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Shenzhen Comen Medical Instruments Co., Ltd.

Version: B00

Date：11/2020

Product Name: Multi-parameter Patient Monitor

Product Model: STAR8000E/STAR8000F/STAR8000H

No.: 046-000939-07

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After-sales Service Unit

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Preface

This manual provides details on the performance, operations and safety instructions of STRA8000E/STAR8000F/STAR8000H Multi-parameter Patient Monitor (hereinafter referred to as the "monitor"). It is the best starting point for new users of the monitor.

Intended Readers

This user manual is only intended to trained professionals who are expected to have working knowledge of medical procedures, practices and terminology as required for monitoring patients.

Illustrations

All illustrations provided herein are for reference only. The menus, options, values and functions shown in the illustrations may be not exactly identical to what you see on the monitor.

Conventions:

■ —>: Indicates operating steps.

■ [Character]: Indicates user interface text.

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Content

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1.1 Safety Information

⚠ **Warning**
- Alerts you to situations that may result in serious consequences or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of user or patient.

⚠ **Caution**
- Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage, or cause more serious injury in the future.

⚠ **Note**
- Emphasizes important precautions and provides instructions or explanations for better use of the product.

⚠ **Warning**
- This monitor is intended for monitoring of clinical patients, and can be used only by trained, qualified doctors and nurses.
- Prior to use, the user must check the monitor and its accessories to ensure their normal and safe operation.
- Do not place the power plug used to disconnect the monitor from grid power supply in a position not easily accessible by the operator.
- Alarm volume and upper/lower alarm limits should be set depending on the patient. When a patient is monitored, do not exclusively rely on the audible alarm system. If the alarm volume is set too low or is completely turned off, the alarm will not be heard and the patient may be put into danger. The most reliable monitoring method is to pay close attention to the patient's actual clinical conditions.
- This monitor can only be connected to a power socket with protective earth. If the power socket is not connected to an earth conductor, please use the rechargeable battery to supply power to the monitor instead of using this socket.

- **Do not open the housing of the monitor to avoid the potential risk of electric shock. The monitor must be maintained and upgraded by service personnel trained and authorized by Comen.**

- **Please observe the local laws and regulations or the waste disposal rules of the hospital when disposing of packaging materials. Keep the packaging materials out of the reach of children.**

- **In order to avoid fire or explosion, never use this monitor in an environment with inflammables such as anesthetics.**

- **Please carefully place the power cord and the cables of various accessories to avoid entanglement and potential strangulation and to keep the patient free from electrical interference.**

- **For patients with implanted pacemakers, the cardiotachometer may count in the pacemaker pulse in the event of cardiac arrest or arrhythmia. Do not completely rely on the alarm function of the cardiotachometer. Patients with implanted pacemakers must be closely monitored. For the pacemaker inhibiting function of the monitor, please refer to relevant section in this Manual.**

- **During defibrillation, the operator should not come into contact with the patient, the monitor or the supporting table; otherwise serious injury or death could result. Before reusing the cables, check to confirm their functions are normal.**

- **The equipment connected with this monitor shall form an equipotential body (effective connection of protective earth).**

- **In order not to cause burns (resulted from electric leakage) to the patient, please do not allow its sensors and sensor cables to contact such equipment when connecting the Monitor to any high-frequency electrosurgical equipment.**

- **The physiological waveforms and parameters, alarm messages and other information displayed by the monitor are only for reference by the doctor, which shall not be directly used as a basis for clinical treatment.**

- **Electromagnetic field can affect the performance of the monitor. Therefore, other devices used near the monitor should conform to the applicable EMC requirements. For example, mobile phones, X-ray machines and MRI devices are all potential sources of interference since they all transmit high-intensity electromagnetic radiation.**

- **This monitor is not a therapeutic device.**

- **After defibrillation, the electrocardiogram (ECG) waveform must recover within 5s, other parameters must recover within 10s.**

⚠ Caution

- **To avoid damage to the monitor and ensure the patient's safety, use accessories specified in this manual.**

- **Handle the monitor carefully to avoid damage caused by drop, collision, strong oscillation or other external mechanical forces.**

- **Before powering on the monitor, confirm that the supply voltage and frequency conform to the requirements specified on the monitor nameplate or in this manual.**

> ● **At the end of their service life, the monitor and its accessories must be disposed of in accordance with the local laws and regulations or the rules of the hospital.**

⚠ **Note**

- ● **Place the monitor at a position where observation, operation and maintenance is convenient.**
- ● **This user manual is based on the maximum configuration; therefore, some contents may not be applicable to your monitor.**
- ● **Keep this manual handy for easy and timely reference.**
- ● **This monitor is not intended for home use.**
- ● **This monitor can be used for only one patient at a time.**
- ● **The service life of this monitor is 5 years.**

1.2 Contraindications

Unclear

1.3 Symbols

● **Symbols Used by the Monitor**

Symbol	Description	Symbol	Description
⚠	NOTE!	CE 1639	Complies with medical device directive 93/42/EEC
EC REP	European community representative	(crossed-out wheeled bin)	Separate collection for electrical and electronic equipment
(refer to manual)	Refer to instruction manual/ booklet	■	Main menu
Type BF	Type BF applied parts, with defibrillation-proof function	IPX1	Ingress protection rating
Type CF	Type CF applied parts, with defibrillation-proof function	(manufacturing date symbol)	Manufacturing date
⊙/Ò	Power on/off key	SN	Serial number
(battery)	Battery level indicator	(equipotential)	Equipotential symbol
∿	AC indicator	(network)	Network connection symbol
⟨↔⟩	Multi-function interface	(USB)	USB port

⚒	Manufacturer	⊠	Alarm volume off
△	Alarm off	△	Alarm reset
⚠	Warning: Only use the ECG cable provided by Comen. Other types of ECG cable may decrease the defibrillation energy delivered to the patient.	⏻	Standby

Note: Keys on the monitor and their functions are described in "*2.2.1* Front View ".

● **Symbols on Package**

↑↑	This Side Up	⊠ 6	Stacking Layer Limit
⚏	Fragile	☂	Keep dry

Chapter 2 Overview

2.1 Product Introduction

2.1.1 Composition

This monitor is mainly composed of a main unit (including battery, bracket, display, recorder, and housing) and functional accessories (ECG cables, NIBP (Non-Invasive Blood Pressure) cuff, IBP (Invasive Blood Pressure) cuff, SpO_2 (blood oxygen saturation) sensor, TEMP (body temperature) sensor, and CO_2 sensor).

2.1.2 Intended Use

The monitor is intended for monitoring critically ill patients in operation rooms, ICUs and CCUs and in bedside environments. It can be used to monitor ECG (including ST segment and arrhythmia), impedance respiration, TEMP, SpO_2, PR (pulse rate), NIBP, IBP, RESP (respiration) and $EtCO_2$ (end-tidal carbon dioxide) of adults, children and neonates. It is also provided with such functions as OxyCRG (Oxygen-Cardio-Respirogram), renal function calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation, drug calculation, and recorder.

2.2 Product Appearance

2.2.1 Front View
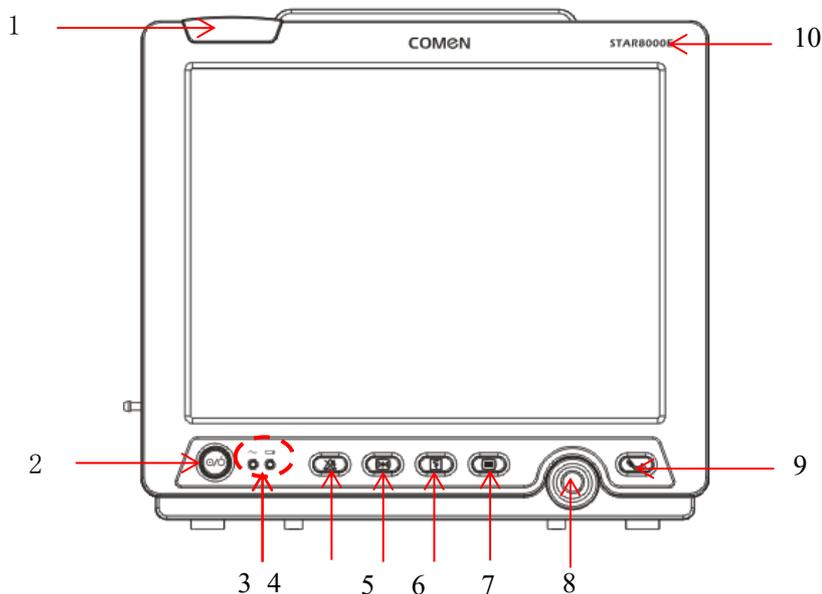
Fig 2-1 STAR8000E Front View

1		Alarm indicator	
2	(power icon)	Power on/off key	Use this key to power on/off the monitor.
3	(power symbol ~)	Power indicator	Indicator on: this monitor is connected to AC power supply. Indicator off: this monitor is disconnected from AC power supply.
	(battery symbol)	Battery indicator	Indicator solid on: battery is being charged. Indicator blinks: battery is used to supply power to the monitor. Indicator off: battery is fully charged, is not installed or malfunctions.
4	(alarm pause icon)	Alarm Pause key	Press this key to pause or resume an alarm.
5	(freeze icon)	Waveform Freeze key	Press this key to freeze or unfreeze a waveform.
6	(record icon)	Record key	Press this key to start or stop recording.

7	▢	Main menu key	Press this key to open/close the main menu.
8	Rotary knob: turn the rotary knob clockwise and counter-clockwise to move the focus; press down the rotary knob to perform an action.		
9	✆	NIBP measurement key	Press this key to start or stop NIBP measurement.
10	Product model		
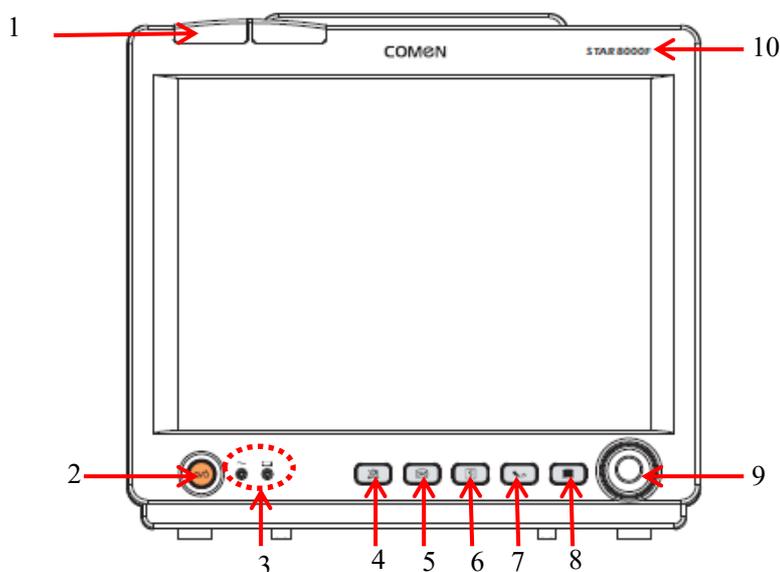
Fig 2-2 STAR8000F Front View

1	Alarm indicator		
2	⊙/Ò	Power on/off key	Use this key to power on/off the monitor.
3	~	Power indicator	Indicator on: this monitor is connected to AC power supply. Indicator off: this monitor is disconnected from AC power supply.
	▭	Battery indicator	Indicator solid on: battery is being charged. Indicator blinks: battery is used to supply power to the monitor. Indicator off: battery is fully charged, is not installed or malfunctions.
4	⚠	Alarm Pause key	Press this key to pause or resume an alarm.
5	⋈	Waveform Freeze key	Press this key to freeze or unfreeze a waveform.

6		Record key	Press this key to start or stop recording.
7		NIBP measurement key	Press this key to start or stop NIBP measurement.
8		Main menu key	Press this key to open/close the main menu.
9	Rotary knob: turn the rotary knob clockwise and counter-clockwise to move the focus; press down the rotary knob to perform an action.		
10	Product model		

Fig 2-3 STAR8000H Front View

1		Alarm indicator	
2	~	Power indicator	Indicator on: this monitor is connected to AC power supply. Indicator off: this monitor is disconnected from AC power supply.
		Battery indicator	Indicator solid on: battery is being charged. Indicator blinks: battery is used to supply power to the monitor. Indicator off: battery is fully charged, is not installed or malfunctions.
3	☉/Ò	Power on/off key	Use this key to power on/off the monitor.
4		Alarm Pause key	Press this key to pause or resume an alarm.
5		Waveform Freeze key	Press this key to freeze or unfreeze a waveform.

6		Record key	Press this key to start or stop recording.
7		NIBP measurement key	Press this key to start or stop NIBP measurement.
8		Main menu key	Press this key to open/close the main menu.
9	Rotary knob: turn the rotary knob clockwise and counter-clockwise to move the focus; press down the rotary knob to perform an action.		
10	Product model		

2.2.2 Left View

TEMP1 jack

ECG cable jack

IBP1 jack

CO$_2$ jack

TEMP2 jack

Comen SpO$_2$ sensor jack

IBP2 jack

NIBP cuff jack

Masimo/Nellcor SpO$_2$ sensor jack
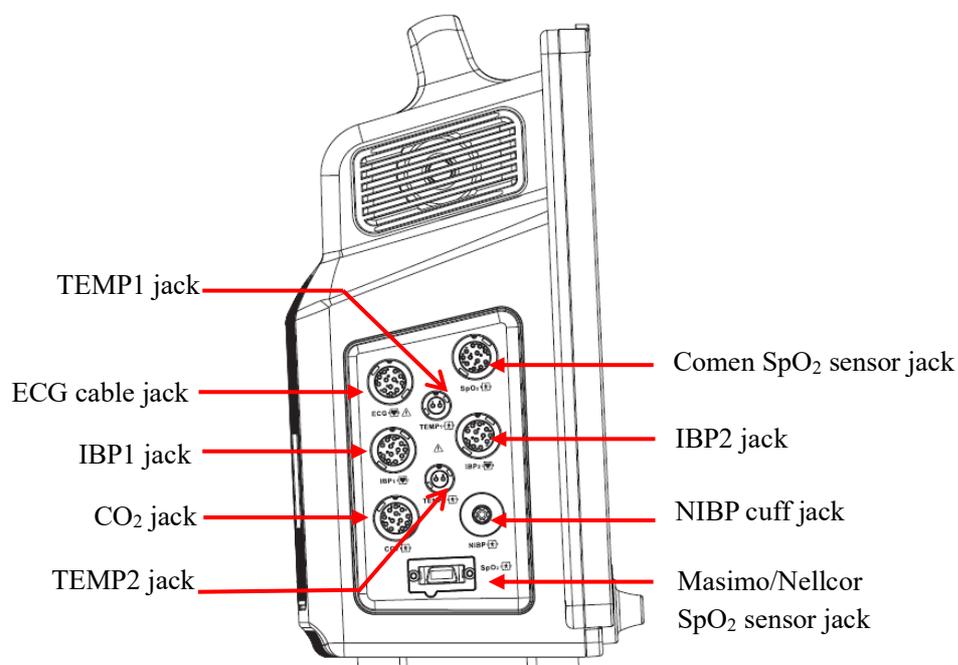
Fig 2-4 STAR8000E/STAR8000F Left View

Temp1 jack

ECG cable jack

IBP2 jack

CO$_2$ jack

Temp2 jack

Comen SpO$_2$ sensor jack

IBP1 jack

NIBP cuff jack

Masimo/Nellcor SpO$_2$ sensor jack
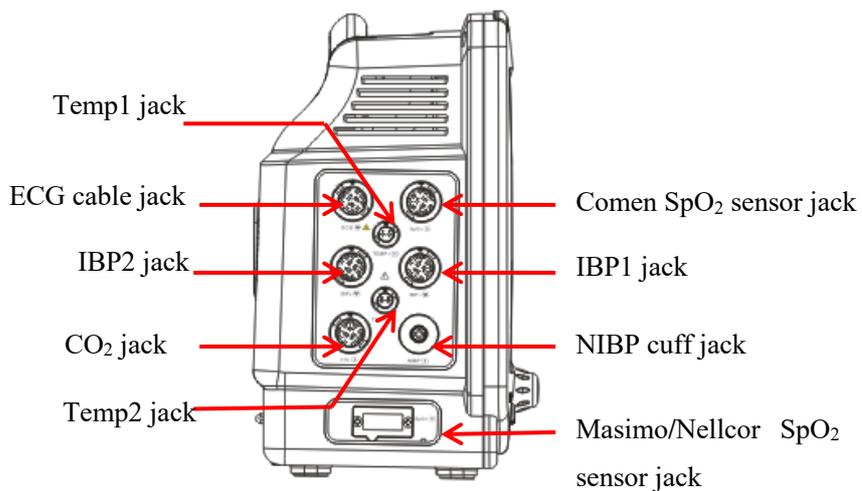
Fig 2-5 STAR8000H Left View

2.2.3 Right View

Recorder
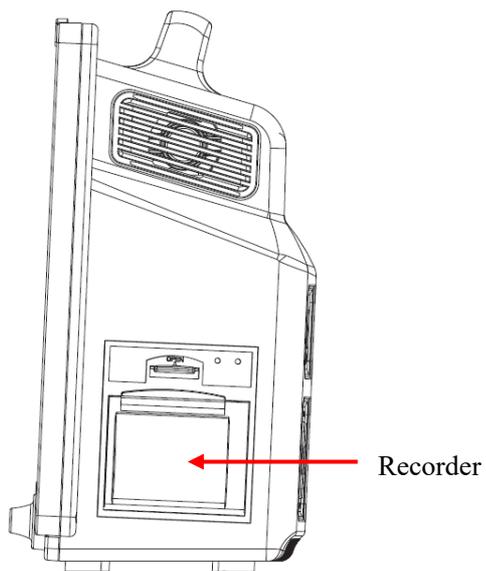
Fig 2-6 STAR8000E/STAR8000F Right View

Recorder
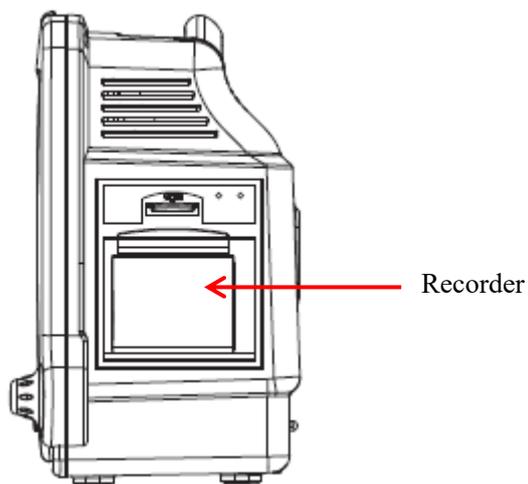
Fig 2-7 STAR8000H Right View

2.2.4 Rear View
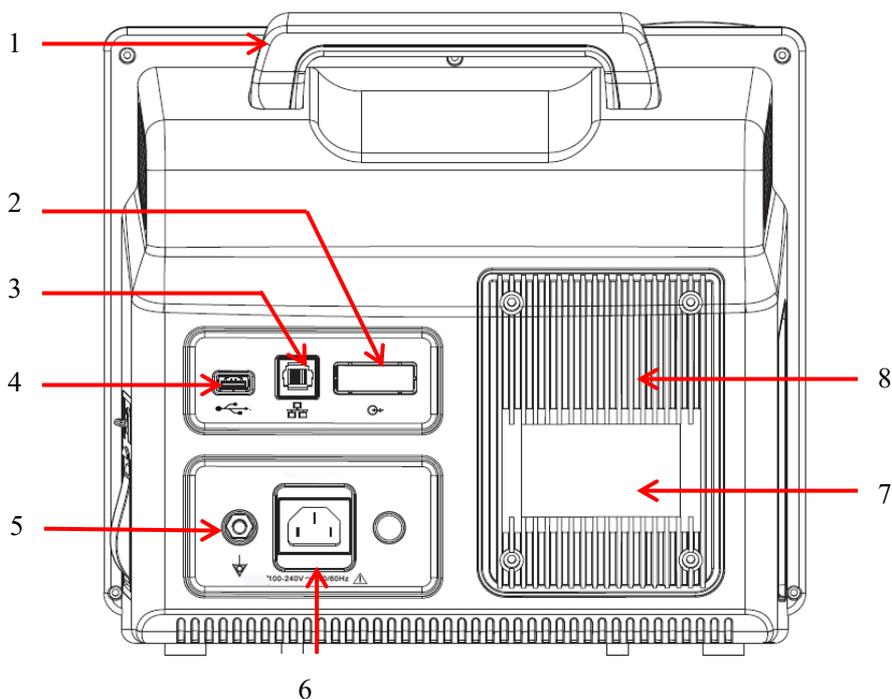
Fig 2-8 STAR8000E/STAR8000F Rear View

1) Handle

2) Multi-function connector: 1. As defibrillation synchronization port: outputs defibrillation synchronization signal; 2. As analog output port: outputs analog signals; 3. As nurse call port: connected to the hospital's

calling system to give nurse call prompts in case of an alarm.

3) Network port: connected to the central monitoring system via network cable.

4) USB port: supporting mouse, keyboard, printer and other USB devices (plug and play)

5) Equipotential jack: When the monitor is used together with another device, use a wire to connect the equipotential terminals of the monitor and that device. This eliminates the ground potential difference, thus to ensure safety.

6) Power socket

7) Nameplate

8) Battery
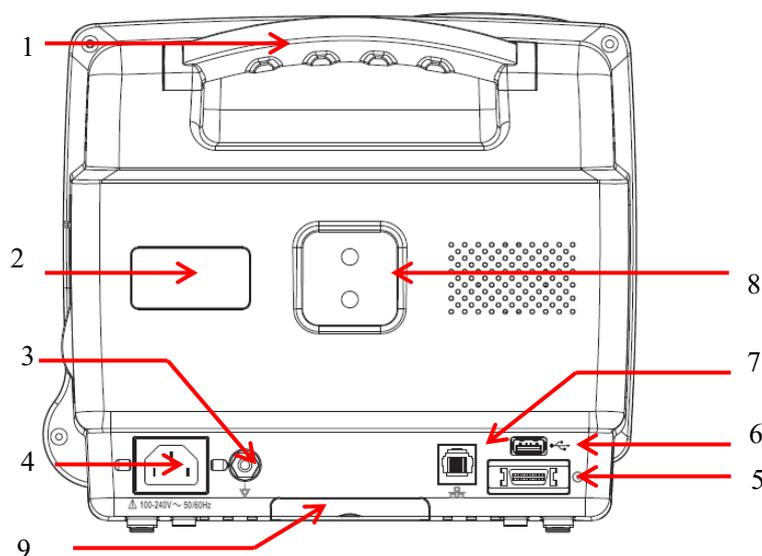
Fig 2-9 STAR8000H Rear View

1) Handle

2) Nameplate

3) Equipotential jack: When the monitor is used together with another device, use a wire to connect the equipotential terminals of the monitor and that device. This eliminates the ground potential difference, thus to ensure safety.

4) Power socket

5) Multi-function connector: Defibrillation synchronization; Analog output; Connected to the hospital's calling system to give nurse call prompts in case of an alarm.

6) USB port: supporting mouse, keyboard, printer and other USB devices (plug and play).

7) Network port: connected to the central monitoring system via network cable.

8) Wall-mounted rack

9) Battery

> ⚠ **Warning**
>
> - Only the analog or digital equipment in compliance with the specified IEC standards (like IEC 60950 for data processing equipment's, IEC 60601-1 for medical equipment, etc.) are allowed to be connected to the monitor. And all configurations should comply with the valid version of the system standard IEC 60601-1. The person who connects external equipment to the signal I/O ports should configure the medical system and ensure the medical system complies with IEC 60601-1-1 standards. If you have any question, please contact the supplier.
> - In normal use, the operator does not touch the signal I/O ports and the patient simultaneously, otherwise patient injury may result.
> - If more than one external equipment is connected to the monitor at one time through the patient cable socket, network connector or other signal interfaces, the total leakage current should be compliant with the specified in IEC 60601-1.

2.3 OSD (On-screen Display)

Touch screen is not available on STAR8000E. It is available on STAR8000F/STAR8000H for touch operation. This monitor uses a backlit LCD color screen which can simultaneously display physiological parameters, waveforms, alarm message, clock, network connection status, bed number, battery level and other prompt messages.

The main screen is divided into four areas: 1. Message prompt area (upper menu bar); 2. Parameter area; 3. Lower menu bar; 4. Waveform area. See the figure below:
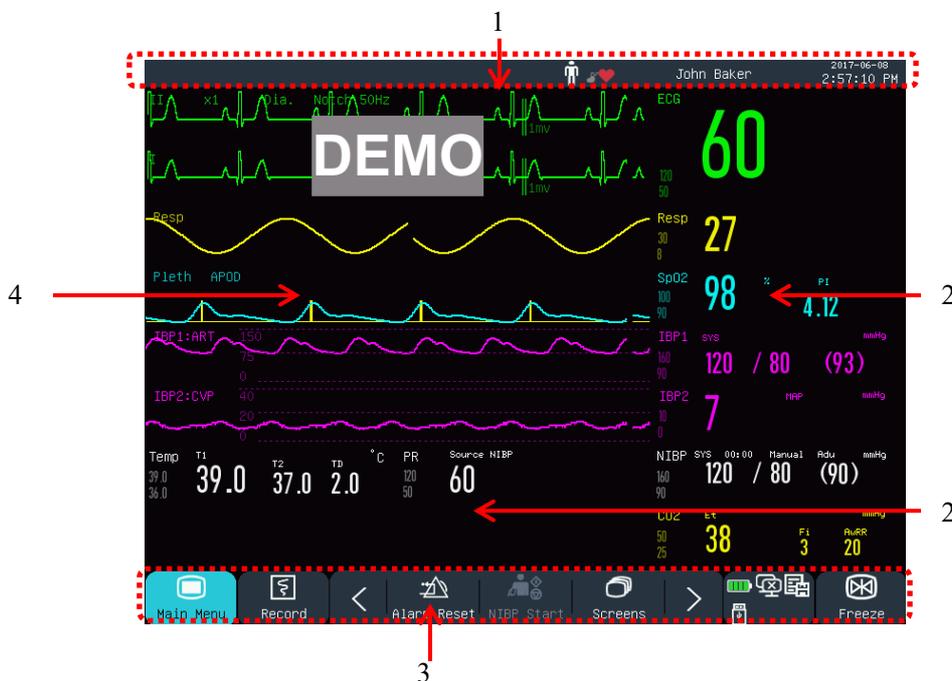
Fig 2-10 Home Screen

Prompt Message Area (1):

This area includes the following sections from left to right:

a) Physiological alarm message:

Display the current physiological alarm (for example: ***RR TOO HIGH). When there are multiple physiological alarms, each alarm message will be displayed in turn. Click on the message to enter the [View Physiological Alarm] window.

b) Technical alarm message:

Display the current technical alarm (for example: ECG LEAD OFF). When there are multiple technical alarms, each alarm messages will be displayed in turn. Click on the message to enter the [View Technical Alarm] window.

c) Prompt icons: Alarm Pause icon ⚠, Alarm Mute icon ⚠.

d) Patient info: Display the patient name, type, and pacemaker status. Click the patient info to enter the [Patient Manage] menu.

For patients with implanted pacemakers, when [Pace] (Pacemaker) in the [Patient Info] menu is enabled, ❙ mark is shown above ECG waveform, and 💓 icon is shown at the upper right corner of this area; when [Pace] (Pacemaker) is disabled, there will be no message prompt.

e) Clock: Show the current system time of the monitor. You can enter the [Time Setup] menu to reset the system clock according to your local time zone.

Parameter Area (2):

- Measured parameters are displayed in this area.
- The parameter is displayed in the same color with the corresponding waveform.
- Click a parameter to open the corresponding setup menu.

Lower Menu Bar (3):

The lower menu bar contains shortcut keys. Depending on configuration of the monitor, different shortcut keys are displayed in this area.

Fig 2-11 Lower menu bar

1	Scroll leftward/rightward to show more shortcut keys
2	Monitor setup area: Central Monitoring System (CMS) status, WIFI connection status, SD card status, battery status, USB drive status

CMS: ![icon] indicates successful connection with CMS; ![icon] indicates no connection with CMS.

USB drive: ![icon] indicates a USB drive is plugged in; this icon disappears when the USB drive is plugged out.

WIFI: ![icon] indicates unsuccessful WIFI connection; ![icon] indicates successful WIFI connection. No icon is shown when the WIFI function is disabled.

Battery status ![icon] : shows the remaining battery power and charging/discharging status.

SD card: ![icon] indicates no SD card is plugged in; ![icon] indicates a SD card is plugged in.

Waveform Area (4):

- 8 waveforms can be displayed, with the name of each waveform shown on the left side above the waveform.
- Click a waveform to open the corresponding setup window.

Chapter 3 Installation

> ⚠ **Note**
> ● To ensure normal operation of the monitor, read this chapter and *"Safety Information"* and *"Patient Safety"* carefully prior to installation of the monitor.

3.1 Unpacking and Inspection

Carefully take the monitor and its accessories out of the packing box and check each of the following points. For any problem or inconsistency, contact Comen or your distributor at once.

1. Check whether all accessories are provided according to the Packing List.

2. Check for damage.

3. Check all exposed lead wires and connectors.

Keep the packaging materials properly for future use.

3.2 Connection of AC Power Cord

Make sure the AC power supply conforms to the following specification: 100~240V, 50/60Hz±1Hz.

Connect one end of the power cord supplied with the monitor to the power socket on the monitor, and insert the other end to a grounded power outlet.

> ⚠ **Note**
> ● Use a medical grade power strip.
> ● When a battery is provided, the battery must be charged after transportation or storage. If the battery is low, startup of the monitor may fail without connecting an AC power supply.
> ● Once connected to an AC power supply, the battery will be charged until it is fully charged.

Connect the equipotential conductor when necessary. See the content about equipotential earthing in the "*Patient Safety*".

3.3 Startup

STAR8000E/STAR8000H:

After the power switch is turned on, the monitor enters self-test process. The red light turns on for 1 second, then the yellow light turns on for 1 second. After the Comen logo is displayed, the monitor shows the main interface, with a "beep" sound indicating the startup has been completed.

STAR8000F:

After the power switch is turned on, the monitor enters the self-test process. The red light and cyan light are on simultaneously for 1s; then the cyan light continues to be on for 1s and the yellow light is on for 1 s at the same time; after that, the company logo is displayed; with a "beep" sound, the monitor shows the main interface.

Prior to patient monitoring, confirm that the monitor is free from mechanical damage and that cables and accessories are correctly connected.

> ⚠ **Note**
> - **The system gives an alarm when a critical error is detected in the self-test.**
> - **Check all monitoring functions to ensure that the monitor can function normally.**
> - **The battery must be charged after each use to ensure sufficient battery power is available.**
> - **After shut-down, in order to extend its service life, wait for at least 1 minute before you restart the monitor.**

> ⚠ **Warning**
> - **If any evidence of failure or any error message is found, Do not use this monitor. Contact a service engineer of Comen or a technician in your hospital.**

3.4 Connection of Sensors

Connect the sensors to the monitor and the patient according to the detailed description in the relevant chapters.

Chapter 4 Patient Safety

4.1 Safety Instructions

This monitor is designed in accordance with international safety standards for medical electrical equipment. It is provided with defibrillation-proof and electrosurgical protection with floating ground. Use correct electrodes (see the chapter "*ECG Monitoring*") and apply them according to the manufacturer's guidance.

4.2 Environmental Requirements

Please observe the following instructions to ensure absolute safety of electrical installation.

The monitor should be used in an environment that can reasonably avoid vibration, dust, corrosive or explosive gases, extreme temperature and humidity, etc.

When the monitor is installed in an enclosed space, make sure the space is well ventilated. Leave at least 2 inches (5cm) free space around the monitor for air circulation. Also, leave sufficient space around it for easy operation and maintenance.

The monitor should be stored and operated within the ambient temperature of -20°C ~+60°C and 0°C ~40°C respectively. Hostile ambient temperature may affect the precision and accuracy of the monitor, and cause damage to the components and circuits.

4.3 Protective Earthing

To protect both the patient and the operator, the housing of the monitor must be earthed. The monitor is supplied with a detachable 3-prong power cord, which shall be inserted into a grounded power outlet to connect the monitor to the earth. If grounded power outlet is not available, contact the electrician in your hospital.

⚠ **Warning**
- **It is forbidden to connect the 3-prong power cord to a 2-prong power outlet.**

Connect the earth wire to the equipotential connector of the monitor. If you have doubt about whether devices used together involves any electrical risks, such as risk caused by accumulation of leakage current, consult an expert in this field to ensure the safety of all devices.

4.4 Equipotential Earthing

The monitor must be connected to a power supply with protective earthing. For cardiac or cerebral examination, the monitor must be separately connected to an equipotential earthing system. Connect one end of the equipotential conductor (potential equalization conductor) to the equipotential connector on the rear panel of the monitor, and connect the other end to a connector of the equipotential earthing system. In the event that the protective earthing system is damaged, the equipotential earthing system can provide protection to the monitor. Cardiac (or cerebral) examination can only be performed in a room installed with a protective earthing system. Before each use, check whether the monitor is in normal working status. Cables connecting the patient to the monitor cannot be tainted with electrolyte.

⚠ **Warning**

- **If the protective earthing system is not stable, use the built-in battery to supply power to the monitor.**

⚠ **Note**

- **If the use of the instrument is affected by equipotential earthing, contact the Company's After-sales Service Department or agents.**

4.5 Condensation

Ensure that the monitor is free from condensation during operation. When the monitor is moved from one room to another, condensation may be formed due to exposure to damp air and temperature difference. In this case, do not use the monitor until it gets dry.

> ⚠️ **Note**
> ● **The distance between the operator and the monitor should be less than 1 m so that the operator can observe the monitor easily.**

5.1 Enter Main Menu

Select Main Menu on the screen or press the ⬛ key on the front panel to enter the [Main Menu] window, where you can set up system menus easily. See the figure below:

Fig. 5-1 Main Menu

1. ✕ button: Press this button to exit the current menu.

5.2 Enter User Maintain Menu

Enter [Main Menu] → [Maintain]. Enter the correct password in the pop-up [Password] dialog to enter the [User Maintain] menu.

5.3 View Monitor Info

Enter [User Maintain] → [Monitor Info] (Monitor Information). Monitor info includes software and hardware version, etc., which facilitate the manufacturer to maintain and trace the monitor.

5.4 Enter Parameter Setup Window

You can set up parameters displayed on the screen after entering the setup windows in the following ways:

■ Via waveform area: Click a waveform to open the corresponding setup window. For example, you can click ECG waveform to open [ECG Wave] window.

■ Via parameter area: Click a parameter to open the corresponding setup window. For example, you can click in the ECG parameter area to open the [ECG Setup] window.

■ Via [Parameter Setup] menu: Press the [Parameter Setup] shortcut key (or enter [Main Menu] → [Parameter Setup]) to open the [Parameter Setup] menu, in which you can select and set up the desired parameter.

5.5 General Setup

5.5.1 Time Setup

Enter [User Maintain] → [Time Setup]. Set up the system clock according to the local time zone, including Year, Month, Day, Hour, Minute (Min), Second (s), Date Format, and Time Format. The settings become effective immediately.

5.5.2 Language Setup

Enter [User Maintain] → [Language]. Select the user interface language that you want.

5.5.3 Measurement Unit Setup

Enter [User Maintain] → [Unit Setup]. Set up the units you want to use for parameters, including [Height Unit], [Weight Unit], [Press Unit] (Pressure Unit), [CVP Unit], [Temp Unit] and [CO_2 Unit].

5.5.4 Shortcut Key Configuration

You can modify shortcut keys on the lower menu bar as needed.

Enter [User Maintain] → [Quick Key Config] to open the menu, as shown in the figure below:
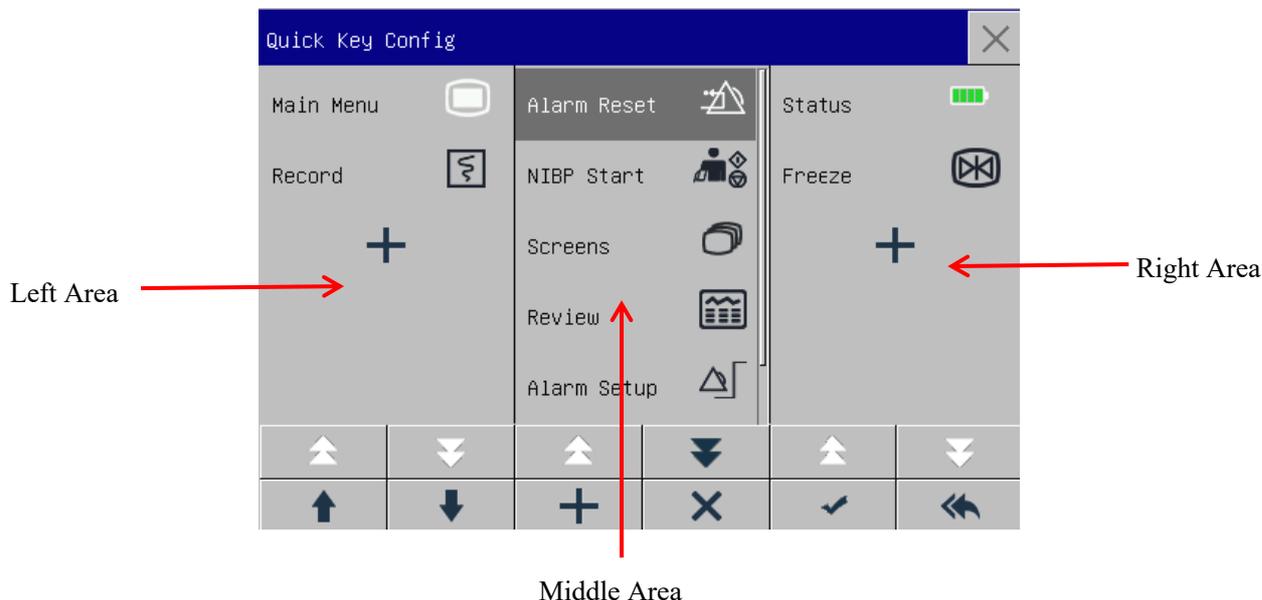
Fig. 5-2 Quick Key Config menu

Three shortcut key areas respectively represent the left, middle and right section of the lower menu bar on the screen.

Click ➕ to open the [Quick key] menu, in which you can select the shortcut keys you want to add. After you have added the shortcut keys, click ✔ to confirm.

⏫⏬	Page up/down to show the hidden shortcut keys.
⬆⬇	Move up/down a shortcut key.
✖	Delete a shortcut key
⏪	Click this key and press the OK button to restore factory settings.

5.5.5 Brightness Setup

1) Enter [Main Menu] → [Screen Config] (Screen Configuration) → [Brightness].

2) Select the appropriate brightness level between 10 (the darkest) ~100 (the brightest).

5.5.6 Key Backlight Setup

In dark environment, you can turn on the backlight for the keyboard.

Enter [Main Menu] → [Screen Config] → [Key Light].

5.5.7 Screen Setup

Enter [Main Menu] → [Screen Config] → [Screen Layout]. In this window, you can adjust the position of waveforms and parameters. Only parameters that have been turned ON are shown on the screen.
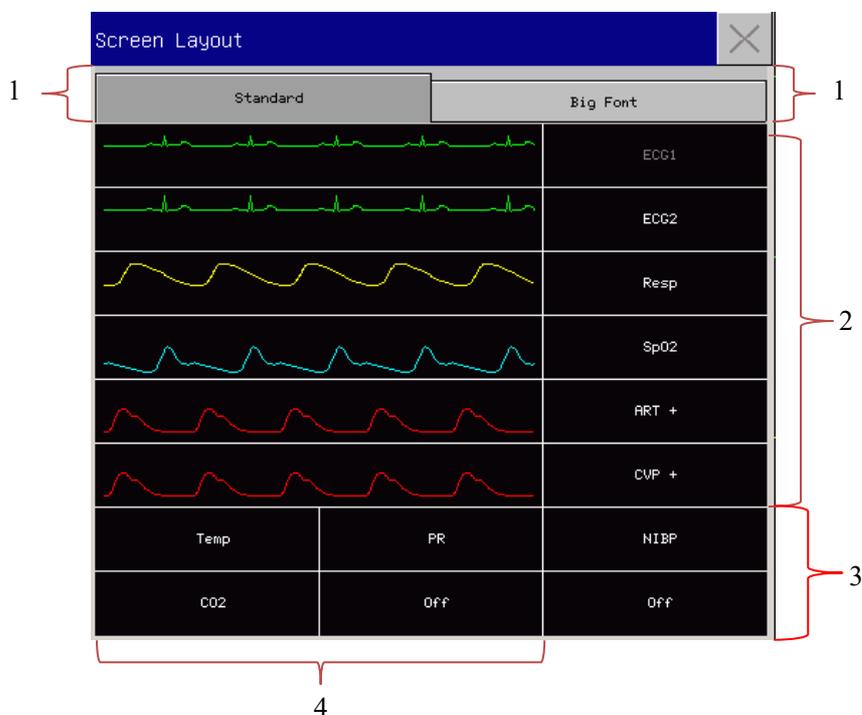
Fig. 5-3 Screen Layout

The first line of this window always shows the first ECG waveform and parameter.

1)   Font size: You can select between [Standard] or [Big Font].

2)   Waveform area: Waveforms are displayed on the left and parameters on the right. The waveform and its corresponding parameter are shown on the same line.

3)   In area 3, you can set waveform and parameter. If a particular line in the area 4 has no parameter, the corresponding line in area 3 will display parameters and waveforms at the same time.

4)   Parameters without waveform: Only data are displayed for parameters in this area.

After layout setup, click ✕ at the upper right corner of the [Screen Layout] window to exit.

