

INFINIUM

CLEO2 Patient Monitor

User's Manual

V1.0

Infinium Medical Inc.

Introduction

Thank you for choosing CLEO2 patient monitor

Before using the product, please read this manual carefully for proper use.

After reading, please properly keep this manual for reference at any time when needed.

Product Name: Patient Monitor

Model Name: CLEO2

General Information:

This monitor can monitor the patient's blood oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), end-expiratory carbon dioxide (EtCO2), and body temperature (Temp). The monitoring information can be displayed, reviewed, stored, and printed.

Product Components:

This product consists of a main unit, a battery and accessories (blood oxygen probe, blood pressure cuff and its extension tube, infrared thermometer).

Indications for Use:

This device is intended for patient use by trained healthcare professionals in a hospital environment.



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【Manufacturer Responsibility】

Infinium is responsible for the effects on safety, reliability and performance of this product, only if:

- 2 All installation operations, expansions, changes, modifications and repairs of this product are conducted by Infinium authorized personnel;
- 3 The electrical installation of the relevant room complies with the applicable national and local requirements;
- 4 The product is used in accordance with the instructions for use.

【Note】

The equipment can't be used at home.

WARNING

- This patient monitor is intended for use only by clinical professionals or at least under their guidance. It must only be used by trained personnel in its use. Anyone unauthorized or untrained must not perform any operation on it.

Preface

【Manual Description】

This manual describes the uses, features, operations and safety messages of the patient monitor. Before using this equipment, observance of the manual is a prerequisite for proper performance and correct operation and ensures patient and user safety.

Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.

【Intended Audience of this Manual】

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices and terminology, as required for the monitoring of all patients.

【Illustrations】

This manual uses illustrations for examples only. Illustrations in this manual may not necessarily reflect all system settings, features, configurations or data display.

【Convention】

Italics: Used to indicate the quoted sections.

【 Character 】 : Used to represent strings in software.

→ : This symbol is used to indicate the steps during an operation.

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Chapter 1 Safety Guide

Safety Information

WARNING

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

CAUTION

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

NOTE

- Emphasize important precautions, provide explanations or clarifications to better use this product.

1.1.1 Warning

WARNING

- — SINGLE PATIENT USE — This equipment is designed for use on one patient at a time.
- To avoid explosion hazard, do not use the equipment in the presence of flammable anesthetics, vapors or liquids.
- Do not use monitoring sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.
- Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.
- Do not touch electrical equipment and the patient at the same time. This may cause an unsafe

electrical shock to the patient.

- Do not come into contact with patients during defibrillation. Otherwise, serious injury or death could occur.
- Do not open the casing of the equipment; otherwise, there may be an electric shock risk. Maintenance must be carried out by the manufacturer or professional technicians authorized and recognized in writing by the manufacturer.
- The installation of the instrument should be carried out in a dry environment free from corrosive gases and strong electromagnetic field interference.
- The alarm volume and limit should be set according to the actual situation of the patient. One cannot rely solely on the sound alarm system to monitor patients. There may be risks in adjusting the alarm sound to a lower volume or turning it off. Close attention should be paid to the actual clinical condition of the patient.
- The waveforms, physiological data and alarm messages displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.
- Wrap and secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel
- Batteries must be taken out when the equipment is not used.
- The software copyright of the equipment is solely owned by the manufacturer. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.

1.1.2 Caution

 **CAUTION**

- To ensure patient safety, use only parts and accessories specified in this manual.
- Magnetic and electrical fields are capable of interfering with the proper performance of this equipment; Thus, this monitor shouldn't be operated with other High frequency equipment (especially high RF equipment) in the same site. High RF equipment shouldn't stay too close to this monitor, otherwise the normal function of this monitor might be affected.
- Do not lift the monitor by pulling on the sensor cable or power cord, as these cables may be disconnected from the monitor and the equipment may fall and injure the patient.
- Patient monitors are precision medical instruments. Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.

Do not pull, twist, or rub the lead wires.

- Please keep the lead wires and patient monitor dry to avoid the inaccurate measurement result, product damage or any potential risks that might harm the patient. Dry the equipment immediately when it gets wet.
- Some configurations are protected by passwords. If you need to use password to access these functions, please contact associated personnel.
- An indicated potential hazard or unsafe practice that, if not avoided, could result in minor personal injury, product malfunction, damage or property loss.
- Both the monitor and the devices that connected to this equipment, must be grounded together.
- Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g., IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration and all lead wires must meet the requirements of the IEC 60601-1 medical electrical systems standard.
- Anyone who configors the medical system when connecting additional devices to the signal input or output port (monitor data port connector) is responsible for ensuring that the system complies with the requirements for the system in IEC 60601-1-1 standard and the requirements for electromagnetic compatibility in IEC 60601-1-2 standard.
- Environment and patient condition must be considered to ensure the precision of measurement. For special safety instructions on these conditions, see chapters of this manual for reference accordingly.
- Chemical leakage from broken LCD is poisonous and adverse health consequences might occur once the leaking liquid enters human body. Please do take care when carrying patient monitors with broken LCD screens.
- Package material may contaminate the environment. Properly dispose of the package material according to applicable waste control regulations and keep it out of children's reach.
- At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.

1.1.3 Notes



5 Put the equipment in a location where you can easily view, operate and maintain it.

- This device uses a power plug to disconnect from the AC power supply. Please place this device in a location where it is convenient to plug and unplug the power plug.
- For proper operation, the operator shall stand in front of the equipment.
- Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.

1.1.4 Cybersecurity Statement

- When communicating between devices, please ensure that identifiers are correct, and manually verify the connection to ensure the device is properly connected and the information is authentic.
- Please connect devices only in secure and trusted network environments, avoiding public Wi-Fi or networks from unknown sources to prevent data leakage.
- Before connecting to the network, ensure that the network has a strong password set and appropriate security measures (such as WPA2 encryption) are enabled.
- An internationally recognized Software Bill of Materials (SBOM) in SPDX format has been generated, and it supports the conversion to other widely-used SBOM formats in the industry, such as CycloneDX and SWID. If needed, please email us, and we will provide the latest SBOM list.
- Please periodically check for software updates in the upgrade interface while connected to the network and have professional technicians perform device upgrades and maintenance.
- Ensure that your network environment has up-to-date firewall and antivirus software installed to protect against malware and virus intrusions.
- Please use the manufacturer's provided charging accessories (e.g., cables, chargers, adapters) to charge the medical device.

6 Avoid using third-party charging accessories, including those made by different manufacturers or for different devices.

7 The manufacturer's provided accessories limit the power supplied for safe battery charging. Third-party accessories may allow higher power, increasing the risk of overheating, sparking, or fire, potentially causing minor to severe injury or burns.

- Place the device away from other electronic devices that may cause interference, such as Wi-Fi routers and microwave ovens, to ensure stable wireless communication.
- During the device's service life, we will provide continuous tracking and resolution of security issues. If the device exceeds its useful life, we cannot guarantee the reasonable

provision of security patches and software updates. Using a device after support has ended may pose security risks, and we recommend discontinuing its use.

- This device will encrypt and protect personal information stored in the app.

After the device is deactivated and the service is terminated, personal information will be processed in strict accordance with the U.S. ADPPA (American Data Privacy Protection Act) and HIPAA (Health Insurance Portability and Accountability Act) security requirements.

Electromagnetic Interference

Due to the dramatic increase in the number of radio frequency transmitters or other sources of electronic interference (such as electronic surgical equipment, cell phones, two-way radar for vehicles, electronic devices, etc.) in medical care settings. The high level of interference caused by the immediate vicinity, or strong transmitter power of the interfering sources may interrupt the normal function of this equipment.

This monitor is designed for use within a specified electromagnetic environment. However, Certain electromagnetic interference may cause blurred or erroneous measurements, even worse, the malfunction of the equipment.

Interference may manifest itself in erratic readings, interruptions in operation or other functional errors. If this occurs, the working environment should be investigated to identify the source of the interference and eliminate it.

- Turn on and off the appliances in the vicinity to find out the interfering appliance.
- Redirect or relocate other receiving devices.
- Keep away from the interfering devices.

This patient monitor may generate or emit the energy of radio frequency, if not used properly according to the manual, it might cause harmful interference with other devices in the vicinity.

Equipment Symbols

Symbols	Explanation
	NOTE! Consult documents accompanying this monitor.
	WARNING!
	Please refer to the random file

	Power ON/OFF (for a part of the equipment)
	Anti-defibrillation CF type application part
	Anti-defibrillation BF type application part
	BF type application part
	Rechargeable battery
	Fuse replacement requirements
	Equipotential grounding
	Computer network
	AC Power
	Battery indicator
	AC/DC dual-use
	DC Power
SN	Serial number
	Date of manufacture
	Manufacturer
	Fragile, handle with care
	This way up.

	Keep dry. Protect from rain.
	Stacking limit by number: Maximum number is 8 for the symbol in the illustration.
	USB Interface
IPX2	Waterproof grade marking
	Non-ionizing radiation



NOTE

- Your device may not have all the above symbols.

Chapter 2 Equipment Introduction

Intended Use

This monitor is used to monitor multiple physiological parameters of adults, pediatrics, and neonates, providing important physiological information of patients for medical clinical diagnosis. It can monitor important parameters such as blood oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), end-respiratory carbon dioxide (EtCO2) and body temperature (Temp) of the human body in real time. Guardianship information can be displayed, reviewed, stored, alarmed, printed and transmitted.

This product is expected to be used in medical institutions. It can monitor the important vital characteristic parameters of patients regularly, continuously and for a long time, and it has important clinical application value in ensuring the life safety of patients.



WARNING

- This patient monitor is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Operation by patient is not prohibited.

Operating Principle

The monitor operates based on the principle that various physiological changes are probed through sensor, amplified through signal booster, and ultimately turned into electrical information for analysis. The monitor software will calculate, analyze and edit the data, and display it in parameter area. You can also record and print it out as needed. When the measured data exceeds the alarm limit, it will trigger the alarm for action.

Contraindications

Non-invasive blood pressure (NIBP) should not be measured in patients with sickle cell disease.

Components

The product consists of a main unit, a battery and accessories (blood oxygen probe, body temperature probe, blood pressure cuff, infrared thermometer).

Main Unit

2.5.1 Front View



Figure 2-1 Front View

Number	Explanation	Symbol
1	<p>Alarm indicator light:</p> <p>Indicate the levels of technical and physiological alarms with different colors and flashing frequencies:</p> <p>High: Red with quick flashes, 2 flashes per second</p> <p>Medium: Yellow with slow flashes, 1 flash per second</p> <p>Low: Blue and green without flashes</p>	
2	Display screen	

3	<p>Battery status indicator light:</p> <p>ON: when the battery is being charged or already fully charged.</p> <p>Flash: when the patient monitor operates on battery power.</p> <p>OFF: when no battery is installed or no AC source is connected.</p>	
3	<p>AC Power indicator:</p> <p>ON: when AC power is connected.</p> <p>OFF: when AC power is connected.</p>	

2.5.2 Side View



Figure 2-2 Side View

Number	Explanation	Symbol
1	Thermal Sensitive Recorder	
2	NIBP Cuff Interface	NIBP
3	SpO2 Sensor Interface	SpO2

4	EtCO ₂ air inlet interface	
5	EtCO ₂ waste discharge outlet	
6	Power on/off key: Used to turn the monitor on/off	

2.7.3 Rear View



Figure 2-3 Rear View

Number	Explanation	Symbol
1	Monitor handle	
2	AC Power Input: 100~240VA, C50/60Hz, 1.3~0.5A	
3	Equipotential Grounding: connecting other instruments and equipment with equipotential grounding system to eliminate the ground potential difference between different equipment to ensure safety	
4	Nurse Call Interface	
5	External DC Power Supply Interface	

6	USB Type-C Interface	Type-C
7	USB Interface	USB
8	RJ45 Enternet Interface	

Display Screen

This patient monitor uses a high-resolution 10.1 inches LCD to display patient parameters and waveforms. A typical display screen is shown below.

2.6.1 Mornitoring View

The conventional display interface under normal monitoring is shown in Figure 2-4.

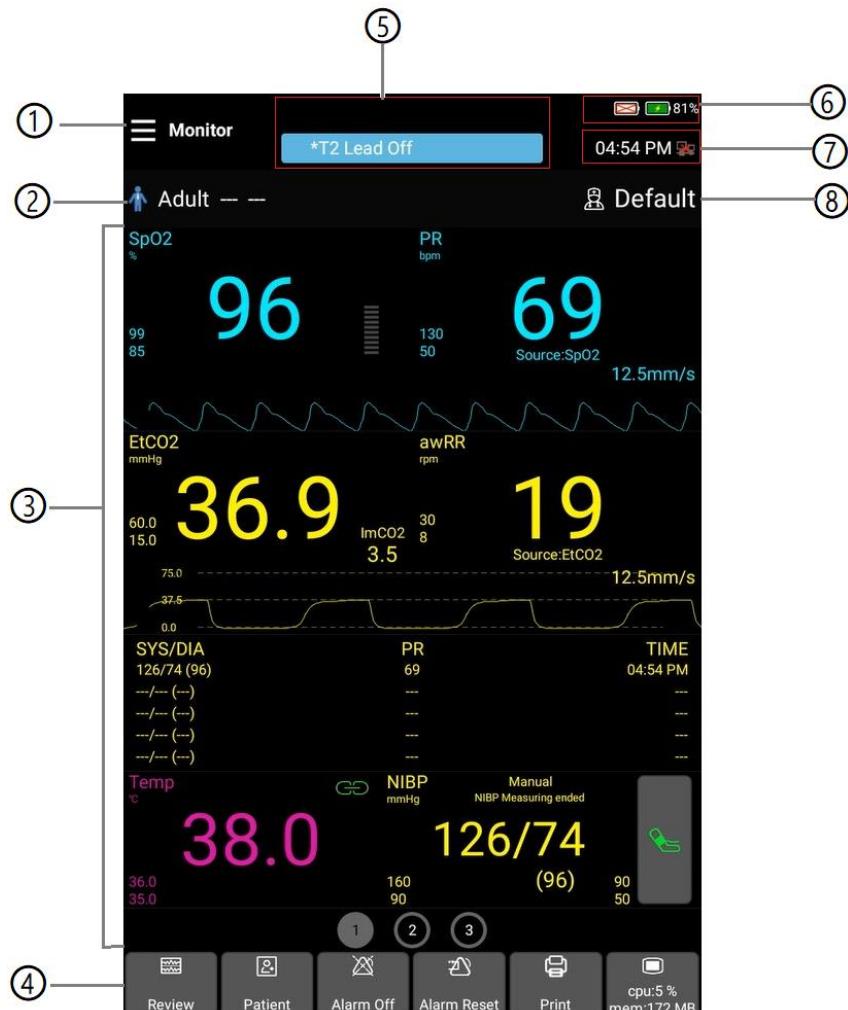


Figure 2-4 Mornitoring View

Number	Explanation
1	Mode selection: Display the current mode and perform mode switching.

2	Patient Information Area: This area shows the patient information such as patient category, name, gender, ID. The displayed patient information is configurable. Click to enter the patient management menu.
3	Parameter Area: Display parameter values, waveforms, alarms, etc. Click to enter the corresponding parameter menu.
4	Shortcut key area: Display the shortcut keys. These shortcut keys will change due to the adjustment of the working mode.
5	Alarm Information Area: The upper part of this area displays physiological alarm information, while the lower part shows technical alarm information. Prioritize the display of high-level alarms. When multiple alarms of the same level exist simultaneously, they will be displayed in a loop. Select this area to view the details of the alarm information.
6	Battery status information area: Display the battery status and battery power.
7	Equipment status information area: Display the network status and time.
8	Configuration information area: Display the current configuration name and select it to enter the configuration management menu.

2.6.2 Shortcut key

These function shortcut keys allow you to quickly access certain functions. The shortcut key area is located at the bottom of the screen. These shortcut keys may vary due to the Settings of the working mode.

The following table shows the available shortcut keys.

Shortcut key	Name	Function
	Main menu	Enter the main menu
	Patient management	Enter the patient management menu
	Alarm Paused	Pause or Recover the current alarm
	Alarm Audio Paused	Pause or Recover the current alarm audio

	Print	Start/Stop printing
	Config Manager	Open configuration management menu
	Trend Review	Open trend review window for current patient
	Alarm Reset	Reset the alarm system
	Alarm Off	Turn off the alarm
	Alarm Audio Off	Turn off the alarm audio
	Save	Save the currently displayed data
	Clear	Clear the current measurement data

2.6.3 Symbols

Symbols	Explanation	Symbols	Explanation
	Adult Patient, male		Adult Patient, female
	Pediatric Patient, male		Pediatric Patient, female
	Neonatal Patient, male		Neonatal Patient, female
	Patient monitor has no network connection		Patient monitor is connected to a wire network successfully.
	Alarms are turned off.		Alarms are paused.
	Alarm audio is turned off.		Alarms audio is paused.
	Alarm reset		No battery is installed
	Battery failure		Full battery
	Batteries work correctly. The solid portion represents the current charge level of the batteries in proportion to its maximum charge level.		Low battery, needs to be charged

Chapter 3 Equipment Preparation

3.1 Description

The following section describes the basic operations of the monitor before it is used.

3.2 Safety Precautions

WARNING

- Please use the installation accessories authorized by us.
- The software copyright of the equipment is solely owned by us. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
- Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g., IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1-1. If you have any question, please contact us.
- If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or else an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.
- **ACCURACY** - If the accuracy of any value displayed on the monitor, central station, or printed on a graph strip is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.
- **The operator should check whether the current alarm preset is suitable for the current patient before use.**

CAUTION

- Please keep the packaging material out of children's reach. When disposing of it, be sure to observe the applicable waste control regulations.
- The equipment might be contaminated during storage and transport. Before use, please verify

whether the packages are intact, especially the packages of single-use accessories. In case of any damage, do not apply it to patients.

- Make sure that the operating environment of the equipment meets the specific requirements. Otherwise, unexpected consequences, e.g., damage to the equipment, could result.
- Please read this manual thoroughly to ensure the proper use of the product and safety of both patient and operator.



NOTE

- Put the equipment in a location where you can easily view, operate and maintain it.
- Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.
- Save the packing case and packaging material as they can be used if the equipment must be reshipped.

3.3 Installation

3.3.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or the manufacturer. If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. If you have any question, please contact us.

3.3.2 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual.

The environment where the equipment is used shall be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances. If the equipment is installed in a cabinet, sufficient space in front and behind shall be left for convenient operation, maintenance and repair. Moreover, to maintain good ventilation, the equipment shall be at least 2 inches (5 cm) away from around the cabinet.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

3.4 Preparations before use

Please read this manual carefully before using this monitor to be familiar with the performance, operation methods and precautions of the instrument.

3.4.1 Install the battery

It is recommended to always install a fully charged battery in the monitor to ensure normal operation in case of unexpected power failure.

Install the battery according to the following steps:

1. Make sure the monitor is turned off and all cables are disconnected.
2. Lay the monitor down to check the bottom of the monitor.
3. Unscrew the fixing screws on the battery compartment cover and slide it down.
4. Place the battery correctly in the battery compartment.
5. Cover the battery compartment cover and screw on the screws.



Figure 3-1 Battery compartment cover

3.4.2 Connecting to AC Power Source

This monitor is powered by an AC power supply. Before connecting the AC power supply, please first confirm that the voltage and frequency of the AC power supply are the same as those marked on the power plug.

