

LEPU MEDICAL

Patient Monitor

(AIVIEW VX)

Operator's Manual

I Preface

Copyright

This manual contains proprietary information protected by copyright law. All rights reserved. Without the prior written consent of the manufacturer, no part of this manual shall be copied or reproduced in any form or by any means.

Manual Purpose

The instructions for safe operation of the product in keeping with its function and intended use are contained in this manual. In order to operate the product properly, and protect patient and operator from injury, compliance with this manual is first priority.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. Please keep in touch with the manufacturer or your local distributor if you have any questions.

As an indispensable portion of the product, this manual should always be placed near the device so that it can be got easily when needed.

Intended Audience

This manual applies to clinical professionals with knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Only clinical professionals, anyone who are under their guidance or people who have been trained adequately can use this monitor. The unauthorized or the untrained are forbidden to operate the product.

About this Manual

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Contact Information

Manufacturer: Shenzhen Creative Industry Co., Ltd.
Address: Floor 5, BLD 9, BaiWangXin High-Tech
Industrial Park, Songbai Road, Xili Street,
Nanshan District, 518110 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA
Website: www.creative-sz.com
E-mail: info@creative-sz.com
Tel: +86 755 26431658
Fax: +86 755 26430930

EC Representative: Shanghai International Holding Corp. GmbH
(Europe)
Address: Eiffestraße 80, 20537, Hamburg Germany

II Manual Conventions

Illustrations

Setup or data displayed on your monitor may not be necessarily shown in all illustrations in this manual, because they are used only as examples.

All names mentioned in this manual and illustrations are fictitious. Any similarity is purely coincidental.

General Notes

- *Italic* text is used to indicate prompt information or quote the referenced chapters or sections.
- [XX] is used to indicate the character string in the software.
- → is used to indicate operational procedures.

Special Notes

The warnings, cautions and notes in this manual are used to remind readers of some specific information.

Warning

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

Caution

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

Note

Provides application tips or other useful information to ensure that you get the most from your product.

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Chapter 1 Safety

1.1 Safety Information

This chapter provides important safety information related to the use of the device. In other chapters, it also contains relevant safety information for specific operations.

1.1.1 Warning

- | | |
|----------------|--|
| Warning | Before putting the system into operation, the operator must verify that the device, connecting cables, and accessories are in correct working order and operating condition. |
| Warning | The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement. |
| Warning | To avoid explosion hazards, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents. |
| Warning | Using the device in the environment of flammable anaesthetic agents may be at risk of explosion. |
| Warning | Please peruse the relative content about the clinical restrictions and contraindication. |
| Warning | If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination. |
| Warning | This device is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this operator's manual before operation, especially all the contents with warnings and attention signs. |
| Warning | To prevent the risk of the short circuit and to ensure the ECG signal quality, the device must be properly grounded. |
| Warning | The summation of leakage current should never exceed leakage current limits while several other devices are used at the same time. |
| Warning | Make sure that the applied parts never contact other conductive parts. |
| Warning | Equipment connected to the device must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). |

Warning

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify that it can run normally in the configuration in which it is used.

Warning

Do not touch the patient or metal parts in contact with the patient during defibrillation. Otherwise serious injury or death could result.

Warning

The monitor is defibrillation-proof. Verify that the accessories can function safely and normally, and the monitor is grounded correctly before conducting defibrillation. Operate the device on battery power if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.

Warning

This device is used for a single patient at a time.

Warning

Disconnect the monitor and sensors from the patient before MRI scanning. Using them during MRI could cause burns or adversely affect the MRI image or the monitor's accuracy.

Warning

If you are in doubt about the accuracy of any measurement, firstly check the patient's vital signs by any alternative means, and then make sure the monitor is functioning properly.

Warning

The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Warning

Do not place the device or accessories in any position that might cause it to fall on the patient.

Warning

All the connecting cables and tubes of the applying parts should be kept away from the patient's neck to prevent any possible suffocation of the patient.

Warning

Before each use, check the device and its accessories for safe and normal operation. Do not use this device to monitor the patient if there are indications of damage or reminders of error. Please contact your local distributor or the manufacturer.

Warning

To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

1.1.2 Caution

Caution

All the parts of the monitor should not be replaced at will, substitution of a component different from that supplied by the manufacturer might result in measurement error. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused. No modification of this device is allowed.

Caution

Do not immerse the monitor or its accessories in liquid to clean.

Caution

Connect only approved equipment to this device. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance with IEC 60601-1-1.

Caution

Store and use the device in specified environmental condition. The monitor and accessories may not meet the performance specification due to aging, stored or used outside the specified temperature and humidity range.

Caution

If the monitor falls accidentally or has other functional failures, it cannot be used any more. The safety performance and technical indicators must be tested in detail, and it can be used only after the test results are qualified.

1.1.3 Notes

Note

The software copyright of the monitor is solely owned by the manufacturer. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.

Note

All combinations of equipment must be in compliance with the standard IEC 60601-1.

The device and accessories must be disposed of in compliance with local regulations at the end of their service lives.

Note

Put the device in a location where it can be easily viewed and operated. Do not locate the device in a place difficult to access the mains plug.

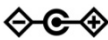
Note

The monitor can be configured with different parameters. This manual describes all features and options. The monitor you purchase may not cover all functions described below.

Note

All illustrations in this manual serve as examples only and may differ from what is seen.

1.2 Device Symbols

Symbols	Function	Symbols	Function
	Power switch		USB connector
	Dispose of in accordance to your country's requirements		Direct current power connector

Symbols	Function	Symbols	Function
	Serial number		Device or part of CF type with defibrillation proof
	Refer to Operator's Manual (Background: blue; Symbol: white)		Non-ionizing electromagnetic radiation
	Manufacturer		Date of Manufacture
	General warning sign (Background: yellow; Symbol and line: black)		

Note

Your device does not necessarily have all of the above symbols.

Note

This manual is printed in Black and White.

Chapter 2 Product Introduction

2.1 Intended Use

The monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, respiration (Resp), body temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), and end-tidal carbon dioxide (EtCO₂). The monitor is to be used in hospitals, clinics, community health centers or other medical care facilities by qualified clinical professionals or under their guidance.

2.2 Contraindication

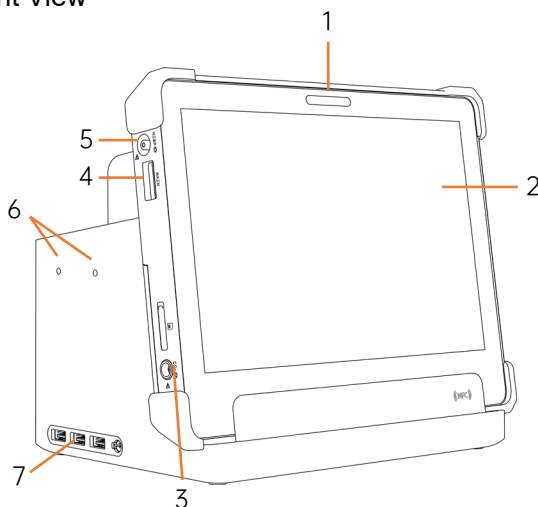
No contraindication.

2.3 Features

- Support patient management.
- Multiple views, which can be easily shifted for different monitoring purpose.
- The view can be flexibly configured.
- Lead off detection function, and able to send out an alarm.
- Support the commonly used clinical tool of early warning score (EWS).
- Waveform freezing.
- Support pulse modulation tone and key tone.
- Support large-capacity storage.
- Support touch screen, multi-touch (zoom, multi-finger slip, etc.).
- Provide quick keys.
- Protection against defibrillator discharge, resistance against the interference from electro-surgical unit, and cardiac pacemaker pulse detection and inhibition.
- Be capable of networking with the central monitoring system.
- USB data export function and application software upgrade are available.
- Provide a recorder for thermal print.

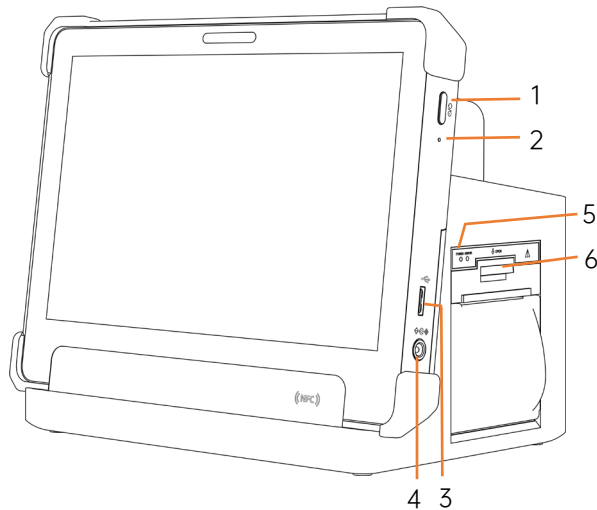
2.4 Product View

2.4.1 Front Right View



- 1 Alarm indicator: When an alarm occurs, this lamp lights and flashes corresponding with the alarm priority.
 - High priority alarms: the lamp flashes red.
 - Medium priority alarms: the lamp flashes yellow.
 - Low priority alarms: the lamp lights in steady blue.
- 2 Touchscreen
- 3 CO₂ module connector
- 4 Multi-function adapter connector: Connect the integrated adapter to the accessories of multiple parameters (ECG, SpO₂, Temp).
- 5 NIBP cuff connector
- 6 Installation holes for CO₂ module support
- 7 USB connector (Base)

2.4.2 Front Left View



- 1 Power switch: Turn on/off the monitor.
- 2 Power switch indicator:

Green (Flashing)	In the state of power-on, the battery is fully charged	
Yellow (Flashing)	In the state of power-on, the battery is not fully charged	
White (Flashing)	In the state of power-on, no external DC power is connected	
Green (Steady)	In the state of power-off, the battery is fully charged	
Yellow (Steady)	In the state of power-off, the battery is not fully charged	
Off	In the state of power-off, no external DC power is connected	

- 3 USB connector (Main Unit)
- 4 DC adapter connector
- 5 Recorder indicator

Green light	On	Normal recorder power supply
	Off	Abnormal recorder power supply
Red light	On	The recorder is out of paper, or the thermal paper is not loaded

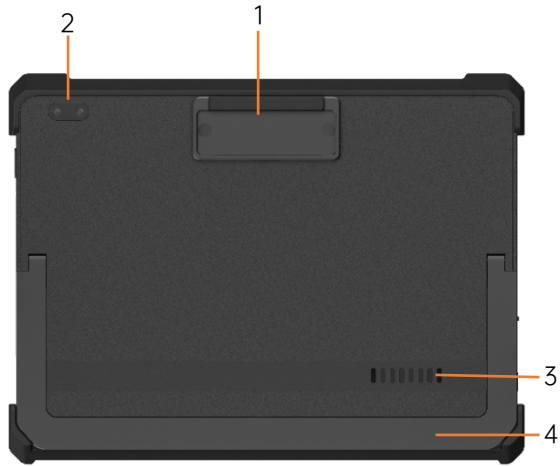
properly

Off

The recorder work normally

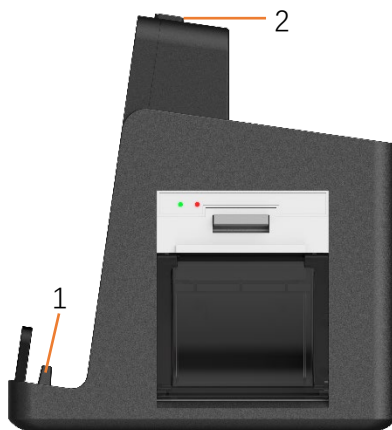
- 6 Open button for recorder door

2.4.3 Rear View of Main Unit



- 1 Latch for main unit and base
- 2 Camera and flash
- 3 Speaker
- 4 Main unit support