5.5.8 Volume Setup

QRS Volume characteristic: beep

Beat Volume characteristic:beep

Click the [Volume Setup] shortcut key, or enter [Main Menu] → [Volume Setup].

1)   Select [Alm Vol] (Alarm Volume): Select the appropriate volume level between X (the lowest volume,

which depends on the setting of the Minimum Alarm Volume) and 10 (the loudest volume). See the "Alarms" chapter for details;

2) Select [QRS Vol] (QRS Volume): Select the appropriate volume within 0~10;

3) Select [Beat Vol]: Select the appropriate volume within 0~10;

4) Select [Key Vol]: Select the appropriate volume within 0~10.

5.5.9 Waveform Freeze

To freeze all waveforms on the screen, click the Freeze shortcut key on the lower menu bar of the screen, or directly press the Freeze button ⊠ on the front panel of the monitor.

Fig. 5-4 Freeze Screen

In the [Freeze] window, use the Forward or Backward key (or use the rotary knob to select the Forward or Backward key and turn the knob) to move the frozen waveform leftward or rightward. A down arrow is shown on the right side above the top waveform, with a time scale displayed to the left of the arrow. The freeze time is marked as [0s↓]. With the leftward movement of the waveform, the time scale will change to [-1s↓], [-2s↓], [-3s↓]... in sequence, indicating how many seconds ago the waveform currently displayed is plotted.

Record Frozen Waveform

In the [Freeze] window, select the waveform you want to print ([Wave1], [Wave2] or [Wave3]) and click the Record key. The recorder will start printing the frozen waveform.

Unfreeze

Click ⊠ at the upper right corner of the [Freeze] window.

Press the Freeze key on the front panel again.

5.5.10 Lock Screen Setup

Set the lock screen if you do not want to use the touch function. Long-press the main menu icon to lock the screen and display [Screen is locked! Long press main menu to unlock.] as a prompt at the lower left on the screen.

5.5.11 Event Setup

Event setup involves saving waveforms for manually triggered events. During patient monitoring, the occurrence of some events may have certain impacts on the patient, resulting in changes in some waveforms or parameters. You can select waveforms for manually triggered events in [Manual Trigger] settings. When an event is triggered, the monitor will mark it and save the corresponding waveforms. You can review the event later to analyze its impacts.

The steps are described below:

1) Enter [Main Menu] → [Event Setup].

2) Choose 3 waveforms from the available options as [Event Save Waves].

3) Enter remarks in the Remark area, if necessary.

4) Select [Manual Trigger]. [Manual Trigger Successful] will be shown at the bottom left of the screen.

5) To review a manually triggered event, select it in the [User Event] menu under [Alarm Event Review].

Fig. 5-5 Event Setup

5.5.12 Module Switch Setup

You can turn ON/OFF parameter modules as needed. When a parameter module is turned OFF, the corresponding waveform and parameter are not displayed on the screen, and the monitor stops measurement, analysis and alarm function for that module.

1) Enter [User Maintain] → [Module Switch Setup].

2) Turn ON/OFF a parameter in the Setup menu.

5.5.13 User Password Setting

Users can set the password for entering the "User Maintenance" according to their own needs.

Enter [User Maintain] → [Set User PassWord].

5.6 Work Mode

5.6.1 Monitoring Mode

Upon startup, the monitor automatically enters the monitoring mode for patient monitoring.

5.6.2 Standby Mode

If you don't want to shut down the monitor when there is no patient to monitor, click the [Standby] shortcut key to put the monitor into standby mode.

In standby mode:

✧ There is no alarm and waveform on the screen.

✧ Patient data is not saved.

✧ [Press any key to exit standby mode] is shown on the screen.

Press any key (except Power key) to exit the standby mode.

5.6.3 Night Mode

This monitor provides night mode to minimize disturbing the patient. After exiting this mode, the monitor will restore the settings before entering night mode.

To activate night mode:

1) Enter [Main Menu] → [Screen Config] → [Night Mode].

2)   The [Night Mode Setup] window pops up. Select [Night Mode] to enter this mode.

3)   Set up [Alm Vol], [QRS Vol], [Key Vol], [Brightness], and [Stop NIBP Measure].

To exit night mode:

1)   Enter [Main Menu] → [Screen Config] → [Night Mode].

2)   The [Night Mode Setup] window pops up. Select [Night Mode].

3)   The warning message [Exit Night Mode?] is displayed. Select [Yes] to exit night mode.

5.6.4 Privacy Mode

In order to protect patient privacy, the monitoring data is not displayed on the screen in this mode. It can be activated only under CMS (Central Monitoring System) monitoring.

To activate privacy mode:

Enter [Main Menu] → [Screen Config] → [Privacy Mode].

When privacy mode is activated:

1)   The message [In monitoring...press any key to exit privacy mode!] is shown on the monitor screen.

2)   The monitoring continues normally but the patient data can be viewed only on the central monitoring station.

3)   Alarms can still be triggered, but alarm sound and alarm light are available only on the central monitoring station.

4)   All system sounds of the monitor are muted, including QRS and beat sounds as well as various prompt tones.

The monitor exits from the privacy mode in any of the following conditions:

✧   You press any key (except Power key).

✧   The monitor is disconnected from the CMS.

✧   Battery level runs low.

5.6.5 Demo

Enter [User Maintain] → [DEMO] to put the monitor into demonstration mode.

⚠ **WARNING**
- **Demo waveforms are used to simulate the actual monitoring process. Demo mode can only be used to demonstrate the device performance and assist in training course. In actual clinical use, it is forbidden to use the demo mode, because medical workers may mistake the demo data for waveforms and parameters of the patient, which will put the patient in danger.**

Chapter 6 Configuration Management

6.1 Overview

For continuous monitoring of a patient, the monitor may require adjustment of some settings according to the actual patient conditions. The assembly of predefined settings used to operate the monitor is called a configuration. In order to configure the monitor more effectively and rapidly, this monitor provides a variety of configurations to meet the requirements of different patient types and different hospital departments. You can also customize a configuration according to actual conditions and save it as a user-defined configuration.

Configuration info of the monitor mainly includes:

Parameter Configuration

Settings related to parameter measurements, such as Wave Gain, Speed, Unit, Alarm ON/OFF, and Alarm Limit Setup.

General Configuration

The monitor's general settings, such as Alarm Setup, Screen Layout, and Record.

Maintenance Configuration

Settings related to maintenance, such as Wave Draw, Language, and Nurse Call.

For default system configuration, see Appendix V Default Configuration.

⚠ **Warning**

- **The Config Manage function is protected with password. It can only be operated and approved by professional medical workers.**

Enter the [Config Manage] menu:

1) Select [Main Menu].

2) Select [Config Manage], and enter the password.

[**Department**]: The department in which the monitor is used. When Department is modified, all user config files of the previous department will be deleted. Each department has 3 factory default configurations (ADU (Adult), PED (Pediatric), NEO (Neonatal)). At most 3 user-defined configurations can be saved to the department configuration directory. Before using the Config Manage function, ensure that the correct department is selected.

Department options: General (General Monitoring)

OR (Operation Room/Anesthesia Monitoring)

ICU (Intensive Care Unit)

NICU (Neonatal Intensive Care Unit)

CCU (Coronary Care Unit)

> ⚠️ **Note**
> - **Upon startup or to admit a new patient, you need to check the current configuration of the monitor. This can be viewed in [Load Config]. The configuration name marked with the symbol —> in front is the currently loaded configuration.**
> - **Use of different configurations on monitors in the same department (e.g., ICU or Cardiac OR) may result in danger.**
> - **Make sure the configuration you select is appropriate for the patient being monitored.**
> - **When the monitor is switched to another department, you need to admit the patient, change the patient type, and load the corresponding default factory configuration.**
> - **The monitor can memorize system configuration.**

[Save as User Config]: You can save the current configuration as a user config file by entering a config file name. The config file name can consist of alphanumeric characters or underscore (_), but cannot be empty. If the name you have entered is already used by another config file, the system will prompt whether you want to overwrite that config file. The system can save at most 3 user config files.

[Delete Config]: Delete user configs currently saved in the monitor. In this menu, all user config files saved under the current department are listed, with patient type in brackets added after each config file name. For example, John (ADU) indicates that the config file "John" is saved when the patient type is ADU.

[Load Config]: The monitor supports up to 6 configurations for one department. Configurations available for loading include the default factory configurations for the current patient type, user-defined configurations, and configurations imported from the USB flash drive. Patient type is marked after the user-defined configuration. After you load configurations, they will replace the current configurations and become effective.

Enter [Load Config]: enter [Main Menu] or [Config Manage] → [Load Config].

[Import Config from USB]: You can import configurations from a USB flash drive if there are less than 6 configurations for the current department in the system.

[Export Config to USB]: Export user-defined configurations in the system to a USB flash drive.

[Startup Configuration]: you can set up the configuration adopted by the monitor when it restarts.

But after the monitor powers off, the configurations will be set according to the following. With 120s after powering off, the monitor will automatically set the latest configurations; 120s later after powering off, the monitor will set the configurations according to [Startup Configuration].

6.2 Example

The operation steps of configuration management are described below, with the user-defined configuration [John] used as an example:

1) Enter [Main Menu] → [Config Manage]. Enter the user password to open the [Config Manage] menu.

Fig. 6-1 [Config Manage] Menu

2) In [Config Manage] menu, select [Department], and choose the appropriate department.
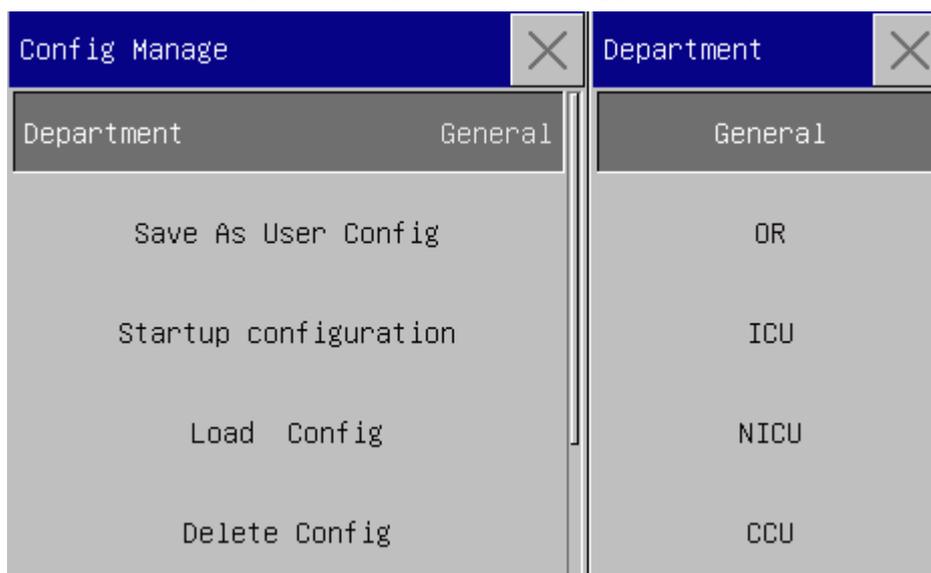
Fig. 6-2 [Department] Menu

3) In [Main Menu] or [Config Manage] menu, select [Load Config] and load a configuration. You can choose a default factory configuration or a user-defined configuration appropriate for the patient type.
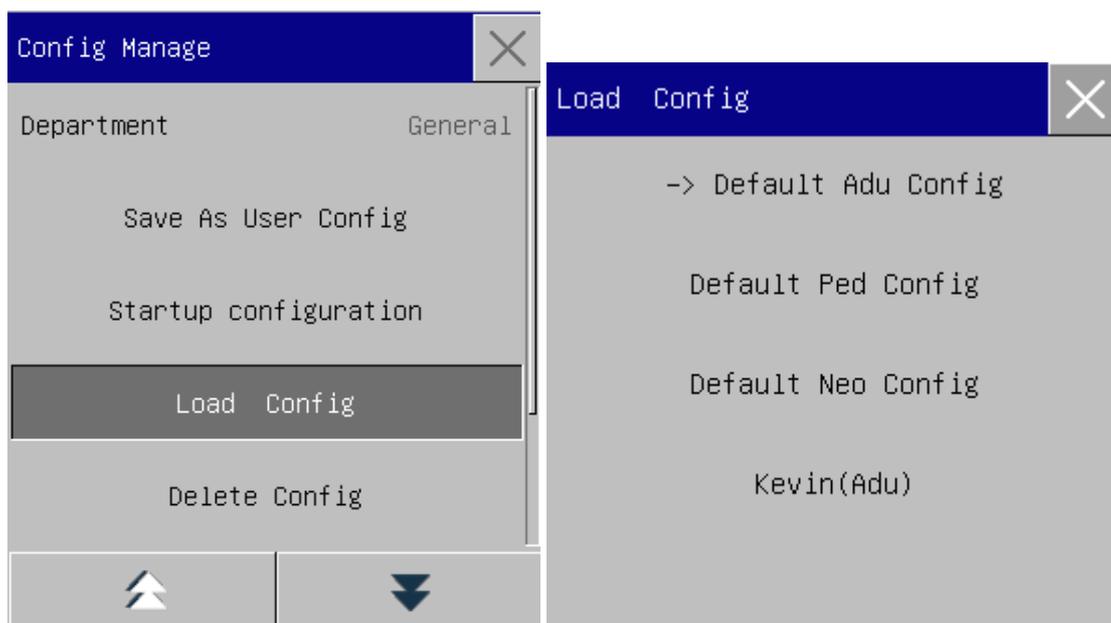
Fig. 6-3 [Default] Menu

4) User can get a user-defined configuration by modifying the current configuration used by the monitor. In [Config Manage] menu, select [Save As User Config] to enter the [Config Name] interface, as shown in figure below. Enter the file name [John], and press the Enter key to save it.
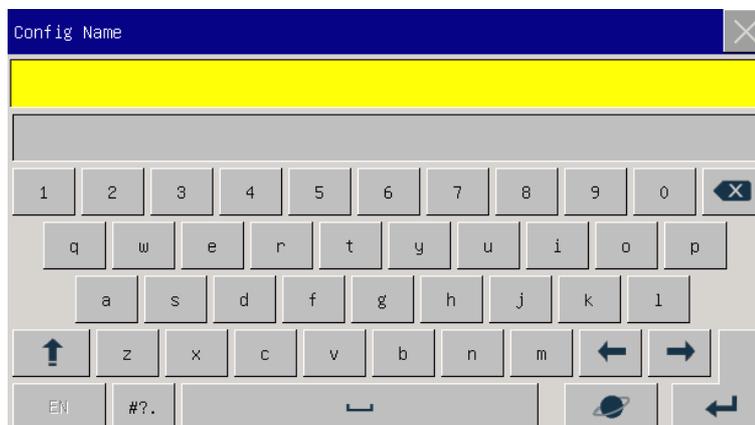
Fig. 6-4 [Config Name] Screen

5) In [Main Menu] or [Config Manage] menu, select [Load Config]. [John] will be shown in the list of configurations. You can select it or select from default factory configurations or other user-defined configurations.
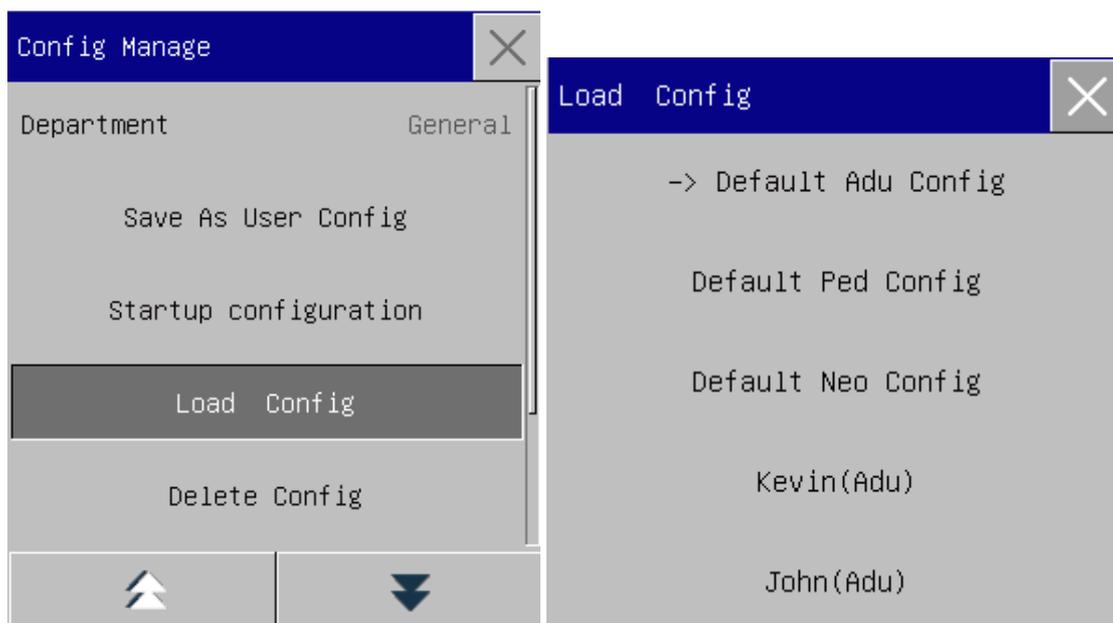
Fig. 6-5 [Load Config] Menu

6)   If this configuration is no longer needed, you can select [Delete Config] in [Config Manage] menu, and then select it in the configuration list to delete it.
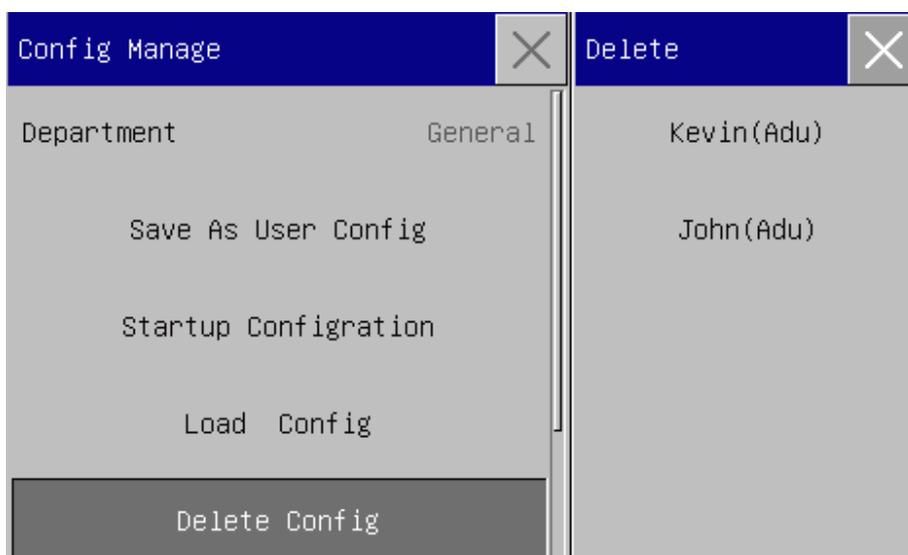
Fig. 6-6 [Delete User Config] Menu

7)   In step 5), you can also import a configuration from a USB flash drive.

Insert a USB flash drive containing config files to the USB port on the monitor. After the USB flash drive is recognized, select [Import Config from USB] in [Config Manage] menu, When [Import Succeeded] is shown at the bottom left of the screen, the imported configurations will appear in the list under [Load Config].

If an imported configuration is no longer needed, you can select [Delete Config] in [Config Manage] menu, to delete it.

If the inserted USB flash drive contains no user config file, the monitor will prompt [No User Config Exists].

Fig. 6-7 Import Config

8) User-defined configurations can also be exported to a USB flash drive for backup purpose.

Insert a USB flash drive, and select [Export Config to USB] in [Config Manage] menu, When [Export Succeeded] is shown at the bottom of the screen, the export is finished.

If no user-defined configuration exists in the monitor, when you select [Export Config to USB], the monitor will prompt [No User Config Exists].

Fig. 6-8 Export Config

9) You can set up the configuration adopted by the monitor when it restarts. In [Config Manage] menu, enter [Configuration on Startup] and select from [Use Last CFG], [Default Adu Config], [Default Ped Config], [Default Neo Config] or user-defined configuration.

Fig 6-9 Startup Configuration

Chapter 7 Patient Management

You can enter the [Patient Manage] menu in three ways: a) Enter [Main Menu] and select [Patient Manage]; b) Click the [Patient Manage] shortcut key on the lower menu bar; c) Click in the patient info area on the upper menu bar.

7.1 Admit

When a patient is connected to the monitor, the monitor can display and save the patient's physiological data even if the patient is not admitted. But correct patient admission is important for patient monitoring.

You can admit and discharge a patient in the [Patient Manage] window.

To admit a hospitalized patient:

1) Enter [Patient Manage] → [Admit].

2) If another patient has been admitted on the monitor, the prompt message [Discharge current patient & admit new patient?] will be shown. Select [Yes] to discharge the existing patient. If no patient has been admitted, the prompt message [Whether to apply the monitor data to the patient to be admitted?] will be shown.

   ➢ [Yes]: Apply the monitor data to the new patient.

   ➢ [No]: Clear the stored data on the monitor.

3) Enter patient info in the [Patient Info] menu. Pay attention that [Pat Type] (Patient Type) and [Pace] (Pacemaker) should be set up correctly. You can user EN or Handwriting input methods to enter information.

   ✧ [Pat Type]: the options include [ADU] (Adult), [PED] (Pediatric), [NEO] (Neonatal). It is essential to select the correct patient type, as it determines the algorithm used to calculate and process the patient data, as well as certain safety limits and alarm limits applied to the patient.

   ✧ [Pace]: This setting determines whether the monitor displays pacemaker pulse. When [Pace] is set to "ON" and pacemaker signal is detected, ❘ symbol will be shown above the ECG waveform, and ❤ will be shown at the upper right corner of the message prompt area. When [Pace] is set to "OFF", no prompt message or symbol will be displayed, and pacemaker pulse will be filtered out.

Fig. 7-1 Patient Info

> ⚠️ **Warning**
> - **No matter whether a patient is admitted, the monitor assigns a default value to both [Pat Type] and [Pace]. Make sure the settings in Patient Info are consistent with the patient's actual conditions prior to monitoring.**
> - **When the patient type is changed, the system will load the factory default configuration. Usually, the alarm limits should be verified before patient monitoring to ensure that these alarm limits suit your patient. When the patient type is not changed, the current configuration is not changed.**
> - **If the patient is not implanted with a pacemaker, [Pace] should be set to "OFF". Otherwise, the system cannot detect arrhythmia related to ventricular premature beats (including PVCs count), and ST segment analysis will not be carried out.**
> - **If the patient is implanted with a pacemaker, [Pace] should be set to "ON". Otherwise, pacemaker pulse may be counted as normal QRS wave, resulting in failure to detect the "ECG Lost" alarm.**

7.2 Quick Admit

The Quick Admit mode can be used in emergency situation when there is not enough time to fill in patient info. You must complete the patient info later.

1) Enter [Patient Manage] → [Quick Admit].

2) If another patient has been admitted on the monitor, the prompt message [Discharge current patient? Admit

new patient?] will be shown. Select [Yes] to discharge the existing patient. If no patient has been admitted, the prompt message [Apply the monitoring data to the patient to be admitted?] will be shown.

> ➢ [Yes]: Apply the monitor data to the new patient.

> ➢ [No]: Clear the stored data on the monitor.

3) Enter the [Patient Info] window, set up [Pat Type] and [Pace], and then close the window.

7.3 Discharge

To discharge a patient from the monitor:

1) Enter [Patient Manage] → [Discharge].

2) The system will give the prompt message [Discharge?].

> ➢ [Yes]: Discharge the current patient. The patient data monitored will be archived automatically if the monitor is mounted with a SD card. You can review the archived patient data in [Pat File Manage].

> ➢ [No]: Cancel the discharge operation.

⚠ **Warning**
- **After the patient is discharged, [Pace] will be automatically set to OFF.**

7.4 Patient File Management

You can inquire, review, delete and export archived patient files in Pat File Manage (Patient File Management). However, patient files cannot be archived if the monitor is not mounted with a SD card.

[Query]: Enter the patient name in the field at the lower left corner of the [Pat File Manage] window and click [Query] to search for the patient's file.

[View]: Select the patient info bar you want to review. Click [View] to open [Review] menu, in which you can view [Patient Info], [Trend Review], [NIBP Review], [Alarm Event Review] and [Wave Review].

[Delete]: Delete the selected patient file.

[Export]: Export the selected patient file to a USB flash drive or PC.

The operation steps of patient file management are described below:

1) Enter [Main Menu] → [Pat File Manage].

2) Enter a patient name in the input field at the lower left corner of the window.

3) Click [Query] the show the patient files found.

If there are multiple patient files found, click the ▲▼ keys to select the one you want to view; click the ◀ ▶ keys to show more information of the patient.

1) You can [View], [Delete] and [Export] the selected patient file.

2) When you check ☐ at the lower left corner, all patient files will be selected. At this time, you can click [Delete] to delete all patient files.

3) You can export patient files following these steps:

   ➢ If a single patient file is selected, select [Export] to open the [Data Export] menu.

      1) Set the [Start Time] and [End Time].

      2) Select [File Format]: options are .bin, .txt or .xls.

      3) Select [Export Media]: options are USB or FTP.

      4) USB: Export to a USB flash drive.

      5) FTP: Export to a FTP server via wired network.

      6) Select [Data Export] to start export. When it is finished, the prompt message [Data export succeeded, please restart.] will be shown.

   ➢ If multiple patient files are selected, operations steps are the same with those for single patient file except that [Start Time] and [End Time] cannot be set.

Fig. 7-2 Patient File Management

⚠ **Warning**
● **As for patient alarm messages, physiological and technical alarms are saved in the patient file.**

- **In the event of a power outage, alarm events can be saved in the patient file.**
- **When exporting data to a USB disk, do not remove the USB disk until the export process is completed in order to prevent data corruption.**
- **When exporting data to a FTP server, do not disconnect the network cable until the export process is completed in order to prevent data corruption.**

⚠️ **Note**

- **When the monitor is shut down, the data for the monitoring period before the shutdown will be saved automatically. Upon startup of the monitor, the system will automatically create a new period (i.e., current period data).**
- **The monitor allows data storage upon power failure.**

7.4.1 Save Tactics

The monitor creates a patient file and save its data even if no patient has been admitted. Such patient file is a blank Temp Case (Temporary Case), which can be automatically deleted in monitor settings. Also, the monitor can automatically delete old cases when the SD card is full.

1) Enter [User Maintain] → [Save Tactics];

2) Select [Auto Del Temp Case] and [Del old case] respectively, and switch them between "ON" and "OFF".

Chapter 8 User Interface

This monitor provides multiple user interface styles, such as Standard, Big Font, Trend, OxyCRG, List, View Bed, 7-Lead ECG, and 7-Lead Half Screen interfaces. You can select appropriate user interface styles according to different demands, so as to obtain different patient information on the screen. The waveform displayed on each channel is depending on the monitor configuration. You can also select the waveforms you want to display in the [Screen Layout] menu. This chapter introduces the characteristics of some work interfaces.

To select your desired user interface style:

1) Select the [Screens] shortcut key, or select [Screens] under [Main Menu].

2) In the [Screens] menu, select the desired interface.

8.1 Standard

The monitor shows the Standard interface by default. If all optional modules are equipped, this interface can display waveforms of at most 7 channels together with their parameters.
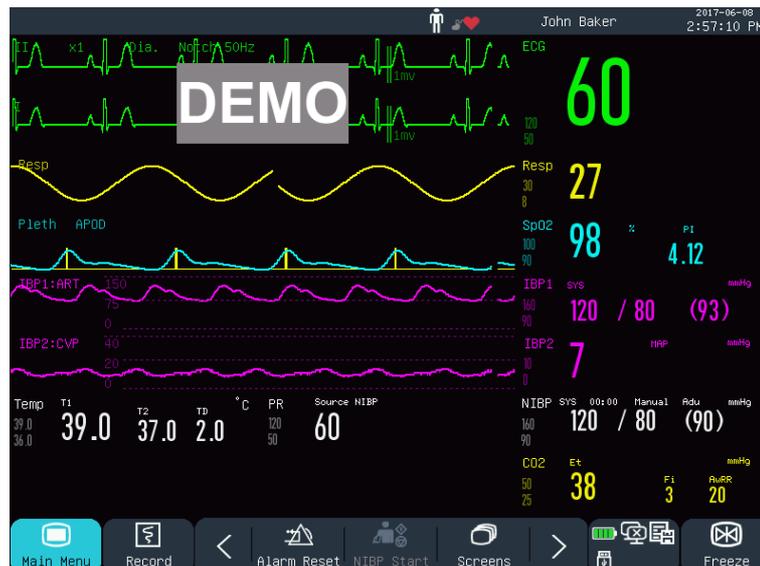
Fig. 8-1 Standard Interface

8.2 Big Font

In Big Font interface, parameters are shown in large font, so that you can see items on the screen within a certain distance. This interface can display four parameters and four waveforms.
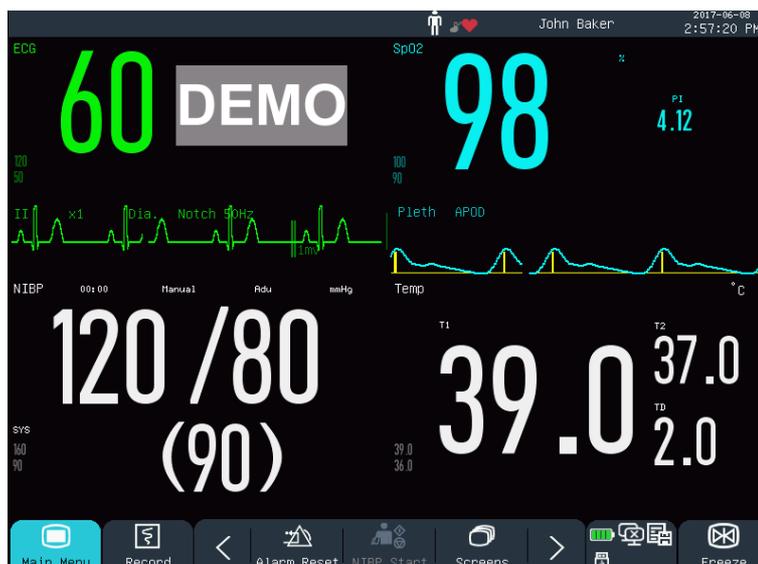
Fig. 8-2 Big Font Interface

8.3 Trend

The Trend interface displays the short-term trend graphs of a range of waveforms and parameters. In each trend graph, on the top is the trend name, on the left is the parameter scale, and at the bottom is the time scale.
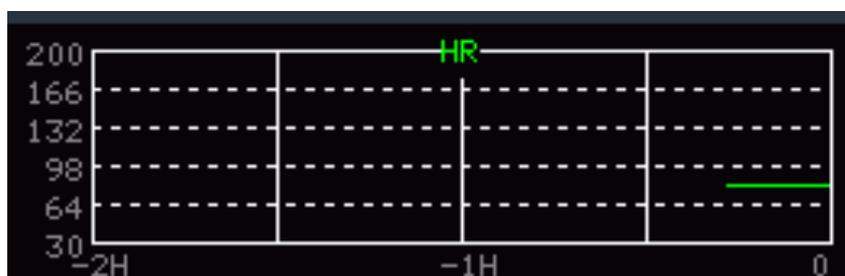
Fig. 8-3 Short-term Trend of HR

You can change trend graphs displayed on the screen.

Take the trend graph of HR for example. To change it to the trend graph of SpO2: select the trend graph of HR to enter the [Trend Setup] menu, and select [SpO2]. The short-term trend graph of SpO2 will be displayed at the same position.
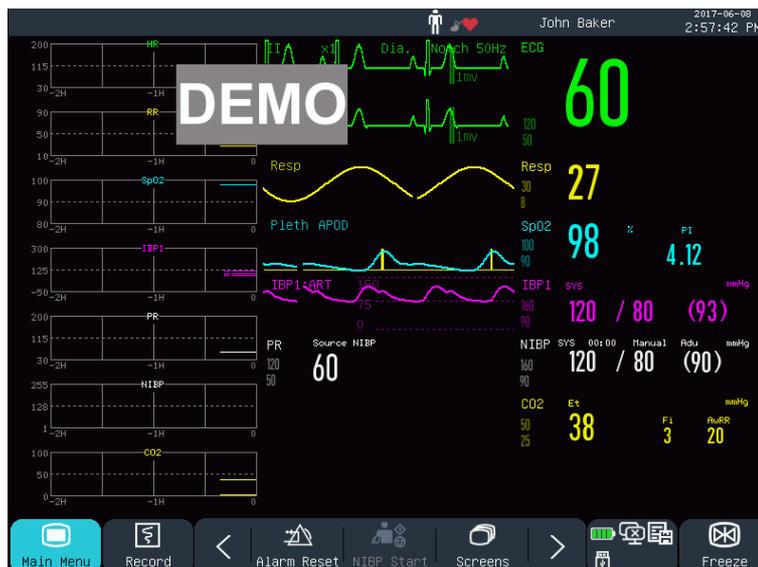
Fig. 8-4 Trend Interface

1) Position of trend graphs

Trend graphs are located to the left of the waveforms. The color of each trend graph is identical to that of the corresponding parameter. To change the position of a trend graph, select it to open the [Trend Parameter Setup] menu, and then select the new position in the [Module Exchange] option.

2) Trend period

Select a trend graph to open the [Trend Setup] menu. Select [Time] to set it to 30 min, 60 min, 120 min, 240 min, or 480 min.

8.4 OxyCRG

OxyCRG interface consists of HR trend graph, SpO2 trend graph and RR trend graph or Resp waveform.
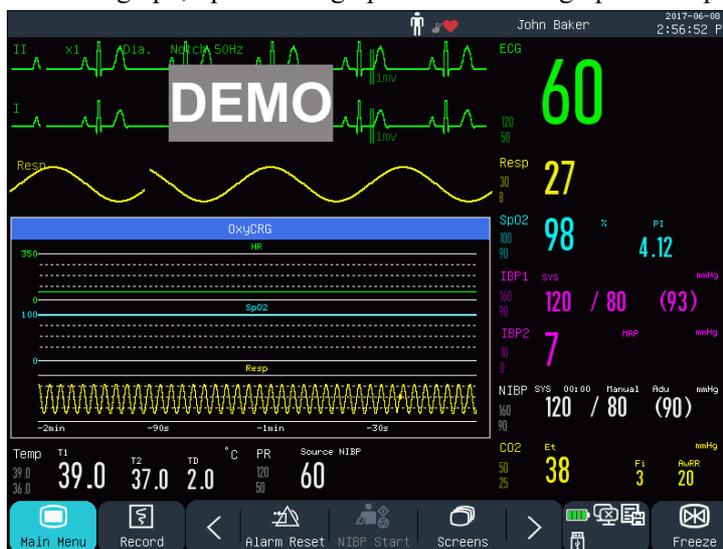
Fig. 8-5 OxyCRG Interface

1) Select the OxyCRG window to open the [OxyCRG] menu.

2) Select the time length of OxyCRG trend.

3) [Time] options include [1 min], [2 min], [4 min] and [8 min].

4) Select "RESP Wave" or "RR Trend":

8.5 List

The list interface occupies half of the waveform area. You can review recently measured parameters in this interface. 7 sets of data are displayed on each page.
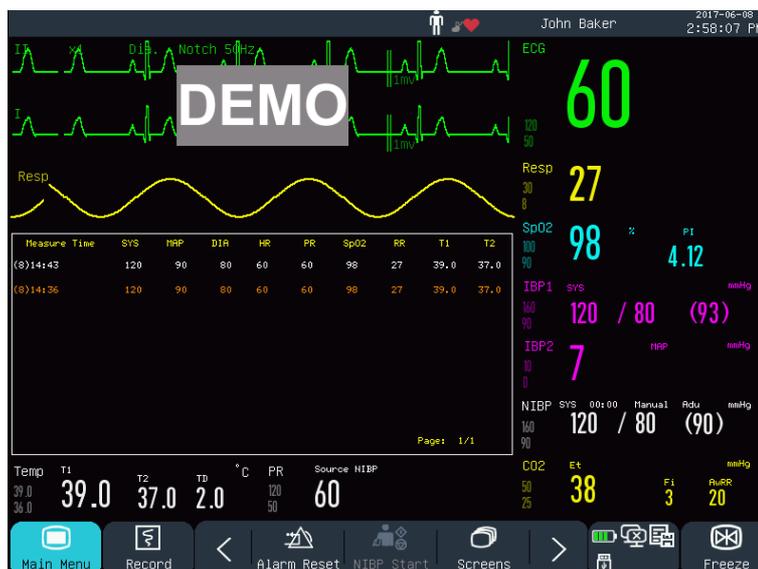
Fig. 8-6 List Interface

For example, you can select the NIBP list to enter the List View interface, in which you can view the measured data for NIBP parameters by pages.
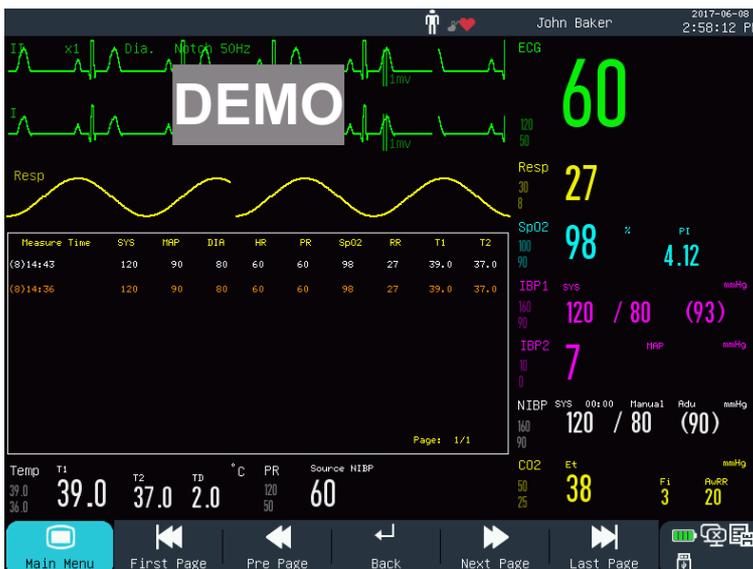
Fig. 8-7 List View Interface

8.6 View Bed

With the View Bed function, the monitor can display contents on the screen of another monitor connected to the central monitoring system (CMS).

⚠️ **Note**
● **This function is optional and only available between monitors provided by Comen.**

Fig. 8-8 [View Bed] Interface
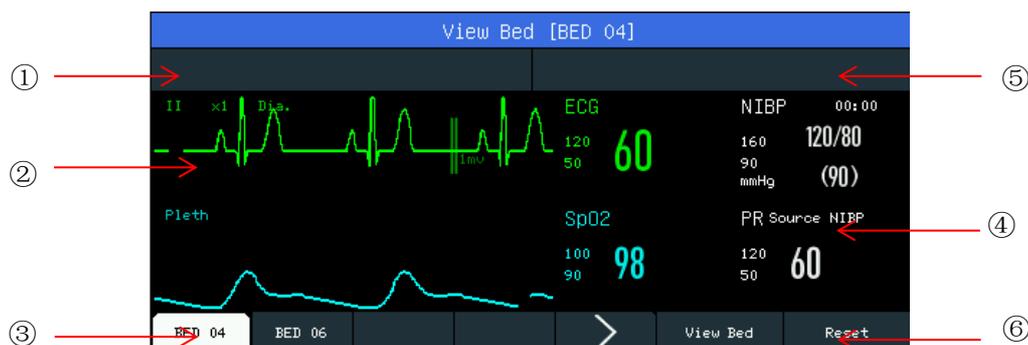
Fig. 8-9 [View Bed] Window

The View Bed interface includes:

①　Physiological alarm message area: When multiple alarm messages exist, each one will be displayed in turn.

②　Waveform area: You can select a waveform to open the setup window, and then set the waveforms to be displayed in the [Wave Exchange] menu.

③　Net Bed (Network Bed): You can monitor another bed by entering its bed number in the CMS system.

④　Parameter area: You can click in this area to open the setup window, and select other parameters to be displayed.

⑤　Technical alarm message area: When multiple technical alarm messages exist, each one will be displayed in turn.

⑥　Function keys:

[View Bed] - Select it to monitor another bed .

[RESET] - Select it to reset alarms of another bed monitor.

