COMEN

CE 1639

Vital Signs Monitor

NC6/NC6A/NC6C/NC6Neo
NC7/NC7A/NC7C/NC7Neo

User Manual

Shenzhen Comen Medical Instruments Co., Ltd.

Copyright

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Product Name: Vital Signs Monitor

Product Model: NC6/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo

Service Life: 10 years

Software Version: V1.0

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The contents in this user manual are subject to change without prior notice.

Warranty

Comen will be responsible for the safety, reliability and performance of the product within the limited warranty period, if all of the following conditions are satisfied:

- The product is used in accordance with this Manual.
- The product is installed, maintained or upgraded by approved or authorized personnel by Comen.
- The storage and operating environments for the product shall comply with the recommended information and product specifications contained in this manual.
- The serial number label or manufacturing mark of the product is clearly legible.
- The damage is not caused by human factors.
- All replaceable components, accessories, and consumables for maintaining are originally supplied or recognized by Comen.

Comen provides services free of charge for all products based on Comen’s Warranty Service conditions. Comen may charge service fees for any service not within the product's warranty. The user shall bear any or all transportation costs (including custom duties) incurred during transportation of the products back to Comen.

Return Procedure

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

Request for product return: Contact Comen's after-sales service department and inform them of the product serial number marked on the product's nameplate. If the product serial number is not clear and legible, product return will not be accepted. Please indicate the product serial number, manufacturing date, and a brief description of the reasons for returning.

After-Sales Service

Name: After-sales Service Department of Shenzhen Comen Medical Instrument Co., Ltd.

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Preface

This manual provides details on the performance, operations, and maintenance, storage and safety instructions of NC6/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo Vital Signs Monitor (hereinafter referred to as the “monitor”). Please read carefully and understand the content of this manual so as to ensure the safety of the patients and operator.

This manual introduces the product of the most complete configurations. Some configurations or functions may not be available on the product you have purchased. If you have any questions, please contact us.

Please keep this manual near the device for easy and prompt access when needed.

Intended Readers

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

Illustrations

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

Conventions

- —>: Indicates operating steps.
- **[Character]**: Indicates user screen text.

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Contents

Chapter 1 Safety

1.1 Safety Information

⚠ WARNING

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

⚠ CAUTION

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

⚠ NOTE

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

⚠ WARNING

- The monitor is intended for monitoring of clinical patients, and shall be used only by trained, professional operator (physicians, nurses and technicians).
- Before using, you must check the monitor and its accessories to ensure that they can work normally and safely.
- Do Not place the power plug/appliance coupler which is used to disconnect the device from supply mains in a position that is not easily accessible to the operator.
- Alarm volume and high/low alarm limits should be set depending on the patient types. When a patient is monitored, do not exclusively rely on the audible alarm system. If the alarm volume is set too low or is completely turned off, the alarm will not be heard, and the patient may be put into danger. Paying close attention to the patient's actual clinical conditions continuously is the most reliable way.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth. If the power socket is not connected to a ground conductor, use the rechargeable battery to supply power to the monitor instead of using the supply mains.
- Do Not open the housing of the monitor to avoid the potential risk of electric shock. The monitor must be maintained and upgraded by service technician trained and authorized by Comen.
- Do not modify this equipment without authorization of the manufacturer.

- Follow the local laws and regulations or the waste disposal rules of the hospital when disposing of packaging materials. Keep the packaging materials out of the reach of children.
- Do Not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Carefully place the monitor power cord and accessories cables to avoid entanglement, potential strangulation, and electrical interference to the patient.
- During defibrillation, the operator should not come into contact with the patient, the monitor or the supporting table; otherwise may result in serious injury or death. Before reusing the cables, check to confirm that their functions are normal.
- Device or applied parts without the function of defibrillation protection should be disconnected from the patient during the process of defibrillation.
- Any equipment connected to the monitor shall form an equipotential body (effective connection of protective ground).
- In order to avoid burns (resulted from electric leakage) to the patient, ensure that the monitor's sensors and sensor cables never come into contact with any high-frequency electrosurgical equipment or metal part.
- The physiological waveform and parameter, alarm message and other information displayed by the monitor are only reference to physicians, and not directly used as a basis for clinical decision.
- Electromagnetic field can affect the performance of the monitor. Therefore, equipment used near the monitor should conform to the applicable EMC requirements. For example, mobile phones and X-ray machines are potential sources of interference, since they transmit high-intensity electromagnetic radiation.
- MR unsafe: the NC Series monitors are not intended to be used in a Magnetic Resonance (MR) environment.
- This monitor is not therapeutic equipment.
- For accessories provided in sterile, please refer to the operating instructions for accessories.
- Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department or your local representative.
- The operator must not touch any Signal Input/Signal Output connectors while simultaneously touching the patient.
- If more than one piece of external equipment is connected to the monitor at one time through the patient cable connector, network connector or other signal ports, the total leakage current should be in accordance with the requirement specified in IEC 60601-1.
- The used and transported environment of the monitor must comply with the specifications claimed in the User Manual, otherwise the accuracy of the instrument may be affected.
- Do Not modify this equipment without authorization of the manufacturer.
- Please use an external power supply in time before the battery runs out.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The NC Series monitors are intended to be used within the electrosurgical environment.

- Do not completely rely on the alarm function of the cardio tachometer. Patients with pacemakers must be closely monitored. For the pacemaker inhibiting function of the monitor, please refer to relevant section in this Manual.

⚠ CAUTION

- To avoid damage to the monitor, and ensure patient's safety, use accessories specified in this Manual.
- Handle the monitor carefully to avoid damage caused by drop, collision, strong oscillation or other external mechanical forces.
- Before powering on the monitor, verify that the supply voltage and frequency conform to the specification of the monitor marked or in this manual.
- At the end of the monitor service life, the monitor and its accessories must be disposed of in accordance with the local laws and hospital's regulations.
- To achieve the galvanic isolation between the monitor and the input power supply, please disconnect the monitor power plug.
- Do Not connect other multi-hole sockets and extension cords to this monitor.

⚠ NOTE

- Place the monitor at a position where observation, operation and maintenance are convenient and not obstructed.
- This manual is based on the maximum configuration; therefore, some contents may not be applicable to your monitor.
- Please read this entire manual before using the system for the first time. Keep this manual handy for your reference.
- The monitor is not intended for home use.
- The monitor can only be used on one patient at a time.
- The operator should be within one meter of the monitor.
- The way to get paper accompanying documents can be provided and specified in electronic files by Comen (If needed).

1.2 Contraindications

Not found yet.

1.3 Symbols

⚠	Note!	MD	Medical device
	Defibrillation-proof Type CF applied part	SN	Serial number

	USB 2.0 connection		Equipotentiality
	ON"/"OFF"		Computer network
	Battery status indicator/ Battery check		Input and Output
	Alternating current		Manufacturer
IPX2	Protected against vertically falling water drops per IEC 60529		Menu
	Non-ionizing electromagnetic radiation/ RF electromagnetic energy emitted for diagnosis or treatment		Standby
	Defibrillation-proof Type BF applied part		Type BF applied part
	Correct Disposal of This Product (Waste Electrical & Electronic Equipment) Statement: Contact the local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories.		Medical Devices Regulation 2017/745 (EU)
	Type B applied part		Refer to instruction manual/ Follow instructions for use
EC REP	Authorized representative in the European Community		Date of manufacture
	Warning	/	/

	This way up		Stacking limit by n
	Fragile, handle with care		Keep dry
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation	/	/

Chapter 2 Overview

This monitor is equipped with a touch screen allowing direct touch operations. The device is designed in accordance with domestic and international safety standards in relation to medical electrical equipment.

2.1 Product Introduction

2.1.1 Product Composition

This monitor is mainly composed of main control unit, an expansion base (optional), NIBP cuff accessories, SpO_2 accessories, $EtCO_2$ accessories (optional) and temperature accessories (optional).

2.1.2 Intended Use

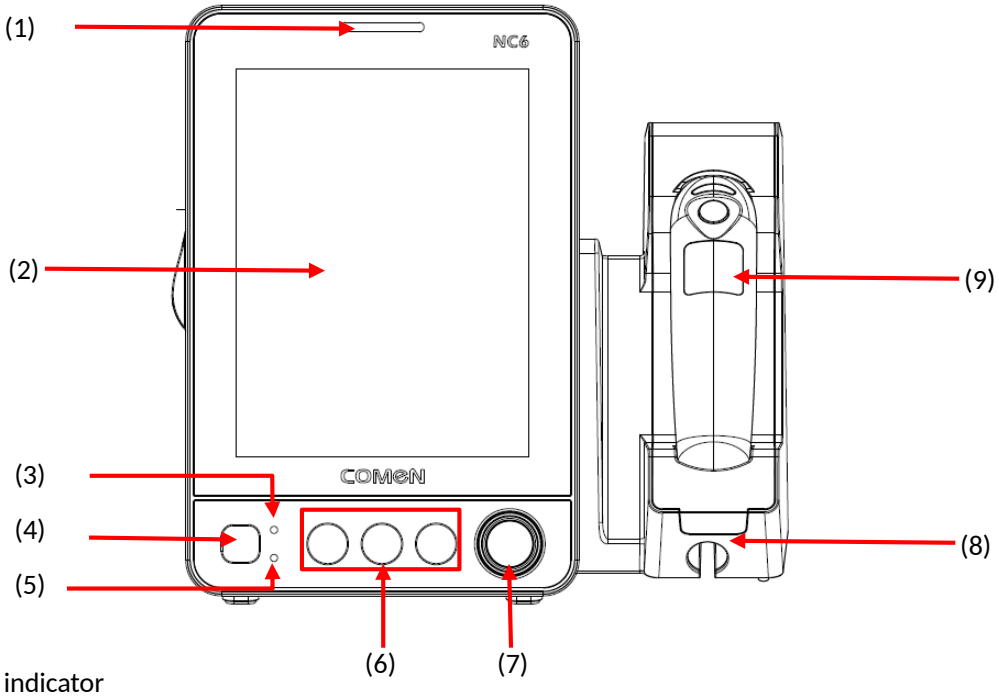
The NC6/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo Vital Signs Monitor is a multi-parameter physiological patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility. The monitors support multiple measurements, including Non-invasive Blood Pressure (NIBP), Pulse Oxygen Saturation (SpO_2), Pulse Rate (PR), Heart Rate (HR), Respiration rate (RR), Temperature (Temp), Carbon Dioxide (CO_2). The monitoring information can be displayed, reviewed, stored, and printed.

The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. The monitors are not intended for emergency and transport use or home use.

All the parameters can be monitored on single adult, pediatric and neonatal patients.

2.2 Monitor Appearance

2.2.1 Front View (NC6/NC6A/NC6C/NC6Neo)



(1) Alarm indicator

The color and flashing frequency of the alarm indicator can reflect different priorities of technical and physiological alarms, which are defined as follows

- High priority alarm: Red, fast blinking frequency.
- Medium priority alarm: Yellow, slow blinking frequency.
- Low priority alarm: Cyan, no blinking, light remaining on

(2) Display screen

(3) Battery indicator

- Indicator light remains on: Battery is being charged.
- Indicator light blinks: Battery is used to supply voltage.
- Indicator light off: Battery is fully charged, is not installed or malfunctions.

(4) Power ON/OFF

(5) AC indicator

- Indicator light on: AC power supply is connected.
- Indicator light off: AC power supply is not connected.

(6) Function keys

(Alarm reset): Press this key to reset current alarm.

(NIBP start/stop): Press this key to start or stop NIBP measurement.

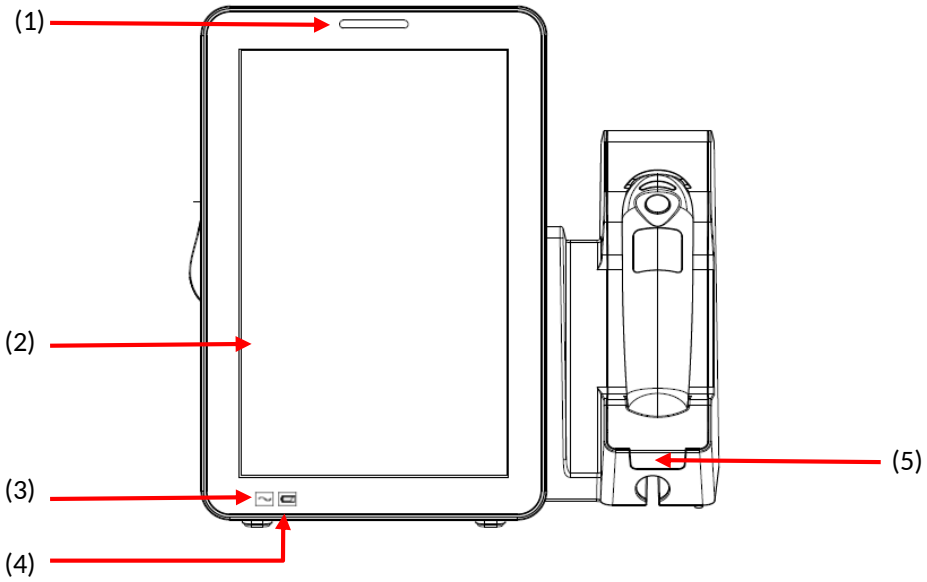
: Receive a new patient. Press this key to view the list of patients

(7) Rotary knob: Used to select menus and switch settings, users can rotate the rotary knob clockwise or counterclockwise to switch selections, and confirm the current selection when pressing it.

(8) Expansion base: This area is used for thermometers.

(9) Thermometer

2.2.2 Front View (NC7/NC7A/NC7C/NC7Neo)



(1) Alarm indicator

The color and flashing frequency of the alarm indicator can reflect different priorities of technical and physiological alarms, which are defined as follows

- High-priority alarm: Red, fast blinking frequency.
- Medium-priority alarm: Yellow, slow blinking frequency.
- Low-priority alarm: Cyan, no blinking, light remaining on

(2) Display screen

(3) AC indicator

- Indicator light on: AC power supply is connected.
- Indicator light off: AC power supply is not connected.

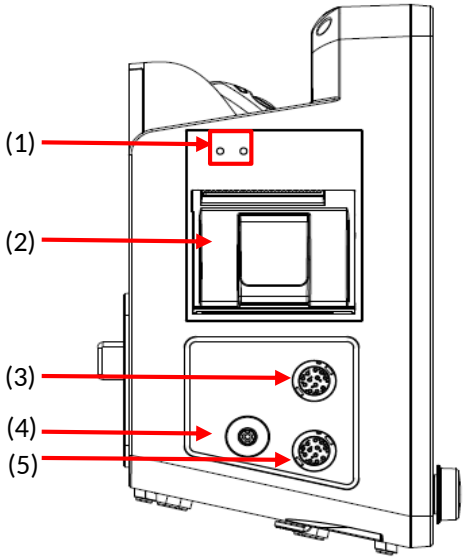
(4) Battery indicator

- Indicator light remains on: Battery is being charged.
- Indicator light blinks: Battery is used to supply voltage.
- Indicator light off: Battery is fully charged, is not installed or malfunctions.

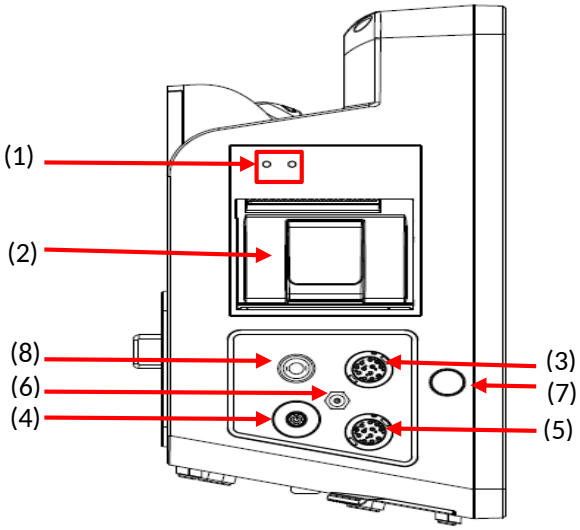
(5) Expansion base: This area is used for thermometers.

2.2.3 Left View

The ports shown in the figure below are provided on the left side of the monitor:



NC6/NC6A/NC6C/NC6Neo Left View



NC7/NC7A/NC7C/NC7Neo Left View

(1) Recorder indicator
- Left: Fault alarm light
- Right: Power indicator

(2) Recorder

(3) SpO_2 cable connector

(4) NIBP cuff connector

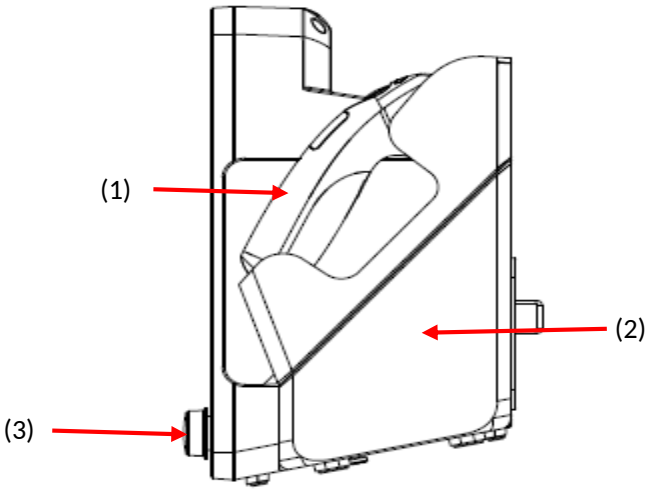
(5) SpO_2 cable connector

(6) CO_2 gas outlet

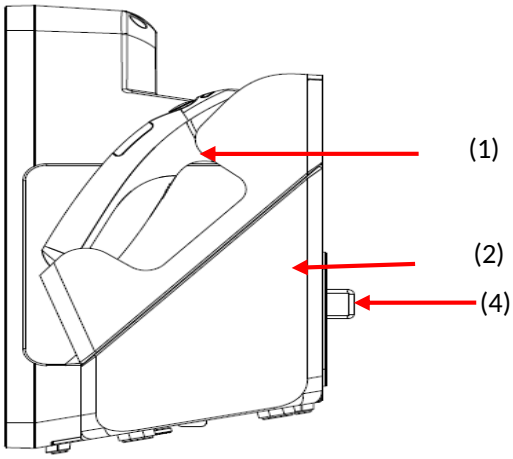
(7) Power ON/OFF

(8) CO_2 gas inlet

2.2.4 Right View



NC6/NC6A/NC6C/NC6Neo Right View



NC7/NC7A/NC7C/NC7NeoRight View

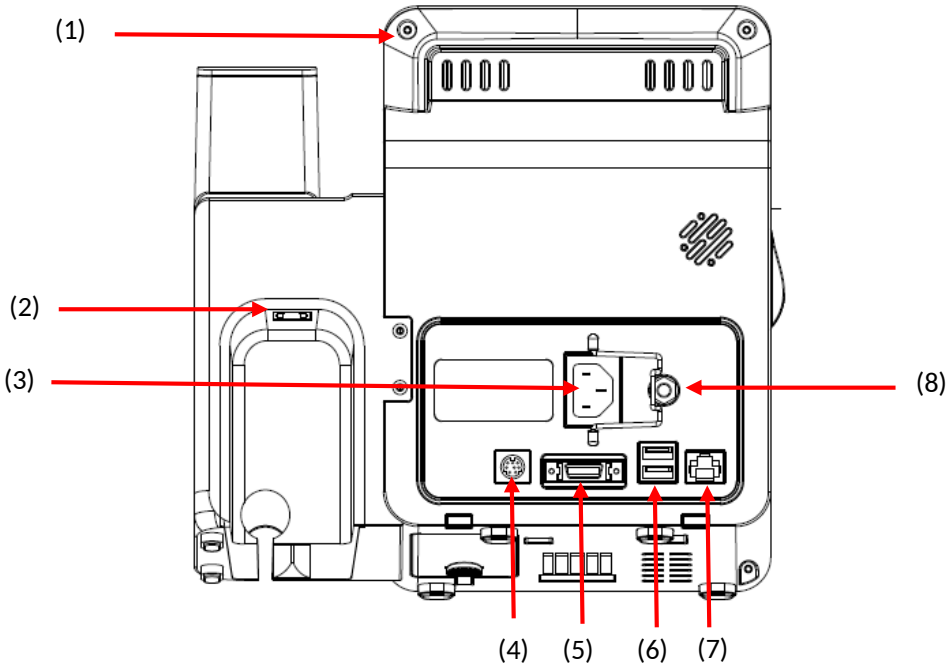
(1) Thermometer

(2) Expansion base: This area is used for thermometers.

(3) Rotary knob: Used to select menus and switch settings, users can rotate the rotary knob clockwise or counterclockwise to switch selections, and confirm the current selection when pressing it.

(4) Power cord anti-pull hook

2.2.5 Rear View



(1) Handle

(2) Thermometer connector: used to connect thermometer.

(3) AC power socket.

(4) Standby power socket

(5) Multi-function port

- ◆ It can be used as the nurse call port. When it is connected to the nurse call system in the hospital, a call signal will be output to alert the nurse if an alarm is generated.

(6) USB ports of monitoring system

For patient monitor, the ports can be used to connect USB mouse, keyboard, printer, scanner and other USB devices.

(7) Network port

A standard network cable is used for networking to the central monitoring system or other devices.

(8) Equipotential conductor

When another device is used together with the monitor, a wire should be used to connect the equipotential port of that device to that of the monitor, thus to eliminate the earth potential difference between different devices and ensure safety.

⚠ WARNING

- **Only the approved analog or digital equipment in accordance with the specified IEC standards (such as IEC 60950-1 or IEC 62368-1 safety standards for Information Technology Equipment, IEC 60601-1, etc.) are allowed to be connected to the monitor. The personnel responsible for the ME system configuration shall ensure the combinations of medical equipment with non-medical equipment must comply with IEC 60601-1 Clause 16.**
- **In normal use, the operator should not touch the signal I/O ports and the patient simultaneously. This action may result in injury to the patient.**
- **If more than one external equipment is connected to the monitor at one time through the patient cable connector, network connector or other signal input/output ports, the total leakage current should comply with the safety limit specified in IEC 60601-1.**

2.3 Cybersecurity

2.3.1 Operating Environment

Hardware configuration	Processing unit	AM3354
	memorizer	SDRAM(256M)
	I/O connector	1) Multi-function port: 1; 2) USB connector: 2; 3) Network connector: 1;

		4) Bluetooth connector: 1; Used to connect iPad; 5) RF interfacey:1; 6) WiFi connector:1; 7) Backup battery interface:1; used to support the cart battery to power the host, and also supports the host to charge the backup battery through this interface; 8) Thermometer integrated interface:1
Soft environment	System environment	Linux
Network condition	Network interface	RJ-45
	Network type	Local area network(LAN)
	Network protocol	TCP/IP
	Bandwidth	100M
	Wired or wireless	wired, wireless
	LIS transport protocol	HL7 transport protocol
	Data type	Bin
	Storage medium	EMMC
	Storage format	Custom
	Storage capacity	4G
Software identification	Software name	NC Series Vital Signs Monitor Software
	Software version	V1

2.3.2 User Access Control

Users should obtain a password from the vendor or administrator before entering the maintenance interface to make changes to module settings.

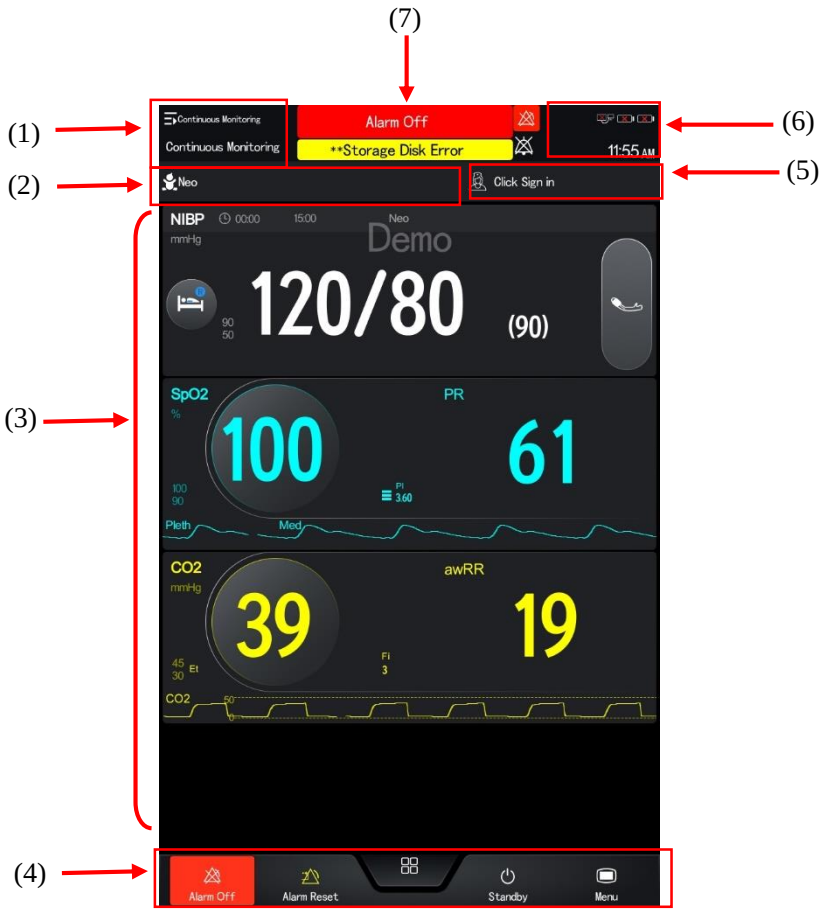
Only the supplier should use the password to enter the factory maintenance interface.

2.3.3 Software Update

Software updates are maintained by factory engineers only.

2.4 On-screen Display

The figure below shows a general interface:



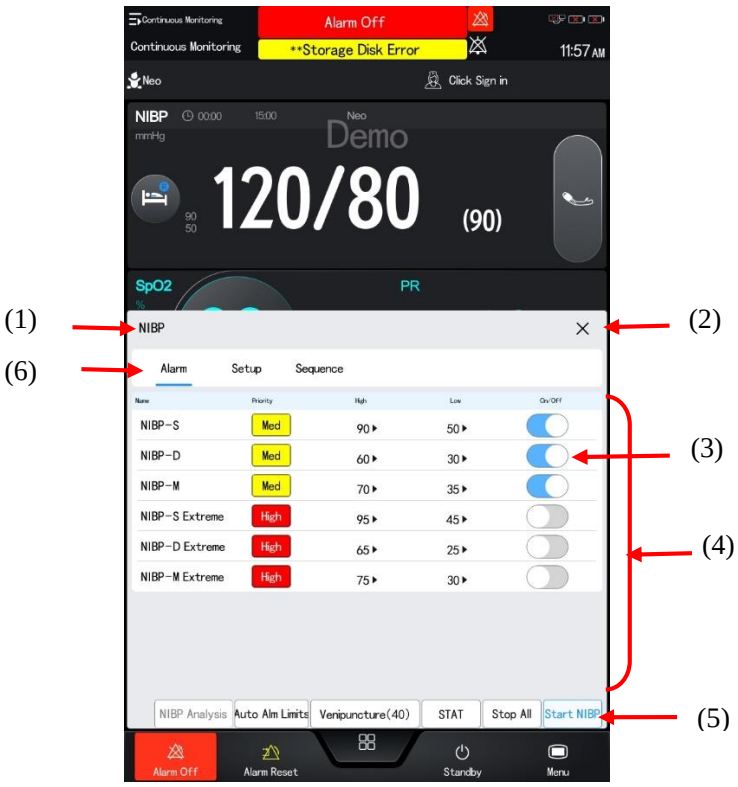
1) Workflow display area: Displays the current workflow. Users can select a workflow in the current or other different working modes by clicking this area.
2) Patient Information Area: Displays patient information, including Room No.(Room Number), , patient type, etc. Select this area to enter the **[Patient Manage]** menu. See "*Chapter 5 Patient Management*"for details.
3) Parameter/waveform Area: Displays parameter values, units, alarm limits, alarm states, etc.. The user can select a parameter area to enter the corresponding parameter setup menu. See *"Section 4.3.1 Enter the Parameter Setup Window"*for details.
4) Hot Key Area: Displays hot keys.
5) Physician Information Area: Displays the doctor's login status and his physician information. This area allows physician to log in and out.
6) System Status Information Area: Displays alarm icon, battery icon, network, connection status of storage device, and system time. See *"Section 2.4.1 Interface Symbols"*for details.
7) Above: physiological Alarm Area: display physiological alarm information.
   Below: prompt and Technical Alarm Area: Displays Alert Information and Technical Alarm Information.

2.4.1 Interface Symbols

The table below lists the symbols shown in the System Information Area and their meanings:

Symbol	Description	Symbol	Description
	Adult, male		Adult, female
	Pediatric, male		Pediatric, female
	Neonate, male		Neonate, female
	Central monitoring system(CMS) has been connected		Central monitoring system (CMS) is not connected.
	Wireless network has been connected. The solid part indicates the network signal intensity; the icon will not be displayed		Bluetooth icon
	Alarm Paused		Alarm Audio Pause
	Alarm Audio Off		Alarm Reset
	Very low battery. It should be charged immediately, otherwise the monitor will shut down automatically.		Alarm Off
	Battery powered; the green part indicates the remaining battery capacity.		Low battery. Charging is needed.
	The battery is not installed or battery failure has been occurred.		The monitor is being charged.
	Battery is damaged.		USB is inserted
	Wireless network hasn't been connected		Physician doesn't log in
	Physician has logged in	/	/

2.4.2 Menus



(1) Menu Title: Name of current menu

(2) Exit Button: Select it to exit the current menu

(3) Function On/Off:

- Green: This function is turned on
- Grey: This function is turned off

(4) Main Display Area: Displays menu options

(5) Operation Button: Click to initiate an operation

(6) Sub-menu tab buttons: Press each button to enter the corresponding sub-menu page

2.4.3 Quick Keys

Quick keys refer to some graphic hot keys shown in the lower part of the screen, allowing you to quickly access some functions. Generally, 4 hot keys are displayed in the Hot Key Area. The **[Menu]** button is always displayed at the lower right corner of the Hot Key Area, and the **[More]** button is always displayed at the middle of the Hot Key Area. Click **[More]** to show more predefined hot keys. You can define the hot keys to be displayed and their order on the screen.

Icon of Quick Key	Name of Quick Key	Function	Icon of Quick Key	Name of Quick Key	Function
	Menu	Enter the main menu		More	Show more hot keys
	Alarm Audio Pause	Pause the alarm audio		Alarm Reset	Confirm the current alarm and reset the alarm system
	Review	Enter the **[Review]** menu		Alarm Paused	Suspend the current alarm
	Patient	Enter the **[Patient Manage]** menu		Standby	Enter standby mode
	Clear	Clear existing values for next monitoring		QR Code	Enter the **[QR Code]** display window
	Save	Save measurement results		Targeted Goal	Enter the **[Targeted Goal]** menu
	Back/Next	Switch interfaces		Alarm Audio Off	Turn off the alarm audio
	Alarm Off	Turn off the alarm	/	/	/

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Chapter 3 Installation and Preparation

NOTE

- **To ensure normal operation of the monitor, please carefully read the contents of this chapter and the "Safety Information" chapter prior to use, and install the monitor according to requirements.**
- **This device shall be installed by personnel designated by our company.**

3.1 Installation

3.1.1 Unpacking and Checking

Carefully take the monitor and its accessories out of the packing box and check according to the following aspects.

1) Check whether all accessories are provided according to the Packing List.
2) Check for damage.
3) Check all exposed lead wires and connectors.
4) For any problem or inconsistencies, contact Comen or your distributor.
5) Keep the packaging materials for future use.

3.1.2 Environmental Requirements

The operating environment for this device must conform to the environmental requirements specified in this manual; otherwise the accuracy of the device may be affected, and damage to components and circuits may be caused.

The patient monitoring system should be used in an environment that can reasonably avoid vibration, dust, corrosive or explosive gases, extreme temperature and humidity, etc. Operating environment of this equipment must meet the environmental specifications in this manual.

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

The device is not intended for hyperbaric operation. Using it in a hyperbaric chamber can result in harm to the patient and/or damage to the device.

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

NOTE

- **Condensation here means the condensation of gas or liquid when it is cold, such as water vapor changing into water when it is cold, and water changing into ice when it is cold. The lower the temperature, the faster the condensation speed.**

3.2 Device Preparation

3.2.1 Connection of AC Power Supply Cord

Before connecting the AC power supply cord, ensure that the AC supply voltage and frequency are consistent with the voltage and frequency indicated on the device.

Steps for connecting the AC power cord:

1) Use the power cord supplied with the monitor; connect one end of the power cord to the inlet of the monitor;
2) Insert the other end of the power cord to a mains socket outlet with protective earth.
3) Confirm that the AC power indicator turns on, which indicates that AC power supply is connected normally.

NOTE

- **Connect the power cord to specific hospital outlet.**
- **When a battery is provided, the battery must be charged after transportation or storage. If the battery is low, the monitor may fail to work without connecting an AC power supply. Once the monitor is connected to an AC power outlet, the battery will be charged whether the monitor is switched on or not.**
- **Connect equipotential grounding wire if necessary.**

3.2.2 Protective Grounding

To protect both the patient and the operator, the housing of the monitor must be grounded. The monitor is equipped with a detachable 3-wire power cord, which shall be inserted into a grounded power outlet to ensure that monitor is grounded. If grounded power outlet is not available, contact the maintenance department in your hospital.

WARNING

- **It is NOT allowed to connect the 3-wire power cord to a 2-wire power socket.**

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

3.2.3 Equipotential Grounding

The monitor must be connected to a power outlet with protective grounding. For cardiac or cerebral examination, the monitor must be connected to a standalone equipotential grounding system. Connect one end of the equipotential conductor (potential equalization conductor) to the equipotential connector on the rear panel of the monitor and the other end to a connector of the equipotential grounding system. In the event the protective grounding system is damaged, the equipotential grounding system can provide protection to the patient and operator.

Cardiac (or cerebral) examination can only be performed in a room installed with a protective grounding system. Before each use, ensure the monitor is in abnormal operating status. Cables connecting the patient to the monitor must not be contaminated by electrolyte.

WARNING

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

NOTE

- **If the use of the equipment is affected by the equipotential grounding, contact the Company's After-Sales Service Department or agents.**

3.3 Connection of Device Components

3.3.1 Connect Patient Leads and Patient Cable

Connect the patient leads or patient cable on the patient according to the subsequent parameter monitoring chapter.

3.4 Startup and Shutdown

3.4.1 Startup

3.4.1.1 Startup Wizard

This monitor is equipped with a startup wizard function. When users start it for the first time, the system will automatically enter the startup wizard interface to assist users in completing the following operations:

1) Set the system language: Select a target language as required.
2) Set **[Import Configuration]**: If users already have a customized configuration and have imported it into a USB flash drive, press **[Import Configuration]** to copy the configuration to the monitor.
3) Set **[Create New Configuration]**, users can:
   - Set system time: See ***Section 4.3.4 Set Date and Time*** for details.
   - Modify parameter units: See ***Section 4.3.3 Set Unit*** for details.
   - Set department information: See ***Section 6.3 Change Department*** for details.

