.6.3 Output Parameter

Abbreviation	Unit	English full name
URNaEx	mmol/24h	Urine sodium excretion
URKEEx	mmol/24h	Urine potassium excretion
Na/K	%	Sodium potassium ratio
CNa	ml/24h	Clearance of sodium
Clcr	ml/min	Creatinine clearance rate
FENa	%	Fractional excretion of sodium
Cosm	ml/min	Osmolar clearance
CH ₂ O	ml/h	Free water clearance
U/P osm		Urine to plasma osmolality ratio
BUN/Cr		Blood urea nitrogen creatinine ratio
U/Cr		Urine-serum creatinine ratio

20.7 MEWS System

- Open the Mean of the **【calculate】**, select **【MEWS System】** button to bring up the **【MEWS System】** menu. Menu display as follows:

The screenshot shows a software window titled "MEWS System". Inside, there are several input fields and buttons. The fields are labeled PR, RESP, NIBP(mmHg), Temp(° C), and Consciousness. The values entered are 60, 20, 120 / 80, 36.0, and Wide awake respectively. Below these fields is a large button labeled "Start Score". At the bottom of the window, there is a label "MEWS" and two more buttons: "Clear Data" and "Warning Process>>".

Fig. 20-1 MEWS System menu

- Select **【Clear Data】** : Clear the entry of parameter values.
- Select **【Warning process】** :Open the view of the Warning process, Warning process default menu as shown below:

Warning Process		
0~0	continue routine MEWS monitoring with every set of observations.	
1~3	Frequency of monitoring, minimum 4 hourly.	
4~6	Registered nurse to urgently inform the medical team caring for the patient within 30 minutes; Urgent assessment by a clinician with core competencies to assess acutely ill patients.	
7~14	Registered nurse to immediately inform the medical team caring for the patient, and this should be at least at Specialist Registrar level; Consider transfer of Clinical care to a level 2 or 3 care facility, i.e. higher dependency or ITU.	
3 in one parameter	Registered nurse to urgently inform the medical team caring for the patient; Increased frequency to a minimum of 1 hourly	

Fig. 20-2 Warning Score process

- Enter the appropriate HR, RESP, NIBP, TEMP measured values and states of consciousness. State of consciousness for the drop-down box, including four: wide awake, respond to voice, respond to pain, no response.
- Select **【start score】** : System start score automatically.

The image shows a software interface titled "MEWS System" with a close button (X) in the top right corner. The interface displays several input fields for patient data, each followed by a circular indicator showing a score. The data and scores are as follows:

Parameter	Value	Score
PR	60	0
RESP	20	1
NIBP(mmHg)	100 / 60	1
Temp(° C)	36.8	0
Consciousness	Wide awake	0

Below the input fields is a "Start Score" button. Underneath this, the word "MEWS" is displayed next to a large blue circle containing the number "2". To the right of the "MEWS" label are two buttons: "Clear Data" and "Warning Process>>".

Fig 20-3 MEWS result

Chapter 21. Spot Check

21.1 Outline

This monitor provides spot metering function, you can measure the patient's heart rate, blood pressure, pulse rate, body temperature, oxygen, MEWS score, spot check data can be transmitted in a timely manner to the CMS.

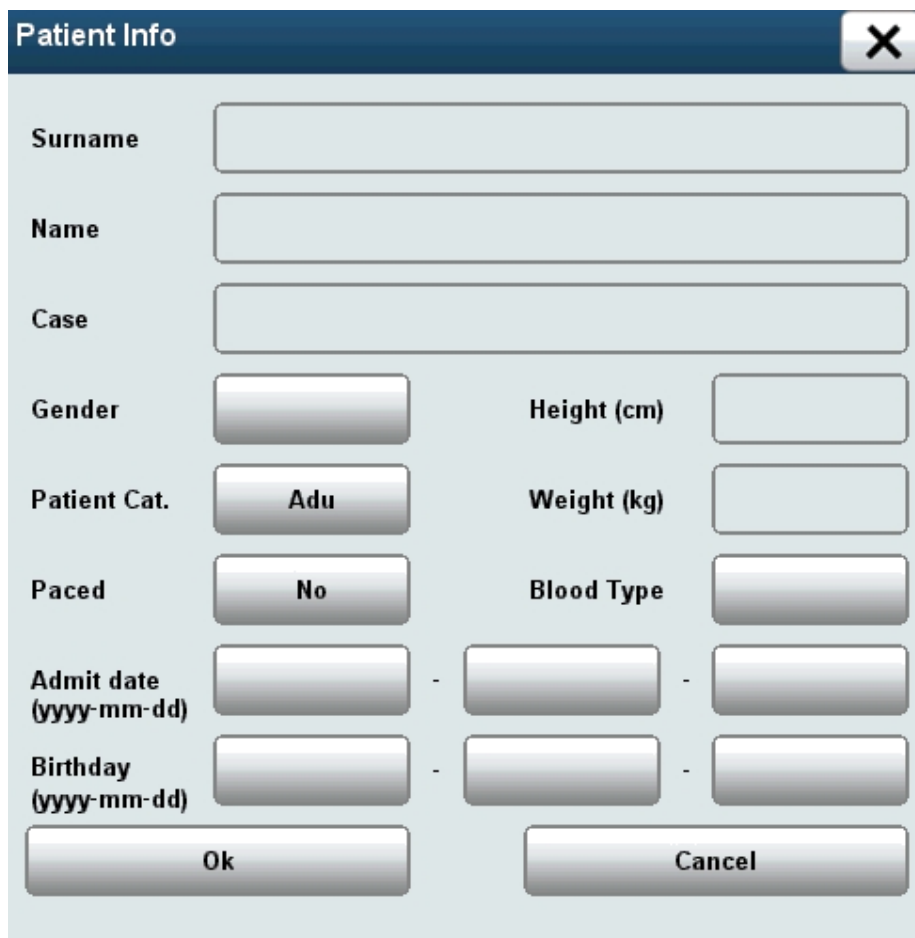
21.2 Set Point Measurement

The monitor can be set to continuous measurement and spot check measurement modes.

The monitor is set to the path spot check mode, **【Factory Maintenance】** → **【spot check】** → **【on】**, then it will open the spot check switch. **【mean】** → **【monitor type>>】** will monitor type is set to spot check, click **【OK】**, the success of the monitor is set to spot check mode.

21.3 Use the Spot Check

Spot check mode is set up, will appear in the hotkey area measured point , click the button to bring up the **【patient info】** menu, as shown below:



The screenshot shows a 'Patient Info' dialog box with a close button (X) in the top right corner. The form contains the following fields and buttons:

- Surname**: Text input field.
- Name**: Text input field.
- Case**: Text input field.
- Gender**: Button with 'Adu' selected.
- Height (cm)**: Text input field.
- Patient Cat.**: Button with 'Adu' selected.
- Weight (kg)**: Text input field.
- Paced**: Button with 'No' selected.
- Blood Type**: Text input field.
- Admit date (yyyy-mm-dd)**: Three text input fields separated by hyphens.
- Birthday (yyyy-mm-dd)**: Three text input fields separated by hyphens.
- Ok**: Button at the bottom left.
- Cancel**: Button at the bottom right.

Fig. 21-1 Patient Info Menu

【Surname】 : The patient's name

【Name】 : The patient's name

【Case】 : Patient Case number cannot be empty, otherwise it will not be able to send data.

【Gender】 : Male, female, other

【Patient Cat.】 : Adu, ped and neo

【Paced】 : Yes, No

【Height】 : The patient's height

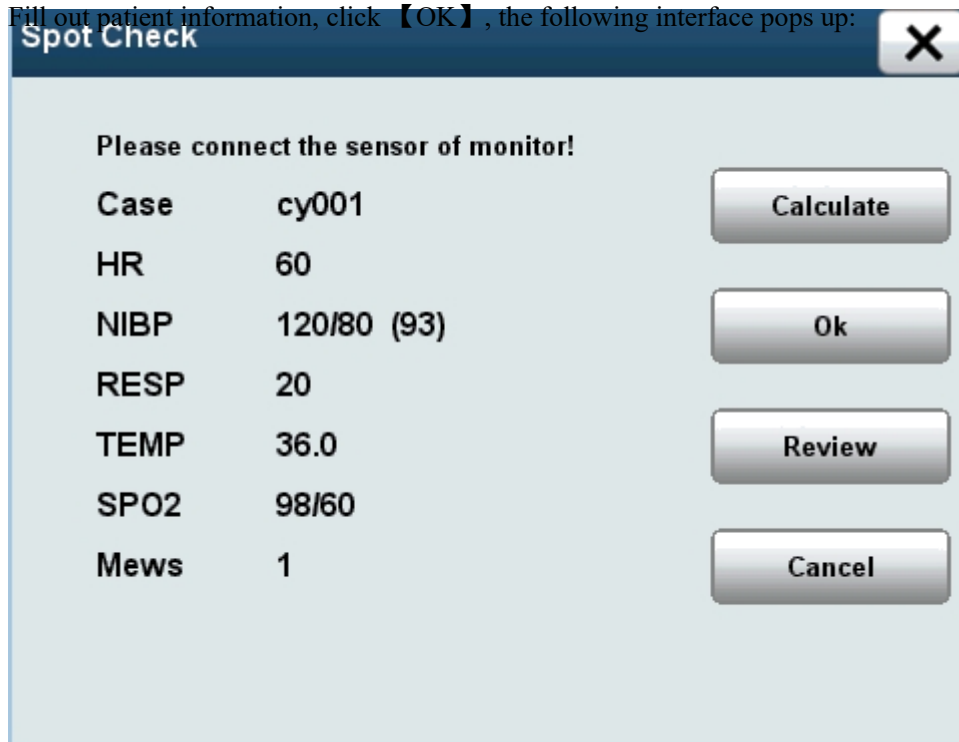
【Weight】 : Patient weight

【Blood Type】 : A, B, AB, O

【Admit date】 : Patient admission date

【Birthday】 : Patient Date of Birth

Fill out patient information, click 【OK】, the following interface pops up:



The image shows a 'Spot Check' dialog box with a title bar containing a close button (X). The main content area has a light blue background and contains the following text and controls:

Please connect the sensor of monitor!