8.7 7-Lead ECG

When the lead type is 5-lead, you can select the 7-Lead ECG interface to show the waveforms of "I, II, III, AVR, AVL, AVF and V" leads. Other waveforms will not be displayed.
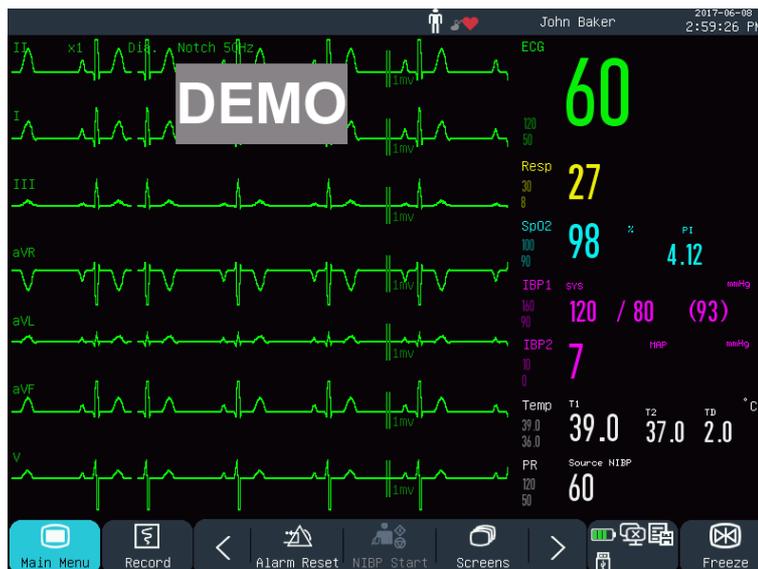
Fig. 8-10 [7-Lead ECG] Interface

8.8 7-Lead Half Screen

When the lead type is 5-lead, you can select the 7-Lead Half Screen interface to display the waveforms of "I, II, III, AVR, AVL, AVF and V" leads in the upper half of the waveform area.
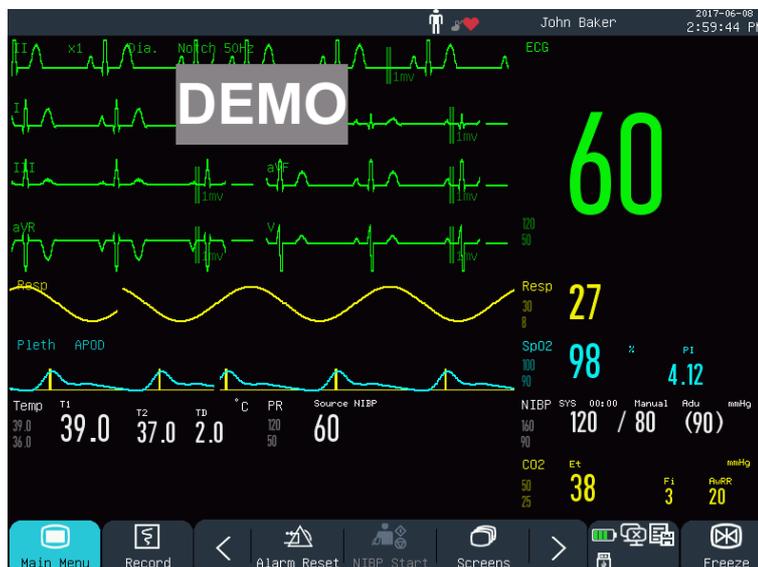
Fig. 8-11 [7-Lead Half Screen] Interface

8.9 Set Interface Style

You can set the interface style as needed, such as:

1)   Wave sweep speed.

2) Wave style.

3) Color of parameters and waves displayed.

4) Parameters shown on the screen.

You can set up the interface style for all parameters using the same method described in this section.

8.9.1 Set Wave Sweep Speed

1) In the Standard interface, select the waveform. For example: Select the ECG wave [II] or [I] → [ECG Wave] → [Sweep].

2) Select the appropriate sweep speed.

8.9.2 Set Wave Style

Enter [User Maintain] → [Wave Type] → [Thin], [Med] (Medium) or [Bold].

8.9.3 Set Module Color

1) Enter [User Maintain] → [Module Color].

2) In the [Module Color] menu, you can select a waveform and set its color to: [Red], [Orange], [Yellow], [Green], [Cyan], [Blue], [Purple] or [White].

8.9.4 Set Wave Draw

Enter [User Maintain] → [Wave Draw] → [Color], [Mono].

8.9.5 Set Wave Fill

1) Enter [User Maintain] → [Wave Fill Setup].

2) Select the parameter as needed.

8.9.6 Change Screen Layout

Enter [Main Menu] → [Screen Config] → [Screen Layout].

In the [Standard] window, you can set parameters and waveforms displayed on the screen. For detailed settings of [Screen Layout], see the *"Screen Setup"* section.

In the [Big Font] window, you can set parameters and waveforms displayed in the Big Font interface.

Chapter 9 Alarms

When a patient under monitoring has abnormal vital signs, or when failure occurs in the monitor, the system will give audio and visual alarm to remind the medical workers.

The alarm system functions in real-time monitoring mode. In standby mode, alarm sound and light will be disabled.

When there are multiple alarms and prompt messages, each message will be displayed in turn.

⚠ **Warning**
- **Use of different configuration on different monitors in one area (e.g., ICU or OR) may result in danger to the patient.**

9.1 Alarm Type

Alarms generated by the monitor are classified into physiological and technical alarms.

◆ Physiological alarm

A physiological alarm is generated when a certain physiological parameter of the patient is beyond the high/low alarm limit or the patient has physiological disorder. Physiological alarm messages are displayed in the physiological alarm area in the upper part of the screen.

◆ Technical alarm

A technical alarm, also known as a system error message, is triggered when a system function cannot work normally or the monitoring result is unreasonable due to improper operation or system failure. A technical alarm message is displayed in the technical alarm area in the upper part of the screen.

NOTE: In addition to physiological and technical alarms, the monitor also show messages about system status. Generally, these messages shown in the system message area are not related to vital signs of the patient.

9.2 Alarm Level

Physiological and technical alarms are classified into high, medium and low-level alarms by severity.

	Physiological alarm	Technical alarm
High-level alarm	The patient is in life-threatening, imminent danger (e.g., asystole, ventricular fibrillation/ventricular tachycardia), and emergency treatment should be carried out.	Serious device failures or mis-operations (e.g., low battery) may result in failure to monitor the critical conditions of the patient, which will threaten

		his/her life.
Medium-level alarm	Abnormality is detected in the patient's vital signs; treatment measures should be taken promptly.	Some device failures or mis-operation may not endanger the patient's safety, but will affect normal monitoring of vital physiological parameters.
Low-level alarm	Abnormality is detected in the patient's vital signs; treatment may be necessary.	Some device failures or mis-operation may result in certain malfunctions, but will not endanger the patient's safety.

The levels of all technical alarms (except ECG and SpO$_2$) and some physiological alarms have been set before delivery of the monitor and cannot be changed by the user. The levels of some physiological alarms can be modified.

9.3 Alarm Mode

When an alarm is generated, the monitor will use the following alarm modes to alert the user:

Light Alarm

Sound Alarm

Alarm Message

Blinking Parameter

For light alarms, sound alarms and alarm messages, the alarm levels are differentiated in the following ways.

9.4 Light Alarm

Two alarm indicators at the upper left corner of the monitor indicate alarm levels with different light colors and blinking frequencies.

STAR8000E/STAR8000H:

Physiological Alarm:

High-level: Red, blinking.

Medium-level: Yellow, blinking.

Low-level: Yellow, remaining on

Technical Alarm:

High-level: Red, blinking.

Medium-level: Yellow, blinking.

Low-level: Yellow, remaining on.

STAR8000F:

Physiological Alarm:

High-level: Red (Left light), blinking.

Medium-level: Yellow (Left light), blinking.

Low-level: Yellow (Left light), remaining on

Technical Alarm:

High-level: Red (Left light), blinking.

Medium-level: Yellow (Left light), blinking.

Low-level: Cyan (Right light), remaining on.

9.5 Sound Alarm

The monitor indicates alarm levels with alarm sounds with different intervals.

High-level: beep-beep-beep--beep-beep----beep-beep-beep--beep-beep

Medium-level: beep-beep-beep

Low-level: beep

> ⚠ **Warning**
>
> - **Both the bedside monitor and the CMS are provided with sound alarm function.**
> - **When this monitor is connected to the CMS, you can use the same upper and lower alarm limits for the monitor and CMS. But if you enable alarm delay on this monitor, it will not give alarm when the CMS has given an alarm.**
> - **When multiple alarms of different levels are generated simultaneously, the monitor will activate the warning sound and light for the highest-level alarm.**

9.6 Alarm Message

Alarm messages are shown in the physiological alarm area or technical alarm area on the screen.

Different marks are added in front of physiological alarm messages to indicate the alarm levels:

High-level: ***

Medium-level: **

Low-level: *

Different background colors are used to indicate the alarm levels:

STAR8000E/STAR8000H:

High-level: Red

Medium-level: Yellow

Low-level: Yellow

STAR8000F:

High-level: Red

Medium-level: Yellow

Low-level: Yellow (Physiological Alarm)/ Cyan (Technical Alarm)

9.7 Alarm Parameter Blink

When a parameter reaches the alarm limit, the parameter and its upper and lower limits will blink once every second, indicating the measured result is beyond the upper or lower limit.

9.8 Alarm Pause

You can press the ⊠ key on the control panel (or the [Alm Pause] shortcut key on the screen) to quickly enter the alarm pause state:

✧   Alarm sound, alarm light and alarm message are disabled for physiological alarms, and no physiological alarms will be triggered.

✧   The physiological alarm message area shows the prompt message "Alm Pause XXXs".

✧   Alarm sound and alarm light are disabled for technical alarms; if a new technical alarm is triggered, only text prompt will be given.

✧   In the event of the "Battery Too Low" alarm, the alarm will be resumed automatically to give alarm sound, alarm light and alarm message.

Every time the monitor is turned on, the system will enter the alarm pause state automatically. After the alarm pause time (set by user) expires, the monitor will cancel alarm pause automatically; user can press the ⊠ key (or the [Alm Pause] shortcut key on the screen) to cancel alarm pause.

Operation steps for alarm pause:

1)   Enter [User Maintain] → [Alarm Setup] → [Alm Pause Time].

2)   Set the appropriate pause time: [1min], [2min], [3min], [5min], [10min], [15min].

9.9 Alarm OFF

The Alarm OFF function is effective just for physiological alarms. When the Alarm OFF function is activated, the Alarm OFF sign ⊠ will be shown on the left side below the corresponding parameter in the parameter area:

✧   For physiological alarms, sound, light and text prompts will be disabled, and no new physiological alarms will be triggered.

Operation steps:

1) Click the parameter value area to open the Setup menu, and then select [Alarm Limit Setup]. You can also select the [Alarm Setup] shortcut key to directly enter [Alarm Limit Setup].

2) Select [All Alarm Off] to disable alarms against all parameters. If the alarm ON/OFF icon ON of a parameter is switched to "OFF", alarms for that parameter will be disabled.

To exit the alarm OFF state of all parameters, select [All Alarm On]; to exit the alarm OFF state of one parameter, switch the alarm ON/OFF icon ON of that parameter to "ON".

⚠ **Warning**

● **If the alarm function is set to "OFF", the monitor cannot trigger alarm when there is an alarm condition. Therefore, the operator should use this function with caution.**

9.10 Set Alarm Record

If the monitor is equipped with a recorder, the monitor will trigger output of the parameter waveform and value by the recorder if all the following conditions are satisfied: when data of a parameter is abnormal; the alarm switch is turned ON; and [Alm Record] is set to ON.

1) Enter [Main Menu] → [Alarm Setup] → [Alarm Record Setup].

2) Set [Alm Rec Time] to [8s] or [16s].

3) To activate alarm recording for a parameter, switch the alarm record icon ON to "ON"; to activate alarm recording for all parameters, select [All Rec. On].

4) User can switch the alarm record icon to "OFF" to deactivate parameters requiring alarm record; to deactivate all parameter alarm records, select [All Rec. Off].

9.11 Set Parameter Alarm

9.11.1 Set Alarm Limit

Colors of Alarm Limits

◆ Red represents high-level alarms

◆ Yellow represents medium-level alarms

◆ Cyan represents low-level alarms

Intelligent alarm gradation is a characteristic of our alarm system. For parameters of intelligent alarm gradation, user can simultaneously set the alarm limit ranges of high, medium and low-level alarms without setting alarm levels. When the measured parameter value is beyond the normal range, the monitor will automatically judge

which alarm level range the measured parameter value belongs to, and then will generate an alarm of the corresponding level.

For parameters of general alarms, user needs to set the alarm level and can only set the alarm limits corresponding to the alarm level selected. When the measured parameter value is beyond the normal range, the monitor will generate an alarm only according to the alarm level selected. Intelligent alarm gradation is available on ECG, NIBP, PR, AwRR and SpO_2 (excluding Nellcor SpO_2) and not available on other parameter.

For parameters subject to intelligent alarm gradation, the alarm limit setup methods are basically the same. Here ECG is taken as an example:

1) Select the ECG parameter area; enter the Setup menu → [Alarm Limit Setup].

2) Set the appropriate upper and lower limits for the parameter.

3) Switch the alarm ON/OFF icon to "ON".

4) When setting is finished, select the Confirm key .

For parameters subject to general alarms, the alarm limit setup methods are basically the same. Here RESP is taken as an example:

1) Select the RESP parameter area; enter the Setup menu → [Alarm Limit Setup].

2) Select the check box at the lower left corner of the Setup window for the corresponding parameter to switch the alarm level.

3) Set the appropriate upper and lower limits for the parameter under the current level.

4) Switch the alarm ON/OFF icon to "ON".

5) When setting is finished, select the Confirm key .

9.11.2 Set Auto Alarm Limit

The monitor can automatically set up the Auto Alarm Limits for the currently measured parameters according to the patient type.

Before applying these alarm limits, make sure they are appropriate for the patient. If not, you need to manually set the alarm limits.

⚠ **Note**
- **When resetting to default factory configurations, alarm limits of the parameters will also change. See Appendix V "Default Configurations" for details.**

⚠ **Warning**
- **When setting alarm limits to extreme values, the alarm system may be useless.**
- **When setting upper and lower alarm limits, make sure the patient type is correct (ADU, PED or**

> **NEO).**
> - **If you have set up the upper and lower alarm limits manually, the monitor will display these upper and lower alarm limits instead of the default alarm limits of the system.**
> - **After powering off accidentally, the equipment will save the latest setting with 120s after powering off, 120s later after powering off, the monitor will set the configurations according to [Startup Configuration].**

9.12 Set Alarm Delay

The system provides five options for parameter alarm delay: [Not Allowed], [5s], [10s], [15s] and [20s]. If [Not Allowed] is selected, when the measured parameter is beyond the alarm limit, the monitor gives alarm immediately. If [5s]/[10s]/[15s]/[20s] alarm delay is selected, the monitor gives alarm when the measured parameter has been beyond the alarm limit for 5s, 10s, 15, 20s, respectively.

NOTE: Alarm delay cannot be applied to ECG and IBP.

Operation steps:

1) Enter [User Maintain] → [Alarm Setup] → [Alarm Delay].

2) Set the appropriate delay time.

9.13 Set Alarm Volume

9.13.1 Set Minimum Alarm Volume

Do not set the minimum alarm volume too low; otherwise, you cannot hear the alarm sound, which may put the patient into danger. Follow the operation steps below to set up the minimum alarm volume:

1) Enter [User Maintain] → [Alarm Setup] → [Min. Alm Volume].

2) Set the appropriate value.

> ⚠️ **Note**
> - **When the alarm volume is turned down, the alarm sound may go unheard; therefore, the minimum alarm volume should be adjusted to be higher than environmental noise.**
> - **The sound pressure level of alarm sounds generated by this monitor is 45-85db.**

9.13.2 Set Alarm Volume

1) Enter [Main Menu] → [Volume Setup], or select the [Volume Setup] shortcut key.

2) Select [Alm Vol] in the pop-up menu.

3) Select the volume within the range of X~10. X represents the lowest volume, which depends on the setting of minimum alarm volume.

When the alarm volume is set to 0, the ⊠ icon will be shown in the message prompt area of the screen, suggesting sound is OFF.

4) Enter the [User Maintain] → [Alarm Setup]. Users can also set the "Advanced Alarm" and "Intermediate Alarm", which can respectively modify the volumes of the advanced alarm and the intermediate alarm.

⚠ **Warning**
- **When the alarm volume of the system is set to 0, the monitor cannot make any alarm sound even if a new alarm is generated. Therefore, the operator should use this function with caution.**
- **Do not exclusively rely on the sound alarm system. Otherwise, the patient may be put in a dangerous situation if the alarm volume is low. User should pay close attention to the patient's actual clinical conditions.**
- **Maximum alarm volume is no more than 10.**

9.13.3 Set Alarm Reminder

When the alarm volume is set to 0, or the alarm function is turned OFF, or the CPB mode is selected, the monitor can provide periodic prompt tone to remind that there is activated alarm in the system. Follow the operation steps below to set up alarm reminders.

1) Enter [User Maintain] → [Alarm Setup].

2) Switch [Alarm Reminder] to "ON" or "OFF".

3) Select [Reminder Interval]: [1 Min], [2 Min] or [3 Min].

4) Select [Reminder Volume]: set it to a value between 1 (the minimum volume) ~10 (the maximum volume).

9.14 Alarm Reset

You can reset the current alarm via the [Alarm Reset] shortcut key ⚠ on the lower menu bar on the screen:

✧ Cease the audio alarm indication of all physiological alarms and technical alarms.

✧ End alarm paused status, thus re-enabling the alarm system to respond to future alarm conditions.

✧ For lead off and sensor off technical alarm condition, clear the alarm lamp flashing and audio alarm indication and the alarm messages turn to prompt messages displayed in the technical alarm message area.

9.15 Other Bed Alarm

When this monitor is connected to another bedside monitor via network, the alarm information on that monitor can be observed on this monitor, including alarm messages, waveforms and parameters.

✧ In the [View Bed] interface, you can view the alarm conditions of the monitor for another bed.

✧ You can reset the alarm of the other bed by selecting the [Reset] button in the [View Bed] window.

9.16 Cardiopulmonary Bypass Mode

When the patient will undergo cardiopulmonary bypass in the [OR] department, you can select the [CPB mode] (Cardiopulmonary Bypass Mode). In this mode, physiological alarms except the following are suspended indefinitely.

✧ $FiCO_2/EtCO_2$ Too High

✧ FiO_2/EtO_2 Too High or Too Low

✧ FiO_2 Critically Low

In the CPB mode, the physiological alarm area shows [CPB Mode] (Cardiopulmonary bypass mode) in red ground color.

Enter the [CPB Mode]:

1) Enter [User Maintain] → [Alarm Setup].

2) Switch [CPB Mode] to "ON".

9.17 Alarm System Self-test

Upon startup of the monitor, the alarm system will perform self-test of alarm light and sound.

Phenomena during self-test:

Upon startup of the monitor:

✧ The red alarm light and the yellow light turn on for 1s in turn, and then the alarm lights turn off.

✧ At the time of alarm light self-test, the alarm system makes a "beep" sound for self-test of alarm sound.

Requirement on sound self-test: The low-level alarm is used, with the alarm volume set to Level 5.

9.18 Alarm System Test

After self-test, the system can be further tested through SpO2 or NIBP parameter. For example:

1) Connect the SpO_2 cable to the monitor.

2) Set the SpO2 alarm limits to 90% and 60%, respectively.

3) Directly select [Alm Vol] on the lower menu bar of the screen. Set [Alm Vol] to any level among 0~10.

4) When the measured value is beyond the upper/lower alarm limit, confirm whether the changes in sound, light and parameter blinking on the monitor conform to the descriptions in the section "Light Alarm", "Sound Alarm", "Alarm Message", and "Alarm Parameter Blink" in this chapter. Meanwhile, the physiological alarm message area shows "SpO_2 Too High" or "SpO_2 Too Low".

5) Pull out the SpO_2 sensor from the monitor; the technical alarm message area shows "SpO_2 Sensor Off".

Chapter 10 PR Setup

10.1 Overview

Mechanical activity of the heart causes artery pulse. PR value can be obtained by measuring the pulse. Color of the PR parameter area is consistent with the color in which the parameter of PR source is shown.

10.2 PR Source

Select the PR parameter area to enter the Setup menu, where you can set PR Source.

[SpO2]: Display the pulse rate value from SpO2;

[NIBP]: Display the pulse rate value from NIBP;

[ART], [PA], [UAP], [BAP], [FAP], [P1], [P2], [P3], [P4], [LV], [AO]: Specific pressure parameters from IBP; display the pulse rate value from IBP. (Which pressure parameter can be selected as the source depends on which pressure parameter is monitored by the monitor)

10.3 Alarm Limit Setup

Select the PR parameter area to enter the Setup menu, where you can carry out alarm limit setup.

Chapter 11 ECG Monitoring

11.1 Definition of ECG Monitoring

Electrocardiography (ECG) monitors continuous electrical activity of the patient's heart, which is reflected on the monitor in the form of wave and value, so as to accurately assess the current physiological status of the patient. Therefore, you must make sure the ECG cables are connected properly to obtain correct measurement values. The device can display 3-lead, 5-lead ECG or 12-lead ECG waves according to your need.

11.2 Precautions for ECG Monitoring

⚠ **Warning**

- **During defibrillation, the operator should not come into contact with the patient, desk or device.**
- **Prior to monitoring, please test the sensor cable to see if it is normal. When the ECG cable is disconnected from the jack, the screen will display the prompt message "ECG Lead Off" and generate the alarm sound.**
- **When this monitor is used for ECG signal monitoring, ECG leads provided by Comen must be used.**
- **When connecting the electrodes or patient cable, please ensure that the patient does not come into contact with any other conductive parts or the ground. Especially, please confirm that all ECG electrodes (including neutral electrode) are attached onto the patient's body and will not come into contact with any conductive parts or the ground.**
- **Check whether the ECG electrode patch can irritate skin every day. If there is any sign of allergy, replace the electrode or change its position.**
- **Prior to ECG monitoring, please check the ECG cable. When the ECG cable is disconnected, the monitor will trigger a sound alarm and display the alarm message "Sensor Off".**
- **Pacemaker fault: When cardiac conduction is completely blocked or the pacemaker cannot be moved away, P wave (> 1/5 of the mean height of R wave) may be wrongly recorded by the device, causing failure to monitor cardiac arrest.**
- **Devices such as defibrillator and remote measurement unit will generate a filtered ECG signal. When this signal is used as the input signal for bedside monitor, it will be filtered again. If such signal after second filtering is transmitted to the arrhythmia algorithm, it may cause failure to detect such conditions as pacemaker pulse, pacemaker capture failure or cardiac arrest. This will degrade the performance of the device when it is used for monitoring patients implanted with**

pacemakers.

- **During defibrillation, the ECG cable connected to the patient may get damaged. To reuse such cable, please check whether the cable function is OK.**

- **After defibrillation, if electrodes are used correctly and are attached properly according to the manufacturer's instructions, the waveforms on screen display will be recovered within 5s. For electrosurgery or defibrillation, the measurement accuracy may be reduced temporarily, but this will not affect the safety of the patient or the device.**

- **When the monitor is connected to an electrosurgical unit (ESU), in order to protect the patient from injury caused by leakage current, the sensors and cables of the device should not come into contact with the ESU.**

- **Do not expose the monitor to X-ray and high-intensity magnetic fields.**

⚠ **Note**

- **Interference from ungrounded devices near the patient and ESU interference may result in wave problem. If the device is operated under conditions specified in EN60601-1-2 (radiation resistance: 3V/m), electric field intensity over 1V/m may cause measurement errors at different frequencies. Therefore, it is suggested not to use any electric radiation device in a place near ECG/RESP measurement.**

- **If the ECG electrode is correctly placed but the ECG wave is still inaccurate, please replace the leads.**

- **To protect the environment, please recycle and treat used electrode patches appropriately.**

11.3 Monitoring Steps

11.3.1 Prepare Skin

Skin is a poor conductor. Therefore, to achieve good contact between electrodes and skin, it is very important to prepare the patient's skin:

1) Choose a skin area without any damage or abnormality.

2) When necessary, shave body hair at positions where electrodes will be placed.

3) Use soapsuds to thoroughly clean the skin. (Do not use diethyl ether or pure alcohol because these substances may increase the skin impedance).

4) Air-dry the skin completely.

5) Use skin preparation paper for ECG to gently rub the skin, so as to remove dead skin and improve the conductivity at the position where the electrode is attached.

11.3.2 Connect ECG Cable

1) First install the spring clip before placing the electrode.

2) Place the electrode on the patient's body; if the electrode used does not contain conductive paste, please apply conductive paste prior to placement.

3) Connect the electrode leads with the patient cable.

4) Insert the patient cable into the ECG port on the monitor. The monitor shows the ECG wave and value.

11.3.3 Install ECG Leads

The table below lists the names of leads in European and American standards, respectively. (RA, LA, RL, LL and V are used to represent leads in American standards, whereas R, L, N, F and C are used in European standards):

See the table below for marks and color codes of 3-lead and 5-lead electrodes:

U.S.A. Standard		EU Standard	
Mark	**Color**	**Mark**	**Color**
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White

11.3.3.1 Place 3-lead Electrodes

Refer to American and European standards for placing electrodes of 3-lead unit (see Fig. 11-1):

White/red (right arm) electrode — Place it below the clavicle, near the right arm.

Black/yellow (left arm) electrode — Place it below the clavicle, near the left arm.

Red/green (left leg) electrode — Place it at the left lower abdomen
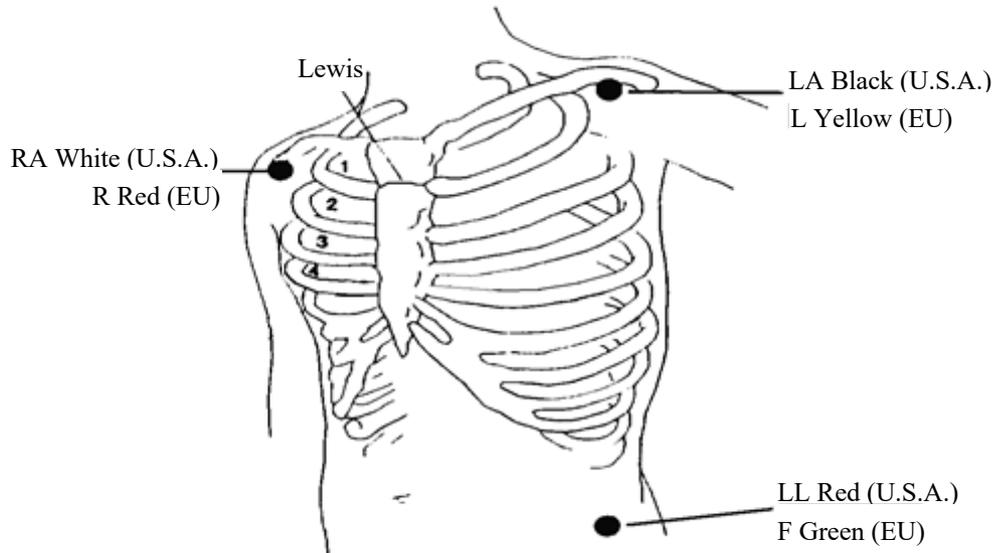
Fig 11-1 Positions for Placing 3-lead Electrodes

11.3.3.2 Place 5-lead Monitoring Electrodes

Refer to American and European standards for placing electrodes of 5-lead unit (see Fig. 11-2):

White/red (right arm) electrode — Place it below the clavicle, near the right arm.

Black/yellow (left arm) electrode — Place it below the clavicle, near the left arm.

Green/black (right leg) electrode — Place it at the right lower abdomen

Red/green (left leg) electrode — Place it at the left lower abdomen

Brown/white (chest) electrode — Place it on the chest wall according to Fig. 11-2.
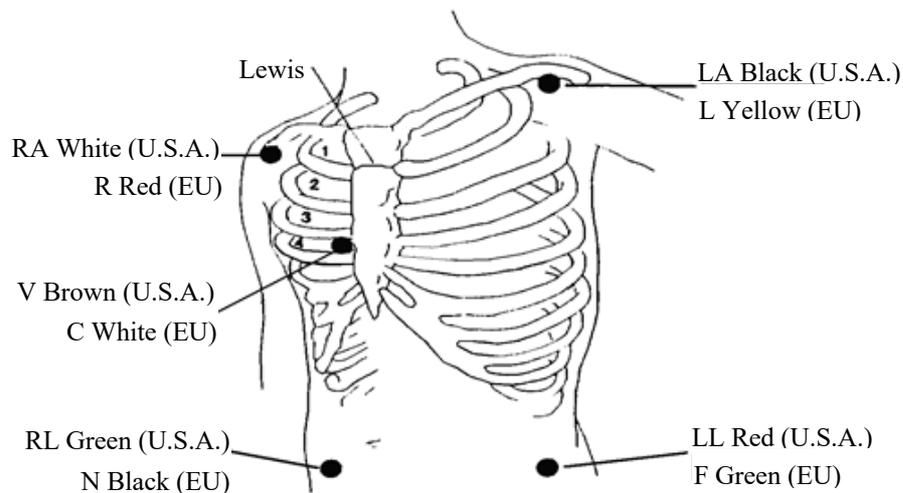
Fig 11-2 Positions for Placing 5-lead Electrodes

For 5-lead configuration, place the chest (V) lead electrode at one of the following positions (Fig. 11-3):

V1: 4th intercostal space, at the right sternal border.

V2: 4th intercostal space at the left sternal border.

V3: In the middle position between V2 and V4.

V4: 5th intercostal space at the left midclavicular line.

V5: In the left anterior axillary line, just parallel to V4.

V6: In the left midaxillary line, just parallel to V4.

V3R-V6R: On the right side of the chest wall, corresponding to
the left-side position.

VE: At the xiphoid eminence position.

V7: 5th intercostal space in the left posterior axillary line at the back.

V7R: 5th intercostal space in the right posterior axillary line at the back.
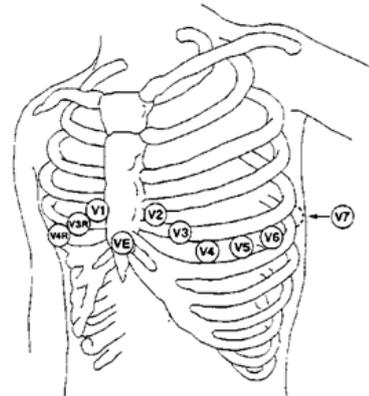
Fig 11-3 Positions for Placing Chest Lead
Electrode of the 5 Leads

11.3.3.3 Recommended ECG Lead Connection for Surgical Patient

⚠ **Warning**
- **Use appropriate ECG cables in the OR. These cables can prevent patient burn and reduce electronic interference through additional circuits. They are not suitable for RESP test.**
- **When using an ESU, never place electrodes close to the earth plate of the ESU; otherwise there will be much interference against ECG signal.**

The placement of ECG lead depends on the type of operation to be performed. For example, when a thoracotomy is to be performed, the electrode can be placed on the side of the chest or on the back. In the OR, artifacts may affect ECG wave due to the use of an ESU. In order to reduce artifacts, the electrodes can be placed at the left and right shoulders, close to the left and right sides of the abdomen; the chest lead can be placed left to the middle of the chest; avoid placing the electrode on the upper arm, or the ECG wave may become very small.

⚠ **Note**
- **To monitor a patient implanted with a pacemaker, [Pace] must be set to "On". If it is set to "Off", pacemaker pulses may be counted as QRS complex, resulting in failure to detect the cardiac arrest alarm. To change patient info or admit/discharge a patient, please check whether [Pace] is set correctly.**
- **When monitoring a patient implanted with a pacemaker, sometimes a part of pacemaker pulses cannot be shielded. If pacemaker pulses are counted as QRS complex, it will result in wrong heart rate calculated and failure to detect cardiac arrest or some arrhythmia. At this point, close attention should be paid to the condition of the patient implanted with a pacemaker.**

11.4 ECG Display
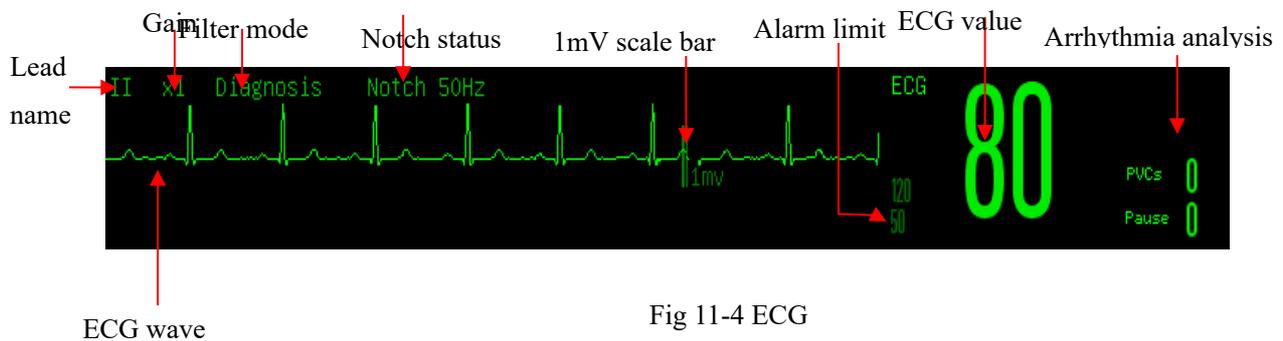
Fig 11-4 ECG

11.5 ECG Setup

11.5.1 Set Lead Type

3-lead and 5-lead ECG cables apply to this monitor. ECG cables with different leads can be used to monitor different ECG waves.

When the 3-lead ECG cable is used, leads that can be monitored include I, II and III. In the Standard interface, ECG wave of at most 1 lead can be displayed.

When the 5-lead ECG cable is used, leads that can be monitored include I, II, III, aVR, aVL, aVF and V. In the Standard interface, ECG wave of at most 2 leads can be displayed.

When the lead type of the monitor is set to Auto, the monitor will automatically judge the leads to be monitored. Set the lead type for the ECG cable supplied with the device:

1)   Select the ECG parameter area to enter the Setup menu → [Lead Type] → [3 Leads], [5 Leads] or [Auto].

11.5.2 Smart Lead Off

When [Smart Lead Off] is ON, if the lead of the current channel comes off, the monitor automatically switches to a channel where the lead is not off. When the lead that comes off is reconnected, the monitor automatically switches back to the original channel.

Enable or disable the function:

1)   Select the ECG parameter area to enter the SETUP menu → [Other Setup].

2)   Select [Smart Lead Off], and switch it to "On" or "Off".

11.5.3 Set Off Level

Enter [User Maintain] → [Alarm Setup] → [ECG Lead Off Level].

11.5.4 Set Lead Name for Key Monitoring

In the Standard interface, when 3 Leads is selected as the lead type, only one ECG wave can be displayed; when 5 Leads is selected, two ECG waves can be displayed.

1) Select the first ECG wave to enter the [ECG Wave] menu → [Lead Name]; select the lead for key monitoring, such lead as [II].

2) If 5 Leads is used, select the second ECG wave; the [ECG Wave] menu will pop up → [Lead Name]; select the lead for key monitoring, such as lead [I].

11.5.5 Set Gain

If the wave size is too big or too small, user can change the display size of wave by gain setup; such setup will not affect ECG signal analysis of the monitor. With the wave and the 1mv scale provided on the right side of the wave, user can obtain the optimal wave.

1) Select one ECG wave to enter the [ECG Wave] menu → [Gain] → [×0.125], [×0.25], [×0.5], [×1], [×2], [×4] or [Auto].

⚠ **Note**

● **When the input signal is too intensive, the wave crest may be cut off. In such case, user can manually change the gain level of ECG wave according to the actual wave, so as to avoid incomplete wave display.**

11.5.6 Set Filter Mode

Filter Mode: Clearer or more accurate waves can be obtained through filtering. Four filter modes are available for selection.

➢ In the Diagnosis mode, ECG waves displayed are those without filtering.

➢ The Monitor mode will filter artifacts that may result in false alarms.

➢ In the OR, the Surgery mode can reduce artifacts and interference from the ESU.

➢ In the ST filter mode, the reflection of distortionless ECG signal ST segment of the patient being measured can be guaranteed, and high-frequency interference signal above 40Hz, including power frequency

interference, can be filtered effectively. In this mode, user can obtain the value of ST segment of the patient being measured by adjusting the position of ST segment analysis point. The filter mode acts on two channels simultaneously, and is displayed above the first ECG wave.

1) Select one ECG wave to enter the [ECG Wave] menu → [Filter Mode] → [Diagnosis], [Monitor], [Surgery] or [ST].

> ⚠️ **Warning**
> - **The system can provide unprocessed real signals only in the diagnosis mode. In the "Monitor" and "Surgery" filter modes, the ECG wave will distort to different degrees. At this moment, the system can only provide the basic ECG info, which will greatly affect the result of ST segment analysis.**

11.5.7 Set Calculate Lead

User can select the leads for HR calculation and arrhythmia analysis, but should ensure the presence of the following wave characteristics under corresponding leads:

a) Tall and narrow without notch.

b) R wave is tall, completely above or below the baseline.

c) T wave is less than 1/3 height of R wave.

P wave should be much smaller than T wave.
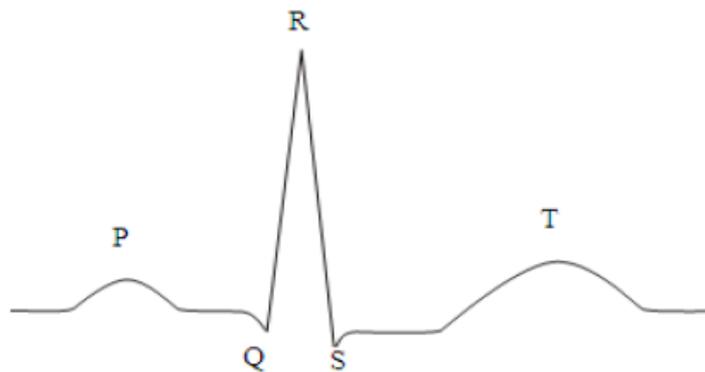
Fig 11-5 Standard ECG Wave

Options of calculation channels are different under different lead types:

3 Leads: Lead II is locked; no other options are provided

5 Leads: Three options are provided: I, II and V.

Select Lead:

1) Select the ECG parameter area to enter the Setup menu → [Calculate Lead]; set the sources of lead

calculation and arrhythmia analysis.

To obtain 1mV calibrated ECG wave, ECG calibration should be performed. For the ECG calibration method, see the *"Maintenance"* chapter.

11.5.8 Set Notch Filter

Notch filter can inhibit the 50Hz or 60Hz frequency component in the signals acquired. When the filter mode is not Diagnosis, the system will turn on Notch Filter automatically; when the filter mode is Diagnosis, Notch Filter can be turned on or off as needed.

1) Select the ECG parameter area to enter the Setup menu → [Other Setup]

2) Set [Notch Filter] as follows:

   [Strong]: Select it when the wave jitters frequently (e.g., the wave has burrs).

   [Weak]: Select it when the wave jitters infrequently.

   [Off]: Notching will not be performed.

3) Enter [User Maintain] → [Other Setup] → [Notch Filter].

4) User can select [50Hz] or [60Hz] according to the power supply frequency.

11.5.9 Set Pacer Reject

Select the ECG parameter area to enter the Setup menu → [Other Setup]. In the pop-up Setup menu, select [Pacer Reject] and switch it to "On" or "Off".

When [Pace] is turned on:

When [Pacer Reject] is set to On, the display of pacing signal will be inhibited. However, when pacing signal is detected, the pacemaker pulse symbol ❙ will still be displayed above the ECG wave.

When [Pacer Reject] is set to Off, the display of pacing signal will not be inhibited. When pacing signal is detected, the pacemaker pulse symbol ❙ will be displayed above the ECG wave.

When [Pace] is turned off, [Pacer Reject] cannot be operated.

11.5.10 HR Source

User can select the HR source to determine the HR value or PR value displayed in the ECG parameter area; the color of HR parameter value is consistent with the source parameter selected. Select the ECG parameter area to enter [ECG Setup], and set [HR Source] as follows:

[ECG]: The ECG parameter area displays the HR value, and the monitor makes the heartbeat sound.

[SpO2]: The ECG parameter area displays the pulse rate value from SpO2, and the monitor makes the pulse sound.

[ART], [PA], [UAP], [BAP], [FAP], [P1], [P2], [P3], [P4], [LV], [AO]: Specific pressure parameters from IBP; display the pulse rate value from IBP. (Which pressure parameter can be selected as the source depends on which pressure parameter is monitored by the monitor)

11.5.11 Mul. Lead Analysis

When Mul. Lead Analysis is turned on, the setting of ECG [Calculate Lead] will become invalid. The module intelligently selects the lead with good ECG wave for HR calculation

1) Select the ECG parameter area to enter the Setup menu.

2) Select [Multi. Lead Analyse], and switch it to "On" or "Off".

11.5.12 Cascade

Cascade is for user to observe the designated realtime ECG wave for a long period of time. In the Cascade interface, the screen will show cascade wave of the same lead. Currently the monitor is in any work interface under the multi-parameter monitoring mode; select ECG in the waveform area; in the pop-up [ECG Wave] menu, turn on [Cascade]. The number of cascade waves displayed depends on the number of ECG waves present in the current interface. The operation over one of the ECG waves also applies to other ECG waves.

> ⚠ **Note**
> ● **Under the interface of [7-Lead Half Screen], [cascade] is not optional.**

11.6 ST Segment Analysis

11.6.1 About ST Segment Analysis

Normal heartbeat and atrial pacing heartbeat are used in ST segment analysis. The monitor analyzes these heartbeats and calculates the elevation and depression of ST segment. On the monitor, the info can be displayed as ST value. All available leads can be monitored continuously. For ST segment analysis, it is unnecessary to display ECG wave on the monitor. For ST segment analysis, special filter that can ensure the diagnosis quality should be used during execution. If you use an ECG filter mode other than [ST] filter to monitor ECG; the ST segment of ECG wave may be slightly different in appearance from the ST segment of ST fragment having the same waveform. To perform diagnostic assessment of ST segment, please always switch to the [ST] filter mode. ST segment analysis can measure the elevation or depression of ST segment on the designated lead.

Meaning of ST segment measurement value: A positive number represents elevation; a negative number represents depression.

ST segment measurement range: -2.0 ~ +2.0mV.

11.6.2 Influence on ST Segment

Some clinical situations may result in difficulty to achieve reliable ST monitoring. For example:

➢ Lead of low noise cannot be obtained.

➢ Presence of arrhythmia (e.g., atrial fibrillation/atrial flutter) that can cause irregular baseline.

➢ The patient is under continuous ventricular pacing.

➢ The patient has left bundle branch block.

Under such circumstances, you should consider turning off ST monitoring.

⚠ **Warning**

● **This monitor provides info about changes in ST level, the clinical significance of which should be determined by the doctor.**

11.6.3 ST Analysis On/Off

1) Select the ECG parameter area to enter the Setup menu → [ST Analysis].