After completing the above settings, users can choose:

4) Restart to start using: Restart the monitor and enters the normal working interface.
5) **[Advanced Setup]**: Press it to continue to set the network of monitor.
6) **[Export Configuration]**: Import the current configuration into a USB flash drive. Before exporting, connect the available USB flash drive to the monitor. See ***Section 6.4 Exporting Configurations*** for details.

3.4.1.2 Startup

1) Prior to startup, check to see if each component of the device has any mechanical damage;
2) Check whether the device can start up normally:
   - After the power switch is turned on, the device enters the self-test process. The red and cyan lights are simultaneously on for 1s; then the cyan light continues to be on for 1s; meanwhile the yellow light is on for 1s; after that, the company logo is displayed, and with a “beep” sound, the monitor enters the main screen.
3) Check whether the screen and each parameter interface display information normally.

⚠ WARNING

- **If any evidence of functional failure of the monitor is found or there is any error message, it is not allowed to use this device to monitor a patient. Please contact a service engineer of our Company or a biomedical engineer of your hospital.**

Note

- The system sounds an alarm when a major error is detected in the self-test.
- Check all monitoring functions to ensure that the monitor can operate normally.
- The battery must be charged after each use to ensure that sufficient battery power is available.
- To extend the service life of the monitor, after shut-down, wait for at least 1 minute before restarting the monitor.

3.4.2 Shutdown

1) Confirm that the device can be stopped.
2) Disconnect the device cable and sensor from the patient.
3) Save or clear patient data as per need.
4) Long press the power key for 3s to turn off the monitor. To completely disconnect the power supply, please pull out the power plug.

CAUTION

- If the device cannot shut down normally under some special circumstances, you can long press the power key for 7s to realize forced shutdown. Forced shutdown is not suggested since it can result in loss of data.

NOTE

- In case of unexpected power supply interruption, if the monitor is restarted within 30min, it will load patient information, monitoring data and configuration data before power failure. If the power is restored after 30 min, it will load the default configuration set as normal startup/shutdown.

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Chapter 4 Basic Operations

4.1 Operation and Browsing

4.1.1 Use of Touch Screen

The monitor can be equipped with a touch screen, allowing touch operations. If you don't want to use the touch function, or to prevent misoperation, you can set to lock the screen. Long press the **[Menu]** hot key to lock the touch screen. At this moment, the screen lock symbol "" is shown above the **[Menu]** hot key.

The screen lock time can be defined according to the following steps:

1) Select the **[Menu]** hot key →**[Device]**
2) Select **[Screen Lock Duration]** from the **[Display]** column.
3) Set **[Screen Lock Duration]**.

Unlocking Operation:

- After reaching the set screen lock duration, the touch screen will be unlocked automatically.
- Long press the **[Menu]** hot key and swipe in the arrow direction to unlock the touch screen.

4.1.2 Use of Rotary Knob (only for NC6/NC6A/NC6C/NC6Neo)

This monitor is equipped with a rotary knob for selecting menus and switching settings.

- Rotate the rotary knob counterclockwise to select the previous area;
- Rotate the rotary knob clockwise to select the next area;
- Press the rotary knob in the selected area to enter/exit the area.

4.1.3 Use of Mouse

This monitor supports "plug and play" USB mouse. You can use the mouse for interface operations.

4.1.4 Use of Soft Keyboard

This monitor provides a soft keyboard for information input. The soft keyboard has the following functions:

- Select characters on the keyboard to input information
- Use the Delete key ← to delete the previous character.

- Use the shift key to switch between upper and lower case letters.
- Use the Enter key to confirm the input and close the soft keyboard.

If the monitor is connected with a physical keyboard, it can be used in conjunction with the soft keyboard.

4.1.5 Use of Scanner

This monitor supports barcode and QR code scanners which can be connected to the monitor via USB port.

4.1.5.1 Clear Data Format

If you use the QR code scanner customized by Comen, it is necessary to clear the previous data format and configure the scanner before initial use. Here are the steps for clearing data format:

1) Scan the barcode or engineering QR code for format clearing to clear the old data format.
2) Scan the engineering QR code used by the hospital to +obtain the QR code format special for this hospital.

NOTE

- **Please contact the scanner manufacturer or Comen to obtain the barcode or engineering QR code for format clearing.**

4.2 Work Mode

4.2.1 Spot Check Mode

The spot check mode is intended for on-site measurement in a short time. When spot check mode is on:

1) Physiological alarms is not allowed, only technical alarms and prompts are available.
2) The alarm setup menu will not be displayed.
3) Alarm limits cannot be set.

Here is the step to enter spot check mode:

Click **[Workflow]** → select**[Spot Check]**.

4.2.2 Continuous Monitoring Mode

Continuous monitoring mode is intended for long-term monitoring for patient.

Here is the step to enter spot check mode:

Click **[Workflow]** → select **[Continuous Monitoring]**

4.2.3 Standby Mode

If patient monitoring is not needed for the time being, but you don't want to shut down the device, standby mode can be used.

Here are the steps for entering standby mode:

1) Select the **[Standby]** hot key
2) Set the patient location in standby.
3) Select OK.
   - ◆ Patient location in standby does not need to be set in Spot Check Mode.

Performance of the device in standby mode:

- ◆ Stop all parameter measurements.
- ◆ All alarm messages (except Low Battery) and prompt messages are shielded.

Exit standby mode:

If monitor enters Standby Mode in Continuous Monitoring Mode:

- ◆ Select **[Monitor]** to exit standby mode and restore monitoring for the current patient.
- ◆ Select **[Discharge Patient]** to discharge the current patient.

If monitor enters Standby Mode in Spot Check Mode: touch anywhere of the screen to exit the Standby Mode.

Prompt On Standby Screen:

The steps to set the prompt in standby mode are as follows:

1) Select the **[Menu]** hot key → select **[Maintain]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select the **[Standby]** hot key → Set **[Prompt On Standby Screen]**.

4.2.4 Demo Mode

Here are the steps for entering demo mode:

Select **[Menu]**; select **[Demo]** from the **[System]** column; input the password to enter demo mode.

Warning

- **Demo waveforms are analog waveforms set by the manufacturer only for the purpose of demonstrating device performance and aiding user training. In actual clinical use, it is forbidden to use the demo function because medical workers may mistake the demo data for waveforms and parameters of the patient being monitored, which will affect patient monitoring and delay diagnosis and treatment.**

4.3 General Settings

4.3.1 Enter Parameter Setup Window

Each parameter shown on the screen can be set. User can enter the Setup window in the following ways:

- Select the waveform area or parameter area corresponding to a parameter (Only under Continuous Monitor mode).
- Select the **[Menu]** hot key; select **[Setup]** from the **[Parameters]** column; then select the corresponding parameter.

NOTE

- **Generally, the first method described above is used to enter parameter setup.**

4.3.2 Change Parameter Color

Take NIBP for example,

1) Select **[Menu]** → select **[NIBP]** from the **[Parameters]** column.
2) Select **[Setup]** from **[NIBP]** column.
3) Set the display color of the parameter currently being monitored.

4.3.3 Set Unit

1) Select the **[Menu]** hot key → select **[Maintain]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select **[Unit]** to set the measurement unit of each parameter.

4.3.4 Set Date and Time

1) Select **[Menu]** → select **[Time]** from the **[System]** column
2) Select **[Date]** and **[Time]** to set the current date and time.
3) Set **[Date Format]**
4) If 12-hour time is required, turn off **[24-Hour Time]**.

When the monitor is connected to the central monitoring system, the system time of the monitor will be synchronous with that of the central monitoring system, and you cannot set the system time of the monitor.

4.3.5 Set Language

1) Select **[Menu]** → select **[Maintain]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select **[Other]** → select **[Language]**

4.3.6 Set Brightness

1) You can enter the **[Display]** page in the following ways:
   - ◆ Select the **[Menu]** hot key →select **[Device]** → **[Display]**.
2) If the monitor uses AC power supply, set **[Brightness]**; if the battery is used to supply voltage, set **[Brightness On Battery]**.

4.3.7 Set Volume

Select **[Menu]** hot key → select **[Device]** → **[Volume]** hot key to respectively set **[Alarm Volume]**, **[High Alarm Volume]**, **[Pulse Volume]** and **[Key Volume]**.

See *"Section 7.8.2 Set Alarm Volume"* for detailed instructions of **[Reminder Volume]**.

4.4 Operation Log

The steps to view the logs of various settings and operations performed by different users on this monitor are as follows:

1) Select **[Menu]** → select **[Maintain]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select **[Other]** → select **[Operation Log]** →select **[OK]** in the pop-up window.
3) Select the operation type as needed, and select to **[Search]** to view the operation time and description.
4) Or, select **[Skip]** in this interface can skip to a specified time to view the operations at that time.

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Chapter 5 Patient Management

5.1 Discharge Patient

The previous patient should be discharged before monitoring a new patient. After discharge, the monitor will enter the idle state. Depending on the circumstance, you can select **[Monitor]** (Quick Admit) or **[Patient Management]** (Normal Admit) to select how to admit a patient.

⚠ WARNING

- **The previous patient should be discharged before monitoring a new patient; otherwise, data of the new patient will be saved to data of the un-discharged patient.**

The patient can be discharged manually in any of the following ways:

- Select the Patient Information Area at the upper left corner of the screen → select **[Discharge]**.
- Select the **[Patient]** hot key→ **[Patient Information]** → select **[Discharge]**.
- Select **[Menu]**, and select **[Discharge]** from the **[Patient Management]** column.
- Select **[Menu]** → **[System]** → **[Maintain]** → input the maintenance password → **[Patient Management]** → **[Discharge]** →turn on the switch of **[Auto Discharge Patient (Switch Workflow)]**.

After select **[Discharge]**, in the pop-up dialog box:

- Select **[Discharge]**: All patient data, including patient information, trend data and physiological alarm messages will be cleared; the technical alarm state will be reset; the system will restore to default configuration and enter the Standby screen.
- Select **[Clear]**: The current configuration is still used while the current patient will be discharged and all patient data will be cleared.
- Select **[Cancel]**: Cancel the current operation of discharging the patient.

5.2 Admit Patient

⚠ WARNING

- **Regardless of whether a patient has been admitted, a default value will be assigned to the [Patient Type]. Therefore, prior to monitoring the patient, please verify that the settings in the patient information align with the actual condition of the patient.**

- **When the patient type is changed, the system loads the factory default configuration. Verify the alarm limits before patient monitoring to ensure that these alarm limits suit your patient. When the patient type is not changed, the current configuration remains.**

5.2.1 Quick Admit

When there is not sufficient time to get complete patient information, a Quick Admit mode can be used. However, the user must subsequently supplement the remaining patient information at a later time.

Here are the steps:

1) After patient discharge, select **[Monitor]** to quickly admit a patient.
2) After admit, please input the patient information as fast as possible. See "***Section 5.3.2 Edit Patient Information***" for detailed instructions.

5.2.2 Normal Admit

After discharging a patient, select **[Patient Management]** → input information of the new patient. See "***Section 5.3.2 Edit Patient Information***".

5.3 Patient Information

5.3.1 Enter Patient Management Menu

You can enter the patient management page in any of the following ways:

- Select the Patient Information Area at the upper left corner of the screen.
- Select the **[Patient]** hot key.
- Select **[Menu]** → select **[Patient Information]** from the **[Patient Management]** column.

5.3.2 Edit Patient Information

After a patient is admitted, if the patient information is incomplete or needs change, you can edit the patient information according to the following steps:

Enter the patient Management page, and edit the patient information as needed.

If your monitor is connected with a barcode scanner, you can input the medical record number or registration number by scanning the barcode.

NOTE

- **When patient type is changed, the monitor will reload a default configuration according to the new patient type.**

5.3.3 Set Items Displayed in the Patient Management Menu

You can set whether or not to display and edit the patient's room No., middle name, race, age and other information according to the following steps:

1) Select the **[Menu]** hot key → select **[Maintain]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select the **[Patient Management]** tab → select the **[Field]** tab.
3) Select the patient information to be displayed and edited in the **[Patient Management]** menu.
4) If necessary, select the Custom Patient Information Area and input the name of this area.

NOTE

- **After the monitor is connected to the central monitoring system, the patient location and custom field will be synchronous with the central monitoring system.**

5.3.4 Set Monitor Information

You can set a name for the monitor in the following way:

1) Select the **[Menu]** hot key → select **[Maintain]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select the **[Device Location]** tab. →Set **[Monitor Name]**, **[Facility]** and **[Department]**.

5.3.5 Set Device Location

If the location of the monitor is fixed, or it is not needed to move the monitor frequently, you can set **[Patient Location]** to **[Fixed]**. Here are the steps for setting device location:

1) Select the **[Menu]** hot key → select **[Maintain]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select the **[Device Location]** tab. →Set **[Patient Location]**.
   - ◆ When **[Fixed]** is selected, the **[Patient Management]** menu can only display the patient's room No. or bed No., and you cannot modify the room No. or bed No..
   - ◆ When **[Unfixed]** is selected, you can enter the **[Patient Management]** menu to modify the patient's room No. and bed No..
3) Input **[Room No.]** and **[Bed No.]**.

NOTE

- **If [Location] is set to [Unfixed], Room No. and Bed No. will be cleared each time after patient discharge; you need to re-input Room No. and Bed No..**

5.4 Patient List

The historical patient information can be viewed in the **[Patient List]** page. Deleting and re-admitting historical patient are also available in this page.

5.4.1 Admit Again

Patients can be admitted again in the following way:

1) Enter the patient management page → select **[Patient List]**.
2) Click on the target patient column → **[Admit Again]**.
3) Edit or complete patient information (If needed) → **[OK]**.

5.4.2 Delete Patient Information

Patient information can be deleted in the following way:

1) Enter the patient management page → select **[Patient List]**.
2) Click **[Select]** →Click on the target patient column/ **[Select All]**.
3) Select **[Delete]** to delete the patient information.

5.5 Patient Information Synchronization

Patient information can be quickly synchronized from CMS to the device. The steps for information synchronization are as follows:

1) Enter the patient management page → select **[Synchronization]**.
2) Input the information of inpatient area and select the target patient information
3) Click **[Synchronize]**.

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Chapter 6 Configuration Management

6.1 Summary

For continuous monitoring, the settings of the monitor should be adjusted based on patients' actual condition, and the set of settings that can be operated on the monitor is called "configuration". In order to achieve the goal of more effective and faster configuration, this monitor provides an integral set of configurations for users according to different clinical requirements and needs from the departments and patients, which is also called "workflow". It can be selected according to actual needs, and the settings in a workflow can also be modified based on usage preferences. For the workflow in **[Continuous Monitor]** mode, the modification for alarm settings is also supported.

Configuration information of the monitor mainly includes:

Parameter Configuration

Setting items related to parameter measurements, such as Speed, Unit, Alarm ON/OFF, and Alarm Limit Setup.

General Configuration

The monitor's general setting items, such as Alarm Setup, and Record.

Maintenance Configuration

Settings related to user maintenance.

Department options:

- Wards
- Emergency
- Physician Office
- Ambulatory Surgery Center
- Neonatology

WARNING

- **Configuration management function is protected by password and must be operated and confirmed by professional clinical medical staff.**

CAUTION

- **Use of different configurations on the same or similar monitors in one area may result in danger.**
- **When selecting a configuration, please ensure that it is appropriate for the patient being monitored.**

NOTE

- **The monitor will load the factory default settings when changing Department, admitting patient and changing patient type.**

6.2 Set Default Patient Type

You can set the patient type when admitting patient next time. Set as follows:

1) Click **[Menu]** hot key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key.
2) Select the drop-down list on the right of **[Default Patient Category]** to set the patient type when admitting patient next time.

6.3 Change Department

1) Click **[Menu]** hot key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key
2) Click **[Department]** button.
3) Select the needed department.
4) Click **[OK]**.

6.4 Export Configuration

You can save the current user settings of the monitor to the U disk as follows:

1) Insert a U disk into the monitor.
2) Click **[Menu]** hot key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key.
3) Click **[Export Configuration]** button.
4) Select the settings to be exported.
5) Click **[Export]**.

6.5 Import Configuration

You can import the settings on a U disk into the monitor as follows:

1) Insert a U disk with settings file into the monitor.
2) Click **[Menu]** hot key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key.
3) Click **[Import Configuration]** button.
4) Select the settings to be imported.
5) Click**[Import]**

6.6 Manage Configuration Password

1) Click **[Menu]** hot key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key
2) Click **[Modify Password]** button.
3) Input old password and new password respectively.
4) Input new password again in the **[Confirm]** column.
5) Click **[OK]**.

6.7 Set Workflow List

The steps to enter the **[Workflow]** list are as follows:

1) Select the **[Menu]**
2) Select **[Workflow]** from the **[Configuration]** column.
3) Enter the administrative password → enter.

The list of workflow is divided into two parts of Spot Check and Continuous Monitor based on different monitoring modes, the alarm settings can be set in the Continuous Monitor workflow while it cannot be set in the Spot Check workflow. In the list, you can:

- Select to change the settings of current workflow.
- Select to copy it and create a new workflow in the list.
- Select to delete the corresponding workflow.
- Select **[Add Workflow]** to add a new workflow, up to 10 workflows can be set here.
- Select **[Save Current Settings]** to save new workflows.
- Select **[Restore Factory Defaults]** to restore factory's default settings, and the workflow customized by the users will be deleted.

6.8 Set Workflow Layout

The steps to set the layout in workflow are as follows:

1) Select corresponding to the target workflow on the **[Workflow]** page.
2) Enter the **[Editing Workflow]** page.

In **[Editing Workflow]** page:

- The name of workflow can be edited, but attempts to modify the name of a workflow which is currently in use will fail.
- Up to three pages can be set in a workflow, each with a maximum of four parameter rows can be included.
- and can be set from the first line of the parameter area on Page 1. Once is selected, the parameter selected in the first row of Page 1 will be fixed on both the second and third pages of the first row, while is selected, it will not be fixed.
- or can be selected in the other three rows(Except the first in the four parameter rows). When is selected, the parameter row is shown as one column, in which only one parameter can be displayed, while is selected, the parameter row will be divided into two columns, and two parameters can be displayed here.
- Select **[Parameter Setup]** to enter the page and the parameters can be modified here.
- Select **[Alarm Setup]** to enter the page, in which the priority, upper alarm limit, lower alarm limit and alarm switch can be modified.

Chapter 7 Alarms

When a patient under monitoring has abnormal vital signs, or when failure occurs in the monitor, the system sounds audible and visual alarm to remind/warn the user.

When there are multiple alarms and prompt messages, messages scroll in a cycle. The alarm audio will be triggered at the highest priority.

7.1 Safety Information

⚠ WARNING

- **A hazard can exist if different alarm presets are used in the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre. The operator should check that the current alarm presets is appropriate prior to use on each patient.**
- **Both the bedside monitor and the CMS are provided with sound alarm function.**
- **When the monitor is connected to the central monitoring system, although the upper and lower alarm limits of the monitor and the central monitoring system can be consistent simultaneously, the monitor may not trigger an alarm at the same time as the central monitoring system due to the alarm delay.**
- **When multiple alarms of different levels are generated simultaneously, the monitor will activate the alarm audio and light for the highest-priority alarm condition.**
- **Some physiological alarms, such as no pulse and RESP heart disturbance, are of exclusive type. The acoustic and optical forms of these alarms are the same as that of the high alarms, but the alarm messages are displayed exclusively, it means that only the exclusive-type alarm message is displayed when a normal alarm and an exclusive-type alarm are generated simultaneously.**
- **Users should set the alarm volume and the alarm limit according to the patent's actual condition. Do not monitor the patient only by relying on the sound alarm system. The patient may be put in a dangerous situation if the alarm volume is low. The minimum alarm volume should be set higher than environmental noise.**
- **To ensure that the alarm limit setting is suitable for the patient under monitoring, the limit value must be checked every time before use.**
- **The type of patient to be monitored (adult, pediatric or neonate) should be determined when setting the upper and lower limits of the alarm limit.**
- **Do not set the parameter alarm limits to extreme values, as this may cause the alarm system to become ineffective.**

NOTE

- **The sound pressure level of alarm signals generated by this monitor is 45-85db.**
- **If the sound pressure level of an auditory alarm signal is lower than the ambient noise, it may hinder the operator's ability to recognize the alarm state.**
- **The outage time of the alarm system will be recorded in the alarm system log.**
- **The alarm system log can store up to ten log entries. When the storage capacity is full, the earliest log entry will be deleted.**

7.2 Alarm Type

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

- Physiological alarm

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

- Technical alarm

  A technical alarm is triggered when the monitor does not operate normally or the monitoring result is unreasonable due to improper operation or system failure. A technical alarm message is displayed in the technical alarm area in the upper part of the screen.

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

7.3 Alarm Priority

- High-priority alarm: The patient is in critical condition or the device has serious failure, and immediate response is necessary
- Medium-priority alarm: The patient’s physical signs are abnormal, the device has failure or is misoperated, and timely response is necessary
- Low-priority alarm: The patient’s physical signs are abnormal, the device has failure or is misoperated, and the user is required to understand the current situation
- Prompt messages: Information on the patient and system status should be provided.

7.4 Alarm Signals

7.4.1 Alarm Indicator Light

The alarm indicator lights will indicate different priorities of alarms generated in different colors and flashing frequencies.

- High-priority alarm: Red, fast blinking frequency.
- Medium-priority alarm: Yellow, slow blinking frequency.
- Low-priority alarm: Cyan, no blinking, light remaining on

CAUTION

- **Prompt message without light indication.**

7.4.2 Audio Alarm

Audio alarms refer to different priorities of alarms generated by the monitor with different sound characteristics.

- High-priority alarm: beep-beep-beep--beep-beep----beep-beep-beep--beep-beep
- Medium-priority alarm: beep-beep-beep
- Low-priority alarm: beep
- Prompt massages: /

CAUTION

- **The pulse tone reminder and its prompt broadcast frequency are related to the pulse frequency, while the higher the pulse frequency is, the higher the tone of the prompt sound will be.**
- **The alarm tone reminder is related to the alarm priorities.**

7.4.3 Alarm Message

- The following signs are used in front of physiological alarm messages to differentiate the priorities of alarm:

  High-priority alarm:***

  Medium-priority alarm: **

  Low-priority alarm: *

- Background colors corresponding to different levels of alarm messages:

  High-priority alarm: Red

  Medium-priority alarm: Yellow

  Low-priority alarm: Cyan

- Background colors corresponding to Prompt messages: /

7.4.4 Alarm Parameter Forms

- High-priority alarm: red background with blinking
- Medium-priority alarm: yellow background with blinking
- Low-priority alarm: cyan background with blinking

7.4.5 Alarm Status Icon

	Alarm Paused		Alarm Off
	Alarm Audio Pause		Alarm Audio Off
	Alarm Reset	/	/

7.5 View Physiological Alarm conditions

View physiological alarm as follows:

1) Select physiological alarm area to enter **[Alarm]** window.
2) Select **[Physiological Alarms]** Tab. The current alarms are in the list displayed.
3) Select **[Details]** to get more information.

7.6 View Technical Alarm conditions

View technical alarm as follows:

1) Select technical alarm area to enter **[Alarm]** window.
2) Select **[Technical Alarms]** tab. The current alarms are in the list displayed.

7.7 Set Parameter Limits Manually

1) Click **[Menu]** hot key → **[Alarm]** → **[Limits]**.
2) Set the alarm parameters in corresponding tabs as required.

You can also set the alarm for one parameter from the parameter menu.

7.8 Set Alarm Volume

7.8.1 Set Minimum Alarm Volume

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and click the Enter key.
2) Select **[Alarm]** tab → **[Audio]** tab.
3) Select **[Minimum Alarm Vol.]**.

7.8.2 Set Alarm Volume

1) Click **[Menu]** hot key → **[Alarm]** → **[Setup]**.
2) Set **[Alarm Volume]**. The range of alarm volume is X ~ 10. X represents the minimum alarm volume, which depends on the Minimum Alarm Volume setting.
3) Set **[High Alarm Volume]**.
4) Set **[Reminder Volume]**. The reminder volume cannot set to 0.

WARNING

- **When the alarm volume is set to 0, the monitor cannot sound an alarm even if a new alarm is generated. Therefore, you should consider this when setting the alarm volume to 0.**
- **Do not rely only the audible alarm. Otherwise, patient safety may be at risk if the alarm volume is low. Pay close attention to the patient's actual clinical conditions.**
- **When the alarm volume is set to 0, the setting of [High Alarm Volume] is invalid.**
- **Maximum alarm volume is 10.**

7.8.3 Set Alarm Reminder

When the alarm volume is set to 0, or the alarm is reset, or the alarm function is turned OFF, the monitor will provide periodic alarm mute reminder to remind user of the situation that there is still activated alarm in the current system. Operation steps:

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** button → **[Pause/Reset]** tab.

3) Set **[Alarm Reset Reminder]** and **[Alarm Off Reminder]**.
   - When **[On]** is selected, the monitor will generate alarm reminder at set intervals.
   - When **[Off]** is selected, the monitor will not generate the alarm reminder, and the confirmed physiological alarm and the non-clearable technical alarm will be muted forever.
4) Select **[Reminder Interval]**: **[1min]**, **[2min]**, **[3min]**, **[5min]** or **[10min]**.

7.8.4 Set the Function of Alarm Volume Enhancing

The monitor has the function of alarm volume enhancing. If the alarm is not confirmed after the specified time, its volume will be increased automatically. Set as follows:

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** → **[Audio]**.
3) Set **[Auto Increase Volume]** as **[Level 2]**, **[Level 1]** or **[Off]**.
   - **[Level 2]**: If the alarm is not confirmed after the specified time, its volume will be increased by Level 2 automatically.
   - **[Level 1]**: If the alarm is not confirmed after the specified time, its volume will be increased by Level 1 automatically.
   - **[Off]**: If the alarm is not confirmed after the specified time, its volume will be no change.
4) Set **[Increase Volume Delay]** and select the increase volume delay time, it cannot be set when **[Auto Increase Volume]** is set to **[Off]**.

7.9 Alarm Paused/Alarm Audio Paused

7.9.1 Pause Definition

You can enable the function of alarm pause or alarm audio pause, which depends on the pause setting. Set as follows:

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** tab → **[Pause/Reset]** tab.
3) Set **[Pause]** to **[Alarm Paused]** or **[Alarm Audio Pause]**. The default value is **[Alarm Paused]**.

7.9.2 Alarm Paused

If the alarm function is defined as **[Alarm Paused]**, Click **[Pause]** hot key to pause the alarm. This function will:

- Mute all physiological alarms.
- Mute the sound of all technical alarms except the alarm lights and alarm messages of them.
- Display the remaining time of alarm pause in the physiological alarm message area

- Display the alarm pause icon in the message area.

The monitor will recover from alarm pause state after the alarm pause time expires. You can also press **[Alarm Paused]** hot key to cancel the alarm pause manually.

7.9.3 Set Alarm Pause Time

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** tab → then **[Pause/Reset]** tab.
3) Set **[Pause Time]**: **[1min]**, **[2min]**, **[3min]**, **[Permanent]**.

7.9.4 Delay Alarm Pause Time

When the monitor is in the alarm pause state, you can delay the pause time of this alarm temporarily. This function is turned on by default. Set as follows:

1) Select physiological alarm message area
2) Select **[Pause 5 min]**, **[Pause 10 min]** or **[Pause 15 min]** on the pop-up menu.

Close the function of delay alarm audio pause time as follows:

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** tab → **[Pause/Reset]** tab.
3) Deselect **[Pause 5 min]**, **[Pause 10 min]** or **[Pause 15 min]** as need.

> ⚠ NOTE
>
> - **The alarm pause time being delayed temporarily has nothing to do with that of set value.**

7.9.5 Alarm All Off

If **[Pause Time]** is set to **[Permanent]** (refer to "*Section 7.9.3 Set Alarm Pause Time*"), all alarms will be shut down if **[Alarm Off]** hot key is pressed. When the alarm function is shut down,

- The light and sound of physiological alarm will be mute.
- The sound of technical alarm will be muted except the alarm light and alarm message of it.
- **[Alarm Off]** with red background will appear in the physiological message area.
- The alarm pause icon will be shown in the message area.

Click **[Alarm Off]** hot key again to exit the alarm off state.

WARNING

- **Risk may exist if the alarm function is paused or turned off. The user should pay close attention to the actual clinical conditions of patients**

7.9.6 Alarm Audio Pause

If the alarm function is defined as **[Alarm Audio Pause]**, Click **[Alarm Audio Pause]** hot key will pause the alarm. When the monitor is in alarm audio pause state,

- The audios of physiological alarm and technical alarm will be mute in the specified time.
- The remaining time of alarm audio pause will appear in the physiological alarm message area.
- The alarm pause icon will be displayed in the message area.

The monitor will exit the alarm audio state automatically when the specified time of alarm audio pause expires. You can also click **[Alarm Audio Pause]** hot key to cancel the state of alarm audio pause.

7.9.7 Set Alarm Audio Pause Time

Set alarm audio pause time: **[1min]**, **[2min]**, **[3min]**, **[Permanent]**. Set alarm audio pause time as the steps in "*Section 7.9.3 Set Alarm Pause Time*".

7.9.8 Delay Alarm Audio Pause Time

When the monitor is in the alarm audio pause state, you can increase the sound pause time of this alarm temporarily. Increase alarm audio pause time as the steps in "*Section 7.9.4 Delay alarm pause time*".

NOTE

- **The alarm audio pause time being increased temporarily has nothing to do with that of set value.**

7.9.9 Alarm Audio Off

If **[Pause Time]** is set to **[Permanent]** (refer to "*Section 7.9.3 Set alarm pause time*"), all alarms will be shut down if **[Alarm Audio Off]** hot key are pressed. When the alarm audio is muted,

- The sounds of physiological alarm and technical alarm will be mute.
- The alarm audio pause icon will be displayed in the message area.

Click **[Alarm Audio Off]** hot key again to exit the alarm audio off state.

⚠ WARNING

- **Risk may exist if the alarm audio is paused or turned off. The user should pay close attention to the actual clinical conditions of patients.**

7.10 Set SpO_2Desat Alarm

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Other]** tab.
3) Set **[SpO_2 Desat. Alm Off]**:
   - **[Disable]**: SpO_2desat alarm will be kept on, and cannot be turned off.
   - **[Enable]**: SpO_2desat alarm can be turned off.

7.11 Set the Switch Status of Apnea Alarm

1) Click **[Menu]** → **[System]** → **[Maintain]**, then enter the maintenance password and click the Enter key.
2) Select **[Alarm]** tab → **[Other]** tab.
3) Select **[Apnea Alarm Off]**:
   - when **[Disable]** is selected： The Apnea Alarm is in its working state, thus any apnea alarms triggered cannot be switched off.
   - when **[Enable]** is selected： The apnea alarms triggered can be switched off.

7.12 Set the Switch Status of CMS Disconnection Alarm

If the monitor is expected to alarm upon disconnecting from the Central Monitoring System (CMS) , user is allowed to set the switch status by following steps:

1) Select **[Menu]** →**[System]**--- **[Maintain]**→input password→click Enter key.
2) Select **[Alarm]** tab→**[Other]** tab.
3) Switch ON or OFF the **[CMS Disconnection Alarm]**: if OFF is selected, the alarm information **[CMS Disconnected]** will not be generated when the monitor is disconnected from the CMS.

7.13 Set the Switch Status of CMS Alarm System Control

User can choose whether to allow the CMS monitoring system to control the Monitor's alarm system by:

1) Select **[Menu]** hotkey→**[System]**--- **[Maintain]**→input password→click Enter key.
2) Select **[Alarm]** tab→**[Other]** tab.
3) Switch ON or OFF the **[CMS Alarm System Control]**.

7.14 Set Alarm Delay Time

Alarm delay time can be set for the alarm triggered by continuous over-limit parameters. The monitor will not make alarm if the conditions that trigger the alarm disappear in the delay time. Set as follows:

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Other]** tab.
3) Set **[Alarm Delay]**.

Note: NIBP alarm has no time-delay function.

7.15 Alarm Reset

Click **[Alarm Reset]** hot key; confirm the existing alarms and reset the alarm system. Then the alarm reset icon will appear in the system status information area.

NOTE

- **If a new alarm is generated when the monitor is in alarm reset state, the alarm reset icon will disappear and the sound/light of the alarm will function normally**

7.15.1 Physiological Alarm Reset

When the physiological alarm is reset,

- The sound of existing physiological alarm will be mute.
- A check mark will appear before the alarm message, indicating that the alarm has been confirmed.
- The background of the measured value of the parameter will be kept on but not flash.

7.15.2 Technical Alarm Reset

When the technical alarm is reset,

- Fully clearable technical alarms will be cleared. The monitor will give no warning of the cleared technical alarms.
- Clearable sound and light alarms will be displayed as a prompt message.
- Not fully clearable technical alarms will be mute. A check mark will appear before the alarm message, indicating that the alarm has been confirmed.

7.15.3 Alarm Light Status Set after Alarm Reset

The alarm light defaults to **[On]**. It can be turned off as follows:

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** tab → **[Pause/Reset]** tab.
3) Set **[Alarm Light]**
   - **[On When Reset]**: The light of existing alarm will flash but the sound of it will be mute after alarm reset.
   - **[Off When Reset]**: The light and sound of existing alarm will be both turned off after alarm reset.

7.16 Set Nurse Call

If the nurse call is set on, the monitor will send request signal to nurse call system for calling a nurse when the user set alarm is triggered. The monitor provides a nurse call interface. After the monitor is connected with the hospital nurse-call system through the specified cable provided in the accessory bag, this interface can realize the Nurse Call function.

The nurse call function will be triggered when the monitor meets all requirements as follows:

- Nurse call function in enable.
- The user set alarm is triggered.
- No alarm pause or reset.

7.16.1 Nurse Call Setup

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Nurse Call]** tab.
3) Select **[Alarm Priority]** to set the priority of alarm that can trigger the nurse call function.
4) Select **[Alarm Type]** to set the type of alarm that can trigger the nurse call function.

WARNING

- **Do not use the nurse call function as the main alarm reminder source; the acoustic and optical alarm sent by the monitor shall be combined with the clinical manifestations and symptoms of the patient.**

7.17 Restore Alarm Defaults

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab.
3) Press the **[Restore Defaults]** button on the below.

7.18 Alarm System Self-test

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

Phenomena during self-test:

- The red alarm light is on for 1s; then the yellow light and the cyan light is on for 1s simultaneously; and then the alarm light is turned off.
- At the time of alarm light self-test, the alarm system makes a “beep” sound for alarm self-test and performs alarm audio self-test.

If the further testing of alarm system is needed, you can use relative simulator to perform it, and adjust the alarm limits to verify whether the correct alarm response can be triggered.

Chapter 8 NIBP Monitoring

8.1 Overview

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

The blood pressure measured by the equipment is equivalent to that measured by invasive method, and its error meets the requirements of IEC80601-2-30. The radial artery is selected for verification in invasive clinical trials.

NIBP measurement is applicable in electrosurgical operations and defibrillator discharges according to IEC80601-2-30.

NIBP monitoring is applicable to adult, pediatric and neonate patients.

8.2 Safety Information

⚠ WARNING

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

- If the measurement time is too long (such as repeated interval and continuous measurement mode), friction between the cuff and the limb may cause purpura. Ischemia and nerve damage. When monitoring patients, always check the color, temperature, and sensitivity of the distal limbs. Once any abnormality is found, the cuff placement position should be changed or blood pressure measurement should be stopped.