Case	cy001	Calculate
HR	60	
NIBP	120/80 (93)	Ok
RESP	20	
TEMP	36.0	Review
SPO2	98/60	
Mews	1	Cancel

Fig. 21-2 Spot Check Results

【Calculate】 : Calculate MEWS score

【OK】 : Sending data to CMS

【Review】 : Review patient information and measurement spot check View

【Cancel】 : Cancel the spot check data

The review of spot check window as shown below:

Spotcheck Review

☐ Succeed

☐ Succeed

☐ Timeout

Time	Case	Name	HR	NIBP	RR	SPO2	TEMP	Mews
(25)14:54	cy003		60	120/80(93)	20	98/60	36.0	1
(25)14:53	cy002		60	120/80(93)	20	98/60	36.0	---
(25)14:53	cy001		60	120/80(93)	20	98/60	36.0	1

Page: 1/1
Unsent: 1

Select all

Delete

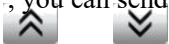
Send

Fig. 21-3 Spot Check Review

Select 【Select all】 , you can select all data in the current page.

Select 【Delete】 , you can delete the selected data.

Select 【Send】 , you can send data to the central station timeout.



You can select and button, up or down to view the spot check review table.

Chapter 22. PWTT (Optional)

22.1 Overview

PWTT (Pulse Wave Transit Time) triggered NIBP measurement increases the chance to detect a sudden change in blood pressure. PWTT can be calculated from ECG and SpO2 non-invasively. If PWTT exceeds a threshold during periodic NIBP measurement, it triggers NIBP measurement.

22.2 Applications

- PWTT threshold can be set according to the patient situation and hospital area. Higher sensitivity detects smaller changes and triggers more frequent NIBP measurements. Lower sensitivity detects only larger changes and triggers less frequent NIBP measurements.
- In the OR, use smaller threshold to trigger more frequent NIBP measurement. In the ICU, CCU or ward, excessive NIBP measurements are a burden on the patient so PWTT threshold can be increased.

22.3 PWTT Setup

1. Select NIBP parameter area → **【NIBP Setup】** menu → **【PWTT Setup>>】**.
2. Select **【On】** or **【Off】** to switch on/off PWTT function.
3. Adjust **【Threshold(ms)】**

The default setting is off, any change of the setting will not be saved.



Fig. 22-1 PWTT Setup Menu

 CAUTION

- Do not measure NIBP with PWTT on a neonate because circulatory kinetics of a neonate change rapidly.
- In the following cases, PWTT triggered NIBP measurement may trigger too often or fail to trigger.
 - ◆ Rapid blood pressure change due to vasoactive drugs, such as phenylephrine and nicardipine.
 - ◆ Unstable pulse wave due to poor peripheral circulation.
 - ◆ Too many arrhythmias.
 - ◆ Patient movement or change of body position.
 - ◆ Noise on ECG due to ESU.
 - ◆ SpO₂ measurement on foot of pediatric.
- Do not decrease the frequency of periodic NIBP measurement when using PWTT. Set the frequency of periodic NIBP measurement to the normal setting you would use if you were not using PWTT.

Chapter 23. Recording (Optional)

23.1 Recorder Profile

The monitor hosts the thermal recorder, supports many recording Types, records patient information, trend graph/table data, up to three waveforms, etc.

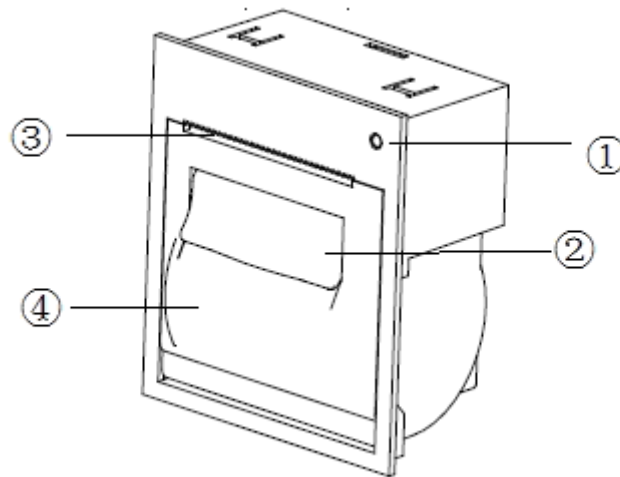


Fig. 23-1 Recorder

1. Indicator
 - ◆ On: when the recorder works correctly.
 - ◆ Off: when the monitor is switched off.
 - ◆ Flashes: if an error occurred to the recorder, e.g., the recorder runs out of paper, jams, over heat, etc.
2. Wrench: Gently pull out the wrench, the printer will automatically open the doors
3. Paper outlet
4. Recorder door

The task-related recordings include:

- ◆ Real time recording
- ◆ 7-Lead waveforms recording
- ◆ Alarm trigger recording
- ◆ Frozen wave recording
- ◆ Graphic trends recording
- ◆ Tabular trends recording
- ◆ NIBP review recording
- ◆ Event review recording

23.2 Loading Paper

1. Pull out the wrench of the recorder, open the door.
2. Insert a new roll into the compartment with the recording side upward, make sure the paper end in the outside of paper outlet port.
3. Close the door of the recorder.
4. Check the position of the paper, make sure the paper aligned to the Recorder outlet.

CAUTION

- Use only specified thermal paper. Otherwise, it may cause damage to the recorder's printer head, the recorder may be unable to print, or poor print quality may result.
- Never pull the recorder paper with force when a recording is in process, otherwise, it may cause damage to the recorder.
- Do not leave the recorder door open unless you reload paper or remove troubles.
- If the recorder works incorrectly or produces unusual sounds, check if there is a paper jam first. If a paper jam is detected, open the recorder door, take out the paper and tear off the draped part, reload the paper and close the recorder door.

23.3 Setting up the Recorder

By selecting [Main Menu] → [Record Setup >>], you can access the [Record Setup] menu. As the following figure:

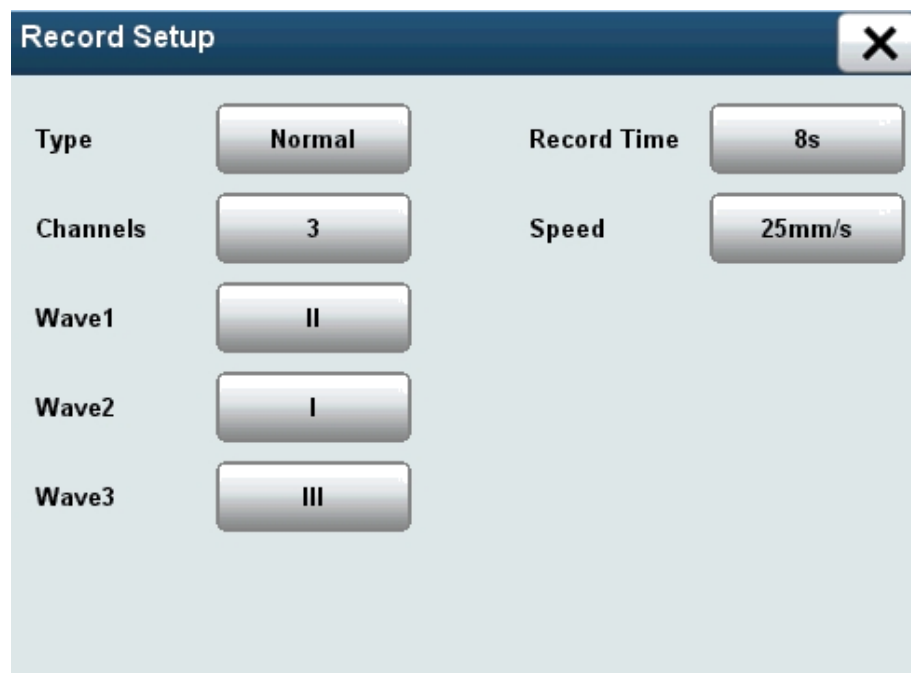


Fig. 23-2 Recorder setup

1. [Types]: normal type, 7-lead type can be setup.
 - ◆ Normal type **【conventional】** : The waveforms that you need to record can be setup in wave options.
 - ◆ 7-lead type **【7lead】** : Press record key, then 7-lead ECG can be record.
2. **【Trace】** : The trace of waveforms can be set up, 3 traces or 2 traces. The wave type can be chosen from wave option.
3. **【Recording time】** : when start one real time record or alarm trigger, the record time is depend on your setting on the monitor.in the menu **【Record Setup】**→[Record time >>] can be set:
 - ◆ 8s/16s/32s: record 8-second waveforms from the current moment.
 - ◆ **【Continuous】** : record the waveforms from the current moment until stopped manually.
 - ◆ **【Recording Speed】**: In the [Record Speed] menu, select [Paper Speed] and toggle between [12.5 mm/s], [25 mm/s] and [50mm/s]. This setting is for all recordings containing waveforms.

23.4 Clearing Recorder

If the recorder has been used for a long time, deposits of paper debris may collect on the printhead compromising the print quality and shortening the lifetime of the roller. Follow this procedure to clean the printhead:

1. Take measures against the static electricity such as Disposable Wrist Strap for the work, Prevent electrostatic damage to the Recorder.
2. Open the recorder door and take out the paper, so as not to impede clean.
3. Gently wipe around the printhead using cotton swabs dampened with alcohol.
4. After the alcohol has completely been dried, reload the paper and close the recorder door.



CAUTION

- Do not use anything that may destroy the thermal element, for example sandpaper.
- Do not add unnecessary force to the thermal head.

Chapter 24. Battery

24.1 Checking Battery Performance

Please refer to the following steps to check the battery performance:

1. Disconnect the monitor from the patient and stop all monitoring or measurement.
2. Connect AC power to the monitor and charge the battery for 10 hours uninterruptedly.
3. Disconnect the AC power and power the monitor with battery until the monitor is turned off.
4. Battery duration reflects the battery performance.

If the battery operating time is significantly shorter than the time stated in specifications, consider replacing the battery or contact our service personnel.