2) Select [ST Analysis], and switch it to "On" or "Off".

11.6.4 Adjust ST Point

Set the reference point of ST measurement point as R wave crest point; the ST measurement value of the complex wave of each heartbeat is the vertical distance difference between the wave crest point and the two measuring points. See the figure below:
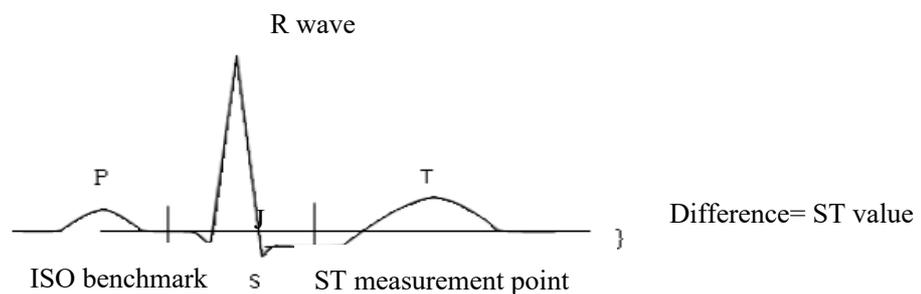
Fig 11-6 ST Point

The ST measurement value of the complex wave of each heartbeat is the vertical distance between the intersections of the wave and the two measuring points.

⚠ **Note**

- **If the HR or ECG wave of the patient changes obviously, the position of ISO and ST points should be adjusted. During ST segment analysis, abnormal QRS complex is not considered.**
- **Please ensure that the position of ST measuring point is suitable for the patient being monitored.**

Method for adjusting ISO and ST points:

1) Select the ECG parameter area to enter the Setup menu → [ST Analysis].

2) Set [ST Analysis] to [On].

3) Select [Adjust ST Point] to enter the [ST Analysis] window: three vertical lines are ISO, J and ST, respectively.

4) Select the appropriate ST measurement lead; select [ST Lead] to switch the measurement lead.

5) Use other keys to adjust the corresponding measuring point.

➢ The cursor position of ISO point is related to R wave crest equipotential. Use to locate the ISO point in the middle of the flattest position of baseline (between P and Q waves or in front of P wave).

➢ The cursor position of J point decides the relative position of J point and R wave crest. This can help user to correctly locate the ST point. Use to place J point at the end of QRS complex and the beginning of ST segment.

➢ Locate ST point:

➢ Select J+60, J+80 or J+40 to convert the value and move J point to locate ST point in the middle of ST segment.

6) When setting is finished, select "" to exit the window.

11.6.5 ST Analysis Review

This monitor can save 20 groups of ST analysis fragments for reference and review. A ST analysis fragment shows a complete QRS wave fragment of all ST leads. Reference data stored are drawn in white; realtime data are drawn in green. Realtime data of ST segment are refreshed every 5s.

Enter [ST Analysis Review]:

1) Select the ECG parameter area to enter the Setup menu → [ST Analysis]; open [ST Analysis] → [ST Analysis Review].
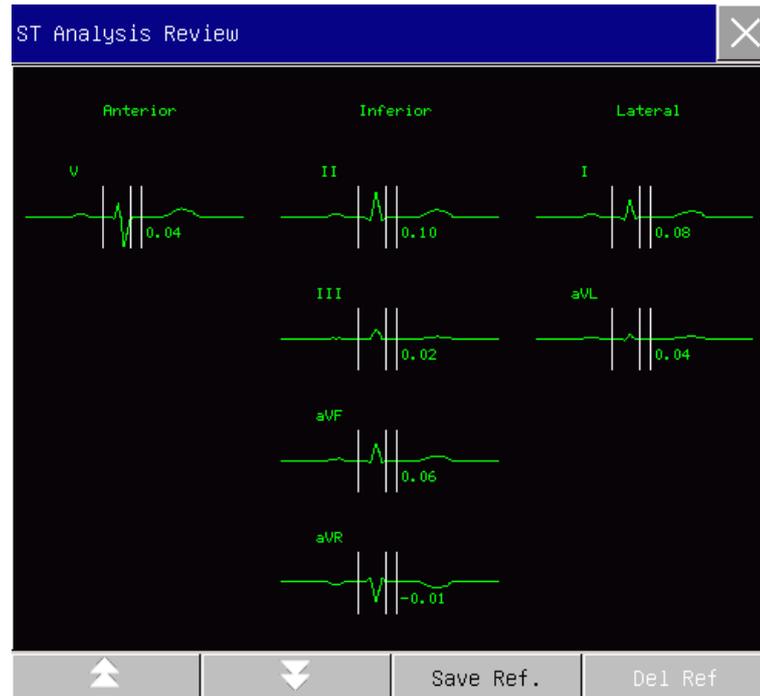
Fig 11-7 ST Analysis Review

➢ To save the current ST fragment as the reference fragment, select [Save Ref.] (Save Reference).

➢ To delete the current reference fragment displayed, select [Del Ref] (Delete Reference).

➢ To view several groups of ST fragments, select ⬆⬇ to turn page up and down.

11.6.6 ST Alarm

Select the ECG parameter area to enter the Setup menu → [ST Analysis]; open [ST Analysis] → [Alarm Limit Setup] to perform parameter alarm setup; the monitor sets alarm limits for each lead. For operation details, see the "Alarm" chapter.

11.7 Arrhythmia Analysis

Arrhythmia analysis is clinically used in patient ECG monitoring to detect HR changes and premature ventricular contractions, save arrhythmia events and generate alarm messages. Arrhythmia analysis can be used for monitoring patients implanted or not implanted with pacemakers. The doctor can evaluate the patient's condition (e.g., HR, PVCs (premature ventricular contractions) frequency, rhythm and abnormal heartbeat) according to arrhythmia analysis, and carry out diagnosis and treatment on this basis. Apart from detection of ECG changes, arrhythmia analysis can monitor the patient and give proper alarms.

The arrhythmia monitoring function of the monitor is Off by default. User can enable this function as needed.

The arrhythmia monitoring function can, through testing and classifying arrhythmia and abnormal heartbeat, remind the doctor of paying attention to the patient's heart rhythm and generate alarms.

This monitor can analyze 26 types of arrhythmia.

11.7.1 Arrhythmia Analysis On/Off

1) Select the ECG parameter area to enter the Setup menu → [ARR Analysis].

2) Select [ARR Analysis], and switch it to "On" or "Off".

11.7.2 Arrhythmia Alarm Setup

1) Select the ECG parameter area to enter the Setup menu → [ARR Analysis].

2) Turn on [ARR Analysis].

3) Select [Alarm Setup] to enter the [ARR Analysis - Alarm Setup] window; user can perform restoration setup, alarm on/off setup, alarm level and record on/off setup for [Asystole], [V-fib], [R ON T], [VT>2], [Couplet], [PVC], [Bigeminy], [Trigeminy], [SVT] (Supraventricular Tachycardia), [Brady] (Bradycardia), [PNC] (Pacer Not Capture), [PNP] (Pacer Not Pace), [Missed Beats], [IHB] (Irregular Heart Beat), [VTAC] (Ventricular Tachycardia), [Tachy] (Tachycardia), [PVCs Too High], [Extreme Tachycardia], [Extreme Bradycardia], [Ventricular Rhythm], [Heart Pause], [Vent. Brady] (Supraventricular Bradycardia), [Multi. PVCs], [Nonsus. Vtac] (Nonsustained Ventricular Tachycardia), [Atrial Fibrillation] and [Pause/min]. Select [Restore] to restore the device to factory settings.

NOTE: The alarm level and alarm on/off status of [Asystole], [V-fib], [VTAC], [Extreme Tachycardia], [Extreme Bradycardia] and [Vent. Brady] are in default, which cannot be changed by the user.

11.7.3 Arrhythmia Threshold Setup

Select [ECG] in the parameter area; in the pop-up [ECG Setup] menu, enter the [ARR Analysis] menu, where user can set the threshold of each arrhythmia type. Parameters can be set in the following ranges:

No.	Arrhythmia Type	Setup Range	Default Value	Step	Unit
1	PVCs	0-31	10	1	PCS
2	Tachycardia	ADU: 60-160 PED: 60-180 NEO: 60-200	ADU: 120 NEO/PED: 160	1	bpm
3	Extreme Tachycardia	ADU: 120-300 PED: 160-300 NEO: 160-350	ADU: 160 PED: 180 NEO: 200	1	bpm

4	Extreme Bradycardia	15-40	40	1	bpm
5	Arrest Time	3-10	4s	1	s
6	Ventricular Tachycardia HR	100-180	Default: 160bpm	1	bpm
7	Ventricular Tachycardia PVC	3-15	Default: 12	1	PCS
8	Bradycardia HR	40-120	Default: 40bpm	1	bpm
9	Supraventricular Bradycardia	15-60	Default: 50bpm	1	bpm
10	Vbrd PVC	3-99	Default: 4	1	PCS
11	Multi. PVCs	3-31	Default: 15	1	PCS
12	Heart Pause Time	1.5-3.5	Default: 2.5s	0.5	s
13	Pause/min	1 -15	Default: 8	1	min

After setting Arrhythmia Threshold, when a value exceeds this threshold, an alarm will be triggered.

11.7.4 Arrhythmia Review

See the "Alarm Event Review" chapter.

11.7.5 ARR Relearn

During ECG monitoring, when the ECG template of the patient changes significantly, user may need to start an ARR Relearn process. ARR Relearn enables the monitor to learn new ECG templates, thus to correct arrhythmia alarms and heart rhythm values.

1)   Select the ECG parameter area to enter the Setup menu → [ARR Analysis].

2)   Select [ARR Relearn]; the system will give the prompt message [ARR Learning].

User can also directly select the [ARR Relearn] quick key.

11.8 RR Intervals

The normal ECG waveform will not change much at RR intervals. However, when abnormal situation occurs on the ECG of patients, the change at RR intervals would be obvious. This monitor will record the change at RR intervals while monitoring the ECG of patients. Having monitored the ECG of patients, this monitor will provide the maximum, average, minimum and standard deviation of the change at RR intervals to doctors for judgement.

11.9 ECG Relearn

During ECG monitoring, if the patient's ECG template changes significantly, you may need to manually start an ECG Relearn process. Changes in the ECG template may result in:

✧   Arrhythmia alarm error

✧   ST measurement data loss

✧   Inaccurate HR value

Start relearning:

Select the ECG parameter area to enter the Setup menu → [Other Setup] → [Relearn].

⚠ **Caution**

- **Please start ECG Relearn during normal rhythm and when ECG signal is relatively noiseless. This is because ECG Relearn during the arrhythmia period may result in relearning the wrong QRS complex as the ECG template.**

11.10 Defibrillation Synchronization

The Defibrillation Synchronization function is to output +5V defibrillation synchronization signal during 100ms via the multi-function port every time the monitor detects R wave; such signal is for use by the defibrillator. The Defibrillation Synchronization function of the monitor is always on.

⚠ **Warning**

- **Improper use of the defibrillation function may cause injury to the patient; user should judge whether defibrillation is necessary or not according to the patient's actual condition.**
- **Prior to defibrillation, user should ensure that the defibrillator and the monitor have undergone system test and these two devices can work in conjunction with each other safely and effectively.**
- **Prior to defibrillation, user should set the filter mode to [Diagnosis].**
- **At the end of defibrillation, user can select the filter mode as needed.**

Chapter 12 Resp Monitoring

12.1 Resp Measurement

The Monitor measures the RESP based on the thoracic impedance between the two electrodes. The changes of such impedance caused by thoracic movements will generate a RESP wave on the screen. The RR is calculated from such wave.

12.2 Placement of Electrodes

In Resp measurement, it is important to prepare the skin properly for electrode placement. Refer to the relevant section on ECG measurement.

The Resp signals are measured through the two ECG electrodes. In case of standard placement of ECG electrodes, the Resp can be measured through the electrode RA and electrode LL.

12.2.1 Optimization of Lead Position

To measure the ECG and Resp simultaneously, it may be necessary to adjust the positions of the two electrodes for some patients. Non-standard placement of ECG electrodes may cause changes to the ECG waveform and affect the ST segment analysis and ARR analysis.

1) Cardiac Superposition

The cardiac activities affecting the Resp waveform are defined as cardiac superposition, which occurs when the electrodes acquire the impedance changes caused by rhythmic blood flow. Proper placement of electrodes can reduce cardiac superposition and protect the liver area and ventricles against the cable between the electrodes, which is especially important to neonates.

2) Lateral Thoracic Expansion

The thoracic cage of some patients, especially neonates, may expand to both sides. To achieve the best Resp waveform, please place the two electrodes respectively at the right mid-axillary line and left outer chest with strongest Resp movements as shown below:
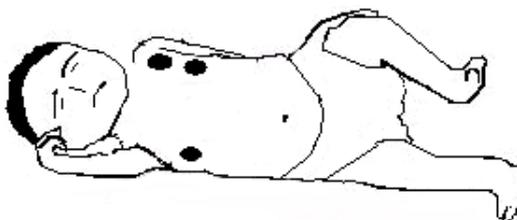
3) Abdominal Respiration

Some patients may have restricted thoracic movements and rely mainly on abdominal respiration. To achieve the best Resp waveform, please place the electrode LL on the left abdomen with strongest expansion as shown below:

12.3 Resp Display

Resp Waveform   Resp Alarm Limit   RR
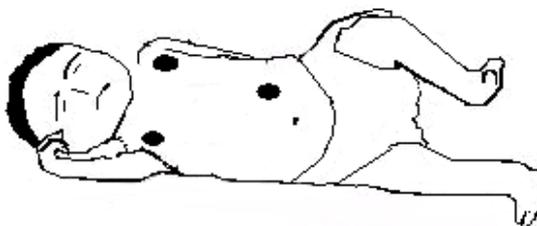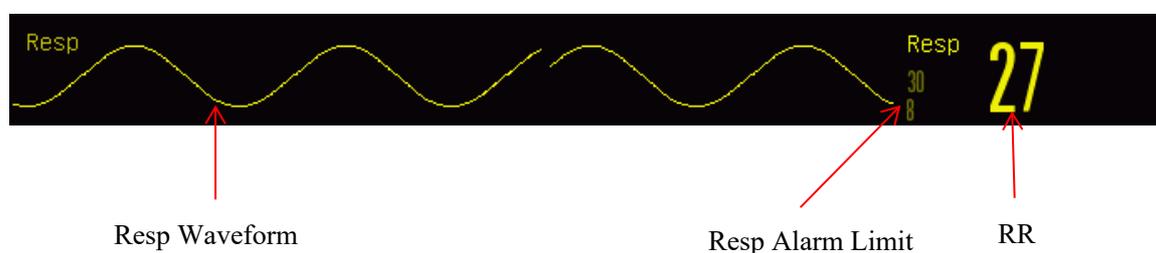
Fig 12-1 Resp Display

12.4 Resp Calculation Mode

Enter [Resp Setup]:

1) Enter [User Maintain] → [Resp Setup] → [Cal. Mode] (Calculation Mode).

2) Select [Auto] or [Manual].

3) In [Manual] mode, you can set the upper and lower dotted line of the Resp waveform.

4) In [Auto] mode, you cannot change the upper or lower dotted line but use the default waveform calculation method.

[Auto] mode:

The Monitor auto adjusts the detection level based on the waveform height and ECG artifact. In [Auto] mode, no dotted line of detection level is displayed on the Resp waveform.

Please select [Auto] mode if:

✦ The RR is not approximate to the HR;

✦ The patient relies on spontaneous Resp with or without CPAP; or

✦ The patient relies on mechanical ventilation (except IMV).

[Manual] mode:

In [Manual] mode, you have to set the Resp detection level. The Monitor does not auto adjust the dotted lines of detection level. When the Resp depth changes or the Resp waveform gain is adjusted, you may need to adjust the position of the dotted lines of detection level on the Resp waveform manually by selecting [Up Line] and [Down Line].

Please select [Manual] mode if:

✧ The RR is approximate to the HR;

✧ The patient relies on IMV; or

✧ The Resp signals are weak (try to improve the signal quality by relocating the electrodes).

In [Manual] mode, the superposition of some cardiac activities may trigger the Resp counter and result in incorrect high RR indication or no-breath detection failure. If you doubt that the cardiac superposition has been treated as Resp activities, improve the RESP detection level until it is higher than the cardiac superposition. If you fail to improve the Resp detection level due to small Resp waveform size, follow Subparagraph 2) Lateral Thoracic Expansion of Section 12.2.1 Optimization of Lead Position to optimize the position of the electrodes.

12.5 Resp Setup

12.5.1 Gain

Gain is used to adjust the amplitude of the Resp wave. You can select ×0.25, ×0.5, ×1, ×2 or ×4 as the gain.

1) Select the Resp parameter area to enter [Resp Setup] and select an appropriate [Gain].

12.5.2 No Breath Alarm Delay

No-breath detection is to detect the longest interval between two adjacent RESPs. When the actual no-breath time of the patient exceeds the set no-breath time, the Monitor will respond to no-breath alarms according to the value of [No Breath Alm Delay].

Set [No Breaths Timeout]:

1) Select the Resp parameter area to enter [Reso Setup] → [No Breaths Timeout] and set an appropriate detection time.

Set [No Breath Alm Delay]:

1) Enter [User Maintain] → [Other Setup].

2) Set [No Breath Alm Delay] to [Off], [10s], [15s], [20s], [25s], [30s], [35s], [40s], [45s], [50s], [55s] or [1min].
   If you select [Off], the alarm delay function will be disabled.

12.5.3 Resp Lead

Resp leads indicate the source of the current Resp waveform. You can set [Resp Lead] to RA-LA (I), RA-LL (II) or [Auto]. If you select [Auto], the Monitor will auto select an appropriate Resp lead.

1) Select the Resp parameter area to enter [Resp Setup] → [Resp Lead].

2) Select RA-LA (I), RA-LL (II) or [Auto].

12.5.4 Enhance Filter

This parameter is designed to filter out the Resp interference. Its default is [On].

1) Select the Resp wave area to enter [Resp Wave].

2) Select [Enhance Filter] to switch between [On] and [Off].

<table>
<tr><td>⚠   Note</td></tr>
<tr><td>●   In Resp measurement, the Monitor cannot recognize any obstructive or mixed no-breath but trigger an alarm when the interval between two adjacent RESPs exceeds the set time.</td></tr>
</table>

Chapter 13 SpO$_2$ Monitoring

13.1 Overview

The SpO$_2$ Photoplethysmography measures the arterial SpO$_2$, namely, the percentage of the oxyhemoglobin count.

The SpO$_2$ is measured with the pulse oximetry, a continuous noninvasive method measuring how many of the lights emitted from the sensor (light source) can penetrate the patient's tissues (fingers or ears) and reach the receiver.

The Monitor measures the following parameters:

Arterial SpO$_2$: the ratio of the oxyhemoglobin to the sum of oxyhemoglobin and non-oxygenated hemoglobin (functional arterial SpO$_2$);

Pleth waveform: a visible indication of the patient's pulse;

PR (calculated from pleth waveform): the patient's pulse count per minute;

PI (perfusion index): the pulsatile blood flow value.

⚠ **Warning**
- **If there is any carboxyhemoglobin (COHb), methemoglobin (MetHb) or dye dilution chemical, the SpO2 value will have a deviation.**

13.1.1 Identification of SpO$_2$ Sensor Type

The SpO$_2$ sensor type is pre-configured before the Monitor is delivered. You can identify it based on the silkscreened logo beside the original SpO$_2$ sensor below the sensor interface on the left side of the Monitor:

◆ Comen SpO$_2$ sensor:

Sensor interface: circular interface at the center of the side panel;

Silkscreened logo: SpO$_2$.

◆ Masimo SpO$_2$ sensor:

Sensor interface: square interface at the bottom of the side panel;

Silkscreened logo: MasimoSET.

◆ Nellcor SpO$_2$ sensor:

Sensor interface: square interface at the bottom of the side panel;

Silkscreened logo: Nellcor.

It is useful for the clinician to know the wavelength range and maximum optical output power of the sensor, for example, for the purpose of photodynamic therapy.

◆ The Comen SpO$_2$ sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).

◆ The Masimo SpO$_2$ sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).

◆ The Nellcor SpO$_2$ sensor can measure a wavelength of 660nm (red LED) or 900nm (IR LED).

◆ The maximum optical output power of the sensor is lower than 15mW.

⚠ **Warning**

● **The Monitor can auto recognize the SpO$_2$ sensor type. However, it will fail to measure the SpO$_2$ properly if you use a sensor incompatible with its internal hardware.**

13.2 Safety Instructions

⚠ **Warning**

● **The Monitor is compatible with the SpO$_2$ sensor designated by Comen only.**

● **Before monitoring the patient, please check if the sensor and extension cord are compatible with the Monitor. Incompatible accessories may reduce the performance of the Monitor.**

● **Before monitoring the patient, please check if the sensor cable works properly. Remove the SpO$_2$ sensor cable from the sensor interface, and the Monitor will display the prompt message "SpO$_2$ sensor off" and trigger the alarm sound.**

● **If the SpO$_2$ sensor or its package seems damaged, do not use it but return it to the manufacturer.**

● **Long-time continuous monitoring may increase the risk of undesired skin characteristic changes (extremely sensitive, turning red, blistered or pressure necrosis), especially for neonates or the patients with perfusion disorder or variable or immature skin morphology diagram. Align the sensor with the light path, fix it properly and check its position regularly based on skin quality changes (change the sensor position in case of reduced skin quality). Perform such check more frequently if necessary (subject to the condition of the patient).**

● **Make sure the sensor cable and electrosurgical equipment cable are not intertwined.**

● **Do not place the sensor on a limb with ductus arteriosus or intravenous tube.**

● **Setting the upper SpO$_2$ alarm limit to 100% will disable the upper-limit alarm. Premature infants may get infected with crystalline posterior fibrous tissue diseases in case of high SpO$_2$. Please set the upper SpO$_2$ alarm limit cautiously based on recognized clinical practices.**

⚠ **Note**

● **Make sure the fingernail covers the lights from the sensor. Place the sensor cable on the back of the hand.**

● **Do not place the SpO$_2$ sensor on a limb with blood pressure cuff, or the blood flow occlusion in blood pressure measurement will affect the SpO$_2$ reading.**

- **The displayed SpO$_2$ waveform is normalized.**
- **The pulse oximeter is calibrated to display the functional oxygen saturation.**
- **Validation of SpO$_2$ measurement accuracy: the measurement accuracy of Masimo SpO$_2$ sensor is validated through a comparison with the reference value of arterial SpO$_2$ measured by CO-oxygen pressure gauge in human experiments. The SpO$_2$ measurement results provided by Masimo SpO$_2$ sensor meet the statistical distribution and, compared with the measurement results provided by CO-oxygen pressure gauge, about two thirds of them are expected to fall within the specified accuracy range.**
- **In a human blood study involving healthy adult volunteers in induced hypoxia state (SpO$_2$: 70%~100%), Masimo SpO$_2$ sensor passes the validation of non-movement accuracy through a comparison with the joint oximeter and monitor in the laboratory. The difference can be recovered by adding or deducting a standard deviation. After adding or deducting a standard deviation, 68% of the samples will be covered.**
- **In a human blood study involving healthy adult volunteers in movement-induced (rub or tap at a 2~4Hz frequency) hypoxia state, Masimo SpO$_2$ sensor passes the validation of movement accuracy. In case of non-repeated movement at a 1~2cm range and 1~5Hz frequency, there will be a 2~3cm range difference from the joint oximeter and monitor in the laboratory in induced hypoxia (SpO$_2$: 70%~100%) study. The difference can be recovered by adding or deducting a standard deviation. After adding or deducting a standard deviation, 68% of the samples will be covered.**

13.3 SpO$_2$ Accuracy Test

⚠ **Warning**
- **The function tester cannot be used to assess the accuracy of the SpO$_2$ sensor.**

Assess the SpO$_2$ accuracy by comparing the readings respectively on the Monitor and CO-oxygen pressure gauge.

13.4 Low Perfusion Accuracy Test

This monitor can measure low perfusion and the recommended method of determining the low perfusion accuracy of the monitor is to conduct this test with CO-oximeter on adult volunteers whose SpO$_2$ ranges from 70% to 100%. The accuracy index is obtained according to statistical distribution, and only about 2/3 of the estimated values are expected to fall within the estimated values of CO-oximeter.

13.5 PR Accuracy Test

Assess the PR accuracy by comparing with the ECG heart rate.

13.6 Monitoring Steps

⚠ **Warning**
- **Place the SpO₂ sensor properly based on the SpO₂ sensor type compatible with the Monitor. This is especially important for neonates.**

SpO₂ Photoplethysmography:

1) Set the patient type;

2) Insert the SpO₂ cable connector into the SpO₂ interface of the Monitor;

3) Fix the sensor to an appropriate position on the patient's finger.
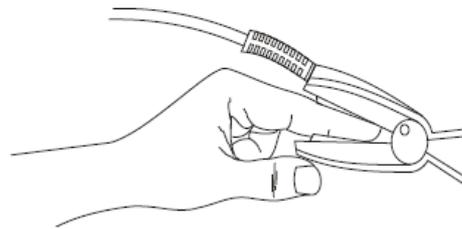
Fig 13-1 Placement of SpO₂ Sensor

SpO₂ Photoplethysmography for neonates:

The SpO₂ Photoplethysmography for neonates is almost the same as that for adults. Here we introduce the neonatal SpO₂ sensor and how to place it.

➢ Neonatal SpO₂ Sensor

The neonatal SpO₂ sensor consists of the Y-shaped SpO₂ sensor and neonatal SpO₂ sensor sheath. Embed the LED end and PD end of the Y-shaped SpO₂ sensor respectively in the upper and lower groove of the neonatal SpO₂ sensor sheath as shown in Fig. 13-2 to achieve the neonatal SpO₂ sensor shown in Fig. 13-3.

Y-shaped SpO₂ Sensor   Neonatal SpO₂ Sensor Sheath
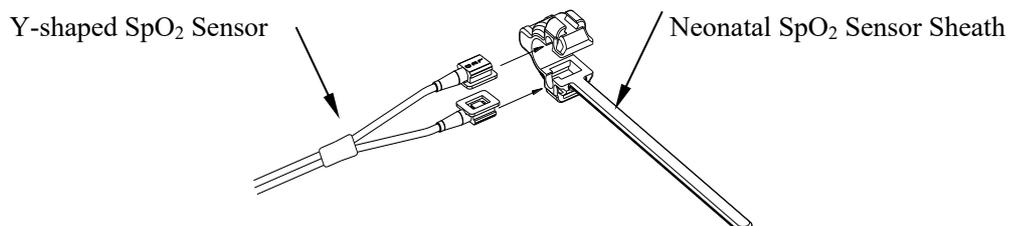
Fig 13-2 Neonatal SpO$_2$ Sensor (1)
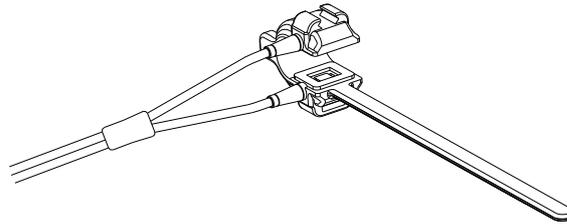
Fig 13-3 Neonatal SpO$_2$ Sensor (2)

➢ Placement of Neonatal SpO$_2$ Sensor

Fig 13-4 Placement of Neonatal SpO$_2$ Sensor

⚠ **Note**
- **The injectable dyes, like methylene blue, and the dysfunctional hemoglobin in blood vessels will lead to inaccurate measurement results.**

⚠ **Warning**
- **Using the SpO$_2$ sensor in the MRI process may cause severe burns. To minimize such risk, please do cabling properly to avoid induction coils. Whenever the SpO$_2$ sensor works improperly, remove it from the patient immediately.**
- **Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another part. Change the wearing part at least every four hours.**

13.7 Measurement Restrictions

In operations, the following factors may affect the SpO$_2$ measurement accuracy:

1) High-frequency radio interference, whether from the host system or from the electrosurgical equipments

connected to the host system.

2) Do not use the oximeter or SpO$_2$ sensor in the MRI process, or the induced current may cause burns.

3) Intravenous dyes.

4) The patient moves frequently.

5) Ambient optical radiation

6) The sensor is fixed improperly or to an improper position on the patient.

7) Improper sensor temperature (optimum temperature: 28℃~42℃).

8) The sensor is placed on a limb with blood pressure cuff, ductus arteriosus or intravenous tube.

9) Concentration of the non-functional hemoglobin, like COHb or MetHb.

10) Low SpO$_2$.

11) Poor circulation perfusion at the tested part.

12) The shock, anemia, hypothermia and application of vasoconstrictors may reduce the arterial blood flow to a non-measurable level.

13) The SpO$_2$ measurement accuracy depends also on the absorption of the lights with special wavelength by oxyhemoglobin and reduced hemoglobin. If any other substance also absorbs such lights, like COHb, MetHb, methylene blue or indigo carmine, you may obtain a false or low SpO$_2$ value.

13.8 SpO$_2$ Setup

13.8.1 Set Off Level

Enter [User Maintain] → [Alarm Setup] → [SpO$_2$ Sensor Lead Off Level].

13.8.2 Smart Alarm

1) Select the SpO$_2$ parameter area to enter [SpO$_2$ Setup] → [Sat second] (Saturation Seconds).

2) Select [10], [25], [50], [100] or [Not Allowed].

Note: this function is available for NELLCOR SpO$_2$ only.

The smart alarm is designed to reduce false alarms and keep the clinician informed of the SpO$_2$ changes more accurately and timely. For example, if you set [Sat second] to [50] and the upper and lower alarm limit of NELLCOR SpO$_2$ respectively to 97% and 90%, maintain the measured SpO$_2$ value at 80% for 3s and then reduce it to 78% for 2s, the Monitor will trigger the alarm sound and indicator 5s after the SpO$_2$ value goes beyond the alarm limit and the circle beside the SpO$_2$ value will return to the origin.

Calculation method:

Percentage points × seconds = Sat second (integer)

The calculated Sat second is displayed as follows:

% SpO$_2$ Seconds   Sat second

(90%-80%)   ×   3   =   30

(90%-78%)   ×   2   =   24

Total Sat second = 54
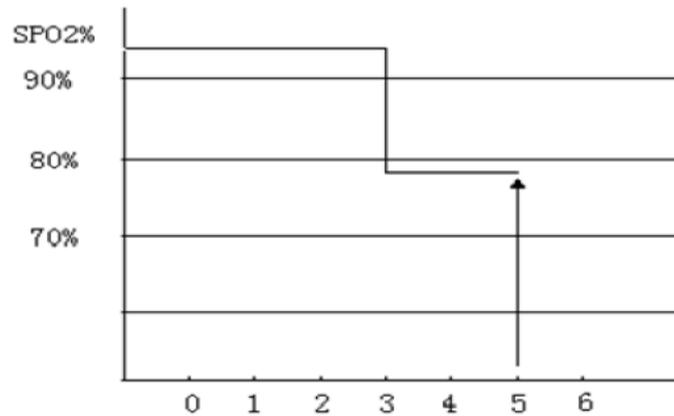
Fig 13-5 Example Diagram

In the above Sat second example:

About 4.9s later, the Monitor will report a Sat second alarm because you've set [Sat second] to [50], smaller than 54.

The SpO$_2$ value may fluctuate in seconds rather than remain unchanged. The patient's SpO$_2$ value usually fluctuates within the alarm limit and sometimes goes beyond the alarm limit discontinuously. The Monitor will accumulate the positive and negative percentage points until the set value of [Sat second] is reached or the patient's SpO$_2$ value remains beyond the alarm limit.

13.8.3 Smart Tone

You will (will not) hear the pulse tone in case of unstable signal or ambient noise if this function is enabled (disabled).

Set [Smart Tone]:

1)   Select the SpO$_2$ parameter area to enter [SpO$_2$ Setup].

2)   Select [Smart Tone] to switch between [On] and [Off].

Note: this function is available for Masimo SpO$_2$ only.

13.8.4 NIBP Same Side

Set [NIBP Same Side]:

1) Select the SpO$_2$ parameter area to enter [SpO$_2$ Setup].

2) Select [NIBP Same Side] to switch to [On].

If you do not select [On], the weak perfusion caused by NIBP measurement will lead to inaccurate SpO$_2$ measurement or trigger a physiological SpO$_2$ alarm when the NIBP measurement and SpO$_2$ measurement are performed on the same limb.

13.8.5 Signal IQ

The magnitude of the SpO$_2$ SIQ waveform provides an assessment of the confidence in the measurement displayed. A higher value indicates higher confidence in the measurement whereas a smaller value indicates lower confidence in the displayed measurement.

Movements usually affect the signal quality. When the arterial pulse reaches the peak, the Monitor will mark its location on the vertical line (signal indicator). The volume of the smart tone (if enabled) remains consistent with the vertical line (the volume of the smart tone will increase or decrease accordingly when the SpO$_2$ value increases or decreases).

The height of the vertical line represents the quality of the measured signal (the higher line, the higher quality).

Set [Signal IQ] (Signal Identification and Quality):

1) Select the SpO$_2$ parameter area to enter [SpO$_2$ Setup].

2) Select [Signal IQ] to switch between [On] and [Off].

Note: this function is available for Masimo SpO$_2$ and simulated SpO$_2$ only.

13.8.6 Average Time

The SpO$_2$ value displayed on the Monitor is the average of the SpO$_2$ values acquired in a given time. Shorter (longer) average time will lead to quicker (slower) response and lower (higher) measurement accuracy of the Monitor when the patient's SpO$_2$ value changes. For a critical patient, please set a short average time so as to analyze his/her condition timely. Set average time:

Masimo SpO$_2$:

1) Select the SpO$_2$ parameter area to enter [SpO$_2$ Setup] → [Average Time].

2) Select [2-4s], [4-6s], [8s], [10s], [12s], [14s] or [16s].

Comen SpO$_2$:

1) Select the SpO$_2$ parameter area to enter [SpO$_2$ Setup] → [Sensitivity].

2) Select [High], [Medium] or [Low].

13.8.7 Fast Sat

FastSat enables rapid response to, and display of, fast changes in SpO$_2$ by giving priority to the most recent data. This aids the clinician in clinical settings requiring fast response time such as those seen with induction, intubation, sleep studies and resuscitation.

1) Select the SpO$_2$ parameter area to enter [SpO$_2$ Setup].

2) Select [Fast Sat] (Fast Saturation) to switch between [On] and [Off].

Note: this function is available for Masimo SpO$_2$ only; if this function is enabled, you can find the prompt message "Fast Sat" at the main interface.

13.8.8 Sensitivity

[Sensitivity] can be set to [Normal], [Maximum] or [APOD] (Adaptive Probe Off Detection). [Maximum] represents the highest sensitivity. In typical monitoring conditions, please select [Normal]. If the sensor is likely to come off the patient due to wet skin, violent movements or other causes, please select [APOD]. If the patient's perfusion level is extremely low, please select [Maximum].

Set [Sensitivity]:

1) Select the SpO$_2$ parameter area to enter [SpO$_2$ Setup] → [Sensitivity].

2) Select [Normal], [Maximum] or [APOD].

Note: this function is available for Masimo SpO$_2$ only.

13.9 Masimo Information

1) Masimo Patents

The Monitor contains one or more of the following U.S. patents: RE38,492, RE38,476, 6,850,787, 6,826,419, 6,816,741, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,584,336, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,206,830, 6,157,830, 6,067,462, 6,011,986, 6,002,952, 5,919,134, 5,823,950, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international patents and one or more patents mentioned on www.masimo.com/patents. A product with Satshare® function also contains the U.S. patent 6,770,028. Other patents are pending.

2) Other Information

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RadNet, Radicalscreen, signal IQ, FastSat, fastStart and APOD are trademarks of Masimo Corporation.

Chapter 14 NIBP Monitoring

14.1 Overview

The Monitor uses the vibration method (measure the cuff pressure vibration amplitude) to measure the noninvasive blood pressure (NIBP). Blood pressure changes will cause cuff vibrations. The cuff pressure at the highest vibration amplitude is the mean pressure. The systolic pressure and diastolic pressure are calculated from the mean pressure.

NIBP measurement is applicable in electrosurgical operations and defibrillator discharges according to IEC 80601-2-30/EN60601-2-30.

NIBP monitoring is applicable to adults, children, neonates, pregnant women and preeclampsia patients.

14.2 Safety Instructions

⚠ **Warning**

- **Before the NIBP measurement, make sure the selected monitoring mode is appropriate for the patient (adult, child or neonate). It is dangerous to select a non-neonatal mode for neonatal patients.**
- **Do not place the cuff on a limb with intravenous tube or cannula, or the tissues around the cannula may be damaged when the infusion is slowed or blocked in the cuff inflation process.**
- **Make sure the inflation tube connecting the blood pressure cuff to the Monitor is not obstructed or tangled.**
- **Do not perform the NIBP measurement to a patient with sickle cell disease or existing or expected skin lesions.**
- **For a patient with severe disturbances of blood coagulation, please determine the applicability of automatic NIBP measurement based on clinical evaluation, or the limb contacting the cuff may suffer from hematoma due to friction.**
- **Frequent measurements may cause blood flow interference and injure the patient.**
- **To prevent further injury, do not place the cuff on any wound.**
- **Do not place the blood pressure cuff on a limb under intravenous infusion, intravenous therapy or arteriovenous shunt, or the transient blood flow interference will injure the patient.**
- **Do not place the cuff on the arm at the same side as mastectomy.**
- **The increasing cuff pressure may cause transient function failure to other monitoring equipment used on the same limb.**

14.3 NIBP Measurement

14.3.1 Preparations for Measurement

1) Connect the inflation tube to the blood pressure cuff.

2) Connect the inflation tube to the NIBP interface of the Monitor without compressing or blocking the pressure tube.

3) Use a cuff of the correct size and make sure the airbag is not folded or twisted.

◆ An incorrect cuff size or a folded or twisted airbag will cause inaccurate measurement. Make sure the cuff is deflated thoroughly. The cuff width should be 40% (50% for neonates) of the limb perimeter or 2/3 of the upper arm length. The inflated part of the cuff should be long enough to circle 50~80% of the limb.
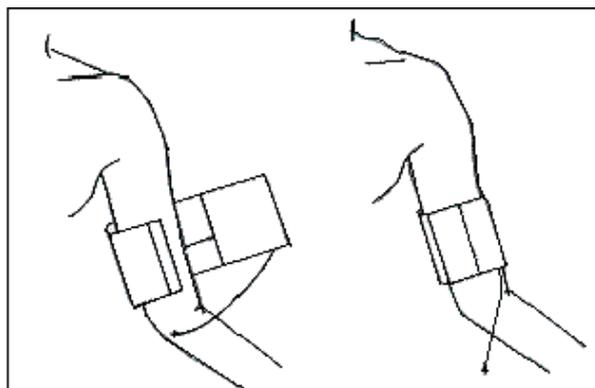
Fig 14-1 Use of Cuff

4) Tie the cuff around the limb and make sure the cuff is at the same level as the patient's heart. If you fail to do so, use the following methods to correct the measurement result:

◆ Make sure the mark "φ" is located at an appropriate artery. Do not tie the cuff too tightly, or the distal extremity may suffer from discoloration or ischemia. Check the skin condition of the contact part and the color, temperature and feeling of the limb wearing the cuff regularly. If the skin condition changes or the blood circulation of the limb is affected, move the cuff to another body part for continued measurement or stop the NIBP measurement immediately. In auto measurement mode, please observe the skin condition more frequently.

◆ If the cuff is not at the same level as the heart, use the following correction formulas:

❖   If the cuff is at a higher level than the heart: displayed NIBP value + 0.75mmHg (0.10kPa) × level difference (cm).

❖   If the cuff is at a lower level than the heart: displayed NIBP value - 0.75mmHg (0.10kPa) × level difference (cm).

Reusable cuff for neonates/children/adults:

Patient Type	Limb Perimeter	Cuff Width	Inflation Tube Length
Neonate	6~11cm	5cm	
Infant	10~19cm	8cm	
Child	18~26cm	10.6cm	
Adult 1	25~35cm	14cm	2m
Adult 2	33~47cm	17cm	
Leg	46~66cm	21cm	

Disposable cuff for neonates/children/adults:

Size	Limb Perimeter	Cuff Width	Inflation Tube Length
Neonate 1	3.0~5.5cm	2.6cm	
Neonate 2	4.0~7.6cm	3.7cm	
Neonate 3	5.6~10.6cm	4.5cm	2m
Neonate 4	7.0~12.8cm	5.3cm	
Neonate 5	8.9~15.0cm	6.0cm	

14.3.2 Measurement Restrictions

The vibration method has some restrictions, depending on the patient's condition. It detects the regular pulse wave generated by arterial pressure. If the patient's condition makes it difficult to detect such wave, the measured pressure value will be unreliable and the pressure measurement time will be increased. In the following cases, the vibration method will be disturbed, causing unreliable or impossible pressure measurement or increased pressure measurement time, depending on the patient's condition.

1) Patient Movements

If the patient is moving, trembling or under cramps, which may disturb the detection of arterial pressure pulse, the NIBP measurement will be unreliable or impossible and the pressure measurement time will be increased.

2) Arrhythmia

If the patient has irregular heart beats due to arrhythmia, the NIBP measurement will be unreliable or impossible and the pressure measurement time will be increased.

3) Heart-lung Machine

Do not perform the NIBP measurement if the patient is connected to a heart-lung machine.

4) Pressure Changes

If the patient's blood pressure changes rapidly within a certain time when the Monitor analyzes the arterial pressure pulse for measurement purpose, the NIBP measurement will be unreliable or impossible.

5) Severe Shock

If the patient is under severe shock or hypothermia, the NIBP measurement will be unreliable as the reduced blood flowing to the periphery will reduce the arterial pulse.

