COMEN

CE 1639

Vital signs monitor

NC5

User manual

Shenzhen Comen Medical Instruments Co., Ltd.

Copyright

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Product name: Vital Signs Monitor

Notice

Warranty

Our company is responsible for the safety, reliability and performance of the product only if all of the following conditions are met:

- The product is used in accordance with the user manual.
- The product is installed, repaired or upgraded by personnel approved or authorized by our company.
- The product’s storage, operating and electrical environment meet product specifications.
- The product’s serial number label or manufacturing mark is clearly legible. It has been certified by our company and confirmed that the product is manufactured by our company.
- Damage is caused by non-human factors.

Our company provides free of charge services for all products based on Warranty Service Regulations. In addition, it also provides paid services for products beyond the scope of the warranty. The products need to be shipped to our company for repair and the user shall bear freight expense (including customs fees).

Returns

If you need to return the product to our company, please follow the below procedure:

Request for product return: Contact our company after-sales service department and inform them of the product number marked on the product's nameplate. If the equipment number is not legible, return will not be accepted. Please indicate the equipment number, production date, and a brief description of the reason for return.

Introduction

This user manual describes in detail the performance, operation methods and other safety information of the Vital Signs Monitor (hereinafter referred to as the monitor or vital signs monitor). This is the best starting point for new users to start using the monitor.

Intended Audience

This user manual is intended for professional clinical staff or personnel experienced in using monitoring equipment. The reader should have knowledge and work experience in medical procedures, practices and terminology necessary to monitor patients.

Illustrations

All illustrations provided in this user manual are for reference only, and the menus, options, values, and functions in the illustrations may not exactly match what you see on the monitor.

Typographical Conventions

- —>: This symbol is used to indicate operating steps.
- [Character]: Is used to represent a string in the software.

Contents

Chapter 1 Safety

1.1 Safety Information

⚠ Warning

- **Used to indicate any serious consequences, adverse event, or situation that may endanger your safety. Failure to follow the warning may result in serious injury or death to the user or patient.**

⚠ Caution

- **Used to indicate a potential hazard or unsafe operation that, if not avoided, could result in minor personal injury, product failure or damage, or property damage. It can also lead to more serious damage in the future.**

⚠ Note

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

⚠ Warning

- **The monitor is used for monitoring of clinical patients, and only well-trained doctors and nurses should use it.**
- **Before using, the user must check that the device and its accessories are working properly and safely.**
- **Do not place the power cord plug that disconnects the device from mains supply in a location that is difficult for the operator to access.**
- **Appropriate alarm volume and upper and lower alarm limits should be set for different patients. When monitoring patients, do not rely solely on the audible alarm system. If the alarm volume is set too low or is muted, the alarm may not be useful and the patient's safety may be endangered. The most reliable monitoring method is to pay close attention to the actual clinical conditions of the patient.**
- **This device should only be connected to a power socket with protective grounding. If the power socket is not connected to grounding wire, do not use the socket, instead, use a rechargeable battery.**
- **Do not open thedevice housing, to avoid potential electric shock hazards. Any repairs and upgrades to the monitor must be performed by service personnel trained and authorized by our company.**
- **When handling packaging materials, it is necessary to follow local laws and regulations or the**

hospital's waste disposal rules and regulations. Packaging materials must be placed out of reach of pediatric.

- **Do not use the instrument in a location where flammable materials such as anesthetics are placed to prevent explosion or fire.**
- **Carefully install power supply lines and cables of various accessories to prevent the patient from being entangled or suffocated, prevent cables from being entangled, or subject to electrical interference.**
- **In case of patients with pacemakers, the heart rate monitor may include the pacemaker pulses during cardiac arrest or arrhythmia. Do not rely solely on the heart rate monitor alarm. Patients with pacemakers should be closely monitored. Please refer to this user manual on how to suppress the pacemaker pulses, when using this device.**
- **An equipotential body should be formed with the devices connected to the monitor (effectively connected to the protective ground).**
- **When the monitor is connected to a high-frequency surgical device, to prevent electrical leakage, which may cause burns to the patient, the monitor's sensor and cable should be prevented from coming into contact with the high-frequency surgical device.**
- **The physiological waveforms, physiological parameters and alarm information displayed on the monitor are for reference only by doctors, and should not be directly used as the basis for clinical treatment.**
- **Electromagnetic fields may affect the performance of this device; hence, the use of other equipment in the vicinity of this device must meet appropriate EMC requirements. For example, mobile phones or X-rays devices can all be sources of interference as they emit high-intensity electromagnetic radiation.**
- **This monitor is not intended for use in MRI environment.**
- **This is not a therapeutic device.**
- **After defibrillation, the electrocardiogram (ECG) waveform must recover within 5s; other parameters must recover within 10s.**

⚠ Caution

- **To avoid instrument damage and ensure patient safety, only use the accessories specified in this user manual.**
- **Please install or transport the instrument as per the appropriate directions to prevent it from falling or colliding, and exposure to strong vibration or other damage by external mechanical force.**
- **Before the device is powered on, please confirm whether the power supply meets the voltage and frequency requirements specified on the device's nameplate or in the user manual.**
- **When the device and/or accessories expire, they must be disposed in accordance with relevant local laws and regulations or the hospital's rules and regulations.**

⚠ Note

- **Install the device in a position that ensures ease of observation, operation and maintenance.**
- **This user manual describes the product based on its most complete configuration, while the product you purchased may not have some components or functions.**

- **Keep this user manual near the device for easy and quick reference when required.**
- **The device is not meant for home use.**
- **The device can only be used by one patient at a time.**
- **Under normal use, the operator's position should be within one meter of the device.**
- **The device has a service life of 5 years.**

1.2 Contraindications

Unclear.

1.3 Device Symbols

- **Device symbols**

	Caution		Environment-friendly use period of electronic products
	Refer to instruction manual/ booklet		Serial number
	Defibrillation-proof type CF applied part		Equipotentiality
	USB port		Network connection symbol
	ON/OFF button		Multi-function interface
	Battery indicator		Manufacturer
	Alternating current	IPX2	Protected against vertically falling water drops
	Standby		Date of manufacture
	Warning: Use only cables supplied by our company. Other cables may reduce the defibrillation energy delivered to the patient.		

Note: Refer to Section 2.2.1 for the button symbols on the monitor panel and their functions.

- **Packaging symbols**

	This way up		Stacking limit
	Fragile		Keep dry

Chapter 2 Overview

2.1 Product Introduction

2.1.1 Components

The monitor consists of the main unit (battery, bracket, display, and housing), corresponding functional module (recorder module) and corresponding functional accessories.

2.1.2 Intended Use

The Vital Signs Monitor is designed for monitoring ECG, non-invasive blood pressure (NIBP), pulse oxygen saturation (SpO_2), and pulse rate (PR) of patients, as well as body temperature (TEMP) of adults, pediatrics and neonates. Monitoring information can be displayed, reviewed, stored and printed. The device is mainly used in places such as internal medicine and surgical wards, outpatient and emergency triage.

2.2 Monitor Appearance

The device comes with an 8-inch LED-backlit touchscreen. Basic functions of the monitor are described below, as shown in Figure 2-1:

2.2.1 Front view

Figure 2-1 Monitor front view

①	LED-backlit touchscreen
②	Infrared ear thermometer
③	From left to right: AC power indicator, battery status indicator, NIBP measurement Start/Stop button **AC power indicator** ➢ On: The monitor is connected to AC power. ➢ Off: The monitor is not connected to AC power. **Battery indicator** ➢ On: The monitor is equipped with a battery and is connected to AC power. ➢ Off: battery is fully charged, is not installed or malfunctions. ➢ Flashing: The monitor is running on battery power. NIBP measurement Start/Stop button ➢ Press this button to inflate the cuff to start blood pressure measurement. If you want to stop measurement during the measurement process, press this button again to stop measurement and deflate.
④	Alarm indicator (left indicator is for physiological alarm and the right indicator is for technical alarm).

2.2.2 Left side view

The monitor has the following interfaces on its left side, as shown below:

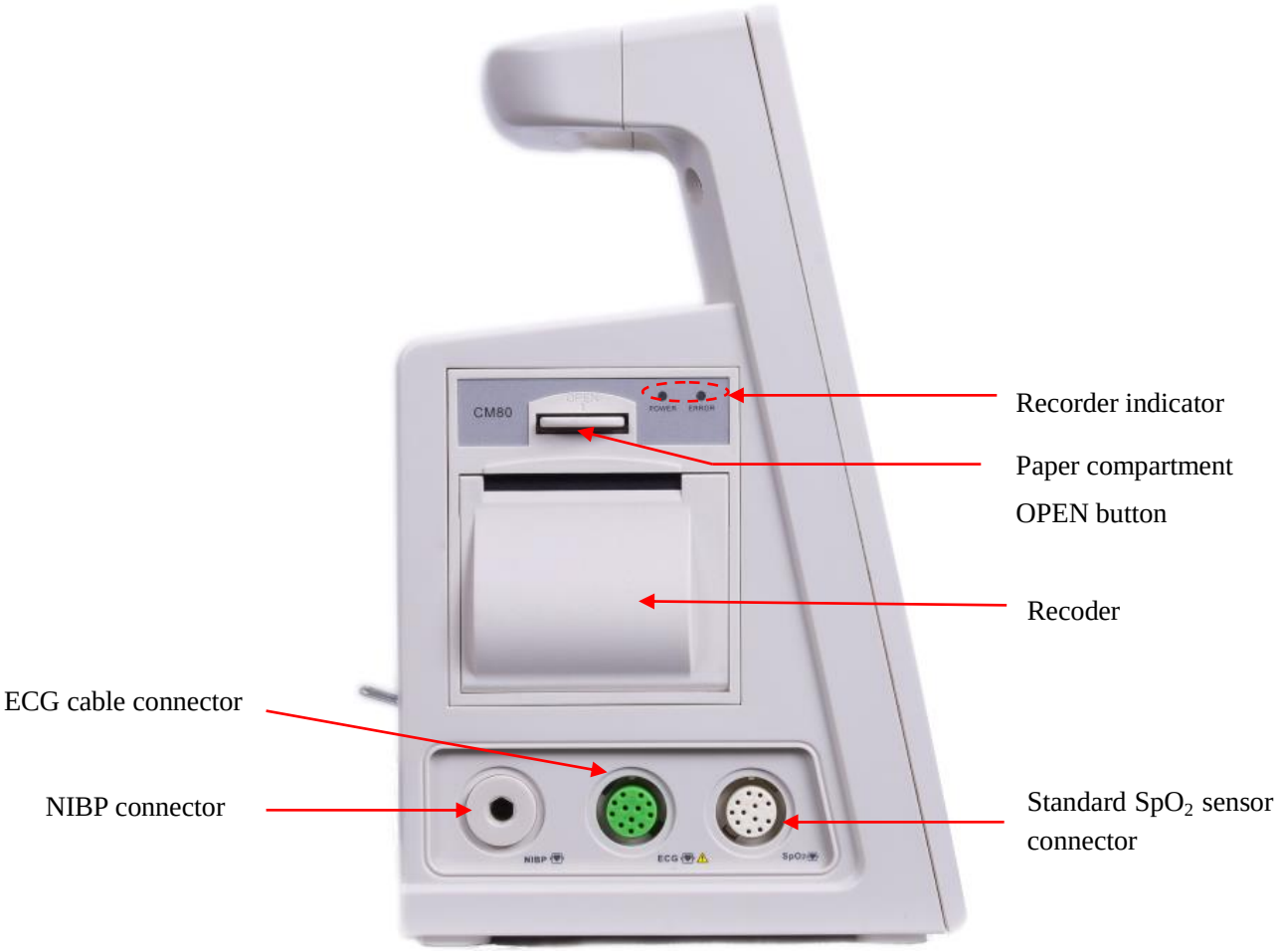


Figure 2-2 Left side view

2.2.3 Right side view

The monitor has following interfaces on its right side, as shown below:

Figure 2-3 Right side view

2.2.4 Rear view

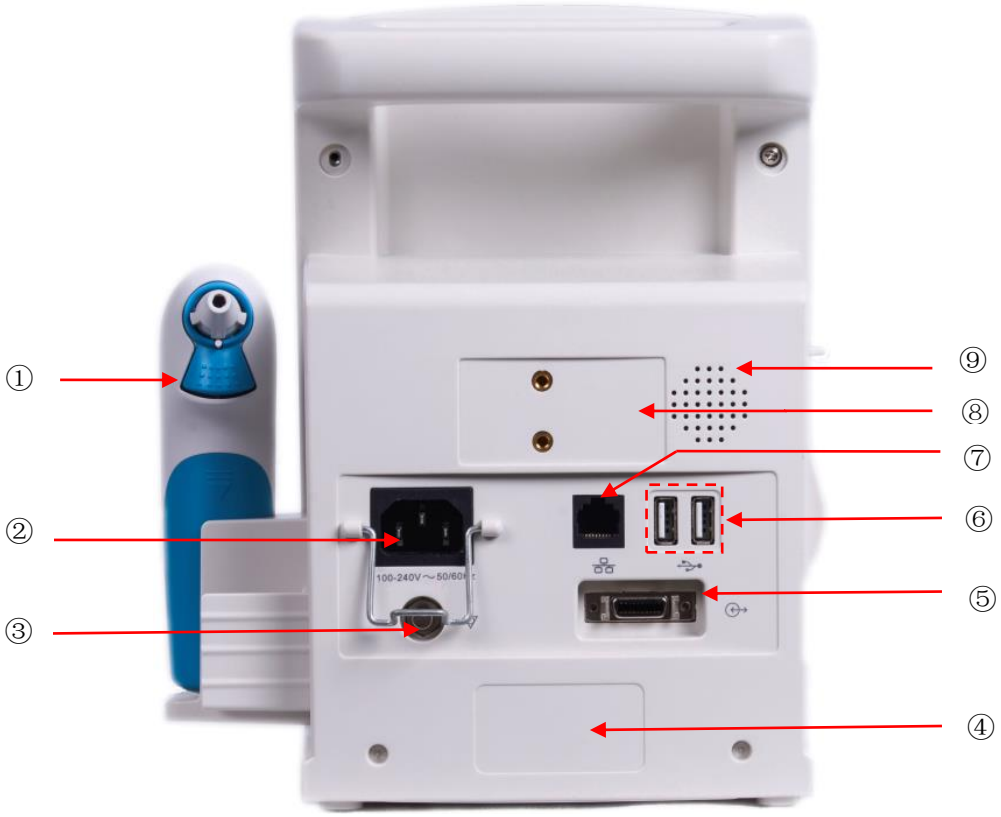


Figure 2-4 Rear cover

①Infrared ear thermometer

②AC power interface

③Equipotential jack

④Nameplate sticker

⑤Multi-function interface: It can be used as a nurse call interface. When connected to the hospital call system, it will output a nurse call signal to inform the nurse that there is an alarm.

⑥USB interface: Supports mouse, keyboard, USB, USB scanner and external USB printer.

⑦Network interface: Supports networking with the central monitoring system via a network cable.

⑧Bracket mounting position

⑨Speaker holes

⚠ Warning

- **All analog and digital equipment connected to this monitor must be certified as perspecific IEC standards (e.g., IEC 60950 Data Processing Equipment Standard and IEC 60601-1 Medical Equipment Standard). All configurations should be carried out in accordance with the valid version of IEC 60601-1 system standard. The person responsible for connecting additional devices to the input/output signal port shall configure the medical system and is responsible for compliance with the IEC 60601-1 standard. If in doubt, please contact your supplier.**
- **When signal interfaces such as patient cable interface or network interface are connected to**

multiple devices at the same time, the total current leakage caused shall not exceed the capacitance value.

- **The ear thermometer equipped with this monitor can only communicate with the monitor of our company.**

2.2.5 Bottom cover

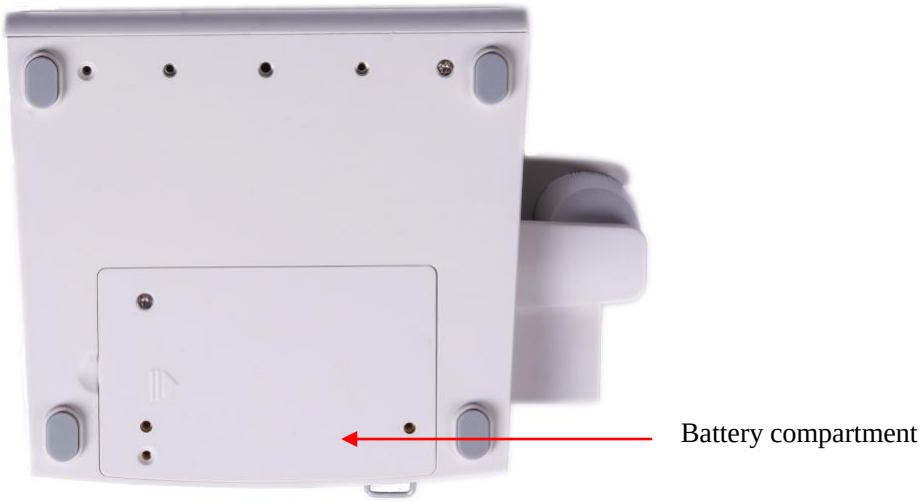


Figure 2-5 Bottom cover

2.3 On-Screen Display

The monitor is equipped with a touchscreen for touch-based operations. The vital signs parameters, waveforms, alarm information, clock, network connection status, bed number, battery and other information can be displayed on the screen simultaneously.

The Main screen of the general interface is divided into three areas: 1. Notificationarea or Upper Menu Bar; 2. Parameter area and Waveform area; 3. Lower Menu Bar, as shown in the following figure:

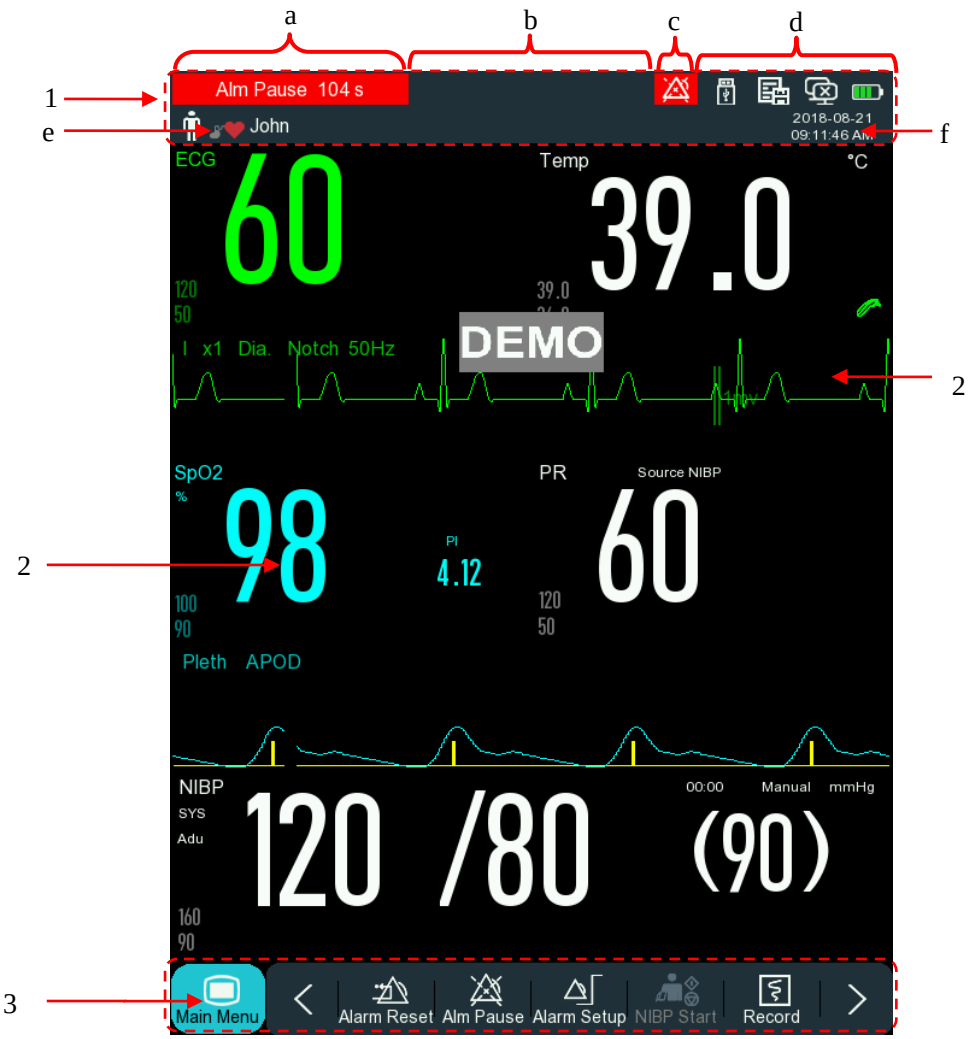


Figure 2-6 Main screen

Prompt Message Area (1):

This area includes the following sections:

(a) Physiological alarm message:

Display the current physiological alarm. For example: [***RR Too High]. When there are multiple physiological alarms, the alarm information is displayed cyclically. Select this area to display the [View Physiology Alarms] window.

(b) Technical alarm message:

Display the current technical alarm. For example: [ECG Lead Off]. When there are multiple technical alarms, the alarm information is displayed cyclically. Select this area to display the [View Technical Alarms] window.

(c) Prompt icons: Alarm pause icon ; Alarm mute icon .

(d) Monitor setup area: CMS status, WIFI connection status, SD card status, battery status, USB card status.

- Central monitoring system (CMS) connection status: indicates successful connection with

CMS;  indicates that CMS is not connected.

- USB device:  indicates that a USB device is connected to the monitor. The icon is not displayed when no USB device is connected.
- WIFI:  indicates that WIFI connection failed;  indicates that WIFI connection is successful. No icon is displayed when WIFI is off.
- Battery status:  indicates the battery level and charge and discharge status.
- SD card:  indicates that the monitor does not have an SD card;  indicates that the monitor has an SD card.

(e) Patient info: Patient type, pacemaker status and name are displayed here. Select this area to display the [Patient Manage] menu.

For a patient who has a pacemaker, when the [Pace] (pacemaker) in the [Patient Info] menu is on, the icon is displayed above the ECG waveform, and  icon is displayed in the upper-right corner of the notification area; there is no notification when the Pacemaker option in the menu is turned off.

(f) Clock: Displays the system time of the current monitor. Enter the [Time Setup] menu and reset the system time of the monitor based on your local time zone.

Parameter area and Waveform area introduction (2):

(a) Parameter introduction

- Displays parameter measurement data.
- Color is consistent with the corresponding parameter waveform.
- Select the Parameter area. A corresponding Setup menu is displayed.

(b) Waveform introduction

- Up to 2 waveforms can be displayed.
- Select the Waveform area. A corresponding Waveform Setting window is displayed.

Lower Menu Bar introduction (3):

The Lower Menu Bar contains onscreen Quick Keys, which enable users to operate the device faster. The Quick Keys are displayed in the Lower Menu Bar depended on the monitor's configuration.

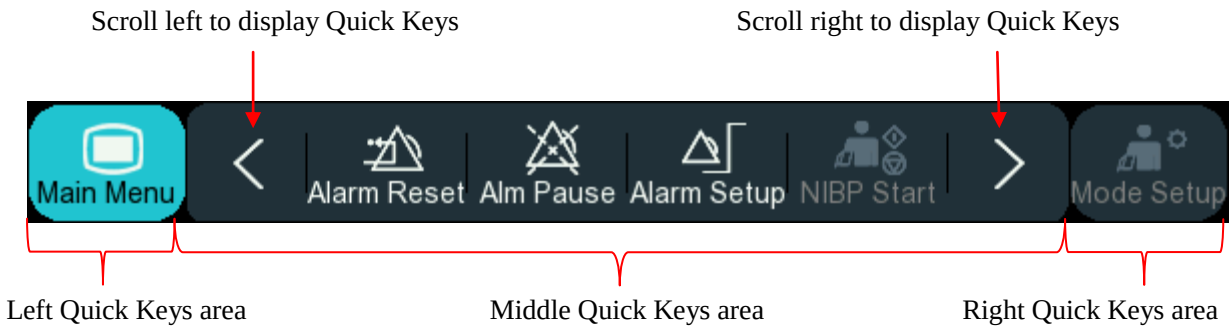


Figure 2-7 Lower Menu Bar

Chapter 3 Monitor Installation

⚠ Attention

- **To ensure the monitor works properly, please read this chapter, safety information and patient safety chapters before installing and using the device.**

3.1 Unpacking and Checking

Carefully remove the monitor and accessories from the box and save the packaging materials for later transportation or storage. Please make an inventory of the accessories according to packing list. Check for any mechanical damage. Check all exposed wires and insertable accessories. If you have any questions, please contact our sales department or agent immediately.

3.2 Connecting the AC Power Cord

Connecting procedures for AC power cord:

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

Use the attached power cord. Connect one end of the power cord to the monitor's power port and the other end to a grounded power socket.

⚠ Attention

- **Connect the power cord to a hospital-specific socket.**
- **When a battery is installed in the device, the battery must be charged after the monitor has been transported or stored for a period of time. If you turn it on directly without connecting to AC power, the instrument may not work properly due to insufficient battery power. When it is connected to AC power, the battery is charged irrespective of whether or not the monitor is turned on.**

Connect an equipotential ground wire if necessary. Refer to the Equipotential Grounding section in the “Patient Safety” chapter.

3.3 Powering On

After the Power switch is turned on, the monitor enters Self-test mode. The yellow indicator lights up and the company logo is displayed. The red and cyan (greenish-blue) indicators light up for one second simultaneously, and then the cyan indicator continues to remain on for one second, followed by the yellow

indicator, which lights up for one second. When you hear a “beep”, the monitor enters its Main interface. After entering the Main interface, the device can be used to monitor the patient. However, before monitoring the patient, please ensure that the monitor is not mechanically damaged, and external cables and accessories are properly connected.

Attention

- **If a major error is found during the Self-test, the system will trigger an alarm.**
- **Check all monitor functions to ensure that the monitor is working properly.**
- **If a battery is installed in the device, the battery must be charged after each use to ensure that there is sufficient battery back up.**
- **It is recommended that you maintain at least a 1-minute interval for power on/off, to prevent reducing service life of the device.**

Warning

- **If the monitor or its accessories are damaged or if there is an error message, do not use the monitor; immediately contact the hospital's biomedical engineer or our maintenance engineer.**

3.4 Connecting the Sensor

Refer to the subsequent monitoring parameter section to connect the required sensor to the monitor and the patient.

Chapter 4 Patient Safety

4.1 Safety Instructions

The patient monitor is designed to meet international safety standards for medical electrical equipment. The device has anti-defibrillator and electrotomeinterfenceprotection for floating ground inputs. It applies correct electrodes (refer tothe "ECG Monitoring" section) and is placed according to the manufacturer's instructions.

4.2 Environment

Follow the below instructions to ensure complete safety in electrical installation.

The patient monitoring system should be used in an environment that appropriately avoids vibration, dust, corrosive or explosive gases, extreme temperatures, humidity, etc.

When it is installed in an instrument cabinet, the air in the cabinet should be circulated, and there must be enough space in the front of the cabinet for ease of operation. In addition, when the cabinet door is opened, there must be enough space in the back for ease of maintenance. At least 2 inches (5 cm) of space around the device should be allowed to ensure air circulation.

The monitoring system meets storage and operating requirements at ambient temperatures of -20℃ to +60℃ (storage) and 0℃ to 40℃ (operating). Ambient temperatures outside this range may affect device accuracy and cause damage to components and wiring.

4.3 Protective Grounding

To protect the patient and operator, the monitor housing must be grounded. Therefore, the patient monitor is equipped with a detachable three-wire cable, which when plugged into a matching three-pin plug socket, grounds the monitor via the ground wire (protective ground). If there is no three-pin plug connector, please contact the hospital's electrical management staff.

⚠ Warning

- **Do not connect the three-pin cable plug of this device to a two-pin socket.**

Connect the ground wire to the device’s equipotential ground terminal. If it is not clear whether a particular combination of devices is dangerous, for example, accumulation of leakage current may be a hazard, and the user should consult relevant manufacturer or other experts to ensure necessary safety for all instruments and devices to avoid damage.

4.4 Equipotential Grounding

Primary protection of the device has been included in the system through protective grounding (PGND) of the housing by groundingthe power plug. For cardiac and craniocerebral examination, the patient monitoring system must be connected separately to the equipotential grounding system. One end of the equipotential grounding conductor (potential equalization conductor) is connected to the equipotential grounding terminal on the rear panel of the instrument, and the other end is connected to a connector of the equipotential system. If the protective grounding system is damaged, the equipotential grounding system can assume the safety function of the protective grounding conductor. Cardiac (or craniocerebral) examinations should only be performed in a medical room provided with a protective grounding system. Check that the instrument is in proper working condition before each use. The cable connecting the patient and the instrument must be free of electrolyte contamination.

⚠ Warning

- **If the protective grounding (protective ground) system is unstable, the monitor will use its internal power supply.**

⚠ Note

- **If equipotential grounding affects use of the device, please contact our after-sales service department or agent.**

4.5 Condensation

During operation, it is necessary to ensure that the instrument is free of condensation. Condensation may form as the instrument moves from one room to another; this is because the instrument is exposed to moist air and different temperatures. To avoid unnecessary problems, if condensation appears on the device, let it dry before use.

Note: Condensation is the change in the physical state of matter from gas phase into liquid phase or from liquid phase into solid phase. For example, water vapor will turn into liquid water and water will turn into ice in a cold atmosphere. The lower the temperature is, the faster the condensation process.

Chapter 5 Basic Operations

Note

- **When using the monitor, the operator should be within 1 meter of the monitor to ensure convenient observation.**

5.1 Entering Main Menu

This monitor's system setup is flexible. You can enter the [Main Menu] window by selecting the Main Menu button on the screen, where you can set various menu items of the system, as shown below:

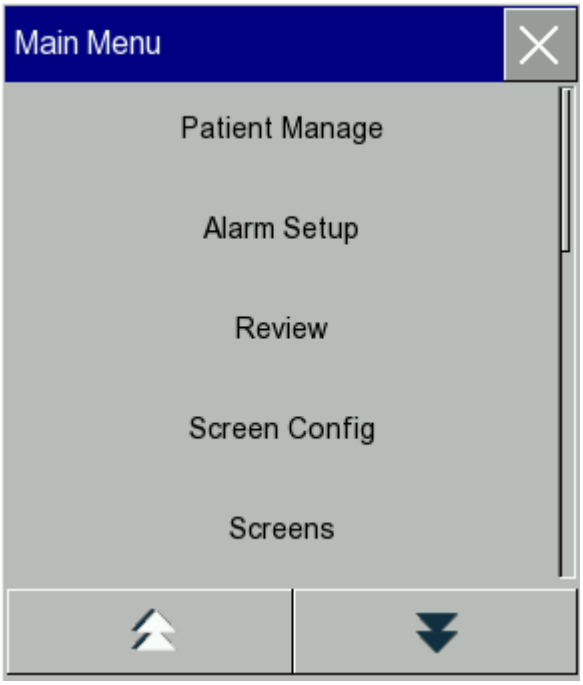


Figure 5-1 Main Menu

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

5.2 Entering User Maintenance

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

5.3 Viewing Monitor Info

Enter [Maintain] → [Monitor Info]. This screen displays the software and hardware version information, etc., to help the manufacturer maintain and trace the device.

5.4 Entering Parameter Setup Window

Each parameter displayed on the screen can be set, and the user can enter the setup window through the following methods:

- Through the waveform area: Select the parameter waveform you want to set and the corresponding setup window is displayed. For example, select an ECG waveform and the [ECG Wave] window is displayed.
- Through the parameter area: Select the parameter area for which you want to set parameters.The corresponding setup window is displayed. For example, select the ECG Parameter area and the [ECG Setup] window is displayed.
- Through [Mea. Setup]: Press the [Mea. Setup] quick key or enter [Main Menu] → [Mea. Setup]; the [Mea. Setup] menu is displayed. Select the parameters to be set.

5.5 General Setup

5.5.1 Setting the Time

Enter [Maintain] → [Time Setup] and reset the system time based onyour local time zone. The set time includes: year, month, day, hour, minute, second, date format and time format. This setting takes effect immediately.

5.5.2 Setting the Language

Enter [Maintain] → [Language] and select the appropriate language.

5.5.3 Setting the Unit of Measurement

Enter [Maintain] → [Unit Setup], where the user can set the appropriate parameter units, including [Height Unit], [Weight Unit], [Press Unit](Pressure Unit) and [Temp Unit].

5.5.4 Configuring Quick Keys

You can modify the quick keys displayed on the lower menu bar as required.

Enter [Maintain] → [Quick Key Config]. The [Quick Key Config] menu is displayed, as shown below:

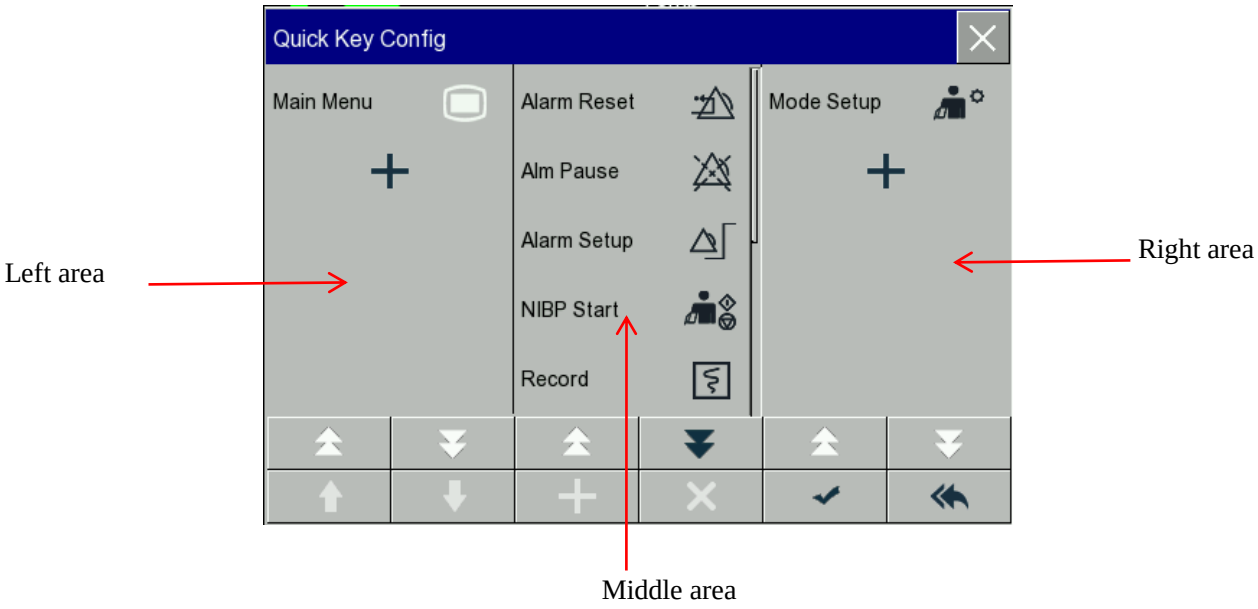


Figure 5-2 Quick Keys Configuration Menu

The three areas of the quick keys represent the left, middle and right areas of the lower menu bar on the screen, respectively.