Connect the AC power supply by following the steps below:

1. Plug the power cord into the AC power source.
2. Plug the other end of the power cord into a grounded three-wire power outlet.
3. Check if the AC power status indicator is on to ensure the proper connection with AC power.

AC power status indicator is on the right side of **ON/OFF** button. The green LED illuminates when the monitor is receiving AC power. Otherwise, the indicator is off.

WARNING

- Use the power cord provided in the product package for power connection.
- Before connecting to the AC power sources, please ensure the voltage and frequency are the same as marked on the device or meet the requirement of this manual.
- To avoid the risk of electrical shock, Use the battery if the integrity of the protective earth (ground) conductor is in doubt.

3.5 Turning Power On

Before you turn on the monitor, please get ready for monitoring:

1. Check the patient monitor, and plug-in modules for any mechanical damage and make sure that cables, modules and accessories are properly connected.
2. Plug the power cord into the AC power source. If you run the patient monitor on battery power, ensure that the battery is sufficiently charged.

Press the Power **ON/OFF** button for 3s to turn on the equipment. The alarm light and the key backlight will illuminate, the welcoming screen will appear with a page indicating “**>LoadingSystem ...**” message, after 1-2min, the initialization of monitoring will begin after the with the **monitoring LOGO** on screen. Around 20s later, the initialization will be completed and the monitor enters the main screen. Now we could start monitoring.



CAUTION

- If the monitor is damaged or fails to work properly, it cannot be used for patient monitoring. Please contact the maintenance personnel or our company immediately.

3.6 Operation and Browsing

All the elements required to operate the monitor are included on its screen, and almost every element on the screen is interactive. These screen elements include parameter measurement values, waveforms, hotkeys, information areas, alarm areas and menus, etc. Usually, you can access the same element in different ways. For example, you can enter the Settings menu of a certain parameter by selecting the parameter area or waveform area of a certain parameter, or by choosing the hotkey of the [Main Menu] on the main interface → selecting [Settings] from the [Parameters] column → selecting parameters.

3.6.1 Using the Touchscreen

Information input can be completed through the touch screen. Some operations can be completed conveniently and quickly by simply clicking on the touch screen.



CAUTION

- The touchscreen must be wiped off with water droplets after being rained on or splashed with water before being used again.

3.6.2 Use the mouse

This monitor can be connected to a mouse via the USB interface of the device.

3.6.3 Use a soft keyboard

This monitor provides a soft keyboard for information input. The functions of the soft keyboard are as follows:

- Select the characters on the keyboard for input.
- Use key to delete the previous character.
- Use key to switch between upper and lower case English letters.
- Use key to confirm that the input is complete and turn off the soft keyboard.

3.7 Equipment configuration

Before using the monitor for the first time, it is necessary to set it up.

3.7.1 Set the working mode

This monitor supports both monitoring mode and spot check mode.

The monitoring mode supports continuous monitoring of physiological parameters.

The spot check mode supports the spot check of physiological parameters.

3.7.2 Set the volume

The key volume can be set according to the following steps:

1. Select the hotkey of **[Main Menu]** → Select **[Volume]** from the **[Device]** column.
2. After entering the volume setting menu, you can set the alarm volume and key volume.

The volume can be set within the range of 0 to 5.

3.7.3 Set the brightness

The screen brightness can be set according to the following steps:

1. Select the hotkey of the **[Main Menu]** → From the **[Device]** column, choose **[Brightness]**.
2. After entering the brightness setting menu, you can set the device's brightness. The adjustable range for brightness is 0 to 10.

3.7.4 Set the language

To change the language Settings, please follow the steps below:

1. Select the hotkey of **[Main Menu]** → From the **[System]** column, select **[Maintenance]**;
2. After entering the password, enter the maintenance function interface and select the language;
3. Then select the target language from the pop-up list to switch.

3.7.5 Set the date and time

The steps for setting the system time are as follows:

1. Select the **[Main Menu]** → From the **[System]** column, select **[Time]** to enter the event Settings menu.
2. Select **[Date]** to set the current date and time.
3. Set the **[Time Display Format]** and manually switch between **[12-hour]** and **[24-hour]**.



CAUTION

- Changing the date and time will affect the storage of trends and events and may lead to data loss.

3.7.6 Set up the network

This monitor supports both wireless WIFI and wired Ethernet Network connections. Select **[Main Menu]** → from the **[Network Setup]** column, choose **[WLAN]** or **[LAN]** to enter the corresponding network configuration page. The network acquires IP addresses by default through DHCP. If a static IP address needs to be set, it should be manually configured in the corresponding interface.

3.7.7 Set parameter units

Set the parameter units and follow the steps below:

1. Select the hotkey of **[Main Menu]** → Select **[Unit Setup]** from the **[Parameters]** column;
2. After entering the unit Settings menu, you can set the units for pressure, body temperature, end-of-breath carbon dioxide, and height/weight.

The following is the list of settable units:

Unit type	Option	Default value
Pressure unit	mmHg、kPa	mmHg

Temperature unit	°C, °F	°C
EtCO2 unit	mmHg, kPa, %	mmHg
Unit of weight/height	kg/cm, lb/inch	Kg/cm

3.8 Start working

3.8.1 The status of the equipment

The equipment has spot check mode, continuous monitoring mode and standby mode.

3.8.1.1 Monitor mode

The continuous monitoring mode is used for long-term patient monitoring. To switch to the monitoring mode, please select the working mode area, and then choose **[Monitor]** in the pop-up menu.

3.8.1.2 Spot check mode

The spot measurement mode is used for on-site measurement within a short period of time. To switch to the spot check mode, please select the working mode area, and then choose **[Spot check]** in the pop-up menu.

In the spot check mode, the physiological alert is disabled.

- There will be no physiological alarm signal.
- The alarm setting menu is not displayed.
- The parameter alarm limit cannot be set.

The difference between the monitor mode and the spot check mode:

Function	Monitor mode	Spot check mode
SpO2 Monitoring	Yes	Yes
NIBP Monitoring	Yes	Yes
Temp Monitoring	Yes	Yes
CO2 Monitoring	Yes	No
Alarm setting	Yes	No
Data preservation	Automatic interval saving	Manual save
Printing of historical data	No	Yes

3.8.1.3 Standby mode

If you want to temporarily interrupt the current patient monitoring and do not want to shut down the device, you can use the standby mode.

The monitor has the following characteristics when it is in standby mode:

- Stop all parameter measurements.
- All alarm and prompt information is blocked except for the low battery alarm.
- After entering the standby mode, adjust the screen brightness to the dimmest.

Enter standby mode

The steps to enter the standby mode are as follows:

Select the hotkey of **[Main Menu]** → Select **[Standby]** in the column of **[Patient Management]**, and the device will enter the standby mode.

WARNING

- Please be vigilant about the potential risks of entering standby mode. In standby mode, the system will stop parameter measurement, block all alarm indications and system prompt sounds, except for the low battery alarm.

Exit standby mode

On the standby interface, select **[Resume Monitoring]** to exit the standby mode and resume the current patient monitoring.

3.8.2 Establish patient information

It is recommended to input the patient information correctly before monitoring. Please follow the steps below:

1. Select the patient information area, and a patient management menu will pop up, as shown in Figure 3-2;
2. Fill in the patient's basic information as required.
3. After confirming that there are no errors, select "OK".



Figure 3-2 Patient Management

3.8.3 Access the parameter Settings menu

Each parameter has a Settings menu where you can adjust the parameter Settings and alarm Settings. The parameter setting menu can be entered by selecting the parameter area or the waveform area.

In the monitor mode, the parameter setting menu includes basic parameter Settings and alarm Settings;

In the spot check mode, the parameter Settings only include the basic parameter Settings.

3.8.4 Check the alarm Settings

For patients under continuous monitoring, please ensure that the alarm limit is appropriate for the currently admitted patients. To check the Alarm Limit value, in the monitoring mode, select the hotkey of [Main Menu], choose [Alarm Limit] from the [Alarm] column to enter the alarm limit setting page, or select each parameter area or waveform area to enter the parameter setting menu and select the alarm page. Make changes when necessary.

3.8.5 Parameter switch setting

According to the monitoring requirements, the parameter switch can be manually turned on or off. The steps for setting the parameter switch are as follows:

1. Select the hotkey of the [Main Menu], choose the [Parameter Switch] from the [Parameter] column, and enter the password to enter the parameter switch Settings

page;

2. Turn on or off the switches of the corresponding parameters as needed.

When a certain parameter switch is in the off state, the parameter module stops working. The monitoring interface will not display the parameter value and waveform of this parameter, and the layout setting interface cannot select this parameter either.

3.8.6 Screen layout Settings

The screen parameter layout can be adjusted according to the monitoring requirements. The steps for setting the screen layout are as follows:

Select the hotkey of the **[Main Menu]**, and choose **[Screen Setup]** from the **[Parameters]** column to enter the screen layout Settings page, as shown in Figure 3-3.

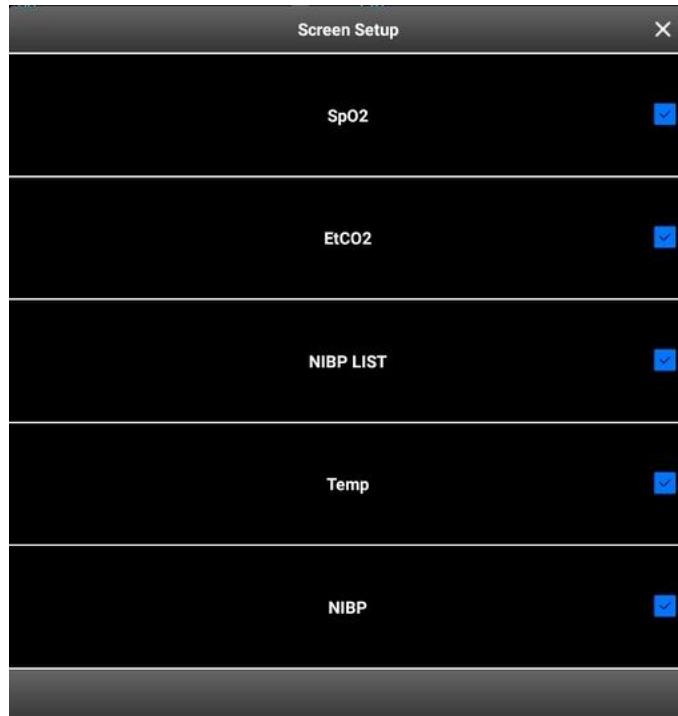


Figure 3-3 Screen layout Settings menu



CAUTION

- If the parameter switch of the measurement module is turned off, the corresponding parameters and waveforms will not be visible.
- After the Settings are completed, the system will save the current layout setting information to the configuration file and automatically arrange it based on the currently displayable waveforms and parameters to ensure the best display effect.

3.8.7 Waveform Freeze

Waveform freezing is only applicable to the monitor mode.

During the monitoring of the patient, you can freeze the waveforms on the screen and then review them to closely observe the patient's condition during this period.

In the non-frozen state, select the hotkey of **[Main Menu]**, and choose **[Freeze]** from the **[Display]** column. The screen waveform will enter the frozen state. In the frozen state, all waveforms will be frozen, the waveforms will no longer be refreshed or scrolled, the data in the parameter area will be refreshed normally, and the alarm information in the alarm area will be refreshed in real time. Therefore, during the freezing operation, there will be no underreporting of parameter alarms or loss of monitoring data.

In the frozen state, you can browse the continuous waveforms of the first 8 seconds and the last 8 seconds of the freezing time point. Slide the progress bar on the freezing Settings page, and the frozen waveform will move to the left or right accordingly, with a waveform movement step of 1 second. Therefore, the form and details of the entire waveform per second can be observed.

3.9 Stop parameter monitoring

To stop monitoring a certain parameter, please follow the steps below:

1. Remove the corresponding sensor from the patient.
2. Disconnect the sensor from the patient's cable.
3. Disconnect the patient's cable from the monitor.
4. If disposable sensors are used, please discard them.

3.10 Shut down

Before shutting down, please perform the following checks:

1. Ensure the completion of the monitoring of the patient.
2. Disconnect all cables and sensors connecting the monitor to the patient.
3. Ensure that patient monitoring data is saved or cleared as needed. To turn off the monitor, please hold down the power switch for 3 seconds and confirm the shutdown in the pop-up shutdown dialog box.

Shutting down the monitor through the power switch will not cut off the AC power supply. If you need to completely disconnect the power, please unplug the power plug.

 **NOTE**

- If the device fails to shut down normally or some special circumstances occur, you can hold down the power button for 10 seconds to force it to shut down. However, forced shutdown may cause data loss on the monitor and is not recommended.

Chapter 4 Patient Management

The monitor provides patient management functions.

4.1 Patient information setting

Select the patient information area, and a patient management menu will pop up. You can view and modify the patient information. The patient information Settings page is shown in Figure 4-1.

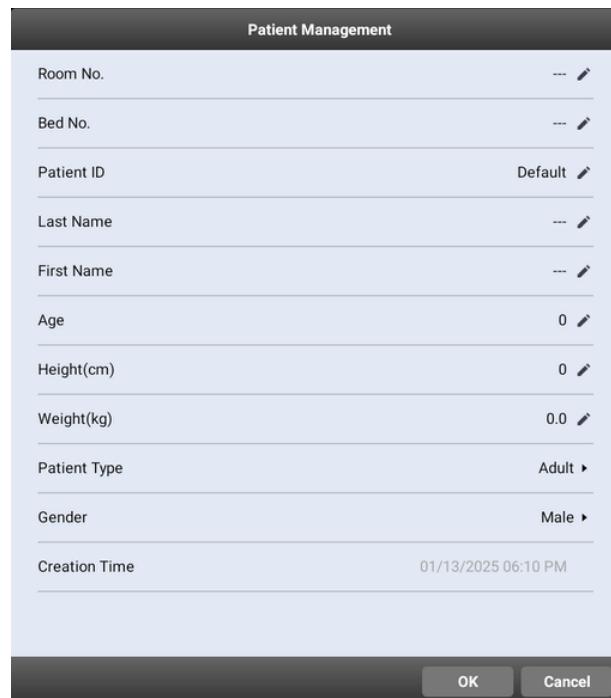


Figure 4-1Patient information setting

The following Settings and operations can be performed on this page:

1) Room No.

Set up the ward where the patient is located. The maximum number of characters that users can input is 18. There is no default value.

2) BedNO.

Set the bed number where the patient is located. The maximum number of characters that users can input is 18. There is no default value.

3) Patient ID

Set the patient identification number. The user can input a maximum of 18 characters, and the patient ID cannot be empty.

4) Patient Name

The patient's Name includes two items: First Name and LastName. The maximum number of characters that users can input is 18.

5) Age

Set the age of the patient. The age can be set within the range of 1 to 120.

6) Height (cm)

Set the patient's height, with the input range being 30 to 255cm.

7) Weight (kg)

Set the patient's weight, with the input range being 0.1kg to 200kg.

8) Patient Type

The patient types can be selected from adults, pediatrics and neonates. The default is for adults.

9) Gender

Set the gender of the patient. The default is male.

4.2 Modify the patient information

To modify the information of the created Patient, select the patient information area of the monitoring interface. In the pop-up Patient Management menu, modify the corresponding patient messages as needed. Except for the ID setting item, all other setting items can be modified.



CAUTION

- If the patient ID is modified, a new patient will be automatically created.

4.3 New patients

There are two ways to set patient information:

- Select the patient information area of the monitoring interface, change the patient ID, and a new patient will be automatically created;
- Select the hotkey of **[Patient]**, enter the Historical Patient management menu, select **[Add Patient]** in the menu, fill in the relevant information of the patient as required, and the creation of the patient is successful after confirmation. As shown in Figure 4-2.

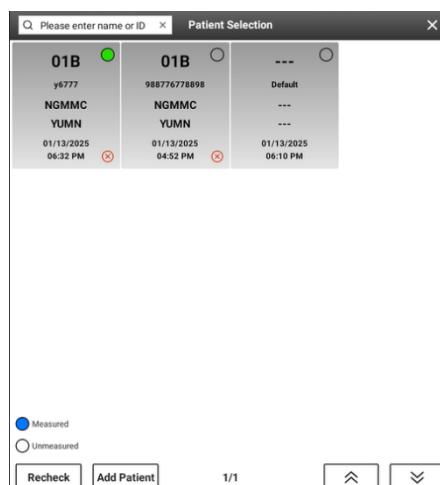


Figure 4-1 Patient Management Menu

4.4 Switch to monitor the patient

In the historical patient management menu, all patients on the monitor are presented in the form of a rectangular grid. Clicking on a single patient rectangular block will switch to the selected patient for monitoring.

4.5 Delete the patient

The monitor can store the historical data of a total of 64 patients.

In the historical patient management menu, all patients on the monitor are presented in the form of A rectangular grid. Click the  at the lower right corner of the rectangular block of a single patient, and after confirmation, the selected patient can be deleted.

Chapter 5 Configuration Management

5.1 Configuration Introduction

Due to the fact that different departments and different types of patients often have different actual monitoring requirements, or medical staff need to adjust certain Settings of the monitor according to the actual condition of the patient, all these adjustable Settings are called configurations. To configure the monitor more effectively and conveniently, the system not only provides default configurations but also supports users in creating and saving custom user configurations.

WARNING

- The configuration management function is password-protected. Configuration management tasks must be carried out by clinical professionals.

5.2 New configuration

Select the hotkey of [Main Menu], choose [Management] from the [Configuration] column, enter the password, enter the configuration management menu, select [Add] in the menu, fill in the configuration name and configuration ID as required, and the new configuration is successfully created after confirmation. The configuration management menu is shown in Figure 5-1.

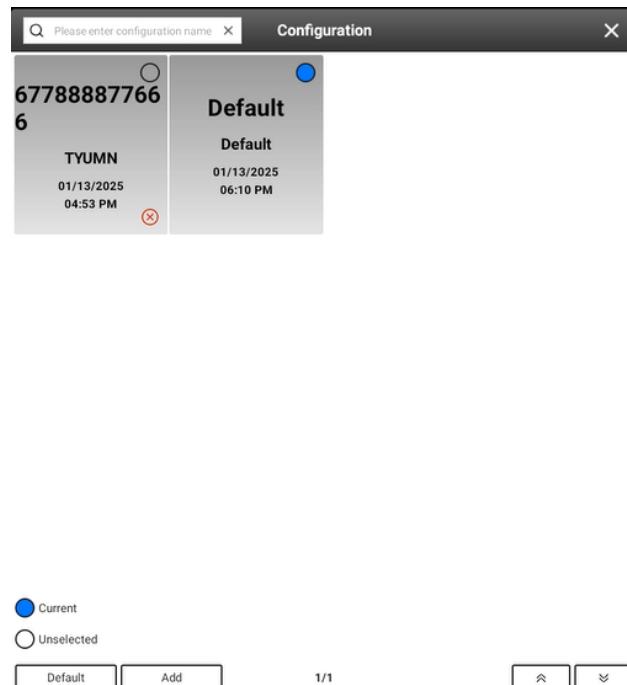


Figure 5-1 Configuration management menu

5.3 Switch configuration

In the configuration management menu, all the configurations of the monitor are presented in the form of a rectangular grid in chronological order. Clicking on a single configuration rectangular block will switch to the selected configuration for monitoring. To switch to the Default configuration, you can select the Default configuration rectangular block or click the default button to do so.

5.4 Delete the configuration

In the configuration management menu, all the configurations of the monitor are presented in the form of A rectangular grid in chronological order. Click the  at the lower right corner of a single configuration rectangular block, and after confirmation, the selected configuration can be deleted.