6) Beyond-limit HR

Do not perform the NIBP measurement if the HR is lower than 40bpm (beats per minute) or higher than 240bpm.

7) Obese Patient

Damped by the thick obese layers of the limb, the vibration from the artery will fail to reach the cuff, causing lower measurement accuracy than in normal cases.

8) Patient with Hypertension

To measure the NIBP of a patient with hypertension accurately, please:

➢ Adjust his/her sitting posture until:

    ✧ He/she sits comfortably;

    ✧ His/her legs are not crossed;

    ✧ His/her feet are laid flat on the ground;

    ✧ He/she leans his/her back against the chair and puts his/her hands on the desk;

    ✧ The middle part of the cuff is at the same level as his/her right atrium.

➢ Ask he/she relaxes as much as possible and not talk during the measurement procedure.

➢ Elapse 5 min before the first reading is taken.

14.3.3 Start the Measurement

14.3.3.1 Start the Manual Measurement

Select the NIBP parameter area to enter the setup menu →[Measure Mode]→[Manual]. Whether to start the NIBP measure depends on the user's need.

14.3.3.2 Start the Whole Point Measurement

1. Select the NIBP parameter area to enter the setup menu→ [Whole point Mea.], and switch it to "On".

2. Select the "⤻" key on the control panel or [NIBP Start] shortcut keys and manually start the first measure. After the first measure, the monitor will automatically and repeatedly start the measure according to the interval time set before.

For example, if you start the first measurement at 08:23, and set [Interval] to [5min], the monitor will operate the next measurement at 08:25. The measurement will start with clock simultaneously, and then at 08:30 by parity of reasoning.

⚠**Note**
- **The monitor operate the [Whole point Mea.] only when the [Interval] is not less than 5min.**

14.3.3.3 Start the Interval Measurement

Users can select all options except for the [Manual] by using short keys of [Model Setup] .Then select the "⤻" key on the control panel or the short keys of [NIBP Start] to start the first measure. After the first measure, the monitor will automatically and repeatedly start the measure according to the interval time set before. Or start the interval measure following the steps below:

1. Select the NIBP parameter area to enter the setup menu →[Measure Mode]→[Auto].

2. Select the [Interval]: from 1 minute to 720 minutes.

3. Select the "⤻" key on the control panel or [NIBP Start] shortcut keys and manually start the first measure. After the first measure, the monitor will automatically and repeatedly start the measure according to the interval time set before.

Select the NIBP parameter area to enter [NIBP Setup] → [Interval], select 1min~720min for interval, then the measure mode is changed to [Auto] automatically, and start the measurement. When the measurement is over, the monitor will start measurement after the interval you set automatically and repeatedly.

14.3.3.4 Start the Continual Measurement

Select the NIBP parameter area to enter [NIBP Setup] → [Continual Measure], then start the 5min measurement continuously.

⚠**Note**
- **If you have any doubt about the reading accuracy, check the patient's vital signs first with the same method as checking the Monitor's functions.**
- **In order not to injure the patient, the [Continual Measure] mode will not be available if the**

> **patient type is [Neo].**
> - **The auto measurement results are affected by the temperature, RH and altitude limit.**

⚠️**Warning**
- **If any liquid splashes onto the Monitor or its accessories, especially when it is likely to flow into the Monitor or its tubes, please contact the maintenance department of the hospital.**

14.3.4 Stop the Measurement

Finished the measurement, the monitor will emission the gas and stop the measurement. During the measurement, you can press the "☎" key on the control panel or [NIBP Start] quick key to stop the measurement.

14.3.5 NIBP Display

The NIBP measurement results are displayed in the parameter area. The figure below is for reference only. The actual display interface of the Monitor may be slightly different from this figure.
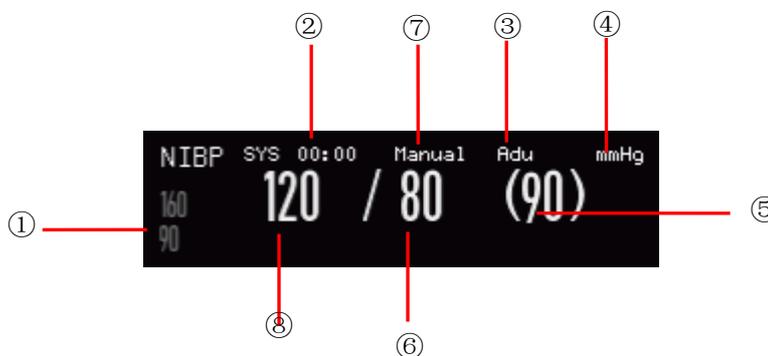
Fig 14-2 NIBP Display

①	Alarm limit of systolic pressure	②	Time of the previous measurement
③	Patient type: ADU, PED or NEO.	④	Pressure unit:mmhg or kPa
⑤	Mean pressure (in the measurement process, display the cuff pressure)	⑥	Diastolic pressure
⑦	Measurement mode: auto, manual or continual.	⑧	Systolic pressure

14.4 NIBP Setup

14.4.1 Patient Type

The patient type includes adult, child and neonate. Please select an appropriate measurement mode based on the value of [PAT Type] in [Patient Info].

1) Select the NIBP parameter area to enter [NIBP Setup] → [PAT Type].

2) Select [ADU], [PED] or [NEO].

14.4.2 Initial Pressure

1) Select the NIBP parameter area to enter [NIBP Setup] → [Initial Pressure].

2) Set an appropriate value for [Initial Pressure].

14.5 NIBP Reset

Select [NIBP] in the parameter area to enter [NIBP Setup] → [Reset]. This function can restore the initial pressure of the blood pressure pump. If the blood pressure pump works improperly, use this function to check it and recover its accidental exceptions.

14.6 Assistance in Venipuncture

Inflate the NIBP cuff to a pressure approximate to the diastolic pressure to block the vein vessel and assist in the completion of venipuncture.

1) Select the NIBP parameter area to enter [NIBP Setup] → [Other Setup] → [Cuff Pressure] and then select an appropriate pressure value.

2) Select [Venipuncture Start].

3) Puncture the vein and take the blood sample.

4) Press the " �'" key or the relevant shortcut key to deflate the cuff. If you fail to do so, the cuff will be auto deflated after a set time.

In the venipuncture process, the NIBP parameter area will display the cuff pressure and remaining time of venipuncture.

14.7 NIBP Analysis

At the NIBP analysis interface, you can view the patient's normal values of systolic pressure and diastolic pressure, the percentage of higher/lower values and the average, maximum and minimum systolic pressure and diastolic pressure within the measurement time.

1)   Select the NIBP parameter area to enter [NIBP Setup] → [Other Setup] → [NIBP Analysis].

Then you can set the following parameters:

[Daily Start Time]: set the NIBP data statistics starting time (hour or minute).

[Daily End Time]: set the NIBP data statistics ending time (hour or minute).

[SYS Nor. Range]: set the upper and lower limit of systolic pressure.

[DIA Nor. Range]: set the upper and lower limit of diastolic pressure.

15.1 Temp Monitoring

The Monitor has two Temp measurement channels and uses a TEMP sensor to measure the Temp.

Place the Temp sensor under the patient's armpit or on the patient's anorectal part, depending on the sensor type. To achieve an accurate measurement result, please measure the Temp for at least 1min.

15.1.1 Temp Measurement

1) Select an appropriate Temp sensor type and size.

2) To use a disposable Temp sensor, please connect it to the Temp cable.

3) Connect the Tempsensor or Temp cable to the Temp sensor interface of the Monitor.

4) Fix the Temp sensor to the patient reliably.

5) Set an appropriate alarm limit.

⚠ **Warning**
- **Work mode of the Temp sensor: immediate mode.**
- **Before the Temp measurement, check if the Temp sensor cable is in good condition. Remove the Temp sensor cable from the Temp sensor interface, and the Monitor will display the prompt message "T1 (T2) sensor off" and trigger the alarm sound.**
- **Handle the Temp sensor and cable with caution. When they are idle, coil them loosely. Tight coiling may cause mechanical damage to the cable.**
- **Calibrate the Temp measurement set at least every two years or as required by the hospital's procedures. Contact the manufacturer for calibration when necessary.**

⚠ **Note**
- **Do not reuse any disposable Temp sensor.**

15.2 Temp Display

The parameter area will display the Temp value and unit of channel [T1] and [T2] and the Temp difference [TD] between the channels. Select [Temp] in the parameter area to enter [Temp Setup].

Fig 15-1 Temp Display

Chapter 16 CO$_2$ Monitoring

16.1 Overview

The Monitor uses the CO$_2$ measurement to monitor the patient's breath state and control his/her ventilation. There are two methods of measuring the CO$_2$ in the patient's airway:

◆ Sidestream measurement method: take samples from the respiratory gas sensor in the patient's airway at a constant flow rate and use the built-in remote CO$_2$ sensor in the measurement system to analyze them.

◆ Mainstream measurement method: install the CO$_2$ sensor onto the airway connector inserted directly into the respiratory system of the patient.

In the above two cases, the measurement principle is IR emission. Use the optical detector to measure the intensity of the infrared rays penetrating the respiratory system. Such intensity depends on the CO$_2$ concentration as some infrared rays will be absorbed by CO$_2$ molecules.

The CO$_2$ measurement involves the following parameters (see the figure below):

✧ CO$_2$ waveform ①

✧ End-tidal CO$_2$ (EtCO$_2$): the maximum partial pressure of CO2 at the end of a breath. ②

✧ EtCO$_2$ alarm limit ③

✧ Fraction of inspiratory CO$_2$ (FiCO$_2$): the minimum CO$_2$ value during inspiration ④

✧ Airway respiration rate (AWRR): the respirations per minute calculated from the CO$_2$ waveform ⑤

✧ Measurement unit ⑥

⚠ **Note**
- **Do not use the Monitor in an environment with any flammable anesthetic gas.**
- **Only the trained professionals familiar with this Manual are allowed to operate the Monitor.**
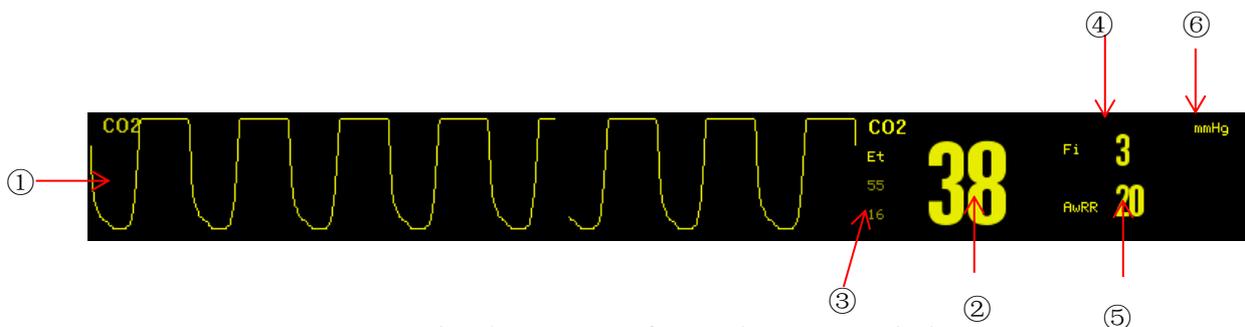
Fig 16-1 CO$_2$ Waveform and Parameter Display

16.2 CO$_2$ Sensor Connection

16.2.1 Preparations for Mainstream CO$_2$ Sensor Connection

1) Connect the mainstream sensor to the CO$_2$ interface of the Monitor.

2) Wait for 10s (Masimo sensor) or 2min (Respironics sensor) until the sensor reaches its working temperature and a stable thermal state.

3) Connect the relevant airway adapter to the sensor head and make sure they engage with each other in place.

4) Zero the sensor.

5) Expose the sensor to the room air and keep it away from all CO$_2$ sources, like respirator,   patient respirations and user respirations.

6) Select the CO$_2$ parameter area to enter [CO$_2$ Setup] → [Zero].

7) Install the airway adapter onto the proximal end of the respiration circuit, exactly speaking, between the elbow and the Y-shaped tube of the respirator as shown in the figure below.
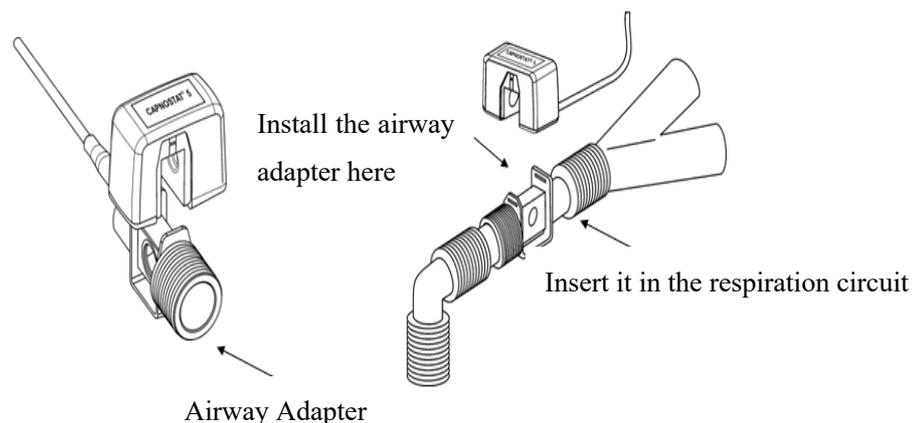
Fig 16-2 Mainstream CO$_2$ Connection

16.2.2 Preparations for Sidestream CO$_2$ Sensor Connection

1) Connect the sensor cable to the CO$_2$ interface of the Monitor.

2) Wait for 10s (Masimo sensor) or 2min (Respironics sensor) until the sensor reaches its working temperature and a stable thermal state.

3) Connect the cannula, airway adapter or sampling tube (as the case may be) to the sensor reliably until you hear a click sound.

Fig 16-3 Respironics Sidestream CO$_2$ Connection Diagram

Connect the sampling tube and airway adapter to the patient

To the Monitor

CO$_2$ Sensor

Sensor Adapter
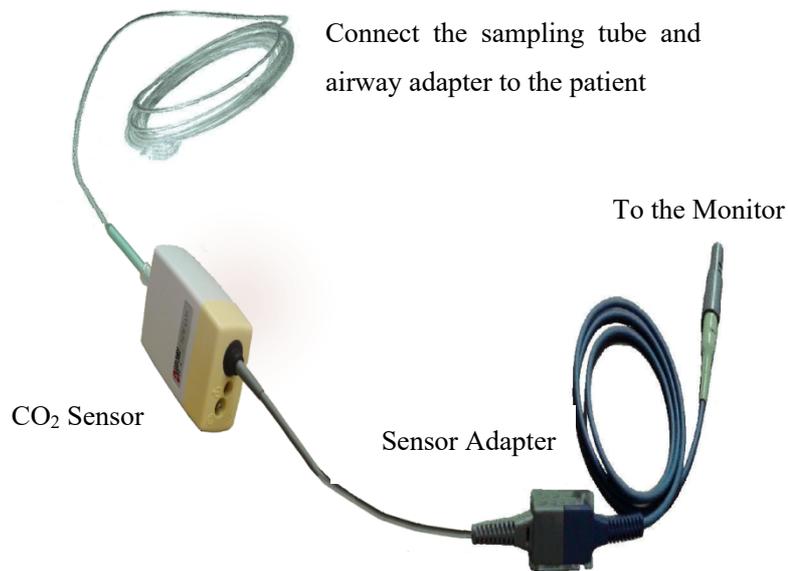
Fig 16-4 Masimo CO$_2$ Connection Diagram for ISA™ Sidestream Analyzer

4) Use the airway adapter for the patient with tracheal cannula: install the airway adapter onto the proximal end of the respiration circuit, exactly speaking, between the elbow and the Y-shaped tube of the respirator.
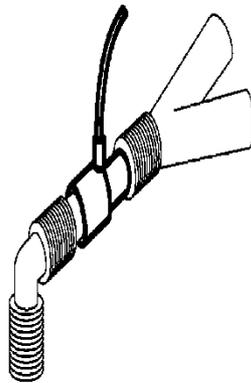
Fig 16-5 Connection of Airway Adapter

5) Wear the nasal cannula for the patient without tracheal cannula: wear the nasal or oral-nasal O_2 cannula onto the patient's face, connect the O_2 supply tube to the O_2 supply system and set the O_2 flow as directed.

⚠ **Warning**
- **Check the airway adapter before use. Replace it if the airway adapter suffers from any exterior damage or breakage.**
- **Turn it off when the CO_2 sensor is idle, or it will remain in working state and its service life will be shortened.**

16.3 Measurement Steps for Respironics Mainstream and Sidestream Analyzer

The Respironics sidestream analyzer and Respironics mainstream analyzer have almost the same measurement steps. Please follow the measurement steps for Respironics sidestream analyzer to operate the Respironics mainstream analyzer.

1) Follow *Section 16.2* to connect the CO_2 sensor based on the CO_2 sensor type.

2) Select [Screen Layout] to call up the CO_2 waveform and parameter to be monitored (skip this step if the CO_2 waveform and parameter are already displayed on the screen).

3) Set [O_2 Compensate] in [CO_2 Setup] to [21] (in order to activate the value of [O_2 Compensate], never skip this step even if [21] is already selected).

4) Set [Balance Gas] in [CO_2 Setup] to [Room Air], [N_2O] or [Helium] (select [Room Air] if there is no N_2O or helium in the room).

5) Set [Altitude] in [CO_2 Setup] to 0~5120.6m (default: 0m), depending on the local altitude. When the CO_2 value is too high or too low, follow Table 16-1 to select the relevant barometric pressure based on the local altitude (the barometric pressure changes with the altitude).

Barometric Pressure Conversion Table – EtCO2 Data Based on Altitude

Altitude		Barometric Pressure	5% CO2
Feet	Meters	mmHg	EtCO2mmhg
Sea Level (0)	Sea Level (0)	760	38
500	152.4	745	37
750	228.6	738	37
1,000	304.8	731	37
1,500	457.2	717	36

2,000	609.6	704	35
2,500	762	690	35
3,000	914.9	677	34
3,500	1066.8	665	33
4,000	1219.2	652	33
4,500	1371.6	640	32
5,000	1524	628	31
5,500	1676.4	616	31
6,000	1828.8	604	30
6,500	1981.2	593	30
7,000	2133.6	581	29
7,500	2286	570	29
8,000	2438.4	560	28
8,500	2590.8	549	27
9,000	2743.2	539	27
10,000	3048	518	26
10,500	3200.4	509	25
11,000	3352.8	499	25
11,500	3505.2	490	24
12,000	3657.6	480	24
12,500	3810	471	24
13,000	3962.4	462	23
13,500	4114.8	454	23
14,000	4267.2	445	22
14,500	4419.6	437	22
15,000	4572	428	21
15,500	4724.4	420	21
16,000	4876.8	412	21
16,500	5029.2	405	20
16,800	5120.6	400	20

Table 16-1

Note: it is assumed that the barometric pressure and temperature at the sea level are respectively 760mmHg and 0℃ (the altitude-based ambient temperature is 0℃).

> ⚠️ **Warning**
>
> - **The Monitor has no auto barometric compensation function. Please set the correct altitude before using the CO_2 measurement function for the first time. Incorrect altitude will cause incorrect CO_2 reading (5% CO_2 error per 1,000m altitude difference).**

6) Select [Zero] in [CO₂ Setup], and the prompt message "Zeroing, please wait 30s" will appear at the lower right corner of the interface. Do not start the CO_2 measurement until such prompt message disappears.

16.4 Measurement Steps for Masimo Mainstream and Sidestream Analyzer

The Masimo sidestream analyzer and Masimo mainstream analyzer have almost the same measurement steps. Please follow the measurement steps for Masimo sidestream analyzer to operate the Masimo mainstream analyzer.

16.4.1 Measurement Steps

Follow the steps below to set the Monitor for gas analysis purpose:

1) Follow *Section 16.2* to connect the CO_2 sensor based on the CO_2 sensor type.

2) Connect the Nomoline sampling tube to the input interface of the ISA analyzer (CO₂ sensor).

3) Connect the interface cable of the ISA analyzer to the CO_2 interface of the Monitor.

4) Enter [User Maintain] and activate the CO_2 sensor.

5) Enter the general interface of the Monitor and select [Screen Layout] to call up the CO_2 waveform and parameter to be monitored (skip this step if the CO_2 waveform and parameter are already displayed on the screen).

6) Set an appropriate value for [O₂ Compensate] and [N₂O Compensate].

7) Connect the gas sample outlet to the exhaust system or make the gas flow back to the patient circuit.

8) The green LED indicates that the ISA analyzer is ready for use.

9) Follow *Section 16.4.2* to perform the checks before use.

10) Start the CO_2 monitoring in case of normal check results.

16.4.2 Checks before Use

Perform the following operations before connecting the Nomoline sampling tube to the respiration circuit:

1) Connect the sampling tube to the gas inlet of the ISA CO_2 sensor.

2) Check if the LED remains green stably (an indication of normal system).

3)   Expire into the sampling tube and check if the Monitor displays the effective CO$_2$ waveform and value.

4)   Block the sampling tube with a fingertip and wait 10s.

5)   Check if the prompt message "Sampling line clogged" appears and the LED flashes in red.

6)   Check the tightness of the patient circuit connected to the sampling tube when appropriate.

⚠ **Note**
● **In order to prevent the condensed water dropping into the gas sampling tube and blocking it, the gas sampling tube connection end of the airway adapter should point up.**

⚠ **Warning**
● **Hang the external CO$_2$ analyzer onto the CO$_2$ sensor holder on the back housing of the Monitor reliably against falling and damage.**
● **Place the IRMA sensor, if not protected by HME, with the status LED pointing up.**
● **Do not stretch the cable of the ISA sidestream gas analyzer.**
● **Operate the ISA sidestream gas analyzer in the specified working temperature environment only.**
● **Make sure all connections are firm and reliable. Any leakage will cause the respiratory gas of the patient to include the ambient air, resulting in incorrect readings.**

16.5 CO$_2$ Setup

16.5.1 Work Mode

Follow the steps below to set its work mode after connecting the CO$_2$ sensor to the Monitor. Turn off the CO$_2$ sensor for service life protection purpose once the CO$_2$ measurement is stopped.

1)   Select the CO$_2$ parameter area to enter [CO$_2$ Setup] → [Work Mode].

2)   Select [Standby] or [Measure].

16.5.2 Pressure Unit

Enter [User Maintain] to set [Press. Unit].

16.5.3 Gas Compensation

1)   Select the CO$_2$ parameter area to enter [CO$_2$ Setup].

◆ Masimo CO$_2$ sensor:

  ✧ Select [O$_2$ Compensate] → [High], [Med] or [Low].

  ✧ Select [N$_2$O Compensate] → [On] or [Off].

◆ Respironics CO$_2$ sensor:

  ✧ Select [O$_2$ Compensate] → set the O$_2$ compensation value.

⚠ **Warning**

● **Please set [O$_2$ Compensate] and [N2O Compensate] based on the actual conditions, or the measurement results may differ greatly from the actual values to cause misdiagnosis.**

16.5.4 No Breath Alarm Delay

No-breath detection is to detect the longest interval between two adjacent RESPs. When the actual no-breath time of the patient exceeds the set no-breath time, the Monitor will respond to no-breath alarms according to the value of [No Breath Alm Delay].

Set [No Breaths Timeout]:

1) Select the CO$_2$ parameter area to enter [CO$_2$ Setup] → [No Breaths Timeout] and set an appropriate detection time.

Set [No Breath Alm Delay]:

1) Enter [User Maintain] → [Other Setup].

2) Set [No Breath Alm Delay] to [Off], [10s], [15s], [20s], [25s], [30s], [35s], [40s], [45s], [50s], [55s] or [1min].

   If you select [Off], the alarm delay function will be disabled. The Monitor will respond to no-breath alarms (if any) immediately.

16.5.5 Altitude

For Masimo CO$_2$ sensor, there is no need to set the altitude.

For Respironics CO$_2$ sensor:

1) Select the CO$_2$ parameter area to enter [CO$_2$ Setup] → [Altitude Unit].

2) Select the CO$_2$ parameter area to enter [CO$_2$ Setup] → [Altitude].

3) Set an altitude value, and the Monitor will auto set [Baro. Pressure] (Barometric Pressure) based on the altitude value.

16.5.6 Balance Gas

Only the Respironics CO$_2$ sensor requires you to set the balance gas manually (for Masimo CO$_2$ sensor, the balance gas is auto set).

1) Select the CO$_2$ parameter area to enter [CO$_2$ Setup] → [Balance Gas].

2) Select [Room Air], [N$_2$O] or [Helium].

16.5.7 Waveform Scale

If you adjust the scale value, the waveform amplitude will change accordingly.

Select the CO$_2$ waveform area to enter [Waveform Setup] → [Scale].

16.6 Maintenance and Cleaning of Respironics Mainstream and Sidestream CO$_2$ Sensor

16.6.1 General Cleaning

Dip a cloth in 70% isopropyl alcohol, water solution (bleach) containing 10% sodium hypochlorite, disinfecting spray cleaner (like Steris Coverage SprayHB), ammonia water or mild soapy water, wash it with water, wring it and then use it to clean the sensor. Dry it and make sure its sight glass is clean before using the cleaned sensor.

16.6.2 Clean the Reusable Airway Adapter of Mainstream Sensor

Wash the airway adapter with mild soapy water, dip it in the disinfectant, like 70% isopropyl alcohol, water solution (bleach) containing 10% sodium hypochlorite, 2.4% glutaraldehyde solvent (Cidex Plus, Steris System 1, etc.) or ammonia water, and then rinse it with sterile water and dry it.

16.6.3 Disinfection of Reusable Airway Adapter

Autoclave: applicable to the airway adapter for adults only.

ETO: disinfect the airway adapter for 1.5h.

Dip in Cidex Plus solvent for 10h.

Dip in Perasafe solvent for 10h.

U.S. Steris System 1 low-temperature sterilization cabinet.

Make sure it is not damaged in operations or in the cleaning/disinfection process and its sight glass is dry without any residue before using the disinfected airway adapter.

16.6.4 Disinfection Frequency of Reusable Airway Adapter

The above disinfection methods allow you to reuse the airway adapter for 100 times.

16.6.5 Zeroing

Usually, the CO$_2$ sensor will be auto zeroed when necessary. You can zero it manually when you consider it necessary: select [CO$_2$] in the parameter area to enter [CO$_2$ Setup] and then select [Zero] to zero the CO$_2$ sensor. Keep the patient circuit in the ambient air (21% O$_2$ and 0% CO$_2$) for 30s in the zeroing process. The CO$_2$ sensor is zeroed successfully when the prompt message "Zeroing, please wait 30s" disappears.

16.7 Masimo Mainstream and Sidestream Module Related Information

16.7.1 Zeroing

In order to eliminate the effect of the baseline drift on measurement results and obtain accurate measurement results, please zero it before using the CO$_2$ sensor to monitor the patient.

Usually, the CO$_2$ sensor will be auto zeroed when necessary. You can zero it manually when you consider it necessary: select [CO$_2$] in the parameter area to enter [CO$_2$ Setup] and then select [Zero] to zero the CO$_2$ sensor. Keep the patient circuit in the ambient air (21% O$_2$ and 0% CO$_2$) in the zeroing process. The CO$_2$ sensor is zeroed successfully when the prompt message "CO$_2$ is zeroing" disappears.

16.7.1.1 Zeroing ISA CO2 Module

The ISA CO$_2$ Module needs to establish a zero reference level for the CO$_2$ measurement. This zero calibration is here referred to as "Zeroing".

The ISA sidestream gas Module performs zeroing automatically by switching the gas sampling from the respiratory circuit to the ambient air. The automatic zeroing is performed every 24 hours and takes less than 3 seconds for ISA CO$_2$ gas module. During zeroing, if ISA's exhaust gas is return to the patient circuit, the return gas level will be different from the gas level at the sampling site.

> ⚠ **Warning**
> - **Since successful zeroing requires the presence of ambient air in the gas module, ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas module before or during the zeroing procedure.**

16.7.1.2 Zeroing IRMA CO₂ Module

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

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the medical backboard device to transmit a Zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air in the IRMA airway adapter is of crucial importance for a successful Zeroing. If a "CO₂ Need Zero" alarm should appear directly after a Zeroing procedure, the procedure has to be repeated.

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

IRMA CO₂ probes:

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

Allow 10 seconds for warm up of the IRMA CO₂ probes after power on before proceeding with the Zeroing Procedure.

Allow the IRMA probe to warm up for at least 10 seconds after changing the IRMA airway adapter before transmitting the Zero reference command.

⚠ **Warning**
- **Incorrect probe Zeroing will result in false gas readings.**

16.7.1.3 Maintenance

Verify the gas readings regularly. Contact the engineers from the manufacturer for maintenance in case of any inaccurate reading.

16.7.1.4 CO₂ Sensor LED

LED indications:

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

16.7.2 Adverse Effects on Performance

1) The following factors have the known adverse effects on the specified performance:

    ● Quantitative effects of RH or condensation;

    ● Quantitative effects of barometric pressure;

    ● Interfering gas or water vapor; and

    ● Other interference sources.

2) Gas Measurement Unit

Use volume percentage as the gas concentration unit. Below is the concentration calculation formula:

$$\%gas = \frac{Partial\ pressure\ of\ gas\ component}{Total\ pressure\ of\ gas\ mixture} * 100$$

Use the cup-making pressure sensor of the ISA gas analyzer to measure the total pressure of the gas mixture.

To convert into any other unit, you can use the actual barometric pressure sent from the ISA sidestream (IRMA mainstream).

CO_2 (mmHg) = (CO_2 Concentration) x (Barometric Pressure from ISA (kPa)) x (750 / 100).

Take 5.0 vol% CO_2 @ 101.3kPa as an example: 0.05 x 101.3 x 750 / 100 = 38 (mmHg).

3) Effects of RH

The partial pressure and volume percentage of the CO_2, N_2O, O_2 and anesthetic gas depend on the water vapor content in the measured gas. Calibrate the O_2 measurement, and the displayed value at the ambient temperature and RH level will be 20.8 vol%, not the actual partial pressure. The 20.8 vol% O_2 represents the actual O_2 concentration of the room air (water concentration: 0.7 vol%) (for example, 25°C and 23% RH @ 1013hPa). The Monitor will keep displaying the actual partial pressure at the current RH level when measuring the CO_2, N_2O and anesthetic gas (like all gases measured by infrared cell).

In the patient's alveoli, the water vapor in the respiratory gas is saturated (BTPS) at the body temperature.

Before the acquired respiratory gas in the sampling tube is transferred to the ISA sidestream gas analyzer, its temperature becomes approximate to the ambient temperature. No water will enter the ISA gas analyzer after the Nomoline sampling tube removes all condensed water. The RH of the acquired gas is approximately 95%.

Use the following formula to calculate the CO_2 value at BTPS:

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

In the above formula:

EtCO2 : $EtCO_2$ value [vol%] sent from ISA

Pamb : barometric pressure [kPa] sent from ISA

3.8 : typical partial pressure [kPa] of the water vapor condensed between the patient circuit and ISA

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

It is assumed that the O_2 is calibrated by the room air at 0.7 vol% H_2O (RH).

16.7.3 Safety Alarm Information

16.7.3.1 ISA Sidestream Gas Analyzer Safety Warning Information

⚠ **Warning**

- The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals only.
- Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
- Do not lift the ISA gas analyzer by the sampling line as it could disconnect from the ISA, causing the ISA gas analyzer to fall on the patient.
- Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.
- Use only airway T-adapters with the sampling point in the center of the adapter.
- Do only use sample lines intended for anesthetic agents if N$_2$O and/or anesthetic agents are being used.
- Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.
- Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
- Since a successful zeroing requires the presence of ambient air (21% O$_2$ and 0% CO$_2$), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.
- Never sterilize or immerse the ISA sidestream gas analyzer in liquid.
- The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.
- Replace the sampling line if the sampling line input connector starts flashing red, or the medical backboard device displays a "Check sampling line" message.
- No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
- The ISA sidestream gas analyzers are not designed for MRI environments.
- During MRI scanning, ISA must be placed outside the MRI suite.
- Use of high frequency electrosurgical equipment in the vicinity of the ISA/medical backboard device may produce interference and cause incorrect measurements.

⚠ **Caution**

- The ISA analyzers should be securely mounted in order to avoid the risk of damage to the ISA.
- Do not operate the ISA sidestream gas analyzer outside the specified operating environment.
- (US Only) Caution: Federal law restricts this device to sale by or on the order of a physician.
- For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

16.7.3.2 IRMA Mainstream Gas Analyzer Safety Warning Information

⚠ **Warning**

- **The IRMA analyzers should be securely mounted in order to avoid the risk of damage to the IRMA.**

- **Do not operate the IRMA sidestream gas analyzer outside the specified operating environment.**

- **(US Only) Caution: Federal law restricts this device to sale by or on the order of a physician.**

- **For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**

- **The IRMA probe is intended for use by qualified medical personnel only.**

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

- **Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.**

- **Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.**

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

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

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

- **Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.**

- **The IRMA probe is not designed for MRI-environments.**

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

- **To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.**

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

- **Incorrect probe zeroing will result in false gas readings.**

- **Replace the airway adapter if rainout/condensation occurs inside the airway adapter.**

- **Use only Masimo manufactured IRMA airway adapters.**

- **The IRMA probe is not intended to be in patient contact.**

- **If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.**

- **No modification of this equipment is allowed.**

⚠ **Caution**

- **Never sterilize or immerse the IRMA probe in liquid.**
- **The IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.**
- **Do not apply tension to the probe cable.**
- **Do not operate the IRMA probe outside the specified operating temperature environment.**
- **(U.S. only) Caution: Federal law restricts this device to sale by or on the order of a physician.**
- **For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**

16.7.4 Airway Obstruction

When the anesthetic gas airway is obstructed, on the screen there will be such a prompt message as "Sampling Line Clogged"; under such a circumstance, replace the Nomoline sampling line.

> ⚠️ **Warning**
>
> - **Do not use the ISA gas analyzer together with a quantitative spraying agent or pulverization treatment; otherwise it may result in the clogging of the germ filter.**

16.7.5 Discharging Waste Gases

When nitrous oxide and/or an anesthetic gas is used, you should prevent these gases from polluting the operating room. Usually the gas discharging outlet should be connected to (via the gas discharging pipe connected to the sample gas outlet of the host equipment):

A discharging system (used for discharging collected gases) or the patient circuit (used for the back flowing of collected gases)

> ⚠️ **Warning**
>
> - **Anesthetics: When an anesthetic which is being used or a patient who recently used an anesthetic is measured, the gas discharging hole on the module must be connected to a waste gas processing system or the patient circuit (on the anesthesia machine or the respirator), so as to prevent medical personnel from inhaling the anesthetic.**

16.7.6 Leakage Check

1. Connect a new Nomoline sampling line with male Luer lock to the ISA gas inlet connector and check that the gas inlet connector shows a steady green light.
2. Connect a short silicon tubing with an inner diameter of 3/32" (2.4 mm) to the Nomoline male Luer.
3. Exhale a long breath into the silicon tubing until the CO$_2$ concentration is greater than 4.5 vol% or 34 mmHg.
4. Quickly connect the silicon tubing tightly to the exhaust port.
5. Wait 1 minute until the CO$_2$ concentration has stabilized. Note the value.
6. Wait 1 minute and check that the CO$_2$ concentration has not decreased more than 0.4 vol% or 3 mmHg. If it has decreased more there is a major leakage in the ISA unit or in the Nomoline. Do not operate the ISA if there is a major leakage in the unit.

16.7.7 Safety Symbols

Symbol	Text, Color Code and Text Format	Description

	Warning: additional information.	"Warning" indicates the hazardous conditions causing possible personal injuries or death. The warning symbol should comply with ISO 7010-W001.
	User's Manual	Refer to the User's Manual.
REF	Reference No.	
SN	Serial No.	
LOT	Lot No.	
	Valid until [YYYY-MM-DD]	Do not use the Monitor after such date.
	Temperature limit	
	Pressure limit	
	RH limit	
	No reuse	
	WEEE directive	Recycle this electrical and electronic equipment according to 2002/96/EC.
	Contain Pb	
IPX4	IP grade	The IP grade indicates the water ingress protection performance.
IP44	IP grade against water and solid object ingress	Protection against tools and short cable ends (>1mm). Protection against water sprays from all directions.
Rx ONLY	Sold on prescription only	Warning (U.S.): the Monitor shall be sold by medical practitioners or on prescription according to U.S. federal laws.
CO$_2$	CO$_2$	The IRMA/ISA analyzer measures CO$_2$ only.
CO$_2$	Multiple gases (AX+ or OR+)	The IRMA/ISA analyzer can measure multiple gases.
	Gas inlet	
	Gas (exhaust) outlet	
	Connect to patient circuit	Illustrate the connection between Nomoline and patient circuit.
	Connect to ISA	Illustrate the connection between Nomoline and ISA.
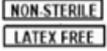
NON-STERILE LATEX FREE	Not sterile, latex free	The Monitor is latex free and not sterile.

16.7.8 Patents and Trademarks

(1) Patent Statement

Masimo Sweden AB owns the following patents for relevant products described in this operating instruction manual: SE519766; SE519779; SE523461; SE524086. Other patents are being applied.

(2) Trademark

Masimo IRMA™, Masimo ISA™, Masimo XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, Masimo GasMaster™ and ISA MaintenanceMaster™ are trademarks of Masimo Sweden AB.

16.7.9 Consumables

16.7.9.1 ISA Nomoline Family

ISA samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO_2 possible for adult, pediatric and infant patients.

The Nomoline Family sampling lines incorporate a unique water separation (NO MOisture) section, which removes condensed water. The NOMO section is also fitted with a bacteria filter that protects the gas analyzer from water intrusion and cross contamination.

As long as no sampling line is connected, the ISA gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the ISA gas analyzer switches to measuring mode and starts delivering gas data.

The Nomoline Family sampling lines are available in a wide variety of versions for both intubated and spontaneously breathing patients and in both disposable and re-sposable configurations –intubated patients can for instance be monitored using the disposable Nomoline Airway adapter Set or a com-bination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter. Spontaneously breathing patients could similarly be monitored using a disposable Nomoline Nasal CO_2 Cannula or a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Nasal CO_2 Cannula with Luer Connector.

OR
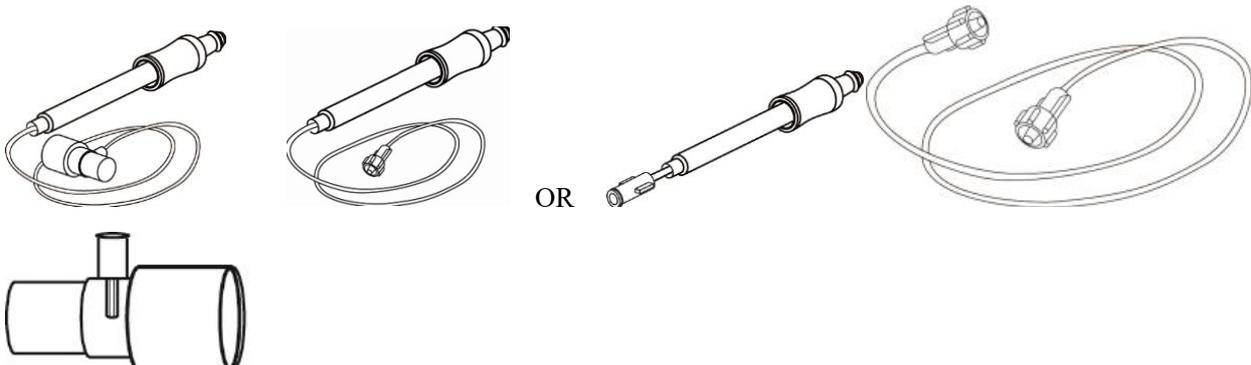
Figure 1.The disposable Nomoline Airway Adapter Set is an alternative to using a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter.

The Nomoline Adapter may be used with other third party sampling lines and cannulas. Please however note that the Nomoline Family of sampling lines are designed for optimal performance and measure-ment fidelity when used with the ISA gas analyzers. For instance, when connecting to a respiratory circuit, the Masimo T-adapter provides a central gas sampling point thereby minimizing the the risk of sampling line occlusion (see below)
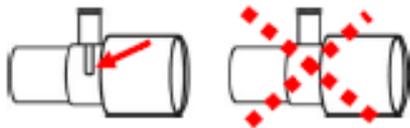
Figure 2. For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left above.

⚠️**Attention**

- **Using sample tubes or cannulas with larger inner diameter than 1 mm will increase ISA's total system response time.**

Nomoline Family sampling line replacement

Nomoline Family sampling lines should be replaced according to good clinical practice or when the sampling line gets occluded. Occlusion occurs when water, secretion etc. is aspired from the respiratory circuit to such extent that ISA cannot maintain the normal 50 sml/min sample flow. This situation is indicated by a red flashing gas inlet connector and an alarm message "Sampling Line Clogged"; Replace the Nomoline and wait until the gas inlet connector switches to green indicating that the ISA gas analyzer is ready for use.

16.7.9.2 IRMA Airway Adapter

The IRMA airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained through the XTP™ windows in the sides of the adapter. The XTP windows are transparent to light in the wavelength ranges of interest and they are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission.

⚠️**Warning**

- **Replace the airway adapter if rainout/condensation occurs inside the airway adapter.**

The IRMA airway adapter is designed as a non-sterile single patient use disposable for both Adult/Pediatric and Infant applications. The IRMA Infant airway adapter has specially designed connectors for minimizing the dead space and can be used even for very small patients.

IRMA airway adapters: Adult/Pediatric (REF: 106220) and Infant (REF: 106260)

⚠️**Warning**

- **Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.**
- **Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.**

16.7.10 Maintenance

The user should verify gas readings regularly; If finding any problems, please contact an engineer of the manufacturer for maintenance.