NOTE

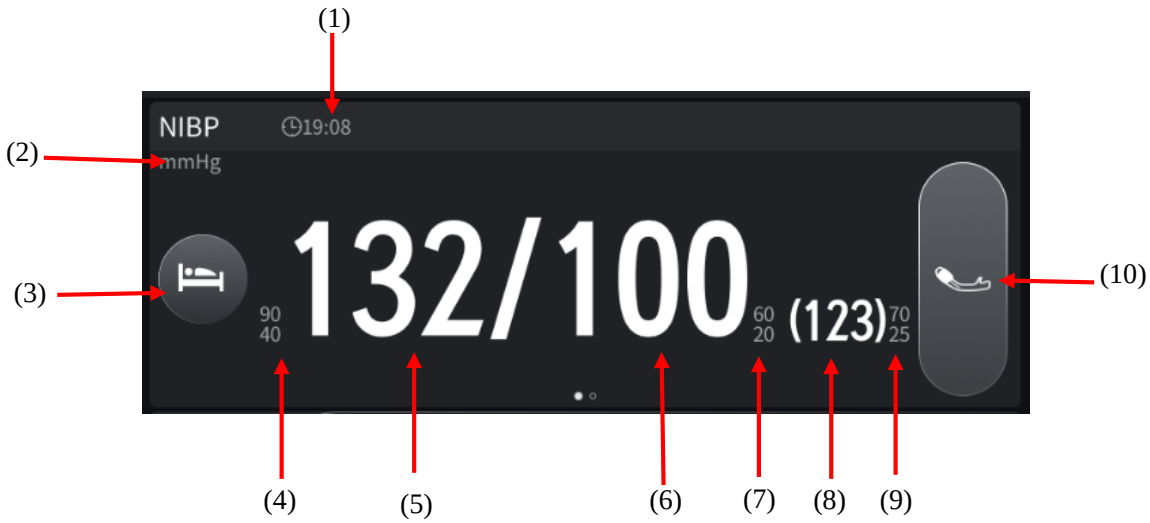
- If you have any doubt about the reading accuracy, check the patient's vital signs by other means first while checking the monitor to make sure the unit is operating properly.
- When unexpected values are measured, check the potential causes, such as
  - The incorrect cuff size was used or the cuff is not placed at heart level.
  - Measurement over-range.
  - Excessive patient movement.

8.3 NIBP Display

1) Enter **[Editing Workflow]** page, please refer to *"Section 6.8 Set Workflow Layout"* for more details.

2) Click on the area where NIBP is to be displayed, and select **[NIBP]** from the drop-down list.

The NIBP measurement results are displayed in the parameter area. The figure below is for reference only. The actual display interface of the monitor may be slightly different from this figure.



(1) Time of the previous measurement

(2) NIBP unit

(3) Patient position and measurement site: displays the current patient position and measurement site

(4) SYS (Systolic Blood Pressure) Alarm Limit

(5) SYS Value

(6) MAP(Mean Arterial Pressure) Value (in the measurement process, display the cuff pressure)

(7) MAP Alarm Limit

(8) DIA

(9) DIA (Diastolic Blood Pressure) Alarm Limit

(10) NIBPmeasurement: press this area the start NIBP measurement

8.4 NIBP Setup

8.4.1 Set Patient Type

Patient type includes Adu, Ped, and Neo. Please select an appropriate type for the monitored patient, and it should be consistent with the type set in **[Patient Category]** under the patient management page. More information about the operation please refer to "***Section 5.3.2 Edit Patient Information***".

8.4.2 Set NIBP Alarm

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

8.4.3 Set Initial Pressure

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Set **[Initial Pressure]**: select a proper initial pressure for cuff as needed.

Note: The initial pressure can only be set when the NIBP is under the algorithm of **[deflation measurement]**.

8.4.4 NIBP End Tone

The monitor will give a single tone prompt when the NIBP measurement is completed. **[NIBP End Tone]** defaults to **[Off]**, but you can turn it on by the following steps:

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Turn on **[NIBP End Tone]**.

8.4.5 Set NIBP Measure Sequence

NIBP sequence measure includes up to five measurement cycles: A, B, C, D and E. You can separately set the times and interval for each measurement cycle by the following steps:

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Sequence]** tab.
3) Set **[Times]** and **[Interval]** for each sequence.

8.4.6 Set NIBP Timeout

NIBP measurements will be displayed as hollow numbers if they exceed the set time, lest the expired measurements are regarded as current NIBP values. You can set NIBP Timeout by the following steps:

1) Select **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Module]** tab → **[Other]** tab.
3) Set **[NIBP Timeout]**.

8.5 Orthostatic BP Measurement

This monitor can provide two blood pressure measurement methods of patients in lying flat position and standing position, and give pressure difference value for clinical evaluation. Orthostatic blood pressure measurement is only indicated for adult patients under Spot Check mode.

8.5.1 Enable Orthostatic Blood Pressure Measurement

Here's how to turn on orthostatic blood pressure measurement:

4) Select the **[Menu]**→ select **[Workflow]** from the Configuration column→ enter the administrative password → enter.
5) Select the corresponding workflow on the right side of the workflow you want to modify. Ensure that the workflow is in Spot Check Mode.
6) Select the **[Parameter Setup]** → **[NIBP]**.
7) Turn on **[Orthostatic BP]**.

8.5.2 Start Orthostatic Blood Pressure Measurement

The steps to start orthostatic blood pressure measurement are as follows:

1) Connecting the cuff.
2) Swipe left and right in the NIBP parameter area to switch to the orthostatic blood pressure measurement interface.
3) Ask the patient to lie still and press the measurement start button corresponding to the blood pressure measurement in the lying position. After the monitor waits for a set lying time, it automatically starts measuring. For more information about how to set the lying down time, see ***8.5.3 Set the Lying Duration***

for details.

4) After the measurement, ask the patient to stand, and press the start button corresponding to the standing blood pressure measurement within one minute after he stands, and the monitor automatically performs multiple measurements according to the set **[Maximum Standing BP Measurements]** and **[Standing BP Measurement Interval]**. For details on how to set Maximum Standing Measurements and Standing Measurement Interval, see ***8.5.5 Set Maximum Standing BP Measurements*** and ***8.5.4 Set Standing BP Measurement Interval***.
5) Add symptoms according to the actual condition of the patient. The list of symptoms can be set, see ***8.5.6 Set Orthostatic BP Symptom***.
6) After the measurement is complete, the NIBP interface displays the evaluation results. Select **[Positive]** or **[Negative]** to view details.

8.5.3 Set the Lying Duration

The steps to set the lying duration are as follows:

1) Select the **[Menu]** → select **[Workflow]** from the **[Configuration]** column → enter the administrative password → select↵.
2) Select the on the right side of the workflow to be modified. Make sure that the workflow is the workflow of point measurement mode.
3) Select **[Parameter Setup]** → **[NIBP]** tab.
4) Set **[Lying Duration]**.

8.5.4 Set Standing BP Measurement Interval

The steps to set standing blood pressure measurement interval are as follows:

1) Select the **[Menu]** hotkey → select **[Workflow]** from the **[Configuration]** column → enter the password → select↵.
2) Select the on the right side of the workflow to be modified. Make sure that the workflow is the workflow of Spot Check Mode.
3) Select **[Parameter Setup]** → **[NIBP]**tab.
4) Set **[Standing BP Measurement Interval]**.

8.5.5 Set Maximum Standing BP Measurements

The steps to set maximum standing BP measurements are as follows:

1) Select the **[Menu]** hotkey → select **[Workflow]** from the **[Configuration]** column → enter the administrative password → select↵.
2) Select the on the right side of the workflow to be modified. Make sure that the workflow is the

workflow of point measurement mode.

3) Select **[Parameter Setup]** → **[NIBP]**.
4) Set **[Maximum Standing BP Measurements]**.

8.5.6 Set Orthostatic BP Symptoms

The steps to set max orthostatic BP symptoms are as follows:

1) Select **[Menu]** → select **[Maintain]** from **[System]** column → enter maintenance password → select **[Module]**.
2) Select the **[NIBP]** tab and select to modify the existing symptom in the **[Symptom]** list.
3) You can also select **[Add Symptom]** to create a new symptom, and then select to modify the symptom description. You can add up to three new symptoms

8.5.7 Set Orthostatic BP Evaluation Criterion

You can set the evaluation criteria for the orthostatic blood pressure measurement, and the results are displayed in the NIBP parameter area as "negative" or "positive" after the measurement. To set the evaluation criteria, proceed as follows:

1) Select the **[Menu]**→ select **[Maintain]** from the **[System]** column → enter the maintenance password → enter→ select the **[Module]** tab.
2) Select the **[NIBP]** tab, and select the corresponding to modify the existing criteria in the **[Evaluation Criterion]** list, you can also select **[Add Criterion]** to create a new criterion.
3) Set **[Parameters]**, **[Type]**, **[Threshold]**, and select **[With Symptoms]** to set whether the patient's symptoms are included in the assessment criteria.
4) Select **[Save]**.

8.6 NIBP Average Measurement

In NIBP average mode, the monitor automatically takes multiple measurements on the patient and displays the average blood pressure on the screen when the measurements are complete.

NIBP Average is only indicated for Spot Check mode.

8.6.1 Enable NIBP Average Measurement

The NIBP average mode can only be set when the **[Department]** setting is **[Physician Office]**. To change the **[Department]** setting, please refer to ***6.3 Change Department***.

The steps to enable NIBP average are as follows:

1) Select the **[Menu]** → select **[Workflow]** from the **[Configuration]** column → enter the administrative password → select.
2) Select the workflow corresponding to the right side of the workflow to be modified. Make sure that the workflow is the workflow of the point measurement mode.
3) Select **[Parameter Setup]** → **[NIBP]** → **[Average]**.
4) Open **[BP Averaging]**.

8.6.2 Start NIBP Average

The steps to start NIBP average are as follows:

1) Connect the cuff.
2) Swipe left and right in the NIBP parameter area to switch to the NIBP average measurement interface.
3) Set the patient position and measurement site.
4) Select  to start the first measurement.
   - If **[Delay Before Starting Measurement]** is set to **[None]**, the monitor starts the first measurement immediately. If **[Delay Before Starting Measurement]** is set to 1 min, 2 min, 3 min, 4 min or 5 min, the monitor will wait for the set time before starting the measurement.
   - After the first measurement is completed, the monitor automatically performs subsequent measurements according to the set **[Measurement Times]** and **[Interval]**.
5) After the measurement is completed, select **[Back]** to view the measured data and the average measurement results.

8.6.3 Set the Delay Before Starting Measurement

The steps to set the delay before starting measurement are as follows:

1) Select the **[Menu]**→ select **[Workflow]** from the **[Configuration]** column→ enter the password → select  .
2) Select the corresponding  on the right side of the workflow you want to modify. Ensure that the workflow is in spot mode.
3) Select the **[Parameter Setup]** → **[NIBP]** → **[Average]**.
4) Set the **[Delay Before Starting Measurement]**.

8.6.4 Set Average Measurement Times

The steps to set measurement times are as follows:

1) Select the **[Menu]** → select **[Workflow]** from the **[Configuration]** column → enter the administrative password → select↵.
2) Select the corresponding  on the right side of the workflow you want to modify. Ensure that the workflow is in spot mode.
3) Select the **[Parameter Setup]** → **[NIBP]** → **[Average]**.
4) Set the **[Measurement Times]**.

8.6.5 Set Interval between Readings

Users can set the interval between the start time of the second and subsequent measurements in the average measurement, as follows:

1) Select the **[Menu]** → select **[Workflow]** from the **[Configuration]** column → enter the administrative password → select↵.
2) Select the corresponding  on the right side of the workflow you want to modify. Ensure that the workflow is in spot mode.
3) Select the **[Parameter Setup]** → **[NIBP]** → **[Average]**.
4) Set the **[Interval]**.

8.6.6 Set Discard First Group of Readings

Users can perform average without including the first set of measurements in the average calculation by setting up the following steps:

1) Select the **[Menu]** → select **[Workflow]** from the **[Configuration]** column → enter the administrative password → select↵.
2) Select the corresponding  on the right side of the workflow you want to modify. Ensure that the workflow is in spot mode.
3) Select the **[Parameter Setup]** → **[NIBP]** → **[Average]**.
4) Set the **[Discard First Group of Readings]**.

8.7 NIBP Measurement

8.7.1 Measurement Restrictions

The oscillometric method has some restrictions depending on the patient's condition. The oscillometric method detects the regular pulse wave generated by arterial pressure. If the patient's condition makes it difficult to detect such waves, the measured value is unreliable, and the cuff inflation time increases. In the following cases, the NIBP measurement is impossible:

1) Patient Movement

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

2) Arrhythmia

If the patient has irregular heartbeats due to arrhythmia, the NIBP measurement is unreliable or even impossible and measurement time increases.

3) Heart-lung Machine

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

4) Pressure Changes

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

5) Severe Shock

If the patient is under severe shock or hypothermia, the NIBP measurement is unreliable as the reduced blood flow to the periphery will cause lower arterial pulse.

6) Extreme HR

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

7) Obese Patient

Due to the thick fat layer of the limb, the vibration from the artery fails to reach the cuff, which causes lower measurement accuracy than in normal weight cases.

8) Patient with Hypertension

To measure the NIBP of a patient with hypertension accurately, follow the steps below:

- Adjust his/her sitting posture until:
  - He/she sits comfortably;
  - His/her legs are not crossed;
  - His/her feet are laid flat on the ground;
  - He/she leans his/her back against the chair and puts his/her hands on the desk;
  - The middle part of the cuff is at the same level as his/her right atrium.
- Ask the patient to relax as much as possible and not talk during the measurement.

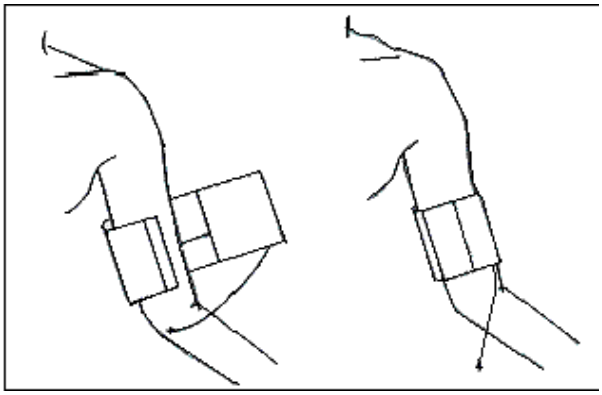
➢ 5 min elapses before the first reading taken.

NOTE

- **The effectiveness of NIBP on pregnant women, including those with preeclampsia, has not been verified.**

8.7.2 Preparations for Measurement

1) Connect the inflation tube to the blood pressure cuff.
2) Connect the inflation tube to the NIBP connector of the monitor without compressing or blocking the pressure tube.
3) Use the correct size cuff and make sure the airbag is not folded or twisted.
   - ◆ An incorrect cuff size or a folded or twisted airbag causes inaccurate measurement. Make sure the cuff is deflated thoroughly. The cuff width should be 40% (50% for neonates) of the limb perimeter or 2/3 of the upper arm length. The inflated part of the cuff should be long enough to circle 50~80% of the limb.



4) Wrap and secure the cuff around the limb and make sure the cuff is at the same level as the patient's heart. If you fail to do so, use the following methods to correct the measurement result:
   - ◆ Make sure the mark "φ" is located at an appropriate artery. Do not wrap or secure the cuff too tightly, or the distal extremity may suffer from discoloration or ischemia. Regularly check the skin condition of the contact part and the color, temperature and feeling of the limb which wearsthe cuff. If the skin condition changes or the blood circulation of the limb is affected, move the cuff to another body part for continued measurement or stop the NIBP measurement immediately. In auto measurement mode, observe the skin condition frequently.
   - ◆ If the cuff is not at the same level as the heart, use the following correction formulas:
     - ✧ If the cuff is at a higher level than the heart: displayed NIBP value + 0.75mmHg (0.10kPa) × level difference (cm).
     - ✧ If the cuff is at a lower level than the heart: displayed NIBP value - 0.75mmHg (0.10kPa) × level difference (cm).

8.7.3 Start Manual Measure

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Set **[Interval]** to **[Manual]**.
4) Set **[Start Mode]** to **[Interval]**.
5) You can select hot key or select **[Start NIBP]** in **[NIBP]** menu to start NIBP measurement.

8.7.4 Start Interval Measure

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Select the drop-down list of on the right of **[Interval]** and set the specific measurement interval.
4) Set **[Start Mode]** to **[Interval]**.
5) Select hot key or select **[Start NIBP]** in **[NIBP]** menu to start the first measurement.

After the first measurement is completed, the monitor will automatically repeat the measurement with the set interval.

8.7.5 Start Clock Measure

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Set **[Start Mode]** to **[Clock]**.
4) Select the drop-down list on the right of **[Interval]** and set the specific measurement interval.
5) Select hot key or select **[Start NIBP]** in **[NIBP]** menu to start the first measurement.

Or you can select **[Clock]**, and then select **[Setup]** → **[Interval]** to start the first measurement.
After the first measurement is completed, the monitor will automatically repeat the measurement with the set interval. For example, if the first measurement begins at 08:23, and the interval is set to **[5 min]**, the monitor will automatically start the next measurement at 08:25. Subsequent NIBP measurements are made synchronously with the clock, then at 08:30, and so on.

NOTE

- **Only when the [Interval] is set to 5 min or more, the monitor performs the clock measurement.**

8.7.6 Start NIBP STAT

You can start NIBP STAT in the following way:

- Enter **[NIBP]** measure → select **[STAT]**.

NIBP STAT process lasts for 5 mins.

8.7.7 Start Sequence Measure

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Set **[Interval]** to **[Sequence]**.
4) Set **[Start Mode]** to **[Interval]**.
5) Set parameters for the sequence; please refer to "*Section 8.4.5 Set NIBP Measure Sequence*" for more information.
6) Select hot key or enter **[NIBP]** menu→ select **[Start NIBP]** or select **[Sequence]** →**[Start NIBP]** to start the first measurement.

After the first measurement is completed, the monitor will start measurement automatically in the times and interval of the set sequence.

8.7.8 Stop NIBP

8.7.8.1 Stop Ongoing Measurement

You can stop the ongoing NIBP measurement in any of the following ways:

- Select hot key.
- Select NIBP parameter tile to enter **[NIBP]** menu → select **[Stop NIBP]**.

8.7.8.2 Stop NIBP STAT

You can stop NIBP STAT in any of the following ways:

- Select hot key.
- Select NIBP parameter tile to enter **[NIBP]** menu → select **[Stop NIBP]**.
- Select NIBP parameter tile to enter **[NIBP]** menu → select **[Stop All]**.

8.7.8.3 Stop All NIBP Measure

You can stop all measurements in the following way:

- Select NIBP parameter tile to enter **[NIBP]** menu→select **[Stop All]**.

8.8 Venipuncture

Inflate the NIBP cuff to a pressure approximate to the diastolic pressure to block the vein vessel and assist in the completion of venipuncture. Steps are as follows:

1) Select NIBP parameter tile → Select **[Setup]** tab.
2) Set **[Venipuncture Pressure]**.
3) Select **[Venipuncture]** button on the lower right corner of the menu.
4) Puncture the vein and take the blood sample.
5) Select  hot key to deflate the cuff manually. If manual deflation is not performed, the venipuncture process lasts for 125s for adult and pediatric patients and 87s for neonate patients. The cuff deflates automatically after the said time period.

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

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Chapter 9 SpO_2 Monitoring

9.1 Overview

The SpO_2 plethysmography measures the arterial SpO_2, namely, the percentage of the oxyhemoglobin count. The SpO_2 is measured with the pulse oximetry; a continuous noninvasive method measuring how many of the lights emitted from the sensor (light source) can penetrate the patient's tissues (fingers or ears) and reach the receiver.

The monitor measures the following parameters (for Comen SpO_2, Masimo SpO_2 and Nellcor SpO_2):

- Arterial SpO_2: the ratio of the oxyhemoglobin to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial SpO_2).
- Pleth waveform: a visible indication of the patient's pulse;
- PR (calculated from pleth waveform): the patient's pulse count per minute;
- PI (perfusion index): the pulsatile blood flow value (PI measurement is unavailable for Nellcor SpO_2).

WARNING

- **If there is any carboxyhemoglobin (COHb), methemoglobin (MetHb) or dye dilution chemical, the SpO_2 value will have a deviation.**

9.1.1 Identification of SpO_2 Type

Two types of SpO_2 module can be used simultaneously, and its measurement values are labeled with SpO_2 and SpO_2b respectively and displayed in SpO_2 menu. Appearance and logo of SpO_2 modules are as below:

- Comen SpO_2: round cable interface; no manufacturer's logo.
- Masimo SpO_2: round cable interface; logo: Masimo.
- Nellcor SpO_2: round cable interface; logo: Nellcor.

The information about wavelength range and maximum optical output power of the sensor is useful to the clinician for some therapy, for example, photodynamic therapy.

- The Comen SpO_2 sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).
- The Masimo SpO_2 sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).
- The Nellcor SpO_2 sensor can measure a wavelength of 660nm (red LED) or 900nm (IR LED).
- The maximum optical output power of the sensor is lower than 15mW.

NOTE

- Functional test equipment or SpO_2 simulator cannot be used to verify the accuracy of SpO_2 monitor and pulse oximeter sensor. The accuracy of SpO_2 monitor and pulse oximeter sensor needs to be verified by clinical data.
- Functional test equipment or SpO_2 simulator can be used to evaluate the accuracy of PR.
- This monitor and its supporting SpO_2 sensor and sensor extension cord have been tested for compliance with ISO 80601-2-61.

9.2 Safety Information

WARNING

- The Monitor is compatible with the SpO_2 sensor specified by Comen only.
- Before monitoring the patient, please check if the sensor and extension cord are compatible with the Monitor. Incompatible accessories may reduce the performance of the Monitor.
- Before monitoring the patient, please check if the sensor cable works properly. Remove the SpO_2 sensor cable from the sensor interface, and the Monitor will display the prompt message "SpO_2 Finger Sensor Off" and trigger the alarm audio.
- If the SpO_2 sensor or its package seems damaged, do not use it but return it to the manufacturer.
- Long-time continuous monitoring may increase the risk of undesired skin characteristic changes (extremely sensitive, turning red, blistered or pressure necrosis), especially for neonates or the patients with perfusion disorder or variable or immature skin morphology diagram. Align the sensor with the light path, fix it properly and check its position regularly based on skin quality changes (change the sensor position in case of reduced skin quality). Perform such check more frequently if necessary (subject to the condition of the patient).
- Make sure the sensor cable and electrosurgical equipment cable are not intertwined.
- Do not place the sensor on a limb with ductus arteriosus or intravenous tube.
- Setting the upper SpO_2 alarm limit to 100% will disable the upper-limit alarm. Premature infants may get infected with crystalline posterior fibrous tissue diseases in case of high SpO_2. Please set the upper SpO_2 alarm limit cautiously based on recognized clinical practices.
- The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse oximeter unless the setup was verified to be correct.
- Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the pulse oximeter if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.

- To protect against injury, follow the directions below:
- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this operator's manual.
- Do not attempt to clean the device while monitoring a patient.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.
- Inaccurate SpO_2 readings may be caused by:
  - Improper sensor application and placement
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Elevated levels of bilirubin
  - Elevated levels of dyshemoglobin
  - Vasospastic disease, such as Raynaud's, and peripheral vascular disease
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Severe anemia
  - Very low arterial perfusion
  - Extreme motion artifact
  - Abnormal venous pulsation or venous constriction
  - Severe vasoconstriction or hypothermia
  - Arterial catheters and intra-aortic balloon
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
  - Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
  - Skin color disorders
- The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- The pulse oximeter is not an apnea monitor.
- The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter should not be used for arrhythmia analysis.
- SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.
- Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another part. Change the wearing part at least every four hours.

- During a technical alarm condition, the SpO_2 monitoring, both displayed values and waveform might not accurate, and the operator should additionally validate the values and the patient's status.

⚠ CAUTION

- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.
- If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the irradiation period.
- Ensure that alarm limits of SpO_2 and PR are appropriate for the patient being monitored.
- Variation in measurements may be significant and may be affected by sampling techniques as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.

⚠ NOTE

- A functional tester cannot be used to assess the accuracy of the pulse oximeter.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.
- Make sure your nails block the light inside the probe. The probe cable should be placed on the back of the hand.
- Do not place the SpO_2 sensor and NIBP cuff on the same limb, because blood flow occlusion during NIBP

measurement will affect the functional oxygen saturation reading.

- The displayed SpO_2 waveform is normalized.
- The pulse oximeter device is calibrated to display functional blood oxygen saturation.
- Validation of the accuracy of SpO_2 measurement: The accuracy of Masimo SpO_2 has been validated in comparison with the reference value of arterial blood samples measured by CO-oxygen manometers in clinical investigation. The pulsation oximeter measurement results conform to the statistical distribution. Compared with the CO-oximeter measurement results, it is expected that about two-thirds of the measurement results will fall within the specified accuracy range.
- Masimo SpO_2 has induced a hypoxic state in human blood with a SpO_2 of 70% to 100% in healthy adult volunteers. By comparing with the laboratory combined photoelectric oximeter and high flow respiratory humidification therapy device, validated the accuracy under no motion. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68%of the population weight.
- Masimo SpO_2 has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

9.2.1 Masimo SpO_2 Specific Information

⚠ CAUTION

- If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor and/or patient cable when a “SpO2 Sensor Expired” and/or “SpO2 Cable Expired”, or a persistent poor signal quality message (such as “SIQ Weak Signal”) is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

⚠ NOTE

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

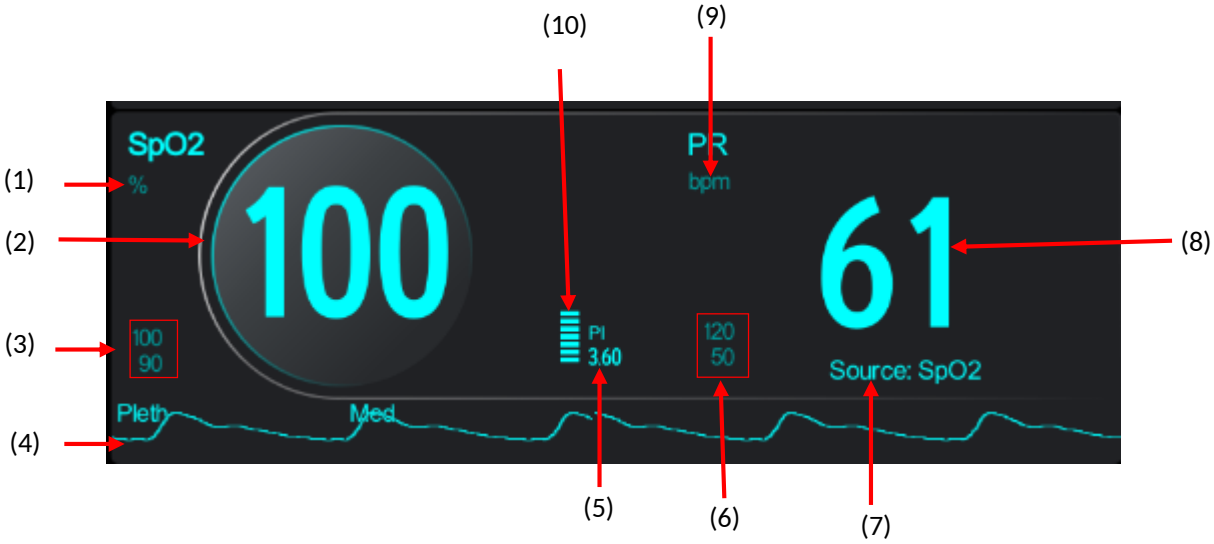
- **Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.**

9.3 Measurement Restrictions

Inaccurate SpO_2 readings may be caused by the following factors:

1) High-frequency radio interference, whether from the host system or from the electrosurgical equipments connected to the host system. To minimize radio interference, other electrical equipment that emits radiofrequency transmissions should not be in close proximity to the instrument.
2) Do not use the oximeter or SpO_2 sensor in the MRI process, or the induced current may cause burns.
3) Intravenous dyes.
4) The patient moves frequently.
5) Ambient optical radiation
6) The sensor is fixed improperly or to an improper position on the patient.
7) Improper sensor temperature (optimum temperature: 28℃~42℃).
8) The sensor is placed on a limb with blood pressure cuff, ductus arteriosus or intravenous tube.
9) Concentration of the non-functional hemoglobin, like COHb or MetHb.
10) Low SpO_2.
11) Poor circulation perfusion at the tested part.
12) The shock, anemia, hypothermia and application of vasoconstrictors may reduce the arterial blood flow to a non-measurable level.
13) The SpO_2 measurement accuracy depends also on the absorption of the lights with special wavelength by oxyhemoglobin and reduced hemoglobin. If any other substance also absorbs such lights, like COHb, MetHb, methylene blue or indigo carmine, you may obtain a false or low SpO_2 value.

9.4 SpO_2 Display



(1) Saturation of pulse oxygen (SpO_2) unit

(2) Saturation of pulse oxygen (SpO_2/ SpO_2b) value (unit of %SpO_2).

(3) SpO_2 alarm limits

(4) Plethysmographic (Pleth) waveform: the amplitude of Pleth waveform can directly reflect the intensity of the patient's pulse signal.

(5) Perfusion indicator (PI): available for Masimo SpO_2 and Comen SpO_2.

(6) Pulse rate(PR) alarm limit

(7) Pulse rate(PR) source

(8) Pulse rate(PR) value

(9) Pulse rate(PR) unit

(10) Bar chart (for Nellcor SpO_2 and Comen SpO_2): proportional to pulse strength. The bar chart can reflect the filling state of the blood

9.5 Low Perfusion Accuracy Test

This monitor can measure low perfusion and the recommended method of determining the low perfusion accuracy of the monitor is to conduct this test with CO-oximeter on adult volunteers whose SpO_2 ranges from 70% to 100%. The accuracy index is obtained according to statistical distribution, and only about 2/3 of the estimated values are expected to fall within the estimated values of CO-oximeter.

9.6 Monitoring Steps

9.6.1 Comen SpO_2 Measurement Steps

1) Choose a proper SpO_2 sensor according to the patient type.
2) Insert SpO_2 cable connector into the SpO_2 interface of the monitor.
3) Fix the sensor to an appropriate position on the patient. Please refer to "***Section9.7 Placement of SpO_2 Sensor***" for more information.

9.6.2 Masimo SpO_2 &Nellcor SpO_2 Measurement Steps

1) Choose a proper SpO_2 sensor according to the module type and patient type.
2) Connect SpO_2 patch cord to SpO_2 sensor.
3) Insert the other end of SpO_2 patch cord into the SpO_2 interface of the monitor.
4) Fix the sensor to an appropriate position on the patient. Please refer to "***Section 9.7 Placement of SpO_2 Sensor***" for more information.

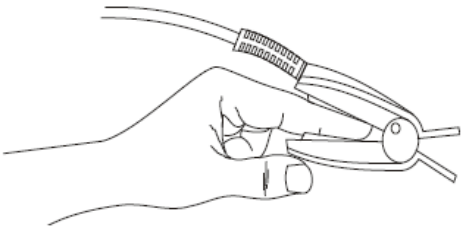
9.7 Placement of the SpO_2 Sensor

WARNING

- **Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another part. Change the wearing part at least every four hours.**
- **Place the SpO_2 sensor properly based on the SpO_2 sensor type compatible with the Monitor. This is especially important for neonates.**

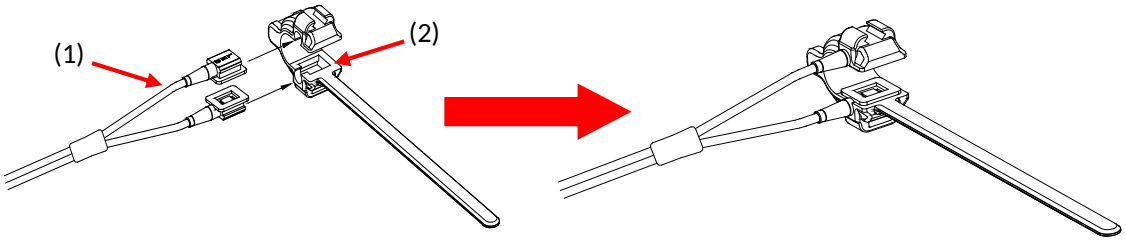
9.7.1 Placement of Adult SpO_2 Sensor

The location of the Adult SpO_2 sensor is shown in the figure below:



9.7.2 Placement of Neonatal/Pediatric SpO_2 Sensor

1) Assembly of Neonate SpO_2 sensor: Embed the LED end and PD end of the Y-shaped SpO_2 sensor respectively in the upper and lower groove of the Neonate SpO_2 sensor sheath, as shown in the figure below:



(1) Y-shaped SpO_2 Sensor (2) NEO SpO_2 Sensor Sheath

2) Placement of SpO_2 sensor: fix it on the foot of neonate, or the finger of pediatric patient.

9.8 SpO_2 Setup

9.8.1 Set SpO_2 Alarm

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

If you use two SpO_2 modules at the same time, you can enter the **[Alarm]** interface of the SpO2b module to set the alarm for ΔSpO_2.

NOTE

- **Only when the [SpO2 Desat. Alm Off] is set to [Enable] can you turn off SpO_2Desat Alarm. Please refer to "*Section7.10 Set SpO_2 Desat Alarm*" for more information.**

9.8.2 Set Off Priority

You can set SpO_2 sensor off Alarm Level by the following steps:

1) Select **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab→**[Other]** tab.
3) Set **[SpO2 Finger Sensor Off]**.

9.8.3 Set Speed

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Speed]** to the appropriate value.

9.8.4 Set NIBP Simul

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[NIBP Simul]** to **[On]** or **[Off]**.
   - ◆ On: to prevent weak perfusion caused by NIBP measurement when NIBP and SpO_2 measurements are performed on the same limb of a patient, which will lead to inaccurate SpO_2 measurements and even trigger SpO_2 physiological alarms.

9.8.5 Set Sat-Seconds (Available for Nellcor SpO_2 Only)

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set Sat-Seconds to the appropriate time.

The smart alarm is designed to reduce false alarms and keep the clinician informed of the SpO_2 changes more accurately and timely. For example, if you set Sat-Seconds to **[50]** and the upper and lower alarm limit of NELLCOR SpO_2 Respectively to 97% and 90%, maintain the measured SpO_2 value at 80% for 3s and then reduce it to 78% for 2s, the Monitor will trigger the alarm audio and indicator 5s after the SpO_2 value goes beyond the alarm limit and the circle beside the SpO_2 value will return to the origin.