24.2 Overview

The monitor has a built-in rechargeable battery to ensure that the monitor can also be used normally in case of patient transfer or power failure. When the monitor is connected to an AC power source, it will charge the battery no matter whether the monitor is turned on or not. In the case of power failure, the system will automatically use the battery to power the monitor to avoid interrupting the monitor working.

The battery icon on the screen indicates the battery status:



Battery is working properly and is fully charged.



Battery is working properly and the green part indicates the battery power.



Battery power is low, and requires charging immediately, or else the monitor will turn off automatically.



Monitor battery is not installed.



Battery is properly installed and being charged.

The battery power can only maintain for some time. Low battery voltage will trigger a high level technical alarm [Battery Low]; in this case, connect the monitor to AC power and charge the battery.

24.3 Installing the battery

Before replacing the battery, please connect the monitor to an AC power supply or turn it off, to avoid monitoring being interrupted.

To install or replace the battery:

- Open the battery cover.
- Push aside the side battery stopper of the battery to be replaced and take out the battery.
- Keep the front side of the new battery (with printed text) downwards, interface toward the inside, insert it into the battery compartment, push back the battery stopper, and hold down the battery.
- Put on the battery cover.

24.4 Battery Usage Guide

Battery life depends on the frequency and time of use. If the battery maintenance and storage are proper, the lithium battery life is about three years. If you do not use the battery properly, its life may be shortened. It is recommended to replace the lithium battery once every three years.

In order to ensure the maximum capacity of the battery, please note the following usage guide:

- Before using the battery, please read the Operator's Manual and labels on the battery surface carefully.
- Do not drop the battery, and do not charge the battery in the charger for more than 24h.
- Before transporting the monitor or if the monitor won't be used over three months, please take out the battery.
- If it won't be used for a long time, please store the battery properly. Charge the battery to 50%, and wrap the battery with non-conductive material in order to avoid direct contact with metal, resulting in damage. Keep the battery in a cool dry place.
- Check the battery performance once every two years. Before servicing the monitor or you suspect that the battery is the fault source, also check the battery performance.



Warning

- Keep the battery out of the reach of children.
- Use only the designated battery.
- If the battery is damaged or leaks, replace it immediately. Do not use a defective battery for the monitor.

24.5 Battery Recycling

If the battery has visible damage or cannot store power, it should be replaced and recycled properly. Follow the appropriate regulations to dispose of used batteries.



Warning

- Do not disassemble the battery, throw it in fire, or short-circuit it. Battery fire, explosion and leakage may lead to personal injury; do not directly touch the leaking battery.

Chapter 25. Caring and Cleaning

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

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's infection control officer or epidemiologist.

25.1 Overview

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- ✧ Do not immerse part of the equipment into liquid.
- ✧ Do not pour liquid onto the equipment or accessories.
- ✧ Do not allow liquid to enter the case.
- ✧ Always dilute according to the manufacturer's instructions or use lowest possible concentration.
- ✧ Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).



Warning

Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.



Caution

To clean or disinfect reusable accessories, refer to the instructions delivered with the accessories.

If you spill liquid on the equipment or accessories, contact us or your service personnel.

25.2 Cleaning

The device should be cleaned regularly. In the heavily polluted environment, increase the frequency of cleaning. Before cleaning, please consult the hospital about device cleaning requirements.

Below are available cleaning agents:

- Mile soap (diluted)
- Ammonia (diluted)
- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

1. Turn off the monitor, disconnect the power cord and remove the battery.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry the device naturally in a ventilated cool environment.

25.3 Disinfection

In order to avoid damage to the product, we recommend that the product is disinfected only when it is deemed necessary by the hospital maintenance procedures. We also recommend that the instrument to be disinfected must first be cleaned.

Disinfection may cause damage to the equipment and is therefore not recommended for this patient monitor unless otherwise indicated in your hospital's servicing schedule. Cleaning equipment before disinfecting is recommended.

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde type 2% liquid disinfectant.



Caution

- Never use EtO or formaldehyde for disinfection.

Chapter 26. Residual Risks

CETUS x12 / x15 Multi-Parameter Patient Monitor is a kind of monitoring instrument, which monitors patients, and measures such as ECG, non-invasive blood pressure, oxygen saturation, body temperature, respiration and pulse rate. According to the requirements and regulations of ISO 14971:2016, the risk of this product is analyzed, and the predicted analysis results are risk-free.

The following residual risks for patients, users and third parties have been identified within the risk management process:

- Safety risks due to inadequate service and maintenance tasks and intervals.
- Safety risks due to inadequate transport processes and materials.
- Safety risks by using the device by unqualified staff and misunderstanding the product and documentation.
- Safety risks by electric shock while using the patient monitor being electrically connected to patients, users and third parties (e.g. ECG).

Please be aware of these risks by using the patient monitor. In order to minimize these risks, the operator has to take care of checking the device before using and in intervals according manufacturer requirements. Also, that the materials and tools for transport and installation are suitable and approved by the manufacturer.

The staff using this product and make decisions related to patient's health need to be qualified and has to understand the product in function and features.

Risks by electric shock can be minimized by using tested and approved accessories and regular electrical safety testing by authorized staff after installation, before using and during lifetime of the product.

Chapter 27. Maintenance



Warning

- If the hospitals or institutions using this instrument can't implement a satisfactory maintenance schedule, it will result in device failure and may endanger human health.

27.1 Checking

Check the following basic items before using the monitor:

- Check for any mechanical damage;
- Check all exposed wires, insertions and accessories;
- Check all instrument functions that may be used for patient monitoring and ensure that the instrument is in good working condition.

If the instrument function has any sign of damage, do not use this monitor for any patient monitoring. Please contact the hospital's professional maintenance personnel or our customer service personnel.

Every 6-12 months or after each repair, a comprehensive examination must be performed by trained and qualified technical service personnel, including functional safety checks; the specific inspection items are as follows:

- Environment and power meet the requirements.
- Device and accessories have no mechanical damage.
- The power supply has no wear, and the insulation is good.
- Specified accessories are used.
- Alarm system is functioning correctly.
- Battery performance meets the requirements.
- Monitoring functions are in good working condition.
- Ground impedance and leakage current meet the requirements.

If the instrument function has any sign of damage, do not use this monitor for any patient monitoring. Please contact the hospital's professional maintenance personnel or our customer service personnel.

All checks that require disassembling the instrument must be performed by qualified service personnel. Safety and maintenance checks may also be carried out by the Company's personnel.

27.2 Viewing Software Version Info

You can view the software version through the following steps:

- Select  [Menu] Smart Hotkey→[Main Menu];
- Select [Monitor Information >>] → [Monitor Info] menu;
- [Monitor Info] menu displays the software version information of the monitor.

The software version of the monitor: V1.1.7

27.3 Maintenance Plan

The following tasks can only be done by qualified service personnel of aXcent. When the following maintenance is needed, please contact your service representative. Before testing or maintenance, clean and disinfect the device.

Inspection / Maintenance Item	Frequency
Check the safety according to IEC 60601-1	At least once every two years, after replacing the power supply or the monitor falls down.
Check all monitoring or measuring functions not listed	At least once every two years, or when you suspect that the measured value is not accurate.
NIBP leakage test	At least once every two years, or follow hospital regulations
NIBP calibration	At least once every two years, or follow hospital regulations

27.4 ECG Calibration

In the process of using the monitor, the displayed ECG signals may be inaccurate due to hardware or software problems, mainly shown as waveform amplitude becoming larger or smaller. At this moment, you need to calibrate ECG.

Prepare the following instruments before testing:

- ECG simulator
- ECG cable
- Vernier caliper

The calibration method is as follows:

- Connect the ECG cable to the monitor.
- Connect the ECG electrodes to the ECG simulator.
- Select  [Menu] Smart Hotkey→[Main Menu];
- Select [User Maintenance >>] → [User Maintenance] menu;
- Select [Module Maintenance >>] → [Module Maintenance] menu;
- Select [ECG >>] → [ECG Maintenance] menu, and select [Calibration] to calibrate the ECG;
- Measure the wave amplitude with a caliper; in different filtering modes, X0.25 is $2.5 \pm 5\%$ (mm), X0.5 is $5.0 \pm 5\%$ (mm), X1 is $10.0 \pm 5\%$ (mm), and X2 is $20.0 \pm 5\%$ (mm). Comparing the amplitude of the square wave with the ruler, the error range should be within 5%;
- When calibration is complete, select [Stop Calibration] to exit.

27.5 Touch Screen Calibration

You can follow the steps below to complete the calibration of the touch screen:

- Select  [Menu] Smart Hotkey→[Main Menu];
- Select [User Maintenance >>]→ [User Maintenance] menu;
- Select [Cal. Touchscreen] to enter the touch screen calibration interface.
- Click on the screen and the alignment mark appears in different positions.
- If the touch screen calibration is finished after clicking three times, select [Ok] to exit the calibration interface; if the touch screen isn't completely calibrated, select [Retry] for re-calibration.

27.6 CO2 Calibration

Sidestream ISA module does not required regular calibration, and users can calibrate the Sidestream module every 1 year if needed or when the measured deviation get too large.

Gas requirements in calibration:

Maintenance master software.

CO2 concentration: 4%-11%

Oxygen concentration: 45%-100%

All the gas must meet the precision: ± 0.03 vol% or $\pm(0.02 \text{ vol\%} + \text{reading's } 0.1\%)$, and pick

the higher value.

Steps of calibration go as follows:

1. Connecting the new Nomoline sampling tube to ISA gas analyzer.
2. Warm up for at least 1 minute.
3. Press "Pre span calibration zeroing" to ensure that the air surrounding gas is normal (21%O₂ and 0% CO₂).
5. Open **【Main Menu】** -> **【User Maintenance】** -> **【Module Maintenance】** -> **【CO2 Maintenance】**, set the value in the **【CO2 Calibration】** to the same value with the input gas concentration.
6. when the measured CO₂ concentration gets stable, lick the **【CO2 Maintenance】** - **【CO2 Calibration】** button.
7. Check the CO₂ parameter area to see if the gas reading is consistent with the measured CO₂ concentration after the gas scale calibration is completed.