16.7.11 Cleaning the Analyzer

The "Plug in and measure" ISA sidestream gas analyzer should be cleaned regularly. Use ethanol or isopropyl alcohol with a maximum concentration of 70% and a wet rag to clean the analyzer..

In order to prevent the cleaning liquid and dust from entering into the ISA gas analyzer from the LEGI interface, the Nomoline sampling line should be connected all the time during analyzer cleaning.

Before cleaning the IRMA probe, take off the disposable IRMA airway adapter.

⚠️**Warning**

- **The Nomoline sampling line is not a germ free device. In order to prevent the sampling line from causing damages, please never carry out high pressure disinfection on any part of the sampling line.**
- **Never sterilize the ISA sidestream gas analyzer and the IRMA probe or soak them into a liquid.**

Chapter 17 IBP Monitoring

17.1 Overview

The Monitor can measure the artery pressure (systolic pressure, diastolic pressure and mean pressure) directly.

Call up the two-channel IBP waveform (see the figure below):
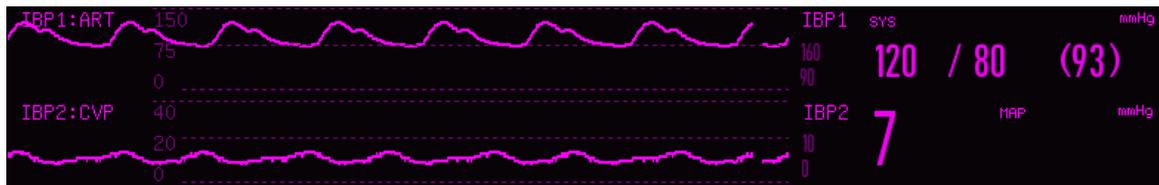
Fig 17-1 Two-channel IBP Monitoring Interface

17.2 Instructions on IBP Monitoring

⚠ **Warning**

- **Use the accessories compliant with the safety requirements on medical equipment only.**
- **Do not touch the metal parts connected to electrical equipment when connecting or using any accessory.**
- **In order not to cause burns (resulted from electric leakage) to the patient, please do not allow its sensors and sensor cables to contact such equipment when connecting the Monitor to any high-frequency electrosurgical equipment.**
- **Never reuse the disposable pressure sensor.**
- **Before monitoring the patient, please check if the sensor cable works properly. Remove the IBP sensor cable from the sensor interface, and the Monitor will display the prompt message "IBP sensor off" and trigger the alarm sound.**
- **If any liquid other than the solution used for the perfusion pressure tube or sensor splashes onto the Monitor or its accessories, especially when it is likely to flow into the Monitor or its sensors, please contact the maintenance department of the hospital.**

⚠ **Note**

- **Use the pressure sensor specified herein only.**

With the protection against electric shock and against the effects of defibrillators, the pressure sensor specified herein can be used for surgical operations. The pressure waves may become disordered in the defibrillation process. Once the defibrillation is completed, the Monitor will go back to normal work with its operation mode and user configurations remaining unaffected.

> ⚠ **Note**
> - **Calibrate the sensor, whether new or used, regularly according to the relevant procedures of the hospital.**
> - **Zero the transducer before monitoring the patient. In the IBP monitoring process, keep the pressure sensor at the same level as the patient's heart. In order not to clog the cannula, irrigate the cannula with continuously fed heparin saline to keep the pressure measurement path unobstructed. Secure the cannula reliably against displacement and disconnection and ensure normal IBP measurement.**

17.3 Monitoring Steps

Preparations for measurement:

1) Prepare the pressure tube and sensor by filling the cannula system with the physiological saline solution. Make sure there is no bubble in the cannula system.

2) Connect the patient cannula to the pressure tube. Make sure there is no air in the cannula, pressure tube or sensor.

3) Insert the cable into the relevant socket and check if the Monitor is powered on.

4) Enter [User Maintain] and activate the IBP sensor.

5) Enter the general interface of the Monitor and select [Screen Layout] to call up the IBP waveform and parameter to be monitored (skip this step if the IBP waveform and parameter are already displayed on the screen).

6) Place the sensor at the same level as the heart (approximately at the mid-axillary line).

7) Zero the sensor and then close its atmosphere channel and open its patient channel.

> ⚠ **Warning**
> - **If there is any bubble in the pressure tube or sensor, use the heparin saline to irrigate the system. Bubbles will lead to inaccurate measurement results.**
> - **To perform the ICP measurement to a sitting patient, please adjust the sensor to the same level as the patient's ears. Incorrect sensor position will lead to inaccurate measurement results.**
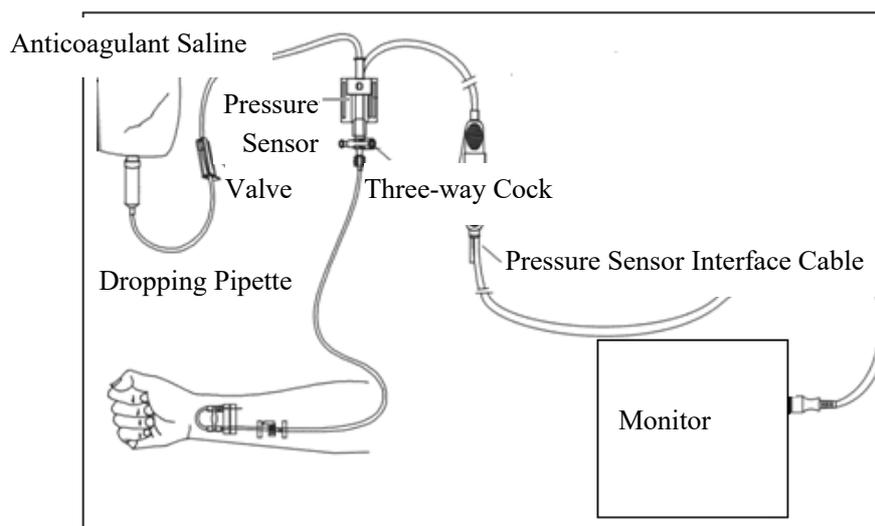
Fig 17-2 IBP Monitoring

17.3.1 Zero the Pressure Sensor

To prevent inaccurate measurement, please zero the sensor on a daily basis or as required by the relevant policies of the hospital. Zero the sensor:

- When using a new pressure tube or sensor;

- When connecting the sensor to the Monitor; or

- If you doubt that the measurement results are inaccurate.

    1) Close the valve of the three-way cock to patient.

    2) The sensor must be open to the atmosphere first.

    3) Select the IBP parameter area (either displayed channel) to enter [IBP Setup] and select [Zero] (the zeroing result will be displayed when the zeroing operation is completed). You can also select [IBP Zero] (shortcut key) in the lower menu bar to zero the sensor.

    4) Once the sensor is zeroed successfully, close its atmosphere channel and open its patient channel.

17.4 IBP Setup

Select [IBPx: XXX] in the waveform area: "x" refers to the IBP channel and "XXX" refers to the current pressure name of such channel. Select [IBPx: XXX] to set channel x.

17.4.1 Pressure Name

Enter [Screen Config] to change the pressure name (select an appropriate pressure name from the table below).

Pressure Name	Description
ART	Arterial pressure
PA	Pulmonary artery pressure
CVP	Central venous pressure
RAP	Right atrial pressure
LAP	Left atrial pressure
ICP	Intracranial pressure
P1/P2	Expansion pressure
LV	Left ventricular pressure
Ao	Aortic pressure
UAP	Umbilical artery pressure
BAP	Brachial artery pressure
FAP	Femoral artery pressure
UVP	Umbilical venous pressure
IAP	Intra-abdominal pressure
P3/P4	Expansion pressure

17.4.2 IBP Superposition

Follow the steps below to enable the Monitor to display a two-parameter waveform in the IBP waveform area:

1) Enter [Main Menu] → [Screen Config] → [Screen Layout].

2) Select [IBP Waveform] and then select the two monitored IBP parameters.

17.4.3 Filter Mode

1) The two channels of the sensor use the same filter mode. Select the waveform of either channel to enter [IBPx: XXX Waveform] and then set [Filter Mode] to [No Filter], [Smooth] or [Normal].

   ➢ No Filter: display the original waveform without filtering it.

   ➢ Smooth: obtain a smooth waveform.

   ➢ Normal: obtain a relatively smooth waveform.

17.4.4 Pressure Scale

You can adjust the waveform's coverage (IBP measurement range) on the screen by adjusting the upper scale and lower scale. The IBP waveform area indicates the waveform scale. The top and bottom of each IBP waveform represent the upper scale and lower scale of such waveform respectively. You can set the upper scale and lower scale. As a non-selectable parameter, the middle scale depends on the upper scale and lower scale.

1) Select [IBPx: XXX] in the waveform area to enter [IBPx: XXX Waveform]. Select an appropriate range for [Upper Scale] and [Lower Scale] respectively.

2) You can set the scale range for the pressure names on both channels:

✧ Upper Scale: the pressure value corresponding to the upper scale limit (selectable range: the measurement range of the current pressure name).

✧ Lower Scale: the pressure value corresponding to the lower scale limit (selectable range: the measurement range of the current pressure name).

✧ Middle Scale: the pressure value corresponding to the middle scale limit (selectable range: depend on the range selected for [Upper Scale] and [Lower Scale]).

17.5 Pressure Unit

This function allows you to enter [User Maintain] to set the unit of all IBP names except CVP. You can enter [User Maintain] to set the CVP unit separately.

17.6 SPV and PPV Display

Select [IBPx: XXX] in the parameter area to enter [IBPx: XXX Setup]. Select [SPV Display] to switch to [On], then the SPV and PPV measured values are displayed in parameter area.

Chapter 18 Data Review

Select the [Review] quick key, or select [Main Menu]; then select [Review] to enter the Review interface.

Data Review includes: NIBP Measurement Review, Alarm Event Review, Trend Graph Review, Trend Table Review, Wave Review.

The monitor provides 160h trend data, 2,000 sets of NIBP measurement data, 200 times of storage of parameter alarm events, and at most 48h wave review of single-channel wave (the specific time is related to the waves saved and the number of waves). This chapter introduces the method for observation of these saved data in detail.

18.1 Wave Save

User can select the wave to be saved according to requirement. Only waves set to be saved can be viewed in [Wave Review]. After admitting a patient, it will be impossible to modify Wave Save selection.

1) Enter [User Maintain] → [Wave Save].

2) Select the parameter whose wave is to be saved, and select [Enter]; make a selection according to the prompt message.

[Rec. Merge]: Admit a new patient and create a patient file, and save current monitoring data to the patient file created.

[Rec. Not Merge]: Admit a new patient and create a patient file, but current monitoring data are not saved to the patient file created.

18.2 Trend Review

Trend is a set of patient data over time manifested in the form of graph or table.

In the [Trend Review] window, select [Trend Graph] or [Trend Table] to review the corresponding data.

The trend graph shows recent data that are updated continuously; the bottom of the screen shows the time scale. User can select the desired wave via the parameter area on the left side of the window; besides, user can browse the trend database via a cursor crossing all measurement items in the window. When moving the cursor, the current parameter trend data and specific time of data are shown on the right side of the corresponding window:
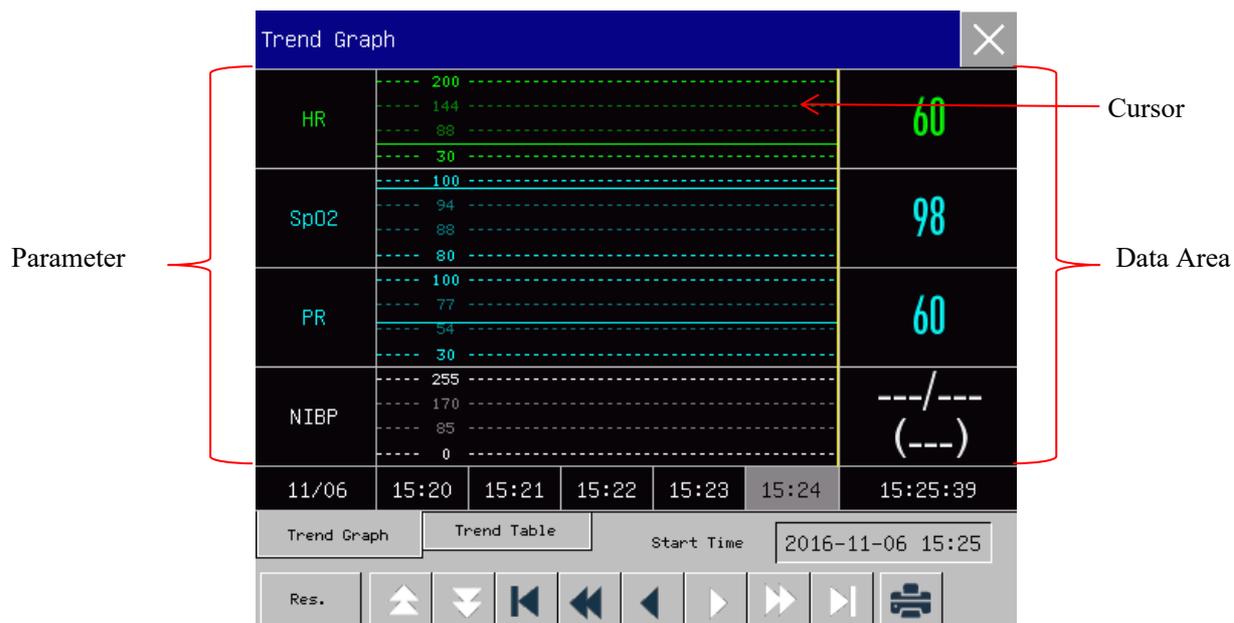
Fig 18-1 Trend Graph Review

Aperiodic measurements can be viewed from the trend table. This table shows measurement data and measurement time. Trend table data during a period of maximally 160h can be viewed.
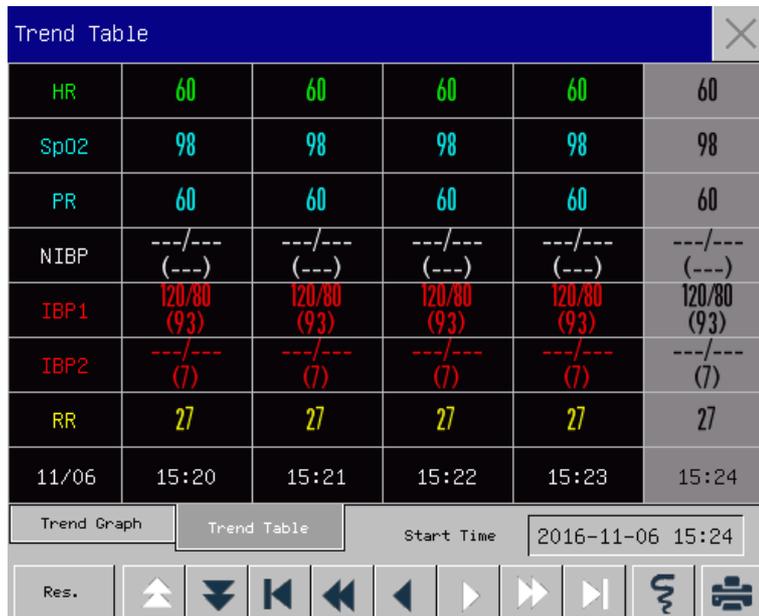
Fig 18-2 Trend Table Review

◆ Symbol Description

Symbol	Introduction
▲▼	Turn page up and down to view other parameter trend graphs not shown in the current view.

◄ ►	Move the cursor left or right by one step to view along the timeline of trend database.
◄◄ ►►	Move the cursor left or right by one page to view along the timeline of trend database.
◄◄ ►►|	Jump to the start point or end point of the trend database to view the farthest (earliest) or nearest (latest) trend info saved.

◆ Select the date field beside [Start Time]; the Setup window will pop up, where user can set the start time of trend graph review.

◆ Trend Interval refers to the resolution of trend data shown on the screen. For neonate monitoring, since the clinical condition of the patient changes fast, a high resolution can be selected; for adult monitoring, since the clinical condition of the patient changes relatively slowly, a low resolution can be selected.

Set [Res.] (Resolution)

1) In the Trend Graph Review window

   ✧ Select [1s] or [5s] to view the short trend during the past 1h.

   ✧ Select [10s] to view the medium trend during the past 4h.

   ✧ Select [1 Min], [5 Min] or [10 Min] to view the long trend during the past 160h.

2) In the Trend Table Review window

   ✧ Select [1 Min], [5 Min], [10 Min], [30 Min], [60 Min], [120 Min] or [180 Min] to view the trend during the past 160h.

◆ In the [Trend Table] menu, select ⑤ to enter the [Trend Table Review Report] menu. User can set the following in this menu:

   ■ Record Time: Determine which period of trend data will be output via [Start Time] and [Forward Time]. For example: If [Start Time] is set to 2015-4-21 10:00:00 and [Forward Time] to [2h], the trend data to be output are those during 2015-4-21 08:00:00~2015-4-21 10:00:00. When [Forward Time] is set to [Auto], trend table data during 30min will be recorded.

   ■ [Res.]: Select the resolution for trend table output.

   ■ [Param.] (Parameter Selection): Select the specific parameter to be output in this menu.

   ■ [Record]: After setting, select [Record] to start data output.

Note: Trend graph has no record setup.

18.3 NIBP Measurement Review

This monitor can display the latest 2,000 sets of NIBP measurement data in NIBP Measurement Review. In the [Review] menu, select [NIBP Review], as shown in the figure below:

Fig 18-3 NIBP Measurement Review

◆ Select [⑤] to enter the [NIBP List Report] menu.

  ■ Record Time: Determine which period of trend data will be output via [Start Time] and [Forward Time]. For example: If [Start Time] is set to 2015-4-21 10:00:00 and [Forward Time] to [2h], the trend data to be output are those during 2015-4-21 08:00:00~2015-4-21 10:00:00. When [Forward Time] is set to [Auto], NIBP list data during 1h will be recorded.

  ■ [Record]: After setting, select [Record] to start data output.

◆ Select [🖶] to set and print a NIBP list review report. See the "Print Setup" chapter for details.

18.4 Alarm Event Review

This monitor can display the latest 200 parameter alarm events in Alarm Event Review, including physiological alarm events, arrhythmia alarm events, and manual events. When an alarm event occurs, the monitor will save the values of relevant parameters at the moment when such event occurs and the waveforms 8s before and after such occurrence. In the [Review] menu, select [Alarm Event Review] to enter the [Alarm Event Review] window → [View Physiology Alarm] → [View Physiology Alarm] menu, See the figure below:
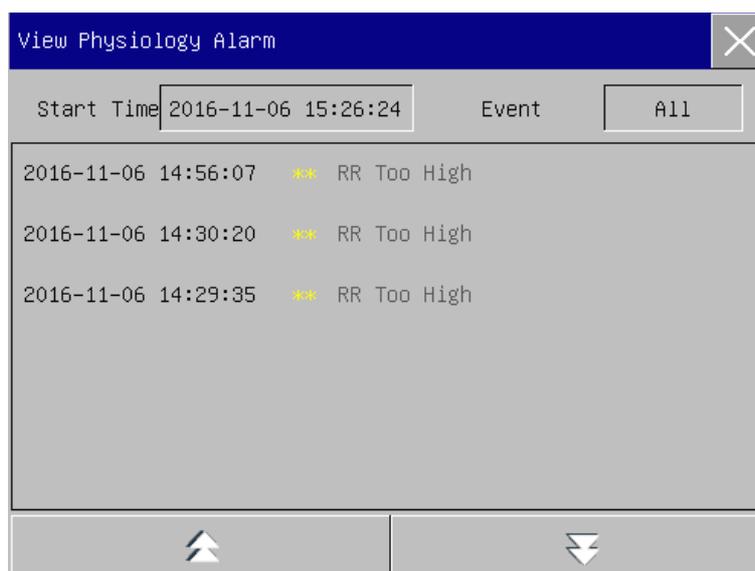
Fig 18-4 Alarm Event Review

◆ User can set the start time of review in [Start Time].

◆ In [Event] under Alarm Review, user can select the alarm info of the parameter to be viewed.

> ⚠ **Warning**
> - **Only current physiological and technical info can be displayed; upon restart of the monitor, the alarm info will be cleared.**
> - **Alarm info in this window will not be classified by patient.**
> - **When the monitor is full of alarm events, the oddest alarm events will be deleted.**

◆ Select the alarm event to be viewed and recorded; enter the [View Physiological Alarm] window to view alarm details; select [icon] to directly record current alarm event data.

◆ Select the alarm event to be printed; enter the [View Physiological Alarm] window; select [icon] to directly print current alarm event data.

Select [View Technical Alarm] → [View Technical Alarm] menu. See the figure below:
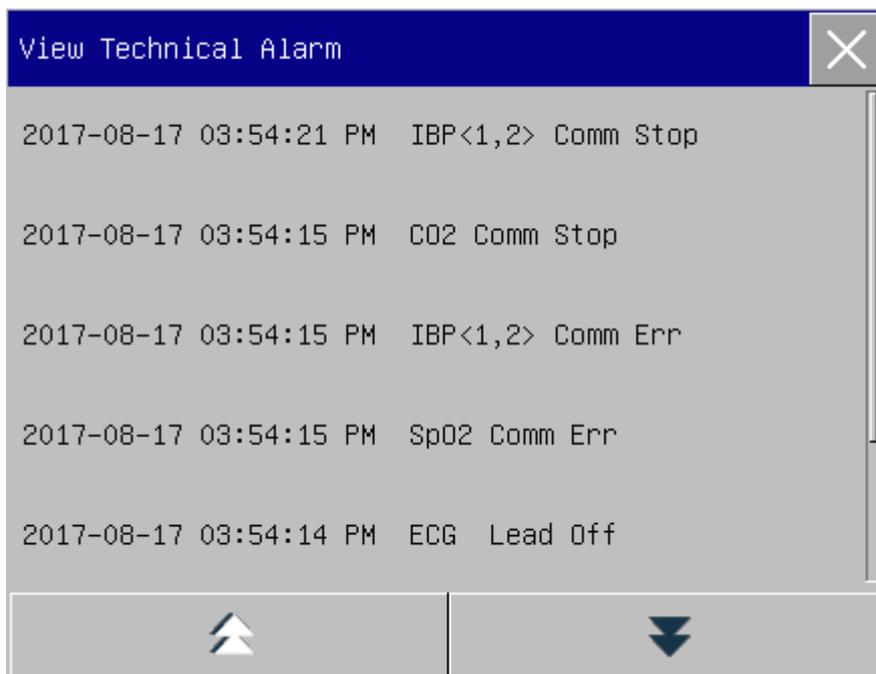
Fig 18-5 Technical Alarm Event Review

⚠ **Note**

- **Technical alarm can only be viewed and cannot be printed.**

18.5 Wave Review

You can review holographic waves only after SD card is installed and waves are set to be saved. This monitor can display single-channel wave playback for maximally 48h in the Wave Review window; with the increase of waves saved, the playback time for each wave reduces. You can review the waveform of any parameter of functions configured on the monitor:
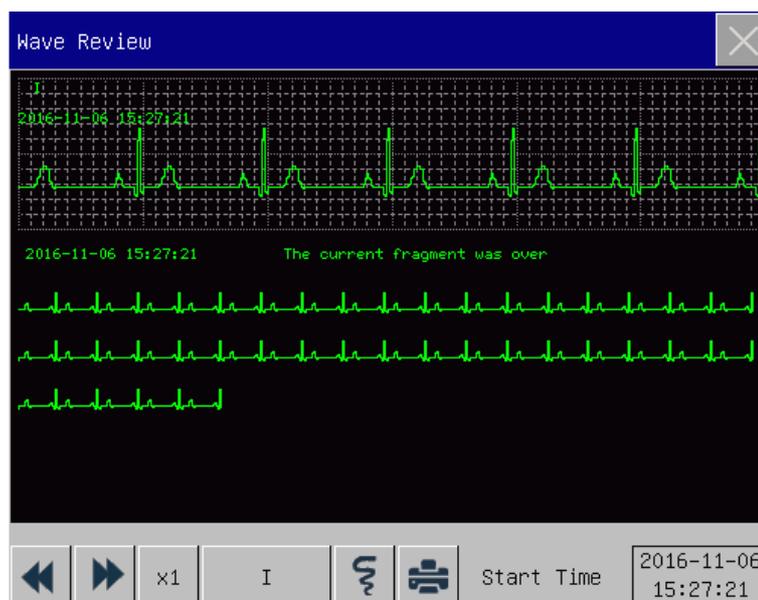
Fig 18-6 Wave Review

Symbol	Introduction
◀▶	Turn page up or down
x1	Waveform gain; select this button to choose the appropriate gain
I	Waveform currently reviewed; select the waveform to be viewed.
Start Time	Start time of waveform view.
⑤	Record holographic data of waveform.
🖶	Connect an external printer to print holographic data of waveform.

➢ **Operation Examples**

ECG Wave Review:

1) Before admitting a patient, enter the [Wave Save] interface under [User Maintain]; select the waveform to be saved.

2) In the [Review] menu, select [Wave Review].

3) In the [Wave Review] window, select the parameter to be reviewed.

4) In the [Wave Review] window, you can use ◀▶ to view changes in trend graph time and trend curve.

5) Select ⑤ to enter the [Record Setup] menu. After setting the record start time in this menu, select [Record] to record holographic data of waveform during 6s.

6) Select ![printer icon] to set and print a wave review report. See the "Print Setup" chapter for details.

7) Press ![X icon] to exit the [Wave Review] window.

Chapter 19 Calculation

This monitor provides the calculation function. The calculated result is not patient data directly measured, but is result calculated by the monitor according to appropriate data provided by the user.

Calculations that can be performed on the monitor include:

✧ Drug calculation

✧ Hemodynamic calculation

✧ Ventilation calculation

✧ Oxygenation calculation

✧ Renal function calculation

To perform a calculation, you can directly select the [Calculate] quick key or select [Calculate] in the [Main Menu] to enter the Setup menu.

⚠ **Note**
- **Prior to calculation, please confirm whether the correct patient type and calculation unit are selected. If you have any question, please consult relevant medical workers.**
- **Select the drug dose and calculation method under the doctor's guidance; the monitor will only perform calculation according to the input values, but will not verify the calculated results.**
- **After power outage, data in [Review] in the Calculate chapter will be cleared.**

19.1 Drug calculation

The monitor provides the calculation and titration display functions for 15 drugs, and can output the titration content on the recorder.

Types of drugs that can be calculated in the system include: Aminophylline, Dobutamine, Dopamine, Epinephrine, Heparin, Isuprel, Lidocaine, Nipride, Nitroglycerin, and Pitocin; besides, drugs A, B, C, D and E are provided to represent any drug.

Fig 19-1 Drug Calculation

Drug dose is calculated by the following equation:

Concentr. = Amount / Volume

Infusion Rate = Dose / Concentr.

Duration = Amount / Dose

19.1.1 Operation Method

In the Drug Calculate window, the operator should first select the name of drug to be calculated; confirm the patient weight; and then input other known values. Select the position of calculation item to be input; the corresponding input window will pop up, where you can input the calculated value. After selecting the calculated value, the result of the calculation item will be displayed at the corresponding position.

⚠ **Note**
- **The values first provided by the system are only a set of random initial values. The operator should not take these values as the calculation standard, but should re-input a set of values appropriate for the patient according to the doctor's advice.**
- **In the same unit series, the unit base will be adjusted automatically according to the current input value.**

Select the drug type: You can select the drug type among 15 drugs; only one type can be selected for calculation at a time.

⚠ **Note**
- **A, B, C, D and E are not real drug names, but are codes of user-defined drugs. However, The units of these five drugs are fixed; the operator can select the appropriate unit according to the**

drug use convention. The units are expressed as follows:

- **Units of drugs A, B and C: g, mg, mcg.**

- **Unit of drug D: unit, k unit, m unit.**

- **Unit of drug E: mEq.**

- **The change in patient weight in the Calculate menu will not affect the current patient info in the monitor.**

19.1.2 Titration

To enter the Titration interface, select [Titration] in the [Drug Calculate] menu.

The Titration interface under Drug Calculate is shown in the figure below:

Titration-Drug A					✕
Amount	400.00	mg	Volume	250.00	ml
Dose/min	2500.00	mcg	Infusion	93.75	ml/hr
Weight	70.00	kg	Drip Rate	31.25	gtt/min

Dose	Infusion	Dose	Infusion	Dose	Infusion
0.00	0.00	10.00	0.37	20.00	0.75
1.00	0.03	11.00	0.41	21.00	0.78
2.00	0.07	12.00	0.45	22.00	0.82
3.00	0.11	13.00	0.48	23.00	0.86
4.00	0.15	14.00	0.52	24.00	0.90
5.00	0.18	15.00	0.56	25.00	0.93
6.00	0.22	16.00	0.60	26.00	0.97
7.00	0.26	17.00	0.63	27.00	1.01
8.00	0.30	18.00	0.67	28.00	1.05
9.00	0.33	19.00	0.71	29.00	1.08

Basic | Dose | Step | 1 | Dose | Dose/min

Fig 19-2 Titration

Operation steps:

1) In Titration, select [Basic]; select [Dose], [Infusion Rate] or [Drip Rate];

2) Select [Step] to set the step size. The selectable range is 1~10.

3) Select [Dose] → [Dose/min], [Dose/hr], [Dose/Kg/min], and [Dose/Kg/hr].

4) To view pages previous and next to the table, select ⬆ and ⬇.

5) To record titration data, select 🔲.

6) To return to the [Drug Calculate] menu, select ✕.

19.2 Hemodynamic Calculation

19.2.1 Calculation Steps

In the [Calculate] menu, select [Hemodynamic]; the menu shown below will pop up.

1) Enter the value to be calculated in [Input]; press the [Calculate] button to obtain the calculated value in the table below.

2) Select [Range]; the unit following the parameter will change to the corresponding reasonable numerical range; you can check whether the calculated value is within the normal range.

3) Select [Review] to review the previously calculated result; in the Review interface, you can select ⌷ to record calculated data.

Fig 19-3 Hemodynamic Calculation

> ⚠ **Note**
> ● **Parameters should be input for hemodynamic calculation; when no parameters are input, the corresponding calculated result will not be displayed.**

19.2.2 Input Parameters

Abbreviation	Unit	Full English Name
HR	bpm	Heart rate
C.O.	L/min	Cardiac output
PAWP	mmHg	Pulmonary artery wedge pressure
Art Mean	mmHg	Artery mean pressure
PA Mean	mmHg	Pulmonary artery mean pressure
CVP	mmHg	Central venous pressure
EDV	ml	End-diastolic volume
Height	cm	Height
Weight	kg	Weight

19.2.3 Output Parameters

Abbreviation	Unit	Full English 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

19.3 Ventilation Calculation

In the [Calculate] menu, select [Ventilation]; the menu shown below will pop up.

1) Enter the value to be calculated in [Input]; press the [Calculate] button to obtain the calculated value in the table below.

2) Select [Range]; the unit following the parameter will change to the corresponding reasonable numerical range; you can check whether the calculated value is within the normal range.

3) Select [Unit]; you can select [Kpa] or [mmHg].

4) Select [Review] to review the previously calculated result; in the Review interface, you can select [image] to record calculated data.

Fig 19-4 Ventilation Calculation

19.3.1 Input Parameters

Abbreviation	Unit	Full English 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	N/A	Respiration quotient
ATMP	mmHg	Atmospheric pressure

19.3.2 Output Parameters

Abbreviation	Unit	Full English 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/m^2	Minute volume
Vd	Ml	Volume of physiological dead space
Vd/Vt	%	Physiologic dead space in percent of tidal volume
VA	L/min	Alveolar volume

19.4 Oxygenation Calculation

1) In the [Oxygenation] interface, enter the value to be calculated in [Input]; press the [Calculate] button to obtain the calculated value in the table below.

2) Select [Range]; the unit following the parameter will change to the corresponding reasonable numerical range; you can check whether the calculated value is within the normal range.

3) Select [Press. Unit], [Hb Unit] and [Unit] to change the corresponding unit; the value of relevant parameter will be converted and refreshed automatically.

4) Select [Review] to review the previously calculated result; in the Review interface, you can select 💲 to record calculated data.

Fig 19-5 Oxygenation Calculation

19.4.1 Input Parameters

Abbreviation	Unit	Full English Name
C.O.	L/min	Cardiac output
FiO_2	%	Percentage fraction of inspired oxygen
$PaCO_2$	mmHg	Partial pressure of carbon dioxide in the arteries
PaO_2	mmHg	Partial pressure of oxygen 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	/	Respiration quotient
ATMP	mmHg	Atmospheric pressure
Height	Cm	Height

Weight	Kg	Weight

19.4.2 Output Parameters

Abbreviation	Unit	Full English Name
BSA	m^2	Body surface area
VO_2 ccalc	ml/min	Oxygen consumption
$C(a\text{-}v)O_2$	ml/L	Arteriovenous oxygen content difference
O_2ER	%	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

19.5 Renal Function Calculation

In the [Calculate] menu, select [Renal] (Renal Function Calculation); the menu shown below will pop up.

1) Enter the value to be calculated in [Input]; press the [Calculate] button to obtain the calculated value in the table below.

2) Select [Range]; the unit following the parameter will change to the corresponding reasonable numerical range; you can check whether the calculated value is within the normal range.

3) Select [Review] to review the previously calculated result; in the Review interface, you can select 🔁 to record renal function calculation data.

Fig 19-6 Renal Function Calculation

19.5.1 Input Parameters

Abbreviation	Unit	Full English Name
URK	mmol/L	Urine pstassium
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

19.5.2 Output Parameters

Abbreviation	Unit	Full English Name
URNaEx	mmol/24h	Urine sodium excretion

URKEx	mmol/24h	Urine potassium excretion
Na/K	%	Sodium potassium ratio
Can	ml/24h	Clearance of sodium
Clcr	ml/min	Creatinine clearance rate
FENa	%	Fractional excretion of sodium
Cosm	ml/min	Osmolar clearance
CH_2O	ml/h	Free water clearance
U/P osm	N/A	Urine to plasma osmolality ratio
BUN/Cr	mmol/L	Blood urea nitrogen creatinine ratio
U/Cr	N/A	Urine-serum creatinine ratio

Chapter 20 Record

20.1 Description of Recorder

This monitor uses a thermal arraycorder which supports several record types and can output patient info, measured data, reviews and at most 3 waves.
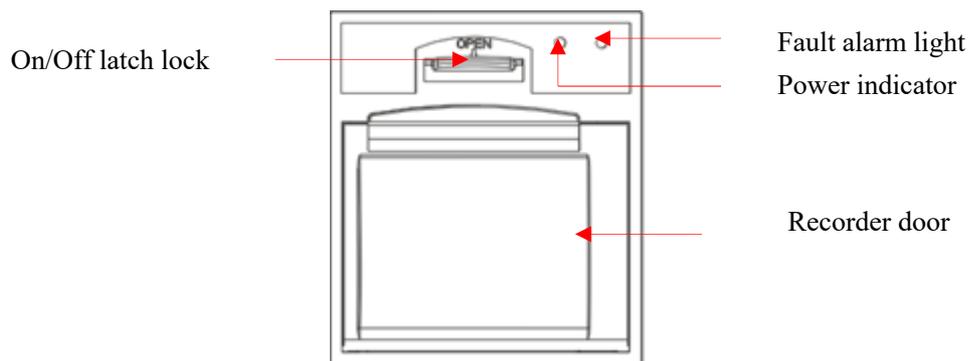
Fig 20-1 Recorder

20.2 Record Type

Records are divided into the following types according to the ways in which they are triggered:

✧ Real-time record triggered manually

✧ Timed record automatically triggered by the recorder at the set interval

✧ Alarm record triggered by parameter exceeding limit, etc.

Records related to specific functions

➢ Waveform Freeze

➢ Events: parameter alarm events, arrhythmia alarm events, and manual events

➢ Drug calculation data

➢ Hemodynamic calculation data

➢ Ventilation calculation data

➢ Oxygenation calculation data

➢ Renal function calculation data

➢ Review data

20.3 Record Operation

◆ Start recording manually:

➢ To start real-time record, select 〔⊊〕 on the front panel of the monitor or the [Record] quick key.

➢ To start records related to specific functions, select the [Record] button in the current menu or window.

◆ Stop recording manually:

➢ Select 〔⊊〕 on the front panel of the monitor or the [Record] quick key.

◆ The recorder will start recording automatically in the following situations:

➢ If the timed record function is enabled, the recorder will start recording automatically at the set interval.

➢ When [Alarm On/Off] and [Alarm Record] of a parameter are both set to [On]; as soon as an alarm is generated for this parameter, the monitor will be triggered to start alarm recording once.

◆ The recorder will stop recording automatically in the following situations:

✧ The recording task is fulfilled

✧ The recorder is lack of paper

✧ The recorder is faulted

20.4 Recorder Setup

Open [Main Menu], and select [Record Setup] to enter relevant interface.

Record waves:

The recorder can output at most 3 waves at a time. In the record output setup interface, set Record Waves 1, 2 and 3. These settings apply to real-time record and timed record.

➢ Set the paper speed.

1) In this menu, select [Paper Speed].

2) Paper speed: [25mm/s], [50mm/s].

➢ Set real-time record:

1) In this menu, select [Rt Record Time] (Realtime Record Interval): select among [3s], [5s], [8s], [16s], [32s] and [Continual] as needed.

If [8s] is selected, waves during 8s after the current moment will be recorded.

If [Continual] is selected, waves after the current moment will be recorded; to stop recording, manual operation will be needed.

➢ Set timed record

User can set the recording interval as needed; the setting of real-time record determines the time length of each recording.

1) In this menu, select [Timed Record Interval].

2) Select the interval: [Off], [1h], [2h], [3h] and [4h].

➢ Grid

Select [Grid] and switch it between "On" and "Off". When set to on, grid is printed out by the printer on the paper; when set to off, grid is not printed out on the paper.

20.5 Load Record Paper

Load the record paper to the thermal recorder (optional) on the right side of the monitor according to the steps shown in the right figure below:

1) Use the latch lock at the top of the recorder door to open the door.

2) Remove the empty paper core.

3) Load new roll paper and fix it onto the paper clip.

4) The roll feeds paper from the bottom; paper runs across the top of the recorder door.

5) At least one inch of paper should extend out of the edge of the door.

6) Turn the recorder door up to close it tightly.

7) To check whether paper is properly loaded, please start recording.

8) If printing is not performed, it indicates paper may be loaded inversely; try reloading the paper.
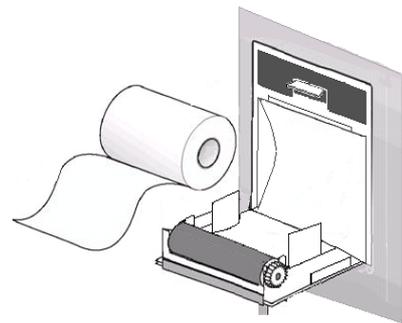
Fig 20-2 Load Record Paper

⚠ **Caution**
- **Load paper carefully; otherwise the thermal print head may get damaged.**
- **During output by the recorder, it is not allowed to pull the record paper outward with force; otherwise the recorder may get damaged.**
- **Do not keep the recorder door open except for paper change or troubleshooting.**

Clear Jammed Paper

If the recorder makes any abnormal sound during operation or the record paper outputs abnormally, please check to see if any paper is jammed. If yes, please clear it according to the following steps:

1) Open the recorder door.

2) Take out the record paper, and cut off the crease part.

3) Reload the record paper, and close the recorder door.

20.6 Recorder Cleaning

After long-term use of the recorder, scraps of paper and impurities will be accumulated on the print head, which will affect the quality of recording and the service life of print head and roll shaft.

Cleaning:

1) Prior to cleaning, measures should be taken to prevent the device from being damaged by static electricity.

2) Open the recorder door; take out the record paper, and use a cotton ball to dip an appropriate amount of alcohol.

3) Gently wipe the surface of the thermal part of print head.

4) When the alcohol becomes completely dry, reload the record paper and close the recorder door.

⚠️ **Note**
- **Do not use any materials (e.g., abrasive paper) that can damage the thermal part.**
- **Do not squeeze the thermal print head with force.**

Chapter 21 Print

21.1 Printer

This monitor can output patient reports by connection to the printer via a USB cable and net.

Currently, the monitor supports the following types of printers:

◆ HP Laserjet pro M403n laser printer

◆ HP laserJet 1505n monochrome laser printer

◆ HP laserJet P2035n laser printer

◆ HP laserJet P4015n laser printer

◆ HP laserJet 1606dn laser printer

◆ Lenovo LJ2650DN laser printer

◆ Lenovo LJ4600DN laser printer

Specification of reports printed by the printer:

◆ Paper: A4

◆ Resolution: 300dpi

◆ Single/double-sided: Support both single and double-sided printing, if supported by the printer.

> ⚠ **Note**
> - **For instructions on the printer, please see the documentation accompanied with the printer. This monitor may support more printers with the upgrade of the product, for which no prior notice will be provided. If you have any question about your printer, please feel free to contact us.**

21.2 Set Printer Type

Enter [User Maintain] → [Other Setup] → [Printer Type], select [USB] or [Net].

21.3 Printer Setup

If you choose to connect the printer via the USB cable, you can set up a report to print directly. If you select the network printer, you need to set the printer properties: Select the [Main Menu] → [Print Setup] →[Printer Setup]. In the [Printer Setup] menu, you can make the following operations:

■ Select the network printer

Select the [External Printer]. In the pop-up list, select any one of the printers in the LAN as the printer of this monitor.

■ Search the printer

If a user-specified printer is excluded in the list or if a new printer is added to the LAN, you can select [Query] to re-search all the printers in the LAN.