Chapter 6 Alarm

6.1 Description

Alarms, triggered by a vital sign that appears abnormal or by technical problems of the patient monitor, are indicated to the user by visual and audible alarm indications.

We'll introduce alarm settings and functions in this chapter.

Physiological alarms are only available in the monitor mode.

6.2 Safety Precautions

WARNING

- A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g., an intensive care unit or cardiac operating room.
- Alarm setting may vary in different monitors to suit patient's needs. Before using the monitor, please ensure the previous alarm setting is suitable for this patient. Essential alarm limits should always be turned on.
- Setting alarm limits to extreme values may cause the alarm system to become ineffective.
- When the alarm sound is switched off, the patient monitor will give no audible alarm tones even if a new alarm occurs. Therefore, the user should be very careful about whether to switch off the alarm sound or not.
- Alarms must be set according to the patient's condition for those without continuous health care from medical professionals.
- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Always keep the patient under close surveillance.

6.3 About Alarms

6.3.1 Alarm Categories

The alarms are classified into two categories: physiological alarms and technical alarms.

- **Physiological Alarms**

Physiological alarms, also called patient status alarms, are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition.

- **Technical Alarms**

Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems. For example, Lead Wire Disconnection, Battery Too Low, Weak ECG Signal etc.

In addition to physiological alarms and technical alarms, the monitor will also display some

prompt information related to the system status or the patient's status.

6.3.2 Alarm Levels

By severity, the patient monitor's alarms can be classified into three categories: high level, medium level and low level:

High level: Indicate that your patient is in a life-threatening situation or a severe device malfunction, an emergency treatment is demanded.

Medium level: Indicate that your patient's vital signs appear abnormal and an immediate treatment is required or a device malfunction, an immediate treatment is required.

Low level: Indicate that your patient's vital signs appear slightly abnormal, a device minor malfunction or an improper operation, an immediate treatment may be required.

Reminder: Provide information on the patient and system status.

6.3.3 Alarm Indicators

When an alarm occurs, this monitor will use different sounds, lights, symbols and colors to indicate different levels of alarms. The specific instructions are as follows:

Alarm Indicator	High Level	Medium Level	Low Level	Reminder	Explanation
Alarm Lamp	Flashing Red Frequency: 2Hz Duty Ratio: 50%	Flashing Yellow Frequency: 0.5Hz Duty Ratio: 50%	Solid Blue Duty Ratio: 100%	/	/
Alarm Sound	du-du-du--du-du- ---- du-du-du--du-du	du-du-du	du	/	Alarm tone is set to be distinct from heartbeat and pulse sound for easy identification.
Alarm Message	Black Text with Red Background	Black Text with Yellow Background	Black Text with Blue Background	White Text	Alarm message appears on the top of the screen. You can click the area to view the alarm message list.
Alarm Level Symbol	***	**	*	/	The symbol will appear before the alarm message

					appear
Alarm Parameter	Flashing		/		/



NOTE

- When multiple alarms of different levels occur simultaneously, the patient monitor will select the alarm of the highest level and give visual and audible alarm indications accordingly.
- When multiple alarms of different levels occur simultaneously in the same area, only **high-level alarm** will be displayed.
- When multiple alarms of same levels occur simultaneously in the same area, the patient monitor give visual and audible alarm indications circularly.

6.3.4 Alarm Status Symbols

Apart from the aforementioned alarm indicators, the patient monitor still uses the following symbols telling the alarm status:



indicates alarm sound is silenced.



indicates alarm sound is paused.



indicates alarms are turned off.



indicates alarms are paused.



indicates alarm has been received, alarm is reset.

6.4 Check Alarm List

6.4.1 Check Technical Alarm List

In Normal View, to check technical alarm list:

- 1) Click **[Alarm List]** window;
- 2) Select **[Technical Alarms]** Tab.

6.4.2 Check Physiological Alarm List

In Normal View, to check physiological alarm list:

- 1) Click **[Alarm list]** window;
- 2) Select **[Physiological Alarms]** Tab.

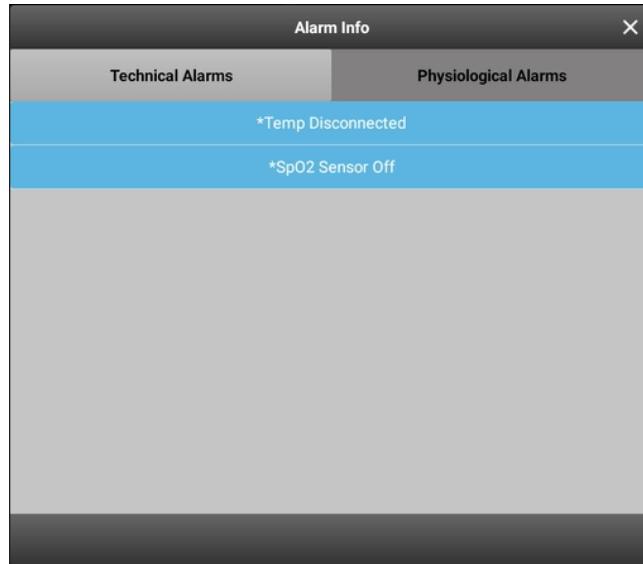


Figure 6-1Alarm List

6.5 Alarm Setup

The alarm attributes can be set centrally. Select [**Alarm Setup**] in the main menu to enter the alarm setup menu and make Settings related to alarms.

You need authorization to enter "Alarm Setup" and enter the password before you can change the configuration.

6.5.1 Set the alarm parameters

There are two ways to set the alarm parameters:

- 1) Select the hotkey of the [**Main Menu**] -- > From the [**Alarm**] column, select [**Alarm Limit**], and switch to the alarm Settings menu of each parameter, where you can set the alarm switch, alarm level, alarm upper limit, alarm lower limit, etc.
- 2) Select a certain parameter on the monitoring interface and switch to the [**Alarm**] page of that parameter in the pop-up Settings menu. On this alarm Settings page, you can set the alarm switch, alarm level, upper limit of alarm, lower limit of alarm, etc.

6.5.2 Alarm setting

Select the hotkey of [**Main Menu**] -- > Select [**Alarm Setup**] from the [**Alarm**] column. After entering the password, you can enter the alarm setup menu. This part mainly performs the following Settings:

- 1) **Pause:** To set the pause type, click the drop-down menu to set [**Alarm Pause**] and [**Alarm Sound Pause**]. The default is alarm pause.
- 2) **Pause Time:** Set the pause time interval. Click the drop-down menu to configure 1 minute, 2 minutes, 3 minutes, and permanent. The default is 2 minutes.
- 3) **Alarm Sound:** Configure the type of alarm sound.

4) Minimum Volume: The minimum volume determines the minimum value of the alarm volume setting. The minimum volume range is 1 to 5 and off.

5) High Alarm Interval: Set the interval for high alarm lamps and alarm tones. Input interval value manually as you desired, valid input range is 3s~15s, the default setting is **10s**.

6) Med Alarm Interval: Set the interval for med alarm lamps and alarm tones. Input interval value manually as you desired, valid input range is 10s~20s, the default setting is **15s**.

7) Low Alarm Interval: Set the interval for low alarm lamps and alarm tones. Input interval value manually as you desired, valid input range is 20s~30s, the default setting is **20s**.

8) Alarm Off Reminder: When the alarm is off or the alarm sound is off, the monitor can provide periodic alarm prompt sound. This function is on by default.

9) Reminder Interval: The reminder interval can be set to 1min, 2min, 3min, 5min and 10min. The default is 5min. When the alarm is closed and alarm off reminder is on, the configuration takes effect.

10) Default: This button can restore the default alarm configuration to the default state.



NOTE

- Alarm sound volume can't exceed the system sound volume. When the system sound is switched off, the patient monitor will give no audible alarm tones even if a new alarm occurs, thus the user should be cautious for setting the system sound.

6.6 PauseAlarm and Pause Audio Alarm

6.6.1 Set the Pause Function

The monitor can pause the alarm or the alarm sound, depending on the pause setting. The steps to set up the pause function are as follows:

In the Alarm Settings menu, set **[Pause]** to **[Alarm Pause]** or **[Audio Pause]**. The default is **[Alarm Pause]**.

6.6.2 Alarm Pause

If the Pause soft key is set to **[Alarm Pause]**, you can select the button to pause alarm:

- All alarms are paused during the set alarm pause time.
- The remaining pause time and the alarm pause symbol will be displayed in the system status bar.

When the alarm pause session expires, the alarm paused status is automatically canceled and the alarm tone will sound. And you can cancel the **[Alarm Pause]** manually by reselecting the **[Alarm Pause]** softkey. The softkey's name and symbol vary with the pre-defined pause function (Alarm Pause or Audio Pause).

6.6.2.1 Set Alarm Pause Time

You can select 1min, 2min, 3min or Infinite, the default alarm pause time is **2 min**. To set the alarm pause time:

In the alarm Settings menu, set **[Pause Time]** to the required time.

6.6.2.2 Turn Off the Alarms

If the “**Pause Time**” is set “**Infinite**” (For more details, please refer to the *6.6.2.1 Set alarm pause time*), Selecting “**Alarm Pause**” softkey will turn off all the alarms:

- No alarm lamps flash , no alarm sound and no alarm messages.
- Display **[Alarm Off]** and the alarm off icon in the system status information area, with a red background color.

To exit the Alarm Off state, please select the **[Alarm Off]** hotkey again.

WARNING

- Alarm Pause and Alarm OFF may cause a potential hazard to patients. Please use the function with careful consideration.

6.6.3 Silencing the Alarm Sound

If the pause function is set to **[Audio Pause]**, selecting **[Audio Pause]** will silence the alarm sound. When the alarm sound is muted:

- Both physiological alarms and technical alarms are off during the set alarm pause time.
- The remaining pause time and the alarm pause symbol will be displayed in the system status bar.

When the muted session expires, the alarm sound paused status will be automatically canceled and the alarm tone will sound. And you can cancel the **[Alarm Pause]** manually by reselecting the **[Alarm Pause]** softkey.

6.6.3.1 Set Alarm Sound Pause Time

You can select 1min, 2min, 3min or Infinite. The default alarm sound pause time is fixed to be **2 min**.

To set the alarm sound pause time: please refer to *the 6.6.2.1*, setting steps are the same.

6.6.3.2 Turn Off the Alarm Sound

If **[Pause]** is set to **[Infinite]**, Selecting **[Audio Pause]** soft key will turn off all alarm sounds:

- Both physiological and technical alarm sounds are off during the set alarm pause time.
- The **[Alarm Sound Off]** message and the **alarm sound pause red symbol** will be

To exit the [Audio Pause] status, please retap the [Alarm Sound Off] soft key..

WARNING

- Pausing or turning off alarm sound may cause a potential hazard to patients. Please use the function with careful consideration.

6.7 Alarm Reset

Select [Alarm Reset] soft key → Reset the alarm system. When the alarm system is reset successfully, the [Alarm Reset] symbol will appear in the system status bar.

NOTE

- When monitor is in **Alarm Reset** state, if a new alarm occurs, the Alarm Reset symbol will disappear, alarm light and sound will be generated normally.

After alarm is reset:

- Current alarm sound and lamp will be blocked.
- “√” appears before the alarm message to indicate that this alarm has been received.
- Numerics stop flashing.

6.8 Testing Alarms

When the monitor starts up, a self-check is performed. In the meantime, alarm lamp is lit in red, yellow and blue respectively. This indicates that the alarm lamps indicators are working properly.

For further testing of a certain parameter measurement alarm, perform the measurement with a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

6.9 Responding to an Alarm

When an alarm occurs, observe the following steps and take proper actions:

- Check the patient's condition.
- Confirm the alarming parameter or alarm category.
- Identify the source of the alarm.
- Take proper action to eliminate the alarm condition.
- Make sure the alarm condition is corrected.

For troubleshooting specific alarms, see appendix *Alarm Messages*.

Chapter 7 Blood Oxygen Saturation (SpO2)

7.1 SpO2 Description

SpO2(Oxygen saturation) is the percentage of saturated hemoglobin compared to total hemoglobin measured by a two-wavelength pulse oximeter (also called functional or In Vivo oxygen saturation). The SpO2 value is measured by light absorption technique: Red and infrared light is emitted from the emitter side of the sensor. The light is partly absorbed when it passes through the monitored tissue. The amount of transmitted light is detected in the detector side of the sensor. When the pulsative part of the light signal is examined, the amount of light absorbed by arterial hemoglobin is discovered and the saturation level can be calculated.

The SpO2 module processes the electrical signal and displays a “Pleth” waveform and digital values for SpO2 and pulse rate.

This device is calibrated to display functional oxygen saturation.

SpO2 measurement is applicable to adults, pediatrics and neonates.

This monitor supports Infinium SpO2 module,Nellcor SpO2 module and Masimo SpO2 module.

Infinium SpO2: No logo on the module;

Nellcor SpO2: Nellcor logo on the module;

Masimo SpO2: Masimo logo on the module.



NOTE

- Each SpO2 sensor connector can only be connected to the same type of extension cable. For example, Masimo SpO2 connector can only be connected to Masimo SpO2 extension cable.
- Functional testing equipment or SpO2 emulator can be used to evaluate the accuracy of PR (pulse rate) measurement.
- A functional tester or SpO2 emulator cannot be used to assess the accuracy of SpO2 sensor and pulse oximeter for monitor. They must be verified with clinical data.
- This monitor, and the SpO2 sensor, probe extension cable bundled with this equipment are all verified in compliance with ISO80601-2-61.

7.2 SpO2 Safety Information



WARNING

- When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by blood gas analyzer to completely understand the patient's condition.

- Do not use SpO₂ sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently. .
- Setting alarm limits to extreme values may cause the alarm system to become ineffective. For example, High oxygen levels may predispose a premature infant to retrosternal fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off.
- **Each pulse oxygen probe and extension line used with the monitor are specially designed for the monitor.**
- **Before use, the responsible party or operator shall check the compatibility of the monitor with the probe and extension cable, otherwise it may cause patient injury.**



CAUTION

- Use only the SpO₂ sensors and other accessories specified in this manual. Follow this manual's instructions for use and adhere to all warnings and cautions.

7.3 SpO₂ Measurement Influencing Factors

Many factors may cause inaccurate measurement:

- Physiological characteristics that may interfere:
 - ◆ Cardiac arrest
 - ◆ Hypotension
 - ◆ Shock
 - ◆ Severe vasoconstriction
 - ◆ Severe anemia
 - ◆ Hypothermia
 - ◆ Venous pulsations
 - ◆ Darkly pigmented skin
 - ◆ Ventricular septal defects (VSDs)
 - ◆ Low perfusion

- Interfering substances:
 - ◆ Intravascular dyes (such as indocyanine green, methylene blue, etc.)
 - ◆ Dysfunctional haemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
 - ◆ Presence of certain dyes on the measured site, such as methylene and indigo carmine
- Environmental conditions:
 - ◆ Excessive ambient light
 - ◆ Electrical interference
 - ◆ Electrosurgery
 - ◆ Defibrillation - May cause inaccurate reading for a short amount of time.
 - ◆ Excessive patient/sensor motion
- Others
 - ◆ Incorrect sensor placement or incorrect SpO2 sensor is used.
 - ◆ Blood pressure cuff or other measuring sensor on the same limb as the SpO2 sensor.

7.4 SpO2 Display

The waveform region and parameter region of SpO2 are shown in Figure 7-1.

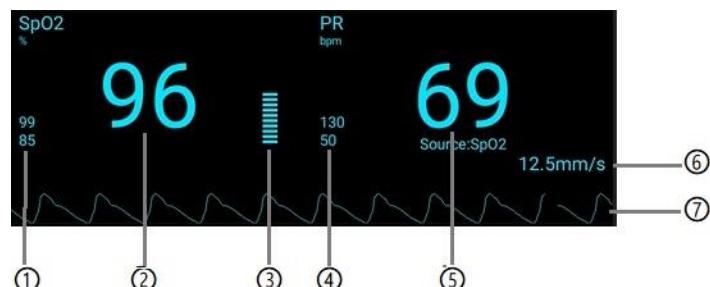


Figure 7-1 SpO2 Parameter View

Number	Explanation	Number	Explanation
1	SpO2 Alarm Range	5	PR Value
2	SpO2 Value	6	PlethWaveform scanning speed
3	Perfusion Indicator: the pulsatile portion of the measured signal caused by arterial pulsation..	7	PlethWaveform
4	PR Alarm Range		

Note:

(1) The amplitude of pleth waveform can directly reflect the strength of the patient's pulse signal.

Pleth waveform is not normalized.

(2) The bar graph is directly proportional to the pulse intensity and can reflect the filling state of blood. As an indication of signal integrity, there are 15 grids in total. When it is less than 3 grids, the signal is weak and the measurement result may be inaccurate.

7.5 SpO2 Measurement Preparation

To prepare:

1. Select an appropriate sensor according to the module type, patient category and weight.
2. Cleanse the surface of reusable sensor.
3. Remove colored nail polish from the application site.
4. Apply the sensor to the patient following "SpO2 placement" guidelines.
5. Select an appropriate adapter cable according to the connector type and plug this cable into the SpO2 connector.
6. Connect the sensor cable to the adapter cable.



CAUTION

- Choose a sensor that matches the selected measurement site, too loose a sensor may cause light leakage, too tight a sensor may cause pulsation of the vein and make the measurement value inaccurate.
- In case of high ambient temperature, special attention should be paid to the selected measurement site with poor perfusion. High ambient temperatures can cause skin damage where the sensor placement positions for prolonged monitoring.
- Do not place sensor on a limb with the NIBP cuff, an intravenous infusion or arterial catheter in place.
- For neonatal patients, make sure that all sensor connectors and adapter cable connectors are outside the incubator. The humid atmosphere inside can cause inaccurate measurements.
- Plug the SpO2 sensor into the socket/connector marked "SpO2" on the monitor panel. Remember to align the protruding part of the sensor plug with the small slot on the connector when plugging or removing it, otherwise it will cause unreliable measurements or damage to the sensor connector.
- Place the finger probe on the finger and align the finger with the direction of the finger indicated on the sensor.

7.6 SpO2 Setting

Select SpO2 waveform area or parameter area → [SpO2 Menu].

7.6.1 SpO2 Normal Setup

On the [SpO2] menu page, select the [Setup]. The page is shown in Figure 7-2 below.

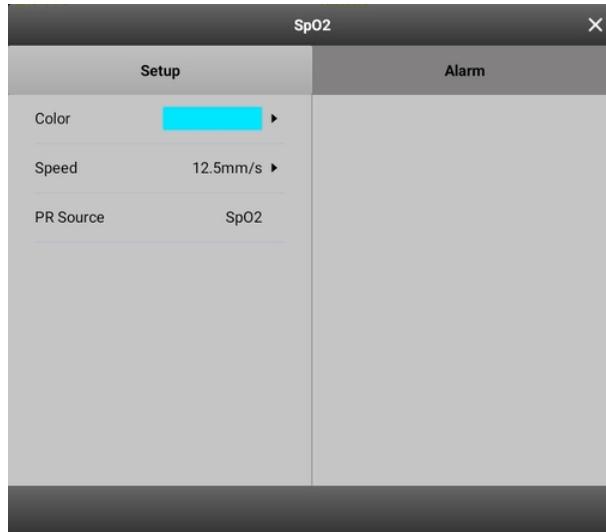


Figure 7-2 SpO2 Setting View

The following Settings can be made:

1) Color

Select the drop-down menu for “Color”, 2 colors are available, as shown in Figure 9-2. The default color is **Cyan**.