27.7 AG Calibration

Sidestream ISA AG module does not required regular calibration, and users can calibrate the ISA AG Sidestream module every 1 year if needed or when the measured deviation get too large. IRMA mainstream module does not require calibration.

Gas requirements in calibration:

Maintenance master software

CO2 concentration: 4%- 11%

Oxygen concentration: 45%-100%

Nitrous Oxide: 30%-100%

AA: TBD

All the gas must meet the precision: ± 0.03 vol% or $\pm(0.02 \text{ vol\%} + \text{reading's } 0.1\%)$,

and

pick the higher value

Steps of calibration go as follows:

1. Connecting the new Nomoline sampling tube to ISA gas analyzer.
2. Warm up for at least 1 minute.
3. Press “Pre span calibration zeroing” to ensure that the air surrounding gas is normal (21%O₂ and 0% CO₂).
4. Supplying the calibration gas and wait at least 30 seconds
5. open **【Main Menu】** -> **【User Maintenance】** -> **【Module Maintenance】** -> **【AG Maintenance】**, set the value in **【CO₂ Calibration】**, **【O₂ Calibration】**, **【N₂O Calibration】** and **【AA Calibration】** same with the input gas concentration ; it is no need to set other items when using one type of gas.
6. when the concentration of measured gas gets table, press **【AG Maintenance】** - **【CO₂ Calibration】** , **【O₂ Calibration】** , **【N₂O Calibration】** , **【AA Calibration】**
7. Check the parameter areas to see if the gas reading is consistent with the measured CO₂ concentration after the gas scale calibration is completed.

Chapter 28. Accessories



Warning

- Use the accessories specified in the Operator's Manual; using other accessories may damage the monitor, or cannot reach the performance claimed in this Manual.
- The operating and storage environment of the monitor should meet the requirements of the accessories. Please refer to the manual of the accessories for these requirements.
- Disposable accessories can only be used once, because repeated use can cause performance degradation.
- If the packaging or accessories have any sign of damage, do not use such accessories.

28.1 Standard Accessory List

Standard accessories are as follows:

No.	Code	Name	Specifications & characteristics	Standard quantity
1	203-002	5-lead ECG cable	Adult 5-lead all-in-one clip	1
2	203-010	Electrode slice	50mm×55mm, adult, disposable	1
3	207-007	SPO2 probe	Adult finger clip	1
4	204-003	Blood pressure cuff	Adult repetitive single-tube cuff	1
	204-007	Blood pressure gas nozzle	Metal	1
		Blood pressure extension tube	3M grey	1
5	209-003	10K-type temperature probe	Adult body surface	1
6	201-006	Lithium battery	4800mAh	1
7	210-002	Ground wire	V0020A	1

No.	Code	Name	Specifications & characteristics	Standard quantity
8	004-001	Power cord	3×0.75mm ² 10A 250V L=1.5/2/3/5M (Selectable type)	1

28.2 ECG

12-pin integrated 5-lead left/right clamp ECG cable

Supported lead wires	Symbol standard	Type	Applicable objects	Length (main cable)	Length (5-lead ECG cable)	Code
3/5 lead	IEC	Defibrillation type	Adult	2.7m	0.9m	203-002

28.3 SpO₂

SpO₂ Sensor

Applicable objects	Applicable parts	Type	Length	Code
Adult	Fingers, toes	Reusable	3m	207-007

Masimo SpO₂ Sensor

Type	Model / PN	Patient category
Reusable	M-LNCS DCI	Adult finger
	M-LNCS DCIP	Pediatric finger
	M-LNCS YI	Neonatal
Disposable	M-LNCS Neo	Neonatal foot
	M-LNCS Inf	Infant toe

Masimo SpO₂ Extension cable

Accessories	Model / PN
Masimo SpO ₂ Patient cable: 10ft	M-LNC-10

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28.4 NIBP

1. Blood pressure cuff

Applicable objects	Applicable parts	Type	Remark	Code
Adult	Arm or thigh	Reusable	Single-tube	204-003

2. Blood pressure gas nozzle and Blood pressure extension tube

Operating temperature	Applicable parts	Mechanical life (connecting and disconnecting)	Remark	Code
-30°C~+60°C	Blood pressure cuff	> 1000 times	Pull-off force of gas connector and extension tube is greater than 5kg	204-007
Adult, child	Reusable	3m	Used together with cuff	

28.5 Temp

10K-type temperature probe

Applicable objects	Applicable parts	Type	Length	Code
Adult	Body surface	Reusable	3m	209-003

Appendix A Specifications

A.1 Safety Specifications

A.1.1 Product Category

In accordance with classification specified in the European Medical Device Directive 93/42/EEC, this monitor is IIb type equipment. The monitor is classified as follows in accordance with IEC 60601-1:

Category Name	Specification
93/42/EEC Medical Devices Directive Category	IIb
Type of electric shock protection	Grade I, internal and external power supply equipment When you question the integrity of the external protective earthing or protective ground conductor parameter of the equipment, the device must be powered by the internal power supply (battery).
Electric shock protection grade	ECG/NIBP/SpO2/PR/TEMP/RESP: CF (defibrillation protection)
Explosion protection grade	Common equipment, no explosion protection
Liquid inlet protection grade	IPX1 (prevent water from entering when the water drips vertically)
Operating mode	Continuous
Movement	Portable
Shelf Life	The lifetime of the product is defined with 5 years

A.1.2 Power Specifications

Parameter	Specification
External AC power	
Input voltage	100-240V~
Input current	1.0-0.5A
Frequency	50/60Hz
Fuse	T1.6A 250V

Internal power supply: Lithium-ion battery	
Rated battery voltage	d.c. 11.1V
Battery capacity	4800mAh, 2600mAh
Maximum supply time	About 4~5 hours(4800mAh), 2~3 hours(2600mAh)
Charging time	About 5~6 hours in power on state
Minimum supply voltage	10.5V

A.2 Hardware Specifications

A.2.1 Physical Specifications

Dimensions	12.1 inch	310×292×174mm (W×H×D)
	15.6 inch	398×302×183mm(W×H×D)
Weight	< 5.5 kg in standard configuration	

A.2.2 Display

Host Monitor	
Type	Color TFT LCD
Size	Resolution
12.1 inch	800×600 pixels (1024×768 optional)
15.6 inch	1366×768 pixels

A.2.3 Host LED

Alarm indicator	1 (yellow / red)
AC power indicator	1 (white)
Battery status indicator	1 (white)

A.2.4 Audio Instruction

Speaker	Alarm sound (45 ~ 85dB), key-pressing sound, QRS sound, PR sound. Alarm sounds meet IEC 60601-1-8 standard.
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A.2.5 Recorder

Category	Thermal spot
Printing width	48mm
Resolution ratio	Flat direction in curve mode 32dot/mm Vertical direction 8dot/mm Flat direction in image mode 8dot/mm
Length of recorder paper	20m
Recording speed	12.5mm/s, 25mm/, 50mm/s
Recording wave	2 waves or 3waves

A.2.6 Alarm Signal

Alarm delay	Off or 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s; depending on the configuration; the default is 4s.
Pause duration	1min, 2min, 3min, 4min, 5min, 10min, 15min or infinite; depending on the configuration; the default is 2min.

A.3 Data Storage

Trend data	Long trend: 120h, minimum resolution: 1min
	Short trend: 1h, minimum resolution: 1s
Parameter alarm event	More than 200 parameter alarm events
NIBP measurement results	More than 1000 groups
Full disclosure waveform	48 Hours for each patient

A.4 Measurement Specifications

A.4.1 ECG/TEMP/RESP Specifications

ECG Specifications		
Standards compliant	EN 60601-2-27/IEC 60601-2-27, GB 9706.25, IEC60601-2-25	
Lead type	3-lead	I, II, III
	5-lead	I, II, III, aVR, aVL, aVF, V
	12-lead	I, II, III, aVR, aVL, aVF, V1-V6
Display sensitivity	2.5mm/mV ($\times 0.25$), 5mm/mV ($\times 0.5$), 10mm/mV ($\times 1.0$), 20mm/mV ($\times 2.0$)	
Wave sweep speed	3.125mm/s, 6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	
Bandwidth	Diagnostic mode	0.05Hz~100Hz
	Monitor mode	0.5Hz~40Hz
	Surgery mode	1Hz~20Hz
	Strong filter mode	5Hz~20Hz
CMRR	>100dB	
Notch	50/60Hz notch filter can be set to on or off	
Differential input impedance	>5M Ω	
Electrode polarization voltage range	± 400 mV	
Baseline recovery time	<3s after defibrillation (in monitor and surgery mode)	
Calibration signal	1mV (peak - peak), accuracy $\pm 3\%$	

Pacing pulse		
Pulse identification	For PACE pulses that meet the criteria below, PAEC will be marked on the screen: Detection range: ± 4 mv ~ ± 700 mv Pulse width: 0.2ms ~ 2.0ms	
Average HR	Calculate from 15s data	
Interval of HR refreshing	Calculate once every second	
HR change response time	Time from 80bpm to 120bpm: ≤ 10 sec Time from 80bpm to 40bpm: ≤ 10 sec	
Tall T-wave suppression	For T-wave with 100ms QRS wave, 350ms QT period, 180ms duration and 1.2mV amplitude, the HR calculation won't be affected	
Alarm specifications	Range (bpm)	Step (bpm)
HR upper limit	Adult: 16~300	1
	Pediatric: 16~350	
HR lower limit	Adult: 15~299	

	Pediatric: 15~349	
HR		
Measuring range	3/5-lead monitoring	Adult: 15bpm~300bpm Pediatric: 15bpm~350bpm
Resolution	1bpm	
Heart rate measurement error	±1bpm or ±1%, whichever is greater	