2.4.4 Base View

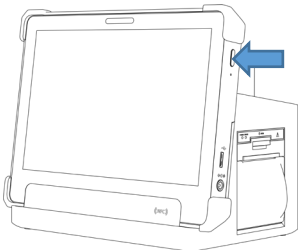
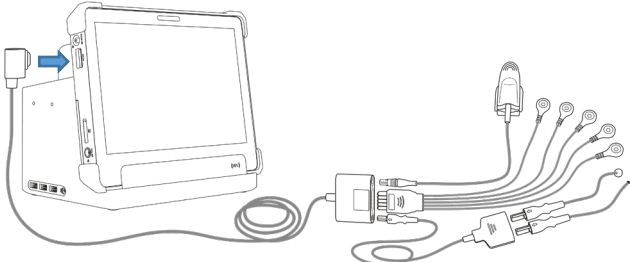
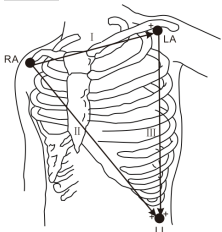
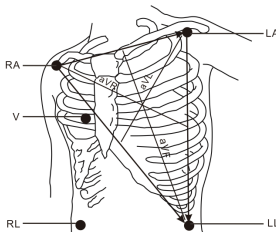
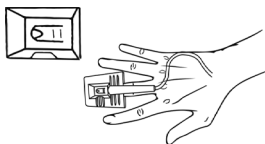


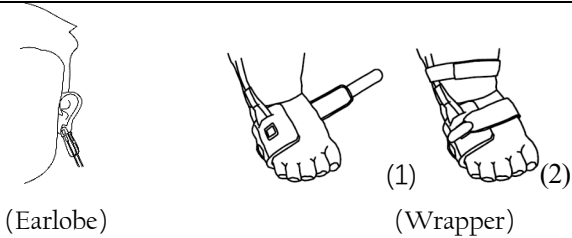
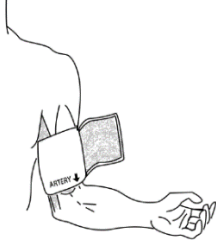
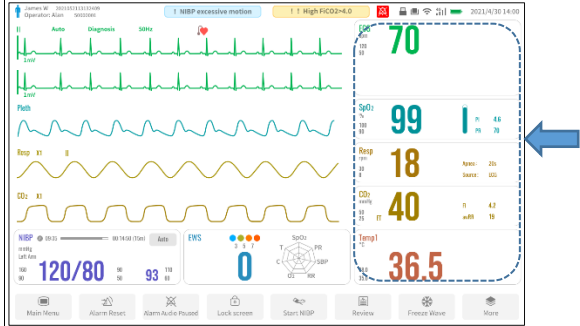
1 Main unit/base connector

2 Main unit release button:

When the main unit is connected to the base, press this button to release the main unit.

Chapter 3 Quick Start

1. Turn on the monitor	
2. Connect	- Connect monitor, multi-functional adapter, and ECG, SpO₂, and Temp accessories.  - Connect the NIBP cable with the NIBP connector.
3. Apply accessories	ECG  (3 electrodes)  (5 electrodes) SpO₂  (Finger clip)  (Finger cot)

	 (Earlobe) (1) (2) (Wrapper) Temp Measurement site: skin, axil, rectum NIBP 
4. Admit a patient	Select [Main Menu] → [Patients] → [New Patient] tab → Select one method to admit a patient (Quick admit or standard admit)
5. Set parameters and alarms	- Set parameters Click any position in the parameter area of the main screen to set each monitoring parameter in the pop-up window.  - Set alarms When setting parameters, select [Alarm Setup] button at the lower part of the pop-up window, and set the alarm of each monitoring parameter in the new pop-up window.

6. Select display screen and work mode	• Select display screen Select [Main Menu] → [Screens] → [Choose Screen] tab. • Select work mode Select [Main Menu] → [Screens] → [Work Mode] tab
7. Discharge the patient	You can discharge the patient when the monitoring is completed. Select [Main Menu] → [Patients] → [Patient Info] tab → [Patient Info] → [Discharge] button.

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Chapter 4 Installation and Connection

4.1 Environment Requirements

The monitor can be installed on a wall, desktop or a trolley. Select a place where the infrastructure and mains supply is well set up. Place the monitor in a safe and stable location where it can easily be viewed and operated.

The operating environment of the device must meet the requirements specified in this manual. Otherwise, unexpected consequences, e.g. damage to the device, could result.

The environment where the monitor is used shall be reasonably free from noise, vibration, dust, corrosive, flammable and explosive substances.

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

Warning	Place the monitor in a location from direct sunlight to avoid abnormal internal temperature rise
----------------	--

Warning	Do not immediately turn on the monitor when it is damp. Wait till it air dries before use.
----------------	--

4.2 Power Supply

4.2.1 Connecting the DC Power

- 1 Take out the accompanying DC power connector from the package.
- 2 Insert one end of the DC power adapter into the DC power connector on the main unit, and the other end to the three-wire outlet of power source with protected-earth.
- 3 Verify that the power switch indicator is On.

4.2.2 Using the Battery

The device will automatically run from battery power in case of power failure of the DC power supply.

Warning

Because of the power consumption during the storage and transportation, the monitor may run out of battery power. The battery must be charged when the monitor cannot be turned on.

Warning

The battery is charged whenever the device is connected to the DC power source regardless of whether or not the device is currently turned on.

4.3 Preparing Recorder

You can use recorders to print patient information and data.

4.3.1 Loading the Recording Paper

- 1 Press and hold down the open button to open the recorder door.
- 2 Insert a new roll of paper into the paper compartment properly, with printing side facing upwards.
- 3 Pull about 2 cm of the paper out, and then close the recorder door.

Chapter 5 Functions

5.1 Turning On/Off Monitor

Turning On the Monitor

Press the power switch for about 2-3 seconds.

After the monitor runs, it displays a start-up screen and then jumps to the main screen. This indicates that the monitor is started successfully.

Turning Off the Monitor

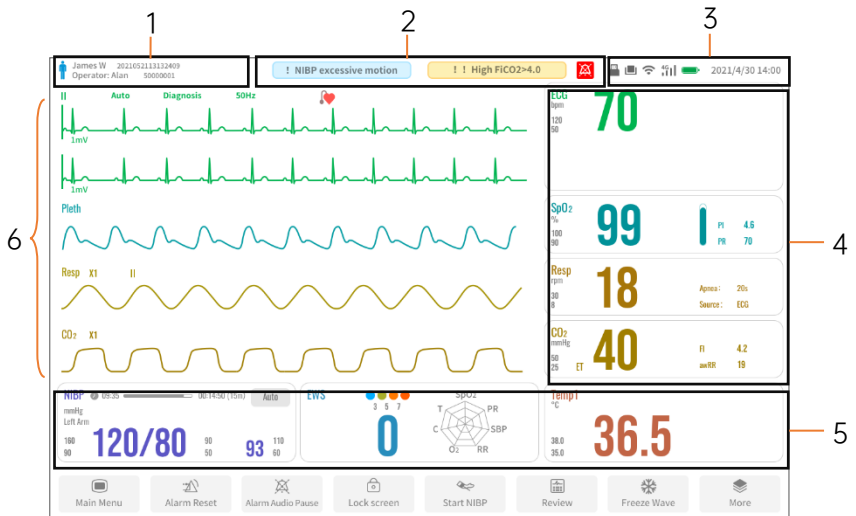
Press the power switch for about 1-2 seconds, and a window will pop up and select **[Power off]**.

You can press and hold the power switch for 10 seconds to forcibly shut down when it cannot be shut down normally. However, this operation may cause loss or corruption of patient data.

5.2 Screen Display

5.2.1 Screen Introduction

The following figure shows the normal screen:



No.	Description
1	Patient information area: displays patient name, gender, identifier, and so on. Operator information area: display operator ID and name. Patient gender description: - Male (blue): Adult  /Pediatric  /Neonate  - Female (pink): Adult  /Pediatric  /Neonate  - Unknown gender (white): Adult  /Pediatric  /Neonate 
2	Alarm information area: displays physiological and technical alarm messages. Alarm icon area: Displays the current alarm status icon.
3	System status area: Displays network status, battery status, and system time. Network icon:  Indicates Wi-Fi signal strength Base icon:  Indicates that the monitor connects with the base. Battery icon:  Indicates that the battery is almost depleted and needs to be charged immediately. Otherwise, the device will automatically shut down after 5 minutes.  Indicates that no battery is installed or battery fault.  Indicates that the battery is being charged. The filled portion represents the remaining capacity of the battery.  Indicates current battery capacity. The filled portion represents the remaining capacity of the battery. USB drive icon:  indicates that a USB drive is connected.
4	Numeric area of parameter: display the numeric of a parameter which has the corresponding waveform in addition.

No.	Description
5	Numeric area of parameter without waveform: displays the numeric of a parameter which does not have the corresponding waveform, also possibly select to display EWS, Timer, and NIBP List in this area.
6	Waveform area: displays waveforms of parameters.

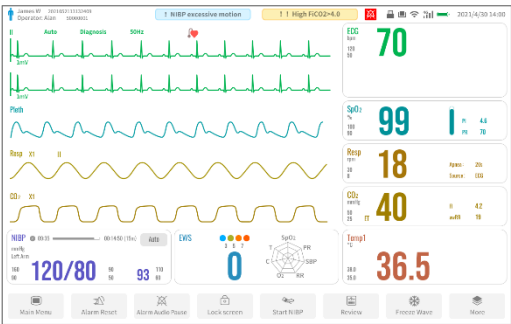
5.2.2 Screen Types

The monitor provides the six kinds of display screens:

Select **[Main Menu]** → **[Screens]** → **[Choose Screen]**, and then select a desirable screen.

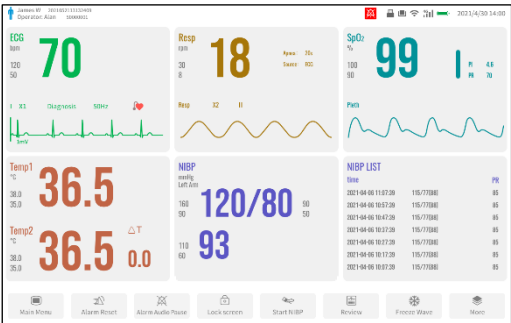
- Normal Screen

Meet most monitoring needs.

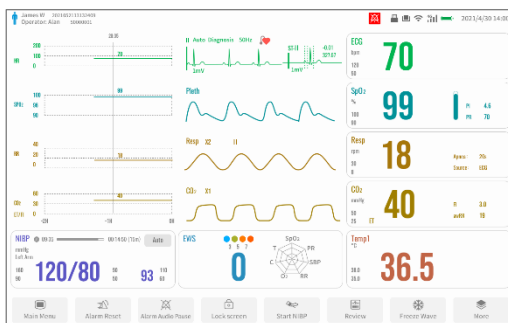


- Big Numerics Screen

Display parameter numerics in big font size and waveform in reduced space. Serve for remote observation.