21.4 Start Report Printing

You can print the following types of reports: Trend Graph, Trend Table, NIBP List, Event Review, Wave Review, and Realtime Wave.

To print a desired report, select [Main Menu] → [Print Setup]; in the pop-up menu, perform report setup as appropriate for your need.

21.5 Stop Report Printing

To stop report printing, select [Main Menu] → [Print Setup] → [Cancel Print].

21.6 Set Report

21.6.1 Set Trend Table Report

In the [Print Setup] menu, select [Trend Table Review Report] to set the following:

◆ Print Time: Determine which period of trend data will be output via [Start Time] and [Forward Time]. For example: If [Start Time] is set to 2015-4-21 10:00:00 and [Forward Time] to [2h], the trend data to be output are those during 2015-4-21 08:00:00~2015-4-21 10:00:00. When [Forward Time] is set to [Auto]: if [Type Priority] is set to [Time Priority], a page with time column will be printed; if it is set to [Param. Priority] (Parameter Priority), a page with parameter column will be printed.

◆ [Res.]: Select the resolution for trend table output.

◆ [Type Priority]: When [Param. Priority] is selected, the column in the output report is parameter; when [Time Priority] is selected, the column in the output report is time.

◆ [Param.] (Parameter Selection): Select the specific parameter to be output in this menu.

21.6.2 Alarm Event Review Report

To set the alarm event review report, select [Main Menu] → [Print Setup] → [Alarm Event Review Report].

Print Time: Determine which period of trend data will be output via [Start Time] and [Forward Time]. For example: If [Start Time] is set to 2015-4-21 10:00:00 and [Forward Time] to [2h], the trend data to be output are those during 2015-4-21 08:00:00~2015-4-21 10:00:00. When [Forward Time] is set to [Auto], only one page of data will be printed.

21.6.3 Set NIBP List Report

To set NIBP List Report, select [Main Menu] → [Print Setup] → [NIBP List Report].

Time Setup is similar to that of Alarm Event Review Report. Please see the description in "Alarm Event Review Report".

21.6.4 Trend Graph Review Report

To set Trend Graph Review Report, select [Main Menu] → [Print Setup] → [Trend Graph Review Report].

[Time of Page]: User can select the time for printing each page as needed; the time that can be selected is less than the forward time.

[Param.]: Select the review parameter to be printed.

Time Setup is similar to that of Trend Table. Please see the description in "Set Trend Table Report".

21.6.5 Set Realtime Wave Report

To set Realtime Wave Report, select [Main Menu] → [Print Setup] → [Realtime Wave Report].

[Sweep]: Set the wave output speed; [Auto] means the wave output speed is consistent with the sweep speed of each wave on the screen.

[Wave Select]: Select the wave to be output in this menu.

21.6.6 Wave Review Report

To set Wave Review Report, select [Main Menu] → [Print Setup] → [Wave Review Report].

Print Time: Determine which period of review data will be output via [Start Time] and [Duration]. For example: If [Print Time] is set to 2015-4-21 10:00:00 and [Duration] to [15s], the trend data to be output are those during 2015-4-21 10:00:00~2015-4-21 10:00:15.

[Gain]: Select the wave print range.

[Sweep]: Set the wave output speed.

[Wave Select]: Select the review wave to be printed.

21.7 Printer Abnormality

21.7.1 Printer Out of Paper

When the printer is out of paper, no response will be given to the print request sent; when there are too many tasks without response, printer abnormality may be caused. At this moment, please properly load paper into the printer and resend the print request; when necessary, restart the printer.

21.7.2 Printer Status Info

When the printer status info shows [USB printer not exists], please check to see if the printer is turned on, connected correctly and loaded with paper.

Chapter 22 Other Functions

22.1 Nurse Call

When a physiological parameter of the patient meets the conditions set under [Nurse Call], the Nurse Call function is triggered. The monitor will make a "click" sound.

Nurse Call Setup:

1)   Enter [User Maintain] → [Nurse Call Setup] → [Nurse Call].

2)   Set options under [Nurse Call].

 ✧ [Alarm Type]: Select which type of alarm will trigger Nurse Call.

 ✧ [Alm Level]: Select which level of alarm will trigger Nurse Call.

22.2 Connection to Central Monitoring System

Wired connection:

1)   Enter [User Maintain] → [Net Protocol] (Network Protocol).

2)   Select the ![icon] (Monitor Setup) shortcut key on the lower menu bar. Enter [Monitor Setup] → [Network Setup].

3)   Set [Net Bed] (Network Bed Number) and [IP Address]. Normally, you only need to set Net Bed and leave other options to the default settings.

 ✧   [Net Bed] is an identification number used by the monitor to communicate with the central monitoring system. Its valid range is 1~254.

Wireless connection:

1)   Enter [User Maintain] → [Net Protocol], and select the appropriate protocol.

2)   In the [User Maintain] menu, turn on [WIFI].

3)   Select the ![icon] (Monitor Setup) shortcut key on the lower menu bar. Enter [Monitor Setup] → [Network Setup].

4)   Enter [WiFi Setup] and select the appropriate network from the Wi-Fi list.

5)   Set [Net Bed], [IP Address], [SSID], [Password], etc. Normally, you only need to set Net Bed and leave other options to the default settings.

There is a central monitoring system (CMS) icon on the lower menu bar. ⬚ is shown when the monitor is not connected to the CMS, and ⬚ is shown when the monitor is connected to the CMS successfully.

> ⚠ **Note**
> - **When WIFI is turned on, wired network will be disabled.**
> - **Network bed number must be unique in one central monitoring system (CMS).**
> - **For details, see the *Instruction Manual* for Comen Central Monitoring System.**
> - **After this monitor is connected to the central monitoring system, [Time Settings] turns to gray, and you cannot make any operations.**

22.3 Format SD Card

This monitor allows user to format SD card. When [Format SD Card] is selected, all data will be removed. Therefore, this function should be used with caution. During SD card formatting, all operations on the screen are disabled. When formatting is finished, the monitor will restart automatically.

Steps for formatting SD card:

1) Enter [User Maintain] → [Format SD Card]. A warning dialog appears, saying [The monitor will auto restart after formatting SD card! Confirm to format?]. Select [Enter] to format the SD card. The monitor will restart automatically after formatting is finished.

22.4 Analog Output

Enter [User Maintain] → [Analog Out].

Output for 3 leads includes Off, I, and II; output for 5 leads includes Off, I, II, and V (varying with the lead type selected). The monitor can be connected to an oscilloscope or other external devices via cables, and outputs analog signals such as lead I or lead II for use by such devices.

Chapter 23 Battery

23.1 Overview

The monitor is equipped with a built-in rechargeable battery. When AC power supply is connected, the battery can be charged automatically till full no matter whether the device is turned on or not. In the event of unexpected power outage, the system will automatically use the battery to supply voltage, thus to avoid interruption of device operation. After AC power supply is cut off, the battery indicator light blinks, indicating the battery is being used to supply voltage, and device operation will not be affected.

The Battery icon shown on the screen indicates the current battery status;

indicates battery level is full.

indicates battery level is not full.

indicates battery level is low and charging should be considered.

indicates the battery is being charged.

indicates absence or damage of the battery.

⚠ **Note**
- **If the battery is to be left unused for a long period of time, please remove the battery and keep it properly.**
- **If the device is provided with a built-in battery, the battery must be charged after each use to ensure sufficient battery reserve.**

⚠ **Warning**
- **Improper replacement of the lithium battery will result in unacceptable risks.**
- **Replacement of the lithium battery by unprofessional personnel may result in risks.**
- **Battery electrolyte is hazardous. In case that battery electrolyte comes into contact with your skin or enters your eyes, please wash with clean water immediately and seek medical advice.**
- **Please keep the battery out of the reach of children.**
- **When the battery is used for operation, the monitor will power off automatically when the battery level is low.**

23.2 Install Battery

Steps for replacement or installation of the battery:

1) Power off the monitor; disconnect the power cord and other connecting cables.

2) Place the monitor with its back facing upward.

3) Remove the screws with a screwdriver, and take out the old battery.

4) Install the new battery into the battery case according the anode and cathode symbols.

5) Tighten the screws, and place the monitor straight.

⚠ **Warning**
- **Only use battery designated by the manufacturer.**
- **Do not remove the battery when the device is working.**

23.3 Optimize and Check Battery Performance

1) Optimize Battery Performance

If it is the first time to use the battery, please ensure that the battery has undergone at least two complete optimization cycles. A complete optimization period means uninterrupted charging till the battery is fully charged, and then discharging it till the monitor shuts down automatically.

When optimizing the battery, please ensure the following:

1) Completely disconnect the monitor from the patient and stop all monitoring and measurement.

2) Put the battery for optimization in the battery case of the device.

3) When charging the battery, please ensure that the battery is charged uninterruptedly for at least 6h till it is fully charged.

4) Disconnect AC power supply, and use the battery to supply voltage to the monitor till the monitor shuts down automatically.

5) Battery optimization is finished.

2) Check Battery Performance

The battery life varies with the storage and operation environments, frequency of battery discharging and use time. The battery performance will degrade gradually even if the battery is not used.

Here are the steps for checking the battery:

1) First, determine whether the battery is damaged. When the battery icon shows ✉, it indicates the battery is damaged or there is no battery in the battery case.

2) Check whether the battery can be charged normally when connected to AC power supply.

3) Completely disconnect the monitor from the patient and stop all monitoring and measurement.

4) When charging the battery, please ensure that the battery is charged uninterruptedly for at least 6h till it is fully charged.

5) Disconnect AC power supply, and use the battery to supply voltage to the monitor till the monitor shuts down automatically; meanwhile record the start time and end time of discharging.

6) The length of discharging time reflects the performance of the battery.

7) When the discharging time reduces to less than 50% of the initial value, please replace the battery.

> ⚠ **Note**
> - **In order to prolong the service life of the rechargeable battery, if the battery is stored for a long period of time, it is suggested that the battery should be charged every three months to prevent excessive discharging.**
> - **The voltage supply time of the battery depends on the configuration and operation of the device. For example, frequent NIBP measurement will reduce the voltage supply time of the battery.**

23.4 Battery Recycling

If the battery is obviously damaged or runs out, it should be replaced. Waste batteries should be properly recycled in accordance with applicable laws and regulations or the rules of the hospital.

> ⚠ **Warning**
> - **Do not disassemble or short-circuit the battery or place it in fire; otherwise battery fire, explosion, leakage of hazardous gas or other hazards may be caused.**

Chapter 24 Cleaning and Maintenance

Only materials and methods listed in this chapter that are accepted by the Company can be used for cleaning or disinfection of the device. For any damage arising from use of unaccepted materials or methods, the Company will not provide any warranty.

The Company will not assume any liability for the effectiveness of listed chemicals or methods when they are used as infection control means. For infection control methods, please consult the Infection Prevention Department or an epidemiologist in your hospital. Besides, please refer to local policies that apply to your hospital and country.

24.1 Overview

Please keep the device and its accessories dustless. After cleaning, please check the device carefully. If there is any evidence of ageing or damage, please stop using it immediately. If it is necessary to send back the device to Comen for repair, first clean it. Please observe the following precautions:

✧ Please dilute detergent and disinfectant as specified by the manufacturer, or use a concentration as low as possible.

✧ Never allow any liquid to flow into the housing.

✧ Never pour any liquid onto any part or accessory of the device.

✧ Never soak the device in any liquid.

✧ Do not use any frictional material, bleaching powder or strong solvent (e.g., acetone or detergent containing acetone).

⚠ **Warning**

- **Only use detergents and disinfectants recommended in this Instruction Manual; use of other detergents and disinfectants will result in damage to the device or safety risks.**
- **Before cleaning the monitor, please power it off and disconnect it from the AC power supply.**
- **Never use EtO (ethylene oxide) to disinfect the monitor.**
- **Never leave any disinfectant on any surface and accessory of the monitor; please use a wet cloth to clean it immediately.**
- **It is not allowed to use detergent mixture; otherwise hazardous gases will be generated.**
- **This chapter only introduces the methods for cleaning reusable accessories. Disposable accessories should not be reused after cleaning and disinfection to avoid cross infection.**
- **To protect the environment, disposable accessories must be recycled or dealt with properly.**

- **After cleaning, if the sensor cable is damaged or shows any evidence of ageing, it should be replaced with a new cable.**
- **High-temperature sterilization of the monitor and all accessories is not allowed.**
- **Never use any cleaning solution not recommended in this manual; failure to do so may result in permanent damage to the device, sensor or cable.**
- **Never soak the sensor or connector in any solution for cleaning or disinfection.**
- **In order to prevent the entry of cleaning solution and dust into the ISA gas analyzer via LEGI port, the Nomoline sampling line should always be connected when cleaning the ISA analyzer. Never soak the ISA sidestream gas analyzer in any liquid for disinfection.**
- **The Nomoline sampling line is not a sterile device. In order to avoid damage, please do not sterilize any part of the sampling line under high pressure.**
- **Before cleaning the IRMA sensor, please remove the disposable IRMA airway adapter. Never disinfect the IRMA sensor or soak it in any liquid.**
- **The IRMA O2 battery and the IRMA airway adapter are not sterile devices. In order to avoid damage, do not sterilize the device under high pressure.**

⚠ **Caution**
- **If you carelessly pour any liquid onto the device or any accessory, please contact the maintenance personnel or Comen immediately.**

24.2 Cleaning and Disinfection of Monitor

The monitor should be kept clean. It is suggested that the external surface of the housing should be cleaned frequently; especially in environments with tough conditions or very windy and dusty places, the cleaning frequency should be increased in order to avoid cross infection, and accessories should be cleaned on a regular basis. Prior to cleaning, please first consult or understand relevant rules of your hospital on device cleaning.

➢ Cleaning steps:

1) Power the device off, and unplug the power cord.

2) Use a soft cloth dipped with an appropriate amount of detergent to wipe the housing of the device.

3) Use a soft cloth dipped with an appropriate amount of detergent to wipe the display screen of the device.

4) When necessary, you can use a soft, dry cloth to remove residual detergent.

5) Put the device in a cool, well-ventilated environment to air-dry it.

The disinfection operation may harm the monitor to a certain extent. It is suggested that the device can be disinfected only when it is considered necessary in the maintenance plan of your hospital. Before disinfection, please clean the device first.

➢ Selectable detergents:

Part for Cleaning/Disinfection	Detergent	Disinfectant
Housing	Isopropanol (70%), hydrogen peroxide	Isopropanol (70%), glutaraldehyde solution (2%), sodium hypochlorite
Power cord		
ECG cable		
ECG electrode	Alcohol-free hand soap, sodium hypochlorite (bleaching powder containing chlorine, 3% aqueous solution), hydrogen peroxide	
Temp sensor		
SpO$_2$ sensor		
Mainstream CO$_2$ module	Isopropanol (70%)	Glutaraldehyde solution (2%)
Sidestream CO$_2$ module	Ethanol (70%), isopropanol (70%)	

24.2.1 Cleaning and Disinfection of BP Cuff

Prior to cleaning, the gasbag must be taken out.

The cuff can be washed by machine or hand with warm water and mild detergent, whereas hand wash can prolong its service time. The gasbag can be cleaned using a wet cloth dipped with clean water. Naturally air-dry it after cleaning.

The cuff can be disinfected using a wet cloth dipped with 70% ethanol or 70% isopropanol. Long-term use of disinfectants may result in color fading or discoloration of the cuff.

⚠ **Warning**

- **Do not squeeze the rubber tube on the cuff.**
- **During cleaning, only wipe the external surface of the connector socket; never wipe its internal surface.**
- **When cleaning the gasbag, care should be taken not to allow any liquid to flow into the gasbag.**
- **It is forbidden to dry-clean the cuff.**
- **The disposable cuff can be cleaned with soap to control infection.**

After cleaning, please reinstall the gasbag into the cuff according to the following steps.

To reinstall the gasbag into the cuff, first put the gasbag at the head of the cuff so that the rubber tube can line up with the big opening of the long end of the cuff; then vertically curl up the gasbag and insert it into the big opening of the cuff; hold the rubber tube and the cuff, and shake the entire cuff till the gasbag is in position. Lead the rubber tube into the cuff, and run it through the liner via the small hole. See the figure below:
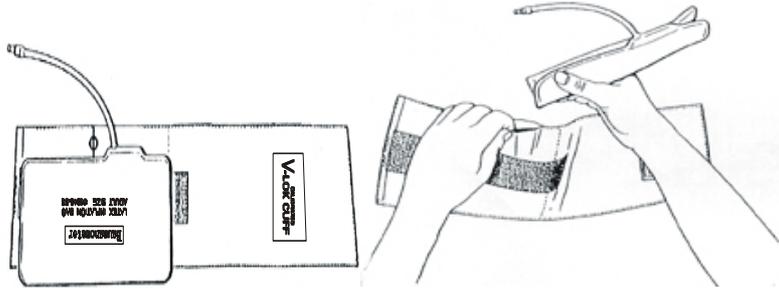
Fig 24-1 Replacement of Rubber Tube in the Cuff

Chapter 25 Maintenance

25.1 Maintenance Checks

Before use of the monitor, or every 6-12 months or after each maintenance or upgrade, a comprehensive check, including functional safety check, of the device should be carried out by qualified technical maintenance personnel having received training.

Items for checking should include:

1) Check to see if the operating environment and the power supply for the monitor conform to relevant requirements.

2) Check to see if the device and its accessories have any mechanical damage.

3) Check to see if the power cord is free from abrasion and has good insulation performance.

4) Check all functions of the device that can be used for patient monitoring, and ensure that the device is in good working status.

5) Check to see if all accessories used are those designated by the manufacturer.

6) Check to see if the battery performance is OK.

7) If the monitor is equipped with a recorder, check to see if the recorder can work normally and if the record paper conforms to the specified requirements.

8) Check to see if the wiring impedance and the leakage current conform to relevant requirements.

If there is any evidence of functional failure of the device, it is not allowed to use this monitor for patient monitoring. Please contact Comen or a biomedical engineer of your hospital.

All safety checks or maintenance work requiring disassembly of the device should be performed by professional maintenance personnel; operation by unprofessional personnel may result in malfunction of the device or safety hazards, and may also endanger personal safety.

Upon request by the user, Comen will conditionally provide relevant circuit diagrams to help the user to repair user-serviceable components of the device by appropriate and qualified technicians.

<table>
<tr><td>⚠ Warning
● The hospital or organization using this monitor should establish a sound maintenance plan; failure to do so may result in malfunction of the device and unpredictable consequences, and may also endanger personal safety.</td></tr>
</table>

25.2 Maintenance Plan

The following tasks can be fulfilled only by professional maintenance personnel recognized by the Company. If the following maintenance is needed, please timely contact the maintenance personnel. Prior to test or maintenance, the device must be cleaned and disinfected.

Test and Maintenance Items	Frequency
Carry out safety check according to IEC 60601-1	At least once every two years. After drop of monitor, replacement of power supply or as needed.
ECG synchronism between monitor and defibrillator	At least once every two years or as needed.
NIBP leakage test	At least once every two years or as needed.
NIBP verification	At least once every two years or as needed.
ECG calibration	At least once every two years or as needed.
IBP calibration	At least once every two years or as needed.
Touch screen calibration	At least once every year or after the touch screen replacement.
Mainstream and sidestream CO_2 calibration and performance check	At least once every two years or when measurement inaccuracy is suspected of.
Battery	Refer to the battery-related chapter in this manual.

25.3 NIBP Leakage Test

It is used to detect whether the NIBP measuring pump leaks. When the NIBP cuff is connected, this button can be used to activate the NIBP inflation process, so as to detect whether the NIBP gas circuit is in good airtight condition. If the result of gas leakage test is OK, the system will not give any prompt; if not, a corresponding error message will be shown in the NIBP info area.

Gas Leakage Test Process:

1) Properly connect the cuff to the NIBP gas hole in the monitor.

2) Wrap the cuff around a cylinder of proper size.

3) Enter [User Maintain] → [Leakage Test].

4) At this moment, [Leakage Testing] will be shown in the lower part of the NIBP parameter area on the screen, indicating that the system starts performing the gas leakage test.

5) The system will inflate automatically till the pressure reaches 180mmHg.

6) About 20s later, the system will turn on the deflation valve automatically, indicating that leakage measurement is finished.

If no prompt message is shown in the NIBP parameter area, it indicates the system has no gas leakage. If [Pneumatic Leak...] is shown, it indicates the gas circuit may leak. At this moment, the operator should check

the complete connection to see if there is any looseness. After confirming the connection is correct, perform the gas leakage test again. If there is still any fault prompt, please contact the manufacturer for repair.
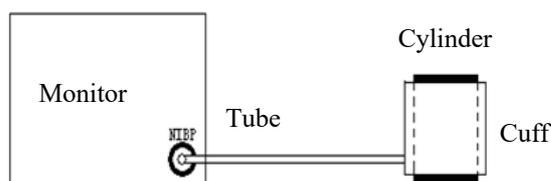
Fig 25-1 Connection Diagram for NIBP Gas Leakage Test

> ⚠️ **Warning**
> ● **This gas leakage test is different from the content described in EN 1060-1. This is for user to simply test whether there is gas leakage during NIBP inflation. If, at the end of the test, the system shows NIBP gas leakage, please contact Comen's service engineer.**

25.4 NIBP Pressure Verification

The manufacturer recommends use of a calibrated pressure gauge (or mercury sphygmomanometer) with accuracy higher than 1mmHg. In the [User Maintain] menu, select [NIBP Verify] to start calibration; meanwhile, this option will change to [Stop NIBP Verify]. If the knob is pressed at this moment, the system will stop calibration.

> ⚠️ **Warning**
> ● **Calibration of NIBP measurement should be performed once every two years (or according to maintenance rules of your hospital). Please check its performance according to the following details.**

Steps for calibration of the pressure sensor:

Use a 500ml+5% metal container to replace the cuff. Connect a calibrated standard pressure gauge (error < 0.8mmHg) and a ball gas pump with T-connector to the NIBP jack on the module. Enter the [User Maintain] menu; select [NIBP Verify]; set the monitor to the verification mode; then use the ball gas pump to inflate the metal container till the pressure of 0, 50 and 200mmhg is reached respectively. At this moment, the difference between the value shown on the standard pressure gauge and the pressure value indicated by the monitor should be within 3mmHg. Otherwise, please contact Comen's service engineer.
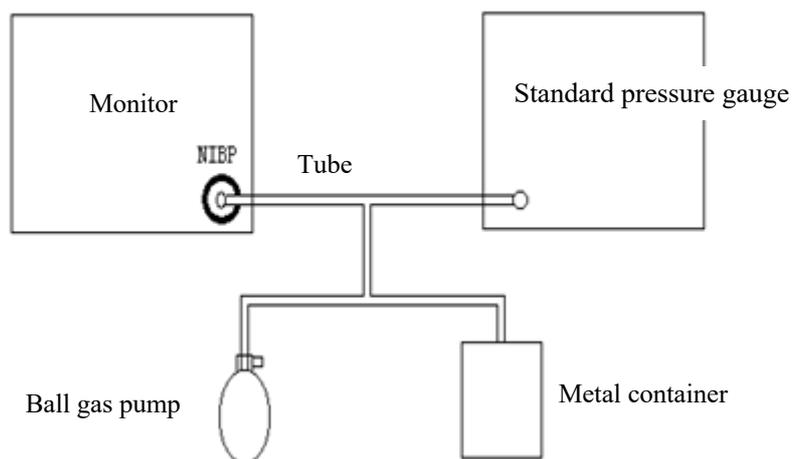
Fig 25-2 Connection Diagram for NIBP Verification

25.5 ECG Calibration

1) Enter [User Maintain] → [ECG Calibrate] to set the system to the calibration status; meanwhile, this option will change to [Stop ECG Cal] (Stop ECG Calibration).

2) To stop ECG calibration, you need to return to the [User Maintain] menu and select [Stop ECG Cal].

During ECG calibration, patient monitoring cannot be performed; meanwhile, "Cal...can't monitor!" (Calculating...can't monitor!) will be shown at the bottom left of the device screen.

25.6 IBP Calibration

When IBP calibration is necessary, please contact the manufacturer.

25.7 Touch Screen Calibration

1) Enter [User Maintain]→[Touch Screen Calibrate]

2) Click the sign on the screen as prompted.

After the calibration, the system returns to the main screen automatically.

Appendix I Product Configuration

functional parameter	China /CE/ Brazil		
	STAR8000E	STAR8000H	STAR8000F
3/5 leads ECG	√	√	√
NIBP	√	√	√
IBP	▲	▲	▲
Temp1	√	√	√
Temp2	▲	▲	▲
CO_2	▲	▲	▲
Comen.SpO₂	√	√	√
Masimo SpO₂	▲	▲	▲
Nellcor SpO₂	▲	▲	▲
Touch screen	/	▲	▲
Temp sensor: body surface /Body cavity	▲	▲	▲
Multi-function connector (Defibrillation synchronization; Analog output, Nurse Call)	▲	▲	▲
Built-in recorder	▲	▲	▲
External printer	▲	▲	▲
Wall-mounted rack	/	▲	/
Small handcart	▲	▲	▲
Notes	1. " √ "means the device of the corresponding type has the function parameter in the table. 2. "▲"means the device of the corresponding type has an optional function parameter in the table. 3. "/" means the device of the corresponding type has no function		

	parameter in the table.
	4. All of the instrument models have the same structure, safety and reliability.

Here we recommend the following accessories for the Monitor.

> ⚠ **Warning**
> - **Use the accessories of designated types only, or the Monitor may be damaged.**
> - **To prevent reduced performance and cross infections, please do no reuse any disposable accessory.**

ECG Accessories

Part No.	Type	Description
040-000908-00	98ME01AD473	3-lead American-standard integral clip-on defibrillation-resistant cable
040-000909-00	98ME01AD474	5-lead American-standard integral clip-on defibrillation-resistant cable
040-000911-00	98ME01EB477	3-lead European-standard integral clip-on defibrillation-resistant cable
040-000912-00	98ME01EB478	5-lead European-standard integral clip-on defibrillation-resistant cable
040-000479-00	98ME01AC458	3-lead. AHA standard
040-000480-00	98ME01AC457	5-lead. AHA standard
040-000485-00	98ME01EC681	3-lead. IEC standard
040-000486-00	98ME01EC680	5-lead. IEC standard
040-000914-00	A3105-EC1	3-lead American-standard integral clip-on defibrillation-resistant cable
040-000915-00	A5105-EC1	5-lead American-standard integral clip-on defibrillation-resistant cable
040-000917-00	A3105-EC0	3-lead European-standard integral clip-on defibrillation-resistant cable
040-000918-00	A5105-EC0	5-lead European-standard integral clip-on defibrillation-resistant cable

SpO$_2$ Sensor

Part No.	Type	Description
040-000334-00	A1418-SW203MU	Strap-on SpO$_2$ sensor for neonates
040-000646-00	A1418-SA203MV	Finger-held SpO$_2$ sensor for adults
040-000869-00	APK/12pin plug (white)	Simulated finger-held SpO$_2$ sensor for adults
040-000726-00	SAS10	Simulated finger-held SpO$_2$ sensor for adults
040-000730-00	SES104	Simulated strap-on SpO$_2$ sensor for neonates
040-000312-00	SAL104	Simulated finger-held SpO$_2$ sensor for adults
040-000769-00	/	Simulated main SpO$_2$ cable
009-000466-00	DOC-10	Nellcor SpO$_2$ extension cord
040-000010-00	DS-100A	Nellcor finger-held SpO$_2$ sensor for adults
040-000075-00	DURA-Y	Nellcor Y-shaped strap-on SpO$_2$ sensor

040-000204-00	M-LNC-10	Masimo sensor extension cord (main cable)
040-000203-00	M-LNCS DCI	Masimo finger-held SpO_2 sensor for adults
040-000361-00	M-LNCS YI	Masimo reusable Y-shaped SpO_2 sensor for neonates

Blood Pressure Cuff

Part No.	Type	Description
040-000592-00	U1880S	Blood pressure cuff for adult, 25-35CM
040-000593-00	U1881S	Blood pressure cuff for pedia, 18-26CM
040-000594-00	U1882S	Blood pressure cuff for neonates, 10-19CM
040-000595-00	U1883S	Blood pressure cuff for neonates, 6-11CM
040-000596-00	U1884S	Thigh, 46-66CM
040-000597-00	U1885S	Small adult 20-28CM
040-000598-00	U1869S	Large adult 33-47CM
040-000599-00	U1889S	Large adult 33-47CM
040-000743-00	U1681S	Blood pressure cuff for neonates, 3-6CM
040-000744-00	U1682S	Blood pressure cuff for neonates, 4-8CM
040-000745-00	U1683S	Blood pressure cuff for neonates, 6-11CM
040-000746-00	U1684S	Blood pressure cuff for neonates, 7-13CM
040-000747-00	U1685S	Blood pressure cuff for neonates, 8-15CM
040-000934-00	98-0400-99	Blood pressure cuff for neonates, 3-6CM
040-000935-00	98-0400-96	Blood pressure cuff for neonates, 4-8CM
040-000936-00	98-0400-97	Blood pressure cuff for neonates, 6-11CM
040-000937-00	98-0400-98	Blood pressure cuff for neonates, 7-13CM
040-000938-00	98-0400-90	Blood pressure cuff for neonates, 8-15CM

Temp Sensor

Part No.	Type	Description
040-000246-00	TAS03-04	Temp sensor /body surface
040-000385-00	TAE03-03	Temp sensor /intracavity
040-000386-00	/	neonates / pedia /intracavity
040-000387-00	TPS03-03	neonates / pedia / body surface
040-000534-00	TPS03-07	adult/ body surface
040-000650-00	TPS03-06	neonates / pedia / body surface
040-000651-00	TPE03-07	neonates / pedia /intracavity
040-000652-00	TAS03-08	adult / intracavity

Respironics CO2 Accessories

040-000021-00	REF:6063-00	Respironics single-patient airway adapter for adults
040-000022-00	REF:6312-00	Respironics single-patient airway adapter for neonates
099-000005-00	REF:1015928	Respironics CAPNOSTAT mainstream CO_2 sensor
099-000004-00	REF:1022054	Respironics LOFLO sidestream CO_2 sensor

PHASEIN CO2 (Masimo)

099-000006-00	CAT.NO.200101	PHASEIN (Masimo) IRMA mainstream CO_2 sensor

099-000007-00	CAT.NO.800101	PHASEIN (Masimo) ISA sidestream CO_2 analyzer
IBP Accessories		
040-000870-00	PT-1 1500	Abbott connector

Appendix III Product Specifications

1) Monitor Type

Classified by	Type
Electric shock protection type	Externally powered Class-I equipment, continuous operation equipment
Defibrillation-proof applied parts	defibrillation resistant equipment with internal power supply.
Electric shock protection level	Equipment with CF applied part (ECG and IBP monitoring part) and BF applied parts (all other monitoring parts).
IP grade	IPX1
Work mode	Continuous operation equipment
Safety standards	IEC 60601-1 IEC 60601-1-8 IEC 60601-2-27 EN 1060-3 IEC 80601-2-30 IEC60601-2-34 IEC60601-2-49 ISO 80601-2-56 ISO 80601-2-61 IEC60601-1-2

2) Environmental Specifications

Item	Specification	
Working conditions	Ambient temperature	0°C ~40°C
	RH	≤93%
	Barometric pressure	700hPa~1060hPa
Transport conditions	Please protect the Monitor against violent impact, vibration, rain and snow in transport. The Monitor should be packed and stored in a well-ventilated room without corrosive gas (ambient temperature: -20°C ~60°C; RH: ≤93%; Barometric pressure: 700hPa~1060hPa).	
Storage conditions	The Monitor should be packed and stored in a well-ventilated room without corrosive gas (ambient temperature: -20°C ~60°C; RH: ≤93%; Barometric pressure: 700hPa~1060hPa).	

3) Power Supply

Item	Specification
AC input voltage	100-240V~
AC input frequency	50/60Hz
Power supply	Powered either by built-in battery or external AC.
Input power	50VA
Built-in battery	Standard: 11.1V === 2200mAh rechargeable lithium-ion battery, supplying power for at least 2 consecutive hours in normal use once fully charged. Optional: 11.1V === 4400mAh rechargeable lithium-ion battery, supplying power for

	at least 4 consecutive hours in normal use once fully charged.
Charge time	11.1V 4400mAh: At least 4 hours from depletion to 90% charge in normal use. 11.1V/2200mA: At least 2 hours from depletion to 90% charge in normal use.
Defibrillation Synchronization	output +5V defibrillation synchronization signal during 100ms Max delay: ≤35ms; Pulse width: 100ms±10; Up/Down time≤1ms
Analog Output	Bandwidth: 0.5-40Hz; Max delay: ≤35ms; error: ±5%;

4) General Specifications

Item	Specification
Dimension	STAR8000E: About 300mm×150mm×278mm STAR8000F: About 300mm×155mm×278mm STAR8000H: About 249mm×220mm×133mm
Weight	STAR8000E: About 2.72kg（without battery） STAR8000F: About 2.72kg（without battery） STAR8000H: About 2.02kg（without battery）
LCD specification	STAR8000E: Size: 12.1 Inch 　　　　　　 Pixel :800×600 STAR8000F: Size: 12.1 Inch 　　　　　　 Pixel :800×600 STAR8000H: Size: 8 Inch 　　　　　　 Pixel :800×600

5) ECG Specifications

Item	Specification	
Applicable standards: IEC 60601-2-27.		
Lead mode	5-lead (R, L, F, N, C; or RA, LA, LL, RL, V)	
Method of leads	I, II, III, avR, avL, avF, V	
Waveform	2 -channel	
Lead mode	3-lead (R, L, F; or RA, LA, LL)	
Method of leads	I, II, III	
Waveform	1-channel	
Overload protection	Load 1V, power frequency, differential-mode AC voltage for 10s without damage (p-v)	
Resp, lead disconnection detection and active noise control	AC waveform: Current :<0.1μA; Frequency 64kHz, ±10%	
Auto identify the type of ECG leads.		
QRS wave amplitude and interval	Amplitude (p-v RTI)	0.5mV~5mV
	Width (adult)	70ms~120ms

	Width (neonate/child)	40ms~120ms
	Not respond to the signals:	a) with amplitude (p-v RTI) not exceeding 0.15mV (except in neonate/child mode); or b) with 10ms width (except in neonate/child mode) in case of 1mV amplitude.
Triggering threshold level	200μV (lead II)	
Power frequency voltage tolerance	>100μV(p-v)	
Drift tolerance	Triangular wave amplitude (p-v RTI)	4mV
	QRS wave amplitude (p-v RTI)	0.5 mV
	QRS wave width	100ms
	QRS wave recurrence frequency	80bpm
HR measurement range and error	Adult	15~300bpm
	Neonate/child	15~350bpm
	Error	±1% or ±1bpm in both 3-lead and 5-lead mode, whichever is greater.
Alarm limit range	Adult	15bpm~300bpm
	neonate/child	15bpm~350bpm
Alarm limit resolution	±1bpm	
Alarm limit error	±1bpm	
Alarm start time for asystole and high/low HR	<10s	
Input dynamic range	Input signal amplitude	±8mV
	Rate (RTI)	320mV/s
	DC offset voltage	-750~+750mV
	Output signal change	±10%
	Failure display (attenuation prior to display)	Maximum attenuation: 50%
Input impedance	Signal attenuation (0.67Hz~40Hz): ≤20%	
System noise (p-v RTI)	<25μV	
Multi-channel crosstalk	<5%	

Gain	1.25mm/mV, 2.5mm/mV, 5.0mm/mV, 10mm/mV, 20mm/mV, 40mm/mV, Auto. Manual replacement. Plus ±750mV DC polarization voltage; sensitivity change range: ±5%.			
	Gain change per minute	≤0.66%/min		
	Total gain change in 1h	≤±10%		
bandwidth	Surgery mode：1 Hz～20 Hz (-3.0dB～+0.4dB)； Monitoring Mode：0.5 Hz～40 Hz (-3.0dB～+0.4dB)； Diagnosis mode：0.05Hz～150 Hz (-3.0dB～+0.4dB)； ST mode：0.05Hz～40Hz(-3.0dB～+0.4dB)			
Time reference selection and accuracy	Time reference selection	Permanent display	25mm/s, 50 mm/s	
		Non-permanent display	6.25mm/s, 12.5mm/s, 25 mm/s, 50 mm/s	
	Maximum time reference error	±10%		
Output display	Channel width	30mm		
	Aspect ratio	0.4s/mV		
Input signal reconstruction accuracy	Use method A and method B in IEC 60601-2-27. to determine the total system error and frequency response.			
	Total system error	±20% or ±100μV, whichever is larger.		
	Frequency response	Sinusoidal input	0.67~40Hz (attenuation: -3dB)	
		Response to 20ms (width) triangular wave	0~25Hz attenuation in amplitude of wave peak	
	Response to 0.3mV·s shock in the shock range	Offset (RTI)	≤0.1mV	
		Slope (RTI)	≤0.30mV/s	
	Electrode weighting factor	≥±5%		
	Hysteresis effect of 15mm offset	≤0.5mm		
Calibration voltage	±5% error at 1mV			
Common mode rejection	<1mV (p-v RTI)			
ECG Common mode rejection ratio	Monitoring Mode：>105dB； Surgery mode：>105dB； Diagnosis mode：>90dB； ST mode: >105dB.			
Baseline control and stability	Recovery time after reset	3s		

	Drift rate in 10s	10μV/s
	Baseline drift in 1h	≤500μV
	Baseline drift at working temperature	≤50μV/°C
Non-overshoot pacemaker pulse inhibition	Amplitude: ±2mV~±700mV; width: 0.1ms~2.0ms; if overshoot < 0.05α p, settling time < 5μs; start time, end time, rise time and fall time of pulse: ≤ 100μs; start time of pulse: 40ms or earlier before the start time of QRS wave; there is an identical pulse 150ms~250ms before the above pacemaker pulse.	
Inhibition of pacemaker pulse detector on quick ECG signals	Minimum input slew rate: 660mV/s±15%RTI	
Pacemaker pulse display capability	Amplitude: ±2MV~±700MV; width: 0.5MS~2MS; maximum rise time: 100μS; the ECG display when the pacemaker pulse appears at 100/min.	≥0.2mV
ST segment measurement	Measurement range	-2.0mV-+2.0mV (-20.0 mm~+20.0 mm)
	Measurement error	-0.8mV~+0.8mV: ±0.02mV or ±10%, whichever is greater. Other ranges: not defined.
ST alarm limit range	-2.0mV-+2.0mV	
ST alarm limit error	±0.1mV	
Resolution	0.01mV (0.1mm)	
Arrhythmia types	Asystole, ventricular fibrillation (VFIB)/ventricular tachycardia (VTAC), PVCs/min, R on T, VT>2, couplet, PVC, bigeminy, trigeminy, tachycardia (TACHY), bradycardia (BRADY), supraventricular tachycardia (SVT), extreme tachycardia, extreme bradycardia, missed beats, multiform PVC (multi. PVCs), VTAC, nonsustained VT (nonsus. VTAC), ventricular rhythm, heart pause, pause/min, irregular rhythm (irr. rhythm), ventricular bradycardia, atrial fibrillation, pacemaker not captured (PNC), pacemaker not paced (PNP).	
Leakage current	<10uA	
Electrosurgical interference inhibition	HR change caused by interference: ≤±10%	
ESU protection	Cut mode: 300W Condense mode: 100W Recovery time: ≤10s	
Power frequency notch	a) Power frequency interference suppression capability: ≥ 20dB; b) Monitoring and surgical modes: Support the 50/60Hz notch function; c) Diagnostic mode: Support the 50/60Hz trap's manual setting and manual selection of strong / weak notch.	

HR Calculation	
Tall T-wave rejection capability	1.2mV
HR calculation	As required in Section 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the HR is calculated

	as follows. If all of the last 3 RR intervals are longer than 1200ms, the average of the last 4 RR intervals is the HR. In other cases, the average of the last 12 RR intervals (with the longest interval and shortest interval excluded) is the HR.
Cardiotachometer accuracy and response to arrhythmia	As required in Section 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the HR is displayed as follows after the 20s stable segment: Figure A1 (bigeminy): 80±1bpm Figure A2 (slowly varying bigeminy): 60±1bpm Figure A3 (quickly varying bigeminy): 120±1bpm Figure A4 (two-way contraction): 90±2bpm
Response time for HR changes	As required in Section 201.7.9.2.9.101 b) 5) of IEC 60601-2-27: the response time for a HR change, whether from 80bpm to 120bpm or from 80bpm to 40bpm, is less than 10s.
Tachycardia alarm start time	As required in Section 201.7.9.2.9.101 b) 6) of IEC 60601-2-27, the waveform: Figure B1 1 - range: 10s Figure B1 0.5 - range: 10s Figure B1 2 - range: 10s Figure B2 1 - range: 10s Figure B2 0.5 - range: 10s Figure B2 2 - range: 10s

6) Resp Specifications

Item	Specification	
Method	Thoracic impedance method	
RR measurement range and accuracy	Measurement range — Adult	0rpm-120rpm
	Measurement range — Child/neonate	0rpm-150rpm
	Measurement accuracy	7rpm~150rpm: ±2rpm or ±2%, whichever is greater. 0rpm~6rpm: not defined.
RR alarm limit range and error	Adult	0rpm~120rpm
	Neonate/child	0rpm~150rpm
	Error	±1rpm
No breath alarm limit range and error	Range	Adult: 10s、15s、20s、25s、30s、35s、40s、45s、50s、55s、1min Child/neonate: 10s、15s、20s、25s、30s、35s、40s
	Error	±5s
No breath alarm delay	10s、15s、20s、25s、30s、35s、40s、45s、50s、55s、1min、Off	
CVA identification	The Monitor will display the relevant alarm message when the HR is identical with the RR.	
Respiratory excitation waveform	< 300 μA RMS, 64kHz (± 10%)	

7) SpO₂ Specifications

Item	Specification	
Display range	0%~100%	
Display resolution	1%	
Data averaging and other signal processing time	2s	
Data update time	8s	

Measurement accuracy	◆ Comen SpO$_2$: measurement range: 0%~100%; measurement accuracy: ±2% (adult/child, in non-motion state) or ±3% (neonate, in non-motion state) within the measurement range of 70%~100%. The measurement accuracy within the measurement range of 1%~69% is not defined.
	