TEMP		
Standards compliant	EN12470-4, ISO 80601-2-56	
Measurement method	Thermistor	
Measuring range	5~50°C (41~122°F)	
Resolution	0.1°C	
Measurement accuracy	±0.2°C	
Number of channels	Two	
Quick Temp (Optional)		
Type	Infrared Ear Thermometer	
Measurement method	Tympanic	
Displayed range:	34~42.2°C (93.2~108 F°)	
Operation ambient temperature range:	10~40°C (50~104°F)	
Accuracy for displayed temperature range:	≥35°C (95.9°F) ~≤42.2°C (107.6°F) range ±0.2°C (0.4°F)	
	<35°C (95.9°F) ~≥34°C (93.2°F) range ±0.3°C (0.5°F)	
Alarm specifications	Range	Step
T1/T2 upper limit	0.1°C~50.0°C	0.1°C 0.1°F
T1/T2 lower limit	0°C~49.9°C	
TD upper limit	0~50°C	

RESP	
Measurement method	Thoracic electrical bioimpedance method
Measuring lead	Lead I, II
Wave gain	×0.25, ×0.5, ×1, ×2
Respiratory impedance range	0.5-5Ω
Measurement range	0~150±1 rpm
Resolution	1 rpm
Baseline impedance	500-4000Ω
Gain	10 grades
Scan speed	3.125mm/s, 6.25mm/s, 12.5 mm/s, 25mm/s

A.4.2 NIBP Specifications

Standards compliant	EN 60601-2-30/IEC 60601-2-30, EN 1060-1, EN 1060-3, EN1060-4 EN/IEC 60601-1.			
Measurement method	Automatic oscillometric method			
Operating mode	Manual, automatic, continuous			
Useful life	100, 000 times			
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min			
Typical measurement time	20~40s			
Normal mode measuring range (mmHg)		Adult	Pediatric	Neonatal
	Systolic blood pressure	40-270	40-200	40-135
	Mean blood pressure	20-230	20-165	20-120
	Diastolic blood pressure	10-210	10-150	10-100
Measurement accuracy	Maximum average error: ±5mmHg Maximum standard deviation: 8mmHg			
Resolution	1mmHg			
Initial inflation pressure		Default	Pressure setting range	
	Adult	150mmHg	80~240mmHg	
	Pediatric	100mmHg	80~200mmHg	
	Neonatal	100mmHg	60~120mmHg	
Overpressure protection point (software)	Adult: 300mmHg Pediatric: 240mmHg Neonatal: 150mmHg			
Overpressure protection point (hardware)	Adult: 320~330mmHg Pediatric: 265~275mmHg Neonatal: 160~165mmHg			
Pressure accuracy	±3mmHg			
Electrical characteristics				
Supply voltage	10V~14V DC			
Maximum power consumption	3.6w			
Quiescent current	50mA			
Maximum current during measurement	180mA			
Maximum current	300mA			

during inflation	
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A.4.3 SpO2 Specifications

SpO2 Module

Standards compliant	ISO 80601-2-61	
Display range	0%~100%	
Parameter monitoring	Perfusion Index(PI) and Pleth Variability Index(PVI)	
SpO2 display resolution	1%	
SpO2 checking accuracy	2% (70%~100%); not define when lower than 70%	
SpO2 alarm preset limits	Upper alarm limit	1%~100%
	Lower alarm limit	0%~99%
SpO2 alarm preset accuracy	±1%	
SpO2 alerting signal generates a delay	No delay	
SpO2 value refresh period	1s/time	
SpO2 value refresh delay	< 10s	
Average period	Low sensitivity	7~8s
	Intermediate sensitivity	4~6s
	Advanced sensitivity	2~3s
Alarm condition delay period	Low sensitivity	<8s
	Intermediate sensitivity	<6s
	Advanced sensitivity	<3s
Alarm sign generates delay period	0s	
PR		
Measuring range	30~254bpm	
Resolution	1%	
Accuracy	±2% or ±2bpm	

Masimo SpO2 Module

SpO2	
Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2% (adult/pediatric, non-motion conditions)
	70% to 100%: ±3% (neonate, non-motion conditions)

	70% to 100%: $\pm 3\%$ (motion conditions) 0% to 69%, unspecified
Average time	2-4s, 4-6s, 8s, 10s, 12s, 14s, 16s
PR	
Measurement range	25 bpm to 240 bpm
Accuracy	± 3 bpm (non-motion conditions) ± 5 bpm (motion conditions)
Resolution	1 bpm
PI	
Measurement range	0.05% to 20%

A.4.4 IBP specification

Required standard	IEC60601-2-34/EN 60601-2-34	
Measurement method	invasive blood testing	
IBP specification		
Range	-30~300mmHg	
Resolution	1mmHg	
Accuracy	±1mmHg or 2%, whichever is greater (not including sensor accuracy)	
renewal period	1 s	
Zero adjustment	Range	±200mmHg
	Accuracy	1 mmHg
	Temp range	0.1 mmHg/°C
Waveform	2or 4 channels	
Zeroing range	± 200mmHg	
PR		
Range	30~280 bpm	
Resolution	1bpm	
Accuracy	±2bpm	
Pressure transducer		
Voltage	5±5% (VDC)	
Power Consumption	<1 W	
Sensitivity	5uV/V/mmHg	
Input impedance	300~3000(Ohm)	
Working environment		
Operating temperature	5~40°C	
Operating Humidity	<80%	
Air pressure	428mmHg~760mmHg(0~1572m)	

A.4.5 CO₂ Specification

Required standard	EN 60601-1
Measurement method	Mainstream IRMA CO ₂ , Sidestream ISA CO ₂

Mainstream module		
CO ₂ Measurement range	0~25%	
Resolution	0.1 mmHg	
Accuracy	0 - 40 mmHg $\pm$ 2 mmHg 41 - 70 mmHg $\pm$ 5% of reading 71 - 100 mmHg $\pm$ 8% of reading 101 - 150 mmHg $\pm$ 10% of reading	
System response time	<1 s	
Warm-up time	10s	
Inspiratory rise time (@10 l/min)	CO ₂ $\leq$ 90ms	
AwRR measurement range	0~150 bpm	
renewal period	Show the inspiration frequency after 3 times inhale& exhale, and update the average after each inhale& exhale.	
Temperature requirement	Operating temperature	5~40°C
	Storage and transportation temperature	-20~55°C
Humidity requirement	Operating Humidity	<80%RH, no condensation
	Storage and transportation Humidity	<93% RH, condensation
Air pressure requirement	Air pressure	525~1200 hpa (525 hpa Corresponding to the altitude of 4572 m / 1500 ft)
	Storage and transportation temperature	500~1200 hpa
*: The accuracy above is under the standard condition. In all situations (valid in the conditions of specified operating temperature and humidity, except the specified interfered gas in the “interference gases and water vapor”, CO₂ measurement accuracy $\pm$ (0.3% + reading’s 4%))		
Impact of interference gases and water vapor		
Gas or water vapor *	Concentration (%)	Impact
Enflurane soflurane,	5%	reading’s +8%

Sevoflurane		
Desflurane	15%	reading's +12%
Xe(xenon)	80%	reading's -10%
He(helium)	50%	reading's -6%
*:1. Nitrous oxide, halothane, ethanol and methane , etc are negligible interference; 2. The instructions above are under the impact of mycelium concentration. For example,50% helium would lower 6% CO2 reading, which means that the measured CO2 concentration will be $(1-0.6)*5.0\% = 4.7\%$ CO2 if the gas measured contains mixture of 5% CO2 and 50% helium 3. Gas is in accordance with EN ISO 21647:2004 standard.		

Sidestream module		
CO2 measurement range	0~25%	
Resolution	0.1%	
Accuracy	0~15 ± (0.2% +2%) 15~25 not specified	
System response time	< 3 s	
Warm-up time	<10s (Report the concentration and achieve the highest accuracy)	
Typical rise time (Sample flow rate of 50 l/min)	CO2 ≤200ms	
AwRR measurement range	0~150±1 rpm	
Renewal period	Show the inspiration frequency after 3 times inhale& exhale, and update the average after each inhale& exhale.	
Temperature requirement	Operating temperature	5~40℃
	Storage and transportation temperature	-20~55℃
Humidity requirement	Operating Humidity	<80%RH
	Storage Humidity	<93% RH, no condensation
Air pressure requirement	Operating air pressure	52.5~120 kpa (525 hpa Corresponding to the altitude of 4572 m / 1500 ft)
	storage air pressure	20~120 kpa
Calibration	No need to make scale calibration of infrared pool; generate the automatical zeroing calibration and execute once every 24 hours	
*: The accuracy above is under the standard condition (a dry gas Suitable for 22 + 5 °C and + 40 1013 hpa).		

In all conditions (valid in the conditions of specified operating temperature and humidity, except the specified interfered gas in the “interference gases and water vapor”), CO₂ measured accuracy $\pm (0.3\% + \text{reading's } 4\%)$

Impact of interference gases and water vapor

Gas or water vapor	Condensation (%)	Impact
Enflurane, Soflurane, Sevoflurane	5%	reading's +8%
Desflurane	15%	reading's +12%
Xe(xenon)	80%	reading's -10%
He(helium)	50%	reading's -6%

- *: 1. Nitrous oxide, halothane, ethanol and methane are negligible interference;
 2. The instructions above are under the impact of mycelium concentration. For example, 50% helium would lower 6% CO₂ reading, which means that the measured CO₂ concentration will be $(1-0.6)*5.0\% = 4.7\%$ CO₂ if the gas measured contains mixture of 5% CO₂ and 50% helium
 3. Gas is in accordance with EN ISO 21647:2004 standard.