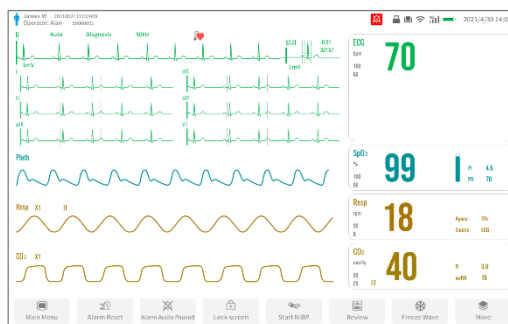
- Minitrends Screen
Display real-time monitoring and short trends on the same screen.



- OxyCRG Screen
Focus on SpO2 and Respiration data.



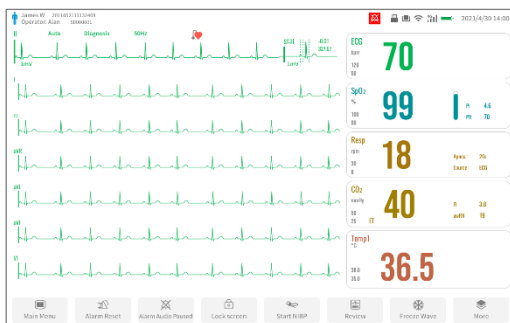
- ECG Half Screen
The half of waveform area displays ECG waves.
The lead type as 5-electrode is applicable.



- ECG Full Screen

The waveform area only displays ECG waves

The lead type as 5-electrode is applicable.



5.3 Operating Modes

The monitor provides the operating modes as listed in the following table. Based on the needs of different monitoring scenarios, each mode is specially designed in the aspects of screen display, system settings, parameter measurement and alarms, etc.

Enter/exit the work mode as follows:

- 1 Select **[Main Menu]** → **[Screens]** → **[Work Mode]** tab.
- 2 Enter or exit work modes, and set the related parameters in the mode.

Mode	Scenario	Remarks
Monitoring Mode	When the monitor is turned on, it automatically enters Monitoring mode, which shows real-time waveform and data.	/
Demo Mode	Demo mode is only used for demonstration purpose and detection of alarm function. The data and waveform in demo mode are generated by the system, and cannot be used to evaluate the physiological condition of patients.	Password 123456
Standby	It is generally used to stop monitoring temporarily	After entering Standby mode for 30 seconds, the

Mode	Scenario	Remarks
	when the patient is changed. Support to enter standby manually or automatically.	screen brightness will be automatically adjusted to the dimmest. Click anywhere on the screen to restore the brightness of the screen. Click [Exit Standby] on the screen to exit standby.
Warning	<Demo Mode> In clinical use, do not set the device to Demo mode, to avoid stimulated data being mistaken for a monitored patient's data, which may cause improper monitoring and delayed treatment.	
Warning	<Standby> In Standby mode, the monitor stops patient monitoring and suppresses all system sounds and alarms except for the battery low alarm. Please pay attention to the potential risks.	

5.4 Managing Patients

Patient management includes the operations of admitting, modifying and discharging a patient, and also includes management of discharged patient data.

Select **[Main Menu] → [Patients]**, operate the following:

- **Admit a patient:** In the **[New Patient]** tab, you can admit a patient by the method of quick admit, and standard admit.
- **Modify patient information:** In the **[Patient Info]** tab → **[Patient Info]**, modify the admitted patient's information.
- **Discharge a patient:** In **[Patient Info]** tab → **[Patient Info]** → **[Discharge]** to discharge the current patient. After a patient is discharged, all patient data, including patient information, trend data, and physiological alarms, are cleared, the technical alarms are reset, and the monitor settings return to their defaults.
- **Manage discharged patient data:** In the **[Discharged Patients]** tab, you can query, export, and delete discharged patient data.

Warning Discharge the previous patient before starting to monitor a new patient.

Warning Failure to do so can lead to data being associated with the wrong

patient.

Warning

The default Patient Type setting is Adult, and Pace setting is Unspecified. Set Paced and check if the Patient Type setting is correct for the patient.

Warning

The monitor will reload the configuration if you changed the patient type.

Warning

After a patient is discharged, the monitor enters the "Patient Not Admitted" state, and the data will be saved as discharged patient data.

Warning

If the patient is not discharged before the monitor is turned off, the patient will still be the one before shutdown when the monitor is turned on again.

Warning

If a patient is deleted, all data related to the patient (such as ECG waveform, alarm events, etc.) will be deleted and cannot be recovered.

Warning

The data of the current patient under monitoring cannot be deleted.

5.5 Scoring in Early Warning System

The Early Warning System (EWS) is an evaluation system, which provides an overall score based on vital signs measurements and observation, followed by corresponding action suggestions.

Warning

The EWS system is not applicable to pregnant women and people under 16 years old.

Warning

NEWS is not applicable to spinal cord injury (SCI) patients.

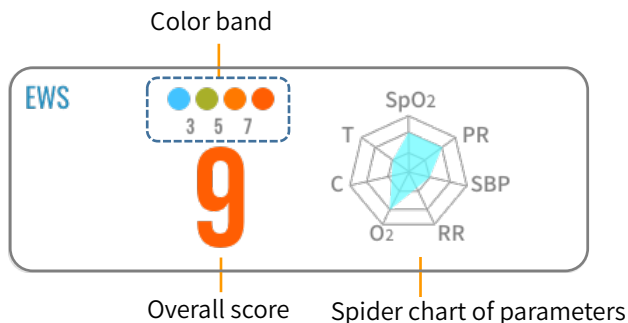
Warning

The EWS scores and recommended actions are for reference only and cannot be directly used for diagnostic interpretation.

Warning

EWS cannot be used as an index of prognosis. It is not a clinical judgement tool. Clinicians must use their clinical judgement in conjunction with the EWS tool at all times.

EWS Parameter Area



- **Color band:** The top of the band shows the color indication, and the bottom shows the threshold value for each color. The risk is gradually increasing from blue to red.
- **Overall score:** The overall score is assessed on the criteria of each scoring system when an individual score for each parameter is obtained. The numerical color of the overall score is displayed according to the color band. For example, when NEWS is adopted, 8-point is displayed in red.
- **Spider chart of parameters:** The outer edge of the chart indicates all the parameters in the scoring system, and the central area is the pattern obtained by connecting the scores of each parameter.

Types of Scoring System

The monitor supports NEWS, MEWS, and CART scoring systems.

Scoring System	Scoring Parameters	Result Description
National Early Warning Score (NEWS)	Consciousness, Supply O ₂ (oxygen supply status), RR, PR, SpO ₂ , Temp, SBP (systolic pressure)	• 0 - 4 points, with the numerics in blue: indicates a low risk • 0 - 4 points, with the numerics in yellow: indicates a medium-low risk, and the score of a certain parameter is high (3 points) • 5 - 6 points: indicates a medium risk • 7 points and above: indicates a high risk
Modified Early	Consciousness, RR, Temp, SBP (systolic	• 0 - 3 points, with the numerics in blue: indicates a low risk

Scoring System	Scoring Parameters	Result Description
Warning Score (MEWS)	pressure), HR	• 0 - 3 points, with the numerics in yellow: indicates a medium-low risk, and the score of a certain parameter is high (3 points) • 4 - 6 points: indicates a medium risk • 7 points and above: indicates a high risk
Cardiac Arrest Risk Triage (CART)	RR, HR, DBP (diastolic pressure), Age	• 0 - 16 points, blue number: indicates a low risk • 17 - 20 points, yellow number: indicates a medium-low risk • 21 - 24 points: indicates a medium risk • 25 points and above: indicates a high risk

Auto/Manual Scoring

Select [Main Menu] → [Parameters] → [EWS] tab, and you can enter the EWS screen.

- **Automatic mode:** automatically scores according to the set refresh cycle.
- **Manual mode:** Click [Calculate] manually to calculate a score.

Note

Before calculating the score, select [Clear] to clear the previous score.

Note

You can get the score only when all required parameters have been measured or entered.

5.6 Assisting Venous Puncture

Inflate the NIBP cuff to cause sub-diastolic pressure to block the venous blood vessel and therefore help venous puncture. To assist venous puncture, follow the steps below:

- 1 Select the NIBP parameter area.
- 2 Set [Venipuncture].
- 3 Select [Venipuncture] button to start inflating the cuff. At the same time, the NIBP parameter area will display the current cuff inflation pressure value and the remaining time of venipuncture.

- 4 Puncture the vein and draw a blood sample.
- 5 Select the **[Stop All]** or **[Stop Measuring]** buttons to deflate the cuff.

5.7 Networked Monitoring

The monitor can be interconnected with a central monitoring system through the wireless network.

5.7.1 Safety Information

- | | |
|----------------|--|
| Warning | Keep network authentication information, for example passwords, safe, to protect the network from being accessed by unauthorized users. |
| Warning | Do not connect non-medical devices to the monitor network. |
| Warning | Always set the wireless network according to local wireless regulations. |
| Warning | If wireless network signal is poor, there may be a risk of data loss in communicating with central monitoring system. |
| Warning | RF interference may result in wireless network disconnection. |
| Warning | Disconnecting from the network may result in central monitoring system-destined data loss and function failure. Check the patient in case of network disconnection and solve the network problem as soon as possible. |
| Warning | Ensure that the monitor IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if there are any problems with the IP address. |
| Caution | Make sure that central monitoring system and the monitor are located in the same network segment. Every monitor should have its unique port number and IP address. Otherwise, its network connection will be failed anytime. |

5.7.2 Connecting Central Monitoring System

To connect the central monitoring system, follow the steps below:

- 1 Select **[Main Menu]** → **[System]** → **[Network]** tab.
- 2 Select the **[Central Station]** tab.
- 3 Switch on **[Central Station]**.
- 4 Set the IP address and port number of the central monitoring system server.
- 5 Click on the **[Test]** button. If the connection status is *Connected*, the connection is successful.

If your monitor is connected to the central monitoring system, it has the following characteristics:

- Simultaneously data display on the monitor and the central monitoring system, such as all patient information, measurement data, alarms.
- Bi-directional control on some functions of your monitor via operation on the central monitoring system, such as editing patient information, admitting/discharging a patient, setting alarms and parameters, starting/stopping NIBP measurements.

5.8 Settings and Operation Overview

Note

An item marked with * indicates that it is followed by relevant warning or prompt information at the end of this section.