Press  to display the [Quick Key] menu. Select the quick keys you want to add under this menu. After all the appropriate quick keys are set, press the  button.

	Scroll up and down to display quick keys
	Shift up and down to display quick keys
	Delete
	Undo button; Press this button and press “Confirm” to restore factory settings.

5.5.5 Setting screen brightness

The specific steps to adjust screen brightness are:

1) Enter [Main Menu] → [Screen Config] → [Brightness].
2) Select a suitable brightness from 10 to 100. “100” means the brightest and “10” means the darkest.

5.5.6 Setting Volume

Press the [Volume Setup] quick key or enter [Main Menu] → [Volume Setup].

1) Select [Alm Vol] (Alarm Volume): Select an appropriate volume from X~10, where X is the minimum volume that depends on the setting of the minimum alarm volume. For details, please refer to the Alarm section.
2) Select [QRS Vol.] (QRS Volume): Select an appropriate volume from 0~10.

3) Select [Beat Vol] (Beat Volume): Select an appropriate volume from 0~10. For masimo SpO_2, user can open and close the function of smart pulse tone in [Smart tone] in [SpO2 setup]. And for standard and Nellcor SpO2, the default setting of this function is on. With this function on, the pulse tone will be increased while the SpO2 reading is decreased.

5.5.7 Freezing the Waveform

In the standard interface and list interface, directly press the Freeze quick key on the Lower Menu Bar of the screen, to freeze all waveforms on the screen.

Figure 5-3 Freeze Interface

After pressing the Freeze button, press either the left-arrow or right-arrow buttons in the Freeze window to move the frozen waveform to the left and right, respectively. A downward arrow appears in the upper-right corner of the top waveform and there is a time scale on the left side of the arrow. The freeze time is marked as [0s]. As the waveform moves to the left, the time scale changes to [-1s], [-2s], [-3s] in order. The current displayed waveform is the one N seconds before freeze time.

Recording frozen waveform

In the Freeze window, you can print the frozen waveform based on [Wave 1] or [Wave 2]. After selecting the appropriate option, press to output the waveform to the recorder.

Releasing frozen waveform

Press the icon in the upper-right corner of the Freeze window.

5.5.8 Locking the Screen

If you don't want to use the touchscreen function, you can lock the screen. Press and hold "Main Menu" to lock the screen. At the bottom left of the screen, [Screen is locked! Long press main menu to unlock] is displayed.

5.5.9 Setting Events

Setting events enables you to set a manual trigger event. While monitoring a patient, certain events can occur that can affect the patient, resulting in changes in certain monitoring waveforms or parameters. To assist you in analyzing these effects, you can set manual trigger events in the monitor, andthe waveform of a manual trigger eventcan be saved. When the event occurs, the monitor saves the mark to make it easier for you to review the event.

The specific steps are:

1) Enter [Main Menu] → [Event Setup].
2) Select 2 waveforms from the options to save the waveform as an event.
3) Enter appropriate comments in the Comment option.
4) Select [Manual Trigger].A [Manual Trigger Successfully] message is indicated at the bottom left of the screen.
5) You can select the events to review in the [View Physiology Alarm] menu of [Alarm Event Review].

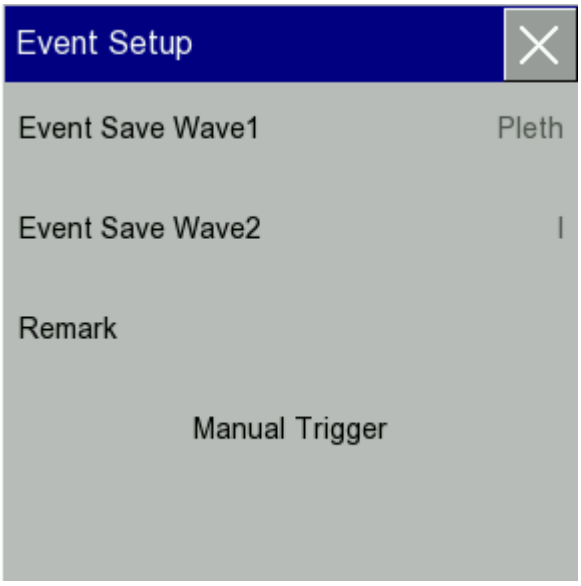


Figure 5-4 Event Setup

5.5.10 Module Switch Setup

You can turn on or off the measurement of a parameter as required. When the Parameter module is turned off, the corresponding waveform and value are not displayed on the screen, and the monitor stops analyzing data and does not trigger an alarm.

1) Enter [Maintain] → [Module Setup].
2) Turn a parameter module on or off under the setup menu.

5.5.11 Setting User Password

You can set the password for entering [Maintain] as per your requirement.

Enter [Maintain] → [Set User PassWord].

5.6 Work Mode

5.6.1 Monitoring mode

The monitoring mode is a work mode for monitoring a patient. The monitor will automatically enter the monitoring mode when it is switched on.

5.6.2 Standby mode

If the monitor is not monitoring a patient at the moment and you do not want to turn it off, it can enter standby mode.

Enter standby mode:

- ✧ Press the ⏻ button on the right side of the device or press the [Standby] quick key in the lower menu bar of the screen. A reminder that [Sure to enter standby mode?] is displayed on the screen. Select [Yes] to enter Standby mode.

Device operationsin Standby mode:

- ✧ Blocks display of any alarms and waveforms.
- ✧ The system screen is completely black and only the [Please press any key to exit Standbymode] message is displayed.

Exit Standby mode:

- ➢ Press anywhere on the screen or press any button on the monitor. The [Choose to exit standby mode] message is displayed on the screen.
- ➢ Select [New Patient] to exit the standby mode and enter the main screenwhere a [Patient Info] setup window is displayed. Set patient information in the window to monitor the new patient.
- ➢ Select [Continue] to exit standby mode and enter the mainscreen, and to continue to monitor the current patient.

5.6.3 Night mode

The monitor provides a night work mode that avoids disturbing the patient at night. After exiting night mode, the monitor resumes the previous settings that were set before entering the night mode.

Starting Night mode:

1) Enter [Main Menu] → [Screen Config] → [Night Mode].
2) The night mode setup window is displayed. Select [Night Mode] to enter this mode.
3) Set [Alm Vol], [QRS Vol], [Key Vol], [Brightness], [Stop NIBPStart].

Exiting night mode:

1) Enter [Main Menu] → [Screen Config] → [Night Mode].
2) The night mode setup window is displayed. Select [Night Mode] and press [Yes] after a popup warning [Exit night mode?] appears.

5.6.4 Privacy mode

When information on the patient monitoring screen needs to be protected, you can start the Privacy mode, which can only be started under the supervision of the CMS.

Start Privacy mode:

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

When the privacy mode is activated, the monitor operates as follows:

1) The monitor's screen is turned off, and the [In monitoring… press any key to exit privacy mode!] message is displayed.
2) Continues to monitor the patient and store patient data, however, the patient data is only visible at the central station.
3) Alarms continue to be triggered; however the alarm sound and alarm light are blocked at the monitor end.
4) All system sounds of the monitor are blocked, including heartbeat sound, pulse sound, and various reminder tones.

Exiting privacy mode:

✧ Press any key (except ON/OFF) to exit privacy mode.
✧ Disconnect from the CMS.
✧ Battery is too low.

5.6.5 Demo

Navigate to [Maintain] → [Demo], the monitor enters the Demo function working state.

Warning

- **Demo waveforms are simulated demonstration waveforms that the manufacturer has set up to demonstrate machine performance and help users to conduct training. In actual clinical use, the demo function should be disabled as it may cause medical staff to mistake them foractual waveforms and parameters of the patient being monitored, thus affecting patient monitoring, and delaying disease diagnosis and treatment.**

Chapter 6 Configuration Management

6.1 Overview

When a patient is continuously monitored, the medical personnel often need to adjust some settings of the monitor according to actual conditions of the patient. Adjusting these entire monitor settings is called configuration. For more effective and quicker configuration, the monitor has a complete set of pre-defnedconfigurations for users to select according to the needs of different types of patient as well as the actual clinical requirements of different departments. Users can also modify some settings in a configuration and save them as custom settings based on actual requirements.

Configuration information of the monitor mainly includes:

Parameter configuration

The settings related to each parameter measurement, such as waveform gain, speed, unit, alarm switch and alarm limit.

General configuration

General settings, such as alarm settings, logging, etc.

Maintenance configuration

User maintenance related settings, such as waveformdraw setting, language, nurse call, etc.

See Appendix VI, **Default Configuration Information**, for default system configuration values.

Warning

- **Access to Configuration Management is password based, and configuration actions must be conducted and confirmed by professional medical staff.**

Enter [Config Manage] menu:

1) Select [Main Menu].
2) Select [Config Manage] and enter the password.

[Department]: This option indicates the department where the monitor is used.When the department is changed; all user profiles of the original department are deleted. Each department has 3 factory default configurations (ADU(adult), PED (Pediatric), NEO (Neonates)). The current department configuration directory can store up to 3 user-defined configurations. Make sure the correct department is selected before you start using the Configuration Management function.

Department options：General (General Monitoring)
OR (Operation Room/Anesthesia Monitoring)
ICU (Intensive Care Unit)
NICU (Neonatal Intensive Care Unit)
CCU (Coronary Care Unit)

Note

- **If different configurations are used for the same monitor when it is in a single area (such as ICU or cardiac operating room), it may bedangerous.**
- **When selecting a configuration, you must ensure that the configuration is appropriate for the patient to be monitored.**
- **When the monitor department is changed or the patient type is changed, the monitor will load the default configuration of the manufacturer.**
- **System Settings of this monitor are stored after they are set up.**

[Save As User Config]: After the configuration file name is entered in the monitor, the configuration is saved as a user configuration. The configuration name must conform to a specific format: the file name must consist of letters, numbers, or undergrades, and the file name cannot be empty. When the configuration file to be saved has the same name as the saved configuration, the system will prompt whether to overwrite the original configuration file. The system can save up to 3 user configurations.

[Delete Config]: Deletes the saved user configuration in the monitor. All saved user configuration files under the current department in the system are listed in this menu, and the corresponding patient type is identified with a bracket after the corresponding configuration file. For example: zhang san (adult) means that the configuration file "zhang san" is a configuration saved for the patient type ‘adult’.

[Load Config]: Configurations that are available for loading (no more than 6 for one department) include the manufacturer configuration corresponding to the current patient type, the user configuration stored in the monitor and the configuration imported using a USB flash drive. The displayed user configuration file name identifies the corresponding patient type after the file name. All saved configurations will replace current configurations and take effect after the configurations have been loaded.

Enter [Load Config] menu: Enter [Main Menu], select [Load Config] in the main menu or enter the [Config Manage] menu and select [Load Configuration].

[Import Config From USB]: The number of configuration files in the current department plus those imported from the USB flash drive cannot exceed 6files for the current department.

[Export Config to USB]: Exports the user configuration in the system to the USB flash drive.

[Startup Configuration]: This setting determines the default configuration to be loaded when the monitor is restarted. However, after the monitor is powered off, it will load the configuration based on the following conditions:

If powered on within 120s after power off, the monitor will automatically load the latest configuration; If powered on after 120s, the monitor will automatically load the configuration according to the [Startup Configration] setting.

6.2 Operation Demonstration

Using the customized [John] configuration file as an example. The operation steps are as follows:

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

Figure 6-1 Config Manage Menu

2) In the [Config Manage] menu, select [Department] and then select the appropriate department type.

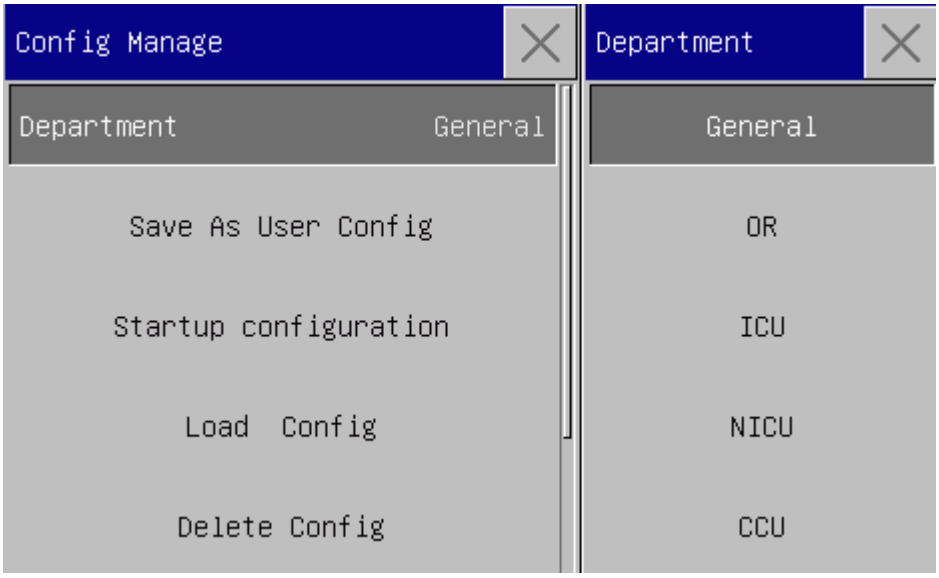


Figure 6-2 Department Menu

3) Select [Load Config] in [Main Menu] or [Config Manage] menu. In this configuration, in addition to loading the corresponding manufacturer configuration, you can also load the user configuration for the corresponding patient type.

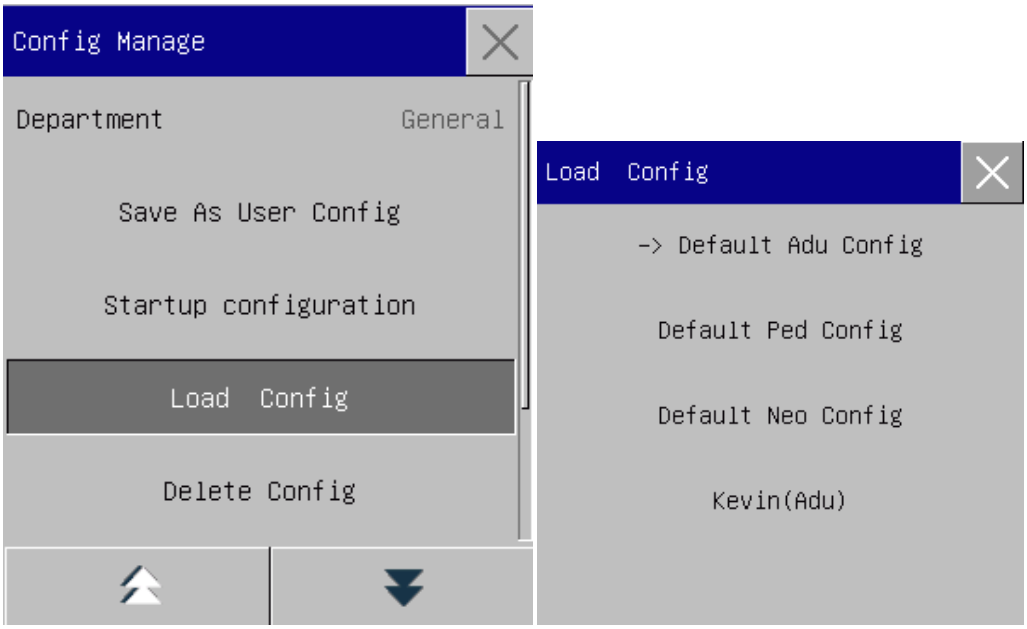


Figure 6-3 Default Menu

4) To create a user configuration you can modify the current monitor configuration and save it for future use. In the [Config Manage] menu, select [Save As User Config].The system displays the [Config Name] interface, as shown below. Enter the appropriate file name [John] and press the Enter key.

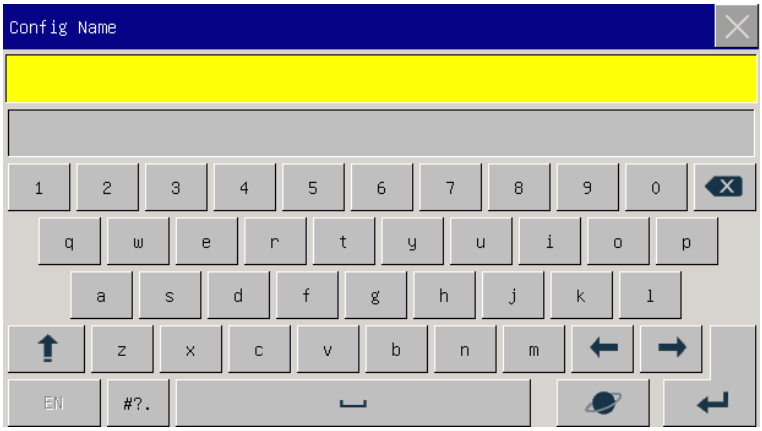


Figure 6-4 Config Name Interface

5) Select [Load Config] in [Main Menu] or [Config Manage] menu again. In this menu, the [John] configuration you have just saved is displayed. You can now select this configuration.

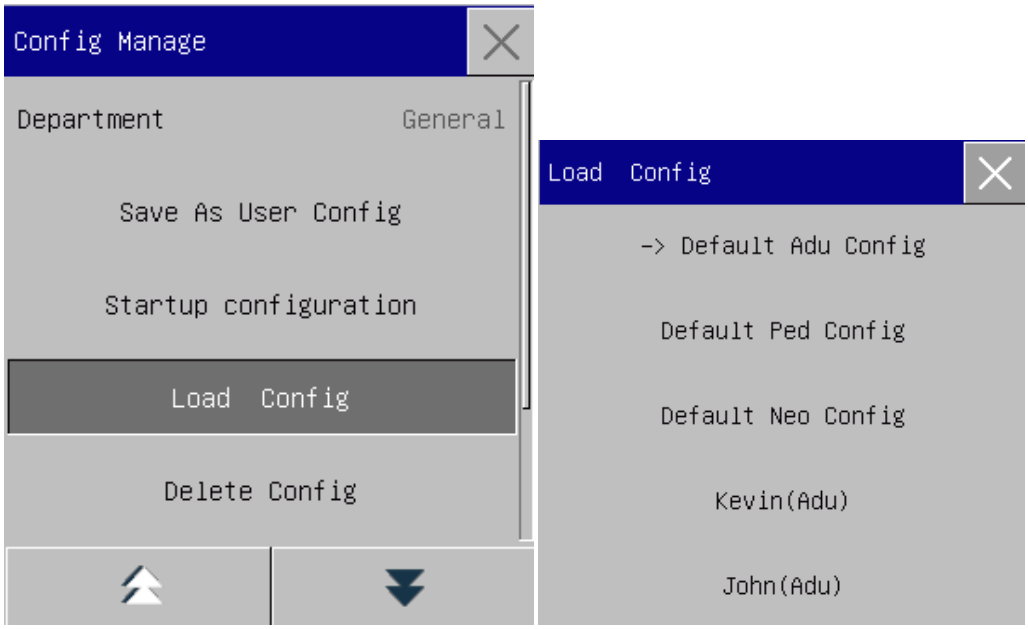


Figure 6-5 Load Config Menu

6) If you don't require the configuration, select [Delete Config] in the [Config Manage] menu and select the items to be deleted.

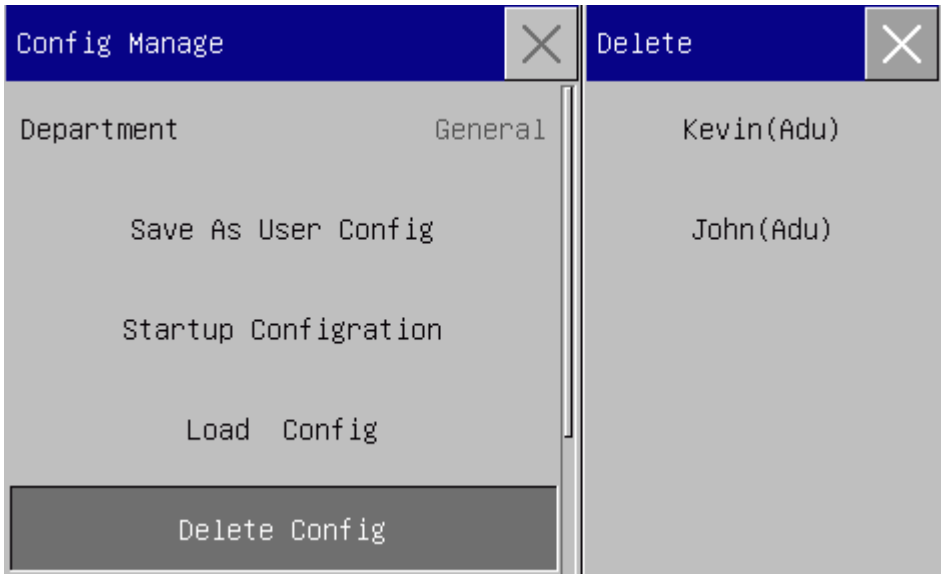


Figure 6-6 Delete User Config Menu

7) When loading the monitor configuration, in addition to the default configuration and saved user configuration, you can also select the configuration imported from the USB flash drive. First, insert a USB flash drive with the configuration file. After the USB flash drive is recognized by the system, select [Import Config from USB] in the [Config Manage] menu. When [Import Succeeded] is displayed at the bottom left of the screen, the imported configuration is added to [Load Config]. If you no longer need the configuration file, you can also select [Delete Config] to delete it; if there is no user configuration

file in the USB flash drive, the monitor will display the [No User Config Exists] message.

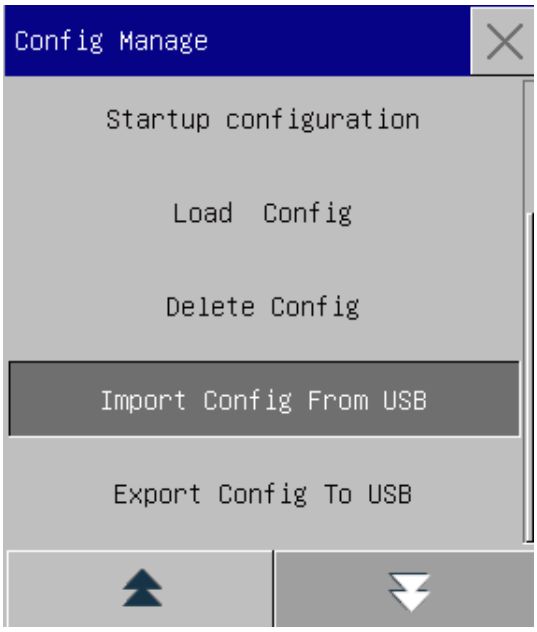


Figure 6-7 Import Config

8) User configurations can be saved in the monitor or exported to a USB flash drive for backup. Insert a USB flash drive and then select [Export Config to USB] in the [Config Manage] menu. When the [Export Succeeded] message is displayed at the bottom left of the screen, the export is completed. If there is no user configuration file in the monitor, the monitor will display the [No User Config Exists] message.

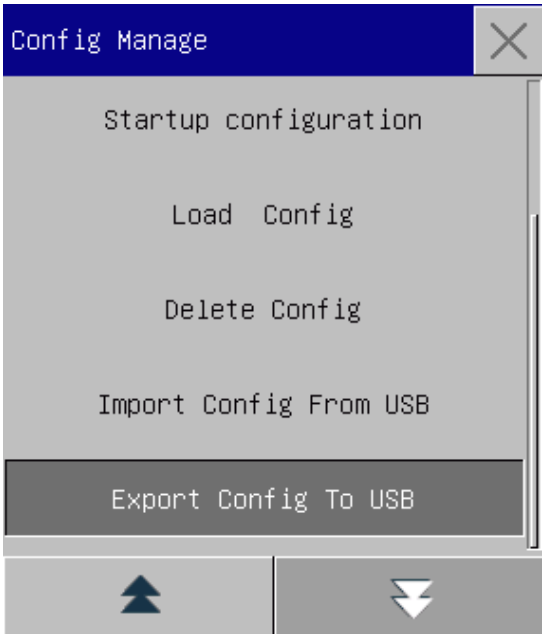


Figure 6-8 Export Config

9) Before turning off the monitor, you can set the configuration to be loaded when the power is turned on again. In the [Config Manage] menu, enter the [Startup Configuration] menu and select [Use Last CFG], [Default Adu Config], [Default Ped Config] or [Default Neo Config].

Figure 6-9 Startup Configuration

Chapter 7 Patient Management

This monitor supports flexible System setup. You can enter the [Main Menu] to select [Patient Manage] or directly select the [Patient Manage] quick key on the Lower Menu Bar or enter [Patient Manage] menu through the patient info area on the Lower Menu Bar.

7.1 Admitting Patient

When a patient is connected to the monitor, the monitor can display and store the patient's physiological data even if the patient is not admitted into the system. However, it is very important to admit the patient correctly. Conduct patient admission and discharge via the [Patient Manage] window and associated buttons

Admitting a patient admitted to the hospital:

1) Enter [Patient Manage] → [Admit].
2) If there is already a patient admitted, the [Discharge current patient? Admit new patient] message is displayed. Select [Yes] to discharge the current patient. If no patient is admitted, the system displays [Do you want to apply the existing data to the patient to be admitted?] message.
   - ➢ [Yes]: Apply the existing data in the monitor to the patient to be admitted.
   - ➢ [No]: Clear the stored data.
3) Enter various information of the patient in the [Patient Info] menu. Ensure you select the correct [Pat Type] and [Pace]. The system supports various input methods such as EN, ABC, Hand Write and WuBi:
   - ✧ [Pat Type]: [Adu], [Ped], [Neo]. It is important to select the correct patient type, as it determines the measurement algorithms that the monitor uses for calculations and processing, as well as the range that applies to certain safety limits and alarm limits.
   - ✧ [Pace]: This setting determines whether the monitor displays pacingpulses. When [Pace] is set to "On" and a pacemaker signal is detected, a “ ▮ ” is indicated above the ECG waveform, and the symbol  is displayed in the upper-left corner of the information reminder area; when [Pace] is set to "Off", no information and symbols are displayed and the pacingpulse is filtered.

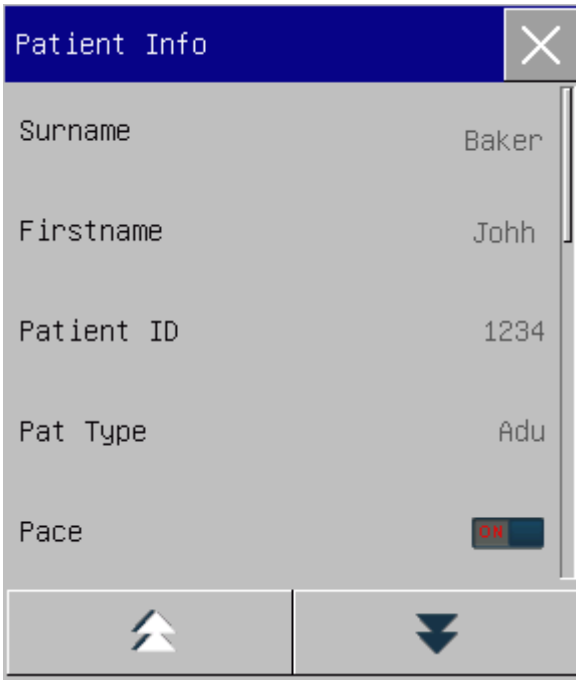


Figure 7-1 Patient Info

⚠ Warning

- **Irrespective of whether a patient is admitted into the system, both [Pat Type] and [Pace] use the default settings. Therefore, before monitoring the patient, please confirm that the settings in Patient Info meet actual conditions of the patient.**
- **When patient type changes, the monitor loads the factory default configuration corresponding to the new patient type; when patient type is not changed, the monitor maintains the current configuration.**
- **For patients with a pacemaker, the pacing pulse analysis function must be turned on. Otherwise, the pacing pulse may be counted as a normal QRS wave, due to which the "ECG signal too weak" alarm may not work appropriately.**

7.2 Quick Admit Patient

When there is insufficient time to enter patient information, the Quick Admit option can be used. The user can add the patient's other information later:

1) Enter [Patient Manage] → [Quick Admit].
2) If a patient has been admitted, the [Discharge the current patient? Admit new patient] message is displayed. Select [Yes] to discharge the current patient. If no patient is admitted, the system displays the [Do you want to apply the existing data to the patient to be admitted?] message.
   - [Yes]: Apply the existing data in the monitor to the patient to be admitted.
   - [No]: Clear the stored data.
3) Enter the [Patient Info] window and set the [Pat Type] and [Pace], and then close the window.

7.3 Discharge Patient

This function is used to discharge a patient from the monitor, who has been discharged from the hospital.:

1) Enter [Patient Manage] → [Discharge].
2) The system displays the [Discharge ?] message.
   - [Yes]: Successfully discharge the current patient. The patient data is automatically archived, and the user can review the archived patient data underPatient File Management.
   - [No]: Cancel discharge of the patient.

⚠ Warning

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

7.4 Document Management

Document Managementhelps the user query, review, delete and transfer archived cases; however, the patient document data cannot be stored when the monitor is not configured with an SD card. Document Management allows the user to automatically match the existing patient documents, or manually query them. The user can view, delete, and export the query results.

[Query]: Find the required Patient Document information by entering patient name in the lower-left corner of the [Document Manage] menu.

[View]: Select the patient information column you want to review and press [View],the [Review] menu is displayed. You can view [Patient Info], [Trend Review], [NIBP Review], [Alarm Event Review] and [Wave Review].

[Delete]: Delete the selected case data.

[Export]: Export the selected case data to a USB flash drive or computer.

The specific steps are as follows:

1) Enter [Main Menu] → [Document Manage].
2) Enter the name of the patient you want to query in the input field at the bottom left.
3) After entering the information, press [Query].
4) Press the ▲▼ button to view more patient documents, and press the ◀▶ button to view more patient information in a document
5) You can perform [View], [Delete], and [Export] operations for the selected patient document.
6) When the ☐checkbox in the lower-left corner is selected, all patient documents are selected. Then, select [Delete] to delete all documents.
7) [Export]
   - After selecting a single patient document, press the [Export] button, the system displays the [Data

Export] menu.

- Set the [Start Time] and [End Time] of the patient document.
- Select [File Format]: bin, txt, xls.
- Select [Export Media]: USB or ftp.
  - Select USB: Exports the file to USB flash drive.
  - Select ftp: Exports the file to the ftp server via the wired network.
- Select [Data Export]. When data export is completed, the system displays the [Export Data Succeeded, Please Restart...] message.
  - When multiple patient documents are selected, other operations are the same as those for a single document except that the document time cannot be set.

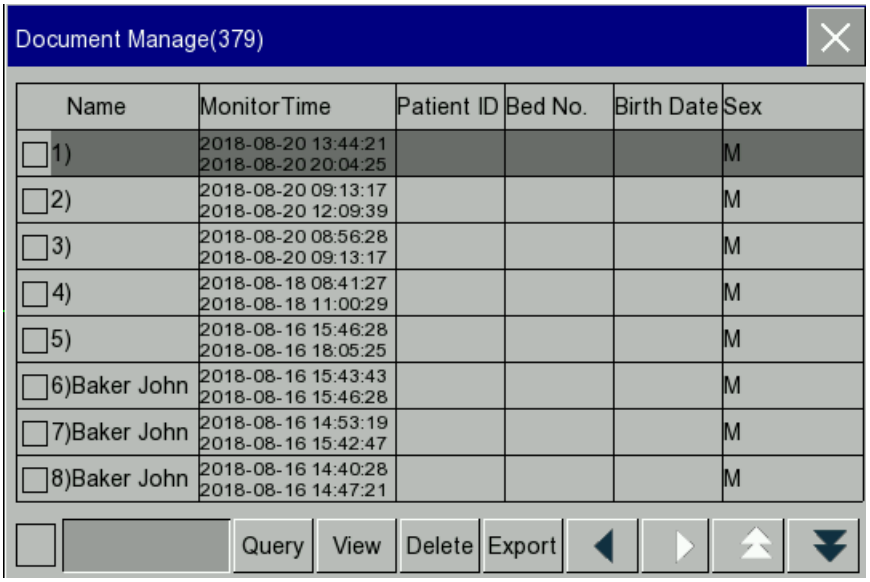


Figure 7-2 Document Manage Interface

Warning

- **With respect to patient alarm information, physiological and technical alarm information can be saved in the patient document.**
- **If the alarm system is suddenly powered off, the alarm events in the document can still be saved.**
- **Do not remove the USB flash drive during data export, otherwise, the data may be corrupted.**
- **During data export using FTP, do not disconnect the monitor from the network, otherwise the data may be corrupted.**

Note

- **When the monitor is turned off, the system automatically stores the data and ends the medical record storage period for the data before power off. When the monitor is turned on, it automatically creates a new time period, which is the current time period data.**
- **This monitor supports power-off data storage function.**

7.4.1 Save Tactics

The monitor can create a new patient document for data storage even if the patient has not been admitted into the system, however, in this scenario, the document is a temporary case file. The monitor supports automatic deletion of temporary case files. In addition, the monitor also supports automaticdeletion ofold files when the SD card is full.

1) Enter [Maintain] → [Save Tactics]
2) Select [Auto Del Temp Case] and [Del old case], and then select either "On" or "Off".

Chapter 8 User Interface

The monitor supports multiple user interfaces. For example: Standard interface, List interface, Point meas interface. Users can choose different workinterfaces based on different needs todisplay different information on the screen. The waveforms on each channel are not fixed, and the waveforms are displayed on the interface based on your device functions. The style and features of some work interfaces are described below.

Enter user interface selection:

1) Select the [Screens] quick key or select [Screens] in the [Main Menu].
2) Select the desired interface in the [Screens] menu.

8.1 Standard Interface

The interface in a fully-equipped monitor can display up to 2 waveforms. The available options are: Continuous and Automatic NIBP Parameter measurement.