A.4.6 AG Specification

Required standard	EN 60601-1
Measurement range	Mainstream IRMA AX+/IRMA OR/OR+, Sidestream ISA OR+/AX+

Sidestream module			
Measurement range	CO ₂	0~25 %	
	N ₂ O	0~100 %	
	HAL, ENF, ISO, SEV, DES	0~25 %	
	O ₂	0~100 %	
	AwRR	0~150 rpm	
Resolution	CO ₂ , N ₂ O, O ₂ , HAL, DES, SEV, ISO, ENF	0.1 %	
	AwRR	1 rpm	
Accuracy	Gas	Range	Accuracy
	CO ₂	0~ 15% 15~ 25%	$\pm (0.2\% + \text{reading's } 2\%)$ Not specified
	N ₂ O	0~100 %	$\pm (2\% + \text{reading's } 2\%)$
	HAL, ENF, ISO	0~8 % 8~25 %	$\pm (0.15\% + \text{reading's } 5\%)$ Not specified
	SEV	0~10 % 10~25 %	$\pm (0.15\% + \text{reading's } 5\%)$ Not specified
	DES	0~22 % 22~25 %	$\pm (0.15\% + \text{reading's } 5\%)$ Not specified

	O2	0~ 100%	± (1% + reading's 2%)
System response time	<3s (use 2m sampling tube)		
Warm-up time	< 20s		
Typical rise time (the sample flow rate of 50 ml/min)	CO2≤ 200ms N2O ≤350ms anesthetic gases ≤ 350ms O2≤ 450ms		
Calibration	No need to make scale calibration of infrared pool; generate the automatical zeroing calibration and execute once every 8 hours		
compensation	Automatic compensating broadening effect of pressure, temperature and carbon dioxide.		
Humidity requirement	Operating temperature	5~40℃	
	Storage and transportation temperature	-20~55℃	
Temperature requirement	Operating Humidity	<80%RH (no condensation)	
	Storage Humidity	<93% RH, no condensation	
Air press requirement	Operating air pressure	52.5~120 kpa (525 hpa corresponds to the altitude of 4572 m / 1500 ft)	
	Storage and transportation air pressure	20~120 kpa	
*the accuracy above is under the standard condition In all conditions (valid in the conditions of specified operating temperature and humidity, except the specified interfered gas in the “interference gases and water vapor”) CO2 measured accuracy ± (0.3% + reading's 4%) N2O measured accuracy± (2% + reading's 5%) anesthetic gases measured accuracy 为±(0.2% + reading's 10%) O2 measured accuracy± (0.2% + reading's 2%)			
Impact of interference gases and water vapor			
Gas or water vapor	Condensation (%)	Impact	
Enflurane soflurane, Sevoflurane	5%	reading's +8%	
Desflurane	15%	reading's +12%	
Xe(xenon)	80%	reading's -10%	
He(helium)	50%	reading's -6%	
*:1. Nitrous oxide, halothane, ethanol and methane , etc are negligible interference; 2. The instructions above are under the impact of mycelium concentration. For example,50% helium would lower 6% CO2 reading, which means that the measured CO2 concentration will be			

(1-0.6)*5.0% = 4.7% CO₂ if the gas measured contains mixture of 5% CO₂ and 50% helium
 3. Gas is in accordance with EN ISO 21647:2004 standard.

Mainstream module			
measurement range	CO2		0~ 25 %
	N2O		0~ 100 %
	HAL,ENF,SEV,ISO,D ES		0~ 25 %
	O2		0~ 100 %
	AwRR		0~ 150 rpm
Resolution	CO2,N2O,O2,HAL,D ES,SEV,ISO,ENF		0.1 %
	AwRR		1 rpm
Accuracy	Gas	Range	Accuracy
	CO2	0~ 10%	± (0.2% + reading's 2%)
		10~ 15%	± (0.3% + reading's 2%)
		15~ 25%	Not specified
	N2O	0~100 %	± (0.2% + reading's 2%)
	HAL,ENF,IS O	0~8 %	± (0.15% + reading's 5%)
		8~25 %	Not specified
	SEV	0~10 % 10~25 %	± (0.15% + reading's 5%) Not specified
DES	0~22 % 22~25 %	± (0.15% + reading's 5%) Not specified	
O2	0~ 100%	± (1% + reading's 2%)	
Warm-up time	IRMA AX+	20 s	
	IRMA OR/OR+	≤ 1min(when OR module measure HAL, warm-up time≤3min)	
System response time	< 1s		
inspiratory rise time (@10 l/min)	CO2 ≤90ms O2≤ 300ms N2O ≤ 300ms HAL,ENF,ISO,SEV,DES ≤ 300ms		
The main gas threshold	0.15%, after recognize the anesthetic gas, it will report the concentration even if then concentration is lower than 0.15%, in the condition of Detecting suffocation.		
Auxiliary anesthetic gas threshold	0.2 % + General anesthetic gas concentration of readings.		
Anesthetic gasses recognition time	<20 s(usually<10s)		
Calibration	When Replacing airway adapter, it is recommended that the executive		

	to zero No need to make scale calibration of Preparation of infrared instrument When Replacement airway adapter, it will trigger automatically indoor air calibration for oxygen battery (less than 5 s)	
Temperature requirement	Operating temperature	5~40℃
	Storage and transportation temperature	-20~55℃
Humidity requirement	Operating Humidity	<80%RH(no condensation)
	Storage Humidity	<93% RH, no condensation
Air pressure requirement	Operating air pressure	52.5~120 kpa (525 hpa Corresponding to the altitude of 4572 m / 1500 ft)
	storage air pressure	20~120 kpa
Calibration	No need to make scale calibration of infrared pool; generate the automatical zeroing calibration and execute once every 24 hours	
*: The accuracy above is under the standard condition (a dry gas Suitable for 22 ± 5 °C and 1013±40 hpa). In all conditions (valid in the conditions of specified operating temperature and humidity, except the specified interfered gas in the “interference gases and water vapor”) CO2 measured accuracy ± (0.3% + reading’s 4%) CO2 measured accuracy± (0.3% + reading’s 4%) N2O measured accuracy± (2% + reading’s 5%) Anesthetic gases measured accuracy± (0.2% + reading’s 10%) O2 measured accuracy± (0.2% + reading’s 2%)		
Impact of interference gases and water vapor		
Gas or water vapor	Condensation (%)	Impact
Enflurane soflurane, Sevoflurane	5%	reading’s +8%
Desflurane	15%	reading’s +12%
Xe(xenon)	80%	reading’s -10%
He(helium)	50%	reading’s -6%
*:1. Nitrous oxide, halothane, ethanol and methane , etc are negligible interference; 2. The instructions above are under the impact of mycelium concentration. For example,50% helium would lower 6% CO2 reading, which means that the measured CO2 concentration will be (1-0.6)*5.0% = 4.7% CO2 if the gas measured contains mixture of 5% CO2 and 50% helium 3. Gas is in accordance with EN ISO 21647:2004 standard.		

A.4.7 C.O. Specification

Measurement method	Thermodilution	
Range	C.O.	0.20~20.00L/MIN
	TB	23.0~45.0°C
	TI	-1.0~27.0°C
Resolution	C.O.	0.01L/MIN
	TB	0.1°C
	TI	
Accuracy	C.O.	±5%
	TB	±0.5°C
	TI	

A.4.8 BIS Specification

type	BISx
BIS measurement range	0~100
Signal quality index (SQI) range	0~100%
EMG range	0~100dB
rejection ratio (SR)	0~100%
spectral edge frequency (SEF)	0.5~30.0HZ
Total paroxysmal (BC)	0~30/min
noise	<0.3uV RMS (2.0uV top-top)
Update frequency	<1s
bandwidth	0.25~100HZ(-3dB)
high-pass filter	0.25HZ,1HZ,2HZ(-3dB)
low pass filter	30HZ,50HZ,70HZ,100HZ(-3dB)
Notch Line filter (frequency)	50HZ,60HZ
Impedance measurement range	0~999KΩ

Appendix B EMC

This product complies with EN 60601-1-2 Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral standard electromagnetic compatibility requirements and tests

Notes:

- Using unqualified accessories, sensors and cables will increase the electromagnetic emission and reduce the electromagnetic immunity of the device.
- Do not put the device close to other devices or stack together. When necessary, observe the device closely to ensure that it runs normally in the environment.
- The device requires special EMC protection, and it is necessary to install and maintain it in the environment that meets the following EMC information.
- Even if other devices comply with CISPR emission requirements, they may also cause interference to this device.
- When the input signal amplitude is smaller than the minimum amplitude specified in the technical specifications, it may result in inaccurate measurements.
- Mobile communication devices or wireless network devices may have an impact on the device.

Electromagnetic Emission Guidelines and Declarations		
Patient Monitor should be used in the specified electromagnetic environment. The user should ensure that the device is used in the following electromagnetic environment.		
Emission test	Compliance	Electromagnetic environment - Guide
RF emission CISPR11	Group 1	The device uses radio frequency energy only when the internal function is running, and thus its RF emission is very low, and won't cause electromagnetic interference to nearby electronic equipment. This device is suitable for the public low-voltage power supply network that isn't connected to residence directly.
RF emission CISPR11	ClassA	
Harmonic emission IEC 61000-3-2	ClassA	
Voltage fluctuations and flicker IEC 61000-3-3	Conform	

Guidance and Declaration - Electromagnetic Immunity			
Patient Monitor is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity	test IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV I/O for input/output lines (>3 m)	±2 kV for power supply lines ±1 kV I/O for input/output lines (>3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity		
Patient Monitor is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity test	IEC 60601 Test level	Compliance level
Conducted RF IEC61000-4-6	3 Vrms 150k to 80M Hz	3 Vrms
Radiated RF IEC61000-4-3	3V/m 80M to 2.5G Hz	3V/m
Electromagnetic environment - guidance		
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: $d = 1.2 \sqrt{\frac{P}{f}} \quad (d = 3.5 \sqrt{\frac{P}{f}})$ $d = 1.2 \sqrt{\frac{P}{f}} \quad (\text{Resp: } d = 3.5 \sqrt{\frac{P}{f}}) \quad 80 \text{ to } 800\text{MHz}$ $d = 1.2 \sqrt{\frac{P}{f}} \quad 800\text{M to } 2.5\text{GHz}$ 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol: 		
Note 1: From 80 MHz to 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. ^b Over the frequency ranges 150kHz to 80MHz, field strengths should be less than 3V/m.		

Recommended Separation Distances between Portable and Mobile RF

Communications Equipment and The device

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

Rated Maximum Output power of Transmitter Watts (W)	Separation Distance Meters (m) Corresponding to Frequency of Transmitter		
	150k to 80MHz	80M to 800MHz	800M to 2.5GHz
	$d=3.5 \sqrt{P}$	$d=3.5 \sqrt{P}$	$d= \sqrt{P}$
0.01	0.35	0.35	0.23
0.1	1.11	1.11	0.74
1	3.5	3.5	2.34
10	11.07	11.07	7.38
100	35	35	23.24

For transmitters at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: From 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

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

Appendix C Alarm Information

This chapter lists some important physiological and technical alarm information, and some alarms are not necessarily listed.