5.8.1 Setup

Items	Function	Entry
Monitoring parameter setup		
Parameter layout	Configure the displayed parameters.	Select [Main Menu] → [Screens] → [Para Layout] tab.
Quick key layout	The system provides a set of optional quick keys, and the screen can display 13 quick keys at most. As required, configure the displayed quick keys.	Select [Main Menu] → [Screens] → [Quick Key Layout] tab.
Parameter color	Set the color of numerics and waveforms for each parameter.	Select [Main Menu] → [Screens] → [Para Color] tab.
Beat mode	Set the pulsatile sound mode.	Select [Main Menu] → [System] → [System Setup] tab.
Display of Timer*, NIBP List*,	Configure if it is displayed on the main screen and its position on the main screen.	Select [Main Menu] → [Screens] → [Para Layout] tab → Select the bottom

Items	Function	Entry
EWS		parameter area → Select [Timer], [NIBP List] or [EWS] in the pop-up list.
Display of patient information field*	Set whether the registration number, ID number, middle name, race, and other fields are displayed in the [Patient Info] screen when admitting patients.	Select [Main Menu] → [Maintenance] → Enter the password → [Patient Mgmt.] tab.
Alarm properties	Set the alarm switch, limits, and priority.	Select [Main Menu] → [Alarms] → select the individual parameter tab.
Alarm volume*	Set alarm volume (levels 1-10).	Select [Main Menu] → [System] → [System Setup] tab.
Alarm audio paused time	Set the alarm audio pause of time (1 min, 2 min, 3 min, permanent).	Select [Main Menu] → [Maintenance] → Enter the password → [Alarms] tab.
Recording wave	Select the wave to be printed by the recorder, and also set the recording duration, interval, and wave speed.	Select [Main Menu] → [Reports] → [Recording Setup] tab.
ECG setup	Set the lead type, filter, gain, etc.	For details, see 7.5 <i>ECG Setup</i>
Arrhythmia setup	Set arrhythmia alarms.	For details, see 7.6 <i>Arrhythmia Setup</i>
Resp setup	Set the respiratory lead, gain, etc.	For details, see 8.4 <i>Resp</i>
SpO ₂ setup	Set the NIBP simultaneous, PI displaying.	For details, see 9.5 <i>SpO₂ Setup</i>
Temp setup	Set temperature label, unit.	For details, see 10.4 <i>Temp Setup</i>

Items	Function	Entry
NIBP setup	Set NIBP measurement mode, initial cuff pressure, etc.	For details, see <i>11.7 NIBP Setup</i>
CO ₂ setup	Set waveform gain, calculation period, balance gas and oxygen concentration, etc.	For details, see <i>12.6 CO₂ Setup</i>
System setup		
Time/date*	Set system date and time format.	Select [Main Menu]→[System]→[System Setup] tab.
Screen brightness	Set screen brightness	Select [Main Menu]→[System]→[System Setup] tab.
Volume*	Set key volume, alarm volume, QRS volume	Select [Main Menu]→[System]→[System Setup] tab.
Wireless network	Set wireless network IP address.	Select [Main Menu]→[System]→[Network Setup].
Admin Password	Modify Admin password	Select [Main Menu] → [Patients] → [Operator Mgmt.] tab → [Modify Password].
Permission Password	Set if the permission password is required to change alarm settings. The permission password is same as the admin password.	Select [Main Menu] → [Maintenance] → Enter the password → [Alarm] tab → [Alarm Setup Password].

Warning

<Timer> Do not use the timer for critically ill patients.

Warning

<Alarm volume> Do not rely exclusively on the audible alarm system for monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Please pay close attention to the actual clinical condition of patients.

Warning

<Alarm volume> When adjusting the alarm volume, if it is impossible to ensure that the medical staff are always in the care of the monitor and the patient, it is recommended that the operator should not adjust the volume below the default setting value of the monitor, otherwise, the alarm may not be easily detected and irreversible injury may occur to the patient.

Note

<Volume> When the volume is set to 0, the sound is turned off. It is not recommended to set the QRS volume to 0. Pay attention to potential risks.

Note

<Display of patient information field> If the monitor is connected to the central monitoring system, information information and user-defined fields are synchronized with the central monitoring system.

Note

<Display of NIBP list> Measurements are not included in the NIBP list when you manually stop measurements.

Note

<Time/date> Changing the date and time affects the storage of trends and events and may result in loss of data.

Note

<Time/date> If the monitor is connected to the central monitoring system, the date and time are automatically taken from the central monitoring system. In this case, you cannot change the date and time on the monitor.

Note

<Timer> You cannot set the timer while it is working.

5.8.2 Operations

Operations	Functions	Entry
Admit a patient	Start monitoring the patient with the patient data saved in the monitor.	Select patient information area → [New Patient] tab.
Editing Patient Information	Modify the current patient information, including patient type, name, age, etc.	Select patient information area → [Patient Info] tab → Modify patient information → [OK] button.
Discharge a patient	End the monitoring of the current patient and turn the patient into the discharged patient.	Select patient information area → [Patient Info] tab → [Patient Info] → [Discharge] button.
Manage discharged patients	View, export, and delete discharged patient data	Select patient information area → [Discharged Patients] tab
EWS scoring	Set the scoring mode	Select [Main Menu] →

Operations	Functions	Entry
	(auto/manual), cycle, tool, etc.	[Parameters] → [EWS] tab
Freezes waveforms*	Freeze the waveform within 120 seconds of the moment forward.	Select the quick key [Freeze Wave]
Print frozen waveforms	Print through the thermal recorder.	Select quick key [Freeze Wave] → [Recorder]
Screenshot	Captures the current screen	Select the quick key [Screenshot]
Managing operators*	Add, edit, delete the operator of the monitor, and set the current operator.	Select [Main Menu] → [Patients] → [Operator Mgmt.] tab

Note

<Freezes wave> In freezing status, all waveforms are frozen and will no longer be refreshed. Nevertheless, the Parameter area refreshes and the data is stored normally.

Note

<Managing Operators> The operator named “admin” preset by the system cannot be set as the current operator or deleted from the operator list.

Note

<Managing Operators> Editing and deleting operations only change the contents of the operator list, and do not change the operator information recorded in discharged patients.

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Chapter 6 Alarms

Alarms are triggered by physiological parameters that appear abnormal or by technical problems of the monitor. When an alarm occurs, the monitor indicates it through visual and audible alarm indications.

6.1 Safety Information

Warning

Each time the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.

Warning

The alarm limit shall be within the measuring range, or it may disable the alarm system. Please refer to the related chapter for alarm limit range.

Warning

Do not silence the audible alarm if patient safety may be compromised.

Warning

Before monitoring a new patient, always check that the monitor can work properly, the alarm system works properly, and the alarm settings are appropriate for the patient before starting the monitoring.

Warning

In order to ensure that the operator can accurately identify the alarms, it is recommended that the distance between the operator and the monitor should not exceed 4 meters. If the alarm event needs to be clearly distinguished, it is recommended that the distance between the operator and the monitor should not be more than 1 m (there should be no obstacle within the visual effective distance above).

Warning

Do not set the alarm limits beyond the measurement ranges, which may cause the alarm system to become ineffective.

Warning

A hazard can exist if different alarm presets are used for the same or similar device in a single area.

Note

When the alarm system is powered off, or loses all power, the monitor will save the alarm settings and alarm logs if the power off time is not more than 30 s. The stored alarm information does not change with the power off time.

Note

The alarm system function of the monitor can be checked and verified in the Demo mode.

Note

Up to 1000 alarm events can be stored. When this limit is exceeded, the earliest event is automatically deleted each time a new event is recorded.

6.2 Alarm Categories

The monitor provides two different types of alarms: physiological alarms and technical alarms.

- **Physiological alarms:** also called patient status alarms, are triggered by parameter measurement exceeding the set alarm limits, or by an abnormal patient condition.
- **Technical alarms:** also called system status alarms, are triggered by a device malfunction or the monitoring result distortion due to improper operation or mechanical problems.

Apart from the physiological and technical alarms, the monitor can also display prompt messages describing the system status or patient status in technical message area at the top of the screen.

For alarm event and prompt messages, see *Appendix B Alarm Messages*.

6.3 Alarm Priorities

By severity, the alarms are classified into the following priority levels:

- **High priority alarms:** indicates a life threatening situation or a severe device malfunction. High priority alarms require an immediate operator response.
- **Medium priority alarms:** indicates abnormal vital signs or a device malfunction. Medium priority alarms require a timely operator response.
- **Low priority alarms:** indicate a discomfort condition, a device malfunction, or an improper operation. Low priority alarms require the operator to be aware of this condition.
- **Prompt messages:** provide additional information about the patient or the monitor.

The monitor has preset alarm priorities for physiological alarm and technical alarm. For more information, see *B.1 Physiological Alarms* and *B.2 Technical Alarms*.

6.4 Alarm Mode

The monitor provides audible and visual alarm indications when an alarm occurs. For more information, see the following table.

Alarm Indication	High Priority Alarm	Medium Priority Alarm	Low Priority Alarm	Prompt Message	Remarks
Alarm lamp	Red flashing, Flashing frequency: 2 Hz, Visual duty cycle 50%	Yellow flashing, Flashing frequency: 0.5 Hz, Visual duty cycle 50%	Cyan On	None	None
Volume	beep-beep-beep-beep-beep-beep-beep-beep-beep-beep	beep-beep-beep	Beep	None	None
Alarm message	White text with a red background	Black text with a yellow background	Black text with a cyan background	White text	Display in the information area at the top of the screen. You can select the alarm messages to show the alarm list.
Alarm level symbol	! ! !	! !	!	None	The symbols appear before the corresponding alarm message.

Warning

When multiple alarms of different priority levels occur simultaneously, the monitor selects the highest priority alarm to light the alarm lamp and issue the alarm tone.

Warning

When multiple alarms of the same priority levels occur simultaneously and should be displayed in the same area, all the alarm messages are displayed cyclically.

6.5 Alarm Status Symbols



Alarm off: indicates that the alarm of a parameter is turned off.



Alarm audio pause: indicates that audible alarm tones are paused.



Alarm audio off: indicates that audible alarm tones are turned off.



Alarm reset: indicates that the alarms are acknowledged and the alarm system is reset. At this time, the audible alarm tones are turned off, but the visual alarm still remains effective.

6.6 Latching Alarms

Physiological alarms are default to “Non-latch” mode and unconfigurable.

Non-latch means that if you do not latch physiological alarms, their alarm indications disappear when the alarm condition ends.

6.7 Resetting Alarms

Select the **[Alarm Reset]** quick key to confirm the ongoing alarms and reset the alarm system. When the alarm system is reset, the alarm reset

symbol  displays in the alarm icon area. If a new alarm is triggered after the alarm system is reset, the alarm reset symbol will disappear and the alarm light and alarm tone will be reactivated.

- **Resetting physiological alarms:** When the alarm system is reset, the sound of the ongoing physiological alarm is silenced.
- **Resetting technical alarms:** When the alarm system is reset, all the active technical alarms have the priority changed to prompt message.

Note

Alarm reset is not a toggle operation, selecting the alarm reset key again or several times only reset the current alarm event, rather than exit the alarm reset state.

6.8 Pausing and Switching Off Alarm Sound

Select the **[Alarm Audio Pause]** quick key to pause the current alarm sound. The pause time is configurable. To exit the alarm audio pause status, select **[Restore Alarm Audio]** quick key.

The monitor has the following features after the alarm sound is paused:

- The sound of all physiological alarms and technical alarms are switched off.
- The alarm audio pause symbol  is displayed in the alarm icon area. The text *Alarm Audio Pause* and remaining time is displayed in the physiological alarm message area.

To configure the alarm audio pause time, follow the steps below:

- 1 Select **[Main Menu]** → **[Maintenance]** → Enter the maintenance password.
- 2 Select the **[Alarm]** tab.
- 3 Set **[Alarm Pause Time]** to 1 min, 2 min, 3 min or permanent. When the option [Permanent] is selected, the alarm is switched off when pressing the [Alarm Audio Pause] quick key.

The monitor has the following features after the alarm sound is switched off:

- The sound of all physiological alarms and technical alarms are switched off.
- The alarm audio off symbol  is displayed in the alarm icon area. The text *Alarm Audio Off* is displayed in the physiological alarm message area.

Warning

Pausing or switching off alarm sound may result in a hazard to the patient. Please pay attention to the potential risks.

To remind the medical staff that the alarm audio is turned off, the monitor is capable of providing the reminder sound. When the reminder for alarm audio off is enabled, the monitor will sound beep every half hour. The method for switching on/off the reminder is as follows:

- 1 Select **[Main Menu]** → **[Maintenance]** → Enter the maintenance password.
- 2 Select the **[Alarm]** tab.
- 3 Enable or disable **[Reminder for Alarm Audio Off]**.