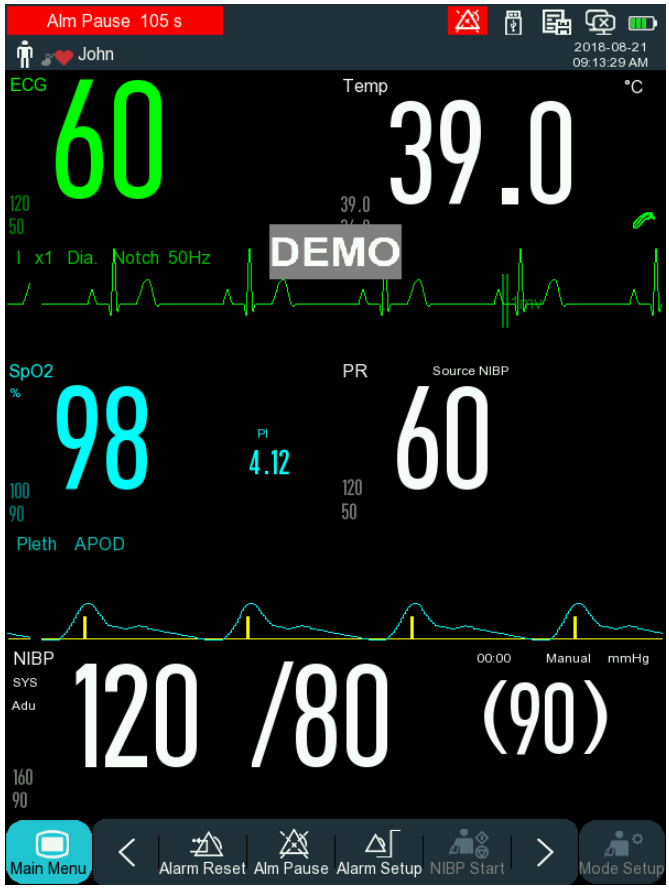


Figure 8-1 Standard Interface

8.2 Point meas

The point meas interface is suitable for short-term on-site measurements of the patient. When this interface is selected:

1. The monitor does not provide a physiological alarm, but only the technical alarm and status message.
2. Continuous and Automatic NIPB Parameter Measurement are not available.
3. Only the spot data is stored, and the trend data is not stored.

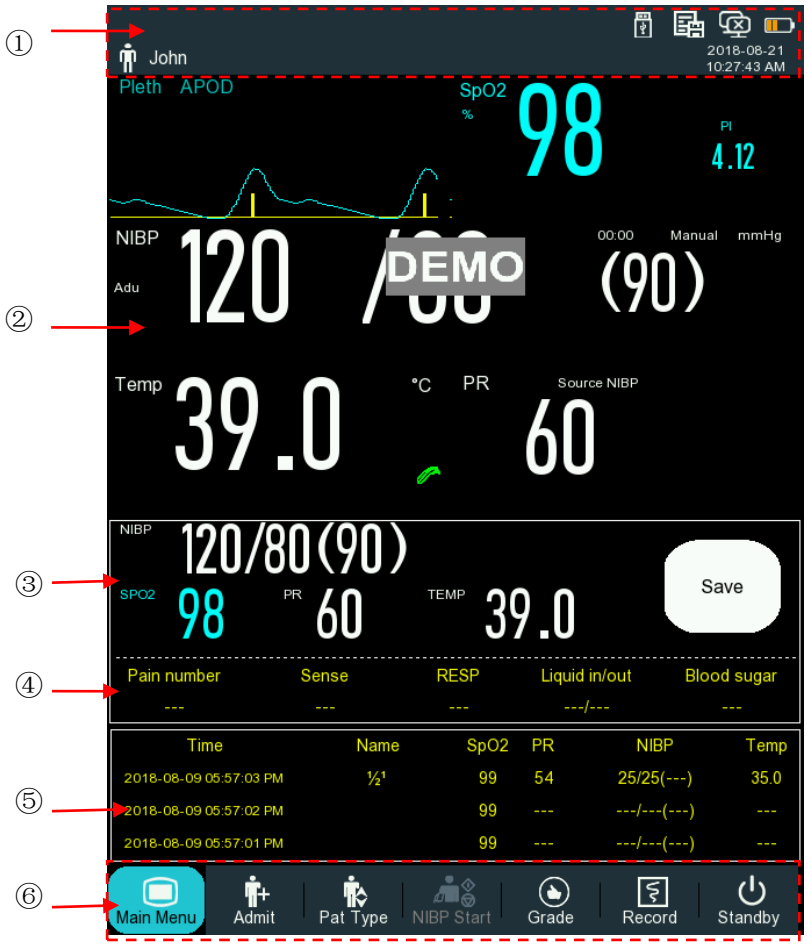


Figure 8-2 Point meas interface

The point meas interface only measures the patient's vital signs. The interface includes: 1 Notification area or Upper Menu Bar; 2 Parameter area and Waveform area; 3 Data to be Saved area; 4 Manual Input Data area; 5 point meas list area;and 6 Lower Menu Bar.

① Notification area or Upper Menu Bar: Specifically includes technical alarm reminder, icon reminder, monitor setup, battery level icon, patient information, system time

② Parameter area and Waveform are

a） Parameter introduction

- Displays parameter measurement data.
- Color is consistent with the corresponding parameter waveform.

- Select the Parameter area. The system displays the corresponding Setup menu.

b） Waveform introduction

- Up to 1 waveform can be displayed.
- Select the Waveform area.The system displays the corresponding waveform setting window.

③ Data to be Saved area

This area displays the stable parameters. Each parameter is the end value or stable value of the measurement. Press on the area to display the menu to modify the data to be saved. Press the Save button to save the data displayed in the area and to update the Point meas List.

④ Manual Input Data area

This area displays the data manually input by users. Press on the area to display the data input menu.

Settinginput data:

1) Enter [Maintain] → [Data pt setting] → [Enter param sett] → “On” or “Off”. If you select “On”, the Manual Input Data area is displayed in the Point meas interface. If “Off” is selected, it is not displayed.
2) Manual Input Data include: [Pain index], [Consc], [RESP], [Liquid in/out], [Blood Sugar], [Temp pos.], [NIBP pos.], [O2 source], [O2], [O2 concentration], which can be selected based on actual requirements.
3) Press the Manual Input Data area in the Point meas interface to manually input various parameter values.

⑤Point meas List area

In the Point meas List area, 3 spot data can be displayed in reverse chronological order. If you press this area, a Spot Data Trend Table menu is displayed, as shown below:

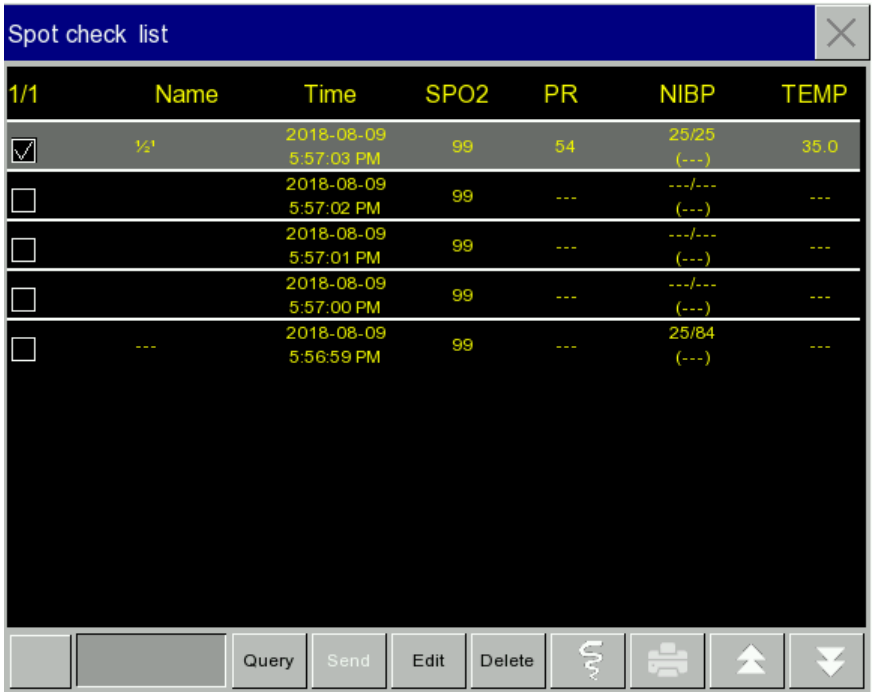


Figure 8-3 Point meas List interface

You can set the following in the Point meas List interface:

- Select the empty field next to [Query] and enter a patient name to query the spot data.

- Select the appropriate spot data and press [Send] to send the data to the Central Monitoring System.
- Select the appropriate spot data and press [Edit] to modify the saved data.
- Select the appropriate spot data and press [Delete] to delete the corresponding data.
- Press , the built-in heat-sensitive recorder directly prints the spot data.
- Press , the external printer directly prints the spot data.
- When the checkbox in the lower-left corner is selected, all spot data are selected. Press [Delete], to delete all data.
- Press to scroll up and down to view other spotcheck lists that are not in the current view.

⑥ Lower Menu Bar

The Lower Menu Bar in the Point meas List interface displays the screen quick keys. The Lower Menu Bar cannot be modified. The available options are shown below:

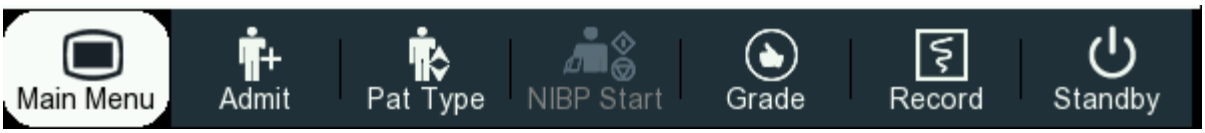


Figure 8-3 Lower Menu Bar in the Point meas List Interface

8.3 List

In this interface, you can review the recently measured data. Each page stores 5 groups of data.

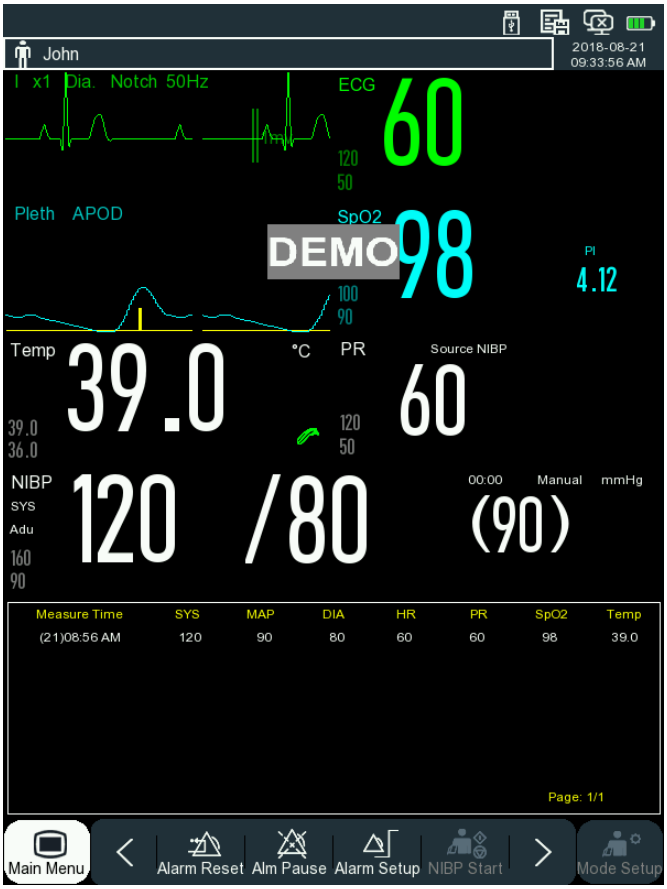


Figure 8-5 List interface

Select NIBP List box to enter the List Page View interface.

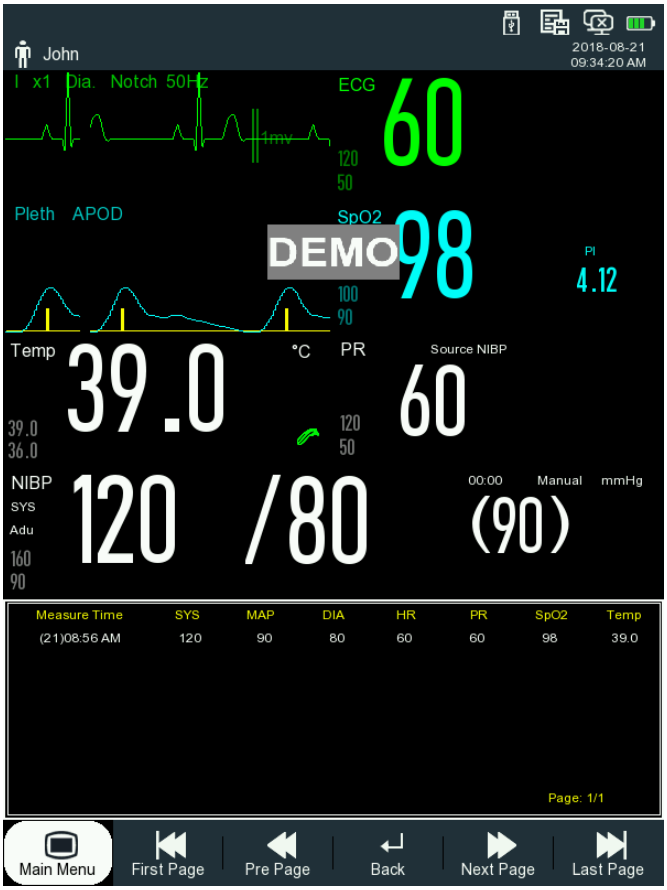


Figure 8-6 List Page View Interface

8.4 Thermometer

When an in-ear thermometer is used with the main unit, the data is transmitted to the main unit wirelessly and displayed on the monitor, as shown below:

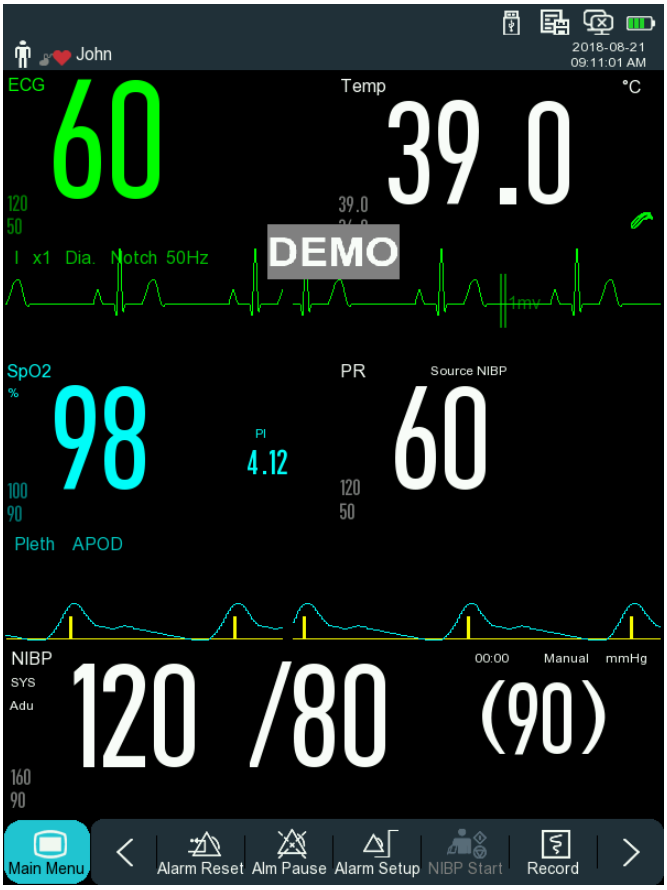


Figure 8-7 In-Ear Thermometer Interface

8.5 Setting the Interface Style

You can set the following stylesfor the interface as required:

1) Waveform sweep speed.
2) Waveform display type.
3) Parameter and wave display color
4) Parameters displayed on the interface

The parameters of the monitor interface style can be set in the same way. This chapter only gives an example of one parameter setting, and other parameters are not explained further.

8.5.1 SettingWaveform Sweep Speed

1) Select the waveform you want to set on the standard interface, for example: select [I] ECG Wave → [ECG Wave] → [Sweep].
2) Select an appropriate sweep speed.

8.5.2 SettingWaveform Type

1) Enter [Maintain] → [Wave Type] → [Thin], [Med] or [Bold].

8.5.3 SettingModule Display Color

1) Enter [Maintain] → [Module Color].
2) Select the waveform you want to set in the [Module Color] menu. Set the color to: [Red], [Orange], [Yellow], [Green], [Cyan], [Blue], [Purple] or [White].

8.5.4 SettingWaveform Draw

1) Enter [Maintain] → [Wave Draw] → [Color], [MONO].

8.5.5 SettingWaveform Fill

1) Enter [Maintain] → [Wave Fill Setup].
2) Select the appropriate parameters according to your requirement.

Chapter 9 Alarm

Alarm refers to sound, light and notification-based reminders that the monitor provides to the medical staff when there is any abnormal change in the vital signs of the patient being monitored or the monitoring itself fails.

The scope of the alarm system is in the Real-time Monitoring mode. The Standby mode does not affect the normal response of the alarm system, but the alarm sound and light are blocked.

When multiple alarms and reminders occur, text messages are displayed in a loop.

Warning

- **In any single area (such as intensive care units or cardiac operating rooms), same or similar equipment with different preset alarm may present a potential hazard.**

9.1 Alarm Type

Based on the properties, the monitor's alarms can be divided into physiological alarm and technical alarm.

- Physiological alarm

  Physiological alarms are usually caused by a patient's physiological parameters exceeding the set high or low value of the alarm, or in case there is any abnormality in the the patient's physiological measurements. The alarm message of the physiological alarm is displayed in the Physiological Alarm area at the top of the screen.

- Technical alarm

  The Technical alarm, also known as a System Error message, is an alarm that is triggered when a certain system function fails to work properly, or the monitoring result is affected due to improper operation or system failure. The alarm message of the technical alarm is displayed in the Technical Alarm area at the top of the screen.

Note: In addition to physiological alarms and technical alarms, the monitor also displays messages related to system status. Generally, these messages do not involve the patient's vital signs and are displayed in the System Notification area as a reminder.

9.2 Alarm Level

Based on alarm severity, the monitor's physiological and technical alarms can be divided into three levels – high, medium and low.

	Physiological alarms	Technical alarms
High	The patient is at a critical condition and may be facing a life-threatening situation; emergency measures forasystole, ventricular fibrillation/ventricular tachycardia should be initiated immediately.	Serious machine fault or mishandling may cause failure to detect the patient's critical conditions, making the situation life-threatening, such as low battery.
Medium	If the patient's physical signs are abnormal, corresponding measures or treatment should be initiated immediately.	Some machine faults or mishandling may not threaten patient safety;however, it may affect normal monitoring of critical parameters.
Low	The patient's physical signs are abnormal and may require appropriate measures or treatment.	Machine faults or mishandling may cause monitoring function to not work properly but does not threaten patient safety.

The level of all technical alarms and some physiological alarms have been set at the factory and cannot be modified by the user, however, the level of some physiological alarms can be modified.

9.3 Alarm Mode

When an alarm occurs, the monitor notifies the user using the following audible and visual alarms:

Light alarm

Audible alarm

Alarm message

Parameters flashing

The light alarm, audible alarm and alarm message differentiate between the alarm level in different ways.

9.4 Light alarm

There are two alarm indicators at the upper part of the monitor. When an alarm occurs, the alarm indicators indicate different levels of alarm with different colors and flashes at different frequencies.

Physiological alarm:

High: Red (left indicator), flashes twice per second.

Medium: Yellow (left indicator), flashes once per 2 seconds.

Low: Yellow (left indicator), no flashing, remains on consistently.

Technical alarm:

High: Red (left indicator), flashes twice per second.

Medium: Yellow (left indicator), flashes once per 2 seconds.

Low: Cyan (right indicator), no flashing, remains on consistently.

9.5 Audible Alarm

In the audible alarm, the monitor provides different levels of alarm reminders based on different sounds when an alarm occurs.

High: Beep- Beep -Beep-- Beep-Beep---- Beep- Beep -Beep-- Beep-Beep

Medium: Beep- Beep -Beep

Low: Beep

⚠ Warning

- **Both the monitor and the Central Monitoring System have an audible alarm function.**
- **When the monitor is connected to the Central Monitoring System, although the upper and lower alarm limits of the monitor and the Central Monitoring System can be the same, since the monitor has an alarm delay function, when the Central Monitoring System alarm is activated, the monitor may not have an alarm at the same time.**
- **When multiple different level alarms occur at the same time, the monitor initiates visual and audible alarms based on the highest level of the alarm.**

9.6 Alarm Message

When an alarm occurs, a corresponding alarm message is displayed in the Physiological Alarm area or Technical Alarm area of the monitor.

Following symbols are displayed in front of the physiological alarm message to distinguish the level of the alarm:

High: ***

Medium: **

Low: *

Background color of alarm message based on alarm level:

High: Red

Medium: Yellow

Low: Yellow (physiological alarm) / cyan (technical alarm)

9.7 Alarm Parameters Flashing

When an alarm occurs for a particular parameter, the respective parameter flashes once per second. The upper or lower limit of the parameter also flashes at the same frequency, indicating that the parameter exceeds the upper or lower limit.

9.8 Alarm Pause

The user can quickly pause the alarm by using the [Alarm Pause] quick key:

- ✧ Suspendsaudible and light alarms, and text message notifications of the physiological alarm and does not trigger other physiological alarms during this period.
- ✧ The Physiological Alarm Message area displays a “Alarm pause XXXs” message.
- ✧ Suspendsaudible and light alarm of the technical alarm; if a new technical alarm is triggered, only text message are displayed.
- ✧ The technical alarm initiated by seriously low battery automatically disables the alarm pause state, and triggers audible and light alarms and text message notifications like a normal alarm.

Each time the monitor is turned on, it automatically enters the Alarm Pause state. The alarm pause time depends on the [Alarm Pause Time] set by the user. After the alarm pause time expires, the monitor automatically cancelsAlarm Pause. In addition, the user can also cancel it by the pressing the [Alarm Pause] quick key.

Setting alarm pause time:

1) Enter [Maintain] → [Alarm Setup] → [Alarm Pause Time].
2) Set an appropriate pause time.

9.9 Alarm Off

The [Alarm Off] function is only available for physiological alarms. When the function is activated, the lower-left corner of the corresponding parameter in the Parameter area displays the  sign, indicating the alarm is off:

- ✧ Stops audible and light alarm and text message display for a physiological alarm; does not trigger a new physiological alarm.

Steps:

1) Select the field of a parameter to display the Setup menu and select [Alarm Limit Setup] or press the

[Alarm Setup] quick key to display the [Alarm Limit Setup].

2) Select [All Alarm Off] to stop the alarm for all parameters; if the alarm switch icon  of a parameter is turned to "Off", the alarm of the corresponding parameter is turned off.

The user can select [All Alarm On] to exit the all alarm off state or turn the alarm switch icon  of a parameter to "On" to exit the alarm off state of the parameter.

Warning

- **When the system alarm is set to "Off", the monitor cannot trigger an alarm if an alarm occurs. Therefore, the operator should use this function with caution.**

9.10 Alarm Record Setup

If the monitor has a recorder, when an error occurs in the data related to a parameter, and the alarm switch is turned on and [Alarm Record] is set to "On", the monitor triggers the recorder to output relevant waveforms and parameter values.

1) Enter [Main Menu] → [Alarm Setup] → [Alarm Record Setup].
2) Set [Alarm Rec Time] to [8s] or [16s].
3) Turn the alarm record icon  to "On" to enable the parameter that requires alarm record; or select [All Rec. On] to enable all parameter alarm records.
4) The user can turn the alarm record icon  to "Off" to disable the parameter that requires alarm record; or select [All Rec. Off] to disable all parameter alarm records.

9.11 Setting Parameter Alarm

9.11.1 Setting Alarm Limit

Alarm limit colors

- Red for high alarm
- Yellow for medium alarm
- Cyan for low alarm

The smart alarm grading function is a feature of the monitor's alarm system. For parameters with smart alarm grading function, the user does not need to set the alarm level but can set the alarm limit range for high alarm, medium alarm and low alarm. When the measured value of a parameter exceeds the normal range, the monitor automatically judges which alarm level range the parameter's measured value falls into, and then triggers an alarm for the corresponding level.

For common alarm parameters, the user needs to set the alarm level and can only set the alarm limit for the selected alarm level. When the measured value of the parameter exceeds the normal range, the monitor only

triggers an alarm according to the selected level. ECG, NIBP, PR and SpO_2 (excluding Nellcor blood oxygen) have smart alarm grading function; the remaining parameters are common alarms.

Note

- **The smart alarm is closed as default setting. If the user needs such function, please contact our company or the agent.**

For parameters with smart alarm grading function, the alarm limit setting method is the same as listed above. Here we have taken ECG as an example.the method is as follows:

1) Select ECG Parameter area to display the Setup menu → [Alarm Limit Setup].
2) Set the appropriate upper and lower limits for the parameter.
3) Set the alarm switch icon  to "On".
4) After setting, press the  button.

For common alarm parameters, the alarm limit setting method is the same as listed above. Here we have taken TEMP as an example. The method is as follows:

1) Select TEMP Parameter area to display the Setup menu → [Alarm Limit Setup].
2) Select the  checkbox in the lower-left corner of the corresponding Parameter Setup window to switch alarm level.
3) Set appropriate upper and lower limits for the parameters at this level.
4) Set the alarm switch icon  to "On".
5) After setting, press the  button.

9.11.2 SettingAuto Alarm Limit

The monitor has an automatic alarm limit setting, which automatically sets the alarm limit value by currently measured parameter values based on the current patient type.

Before applying these alarm limits, please confirm that they are suitable for the current patient. If not, you should manually set the alarm limits.

Note

- **When the factory configuration is used, the alarm limit of the corresponding parameter also changes. For details, please refer to the appendix "Default Configuration".**

Warning

- **Do not set the Parameter Alarm Limit to the extreme value, or else, the alarm system will not work.**
- **When setting the upper and lower limit values of the alarm limit, make sure it is appropriate for the type of patient you are monitoring – adult, pediatric or neonates.**

- **When the alarm limit is turned on, and the alarm's upper and lower limit values are manually set, the monitor continues to display the upper and lower limits without additionally providing the system's initial alarm preset value.**
- **When the monitor suddenly powers off during use, the alarm settings before power off are saved and reloaded if the monitor is restarted within 120s, however, if the monitor is restarted after 120s, the monitor will automatically load the configuration according to the [Startup Configration] setting..**

9.12 Setting Alarm Delay Time

There are five options for Parameter Alarm Delay Time: [Disable], [5 seconds], [10 seconds], [15 seconds] and [20 seconds]. If [Disable] is selected, when the parameter measured exceeds the alarm limit, the monitor responds and the alarm is triggered immediately; if [5 seconds] is selected, when the parameter measured has exceededthe alarm limit for 5 seconds, the monitor responds, and the alarm is triggered. It is similar for the remaining delay time settings.

Note: Alarm delay does not apply to ECG measurements.

Specific steps:

1) Enter [Maintain] → [Alarm Setup] → [Alarm Delay].
2) Set an appropriate delay time.

9.13 Setting Alarm Sound

9.13.1 SettingMinimum Alarm Volume

The minimum alarm volume determines the minimum value that can be set for the alarm, to prevent incorrect setting of alarm volume and thus avoid delay treatment. The specific steps are as follows:

1) Enter [Maintain] → [Alarm Setup] → [Min. Alm Volume].
2) Set an appropriate value.

Note

- **When the alarm volume is turned down, the ambient noise may cover the alarm sound. Hence, make sure that the minimum alarm volume is higher than the ambient noise.**
- **The sound level for the monitor's alarm signal is 45 to 85 decibels.**

9.13.2 SettingAlarm Volume

1) Enter [Main Menu] → [Volume Setup] or select the [Volume Setup] quick key.
2) Select [Alarm Volume] from the displayed menu.
3) Select the volume from X ~ 10 levels. X is the minimum volume; it depends on the minimum alarm

volume setting.

When the alarm volume is set to 0, the  icon is displayed on the screen's Message Notification area, indicating that the sound is off.

1) Enter [Maintain] → [Alarm Setup]. You can also set [High Alarm] and [Medial Alarm] and can modify the volume of high alarm and medium alarm, respectively.

Warning

- **When the alarm volume of the system is set to 0, no audible alarm is triggered even if a new alarm occurs. Therefore, the operator should use this function with caution.**
- **Do not rely solely on an audible alarm to monitor a patient. Adjusting the audible alarm to a low volume may result in a dangerous situation for the patient. Users should pay close attention to the actual clinical condition of the patient.**

9.13.3 Setting Alarm Reminder Tone

In the case the alarm volume is zero and the alarm is turned off, the monitor can provide a periodic alarm mute reminder tone, reminding the user that there is still an active alarm condition in the current system. The specific steps are as follows:

1) Enter [Maintain] → [Alarm Setup].
2) Switch the [Alarm Reminder] to "On" or "Off".
3) Select [Reminder Interval]: [1 minute], [2 minutes] or [3 minutes].
4) Select [Reminder Volume]: Select the appropriate volume from 1 to 10.

9.14 Resetting Alarm

Reset the current alarm by pressing the [Alarm Reset] quick key  in the Lower Menu Bar of the monitor interface:

- ✧ Cancel the alarm sound singal.
- ✧ Maintain the message and light signals of the current alarm.
- ✧ Turn the technical alarm of "XX falling off" into a promot message.
- ✧ Resume the alarm sound singal when a new alarm condition occurs.

9.15 Alarm System Self-Test

After the device is started, the alarm system performs a self-test for the alarm lights and sounds.

Self-test action:

1) After the device is started:
   - ✧ The red and cyan alarm indicators light up for one second simultaneously, then the cyan indicator continues to remain on for one second, while the yellow indicator lights up for one second. Then, the alarm indicators are turned off.
   - ✧ During the alarm light self-test, the alarm system gives a “beep” sound to perform alarm sound self-test.
2) Sound requirements: Uses the alarm system low-level alarm sound, and the alarm volume is level 5.

9.16 Testing Alarm System

After system self-test, the alarm can be further tested for SpO_2 or NIBP, for example:

1) Connect anSpO_2 cable to the monitor.
2) Set SpO2 [Alarm Limit] to: 90%, 60%.
3) Directly select [Alarm Volume] in the Lower Menu Bar and set the [Alarm Volume] to any level from 0 to 10.
4) When the measured value exceeds the upper and lower alarm limits, confirm whether the changes in sound and light alarms and parameter flashing on the monitor screen comply with the “Audible alarm, light alarm, alarm message, and alarm parameter flashing” process described in this chapter. At the same time, there should be a notification in the Physiological Alarm Information area that SpO2 is too high or SpO2 is too low.
5) Disconnect the SpO2 sensor from the monitor; a notification should be displayed in the Technical Alarm Information area that the SpO2 sensor is off.

Chapter 10 PR Setup

10.1 Overview

The physical action of the heart causes the pulses in the artery. The PR value can be obtained by measuring the pulses. The color of the PR Parameter area is consistent with the display color of the PR source parameter.

10.2 PR Source

Select the PR Parameter area to display the Setup menu, where you can set the PR source.

[SpO2]: Displays the pulse rate value from SpO_2.

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

10.3 Alarm Limit Setup

Select the PR Parameter area to display the Setup menu, to set the alarm limit.

Chapter 11 ECG Monitoring

11.1 Definition of ECG Monitoring

Electrocardiogram (ECG) produces continuous electrical activity of the patient's heart and displays it on the monitor in the form of waves and values, to accurately assess the patient's current physiological state. For this purpose, the ECG cable should be properly connected to ensure measurement accuracy.

11.2 Precautions for ECG Monitoring

⚠ Warning

- **Check if the sensor cable is connected properly before monitoring. Unplug the ECG cable from the jack; the screen displaysthe "ECG Lead Off" message and sounds an alarm.**
- **When using this monitor for ECG signal monitoring, you must use the ECG lead cable provided by our company.**
- **When you connect the electrode or patient cable, make sure that the patient is not in contact with any other conductive parts or the ground. In particular, it is necessary to determine that all ECG electrodes, including neutral electrodes, are attached to the patient to prevent them from coming into contact with conductive parts or the ground.**
- **Check daily if the ECG electrode patch irritates the skin. If there are signs of allergies or rashes, replace the electrodes or change the position.**
- **Check the ECG cable before ECG monitoring. After the ECG cable is disconnected, the monitor triggers an audible alarm and displays the "Sensor Off" alarm message.**
- **Pacmaker failure: When cardiac conduction is completely blocked or the pacemaker cannot be removed, the P wave (greater than 1/5 of the average height of R wave) may be erroneously recorded by the instrument, resulting in failure to monitor the cardiac arrest.**
- **Instruments such as a telemetry unit may produce a filtered ECG signal. When this signal is used as an input signal for the bedside monitor, it is filtered again.**
- **In case of electrosurgery (ESU), the measurement accuracy may be temporarily reduced, but it does not affect the safety of the patient and the device.**
- **When the monitor is connected to a high-frequency surgical equipment, to prevent current leakage which may burn the patient, avoid the monitor's sensors and cables coming in contact with the equipment.**
- **Do not expose the monitor to X-rays and strong magnetic fields.**

⚠ Note

- **Interference from ungrounded instruments near the patient and ESU interference may cause**

problems with the waveforms. If operated in accordance with the conditions specified in EN60601-1-2 (radiation resistance is 3 volts/meter), electric field strength exceeding 1 volt/meter may cause measurement errors at various frequencies. Therefore, it is not recommended to use equipment with electrical radiation near the ECG/respiratory measurement.

- **If the ECG electrode is placed correctly, but the ECG waveform is still inaccurate, replace the lead cable.**
- **To protect the environment, please recycle and dispose used electrodes properly.**

11.3 Monitoring Steps

11.3.1 Preparing the skin

The patient's skin is a poor conductor, so to get good contact between the electrodes and the skin, preparing the skin is very important:

1) Choose an area of the skin that is not damaged and has no abnormalities.
2) If necessary, shave body hair at the electrode placement location.
3) Wash the skin thoroughly with soap and water. (Do not use ether or sprinkle it, as this may increase skin impedance).
4) Wait until the skin is completely dry.
5) Use an ECG skin preparation paper to gently rub the skin to remove dead skin, so as to improve conductivity at the electrode attachment site.

11.3.2 Connecting ECG cable

1) Install the spring clip before placing the electrode.
2) Place the electrode on the patient's skin. If you are using an electrode that does not contain a conductive paste, apply a conductive paste before placing it.
3) Connect the electrode lead to the patient cable.
4) Insert the patient cable into the monitor's ECG port. The monitor displays the ECG waveforms and values.

11.3.3 Installing the ECG Lead

The names of leads as per European and US standards are listed in the table below. (In the US standard, RA, LA, LL are used, and in European standards, R, L, F are used to indicate each lead):

Three-lead electrode identification and color coding are displayed below:

US Standard	European Standard

Identification	Color	Identification	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green

11.3.3.1 Three-lead Electrode Placement

The three-lead device electrodes should be placed as per the US or European standards:
White/red (right arm) electrode – placed under the collarbone, near the right shoulder.
Black/yellow (left arm) electrode – placed under the collarbone, near the left shoulder.
Red/green (left leg) electrode – placed at the left lower quadrant.