2) Speed

Select “Speed” drop-down menu, you can choose 12.5 mm/s,25mm/s or 50mm/s. The default speed is **25mm/s**. The larger the value is, the faster the wave sweep speed.

3) Pulse Source

Select “PR Source” drop-down menu, you can choose SpO2, IBP1 or IBP2.

4) FastSAT

You can set FastSat only when Masimo SpO2 module is used. Select “FastSAT” drop-down menu, and toggle between ON and OFF. The default setting is **OFF**.

5) Sensitivity Mode

You can set “Sensitivity Mode” only when Masimo SpO2 module is used. Select “Sensitivity Mode” drop-down menu → Select Masimo mode, Normal mode or APOD mode. The default setting is **Normal mode**.

Masimo mode is used for critically ill patients that are difficult to obtain parameter values; **Normal mode** is suitable for most patients, and **APOD** (Adaptive Probe Dislodgement Detection) mode applies for cases where the probe contact with the patient is intermittent.

6) Averaging Time

When the SpO2 plug-in module is the Masimo blood oxygen module, this setting item can only be seen in the Settings. Select the drop-down selection menu of "Averaging Time" to

configure the average time for blood oxygen calculation. The options are 2-4s, 5-6s, 8s, 10s, 12s, 14s, and 16s.

7.6.2 SpO2 Alarm Setup

On the [SpO2] menu page, select the [Alarm] . The page is shown in Figure 7-3 below.

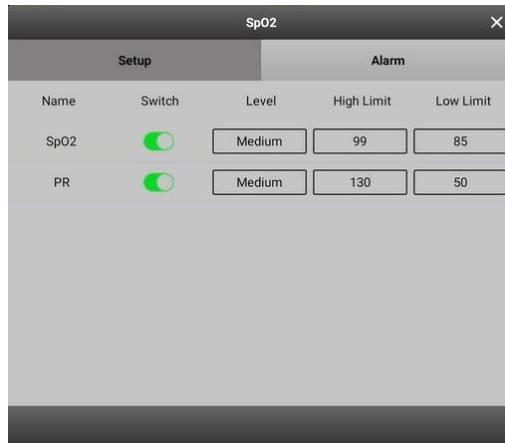


Figure 7-3 SpO2 Alarm Setting View

The alarm parameters that can be set for the SpO2 module include: SpO2, PR, and PI. Among them, PI is only visible when the SpO2 module is the Masimo blood oxygen module. Set the alarms for SpO2, PR and PI as needed, including the alarm switch, alarm level and upper and lower limit values of the alarm.

7.7 SpO2 Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

The following message may appear in “Pleth” waveform area:

Message	Explanation
Long searching time	SpO2 searching time is too long
Searching pulse...	This monitor is searching the pulse signal
SpO2 sensor off	The SpO ₂ sensor has become detached from the patient or the module
SpO2 signal weak	Low perfusion
SpO2 communication error	SpO2 communication error

Problem	Corrective Action
No SpO2 parameter window and waveform area are displayed	<ol style="list-style-type: none"> 1、Check if SpO2 module is plugged properly; 2、Check if the SpO2 parameter and waveform display is turned ON in “View Layout”. 3、Make sure SpO2 module and Main Unit of the monitor are

	connected.
“---” appears in SpO2 value	1、Check if the SpO2 sensor and adapter cable are connected tightly. Replace the SpO2 sensor or cable if necessary. 2、Check "SpO2 sensor off" alarm occurs, reconnect the sensor.
Pleth waveform size too low	1、NIBP cuff on the same limb as the SpO2 sensor. Change measured site if necessary. 2、PI value too low. Adjust the sensor position and connect to site with better perfusion. 3、Check sensor condition and sensor placement.
Inaccurate measurement	4、Check patient vital signs. 5、check for conditions that may cause inaccurate SpO2 readings. 6、check the monitor and the SpO2 module, cable, or sensor for proper functioning



NOTE

- For physiological and technical alarm message, please refer to *Appendix C Alarm messages*.

7.8 Manufacturer Information

This monitor supports 3 SpO2 module: BCI, Nellcor and Masimo module. For more information, please contact technical support or after-sales service personnel.。

7.8.1 Masimo Information



- **Masimo Patents:**

For more information, please refer to Masimo website: <http://www.masimo.com/patents.html>.

- **No Implied License:**

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

7.8.2 Nellcor Information



- **Nellcor Patents:**

This device is covered under one or more the following U.S. Patents: 4,802,486; 4,869,254; 4,928,692; 4,934,372; 5,078,136; 5,351,685; 5,485,847; 5,533,507; 5,577,500; 5,803,910; 5,853,364; 5,865,736; 6,083,172; 6,463,310; 6,591,123; 6,708,049; Re.35,122 and international equivalents. U.S.A international patents pending.

- **No Implied License**

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

Chapter 8 Non-invasive Blood Pressure (NIBP)

8.1 NIBP Description

This monitor uses the oscillometric method for measuring the non-invasive blood pressure (NIBP). It is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. Oscillometric devices use a blood pressure cuff to sense these oscillations that appear as tiny pulsations in cuff pressure. By measuring and analyzing at various cuff pressures, the amplitude (which changes based on the pressure within the cuff) and the frequency of these pulsations (which is dependent on the patient's heart rate), oscillometric devices can non-invasively determine blood pressure. Once the mean pressure is determined, the systolic and diastolic pressures are calculated with reference to the mean.

This measurement can be used for adults, pediatrics and neonates.



NOTE

- Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the deviations specified by IEC 60601-2-30.
- NIBP measurement can be performed during electro-surgery and discharge of defibrillator.

8.2 NIBP Safety Information



WARNING

- Be sure to select the correct patient category setting for your patient before measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise, it may present a safety hazard.
- Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
- Use clinical judgement to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.
- **Do not wear the cuff on the wound, otherwise it will cause further injury.**

- Avoid applying the cuff on the side of the mastectomy.
- Cuff pressurization may cause temporary loss of the function of monitoring equipment used simultaneously on the same limb.
- Kinked or otherwise restricted tubing can lead to a continuous cuff pressure, causing blood flow interference and potentially resulting in injury to the patient.
- The measurement site, patient's position (standing, sitting, lying down), exercise, or physiologic condition can all affect the NIBP readings. If you doubt the NIBP readings, determines the patient's vital signs by alternative means and then verify that the monitor is working correctly
- Continuous non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. More frequent checks are required when performing automatic or continuous measurements. If any abnormality occurs, move the cuff to another site or stop the blood pressure measurements immediately. The 1 and 2-minute intervals are not recommended for extended periods of time.
- NIBP diagnostic significance must be decided by the doctor who performs the measurement.



CAUTION

- Use only the modules and accessories specified in this manual. Follow this manual's instructions for use and adhere to all warnings and cautions.
- Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and choose the proper size cuff.

8.3 NIBP Measurement Influencing Factors

Measurements are impossible with heart rate extremes of less than 30bpm or greater than 300bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

- If a regular arterial pressure pulse is hard to detect
- With excessive and continuous patient movement such as shivering or convulsions
- With cardiac arrhythmias
- Rapid blood pressure changes
- Severe shock or hypothermia that reduces blood flow to the peripheries

- Obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery
- On an edematous extremity



NOTE

- e NIBP feature is not validated for pregnant, including preeclamptic patients use.

8.4 Measurement mode

In spot check mode, only manual measurement mode is supported.

In monitor mode, the following measurement modes are available:

- **Manual:** measurement on demand.
- **Auto:** continually repeated measurements at set intervals.
- **STAT:** continually rapid series of measurements over a five-minute period, then return to the previous mode.

8.5 NIBP 显示

The NIBP measurement has no waveform display and only shows the measurement results in the parameter area. The display pages are slightly different under different measurement modes. Taking the manual measurement mode as an example for introduction, its interface is shown in Figure 8-5.

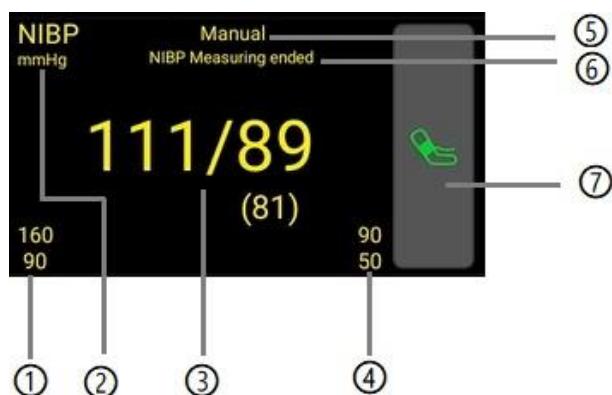


Figure 8-5 NIBP Parameter View

Number	Explanation
1	Upper and lower limits of systolic blood pressure alarm
2	NIBP unit: mmHg or kPa. The default unit is mmHg.

3	<p>Systolic / Diastolic Pressure: if the real-time pressure value has risen above the high alarm limit or fallen below the low alarm limit, the numerics will flash.</p> <p>Mean Pressure: Mean pressure obtained after the measurement and the real-time cuff pressure obtained during the measurement.</p>
4	Upper and lower limits of diastolic blood pressure alarm
5	<p>Measurement Mode: Display the measurement mode adopted for the current measurement.</p> <p>In monitor mode: Measurement mode have Manual、Auto and STAT.</p> <p>In spot check mode: Measurement mode is only manual.</p>
6	Measurement status
7	starting/stopping measurement

8.6 NIBP Measurement Preparation

8.6.1 NIBP Patient Preparation

When taking routine resting blood pressure, ensure that:

- The patient is comfortably seated, with their legs uncrossed and feet flat on the floor.
- The patient's arms and back are supported.
- The middle of the cuff is at the level of the right atrium of the patient's heart.



NOTE

- Ensure that the patient is relaxed and does not talk during the measurement.
- Allow 5 minutes to pass before taking the first measurement.
- Other factors that cause high blood pressure measurements include dyspnea, bladder fullness, pain, etc.

8.6.2 NIBP Patient Connection

Position the NIBP cuff on the patient:

1. Be sure to select the correct patient category setting for your patient before measurement. Verify the patient category and replace the cuff.
2. Connect the NIBP cuff hose to the module's NIBP connector.
3. Choose the appropriate cuff and make sure that the cuff has been completely deflated. Position the NIBP cuff on the patient:
 - a. Determine the patient's limb circumference.

- b. Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb.
- c. Apply the cuff to an upper arm or leg of the patient and make sure the Φ marking on the cuff matches the artery location. Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities. Make sure that the cuff edge falls within the marked range. If it does not, use a larger or smaller cuff that will fit better.
- d. Ensure that cuffed limb is supported to maintain the cuff at level of patient's heart.

Correcting the Measurement if Limb is not at Heart Level:

- Add 0.9 mmHg (0.12 kPa) for each centimeter higher, or
- Deduct 0.9 mmHg (0.12 kPa) for each centimeter lower



CAUTION

- Improper NIBP cuff size or compression of the cuff may lead to measurement inaccuracy.
- Avoid touching or squeezing the cuff and air tubing, otherwise the measurement may be inaccurate.
- Please be cautious about the accuracy when measuring other physiological parameters with NIBP cuff placement on the limb.

8.7 Starting/ Stopping NIBP Measurement

Task	Steps
Starting or Stopping a Single NIBP Measurement	<p>1、 Set NIBP measurement method to “Manual”</p> <p>2、 Start the measurement by selecting NIBP “Start”.</p> <p>3、 Stop the measurement by selecting NIBP “Stop”.</p> <p>4、 Measurement ends When the procedure is completed or measurement anomalies occur. You could also select “Stop” terminate the NIBP measurement manually.</p>
Starting / Stopping NIBP Auto Measurement	<p>1、 Set NIBP measurement method to “Auto” and set the required interval.</p> <p>2、 Select NIBP “Start” → Start NIBP Auto measurement.</p>

	<p>3、Start a measurement manually. The monitor will then automatically repeat NIBP measurements at the set time interval.</p> <p>4、During the measurement, Select NIBP “Stop” at any time to terminate measurement procedure, and the count-down timer will be reset.</p>
Starting / Stopping NIBP STAT Measurement	<p>1、Set NIBP measurement method to “STAT”;</p> <p>2、Select NIBP “Start”</p> <p>3、In STAT mode, when the first measurement is complete, it will continue the 2nd measurement. The automatic NIBP measurement process will stop after 5 measurements.</p> <p>4、During the measurement, Select NIBP “Stop” at any time to terminate measurement process.</p>

8.8 NIBP Settings

Select the NIBP parameter area, and the [NIBP] menu will pop up.

8.8.1 NIBP Normal Setup

On the [NIBP] menu page, select the [Setup], and its page is shown in Figure 8-2.

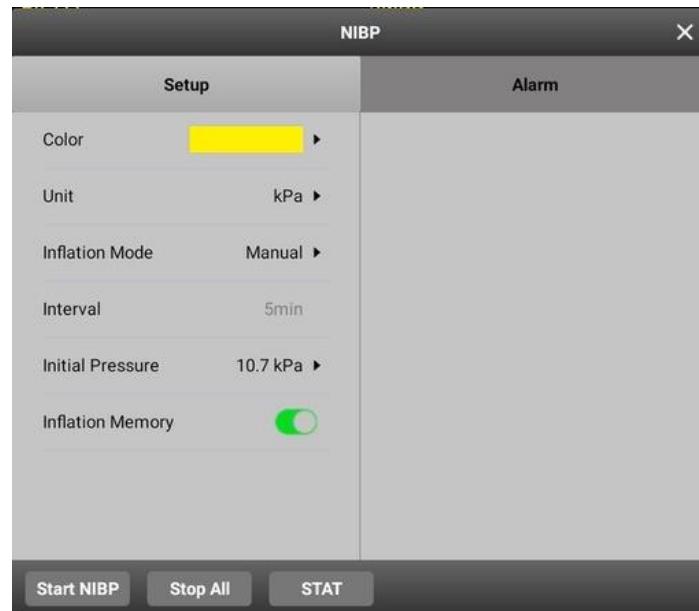


Figure 8-2 NIBP Setup Menu

The following Settings can be made:

1) Color

Select the [Color] menu, and a parameter color configuration window will pop up. You can choose from 32 colors. The default is yellow.

2) Unit

Select the **[Unit]** drop-down menu to set the pressure unit, which can be mmHg or kPa. The default is mmHg.

3) Inflation Mode

Select the drop-down selection menu of **[Inflation Mode]**, set the inflation mode and working mode. The selectable inflation modes are: Manual (Manual), automatic (Auto). The default is manual.

4) Interval)

When inflation mode is set to **[Auto]**, **[Interval]** setting will be enabled. Select **[Interval]** and then select a desired time interval. The interval range is 1 min — 4 hrs. The default Interval is **5 min.**

5) Initial Pressure

Select **[Initial Pressure]** drop-down menu → Set the initial cuff inflation pressure manually, setting options may vary with the patient category.

- **Adult:**

Represents Adult Mode, during the initial measurement, the cuff is inflated to 180 mmHg, and if the blood pressure hasn't been captured, a second inflation, which is no more than 297mmHg, will start.

- **Pediatric:**

Represents Pediatrics Mode, during the initial measurement, the cuff is inflated to 140 mmHg, and if the blood pressure hasn't been captured, a second inflation, which is no more than 237mmHg, will start.

- **Neonate:**

Represents Neonates Mode, during the initial measurement, the cuff is inflated to 100 mmHg, and if the blood pressure hasn't been captured, a second inflation, which is no more than 147mmHg, will start.

6) Inflation Memory

Select **[Inflation Memory]** drop-down menu → Turn **ON/OFF [Inflation Memory]**, When **[Inflation Memory]** is turned **ON**, the monitor will save the inflation pressure as baseline and set the inflation pressure as baseline + 30mmHg for next measurement automatically in order to reduce the measurement duration by decreasing the number of inflations. When **[Inflation Memory]** is turned **OFF**, then the monitor sets the inflation pressure automatically according to the previous measurement.

8.8.2 NIBP Alarm Setup

In **[NIBP Menu]** window → Select **[Alarm Setup]** tab, as shown in Figure 8-3.

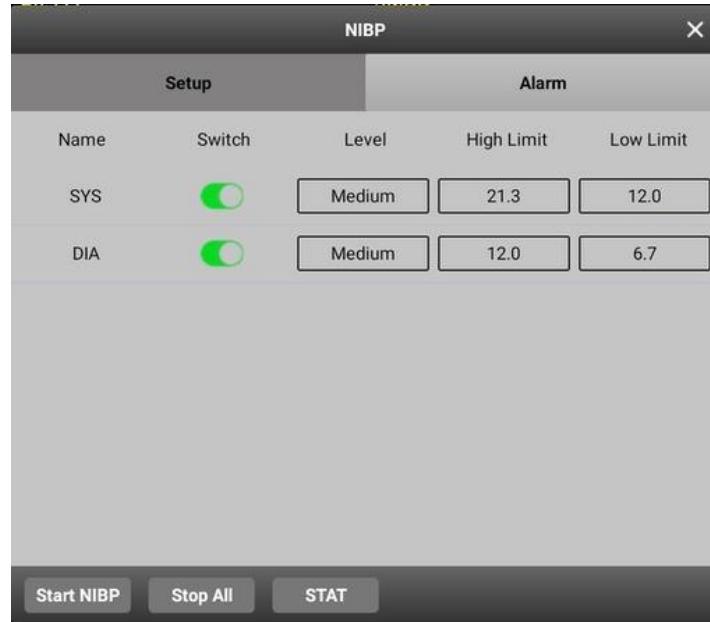


Figure 8-3 NIBP Alarm Setup Menu

This page can set the alarms for the NIBP parameters: SYS (systolic blood pressure) and DIA (diastolic blood pressure). The settable range varies for different patient types. Set the alarm of SYS and DIA as needed, including alarm switches, alarm levels, and upper and lower limit values of alarms.

Patient Category \ Range	SYS High alarm limit (mmHg)	SYS Low alarm limit (mmHg)	DIA High alarm limit (mmHg)	DIA Low alarm limit (mmHg)
Adult	30~240 Factory Default Setting: 150	30~240 Factory default setting: 100	15~180 Factory default setting: 90	15~180 Factory default setting: 50
Neonatal	30~240 Factory default setting: 90	30~240 Factory default setting: 40	15~180 Factory default setting: 60	15~180 Factory default setting: 20
Pediatric	30~240 Factory default setting: 120	30~240 Factory default setting: 70	15~180 Factory default setting: 70	15~180 Factory default setting: 40

8.9 NIBP List

You can set **[NIBP List]** to be displayed in **View Layout** Menu. Then, multiple sets of most recent NIBP measurements will be displayed. And PR displayed is derived from NIBP.

SYS/DIA	PR	TIME
114/86 (84)	81	07:10 PM
122/78 (92)	73	07:05 PM
115/85 (85)	80	07:00 PM
115/85 (85)	80	06:55 PM
120/80 (90)	75	06:50 PM

Figure 11-4 NIBP List

Due to the screen size limit, The NIBP List displays only the most recent few NIBP measurements. The device can store a maximum 86,400 blood pressure measurement sets in its storage for NIBP List. To see more measurements, select the NIBP List display area → Enter the “**NIBP Tabular Trends**” Tab, as shown in Figure 11-4. Check the data by scrolling the data list, and you can manually set the number of viewable items on the current page by clicking the button to the right of "Number" according to your needs.