6.9 Acknowledging and Reviewing Alarms

Select the technical or physiological alarm message area to open the corresponding alarm list window. The alarm list shows all the active physiological or technical alarms, with the most recent one at the top of the list.

- **Acknowledging alarms:** select the check box before alarm(s), and then select the **[Confirm Alarm]** button. The selected alarms are audio off.
- **Reviewing alarms:** Select **[Review]** to enter the alarm event review screen. For more information, see *13.3 Events Review*.

6.10 Handling Alarms

When the monitor gives an alarm, please refer to the following steps and take proper measures:

- 1 Check the patient's condition.
- 2 Confirm the parameter of the ongoing alarm or alarm category.
- 3 Identify the source of the alarm.
- 4 Take proper action to eliminate the alarm condition.
- 5 Make sure the alarm condition is corrected.

For the cause of technical alarms, refer to *B.2 Technical Alarms*.

Chapter 7 Monitoring ECG

The monitor provides 3-electrode and 5-electrode ECG monitoring.
ECG monitoring is intended for adult, pediatric, and neonatal patients.

7.1 Safety Information

Warning

WARNING for PACEMAKER PATIENTS: Although the pacemaker pulse inhibition function is available in this device, the heart rate meter may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this device.

Warning

Only use the lead wires provided by the manufacturer. Using those from other suppliers may cause improper performance or poor protection during defibrillation.

Warning

Check if the patient category setting is correct for the patient.

Warning

Ensure that the conductive parts of ECG electrodes and associated connectors, including the neutral electrode, do not come into contact with any other conductive parts including earth. Make sure that all electrodes are connected to the patient correctly.

Warning

For paced patients, set [Paced] to be enabled. Otherwise, it may cause the pacing pulse to be treated as a regular QRS complex, and when the ECG signal is too weak, the system cannot detect it and give alarms. For ventricular paced patients, episodes of ventricular tachycardia may not always be detected. For non-paced patients, set [Paced] to be disabled.

Warning

Some pacemakers may cause false low heart rate or arrest alarms, because pacemaker artifacts, such as pacemaker overshoot, may cover the real QRS complex.

Warning

Pacemaker automatic recognition function is not suitable for pediatric and neonate patients, as well as patients receiving NMT stimulation.

Warning

Do not use dissimilar metal electrodes, otherwise it will cause high polarization voltage. Reusable electrodes will withstand a large bias potential due to polarization, and the recovery time after defibrillation will be particularly long (more than 10 seconds). It is recommended to use disposable electrodes.

Warning

In surgical mode, the monitor can be used with high frequency surgical equipment. When used with electrosurgical equipment, the operator should pay attention to ensure the safety of the monitored patients and operate in strict accordance with this manual. After the elimination of high frequency signal and high frequency electromagnetic field, it can

return to the previous operating mode within 10 seconds without losing any permanent stored data.

Warning

To minimize the hazard of burns during use of high-frequency surgical unit (ESU), the ECG electrodes should not be located between the surgical site and the ESU return electrode.

Warning

To minimize the hazard of burns during high-frequency surgical procedures, ensure that the monitor's cables and transducers never come into contact with the electrosurgery unit (ESU).

Warning

The improper connection with the electrosurgical unit may not only cause burns but also damage the monitor or arouse deviations of measurement. You can take some steps to avoid this situation, such as do not use small ECG electrodes, choosing the position which is far away from the estimated Hertzian waves route, using larger electro-surgical return electrodes and connecting them with the patient properly.

Warning

If any side-effect such as allergic or itchy reaction is found, remove the electrodes from the patients immediately.

Warning

Use only the same type of electrodes recommended by the manufacturer on the same patient to avoid the change of resistance.

Note

Interference from an ungrounded instrument near the patient or electrosurgery usage can induce noise and artifact into the waveforms.

Note

When the monitor is inoperable due to overload of ECG signal or saturation of any part of the amplifier, it will prompt "Lead off" to remind the operator.

Note

Transient caused by cable circuitry blocks while monitoring may cause artifact on ECG signals yielding wrong heart rate reading and even triggering false alarm. If the electrodes and cable are located in proper places according to this manual's instructions for using electrodes, the chance of this transient occurrence will be decreased.

7.2 ECG Monitoring Preparation

7.2.1 Preparing the Patient Skin

The state of patient's skin directly affects the strength of ECG signal and the accuracy of monitoring information. To properly prepare the patient skin, please refer to the following steps:

- 1 Select sites with intact skin, without impairment of any kind. Shave hair from sites, if necessary.
- 2 Wash sites thoroughly with soap and water (Never use ether or pure alcohol, because this increases skin impedance).

- 3 Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

7.2.2 Connecting ECG Cable and Applying Electrodes

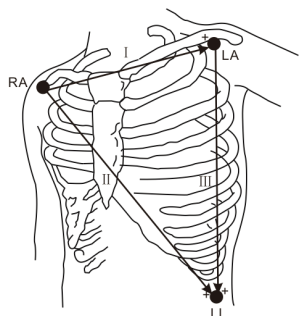
- 1 Connect the ECG cable to the multi-function adapter installed on the main unit.
- 2 Press the electrode into the electrode connector on the lead wire.
- 3 Remove the protective package on the back of the electrode.
- 4 Place the electrodes to the prepared sites according to the following content or doctor's instruction. Refer to the following section for ECG electrode placements.

7.2.3 ECG Electrode Placements

The electrode identifier and color code are classified into IEC (European standard) and AHA (American standard). The electrode identifier and color are shown as below:

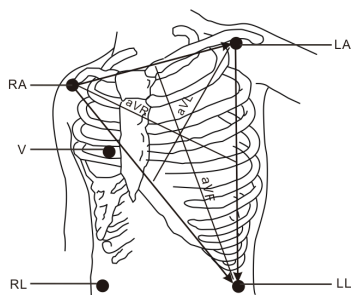
IEC Standard		AHA Standard	
Identifier	Color Code	Identifier	Color Code
R	Red	RA	White
L	Yellow	LA	Black
F	Green	LL	Red
N or RF	Black	RL	Green
C	White	V	Brown

3-Electrode Placement



- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement: on the left lower abdomen.

5-Electrode Placement



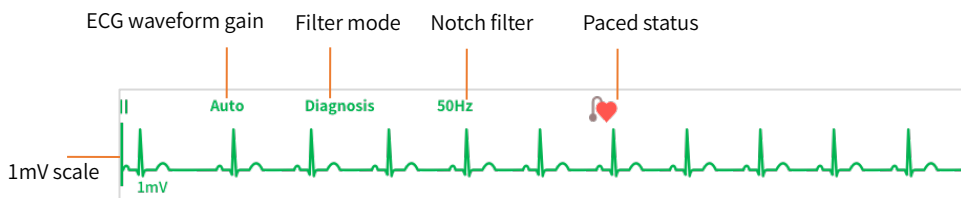
- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement: on the left lower abdomen.
- RL placement: on the right lower abdomen.
- V placement: on the chest, the position depends on your required lead selection. Or place it at a site according to the doctor's instruction.

7.2.4 Factors Affecting ECG Signal

- Interference from electrosurgical units.
- Unreasonable filter mode setting.
- Poor grounding.
- Incorrect placement of electrodes.
- Use expired electrodes or use disposable electrodes repeatedly.
- The skin on which the electrodes are placed is unclean or poor contact caused by scurf and hair.

7.3 ECG Display

ECG waveform area

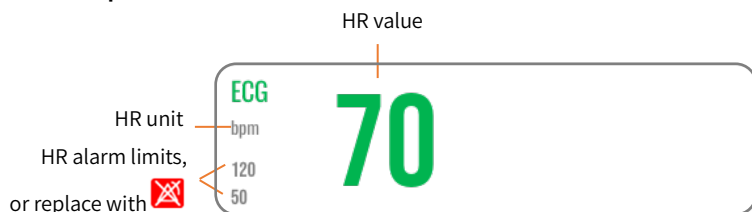


Indicates **[Paced]** is enabled.



Indicates **[Paced]** is disabled.

ECG parameter area



7.4 Arrhythmia

Arrhythmia monitoring is intended for adult, pediatric, and neonatal patients.

7.4.1 Safety Information

Warning

If you switch off all the arrhythmias alarms, the monitor cannot give any arrhythmias alarm when that situation occurs. This may result in a hazard to the patient. Keep the patient under close surveillance.

Warning

Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmias. Always keep these patients under close surveillance.

Caution

The priority of lethal arrhythmia alarms is always high. It cannot be changed.

Note

Because arrhythmia detection needs a template ECG waveform as reference which is a piece of normal ECG waveform with regular rhythm and stable amplitude, it is necessary to re-activate the template learning

when the patient is changed, or the arrhythmia detection is incorrect. For stronger arrhythmia detection, it is recommended to wait for a clean and stable ECG waveform before starting ARR detection during the monitoring.

Note

During arrhythmia detection, incorrect detection might occur if the non-ECG waveforms (e.g., square or triangle waveform) appear.

Note

Before starting the 1mV calibration signal, please turn off the arrhythmia detection.

Note

During Arrhythmia detection, the template learning is very important. The device requires a group of stable QRS complex waveforms to build up this template. If the system detects Arrhythmia incorrectly, please re-activate the template learning and obtain the correct template.

7.4.2 Arrhythmia Analysis Classifications

Arrhythmia Event (Abbreviation)	Arrhythmia Event (In Full or Description)
Lethal Arrhythmia Events	
Asystole	Asystole
V-Fib/V-Tach	Ventricular-Fibrillation/Ventricular-Tachycardia
Vent Tachy	Ventricular Tachycardia
Vent Brady	Ventricular Bradycardia
Extreme Brady	Extreme Bradycardia
Extreme Tachy	Extreme Tachycardia
Non-lethal Arrhythmia Events	
Nonsus V-Tach	Nonsustained Ventricular Tachycardia
Vent Rhythm	Ventricular Rhythm
Run PVCs	More than two consecutive Premature Ventricular Contractions
PVCs Couplet	A Pair of Premature Ventricular Contractions
R on T	R Waves Interrupting T Waves
Vent Bigeminy	Ventricular Bigeminy
Vent Trigeminy	Ventricular Trigeminy
PVCs/min	Premature Ventricular Contractions per Minute
Multiform PVC	Multiform Premature Ventricular Contractions
PVC	Premature Ventricular Contractions
Tachy	Tachycardia

Arrhythmia Event (Abbreviation)	Arrhythmia Event (In Full or Description)
Brady	Bradycardia
A-Fib (HR High)	Atrial-Fibrillation (High Heart Rate)
A-Fib	Atrial Fibrillation
A-Fib End	Atrial Fibrillation End
Irr Rhythm	Irregular Rhythm
Irr Rhy End	Irregular Rhythm End
Pause	Heartbeat Pause
Missed Beats	Missed Beats
Pauses/min	Heartbeat Pauses per Minute
Pacer Not Pacing	Pacer Not Pacing
Pacer Not Capture	Pacer Not Capture
PAC	Premature Atrial Contractions
PACs Couplet	A Pair of Premature Atrial Contractions
SV Bigeminy	Supraventricular Bigeminy
SV Trigeminy	Supraventricular Trigeminy
2nd Degree A-V Block	2nd Degree Atrioventricular Block
1st Degree A-V Block	1st Degree Atrioventricular Block

7.4.3 Arrhythmia Alarm Threshold

When an arrhythmia exceeds its threshold, an alarm will be triggered. The arrhythmia alarm threshold is not configurable. The monitor will use the following thresholds for arrhythmia monitoring.