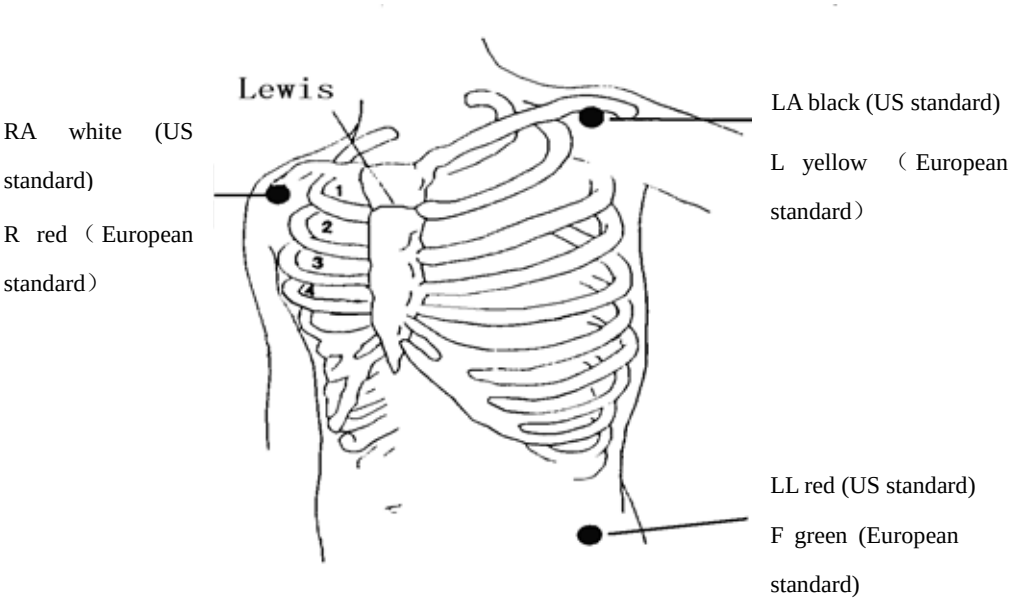


Figure 11-1 Three-Lead Electrode Placement Position

11.3.3.2 Recommended ECG lead connections for surgical patients

⚠ Warning

- **Use appropriate ECG cables in the operating room. These cables can prevent patient burns and reduce electrical interference caused by additional wires. These cables are not suitable for respiratory testing.**
- **When using an electrical surgical unit (ESU), never place the electrodes on the grounding plate close to the unit, otherwise there will be a lot of interference to the ECG signal.**

The placement of the ECG lead depends on the type of surgery performed. For example, for thoracotomy, the electrodes can be placed on the side or back of the chest. In an operating room, due to the use of ESU, sometimes artifacts may affect the ECG waveform. In order to help reduce artifacts, the electrodes can be placed on the left and right shoulders, close to the left and right sides of the abdomen, while the chest leads

can be placed on the left side of the chest. Avoid placing the electrode on the upper arm, or the ECG waveform will become very small.

Note

- **When monitoring a patient with a pacemaker, you must set [Pacer] to "On". When set to "Off", it may cause the pacmaker'spulse to be counted as a QRS complex, resulting in the inability to detect asystole alarm. When changing patient information or admitting/discharging a patient, check that the [Pacer] settings are correct.**
- **When a patient with a pacemaker is being monitored, sometimes part of the pacing pulses cannot be blocked. When the pacing pulse is counted as a QRS complex, a wrong heart rate is calculated and a new asystole cannot be detected. In such a case, you should pay close attention to the patient with a pacemaker.**

11.4 ECG Display

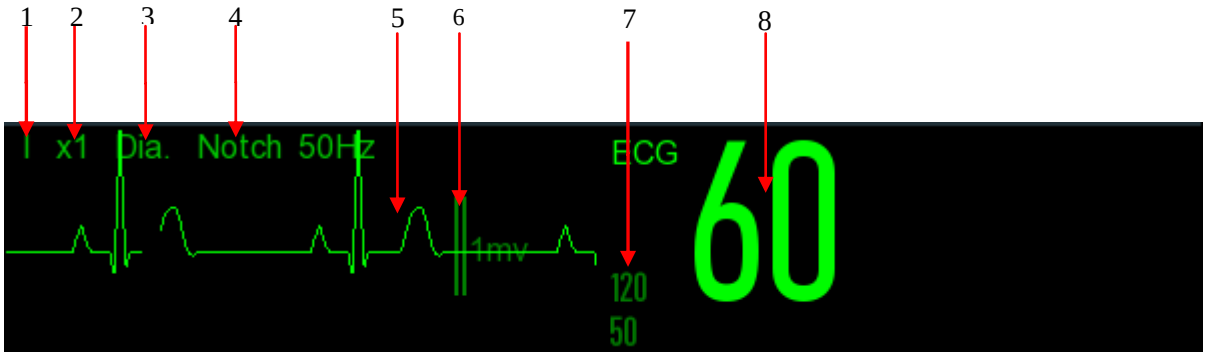


Figure 11-2 ECG

1	Lead Name	2	Gain	3	Filter Mode
4	Notch status	5	ECG Wave	6	1 millivolt scale stick
7	Alarm Limit	8	ECG Value		

11.5 ECG Setup

11.5.1 Setting ECG Lead Off Level

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

11.5.2 Setting the Gain

If the waveformsize is too large or too small, users can change the size displayed by setting the gain. This

setting does not affect the monitor's analysis of the ECG signal. Users can get the best waveform based on the waveformand the 1mV scale on the right side of the waveform.

1) Select an ECG waveform and enter the [ECG Wave] menu → [Gain] → [×0.125], [×0.25], [×0.5], [×1], [×2], [×4] or [Auto].

Note

- **When the input signal is too large, the peak may be truncated. At this point, the user can manually change the gain grade of the ECG waveform by referring to the actual waveform to avoid incomplete waveformdisplay.**

11.5.3 Setting Filter Mode

Filter mode: Filtering can be used to obtain cleaner or more accurate waveforms. Four filter modes are available.

- In Diagnosis mode, the unfiltered ECG waves are displayed.
- In Monitoring mode, artifacts that may cause false alarms are filtered.
- During surgical procedures in the operating room, artifacts and interference from ESU can be reduced.

1) Select an ECG waveform and enter the [ECG Wave] menu → [Filter Mode] → [Dia.], [Monitor], [Surgery].

Warning

- **The system can provide unprocessed real signals only when it is in the Diagnosis mode. In the "Monitoring" and "Surgery" filter modes, the ECG waveforms havehave different degrees of distortion. At this point the system can only provide basic status of the ECG. Therefore, it is recommended to use the Diagnosis mode for patient monitoring when the interference is small.**

11.5.4 SettingNotch Filter

The notch filter suppresses the 50Hz or 60Hz frequency components of collected signals. When the Filter mode is not set to Diagnosis, the system automatically turns on the notch filter. When the Filter mode is set to Diagnosis, the notch filter can be turned on or off as required,

1) Select the ECG Parameter area and enter the Setup menu → [Other Setup]
2) Set the [Notch Filter] to:
   [Strong]: Used when waveform jitter is frequent (such as a glitch in the wave).
   [Weak]: Used when waveform jitter is less.
3) Enter [Maintain] → [Other Setup] → [Notch Filter].
4) You can select [50Hz] or [60Hz] based on the power supply frequency.

11.5.5 Setting Pacemaker Reject

Select the ECG Parameter area and enter the Setup menu → [Other Setup]. In the Setup menu that is displayed, select [Pacer Reject] and toggle "On" or "Off".

[Pace] is turned on:

When [Pacer Reject] is set to "On", the display of pacing signals is suppressed, but when the pacing signal is detected, the pacing pulse symbol " ▮ " is still displayed above the ECG waveform.

When [Pacer Reject] is set to "Off", the display of pacing signals are not suppressed, but when the pacing signal is detected, the pacing pulse symbol " ▮ " is displayed above the ECG wave.

[Pace] is turned off:[Pacer Reject] cannot be used.

11.5.6 HR Source

You can select HR source to determine HR value or PR value to be displayed in the ECG Parameter area. The HR parameter value color is consistent with the selected source parameter. Select the ECG Parameter area and enter [ECG Setup], and then set [HR Source] to:

[ECG]: The ECG Parameter area displays the HR value, and the monitor sounds the heartbeat.

[SpO2]: The ECG Parameter area displays the SpO_2 PR value, and the monitor sounds the pulse.

11.6 ECG Relearn

In the case of ECG monitoring, if the patient's ECG template changes significantly, you may need to manually start an ECG Relearn. When the ECG template changes, it may result in:

✧ Inaccurate heart rate value

Starting a relearn:

Select the ECG Parameter area and enter the Setup menu → [Other Setup] → [Relearn].

⚠ Caution

- **Start ECG relearn during normal rhythm and when the ECG signal is relatively noise free.**

Chapter 12 SpO2 Monitoring

12.1 Overview

The SpO_2 plethysmographic parameter measures arterial oxygen saturation, which is the percentage of total oxyhemoglobin.

Oxygen saturation is measured using pulse oximetry. This is a continuous, non-invasive method for measuring hemoglobin oxygen saturation. It measures how much light emitted from one side of the sensor source passes through the patient's tissue (such as a finger or ear) and reaches the receiver at the other side.

The monitor provides the following measurements:

Arterial oxygen saturation (SpO_2) –The ratio of oxyhemoglobin to the sum of oxyhemoglobin plus non-oxyhemoglobin (Functional arterial oxygenation saturation).

Pleth Wave –Patient pulse visual indication.

Pulse rate (calculated from the pleth wave) – used to detect the pulse rate per minute of the patient.

Perfusion index – Uses numerical values to indicate pulsatile blood flow.

⚠ Warning

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

12.1.1 Identification of SpO_2 Sensor Type

The SpO2 sensor type is pre-configured before the Monitor is delivered. You can identify it based on the silkscreened logo beside the original SpO2 sensor below the sensor interface on the left side of the Monitor:

- Standard SpO_2 sensor:

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

  Silkscreened logo: SpO_2.

- Masimo SpO2 sensor:

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

  Silkscreened logo: Masimo.

- Nellcor SpO2 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 Analog 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 SpO2 sensor type. However, it will fail to measure the SpO2 properly if you use a sensor incompatible with its internal hardware.**

12.2 Indications, Applicable scope, Contraindication and Precautions

1. Indications

It is suitable for all patients who shall suffer from oxygen saturation monitoring.

2. Applicable scope

It is suitable for the oxygen saturation monitoring in the surgery anesthesia, general departments and the critically ill patients in the ICU and CCU.

3. Contraindication

Please don't clip oxygen saturation probe on the same position for long period.

The patients who are allergic to the rubber materials shall not use it.

4. Precautions

- Please don't monitor the same position continuously for long period.
- Please don't place blood oxygen probe and blod pressure cuff on the same arm.
- The optical receiver is likely to deviate from the normal positon to cause the inaccurate measurement when the bright light shines on the blood oxygen probe.
- The peripheral circulation difference is likely to lead to inaccurate or failing measurement.

The nail polish will put influence on the light transmission and measurement result.

12.3 Safety Instructions

⚠ Warning

- **The Monitor is compatible with the SpO2 sensor designated by our company 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 SpO2 sensor cable from the sensor interface, and the Monitor will display the prompt message "SpO2 sensor off" and trigger the alarm sound.**
- **If the SpO2 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 SpO2 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 SpO2. Please set the upper SpO2 alarm limit cautiously based on recognized clinical practices.**
- **The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.**
- **As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
- **Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.**
- **Do not start or operate the pulse oximeter unless the setup was verified to be correct.**
- **Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.**
- **Do not use the pulse oximeter if it appears or is suspected to be damaged.**
- **Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.**
- **To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.**
- **To protect against injury, follow the directions below:**
- **Avoid placing the device on surfaces with visible liquid spills.**
- **Do not soak or immerse the device in liquids.**
- **Do not attempt to sterilize the device.**
- **Use cleaning solutions only as instructed in this operator's manual.**
- **Do not attempt to clean the device while monitoring a patient.**
- **To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.**
- **If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.**
- **Inaccurate SpO_2 readings may be caused by:**
  - **Improper sensor application and placement**
  - **Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.**
  - **Elevated levels of bilirubin**
  - **Elevated levels of dyshemoglobin**
  - **Vasospastic disease, such as Raynaud's, and peripheral vascular disease**

- **Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.**
- **Hypocapnic or hypercapnic conditions**
- **Severe anemia**
- **Very low arterial perfusion**
- **Extreme motion artifact**
- **Abnormal venous pulsation or venous constriction**
- **Severe vasoconstriction or hypothermia**
- **Arterial catheters and intra-aortic balloon**
- **Intravascular dyes, such as indocyanine green or methylene blue**
- **Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.**
- **Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.**
- **Skin color disorders**

- **Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.**
- **The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.**
- **The pulse oximeter is not an apnea monitor.**
- **The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.**
- **The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.**
- **The pulse oximeter should not be used for arrhythmia analysis.**
- **SpO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).**
- **Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.**
- **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.**

⚠ Cautions

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

zero for the duration of the active irradiation period.

- **To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.**
- **Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.**
- **Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.**
- **Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.**
- **Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.**
- **To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.**
- **The displayed SpO_2 waveform is normalized.**

Notes

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

12.3.1 Masimo SpO2 Specific Information

Cautions

- **If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.**
- **Change the application site or replace the sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.**
- **Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.**

Notes

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

12.4 SpO2 Accuracy Test

Warning

- **The function tester cannot be used to evaluate the accuracy of the SpO_2sensor.**

It is recommended to compare the readings of CO-Oxygenometer with the readings on the monitor, to determine the SpO_2 accuracy.

12.5 Low Perfusion Accuracy Test

This type of monitor can measure weak perfusion. A recommended method for determining the accuracy of weak perfusion is: use the carbon monoxide-blood gas analyzer on adult volunteers with a SpO_2 range of 70% to 100% and obtain the accuracy by statistical distribution results. Only about 2/3rd of the estimated value is expected to be within the estimated value of the carbon monoxide-blood gas analyzer.

12.6 PR Accuracy Test

It is recommended to determine the PR accuracy by comparing with HR readings.

12.7 Monitoring Steps

Warning

- **Select an appropriate placement method on your hand based on the device and the SpO_2sensor configured with it. This is especially important for placement of the SpO_2sensor for neonates.**

SpO2 plethysmography:

1) Set patient type.
2) Insert the SpO2 cable connector into the monitor's SpO2 interface.
3) Attach the sensor at the appropriate position on the patient's finger.

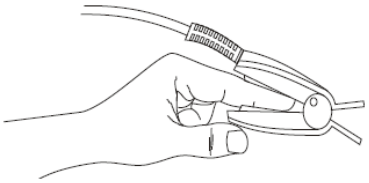


Figure 12-1 Placement of Sensor

SpO_2 plethysmography for Neonates:

The SpO_2 plethysmography process for neonates is essentially the same as that for adults. The neonates SpO_2sensor and its placement method are described below.

- NeonatalSpO2sensor

The neonatal SpO_2 sensor consists of a Y-shaped sensor anda sensor sheath. Insert the LED end and PD end of the Y-shaped sensor into the upper and lower grooves of the sensor sheath (as shown in Figure 12-2). The neonatal SpO_2 sensor is shown in Figure 12-3.

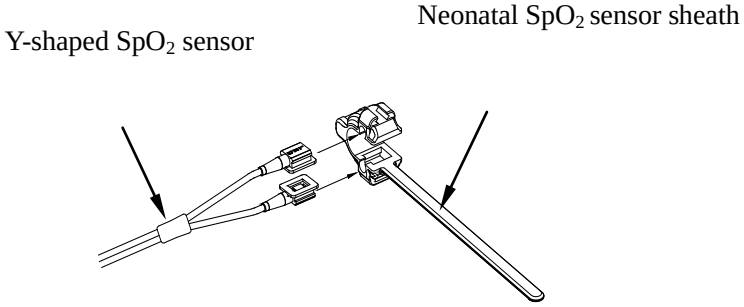


Figure 12-2 Neonatal SpO_2 sensor (1)

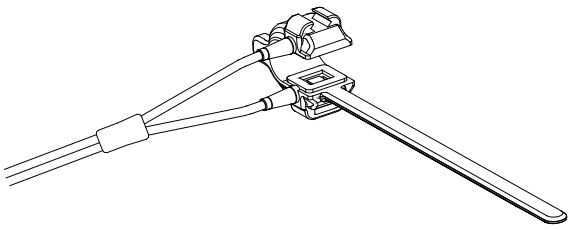


Figure 12-3 Neonatal SpO_2 sensor (2)

- Placement of neonatal SpO_2 sensor

Figure 12-4 Placement of neonatal SpO_2 sensor

Note

- **Injection dyes such as subunit blue or hemoglobin with dysfunction in blood vessels can lead to inaccurate measurement results.**

Warning

- **Using an SpO_2 sensor during magnetic resonance imaging can cause severe burns. In order to minimize such risks, the cable should be properly routed to ensure that it does not form an induction coil. If it is found that the sensor is not working properly, immediately remove it from the patient.**
- **Check the skin every two hours to ensure good skin texture and light. If there are any changes in the skin, move the sensor to another position. Change the placement position at least every four hours.**

12.8 Measurement Limit

During use, the following factors can affect the SpO_2 measurement accuracy:

1) High frequency radio wave interference, including interference generated by the main unit itself or interference from an electrosurgical instrument connected to the system.
2) Do not use a photoelectric oximeter or a blood oxygen sensor during magnetic resonance imaging (MRI), as it may cause burns.
3) Intravenous dyes.

4) The patient moves too frequently.
5) External light radiation.
6) Improper installation of sensor or improper contact position on the subject.
7) Sensor temperature (optimal temperature should be in the range of 28℃ - 42℃).
8) Placing the sensor on a limb with a blood pressure cuff, an arterial catheter, or a lumen tube.
9) Concentrations of non-functional hemoglobin such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
10) SpO2 is too low.
11) Poor cyclic perfusion at the test position.
12) Shock, anemia, hypothermia, and the use of vasoconstrictor drugs may reduce arterial blood flow to an unmeasurable level.
13) The measurement also depends on the absorption of light at specific wavelengths by oxyhemoglobin and reduced hemoglobin. If other substances that absorb light at the same wavelength are present, they can cause measurement of false or low SpO2 values,such as: carbonized hemoglobin, methemoglobin, methylene blue, indigo carmine.

12.9 SpO2 Setup

12.9.1 Setting Sensor Off Level

Enter [Maintain] → [Alarm Setup] → [SpO2 Sensor Off Level].

12.9.2 Setting Smart Alarm

1) Select the SpO_2 Parameter area to display the menu, and then select → [sat second].
2) Select [10], [25], [50], [100] seconds or [Not Allowed].

Note: This function is only valid for NELLCOR SpO_2

The purpose of the smart alarm is to reduce false alarms and allow doctors to grasp SpO_2 changes more accurately and in a timely manner. For example, the smart alarm range is set to 50, the upper limit of NELLCOR SpO_2 is 97%, the lower limit is 90%, the measured SpO_2 value is 80% and maintains for 3 seconds, then falls to 78% for 2 seconds. So, from the time when the alarm limit is exceeded, the sound and light alarm are immediately triggered after the alarm limit is exceeded for 5 seconds, and the circle next to the SpO_2 value is also drawn back to the origin.

Its calculation method is:

Points * seconds = SatSeconds integer

The calculated SatSeconds values are shown below:

%SpO_2seconds SatSeconds

（90%-80%）* 3 =30

（90%-78%）* 2 =24

Total SatSeconds=54

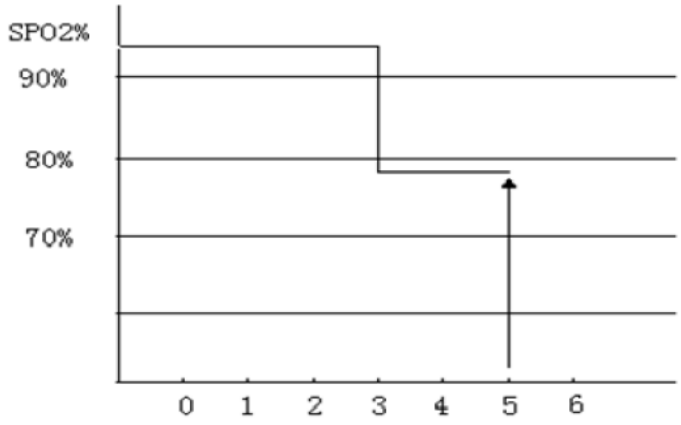


Figure 12-5 Sample Graph

SatSeconds example:

After about 4.9 seconds, the device reports the SatSeconds alarm because 54 has exceeded the smart alarm range of 50SatSeconds.

In several seconds, the SpO_2 mayfluctuate rather than be stabilized. Typically, a patient's SpO_2 may fluctuate between the upper and lower limits of the alarm and may re-enter the non-alarm range several times. During this fluctuation, the system integrates the positive and negative points of SpO_2 until the SatSeconds limit is reached or the patient SpO_2 returns to the non-alarm range and remains within the range.

12.9.3 Setting Smart Pulse Tone

When Pulse Tone is turned on, a reminder for PULSE (pulse) tone is triggered even when the signal is unstable or the environment is noisy; after it is turned off, there is no reminder for PULSE (pulse) tone when the signal is unstable or the environment is noisy.

The steps for setup are:

1) Select the SpO_2 Parameter area to display the Setup menu.
2) Select [Smart Tone], and switch to "On" or "Off".

Note: This feature is only valid for Masimo SpO_2.

12.9.4 Setting Same Side NIBP

Set [NIBP Same Side]:

1) Select the SpO_2 Parameter area to display the Setup menu.
2) Select [NIBP Same Side], and switch to "On".

Set to "On": Prevent sin accurate SpO_2 measurement or even triggering of SpO_2 physiological alarm resulting

from weak perfusion through NIBP measurements when NIBP and SpO_2 measurements are taken on the same limb of a patient.

12.9.5 Setting Signal IQ

When this feature is turned on and the displayed SpO_2 value is not based on appropriate signal quality, the monitor displays a visual plethysmographic signal quality indication. It can be used to confirm the patient's pulse events and the associated measured signal quality.

The signal is often affected due to movement. When the artery pulse reaches the highest point, the monitor marks it using a signal IQ displayed by a vertical line, enabling the system to find the artery pulse position. The volume of the smart pulse (on) is consistent with the vertical line of signal IQ. When SpO_2 increases or decreases, the pulse tone increases or decreases accordingly.

The vertical line level of the signal IQ indicates the quality of the measured signal. The steps for setup are as follows:

1) Select the SpO_2 Parameter area to display the Setup menu.
2) Select [Signal IQ], and switch to "On" or "Off".

Note: This feature is only available for Masimo and Simulated SpO_2.

12.9.6 Setting Average Time

The average time means that the SpO_2 value displayed on the monitor is a result obtained after the average calculation of the data collected over a period of time. The shorter the average time, the faster the monitor responds when the patient's SpO_2 value changes, however, the accuracy of the measurement is lower. Conversely, the longer the average time, the slower the monitor responsds when the patient's SpO_2 value changes, however, the accuracy of the measurement is higher. When monitoring critically ill patients, setting a smaller average time is beneficial to promptly analyze the patient condition. The steps for setup are:

Masimo SpO_2:

1) Select the SpO_2 Parameter area to display the Setup menu → [Average Time].
2) Select [2-4s], [4-6 s], [8s], [10s], [12s], [14s] or [16s].

Standard SpO_2:

1) Select the SpO_2 Parameter area to display the Setup menu → [Sensitivity]
2) Select [High], [Med] or [Low], the corresponding average time increases in turn.

12.9.7 Setting Fast Sat

When Fast Sat is turned on, the blood oxygen saturation is measured rapidly every 2-4 seconds on average.

1) Select the SpO_2 Parameter area to display the Setup menu
2) Select [Fast Sat], and then switch it "On" or "Off".

Note: This function is only valid for Masimo SpO_2. When this option is turned on, the main interface

displays a "Fast Sat" notification.

12.9.8 Setting Calculation Sensitivity

The calculation sensitivity can be set to: [Normal], [Maximum] and [APOD] (anti-sensor off). Based on the level, [APOD] is the highest sensitivity. For typical patient monitoring, use [Normal]. Due to moist skin, strenuous exercise or other reasons, the sensor may fall off the patient's body, in which case, please use [Maximum]. If the patient's perfusion level is extremely low, to improve sensitivity, use [APOD].

The setup steps are:

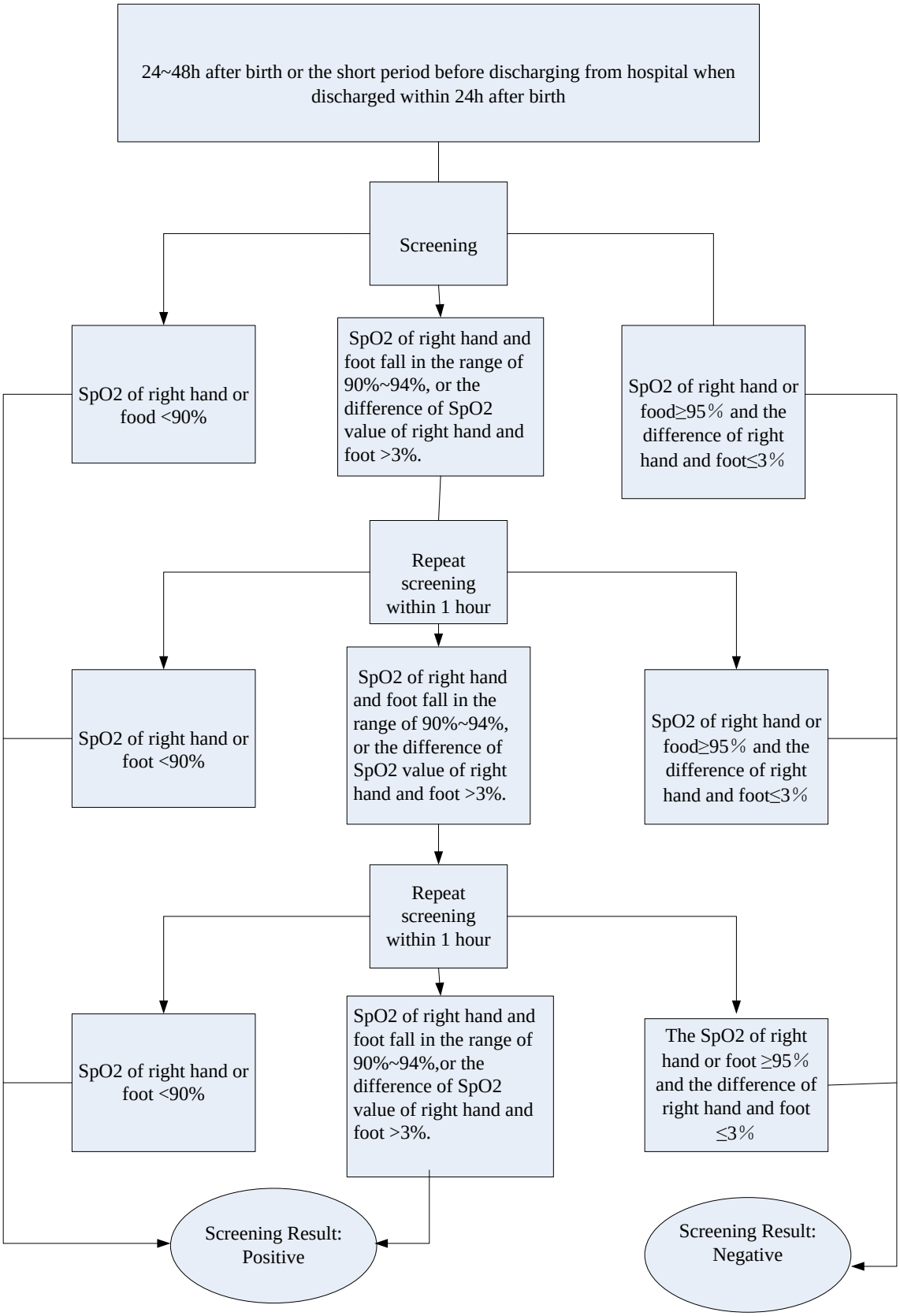
1) Select the SpO_2 Parameter area to display the Setup menu → [Sensitivity]
2) Select the appropriate [Sensitivity].
   Masimo SpO_2: [Normal], [Maximum], [APOD]

Note: This feature is only valid for Masimo SpO_2.

12.9.9 CCHD Screening

Critical congenital heart disease (CCHD) is one of the congenital malformations that severely threaten the health of babies. If newborns with CCHD don't get timly diagnosis and treatment, they will be put into risks of death and disability. The monitor provides screening for CCHD. Screening can be performed by measuring the SpO2 of the right hand and a random foot and compare the difference of these two values.

12.9.9.1 Screening produre



12.9.9.2 Eneter CCHD screening interface

1) Click SpO2 parameter area or waveform area on the main screen to enter into [SpO2 setup] menu.
2) Choose [CCHD screening] and enter into CCHD screening interface.

12.9.9.3 CCHD screening operational procedure

Perform CCHD screening following the steps below:

1) Put SpO2 sensor onto the right hand and a random foot of the newborn.
2) Click SpO2 parameter area or waveform area on the main screen to enter into [SpO2 setup] menu.
3) Choose [CCHD screening] and enter into CCHD screening interface.
4) In [Measuring Position], choose the place where SpO2 sensor is put.
5) Observe the PLETH waveform on the main screen.Click [OK] until the waveform is stable. The measured data of SpO2 will be listed in the right column.
6) Get the screening result and proceed to the next:
   - Negative: Pass the CCHD screening, which means CCHD can be ended.
   - Positive: Fail the CCHD screening, which needs diagnostic treatment from medical stuff.

12.9.9.4 CCHD Screening interface

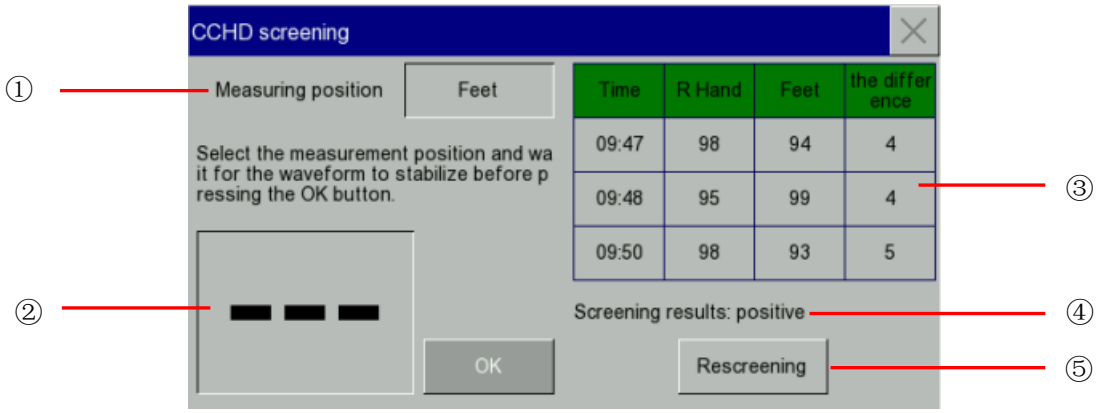


Figure 12-6CCHD Screening Interface

①	Measuring position（Right hand/feet）
②	SpO_2 Value
③	The difference of SpO2 value of right hand and foot
④	Screening result (negative/positive)
⑤	Re-screening

12.9.9.5 Judgement standard for screening result

If screening meets the following item, the result is positive:

1) SpO2 are less than 90%.
2) Take SpO2 threes times every 1 hour and the values are less than 95%.
3) Take 3 measurements every 1 hour, the differences between right hand's SpO2 and foot's are more than 3%.

If screening meets the following criteria, the result is negative.

1) The SpO2 of any limb is no less than 95% and the absolute difference of upper limb's SpO2 and lower limb's is no more than 3%, which can be considred acceptable and the screening can be ended.

12.10 Masimo Information

1) Masimo Patent Information

Masimo Patents: www.masimo.com/patents.htm

2) No Implied License Statement

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

3) Other Information

Chapter 13 NIBP Monitoring

13.1 Overview

This monitor measures the non-invasive blood pressure (NIBP) using an oscillating method. What the monitor measures is vibration amplitude of the cuff pressure. The change in blood pressure causes the cuff to vibrate. When the amplitude reaches the maximum, the corresponding cuff pressure is the average pressure. After the average pressure is measured, the systolic and diastolic pressures can be calculated.

NIBP measurements can be applied during electrosurgery and defibrillator discharge according to IEC 80601-2-30/EN60601-2-30.

It can be used in adults, pediatric, neonates, pregnant women and preeclampsia patients.

13.2 Applicable Disease, Scope of Aplication, Contraindications and Precautions

1. Aplicable disease: Applicable to all patients requiring blood pressure monitoring.
2. Scope of application: Applicable to surgical anesthesia and blood pressure monitoring of the critical patient in general department, ICU and CCU.
3. Contraindications

- ◆ It is forbidden to bundle the curff in the area of the upper arm where there is inflammation or ulceration for blood pressure measurement.
- ◆ Those who are allergic to cuff rubber material are prohibited from use.
- ◆ Those with local skin damages on the upper arms are prohibited from using the blood pressure cuff.

4. Precautions

- ◆ For the patients with cardiopulmonary bypass discorder or severe bleeding tendency, non-invasive blood pressure measurement may cause subcutaneous hemorrhage.
- ◆ Try to avoid measuring non-invasive blood pressure on the limbs with intravenous infusion pathways or catheters. Otherwise, it is easy to slow or block the infusion, and may even cause tissue damages.

For the patients with limb shaking, severe vascular spasm, severe arrhythmia, excessively fast blood pressure changes, the non-invasive blood pressure measurement may not be accurate.

13.3 Safety Information

⚠ Warning

- **Before measurement, make sure that the monitoring method you have selected is appropriate for your patient (adult, pediatric or neonateneonates). The use of non-neonatal mode on neonatal patients may be dangerous.**
- **Do not install a cuff on alimb with IV infusion tube or a catheter. While inflating the cuff, if the infusion is slowed or blocked, it may cause damage to the tissue surrounding the catheter.**
- **The inflation tube connecting the blood pressure cuff and the monitor should be kept unobstructed and untangled.**
- **Non-invasive blood pressure measurement should not be conducted on patients with sickle cell disease and any skin damage or expected damage.**
- **For patients suffering from severe coagulopathy, decide whether to perform automatic blood pressure measurement based on clinical evaluation, as there is a risk of hematoma generated due to the friction between limb and cuff.**
- **Extremely frequent measurements may harm the patient due to blood interference.**
- **Do not place the cuff on a wound, as it may further harm the patient.**
- **Do not place a blood pressure cuff on a limb that is undergoing intravenous injection, treatment, or arteriovenous shunt. Otherwise, it may cause transient blood flow disruption that may result in injury to the patient.**
- **Do not place the cuff on the arm at the side where a breast incision is to be conducted.**
- **Do not place the cuff on the arm at the same side as mastectomy.**
- **Cuff pressurization may cause temporary failure of functionality of the monitor used on the same limb.**
- **If the measurement lasts too long (e.g. repeatedly during the interval measurement mode or the continuous measurement mode), the friction between the cuff and the limb may lead to purpura, ischemia or nerve injury. When a patient is monitored, there is need to frequently check the color, temperature and sensitivity of the distal limb. Once something abnormal is found, change the position of the cuff or stop measuring the blood pressure.**

13.4 NIBP Measurement

13.4.1 Preparations

1) Connect the inflation tube to the blood pressure cuff.
2) Connect the inflation tube to the NIBP interface of the monitor, and avoid pressing or blocking the pressure tube.
3) Use an appropriate sized cuff and ensure that the air bag is not folded and twisted.
   - ◆ A wrong size cuff or a twisted or folded airbag can result in inaccurate measurements. Make sure the cuff is completely deflated. The cuff width should be 40% of the limb circumference (50% for neonates), or 2/3 of the length of upper arm. The length of the inflation part of the cuff should be

sufficient to surround 50 to 80% of the limb.