8.10 NIBP Maintenance

8.10.1 NIBP Leakage Test

The NIBP leakage test checks the integrity of the system and of the valve. It is required at least once every two years or when you doubt the measured NIBP. Leakage Test must be performed by your service personnel.

8.10.2 Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure transducers must be verified and calibrated once every two years by a qualified service professional. Contact your service personnel when a calibration is necessary.

8.11 NIBP Troubleshooting

Refer to *Appendix C alarm messages*

Chapter 9 EtCO2

End-tidal CO2 or partial pressure (EtCO2) reflects pulmonary ventilation and also pulmonary blood flow. When no significant cardiopulmonary disease exists and V/Q ratio is normal, EtCO2 reflects PaCO2 (arterial blood carbon dioxide), with a normal EtCO2 value of 5% corresponding to 5KPa (38mmHg).

There are two methods for measuring CO2 in the patient's airway:

Sidestream/Microstream measurement samples expired patient gas at a constant sample flow from the patient's airway and analyzes it with a CO2 sensor built into the CO2 module.

CO2 measurement is applicable to adults, children and newborns.

When the monitor is in the monitor mode, CO2 measurement can be carried out.

In the spot check mode, the measurement of CO2 is not supported.

9.2 EtCO2 Safety Information

WARNING

- EtCO2 monitoring is an external function of the patient monitor, please read thoroughly the manual that comes with the EtCO2 sensor before use.
- Route all tubing away from the patient's throat to avoid strangulation.

CAUTION

- Disconnect the airway adapter during nebulization of medications.
- EtCO2 values may differ from blood gas readings.
- Mechanical Shock must be avoided when using sidestream CO2 with paramagnetic oxygen.

NOTE

- When monitoring patient with EtCO2 module, please make sure the proper connection between the patient and module.
- **Explosion Hazard:** Do not use in the presence of flammable anesthetics or gases, such as a flammable anesthetic mixture with air, oxygen or nitrous oxide. Use of the devices in such an environment may present an explosion hazard.
- **Failure of operation:** if the measurement or a sensor fails to respond as described, do not use it until the situation has been corrected by qualified personnel.

9.3 Measurement Influencing Factors

The following factors may influence the accuracy of measurement:

- Leaks or internal venting of sampled gas
- Mechanical shock
- Cyclic pressure up to 10 kPa (100 cmH₂O)
- Other sources of interference, if any

9.4 EtCO₂ Display

EtCO₂ waveform display area and parameter display area are shown in Figure 9-1.

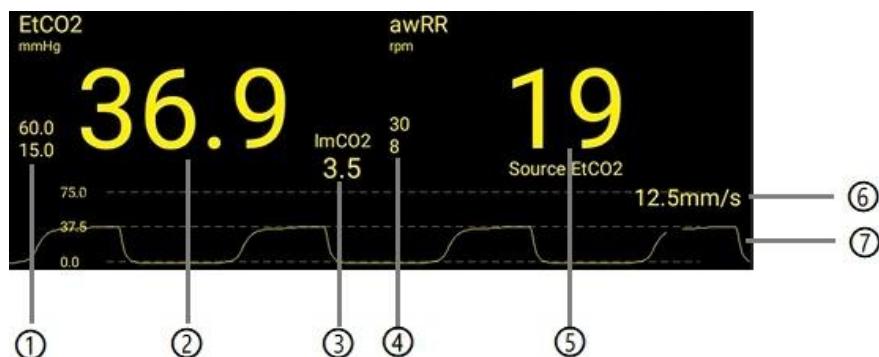


Figure 9-1 EtCO₂ Waveform and Parameter Display View

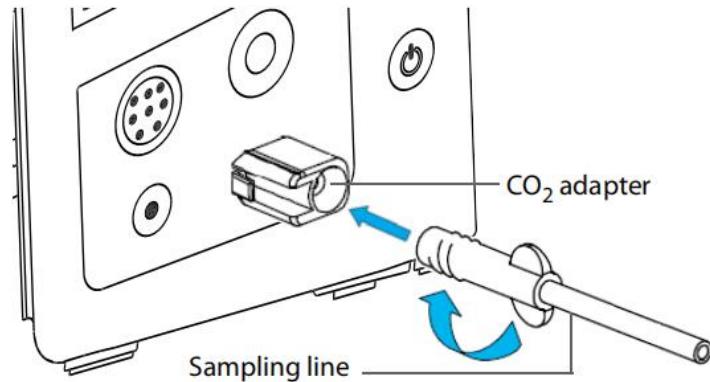
Number	Explanation	Number	Explanation
1	EtCO2 Alarm Range	5	awRR Value
2	EtCO2 Value	6	EtCO2 Waveform scanning speed
3	ImCO2 Value	7	EtCO2 Waveform
4	awRR Alarm Range		

9.5 EtCO₂ Sensor Preparation

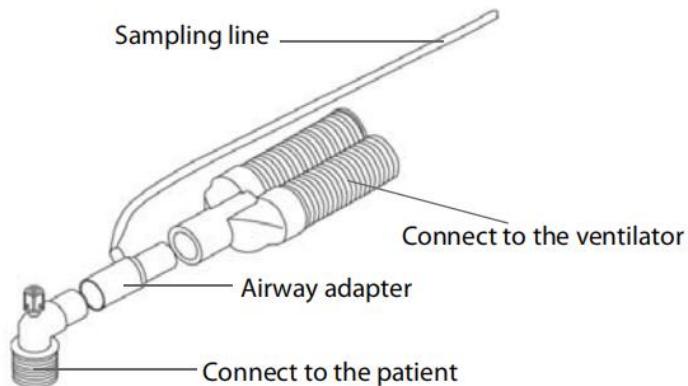
CO₂ measurement should be carried out in accordance with the following steps:

Each time the ambient temperature changes by more than 10°C (for example, during the transfer process), zeroing must be carried out as described in this manual.

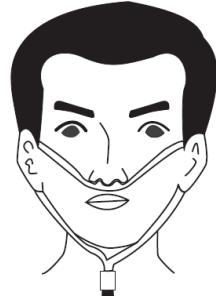
1. Select the correct sampling tube according to the patient type.
2. Connect the sampling tube to the CO₂ adapter installed on the monitor.



3. Connect the other end of the sampling tube to the patient.
 - ◆ For patients with tracheal intubation, an adapter is needed. Connect the two ends of the adapter respectively between the patient and the Y tube of the ventilator.



- ◆ For patients who are not intubated, nasal sampling tubes should be worn for them.



4. Connect an exhaust pipe to the exhaust hole on the module and discharge the exhaust gas to the exhaust gas treatment system.
5. Sensor zero calibration
 - Expose the sensor to room air and keep it away from all sources of CO2 including the ventilator, the patient's breath and your own.
 - In the setup menu for the CO2, select **Zero**.
 - After clicking the "zero" button, the prompt message "**zero calibration in progress**" will appear on screen. When it disappears, the zero calibration has been completed and you can start monitoring.

 **WARNING**

- Neonatal patients should not use adult or pediatric sampling tubes, otherwise it may cause harm to the patients.
- The exhaust holes on the module must be connected to the waste gas treatment system.
- During the measurement process, to zero the sensor, it is necessary to first disconnect the sensor from the patient's airway.
- Do not rely on the gas readings when zeroing.

 **NOTE**

- The presence of air leakage in the sampling system may cause the displayed EtCO₂ value to be significantly lower. Please ensure that all components are securely connected and check for any air leakage.
- Before connecting the gas path adapter to the patient end, it should be ensured that the gas path adapter is tightly connected to other components and can be used normally.
- When conducting CO₂ measurement, be careful not to squeeze or bend the sampling tube. Otherwise, it may cause the CO₂ module to have no reading or incorrect reading.

 **NOTE**

- When the sampling gas temperature is 37 °C, the sampling flow rate is 50 milliliters per minute, the room temperature is 23 °C, and the relative humidity is 100%, the sampling pipeline of the common type should be replaced no later than every 8 hours, while that of the humidification type should be replaced no later than every 72 hours.
- If not necessary, do not remove the CO₂ adapter from the monitor after the first installation. This can reduce the risk of losing or damaging the CO₂ adapter.

9.6 EtCO₂ Setup

Select the EtCO₂ parameter area or waveform area and enter the [EtCO₂] menu.

9.6.1 EtCO₂ Normal Setup

On the [EtCO₂] menu page, select the [Setup], and its page is shown in Figure 9-2.



Figure 9-2 EtCO2 Setup Menu

The following Settings can be made:

1) Color

Select [Color] drop-down menu to set ECG waveform and parameter color. 32 colors are available, as shown in Figure 13-2. The default color is **Yellow**.

2) Speed

Select [Speed] drop-down menu, you can choose **6.25 mm/s, 12.5 mm/s, 25mm/s**. The default speed is **12.5mm/s**. The larger the value is, the faster the wave sweeps.

3) Waveform Type

Select the dropdown selection menu of [Waveform Type], configure the waveform type, choose whether to Fill the waveform, select **Draw** as the linear waveform, and select **Fill** as the filled waveform. The default is **Fill**.

4) EtCO2 Unit

Select [EtCO2 Unit] drop-down menu to set EtCO2 unit, there are 3 options: **mmHg, kPa** and **%**. The default unit is **mmHg**.

5) Waveform Scale

Select “Waveform Scale” drop-down menu to change the size of the CO2 waveform. → You can choose “**0-75mmHg**” or “**0-150mmHg**”.

6) EtCO2 Period

Select “EtCO2 Period” drop-down menu to set EtCO2 Period for calculation and toggle between **1Breath, 10s** and **20s**. The default Period is **1 Breath**.

7) Apnea Delay

Select [Apnea Delay] → Manually enter parameter value of 10-60s, the monitor will alarm if the patient has stopped breathing for longer than the preset apnea time. The default setting is **10s**.

8) Zero Gas Type

Select “**Zero Gas Type**” drop-down menu → Toggle between **Room Air** and **N2**. The default setting is **Room Air**.

9) Oxygen %

Select “**Oxygen**” → Enter the concentration value for **Oxygen Compen**. For relevant setting, follow instructions specified by the module manual. The default setting is **16%**.

10) Balance Gas

Select [**Balance Gas**] drop-down menu to set Gas Type and toggle between **Room Air**, **Nitrogen** and **Helium**. The default balance gas is **N2O**.

11) Anesthetic %

Select [**Anesthetic**] menu to set concentration value → Enter the parameter value manually. The default setting is **0.0%**.

12) Barometric Pressure

Select [**Barometric Pressure**] menu to set current Barometric Pressure value to which the patient monitor is exposed to → Enter the parameter value, the default barometric pressure is **760 mmHg**.

13) Gas Temp

Select [**Gas Temp**] menu → Enter the parameter value of $10^{\circ}\text{C} \sim 50^{\circ}\text{C}$ ($50^{\circ}\text{F} \sim 122^{\circ}\text{F}$), the default gas temp is **35.0°C**.

14) Zero

Select [**Zero Setup**] → Zero the EtCO₂ parameters.

15) Pump On/Off

Click the [**Pump On/Off**] button to control the operation and shutdown of the air pump.

 **WARNING**

- Please set various compensations according to the actual situation; otherwise, the measurement results may deviate seriously from the actual values, leading to misdiagnosis.

9.6.2 EtCO₂ Alarm Setup

On the [**EtCO₂**] menu page, select the [**Alarm**], and its page is shown in Figure 9-3. On this alarm setting page, configure the alarms for the two parameters, EtCO₂ and awRR, as needed, including the alarm switch, alarm level, and upper and lower limit values of the alarm.



Figure 9-3 EtCO2 Alarm Setup Menu

9.7 Calibrating EtCO2 Sensor

For sidestream CO2 modules, a calibration should be performed once every year or when the readings go far beyond the range. If mncalibration is needed, please contact the service personnel.

NOTE

- When Calibrating EtCO2 module, the sample gas must be connected to a scavenging system.

9.8 CO2 Trouble shooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

Problem	Corrective Method
EtCO2 measurement values are too low	<p>1、Check whether the CO2 concentration of the measurement site. If the environmental concentration is a bit high, measured value tends to be lower than expected. In the worst scenario, the too high concentration may lead to zeroing failure. Please ventilate the environment.</p> <p>2、Check the sampling line and connectors for leakage.</p>

	3、Check the patient status
Elevated baseline	1、Check the patient status. 2、Check the sensor.

**NOTE**

- For the physiological and technical alarm messages, refer to *Appendix C Alarm messages*.

Chapter 10 Temperature

10.1 Temp Description

This monitor supports infrared body temperature measurement. They are connected to the host via a USB interface.

The supported thermometer models are as follows:

- Heteida infrared thermometer
- Exergen infrared thermometer

Temp measurement is intended to use for adults, pediatrics and neonates.

10.2 Temp Display

Temp waveform area and parameter area are shown in Figure 10-1.



Figure 10-1 Temp Display

Number	Explanation
1	Temp Alarm Range
2	Temp Value
3	Thermometer connection status

10.3T Temp Measurement Preparation

Prepare for a Temp measurement by the following steps:

- 1) Insert the USB plug of the external thermometer into the USB port on the back of the monitor.
- 2) Aim the thermometer gun at the corresponding part of the patient in accordance with the instructions for using the thermometer.

10.4 Temp Setting

Select Temp parameter area → “Temp Menu” will pop up.

10.4.1 Temp Normal Setup

On the [Temp] menu page, select the [Setup] TAB, and its page is shown in Figure 10-2.

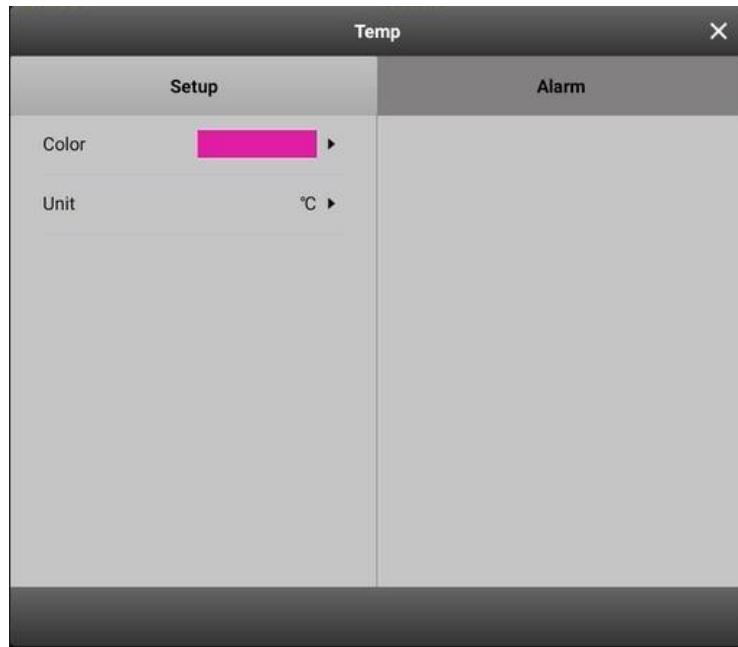


Figure 10-2 Temp Settings page

The following Settings can be made:

1) Color

Select [Color] → Color setting window will pop up → 32 colors are available to choose. The default color is **White**.

2) Unit

Select [Temp Unit] drop-down menu to set **Temp unit** and toggle between **°C** and **°F**. The default temp is **°C**.

10.4.2 Temp Alarm Setup

Select [Temp Menu] → Select [Alarm Setup] tab, as shown in Figure 10-3. On this alarm setting page, configure the Temp parameter for alarms as needed, including the alarm switch, alarm level, and upper and lower limit values of the alarm.

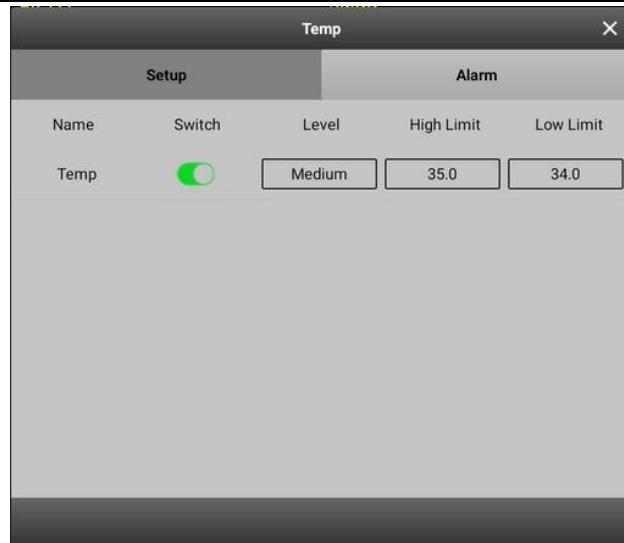


Figure 10-3 Temp Alarm Setup Settings page

10.5 Temp Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

Problem	Corrective Method
No Temp parameter area is display.	Check if Temp parameter is set to ON in "Screen Setup"
Measurement failure or “---” shown in Temp value	If you are using a disposable probe, check whether the connection between the probe to the temperature cable is tight and secure. If any physical damage occurs on the probe, replace it with an intact one.



NOTE

- For physiological and technical alarm message, please refer to *Appendix C Alarm Message*.

Chapter 11 Clinical Auxiliary Applications (CAA)

Clinical decision support is a comprehensive analysis and centralized presentation based on existing monitor measurements and serves as a digital tool of commonly used clinical guidelines and tools.

The primary purpose of clinical decision support is to improve doctor efficiency, it is not used for diagnosis, can not be a substitute for medical personnel to make decisions.

11.1 Early Warning Score (EWS)

Early warning scores can help identify early signs of deterioration and are an early warning indicator of critical or potentially critical illness.

Early Warning Scoring System obtains the corresponding score by monitoring and observing the patient's vital signs and status, and clinical responses are provided according to the results of the score.

This monitor provides the following scoring systems:

- Modified Early Warning Score (MEWS)
- National Early Warning Score (NEWS)

There are two kinds of scoring systems: totalscoring and individual parameter scoring (IPS).

■ Total Scoring: Rate each parameter you select and calculate an aggregate score. Each parameter is scored with a color mark indicating the appropriate severity level. Clinical responses are provided when the total score exceeds the limit. MEWS and NEWS are total scoring systems.

■ Individual Parameter Scoring (IPS): Score individual parameters and clinical responses are provided when the any parameter score exceeds the limit.

Customized scoring systems are based on parameters selected by users. Custom scoring systems can be either total scoring system or IPS.

Customized scoring systems are only available for adults.



WARNING

- Early warning score results and medical actions provided are for reference only and cannot be used directly as a basis for clinical treatment.
- Early warning score results and treatment recommendations must be used in conjunction with the patient's clinical symptoms and signs.
- Early warning scores are not available for pregnant women, people with COPD (chronic obstructive pulmonary disease) and people under 16.

11.1.1 Scoring Parameters

Different scoring systems utilize different scoring parameters, see the following table:

Modified Early Warning Score (MEWS)	National Early Warning Score (NEWS)	Individual Parameter Scoring (IPS)	Customized Total Scoring
RR, Temp, NIBP-SYS, PR/HR, AVPU	RR, SpO2, Oxygen saturations, Temp, NIBP-SYS, PR/HR, AVPU	RR, SpO2, Oxygen saturations, Temp, NIBP-SYS, PR/HR, AVPU Real scoring parameters are defined by Clinical Grading System Configuration Tool	RR, SpO2, Oxygen saturations, Temp, NIBP-SYS, PR/HR, AVPU, blood sugar, urine volume, urinary conduction, pain score, pain, EtCO2, inhalation oxygen concentration, airways, users can select up to 3 parameters for customization. Real scoring parameters are defined by Clinical Grading System Configuration Tool

11.1.2 Display EWS Parameter Area

Select **Screen Setup** Quick key to open **Screen Setup**, to display EWS on screen. EWS parameter example is shown as Figure 19-1.