Arrhythmia	Default Threshold		
	Adult	Pediatric	Neonate
Asystole time	5 s	5 s	5 s
Pause time	2.0 s	2.0 s	2.0 s
Nonsus V-Tachy	5 beats	5 beats	5 beats
Run PVCs	5 beats	5 beats	5 beats
V-Tachy	130 bpm	130 bpm	160 bpm
V-Brady	40 bpm	40 bpm	40 bpm
Extreme Tachy	160 bpm	180 bpm	220 bpm
Extreme Brady	35 bpm	50 bpm	60 bpm

Arrhythmia	Default Threshold		
	Adult	Pediatric	Neonate
Tachy	120 bpm	160 bpm	200 bpm
Brady	50 bpm	75 bpm	100 bpm
PVCs/min	10	10	10
A-Fib (HR High)	150 bpm	150 bpm	150 bpm
Pauses/min	8	8	8
AF/Irr Rhy End Time	2 min	2 min	2 min
Multif PVCs Window	15 beats	15 beats	15 beats

7.5 ECG Setup

Access ECG parameter setup screen in either of the following ways:

- Select the ECG parameter area
- Select **[Main Menu]** → **[Parameters]** → **[ECG]** tab

Access ECG alarm setup screen in either of the following ways:

- Select the ECG parameter area → **[Alarms Setup]** button
- Select **[Main Menu]** → **[Alarms]** → **[ECG]** tab

Items	Functions	Details
Lead Type	Set which type of lead is used.	3 lead, 5 lead
Speed	Set ECG waveform speed.	The default is 25mm/s.
ECG1	Set which ECG wave is displayed in the first channel	The default is lead II.
ECG2	Set which ECG wave is displayed in the second channel	The default is lead V.
Filter*	Diagnosis, Monitor, Surgery	[Monitor] : Use under normal monitoring conditions. [Diagnosis] : Improve waveform display quality and enhance waveform change effect, such as R wave notch, ST segment elevation or depression.

Items	Functions	Details
		[Surgery]: Use when the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to drifting or rough baseline.
Gain*	Set ECG waveform amplitude.	The 1mV ECG waveform signal corresponding to 10mm height is used as a reference (i.e. [$\times 1$]), and different ratios of display are provided.
Notch Filter	Filter the interference from power line frequency.	Filter the waveform at 50 Hz or 60 Hz frequency.
Alarm source	Select the source for heart rate meter.	The source can be HR, PR, both (HR+PR), or auto. When the option [Auto] is selected, the source depends on the availability of HR and PR. When both the sources are available, the source is HR. If HR is unavailable, the source is PR.
[ECG] alarm tab	Set alarm properties of HR, extreme tachy, extreme brady.	Set alarm switch, high/low limit, or priority.

Note

If the amplitude of ECG waveform is too large, the wave peak or the wave valley might not be displayed. In this case, you should change the waveform gain appropriately.

Note

Under normal measurement conditions, selecting this filter mode may suppress certain features or details of the QRS complexes.

7.6 Arrhythmia Setup

Access ARR alarm setup screen in either of the following ways to set arrhythmia alarms:

- Select the ECG parameter area → **[ECG]** tab → **[ARR Alarm]** tab.

- Select **[Main Menu]** → **[Parameters]** → **[ECG]** tab→**[ARR Alarm]** tab.

Items	Functions	Details
Arrhythmia alarms	Set the alarm switch and priority.	• Alarm switch for Asystole, Vent Tachy, Vent Bray, Extreme Trachy, Extreme Brady can not be set to Off. • Alarm switch for V-Fib/V-Tachy can be turned off by the authorised personnel.
Restore Defaults	Reset all settings to the defaults.	/

Chapter 8 Monitoring Respiration (Resp)

Respiration monitoring is intended for adult, pediatric and neonate patients.

8.1 Safety Information

Warning

The respiration measurement does not recognize the cause of Apneas. It only indicates an alarm if no breath is detected when a preset time has elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purpose.

Warning

Do not use the equipment of high electrical radiation in close proximity to the impedance respiration measurement unit.

Warning

To avoid the hazard of burns during use of high-frequency electrosurgical unit (ESU), the electrodes should not be located between the surgical site and the ESU return electrode. Place the ESU return electrode close to the operation area.

Caution

Impedance respiration monitoring is not suitable for patients who are very active, otherwise it may lead to false alarm.

8.2 Measuring Resp

Respiration is monitored by measuring the impedance across the thorax via two ECG electrodes places on chest.

- Electrode RA and LA (Lead I), or
- Electrode RA and LA (Lead II)

For electrode placement, see *7.2.2 Connecting ECG Cable and Applying Electrodes*.

Note

Some patients (especially neonates) expand their chests laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two respiration electrodes in the right midaxillary and the left lateral chest areas at the patient's maximum point of the breathing movement to optimize the impedance respiration waveform.

Note

Correct electrode placement can help to reduce interference from cardiac related impedance changes: avoid including the liver area and the ventricles of the heart between the respiratory electrodes. This is particularly important for neonates.

Note

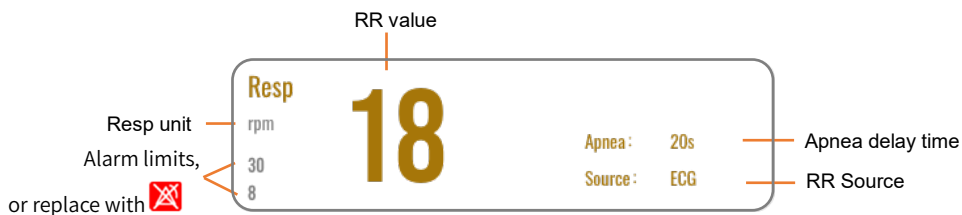
Some patients with restricted movements breathe mainly through the abdomen. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory waveform.

8.3 Resp Display

Resp waveform area



Resp parameter area



8.4 Resp Setup

Access Resp setup screen in either of the following ways:

- Click Resp parameter area
- Select **[Main Menu]** → **[Parameters]** → **[Resp]** tab

Access Resp alarm setup screen in either of the following ways:

- Select the Resp parameter area → **[Alarms Setup]** button
- Select **[Main Menu]** → **[Alarms]** → **[Resp]** tab

Item	Functions	Details
Speed	Set respiration waveform sweeping speed.	The default is 6.25 mm/s.
Gain	Set the amplitude of respiration waveform.	The default is ×2
Resp Lead	Set the ECG lead used to measure respiration	For adult/pediatric, the default is [Auto] For neonate, the default is lead II.

Item	Functions	Details
RR Source	Select the respiration signal source	Options are Auto, CO ₂ , ECG. When the manually selected RR source is not available, the monitor automatically switches the [RR Source] to [Auto]. The default is [Auto].
Apnea delay	Set the delay time from the time when the patient suffocates to trigger the Apnea alarm.	For adult/pediatric, the default is 20 s For neonate, the default is 15 s
[Resp] alarm tab	Set the alarm properties.	Set the alarm switch, high/low limits, or priority of RR and Apnea. Set the Apnea delay time.

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Chapter 9 Monitoring Pulse Oxygen Saturation (SpO₂)

SpO₂ monitoring is intended for adult, pediatric and neonatal patients.

9.1 Safety Information

- | | |
|----------------|--|
| Warning | Check the SpO ₂ sensor and cable before use. Do not use the damaged SpO ₂ sensor. |
| Warning | Check the compatibility of the monitor, probe, and cable before use to avoid patient injury. |
| Warning | Do not stare into the light of the SpO ₂ sensor (infrared light is invisible) when it is on, as the infrared light can cause damage to the eyes. |
| Warning | SpO ₂ measuring site must be examined more carefully for some special patient. Do not place the SpO ₂ sensor on the site with edema or fragile tissue. |
| Warning | Continuous use of SpO ₂ sensor may result in discomfort or pain, especially for those patients with microcirculatory problem. It is recommended that the sensor should not be applied to the same site for over two hours. |
| Warning | Inspect the SpO ₂ sensor application site every one to two hours to ensure skin quality and correct optical alignment, and change the measuring site periodically if necessary. If the skin quality changes, move the sensor to another site. |
| Warning | If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema, hypoxia, tissue ischemia, and inaccurate oxygen saturation measurements. |
| Warning | Do not apply sensor too tightly as this results in venous pulsation which may severely obstruct circulation and lead to inaccurate measurements. |
| Warning | At elevated ambient temperatures, be careful with measurement sites that are not well perfused, because this can cause burns after prolonged application. |
| Warning | For neonatal patients, make sure that all sensor connectors and adapter cable connectors are outside the incubator. The humid atmosphere inside can cause inaccurate measurements. |
| Warning | Please do not use the SpO ₂ sensor and the monitor when doing the MRI imaging, or burn may be caused by faradism. |
| Caution | For disposal SpO ₂ sensor, if the sterile packaging is damaged, do not use it any more. |

Caution

When the temperature of SpO₂ sensor is abnormal, do not use it any more.

Note

The clinical study for SpO₂ measurement accuracy was done on human subjects according to Standard ISO 80601-2-61.

Note

A functional tester or SpO₂ simulator cannot be used to assess the accuracy of the oximeter or a SpO₂ sensor. However, it can be used to check how accurately a particular oximeter is reproducing the given calibration curve. Before testing the oximeter by a functional tester, please firstly ask the manufacturer which calibration curve is used, if necessary, request the manufacturer for its dedicated calibration curve and download it into the tester.

Note

The SpO₂ calibration of the monitor has been carried out before delivery, and user does not need to calibrate it again during the operation.

9.2 Measurement Interferences

- The SpO₂ measurement of the monitor may not work effectively for all kinds of patients, for whom with weak pulse due to shock, low ambient / body temperature, major bleeding, or use of vasoconstriction medications, the measurement will be more sensitive to interference, if stable readings cannot be obtained at any time, stop using the SpO₂ monitoring function.
- For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO₂ measurements may be inaccurate.
- The medicines such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO₂ measurements.
- As the SpO₂ value serves as a reference value for judgment of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO₂ value.
- The high-pressure oxygen environment can affect measurement accuracy.
- Peripheral vasospasm, or constriction of blood vessels caused by a decrease in temperature, can affect measurement accuracy.

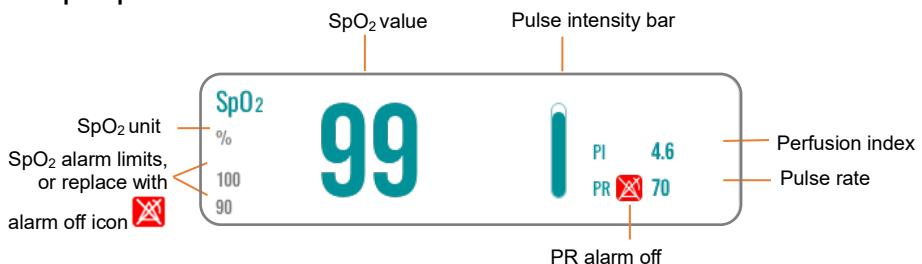
- Avoid placing the sensor on extremities with an arterial catheter, an NIBP cuff or an intravascular venous infusion line.
- Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate oxygen saturation measurements.
- Excessive ambient light may affect the measurement result, including includes fluorescent lamp, dual ruby light, infrared heater, and direct sunlight etc.
- The fingernail should be of normal length when use the finger clip or finger cot sensor.
- Please do not use nail polisher or other cosmetic product on the nail.
- Vigorous patient movement, strong ambient light, or extreme electrosurgical interference may also affect the SpO₂ measurement accuracy.
- Low perfusion may affect the measurement accuracy.