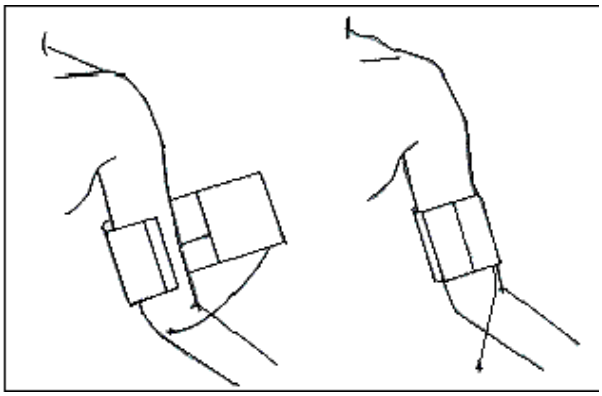


Figure 13-1 Usage of the Cuff

4) Wrap the cuff around the patient's limb at the same level as the patient's heart. If this is not possible, the following calibration methods should be used to correct the measurement results.

- Make sure the φ mark is located just above the appropriate artery. Make sure that the cuff is not too tightly wrapped around the limb, or it may cause skin discoloration or even ischemia at the distal end of the limb. Check the bindings regularly to ensure that the skin is intact and check that the color, temperature and perception of the limb on which the cuff is placed is normal. If the skin color changes or the limb's blood circulation is affected, place the cuff on another position to measure or stop measurement immediately. In the auto measurement mode, the skin condition should be observed more frequently.
- If the cuff around a limb is not at the same level as the heart, use the following formula to calibrate:
  - ✧ If the cuff is over the horizontal position of the heart, the difference per cm should be increased by 0.75mmHg (0.10kPa).
  - ✧ If the cuff is below the horizontal position of the heart, the difference per cm should be reduced by 0.75mmHg (0.10kPa).

Reusable cuffs for neonatess/pediatricren/adults:

Patient type	Limb circumference	Cuff width	Inflation tube length
Neonate	6~11cm	5cm	2 m
Infants	10 ～19 cm	8 cm	
Pediatricren	18 ～ 26 cm	10.6 cm	
Adult 1	25 ～ 35 cm	14 cm	
Adult 2	33 ～ 47 cm	17 cm	
Leg	46 ～ 66 cm	21 cm	

Disposable cuffs for neonatess/pediatricren/adults:

Size	Limb circumference	Cuff width	Inflation tube length
Neonate 1	3.0 ～ 5.5 cm	2.6cm	2m
Neonate 2	4.0 ～ 7.6 cm	3.7 cm	
Neonate 3	5.6 ～ 10.6 cm	4.5 cm	
Neonate 4	7.0 ～ 12.8 cm	5.3 cm	
Neonate 5	8.9 ～ 15.0 cm	6 cm	

13.4.2 Measurement Limit

Depending on the patient's conditions, there are certain limitations in oscillating measurement. This measurement looks for regular pulse waves generated by arterial pressure. In a case where the patient's condition makes such detection method difficult, the measured value is unreliable and the time for pressure measurement increases. The user should be aware that the following conditions can interfere with the measurement method, making the pressure measurement unreliable or increase the pressure measurement time. In this case, the patient's condition may make measurement impossible.

1) Patient movement

If the patient is moving, trembling or in spasms, the measurement will be unreliable or even impossible, as these conditions may interfere with the detection of arterial pressure pulsations and the pressure measurement time will be prolonged.

2) Heart-lung machine

If the patient is connected to an artificial heart-lung machine, measurement will not be possible.

3) Pressure change

If at a certain time, the arterial pressure pulsation is being analyzed to obtain a measurement, and the patient's blood pressure changes rapidly, the measurement will be unreliable or even impossible.

4) Severe shock

If the patient is in severe shock or hypothermia, the measured pressure will be unreliable, as the decrease in blood flow to the outer periphery causes a decrease in arterial pulsation.

5) Non-optimal heart rate

Blood pressure measurement is not possible when the heart rate is below 40 bpm or above 240 bpm.

6) Obese patients

The thick layer of fat surrounding a limb dampens the oscillations from the artery so that they cannot reach the cuff. Therefore, accuracy is lower than normal.

7) Hypertensive patients

In order to accurately measure blood pressure of hypertensive patients, please:

- Adjust the patient's sitting posture:
  - ✧ Sit comfortably.
  - ✧ Legs should be uncrossed.
  - ✧ The feet should be flat on the ground,
  - ✧ Back against the chair, with hands on the table.
  - ✧ The middle of the cuff should be level with the right atrium.
- Make the patient as relaxed as possible, and ask the patient to not talk during the measurement.
- At least 5 minutes of interval is required after each measurement

13.4.3 Measurement Mode

There are three measurement modes:

- Manual: Measurement can be conductedaccording toneeds.
- Auto: Automatic repeated measurement (measurement interval is set from 1 minute to 720 minutes).
- Continuous measurement: The continuous measurement process lasts for 5 minutes.

13.4.4 Starting Measurement

13.4.4.1 Starting Manual Measurement

Select the NIBP Parameter area to display the Setup menu → [Measure Mode], then select [Manual]. You can start NIBP measurement as per the actual requirements.

13.4.4.2 Starting Whole Point Measurement

Select the NIBP Parameter area to display the Setup menu → [Whole point Mea.], and then switch to [On] and manually start the first measurement. After measurement is completed, the monitor automatically repeats the measurement as per the set [interval].

For example, if the first measurement starts at 08:23 and the [interval] is [5 minutes], the monitor automatically performs the next measurement at 08:25. The NIBP measurements thereafter are synchronized with the clock, and the next measurement is at 08:30, and so on and so forth.

Note

- **The monitor performs whole point measurement only when the [Interval] is set to 5 minutes or longer.**

13.4.4.3 Starting Measurement at Intervals

Users can select the other options except manual measurement by pressing the [Mode Setup] quick key and then manually starting the first measurement. After the measurement is completed, the monitor automatically repeats the measurement according to the set [Interval], or starts measurements at intervals as follows:

1. Select the NIBP Parameter areato display the Setup menu → [Measure Mode] and then select [Auto].
2. Select [Interval]: 1~720 minutes.
3. Start the first measurement manually. The monitor will automatically repeat the measurement according to the set [Interval].

13.4.4.4 Starting Continuous Measurement

Select the NIBP Parameter areato display the Setup menu → [Continual Measure], that is, change the NIBP measurement mode to Continual and directly start the NIBP measurement for 5 minutes.

Note

- **If there is doubt about the accuracy of readings, check the patient's vital signs in the same way before checking the monitor functionality.**
- **If the patient type is [Neo], the monitor does not support the [Continual Measure] function. This is done in order to avoid injury to the patient.**
- **Automatic measurements are affected by extremes of temperature, humidity and altitude.**

Warning

- **If liquid splashes on the equipment or accessories, please contact the hospital's service department, especially if the liquid is likely to enter the tube or monitor.**

13.4.5 Stopping Measurement

After the measurement is completed, the monitor automatically deflates and stops measurement. During measurement, you can stop automatic measurement by pressing the key on the panel or the [NIBP Measure] quick key.

13.4.6 NIBP Display

NIBP measurement results are displayed in the Parameter area. The following figure is for reference only. The graphics displayed on your monitor may be slightly different:

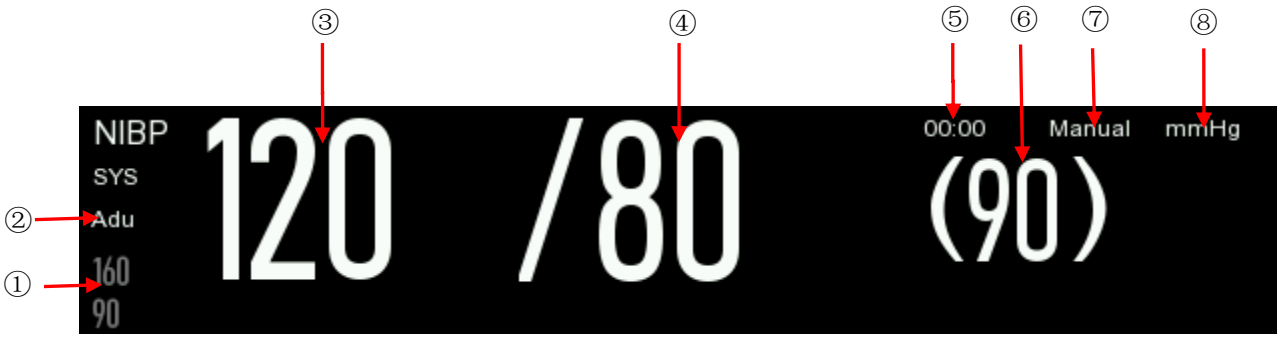


Figure 13-2 NIBP Display

①	Display SYS alarm limit	②	Patient type: adult, pediatrics or neonate
③	Systolic pressure (SYS)	④	Diastolic pressure (DIA)
⑤	Last measurement time	⑥	Average pressure (cuff pressure displayed during measurement)
⑦	Measure mode: manual, auto or continual	⑧	Pressure unit: mmHg or kPa

13.5 NIBP Setup

13.5.1 SettingPatient Type

Patient types are divided into: adults, pediatrics and neonates. Please choose the mode that is appropriate for monitoring the patient. This mode is the same as the [Pat Type] set in [Patient Info].

1) Select the NIBP Parameter area to display the Setup menu → [Pat Type].
2) Select [Adu], [Ped] or [Neo].

13.5.2 Setting Initial Pressure

1) Select the NIBP Parameter area to display the Setup menu → [Initial Pressure].
2) Set the appropriate initial pressure.

13.6 NIBP Reset

Select [NIBP] in the Parameter area and then select [Reset] in the [NIBP Setup] menu that is displayed. The reset option allows you to reset the inflation value of the blood pressure pump to its initial setting. When the blood pressure pump is not working properly, it can be checked by using reset, and any abnormality caused by an unexpected factor is automatically rectified.

13.7 Assisting Venipuncture

The user can inflate the NIBP cuff to create a pressure close to the diastolic pressure, thus blocking the venous vessels and assisting in venipuncture.

1) Select the NIBP Parameter area to display the Setup menu → [NIBP Setup] → [Other Setup] → [Cuff Pressure] and select an appropriate pressure value.
2) Select [Venipuncture Start].
3) Puncture the vein and extract a blood sample.
4) Press the key or corresponding quick key to deflate the cuff. If the cuff is not deflated, the cuff will automatically deflate after a set period of time.

During venipuncture, the NIBP Parameter areadisplaysthe inflation pressure of the cuff and the remaining time for the venipuncture.

13.8 NIBP Analysis

You can view the normal data of systolic and diastolic pressure as well as the lower and higher percentage than the normal data during patient measurement period, in the NIBP Analysis interface. In addition, the average, maximum and minimum values of systolic and diastolic pressure can also be viewed.

1) Select the NIBP Parameter area to display the Setup menu → [Other Setup] → [NIBP Analysis].

In the analysis menu, you can set:

[Daily Start Time]: Set the start time of NIBP Data Statistics. The set time includes hours and minutes.

[Daily End Time]: Set the end time of NIBP Data Statistics. The set time includes hours and minutes.

[SYS Nor. Range]: Set the upper and lower limits of SYS.

[DIA Nor. Range]: Set the upper and lower limits of DIA

Chapter 14 TEMP Monitoring

14.1 Temperature Monitoring

The monitor measures the patient's body temperature through a fast infrared in-ear thermometer. For more detailed descriptions, please refer to the infrared in-ear thermometer user manual.

14.2 In-ear Thermometer

14.2.1 Infrared In-ear Thermometer Front View

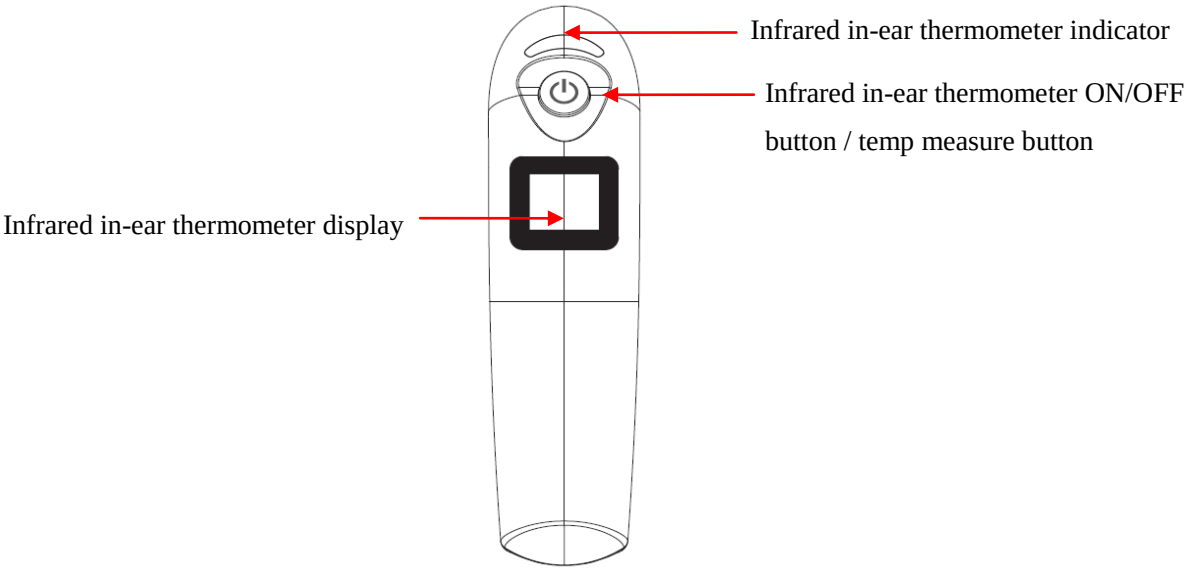


Figure 14-1 Infrared In-ear Thermometer Front View

14.2.2 Infrared In-ear Thermometer Side View

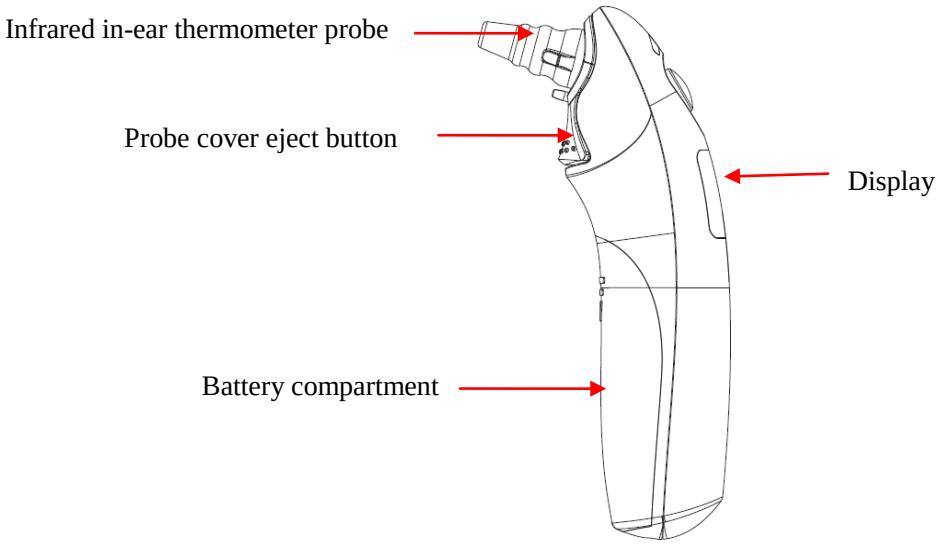


Figure 14-2 Infrared In-ear Thermometer Side View

14.2.3 Measuring the Temperature

1) Make surethe appropriate battery has been placed in the in-ear thermometer.
2) Pull out the infrared in-ear thermometer from its sleeve, press the eject button to remove the used probe cover and throw it in the trash. Take a new disposable cover from the storage site and install it.
3) Place the infrared in-ear thermometer at the patient's ear measurement position and press the temperature measurement button. Wait a few seconds until you hear a beep.
4) Remove the infrared in-ear thermometer and see the temperature value on the display.
5) Press the eject button to remove the probe cover and then return the infrared in-ear thermometer to its sleeve.

14.2.4 Wireless Transmission Function

When the infrared in-ear thermometer is used with the main unit, the data can be transmitted to the main unit through the wireless transmission function, and displayed as follows:

Figure 14-3 Monitor Temperature Display Interface

- Wireless connection mode: In the power off state, press and hold the “Probe Cover Eject” button, and at the same time press the “Temp Measure” button to turn the power on. When the infrared in-ear thermometer displays the character SE (after the ℃ and ℉ characters are displayed twice alternately), release the “Probe Cover Eject Button” and within 10s, press the Temperature Parameter area displayed on the monitor screen, and select [Connect Thermometer].
- Wireless connection/transmission status:

  When the wireless connection is successful, the “  ” icon is displayed.

  When the wireless connection failed, the “  ” icon is displayed.

  When wireless transmission is successful, the “  ” icon does not flash

- Common faults and troubleshooting methods

Faults	Possible causes	Troubleshooting methods
Er0	Wireless module does not work	Contact your dealer to send it to the factory for repair
Wireless transmission failed	The infrared in-ear thermometer is too far away from the receiving instrument	Please keep the distance between the infrared in-ear thermometer and the receiving instrument within 10M and ensure there is no obstruction.
	The infrared in-ear thermometer is not connected to any receiving instrument, or the receiving instrument is in power off or standby state.	Conduct wireless connection pairing again and make sure the receiving instrument is turned on
	Wireless transmission still fails	Contact your dealer to send it to the factory for repair

⚠Warning

- **Calibrate the thermometer at least every two years (or according to hospital instructions). When you need to calibrate, please contact the manufacturer.**
- **Use the temperature probe and probe cover specified in this user manual. Using other probes, probe covers, or inapplicable probe covers may damage the monitor or fail to meet the specifications stated in this user manual.**
- **The body temperature probe cover is a disposable accessory. Repeated use may result in cross-contamination.**
- **For temperature measurement, a disposable probe cover must be used. Failure to use a disposable probe cover may result in inaccurate measurements or cross-contamination.**
- **Check that the disposable probe cover is intact before use; if there are signs of damage or contamination; do not use it for measurement.**
- **Carefully handle the temperature probe; when not in use, return the probe to the sleeve.**
- **Dispose the disposable body temperature probe cover in accordance with local regulatory requirements or hospital procedures.**

⚠Note

- **The disposable temperature probe should only be used once.**
- **The thermometer automatically conducts self-test every hour during temperature measurement. Self-test lasts for 2 seconds and does not affect the normal operation of the thermometer.**

14.3 TEMP Display

The parameter area on the monitor screen can display [TEMP] value and unit. Select [TEMP] in the parameter area to display the [TEMP Setup] menu.

Figure 14-4 TEMP Display

Chapter 15 Data Review

Press the [Review] quick key or select [Main Menu] and then select [Review] to display the Review interface.

Data review includes: NIBP measure review, alarm event review, trend graph review, trend table review, and wave review.

The monitor provides 160 hours of trend data, 2000 sets of NIBP measurement data and 200 times of parameter alarm event storage for all monitoring parameters, and a single-channel waveform review up to 48 hours (specific time is related to the saved waveforms and the number of waveforms saved). This chapter describes detailed methods for observing these saved data.

15.1 Saving Waveform

You can select the waveforms to be saved as per your requirement. Only waveforms that are saved can be viewed in [Wave Review]. The selected waveforms that are saved cannot be modified after the patient is admitted in the system.

1) Enter [Maintain] → [Wave Save].
2) Select the parameters of the waveform to be saved, press [Enter], and select according to the prompt:
   [Rec. Merge]: Admit new patient and create a new patient document to save the current monitoring data.
   [Rec. Not Merge]: Admit new patient and create a new patient document, but the current monitoring data is not saved in the new document.

15.2 Reviewing Trends

A trend is a set of patient data that is displayed graphically or in a tabular form over time.

In the [Trend Review] window, select [Trend Graph] or [Trend Table] to review the corresponding data.

The trend graph shows recently updated data, and the time scale is displayed at the bottom of the screen.

You can select the waveform to be viewed through the Parameter area on the left side of the window and browse the trend database by moving the cursor across the measurement items in the window. When moving the cursor, the current parameter trend data and the specific time of the data are displayed on the right side of the corresponding window:

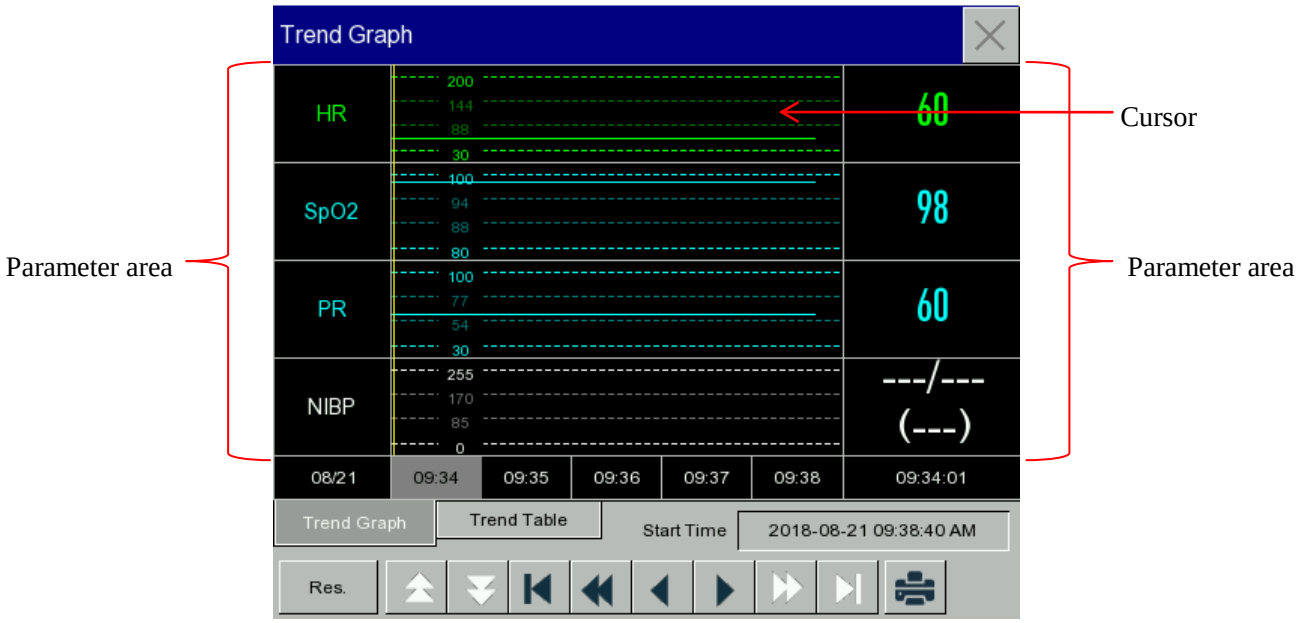


Figure 15-1 Trend Graph Review

Aperiodic measurements can be viewed through the trend table. The measurement data and measurement time are shown in the table. Up to 160 hours of data can be observed in the table.

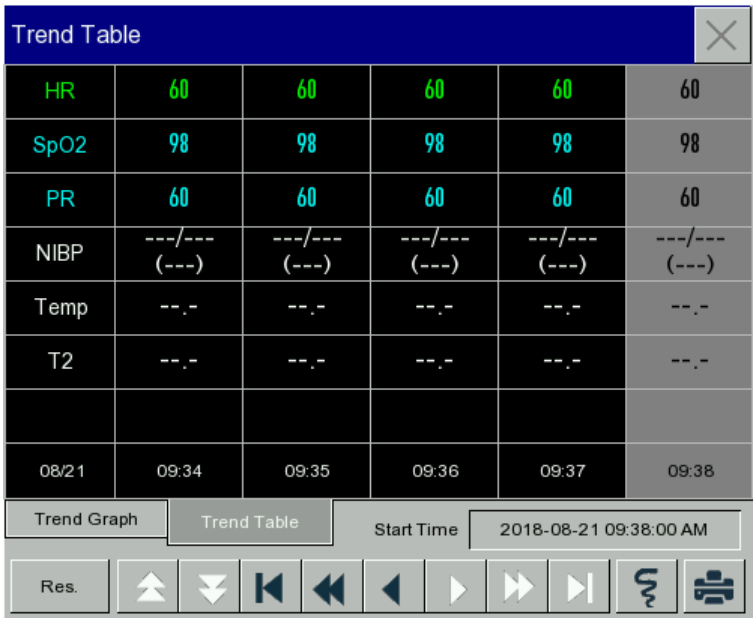


Figure 15-2 Trend Table Review

◆ Symbols Description

Symbols	Description
	Page up and down; used to view other parameter trend graphs that are not in the current view.
	Move the cursor one step to the left or right; used to browse along the trend

	database timeline.
	Move the cursor one page to the left or right; used to browse along the trend database timeline.
	Jump to the start or end of the trend database; used to view the farthest (early) or most recent (late) trend information saved.

- Select the date field next to [Start Time] to display the Setup window, then set the start time for trend review.
- The trend interval is the resolution of trend data displayed on the screen. As the clinical conditions of neonate change rapidly, higher resolution data can be selected, whereas, in adult monitoring, the patient's conditions change relatively slowly, so a lower resolution can be selected.

Setting [Res.] （Resolution）

1) In the Trend Graph Review window
   - ✧ Select [1 second] or [5 seconds] to observe a short trend of the last hour.
   - ✧ Select [10 seconds] to observe a mid-term trend of the last 4 hours.
   - ✧ Select [1 minute], [5 minutes], [10 minutes] to observe a long trend of 160 hours.
2) In the Trend Table Review window
   - ✧ Select [1 minute], [5 minutes], [10 minutes], [30 minutes], [60 minutes], [120 minutes], [180 minutes] to observe a trend of 160 hours.

- Select  in the [Trend Table] menu to display the [Trend Table Review Report] menu. In this menu you can set:
  - ■ Record time: Use the [Start Time] and [Forward Time] options to determine the time period of trend data to output. For example, when [Start Time] is set to 2015-4-21 10:00:00 and [Forward Time] is set to [2 hours], the trend data that is output is 2015-4-21 08:00:00~2015 -4-21 10:00:00. When [Forward Time] is set to [Auto]: The system records the trend table data for 30 minutes.
  - ■ [Res.]: Select the resolution of the trend table output.
  - ■ [Param.]: In this menu, you can select specific output parameters.
  - ■ [Record]: After setting is completed, select [Record] to output the data.
- Select  to set and print Trend Review report. For details, see the “Print Setup” section

Note: The trend graph has no record setup.

15.3 NIBP Measurement Review

This monitor can display the most recent 2000 sets of NIBP measurement data in the NIBP measurement review. In the [Review] menu, select [NIBP Review], as shown below

Figure 15-3 NIBP Measurement Review

- Select to display the [NIBP List Report] menu.
  - Record time: Use the [Start Time] and [Forward Time] options to determine the time period of trend data to output. For example, when [Start Time] is set to 2015-4-21 10:00:00 and [Forward Time] is set to [2 hours], the trend data that is output is 2015-4-21 08:00:00~2015 -4-21 10:00:00. When [Forward Time] is set to [Auto]: The system records the NIBP list data for 1 hour.
  - [Record]: After setting is completed, select [Record] to output the data.
- Select to set and print NIBP list review report. For details, see the "Print Setup" section.

15.4 Alarm Event Review

The monitor can display the last 200 parameter alarm events in Alarm Event Review, including physiological alarm events, technical alarms and manual events. When an alarm event occurs, the monitor saves the values of relevant parameters at the time of occurrence and waveforms 8 seconds before and after the event. In the [Review] menu, select [Alarm Event Review] to display the [Alarm Event Review] window → [View Physiology Alarm]. As shown below:

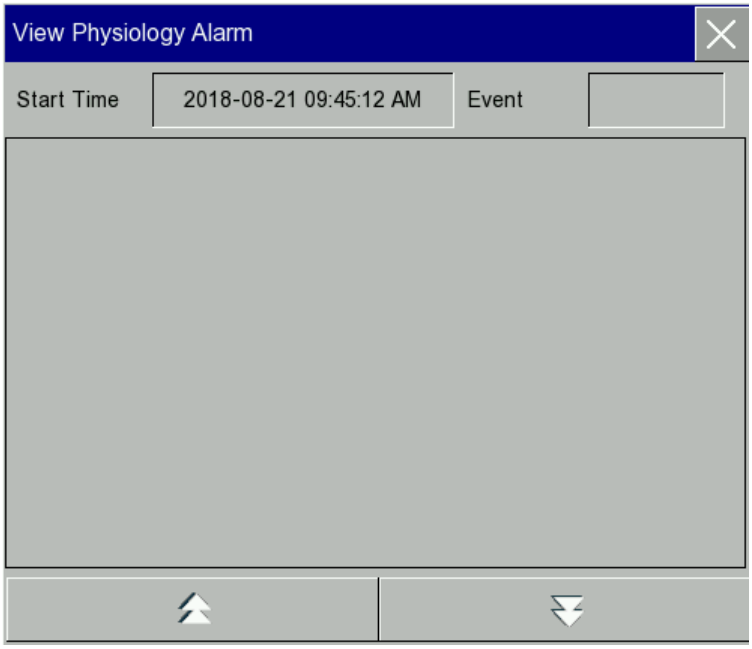


Figure 15-4 Physiological Alarm Event Review

- You can set the review start time in the [Start Time] item.
- In Alarm Review [Event], you can select the alarm message of the parameter to be viewed.

Warning

- **Only the current physiological and technical alarms can be displayed. After the monitor is restarted, alarm messages will be cleared.**
- **Alarm messages in this window are not classified according to the patient.**
- **When alarm event data is full, the previous alarm event will be overwritten.**

- Select the physiological alarm event you want to view and record, then enter the [View Physiology Alarm] window, where you can view the alarm details, and select to directly record the current alarm event data.
- Select the physiological alarm event you want to print, then enter the [View Physiological Alarm] window, where you can select to directly print the current alarm event data.

Select [View Technical Alarm] to display the [View Technical Alarm] window, as shown below:

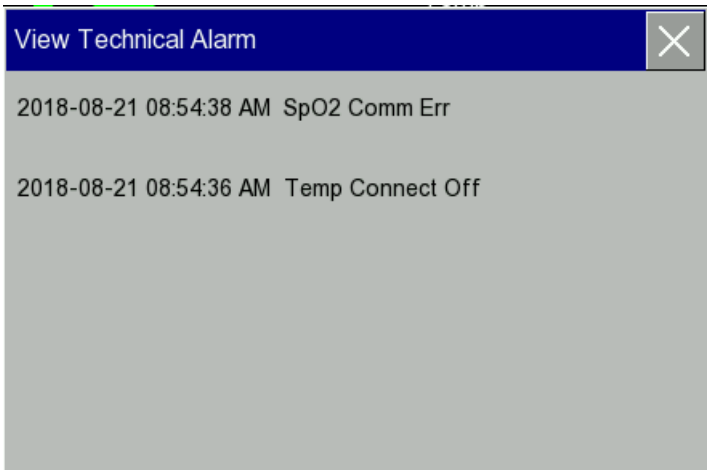


Figure 15-5 Technical Alarm Event Review

Note

- **Technical alarms can only be viewed and cannot be printed.**

15.5 Reviewing Waveform

You can review the waveforms only when an SD card is configured and wave save is set. The monitor can display up to 48 hours of single-channel waveform playback in the waveform review window. When the saved waveforms increase, the playback time of each waveform can be reduced. You can review the waveform for any parameter of a function configured on the monitor, as shown below:

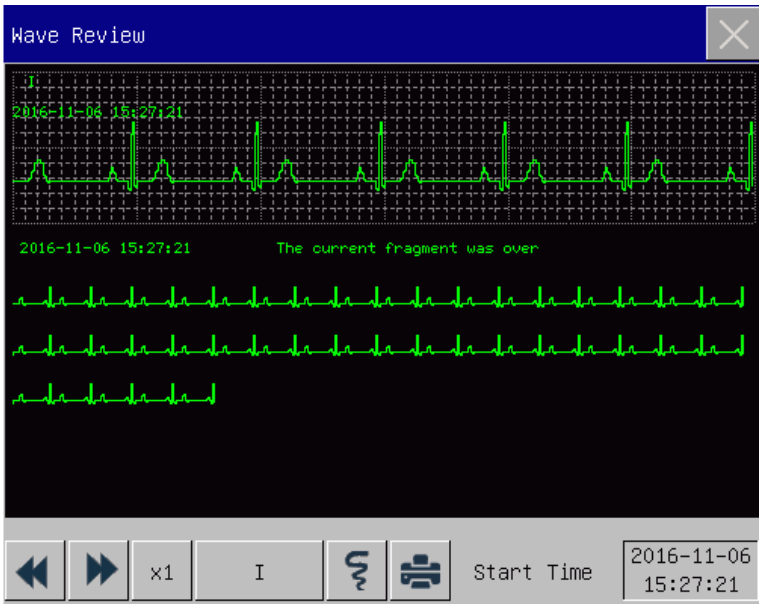


Figure 15-6: Waveform Review

Symbols	Description
	Page forward or backward
	Waveform gain, press this button to select the appropriate gain
	The waveform being reviewed, select the waveform you want to view.
	The start time of waveformreview.
	Record waveformdata.
	Connected to an external printer for printing of waveformdata.

➢ Operation example

ECG waveform review:

1) Before admitting a patient to the system, enter [Maintain] – [Wave Save] screen and select the waveforms to be saved.
2) In the [Review] menu, select [Wave Review].
3) In the [Wave Review] window, select the parameters to be reviewed.
4) In the [Wave Review] window, you can observe the change in trend graph time and the change in trend curves by operating the  keys.
5) Select  to display the [Record Setup] menu. After setting the start time for recording in this menu, select [Record] to record waveformdata for 6 seconds.
6) Select  to set and print waveform review report. For details, see the “Print Setup” section
7) Press the  key to exit the [Wave Review] window.