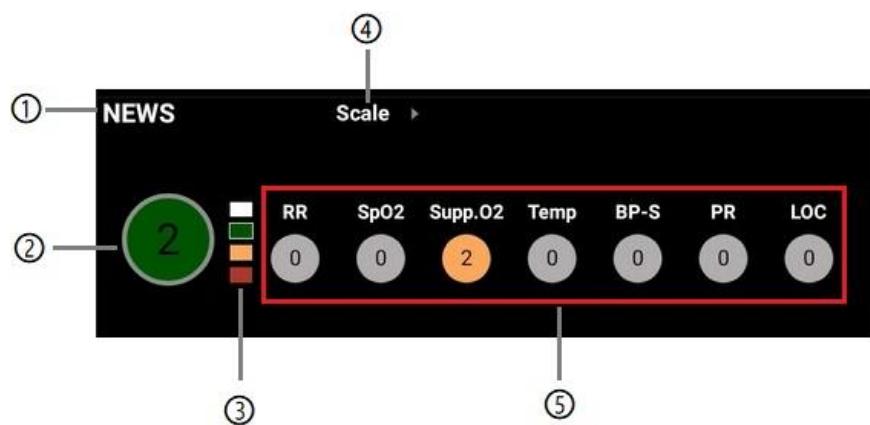


Figure 19-1 EWS Parameter Area

Number	Function Explanation
1	Early Warning Score System Name
2	Total Score, Circle color represents current score level.

3	Score Level Indicators: Increase in the order of warning hazards from top to bottom. The box shows the current level.
4	Selection of scoring system
5	Sub-score area: Displays the score of each parameter

11.1.3 EWS parameter interface

The EWS view interface is shown in Figure 11-2. The actual interface display may vary depending on the selected scoring system and Settings.

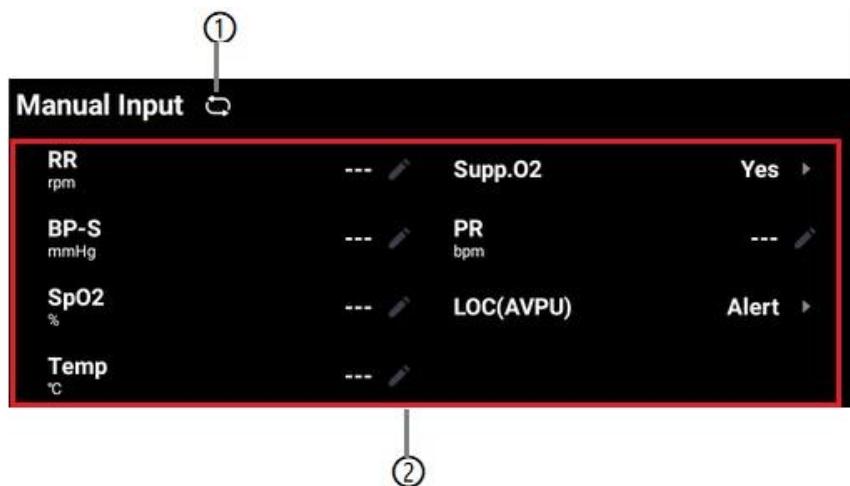


Figure 19-2 EWS Page

Number	Function Explanation
1	Parameter reset
2	Parameter area: Displays the parameter values of each parameter. The keyboard icon indicates that the parameter value is derived from manual input.

11.1.4 Calculate the score

The monitor automatically acquires the parameter values and the corresponding parameter scores, and automatically calculates the total score.



NOTE

- Before each rating, please press the "Reset" key to clear the previous rating result.
- The keyboard symbol on the right side of the parameter value indicates that the parameter value is manually entered.

- You can calculate the score only when the parameter values of all the parameters involved in the calculation are valid.
- The monitor provides two default rating systems, MEWS and NEWS, and they cannot be deleted.

11.1.5 Review of Ratings

Select the review hotkey to enter the review menu, where you can view the EWS historical ratings.

11.2 Glasgow Coma Index (GCS)

Glasgow Coma Index (1974_Lancet_ Teasdale Assessment of Comaand Impaired Consciousness-A Practical Scale) can be used to objectively express the AVPU status of patients in coma caused by various causes. The GCS score consists of three aspects: eye response, verbal response, and motor response.

The GCS score is suitable for adults and pediatrics.



CAUTION

- The results of the GCG score are for reference only, please use other clinical evidence for diagnosis.
- GCS is not suitable for patients with sedation or myosone, artificial airways, drunkenness and epilepsy.
- GCS is not available for people with language impairment, deafmutism and mental disorders.
- GCS is not available for people with language impairment, deafmutism and mental disorders.

11.2.1 Calculation and Display of GCS

The GCS calculation and display interface is shown in Figure 11-4 as follows.

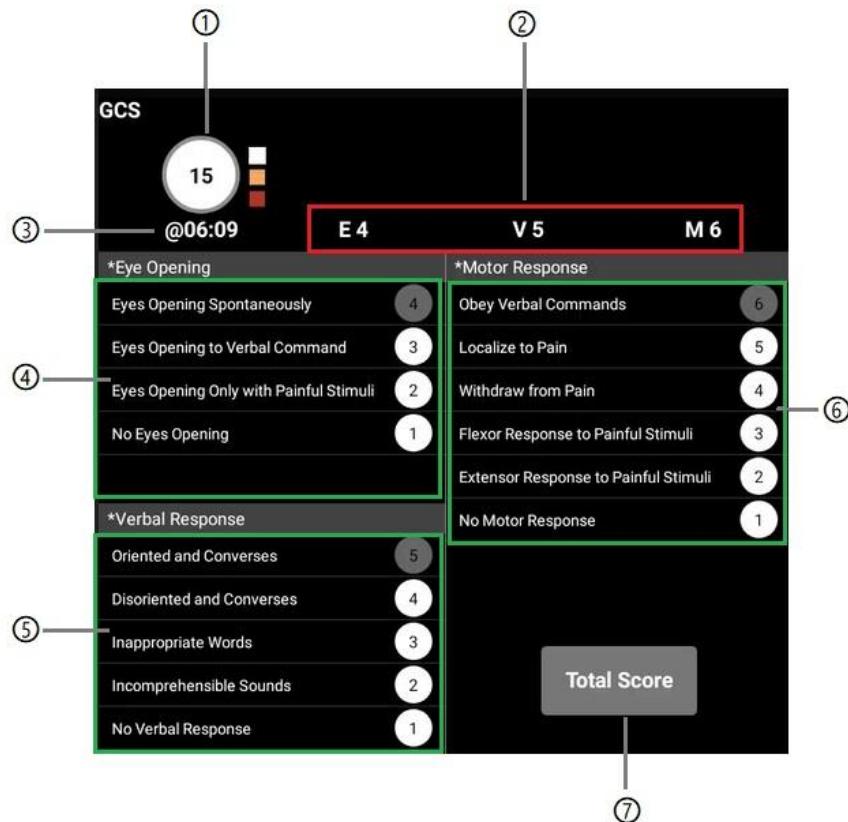


Figure 19-4 GCSParameter Area

Number	Function Explanation
1	Total score (Coma Index)
2	Single item score E: Eye-opening response V: Verbal response M: Limb movement
3	The time of this scoring
4	Eye-opening response scoring area
5	Verbal response scoring area
6	Limb motor response scoring area
7	Total score calculation button

11.2.2 Calculate GCS

Calculate the score as follows:

1、 In the 'GCS' menu, select an option that corresponds to the patient's status from the eye response, verbal response, and motor response.

2、 Select 'Calculate'

The following table lists the default range and colors for each rating level:

Level	Score Range	Background Color	Explanation
Mild	12 ~ 15	White	Normal or mild brain impairment
Moderate	5 ~ 11	Yellow	Moderate to severe impairment of brain function
Severe	3 ~ 4	Red	Dead brain or vegetative state

11.2.3 Review of Scoring

Select the review hotkey to enter the review menu, where you can view the historical GCS scores.

11.3 Pain Score

The monitor provides a pain scoring function to help assess the patient's pain. By default, the following scales are provided:

- VAS-cm: A visual simulation method ranging from 0 to 10 centimeters.
- VAS-mm: A visual simulation method ranging from 0 to 100 mm.
- NRS: Numerical Rating Scale, which uses numbers to score pain.
- Oral scoring scale of VRS-5 from 0 to 5.
- Ofc-r: Facial Pain Scale.
- FLACC: Represents face, legs, activity, crying and consolability.

11.3.1 The pain score is shown

The pain score interface is shown in Figure 11-5 below. Different score types will have different displays.

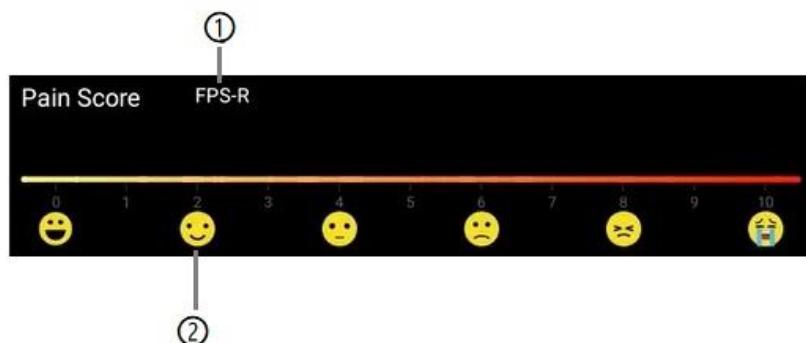


Figure 11-5 Pain Score scoring interface

Number	Function Explanation
1	Name of Pain Scale
2	Scoring area, manually selected

11.3.2 Conduct pain scoring

Please operate according to the following steps:

1. Select the type of scoring scale.
2. Press the scoring area gently to select the scoring value or option.
3. The result will be saved automatically.

11.3.3 Review of Scoring

Select the review hotkey to enter the review menu, where you can view the historical Pain Score.

Chapter 12 Printing

12.1 Chapter Twelve Thermal Printing

This monitor uses the thermal recorder to print patient information, measurement numerics, waveforms (Up to 2 waveforms per printing) etc.

Waveform printing is supported only in the monitor mode.

12.2 Start Printing

You can manually start a recording or automatic recording will be triggered in certain conditions.

12.2.1 Start Printing Manually

To manually start a recording, you can either:

- Select “**Print**” in soft keys area.
- Select “**Print**” button from the current menu or window.

12.2.2 Automatic Printing

Automatic printing is only applicable to the monitor mode.

You can set automatic recordings in the following conditions:

- Timed recordings will start automatically at preset intervals.
- If the Alarm is set on, an alarm recording will be triggered automatically as alarms occur.

12.3 Stop Printing

You can manually stop a recording or recording stop automatically.

12.3.1 Stop Printing Manually

To manually stop a recording, you can either:

- Select **[Stop Printing]** Soft keys to stop printing.

12.3.2 Printings Stop Automatically

Recordings stop automatically when:

- The runtime is over.
- The recorder runs out of paper.
- When the recorder has an alarm condition or technical issue.

12.4 Print Configuration

Select [**Main Menu**] → From the [**Configuration**] column, select [**Print Configuration**] to enter the Print Configuration menu. As shown in Figure 12-1.

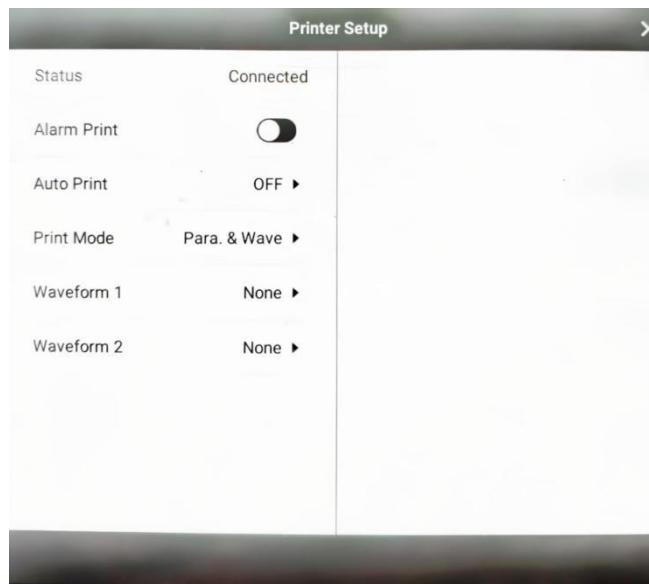


Figure 12-1 Print Configuration

The following Settings can be made:

1) Status

Display the current connection status between the printer and the host.

2) Alarm Print

Alarm printing can be turned on or off. If the alarm print is turned on, when a high-level alarm occurs, it will automatically print and record the parameters and waveforms at the time of the alarm. If the alarm print is turned off, the alarm will not trigger the print.

3) Auto Print

It can be configured to automatically print or turn off at regular intervals. When configured for timed automatic printing, that is, starting the printing once after a fixed interval of the configured time, record the parameters and waveforms at the time of starting the printing. When configured to be off, automatic printing will not be triggered.

4) Print Mode

It is possible to configure parameter-only printing and parameter-& waveform printing.

5) Waveform1 & Waveform2

If the print mode is parameter and waveform printing, when the waveform type configuration for printing is not empty, after the print starts, it will print according to the configured waveform type.

12.8 Install thermal printing paper

1. Press the door latch to open the recorder door. Remove the paper core. Place a new paper roll between the tabs of the paper holder.
2. Make sure the paper unrolls from underneath the paper roll. Close the recorder door, make sure the new paper roll fits snugly into its housing and the paper end is feeding from the top. Otherwise, it would be hard to feed the paper under the roller.



NOTE

- Use only specified thermal paper. Otherwise, it may cause damage to the recorder's printhead, the recorder may be unable to print, or poor print quality may result.
- Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.
- Do not leave the recorder door open unless you reload paper or remove troubles.

12.9 Removing Paper Jam

If the recorder works incorrectly or produces unusual sounds, check if there is a paper jam first. If a paper jam is detected, follow this procedure to remove it:

1. Open the recorder door.
2. Take out the paper and tear off the draped part.
3. Reload the paper and close the recorder door.

Chapter 13 Trend Review

13.1 Description

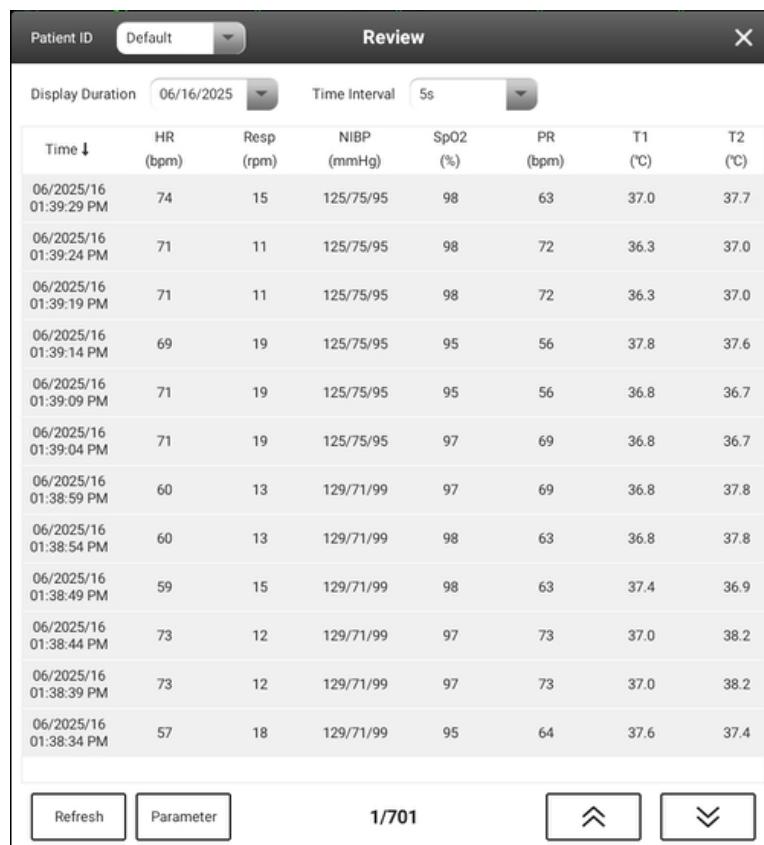
During the patient monitoring process, the trend is to collect patient data in chronological order and then display it in the form of a table so that you can understand the development of the patient's condition.

This monitor can store the monitoring data of a single patient for up to 120 hours (5 days, 24 hours a day) at most. The saved guardianship data is supported to be exported via a USB interface.

13.2 View Graphic Trends

There are some differences in the review page between the monitoring mode and the spot test mode. The following introduction takes the guardianship mode as an example.

There are some differences in the review page between the monitoring mode and the spot test mode. The following introduction takes the guardianship mode as an example.



Time ↓	HR (bpm)	Resp (rpm)	NIBP (mmHg)	SpO2 (%)	PR (bpm)	T1 (°C)	T2 (°C)
06/2025/16 01:39:29 PM	74	15	125/75/95	98	63	37.0	37.7
06/2025/16 01:39:24 PM	71	11	125/75/95	98	72	36.3	37.0
06/2025/16 01:39:19 PM	71	11	125/75/95	98	72	36.3	37.0
06/2025/16 01:39:14 PM	69	19	125/75/95	95	56	37.8	37.6
06/2025/16 01:39:09 PM	71	19	125/75/95	95	56	36.8	36.7
06/2025/16 01:39:04 PM	71	19	125/75/95	97	69	36.8	36.7
06/2025/16 01:38:59 PM	60	13	129/71/99	97	69	36.8	37.8
06/2025/16 01:38:54 PM	60	13	129/71/99	98	63	36.8	37.8
06/2025/16 01:38:49 PM	59	15	129/71/99	98	63	37.4	36.9
06/2025/16 01:38:44 PM	73	12	129/71/99	97	73	37.0	38.2
06/2025/16 01:38:39 PM	73	12	129/71/99	97	73	37.0	38.2
06/2025/16 01:38:34 PM	57	18	129/71/99	95	64	37.6	37.4

Figure 13-1 Trend table page

On the review page, historical measurement data are presented in the form of tables.

1) Parameter type filtering

Select the **[Parameters]** button on the page. In the pop-up menu, choose the parameters to be displayed and configure the display of a single Parameter or a combination of multiple parameters.

2) Date filtering

Select the **[Display Duration]** drop-down list on the page to choose the date. After selection, the data of the selected date will be automatically filtered out and presented in chronological order.

3) Patient ID filtering

Select the **[Patient ID]** drop-down list on the page to choose the user ID. The data list will switch to the patient's historical data corresponding to the selected ID for display.

4) Time interval screening

Select the **"Time Interval"** drop-down list on the page and choose the time interval to configure the time interval between two data points in the trend table. The selectable time intervals are: There are a total of 12 Settings: 5s, 10s, 20s, 30s, 40s, 50s, 1min, 2min, 4min, 6min, 8min and 10min.

5) Refresh the data

Select the **"Refresh"** button at the bottom of the page to manually refresh the trend data.

6) Page turning display

The trend table shows 12 sets of measurement data per page. You can use the  and  page-turning buttons at the bottom to turn the pages and view them.