9.3 SpO₂ Display

Plethysmogram



SpO₂ parameter area



Note

The plethysmogram (Pleth) waveform is processed by amplitude normalization.

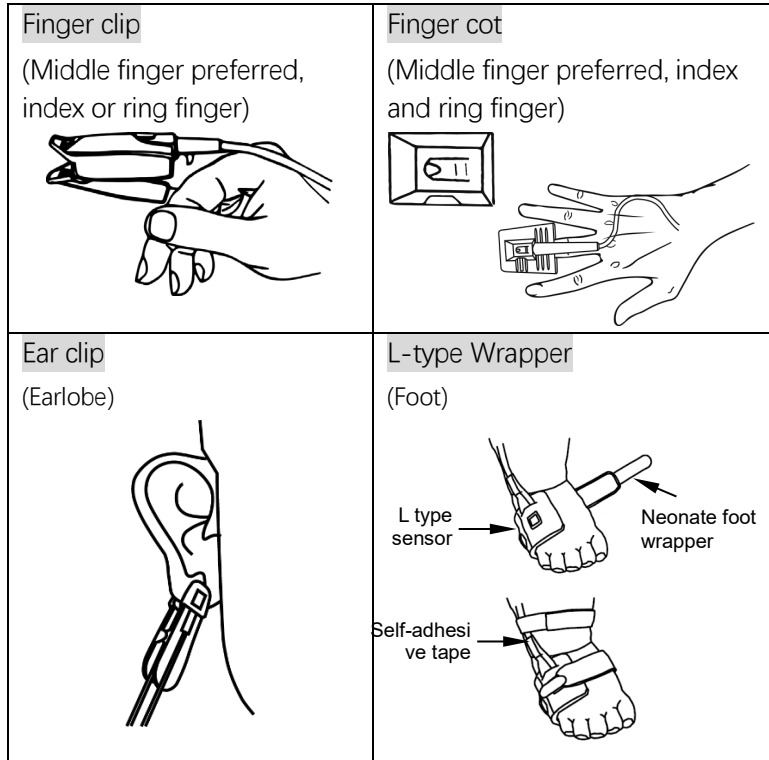
Note

If the PR signal is incomplete (excessive noise, degraded quality or loss of signal), the SpO₂ and PR values will not be shown, and the screen

will display "--" instead.

9.4 SpO₂ Monitoring

- 1 Select proper SpO₂ sensor according to characteristics of each type, and then place the sensor according to the following.



- 2 Connect the SpO₂ extension cable to the multi-function adapter installed on the main unit.
- 3 Connect the sensor to the extension cable.

9.5 SpO₂ Setup

Access the SpO₂ setup screen in either of the following ways:

- Select the SpO₂ parameter area
- Select **[Main Menu]** → **[Parameters]** → **[SpO2]** tab

Access SpO₂ alarm setup screen in either of the following ways:

- Select the SpO₂ parameter area → **[Alarms Setup]** button

- Select **[Main Menu]** → **[Alarms]** → **[SpO2]** tab

Item	Functions	Details
Speed	Set the Pleth waveform sweeping speed.	The larger the value, the faster the sweeping speed.
Display PI	Set whether to display the PI value in the SpO ₂ parameter area.	It can be turned on or off.
NIBP Simul.	When monitoring SpO ₂ and NIBP on the same limb simultaneously, you can switch on NIBP Simul to lock the SpO ₂ alarm status until the NIBP measurement is completed.	If you switch off NIBP Simul, low perfusion caused by NIBP measurement may lead to inaccurate SpO ₂ readings and therefore cause false physiological alarms.
[SpO2] alarm tab	Set alarm properties of SpO ₂ , SpO ₂ desaturation, SpO ₂ drop-down event.	Set alarm switch, high/low limit, or priority.
[PR] alarm tab	Set alarm properties of PR.	Set alarm switch, high/low limit, or priority.

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Chapter 10 Monitoring Temperature (Temp)

Up to two temperature sites can be monitored simultaneously and the difference (ΔT) between two measured sites is calculated. Temperature monitoring is intended for adult, pediatric and neonate patients.

10.1 Safety Information

Caution

The user is responsible for checking the compatibility of the monitor, the probe, and probe cable extender before use.

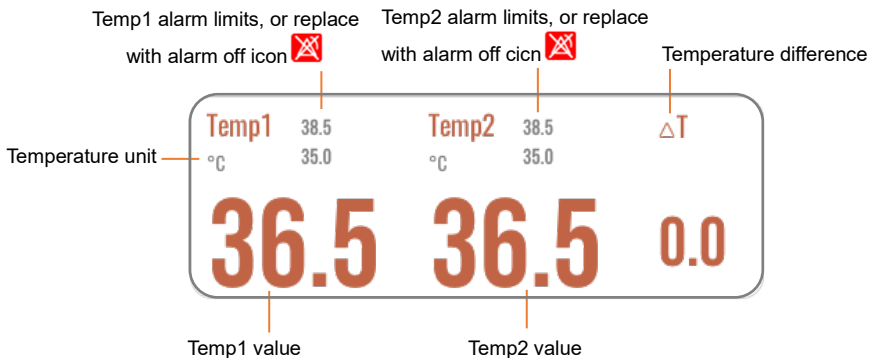
Caution

Incompatible components can result in degraded performance.

Caution

There is a range of normal body temperature. At the same time, the temperature of different measurement sites is different. Therefore, the readings of different sites should not be compared directly.

10.2 Temp Display



10.3 Temp Monitoring Preparation

- 1 Select an appropriate probe for your patient according to patient type and measured site.
- 2 Connect temp probe or the Y-type adapter (for two-way measurement) to the multi-function adapter installed on the main unit.
- 3 Connect the probe to the patient.

10.4 Temp Setup

Access Temp setup screen in either of the following ways:

- Press Temp parameter area.
- Select [Main Menu] → [Parameters] → [Temp] tab.

Access Temp alarm setup screen in either of the following ways:

- Select the Temp parameter area → **[Alarms Setup]** button
- Select **[Main Menu]** → **[Alarms]** → **[Temp]** tab

Item	Functions	Details
Temp1/2 label	Select measurement site.	Options in monitoring mode: Temp 1/2, Skin, Axil, Rectum.
Unit	Select temperature unit.	Options are °C and °F . (°F = °C × 9/5 + 32)
[Temp] alarm tab	Set the alarm properties of Temp1, Temp2, ΔT	Set alarm switch, high/low limit, or priority.

Chapter 11 Monitoring Non-Invasive Blood Pressure (NIBP)

The monitor uses the oscillometric method to measure non-invasive blood pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. A cuff is used to occlude the artery by inflating it above the patient's systolic pressure, the oscillometric devices measure the amplitude of pressure changes with pulsation in the cuff as the cuff pressure decreases. The pulsations increase in amplitude, and reach a maximum, then diminish along with the decrement of cuff pressure. The cuff pressure at the pulse amplitude backward reduced according to proper proportion is defined as systolic pressure (SYS), and the cuff pressure at the pulse amplitude forward reduced according to proper proportion is defined as diastolic pressure (DIA).

NIBP monitoring is intended for adult and pediatric patients.

11.1 Safety Information

- | | |
|----------------|--|
| Warning | Before the measurement is carried out, select an appropriate measuring mode depending on the patient type. |
| Warning | If any abnormality occurs, move the cuff to another place or stop the blood pressure measurement immediately. |
| Warning | It is recommended to take the blood pressure measurement manually. Medical staff must be present when performing auto or sequential measurement. |
| Warning | If the patient is moving or suffering tremble, hyperkinesia or arrhythmia, it may cause the inflation time of inflatable balloon endures longer, which may not only prolong the measurement time, but also result in the body wrapped by the cuff is troubled by purpura, hypoxemia and neuralgia because of the friction. |
| Warning | The monitor can be used on the patients who are pregnant or pre-eclamptic, but close attention should be paid to such patients. |
| Warning | Do not wrap the cuff on limbs with transfusion tube or intubations or skin lesion area, otherwise, injury may be caused to the limbs. |
| Warning | The air-hose which connects the cuff and monitor should be straightway without any tangle. |
| Warning | The measurement site, patient position, motion, and physiological status can all affect the NIBP reading. If you have doubts about the |

accuracy of the measurement results, please use other methods to check the patient's vital signs first, and then check whether the monitor's function is abnormal.

Warning

NIBP monitoring is prohibited to those who have severe hemorrhagic tendency or with sickle cell disease, otherwise, partial bleeding will appear.

Caution

Do not apply or pressurize the cuff on the arm on the side of a mastectomy or lymph node clearance.

Caution

Do not take the measurement when the patient uses diuresis or vasodilator.

Caution

The blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, manual, electronic, or automated sphygmomanometers.

Caution

Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring medical equipment on the same limb.

Caution

The NIBP measurement will not be affected when the monitor is connected to the patient on whom the electro-surgical unit and defibrillator is being used.

11.2 Measurement Interferences

- Do not apply cuff on the limb where skin damage has occurred or is expected.
- For patients with severe coagulation disorders, it is necessary to determine whether to carry out automatic blood pressure measurement according to clinical evaluation, because there is a risk of hematoma at the friction between the limb and the cuff.
- The patient has serious angiospasm, vasoconstriction, or weak pulse.
- When extremely low or high heart rate or serious arrhythmia of the patient occurs. Especially auricular fibrillation will lead to unreliable or impossible measurement.
- When the patient is suffering from massive hemorrhage, hypovolemia, shock and other conditions with rapid blood pressure change or when the patient has too low body temperature, the reading will not be reliable, for reduced peripheral blood flow will lead to reduced arterial pulsation.

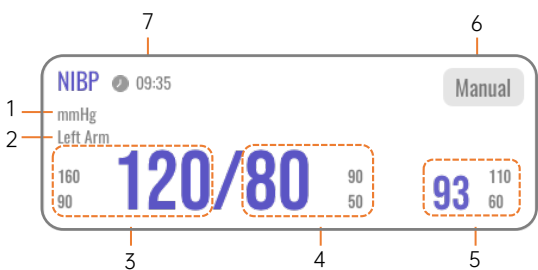
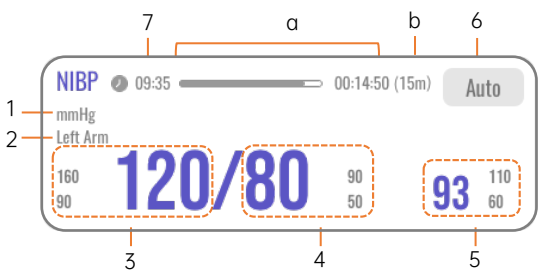
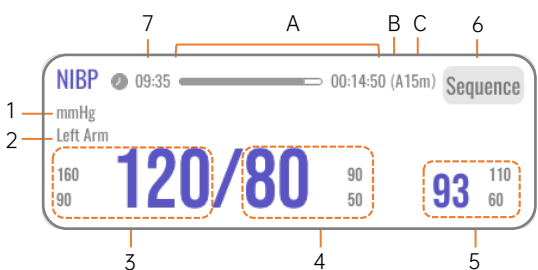
- The cuff should be at the same level with the heart. If not, the measurement may be inaccurate.
- Speak or motion during measurement may affect the measurement accuracy.
- The measurement interval should not be too short (should be greater than 2 minutes). For continuous blood pressure measurements, if the interval is too short, it can cause the arm to be compressed, resulting in a decrease in blood volume and thus a decrease in blood pressure.