Chapter 16 Calculations

In the calculation function provided in this monitor, the calculated value is not the directly measured patient data, but the result calculated by the monitor according to the appropriate data provided by the user.

The calculations that can be performed on this monitor are:

- ✧ Drug Calculation
- ✧ Hemodynamic Calculation
- ✧ Ventilation Calculation
- ✧ Oxygenation Calculation
- ✧ Renal Calculation

To perform some calculation, you can directly press the [Calculate] quick key or enter the Setup menu by selecting [Calculate] in the [Main Menu].

Note

- **Please confirm whether the patient type and calculation unit are correct before calculation. If you have any questions, please consult the relevant medical personnel.**
- **Select drug measurement and calculation method under the guidance of a physician. The monitor only processes and calculates according to the input value,and does not verify the calculation result.**
- **After the power is turned off, the [Review] data in the calculation section will be cleared.**

16.1 Drug Calculation

The monitor provides 15 kinds of drug calculation and titration display function and can output the contents of titration to the recorder.

The types of drugs that can be calculated in the system are: AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN and PITOCIN; drugs A, B, C, D, E are also available to flexibly replace any drug.

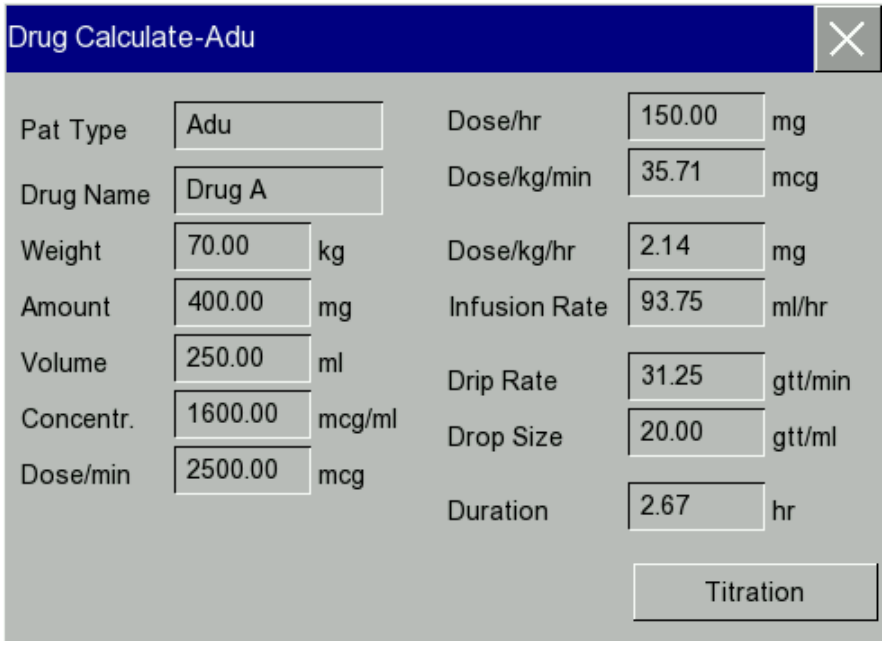


Figure 16-1 Drug Calculation

The drug dosage is calculated using the following formula:

Drug concentration = Amount /volume

Infusion rate = Dose / concentration

Duration = Amount/ dose

16.1.1 Operation Method

In the Drug Calculation window, first select the name of the drug to be calculated, next, confirm the patient's weight, and then enter other known values. Select the position of the calculated item to be entered, the corresponding input window is displayed. Enter the calculated value. When the calculated value is selected, the result of the calculated item is displayed in the corresponding position.

Note

- **The valuesfirst given in the system are only a random set of initial values. Do not use these values as a basis of calculation. Instead, a set of values applicable to the patient must be re-enteredaccording to the doctor’s suggestions.**
- **In the same unit series, the unit's decimal will be automatically adjusted with the current input value.**

Select the type of drug: You can choose from 15 drugs; you can only calculate one drug at a time.

Note

- **A, B, C, D and E are not the real names of drugs, but the codes of user-defined drugs. However, the units of these five drugs are fixed, and you can select the appropriate unit according to**

usage rules of the drug. The unit's representation rules are as follows:

- **The units for drugs A, B and C series are: g (gram), mg (mg), mcg (microgram).**
- **The units for drug D series are: unit (unit), k unit (kilounit), m unit (megaunit).**
- **The unit for drug E is: mEq (milligram equivalent).**

- **The change in patient weight in the calculation menu does not affect the data of patient information in the current monitor.**

16.1.2 Titration table

Select [Titration] in the [Drug Calculate] menu to display the titration table interface.

The interface for drug calculation titration table is shown below:

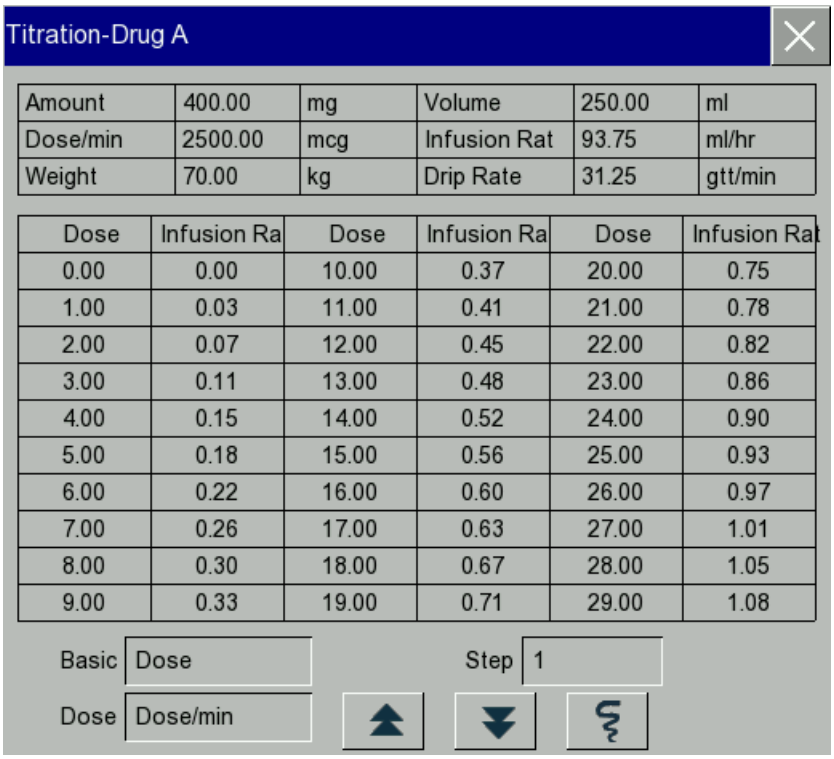


Figure 16-2 Titration Table

The specific steps are as follows:

1) In the Titration table, select [Basic] and then select [Dose], [Infusion Rate] or [Drip Rate].

2) Select the [Step] item and set the step. The range is from 1 to 10.

3) Select [Dose] → [Dose/min], [Dose/hr], [Dose/Kg/min], [Dose/Kg/hr].

4) Press and keys to view the front and back pages of the table.

5) Press to record the data in titration table.

6) Press to return to the [Drug Calculate] menu.

16.2 Hemodynamic Calculation

16.2.1 Calculation Steps

In the [Calculate] menu, select [Hemodynamic]. The appropriate menu is displayed, as shown below.

1) Enter the value you want to calculate in the [Input] fields and press the [Calculate] button to get the calculated value in the table below.
2) Select [Range]; the unit after the parameter will be converted into the corresponding reasonable value range. It can be checked whether the calculated value is within the normal range.
3) Select [Review] to review the previous calculation results and press in the Review interface to record the calculation data.

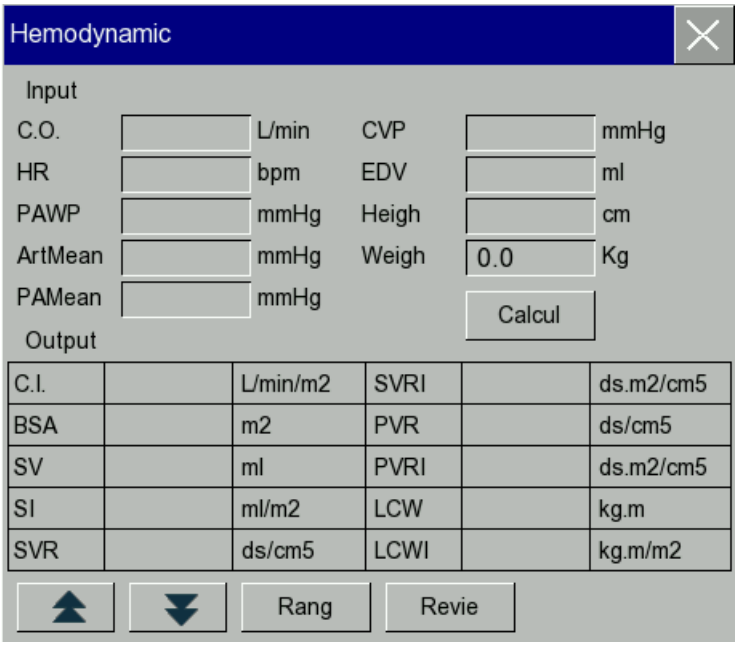


Figure 16-3 Hemodynamic Calculation

Note

- **Hemodynamic calculation requires input of parameters. When no parameters are input, the corresponding calculation result will not be displayed.**

16.2.2 Input Parameters

Abbr.	Unit	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

16.2.3 Output Parameters

Abbr.	Unit	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

16.3 Ventilation Calculation

In the [Calculate] menu, select [Ventilation]. The appropriate menu is displayed as shown below.

1) Enter the value you want to calculate in the [Input] fields and then press the [Calculate] button to get the calculated value as per the below table.
2) Select [Range]. The unit after the parameter is converted into the corresponding reasonable value range. Check whether the calculated value is within the normal range.
3) Select [Unit]. The available options are [Kpa] or [mmHg].
4) Select [Review] to review the previous calculation results and press  in the Review interface to record the calculation data.

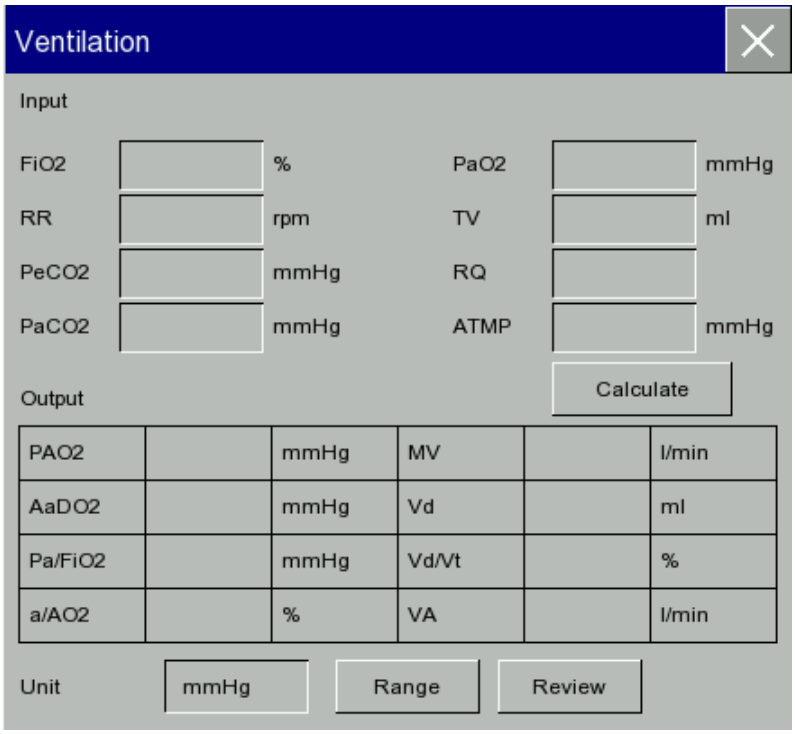


Figure 16-4 Ventilation Calculation

16.3.1 Input Parameters

Abbr.	Unit	Name
FiO_2	%	Percentage fraction of inspired oxygen
RR	Rpm	Respiration rate
$PeCO_2$	mmHg	Partial pressure of mixed expiratory carbon dioxide
$PaCO_2$	mmHg	Partial pressure of carbon dioxide in the arteries
PaO_2	mmHg	Partial pressure of oxygen in the arteries
TV	ml	Tidal volume
RQ	None	Respiration quotient
ATMP	mmHg	Atmospheric pressure

16.3.2 Output Parameters

Abbr.	Unit	Name
PAO_2	mmHg	Partial pressure of oxygen in the alveoli
$AaDO_2$	mmHg	Alveolar-arterial oxygen difference
Pa/FiO_2	mmHg	Oxygenation ratio
a/AO_2	%	Arterial to alveolar oxygen ratio
MV	l/min	Minute volume
Vd	ml	Volume of physiological dead space
Vd/Vt	%	Physiologic dead space in percent of tidal volume
VA	L/min	Alveolar volume

16.4 Oxygenation Calculation

1) In the [Oxygenation] interface: Enter the value you want to calculate in the [Input] fields and then press the [Calculate] button to get the calculated value as per the below table.
2) Select [Range]. The unit after the parameter is converted into the corresponding reasonable value range. Check whether the calculated value is within the normal range.
3) Select [Press. Unit], [HB Unit] and [Unit] to change corresponding units. The values of relevant parameters are automatically converted and refreshed.
4) Select [Review] to review the previous calculation results and press in the Review interface to record the calculation data.

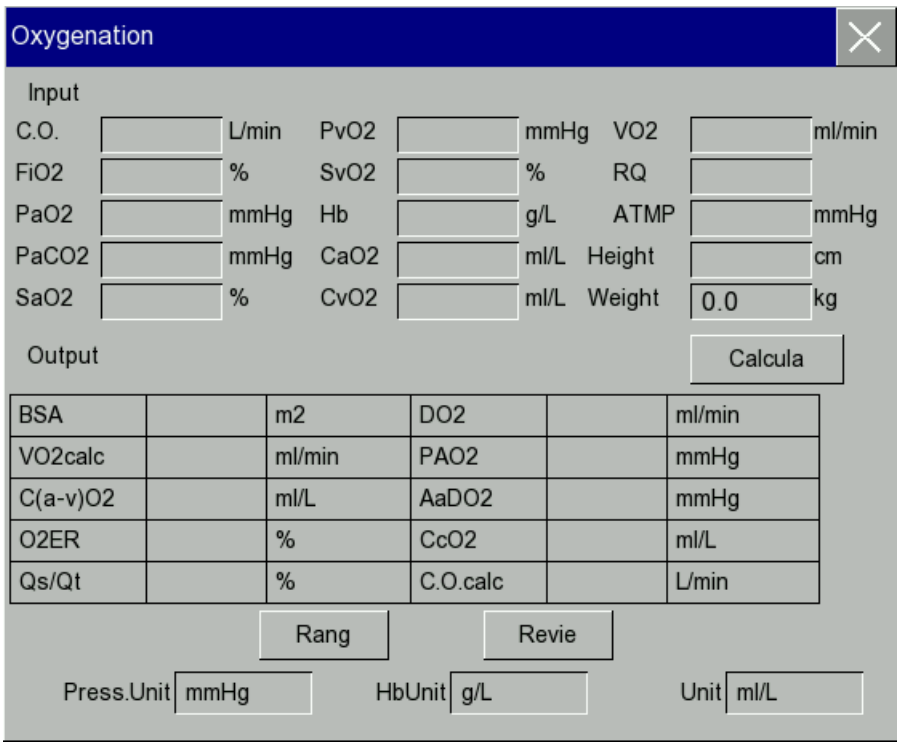


Figure 16-5 Oxygenation Calculation

16.4.1 Input Parameters

Abbr.	Unit	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	None	Respiration quotient
ATMP	mmHg	Atmospheric pressure
(height)	cm	Height
(weight)	Kg	Weight

16.4.2 Output Parameters

Abbr.	Unit	Name
BSA	m^2	Body surface area
VO_2 calc	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

16.5 Renal Calculation

In the [Calculate] menu, select [Renal]. The appropriate menu is displayed as shown below.

1) Enter the value you want to calculate in the [Input] fields and then press the [Calculate] button to get the calculated valuesas per the below table.
2) Select [Range].The unit after the parameter is converted into the corresponding reasonable value range. Check whether the calculated value is within the normal range.
3) Select [Review] to review the previous calculation results and press  in the Review interface to record the calculation data.

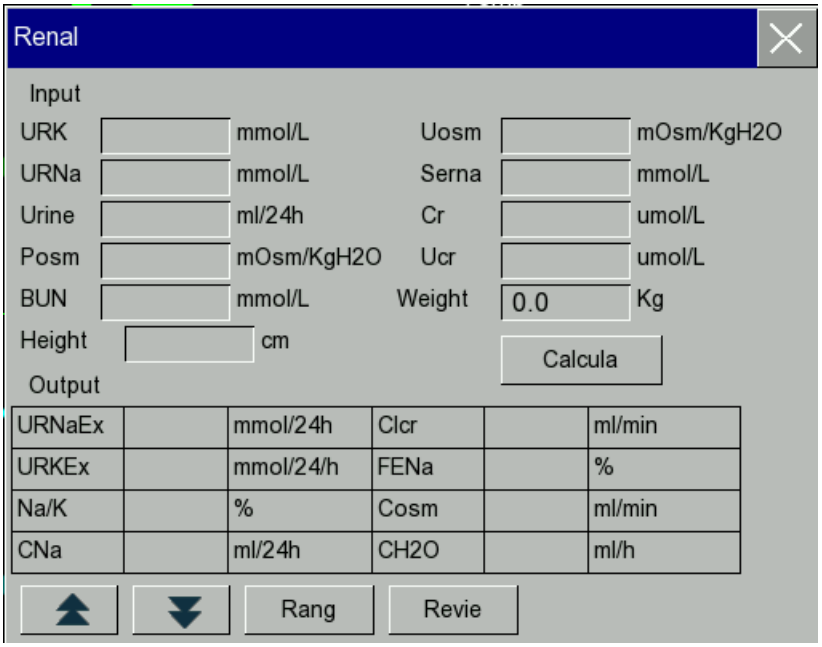


Figure 16-6 Renal Calculation

16.5.1 Input Parameters

Abbr.	Unit	Name
URK	mmol/L	Urine potassium
URNa	mmol/L	Urinare sodium
Urine	ml/24h	Urine
Posm	mOsm/kgH_2O	Plasma osmolality
Uosm	mOsm/kgH_2O	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

16.5.2 Output Parameters

Abbr.	Unit	Name
URNaEx	mmol/24h	Urine sodium excretion
URKEx	mmol/24h	Urine potassium excretion
Na/K	%	Sodium/potassium ratio
Can	ml/24h	Sodium clearance
Clcr	ml/min	Creatinine clearance rate
FENa	%	Fractional sodium excretion
Cosm	ml/min	Osmolar clearance

CH_2O	ml/h	Free water clearance
U/P osm	None	Urine/plasma osmolality ratio
BUN/Cr	mmol/L	Blood urea nitrogen/creatinine ratio
U/Cr	None	Urine/serum creatinine ratio

Chapter 17 Clinical Assistance Function

17.1 Early Warning Grade (EWS)

Early warning grade (EWS) is part of the clinical assistance function. EWSatcs as the early warning index for severe illnesses and potential ones, helpful with identifying the early signs of deterioration.

EWS provides the corresponding grade by monitoring and observing the vital signs and state of the patient. And the system will provide advices and measures that should be taken according to the grade.

17.2 Grading System Type

The device provides the following grading system:

- Modified Early Warning Grade（MEWS）
- National Early Warning Grade（NEWS）
- Early Warning Grade（EWS）

It can be divided into two types: OverallGrading and IndividualGrading.

- OverallGrading Type: Grade each parameter that has been chosen and output a total grade. The grade of each parameter is marked with particular color that matches each critical level. When the total grade exceeds the range, action and measures should be provided.
- Individual Parameter Grading: Grade each parameter and when one parameter exceeds the range, the action and measures should be taken.

  MEWS and NEWS belong to overall grading system and only apply to adult.

⚠ Warning

- **The result of grading system only serves as reference and cannot be directly used for clinical diagnosis.**
- **Grading cannot be used for comprehensive clinical diagnosis and should never replace the doctors' assessment on patient totally.**

17.3 Involved paremeents of grading.

Different grading system involves different parameters.Please refer to the following table:

Modified Early Warning Grade（MEWS）	National Early Warning Grade（NEWS）	Early Warning Grade（EWS）

RR、Temp, NIBP-Sys, PR/HR, Conscious	RR, SpO2, O2 Absorption, Temp（Armpit Temp）, NIBP-Sys, PR/HR, Conscious	RR, Temp, NIBP-Sys, PR/HR, Conscious

17.4 Enter the grading screen

1) Click【Main Menu】-【Interface Change】-【Spot Check】.

2) In spot check interface, click " 

" shortcut key and enter grading system.

3) In grading system, three options are available: MEWS, NEWS and EWS.

Different grading system interfaces involve different parameter settings, as shown below:

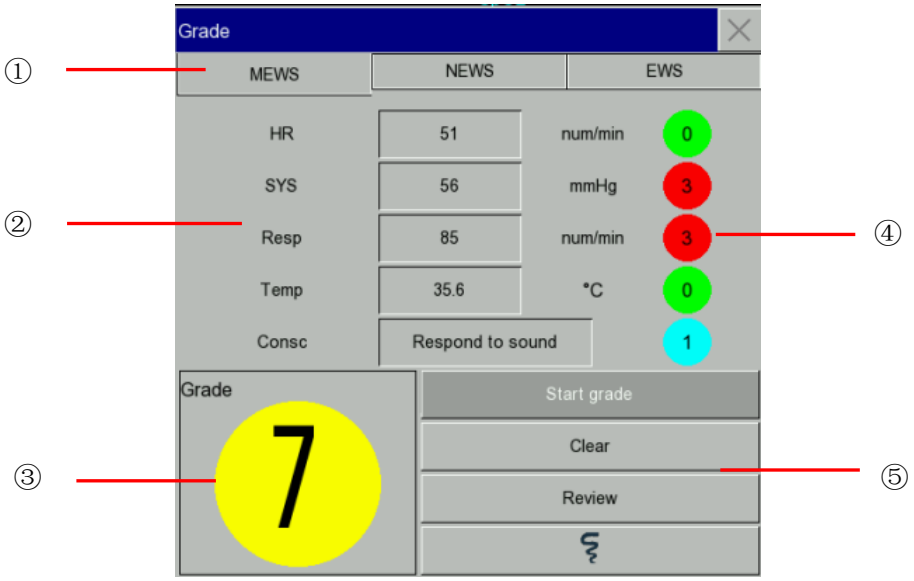


Figure 17-1MEWS Grading Interface

Figure 17-2NEWS Grading interface

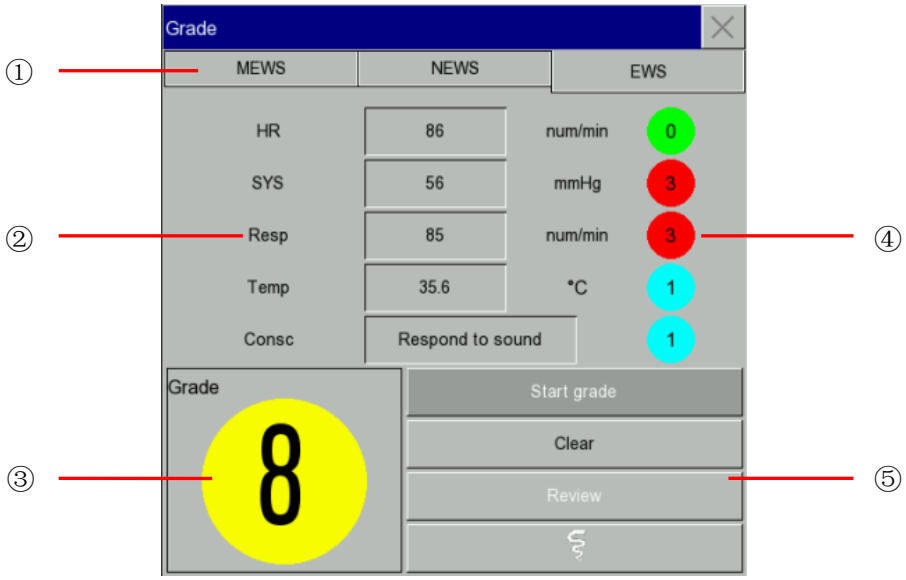


Figure 17-3EWS Grading Interface

①	The name of grading system
②	The involved parameter in grading
③	Total grade
④	Grade for each parameter
⑤	Functional Key

17.5 Calculate grades

The steps of grading are as follows:

1) Choose[Clear] to clear the previous results and click " 

" shortcut key to update the value thatobtained automatically by the monitor.
2) Input the parameter value of other parameter manually.
3) Obtain the grading result by clicking [Start grade].

Note

- **Click [Clear] to clear previous grading result prior to each grading.**

17.6 Grading table and clinical contermeasures

17.6.1 Modified Early Warning Grade（MEWS）

Table1Modified Early Warning Grade（MEWS）Grading Table

Item	Grade						
	3	2	1	0	1	2	3
HR（num/min）		<40	41-50	51-100	101-110	111-129	≥130
SYS（mmHg）	<70	71-80	81-100	101-199		≥200	
Resp （num/min）		<9		9-14	15-20	21-29	≥30
Temp(℃)		<35		35-38.4		≥38.5	
Consc				Sober	Respond to sound	Respond to pain	No resp

Table 2MEWS Grading Level Classification and Clinical Countermeasures

MEWS Grading	Contermeasures
【0,0】Green	No special treatment
【1,3】Cyan	Inspect patients at least every 4 hours.
【4,6】Yellow	Nurse should inform the emergency doctors to check patients within 30mins and increase the frequency of the inspection. Doctor should adopt the treatment advice from higher level doctor in medical group when necessary.
【7,14】Red	All members in medical group should be engaged in the treatment of the patient

	immediately.And contact critical care contact group.
Individual Grading=3	Nurse should inform the emergency doctors to check patients immediately and increase the frequency of the inspection.

Table 2 shows the clinical responsive information of this monitor. In clinical response, when "individual grades=3" appears in the grading, the response to "individual grading=3" should be added based on the corresponding measures to the total grades.

17.6.2 National Early Warning Grade(NEWS)

The temperature refers to the axillary. Rapid Grading System on Consciousness Level (Avake-verbal response-painful responses-unresponsive response, AVPU) is adopted to determine the level of consciousness. (A=avake, V=verbal response, P=painful response, U=unresponsive.)

Table 3National Early Warning Grade（NEWS）Grading Table

Physiological Index	3	2	1	0	1	2	3
Resp（num/min）	≤8	-	9-11	12-20	-	21-24	≥25
SpO2（%）	≤91	92-93	94-95	≥96	-	-	-
O2 Absorption	-	Yes	-	No	-	-	-
Armpit Temp（℃）	≤35.0	-	35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
SYS（mmHg）	≤90	91-100	101-110	111-219	-	-	≥220
PR（num/min）	≤40	-	41-50	51-90	91-110	111-130	≥131
Consc（AVPU）	-	-	-	A	-	-	V,P,U

Table4 Danger Level to NEWS Grading

NEWS grades	Danger Level
0-4	Minor
5-6 or any individual parameter reaches 3	Moderate
≥7	High

Table 5 NEWS Grading Classification and clinical countermeasures

NEWS Grading	Countermeasures
【0,0】Green	● Conduct regular NEWS monitoring to each group. ● At least every 12 hours.
【1,4】Cyan	● Inform the registered nurse. And the registered nurse must make an evaluation ● Registered nurse should determine whether inspection frequency and/or

	upgrade caring level. ● At least every 4 to 6 hours
Individual grade=3 or/and [5,6] yellow.	● Registered nurse should issue an emergency notice to treatment group of caring for patients. ● The supervising doctor should make an evaluation to the acute patients with emergency. ● Perform clinical nursing with monitoring device. ● Increase the frequency to at least every one hour.
【7,20】Red	● Registered nurse should inform the treatment group (at least including expects) inmmediately to care for patients. ● The treatment group with critical care qualification should perform urgent evaluation on the patient and the group should include medical practitioner with airway handling skill. ● Considering transferring the patient to care unit of higher level. ● Continously monitoring vital signs.

17.6.3 Early Warning Grade（EWS）

Table6Early Warning Grade（EWS）Grading Table

Item	Grades						
	3	2	1	0	1	2	3
HR（num/min）		<40	41-50	51-100	101-110	111-130	>130
SYS（mmHg）	<70	70-80	81-100	101-199		≥200	
Resp（num/min）		<9		9-14	15-20	21-29	≥30
Temp(℃)		<35	35.1-36.5	36.6-37.4	>37.5		
Consc				Sober	Respond to sound	Respond to pain	No resp

Table7EWS grading classification and clinical countermeasures

EWS Grades	Countermeasures
【< 3】Green	No special treatment
【>=3】Yellow	Remind the doctor or ICU staff to evaluate and adjust the treatment plan.

Chapter 18 Recording

18.1 Recorder Introduction

The monitor uses a thermosensitive dot matrix recorder that supports multiple record types and can output patient information, measurement data, review and up to 2 waveforms.

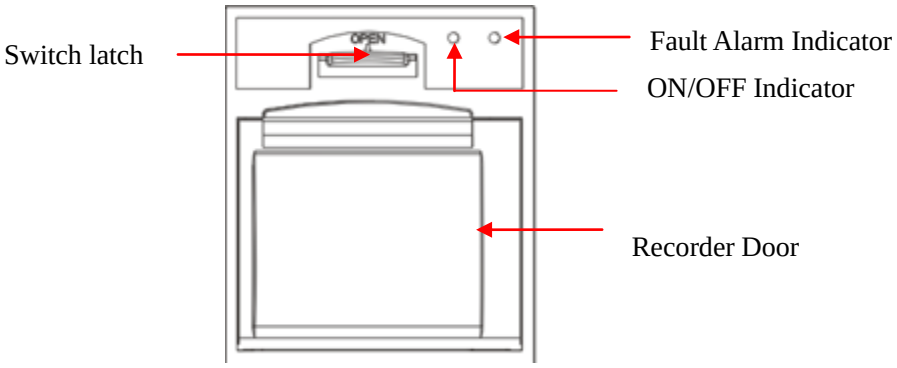


Figure 18-1 Recorder

18.2 Record Type

Based on the triggered method, records can be divided into:

- ✧ Manually activated real-time record.
- ✧ Timed record – the recorder automatically starts at set intervals.
- ✧ Alarm record triggered by parameter overrun, etc.

Records related to certain specific functions

- ➢ Freeze waveform
- ➢ Event: parameter alarm event, manual event
- ➢ Drug calculation data
- ➢ Hemodynamic calculation data
- ➢ Ventilation calculation data
- ➢ Oxygenation calculation data
- ➢ Renal calculation data
- ➢ Review data

18.3 Recording Operations

- Manually start recording:
  - Select the monitor [Record] quick key to start real-time recording.
  - Select the [Record] button on the current menu or window to start recording certain specific functions.
- Manually stop recording:
  - Select the monitor [Record] quick key
- The recorder automatically starts recording in the following situations:
  - If the record timer function is enabled, the recorder automatically starts recording at the set interval.
  - When [Alarm Switch] and [Alarm Record] of a parameter are set to [On], when the parameter alarm is triggered, the monitor startsan alarm record.
- The recorder automatically stops recording in the following situations:
  - Record task completed
  - Recorder out of paper
  - Recorder failure

18.4 Recorder Setup

Open [Main Menu] and select [Record Setup] to display the relevant interface.

Record waveform:

The recorder can output up to 2 waveforms at a time. In the Record Output Setup interface, set the record waves 1, 2. These settings are for real-time record and timed record.

- Set the paper speed
  1) Select [Paper Speed] in this menu.
  2) Paper speed: [25mm/s], [50mm/s].
- Set up real-time record:
  1) In this menu, select [RT Record Time]: Select [3s], [5s], [8s], [16s], [32s], or [Continual] as per your requirement.
  - If [8s] is selected, it means that waveforms of 8s after the current time will be recorded.
  - If [Continual] is selected, the waveforms after the current time are recorded, and record should be stopped manually.
- Setting up timed record

  You can set the record interval according to your requirement. Setting of real-time record determines the length of each record.
  1) In this menu, select [Timed Record Interval].
  2) Select the interval time: [Close], [1h], [2h], [3h], [4h].

- Grid

  Select [Grid], then to switch it to "On" or "Off". If it is “On”, a grid will be printed on the print paper when the recorder outputs.

  If it is “Off”, no grid will be printed on the print paper when the recorder outputs

18.5 Installing Recorder Paper

The recorder paper installation steps for the thermosensitive recorder (optional) on the right side of the monitor are as shown below:

1) Open the recorder door using the upper latch
2) Remove the empty paper core.
3) Load a new paper roll and attach it to the paper clip.
4) Paper is delivered from the bottom and passes over the top of the recorder door.
5) Let at least one inch of paper protrude from the edge of the door.
6) Lifthe recorder door up and close it.
7) Check if the paper is loaded properly, and then start recording.
8) If printing doesn’t work, the paper may be reversed; try to reload the paper.

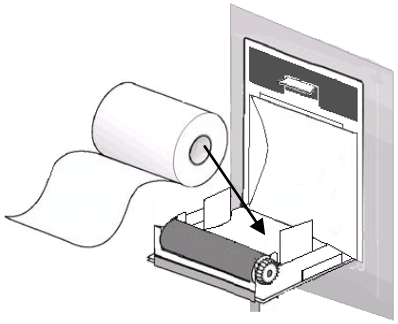


Figure 18-2 Installation of Record Paper

⚠ Caution

- **Carefully install recorder paper as incorrect installation may damage the thermal printer head.**
- **During output of the recorder, do not pull out the record paper by force, or the recorder may be damaged.**
- **Do not leave the recorder door open unless it is necessary to change paper or for troubleshooting.**

Clearing a paper jam

When the recorder makes an abnormal sound or there is a problem with the recorder paper output, please check if the paper is jammed. If it is, please follow the steps below to clear the jam:

1) Open the recorder door.
2) Remove the jammed record paper and cut the wrinkled part.
3) Reinstall the record paper and close the recorder door.

18.6 Cleaning the Recorder

After long-term use, scraps of paper and dust canaccumulate on the recorder’s printer head, affecting record quality and the life ofthe printer head and roller.

Cleaning

1) Before cleaning, take measures to prevent damage to the recorder caused by static charge.
2) Open the recorder door and remove the record paper.Then take a cotton ball dipped in an appropriate amount of alcohol.
3) Gently wipe the surface of tethermosensitive part of the printer head.
4) After the head is completely dry, reinstall the record paper and close the recorder door.