Note that in this chapter: L column indicates the default alarm level: H indicates high level, M indicates middle level, L indicates low level, and “*” indicates level set by the user.

Corresponding countermeasures are listed for each alarm message. If you operate in accordance with the countermeasures but the problem persists, contact your service personnel.

C.1 Physiological Alarm Information

Source	Alarm message	L	Causes and countermeasures
ECG	HR Too High	M*	HR value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	HR Too Low		
	PVCS Too High	M*	PVCs value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	Asystole	H	The patient has arrhythmia. Check the patient's condition, electrodes, cables and lead wires.
	VF/VTA	H	
	R on T	M*	
	Frequent PVC	M*	
	Couplet PVC	M*	
	Single PVC	M*	
	PVC Bigeminy	M*	
	PVC Trigeminy	M*	
	Tachycardia	M*	
	Bradycardia	M*	

Source	Alarm message	L	Causes and countermeasures
	Miss Beat	M*	Pacemaker works abnormally; check the pacemaker.
	Pacemaker Not Capture	H	
	Pacemaker Not work	H	
	ECG Signal weak	H	The patient ECG signal is too weak, and the system can't analyze. Check the patient's condition, electrodes, cables and leads.
	ST-I Too High	M*	ST value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	ST-I Too Low		
	ST-II Too High		
	ST-II Too Low		
	ST-III Too High		
	ST-III Too Low		
Resp	RR Too High	M*	Patient PR value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	RR Too Low		
	Apnea(Resp)	H	The patient's respiratory signal is too weak, and the system can't analyze. Check the patient's condition, electrodes, cables and leads.
	RESP ARTIFACT	H*	Respiration heartbeat interference
Temp	T1 Too High	M*	T1/T2 value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	T1 Too Low		
	T2 Too High		
	T2 Too Low		
	TD Too High		TD value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
SpO2	SPO2 Too High	M*	SpO2 value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient
	SPO2 Too Low		

Source	Alarm message	L	Causes and countermeasures
			category and alarm limit settings are appropriate for the patient.
	PR Too High		SpO2 value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	PR Too Low		
NIBP	NIBP signal weak	M*	NIBP value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	NIBP-Sys Too High		
	NIBP-Sys Too Low		
	NIBP-Mean Too High		
	NIBP-Mean Too Low		
	NIBP-Dia Too High		
IBP	Art-Sys too high	M*	ArtSys value has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct. The other entitles corresponding pressure exceed the limit in the same way.
	Art-Sys too low	M*	
CO2	EtCO2 too high	M*	CO2 value has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct.
	EtCO2 too low	M*	
			The patient stops breathing, or the respiration signal was so weak that the monitor cannot perform respiration analysis. Check the patient's condition and the RM connections.
	FiCO2 too high	M*	
	AWRR too high	M*	
	AWRR too low	M*	
	CO2 Apnea	H	
AG	EtCO2 too high	M*	CO2, N2O, O2 value has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct.
	EtCO2 too low	M*	
	FiCO2 too high	M*	
	AwRR too high	M*	
	AWRR too low	M*	

Source	Alarm message	L	Causes and countermeasures
	EtN2O too high	M*	
	EtN2O too low	M*	
	FiN2O too high	M*	
	FiN2O too low	M*	
	EtO2 too high	M*	
	EtO2 too low	M*	
	FiO2 too high	M*	
	FiO2 too low	M*	
	EtAA too high	M*	AG AA(AA include: HAL,DES,ISO,SEV,ENF) value has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct.
	EtAA too low	M*	
	FiAA too high	M*	
	FiAA too low	M*	
	AG Apnea	H	The patient stops breathing, or the respiration signal was so weak that the monitor cannot perform respiration analysis. Check the patient's condition and the RM connections.
C.O.	TB too high	M*	The blood temperature is too high, reduce the injection temperature.
	TB too low	M*	The blood temperature is too low, increase injection temperature, or to reduce the frequency of intra-articular injections of saline solution
BIS	BIS too high	M*	Patient with clear consciousness than expected, Adjust narcotic injection quantity.
	BIS too low	M*	Patients with low degree of consciousness than expected, adjust narcotic injection quantity.

C.2 Technical Alarm Information

Source	Alarm message	L	Causes and countermeasures
System	Battery Low	H	Connect to AC power supply, and charge the battery, and power with the battery as needed after fully charged.
ECG	ECG Comm. Stop	H	ECG module failure, or communication failure between the module and the host; please restart the device.
	ECG Comm. Error	H	
	ECG Config Error	H	
	ECG Self check Error	H	
	ECG Lead Off	M*	The electrodes are not connected to the patient firmly or fall off, or lead wires and the main cable fall off. Check the connection of electrodes and lead wires.
	ECG YY OFF (YY is a lead name)	M*	
Temp	TEMP1 Sensor Off	L	The temperature sensor falls off from the patient. Check the sensor connection.
	TEMP2 Sensor Off	L	
SpO2	SPO2 Comm. Stop	H	SpO2 module failure, or communication failure between the module and the host; please restart the device.
	SPO2 Comm. Error	H	
	SPO2 No Sensor	L	SpO2 sensor falls off from the patient or monitor, malfunctions, or sensor other than specified in this Manual is used. Check the sensor mounting position, whether the sensor is damaged or sensor type. Reconnect the sensor or use new sensor.
	SPO2 Sensor Off	L	
	SPO2 Sensor Error	L	
	SPO2 Search Timeout	L	
	SPO2 Search Pulse	L	Sensor signal is poor or too weak. Check the patient's condition, and place the sensor in a suitable position. If the failure persists, replace the sensor.
	SPO2 Signal Unstable	L	
	SPO2 Failure	L	
	SPO2 Signal Weak	L	
SpO2 (Masimo)	SPO2 No Cable Connected	L	No Cable
SpO2 module)	Cable Expired	L	Cable Life Expired
	Incompatible Cable	L	Incompatible Cable
	Unrecognized Cable	L	Unrecognized Cable

Source	Alarm message	L	Causes and countermeasures
	Replace cable	L	Defective Cable/Cable Life Expired
	Cable Near Expiration	L	Cable Life Near Expiration
	SPO2 No Sensor Connected	L	No Sensor Connected
	Sensor Expired	L	Sensor Life Expired
	Incompatible Sensor	L	Incompatible Sensor
	Unrecognized Sensor	L	Unrecognized Sensor
	Replace sensor	L	Defective Sensor
	Check Cable / Sensor Fault	L	Check Cable and Sensor Fault
	Sensor Near Expiration	L	Sensor Life Near Expiration
	SPO2 No Adhesive Sensor	L	No Adhesive Sensor
	Adhesive Sensor Expired	L	Adhesive Sensor Life Expired
	Defective Adhesive Sensor	L	Defective Adhesive Sensor/Adhesive Sensor Life Expired
	Incompatible Adhesive Sensor	L	Incompatible Adhesive Sensor
	Unrecognized Adhesive Sensor	L	Unrecognized Adhesive Sensor
	Defective Adhesive Sensor	L	Defective Adhesive Sensor
	Sensor Initializing	L	Sensor Initializing
	SPO2 Sensor Off Patient	L	Sensor Off Patient
	SPO2 Pulse Search	L	Pulse Search
	SPO2 Interference Detected	L	Interference Detected
	SPO2 Low Perfusion Index	L	Low Perfusion Index
	SPO2 Demo Mode	L	Demo Mode
	Adhesive Life Near Expiration	L	Adhesive Life Near Expiration
	Check Sensor Connection	L	Check Sensor Connection
	SpO2 Only Mode		SpO2 Only Mode

Source	Alarm message	L	Causes and countermeasures
	SPO2 Low Signal IQ	L	Low Signal IQ
	Masimo SET Processing Active	L	Masimo SET Processing Active
	SPO2 Too Much Ambient Light	L	Too Much Ambient Light
NIBP	NIBP Comm. Stop	H	NIBP module failure, or communication failure between the module and the host; please restart the device.
	NIBP Comm. Error	L	
	NIBP Self check error	H	
	NIBP CFG Error	H	
	NIBP system error	H	If failure occurs during measurement, the system can't analyze and calculate. Check the patient's condition, check the connections or replace the cuff, and then re-test.
	Measurement timeout	L	
	Cuff type error	L	The used cuff does not match the set patient category. Verify the patient category and replace the cuff.
NIBP	Cuff loose or no cuff	L	NIBP cuff isn't placed or connected properly, or there is gas leak.
	Cuff leak	L	Check cuff and inflation tube.
	Air pressure error	L	Ambient atmospheric pressure is abnormal. Confirm that the environment complies with the monitor's specifications, and check whether there are special reasons affecting ambient pressure.
	NIBP over range	L	The measured blood pressure of the patient exceeds the measuring range.
	NIBP signal weak	L	Patient's pulse may be weak or cuff is too loose. Check the condition of the patient, and place the cuff in a suitable position. If the failure persists, replace the cuff.
	NIBP signal unstable	L	Excessive movement may result in too much motion artifact or interference in the signal during measurement.