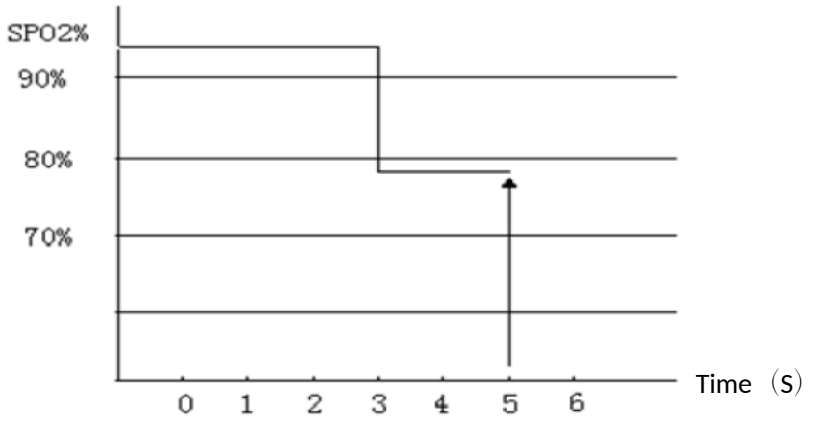
Calculation method:

Percentage points × seconds = Sat-Seconds (integer)

The calculated Sat-Seconds is displayed as follows:

%SpO_2	Seconds	Sat-Seconds
（90%-80%）	× 3 =	30
（90%-78%）	× 2 =	24

Total Sat-Seconds = 54



In the above Sat-Seconds example:

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

The SpO_2 value may fluctuate in seconds rather than remain unchanged. The patient's SpO_2 value usually fluctuates within the alarm limit and sometimes goes beyond the alarm limit discontinuously. The Monitor will accumulate the positive and negative percentage points until the set value of Sat-Seconds is reached or the patient's SpO_2 value remains beyond the alarm limit.

9.8.6 Set Sensitivity (Unavailable for Nellcor SpO_2)

The **[Sensitivity]** of Masimo SpO_2 can be set to **[Normal]**, **[High]** or **[APOD]**. **[High]** represents the highest sensitivity. In typical monitoring conditions, please select **[Normal]**. If the sensor is likely to come off the patient due to wet skin, violent movements or other causes, please select **[APOD]**. If the patient's perfusion level is extremely low, please select **[High]** to increase the sensitivity. And the **[Sensitivity]** of Comen SpO_2 can be set to **[High]**, **[Med]** or **[Low]**

Steps to set **[Sensitivity]**:

1) Select the SpO_2 parameter tile to enter SpO_2 setup menu→ **[Sensitivity]**.
2) Select an appropriate sensitivity.

CAUTION

- **In Continuous Monitor, the settings for Masimo SpO_2 load the factory default configuration when the device reboots.**
- **In Spot Check, the setting of Masimo SpO2 sensitivity is consistent with the workflow settings loaded by the monitor when the device reboots.**

9.8.7 Set Average Time (Unavailable for Nellcor SpO_2)

The SpO_2 value displayed on the monitor screen is the average of data collected within a specific time. The shorter the average time is, the quicker the monitor responds to changes in the patient's oxygen saturation level. Similarly, the longer the average time is, the slower the monitor responds to changes in the patient's oxygen saturation level, but the SpO_2 measurement is more stable. For critically ill patients, selecting a shorter average time will help with understanding the patient's state.

9.8.7.1 Average Time for Masimo SpO_2

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Average Time]** to **[2-4]**, **[4-6]**, **[8]**, **[10]**, **[12]**, **[14]** or **[16]**, the unit is s.

9.8.7.2 Average Time for Comen SpO_2

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Sensitivity]** to **[High]**, **[Med]** or **[Low]**, and the corresponding average time will increase in turn.

9.8.8 Set Smart Tone (Available for Masimo SpO_2 Only)

When smart tone is set to on the QRS volume would still be heard in case of an unstable signal or ambient noise.

To set **[Smart Tone]**:

1) Select the SpO_2 parameter area to enter **[SpO_2]** menu.
2) Turn on or off **[Smart Tone]**.

9.8.9 Set Signal IQ (Unavailable for Nellcor SpO_2 Only)

The magnitude of the SpO_2 SIQ waveform provides an assessment of the confidence in the measurement displayed. A higher value indicates higher confidence in the measurement whereas a smaller value indicates lower confidence in the displayed measurement.

Movements usually affect the signal quality. When the arterial pulse reaches the peak, the monitor marks its location on the vertical line (signal indicator). The smart tone volume (if enabled) remains consistent with the indication in the vertical line (the volume of the smart tone will increase or decrease accordingly when the SpO_2 value increases or decreases).

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

Set **[Signal IQ]**:

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Turn on or off **[Signal IQ]**.

9.8.10 Display PI (Unavailable for Nellcor SpO_2 Only)

[Display PI] defaults to **[On]**. Steps to set it to Off:

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Display PI]** to **[Off]**.

9.9 Masimo Information

1) Masimo Patent Information

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

2) No Implied License Statement

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

3) Other Information

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Chapter 10 PR Monitoring

10.1 Overview

The mechanical activity of the heart causes the pulsation of the artery and the PR value is obtained by measuring this pulsation. The color of the PR parameter area corresponds to the color its source.

10.2 Set PR Alarm

You can set the PR alarm by the following steps:

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[PR]** tab →**[Alarm]** tab.
3) Set the alarm as needed.

10.3 Set Pulse Volume

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu → **[PR]** tab.
2) Select **[Setup]** tab.
3) Set **[Pulse Volume]** to a proper value.

When there is a valid SpO_2 measurement value, the system will also adjust the pitch tone according to the value of SpO_2.

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Chapter 11 Resp Monitoring

11.1 RESP (Respiration) Measurement

The RR values displayed by this monitor come from different sources in different operating modes. In spot check mode, the RR value can come from Comen SpO_2 (inapplicable to neonates) and manual input; in continuous monitoring mode, the RR value can come from CO_2 measurement and manual input, and when CO_2 measurement is performed, the default source is CO_2.

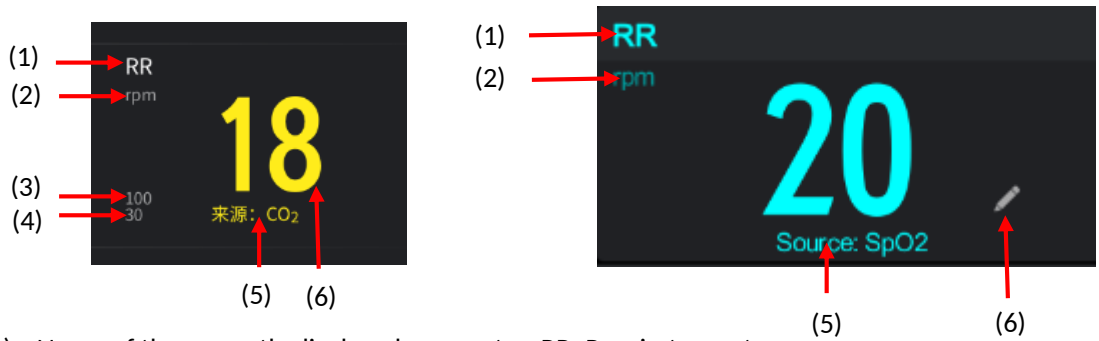
11.2 Safety Information

⚠ CAUTION

- **Resp measurement is not intended for patients with a large range of activities, otherwise it may lead to a false alarm.**
- **Impedance Resp measurement may lead to a change in the pacing frequency of the adaptive pacemaker's ventilation rate per minute. In this case, please turn off the pacemaker's ventilation rate response mode per minute or turn off impedance resp measurement.**

11.3 Resp Display

The value of RR can be displayed in the parameter area of the monitor.



(1) Name of the currently displayed parameter; RR: Respiratory rate

(2) RR unit

(3) RR upper alarm limit (only for continuous monitoring mode)

(4) RR lower alarm limit (only for continuous monitoring mode)

(5) RR source: from Comen SpO_2 and manual input in spot check mode; from CO_2 and manual input in continuous monitoring mode, and from CO_2 by default when performing CO_2 measuremen.t

(6) RR value manual input area: select this area or to manually input RR value.

11.4 Manual input of RR Value

Users can enter the RR value manually. The steps are as follows:

1) Select the icon in the Resp area and a timer will be displayed on the screen and start timing for 60 seconds.
2) During the 60 second timer, the actual number of breaths taken by the patient will be calculated.
3) When the timer ends, enter the RR value.
4) Click the save button to save the data.

11.5 Resp Setup

11.5.1 Turn on the Resp Alarm Switch

In continuous monitoring mode, users can turn on the Resp alarm switch. The steps are as follows:

1) Select the CO_2 parameter area or waveform area to enter the **[CO_2]** menu.
2) Select the **[Alarm]** tab.
3) Turn on the **[RR]** switch.

11.5.2 Set Resp Alarm

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

11.5.3 Set Apnea Timeout

Apnea detection is to detect the longest interval between two adjacent RESPs. When the actual apnea time of the patient exceeds the set apnea time, the Monitor will respond to apnea alarms according to the value of **[Apnea Timeout]**.

To set **[Apnea Timeout]**:

1) Select the CO_2 parameter area or waveform area to enter **[CO_2]** menu.
2) Select **[Alarm]** tab.
3) Set **[Apnea Timeout]**.

11.5.4 Set Interval of Timer Reminder

When manual input of RR value is selected, a timer will be displayed on the interface of the monitor, and the user should calculate the actual number of breaths of the patient within the corresponding time and enter the value into the manual input value field and save it after the timer is over. The value will be displayed on the screen after saving it..

The user can set the timer prompt interval according to the following steps:

1) Select the **[Menu]** hotkey → select **[Workflow]** from the **[Configuration]** column → enter the administrative password → select  .

2) Select the  to modify the corresponding workflow.

3) Select **[Parameter Setup]** → **[RR]**.

4) Set **[Interval of Timer Reminder]**.

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Chapter 12 Temp Monitoring

12.1 Overview

This monitor measures the body temperature by an external thermometer. Depending on the type of thermometer, the temperature can be measured from the following sites: axilla, tympanic membrane, oral cavity, core, rectum, and temporal artery. Please refer to the supplied thermometer manual for a more details.
The monitor can measure temperature with IRT10
The Thermometer used with the monitor will have a separate user manual, please refer to the relevant user manuals for more details.

12.2 Safety Information

⚠ WARNING

- **The thermometer used is in direct mode.**
- **Calibrate the Temperature at least every two years or as required by the hospital's regulations. Contact the manufacturer for calibration when necessary.**
- **Use the temperature probe and probe sheath specified in this manual. Use of other probes, probe sheaths, or failure to use probe sheaths may damage the monitor or prevent it from meeting the specifications claimed in this manual.**
- **The temperature probe sheath is a disposable accessory. Reuse of it may result in cross-contamination.**
- **Disposable probe sheath must be used for temperature measurements. Failure to use it may result in inaccurate measurements or patient cross-contamination.**
- **Check that the disposable sheath is in good condition before use; if there are signs of damage or contamination, do not use it again for measurements.**
- **Hold the temperature probe carefully; when not in use, place the probe back into the sheath.**
- **Dispose of disposable temperature probe sheaths in accordance with local regulatory requirements or hospital protocols.**

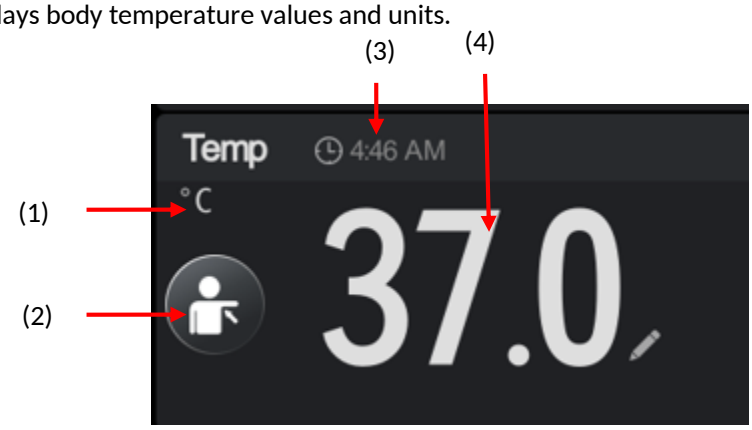
⚠ CAUTION

- **During the measurement process the temperature measuring instrument, IRT10 will automatically self-test once per hour. The self-test lasts for 2 seconds and does not affect the normal operation of the temperature monitor.**

12.3 Temp Display

1) Enter **[Editing Workflow]** page, please refer to ***"Section 6.8 Set Workflow Layout "***for more detail steps.
2) Click the location where you want to display the temp value in the parameter area and select **[Temp]** from the drop-down list.

The monitor displays body temperature values and units.



(1) Temp unit
(2) Measuring site: display the current measuring site, select the area to change measurement site
(3) The last measurement time
(4) Temp value

12.4 IRT10 Temperature Monitoring

The IRT10 thermometer is suitable for measuring the ear temperature of adults, pediatrics and neonates. The steps to measure the temperature are as follows:

1) Make sure the ear temperature probe is placed with batteries.
2) Pull out the infrared ear thermometer from the cannula, press the eject button, dispose of the used sheath in the waste basket, take out a new sheath from the disposable sheath place, put it on the probe and snap it in place.
3) Place the infrared ear thermometer inside the patient's ear, press the temperature measurement button, wait a few seconds and hear a "beep—".
4) Remove the infrared ear thermometer and see the temperature value in the thermometer display.
5) Press the eject button of the infrared ear thermometer probe to exit the sheath, and then put the infrared ear thermometer back into the sheath.

Note: The maximum response time for temperature measurement by the monitor after entering a 23 ℃/27 ℃ environment from a 25 ℃ environment can be found in the corresponding User Manual of the thermometer.

NOTE

- The ear thermometer will be calibrated once at the factory; During use, there is no need to calibrate it regularly. If inaccurate measurements or other problems with the device are found, please contact Comen's after-sales service. When measuring the temperature, please hold the thermometer at the position of the center of the forehead and press the measuring button at a distance of 10-15cm.
- Before measuring, please confirm that the forehead is not covered by hair, sweat, cosmetics, or hats.
- When the tested person comes from a place with a significant temperature difference from the measuring environment, there should be at least a waiting time of 5 minutes before taking measurements.
- Temperature measurement should not be taken after cold compress or other cooling measures are applied to patients having a fever.
- The ambient temperature around the person being tested should be stable and measurements should be avoided in areas with high airflow such as fans and air conditioning.
- When taking the thermometer from a place with a significant temperature difference from the measuring environment, the thermometer should be left in current environment for 30 min before measurement.
- Do not use this thermometer in areas with strong sunlight.
- The measurement of forehead temperature should be based on the "body temperature mode", while the temperature measurement of other objects such as liquids, food, etc. should be taken on the "surface temperature mode".
- If the temperature of the forehead is low for some reason, the measurement of the ears is also effective.

12.5 Temp Setup

12.5.1 Set Temp Measurement Site

1) Select **[Menu]** → select **[Maintain]** from **[System]** column → enter maintenance password → select ↵.
2) Select **[Module]** → **[Temp]**.
3) Select the target sites

12.5.2 Set Temp Timeout

1) Select **[Menu]** → select **[Maintain]** from **[System]** column → enter maintenance password → select ↵.
2) Select **[Module]** → **[Other]**.
3) Set **[Temp Timeout]**.

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Chapter 13 CO_2 Monitoring

13.1 Overview

The monitor uses the CO_2 measurement to monitor the patient's respiration status and control patient's ventilation. There are two methods of measuring the CO_2 in the patient's airway:

- Sidestream measurement method: take sample from the respiratory gas module in the patient's airway at a constant flow rate and use the built-in remote CO_2 module in the measurement system to analyze them.

In the above method, the measurement principle is IR emission. Use the optical detector to measure the intensity of the infrared rays penetrating the respiratory system. The intensity depends on the CO_2 concentration as some infrared ray is absorbed by CO_2molecules.

CO_2 measurement is intended for adult, pediatric and neonate patients.

13.1.1 Indication on CO_2 Module

Masimo Sidestream Module:

The light emitting gas inlet (LEGI), detects the presence of a NomoLine sampling line and presents color coded status information:

LEGI Indication	Status
Steady green light	System OK
Flashing green light	Zeroing in progress
Steady red light	Sensor error
Flashing red light	Check sampling line

13.2 Safety Information

⚠ WARNING

- **Place sampling line and other pipes well to prevent the patient from being entangled and thus suffering from apnea.**
- **Never use this device in an environment with inflammable anesthetic gases.**
- **Only the trained professionals familiar with this Manual are allowed to operate the device.**
- **If the patient is connected to mechanical ventilation equipment supplied by oxygen 93 or an oxygen concentrator, the accuracy of CO_2/AG monitoring may not be maintained. It shall not be used with gas supplied from oxygen concentrators.**
- **All parts or accessories except the Respironics pathway adaptor does not contain phthalates or other**

substances, which are classified as endocrine disrupting, carcinogenic, mutagenic.

- The Respironics pathway adaptor contains phthalates, such an indication is marked on the packaging.
- Take increased care during the treatment of children and the treatment of pregnant and nursing women, who may have an allergy to this substance.
- Masimo CO_2 has the automatic barometric pressure compensation function.
- Respironics and Comen CO_2 sensors have no function of barometric pressure compensation, and have been set with a fixed value before delivery. If the value needs updating due to altitude, contact the maintenance personnel.
- If Luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.

⚠ CAUTION

- When the patient is being treated with nebulized drugs, the measured $EtCO_2$ value may be inaccurate, and thus it is not recommended to use it under such a circumstance.
- The $EtCO_2$ measured by CO_2 module may differ slightly from the partial pressure of carbon dioxide (PCO_2) measured by arterial blood gas analyzer.

13.3 Adverse Effects on Performance

1) The following factors are known adverse effects on the specified performance:

- Quantitative effects of RH or condensation;
- Quantitative effects of barometric pressure;
- Interfering gas or water vapor;
- leaks or internal venting of sampled gas;
- Cyclical pressure of up to 10 kPa (100 cmH_2O);
- Other sources of interference.

2) Gas Measurement Unit

Use volume percentage as the gas concentration unit. The concentration calculation formula is:

$$\%gas = \frac{Partial\ pressure\ of\ gas\ component}{Total\ pressure\ of\ gas\ mixture} * 100$$

Use the cup-making pressure sensor of the ISA gas analyzer to measure the total pressure of the gas mixture. To convert into any other unit, use the actual barometric pressure sent from the ISA sidestream (IRMA mainstream).

CO_2 (mmHg) = (CO_2 Concentration) x (Barometric Pressure from ISA (kPa)) x (750 / 100).

Take 5.0 vol% CO_2 @ 101.3kPa as an example: 0.05 x 101.3 x 750 / 100 = 38 (mmHg).

3) Effects of RH

The partial pressure and volume percentage of the CO_2, N_2O, O_2 and anesthetic gas depend on the water vapor content in the measured gas. Calibrate the O_2 measurement, and the displayed value at the ambient

temperature and RH level will be 20.8 vol%, not the actual partial pressure. The 20.8 vol% O_2 represents the actual O2 concentration of the room air (water concentration: 0.7 vol %) (for example, 25℃ and 23% RH @ 1013hPa). The monitor displays the actual partial pressure at the current RH level when measuring the CO_2, N2O and anesthetic gas (like all gases measured by infrared cell).

In the patient's alveoli, the water vapor in the respiratory gas is saturated (BTPS) at the body temperature. Before the acquired respiratory gas in the sampling tube is transferred to the ISA sidestream gas analyzer, its temperature becomes approximate to the ambient temperature. No water enters the ISA gas analyzer after the Nomoline sampling tube removes all condensed water. The RH of the acquired gas is approximately 95%. Use the following formula to calculate the CO_2 value at BTPS:

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

In the above formula:

$EtCO_2$: $EtCO_2$ value **[vol%]** sent from ISA

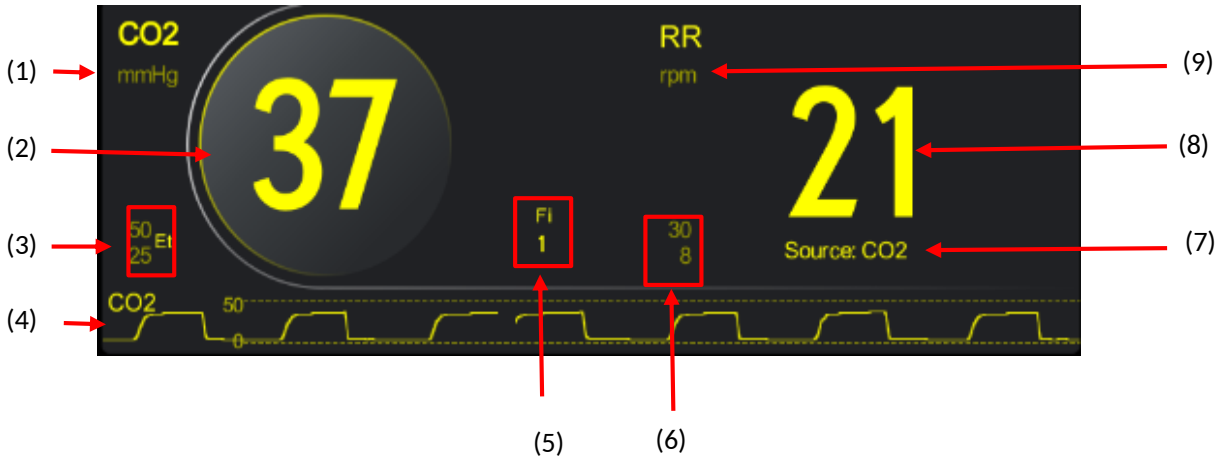
Pamb: barometric pressure **[kPa]** sent from ISA

3.8 : typical partial pressure **[kPa]** of the water vapor condensed between the patient circuit and ISA

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

It is assumed that the O_2 is calibrated by the room air at 0.7 vol% H_2O (RH).

13.4 CO_2 Display



(1) CO_2 unit

(2) CO_2 value

(3) $EtCO_2$ alarm limits

(4) CO_2 waveform

(5) $FiCO_2$ value

(6) RR alarm limits

(7) RR source

(8) RR value

(9) RR unit

13.5 CO_2 Measurement

WARNING

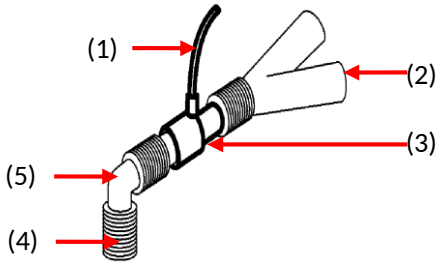
- **Check the airway adapter before use. Replace it if the airway adapter suffers from any exterior damage or breakage.**
- **Turn it off when the CO_2 module is idle, or it will remain in working state and its service life will be shortened.**

Note

- **To prevent the condensed water from dropping into the gas sampling tube and blocking it, the gas sampling tube connection end of the airway adapter should point upwards.**
- **For saturated moisture with a temperature of 37 ℃ and a relative humidity of 100%, the sampling tube can be used continuously for 120 h when used in conjunction with a drying tube at the indoor temperature of 23 ℃ and a flow rate of 50ml/min. And the sampling tube needs to be replaced for a maximum of 12 h theoretically when it is not used in conjunction with a drying tube.**

The steps for performing CO_2 measurement is as follows

1) Select the corresponding sampling tube according to the type of patient.
2) Connect one end of the sampling tube to the CO_2 interface of the monitor.
3) Connect the other end of the sampling tube to the patient.
4) Airway adapter is required for intubated patients: The airway adapter is installed at one end of the patient circuit, between the elbow tube and the Y tube. As shown in the following figure:



(1) Sampling line (2) Y-shaped tube (3) Airway adapter (4) Respiration circuit port (5) Elbow tube

5) For patients who are not endotracheal intubated: Wear nasal cannula for the patient. For nasal or nasal cannula for oxygen delivery, the catheter should be placed on the patient's face, and then the oxygen supply tube should be connected to the oxygen supply system to set the oxygen flow rate prescribed by the doctor.
6) Use an exhaust pipe to connect with the exhaust hole on the module to discharge the exhaust gas to the system.

13.6 Zero CO_2 Sensor

WARNING

- **If the alarm message "CO_2 Need Zero" appears directly after zeroing, please re-zero it.**

13.6.1 Zero Masimo CO_2 Sensor

The Masimo CO_2 sensor performs auto zeroing by switching the gas sample source from respiration circuit to ambient air. Auto zeroing starts after the sensor reaches its working temperature (usually 30min after startup) and is performed then every 24 hours. Masimo CO_2 sensor finishes auto zeroing within 3s.

13.6.2 Zero Comen Sidestream CO_2 Sensors

1) Connect the sampling line to CO_2 sensor.
2) After preheating, expose the sampling line to room air and keep it away from all CO_2 sources, including ventilator, patient's breath and user's breath.
3) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
4) Select **[Zero]** to zero CO_2 sensor, and the message **[Zero in Progress]** will be displayed on the screen; after zero calibration, the corresponding message will also be displayed on the screen.

13.7 CO_2 Setup

13.7.1 Set CO_2 Alarm

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

13.7.2 Set Apnea Timeout

Apnea detection is to detect the longest interval between two adjacent RESPs. When the actual apnea time of the patient exceeds the set apnea time, the monitor will respond to apnea alarms according to the value of **[Apnea Timeout]**. Steps to set **[Apnea Timeout]** are as follows:

Set [Apnea Timeout]:

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.→Select **[Alarm]** tab.
2) Set **[Apnea Timeout]**.

13.7.3 Set Work Mode

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Work Mode]** to **[Measure]** or **[Standby]**.
   - Standby: when stopping CO_2 measurement, it is recommended to set the Work Mode to Standby so as to extend the service life of CO_2 module.
   - Measure: when measuring with CO_2 module, make sure the Work Mode is set to Measure.

13.7.4 Set Speed

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Speed]** of CO_2 waveform.

13.7.5 Set Scale

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Scale]** of CO_2 waveform.

13.7.6 Set Waveform Type

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Waveform Type]** of CO_2 waveform.

13.7.7 Set Gas Compensation

In some cases, such as ventilating with an anesthetic machine or ventilator, the patient's respiratory gas is mixed with other gases that interfere with CO_2 measurement, and then gas compensation is required to eliminate the interference of these gases in CO_2 measurement. The concentration of gas compensation should be set based on the actual concentration of interfering gases.

Set gas compensation for sidestream CO_2 modules as below:

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set gas compensation as below:

MASIMO CO_2 Module:

- **[O_2 Compensation]**:

  [High]: The default O2 Compensation is 85%.

  [Med]: The default O2 Compensation is 50%.

  [Low]: The default O2 Compensation is 21%.

- **[N_2O Compensation]**: set as needed.

RESPIRONICS CO_2 Module:

- **[O_2 Compensation]**: Choose the appropriate value according to the O_2 content in the measured gas.

COMEN CO_2 Module:

- **[O_2 Compensation]**: Choose the appropriate value according to the O_2 content in the measured gas.

⚠ WARNING

- **Please set gas compensation based on the actual conditions, or the measurement results may differ greatly from the actual values to cause misdiagnosis.**

13.7.8 Set Balance Gas

Manual setup of balance gas is available for RESPIRONICS and COMEN CO_2 modules only, and balance gas is set automatically for MASIMO CO_2 module.

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Balance Gas]**.

13.7.9 Set CO_2 Unit

1) Select **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Unit]** tab.
3) Set **[CO_2 Unit]**.

13.7.10 Set Altitude

The monitor is equipped with automatic atmospheric pressure compensation, for both the MASIMO CO_2 module and COMEN CO_2 module, there is no need to set the altitude here and it can be automatically adjusted.

13.8 Discharging Waste Gases

When nitrous oxide and/or an anesthetic gas are/is used, prevent these gases from polluting the operating room. The gas discharging outlet should be connected to (via the gas discharging pipe connected to the sample gas outlet of the host equipment):

A discharging system (used for discharging collected gases) or the patient circuit (used for the back flowing of collected gases)

⚠WARNING

- **Anesthetics: If you measure the parameter ofa patient who is using or recently has usedan anesthetic, the gas discharging port on the module must be connected to a scavenging system or the patient circuit (on the anesthesia machine or the ventilator), so as to prevent medical personnel from inhaling the anesthetic.**
- **When the sidestream CO_2 module is used, please confirm that gas discharging port on the module is connected to the scavenging system. If the sampled gas returns to the resp system, there may be a risk of cross-infection.**

13.9 Information on Masimo Sidestream Gas Modules

13.9.1 Safety Information (Sidestream)

⚠WARNING

- **The gas analyzer of the Masimo ISA sidestream module is intended for use by authorized healthcare professionals only.**
- **Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.**
- **Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.**
- **Do not lift the NomoLine ISA CO_2 by the NomoLine capno graphy sampling line as it could disconnect from the NomoLine ISA CO_2, causing the device to fall on the patient.**
- **Dispose of Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.**
- **Use only airway T-adapters with the sampling point in the center of the adapter.**
- **Do only use sample lines intended for anesthetic agents if N2O and/or anesthetic agents are being used.**
- **Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.**
- **Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.**
- **Since a successful zeroing requires the presence of ambient air (21% O2 and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.**
- **Never sterilize or immerse the ISA sidestream gas analyzer in liquid.**

- The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.
- Replace the sampling line if the sampling line input connector starts flashing red, or the monitor shows a "CO_2 Line Blocked" message.
- No modification to the equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
- The ISA sidestream gas analyzers are not designed for MRI environments.
- During MRI scanning, the ISA must be placed outside the MRI suite.
- Use of high frequency electrosurgical equipment in the vicinity of the ISA/medical device may produce interference and cause incorrect measurements.
- To avoid water condensation inside the NomoLine ISA Capno Module and the connecting tubing, ensure that the surrounding temperature of the NomoLine ISA Capno module and the connecting tubing does not fall below the ambient temperature of the NomoLine sampling line.
- Too strong positive or negative pressure in the patient circuit might affect the sample flow.
- Strong scavenging suction pressure might affect the sample flow.
- NomoLine ISA CO_2 is not intended to be used for returning exhaust gases to the patient circuit. Exhaust gases should be returned to a scavenging system.
- NomoLine ISA CO_2 should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- Use of high-frequency electrosurgical equipment in the vicinity of NomoLine ISA CO_2 may produce interference and cause incorrect measurements.
- NomoLine ISA CO_2 should be mounted securely to avoid risk of damage to the NomoLine ISA CO_2.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.
- Do not use NomoLine ISA CO_2 if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.
- Do not adjust, repair, open, disassemble, or modify the NomoLine ISA CO_2. Damage to the device may result in degraded performance and/or patient injury.
- Do not use the NomoLine ISA CO_2 during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not re-use disposable single-patient use NomoLine Family sampling lines due to the risk of cross contamination.
- Do not start or operate the NomoLine ISA CO_2 unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.
- Do not place the NomoLine ISA CO_2 or accessories in any position that might cause it to fall on the patient.
- Only use Masimo authorized devices with NomoLine ISA CO_2. Using unauthorized devices with NomoLine ISA CO_2 may result in damage to the device and/or patient injury.
- Do not use the NomoLine Infant/Neonate Airway Adapter Sets for adults/pediatrics as they may cause excessive flow resistance (0,7 ml dead space).
- Do not use the NomoLine Adult/Pediatric Airway Adapter Sets for infants/neonates as the airway adapter

adds 6 ml dead space.

- Do not apply negative pressure to remove condensed water from the NomoLine Family sampling line.
- Disconnect the device from AC mains by removing the device cable connection from the host device.
- Properly apply sampling lines according to the sampling lines directions for use. Misapplied sampling lines that become partially dislodged may cause no or incorrect readings.
- To avoid electric shock, always physically disconnect the NomoLine ISA CO_2 and all patient connections before cleaning.
- Do not attempt to remanufacture, recondition or recycle the NomoLine ISA CO_2 as these processes may damage the electrical components, potentially leading to patient harm.
- Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.
- Do not operate NomoLine ISA CO_2 outside of the specific operating environment.
- Dispose NomoLine Family sampling lines in accordance with local regulations for biohazardous waste.

⚠ CAUTION

- The ISA analyzers should be securely mounted in order to avoid the risk of damage to the ISA.
- Do not operate the ISA sidestream gas analyzer outside the specified operating environment.
- (US Only) Caution: Federal law restricts this device to sale by or on the order of a physician.
- For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.
- Do not operate the ISA sidestream gas analyzer outside the specified operating environment.
- NomoLine ISA CO_2 is to be operated by, or under the supervision of, qualified personnel only. Read this Operator's Manual, accessories directions for use, all precautionary information, and specifications before use. Refer to the host device operator's manual or user's guide for additional safety information, warnings and cautions.
- Do not sterilize or immerse NomoLine Family sampling lines in liquid.
- To avoid permanent damage to the NomoLine ISA CO_2, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.
- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the NomoLine ISA CO_2. These substances affect the device's materials and device failure can result.
- Do not submerge the NomoLine ISA CO_2 in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.
- To prevent damage, do not soak or immerse NomoLine ISA CO_2 in any liquid solution.
- Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.

⚠ NOTE

- Disconnect the device from AC mains by removing the device cable connection from the host device.
- Use and store the NomoLine ISA CO_2 in accordance with specifications. See the Specifications section in this manual.

13.9.2 Airway Obstruction

When the anesthetic gas airway is obstructed, on the screen there will be such a prompt message as “Sampling Line Clogged”; under such a circumstance, replace the Nomoline sampling line.

13.9.3 Leakage Check

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

13.9.4 Safety Symbols

Symbol	Text, Color Code and Text Format	Description
	Warning: additional information.	“Warning” indicates the hazardous conditions causing possible personal injuries or death. The warning symbol should comply with ISO 7010-W001.
	User’s Manual	Refer to the User’s Manual.
	Reference No.	/
	Serial No.	/
	Lot No.	/
	Valid until **[YYYY-MM-DD]**	Do not use the Monitor after such date.
	Temperature limit	/
	Pressure limit	/

	RH limit	/
	No reuse	/
	WEEE directive	Recycle this electrical and electronic equipment according to 2002/96/EC.
	Contain Pb	/
IPX4	IP grade	The IP grade indicates the water ingress protection performance.
IP44	IP grade against water and solid object ingress	Protection against tools and short cable ends (>1mm). Protection against water sprays from all directions.
Rx ONLY	Sold on prescription only	Warning (U.S.): that Monitor shall be sold by medical practitioners or on prescription according to U.S. federal laws.
	CO_2	The IRMA/ISA analyzer measures CO_2 only.
	Multiple gases (AX+ or OR+)	The IRMA/ISA analyzer can measure multiple gases.
	Gas inlet	/
	Gas (exhaust) outlet	/
	Connect to patient circuit	Illustrate the connection between Nomoline and patient circuit.
	Connect to ISA	Illustrate the connection between Nomoline and ISA.
	Not sterile, latex free	The Monitor is latex free and not sterile.

13.9.5 Patents and Trademarks

(1) Patent Statement

Masimo Sweden AB owns the following patents for relevant products described in this operating instruction manual: SE519766; SE519779; SE523461; SE524086. Other patents are being applied.

(2) Trademark

Masimo IRMA™, Masimo ISA™, Masimo XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, Masimo GasMaster™ and ISA MaintenanceMaster™ are trademarks of Masimo Sweden AB.

13.9.6 Consumables

13.9.6.1 ISA Nomoline Family

ISA samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO_2 possible for adult, pediatric and infant patients.

The Nomoline Family sampling lines incorporate a unique water separation (NO MOisture) section, which removes condensed water. The NOMO section is also fitted with a bacteria filter that protects the gas analyzer from water intrusion and cross contamination.