Chapter 14 Internal Batteries

14.1 Description

The number of Lithium battery charge and discharge is more than 300 times (300-500 times, depending on the use of the situation). Battery lifespan depends on how frequent and how long it is used. If the battery is properly maintained and stored, its lifespan is about 3 years. If the battery is used improperly, its lifespan may decrease. When the battery is used frequently, replacing the lithium battery every 2 years is recommended; when it is not used frequently, it is recommended to replace the battery every 3 years.

The monitor is designed to operate on rechargeable Lithium-ion battery to ensure the normal operation of the monitor even when the AC power supply is interrupted. The patient monitor will prioritize the external AC as power source when available. If the AC power is cut off, the patient monitor will automatically run power from the internal batteries.

14.2 Safety Information

WARNING

- Keep the battery out of children's reach.
- Use only batteries specified in the chapter on "Accessories". Use of a different battery may present a risk of fire or explosion.
- Keep batteries in their original package until you are ready to use them.
- Do not expose batteries to liquids.
- Do not crush, drop or puncture batteries - mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally. If a battery has been dropped or banged against a hard surface, whether damage is visible externally or not, its use should be stopped.
- If the battery is damaged or leaking, replace it immediately.
- Only this monitor can be used to charge the battery.
- Extremely high ambient temperatures may cause the battery to overheat, resulting in interruption of power to the monitor.
- The lifespan of a lithium battery is two years. Replace the battery when its lifetime is expired. Failure to replace the battery on schedule may cause the battery to overheat during the monitoring process and cause serious damage to the device.
- Please install the battery into the equipment for charging before first use. When inserting the

battery, Load the batteries in the chamber as indicated by the polarity symbols (+/-) marked inside, inserting the battery backward is not allowed.

- Do not open batteries, heat above 60 °C (140 °F), incinerate batteries, or cause them to shortcircuit. They may ignite, explode, leak or heat up, causing personal injury.

CAUTION

- Take out the battery before the monitor is transported or will not be used for a long time.
- When using battery power, if the too many measurement modules are connected to the equipment for measurement, the monitor may automatically shut down due to excessive load.

14.3 Battery Installation

Batteries are not installed by default. Battery installation and replacement must be performed by our trained and authorized service personnel.

WARNING

- Untrained personnel installing and replacing batteries may cause dangers (such as overheating, fire or explosion).

14.4 Battery Status

Battery Power Indicators, On-screen battery symbols and battery alarm message indicate the current status of the battery.

14.4.1 Battery Power Indicators

The battery status indicator light is located at the lower right corner of the monitor. Its instructions are as follows:

- Green-light always on: Indicates that the batteries are charging.
- Green-light Flashing: The monitor is powered by batteries.
- No Green-light: The battery is not installed, the battery is faulty, or the monitor is off and the external AC power supply is not connected.

14.4.2 Battery Symbols

The battery icon in the system status information area of the monitor interface indicates the status of the battery:

-  Indicates that no batteries are installed
-  Indicates that batteries work correctly. The solid portion represents the current charge level of the batteries in proportion to its maximum charge level.
-  Indicates that the batteries have low charge level and need to be charged.
-  Indicates that the batteries are charging.
-  Indicates that the batteries are fully charged.
-  Indicates that the batteries malfunction.

14.4.3 Battery power indication

The battery power information is displayed on the right side of the battery icon, as shown in the following figure:



14.4.4 Battery Alarm

If the battery capacity is too low, a technical alarm will be triggered and the [Battery Too Low] message displayed. At this moment, apply AC power to the patient monitor. Otherwise, the patient monitor will power off automatically in 15s.

14.5 Charging a Battery

To maintain the good performance of the battery, nearly fully discharged battery must be charged as soon as possible. The battery is charged whenever the patient monitor is connected to an AC power source regardless of whether or not the patient monitor is currently on.

14.6 Conditioning Battery

14.6.1 Conditioning Battery

The performance of rechargeable batteries may deteriorate over time. Battery performance check is recommended to be performed every 3 months. If the battery is not optimized for a long time, it may cause the inaccuracy of battery indicator, resulting in a wrong judgment of the remaining battery operating time.

The battery optimization steps are as follows:

1. Disconnect the monitor from the patient and stop all monitoring or measurement.
2. Turn off the monitor and connect an external power supply.
3. Charge the battery continuously until it is fully charged.

4. Disconnect the external power supply and turn on the monitor. Power the monitor with the battery until the battery runs out, and the monitor will automatically shut down.
5. If you want to use the battery, recharge it. If you want to store the battery, recharge it to 40-60% of its capacity.

 **NOTE**

- If battery maintenance is not carried out for a long time, it may cause inaccurate display of battery power, leading to incorrect judgment of battery working time. In addition, if the battery remains fully charged for a long time without regular maintenance, it will accelerate battery aging and lead to premature battery failure.
- Do not monitor patients when the batteries are conditioned.
- Do not stop charging or discharging cycle when batteries during conditioning.

14.6.2 Check Battery Performance

The service life of a battery depends on the frequency and duration of its use. If the battery is used and stored properly, the service life of a lithium battery is approximately two years. Improper use of batteries may shorten their lifespan. We recommend replacing the battery every two years.

The performance of rechargeable batteries may deteriorate over time. Battery performance check must be performed every 3 months.

Refer to Steps 1 to 5 in 18.6.1 Battery Optimization for battery inspection. The length of battery power supply time reflects the performance of the battery. If the battery's power supply time is significantly shorter than the time claimed in the specification, it indicates that the battery may have reached its service life, been damaged or malfunctioned. Please contact the maintenance personnel.

If the battery condition is normal, Reconnect the monitor to mains power and charge the battery until it is full for use or charge to 40~60% for storage.

 **NOTE**

- The operating time depends on the configuration and operation. For example, Screen brightness too high or monitoring NIBP repeatedly will all shorten the operating time of the batteries.

14.7 Storing a Battery

When storing the battery, make sure the electrodes of the battery are not in contact with metal

objects. If the battery needs to be stored for prolonged period, it should be placed in a cool environment and charged to 40%-60%.

Stored batteries should also be conditioned periodically.

NOTE

- Remove the battery from the monitor when it is not used for a longer period of time, to avoid potential damage caused by battery leakage.
- Storing batteries in high temperatures for long periods of time will significantly reduce the battery lifespan.
- The temperature range for battery storage is -5°C~35°C. Storing the battery in a cool environment can slow down the battery aging. Ideally, batteries should be stored at 15 °C.

14.8 Disposing of Used Batteries

Please replace the battery and recycle it in the following situations:

- There is clear damage
- There is a malfunction
- Battery ages or the discharging time of a battery is noticeably shorter than that indicated in the specifications
- Battery lifespan has expired

Dispose of used batteries promptly and follow local government regulations in an environmentally-responsible manner.

Chapter 15 Maintenance and Cleaning

15.1 Description

In this chapter we only describe cleaning and disinfection of the main unit. For the cleaning and disinfection of reusable accessories, refer to instructions for use of corresponding accessories.

15.2 Safety Information

WARNING

- Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.
- Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.
- We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.
- The responsible hospital or institution shall carry out all cleaning and disinfection procedure specified in this chapter.

CAUTION

- Do not immerse part of the equipment into liquid.
- Any contact of disinfectant solutions with metal parts may cause corrosion.
- Do not allow liquid to enter the case.
- If you spill liquid on the equipment or accessories, please disconnect from power, erase the liquid and contact us or your service personnel immediately.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).
- Dilute and use cleaning and disinfecting agents following instructions specified in product manual.
- After cleaning and disinfection, check the equipment carefully. Do not use if you see signs of deterioration or damage.

15.3 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

The following are the available cleaning agents:

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

To **clean your equipment**, follow these rules:

1. Shut down the patient monitor and disconnect it from the power line.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated, cool place.

15.4 Disinfecting

Disinfect the equipment and modules in accordance with the disinfection procedures of the hospital where they are located. Cleaning should be carried out before disinfection.

Disinfection operations may cause a certain degree of damage to the monitor. It is recommended to carry out disinfection operations only when your hospital maintenance plan deems it necessary.

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

 **NOTE**

- Never use EtO or formaldehyde for disinfection.

Chapter 16 Maintenance

16.1 Description

Regular maintenance of equipment and accessories is the key to ensure the normal operation of equipment. This chapter introduces the inspection and testing methods of the equipment.

16.2 Safety Information

WARNING

- Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure, possible health hazards, and may endanger personal safety.
- Hospitals or medical institutions that use this equipment should establish a complete maintenance plan; otherwise, it may lead to equipment failure and unexpected consequences, and may also endanger personal safety.
- No changes should be made to this device itself.
- This equipment does not contain any repairable parts for users. If maintenance is needed, please contact the maintenance personnel.
- The safety checks or maintenance involving any disassembly of the equipment should be performed by professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.
- Do not disassemble the battery, store it in an environment above 60 °C, incinerate it or short-circuit it, as these may cause battery burning, explosion, leakage or overheating, and serious injury or death could result.
- Personnel that is responsible for maintain this equipment must be qualified and familiar with the operation of the product.

CAUTION

- Maintenance and conditioning of the monitor are not allowed when the patient is monitored.
- If you discover a problem with any of the equipment, contact your service personnel or us.
- Do not use or store equipment outside the specified temperature, humidity, or altitude ranges.
- Disposal of packaging materials must comply with local regulations or the hospital's waste disposal policy.
- When the equipment and its accessories have reached the expiration date, they must be

disposed of in accordance with local regulations. If you have any questions regarding the disposal, please contact our company.

NOTE

- When the equipment and its accessories have reached the expiration date, they must be disposed of in accordance with local regulations. If you have any questions regarding the disposal, please contact our company.

Before every use, after your patient monitor has been used for 6 to 12 months, or whenever your patient monitor is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect all power cords for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Inspect if the alarm system functions correctly.
- Make sure that the batteries meet the performance requirements.
- Make sure that the patient monitor is in good working condition.
- Make sure that the grounding resistance and leakage current meet the requirement.

In case of any damage or abnormality, do not use the patient monitor. Contact the hospital's biomedical engineers or your service personnel immediately.

16.3 Maintenance Plan

Ensure that maintenance tasks are performed in accordance with the maintenance plan or local regulations. Before testing and maintenance, the equipment must be cleaned and disinfected. Test and maintenance items and frequencies of recommendation are as follows:

Test / maintenance items	Frequency of recommendation
Performance Testing	
Visual inspection	Before first use every day
Parameter module performance test and calibration	1、When the user suspects that the measured value is inaccurate; 2、After maintenance or replacement of relevant modules;

	3、 The CO2 module should be carried out at least once a year; 4、 Other modules shall be at least every two years.	
Security Testing		
Select test items based on the requirements of IEC60601-1	1. When the power module is repaired or replaced; 2. After the monitor falls; 3. At least once every two years or as required.	
Other Tests		
Startup inspection	Before each use	
Thermal sensitive recorder test	1、 During the first installation; 2、 After repairing or replacing the recorder.	
Startup inspection	Before each use	Startup inspection
Startup inspection	Before each use	Startup inspection

16.4 Checking Version Information

You may be asked for information on monitor and module version.

To view system software version information, select the **[Main Menu]** quick key → from the **[System]** column select **[About]**.

16.5 Test methods and steps

Except for the following maintenance tasks, all testing and maintenance can only be completed by professional maintenance personnel approved by the company.

- Routine inspection, including visual inspection and startup inspection
- Thermal sensitive recorder inspection
- Battery inspection

When other tests and maintenance are required, please contact the maintenance personnel in time.

16.5.1 Visual Inspection

Check the appearance of the equipment before use every day. In case of damage or failure of equipment and accessories, please stop using immediately and contact the equipment engineer of the hospital or the maintenance personnel of the company.

Visual inspection includes the following items:

- The environment and power supply meet the requirements;
- The equipment shell shall be free of stains, and the panel and display screen shall not be broken or damaged;

- The power supply is free of wear and has good insulation performance;
- The interface, plug and cable shall be free from damage and winding;
- Firmly connect the module and cable to the equipment.

16.5.2 Startup Inspection

The monitor performs self-test after startup, and the startup inspection items are as follows:

- The equipment can be started normally;
- Alarm system works normally;
- The equipment displays normally.

16.5.3 Thermal sensitive recorder test

Check whether the thermal sensitive recorder is working properly by following the steps below:

- 1、Start the printing task to print the waveform and report;
- 2、Check whether the recorder is feeding paper normally;
- 3、Check whether the waveform and text are clear and free of any omissions.

16.5.3 Battery check

Refer to 14.6.2 to check battery performance.

16.6 Waste monitor

After the equipment reaches its service life, please dispose of the monitor and accessories according to local regulations.

WARNING

- For the disposal of components and accessories, if there are no corresponding regulations, the local regulations on the disposal of hospital waste can be followed.

Chapter 17 Annex

All accessories listed in this chapter meet the requirements of IEC 60601-1-2 when used with a monitor. Accessory materials in contact with the patient have been tested for biocompatibility and verified to meet the requirements of ISO 10993-1. Detailed information on accessories can be found in the relevant accessory manual.



WARNING

- Use accessories specified in this chapter. Using other accessories may cause damage to the patient monitor or not meet the claimed specifications.
- The accessories should be used with this monitor only. It is the responsibility of the user to read this manual carefully (including accessories) or contact us to confirm the compatibility of the accessories with the device prior to use. Failure to do so may cause injury to patient.
- Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.



CAUTION

- If the usage or storage environment of the accessory exceeds the specified temperature or humidity range, the performance of the accessory may not meet the claimed specifications. If the performance of the accessory declines due to aging or environmental conditions, please contact the user.
- Check whether the accessories and their packaging are intact. If any damage is found, do not use them.
- Before use, please check the compatibility of the equipment, connection cables and accessories. Incompatible accessories may cause a decline in equipment performance or damage.
- Please do not use the attachment if it has expired.
- The handling of disposable attachments must comply with local regulations or hospital systems.


NOTE

- For attachments with a safe service life, the service life is indicated on the attachment packaging.
- Sterilization attachments can be found in the attached packaging.

See the accessory identification label for accessory information. If you need to buy, please contact the sales agent.

17.1 SpO₂ Accessories

Name	Model	Type	Patient Category	Remark	Manufacturer
Extensi on Cable	M0511027	Reusable	Adult, Pediatric, Neonate	Length 3m	Qingdao Bright Medical Manufacturing Co Ltd

Name	Model	Type	Patient Category	Remark	Manufacturer
SpO ₂ Sensors	DP400N/A-090103	Single use	Adult/ Neonate	Suitable for BCI module Length 1.6m	Beijing Rongrui-Century Science & Technology Co., Ltd.
	RSJ001DA	SpO ₂ Sensors	DP400N/A-090103		
	RSY001D N	SpO ₂ Sensors	DP400N/A-090103		

Wavelength emitted by pulse oximetry probe is 600 ~ 1000nm, The maximum photic output consumption of the sensor is less than 18 mW.

The information about the wavelength range and maximum photic output consumption can be especially useful to clinicians, for example, clinicians performing photodynamic therapy.

17.2 NIBP Accessories

Name	Model	Type	Patient Category	Remark	Manufacturer
Tubing	L340	Reusable	Adult, Pediatric, Neonate	Length 3.4m	InfiniumElectronics Co., Ltd.

Name	Model	Type	Patient Category	Remark	Manufacturer
Cuff	LF1101S	Reusable	Neonate	/	Lifemed Co., Ltd
	LF1102S		Pediatric		
	LF1103S		Adult		
	LF1204S		Adult		

17.3 CO2 Accessories

Name	Model	Type	Remark	Manufacturer
Gas conduit	YSK-CYG-M	One-time use	/	Jilin Province Youxian Kangjian Medical Devices Co., LTD
Nasal sampling	DM-4100-AF	One-time use	/	Dispo-Med

17.4 Temp Accessories

Name	Model	Type	Patient Category	Remark	Manufacturer
Thermometer	HTD8808E	Reusable	Adult, Pediatric, Neonate	Forehead	Hetaida Technology Co., Ltd copyright

17.5 Other Accessories

Name	Model	Type	Patient Category	Remark	Manufacturer
Lithium battery	XHL18650-3 S2P	Reusable	/	/	ShenZhen New Light Energy Technology Co., Ltd
Direct power cord	/	/	/	Length 2m	

A Specifications

A.1. Safety Specifications

A.1.1 Product Category

According to the classification of the National Drug Administration of China, this monitor is Class III equipment.

This monitor is classified according to IEC60601-1 as follows:

Type of protection against electrical shock	Class I, with internal power
Degree of protection against electrical shock	Type CF defibrillation proof for SpO2, NIBP
Mode of operation	Continuous
Degree of protection against harmful ingress of water	IPX2
Portability type	Portable

A.1.2 Environmental Specifications

Item	Temperature (°C)	Relative Humidity(non-condensing)	Barometric (kPa)
Operating conditions	5°C~40°C	15%~95%	80kPa~105kPa
Storage conditions	-20°C~55°C	10%~95%	80kPa~105kPa

WARNING

Operation within the specified environmental specifications is a must. Otherwise, it may cause damage to the patient monitor or not meet the claimed specifications. If aging or any performance change that results from the environment condition, please contact the service personnel.

NOTE

Unspecified modules' environment specifications are the same with the main unit's.

A.2 Power Supply Specifications

A.2.1 External AC Power

Input Voltage	100 ~ 240V
Input Current	1.3 ~ 0.5A
Input Line Frequency	50/60 Hz

A.2.2 Battery

Type	Lithium-ion battery, rechargeable
Rated Voltag	11.1V DC
Volume	5200 mAh * 2
Run Time	Brand new fully charged battery, ambient temperature 25°C, under normal working conditions: Two batteries: no less than 8 hours One battery: no less than 4 hours
Charge Time	Monitor OFF: 0-90%: < 4h 0-100%: < 5h Monitor ON: 0-90%: < 7h 0-100%: < 10h
Shutdown delay	At least 15 minutes (since the first low battery alarm)

A.3 Physical specification

Name	Model	Weight	Size
Mainframe	CLEO2	≤3.250kg	200mm×275mm×165mm
Battery	XHL 18650-2S2P	340g	145mm×64mm×21.5mm

A.4 Hardware specification

A.4.1 Display Specification

Screen Type	TFT-LCD
Screen Size	10.1 inch
Resolution	1280×800 @ 60hz (24bit Colors)
Touch-Screen Type	Multi-Touch Capacitive Screen

A.4.2 Thermal Printer Specification

Type	Thermal dot array
Paper Width	60mm
Paper Speed	25mm/s
Number of Waveform Channels	1, 2 or 3

A.4.3 LEDs on Main Units

Alarm Lamp	1 (3 colors: red, yellow, blue)
AC Power Indicator	1 (green)
Battery Status Indicator	1 (green)

A.4.4 Audio indication

Speaker	The emitted sounds include but are not limited to alarm sounds (45-85 dB), button sounds and pulse sounds; Support multi-level volume function; The alarm sound complies with the requirements of the IEC 60601-1-8 standard.
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A.4.5 Interface Specifications

Power	1 AC power connector
Ethernet Port	1 1000M Ethernet port
USB	Three USB2.0 protocol USB interfaces, two Type-A and one Type-C
Equipotential End	1
Nurse call interface	1
External DC power supply interface	1, 11.1V 5.2A

A.4.6 Signal Outputs Specifications

Alarm output	
Alarm signal sound pressure level range	40 dB(A) to 80 dB(A) within a range of one meter

A.5 Software Specifications

General Specifications	
Layout	Up to 4physiological parameters supported 32 sets of colors

	Support two working modes: <ul style="list-style-type: none"> ● Guardianship mode ● Point test mode
InternalStorage	8 GB storage, usable size is 3GB
External File System	USB Flash Disk, FAT32 and NTFS format supported
Brightness	6 levels. Adjustable range is 0~5, 0 is the darkest, 5 is the brightest. Default setting is 3. Night mode brightness level is 0.
Sound Volume	6 levels. Adjustable range is OFF and 1~5, choose OFF to silence the audio, level 5 is the highest volume. Default setting is 2.
System Time	24H/12H format supported: 24H: YYYY/MM/DDHH:MM 12H: YYYY/MM/DDH:MM AM/PM Turn on automatic synchronization, when the monitor is connected to WLAN. Time is automatically synchronized with network time.
USB Extension	USBKeyboard USBMouse USB Flash Disk USBCode Scanner USB Hub (supported, connection with too many devices is not recommended)
Patient Information Management	
Patient Setup	Supported, indexed with patient ID.
Trend Data Saving	5×24h Parameter data saving
Patient Review	Patient information display supported Sorting by time supported
Data Export	USB FlashDisk exportation supported Exportation through DataManager application within WLAN connection supported
Data Protection/ Deletion	Data protection supported to avoid accidental deletion or overwritten Deletion confirmation window to avoid accidental deletion.
Management Capacity	20 patient information sets at most
Module Setup Management	
General Module	NIBP Module SpO2 Module CO2 Module Temp Module
Config Manager	Up to 30 configurations supported.