Source	Alarm message	L	Causes and countermeasures
	NIBP signal saturated	L	Motion signal amplitude is too large due to movement and other reasons.
	NIBP over pressure	L	Cuff overpressure, and gas blockage may occur; check the gas path, and then re-measure.
	Module reset failed	L	NIBP module reset error; check the gas path is blocked, and then restart the measurement.
IBP	XX sensor off (XX represents an IBP label)	L	Check the sensor connection and reconnect the sensor.
CO2	CO2 communication stop	H	The CO2 module fails or module and host connection disconnected, reconnect the CO2 module to monitor.
	CO2 communication error	H	
	CO2 pipe off	L	Check CO2 pipe connection situation
	Check adapter	L	Check CO2 connected adapter or sampling pipes
	Check sampling pipe	L	
	Software error(CO2)	H	CO2 module fail, contact the maintenance staff.
	Sensor error(CO2)	L	Check CO2 sensor matched or not.
	CO2 exceed the measurement range.	L	The measured value exceed the measurement range claimed.
	CO2 sensor high temp	L	Check, remove heat source or waiting for the module to recover.
	CO2 Airway high press	L	An error occurred in the airway pressure. Check the patient connection and patient circuit, and then restart the monitor.
	CO2 check Cal	L	CO2 preform a calibration
	CO2 checking Cal failure	L	CO2 calibration module fails, please make sure the gas path etc, to recalibrate.
AG	AG module communication stop.	H	AG module fails or module and host connection disconnected, reconnect the module to monitor.
	AG module communication error	H	

	AG sensor off	L	Check AG module sensor connection situation.
	AG sensor error	L	Check AG module sensor match or not.
	AG software error	H	AG module fail contact the maintenance staff.
	AG hard ware error	H	
	AG precision range exceeded.	H	Measuring the range exceeded.
	AG temp range exceeded.	H	
	AG airway precision exceeded.	L	
	AG defaulted calibration is missing.	H	Re-calibrate the AG module.
	AG need zero calibrate	L	Perform a zero calibration.
	AG ID& Conc error	H	AG module ID error
	AG calibrating	L	AG module calibrating
	AG standby	L	AG module under standby
	AG measurement range calibrating	L	AG module calibrating.
	AG measurement range calibrated failed	H	Check AG airway and re-calibrate.
	Anesthetic Mixture	L	The system has detected more than one anesthesia gas. Check the ventilated anesthesia gas.
C.O.	TB sensor off	L	Check the sensor connection and reconnect the sensor.
	TI sensor off	L	Check the sensor connection and reconnect the sensor.
	C.O. measurement range exceed.	M	CO measurement value exceed the range, re-measure or check the patient conditions.
	C.O. communication error	H	C.O. module appear failed, connect the manufacturer
	C.O. communication error	H	C.O. module and host communication appear flailed, connect manufacturer

BIS	BIS communication stop	H	BIS module and host communication stop, check BIS module and host socket connected situation; plug-out BIS module and reconnect.
	BIS Confi error	H	BIS module can't working, check BIS module, replace the module if needed.
	BIS impedance too high	M	BIS sensor impedance check failed. Check placement of sensors and the connection, press the sensor in every electrode. Ensure the sensor connection of dry skin.
	BIS sensor off	M	BIS sensor connection off, check the sensor connection, reconnect the BIS sensor.
	BIS DSC error	H	BIS digital signal converter is not properly communication or work. Please contact maintenance staff.
	BIS DSC faulted	H	
	BIS disconnected cable	L	BIS cable not connected, check BIS cable connection, or reconnect.
	BIS disconnected sensor	L	Sensor not connected, BIS sensors need to Connected to reliable sensor before measurement.
	BIS sensor using exceed limited	M	Sensor using the frequency or time too long, more than sensor using rules, Change the new sensor.
	BIS SQI<50%	L	The BIS signal quality reliability is low, cannot be deduced, pseudo poor or too much interference EMG activity monitoring. 1. check the sensor; 2. Make sure that the BIS module is not close to other electrical radiation equipment.
	BIS SQI<15%	L	
	BIS sensor error	M	Not support the current BIS sensor, replace for new sensor.
	BIS need to reconnect	M	BIS connection failure, reconnect the BIS module
	BIS sensor invalid	M	BIS sensor failure, too old for use time more than the efficient time. The new sensor need to be replaced.

	BIS connected simulator.	L	BIS connected demo simulator, At this moment is to demonstrate, not measuring patient.
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Appendix D Default Parameter Configuration

This chapter lists the important factory default settings of different departments in monitor configuration mode. Users can not change the default configuration, but can modify the settings as required and save as user-defined configuration.

Module	Option		Module defaults			
			Adult	Pediatric	Neonatal	
ECG	Alarm level		Mid	Mid	Mid	
	Alarm record		Off	Off	Off	
	Lead type		5-lead	5-lead	5-lead	
	Calculation channel		Auto	Auto	Auto	
	Power frequency suppression		On	On	On	
	Alarm limits		50~120 on	75~160 on	100~200 on	
	ST segment analysis	ST segment analysis		Off	Off	Off
		Alarm level		Mid	Mid	Mid
		Alarm record		Off	Off	Off
		Alarm limits		-0.2~0.2 on	-0.2~0.2 on	-0.2~0.2 on
	Arrhythmia analysis	Alarm level		Mid	Mid	Mid
		Alarm record		Off	Off	Off
		Alarm limits		0~10 on	0~10 on	0~10 on
		ARR alarm settings	Alarm switch	On	On	On
			Alarm level	Mid	Mid	Mid
			Alarm record	Off	Off	Off
	Gain		x1	x1	x1	
	Wave velocity		25.0mm/s	25.0mm/s	25.0mm/s	
	Filter mode		Monitor	Monitor	Monitor	
	Wave color		Green	Green	Green	
	Wave style		Color scale	Color scale	Color scale	
NIBP	Alarm level		Mid	Mid	Mid	
	Alarm record		Off	Off	Off	
	Pressure unit		mmHg	mmHg	mmHg	
	Measurement mode		Adult	Child	Infant	
	Interval		Manual	Manual	Manual	
	Display color		White	White	White	
	Pre-inflation value		150	100	100	

	Systolic blood pressure limit		90~160 on	70~120 on	40~90 on
	Mean blood pressure limit		60~110 on	50~90 on	25~70 on
	Diastolic blood pressure limit		50~90 on	40~70 on	20~60 on
SPO2	Alarm level		Mid	Mid	Mid
	Alarm record		Off	Off	Off
	Alarm limits		90~100 on	90~100 on	90~95 on
	Wave velocity		25.0	25.0	25.0
	Wave color		Cyan	Cyan	Cyan
	Wave style		Line	Line	Line
RESP	Alarm level		Mid	Mid	Mid
	Alarm record		Off	Off	Off
	Apnea alarm		20 sec	20 sec	20 sec
	Alarm limits		8~30 on	8~30 on	30~100 on
	Gain		x1	x1	x1
	Wave velocity		12.5	12.5	12.5
	Wave color		Yellow	Yellow	Yellow
	Wave style		Line	Line	Line
PR	Alarm source		SPO2	SPO2	SPO2
	Alarm level		Mid	Mid	Mid
	Alarm record		Off	Off	Off
	Alarm limits		50~120 on	75~160 on	100~200 on
TEMP	Alarm level		Mid	Mid	Mid
	Alarm record		Off	Off	Off
	Display color		White	White	White
	Temperature unit		°C	°C	°C
	T1 alarm limits		36.0~39.0 on	36.0~39.0 on	36.0~39.0 on
	T2 alarm limits		36.0~39.0 on	36.0~39.0 on	36.0~39.0 on
	TD alarm limits		0.0~2.0 on	0.0~2.0 on	0.0~2.0 on
IBP	Alarm switch		On	On	On
	Alarm level		Mid	Mid	Mid
	Alarm record		Off	Off	Off
	Pressure unit		mmHg	mmHg	mmHg
	Scale range		Auto	Auto	Auto
	Filter		40Hz	40Hz	40Hz
	Art, Ao, UAP, BAP, FAP, P1, P2, P3, P4 alarm limits	SYS	90~160	70~120	55~90
		DIA	50~90	40~70	20~60
		Mean	70~110	50~90	35~70
	PA alarm limits	SYS	10~35	24~60	24~60
		DIA	0~16	-4~4	-4~4
		Mean	0~20	12~26	12~26
	CVP, LAP, RAP, ICP,	Mean	0~10	0~4	0~4

	UVP alarm limits				
CO2	Alarm switch		On	On	On
	Alarm level		Mid	Mid	Mid
	Alarm record		Off	Off	Off
	Pressure unit		mmHg	mmHg	mmHg
	Operation mode		Standby	Standby	Standby
	Apnea time		20s	20s	20s
	O2 compensation		Low	Low	Low
	N2O compensation		Off	Off	Off
	Wave scale		40	40	40
	EtCO2 alarm limits		15~50	20~50	30~45
	FiCO2 alarm limits		0~4	0~4	0~4
	AwRR alarm limits		8~30	8~30	30~100
AG	Alarm switch		On	On	On
	Alarm level		Mid	Mid	Mid
	Alarm record		Off	Off	Off
	Operation mode		Standby	Standby	Standby
	Apnea time		20s	20s	20s
	O2 compensation		Low	Low	Low
	Wave style		Line	Line	Line
	Waveform speed		12.5mm/s	12.5mm/s	12.5mm/s
	CO2 wave scale		40	40	40
	O2 wave scale		50	50	50
	N2O wave scale		100	100	100
	AA wave scale		9	9	9
	Unit	N2O	%		
		O2	%		
		AA	%		
		CO2	mmHg		
	CO2 alarm limits	EtCO2	15~50	20~50	30~45
		FiCO2	0~4	0~4	0~4
		AwRR	8~30	8~30	30~100
	O2 alarm limits	EtO2	18~90		
		FiO2	18~88		
	N2O alarm limits	EtN2O	0~55		
		FiN2O	0~53		
	HAL/ISO/ENF alarm limits	EtHAL/ISO/ENF	0~3		
		FiHAL/ISO/ENF	0~2		
	SEV alarm limits	EtSEV	0~6		
		FiSEV	0~5		
	DES alarm limits	EtDES	0~8		
		FiDES	0~6		

C.O.	Alarm switch	On	On	On
	Alarm level	Mid	Mid	Mid
	Alarm record	Off	Off	Off
	Temp source	Manual		
	Unit	°C		
	Interval	35s		
	TB alarm limit	36.0~39.0°C		
	Liquid temp	0.0°C		
BIS	Alarm switch	On	On	On
	Alarm level	Mid	Mid	Mid
	Alarm record	Off	Off	Off
	Filter	On		
	Smoothing rate	30s		
	Wave scale	100uV		
	Wave speed	25mm/s		
	Con. Imped. Check	On		
	Cyc. Imped. Check	Off		
	BIS alarm limit	30~70		



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