	◆ Masimo SpO$_2$: measurement range: 1%~100%; measurement accuracy:
	
	During No Motion Conditions[1]
	Adults and Pediatric 70% - 100% ± 2 digits
	                       0% - 69% unspecified
	Neonates 70% - 100% ± 3 digits
	                       0% - 69% unspecified
	
	During Motion Conditions[2,3]
	Adults and Pediatric 70% - 100% ± 3 digits
	                       0% - 69% unspecified
	Neonates[3] 70% - 100% ± 3 digits
	                       0% - 69% unspecified
	
	Low Perfusion Performance[4]
	>0.02% Pulse Amplitude and % Transmission > 5%:
	Saturation %SpO$_2$: ± 2 digits
	
	◆ Nellcor SpO$_2$: measurement range: 0%~100%; measurement accuracy: ±2% (adult/child, in non-motion state) or ±3% (neonate, in non-motion state) within the measurement range of 70%~100%. The measurement accuracy within the measurement range of 0%~69% is not defined.	

Alarm limit range and accuracy	Range	Comen SpO$_2$:0%～100%, upper limit : (lower limit+1%)~100% lower limit: 0%~(upper limit-1%) Masimo SpO$_2$:1%～100%, upper limit : (lower limit+1%)~100% lower limit: 1%~(upper limit-1%) Nellcor SpO$_2$:20%～100%, upper limit : (lower limit+1%)~100% lower limit: 20%~(upper limit-1%)
	Accuracy	±1%
Perfusion index (PI)	Range for Masimo SpO$_2$: 0.02%~20%; accuracy: not defined. Resolution: 0.01% (within 0.02%~9.99% range) or 0.1% (within 10.0%~20.0% range). Range for Comen SpO$_2$: 0.05%～20%; accuracy: not defined.	

	Resolution: 0.01% (within 0.05%~9.99% range) or 0.1% (within 10.0%~20.0% range).

8) PR Specifications

Item	Specification
Measurement range and accuracy	◆ Comen SpO$_2$ sensor: Measurement range: 20bpm~300bpm; resolution: 1bpm; measurement error: ±2bpm. ◆ Masimo SpO$_2$ sensor: Measurement range: 25bpm~240bpm; resolution: 1bpm; Accuracy: **During No Motion Conditions[1]** Adults, Pediatric and Neonates 25 – 240 bpm ± 3 digits **During Motion Conditions[2,3]** Adults, Pediatric and Neonates 25 – 240 bpm ± 5 digits **Low Perfusion Performance[4]** >0.02% Pulse Amplitude and % Transmission > 5% Pulse Rate: ± 3 digits ◆ Nellcor SpO$_2$ sensor: Measurement range: 20bpm~300bpm; resolution: 1bpm; measurement error: ±3bpm within 20bpm~250bpm range. The measurement accuracy within 251bpm~300bpm range is not defined. ◆ NIBP sensor: Measurement range: 40bpm~240bpm; resolution: 1bpm; measurement error: ±3bpm or ±3%, whichever is greater. ◆ IBP sensor: Measurement range: 20bpm~350bpm; resolution: 1bpm; measurement error within 20bpm~350bpm range: ±1bpm or ±1%, whichever is greater (excluding the sensor error).
PR alarm limit range and accuracy	upper limit : (lower limit+1bpm)~350bpm lower limit: 20bpm~(upper limit-1bpm)
	±1bpm

Masimo Accuracy Foot notes:

1 The Masimo SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO$_2$ against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus onestandard deviation encompasses 68% of the population. 2 The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-

100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses68% of the population.

3 The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greaterthan 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

4 The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to darkskin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at anamplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus orminus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.

5 The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2™ simulator. Thisvariation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

6 Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbersrepresent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fallwithin a range of ± Arms compared to the reference value. Unless otherwise noted, SpO_2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.

7 Masimo M-LNCS, LNOP, RD SET, and LNCS sensors types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cablelengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8 pin modular plug, RD 15 pin modular plug, LNCS9 pin, cable based, and M-LNCS 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.

9) Temp Specifications

Item	Specification	
Measurement range and accuracy	Measurement range	0°C ~50°C
	Measurement error	±0.2°C (including the sensor error)
Temp alarm limit range and error	Alarm limit range	0°C ~50.0°C
	Alarm limit error	±0.1°C
Resolution	0.1°C	
Number of channels	2	
Operating mode	Direct mode	
Transient response	No greater than 40 seconds	

10) CO₂ Specifications

Item	Specification
The EtCO₂ sensor complies with ISO 80601-2-55.	
Masimo EtCO₂ sensor (mainstream)	Masimo EtCO₂ sensor (sidestream)

CO_2 measurement range	0mmHg~190mmHg, 0~25% (at 760mmHg)	0mmHg~190mmHg, 0~25% (at 760mmHg)
CO_2 resolution	1mmHg, 0.1kPa or 0.1%	1mmHg, 0.1kPa or 0.1%
CO_2 accuracy	Standard environment 22 ±5℃,1013 ± 40hpa： 0~15%: ± (0.2%+reading×2%) 15~25%: not defined All environment: ±(0.3kPa+reading×4%)	Standard environment 22 ±5℃,1013 ± 40hpa： 0~15%: ± (0.2%+reading×2%) 15~25%: not defined All environment: ±(0.3kPa+reading×4%)
Sampling flow velocity	/	50±10 ml/min
Data sample rate	/	20Hz/channel
Breath detection	/	Adapter threshold, minimum 1 vol% change in CO_2 concentration
Typical rise time	/	Typical rise time at 50 ml/min sample flow: ≤200ms
Total system response time	/	<3s (with 2m sampling line)
Fi and ET	/	Fi and ET are displayed after one breath and have a continuously updated breath average
CO_2 alarm limit range	0~190mmHg	0~190mmHg
CO_2 alarm resolution	±0.1kPa or ±1mmHg	±0.1kPa or ±1mmHg
awRR measurement range	0~150rpm	0~150rpm
awRR measurement accuracy	±1rpm	±1rpm
awRR alarm limit range	0rpm~150rpm	0rpm~150rpm
awRR alarm resolution	1rpm	1rpm
No breath alarm limit range and error	Range	Adult:10s、15s、20s、25s、30s、35s、40s、45s、50s、55s、1min Child/neonate: 20s、25s、30s、35s、40s
	Error	±5s
No breath alarm delay	10s、15s、20s、25s、30s、35s、40s、45s、50s、55s、1min、Off	
Respironics/Nmed/Palconn EtCO₂ sensor (mainstream)		**Respironics/Nmed/Palconn EtCO₂ sensor (sidestream)**

CO$_2$ measurement range	0~150mmHg 0%~19.7% (0~20.0kPa)	0~150mmHg 0%~19.7% (0~20.0kPa)
CO$_2$ resolution	0~69mmHg: 0.1mmHg 70~150mmHg: 0.25mmHg	0~69mmHg: 0.1mmHg 70~150mmHg: 0.25mmHg
CO$_2$ accuracy	0~40mmHg: ±2mmHg 41~70mmHg: ±5%×reading 71~100mmHg: ±8%×reading 101~150mmHg: ±10%×reading	0~40mmHg: ±2mmHg 41~70mmHg: ±5%×reading 71~100mmHg: ±8%×reading 101~150mmHg: ±10%×reading
CO$_2$ alarm limit range	0~150mmHg	0~150mmHg
CO$_2$ alarm resolution	±0.1kPa or ±1mmHg	±0.1kPa or ±1mmHg
awRR measurement range	0~150rpm	0~150rpm
awRR measurement accuracy	±1rpm	±1rpm
awRR alarm limit range	0~150rpm	0~150rpm
awRR alarm resolution	1rmp	1rmp
No breath alarm limit range and error	Range	Adult:10s、15s、20s、25s、30s、35s、40s、45s、50s、55s、1min Child/neonate: 10s、15s、20s、25s、30s、35s、40s
	Error	±5s
No breath alarm delay	10s、15s、20s、25s、30s、35s、40s、45s、50s、55s、1min、Off	

11) NIBP Specifications

Item	Specification		
The NIBP sensor complies with IEC 80601-2-30.			
Measurement method	Auto oscillation method		
Measurement range and accuracy	Measurement range (adult)	Systolic pressure	5.3-36kPa (40-300mmHg)
		Diastolic pressure	1.3-28.7kPa (10-215mmHg)
		Mean pressure	2.7-31.3kPa (20-235mmHg)
	Measurement range (child)	Systolic pressure	5.3-26.7kPa (40-200mmHg)
		Diastolic pressure	1.3-20kPa (10-150mmHg)

		Mean pressure	2.7-22kPa (20-165mmHg)
	Measurement range (neonate)	Systolic pressure	5.3-18kPa (40-135mmHg)
		Diastolic pressure	1.3-13.3kPa (10-100mmHg)
		Mean pressure	2.7-14.7kPa (20-110mmHg)
	Measurement accuracy		Maximum average deviation: ±5mmHg (±0.667kPa); maximum standard deviation: ±8mmHg (±1.067kPa).
Overpressure protection range and tolerance	Adult mode		300mmHg
	Child mode		240mmHg
	Neonate mode		147mmHg
	Tolerance		±3mmHg
Alarm limit range and error	Adult	Systolic pressure	5.3kPa~36kPa (40mmHg~300mmHg)
		Diastolic pressure	1.3kPa~28.7kPa (10 mmHg~215mmHg)
		Mean pressure	2.7kPa~31.3kPa (20mmHg~235mmHg)
	Child	Systolic pressure	5.3kPa~26.7kPa (40mmHg~200mmHg)
		Diastolic pressure	1.3kPa~20kPa (10mmHg~150mmHg)
		Mean pressure	2.7kPa~22kPa (20mmHg~165mmHg)
	Neonate	Systolic pressure	5.3kPa~18kPa (40mmHg~135mmHg)
		Diastolic pressure	1.3kPa~13.3kPa (10 mmHg~100mmHg)
		Mean pressure	2.7kPa~14.7kPa (20mmHg~110mmHg)
	Error		±0.1kPa or ±1mmHg, whichever is greater.
NIBP measurement mode	Manual, auto (cyclic) or continual (not applicable to neonates)		
	Interval for auto mode		1/2/2.5/3/4/5/10/15/30/60/90/120/180/240/480/720min
	Continual		5min
Initial pressure range	Adult：80～280；Child：80～210；Neonate：60～140		

12) IBP Specifications

Item	Specification
Number of IBP channels	2
Pressure name	ART (arterial pressure), PA (pulmonary artery pressure), CVP (central venous pressure), RAP (right atrial pressure), LAP (left atrial pressure), ICP (Intracranial pressure), AO (aortic pressure), UAP (umbilical artery pressure), BAP (brachial

		artery pressure), FAP (femoral artery pressure), UVP (umbilical venous pressure), LV (left ventricular pressure), IAP (Intra-abdominal pressure), P1, P2, P3 and P4..
Measurement range and accuracy	ART	0~40kPa (0~300mmHg)
	PA	-0.8~16kPa (-6~120mmhg)
	CVP	-1.3~5.3kPa (-10~40mmHg)
	RAP	-1.3~5.3kPa (-10~40mmHg)
	LAP	-1.3~5.3kPa (-10~40mmHg)
	ICP	-1.3~5.3kPa (-10~40mmHg)
	P1, P2	-6.6~40kPa (-50~300mmHg)
	P3, P4	-6.6~40kPa (-50~300mmHg)
	LV	0~40kPa (0~300mmHg)
	AO	0~40kPa (0~300mmHg)
	UAP	0~40kPa (0~300mmHg)
	BAP	0~40kPa (0~300mmHg)
	FAP	0~40kPa (0~300mmHg)
	UVP	-1.3~5.3kPa (-10~40mmHg)
	IAP	-1.3~5.3kPa (-10~40mmHg)
Static pressure measurement range		-6.6kPa~+40kPa(-50mmHg~+300mmHg)
Display resolution for static pressure measurement		0.1kPa or 1mmHg
Static pressure measurement error		±1mmHg or ±2%, whichever is greater (excluding the sensor error).
IBP alarm limit range (SYS, DIA, MAP)	ART	0mmHg -300mmHg
	PA	-6mmHg~120mmHg
	CVP	-10mmHg~40mmHg
	RAP	-10mmHg~40mmHg
	LAP	-10mmHg~40mmHg
	ICP	-10mmHg~40mmHg
	P1	-50mmHg~300mmHg
	P2	-50mmHg~300mmHg
	P3	-50mmHg~300mmHg
	P4	-50mmHg~300mmHg
	LV	0mmHg~300mmHg
	AO	0mmHg~300mmHg
	UAP	0mmHg~300mmHg
	BAP	0mmHg~300mmHg

	FAP	0mmHg~300mmHg
	UVP	-10mmHg~40mmHg
	IAP	-10mmHg~40mmHg
IBP alarm error	±0.1kPa or ±1mmHg	
Pressure sensor	Sensitivity: 5μV/V/mmHg	
	Impedance range: 300~3000Ω	
Pressure zero calibration	Each channel should feature a pressure zero calibration function, with an accuracy of ± 1mmHg or ± 0.1kPa.）	

13) Recording Specifications

Item	Specification
Recording paper width	50mm
Effective recording width	48mm
Paper speed	25/50 mm/s
RT record time	3s, 5s, 8s, 16s, 32s or continual
Number of waveforms	3
Any alarm record?	Yes

14) Alarm System

Item	Specification
The alarm system complies with IEC 60601-1-8.	

Appendix IV System Alarm Messages

Here we list some of the most important physiological and technical alarm messages.

"XX" represents HR, ST, RR, Temp (Temp1, Temo2 and TD), SpO$_2$, PR, CO$_2$ (AwRR, INS and Fi), NIBP, IBP or any other module name or physiological parameter in the system.

If the problem still exists after you implement the relevant solution provided below, please contact our maintenance engineers.

Technical alarm types: A (fully clearable), B (the alarm sound and indicator are clearable) or C (not fully clearable).

The level of each technical alarm is not adjustable (except ECG and SpO$_2$).

1) Physiological Alarm Messages

Source	Default Level	Adjustable Level	Cause	Solution
ECG				
XX too high	Medium	High, medium, low		
XX too low	Medium	High, medium, low		
"XX" represents ST, ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-V, ST-V1, ST-V2, ST-V3, ST-V4, ST-V5 or ST-V6.				
HR too high	Medium	High, medium		
HR too low	Medium	High, medium		
PVCs too high	Medium	High, medium, low		
PVCs too low	Medium	High, medium, low		
ECG lost	Low	Low	The ECG signal of the patient is too weak to be analyzed by the system.	Check the patient's condition, electrode, cable and lead.
ECG noise	Low	Low		
Heart pause	Medium	High, medium		
Ventricular rhythm	Medium	High, medium		
Asystole	High	High	Arrhythmia occurs to the patient.	
VFIB/VTAC	High	High		

Vent. brady	High	High		
Heart pause/min	Medium	High, medium		
R ON T	Medium	High, medium		
VT>2	Medium	High, medium		
Couplet	Medium	High, medium		
PVC	Medium	High, medium		
Bigeminy	Medium	High, medium		
Trigeminy	Medium	High, medium		
SVT	Medium	High, medium		
Tachy	Medium	High, medium		Check the patient's condition, electrode, cable and lead.
PNC	Medium	High, medium		
PNP	Medium	High, medium		
Brady	Medium	High, medium		
Missed beats	Medium	High, medium		
Arrhythmia	Medium	High, medium		
Noise signal	Medium	High, medium		
Signal amplitude too low	Medium	High, medium		
SVT	Medium	High, medium		
Extreme tachycardia	High	High		
Extreme bradycardia	High	High		
SpO₂				
SpO₂ too high	High	High, medium	The measured value is greater than the upper alarm limit or smaller than the lower alarm limit.	Check the patient's physiological condition and check if the selected patient type and alarm limit are applicable to the patient.
SpO₂ too low	High	High, medium		
PR too high	High	High, medium, low		
PR too low	High	High, medium, low		
No pulse	High	High	The pulse signal of the patient is too weak to be analyzed by the system.	Check the patient's condition, SpO₂ sensor and measured part.
NIBP				

SYS/MAP/DIA too high	Medium	High, medium	The measured value is greater than the upper alarm limit or smaller than the lower alarm limit.	Check the patient's physiological condition and check if the selected patient type and alarm limit are applicable to the patient.
SYS/MAP/DIA too low	Medium	High, medium		
Resp				
RR too high	Medium	High, medium, low	The measured value is greater than the upper alarm limit or smaller than the lower alarm limit.	Check the patient's physiological condition and check if the selected patient type and alarm limit are applicable to the patient.
RR too low	Medium	High, medium, low		
No breaths	High	High	The Resp signal of the patient is too weak to be analyzed by the system.	Check the patient's condition, electrode, cable and lead.
Resp artifact	High	High	The patient's heartbeats interfere with his/her respiration, causing RR measurement failure.	
IBP				
ZZ too high	Medium	High, medium	The measured value is greater than the upper alarm limit or smaller than the lower alarm limit.	Check the patient's physiological condition and check if the selected patient type and alarm limit are applicable to the patient.
ZZ too low	Medium	High, medium		
"ZZ" represents IS1, ID1, IM1, IS2, IM2 or ID2.				
Temp				
T1 too high	Medium	High, medium, low	The measured value is greater than the upper alarm limit or smaller than the lower alarm limit.	Check the patient's physiological condition and check if the selected patient type and alarm limit are applicable to the patient.
T1 too low	Medium	High, medium, low		
T2 too high	Medium	High, medium, low		
T2 too low	Medium	High, medium, low		
TD too high	Medium	High, medium, low		
CO_2				
$FiCO_2$ too high	Medium	unadjustable	The measured value is greater than the upper alarm limit or smaller	Check the patient's physiological condition and check if the selected patient
$FiCO_2$ too low	Medium	unadjustable		
$EtCO_2$ too high	Medium	unadjustable		

EtCO$_2$ too low	Medium	unadjustable	than the lower alarm limit.	type and alarm limit are applicable to the patient.
AwRR too high	Medium	High, medium, low		
AwRR too low	Medium	High, medium, low		
INS too high	Medium	unadjustable		
INS too low	Medium	unadjustable		

2) Technical Alarm Messages

Source	Alarm Message	Alarm Level	Alarm Type	Cause	Solution
XX	XX Init err	High	A	Error X occurs in the XX module initializing process.	Restart the Monitor to try again. If the error still exists, contact us for service.
	XX comm stop	High	C	The XX module fails to communicate with the main system.	
	XX comm err	High	A	The XX module fails to communicate normally with the main system.	
XX	XX alm lmt err	Low	C	The alarm limit of parameter XX is accidentally changed.	Contact us for service.
XX	XX overrange	Low	C	The measured value of parameter XX goes beyond the specified measurement range.	
ECG	ECG lead off	Low	B	The ECG lead is connected unreliably.	Check if the ECG lead is connected properly.
	ECG lead YY off ("YY" represents V, LL, LA, RA, V1, V2, V3, V4, V5 or V6)	Low	B	The ECG lead YY is connected unreliably.	Check if the ECG lead YY is connected properly.
	ECG noise	Low	A	The ECG signal contains strong interfering signal.	Check if the ECG lead is connected properly and if the patient performs any major movement.

Source	Alarm Message	Alarm Level	Alarm Type	Cause	Solution
SpO₂	SpO₂ finger off	Low	B	The SpO₂ sensor is disconnected from the finger.	Check if the SpO₂ sensor is connected properly.
	SpO₂ no sensor	Low	B	The SpO₂ sensor is connected unreliably.	
	Weak SpO₂ signal	Low	C		
	SpO₂ sensor off	Low	B		
	NELLC error, resetting	Low	C	There is a Nellcor module error. The system is resetting.	If system resetting fails, or the error still exists after you restart the Monitor, please contact us for service.
	Search pulse	Low	B	The SpO₂ sensor is connected unreliably or the patient moves his/her arm.	Check the patient's condition and if the SpO₂ sensor is connected properly.
	SpO₂ overrange	Low	C	The measured value goes beyond the specified measurement range.	Follow the specified measurement range.
	SpO₂ low perfusion (Masimo)	Low	C	The peripheral circulation is poor.	Replace the finger or check if any limb is compressed.
	SpO₂ sensor fault (Masimo)	Low	C	The sensor has a fault.	Check and replace the sensor. If the fault still exists, contact us for service.
	SpO₂ interference (Masimo)	Low	C	The external interference is too strong.	Check the patient's condition (any major movement?) and if the SpO₂ lead is connected properly.
	Much light (Masimo)	Low	C	The patient (sensor) receives too much light. The sensor is covered with inappropriate fabric.	Check if the SpO₂ sensor is fixed reliably, remove or reduce the light, cover the sensor against light or relocate the sensor.
	SpO₂ unknown	Low	C	The SpO₂ module fails to identify the sensor.	Check and replace the sensor. If the fault still

Source	Alarm Message	Alarm Level	Alarm Type	Cause	Solution
	sensor (Masimo)				exists, contact us for service.
	SpO$_2$ no cable (Masimo)	Low	B	The cable is connected unreliably or not connected.	Check and replace the cable. If the fault still exists, contact us for service.
	SpO$_2$ no adhesive sensor (Masimo)	Low	C	The SpO$_2$ module fails to identify the sensor.	Check and replace the sensor. If the fault still exists, contact us for service.
	SpO$_2$ module error (Masimo)	Low	C	The module has a fault.	Return to us for repair.
Temp	Temp1 sensor off	Low	A	The Temp sensor is connected unreliably.	Check if the Temp sensor is connected properly.
	Temp2 sensor off	Low	A		
NIBP	NIBP selftest error	High	A	An error occurs in the NIBP module initializing process.	Enable the reset function in the NIBP menu. If the error still exists, contact us for service.
	NIBP comm error	High	A	The NIBP communication part has a fault.	
	Loose cuff	Low	A	The NIBP cuff is connected unreliably.	Reconnect the NIBP cuff.
	Pneumatic leak	Low	A	The NIBP air circuit leaks air.	Check the connection condition of each part or replace the NIBP cuff. If the fault still exists, contact us for service.
	Pressure overrange	Low	A	An error occurs in the measurement process. The system fails to do measurement, analysis and calculation.	
	Air leak	Low	A	The NIBP cuff is connected unreliably or the air circuit leaks air.	
	Air pressure error	Low	A	An error occurs in the measurement process. The system fails to do measurement, analysis and calculation.	

Source	Alarm Message	Alarm Level	Alarm Type	Cause	Solution
	Weak signal	Low	A	An error occurs in the measurement process. The system fails to do measurement, analysis and calculation.	Check if the selected patient type is correct. Check the connection condition of each part or replace the NIBP cuff. If the fault still exists, contact us for service.
	Cuff type error	Low	A	The NIBP cuff is incompatible with the selected patient type.	
	Excessive motion	Low	A	The patient moves his/her arm.	Check the patient's condition and the connection condition of each part, and then try the measurement again. If the fault still exists, contact us for service.
	Signal saturated	Low	A	An error occurs in the measurement process. The system fails to do measurement, analysis and calculation.	
	NIBP system failure	High	A		
	NIBP measure timeout	Low	A		
	NIBP measure failed	Low	A		
	Over pressure	Low	A	The air circuit is folded.	Check the patient's condition and if the air circuit is unobstructed, and then try the measurement again. If the fault still exists, contact us for service.
	NIBP reset error	Low	A	Illegal reset occurs in the NIBP measurement process.	Check if the NIBP air circuit is clogged and then try the measurement again. If the error still exists, contact us for service.
IBP	IBP1 lead off	Low	B	The IBP sensor is in poor contact.	Check or reconnect the IBP sensor. If the fault still exists, contact us for service.
	IBP2 lead off				
CO_2	CO_2 is sleeping	Low	C	[Standby] is selected as the CO_2 work mode.	Select [Measure] as the CO_2 work mode.
	CO_2 sampling line clogged	Low	B	The sampling tube is clogged.	Check and replace the sampling tube. If the

Source	Alarm Message	Alarm Level	Alarm Type	Cause	Solution
	CO2 no sampling line (Masimo)	Low	B	The sampling tube is in poor contact or not connected.	fault still exists, contact us for service.
	CO2 out of accuracy range	Low	C	The measured value goes beyond the specified accuracy range.	Follow the specified accuracy range.
	CO2 Temp out of range	Low	C	The module has a fault.	Return to us for repair.
	CO_2 span cal error (Masimo)	Low	C		
	CO_2 factory calibration lost (Masimo)	Low	C		
	CO_2 speed out of bounds (Masimo)	Low	C		
	CO_2 pressure overrange (Masimo)	Low	C		
	CO_2 span calibrating... (Masimo)	Low	C	The CO_2 span is being calibrated.	Return to us.
	Replace adapter (Masimo)	Low	C	The adapter has a fault.	Check and replace the adapter. If the fault still exists, contact us for service.
	No adapter (Masimo)	Low	C	The adapter is in poor contact or not connected.	
	CO_2 Need Zero (Masimo)	Low	C	The CO_2 module needs zeroing.	Enter [CO_2 Setup] to select [Zero].
	Software error (Masimo)	Low	C	The software has a fault.	Restart the Monitor.
	Hardware error (Masimo)	Low	C	The hardware has a fault.	Check and replace the sensor. If the fault still exists, contact us for service.

Source	Alarm Message	Alarm Level	Alarm Type	Cause	Solution
	CO_2 is zeroing	Low	C	CO_2 analyzer is in calibration	None
Other alarm messages	Keyboard error	High	C	The system has a fault.	Restart the Monitor. If the fault still exists, contact us for service.
	Low battery	Medium	B	The battery power is low.	Connect the Monitor to the AC power supply to charge the battery. If the fault still exists after 6-hour charging, contact us for service.
	Low battery, shut down in xxS	High	C	The battery power is so low that the system is forced to shut down.	Connect the Monitor to the AC power supply to charge the battery.

3) System Prompt Messages

SOURCE	ALARM MESSAGE	ALARM LEVEL	CAUSE
NIBP	Manual measure...	None	A system prompt message can indicate that the Monitor is performing a certain function or operation.
	Calibrating...	None	
	Leakage testing...	None	
	Resetting...	None	
	Continual measuring...	None	
	Please start	None	
	Reset for error	None	
	Module resetting...	None	
	Auto measuring...	None	
	Calibrate stopped	None	
	Leakage test stopped	None	
	Measure stopped	None	
	Over pressure	None	
	Reset failed	None	
	Venipuncture start	None	
	Venipuncture stop	None	

SOURCE	ALARM MESSAGE	ALARM LEVEL	CAUSE
IBP	IBP1 zeroing	None	
	IBP2 zeroing	None	
	IBP1 zero succeeded	None	
	IBP2 zero succeeded	None	
	IBP1 zero failed	None	
	IBP2 zero failed	None	
CO_2 zero	Zero in progress, please wait xS	None	
Prompt message for disabled alarm	ECG alarm disabled!	None	
	Cal, can't monitor!	High	
	Resp alarm disabled!	None	
	Temp alarm disabled!	None	
	SpO_2 alarm disabled!	None	
	NIBP alarm disabled!	None	
	CO_2 alarm disabled!	None	
	Alarm muted	None	
Prompt message for module unloading	Unload module	None	
Other prompt messages	Screen is unlocked!	None	
	Screen is locked! Long press main menu to unlock.		
	Ip conflict	None	
	Import succeeded	None	
	Import failed	None	
	Loading config successfully	None	
	Load config fail	None	
	Delete config succeed	None	
	Delete config fail	None	
	Sampling	None	
	Relearn	None	
	ARR learning	None	

SOURCE	ALARM MESSAGE	ALARM LEVEL	CAUSE
	The same module exists, only one will be left!	None	
	Demo	None	

Appendix V Default Settings

Here we list the configurations for different departments in configuration management and some of the most important default settings. You have no permission to change the default settings. However, you can change the settings as needed and save them as user-defined settings.

1) General Configurations

1. Alarm

Item	General	OR	ICU	NICU	CCU
Alm vol	2				
Alm rec time	8s				

2. Module Color

Item		General	OR	ICU	NICU	CCU
Waveform/parameter color	ECG	Green				
	SpO$_2$	Cyan				
	Resp	Yellow				
	NIBP	White				
	Temp	White				
	CO$_2$	Yellow				
	IBP	Red				

3. Review

Item	General	OR	ICU	NICU	CCU
Trend graph resolution	1s				
Trend table resolution	1min				

4. Layout

Item		General	OR	ICU	NICU	CCU
Screen select		Standard				
Quick key		Default: main menu – alarm reset – NIBP start – screens – review – alarm setup – standby – monitor state				
Waveform sequence on standard screen	1	ECG1				
	2	ECG2				
	3	Resp				
	4	SpO$_2$				
	5	ART+				
Waveform sequence on big font screen	Parameter 1	ECG				
	Parameter 2	SpO$_2$				

	Paramete r 3	NIBP			
	Paramete r 4	Temp			

5. Event Setup

Item	General	OR	ICU	NICU	CCU
Waveform 1	I				
Waveform 2	II				
Waveform 3	PLETH				

6. Record

Item	General	OR	ICU	NICU	CCU
Waveform 1	II				
Waveform 2	I				
Waveform 3	Off				
Waveform record output speed	25mm/s				
RT record time	8s				
Timed record interval	Off				
Grid	On				

7. Maintain

Item		General	OR	ICU	NICU	CCU
Wave draw		Mono				
Wave line		Thin				
Analog out		Off				
Alarm setup	Alm mute	Off				
	Reminder interval	1min				
	Reminder volume	1				
	Min. Alm volume	2				
	Alm pause time	2min				
	Alm delay time	Not allowed				
Nurse call	Nurse call	Off				
	Alm level	High				
	Alm type	Technical + physiological				

8. Default Alarm Limit of Smart Module Parameters

item		General	OR	ICU	NICU	CCU
HR	ADU	H 40 M 50 --- 120 M 130 H				

	PED	H 60 M 75 --- 160 M 170 H
	NEO	H 90 M 100 --- 200 M 210 H
SpO2	ADU	H 85 M 90 --- 100 M 100 H
	PED	
	NEO	
PR	ADU	H 30 M 40 L 50 --- 120 L 130 M 140 H
	PED	H 55 M 65 L 75 --- 160 L 170 M 180 H
	NEO	H 80M 90L 100 --- 200 L 210 M 220 H
SYS (NIBP)	ADU	H 80 M 90 --- 160 M 170 H
	PED	H 50 M 70 --- 120 M 140 H
	NEO	H 40 M 40--- 90 M 100 H
MAP (NIBP)	ADU	H 50 M 60--- 110 M 120 H
	PED	H 40 M 50--- 90 M 100 H
	NEO	H 20 M 25 --- 70 M 80 H
DIA (NIBP)	ADU	H 40 M 50--- 90 M 100 H
	PED	H 30 M 40 --- 70 M 80 H
	NEO	H 10 M 20--- 60 M 70 H
AwRR (CO_2)	ADU	H 4 M 6 L 8 --- 30 L 35 M 40 H
	PED	H 4 M 6 L 8 --- 30 L 35 M 40 H
	NEO	H 10 M 20 L 30 --- 100 L 110 M 120 H

Note: if the PR alarm limit is "H 30 M 40 L 50 --- 120 L 130 M 140 H":

The alarm level will be auto set to "H" (High) at PR<30 or 140<PR;

The alarm level will be auto set to "M" (Medium) at 30≤PR<40 or 130<PR≤140;

The alarm level will be auto set to "L" (Low) at 40≤PR<50 or 120<PR≤130;

No alarm will be triggered at 50≤PR≤120 (normal PR).

2)   Default Settings

1.   Default ECG Settings

Item	General	OR	ICU	NICU	CCU
Cascade	Off				
Lead name	II				
Gain	X1				
Sweep	25mm/s				
Channel format	2x6+1				
Filter mode	Monitor				
Lead type	5-lead				
Calculate lead	II				
HR source	ECG				
Alarm	On				
Alm record	Off				
Alm level	Medium				
PF inhibition	On (50HZ)				

Smart lead off	Off
HR alarm limit	Note: refer to Table 8 in *Section 1) General Configurations* for default HR alarm limit.

2. Default ST Settings

Item	General	OR	ICU	NICU	CCU
ST analysis	Off				
Alarm	Off				
Alm level	Medium				
Alm record	Off				
Alm limit	(-0.20, 0.20)				

3. Default Resp Settings

Item		General	OR	ICU	NICU	CCU
Gain		X1				
Enhance filter		On				
Sweep		12.5mm/s				
Apnea alarm		20s				
Resp lead		RA-LL(II)				
Alarm		On				
Alm level		Medium				
Alm record		Off				
Alm limit	ADU	(8 --- 30)				
	PED					
	NEO	(30--- 100)				

4. Default ARR Settings

Item		Genera	OR	ICU	NICU	CCU
ARR analysis		Off				
Tachy threshold	ADU	120				
	PED	160				
	NEO					
Extreme tachy threshold	ADU	160				
	PED	180				
	NEO	200				
Brady threshold	ADU	40				
	PED					
	NEO					
Extreme brady threshold	ADU	40				
	PED	40				
	NEO					
ARR alarm		All off				
ARR Alm record		All off				
ARR Alm level		Asystole, VTAC, VFIB, extreme tachy and extreme brady: high;				

	Other ARRs: medium.

5.   Default SpO₂ Settings

Item	General	OR	ICU	NICU	CCU
Sweep	25 mm/s				
Sat-Second(Nellcor)	50s				
Fast Sat	Off				
Average time (Masimo)	8s				
Smart tone	On				
Sensitivity (Masimo)	APOD				
Signal IQ	On				
Alarm	On				
Alm record	Off				
Alm level (Nellcor)	High				
SpO₂ Alm limit (Nellcor) ADU	(90 --- 100)				
PED					
NEO	(90 --- 100)				
SpO₂ Alm limit	Refer to Table 8 in *Section 1) General Configurations* for default SpO₂ alarm limit.				

6.   Default PR Settings

Item	General	OR	ICU	NICU	CCU
Alarm	On				
Alm record	Off				
PR source	SpO₂				
Alm level	High				
PR Alm limit	Refer to Table 8 in *Section 1) General Configurations* for default PR alarm limit.				

7.   Default NIBP Settings

Item	General	OR	ICU	NICU	CCU
PAT Type	ADU				
Measure mode	Manual				
Interval	1min				
Initial pressure ADU	160				
PED	120				
NEO	100				
Alarm	On				
Alm record	Off				
Alm level	Medium				
NIBP Alm limit	Refer to Table 8 in *Section 1) General Configurations* for default NIBP alarm limit.				

8.   Default Temp Settings

Item	General	OR	ICU	NICU	CCU

Alarm		On
Alm record		Off
Alm level		Medium
T1 Alm limit	ADU	(36.0 --- 39.0)
	PED	
	NEO	
T2 Alm limit	ADU	(36.0 --- 39.0)
	PED	
	NEO	
TD Alm limit	ADU	(0 .0 --- 2.0)
	PED	
	NEO	

9. Default CO2 Settings

Item	General	OR	ICU	NICU	CCU
Gain	X1				
Sweep	6.25mm/s				
Work mode	Measure				
O_2 compensate (Respironics)	16				
O_2 compensate (Masimo)	High				
Balance gas (Nmed/Palconn)	Room air				
Altitude unit	m				
Altitude (Nmed/Palconn)	0.0m				
Baro. pressure	760mmHg				
N_2O compensate (Masimo)	Off				
No breaths timeout	20s				
Alarm	On				
Alm record	Off				
CO2 Alm limit	（30 --- 45）				
INS Alm limit	（0 --- 4）				
AWRR(CO2) Alm limit	Refer to Table 8 in *Section 1) General Configurations* for default AWRR(CO_2) alarm limit.				

10. Default IBP Settings

Item		General	OR	ICU	NICU	CCU
Pressure name	IBP1	ART				
	IBP2	CVP				
		PA				
		LAP				
Sweep		25 mm/s				
Filter mode		Normal				
SPV display		Off				
Alarm		On				
Alm record		Off				
Alm level		Medium				
ART, P1, P2, P3, P4, LV, Ao, UAP, BAP and FAP Setup						
Scale		(0, 150)				
Sys Alm limit	ADU	(90, 160)				
	PED	(70, 120)				
	NEO	(55, 90)				
Map Alm limit	ADU	(70, 110)				
	PED	(50, 90)				
	NEO	(35, 70)				
Dia Alm limit	ADU	(50, 90)				
	PED	(40, 70)				
	NEO	(20, 60)				
PA Setup						
Scale		(0, 100)				
Sys Alm limit	ADU	(10, 35)				
	PED	(24, 60)				
	NEO					
Map Alm limit	ADU	(0, 20)				
	PED	(12, 26)				
	NEO					
Dia Alm limit	ADU	(0, 16)				
	PED	(-4, 4)				

	NEO	
CVP, LAP, RAP, ICP, UVP and IAP Setup		
Scale		(0, 40)
Map Alm limit	ADU	(0, 10)
	PED	(0, 4)
	NEO	

⚠**Attention**

- **The monitor meets the requirement of electromagnetic compatibility in IEC60601-1-2.**
- **The user needs to install and use according to electromagnetism compatibility information which is attached with it.**
- **Portable and mobile RF communication devices may influence the monitor performance, so the monitor should be kept away from them during using.**
- **Guidance and manufacturer's declaration stated in the appendix.**

⚠**Warning**

- **The monitor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.**
- **Class A equipment is intended for use in an industrial environment. The monitor may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the monitor could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation**
- **It may lead to inaccurate consequences if the physiological parameters measured by the device are less than the specified minimum.**
- **This device is intended for use in professional healthcare facility environment only. If it is used in a special environment, such as a magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result**

Guidance and manufacturer's declaration –electromagnetic emissions		
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	

Harmonic emissions IEC 61000-3-2	Class A	The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 for input/output lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz)	30 A/m	30 A/m	Power frequency magnetic fieldsshould be

magnetic field IEC 61000-4-8			at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150MHz to 80MHz $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7GHz 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:
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m	
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptionand 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 monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.
>
> [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

<table>
<tr><th colspan="4">Recommended separation distances between
portable and mobile RF communications equipment and the monitor</th></tr>
<tr><td colspan="4">The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><td rowspan="2">Rated maximum output power of transmitter (W)</td><td colspan="3">Separation distance according to frequency of transmitter (m)</td></tr>
<tr><td>150kHz to 80MHz
$d = 1.2\sqrt{P}$</td><td>80MHz to 800MHz
$d = 1.2\sqrt{P}$</td><td>800MHz to 2.7GHz
$d = 2.3\sqrt{P}$</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.23</td></tr>
<tr><td>0.1</td><td>0.38</td><td>0.38</td><td>0.73</td></tr>
<tr><td>1</td><td>1.2</td><td>1.2</td><td>2.3</td></tr>
<tr><td>10</td><td>3.8</td><td>3.8</td><td>7.3</td></tr>
<tr><td>100</td><td>12</td><td>12</td><td>23</td></tr>
<tr><td colspan="4">For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80MHz and 800MHz, 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.</td></tr>
</table>

<table>
<tr><th colspan="7">Immunity to proximity fields from RF wireless communications equipment</th></tr>
<tr><td colspan="7">The monitor is intended for use in an electromagnetic environment in which RF wireless communications equipment are controlled.</td></tr>
<tr><td rowspan="2">Immunity test</td><td colspan="4">IEC60601 test level</td><td rowspan="2">Compliance level</td><td rowspan="2">Electromagnetic environment - guidance</td></tr>
<tr><td>Test frequency</td><td>Modulation</td><td>Maximum power</td><td>Immunity level</td></tr>
<tr><td rowspan="3">Radiated RF IEC 61000-4-3</td><td>385 MHz</td><td>**Pulse Modulation: 18Hz</td><td>1.8W</td><td>27 V/m</td><td>27 V/m</td><td></td></tr>
<tr><td>450 MHz</td><td>*FM+ 5Hz deviation: 1kHz sine</td><td>2 W</td><td>28 V/m</td><td>28 V/m</td><td></td></tr>
<tr><td>710 MHz
745 MHz
780 MHz</td><td>**Pulse Modulation: 217Hz</td><td>0.2 W</td><td>9 V/m</td><td>9 V/m</td><td></td></tr>
</table>

	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m	
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	

Note * - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

Appendix VII Toxic/Hazardous Substances/Elements

Component		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Housing	Front housing	O	O	O	O	O	O
	Back housing	O	O	O	O	O	O
	Keys	O	O	O	O	O	O
	Facing	O	O	O	O	O	O
	Labels	O	O	O	O	O	O
Monitor	Monitor	×	×	×	×	×	×
Main unit	Hardware	O	O	O	×	O	O
	Internal wires	O	O	O	O	O	O
	PCBA	×	O	O	O	O	O
Package	Packing materials	×	×	O	O	×	×
General components	Connectors	O	O	O	×	O	O
	Power cord	O	O	O	O	O	O
Battery	Lithium battery	×	×	×	×	×	×
Accessories	ECG accessories	×	O	O	O	O	O
	SpO$_2$ accessories	×	O	O	O	O	O
	Temp accessories	×	O	O	O	O	O
	NIBP accessories	×	O	O	O	O	O
	CO$_2$ accessories	×	O	O	O	O	O
Note	O: Such hazardous/toxic substance contained in all homogeneous materials of such component falls within the content limit specified in SJ/T11363-2006. ×: Such hazardous/toxic substance contained in one or more homogeneous materials of such component goes beyond the content limit specified in SJ/T11363-2006.						

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