Configuration Export/Import	Yes
Ethernet Setup	IPv4 address supported, DHCP and Static IP supported. The system default is DHCP.
Alarm Management	
Alarm Levels	Classified into 3 levels: High: Flashing red with 2Hz frequency (twice per second) Medium: Flashing yellow with 1Hz frequency (once per second) Low: Cyan You can set alarm sound type and alarm interval
Physiological Parameters	SpO2, PR, NIBP-SYS, NIBP-DIA, EtCO2, awRR, Temp
Physiological Alarm List	Summary of current physiological alarms for review. Summary of history alarms for a specific parameter in Alarm Review, capacity: 100 sets.
Physiological Alarm	Sensor Off, Low Battery, Hardware malfunction, Module Disconnection, Signal out of range
Technical Alarm List	Current technical alarm list for review. History alarm list for technical alarms in Alarm Review, Capacity: 100 sets.
Data Communication	
Health Level 7 Protocol	HL7 two-way communication supported HL7 patient management supported HL7 view report For more information about the HL7 standards process, please refer to the HL7 standards process document that we provide
Data Transmission	Data export/import mode through network supported Exportation content: Patient data and config Importation content: Config
History Patient Data Export	Installation of our DataManager software on PC allows you to view historical patient data stored in different devices within the LAN. When the DataManager Service is enabled on the monitor, your PC can connect to the monitor through the DataManager software and export the history patient data from the device, including measurement data and alarm recordings.
Smart Upgrade	
System Firmware Upgrade	Yes

Automated Upgrade by Network	Yes
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A.6 Measurement Specifications

A.6.1 SpO2

General Specification	
Standard	ISO 80601-2-61:2017
Speed	12.5mm/s, 25.0mm/s
Module Type	Infinium module, Nellcormodule, Masimomodule
Alarm Limit	Range
SpO2 Alarm High	(Low limit + 1) ~100% Infinium/Nellcor module: Default value: 99% Masimomodule: Default value: 99.9%
SpO2 Alarm Low	0~ (high limit - 1) % Infinium/Nellcor module: Default value: 85% Masimomodule: Default value: 85.0%
PR Alarm High	(High limit + 2) ~300bpm
PR Alarm Low	15~ (low limit - 2) bpm
PI Alarm High (Masimo)	(Low limit + 0.2) ~20.0% Default value: 20.0%
PI Alarm Low (Masimo)	0.0%~ (high limit - 0.2) % Default value: 0.3%
SpO2 Alarm Response Time	≤12s
Infinium Module	
Measurement Range	0%~100%
Resolution	1%
Accuracy	70%~100%: $\leq\pm2\%$ 0%~69%: Not specified
Refreshing rate	1s
Low Perfusion Conditions	0.3%~20%
Pulse Rate	
Measurement Range	30bpm~250bpm
Resolution	1bpm
Accuracy	$\leq\pm2$ bpm (measured without motion) $\leq\pm3$ bpm (measured with motion)

Nellcor Module	
Measurement Range	0%~100%
Resolution	1%
Accuracy	Adult/Pediatric: 70%~100%: $\leq\pm2\%$ Neonate: 70%~100%: $\leq\pm3\%$ 0%~69%: Not specified
Refreshing rate	1s
Low Perfusion Conditions	NA
Pulse Rate	
Measurement Range	20bpm~250bpm
Resolution	1bpm
Accuracy	20bpm~250bpm: ±3 bpm
Masimo Module	
Measurement Range	0%~100%
Resolution	0.1%
Accuracy	Adult/Pediatric 70%~100%: $\leq\pm2\%$ Neonate 70%~100%: $\leq\pm3\%$ 1%~69%: Not specified
Refreshing rate	1s
Low Perfusion Conditions	0.02%~20%
Pulse Rate	
Measurement Range	20bpm~250bpm
Resolution	1bpm
Accuracy	20bpm~250bpm: ±3 bpm

A.6.2 NIBP

General Specification	
Standard	ISO 80601-2-30:2019
Measurement Method	Oscillometry
Mode of Operation	Manual, Auto and STAT
Auto Mode Repetition Intervals	2min~240min
Number of STAT Mode Cycle	5
Total Number of NIBP Listings	1024
Measurement Type	Adult, Pediatric, Neonate

Initial Cuff Inflation Pressure	Adult options: 80mmHg 100mmHg 120mmHg 140mmHg 150mmHg 160mmHg 180mmHg (Default) 200mmHg 220mmHg 240mmHg	Pediatric options: 80mmHg 100mmHg 120mmHg 140mmHg (Default) 160mmHg 180mmHg 200mmHg 220mmHg 240mmHg	Neonate options: 60mmHg 70mmHg 80mmHg 100mmHg (Default) 120mmHg
	Inflation Memory Mode	Yes	
	Alarm Limit	Range	
	Sys High	Adult: (low limit + 5) ~270mmHg Pediatric: (low limit + 5) ~230mmHg Neonate: (low limit + 5) ~135mmHg Default value: 160mmHg (Adult) 120mmHg (Pediatric) 90mmHg (Neonate)	
	Sys Low	40~ (high limit - 5) mmHg Default value: 90mmHg (Adult) 70mmHg (Pediatric) 40mmHg (Neonate)	
	Dia High	Adult: (low limit + 5) ~210mmHg Pediatric: (low limit + 5) ~150mmHg Neonate: (low limit + 5) ~95mmHg Default value: 90mmHg (Adult) 70mmHg (Pediatric) 60mmHg (Neonate)	
	Dia Low	10~ (high limit - 5) mmHg Default value: 50mmHg (Adult) 40mmHg (Pediatric) 20mmHg (Neonate)	

Infinium Module	
Standard	ISO80601-2-30:2019
Measurement Method	Upper arm, Oscillometry
Mode of Operation	Manual, Auto and STAT
Max Measurement Time	180s (Adult/Pediatric) 90s (Neonate)
Static Pressure Measurement Range	0~300mmHg
Accuracy	±3mmHg
Dynamic Pressure Measurement Range	Adult: SYS: 40mmHg~270mmHg DIA: 10mmHg~210mmHg Pediatric: SYS: 40mmHg~230mmHg DIA: 10mmHg~150mmHg Neonate: SYS: 40mmHg~135mmHg DIA: 10mmHg~95mmHg
Dynamic Pressure Accuracy	Max mean error: ±5mmHg Max standard deviation: 8mmHg
Resolution	1mmHg
Software Overpressure Protection	Adult: 297mmHg ±3mmHg Pediatric: 237mmHg ±3mmHg Neonate: 147mmHg ±3mmHg
PR Measurement Range	40~240bpm
PR Accuracy	2% or ±3bpm, whichever is greater

A.6.3 EtCO₂

General Specification C200	
Standard	ISO 80601-2-55:2018
Measurement Range	0 - 20% Volume ratio (0-152mmHg@BTPS)
Accuracy*	0-5% CO ₂ (ATPS): ±2mmHg 5%-20% CO ₂ (ATPS): <10%
Response Time	5s
Flow Control	100ml/min
Flow Control Accuracy	±15% or ±15 ml/min, whichever is greater.

Warm-up Time	10s	
Rise time	$\leq 200\text{ms}$	
awRR		
Measurement Range	2 rpm~150 rpm	
Measurement Accuracy	$1\% \pm 1\text{rpm}$	
Resolution	1 rpm	
Effect of interference gases on CO ₂ measurements		
Gas	Concentration	Quantitative effect*
N ₂ O	$\leq 60\text{ \%}$	$\pm 1\text{ mmHg}$
HAL	$\leq 4\text{ \%}$	
SEV	$\leq 5\text{ \%}$	
ISO	$\leq 5\text{ \%}$	
ENF	$\leq 5\text{ \%}$	
He	$\leq 50\text{ \%}$	
Xe	$\leq 100\text{ \%}$	
DES	$\leq 15\text{ \%}$	$\pm 2\text{ mmHg}$
*: means an extra error should be added in case of gas interference when CO ₂ measurements are performed between 0 to 40 mmHg. Inaccuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15 bpm and I:E ratio smaller than 1:1 relative to the gas readings without breath.		
Alarm Limit	Range	
EtCO ₂ Alarm High	(Low limit + 2) ~150mmHg manual input required Default value: 60mmHg	
EtCO ₂ Alarm Low	0~(high limit - 2) mmHg manual input required Default value: 15mmHg	
awRR Alarm High	(Low limit + 2) ~150rpm manual input required Default value: 30rpm (Adult) 100rpm (Neonate)	
awRR Alarm Low	0~(high limit - 2) rpm manual input required Default value: 5rpm (Adult) 30rpm (Neonate)	

A.6.4 Temp

Temp	
Working mode	Adjustment mode
Response time	0.5s
Measurement method	Infrared
Measurement range	34.0°C~42.9°C (93.2°F~109.2°F)
Measurement accuracy	±0.2°C
Resolution ratio	0.1°C
Display unit	°C/°F
Sensor type	Infrared temperature sensor
Communication type	USB
Alarm specification	
Alarm High limit	(Low limit + 1) ~42.9 °C Default value: 37.4°C
Alarm Low limit	34.0 ~ (high - 1) °C Default value: 36.0°C

B Factory Defaults

B.1 SpO2 Setup

Item	Factory Default Settings				
SpO2	Alarm ON/OFF	ON			
	Alarm High	99%			
	Alarm Low	85%			
	Alarm Level	Medium			
	Alarm Record	OFF			
PR	Alarm ON/OFF	ON			
	Alarm High	Adult	130bpm		
		Pediatric	160bpm		
		Neonate	200bpm		
	Alarm Low	Adult	50bpm		
		Pediatric	75bpm		
		Neonate	100bpm		
	Alarm Level	Medium			
	Alarm Record	OFF			
Color					
Speed	12.5mm/s				
PR Source	SpO2				

B.2 NIBP Setup

Item	Factory Default Settings		
NIBP-SYS	Alarm ON/OFF	ON	
	Alarm High	Adult	160mmHg
		Pediatric	120mmHg
		Neonate	90mmHg
	Alarm Low	Adult	90mmHg
		Pediatric	70mmHg
		Neonate	40mmHg
	Alarm Level	Medium	
	Alarm Record	OFF	
NIBP-DIA	Alarm ON/OFF	ON	
	Alarm High	Adult	90mmHg
		Pediatric	70mmHg
		Neonate	60mmHg

	Alarm Low	Adult	50mmHg
		Pediatric	40mmHg
		Neonate	20mmHg
	Alarm Level	Medium	
	Alarm Record	OFF	
Color			
Pressure Unit		mmHg	
Mode of Operation		Manual	
Initial Pressure	Adult	180mmHg	
	Pediatric	140mmHg	
	Neonate	100mmHg	

B.3 EtCO2 Setup

Item	Factory Default Settings			
EtCO2	Alarm ON/OFF		ON	
	Alarm High		60	
	Alarm Low		15	
	Alarm Level		Medium	
	Alarm Record		OFF	
awRR	Alarm ON/OFF		ON	
	Alarm High	Adult	30	
		Pediatric	30	
		Neonate	100	
	Alarm Low	Adult	8	
		Pediatric	8	
		Neonate	30	
Alarm Level		Medium		
Alarm Record		OFF		
Color				
Unit		mmHg		
Speed		12.5mm/s		
Waveform Type		Fill		
Waveform Scale		0~75mmHg		
Apnea Delay		10s		
Zero Gas Type		Room air		
Oxygen (%)		16%		

Balance Gas	N2O
Anesthetic	0.0%
Barometric Pressure	760mmHg
Gas Temp	35°C

B.4 Temp Setup

Item	Factory Default Settings	
Temp	Alarm ON/OFF	ON
	Alarm High	37.4°C
	Alarm Low	36.0°C
	Alarm Level	Medium
	Alarm Record	OFF
Color	White	
Temperature Unit	°C	

C Alarm Messages

C.1 Physiological Alarm Messages

General Physiological Alarm

Alarm Messages	Default Level	Cause and Solution
XXX Too High	Medium	XX value has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct.
XXX Too Low	Medium	
Resp Apnea	High	Patient can't respirate or the respiration signal was so weak that the monitor cannot perform respiration analysis. Check the patient's Condition, electrode placement and the Resp connections.

Note: XXX represents Physiological parameter, like SpO2, PR, NIBP-SYS, NIBP-DIA, EtCO2, awRR and Temp etc.

C.2 Technical Alarm Messages

Module	Alarm Messages	Default Level	Cause and Solution
SpO2	SpO2 Sensor Off	Low	The SpO2 sensor has become detached from the patient or the module, check the connection. If the alarm persists, replace it with a new sensor.
NIBP	NIBP Self-check Error	Low	Check NIBP module or replace it.
	NIBP Cuff Off	Low	Reconnect the cuff.
	NIBP Loose Cuff or Pneumatic Leak	Low	Check the leakage in cuff or airway.
	NIBP Weak Signal	Low	The patient's pulse is weak or the cuff is loose. Check the patient's condition and change the cuff application site.
	NIBP Overrange	Low	The measured NIBP value is not within the specified range. Check the patient's condition.
	NIBP Excessive Motion	Low	Please keep quiet and remeasure.

	NIBP Overpressure	Low	The NIBP airway may be occluded. Check the airway and measure again. If the alarm persists, replace it with a new sensor.
	NIBP Signal Saturated	Low	The NIBP signal is saturated due to excess motion or other sources.
	NIBP Air Leak	Low	Check the NIBP cuff and pump for leakages.
	NIBP System Error	Low	Re-plug the module or restart the monitor.
	NIBP Timeout	Low	An error occurred during NIBP measurement and therefore the monitor cannot perform analysis correctly. Check the patient's condition and NIBP connections, or replace the cuff.
Temp	The thermometer is not connected	Low	Check the connection of the thermometer.
EtCO2	EtCO2 Error	Low	Re-plug the module or restart the monitor.
	EtCO2 Sensor High Temp	Low	High ambient temperature or module malfunction. 1、Lower the ambient temperature. 2、Reconnect the module. 3、If the alarm persists, please contact the service personnel.
	EtCO2 Zero Failed	Low	Check the CO2 connections. After the sensor's temperature becomes stabilized, perform a zero calibration again.
	EtCO2 Overrange	Low	
	EtCO2 Airway Adapter Error	Low	Check, clean or replace the adapter.

	EtCO2 Pump Life Expired	Low	Replace the pump.
Battery	Battery Low	Low	Battery Low, please charge the battery.
	Battery Too Low	High	Battery Too Low, please charge it immediately, otherwise, the monitor will shut down automatically.

D EMC and Radio Regulatory Compliance

The product is in radio-interference protection class A in accordance with EN55011. The product complies with the requirement of standard EN60601-1-2:2007 'Electromagnetic Compatibility – Medical Electrical Equipment'.



NOTE

Using accessories, transducers and cables other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the patient monitoring equipment.

The device or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or its components should be observed to verify normal operation in the configuration in which it will be used.

The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

Other devices may affect this monitor even though they meet the requirements of CISPR.

When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

Portable and mobile communication devices can affect their performance.

Other devices containing RF emission may affect this device (e. g., mobile phone, PAD, computer with wireless functionality).

Monitor Performance Specifications:

Item	Performance Specifications
SpO2	Measurement Range: 0~100%
PR	Measurement Range: 30~250bpm
NIBP	Measurement Range: Adult: SYS (40~270) mmHg DIA (10~210) mmHg Pediatric: SYS (40~230) mmHg DIA (10~150) mmHg Neonate: SYS (40~135) mmHg DIA (10~90) mmHg Mode of operation: Auto, Manual, STAT
Temp	Measurement Range: 0~50°C
Display	10.1-inch multi-colored display, Resolution: 1280*800
Operation method	Use touchscreen
Alarm Indicator	Audio alarm, Lamp alarm
Data Communication	Ethernet supported
Power Supply	AC power: 100~240V, 50/60Hz, 1.3~0.5A

	Battery power supply: It can support two rechargeable lithium batteries of 11.1V/5200mAh.
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Guidance and Declaration - Electromagnetic Emissions		
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	Compliance	Electromagnetic environment - guidance
Radio frequency (RF) emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC61000-3-2	Class A	The device is suitable for use in all establishments other than domestic and those indirectly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

 **WARNING**

This equipment is expected to be operated by medical professionals, as it may cause electromagnetic interference or interfere with other devices in the vicinity. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment or shielding the relevant electromagnetic site.

Guidance and Declaration - Electromagnetic Immunity			
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Guidance and Declaration - Electromagnetic Immunity			
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2 kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differentialMode ±2 kV differentialMode	±1 kV differentialMode ±2 kV differentialMode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at level typical location in a commercial or hospital environment.
Note: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity

The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance, which can be calculated using the formula applicable to the frequency of the transmitter.</p> <p>The formulas for calculating the recommended separation distance are as follows:</p> $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80%AM@2Hz 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = 2.3 \sqrt{P}$ <p>800 MHz to 2.5 GHz</p>
Only ISA CO2 is tested at 20 V/m	20 V/m 80%AM@1kHz 80 MHz to 2.5 GHz	20 V/m	<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a), should be less than the compliance level in each frequency rangeb).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

[NOTE 1]: At 80 MHz and 800 MHz, the higher frequency range applies.

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

a). Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio and TV broadcasters cannot be accurately predicted theoretically. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be conducted. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level, verify that the device works normally. If you observe abnormal performance, you may need to reorient or relocating the device.

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and The device

The device is suitable for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter Watts (W)	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: From 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

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

Radio Management Compliance**RF Parameter**

Project	IEEE 802.11b/g/n (2.4G)
Operating Frequency	IEEE 802.11b/g/n(HT20): 2412MHz to 2462MHz IEEE 802.11n(HT40): 2422MHz to 2452MHz
Modulation	IEEE for 802.11b:DSSS(CCK, DQPSK, DBPSK) IEEE for 802.11g: OFDM(64QAM, 16QAM, QPSK, BPSK) IEEE for 802.11n(HT20 and HT40): OFDM (64QAM, 16QAM, QPSK, BPSK)
Effective Radiation Power (dBm)	<20dBm (Average) <30dBm (Peak)

FCC

 FCC WARNING

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

INFINIUM

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