Caution

- **Do not use anything that can damage thermosensitive parts, such as sandpaper.**
- **Do not squeeze the printer head.**

Chapter 19 Printing

19.1 Printer

The monitor can connect to an external printer via a USB cable to output patient reports.

Currently, this monitor supports the following types of printers:

- HP laserJet 1505n black and white laser printer
- HP laserJet P2035n laser printer
- HP laserJet P4015 nlaser printer
- HP laserJet 1606dn laser printer
- Lenovo LJ2650DN laser printer
- Lenovo LJ4600DN laser printer

The specifications for report printing using the external printer are:

- Paper: A4
- Resolution: 300dpi
- Single and double-sided: Supports single and double-sided printing if the printer supports it.

Note

- **For instructions, please refer to the documentation provided with the printer. As and when the product is upgraded, the monitor may support more printers, and no notice will be provided for the same. If you have any questions about purchasing a printer, please contact us.**

19.2 Start Printing the Report

You can print the following reports: Trend Graph Review, Trend Table Review, NIBP List, Alarm Event Review, Wave Review and Real-Time Wave.

Enter [Main Menu] → [Print Setup] and select the report you want to print. Conduct the appropriate report setup in the menu that is displayed based on your requirements.

19.3 Stop Printing Report

To stop printing the report: Enter [Main Menu] → [Print Setup] → [Cancel Print].

19.4 Setting-up Report

19.4.1 Setting-up Trend Table Review Report

Enter [Print Setup] → [Print Report], and then select the [Trend Table Review Report] to set:

- Print time: Use the [Start Time] and [Forward Time] options to determine the time period of trend data to output. For example, when [Start Time] is set to 2015-4-21 10:00:00 and [Forward Time] is set to [2 hours], the trend data output is 2015-4-21 08:00:00~2015 -4-21 10:00:00. When [Forward Time] is set to [Auto]: When [Type Priority] is set to [Time Priority], one page is printed using Time as column; when set to [Param. Priority], one page is printed using Parameter as column.
- Resolution]: Select the resolution of the trend table output.
- [Type Priority]: When [Param. Priority] is selected, the column on the output report is Parameter; when [Time Priority] is selected, the column on the output report is Time.
- [Param.]: In this menu, you can select specific output parameters.

19.4.2 Setting-up Alarm Event Review Report

To set up the alarm event review report: Enter [Main Menu] → [Print Setup] → [Print Report] → [Alarm Event Review Report].

Print time: Use the [Start Time] and [Forward Time] options to determine the time period of alarm event to output. For example, when [Start Time] is set to 2015-4-21 10:00:00 and [Forward Time] is set to [2 hours], the alarm event output is 2015-4-21 08:00:00~2015 -4-21 10:00:00. When [Forward Time] is set to [Auto]: only one page of data is printed.

19.4.3 Setting-up NIBP List Report

To set up the NIBP list report: Enter [Main Menu] → [Print Setup] → [Print Report] → [NIBP List Report].

The time setup is similar to the Alarm Event Review Report. Please refer to the description in “Setting-up Alarm Event Review Report”.

19.4.4 Setting-up Trend Graph Review Report

To set up the trend graph review report: Enter [Main Menu] → [Print Setup] → [Print Report] → [Trend Graph Review Report].

[Time of Page]: You can select the time for printing each page of paper according to your requirement. The selectable time is less than the forward time.

[Param.]: Select the review parameters to be printed.

The time setup is similar to the Trend Table Review Report, please refer to the description in “Setting-up

Trend Table Review Report".

19.4.5 Setting-upReal-time Waveform Report

To set up the realtime review report: Enter [Main Menu] → [Print Setup] → [Print Report] → [Realtime Review Report].

[Wave Speed]: Set the waveformoutput speed; [Auto] means that the waveformoutput speed is consistent with the sweep speed of each waveformon the screen.

[Wave Select]: Select the waveformto be output in this menu.

19.4.6 Setting-upWaveform Review Report

To set up the waveformreview report: Enter [Main Menu] → [Print Setup] → [Print Report] → [Wave Review Report].

Print time: Use the [Start Time] and [Forward Time] options to determine the time period of review data to output. For example, when [Start Time] is set to 2015-4-21 10:00:00 and [Duration] is set to [15s], the trend data output is 2015-4-21 10：00：00~2015-4-21 10：00：15.

[Gain]: Select the waveformprint range.

[Wave Speed]: Set the waveformoutput speed

[Wave Select]: Select the review waveformto be printed, in this menu.

19.5 Printer Exceptions

19.5.1 No Recorder Paper

When the printer is out of paper, there will be no response to the print request sent; when there are too many tasks that cannot be responded to, a printer exception may occur. In this case, load paper appropriately and resend the print request; restart the printer if necessary.

19.5.2 Printer status message

When the [USB Printer does not exist] printer status message is displayed, please check if the printer is turned on, the printer is connected properly, and the printer has paper.

Chapter 20 Other Functions

20.1.1 Nurse Call Setup

The nurse call function is triggered when the physiological alarm of the monitor meets the settings in nurse call. When the nurse call is triggered, the monitor beeps.

Nurse call setup:

1) Enter [Maintain] → [Nurse Call Setup] → [Nurse Call].
2) Nurse call setup options.
   - ✧ [Alarm Type]: Select which type of alarm will trigger a nurse call.
   - ✧ [Alarm Level]: Select which level of alarm will trigger a nurse call.

20.1.2 Central Monitoring System Connection

Wired connection:

1) Enter [Maintain] → [Net Protocol] → [COMEN].
2) Select  in the upper-right corner of the screen ([Monitor Setup]), enter [Monitor Setup] → [Network Setup].
3) Set [Net Bed] and [IP Address]. Usually, we only need to set the network bed number.The other options are the default setting.
   - ✧ Network bed number: Indicates the network bed number of the monitor connected to the Central Monitoring System. The valid values range from 1 to 254.

Wireless connection:

1) Enter [Maintain] → [Network Protocol] and select the appropriate protocol.
2) Turn on [WIFI] in the [Maintain] menu.
3) Select  in the upper-right corner of the screen ([Monitor Setup]), enter [Monitor Setup] → [Network Setup].
4) Enter [WIFI Setup] and select the appropriate network in the LAN.
5) Set [Net Bed], [IP Address], [SSID] and [Login Password]. Usually, we only need to set the network bed number. The other options are the default setting.

An icon for the Central Monitoring System is displayed in the Lower Menu Bar of the screen. When "  "is displayed, it indicates that the Central Monitoring System is not connected; when "  " is displayed, it indicates that the Central Monitoring System is connected.

Note

- **When the WiFi switch is turned on, the wired network is not available.**
- **The network bed number of this monitor must be unique and cannot conflict with that of other equipementconnected to the Central Monitoring System.**
- **For details, please refer to the Central Monitoring System user manual.**

20.1.3 Formatting SD card

This monitor allows the user to format the SD card. When [Format SD Card] is selected, all data in the card will be removed. Therefore, please use this function with caution. During SD card formatting, all interface operations are not available. Wait until the formatting ends, the monitor will automatically power off.

SD card formatting procedure:

1) Enter [Maintain] → [Format SD Card]. The [The monitor will auto restart after formatting SD card! Confirm to format?] warning message is displayed. Select [Yes] to format the SD card. The monitor will automatically power off after formatting the SD card.

Chapter 21 Battery

21.1 Overview

The monitor has a built-in rechargeable battery. When an AC power supply is connected, the battery is automatically charged irrespective of whether or not the device is turned on or off, until it is fully charged. In the event of a sudden power failure, the system automatically uses the battery to power the device without interrupting the operation. After the AC power is disconnected, the battery indicator flashes to indicate that battery mode is in use and the instrument operation is not affected.

The battery icon displayed on the screen indicates the current battery status:

 Indicates that the battery is fully charged.

 Indicates that the battery has been used.

 Indicates that the battery is low and should be charged.

 Indicates that the battery is charging.

 Indicates that there is no battery or the battery is damaged.

Note

- **When the battery has not been used for a long time, please remove and keep it in a safe place.**
- **If the device has a built-in battery, the battery must be recharged after each use to ensure that the battery has sufficient power reserve.**

Warning

- **Incorrect replacement of lithium battery may lead to unacceptable risks.**
- **Replacement of lithium battery by a non-professional person may lead to risks.**
- **Battery electrolyte is hazardous. In case the battery electrolyte gets on your skin or in your eyes, rinse immediately with water and consult a doctor.**
- **Keep the battery out of reach of pediatric.**
- **When working with a battery, the monitor automatically powers off when the battery is low.**

21.2 Installing the Battery

Steps to replace or install the battery:

1) Turn off the monitor and disconnect the power cord and other cables.

2) Place the monitor with its base facing up.
3) Use a screwdriver to remove the screws and remove the old battery.
4) Connect the battery based on the appropriate negative and positive pole positions indicated in the battery compartment.
5) Tighten the screws and place the monitor properly.

Warning

- **Use only the battery specified by the manufacturer.**
- **Do not remove the battery while the instrument is working.**

21.3 Optimize and Check Battery Performance

1） Calibrate battery performance

When the battery is used for the first time, it should be calibrated for at least two complete cycles. A complete calibration cycle should be: uninterrupted charging until the battery is fully charged and then discharging until the monitor automatically powers off.

When calibrating the battery, ensure that:

1) All connections between the monitor and the patient are disconnected, and all monitoring and measurement tasks are stopped.
2) The battery is installed properly in the battery compartment.
3) When charging the battery, ensure that the battery is charged for more than 6 hours without interruption until it is full.
4) Disconnect AC power supply and use the battery to power the monitor until the monitor automatically powers off.
5) Battery calibration is completed.

2）Check battery performance

Battery life varies with storage, usage environment, battery discharge frequency, and time of use. Even if the battery is not in use, its performance will gradually decrease.

Battery inspection steps are as follows:

1) First determine if the battery is damaged. When the battery icon displayed on screen turns to “  ”, it indicates that the battery is damaged or there is no battery in the compartment.
2) Check if the battery can be charged normally when the monitor is connected to AC power.
3) Disconnect all connections between the monitor and the patient and stop all monitoring and measurement tasks.
4) When charging the battery, ensure that the battery is charged for more than 6 hours without interruption until it is full.
5) Disconnect AC power supply and use the battery to power the monitor until the monitor automatically powers off. Record the battery discharge start time and end time.

6) The length of discharge time reflects the performance of the battery.

7) When discharge time drops below 50% of the initial value, the battery should be replaced.

Note

- **In order to extend the life of the rechargeable battery, if the battery is to be stored for a long time, it is recommended to charge the battery once every three months to prevent the battery from being over-discharged.**
- **Power supply time of the battery depends on device configurations and operation. For example, frequent NIBP measurement will shorten the battery's power supply time.**

21.4 Recycling the Battery

If the battery is obviously damaged or the battery cannot hold a charge any longer, it should be replaced, and the scrapped old battery should be properly recycled according to relevant laws and regulations or the hospital's rules.

Warning

- **Do not disassemble the battery or short-circuit it or disposein a fire, or else there may risk of fire, explosion, leakage of hazardous gases or other hazards.**

Chapter 22 Cleaning and Maintenance

Use only materials and methods listed in this chapter that is approved by the company, to clean or disinfect the equipment. The company does not provide any warranty if damage is caused by use of unapproved materials or methods.

The company assumes no responsibilities for the effectiveness of the listed chemicals or methods as a means of controlling infection. For information on how to control infection, please consult your hospital's infection prevention department or epidemiologist. Also see all local policies for your hospital and country.

22.1 Overview

This chapter describes the cleaning and disinfection methods of the monitor and some accessories. For the cleaning and disnfection methods of other reusable accessories, please refer to the attached random file.

Please keep your device and accessories dust free. After cleaning, please check the equipment carefully. If you notice any signs of aging or damage, stop using it immediately. If you need to return the device to our company for repair, please clean it first. Please observe the following notes:

⚠ Warning

- **Use only cleaning agents and disinfectants recommended in this user manual. Using other cleaning agents and disinfectants can damage the device or cause a safety hazard.**
- **The power must be turned off and the AC power supply disconnected before cleaning the monitor.**
- **Do not use EtO (ethylene oxide) to disinfect the monitor.**
- **Do not leave disinfectant on any surface or accessories of the monitor. If ther is any disinfectant residue, wipe it off with a damp cloth.**
- **Cleaning agents should not be mixed, or hazardous gases may be produced.**
- **This section only describes how to clean reusable accessories. Disposable accessories cannot be cleaned and must not be reused, to avoid cross-contamination.**
- **In order to protect the environment, disposable accessories must be recycled or properly disposed.**
- **After cleaning, if there is damage or aging signs on the sensor cable, replace the cable with a new one.**
- **Do not conduct high temperature sterilization of the monitor and any of its accessories.**
- **Do not use any cleaning solutions other than those recommended here, as this may permanently damage the device, sensors, and cables.**
- **Do not immerse the sensor or connector in any solution for cleaning or disinfecting.**

⚠ Caution

- **If you accidentally pour liquid on the equipment or accessories, please contact our service person or our company immediately.**
- **If the equipment is accidentally wet, immediately place the equipment in the vent, and then contact our service person or our company immediately.**

22.2 Monitor Cleaning and Disinfection

The monitor should be kept clean. It is recommended to clean the outer surface of the monitor housing frequently, especially in areas with harsh environment or heavy wind and sand, cleaning frequency should be increased. Before cleaning, please consult or understand the hospital's regulations on equipment cleaning.

Cleaning steps:

1) Turn off the power and disconnect the power cord first.
2) Use a soft cloth, absorb an appropriate amount of cleaning agent, and then wipe the housing of the device.
3) Use a soft cloth, absorb an appropriate amount of cleaning agent, and then wipe the screen of the device.
4) Use a soft dry cloth to wipe off excess cleaning agent.
5) Place the device in a cool, ventilated environment to dry.

Disinfection may cause a certain degree of damage to the monitor. It is recommended that the device is disinfected only when necessary as per the hospital maintenance program. Clean the device before disinfection.

Optional cleaning agents and disinfectants:

Parts to be cleaned/disinfected	Cleaning agents	Disinfectants
Display screen	Ethanol （ 75%±5 ） ,Isopropyl alcohol（70%）	Ethanol（75%±5）, Isopropyl alcohol （70%）
Housing	Ethanol （ 75%±5 ） ,Isopropyl alcohol（70%）	Isopropyl alcohol （ 70% ） , Glutaraldehyde solution （2%）,Sodium hypochlorite（2.5%）,Hydrogen peroxide （2.7%～3.3%）

22.3 Cleaning and disinfection of accessories

Before cleaning, please consult or understand the hospital's regulations on equipment cleaning. It is recommended that the accessories are disinfected only when necessary as per the hospital maintenance program. Clean the accessories before disinfection.

22.3.1 Cuff Cleaning and Disinfection

Our recommendeded cleaning agents are Ethanol（75%±5） and Isopropyl alcohol（70%）, and disinfectants are Isopropyl alcohol（70%）, Glutaraldehyde solution （2%）,Sodium hypochlorite（2.5%） and Hydrogen peroxide（2.7%～3.3%）.

The air bag must be removed before cleaning.

The cuff can be washed by machine or hand with mild cleaning agent. Hand washing can extend service life.

The air bag can be wiped by a moist cloth dampened with water. Naturally dry it after washing.

The cuff can be disinfected by wiping with a moist cloth dampened with disinfectant. Long-term use of disinfectants may cause color fading and discoloration.

⚠ Warning

- **Do not squeeze the rubber tube of the cuff.**
- **When cleaning, only wipe the outer circumference of the connector socket, and not the inside.**
- **When cleaning the air bag, take care not to allow any liquid to enter the air bag.**
- **The cuff should not be dry cleaned.**
- **Disposable cuff can be cleaned with soap to control infection**

After cleaning, please reinstall the airbag into the cuff as follows.

1) To reinstall the airbag into the cuff, first place the airbag on the front end of the cuff so that the rubber tube is lined up with the large opening at the long end of the cuff.
2) Then roll the airbag longitudinally and insert it into the large opening of the cuff. Hold the tube and cuff and shake the entire cuff until the balloon is in place.
3) Introduce the tube into the cuff and pass it through the small hole. See below:

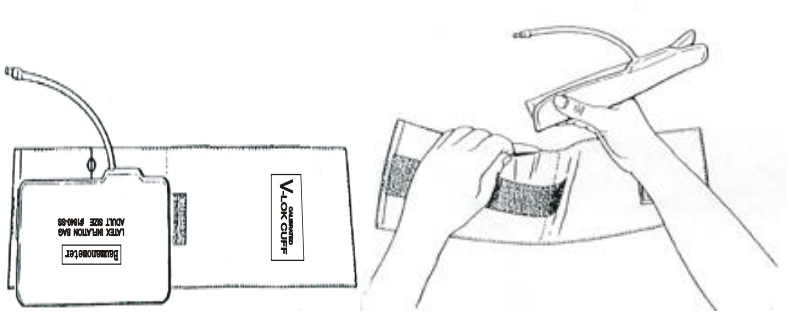


Figure 22-1 Replace Tape in the Cuff

22.3.2 Cleaning and disinfection of other accessories

Cleaning steps:

1) Use a soft cloth, absorb an appropriate amount of cleaning agent, and then wipe the accessories.
2) Use a soft dry cloth to wipe off excess cleaning agent.

3) Place the accessories in a cool, ventilated environment to dry.

Optional cleaning agents and disinfectants:

Parts to be cleaned/disinfected	Cleaning agents	Disinfectants
ECG cable	Ethanol（75%±5）,Isopropyl alcohol（70%）	Isopropyl alcohol（70%）, Glutaraldehyde solution（2%）,Sodium hypochlorite（2.5%）,Hydrogen peroxide（2.7%～3.3%）
TEMP probe		
SpO_2 sensor		
Blood pressure catheter		

Chapter 23 Maintenance

23.1 Maintenance and Inspection

Before the monitor is used, after it has been used for 6-12 months or after each maintenance or upgrade, a comprehensive inspection, including function safety inspection, must be performed by trained and qualified technical service personnel.

The inspection items should include:

1) Inspect the environment and power supply of the monitor for compliance.
2) Inspect the equipment and accessories for mechanical damage.
3) Inspect the power cord for wear and insulation performance.
4) Inspect all functions that may be used to monitor the patient and ensure that the instrument is in a good working condition.
5) Inspect if the accessories used are manufacturer-specified ones.
6) Inspect the battery and check its status.
7) If the monitor is equipped with a recorder, inspect if the recorder is working properly and the recorder paper meets specified requirements.
8) Inspect if the wiring impedance and current leakage meet the requirements.

If there are any signs of damage on the device, do not use the monitor to perform any monitoring on the patient. Please contact the hospital's biomedical engineer or our company.

All safety inspections or maintenance that requires disassembly of the instrument should be performed by professional service personnel. Operation by non-professionals may result in failure of functions of the equipment or potential safety hazards and may endanger personal safety.

our company will conditionally provide circuit diagrams when requested by the user to assist the appropriate and qualified technicians in maintaining the parts of the monitor that the company has classified as user-maintainable.

Warning

- **The hospital or institution using this monitor should establish a complete maintenance plan, or it may lead to failure of device functions and unpredictable consequences, and may endanger personal safety.**

23.2 Maintenance Plan

The following tasks can only be completed by professional maintenance personnel approved by the company. If you need to perform the following maintenance tasks, please promptly contact the maintenance personnel.

The device must be cleaned and disinfected before inspection or maintenance.

Inspection and maintenance items	Frequency
Safety inspection according to IEC 60601-1	At least once every two years. Conduct after the monitor falls, power supply is replaced, or as required.
NIBP leak test	At least once every two years, or as required.
NIBP verification	At least once every two years, or as required.
ECG calibration	At least once every two years, or as required.
Battery	See relevant sections on battery.

23.3 NIBP Leakage Test

It is used to test if there is any leakage in the the NIBP measuring pump. When the NIBP cuff is connected, the NIBP inflation process can be started by pressing the button to check whether the sealing condition of the NIBP tube is good. If the leakage test is passed, the system will not give any prompt; if it fails, there will be a corresponding error message in the NIBP Information area.

Leakage test procedures:

- Connect the cuff to the NIBP air vent of the monitor.
- Wrap the cuff around a properly sized cylinder.
- Enter [Maintain] → [Leakage Test].
- At this time, [Leakage Testing...] will be displayed at the lower part of the NIBP Parameter area on the screen, indicating that the system has started to perform the air leakage test.
- The system automatically inflates to a pressure of 180mmHg.
- After about 20 seconds, the system will automatically open the deflation valve. This represents the completion of the leakage test.

If there is no prompt message in the NIBP Parameter area, it means that there is no air leakage in the system. If [Pneumatic Leak...] is displayed, there may be a leakage in the tube. At this point, check whether the connection is loose. After confirming that the connection is proper, perform another leakage test. If there is still a fault indication, please contact the manufacturer for repair.

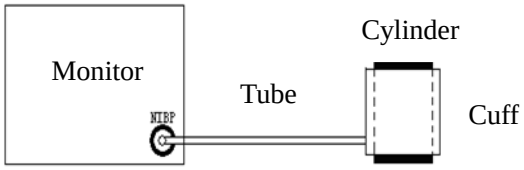


Figure 23-1 NIBP Leakage Test Connection Diagram

Warning

- **This leakage test is different from what is described in the EN 1060-1 standard. This is for the user to simply check for leakage when the NIBP is inflated. If the system shows NIBP leak at the end of the test, please contact a service engineer of our company.**

23.4 NIBP Pressure Check

The manufacturer recommends using a calibrated pressure gauge (or mercury sphygmomanometer) with a precision higher than 1 mmHg for calibration. Select [NIBP Check] in the [Maintain] menu to start calibration; this item will change to [Stop NIBP Check]. If you press the knob at this time, the system will stop calibration.

Warning

- **Calibration of NIBP measurement should be performed every two years (or according to your hospital's maintenance regulations). The performance should be checked as per the following details.**

Pressure sensor calibration steps:

Replace the cuff with a metal container with a volume of 500 ml ±5%. Connect a calibrated standard pressure gauge with a tolerance of less than 0.8 mmHg and a ball pump with a T-connector and inflation tube to the NIBP port on the module. Enter the [Maintain] menu, select [NIBP Check], and set the monitor to Check mode, and then use the ball pump to change the pressure in the metal container to 0, 50 and 200 mmHg. At this time, the difference between the value of the standard pressure gauge and the pressure value indicated on the monitor should be within 3 mmHg. Otherwise, please contact a service engineer of our company.

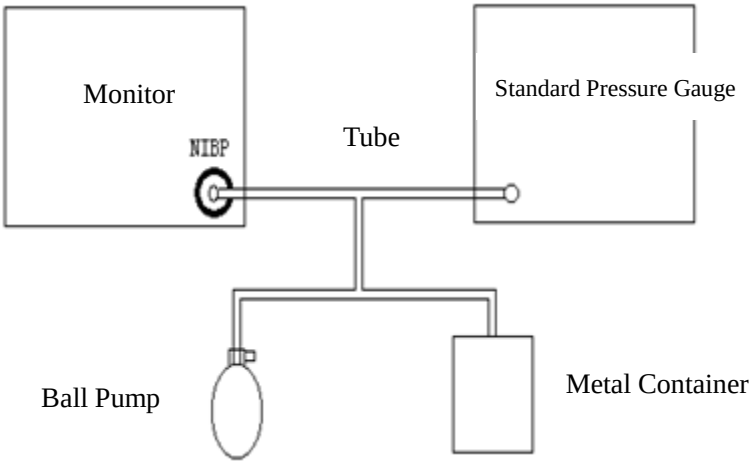


Figure 23-2 NIBP Check Connection Diagram

23.5 ECG Calibration

1) Enter [Maintain] → [ECG Calibrate]. Then set it to a Calibration state, the item changes to [Stop ECG Cal].
2) To stop calibration, go back to the [Maintain] menu and select [Stop ECG Cal].

When the ECG is being calibrated, the patient cannot be monitored. There isprompt message at the bottom-left of the screen: Cal. can't monitor!

Appendix I Accessories

The manufacturer recommends the following accessories for using this monitor

Warning

- **Please use the accessory models specified by the manufacturer. Using other accessory models may damage the monitor.**
- **Single-use accessories can only be used once. Repeated use may result in performance degradation or cross-infection.**

Code	Description	Model
ECG		
040-000479-00	3-Lead AHA standard split clip anti-defibrillator interference	98ME01AC458
040-000485-00	3-Lead IECstandard split clip anti-defibrillator interference	98ME01EC681
040-000908-00	3-Lead AHA standard one-piece clip anti-defibrillator interference	98ME01AD473
040-000911-00	3-Lead IEC standard one-piece clip anti-defibrillator interference	98ME01EB477
040-000413-00	3-Lead neonatelead main cable	98ME01EB046
040-000914-00	3-Lead AHAstandard one-piece clip anti-defibrillator interference ECG cable	A3105-EC1
040-000917-00	3-Lead IECstandard one-piece clip anti-defibrillator interference ECG cable	A3105-EC0
040-000492-00	3-Lead pediatric/neonateIECstandard split clip lead branch cable	98ME01AC658
040-001219-00	ECG electrode holder	/
Standard SpO_2		
040-000869-00	Simulated adult finger-clip SpO_2sensor	A0816-SA105PV
040-000769-00	Probe extension cable	SLZ122
040-000726-00	Simulated adult finger-clip SpO_2sensor	SAS104
040-000730-00	Simulated neonate binding SpO_2sensor	SES104
040-000312-00	Simulated adult finger-clip SpO_2sensor	SAL104
MASIMO SpO_2		
040-000204-00	Probe extension cable	M-LNC-10
040-000203-00	Adult finger-clip SpO_2sensor	M-LNCS DCI
040-000361-00	Reusable neonate Y-shaped SpO_2sensor	M-LNCS YI
NELLCOR SpO_2		
009-000466-00	Probe extension cable	DOC-10
040-000010-00	Adult finger-clip SpO_2sensor	DS-100A
040-000075-00	Y-shaped binding SpO_2sensor	D-YS

NIBP Cuff (Unimed Medical)		
040-000592-00	Adult blood pressure cuff	U1880S
040-000593-00	Pediatric blood pressure cuff	U1881S
040-000594-00	Neonate blood pressure cuff	U1882S
040-000595-00	Neonate blood pressure cuff	U1883S
040-000596-00	Thigh blood pressure cuff	U1884S
040-000597-00	Small adult blood pressure cuff	U1885S
040-000598-00	Large adult blood pressure cuff	U1869S
040-000743-00	Neonate blood pressure cuff	U1681S
040-000744-00	Neonate blood pressure cuff	U1682S
040-000745-00	Neonate blood pressure cuff	U1683S
040-000746-00	Neonate blood pressure cuff	U1684S
040-000747-00	Neonate blood pressure cuff	U1685S
NIBP Cuff (SunTech Medical)		
040-000934-00	Disposable neonate 1# 3-6CM	98-0400-99
040-000935-00	Disposable neonate 2# 4-8CM	98-0400-96
040-000936-00	Disposable neonate 3# 6-11CM	98-0400-97
040-000937-00	Disposable neonate 4# 7-13CM	98-0400-98
040-000938-00	Disposable neonate 5# 8-15CM	98-0400-90
Body temperature accessories		
115-004974-00	Infrared in-ear thermometer	/
043-001696-00	Transparentear cap	/

Appendix II Accessory service life

Accessory	Service life
ECG lead	two years
Standard SpO_2 sensor	two years
Masimo/Nellcor sensor	4380 hours
Blood pressure cuff	18 months

Appendix III Product Specifications

a) Monitor Classifications

Name	Classifications
Classified by type of electric shock protection	Class I, with internal power supply.
Classified by degree of electric shock protection	ECG, NIBP, pulse SpO_2, and pulse rate/pulse detection parts belong to defibrillation-proof type CF applied parts. TEMP belongs to defibrillation-proof type BF applied parts.
Classified by medical device management	This monitor is Class IIa.
Safety standard	IEC 60601-1, IEC 60601-2-27, ISO 80601-2-61, EN 1060-3, IEC 80601-2-30, ISO 80601-2-56，IEC60601-2-49 .
Water ingress protection level (main unit)	Common device (Device with water ingress resistant housing: IPX2)
Water ingress protection level (Infrared ear thermometer)	IPX0
Classified by safety degree in the case of using in an environment with a mixture of flammable anesthetic gas and air or mixture of flammable anesthetic gas and oxygen or nitrous oxide	Do not use in an environment with flammable anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide.
Working mode	Continuously working device

b) Monitor Specifications

（1）Size and Weight

Name	Specifications
Size and weight	Size: 〈165mm (width) ×250mm (height) ×165mm (length)
	≤2.5Kg

（2）Environmental requirements

Name	Specifications	
Working environment	Ambient temperature range	0 °C ~ 40 °C (without infrared in-ear thermometer) 15 °C ~ 36 °C (with infrared in-ear thermometer)
	Relative humidity range	≤93% non-condensing (without infrared in-ear thermometer) ≤85% non-condensing (with infrared in-ear thermometer)

	Atmospheric pressure range	700hPa～1060hPa
Supply voltage requirement	Voltage	100-240V～
	Frequency	50/60Hz
	Input current	0.5-0.3A
Transportation	Protect from severe shock, vibration, and rain and snow during transportation.	
Storage	Store in a well-ventilated indoor environment with an ambient temperature of -20℃ ~ +60 C, relative humidity ≤93% (non-condensing), without corrosive gas (without infrared in-ear thermometer) Store in a well-ventilated indoor environment with an ambient temperature of -20℃ ~ +55°C, relative humidity ≤85% (non-condensing), without corrosive gas (with infrared in-ear thermometer)	

（3）Display specifications

Name	Specifications
Display	8-inch screen, TFT display, color LCD
Display information	Up to 2 waveforms
Resolution	800 ×600 pixels

（4）Recorder (optional part)

Name	Specifications
Recorder paper width	50mm
Effective record width	48 mm
Paper speed	25mm/s, 50 mm/s
Real-time record time can be set to	3s, 5s, 8s, 16s, 32s, continual
Trace waveform	Up to 2 waveforms
Alarm trigger record	Present

（5）Battery

Name	Specifications
Main unit battery	
Battery specification	Standard: 11.1V 2200mAh, rechargeable lithium-ion battery, providing continuous sustainable power supply for at least 3 hours under full charge and normal use. Optional: 11.1V 4400mAh, rechargeable lithium-ion battery, providing continuous sustainable power supply for at least 8 hours under full charge and normal use. With +5%, -10% relative error (built-in battery).
Charging time	Standard:11.1V 2200mAh, Power off state：3 hours from depletion to 90% charge in normal use Power on state:5.5 hours from depletion to 90% charge in normal use (apply semi-charge mode in power on state)： Optional: 11.1V 4400mAh Power off state：5.5 hours from depletion to 90% charge in normal use

	Power on state:10.5 hours from depletion to 90% charge in normal use (apply semi-charge mode in power on state)
Power off delay	20-30min (from the first low battery alarm)
Infrared in-ear thermometer battery	
Battery specification	3V (2 AAA alkaline batteries)
Power off delay	The in-ear thermometer automatically powers off after 60±10 seconds from the end of temperature measurement.

（6）Data storage

Name	Specifications	
Trend data	Short trend	1 hour, resolution 1 second
	Medium trend	4 hours, resolution 10 seconds
	Long trend	160 hours, resolution 1 minute
Trend graph and trend table	160 hours	
Parameter alarm event	200 parameter alarm events	
NIBP measurement data	2000 sets	
Waveform review	The time for single-channel waveformcan be up to 48 hours; the specific time is related to the saved waveformand the number of waveforms.	

（7）Wifi Moduel

Specification	Specification parameter	Remark
Working frequency	2.4GHz-2.527GHz	
Channel number	125	
Modulation type	GFSK	Gauss frequency shift keying
Maximum transmitted power	0dBm	1mW
Wireless communication speed	250/1000/2000kbps	
Working pressure	1.9-3.6 VDC	
Working current under transmission mode	11mA@0dBm output	
Working current when sending and receiving	13mA@2Mbps	
Working current of MCU	4mA@8MHz 3V	
Working temperature	-40~+85℃	
Tipical sensitivity	-94dBm@250kbps	

（8）ECG specifications

Name	Specifications
ECG shall meet the requirements of IEC 60601-2-27	
Lead type	3 lead
Sensitivity (gain) and error	1.25mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10

	mm/mV (×1), 20 mm/mV (×2), 40 mm/ mV (×4) and automatic gain, the error is less than ±5% Add ±750mV DC polarization voltage, sensitivity variation range ±5%	
Sweep speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s with an error of no more than ±10%.	
Frequency characteristics	Surgery mode: 1 Hz ~ 20 Hz (-3.0 dB to +0.4 dB). Monitoring mode: 0.5Hz ~ 40Hz (-3.0dB ~ +0.4dB); Diagnosis mode: 0.05Hz ~ 150Hz (-3.0dB ~ +0.4dB);	
Notch Filter	a) Power frequency interference rejection ≥20dB; b) Monitoring and surgery mode: 50/60 Hz notch function supported; c) Diagnosis mode: 50/60 Hz notch manual setting supported.Strong/weak notch should be manually selected.	
Common mode rejection	a) Diagnosis mode: >90dB; b) Monitoring mode: >105dB; c) Surgery mode: >105dB;	
Differential input impedance	≥5MΩ	
Input signal range	±8 mV (peak-to-peak)	
Heart rate detection level trigger threshold	Heart rate detection level trigger threshold 200Mv	
Input dynamic range	DC bias voltage up to ±750mV	
ECG relearn function	Provides a function for manually starting ECG relearn	
Lead-off detection current	DC current <0.1μA	
System noise	≤25μVP-P.	
Calibration voltage	1 mV, error range ±5%	
Heart rate resolution	1bpm	
Heart rate detection range and accuracy	Range: 15 ~ 300 bpm for adults; 15 bpm ~ 350 bpm for neonate/pediatric. Accuracy: ±1% or ±1bpm (both maximum).	
Electrotome noise suppression	Use standard-compliant ECG leads with peak-to-peak noise ≤ 2 mV relative to the ECG baseline.	
Input signal reproduction accuracy	Determine the total system error and frequency response according to EC 60601-2-27 use method A and B	
Baseline recovery time after defibrillation	<5s	
Patient leakage current	<10μA	
Electrotome protection	Recovery time is less than 10s	
Alarm upper and lower limits and error	Adult	Alarm upper limit 17bpm~300bpm
		Alarm lower limit 15bpm ~ 298bpm
	Pediatric/neonate	Alarm upper limit 17bpm~350bpm
		Alarm lower limit 15bpm ~ 348bpm
	Error	Set value ±1bpm
Lead selection	Standard single lead	
Electrode-off indication	Automatic detection and display	
Time constant	Monitoring and surgery modes: ≥0.3s;	

	Diagnosis mode: ≥3.2s.
Anti-interference measures	Resistance to power frequency interference, high frequency electrotome interference, defibrillation interference
Non-overshoot pacemaker pulse inhibition	Amplitude: ±2mV~±700mV; width: 0.1ms~2.0ms; if overshoot < $0.05a_q$, 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

Heart rate algorithm	
Giant T wave rejection	When tested according to Clause 201.12.1.101.17 of IEC 60601-2-27, the heart rate meter can effectively reject the giant T wave of 1.2 mV.
Heart rate average	Calculate the heart rate average by the following method according to the requirements of Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27: If the last three consecutive RR intervals are over 1200 ms, the four latest RR intervals are averaged to calculate the heart rate; otherwise, take 12 latest RR intervals, maximum and minimum deceleration values, and then take the average to calculate the heart rate.
Heart rate meter accuracy and arrhythmia response	According to the requirements of Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the heart rate values displayed are: A1 (Bigeminy) 80 ±1 bpm; A2 (slow-change Bigeminy) 60 ±1 bpm; A3 (fast change Bigeminy) 120 ±1 bpm; A4 (bidirectional contraction) 90 ±2 bpm.
Heart rate change response time	According to the requirements of Clause 201.7.9.2.9.101 b) 5) of IEC 60601-2-27, the heart rate increases from 80 to 120 bpm: less than 10s; the heart rate increases from 80 to 40 bpm: less than 10s.
Start time of tachycardia alarm	According to the requirements of Clause 201.7.9.2.9.101 b) 6) of IEC 60601-2-27, the waveforms: B1 1-range: 10s; B1 0.5-range: 10s; B1 2-range: 10s; B2 1-range: 10s; B2 0.5-range: 10s; B2 2-range: 10 s.