As long as no sampling line is connected, the ISA gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the ISA gas analyzer switches to measuring mode and starts delivering gas data.

The Nomoline Family sampling lines are available in a wide variety of versions for both intubated and spontaneously breathing patients and in both disposable and re-sposable configurations –intubated patients can for instance be monitored using the disposable Nomoline Airway adapter Set or a com-bination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter. Spontaneously breathing patients could similarly be monitored using a disposable Nomoline Nasal CO_2 Cannula or a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Nasal CO_2 Cannula with Luer Connector.

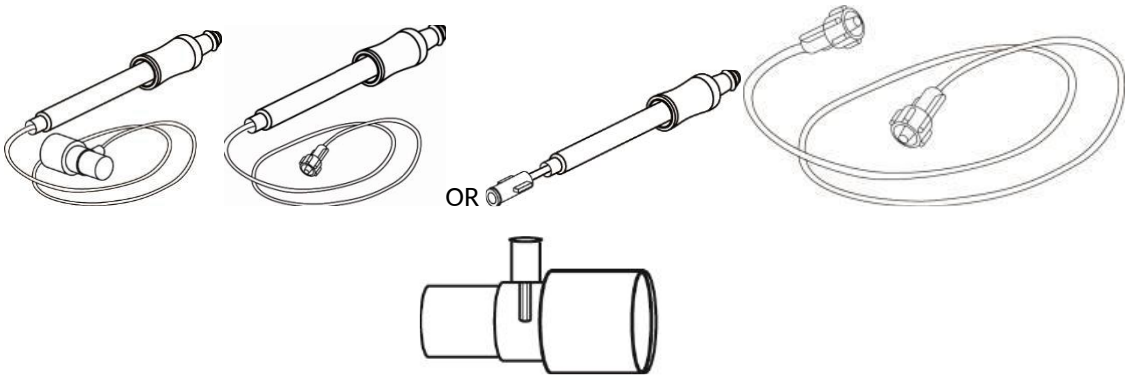


Figure 1.The disposable Nomoline Airway Adapter Set is an alternative to using a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter.

The Nomoline Adapter may be used with other third party sampling lines and cannulas. Please however note that the Nomoline Family of sampling lines are designed for optimal performance and measure-ment fidelity when used with the ISA gas analyzers. For instance, when connecting to a respiratory circuit, the Masimo T-adapter provides a central gas sampling point thereby minimizing the the risk of sampling line occlusion (see below)

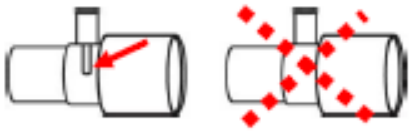


Figure 2. For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left above.

⚠NOTE

- **Using sample tubes or cannulas with larger inner diameter than 1 mm will increase ISA's total system response time.**

Nomoline Family sampling line replacement

Nomoline Family sampling lines should be replaced according to good clinical practice or when the sampling line gets occluded. Occlusion occurs when water, secretion etc. is aspired from the respiratory circuit to such extent that ISA cannot maintain the normal 50 sml/min sample flow. This situation is indicated by a red flashing gas inlet connector and an alarm message "Sampling Line Clogged"; Replace the Nomoline and wait until the gas inlet connector switches to green indicating that the ISA gas analyzer is ready for use.

13.9.7 Maintenance

The user should verify gas readings regularly; If any problem, contact an engineer of the manufacturer for maintenance.

Chapter 14 Clinical Assistant Assessment (CAA)

14.1 Manual Parameters

Users can manually input some data that the monitor cannot detect. When the user needs to record or review some physiological information of the patient, but the monitor does not provide the monitoring of them, then the user can choose the manual parameters such as blood glucose, height, etc. that come with the monitor in the manual parameters area, or customize the manual parameters according to the actual needs.

14.1.1 Input Parameters

The following are the manual parameters provided by this monitor, including: blood glucose, height, weight, FiO2, oxygen supply, oxygen flow rate, oxygen source, in/out fluid, LOC (GCS), LOC (AVPU), and LOC (ACVPU). Optional ranges are set for the above parameters.

Parameter	Range
Blood glucose(BG)	1.0 mg/dl -720.0 mg/dl (0.06 mmol/L -40.00 mmol/L)
Height	20.0 cm - 300.0 cm
Weight	0.1 kg -499.0 kg
FiO_2	21% ~100%
Supp O_2	Yes, No
O_2 Flow Rate	1.0 L/min ~ 20.0 L/min
O_2 source	Room Air, Aerosol Mask, Bi PAP, C PAP, Face Mask Inhaler, Mask, Nasal Cannula, Nonrebreather, Partial Nonrebreather, T-Piece, Trach Collar, Ventilator, Venturi Mask, Oxymizer
in/out fluid	1 ml ~ 10000ml/0.001 L ~ 10.000 L
LOC(GCS)	3 ~ 15
LOC(AVPU)	Alert, Respond to Voice, Respond to Pain, Unresponsive
LOC(ACVPU)	Alert, Confusion, Respond to Voice, Respond to Pain, Unresponsive

After selecting the parameters to be displayed and determining the value of the parameters, press the **[Confirm]** to save the relevant information. Only the saved parameters can be viewed, printed or sent to other devices under the review screen. Or the information will be lost after the patient is released or the workflow is switched.

14.1.2 Add New Parameters

In addition to the manual parameters that come with this monitor, users can also customize new parameters according to actual needs. The steps to set the customized manual parameters are as follows:

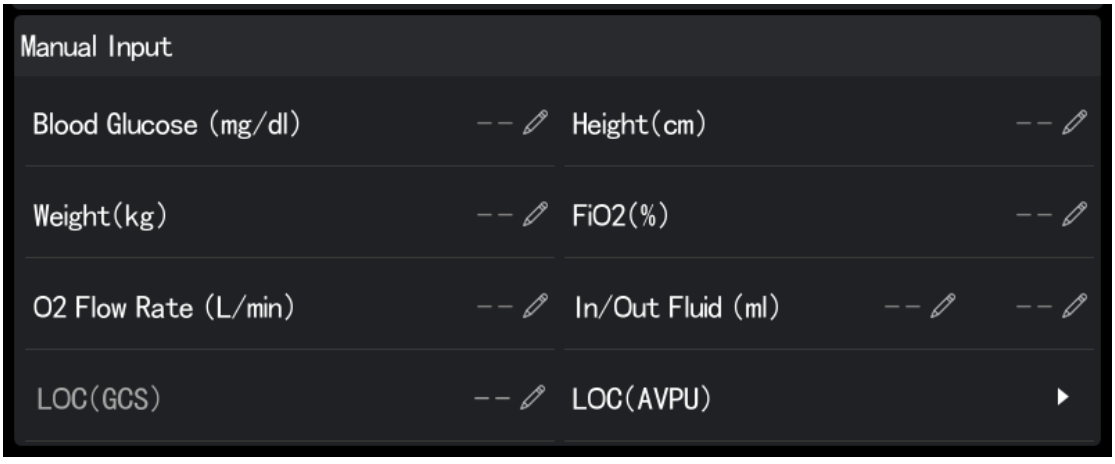
1) Select **[Menu]** → select **[Maintain]** from **[System]** column → enter maintenance password → select ↵.
2) Select **[Module]** → **[Manual Input]** tab, select **[Add]**, the system pops up **[Add New Parameter]**.
3) Select **[Name]** and enter the name of the new parameter via soft keyboard.
4) Select **[Type]** and choose **[Numeric]** (e.g. parameters that require numeric input such as blood glucose, height, etc.) or **[Text]** (e.g. parameters that require text description input such as LOC(AVPU), LOC(ACVPU), etc.) from the pop-up list. For **[Numeric]** parameters, **[Unit]** and **[Accuracy]** need to be set; for **[Text]** parameters, text options need to be set. At least 2 options need to be set for text-type parameters. If necessary, you can select **[Add]** to set more options.
5) Select **[Save]**. Only saved parameters can appear in the manual parameter list.

⚠ CAUTION

- **After saving, the parameter type cannot be modified**

14.1.3 Manual Parameter Area Display

The following is a diagram of the manual parameter area; the actual display on the monitor may be different.



14.1.4 Manual Parameter Setup

The type of parameters displayed in the manual parameter area and the display position can be changed by the user.

The steps are as follows:

1. Select the **[Menu]** hotkey→ select **[Workflow]** from the **[Configuration]** column→ enter a password → select ↵.

2. Select the on the right side of the workflow you want to modify, and choose the destination of the manual parameter area, and select **[Manual Parameter]** from the pop-up parameter list.

3. Select the **[Parameter Setup]** → **[Manual Input]** tab, and select the parameter to be displayed in the pop-up list.

4. Switch the workflow on the main interface. After the switch, the settings take effect.

14.2 Early Warning Score (EWS)

Early Warning Score is a component of clinical auxiliary function. EWS can help identify early signs of deterioration on the patient, serving as an early warning indicator of critical or potentially critical illness.

The EWS system obtains corresponding scores by monitoring and observing the vital signs and physiological states of patients, comparing them with corresponding indicators and then provides current response measures for the patient based on the score results.

14.2.1 Type of EWS Score System

This patient monitor offers three scoring systems as follows:

- Modified Early Warning Scoring (MEWS)
- National Early Warning Scoring (NEWS)
- National Early Warning Scoring 2 (NEWS2)

⚠ WARNING

- **EWS scoring is not intended for neonates and pediartric patient**
- **The early warning score results and the suggested measures are provided for reference only, and are not provided as the direct basis for clinical treatment.**
- **The early warning score cannot be used as a predictor of patient development or overall prognosis; it is not a tool for clinical judgment and cannot completely replace the clinician's assessment of patients.**
- **The early warning score system is not intended for pregnant women, COPD (chronic obstructive pulmonary disease) patients or patients under 16 years old.**

14.2.2 EWS Display

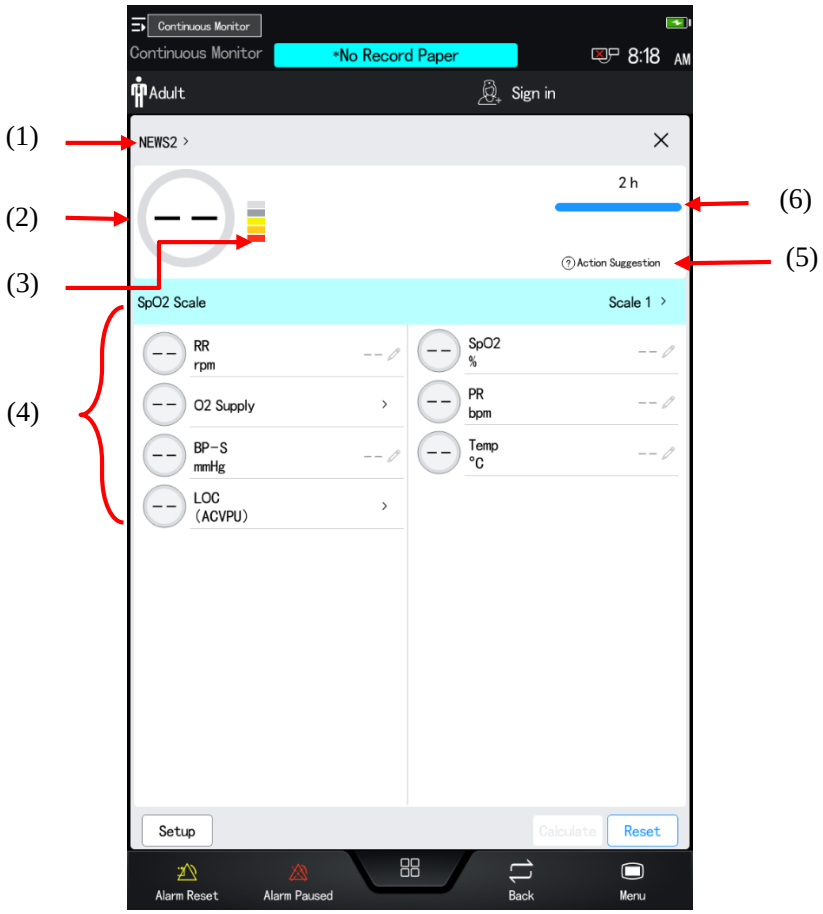
1) Enter **[Editing Workflow]** page, please refer to ***"Section 6.8 Set Workflow Layout"*** for more detail steps.
2) Select the parameter area where you want to display EWS, and select **[EWS]** from the pop-up list of parameters.

14.2.3 Enter the EWS Screen

The Monitor provides an independent EWS screen. Follow one of the steps below to enter the EWS screen:

- Click EWS parameter area to enter the page.
- Click **[Menu]** hot key → **[CAA]** →**[EWS]**.

The EWS screen is illustrated below, and the actual EWS screen may be different, depending on the selected scoring system and settings.



(1) Score system name.

(2) Total score. The color of the circle indicates the current score level. Red means early warning, and white means normal.

(3) Score level boxes: the criticality level increases gradually from top to bottom. The current score level is indicated in the circle.

(4) Parameter area: displays the parameter value and score of individual parameters. The keyboard symbol indicates that the parameter value was entered manually.

(5) Suggested measures.

(6) Scoring interval: it will automatically score again after the countdown ends when the Auto Scoring switch is turned on; and once the switch is turned off, the scoring will be invalidated when the countdown ends.

14.2.4 Score Calculation

1) Click **[Reset]** to clear the last score results and refresh the parameter values and their scores automatically obtained from the Monitor.
2) Measure the values of other parameters or enter them manually.
3) Click **[Calculate]** to obtain the score results.

NOTE

- **Please click [Reset] to clear the last score results before each scoring.**
- **The keyboard symbol to the right of the parameter value indicates that such value was entered manually.**
- **To calculate the scores, make sure the values involved in the calculation are valid.**

14.2.5 Auto Scoring

1) On the EWS screen, click **[Setup]**.
2) In the **[Auto Scoring]** area, check an option as required:
   - **[Interval]**: The Monitor will automatically calculate scores at the selected interval.
   - **[NIBP]**: The Monitor will automatically calculate scores at the end of each NIBP measurement.
   - **[Alarm]**: The Monitor will automatically calculate scores when a physiological alarm occurs to any parameter involved in scoring.

14.2.6 EWS Setup

14.2.6.1 Select a Score System

The Monitor provides a default score system. You can also follow the steps below to select other score systems as required:

1) On the EWS screen, click **[Setup]**.
2) Set the **[Scoring]**.

14.2.6.2 Set the Scoring Interval

1) On the EWS screen, click **[Setup]**.
2) Set the **[Interval]** as required:
   - If **[Interval]** is set to **[By Score]**: the scoring interval needs to be set manually.
   - If **[Interval]** in the **[Auto Scoring]** is set to a certain duration: the scoring interval is consistent with the set duration.

14.2.6.3 Set the Timeout of Data

You can follow the steps below to set the timeout of manually entered parameter values:

1) On the EWS screen, click **[Setup]**.
2) Set the **[EWS Data Timeout]**.

14.2.6.4 Set the Score Confirmation

You can follow the steps below to set the **[Score Confirmation]**:

1) On the EWS screen, click **[Setup]**.
2) Turn on/off the switch of **[Score Confirmation]**:
   - Off: The score will be automatically saved.
   - On: There is a need to confirm manually whether to save the score.

14.2.7 EWS Alarm

In Continuous Monitor, the monitor will alarm in the following situations after the alarm function is enabled:

- The total score exceeds the set threshold
- The single parameter scores automatically obtained is 3

You can follow the steps below to set the **[EWS Alarm]**:

You can set EWS alarms as needed, and the steps are as follows:

1) On the EWS screen, click **[Setup]**.
2) Select **[Alarm]** →turn on the switch of **[Alarm]**:
3) Set the alarm switch and threshold for the total score in the **[EWS Score]** area.
4) Set the alarm priority and switch for single parameter in the **[3 in single parameter]** area.
5) Turn on/off **[Dynamic Refresh Score]** as needed.

14.3 Glasgow Coma Scale (GCS)

The Glasgow Coma Scale (GCS) can be used on comatose patients induced by a variety of causes to express their state of consciousness objectively. GCS scoring involves three aspects: eye opening, verbal response and motor response. The three scores add up to the GCS score.

GCS scoring is intended for adult and pediatric patients.

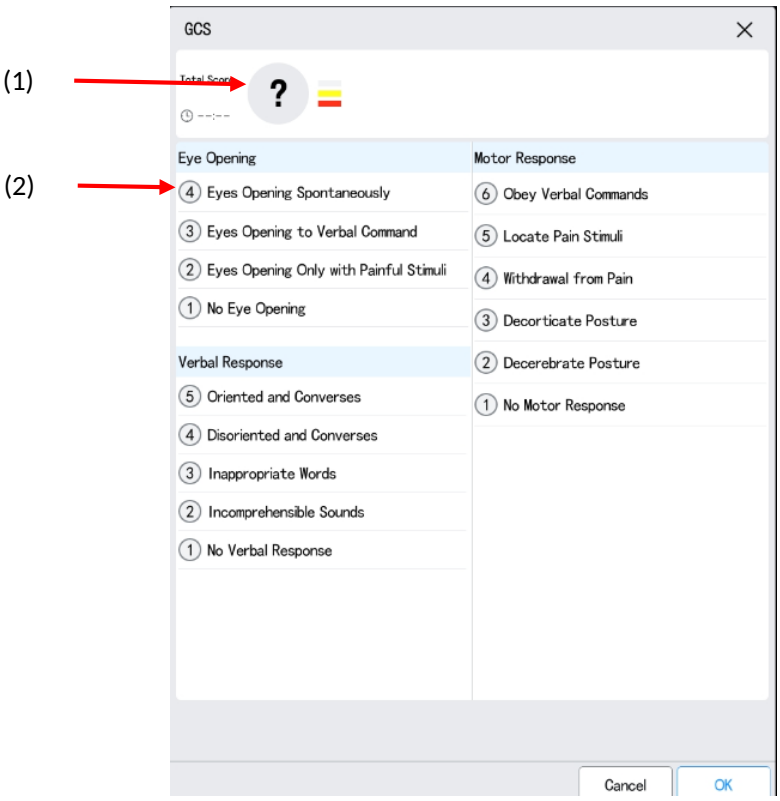
NOTE

- **The GCS score is provided for reference only. Please make a diagnosis in combination with other clinical evidence.**
- **GCS scoring is not intended for comatose patients induced by sedative, muscle relaxant, artificial airway, drunkenness or status epilepticus.**
- **GCS scoring is not intended for people with impaired language, deaf-mute or mental disorder.**
- **GCS scoring is prone to score deviation when used on children under 5 years old or the unresponsive elderly.**

14.3.1 Enter the GCS Screen

◆ Ensure that the **[LOC(GCS)]** has been set in manual parameter area, refer to ***"Section 14.1.4 Manual Parameter Setup"*** for detailed information.

◆ Select manual parameter area→ select **[LOC(GCS)]**→ **[GCS]**.



(1) Total Score (2) Individual Score

14.3.2 GCS Scoring

1) On the GCS screen, check an option in the **[Eye Opening]**, **[Verbal Response]** and **[Motor Response]** area respectively based on the patient's actual condition.
2) Click **[OK]** to confirm the score results.

The score range and background color of each score level is listed in the table below:

Level	Score Range	Background Color	Description
Mild	13~15 points	Grey	Normal or slightly impaired brain function
Moderate	9~12 points	Yellow	Moderately or severely impaired brain function
Severe	3~8 points	Red	Brain death or vegetative

14.4 CCHD (Critical Congenital Heart Disease) Screening

The pulse-oximetry monitoring can be used for screening for critical congenital heart disease (CCHD). CCHD screening primarily targets seven specific lesions: hypoplastic left heart syndrome, pulmonary atresia, Tetralogy of Fallot (TOF), total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia and truncus arteriosus.

This Monitor provides two set of CCHD screening rules: American Standard and Two Standards:

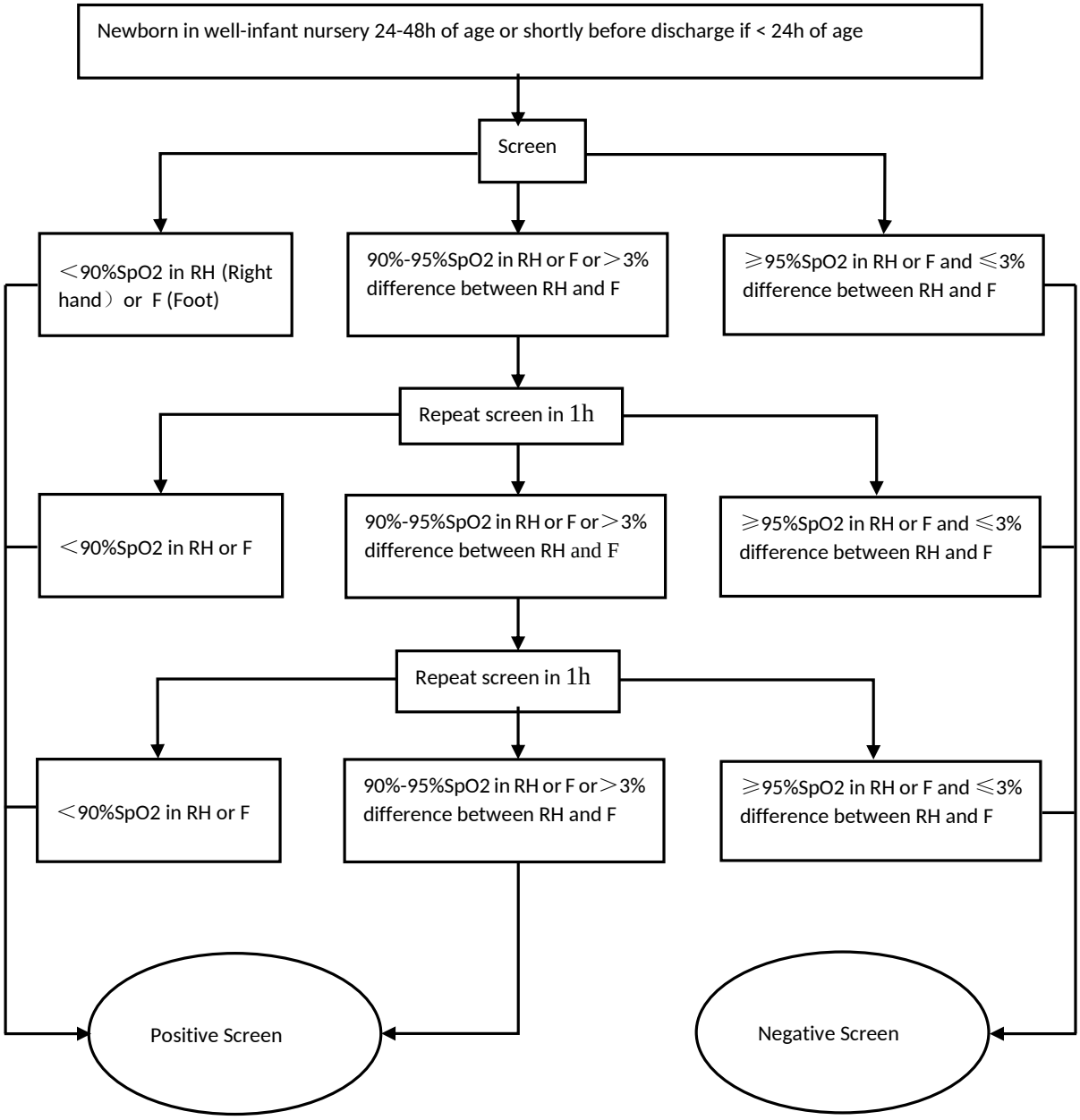
American Standard recommends that the screening for CCHD should be carried out on neonates between 24 and 28 hours after birth. Neonates who are less than 24 hours old and waiting to be discharged from the hospital should be screened for CCHD as soon as possible. The CCHD is carried out by measuring the neonatal patient's right hand and one foot for SpO_2 values, and then comparing the difference between these two values for ΔSpO_2.

Two Standards uses pulse oximetry combined with cardiac auscultation in screening for CCHD, which is recommended to be carried out to the neonates between 6 -72 hours after birth by measuring both the neonatal patient's right hand and one foot for SpO_2 values and comparing these two values for ΔSpO_2, and combining the heart murmur level for final results.

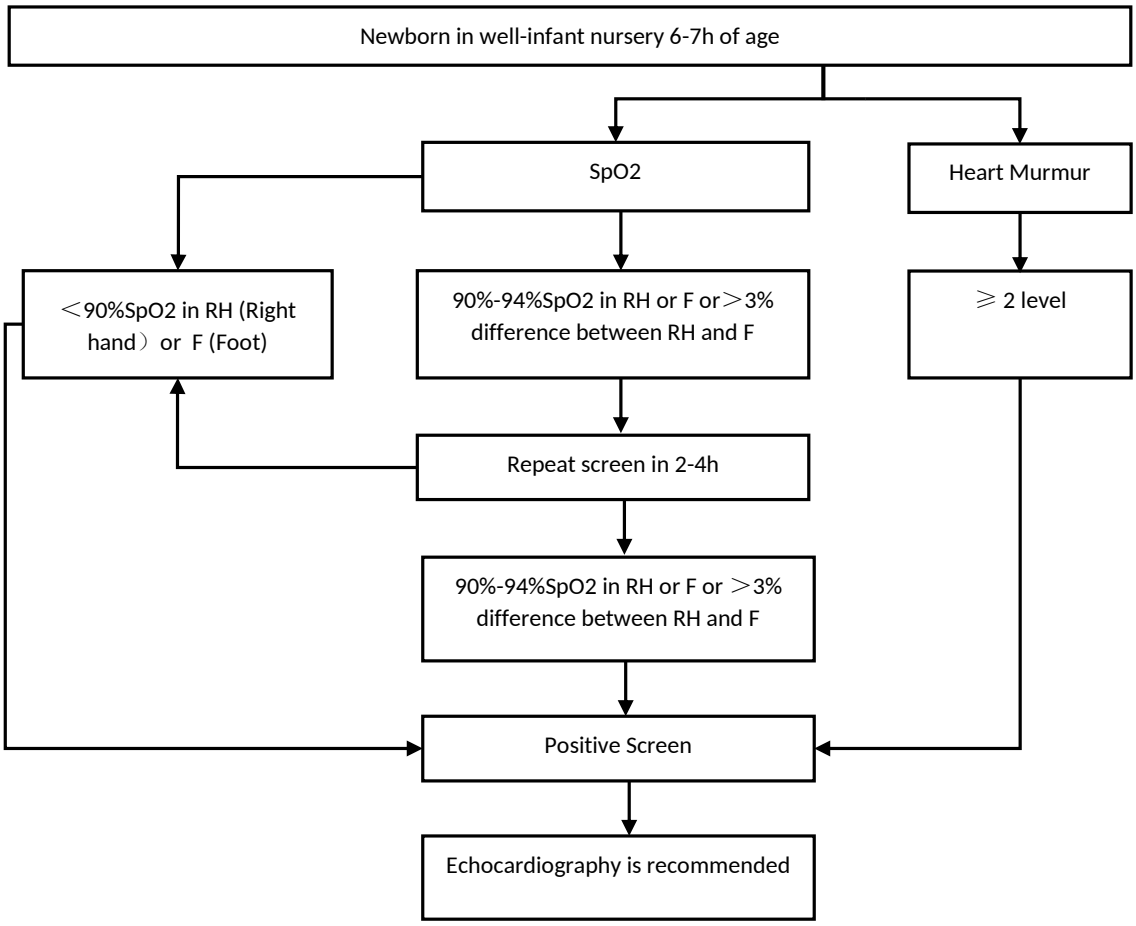
CCHD screening is only applicable to neonatal patients.

14.4.1 CCHD Detection procedure

American Standard, one of the screening rules provided in this monitor, comes from the neonatal screening procedures recommended by a working group composed of the members designated by Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), American Academy of Pediatrics (AAP), American College of Cardiology Foundation (ACCF) and American Heart Association (AHA). The procedure is shown below:


Newborn in well-infant nursery 24-48h of age or shortly before discharge if < 24h of age
Screen
＜90%SpO2 in RH (Right hand） or F (Foot)
90%-95%SpO2 in RH or F or＞3% difference between RH and F
≥95%SpO2 in RH or F and ≤3% difference between RH and F
Repeat screen in 1h
＜90%SpO2 in RH or F
90%-95%SpO2 in RH or F or＞3% difference between RH and F
≥95%SpO2 in RH or F and ≤3% difference between RH and F
Repeat screen in 1h
＜90%SpO2 in RH or F
90%-95%SpO2 in RH or F or＞3% difference between RH and F
≥95%SpO2 in RH or F and ≤3% difference between RH and F
Positive Screen
Negative Screen

Another screening rule of CCHD is Two Standards (SpO_2 and Heart Murmur), which follows the procedure as shown below:



14.4.2 Select CCHD Screening Rule

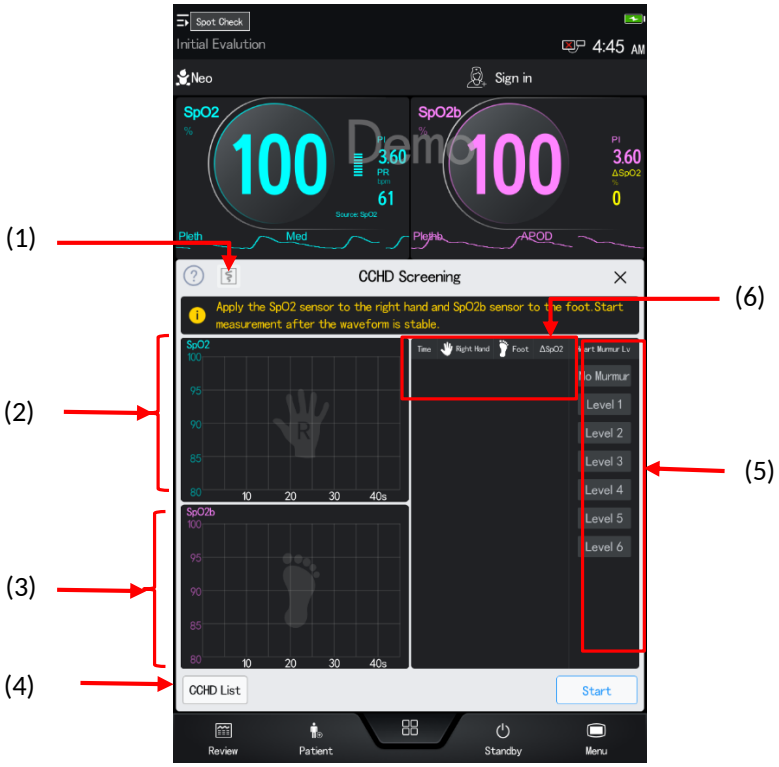
The user is allowed to select either the American Standard or Two Standards by:

1) Select **[Menu]** → **[System]** → **[Maintain]** → input Maintenance password → click Enter.
2) Select **[CAA]** tab → **[CCHD]** tab.
3) Set **[Screening Rule]**
   - **[American Standard]**: by screening SpO_2 values.
   - **[Two Standards]**: by screening SpO_2 values and heart murmur level.

14.4.3 Enter CCHD Screening

You can access the CCHD Screening window according to the following way:

- Select **[Menu]** hot key → **[CCA]** → **[CCHD]**



1) Record Button
2) SpO_2 value measured on the right hand
3) SpO_2 value measured on one foot
4) CCHD list, click to view CCHD screening data of patients
5) Set heart-murmur level
6) SpO_2 measurement values and Screening results. Click on this icon to switch the SpO_2 measurement values between right hand and foot if required

14.4.4 Start CCHD Screening

Only one SpO_2 module is configured in the monitor, you can measure the SpO_2 on the right hand first and then change to the foot. This screening steps can be done in the following way:

1) Enter CCHD screening, see ***"Section 14.4.3"Enter CCHD Screening"*** for detailed information.
2) Measure SpO_2 values
3) Check if the SpO_2 values displayed correspond to the measurement sites. If not, click the icon to record the SpO_2 in right hand or foot.
4) Select heart murmur level if the **[Two Standards]** screening rule is applied,
5) Select **[Accept]** to acknowledge current measurement results and complete a CCHD screening.

The SpO_2 measurement result and the CCHD screening result are displayed on the CCHD screening window:

- "Positive": the CCHD screening is completed.
- "Negative": the CCHD screening has failed and Echocardiography is strongly recommended.

- ✧ “Repeat screen in 1 hour” (American Standard）: the CCHD screening is not confirmed and the user should repeat the measurement in one hour.
- ✧ “Repeat screen in 2-4 hour” (Two Standards): the CCHD screening is not confirmed and the user should repeat the measurement after 2-4 hours.

NOTE

- **During the measurement of SpO_2, keep the newborn calm.**

14.4.5 Screening again

If you have doubts about the screening result, please repeat the CCHD screening again. This action will clear the measurement result and the screening result.

Select **[Restart CCHD]** button, click **[Yes]** to start again.

14.4.6 View CCHD List

Select **[CCHD List]** on the interface to view or delete(if needed) the CCHD screening data of patients, click **[Continue]** to return to the CCHD screening interface to continue screening.

14.5 Pain Score

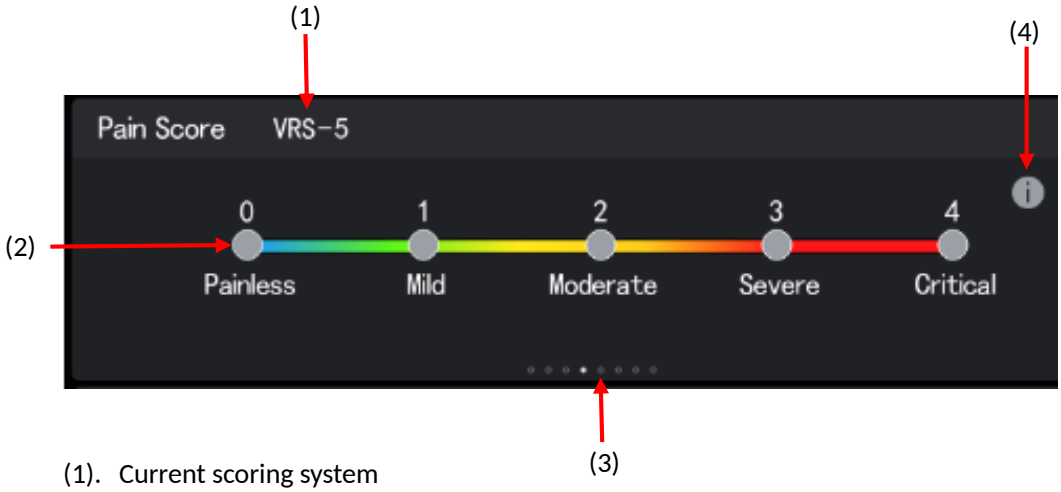
The monitor provides a pain score to assist users in assessing the patient's pain level, here are the scoring methods:

1) VAS-cm: a visual analogue scoring method with a scale of 0~10 cm.
2) VAS-mm: a visual analogue scale with a scale of 0 ~ 100 mm.
3) NRS: a numerical scoring method that uses numbers to indicate pain levels.
4) VRS-5: a verbal description scoring method with a scale of 0~5.
5) FPS-R: Facial expression scale method. 5.
6) FLACC: "F" for "facial expression", "L" for "lower limb movement", and "A" for "activity". "A" for "Activity", and two "C" indicate the degree of "crying" and "easy to comfort" respectively.

In addition, you can customize the scoring system. See ***14.5.3 Adding Custom Scoring Systems*** for details. Pain scoring is available for adult, pediatric and neonatal patients.

14.5.1 Pain Score Display

The following is a diagram of the pain scoring screen; your monitor may display slightly differently.



(1). Current scoring system

(2). Scoring area: select a value in this area, or select an option in the pop-up list to get a rating

(3). Indicates the number of currently available scoring systems

(4). Pain description

14.5.2 Start Pain Scoring

To perform a pain score, proceed as follows:

1) Swipe left and right in the pain scoring area to select a scoring method.
2) Touch the scoring area to select a value, or select an option in the pop-up list.
3) Select the **[Save]** to save the data.

14.5.3 Add Custom Pain Scale

Users can add up to two custom scoring scales. The steps are as follows:

1) Select the **[Menu]**→ select **[Maintain]** from the **[System]** column → enter the maintenance password → select↵.
2) Select **[Module]** → **[Pain Score]** tab.
3) In the **[Custom Pain Score]** area, edit the scoring scale name and modify the scoring limit.
4) Turn on the switch below the **[Display]** column.

14.5.4 Add Custom Pain Description

Users can add up to 15 custom pain descriptions. The steps are as follows:

1) Select the **[Menu]** → select **[Maintain]** from the **[System]** column → enter the maintenance password → select↵.
2) Select **[Module]** → **[Pain Score]** tab and select **[Add Description]**.
3) In the **[Add Description]** menu, select **[Name]** to enter the name of the description information.
4) Select **[Type]** and choose **[Numeric]** or **[Text]** from the pop-up list.
5) For **[Numeric]** description, users need to set **[Unit]** and **[Accuracy]**; for **[Text]** description, users need to set the text option. At least 2 options need to be set for the text type description. If necessary, users can select **[Add]** to set more options.
6) Select **[Save]**.

> ⚠ **NOTE**
>
> - **After saving, the description type cannot be changed.**

14.6 Targeted Goal

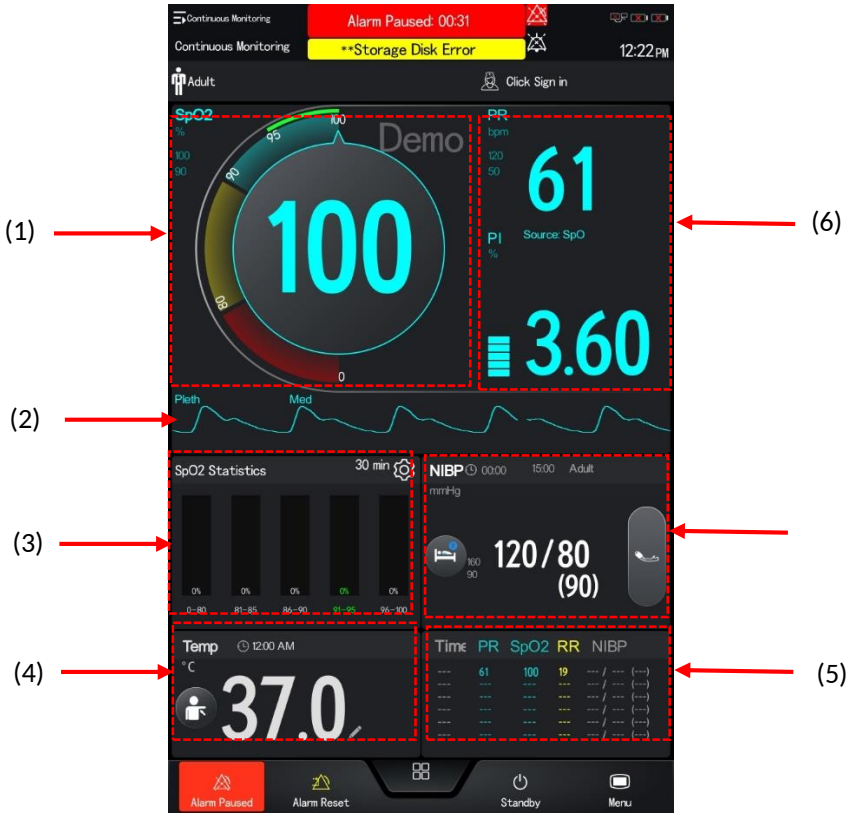
For patients in continuous monitoring mode who need to focus on only one of their specific parameters and its changes, the user can select the Targeted Goal interface. This interface displays the values of the specific parameter to be focused on in a large font display, allowing the user to more visually view the real-time status of the target parameter based on the dashboard and review the segmented statistics of the target parameter through the statistics area.

14.6.1 Enter Targeted Goal Interface

1) In continuous monitoring mode, select SpO_2 parameter area or waveform area to **[SpO_2]** menu →**[Targeted Goal]**.
2) Select **[Targeted Goal]** to enter the target goal interface.

14.6.2 Targeted Goal Interface Display

The following is a diagram of the target monitoring interface; the graphics displayed on your monitor may be slightly different.



(1) Target parameter area: displays SpO_2 value, target range and alarm limit in large font.

- The green section of the outer circle of the dashboard indicates the target range.
- The inner circle protrusion of the dashboard indicates the current measured value.

(2) Target parameter waveform area: displays the SpO_2 waveform.

(3) Target parameter statistics area: displays the segmented statistics of SpO_2.

(4) Other parameter area: display the parameter values and alarm limits of other parameters except target parameters and secondary parameters.

(5) Parameter trend area: displays the trend of the secondary parameters of the target parameter.

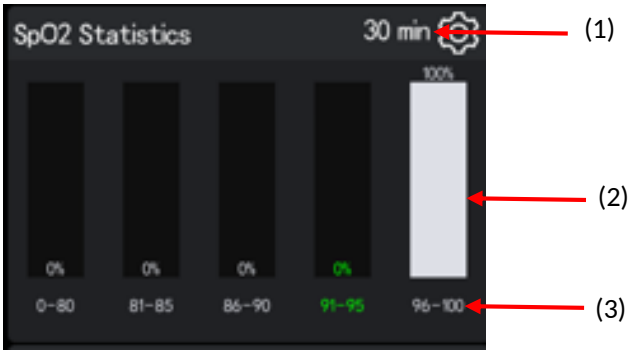
(6) Secondary parameter area: displays PR and PI values in large font, as well as their sources and alarm limits.

14.6.3 Targeted Goal Interface Setup

Users can access the parameter setup menu and review the parameter trends through the target monitoring screen. The operation method is as follows:

1) Click the parameter trend data to enter the **[Tabular Trends]** review page.
2) Click the parameter statistics area to enter the statistics setup menu of the corresponding parameter, and set the parameter segment end value and target segment.
3) Click the parameter area, waveform area or main parameter dashboard to enter the setup menu of the corresponding parameter.

14.6.4 SpO_2 Statistics Display



(1) Duration of statistics

(2) Statistical results

(3) Statistical segment: the green part is the target range

14.6.4.1 Set the SpO_2 Segment Range and Target Segment

You can define the scope of each segment and select the target segment. The steps are as follows:

1) Select the SPO_2 statistical area.
2) Select the SPO_2 value corresponding to the end of the segment from the **[To]** column.
3) Select the targeted segment from the **[Target]** column. Targeted segment is highlighted in green.

14.6.4.2 Set the SpO_2 Statistics Duration

The SPO_2 statistics duration can be set. Click Statistics Duration in the SPO_2 Statistics area to select the statistics duration again.

Chapter 15 Data Review

15.1 Overview

Users can view trend data, alarm event records, waveform information, etc. through the review interface. Users can also view trend data through the Minitrends screen, and the data information under different mode that can be reviewed varies.

Spot Check: Tabular Trends, Scoring Review and CCHD Review can be reviewed.

Continuous monitor: Tabular Trends, Graphic Trends, Scoring Review, Events and CCHD Review can be reviewed.

The monitor provides 240-hour trend data of all monitoring parameters, 5000 sets of NIBP measurement data, 1000 alarm events, scoring and the storage and review of CCHD. This chapter details the observation methods for these stored data.

15.2 Review Screen

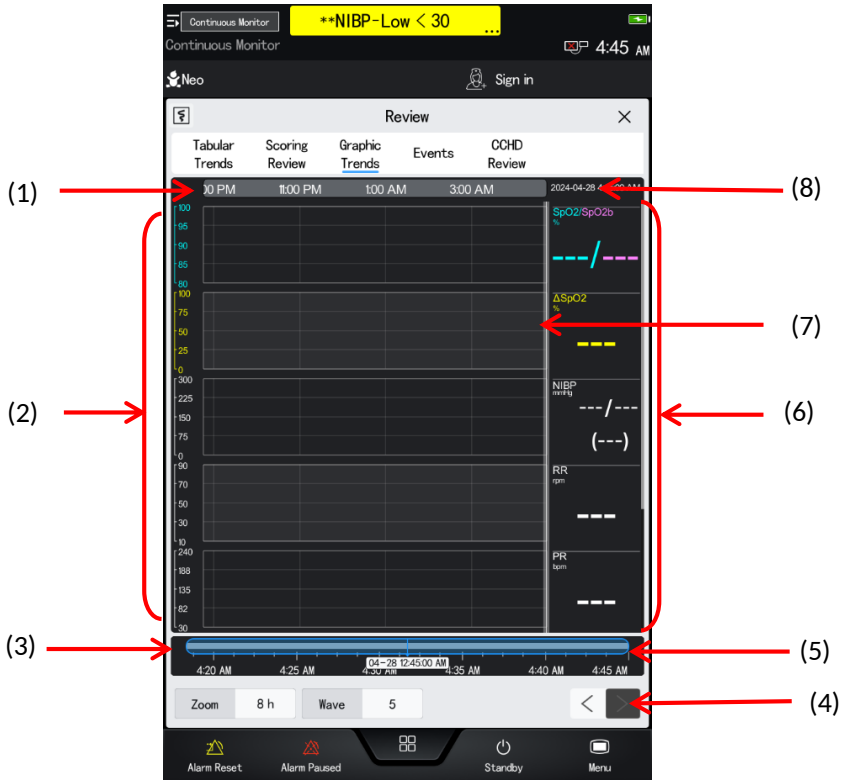
15.2.1 Enter the Review Screen

Follow any path described below to go to the Review screen:

1) Click **[Review]** hot key; or
2) Click **[Menu]** hot key → **[Review]** and then click the desired tab.

15.2.2 Review Screen Display

The Review Screens have a common structure. The Graphic Trends Review Screen is shown here as an example:



(1) Current window time bar: indicates the time range of the current window.

(2) Waveform area: displays the trend curve of parameters. The trend curve is displayed in the same color as the corresponding parameter name.

(3) Timeline buttons.

(4) Button area.

(5) Slider: indicates the position of the current screen as part of the full time period. You can move the slider left or right to locate the trend data at a specific time, and the trend data displayed in the current screen will be updated accordingly.

(6) Parameter area: displays the parameter values at the cursor time. The parameter values are displayed on a background of different colors, depending on their respective Alarm Priority.

(7) Cursor

(8) The cursor time.

15.3 Icons on Review Screen

Icon	Description
	Slider: indicates the position of the current screen as part of the full time period. You can move the slider left or right to locate the trend data at a specific time, and the trend data displayed in the current window will be updated accordingly.
 or	Locate the previous or next event.

	Event list: displays events in the order of the time they occurred. The event that occurred at the last moment is displayed at the top of the list. The number of "*" marks in front of the event indicates the Alarm Priority.
	Record button: click it to output data through the recorder.

15.4 Tabular Trends

Tabular trends are a table of patient data displayed over time.

15.4.1 Enter the Tabular Trends Page

Follow either path described below to go to the Tabular Trends page:

- Click **[Review]** hot key → **[Tabular Trends]** tab; or
- Click **[Menu]** hot key → **[Review]** → **[Tabular Trends]**.

15.4.2 Change the Time Step of Tabular Trends

Time step refers to the time interval of the trend data displayed on the screen. You can select a larger time step for neonatal patients as their clinical conditions may change rapidly, and select a smaller time step for adult patients as their clinical conditions will change relatively slowly.

Follow the steps below to set the time step:

1) On the **[Tabular Trends]** page, set **[Search]** to:

- **[30s]**: to observe the parameter trends of the last 4h at 30s interval;
- **[1min]**, **[5min]**, **[15min]**, **[30min]**, **[1h]**, **[2h]** or **[3h]**: to observe the parameter trends of the last 240h at the selected interval; or
- **[NIBP]**: to display the values of such parameter at the time of measurement.

15.4.3 Record the Tabular Trends Report

1) On the review page of Tabular Trends, click "  " to go to the **[Record Setup]** menu.
2) Set the Tabular Trends Report, such as Date, Time, Period and Interval.
3) Click "  " or **[Record]** to start recording; click "  " again or select **[Stop Recording]** to stop recording.

15.5 Graphic Trends

Graphic trends are a set of patient data displayed graphically over time.

15.5.1 Go to the Graphic Trends Page

Follow either path described below to go to the Graphic Trends page:

- Click **[Review]** hot key → **[Graphic Trends]** tab; or
- Click **[Menu]** hot key → **[Review]** → **[Graphic Trends]**.

15.5.2 Set the Window Time

You can follow the steps below to set the time length of the trend data displayed in each screen:

1) Go to the Graphic Trends page;
2) Set **[Zoom]** to:
   - **[8min]**: to display 8min trend data in each screen (you can view the trends of the last 1h);
   - **[30min]**, **[1h]**, **[2h]** or **[4h]**: to display the trend data of the selected time length in each screen (you can view the trends of the last 4h); or
   - **[8h]**, **[12h]**, **[24h]** or **[48h]**: to display the trend data of the selected time length in each screen (you can view the trends of the last 240h).

15.5.3 Set the Number of Waveforms

You can follow the steps below to set the number of waveforms displayed in graphic trends:

1) Go to the **[Graphic Trends]** page;
2) Set the value of **[Wave]**.

15.5.4 Record the Graphic Trends Report

1) Select "  " on the review page of Graphic Trends to start printing.
2) Click "  " again to stop printing.

⚠NOTE

- **In the graphic trends report, if any parameter name is preceded by a "+" mark, that means this is the trend data of an external device.**

15.6 Events Review

The Monitor can save and review alarm events in real time, including physiological alarm events and technical alarm events. When an event occurs, the monitor will save the values of corresponding parameters at the time of the event and totally 32s waveforms before and after the event, please refer to *"Section 4.4 Operation Log"* for details.

⚠NOTE

- **The stored events will never be lost due to power failure.**
- **When exceeding 1000, the earliest record will be overwritten by the latest event.**
- **The system will save the logs before the power is cut off normally. When the power is cut off abnormally, ensure that the logs are saved 3s before the power cut.**
- **The time of a normal powering down is captured in the log, but the time of sudden powering down is not captured in the log.**
- **No matter how long the power loss, the log will be saved.**
- **The contents of the alarm system log cannot be erased or modified by the healthcare professional operator.**

15.6.1 Enter the Events Review Page

Follow either path described below to go to the Events page:

1) Click **[Review]** hot key → **[Events]** tab; or
2) Click **[Menu]** hot key → **[Review]** → **[Events]**.

On the Events page, the events are listed in the order of occurrence time. The event that occurred at the last moment is displayed at the top of the list. The number of "*" marks in front of the event indicates the Alarm Priority.

The identification bar on the left of the listed events uses different color blocks to identify events:

- Red: high-priority alarm event.
- Yellow: medium-priority alarm event.
- Cyan: low-priority alarm event.

The total number of events and the sequence number of the current event are displayed at the top right corner of the event list. For example, "3/5" means that a total of 5 events and the current event is the 3rd event.

15.6.2 View Details of Events

1) Enter the Events page;
2) Click **[Details]**.

In the Details window, you can set the **[Speed]** and click **[List]** to return to the event list.

15.6.3 Record Events

1) Select "  " on the review page of events to start printing.

2) Click "  " again to stop printing.

15.7 Scoring Review

The operations of scoring review are similar to those of CCHD review. Since this manual only provides an introduction to scoring review, please refer to the content of this chapter for more operations of CCHD review.

15.7.1 Enter the Scoring Review Page

Follow either path described below to go to the scoring review page:

3) Click **[Review]** hot key → **[Scoring Review]** tab; or

4) Click **[Menu]** hot key → **[Review]** → **[Events]**.

15.7.2 View Details of Scores

3) Enter the scoring review page;

4) Click **[Details]**.

In the Details window, the selected scoring information can be deleted and sent here.

15.7.3 Record Scores

3) Select "  " on the review page of scoring review to start printing.

4) Click "  " again to stop printing.

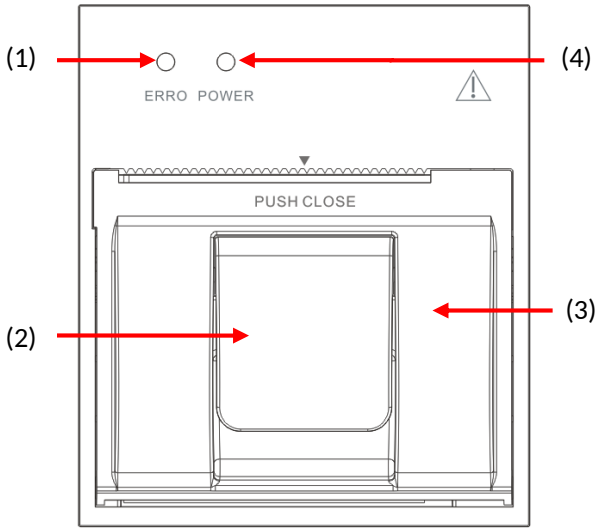
15.8 CCHD Review

All CCHD data saved can be viewed on CCHD review page, please refer to ***"Section 15.7 Scoring Review"*** for more operation details.

Chapter 16 Record

16.1 Description of Recorder

This monitor uses a thermal arraycorder which supports several record types and can output patient info, measured data, reviews and at most 3 waves.



(1) Fault alarm light (2) On/Off latch lock (3) Recorder door (4) Power indicator

16.2 Start Recording

16.2.1 Start Recording Manually

◆ Click "" in the current menu or window to start recording.

16.2.2 Start Recording Automatically

The recorder can automatically start recording according to the set interval and please refer to ***"Section 16.4 Set the Recorder"*** for detailed instructions.

16.3 Stop Recording

16.3.1 Stop Recording Manually

In the recording process, click "  " to stop recording.

Go to the **[Record Setup]** menu to click **[Clear All]**, and please refer to ***"Section 16.5 Clear Record Task"*** for detailed instructions.

16.3.2 Stop Recording Automatically

The Recorder will stop recording automatically in the following cases:

- The recording task has been completed;
- The recorder has run out of paper; or
- The recorder fails to work properly due to a technical fault.

16.4 Set the Recorder

1) Click **[Menu]** hot key → **[Device]** → **[Record Setup]**.
2) Set the **[Record Wave1]**, **[Record Wave2]** and **[Record Wave3]** and select their waveform labels from the pop-up list. The recorder can output up to 3 waveforms at a time.
3) Set the **[Timed Record Interval]**. The recorder will automatically starting recording at the selected interval.
4) Set the **[Sweep Speed]**. This set value will be applied to all recording tasks involving waveform.

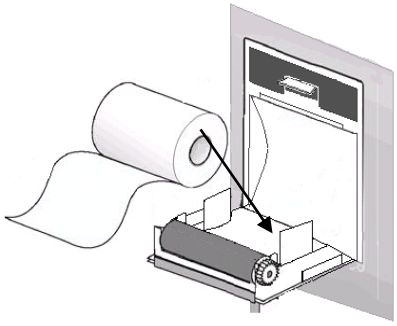
16.5 Clear Record Task

1) Click **[Menu]** hot key → **[Device]** → **[Record Setup]**.
2) Click **[Clear All]** to clear all reports to be output and to stop the current recording task.

16.6 Install Recording Paper

1) Operate the latch to open the recorder door.

2) Remove the empty paper core to load new roll paper, and then fix the paper core back to the paper clip.
3) The paper will be ejected from the bottom to cross the top of recorder door. Make sure at least one inch of paper will stretch beyond the edge of recorder door.
4) Turn the recorder door upward to close it tightly.
5) Start recording in order to check whether the paper is loaded correctly.
6) If the printing process fails to be initiated, the paper may have been loaded upside down. Try to reload the paper.



Install Recording Paper

⚠ CAUTION

- **Load paper carefully; otherwise the thermal print head may get damaged.**
- **During output by the recorder, it is not allowed to pull the record paper outward with force; otherwise the recorder may get damaged.**
- **Do not keep the recorder door open except for paper change or troubleshooting.**

16.7 Clear Jammed Paper

If the recorder makes any abnormal sound during operation or the record paper outputs abnormally, please check to see if any paper is jammed. If yes, please clear it according to the following steps:

1) Open the recorder door.
2) Take out the record paper, and cut off the crease part.
3) Reload the record paper, and close the recorder door.

16.8 Recorder Cleaning

After long-term use of the recorder, scraps of paper and impurities will be accumulated on the print head, which will affect the quality of recording and the service life of print head and roll shaft.

Cleaning:

1) Prior to cleaning, measures should be taken to prevent the device from being damaged by static electricity.
2) Open the recorder door; take out the record paper, and use a cotton ball to dip an appropriate amount of alcohol.
3) Gently wipe the surface of the thermal part of print head.
4) When the alcohol becomes completely dry, reload the record paper and close the recorder door.

NOTE

- Do not use any materials (e.g., abrasive paper) that can damage the thermal part.
- Do not squeeze the thermal print head with force.

Chapter 17 Other Functions

17.1 Network Connection

⚠ WARNING

- Use only secure Local Area Network connection. Make sure your hospital's firewall software is configured correctly, thus blocking incoming connection requests from the Internet. Improper use of network connection may cause virus infections of the Windows system and eventually malfunctions may occur.
- The following changes to the IT network require additional analysis:
  - Changes in network configuration
  - Connection and disconnection with other devices
  - Device updates and upgrades

⚠ NOTE

- Additional network security features may be established by the local security policy.
- Connection of the monitor to an IT NETWORK that includes other medical equipment could result in previously unidentified risks to the patient, operators or other function units.
- Personnel responsible for connecting this system should identify, analyze, evaluate and control these risks and be liable to verify if the system complies with IEC 60601-1. If you have any questions, please contact us.
- When you change the IT network configuration; like adding connection of other items to the IT NETWORK; or disconnecting items from the IT NETWORK; you shall follow the regulation of Local Area Network connection, and the user manual of CMS.
- If the following changes occur on the IT NETWORK, please communicate with our professional service personnel:
  • update of equipment connected to the IT NETWORK; and
  • upgrade of equipment connected to the IT NETWORK.
- The system has been verified for compatibility, and compliance for connection to a local area network (LAN) which complies with IT safety standard of IEC 60950-1/IEC 62368-1.
- The hospital LAN must be equipped with antivirus software and a firewall to supervise, defend and clean up viruses and malware.

17.1.1 Set Network Type

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and click the Enter key.

2) Select **[Network Setup]** tab → **[Network Type]** tab.
3) Set the **[Network Protocol]**.

17.1.2 Set Wired Network

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and click the Enter key.
2) Select **[Network Setup]** tab → **[LAN1 IP]** tab.
3) Set **[IP Address]**, **[Subnet Mask]** and **[Gateway]**.

17.1.3 Set BLE

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and click the Enter key.
2) Select **[Network Setup]** tab → **[BLE Setup]** tab.
3) Turn on/off the switch of BLE.
4) Set the **[BLE Name]** and **[SpO2 Type]**.

17.2 Central Monitoring System Connection

1) Set network to **[CMS]** according to *"Section 17.1.2 Set Wired Network"*.
2) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and click the Enter key
3) Select **[Network Setup]** tab →**[CMS Configuration]**→set **[Net Bed]**, **[IP Address]** (CMS address), **[Port]** (CMS Port).

There is a central monitoring system icon at the top of the interface, when it shows  , it means that the central monitoring system is not successfully connected; When it displays  , it means that the central system has been successfully connected.

Refer to Comen Central Monitoring System Instructions Manual for detailed function descriptions when the connection to the central monitoring system is established.

NOTE

- **When the WiFi is on, the wired network is not available.**
- **The Net Bed on the monitor must be unique to avoid conflicts with other Net Beds connecting to the central monitoring system.**
- **Refer to the instruction manual of our central monitoring system for details.**
- **[Time Setup] on the monitor will turn grey and cannot be operated when it is connected to the central monitoring system.**

- **The alarm delay time from alarm signal generation on the monitor to the alarm signal generation on the remote equipment is ⩽3 seconds, measured at the monitor signal output connector. And alarm delay time on the monitor is about 1s.**

17.3 Connect to Hospital's Information System by HL7 Protocol

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and click the Enter key.
2) Select **[Network Setup]** tab → **[HL7 Configuration]** tab.
3) Turn on the switch of **[Send Data]** as required.
4) Select **[Destination IP]** and **[Port]** to set the IP address and port of the server that receives real-time data and waveforms.
5) Set **[Data Interval]**.

Users can view the server connection status through this page.

17.4 Send Setup

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and click the Enter key.
2) Select **[Network Setup]** tab → **[Send Setup]** tab.
3) Set **[Sending Form]**.

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Chapter 18 Battery

18.1 Overview

The monitor is equipped with a built-in rechargeable battery, and the monitor can also be connected to a trolley battery via the backup power interface. When AC power supply is connected, the battery can be charged automatically till full no matter whether the device is turned on or not. In the event of unexpected power outage, the system will automatically use the battery to supply voltage, thus to avoid interruption of device operation. After AC power supply is cut off, the battery indicator light blinks, indicating the battery is being used to supply voltage, and device operation will not be affected.

The Battery icon shown on the screen indicates the current battery status;

 indicates battery level is full.

 indicates battery level is not full.

 indicates the battery is being charged.

 indicates absence or damage of the battery.

⚠ WARNING

- **Improper replacement of the lithium battery will result in unacceptable risks.**
- **Replacement of the lithium battery by unprofessional personnel may result in risks.**
- **Battery electrolyte is hazardous. In case that battery electrolyte comes into contact with your skin or enters your eyes, please wash with clean water immediately and seek medical advice.**
- **Please keep the battery out of the reach of children.**
- **When the battery is used for operation, the monitor will power off automatically when the battery level is low.**

⚠ NOTE

- **If the battery is to be left unused for a long period of time, please remove the battery and keep it properly.**
- **If the device is provided with a built-in battery, the battery must be charged after each use to ensure sufficient battery reserve.**
- **Please use the external power supply in time before the battery is exhausted.**

18.2 Install Battery

The Monitor's battery must be installed and replaced by the maintenance personnel trained and authorized by us. The battery is not installed when the Monitor leaves the factory. Please contact a maintenance engineer for battery installation before using the Monitor for the first time.

⚠ WARNING

- **Only use battery designated by the manufacturer.**
- **Do not remove the battery when the device is working.**

18.3 View Battery Information

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key;
2) Click **[Battery Information]** tab.

18.4 Optimize and Check Battery Performance

18.4.1 Optimize Battery Performance

The battery must undergo at least two complete optimization cycles before first use. The battery's performance will gradually decrease as the time of use increases. It is recommended that you optimize the battery every three months. If it is not optimized during a long time, the displayed battery voltage level may not be accurate.

When optimizing the battery, please ensure the following:

1) Completely disconnect the monitor from the patient and stop all monitoring and measurement.
2) Put the battery for optimization in the battery case of the device.
3) Please ensure that the battery is charged uninterruptedly till it is fully charged.
4) Disconnect AC power supply, and use the battery to supply voltage to the monitor till the monitor shuts down automatically.
5) Battery optimization is finished.

18.4.2 Check Battery Performance

The battery life varies with the storage and operation environments, frequency of battery discharging and use time. The battery performance will degrade gradually even if the battery is not used. A battery performance check must be performed every three months. When you suspect a battery fault, you will also need to perform a battery performance check.

For the battery performance check procedure, see steps 1 to 4 in "*Section 18.4.1 Optimize Battery Performance*". The length of discharge time reflects the performance of the battery. If the battery's power supply time is significantly lower than the time stated in the Specifications, the battery should be replaced.

NOTE

- **In order to prolong the service life of the rechargeable battery, if the battery is stored for a long period of time, it is suggested that the battery should be charged every three months to prevent excessive discharging.**
- **The voltage supply time of the battery depends on the configuration and operation of the device. For example, frequent NIBP measurement will reduce the voltage supply time of the battery.**

18.5 Battery Recycling

If the battery is obviously damaged or runs out, it should be replaced. Waste batteries should be properly recycled in accordance with applicable laws and regulations or the rules of the hospital.

WARNING

- **Do not disassemble or short-circuit the battery or place it in fire; otherwise battery fire, explosion, leakage of hazardous gas or other hazards may be caused.**

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Chapter 19 Cleaning and Disinfection

Only materials and methods listed in this chapter that are accepted by the Company can be used for cleaning or disinfection of the device. For any damage arising from use of unaccepted materials or methods, the Company will not provide any warranty.

The Company will not assume any liability for the effectiveness of listed chemicals or methods when they are used as infection control means. For infection control methods, please consult the Infection Prevention Department or an epidemiologist in your hospital. Besides, please refer to local policies that apply to your hospital and country.

19.1 Overview

This chapter describes the cleaning and disinfection methods of the monitor, plug-in box and some accessories. The cleaning and disinfection methods for other non-disposable accessories refer to the corresponding files attached with the accessories.

Please keep the device and its accessories dustless. After cleaning, please check the device carefully. If there is any evidence of ageing or damage, please stop using it immediately. If it is necessary to send back the device to Comen for repair, first clean it. Please observe the following precautions:

⚠ WARNING

- **Only use detergents and disinfectants recommended in this Instruction Manual; use of other detergents and disinfectants will result in damage to the device or safety risks.**
- **Never soak the device in any liquid.**
- **Never pour any liquid onto any part or accessory of the device.**
- **Never allow any liquid to flow into the housing.**
- **Please dilute detergent and disinfectant as specified by the manufacturer.**
- **Before cleaning the monitor, please power it off and disconnect it from the AC power supply.**
- **Never leave any disinfectant on any surface and accessory of the monitor; please use a wet cloth to clean it immediately.**
- **It is not allowed to use detergent mixture; otherwise it will be dangerous.**
- **This chapter only introduces the methods for cleaning reusable accessories. Disposable accessories should not be reused after cleaning and disinfection to avoid cross infection.**
- **To protect the environment, disposable accessories must be recycled or dealt with properly.**
- **Never soak the sensor or connector in any solution for cleaning or disinfection.**
- **DO NOT touch the metal connectors for avoiding corrosion when cleaning and disinfecting the device and its accessories.**
- **After cleaning, if the sensor cable is damaged or shows any evidence of ageing, it should be replaced**

with a new cable.

- **High-temperature sterilization of the monitor and all accessories is not allowed.**
- **Never use EtO (ethylene oxide) to disinfect the monitor.**
- **Do not use any frictional material, bleaching powder or strong solvent (e.g., acetone or detergent containing acetone).**

⚠ CAUTION

- **If you carelessly pour any liquid onto the device or any accessory, please contact the maintenance personnel or our Company immediately.**
- **If the device gets damped accidentally, put it in a ventilated place and then contact maintenance personnel or our company immediately.**

19.2 Cleaning of Monitor and Modules

The monitor and modules should be kept clean. It is suggested that the external surface of the housing should be cleaned frequently; especially in environments with tough conditions or very windy and dusty places, the cleaning frequency should be increased. Prior to cleaning, please first consult or understand relevant rules of your hospital on device cleaning. Detergents recommended: water, 75% alcohol (diluted concentration), 70% alcohol (diluted concentration).

Cleaning steps:

1) Power the device off, and unplug the power cord.
2) Use a soft cloth with a proper amount of detergent to wipe outside shells of the device and plug-in box. Take care of not touching their connectors and metal parts.
3) Use a soft, dry cloth to remove residual detergent.
4) Put the device in a cool, well-ventilated environment to air-dry it.

Occasionally, as required, clean the display using a soft, lint-free cloth sprayed with an alcohol free glass cleaner. Do not use either isopropyl alcohol or solvent which may cause damage when cleaning the display. The use of paper towels is not recommended as it may scratch the surface.

19.3 Disinfection of Monitor and Modules

The device, Plug-in Modules and Module Rack are disinfected only when it is considered necessary in the hospital's maintenance plan. Please clean them before disinfection.

Recommended disinfectants are as follows: isopropanol (70%), n-propanol (70%), glutaraldehyde solution (2%), phthalaldehyde (0.5%), sodium hypochlorite solution 2.5%, sodium hypochlorite solution 9% disinfectant, hydrogen peroxide (3.0%).

19.4 Cleaning and Disinfection of Accessories

Prior to cleaning, please first consult or understand relevant rules of your hospital on device cleaning. The accessories are disinfected only when it is considered necessary in the hospital's maintenance plan. Please clean accessories before disinfection.

19.4.1 Cleaning and Disinfection of BP Cuff

Detergents recommended: water, 75% alcohol (diluted concentration), and 70% alcohol (diluted concentration).

Disinfectants recommended: isopropanol (70%), n-propanol (70%), phthalaldehyde (0.5%), sodium hypochlorite solution 2.5%, hydrogen peroxide (3.0%).

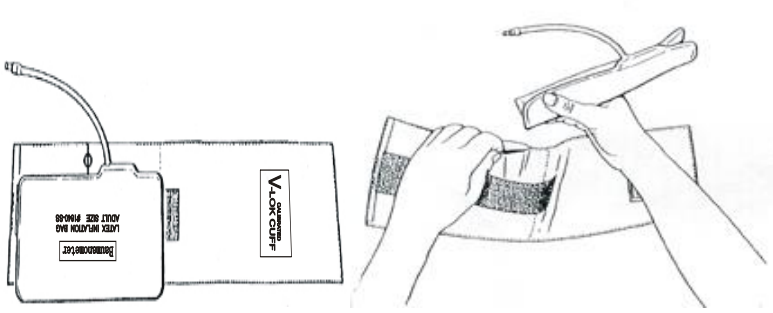
- Prior to cleaning, the gasbag must be taken out.
- The cuff can be washed by machine or hand with detergent, whereas hand wash can prolong its service time. The gasbag can be cleaned using a wet cloth dipped with clean water. Naturally air-dry it after cleaning.
- The cuff can be disinfected using a wet cloth dipped with detergent. Long-term use of disinfectants may result in color fading or discoloration of the cuff.

⚠ WARNING

- **Do not squeeze the rubber tube on the cuff.**
- **During cleaning, only wipe the external surface of the connector socket; never wipe its internal surface.**
- **When cleaning the gasbag, care should be taken not to allow any liquid to flow into the gasbag.**
- **It is forbidden to dry-clean the cuff.**
- **The disposable cuff can be cleaned with soap to control infection.**

After cleaning, please reinstall the gasbag into the cuff according to the following steps.