（9）NIBP Specifications

Name	Specifications		
NIBP shall meet the requirements of IEC 80601-2-30			
Measurement method	Pulse wave oscillation		
Measurement range	Adult	SYS	5.3kPa - 36.0kPa（40mmHg - 270mmHg）
		DIA	1.3kPa - 28.7kPa（10mmHg - 215mmHg）

			MPA	2.7kPa - 31.3kPa（20 mmHg - 235mmHg）
	Pediatric		SYS	5.3kPa - 26.7kPa（40 mmHg - 200mmHg）
			DIA	1.3 kPa - 20kPa（10mmHg - 150mmHg）
			MPA	2.7 kPa - 22kPa（20 mmHg - 165mmHg）
	Neonate		SYS	5.3 kPa - 18kPa（40 mmHg - 135mmHg）
			DIA	1.3 kPa - 13.3kPa（10mmHg - 100mmHg）
			MPA	2.7 kPa - 14.7kPa（20 mmHg - 110mmHg）
Static pressure measurement range and accuracy	Range		0kPa ～ 40.0kPa (0 mmHg～300 mmHg)	
	Accuracy		Shall not exceed ±0.4kPa (±3 mmHg)	
Overpressure protection range and error	Adult		297mmHg±3mmHg	
	Pediatric		240mmHg±3mmHg	
	Neonate		147mmHg±3mmHg	
Alarm preset range and resolution	Adult	SYS	Range: 40mmHg ~ 270mmHg; Upper limit: 5.6 kPa ~ 36 kPa (42 mmHg ~ 270 mmHg) Lower limit: 5.3 kPa ~ 35.7 kPa (40 mmHg ~ 268 mmHg)	
		DIA	Range: 10 mmHg ~ 215mmHg) Upper limit: 1.6kPa ~ 28.7kPa (12 mmHg ~ 215mmHg) Lower limit: 1.3kPa ~ 28.4kPa (10mmHg ~ 213mmHg)	
		MAP	Range: 20 mmHg ~ 235mmHg Upper limit: 2.9kPa ~ 31.3kPa (22 mmHg ~ 235mmHg) Lower limit: 2.6 kPa ~ 31.1 kPa (20 mmHg ~ 233 mmHg)	
	Pediatric	SYS	Range: 40 mmHg ~ 200mmHg Upper limit: 5.6kPa ~ 26.6kPa (42mmHg ~ 200mmHg) Lower limit: 5.3 kPa ~ 26.3 kPa (40 mmHg ~ 198 mmHg)	
		DIA	Range: 10mmHg ~ 150mmHg Upper limit: 1.6kPa ~ 20kPa (12mmHg ~ 150mmHg) Lower limit: 1.3 kPa ~ 19.7 kPa (10 mmHg ~ 148 mmHg)	
		MAP	Range: 20 mmHg ~ 165mmHg Upper limit: 2.9 kPa ~ 22 kPa (22 mmHg ~ 165 mmHg) Lower limit: 2.6 kPa ~ 21.7 kPa (20 mmHg ~ 163 mmHg)	
	Neonate	SYS	Range: 40 mmHg ~ 135mmHg Upper limit: 5.6 kPa ~ 18 kPa (42 mmHg ~ 135	

			mmHg), Lower limit: 5.3 kPa ~ 17.7 kPa (40 mmHg ~ 133 mmHg)
		DIA	Range: 10mmHg ~ 100mmHg Upper limit: 1.6kPa ~ 13.3kPa (12 mmHg ~ 100mmHg) Lower limit: 1.3 kPa ~ 13.1 kPa (10 mmHg ~ 98 mmHg)
		MAP	Range: 20 mmHg ~ 110mmHg Upper limit: 2.9kPa ~ 14.7 kPa (22mmHg ~ 110mmHg) Lower limit: 2.6 kPa ~ 14.4 kPa (20 mmHg ~ 108 mmHg)
	Resolution	±0.1kPa or ±1mmHg, whichever is greater	
Blood pressure measurement mode	Manual, automatic (interval), continuous (not for neonate)		
	Automatic mode test interval (min)	1 min, 2 min, 2.5 min, 3 min, 4 min, 5 min, 10 min, 15 min, 30 min, 60 min, 90 min, 120 min, 180 min, 240 min, 480min, 720min	
Maximum measurement period	Adult, pediatric: 120s; neonate: 85s		
Venipuncture	The user can inflate the NIBP cuff to create a pressure close to the diastolic pressure, thus blocking the venous vessels and assisting in completion of the venipuncture.		
Initial inflation pressure setting range (mmHg)	Adult: 80 ~ 280; Pediatric: 80 ~ 210; Neonate: 60 ~ 140		

（10）SpO2 Specifications

Name	Specifications
Pulse SpO_2 shall comply with the requirements of ISO 80601-2-61	
Pulse SpO_2 display	Display of pulse wave, pulse SpO_2
Display resolution	1%
Data averaging and other signal processing time	2s
Data update time	8s
Detection range and accuracy	● Standard SpO_2: the measurement range is 0% ~ 100%; in the range of 70% ~ 100%, the adult/pediatric measurement accuracy is ±2% (non-movement state), and the neonate is ±3% (non- movement state); the measurement accuracy is not defined in the range of 1% ~ 69%; ● Masimo SpO_2: the measurement range is 1% ~ 100%; in the range of 70% ~ 100%, the adult/pediatric measurement accuracy is ±2% (non-movement state) and ±3%(movement state), and the neonate is ±3% (non-movement and movement state); the measurement accuracy is not defined in the range of 1% ~ 69%;

	● NellcorSpO$_2$: the measurement range is 0% ~ 100%; in the range of 70% ~ 100%, the adult/pediatric measurement accuracy is ±2% (non-movement state), and the neonate is ±3% (non-movement state); the measurement accuracy is not defined in the range of 1% ~ 69%;	
Alarm preset limit and resolution	Standard SpO$_2$	Range: 0 ~ 100% Alarm upper limit: (lower limit + 1%) ~ 100% Alarm lower limit: 0%~ (upper limit -1%)
	Masimo SpO$_2$	Range: 0 ~ 100% Alarm upper limit: (lower limit + 1%) ~ 100% Alarm lower limit: 1%~ (upper limit -1%)
	NellcorSpO$_2$	Range: 20 ~ 100% Alarm upper limit: (lower limit + 1%) ~ 100% Alarm lower limit: 20%~ (upper limit -1%)
	Resolution	±1%
Set NIBP and SpO$_2$measurement on the same side	If NIBP and SpO$_2$ are measured on the same side of an arm, you can turn on the NIBP same side switch. The SpO$_2$ physiological alarm state does not change when NIBP measurement is conducted.	
Perfusion index (PI) measurement range, accuracy and resolution	Masimo SpO2 Range: 0.02% ~20%, accuracy is not defined; Resolution: 0.02% ~ 9.99%: 0.01%; 10.0%~ 20.0%: 0.1%. Standard SpO2 Range: 0.05% ~20%, accuracy is not defined; Resolution: 0.05% ~ 9.99%: 0.01%; 10.0%~ 20.0%: 0.1%.	
Signal quality index SIQ indication function	Masimo SpO$_2$ module and Standard SpO$_2$ module should have signal quality index indication function	

（11）Pulse rate specifications

Name	Specifications
Detection range, resolution and error	（1）Standard SpO$_2$ module Measurement range is 20bpm to 254bpm; resolution is 1bpm and measurement error is ±2bpm. （2）Masimo SpO$_2$module Detection range is 25bpm~240bpm; resolution is 1bpm, and measurement error is ±3bpm (in non-movement state) and ±5bpm (in movement state). （3）Nellcor SpO$_2$module Detection range is 20bpm~300bpm; resolution is 1bpm, measurement error is ±3bpm in the range of 20bpm~250bpm; measurement accuracy is not defined in the range of 251bom~300bpm （4）NIBP module Detection range is 40bpm~240bpm; resolution is 1bpm, and measurement error is ±3bpm or ±3%.
Pulse rate alarm preset range and resolution	20~350bpm, alarm upper limit: low limit +1bpm~350bpm, alarm lower limit: 20 bpm~ high limit-1bpm

（12）Body temperature specifications

Name	Specifications	
Detection range and error	Range	34.0℃～42.2℃（93.2℉～108℉））
	Error	At 35.0 ℃ to 42.0 ℃, the measurement error is ±0.2 ℃ (±0.4 ℉) (with sensor error); Other range ±0.3 ℃ (±0.5 ℉)
Display resolution	0.1°C（0.1℉）	
Measurement time	Within 4 seconds	
Unit	℃, ℉	

（13）Wireless connection (optional function)

The monitor features a wireless connection with the infrared in-ear thermometer and adopts 2.4GHz RF wireless transmission mode. In an unobstructed environment, the maximum distance between the monitor and the in-ear thermometer for normal communication is no less than 10m.

（14）Alarm system

Name	Specifications
The alarm system shall meet the requirements of the IEC 60601-1-8 standard	

Appendix IV System Alarm Messages

Some of the most important physiological alarm messages and technical alarm messages are listed in this section. Some alarm messages may not be listed.

XX stands for: a module name or physiological parameter of a system such as HR, TEMP, SpO2, PR, NIBP (SYS, MAP, DIA).

Corresponding solutionsare listed for alarm messages. If the problem persists after the solutionshave been attempted, please contact the maintenance personnel.

In technical alarm classification: A means that it can be completely cleared, B means that the sound and light can be cleared, and C means that it cannot be completely cleared.

The technical alarm level cannot be modified after delivery of monitor.

（1）Physiological alarm messages:

Source	Default level	Adjustable level	Causes	Solution
ECG				
HR too high	Medium	High, medium	The value of measured parameter is above the alarm high limit or below the alarm low limit.	Check the patient's physiological conditions and verify if patient type and alarm limit settings are suitable for the patient.
HR too low	Medium	High, medium		
ECG Lost	Low	Low	The patient's ECG signal is too weak for the system to analyze.	Check the patient's conditions, electrodes, cables and leads.
SpO2				
SpO_2 too high	High	High, medium	The value of measured parameter is above the alarm high limit or below the alarm low limit.	Check the patient's physiological conditions and verify if patient type and alarm limit settings are suitable for the patient.
SpO_2 too low	High	High, medium		
PR too high	High	High, medium, low		
PR too low	High	High, medium, low		
No Pulse	High	High	Patient pulse signal is too weak for the system to analyze.	Check the patient's conditions, SpO_2sensor and measurement part.

NIBP				
SYS/MAP/DIA too high	Medium	High, medium	The value of measured parameter is above the alarm high limit or below the alarm low limit.	Check the patient's physiological conditions and verify if patient type and alarm limit settings are suitable for the patient.
SYS/MAP/DIA too low	Medium	High, medium		
TEMP				
T1 too high	Medium	High, medium, low	The value of measured parameter is above the alarm high limit or below the alarm low limit.	Check the patient's physiological conditions and verify if patient type and alarm limit settings are suitable for the patient.
T1 too low	Medium	High, medium, low		

（2）Technical alarm messages:

Source	Alarm messages	Alarm Level	Alarm category	Causes	Solution
XX	XX Init err	High	A	Error X occurred during XX module initialization	Restart and try again. If the error still exists, contact the manufacturer for repair.
	XX comm stop	High	C	The XX module failed to communicate with the main system.	
	XX comm err	High	A	The XX module failed to communicate normally with the main system.	
XX	XX alm lmt err	Low	C	The alarm limit of XX parameter was accidentally changed.	Contact the manufacturer for repair.
XX	XX overrange	Low	C	The measured value of XX parameter is beyond the measurement range that the system can perform.	
ECG	ECG Lead Off	Low	B	ECG lead is not connected properly.	Check the connection of ECG

Source	Alarm messages	Alarm Level	Alarm category	Causes	Solution
					lead.
	ECG Noise	Low	A	Large interference signal appear in the ECG signals.	Check the connection of ECG lead, check the current conditions of the patient, whether there is a big movement.
SpO2	SpO_2finger off	Low	B	The SpO_2sensor has been removed from the finger.	Check the connection of SpO_2sensor.
	SpO2 No Sensor	Low	B	The SpO_2sensor is not connected properly.	
	SpO2 Low Signal	Low	B		
	SpO_2sensor off	Low	B		
	Nellcor Error, Resetting	Low	C	NELLCOR module error, system is in reset	If the system cannot be reset or if the error still exists after monitor is restarted, please contact the manufacturer for repair.
	Search Pulse	Low	B	The SpO_2sensor is not connected properly, or the patient's arm is moving.	Check the connection of SpO_2sensor and check the current conditions of the patient.
	SpO2 Overrange	Low	C	The measured value is beyond the claimed measurement range	Please follow the manufacturer's stated range for measurement.
	SpO_2low perfusion (masimo)	Low	C	Peripheral circulation is not smooth	Replace other finger or detect if there is limb compression resulting in poor peripheral circulation.

Source	Alarm messages	Alarm Level	Alarm category	Causes	Solution
	SpO_2sensor fault (masimo)	Low	C	Sensor fault	Check and replace the sensor. If the fault still exists, please contact the manufacturer for repair.
	SpO_2 interferenc e (masimo)	Low	C	External interference is too strong	Check the connection of SpO_2lead and check the current condition of the patient for largeactivity.
	Too Much Light (masimo)	Low	C	The patient (sensor) receives too much light. Improper fabric covers the sensor detector.	Check if the SpO_2sensor is clamped properly, remove or reduce the light, cover the sensor from light, and reattach the sensor.
	SpO2 Unknown Sensor (masimo)	Low	C	The sensor is not recognized by the SpO_2module	Check and replace the sensor. If the fault still exists, please contact the manufacturer for repair.
	SpO2 No Cable (masimo)	Low	B	The cable is not connected or not connected properly.	Check and replace the cable. If the fault still exists, please contact the manufacturer for repair.
	SpO2 No Adhesive Sensor (masimo)	Low	C	The sensor is not recognized by the SpO_2module	Check and replace the sensor. If the fault still exists, please contact the manufacturer for repair.
	SpO_2 module error (masimo)	Low	C	Module failure	Return to the manufacturer for repair.
NIBP	NIBP self-test	High	A	Error in NIBP initialization	Select the reset function in the NIBP

Source	Alarm messages	Alarm Level	Alarm category	Causes	Solution
	error				menu. If the error still exists, please contact the manufacturer for repair.
	NIBP comm error	High	A	There is a problem with the NIBP communication section.	
	NIBP init error	High	A		
	Loose cuff	Low	A	NIBP cuff is not connected properly	Please reconnect the NIBP cuff.
	Pneumatic leak	Low	A	NIBP tube has a leak.	Check the connection of each part or change the cuff. If the problem still exists, please contact the manufacturer for repair.
	Pressure Overrange	Low	A	There was a problem with the measurement curve and the system could not perform measurement analysis calculation.	
	Air Leak	Low	A	NIBP cuff is not connected well, or the tube has a leak.	
	Air pressure error	Low	A	There was a problem with the measurement curve and the system could not perform measurement analysis calculation.	
	Weak signal	Low	A	There was a problem with the measurement curve and the system could not perform measurement analysis calculation.	Check if the Patient Type setting is correct, check the connection of each part, or change the cuff. If the problem still exists, please contact the manufacturer for repair.
	Cuff type error	Low	A	It may be that the cuff used does not match the patient type being set.	
	Excessive motion	Low	A	The patient's arm was moving.	Check the connection of each part, and the condition of the patient, and measure again. If the fault still exists, please
	Signal saturated	Low	A	There was a problem with the measurement curve and the system could not perform the measurement analysis	
	NIBP system failure	High	A		

Source	Alarm messages	Alarm Level	Alarm category	Causes	Solution
	NIBP Measure timeout	Low	A	calculation.	contact the manufacturer for repair.
	NIBP Measure Failed	Low	A		
	Over pressure	Low	A	May be the tube is folded	Check if the airway is blocked, check the patient's condition, and measure again. If the fault still exists, please contact the manufacturer for repair.
	NIBP reset error	Low	A	An illegal reset occurred during NIBP measurement.	Check the NIBP tube to see if there is any blockage, and then measure again. If the error still exists, please contact the manufacturer for repair.
	Poor signal (SQI<15%)	Low	B	Signal is poor	
Other alarm messages	Keyboard error	High	C	The system has a fault	Restart the monitor. If the fault still exists, please contact the manufacturer for repair.
	Low battery	Medium	B	Battery is low.	Connect AC power supply to charge the battery. If the fault still exists after the battery has been charged for at least 6 hours, please contact the manufacturer for repair.
	Low battery, shut down in xxS	High	C	The battery is too low, and the system is forced to power off.	Connect AC power supply to charge the battery in time.

（3）System reminder messages:

Source	Alarm messages	Alarm level	Causes
NIBP	Manual Measuring...	None	Thesystemremindermessagesare onlythoseprovidedbythemonitor forafunctionoranactionbeingope rated.
	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	
Alarm disabled reminders	ECG Alarm Disabled!	None	
	Cal...can't monitor!	High	
	Temp Alarm Disabled!	None	
	SpO_2 Alarm Disabled!	None	
	NIBP Alarm Disabled!	None	
Uninstall module reminder	Unload module	None	
Others	Demo	None	
	Screen is locked! Long press main menu to unlock.	None	
	Ip conflict	None	
	Import Succeeded	None	
	Import Failed	None	
	Config Loading Succeeded	None	
	Config Loading Failed	None	
	Delete Config Succeeded	None	
	Delete Config Failed	None	
	Sampling	None	
	Relearn	None	
	The same module exists,only one can be kept!	None	

Appendix V Default Configuration

The following is a list of the various department configurations in the Monitor Configuration Management and some of the most important factory default settings. The user cannot change the factory default configuration but can change the settings as required and save them as a custom user configuration.

1) General configuration

1. Alarm

Name	General	OR	ICU	NICU	CCU
Alarm volume	2				
Alarm record time	8s				

2. Module color

Name		General	OR	ICU	NICU	CCU
Waveform/parameter colors	ECG	Green				
	SpO_2	Black				
	NIBP	White				
	TEMP	White				

3. Review

Name	General	OR	ICU	NICU	CCU
Trend graph resolution	1 second				
Trend table resolution	1 second				

4. Event setup

Name	General	OR	ICU	NICU	CCU
Wave 1	PLETH				
Wave 2	I				

5. Record

Name	General	OR	ICU	NICU	CCU
Wave 1	PLETH				
Wave 2	Off				
Waveform record output speed	25 mm/s				
Realtime record time	8 seconds				
Timed record interval	Off				
Grid	On				

6. Maintenance items

Name		General	OR	ICU	NICU	CCU
Waveform draw		Laddering				
Waveform line		Thin				
Alarm setup	Alarm mute reminder	Off				
	Alarm tone	1 minute				

	interval	
	Alarm tone volume	1
	Min alarm volume	2
	Alarm pause time	2 minutes
	Alarm delay time	Disabled
Nurse call	Nurse call switch	Off
	Alarm level	High
	Alarm type	Technical + Physiological

7. Module smart parameter alarm limit default

Name		General	OR	ICU	NICU	CCU
HR	ADU	H40 M50 -- M120 H130				
	PED	H60 M75 -- M160 H170				
	NEO	H90 M100 -- M200 H210				
SpO_2	ADU	H85 M90 -- M100 H100				
	PED	H85 M90 -- M100 H100				
	NEO	H85 M90 -- M100 H100				
PR	ADU	H30 M40 L50 -- L120 M130 H140				
	PED	H55 M65 L75 -- L160 M170 H180				
	NEO	H80 M90 L100 -- L200 M210 H220				
SYS(NIBP)	ADU	H80 M90 -- M160 H170				
	PED	H50 M70 -- M120 H140				
	NEO	H40 M40 -- M90 H100				
MAP(NIBP)	ADU	H50 M60 -- M110 H120				
	PED	H40 M50 -- M90 H100				
	NEO	H20 M25 -- M70 H80				
DIA(NIBP)	ADU	H40 M50 -- M90 H100				
	PED	H30 M40 -- M70 H80				
	NEO	H10 M20 -- M60 H70				

Note: The PRsmart alarm limit is H 30 M 40 L 50 --- 120 L 130 M 140 H

When PR<30 or 140<HR, the alarm level is automatically set to H (High)

When 30≤PR<40 or 130<PR≤140, the alarm level is automatically set to M (Medium)

When 40≤PR<50 or 120<PR≤130, the alarm level is automatically set to L (low)

When 50 ≤PR ≤ 120, it is a normal value and does not trigger an alarm.

8. Module common parameter alarm limit default

Name		General	OR	ICU	NICU	CCU
HR	ADU	50 -- 120 M				
	PED	75 -- 160 M				
	NEO	100 -- 200 M				

SpO_2	ADU	90 -- 100 H
	PED	90 -- 100 H
	NEO	90 -- 100 H
PR	ADU	50 -- 120 H
	PED	75 -- 160 H
	NEO	100 -- 200 H
SYS(NIBP)	ADU	90 -- 160 M
	PED	70 -- 120 M
	NEO	40 -- 90 M
MAP(NIBP)	ADU	60 -- 110 M
	PED	50 -- 90 M
	NEO	25 -- 70 M
DIA(NIBP)	ADU	50 -- 90 M
	PED	40 -- 70 M
	NEO	20 -- 60 M
TEMP	ADU	36.0-39.0 M
	PED	36.0-39.0 M
	NEO	36.0-39.0 M

2) Default settings

1. ECG default settings

Name	General	OR	ICU	NICU	CCU
Lead name	I				
Gain	X1				
Sweep	25 mm/s				
Filter mode	Monitoring				
HR source	ECG				
Alarm switch	ON				
Alarm record	Off				
Alarm level	Medium				
Power frequency reject	ON (50HZ)				
HR alarm limit	Note: The HR parameter adopts smart alarm. The default alarm limit is shown in Table 7 in General Settings.				

2. SpO_2 default settings

Name	General	OR	ICU	NICU	CCU
Sweep	25 mm/s				
Sat-Second(Nellcor)	50s				
Average time (Masimo)	8s				
NIBP Same Side	OFF				
Smart Tone	ON				
Sensitivity (Masimo)	APOD				
Signal IQ	ON				
Alarm switch	ON				

Alarm record		OFF
Alarm level (Nellcor)		High
SpO_2alarm limit (Nellcor)	ADU	(90 --- 100)
	PED	
	NEO	(90 --- 100)
SpO_2alarm limit		Smart alarms are used for Masimo and Digital SpO_2parameters. The default alarm limits are shown in Table 7 in "General Configuration".

3. PR default settings

Name	General	OR	ICU	NICU	CCU
Alarm switch	ON				
Alarm record	OFF				
PR source	SpO_2				
Alarm level	High				
PR alarm limit	Smart alarm is used for PR parameters. The default alarm limit is shown in Table 7 in "General Configuration"				

4. NIBP default settings

Name		General	OR	ICU	NICU	CCU
Patient type		Adult				
Measure mode		Manual				
Interval		1 minute				
Initial pressure	ADU	160				
	PED	120				
	NEO	100				
Cuff pressure	ADU	80				
	PED	60				
	NEO	40				
Alarm switch		ON				
Alarm record		OFF				
Alarm level		Medium				
NIBP alarm limit		Smart alarm is used for NIBP parameters. The default alarm limit is shown in Table 7 in "General Configuration"				

5. TEMP default settings

Name	General	OR	ICU	NICU	CCU
Alarm switch	ON				
Alarm record	OFF				
Alarm level	Medium				

Appendix VI EMC

Note

- **The Vital Signs Monitor meets the requirements of IEC60601-1-2 standard for electromagnetic compatibility.**
- **Users should install and use the electromagnetic compatibility information provided in the attached document.**
- **Portable and mobile RF communication equipment may affect the performance of the Vital Signs Monitor. So, avoid strong electromagnetic interference during use, such as mobile phones, microwave ovens, etc.**
- **For guide and manufacturer statement, see the attachment.**

Warning

- **The device or system should not be used close to or stacked with other devices. If it is necessary to do so, observe and confirm that the device can operate normally in the configuration in which it is used.**
- **Class A equipment is intended for use in industrial environments. Due to conducted disturbances and radiated disturbances of the Vital Signs Monitor, it may be potentially difficult to ensure electromagnetic compatibility in other environments.**
- **If the physiological parameters measured by the device are less than the specified minimum amplitude (heart rate: 15 bpm, blood pressure: systolic blood pressure 40 mmHg, diastolic blood pressure 10 mmHg, average pressure 20 mmHg, pulse rate 20 bpm), it may lead to inaccuracies.**
- **In addition to the cables sold by the manufacturer of the Vital Signs Monitor as spare parts for internal components, the use of other accessories and cables not specificed may result in increased emissions or reduced immunity of the Vital Signs Monitor.**

Attachments:

The following cables must be used to meet electromagnetic emissions andinterference immunity requirements:

No.	Name	Cable length (m)	Shielded or not	Notes
1	Power cord	3.0	No	/
2	ECG lead	3.6	Yes	98ME01EC681
3	ECG lead	3.6	Yes	98ME01AC458
4	ECG lead	4.1	Yes	98ME01AD473

No.	Name	Cable length (m)	Shielded or not	Notes
5	ECG lead	4.1	Yes	98ME01EB477
6	ECG lead	3.2	Yes	A3105-EC1
7	ECG lead	3.2	Yes	A3105-EC0
8	Simulated adult finger-clip SpO_2 sensor	1.0	Yes	SAS104
9	Simulated binding SpO_2 sensor	1.0	Yes	SES104
10	Simulated adult finger-clip SpO_2 sensor	1.0	Yes	SAL104
11	Simulated adult finger-clip SpO_2 sensor	3.0	Yes	A0816-SA105PV
12	SpO_2 sensor extension cord	3.0	Yes	SLZ068
13	Pulse SpO_2 sensor	0.9	Yes	M-LNCS YI
14	Sensor	0.9	Yes	M-LNCS DCI
15	Masimo SpO2 sensor extension cord (main cable)	3.0	Yes	M-LNC-10
16	SpO_2 sensor	0.9	Yes	D-YS
17	SpO_2 sensor	0.9	Yes	DS100A
18	NELLCOR SpO_2 extension cord	3.0	Yes	DOC-10

Table1

Guide and manufacturer statement - Electromagnetic emission		
The monitor is intended for use in the electromagnetic environment specified below, and the purchaser or user of the monitor should ensure that it is used in this electromagnetic environment:		
Emission test	**Conformity**	**Electromagnetic environment – guide**
Radio frequency(RF) emissions CISPR 11	Group 1	The monitor uses RF energy for its internal functions only. Therefore, its RF emissions are low and do not cause any interference to nearby electronic devices.
RF emission CISPR 11	Class A	The monitor is suitable for use in all facilities that are not in a home and are not directly connected to residential public low-voltage power supply network for domestic use.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/flicker IEC61000-3-3	Compliant	

Table2

Guide and manufacturer statement - Electromagnetic Immunity			
The monitor is intended for use in the electromagnetic environment specified below, and the purchaser or user of the monitor should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC60601test level**	**Compliance level**	**Electromagnetic environment – guide**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	The floor should be wood, concrete or ceramic. If the floor is 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	The network power supply should meet the quality used in 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	The network power supply should meet the quality used in 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 for 0.5 cycle: at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 ° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles: at 0 ° 0 % U_T for 250/300 cycle	0 % U_T for 0.5 cycle: at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 ° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles: at 0 ° 0 % U_T for 250/300 cycle	The network power supply should meet the quality used in a typical commercial or hospital environment. If the user of the monitor needs operate it continuously during a power outage, it is recommended to power the monitor with an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m,50/60 Hz	30 A/m	The power frequency magnetic field should have a power frequency magnetic field level characteristic in a typical commercial or hospital environment.
Note: U_T refers to the AC network voltage before the test voltage is applied.			

Table3

<table>
<tr><th colspan="4">Guide and manufacturer statement - Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The monitor is intended for use in the electromagnetic environment specified below, and the purchaser or user of the monitor should ensure that it is used in this electromagnetic environment:</td></tr>
<tr><td>Immunity test</td><td>IEC60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guide</td></tr>
<tr><td>RF Conduction
IEC 61000-4-6</td><td>3 V
150 kHz to 80 MHz
6 V in the ISM band between 0.15 MHz and 80 MHz</td><td>3 V
6 V in the ISM band between 0.15 MHz and 80 MHz</td><td rowspan="2">Portable and mobile RF communication equipment should not be used closer to any part of the monitor, including cables, other than at the recommended isolation distance. This distance should be calculated by the formula corresponding to the transmitter frequency.
Recommended isolation distance
$d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ 150 KHz to 80 MHz
$d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 80 MHz to 2.7 GHz
Wherein, P is based on the transmitter's maximum output rated power, in watts (W), and d is the recommended isolation distance in meters (m). The field strength of a fixed RF transmitter is determined by surveying the electromagnetic field [a], and each frequency range [b] should be lower than the compliance level.
Interference may occur near devices marked with the symbol  .</td></tr>
<tr><td>RF Radiation
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.
Note 2: These guides may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.</td></tr>
<tr><td colspan="4">a) For fixed transmitter field strength such as wireless (cellular / cordless) phones and ground mobile radio base stations, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts and television broadcasts, etc., the field strength is not theoretically accurate and cannot be predicted. In order to assess the electromagnetic environment of a stationary RF transmitter, an electromagnetic field survey should be considered. If the field strength at the site where the monitor is located is higher than the RF compliance level for the above application, the monitor should be observed to verify proper operation. Additional measures may be necessary if abnormal performance is observed, such as reorienting or repositioning the monitor.
b) The field strength should be less than 3 V/m over the entire frequency range from 150 kHz to 80 MHz.</td></tr>
</table>

Table4

Recommended isolation distance between the portable and mobile RF communication device and the Monitor			
The monitor is expected to be used in an electromagnetic environment where radiated RF disturbances are controlled. Depending on the maximum output power of the communication device, the purchaser or user of the monitor can maintain the minimum distance between the portable and mobile RF communication device (transmitter) and the monitor as recommended below, preventing electromagnetic interference.			
Transmitter rated maximum output power / W	**Isolation distances corresponding to different frequencies of the transmitter /m**		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	**80 MHz ～ 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz～ 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the rated maximum output power of the transmitter not listed above, the recommended isolation distance *d*, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where *P* is provided by the transmitter manufacturer. Transmitter maximum output rated power in watts (W). Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used. Note 2: These guides may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.			

Table5

declaration - IMMUNITY to proximity fields from RF wireless communications equipment						
The monitor is intended for use in an electromagnetic environment in which RF wireless communications equipment are controlled.						
Immunity test	IEC60601 test level				Compliance level	Electromagnetic environment - guidance
	Test frequency	Modulation	Maximum power	Immunity level		
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m	
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m	
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
	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 Hazardous Substances or Elements

Part name		**Pb**	**Hg**	**Cd**	**Cr(VI)**	**PBB**	**PBDE**
Housing	Front housing	O	O	O	O	O	O
	Rear housing	O	O	O	O	O	O
	Button	O	O	O	O	O	O
	Facing	O	O	O	O	O	O
	Label	O	O	O	O	O	O
Display	Display	×	×	×	×	×	×
Main unit	Hardware	O	O	O	×	O	O
	Internal connection cable	O	O	O	O	O	O
	PCBA	×	O	O	O	O	O
Package	Packaging materials	×	×	O	O	×	×
General	Connectors	O	O	O	×	O	O
	Power cord	O	O	O	O	O	O
Battery	Li-battery	×	×	×	×	×	×
Accessories	ECG accessories	×	O	O	O	O	O
	SpO_2 accessories	×	O	O	O	O	O
	In-ear thermometer accessories	×	O	O	O	O	O
	NIBP accessories	×	O	O	O	O	O
Notes	O：Indicates that the content of the toxic and hazardous substance in all homogeneous materials of this part is below the limit requirement specified in SJ/T11363-2016. ×：Indicates that the content of toxic and hazardous substance in a certain homogeneous material of the part at least exceeds the limit requirement specified in SJ/T11363-2016.						

Appendix VIII List of Key Components

Kind of Component	Type
Plug (EU)	BP-370L
Supply cord (EU)	H05VV-F
Connector (EU)	BC-313
Power inlet	SS-120
Internal primary wires	1015
Internal primary wire connector (female)	2139
SMPS	MEP-25A15J
Mylar sheet	MYLAR A(PET)
Plastic enclosure	ABS(AF342)
LCD display	EJ080NA-05B
Lithium battery(Low capacitor)	022-000113-00
Lithium battery(High capacitor)	022-000114-00
Transformer of SpO_2 (U6)	MKB15-039
- primary and secondary coil	2UEW
- bobbin	T375J
- nsulation tape	PZ/CT
- margin tape	WF-2902
- tube	CB-TT-L
- vanish	8562/A
Optocoupler U10	VO615A- 9X017T
Non-optical isolator (U11)	ADuM2201BRIZ
High voltage resistor (R97)	MHR0314SA107F70
PCB	HF-4
Transformer of ECG (BT1)	MKB15-039
- primary and secondary coil	2UEW
- bobbin	T375J
- insulation tape	PZ/CT
- margin tape	WF-2902
- tube	CB-TT-L
- vanish	8562/A
Optocoupler U13	VO615A- 9X017T
Non-optical isolator (U14)	ADuM2201BRIZ
High voltage resistor (R105)	MHR0314SA107F70

Surge arrester of ECG (D7; D11)	B3D090L
PCB	HF-4
NIBP pressure sensor (U1; U2)	MPS3117-006GC
NIBP pressure relief valve (fast and slow)	CJV13-A12A22
NIBP pump	CJP37-C12B1