1) To reinstall the gasbag into the cuff, first put the gasbag at the head of the cuff so that the rubber tube can line up with the big opening of the long end of the cuff;
2) Then vertically curl up the gasbag and insert it into the big opening of the cuff; hold the rubber tube and the cuff, and shake the entire cuff till the gasbag is in position.
3) Lead the rubber tube into the cuff, and run it through the liner via the small hole. See the figure below:



19.4.2 Cleaning and Disinfection of Other Accessories

19.4.2.1 Cleaning of accessories

Cleaning steps:

1) Use a soft cloth dipped with an appropriate amount of detergent to wipe the accessories.
2) You can use a soft, dry cloth to remove residual detergent.
3) Put the accessories in a cool, well-ventilated environment to air-dry it.

See the table below for detergents recommended:

Part for Cleaning/Disinfection	Detergent
Power cord	Water, 75% alcohol
Comen SpO_2 cable, CO_2 extended cable,	Water, 75% alcohol
Masimo SpO_2 sensor, Nellcor SpO_2 sensor, and cable	Water, 75% alcohol
NIBP airway tube	Water, 75% alcohol

19.4.2.2 Disinfection of accessories

See the table below for disinfectants recommended:

Part for Cleaning/Disinfection	Disinfectant
simulator SpO_2 cable, CO_2 extended cable, SpO_2 sensor and cable	Isopropanol 70%, n-propanol 70%, glutaraldehyde 2%, hydrogen peroxide 3%, phthalaldehyde 0.5%, sodium hypochlorite solution 2.5%
Masimo and NellcorSpO_2 cable	Isopropanol 70%, n-propanol 70%, glutaraldehyde 2%, hydrogen peroxide 3%, phthalaldehyde 0.5%, sodium hypochlorite solution 2.5%
NIBP airway tube	Isopropanol 70%, n-propanol 70%, hydrogen peroxide 3%, phthalaldehyde 0.5%, sodium hypochlorite solution 2.5%

19.5 Sterilization

DO NOT sterilize the monitor, detachable parts and specified accessories. NO sterilization procedure is required before use.

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Chapter 20 Maintenance

20.1 Maintenance Checks

Before use of the monitor, or every 6-12 months or after each maintenance or upgrade, a comprehensive check, including functional safety check, of the device should be carried out by qualified technical maintenance personnel having received training.

If there is any evidence of functional failure of the device, it is not allowed to use this monitor for patient monitoring. Please contact our company or a biomedical engineer of your hospital.

All safety checks or maintenance work requiring disassembly of the device should be performed by professional maintenance personnel; operation by unprofessional personnel may result in malfunction of the device or safety hazards, and may also endanger personal safety.

Upon request by the user, Comen will conditionally provide relevant circuit diagrams to help the user to repair user-serviceable components of the device by appropriate and qualified technicians.

⚠ WARNING

- **The hospital or organization using this monitor should establish a sound maintenance plan; failure to do so may result in malfunction of the device and unpredictable consequences, and may also endanger personal safety.**
- **DO NOT use the monitor when finding its outer shell crack for preventing electric shock caused by leakage current. Contact maintenance personnel to deal with it.**
- **DO NOT refit the device without permission.**
- **No parts on the device can be repaired by the user. Contact maintenance personnel if needed.**
- **All safety checks or maintenance work requiring disassembly of the device should be performed by professional maintenance personnel; operation by unprofessional personnel may result in malfunction of the device or safety hazards, and may also endanger personal safety.**
- **DO NOT disassemble the battery, short circuit it, place it in an environment above 60°C or burn it. These operations may cause the battery to burn, explode, leak or become hot, resulting in personal injury.**
- **The maintenance personnel should have certified qualifications and be familiar with the device.**
- **If the device gets damped accidentally, put it in a ventilated place and then contact maintenance personnel or our company immediately.**

20.2 Maintenance Plan

The following tasks can be fulfilled only by professional maintenance personnel recognized by the Company. If the following maintenance is needed, please timely contact the maintenance personnel. Prior to test or maintenance, the device must be cleaned and disinfected.

Test and Maintenance Items		Frequency
Visual inspection and performance inspection		
Visual inspection		Before first use every day
Parameter module performance inspection and calibration		1. When measurement inaccuracy is suspected 2. When the relative module is maintained or replaced. 3. At least once every year for CO_2 module and AG module 4. At least once every two years for other modules
Nurse Call test		When the malfunction of nurse call is suspected
Safety inspection		
Perform safety inspection according to GB9706.1/IEC 60601-1		1. When the power module is maintained or replaced 2. When the monitor drops down 3. At least twice every year or as needed
Other inspections		
When the device starts		Before use every time
Recorder test		Before first use When the recorder is maintained or replaced
Network printing test		1. After the initial installation 2. When the printer is maintained or replaced
System integrated test		1. After the initial installation 2. When the integrated device is maintained or replaced
Battery inspection	Function test	1. After the initial installation 2. After the battery is replaced
	Performance test	Every three months or the battery running time is shortened noticeably.
NIBP leakage test		At least once every two years or as needed.
NIBP verification		At least once every two years or as needed.
Battery		Refer to the battery-related chapter in this manual.

20.3 Service Life of Reusable Accessories

Name	Service life
Comen SpO_2 sensor	2 years
Nellcor/Masimo SpO_2 sensor	4380 hours
Reusable BP cuff	18 months
CO_2 module, CO_2 sensor	5 years

20.4 Service Life of Disposable Accessories

Name	Service life
BP cuff	2 years
Disposable SpO_2 sensor	3 years
CO_2 filter tube	3 years
CO_2 sampling tube	3 years
CO_2 dehumidification tube	3 years
CO_2 nasal tube	3 years
Sidestream CO_2/AG sampling tube	2 years
Earmuff	5 years

20.5 Version Information

Click **[Menu]** hot key → **[System]** → **[Version]** to view the system software information.

To view more version information as follows:

1) Click **[Menu]** hot key → **[System]** → **[Maintain]**, enter the maintenance password and hit the Enter key.
2) Select **[Version]** tab. You can view the information of system software version, module software version, hardware version and fixed version.

20.6 Testing Methods and Steps

All tests and maintenance work can be fulfilled only by professional maintenance personnel recognized by the Company except the follow tasks.

- General inspection, including visual inspection and startup inspection
- Printer and recorder test
- Battery inspection

If other maintenance is needed, please timely contact the maintenance personnel.

20.6.1 Visual Inspection

Perform a visual inspection of the device appearance before the first use every day. If any damage or malfunction occurs, stop use the device immediately and contact the hospital's equipment engineer or our maintenance personnel.

Visual inspection items:

- The environment and power supply meet the requirements.
- No dirt on the outer shell of the device; no crack or damage on the panel or screen.
- Power cord is not worn out and has a good insulation performance.
- The connector, plug and cable are not damaged or entangled.
- Cables are well connected with the device and modules.

20.6.2 Startup Inspection

The monitor will perform a self-inspection after startup. The inspection items are listed as follows:

- The monitor can boot normally
- The alarm system works normally
- The screen displays normally

20.6.3 Recorder Test

- Enable a record print task to print the waveform and report.
- Check whether the paper is fed normally
- Check whether the waveform and texts are displayed clearly and completely.

20.6.4 Battery Inspection

Refer to *"Section 18.4.1 Optimize Battery Performance"*.

20.6.5 Monitor Disposal

When the monitor reaches the end of its service life, dispose it and its accessories according to local laws and regulations.

⚠ Warning

- **Local regulations on the disposal of hospital waste can be followed when there is no corresponding regulation for the disposal of components and accessories.**

20.7 NIBP Leakage Test

The test is used to ensure the airtightness of NIBP gas circuit by detecting whether the NIBP measurement pump is leaking. NIBP leakage test should be performed once every two years or the readings seem not correct. NIBP leakage test shall be performed by the maintenance personnel.

20.8 NIBP Verify

NIBP verification should be performed once every two years or the reading displayed seems not correct. A calibrated pressure gauge (or mercury blood pressure gauge) with an accuracy higher than 1mmHg is recommended by the manufacturer, and its verification is performed through the NIBP calibration module in the maintenance interface. NIBP leakage test shall be performed by the maintenance personnel.

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Appendix I Accessories

Here we recommend the following accessories for the Monitor.

WARNING

- **Use the accessories of designated types only, or the Monitor may be damaged.**
- **To prevent reduced performance and cross infections, please do not reuse any disposable accessory.**
- **Check the package of accessory before using. If the package or accessory itself is damaged, please do not use.**
- **The expired or damaged accessories, if disposed of at will, will cause environment pollution and therefore must be disposed of in accordance with local laws or hospital regulations.**
- **Refer to the User Manual of accessory when use it and the working temperature must be considered.**
- **Disposable accessories must be used in the period of validity.**
- **Accessories equipped with this Monitor have been tested to verify their compliance with the Monitor in accordance with relative standards.**
- **Before monitoring patients, please check whether the accessory is compatible with the Monitor. Incompatible accessories will reduce the performance of the Monitor.**

1. Blood pressure cuff

Description	Models	Remarks	Description
Blood pressure cuff	U1880S	25-35cm	Unimed Medical Supplies. INC
Blood pressure cuff	U1881S	18-26cm	
Blood pressure cuff	U1882S	10-19cm	
Blood pressure cuff	U1883S	6-11cm	
Blood pressure cuff	U1884S	46-66cm	
Blood pressure cuff	U1885S	20-28cm	
Blood pressure cuff	U1869S	33-47cm	
Blood pressure cuff	U1889S	33-47cm	
Blood pressure cuff	U1681S	3-6cm	
Blood pressure cuff	U1682S	4-8cm	
Blood pressure cuff	U1683S	6-11cm	
Blood pressure cuff	U1684S	7-13cm	
Blood pressure cuff	U1685S	8-15cm	
Blood pressure cuff	CM-M04-001	46-66cm	Shenzhen Comen Medical Instruments Co., Ltd.
Blood pressure cuff	CM-M04-002	33-47cm	
Blood pressure cuff	CM-M04-003	25-35cm	
Blood pressure cuff	CM-M04-004	18-26cm	
Blood pressure cuff	CM-M04-005	10-19cm	
Blood pressure cuff	CM-M04-006	7-13cm	

Blood pressure cuff	CM-M04-007	46-66cm	
Blood pressure cuff	CM-M04-008	33-47cm	
Blood pressure cuff	CM-M04-009	33-47cm	
Blood pressure cuff	CM-M04-010	25-35cm	
Blood pressure cuff	CM-M04-011	25-35cm	
Blood pressure cuff	CM-M04-012	18-26cm	
Blood pressure cuff	CM-M04-013	10-19cm	
Blood pressure cuff	CM-M04-014	7-13cm	
Blood pressure cuff	CM-M04-015	3-6cm	
Blood pressure cuff	CM-M04-016	4-8cm	
Blood pressure cuff	CM-M04-017	6-11cm	
Blood pressure cuff	CM-M04-018	7-13cm	
Blood pressure cuff	CM-M04-019	8-15cm	

2. Comen SpO_2

Specifications	Models	Part of body applied/ Intended patient population	Remarks	Manufacturer
Comen SpO_2 probe (Adult use, finger clip type)	SAL001	Finger, Adult	Reusable	Shenzhen Launch Electrical Co. Ltd.
Comen SpO_2 probe (Adult use, finger clip type)	SAS001	Finger, Adult	Reusable	
Comen SpO_2 probe (Pediatric use, bandage type)	SES001	Foot /Toe/Finger, Pediatric	Reusable	
Comen SpO_2 cable extender	SLZ122	/	Reusable	
Comen SpO_2 probe (Adult use, finger clip type)	A0816-SA105PV	Finger, Adult	Reusable	APK Technology Co., Ltd
Comen SpO_2 probe (Adult use, finger clip type)	CM-M02-001	Finger, Adult	Reusable	Shenzhen Comen Medical Instruments Co., Ltd.
Comen SpO_2 probe (Adult use, finger clip type)	CM-M02-003	Finger, Adult	Reusable	
Comen SpO_2 probe (Pediatric use, finger clip type)	CM-M02-004	Finger, Pediatric	Reusable	

Comen SpO_2 probe (Pediatric use, finger clip type)	CM-M02-006	Finger, Pediatric	Reusable	
Comen SpO_2 probe (Adult use, finger wrap type)	CM-M02-007	Finger, Adult	Reusable	
Comen SpO_2 probe (Adult use, finger wrap type)	CM-M02-009	Finger, Adult	Reusable	
Comen SpO_2 probe (Pediatric use, finger wrap type)	CM-M02-010	Finger, Pediatric	Reusable	
Comen SpO_2 probe (Pediatric use, finger wrap type)	CM-M02-012	Finger, Pediatric	Reusable	
Comen SpO_2 probe (Adult/ pediatric/ neonate use, bandage type)	CM-M02-013	Finger/Sole, Adult/pediatric/ neonate	Reusable	
Comen SpO_2 probe (Pediatric/ neonate use, bandage type)	CM-M02-014	Finger/Sole, Pediatric/ neonate	Reusable	
Comen SpO_2 probe (Adult/pediatric use, ear clip type)	CM-M02-015	Ear, Adult/pediatric	Reusable	
Comen SpO_2 probe (Adult/neonate use, bandage type)	CM-M02-020	Finger/Sole, Adult/neonate	Disposable	
Comen SpO_2 probe (Adult use, bandage type)	CM-M02-021	Finger, Adult	Disposable	
Comen SpO_2 probe (Pediatric use, bandage type)	CM-M02-022	Finger, Pediatric	Disposable	
Comen SpO_2 probe (Infant use, bandage type)	CM-M02-023	Big toe, Infant	Disposable	
Comen SpO_2 probe (Adult/ pediatric/ neonate use, adhesive type)	CM-M02-024	Finger/Sole, Adult/ neonate	Disposable	

Comen SpO_2 probe (Adult use, adhesive type)	CM-M02-025	Finger, Adult	Disposable	
Comen SpO_2 probe (pediatric use, adhesive type)	CM-M02-026	Finger, Pediatric	Disposable	
Comen SpO_2 probe (Infant use, bandage type)	CM-M02-027	Big toe, Infant	Disposable	
SpO_2 adapting cable	CM-M20-001	/	Reusable	

3. Masimo SpO_2

Specifications	Models	Part of body applied	Intended patient population	Manufacturer
Adult Reusable finger clip SpO_2 sensor	RD SET DCI	Toe/Finger, Reusable	Adult/ Pediatric (>30 kg)	MASIMO CORPORATION
Pediatric/Slender digit Reusable finger clip SpO_2 sensor	RD SET DCI-P	Toe/Finger, Reusable	Adult/ Pediatric (10-50kg)	
Masimo SpO_2 sensor, Neonate use, Y- type)	RD SET YI	Foot, Reusable	Neonate(<3 kg)	
Masimo SpO_2 cable	CM12-RD-L	Reusable	/	Shenzhen Launch Electrical Co. Ltd.

4. Nellcor SpO_2

Specifications	Models	Part of body applied	Intended patient population	Manufacturer
Nellcor SpO_2 probe (Adult use, finger clip type)	DS100A	Finger, Reusable	Adult/ Pediatric (>40kg)	Nellcor Puritan Bennett Inc
Nellcor SpO_2 probe (Adult use, Y- type, bandage type)	D-YS	Foot /Toe/Finger, Reusable	Adult/ Pediatric	
Nellcor SpO_2 cable	SLZ068	Reusable	/	Shenzhen Launch Electrical Co. Ltd.

5. CO_2 accessories

Description	Models	Intended patient population/ remarks	Manufacturer
Sidestream CO_2/AG Sampling tube	3827	Adult	MASIMO CORPORATION
Sidestream CO_2/AG Sampling tube	3828	Pediatric	
Sidestream CO_2/AG Sampling tube	4367	Neonate	
Sidestream CO_2/AG Sampling tube	3830	Adult	
Sidestream CO_2/AG Sampling tube	3831	Pediatric	
Sidestream CO_2/AG Sampling tube	3832	Neonate	
Sidestream CO_2/AG Sampling tube	3833	Adult	
Sidestream CO_2/AG Sampling tube	3834	Pediatric	
Sidestream CO_2/AG Sampling tube	3835	Adult	
Sidestream CO_2/AG Sampling tube	3836	Pediatric	
Sidestream CO_2/AG Sampling tube	3837	Adult	
Sidestream CO_2/AG Sampling tube	3838	Pediatric	
Sidestream CO_2/AG Sampling tube	3839	Adult	
Sidestream CO_2 filter tube	CM-M05-001	Sidestream	Shenzhen Comen Medical Instruments Co., Ltd.
Sidestream CO_2 Sampling tube	CM-M05-002	Sidestream	
Sidestream CO_2 Sampling tube	CM-M05-003	Sidestream	
Sidestream CO_2 Dehumidification Tube	CM-M05-004	Sidestream	
Sidestream CO_2/AG Sampling tube	CM-M05-005	Adult	
Sidestream CO_2/AG Sampling tube	CM-M05-006	Pediatric	
Sidestream CO_2/AG Sampling tube	CM-M05-007	Neonate	

6. Temp accessories

Description	Models	Intended patient population	Manufacturer
Infrared In ear Thermometer Front View	IRT10	/	Shenzhen Comen Medical Instruments Co., Ltd.
Earmuff	BRAUN	/	Hangzhou Braun Medical Equipment Co., Ltd.

Appendix II Product Specifications

1) Monitor Type

Classified by	Type
Compliance with relevant standards	EN 60601-1:2006+A2:2020, EN IEC 80601-2-49:2019, EN IEC 80601-2-30:2019, EN ISO 80601-2-55:2018, EN ISO 80601-2-61:2019, EN 60601-1-2:2015+A1:2021, EN 60601-1-8:2007+A1:2013+AC:2014+A11:2017+A2:2020, EN ISO 80601-2-56:2017+A1:2020
Protection against electric shock	Class I; with internal power supply;
Degree of protection against electrical shock	Defibrillation-proof type CF: SpO_2, NIBP; Defibrillation-proof type BF: CO_2; Type BF: IRT10
Operation mode	Continuous operation equipment.
Mobile level	Portable
Protection against ingress of liquid	IPX2
The degree of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide or within an oxygen-rich environment	Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide or within an oxygen-rich environment.
Explosion protection level	Ordinary device, no explosion protection, not safe to work with inflammable respirator

2) General Specifications

Item	Specification
Dimension	NC6/NC6A/ NC6C/NC6Neo: ≦260mm×150mm×250mm NC7/NC7A/NC7C/NC7Neo：≦270mm×150mm×265mm
Main unit weight	NC6/NC6A/NC6C/NC6Neo：≦3.5kg NC7/NC7A/NC7C/NC7Neo：≦4.2kg
Display screen	NC6/NC6A/NC6C/NC6Neo: size: 8 inch; screen: TFT; resolution: 1024×768 NC7/NC7A/NC7C/NC7Neo: size: 10.1 inch; screen: TFT; resolution: 1280×800

3) Environmental Specifications

Item	Specification	
Main unit		
Operating condition	Ambient temperature	0℃-40℃
	Relative humidity	15% -95%, non-condensing
	Barometric pressure	57.0 kPa ~107.4kPa
Transient condition	Protect the device against violent impact, vibration, rain and snow during transportation.	
Storage	The packaged monitor shall be kept in a well-ventilated, non-corrosive gas environment with ambient temperature (-20℃-+60℃), relative humidity (10%-95%) non-condensing, and barometric pressure (57.0KPa～107.4KPa).	
Shock & Vibration (robustness)	Conform to standards of IEC 80601-2-30:2018, ISO 80601-2-55:2018, ISO80601-2-61:2017	

4) Power Supply

Item	Specification
AC input voltage	100-240V~
AC input frequency	50/60Hz
Input power	0.5～1.0A
Battery specification	This monitor is equipped with 1 lithium-ion battery. Standard battery: 10.8V ⎓ 2500mAh; Optional battery: 10.8V ⎓ 5000mAh
Battery operation time	Full battery, NIBP measurement with an interval of 15 min, environmental temperature(25±5℃), connected with SpO_2 sensor, no built-in printing, and screen brightness set as 1 (lowest level): a) 10.8V ⎓ 2500mAh: no less than 3 hours,; b) 10.8V ⎓ 5000mAh: no less than 8 hours; c) Spare battery on the trolley 10.8V ⎓ 5000mAh: no less than 8 hours; d) 5000mAh internal battery + 5000mAh Spare battery: no less than 16 hours; e) 2500mAh internal battery + 5000mAh Spare battery: no less than 11 hours;
Battery charging time	a) 10.8V ⎓ 2500mAh: In power-on state: no more than 7.5h to charge the exhausted battery to 90% of its capacity. In power-off state: no more than 3h to charge the exhausted battery to 90% of its capacity. b) 10.8V ⎓ 5000mAh: In power-on state: no more than 11.5h to charge the exhausted battery to

	90% of its capacity. In power-off state: no more than 4.5h to charge the exhausted battery to 90% of its capacity.
Delay time of shut down	20~30min(after the first warning of low battery)
IRT10 Temp	2 AAA batteries

5) Data Storage Specifications

Name	Specifications
Functions	The monitor has the functions of storing and reviewing data.
Trend data	240h (minimum resolution of 1 minute)
Alarm Event/Score review/ CCHD review	1000groups-
Trend List	5000 groups

6) Record Specifications

Name	Specification
Record Paper Width	50mm
Record width	48mm
Paper speed	12.5mm/s, 25 mm/s, 50mm/s
Record time	8s, 16s, 32s, Continual
Record waveform	2 channels and 3 channels waveform recording, the default is 3 channels waveform recording; Record waveform selection: You can select to record any currently valid waveform on channels 1, 2, 3 of the recorded waveform or turn them off
Timed Record Interval	10min, 20min, 30min, 40min, 50min, 1h, 2h, 3h, 4h and Off

7) NIBP Specifications

Name	Specification		
Meets the requirement of IEC 80601-2-30			
Measurement method	Oscillation method		
Displayed measurement	Systole blood pressure (SYS), Diastolic blood pressure (DIA), Mean arterial pressure (MAP) Pulse Rate (PR) in NIBP list		
NIBP measurement range	Measurement range in Adu mode	SYS	25mmHg ~290mmHg (3.3kPa~38.7kPa)
		DIA	10mmHg ~250mmHg (1.3kPa~33.3kPa)
		MAP	15mmHg ~ 260mmHg (2.0kPa~34.7kPa)
		SYS	25mmHg ~240mmHg (3.3kPa-32.0kPa)

<table>
<tr><td rowspan="5"></td><td rowspan="2">Measurement range in Ped. mode</td><td>DIA</td><td>10mmHg - 200mmHg (1.3kPa-26.7kPa)</td></tr>
<tr><td>MAP</td><td>15mmHg - 215mmHg (2.0kPa-28.7kPa)</td></tr>
<tr><td rowspan="3">Measurement range in Neo. mode</td><td>SYS</td><td>25mmHg - 140mmHg (3.3kPa-18.7kPa)</td></tr>
<tr><td>DIA</td><td>10mmHg - 115mmHg (1.3kPa-15.3kPa)</td></tr>
<tr><td>MAP</td><td>15mmHg - 125mmHg (2.0kPa-16.7kPa)</td></tr>
<tr><td>Measurement Error</td><td colspan="3"></td></tr>
<tr><td>Static pressure measurement range and accuracy</td><td colspan="3">Measurement range: 0mmHg - 300mmHg (0 kPa - 40.0 kPa);
Measurement accuracy: ±3mmHg (±0.4 kPa)</td></tr>
<tr><td rowspan="3">Software Over pressure protection range and accuracy</td><td>Adu. mode</td><td colspan="2">297mmHg ±3mmHg (39.6kPa±0.4kPa)</td></tr>
<tr><td>Ped. mode</td><td colspan="2">297mmHg ±3mmHg (39.6kPa±0.4kPa)</td></tr>
<tr><td>Neo. mode</td><td colspan="2">147mmHg ±3mmHg (19.6kPa±0.4kPa)</td></tr>
<tr><td rowspan="4">NIBP alarm limit setting</td><td colspan="3">Alarm setting rules:
a) 4 types of alarm alarm limits, including extreme high alarm limit, upper alarm limit, lower alarm limit, and extreme low alarm limit.
b) Step:
10mmHg ~50mmHg: 1mmHg.
51mmHg ~290mmHg: 5mmHg</td></tr>
<tr><td rowspan="3">Adu.</td><td>SYS</td><td>Extreme high alarm limit: 28mmHg~290mmHg
Upper alarm limit: 27mmHg ~ 285mmHg
Lower alarm limit: 26mmHg ~ 280mmHg
Extreme low alarm limit: 25mmHg ~275mmHg</td></tr>
<tr><td>DIA</td><td>Extreme high alarm limit: 13mmHg ~ 250mmHg
Upper alarm limit: 12mmHg ~ 245mmHg
Lower alarm limit: 11mmHg ~ 240mmHg
Extreme low alarm limit: 10mmHg ~ 235mmHg</td></tr>
<tr><td>MAP</td><td>Extreme high alarm limit: 18mmHg ~ 260mmHg
Upper alarm limit: 17mmHg ~ 255mmHg
Lower alarm limit: 16mmHg ~ 250mmHg
Extreme low alarm limit: 15mmHg ~ 245mmHg</td></tr>
<tr><td>Ped.</td><td>SYS</td><td>Extreme high alarm limit: 28mmHg ~ 240mmHg
Upper alarm limit: 27mmHg ~ 235mmHg
Lower alarm limit: 26mmHg ~ 230mmHg
Extreme low alarm limit: 25mmHg ~ 225mmHg</td></tr>
</table>

		DIA	Extreme high alarm limit: 13mmHg ~ 200mmHg Upper alarm limit: 12mmHg ~ 195mmHg Lower alarm limit: 11mmHg ~ 190mmHg Extreme low alarm limit: 10mmHg ~ 185mmHg
		MAP	Extreme high alarm limit: 18mmHg ~ 215mmHg Upper alarm limit: 17mmHg ~ 210mmHg Lower alarm limit: 16mmHg ~ 205mmHg Extreme low alarm limit: 15mmHg ~ 200mmHg
	Neo.	SYS	Extreme high alarm limit: 28mmHg ~ 140mmHg Upper alarm limit: 27mmHg ~ 135mmHg Lower alarm limit: 26mmHg ~ 130 mmHg Extreme low alarm limit: 25mmHg ~ 125mmHg
		DIA	Extreme high alarm limit: 13mmHg ~ 115mmHg Upper alarm limit: 12mmHg ~ 110mmHg Lower alarm limit: 11mmHg ~ 105mmHg Extreme low alarm limit: 10mmHg ~ 100mmHg
		MAP	Extreme high alarm limit: 18mmHg~ 125mmHg Upper alarm limit: 17 mmHg ~ 120 mmHg Lower alarm limit: 16mmHg ~115 mmHg Extreme low alarm limit: 15mmHg ~110mmHg
Blood measurement mode	Continuous Monitoring Mode		Supported NIBP measurement mode: Manual, auto, sequence, hourly and STAT mode Intervals to be chosen in auto mode: 1min, 2min, 2.5min, 3min, 4 min, 5 min, 10 min, 15 min, 30 min, 60 min, 90min, 120 min, 180 min, 240 min, 480 min, 720min
	Spot Check Mode		Supported NIBP measurement mode: manual measurement, average blood pressure measurement, orthostatic blood pressure measurement (only for adults)
	NIBP inflation measurement		Supported inflation measurement, the value can be produced in as fast as 15s(not intended for neonates)
Max. measuring period	120s in Adu./Ped. mode; 85s in Neo. mode		

Max. venipuncture time	125±3s in Adu/Ped. Mode; 87±3s in Neo. mode
Initial inflation pressure range	a) In Adu. mode: 80mmHg - 290mmHg (10.7kPa - 38.7kPa); b) In Ped. mode: 80mmHg - 240mmHg (10.7kPa - 32.0kPa); c) In Neo. mode: 60mmHg - 140mmHg (8.0kPa - 18.7kPa);

8) SpO_2 Specifications

Name	Specification
Meets the requirements of ISO 80601-2-61	
Displayed measurements	Pulse waveform; %SpO_2 and PR
Display resolution	1%
Respond time	With normal perfusion without interference: ＜30s（SpO_2 value soars from70% to100%） ＜30s（PR value soars from 25bpm to 220bpm）
Data update period	1s
SpO_2 Measurement range and accuracy	◆ **Comen SpO_2:** Range: 0% ～ 100% Accuracy: within range 70% ～ 100%: ±2% in Adu/Ped. mode (non-motion), ±3% in Neo. mode (non-motion); within range 0% ～ 69%: not defined. ◆ **Masimo SpO_2:** Range: 1% ～ 100% Accuracy: with range 70% ～ 100%: ±2% in Adu./Ped. Mode (non-motion), ±3% in Adu./Ped. mode (during motion), ±3% in Neo. mode (motion and non-motion); within range 1% ～ 69%: not defined. ◆ **Nellcor SpO_2:** Range: 0% ～ 100% Accuracy: within range 70% ～100%: ±2% in Adu./Ped. mode (non-motion), ±3% in Neo. mode (non-motion); within range 0% ～ 69%: not defined.
SpO_2 Alarm limit setting	Alarm rules and step: 1) Three types of alarm limit are set: upper alarm limit, lower alarm limit, and extreme low alarm limit 2) Step: 1%

	Comen SpO_2	1) Upper alarm limit: 4% ～ 100% 2) Lower alarm limit: 2% ～ 98% 3) Extreme low alarm limit: 0% ～96%
	Masimo SpO_2	1) Upper alarm limit: 5% ～ 100% 2) Lower alarm limit: 3% ～ 98% 3) Extreme low alarm limit: 1% ～96%
	Nellcor SpO_2	1) Upper alarm limit: 22% ～100% 2) Lower alarm limit: 20% ～ 98% 3) Extreme low alarm limit: 0% ～ 96%
NIBP simul	If NIBP and SpO_2 measurements are performed on the same arm, the NIBP simul switch can be turned on. When NIBP measurements are performing, the physiological alarm status of SpO_2 does not change.	
Perfusion Index (PI)	PI measurement range and accuracy ◆ Comen SpO_2 range: 0.05 ～20%; accuracy: not defined; ◆ Masimo SpO_2: 0.02% ～20%; accuracy: not defined;	
	PI Resolution ◆ Comen SpO_2: 0.05%～9.99%, resolution: 0.01%, 10.0% ～20.0%, resolution: 0.1%. ◆ Masimo SpO_2: 0.02% ～9.99%, resolution: 0.01%. 10.0%～20.0%, resolution: 0.1%.	
Signal IQ (SIQ) indicator	Masimo SpO_2 and Comen SpO_2 modules have the SIQ feature.	
Setting of pitch tone	Provide setting of Pitch Tone: the pitch of a pulse can vary with SpO_2 value	

9) PR Specifications

Item	Specification
Measurement range resolution, and accuracy	1) Comen SpO_2: ◆ Measurement range: 20bpm-300bpm; ◆ Resolution: 1bpm; ◆ Measurement error: ±2bpm. 2) Masimo SpO_2:

	◆ Measurement range: 25bpm-240bpm; ◆ Resolution: 1bpm; ◆ Measurement error: ±3bpm (non-motion) or ±5bpm (during motion). 3) Nellcor SpO_2 ◆ Measurement range: 20bpm-300bpm; ◆ Resolution: 1bpm; ◆ Measurement error: ±3bpm in 20bpm~250bpm range; 251 bpm～300 bpm: not defined 4) Comen NIBP: ◆ Measurement range: 30bpm-300bpm; ◆ Resolution: 1bpm; ◆ Measurement error: ±3bpm or ±3%, whichever is greater.	
Setting of average time of PR from SpO_2	For Comen SpO_2, the sensitivity of SpO_2 can be set to high, med and low, and the corresponding pulse rate average time is short, medium and long	
PR alarm settings	Adu mode	Upper alarm limit: (lower alarm limit + step) bpm~300bpm; lower alarm limit: 20bpm~ (upper alarm limit-step) bpm.
	Ped/Neo mode	Upper alarm limit: (lower alarm limit + step) bpm~300bpm; lower alarm limit: 20bpm ~ (upper alarm limit-step) bpm.
	Step	20～40 bpm: 1bpm; 41～300bpm: 5bpm

10) Resp Specification

Name	Specification	
Resp measurement range and accuracy	Range	4 rpm~70rpm
	Accuracy	±3rpm
	Resolution	1rpm
Manual entry range of RR	0rpm~150rpm。	
Time to first measurement (from Comen SpO_2)	≤30s	

11) Temp Specifications

Name	Specification	
The body temperature measurement meets the requirements of ISO 80601-2-56+A1		
Measurement range and accuracy	IRT10 TEMP	Range: 34.0℃～42.2℃(93.2℉~108℉) Error: 35.0℃～42.0℃, Error: ±0.2℃(±0.4℉) (Excluding sensor errors); Other range: ±0.3℃(±0.5℉)

		Clinical accuracy: The 95% CI of clinical deviation for the two groups aged 0 to 1: -0.04~0.00; The 95% CI of clinical deviation for the two groups aged 1 to 5 years old: -0.05~0.01; The 95% CI clinical deviation for the two groups aged 5 and above: -0.06~0.03.
Display resolution	0.1℃ (0.2℉)	

12) CO_2 Specifications

Name	Specification	
Meets the requirements of ISO 80601-2-55		
Comen Capno CO_2 (Sidestream)		Masimo Capno CO_2(Sidestream)
CO_2 Measurement range	0mmHg～150mmHg， 0.0%～19.7%， 0.0kPa~20.0kPa(at760mmHg)	0mmHg～190mmHg， 0.0% ～ 25.0%(at760mmHg)
CO_2 Measurement Accuracy	Under all conditions: a) 0mmHg~40mmHg: 2mmHg; b) 41mmHg~70mmHg: ±5% of reading; c) 71mmHg~100mmHg: ±8% of reading; d) 101mmHg~150mmHg: ±10% of reading	Under all conditions: a) 0 mmHg ～114 mmHg : ± (2.25mmHg+ 4% of reading); b) not defined in the range of 115~190 mmHg
Sampling rate	50ml/min	50ml/min
Sampling rate accuracy	±10ml/min	±10ml/min
Sampling rate	/	20Hz/channel
Total system response time	<5s	<3s (using a 2m sampling line)
CO_2 Stability	a) Short Term Drift: Drift over four hours shall not exceed 0.8 mmHg maximum; b) Long Term Drift: Accuracy specification will be maintained over a 120 hour period	No drift
Warm-up time	CO_2 waveform extraction: <20s; ≤2 min for full accuracy specification under 25℃	<10s (Note: use after being stored in a temperature of -40 ℃, the warm-up time is 10 min.)
10% to 90% Rise time	＜550ms	＜250ms

awRR measurement range	0 ~ 150rpm	0~150rpm
awRR measurement accuracy:	±1rpm	±1rpm
awRR alarm limit setting	Upper alarm limit: (lower alarm limit + step) ~ 150rpm; Lower alarm limit: 0 rpm ~ (upper alarm limit - step). Step: 0rpm ~20rpm: 1rpm; 21rpm ~ 150rpm: 5rpm	Upper alarm limit: (lower alarm limit + step) ~ 150rpm; Lower alarm limit: 0 rpm ~ (upper alarm limit - step). Step: 0rpm ~20rpm: 1rpm; 21rpm ~ 150rpm: 5rpm
$EtCO_2$ alarm limit setting	Upper alarm limit: (lower alarm limit + 2mmHg) ~ 150mmHg; Lower alarm limit: 0mmHg ~ (upper alarm limit – 2mmHg).	Upper alarm limit: (lower alarm limit + 2mmHg) ~ 190mmHg; Lower alarm limit: 0mmHg ~ (upper alarm limit – 2mmHg).
	Step: 1mmHg	Step: 1mmHg
$FiCO_2$ alarm limit setting	Upper alarm limit: 0mmHg - 76mmHg; lower alarm limit: N/A	Upper alarm limit: 0mmHg - 99mmHg; lower alarm limit: N/A
	Step: 1mmHg	Step: 1mmHg
No Breath time range and step	Adu.: 10s~60s; Neo. /Ped.: 10s~40s. Step:5s	Adu.: 15s~60s; Neo. /Ped.: 15s~40s. Step:5s
Remote alarm delay	The alarm delay time measured from the device signal output port to the remote device: ≤ 2S	
I: E influence	a) When I: E < 2:1: no effect on the measurement accuracy of $EtCO_2$ mentioned above b) When I: E >2:1, the accuracy specifications for $EtCO_2$ are as follows: ◆ IE2: 1: -7%+-4% x every 10bpm (bpm>40) ◆ IE3: 1: -7%+-5% x every 10bpm (bpm>30) ◆ IE4:1: -12%+-6% x every 10bpm (bpm>30)	

13) Wireless Connection (optional function)

The monitor features a wireless connection with IRT10 TEMP produced by Shenzhen Comen Medical Instruments Co., Ltd. and adopts 2.4GHz RF wireless transmission mode. In an unobstructed environment, the maximum distance between the monitor and the in-ear thermometer for normal communication is no less than 10m.

14) Alarm system

Name	Specification
The alarm system meets the requirements of IEC 60601-1-8.	

Appendix III System Alarm Messages

Here we list some of the most important physiological and technical alarm messages.

If the problem still exists after you implement the relevant solution provided below, please contact our maintenance engineers.

Technical alarm types: A fully clearable, B the alarm audio and light are clearable or C Not clearable.

The level of each technical alarm is not adjustable (Except for ECG and SpO_2).

1) Physiological Alarm Messages:

1.1) General Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
XX High	Configurable for High and Med alarms	The corresponding measured parameter value exceeds the upper alarm limit.	Check the patient's condition, and confirm that the patient type and alarm limits are appropriate to the patient.
XX Low	Configurable for High and Med alarms	The corresponding measured parameter value goes below the alarm lower alarm limit.	

Note: "XX" represents the label of physiological parameter such as NIBP, RR, SpO_2, CO_2, PR, etc.

1.2) SpO_2 Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
SpO_2 Desat.	High	The value of patient's SpO_2 is below the alarm lower alarm limit.	Check the patient's condition. Confirm that the patient type and alarm limits are appropriate to the patient.
ΔSpO_2 High	Configurable for High and Med alarms	ΔSpO_2 exceeds alarm limits	Check the patient's condition and confirm whether the alarm settings are appropriate to this patient.

1.3) PR Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
SpO_2 No Pulse	High	Pulse is too weak to be detected.	Check the patient's condition, and the SpO_2 or IBP sensor and sensor's application site.

1.4) NIBP Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
NIBP-S/NIBP-D/NIBP-M Extremely High	High	The value of patient's NIBP exceeds the alarm upper limit of NIBP.	Check the patient's condition. Confirm that the patient type and alarm limits are appropriate to the patient.
NIBP-S/NIBP-D/NIBP-M Extremely Low	High	The value of patient's NIBP is below the alarm lower alarm limit of NIBP.	

1.5) CO_2 Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
Apnea	High	Respiratory rate cannot be measured due to no breaths or weak respiratory signal.	Check the patient's condition; Ensure electrodes, power cables and lead wires are well connected.

1.6) EWS Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
EWS score>N	High or medium	The patient's total EWS score is above the alarm limit.	Check the patient's condition
XX2parameter score=3	medium	The patient's individual parameter score is equal to 3 points.	Check the patient's condition

Note: "N" stands for numbers, and "XX" stands for physiological parameter names, such as RR, SPO_2, BP-S, BP-D, BP-M, PR, Temp, $EtCO_2$, etc.

2) Technical Alarm

Major technical alarms are listed here, including their alarm levels, methods of alarm clearing, and the corresponding causes and solutions.

Technical alarms respond differently when the alarm system is reset. For easy clarification, in this section the technical alarms are classified into three categories according to the responses when the alarm system is reset:

Fully clearable: the technical alarms will be completely cleared.

Partially clearable (the alarm audio and light can be cleared): these technical alarms can have the audio silenced and LED alarms turned off, but a text message remains on screen indicating an alarm has occurred.

Not clearable: the audio reminder of a technical alarm will be muted, and the text message will be displayed with a "√" in front of the message to indicate that this alarm has been checked and confirmed, and the LED alarms keep flashing.

2.1) General Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
XX Comm Stop	High	Not clearable	XX module cannot communicate with the main system.	Contact the manufacturer for maintenance.
XX Comm Error	High	Fully clearable	XX module cannot communicate normally with the main system.	
ZZ Overrange	Low	Not clearable	The measured value of XX parameter exceeds the allowed measuring range of the system.	

Note:

"XX" represents a module name, such as ECG,etc.

"ZZ" represents a label name of physiological parameter, such as PR.

2.2) SpO_2 Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
SpO_2 No Sensor	Low	Fully clearable	SpO_2 main cable is disconnected from the module, or the SpO_2 sensor is not firmly connected with the SpO_2 main cable.	Ensure the sensor and main cables of SpO_2 are well connected. If the alarm still cannot be cleared, please contact the manufacturer for maintenance.
SpO_2 Nellcor Fault. Resetting	Low	Not clearable	There is a Nellcor module error. The system is resetting.	If system resetting fails, or the error still exists after you restart the Monitor, contact the manufacturer for maintenance.
SpO_2 Search Pulse	Prompt	/	The SpO_2 sensor is searching pulse.	Check the patient's condition and if the SpO_2 sensor is connected properly.
SpO_2 Low Perfusion	Low	Not clearable	The SpO_2 sensor is not placed properly or the patient's PI is too low.	1. Connect the SpO_2 sensor correctly.

				2. Change the sensor to another measurement site.
SpO_2 Interference Detected	Low	Not clearable	Patient's excessive movement or electromagnetic interference such as electrotome.	Ensure there is no interference around the sensor; check the connection of SpO_2 lead wire; check the patient's condition and whether a big body movement is made.
SpO_2 Too Much Ambient Light	Low	Not clearable	The ambient light is too strong around the SpO_2 sensor.	Place the sensor in an environment with weak light or cover the sensor end to reduce light interference.
SpO_2 Unknown Sensor	Low	Not clearable	SpO_2 module cannot recognize the sensor.	Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.
SpO_2 Poor Signal Quality	Low	Not clearable	SpO_2 sensor is connected improperly	Check the connection of SpO_2 sensor.
SpO_2 Diagnostic Failed	Low	Not clearable	The diagnosis fails	Reinsert the module.
SpO_2 No Cable	Low	Fully clearable	The Power cable is not connected.	Ensure the cable is well connected; if the error still exists, please replace the sensor.
SpO_2 Incompatible Cable	Low	Not clearable	An incompatible cable is used.	Check the cable, and replace it with a proper one.
SpO_2 Unknown Cable	Low	Not clearable	An unknown cable is used.	
SpO_2 Cable Failure	Low	Not clearable	A defective cable is used.	
SpO_2 Cable Expired	Low	Not clearable	An expired cable is used.	
SpO_2 Incompatible Sensor	Low	Not clearable	An improper sensor is used.	Check the sensor and replace it with a proper one if needed.

SpO_2 Sensor Fault	Low	Not clearable	A defective sensor is used.	
SpO_2 Sensor Expired	Low	Not clearable	An expired sensor is used.	
Check the Default SpO_2 Cable and Sensor	Prompt	/	Check the default SpO_2 Cable and Sensor	/
SpO_2 Cable Near Expiration	Prompt	/	Cable Near Expiration is prompted.	/
SpO_2 Sensor Near Expiration	Prompt	/	Sensor Near Expiration is prompted.	/
Check SpO_2 Sensor Connection	Low	Not clearable	It needs to check the connection of SpO_2 sensor.	Please check the connection of SpO_2 sensor.
SpO_2 Sensor Initializing...	Prompt	/	SpO_2 Sensor Initializing is prompted.	/
Only SpO_2 Reliable	Low	Not clearable	Only SpO_2 is reliable	/
SpO_2 Finger Sensor Off	High/Med,/Low	The alarm audio and light are clearable.	The SpO_2 Sensor is disconnected with the finger.	Check the condition of SpO_2 sensor.

2.3) NIBP Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
NIBP Selftest Error	Low	Fully clearable	An error occurs during NIBP initialization.	Restart the system; if the error still exists, contact the manufacturer for maintenance.
NIBP Pneumatic Leak	Low	Fully clearable	A leak exists in the NIBP gas circuit.	Check the connection of each part or replace the cuff with a new one. If the error still exists, contact the manufacturer for maintenance.
NIBP Pressure Overrange	Low	Fully clearable	An error occurs during measuring the curve, and the system cannot perform the measurement analysis calculation.	

NIBP Air Leak	Low	Fully clearable	NIBP cuff is poorly connected, or a leak exists in the NIBP gas circuit.	
NIBP Air Pressure Error	Low	Fully clearable	An error occurs during measuring the curve, and the system cannot perform the measurement analysis calculation.	
NIBP Weak Signal	Low	Fully clearable	An error occurs during measuring the curve, and the system cannot perform the measurement analysis calculation.	Check whether the patient type is selected correctly; Check the connection of each part replace the cuff with a new one. If the error still exists, contact the manufacturer for maintenance.
NIBP Excessive Motion	Low	Fully clearable	The patient moves his/her arm.	Check the connection of each part and patient's condition, and measure again. If the error still exists, contact the manufacturer for maintenance.
NIBP Signal Saturated	Low	Fully clearable	An error occurs during measuring the curve, and the system cannot perform the measurement analysis calculation.	
NIBP System Failure	High	Fully clearable		
NIBP Measure Timeout	Low	Fully clearable		
NIBP Overpressure	Low	Fully clearable	The gas circuit may be folded or the module fails.	Check whether the gas circuit is blocked. Check the patient's condition. If the error still exists, contact the manufacturer for maintenance.
NIBP Block	Low	Fully clearable	The discharge valve may be blocked.	Check whether the airway tube is bent sharply or blocked; if the error still exists, contact the manufacturer for maintenance.

NIBP Need Calibration	Prompt	/	NIBP Need Calibration is prompted	/
NIBP Cuff Type Error	Low	Fully clearable	The cuff type may not match with the set patient type.	Check whether the patient type is selected correctly; Check the connection of each part or replace the cuff with a new one. If the error still exists, contact the manufacturer for maintenance.

2.4) CO_2 Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
CO_2 Standby	Prompt	/	CO_2 work mode is standby	Set CO_2 work mode to measuring mode.
CO_2 Sampling Line Clogged	Low	Not clearable	AG Sampling Line Clogged	Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
CO_2 No Sampling Line	Low	Fully clearable	The sampling line is not or poorly connected.	1. Ensure the sampling line is properly connected. 2. Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
CO_2 Replace Adapter	Low	Not clearable	The adapter malfunctions.	Check and replace the adapter; if the error still exists, contact the manufacturer for maintenance.
CO_2 No Adapter	Low	Fully clearable	The adapter is not or poorly connected.	
CO_2 Out Of Accuracy Range	Low	Not clearable	The measured value exceeds the nominal accuracy range.	Follow the nominal accuracy range specified by the manufacturer.
CO_2 Inner Temp Overrange	Low	Not clearable	The ambient temperature is too	1. Decrease the ambient temperature.

			high or the module fails.	2. Take out and reinsert the CO_2 module. 3. If the error still exists, the module may be inoperative. Contact the service personnel for maintenance.
CO_2 Factory Calibration Lost	Low	Not clearable	The factory calibration data of CO_2 module is lost.	Reinsert the module; If the error still exists, please contact the manufacturer for maintenance.
CO_2 Motor Speed Out Of Bounds	Low	Not clearable	The CO_2 motor speed exceeds the allowed range.	
CO_2 Atm Pressure Overrange	Low	Not clearable	The ambient pressure exceeds the allowed module working pressure range or the module fails.	1. Confirm the current ambient baropressure does not exceed the environmental specifications required by this monitor, and the baropressure is not affected by external interference sources. 2. Reinsert the CO_2 module. If the error still exists, contact the service personnel for maintenance.
CO_2 Need Zero	Low	Not clearable	CO_2 Zero is required.	Perform the CO_2 Zero in the interface of the CO_2 settings.
CO_2 Software Error	Low	Not clearable	A software error occurs in the CO_2 module.	Reinsert the module; If the error still exists, please contact the manufacturer for maintenance.
CO_2 Hardware Error	Low	Not clearable	A hardware error occurs in the CO_2 module.	
CO_2 Calibration Required	Low	Not clearable	CO_2 module calibration required	Return to the manufacturer for calibration.

2.5) IT-Network Technical Alarm

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
CMS Disconnected	Low	The alarm audio and light are clearable	The connection between the monitor and CMS is disrupted.	Check the IT-Network connection.
CMS Network Conflict	Low	The alarm audio and light are clearable	There are monitors with the same IP connected to CMS.	Check the configuration of IP address,
IP Conflict	Prompt	/	The IP address of monitors are the same.	Check the network connection.
MAC Conflict	Prompt	/	The MAC address of monitors are the same.	Check the network connection.

Note: XX represents the department; YY represents the room number; ZZ represents bed number. If the bed number is not entered, the network bed number will be displayed.

2.6) Power Supply Technical Alarm

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
Low Battery	Med	Not clearable	The battery capacity is low.	Connect to mains supply and charge the battery.
Battery is critically low	High	Not clearable	The battery is near depletion and would shut down.	Connect to mains supply and charge the battery.

2.7) Recorder Technical Alarm

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
Recording…	Prompt	/	The recorder is printing.	/
Recorder Head Hot	Low	Not clearable	The recorder is printing for a long time.	Stop printing and wait until it cools down.
No Record Paper	Low	The alarm audio and light are clearable	There is no recorder paper or it is not installed well.	Reload the recorder paper.
No Recorder Connected	Prompt	/	No recorder connected.	Please insert the recorder module.

2.8) EWS Technical Alarm

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
EWS Score needs to be confirmed	Med	Fully clearable	The setting of confirming to save has been enabled in EWS	After confirming, the score will be saved, and then the alarm will stop
EWS param Supp.O_2 is timeout	Low	Fully clearable	param Supp.O2 exceeds the set duration	After it's timeout, the value can be manually updated or automatically cleared after 5 minutes, and then the alarm will stop
EWS param SpO2 is timeout	Low	Fully clearable	param SpO2 exceeds the set duration	After it's timeout, the value can be manually updated or automatically cleared after 5 minutes, and then the alarm will stop
EWS param PR is timeout	Low	Fully clearable	param PR exceeds the set duration	After it's timeout, the value can be manually updated or automatically cleared after 5 minutes, and then the alarm will stop
EWS param LOC is timeout	Low	Fully clearable	param LOC exceeds the set duration	After it's timeout, the value can be manually updated or automatically cleared after 5 minutes, and then the alarm will stop

2.9) Other Technical Alarm/information message

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
Storage Space Full	High, Med or Low	The alarm audio and light are clearable	History profile has filled the available disk memory. Or admitted too many patients.	Usually the monitor will delete the history profile. If the alarm condition last long, please contact the service personnel for maintenance.
Storage Disk Error	/	Fully clearable	Storage disk failure or file corruption.	Restart the monitor and Format the storage disk. If the alarm condition remains, contact the service personnel for maintenance.

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Appendix IV Default Configuration Information

1. **Parameters Settings**

1) NIBP Default Settings

Name	Default settings	
NIBP-S	Alarm On/Off	On
	Alarm Limits (mmHg)	ADU: 90~160 PED: 70~120 NEO: 50~90
	Alarm Priority	Med
NIBP-D	Alarm On/Off	On
	Alarm Limits (mmHg)	ADU: 50~90 PED: 40~70 NEO: 30~60
	Alarm Priority	Med
NIBP-M	Alarm On/Off	On
	Alarm Limits (mmHg)	ADU: 60~110 PED: 50~90 NEO: 35~70
	Alarm Priority	Med
NIBP-S Extreme	Alarm On/Off	Off
	Alarm Limits (mmHg)	ADU: 75~175 PED: 60~130 NEO: 45~95
	Alarm Level	High
NIBP-D Extreme	Alarm On/Off	Off
	Alarm Limits (mmHg)	ADU: 35~105 PED: 30~80 NEO: 25~65
	Alarm Level	High
NIBP-M Extreme	Alarm On/Off	Off
	Alarm Limits (mmHg)	ADU: 45~125 PED: 40~100 NEO: 30~75
	Alarm Level	High
Initial Pressure (mmHg)	ADU: 160 PED: 120 NEO: 100	
Measurement Interval	Wards: 1h Emergency Department: sequence	

	Physician Office: 1h Neo (Neonatal Intensive Care Unit): 1h		
Start Mode	Emergency Department/Ambulatory Surgery Center/:Interval Others: Clock		
Measurement mode	Inflation measurement		
NIBP End Tone	Off		
Venipuncture Pressure	Auto		
Display Alarm Limits	Off		
NIBP Timeout	5min		
Sequence	Phase A	Measurement Times	1
		Measurement Interval	1min
	Phase B	Measurement Times	2
		Measurement Interval	1min
	Phase C	Measurement Times	2
		Measurement Interval	2min
	Phase D	Measurement Times	Off
		Measurement Interval	2.5min
	Phase E	Measurement Times	6
		Measurement Interval	2.5min

2) SpO_2 Default Settings

Masimo, Nellcor and Comen SpO_2

Name	Default settings	
SpO_2	Alarm On/Off	On
	Alarm Limits (%SpO_2)	ADU: 90~100 PED: 90~100 NEO: 90~100
	Alarm Priority	Med
SpO_2 Desat	Alarm On/Off	On
	Alarm Lower Limit (%)	80
	Alarm Priority	High
Sensitivity	Masimo SpO_2: ADU/PED: normal; NEO: APOD Comen SpO_2: High	
Waveform Speed	25mm/s	
PI Display (Masimo and Comen SpO_2)	On	
Signal indicator (Masimo, Nellcor and Comen SpO_2)	Off	
NIBP Simul	Off	
Smart pulse tone (Masimo SpO_2)	On	
Average Time (Masimo and Comen SpO_2)	8s	

SatSecond (Nellcor SpO_2)	Off	
PR	Alarm On/Off	On
	Alarm Limits (bpm)	ADU: 50~120; PED: 75~160; NEO: 100~200
	Alarm Priority	Med
	Alarm Source	Auto
	PR Source	Auto
	Pulse volume	2

3) CO_2 Default Settings

Name	Default settings	
$EtCO_2$	Alarm On/Off	On
	Lower/Upper Alarm Limits (mmHg)	ADU: 25~50 PED: 25~50 NEO: 30~45
	Alarm Priority	Med
	Alarm Outputs	Off
$FiCO_2$	Alarm On/Off	On
	Alarm Upper Limit (mmHg)	4
	Alarm Priority	Med
	Alarm Outputs	Off
Apnea Timeout	ADU: 20s PED: 20s NEO: 15s	
Apnea Time range and step	Range	step
	ADU: 10s~60s	5s
	PED/NEO: 10s~40s	
Work Mode	Measurement	
O_2 Compensation (Comen)	Ambulatory surgery center: 100%; other departments: 16%	
O_2 Compensation (Masimo)	Low	
N_2O Compensation (Masimo)	Off	
Waveform Speed	6.25mm/s	
Scale	50	
Waveform Type	Line	
Balance gas (Comen)	Room air	

4) EWS Default Settings

Name	Default settings	
Score type	NEWS2	
Score confirmation	On	
Auto scoring	Off	
	Intervals	By score

		4h(score: 0)
		2h(score: 1~4)
		1h(score: 5~6)
		30min(score: 7~20)
Manual data timeout	SpO_2	4h
	Support O_2	24h
	PR	1h
	LOC	24h
Auto refresh score	on	
Alarm	off	
EWS score	Alarm on/off	On
	Upper alarm limit	5
	Alarm priority	Med
	Alarm on/off	On
	Upper alarm limit	7
	Alarm priority	High
3 in single parameter	RR	Off
	SPO_2	Off
	BP-S	Off
	PR	Off
	Temp	Off

2. General Settings

1) Alarm

Name	Default settings
Alarm audio volume	2
High priority alarm audio volume	Alarm Vol+2
Reminder Volume	2
Printing Duration On Alarm	20s
Minimum Alarm Volume	2
Alarm audio volume enhance	Off
Increase Volume Delay	30s
Alarm paused/ Alarm audio paused	Alarm paused
Passed time	2 min
Pause 5 min	On
Pause 10 min	On
Pause 15 min	On

Alarm Light	On When Reset (the alarm lights ON when the alarm is reset)
Alarm Reset Reminder	On
Alarm Off Reminder	On
Reminder interval	1 min
SpO_2 Sensor Off	Low
Alarm Delay	6s
SpO_2 Desat. Alm Off	Disabled
Apnea Alarm Off	Disabled
Print Option	Printer

2) Review

Name	Default settings
Review window duration	8 h
Channel of waveform	5
Tubular trend time setting	5 min

3) Screen Setup

Name	Default settings	
Display	Screen Lock Duration	10s
	Brightness	8
	Brightness On Battery	4

4) Record

Name	Default setting
Recording Speed	25mm/s
Record Time	8s
Timed Record Interval	Off

5) Print

Name	Default setting
Printer Type	NET
Printer IP Address	200.200.200.200
Paper Size	A4

6) Manage

Name	Default settings
Department	General monitoring
Default configuration	Load the Latest Configuration

7) Time

Name	Default settings
Date	YYYY-MM-DD
Time	12-hour

Appendix V EMC

NOTE

- The NC serial vital signs monitor complies with the applicable EMC requirements in IEC 60601-1-2, IEC 60601-2-25, IEC 60601-2-27, IEC 80601-2-30, IEC 60601-2-34, ISO 80601-2-55, ISO 80601-2-56, ISO 80601-2-61.
- Please follow the EMC instructions in the User's Manual to install and use the Monitor.
- Portable and mobile RF communication equipment may affect the performance of the monitor. To protect the Monitor against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.
- Refer to the attached guidance and manufacturer's statement.

WARNING

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify the normal operation.
- Class-A equipments are intended to work in industrial environments. Considering this product's conduction disturbance and radiation disturbance, it may be difficult to ensure its EMC in non-industrial environments.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

1. Accessory Information:

The following cables shall be used in accordance with electromagnetic emission and immunity requirements:

Number	Name	Cable length (m)	With shielding	Remarks
1.	SpO_2 probe cable	3.0m	Yes	Selected for test
2.	SpO_2 probe cable	1.0m	Yes	/
3.	SpO_2 probe cable	1.0m	Yes	/
4.	SpO_2 main cable	2.5m	Yes	/
5.	Reusable SpO_2 probe cable	3.0m	Yes	/
6.	Reusable SpO_2 sensor cable	3.0m	Yes	/
7.	Reusable SpO_2 sensor cable	1.0m	Yes	/
8.	Reusable SpO_2 sensor cable	3.0m	Yes	/
9.	Reusable SpO_2 sensor cable	1.0m	Yes	/
10.	Reusable SpO_2 sensor cable	3.0m	Yes	/
11.	Reusable SpO_2 sensor cable	1.0m	Yes	/
12.	Reusable SpO_2 sensor cable	3.0m	Yes	/

Number	Name	Cable length (m)	With shielding	Remarks
13.	Reusable SpO_2 sensor cable	1.0m	Yes	/
14.	Reusable SpO_2 sensor cable	1.0m	Yes	/
15.	Reusable SpO_2 sensor cable	1.0m	Yes	/
16.	Reusable SpO_2 sensor cable	1.0m	Yes	/
17.	Disposable SpO_2 sensor cable	0.9m	Yes	/
18.	Disposable SpO_2 sensor cable	0.5m	Yes	/
19.	Disposable SpO_2 sensor cable	0.5m	Yes	/
20.	Disposable SpO_2 sensor cable	0.9m	Yes	/
21.	Disposable SpO_2 sensor cable	0.9m	Yes	/
22.	Disposable SpO_2 sensor cable	0.5m	Yes	/
23.	Disposable SpO_2 sensor cable	0.5m	Yes	/
24.	Disposable SpO_2 sensor cable	0.9m	Yes	/
25.	SpO_2 main cable	2.5m	Yes	/
26.	SpO_2 sensor cable	0.9m	Yes	/
27.	SpO_2 sensor cable	0.9m	Yes	Selected for test
28.	SpO_2 sensor cable	0.9m	Yes	/
29.	SpO_2 main cable	3.0m	Yes	Selected for test
30.	SpO_2 sensor cable	1.1m	Yes	Selected for test
31.	SpO_2 sensor cable	1.1m	Yes	/
32.	SpO_2 main cable	3.0m	Yes	Selected for test
33.	Power cable	3.0 m	No	Selected for test
34.	Ground cable	2.5 m	No	Selected for test
35.	Spare battery connection cable	1.5m	No	Selected for test

2. Essential Performance

1. HR/Resp Measurement Accuracy
2. SpO_2 Measurement Accuracy
3. PR Measurement Accuracy
4. Body Temperature Measurement Accuracy
5. NIBP Measurement Accuracy
6. $EtCO_2$ Measurement Accuracy

Guidance and manufacturer's declaration –electromagnetic emission		
NC/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo vital signs monitor is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Conducted and radiated RF emissions CISPR 11	Group 1	NC/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo vital signs monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted and radiated RF emissions CISPR 11	Class A	NC/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo vital signs monitor is suitable for use in all establishments other than domestic ones and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guide and Manufacturer's Statement – Electromagnetic Immunity			
NC/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo vital signs monitor is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guide**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV, 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 (EFT/B) IEC 61000-4-4	± 2 kV for input AC and DC power input port ± 1 kV for SIP/SOP port 100 kHz repetition frequency	± 2 kV for input AC and DC power input port ± 1 kV for SIP/SOP port 100 kHz repetition frequency	Connect the equipment to supply mains of professional healthcare facility other than public supply mains SIP/SOPS whose maximum cable length is less than 3 m in length are excluded

Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Connect the equipment to supply mains of professional healthcare facility other than public supply mains
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T; 0.5 cycle (＞95 % dip in U_T) 40 % U_T; 5 cycle (60 % dip in U_T) 70 % U_T; 25cycle (30 % dip in U_T) <5% U_T; 5s (＞95 % dip in U_T)	<5 % U_T; 0.5 cycle (＞95 % dip in U_T) 40 % U_T; 5 cycle (60 % dip in U_T) 70 % U_T; 25cycle (30 % dip in U_T) <5% U_T; 5s (＞95 % dip in U_T)	The mains power supply should be of typical quality for commercial or hospital use. To ensure the continuously safe use running of the monitor, It is recommended to use an uninterruptable power supply or a battery.
Rated power frequency magnetic fields IEC 61000-4-8 (50 /60Hz)	30 A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T refers to the AC voltage when the test voltage is not applied yet.			

Guide and Manufacturer's Statement – Electromagnetic Immunity			
NC/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo vital signs monitor is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guide**
RF conduction IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 Vrms 3 V/m	Do not use any portable or mobile RF communication equipment within the recommended distance from any part of the monitor (including the cable). Except as indicated on page V-11, such recommended separation distance calculated from the equation according to the frequency of the transmitter. .

RF radiation IEC 61000-4-3			Recommended separation distance: d = $1.2\sqrt{P}$ d = $1.2\sqrt{P}$ 80 MHz to 800 MHz d = $2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) The field intensity of fixed RF transmitters is measured by surveying[a] the electromagnetic field and should be lower than the compliance level in either frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency band was applied.

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

a Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify essential performance. This equipment may cause radio interference or may disrupt the operation of nearby equipment. If anything abnormal occurs, it may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.

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

Recommended Separation Distance between Portable and Mobile RF Communication Equipment and The Device

NC/NC6A/NC6C/NC6Neo/NC7/NC7A/NC7C/NC7Neo vital signs monitor is intended to work in an electromagnetic environment with controlled RF radiation disturbance. The consumer or user of the monitor should prevent electromagnetic interference by maintaining the following recommended separation distance between the portable and mobile RF communication equipment (transmitters) and this product according to the maximum output power of the communications equipment except as indicated.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz- 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

In case of any maximum rated output power other than listed above, use the formula ("*P*" refers to the transmitter's maximum rated output power (W) learnt from the transmitter manufacturer) in the relevant transmitter frequency column to calculate the recommended isolation distance "d" (m).

Frequencies of portable and mobile transmitters for which the recommended separation distance is 30 cm (12 inches)

NOTE 1: At 80 MHz and 800 MHz, the higher frequency band was applied.

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

2 Radio Management Compliance

RF Parameters

Parameters	IEEE 802.11b/g/n (2.4G)	IEEE 802.11a/n (5G)
Frequency	ETSI: 2.4GHz ~2.483GHz FCC: 2.4GHz ~2.483GHz MIC: 2.4GHz ~2.495GHz SRRC: 2.4 GHz ~2.483GHz	ETSI: 5.15GHz ~5.35GHz, 5.47GHz ~5.725GHz FCC: 5.15GHz ~5.35GHz, 5.725GHz ~5.82GHz MIC: 5.15GHz ~5.35GHz, 5.47GHz ~5.725GHz SRRC: 5.15GHz ~5.35GHz, 5.725GHz ~5.85GHz
Modulation	DSSS, OFDM	
Transmit power	⩽20 dBm (Average) ⩽33 dBm (Max)	

Appendix VI Consideration for Environmentally Conscious Design

1. Instructions for Minimizing Environmental Impact during Normal Use

This part is compiled based on the requirements of *Clause 4 Protection of Environment, 4.5.2 Instructions for minimizing environmental impact during normal use* of IEC 60601-1-9.

According to the requirements of this clause, manufacturer shall provide instructions for minimizing the environmental impact of the ME equipment during normal use in the accompanying documents.

The instructions cover the following items (Table 1).

Table 1 The requirements of Clause 4.5.2 and Instructions provided by manufacturer

The requirements of Clause 4.5.2	Instructions provided by manufacturer
1) Instructions on how to install the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Try to keep the integrity of the non-disposable packing material and put away the packing materials for future use or put into the specified location where complying with the rules and regulations of the Local and the Hospital. Avoid overusing the cleaning reagents and other substances. For the reusable accessories, clean it with specified reagent and put away, and for the disposable one, deal with it in a collective way and put into the specified location where complying with the rules and regulations of the Local and the Hospital. If not specified, please follow the rules and regulations of the Local and the Hospital.
2) Instructions on how to use and maintain the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Use the specified accessories and cleaning and disinfection reagent to avoid harm to the machine and accessories and reduction of the service life. Use the medical device strictly following the instruction manual. And for maintaining the medical device, always dilute according to the manufacturer's instructions or use lowest possible concentration. Never use bleach. Do not mix disinfecting solutions (such as bleach and ammonia) as this may result in hazardous or poisonous gases or liquids. When there is a need to maintain, please follow the Instruction for Use or follow the rules and regulations of the Hospital.
3) Consumption during NORMAL USE (e.g. energy, consumable materials/parts, disposables, water,	During normal use of this device, it will consume electricity (alternate current and direct current-battery). The disposable electrode is also consumed and shall be disposed following the

gasses, chemicals/reagents etc.);	rules. For cleaning or disinfection for the cables and machine, the water and ethanol or isopropanol will be used and the waste liquid shall be thrown following the rules.
4) Emissions during NORMAL USE (e.g. WASTE water, WASTE consumable materials, acoustic energy, heat, gasses, vapours, particulates, HAZARDOUS SUBSTANCES and other WASTE);	During normal use, it is expected there will be some consumption of the medical device. To avoid unnecessary consumption such as acoustic energy, heat, gases, hazardous substances, etc, it's recommended that on the premise of normal operation, turn down the volume of alarm so that much interference will not be exerted to the environment. Also turn off the unused module in time to reduce the unnecessary heat emission and electricity consumption.
5) Information on the location within the ME EQUIPMENT of HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials.	The battery is located on the back of the machine. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

2. **Information for End of Life Management**

This part is compiled based on *Clause 4 Protection of Environment, 4.5.3 Information for end of life management* of IEC 60601-1-9.

According to the requirements of this clause, the manufacturer shall provide the responsible organization with information for the proper disposal of the ME equipment at *End of Life* (EOL). And the manufacturer shall make available information to waste treatment facilities necessary for the environmentally responsible management of end of life ME equipment.

The information shall contain the following items (Table 2).

Table 2 The requirements of Clause 4.5.3 and Instructions provided by manufacturer

The requirements of Clause 4.5.3	Instructions provided by manufacturer
1) The location of components and parts within the ME equipment that contain stored energy or pose other hazards that can result in an unacceptable risk to disassemblers or others and methods for controlling such risks.	The battery is located on the back of the device. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.
2) The identity and location of hazardous substances requiring special handling and treatment	The battery is located on the back of the device. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

3) Disassembly instructions sufficient for the safe removal of these hazardous substances including radioactive sources and induced radioactive materials within the ME equipment.	For other hazards that may result in unacceptable risk, the main concern is the handling with battery: Risk of fire, explosion, or burns. Do not crush, puncture, disassemble or short circuit the battery. Do not dispose of the battery in fire or water. Do not place the battery in an environment whose temperature is above 60℃（140℉）. Store the battery in the -20℃（-4℉）to 60℃(140℉) environment. Use the specified charger only. Read instructions for use. Maximum Recommended Ambient is 45℃(125℉). Dispose of used batteries promptly and in an environmentally-responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements. As for disposing of the medical device, to avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the medical device appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories such as thermometers, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

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Appendix VII Terminology List

Term	Meaning
AAP	American Academy of Pediatrics
AC	Alternating Current
ACCF	American College of Cardiology Foundation
AG	Anaesthesia Gas
AHA	American Heart Association
AM	Amplitude Modulation
ATMP	Atmospheric Pressure
awRR	Airway Respiratory Rate
bpm	Beat Per Minute
BTPS	Body Temperature and Pressure, Saturated
CAA	Clinical Assistive Application
CCHD	critical congenital heart disease
cm	centimeter
DIA	diastolic
ESD	Electrostatic discharge
ESU	electrosurgical unit
$EtCO_2$	end-tidal carbon dioxide
EWS	Early warning system
$FiCO_2$	fraction of inspired carbon oxygen
FiO_2	fraction of inspired oxygen
FM	frequency modulation
GCS	Glasgow Coma Scale
GHz	gigahertz
HR	heart rate
Hz	hertz
ICU	intensive care unit
IEC	International Electro-technical Commission
IP	internet protocol
kg	kilogram
kPa	kilopascal
MAP	Artery mean pressure
NIBP	noninvasive blood pressure
PCBA	Printed Circuit Board Assembly
PI	Perfusion index
PR	pulse rate
Resp	respiration
RL	right leg

Term	Meaning
rpm	breaths per minute
SACHDNC	Secretary's Advisory Committee on Heritable Disorders in Newborns and Children
SpO_2	arterial oxygen saturation from pulse oximetry
SYS	systolic pressure
TD	temperature difference
Temp	temperature
USB	universal serial bus

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