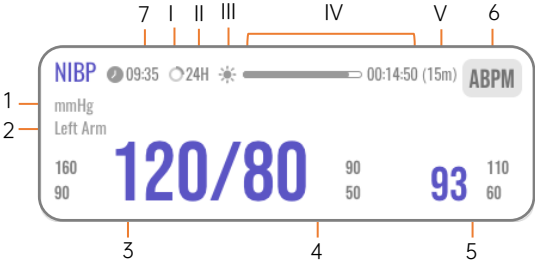
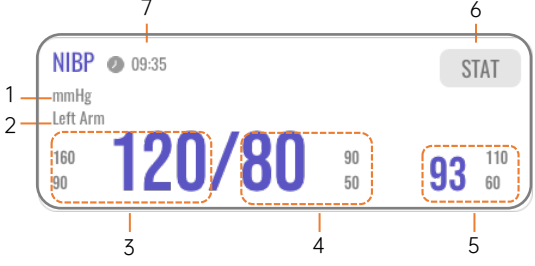
Requirements for patient posture, setting and operation:

- The patient should be positioned in a supine position with legs uncrossed, so that the cuff and the heart are in a horizontal position and the most accurate measurement is taken. Other postures may lead to inaccurate measurement.
- Do not speak or move before or during the measurement. Care should be taken so that the cuff will not be hit or touched by other objects. The air tube which connects the cuff and monitor should be straight without any tangles.
- It is recommended to take the first reading after the device runs for at least 5 minutes to ensure the stability of the measurement.
- The measurement should be taken at appropriate intervals. Continuous measurement at too short intervals may lead to pressed arm, reduced blood flow and lower blood pressure, and resulting inaccurate measurement of blood pressure. It is recommended the measurement be taken at intervals of more than two minutes.
- Patients should be measured in a relaxed and calm state, otherwise the accuracy of blood pressure measurement data will be affected.
- When taking NIBP measurements on adult patients, the monitor may fail to give the blood pressure measurement if the pediatric patient type is selected. When taking NIBP measurement on pediatric or neonatal patients, the operator must select the correct patient type depending on different patients and do not operate with the adult patient type setting. The high inflation pressure for an adult is not suitable for pediatric patients.

- If the original parts are replaced with parts not provided by the manufacturer, it may cause measurement errors.

11.3 NIBP Display

Manual  The manual display screen shows the following information: 1. Unit: mmHg, 2. Measurement site: Left Arm, 3. Systolic pressure and alarm limits: 160/90, 4. Diastolic pressure and alarm limits: 80/50, 5. Mean arterial pressure and alarm limits: 93/60, 6. Measurement mode: Manual, 7. Measurement start time: 09:35.	Common symbol description: 1 NIBP unit 2 Measurement site 3 Systolic pressure and alarm limits 4 Diastolic pressure and alarm limits 5 Mean arterial pressure and alarm limits 6 Measurement mode 7 Measurement start time
Auto measurement  The auto measurement display screen shows the following information: 1. Unit: mmHg, 2. Measurement site: Left Arm, 3. Systolic pressure and alarm limits: 160/90, 4. Diastolic pressure and alarm limits: 80/50, 5. Mean arterial pressure and alarm limits: 93/60, 6. Measurement mode: Auto, 7. Measurement start time: 09:35. A progress bar is shown between the start time and the next measurement time (00:14:50 (15m)).	Auto Measurement: - a Countdown and progress bar to the next measurement - b measurement interval
Sequential measurement  The sequential measurement display screen shows the following information: 1. Unit: mmHg, 2. Measurement site: Left Arm, 3. Systolic pressure and alarm limits: 160/90, 4. Diastolic pressure and alarm limits: 80/50, 5. Mean arterial pressure and alarm limits: 93/60, 6. Measurement mode: Sequence, 7. Measurement start time: 09:35. A progress bar is shown between the start time and the next measurement time (00:14:50 (A15m)). The progress bar is divided into three phases: A (Countdown and progress bar to the next measurement), B (Current phase), and C (Measurement interval).	Sequential Measurement: - A Countdown and progress bar to the next measurement - B Current phase - C Measurement interval

ABPM measurement 	ABPM Measurement: - I Progress of completion - II Total duration - III Period (adaption, day and night) - IV Countdown and progress bar to the next measurement - V Measurement interval
STAT 	

Note

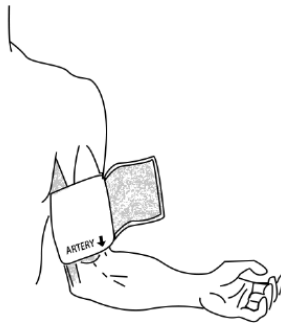
If NIBP measurement fails, "XX" is displayed in the numerics area; if NIBP measurement is untaken, stopped, reset, or venous puncture is completed, no parameter is displayed.

11.4 NIBP Monitoring Preparation

Before starting the NIBP measurement, make sure that the patient remains calm and is relaxed.

- 1 Make sure that the patient type setting is correct.
- 2 Select an appropriate cuff according to the patient's age and limb circumference. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the length of the upper arm or the thigh. The inflatable part of the cuff should be long enough to encircle to overlap at least 50% to 80% of the limb.
- 3 Empty the cuff until there is no residual air inside it to ensure accurate measurement.
- 4 Connect the cuff to the air tubing.

- 5 Connect the air tubing to the NIBP connector on the monitor.
- 6 Put on the cuff, unfold and wrap it around the patient's upper arm or thigh evenly to appropriate tightness.
- 7 Locate the cuff in such a way that the "ARTERY" mark  is at a location where the clearest pulsation of brachial artery is observed. The cuff should fit snugly, but with enough room for two fingers to be placed between the cuff and the patient's arm (on adults). The cuff should be at the same level with the heart, and the lower end of the cuff should be 2 cm above the elbow joint, as shown in the figure below:



11.5 Starting and Stopping NIBP Measurements

Warning

Before start measuring, make sure the mode and its settings are proper. For the auto-typed measurement modes (Auto, Sequence, ABPM), check the interval and duration and ensure the safe use for current patient.

Warning

STAT mode can only be used for adults.

Start NIBP measurement	• Enter NIBP setup screen → Select [Start NIBP] • Select quick key [Start NIBP]
Start STAT measurement	• Enter NIBP setup screen → Select [STAT]
Stop current NIBP measurement	• Enter NIBP setup screen → Select [Stop NIBP] • Select quick key [Stop NIBP]
Stop all NIBP	• Enter NIBP setup screen → Select [Stop All] When select [Stop All], all the follow-up measurements preset in auto-typed mode are cancelled in the auto-typed mode. The venous puncture stops together.

11.6 Correcting the NIBP Measurements

The middle of the cuff should be at the level of right atrium. If the limb is not at the heart level, the measurement should be corrected as follows:

- Add 0.75 mmHg (0.10 kPa) to the displayed value for each centimetre higher.
- Deduct 0.75 mmHg (0.10 kPa) to the displayed value for each centimetre lower.

11.7 NIBP Setup

Access NBIP setup screen in either of the following ways:

- Select the NIBP parameter area.
- Select **[Main Menu]** → **[Parameters]** → **[NIBP]** tab.

Access NIBP alarm setup screen in either of the following ways:

- Select the Temp parameter area → **[Alarms Setup]** button
- Select **[Main Menu]** → **[Alarms]** → **[NIBP]** tab

Item	Functions	Details
Mode	Set up NIBP measurement mode.	Mode options: Manual, Auto, Sequence, ABPM, STAT • Manual: Conduct one NIBP measurement. • Auto: Automatically repeat NIBP measurement according to the preset interval. • STAT: Continual rapid series of measurements over a five-minute period, then return to the previous mode. The monitor will not stop making measurement until the measuring time is over 5 minutes or the operator stops it manually. • Sequence: Continual automatic measurement at set duration and interval of each phase. In this mode, a complete measurement includes up to 7 phases (A, B, C, D, E, F, G). When the duration of a certain phase is set to Off, measurements after that

Item	Functions	Details
		phase are not performed. • ABPM: Continual automatic measurement at set duration and interval of adaptation period, day and night for 24 hours and above.
Site	Set NIBP measurement site	NIBP measurement site includes left arm, right arm, left leg, right leg.
Interval*	Set the interval between two NIBP measurements.	Provide the fixed interval and clock interval. Fixed interval example: When the interval is set to [30 min], after the the monitor start the first measurement at the time of 13: 03, the followed measurement time will be 13:33, 14: 03,... Clock interval example: When the interval is set to [Clock 30 min], the NIBP measurement time based on the clock time. After the the monitor starts the first measurement at the time of 13: 03, the followed measurement time will be 13:30, 14: 00,...
Initial Pressure	Set the initial cuff inflation pressure	See A.7 NIBP Specifications for inflation range.
Unit	Set the NIBP unit	mmHg or kPa, in which 1 kPa=7.5 mmHg
[NIBP] alarm tab	Set the alarm properties of systolic, diastolic and mean arterial pressure (MAP)	Set alarm switch, high/low limit, or priority.

Chapter 12 Monitoring Carbon Dioxide (CO₂)

CO₂ measurement is used to monitor the patient's respiratory status. This monitor provides the mainstream and sidestream methods for CO₂ monitoring.

- Mainstream measurement: directly insert a mainstream CO₂ sensor attached to an airway adapter into the patient's breathing system, allowing the inspired and expired gas to pass directly across the IR light path. The major advantages of mainstream sensors are fast response time.
- Sidestream measurement: sidestream CO₂ sensors are located away from the airway, requiring a gas sample to be continuously aspirated from the breathing circuit and transported to the sensor by means of a pump. This type of system is needed for non-intubated patients.

CO₂ monitoring is intended for adult, pediatric and neonatal patients.

12.1 Safety Information

- | | |
|---------|---|
| Warning | Only use the manufacturer's approved accessories. |
| Warning | Explosion Hazard: Do not use in the presence of flammable anesthetics or other flammable gasses. Use of the CO ₂ Sensor in such environment may present an explosion hazard. |
| Warning | Electric Shock Hazard: Do not open the sensor cabinet at will, the CO ₂ Sensor contains no user serviceable parts. |
| Warning | Electrical Shock Hazard: Always disconnect the CO ₂ Sensor before cleaning. Do NOT use if it appears to have been damaged. Contact service personnel for help. |
| Warning | Do not sterilize or immerse the CO ₂ sensor in liquids. |
| Warning | Do not use the CO ₂ sensor when it is wet or has exterior condensation. |
| Warning | Do not apply excessive tension to any sensor cable or pneumatic tubing. |
| Warning | If the CO ₂ sensor fails to respond as described in this manual, do not use it until approved for use by qualified personnel. |
| Warning | Reuse, disassembly, cleaning, disinfecting the single patient use CO ₂ cannula kits and on-airway adapters may compromise functionality and system performance, leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused. |

Warning	Inspect the sidestream on-airway adapters and sidestream sampling kits for damage prior to use. Do not use the sidestream on-airway adapters and sidestream sampling kits if they appear to be damaged or broken.
Warning	The risk of patient cross-infection will occur if the sampled gas is returned to the breathing system. The risk could be reduced by cleaning and disinfecting the sidestream on-airway adapters and the exhaust vent.
Warning	The monitor should not be used with gas supplied from oxygen concentrators.
Warning	If the CO ₂ waveform (Capnogram) appears abnormal, inspect the CO ₂ airway adapters and replace if needed.
Warning	Place the exhaust vent of the CO ₂ sensor in drafty ambient and do not let anything block the exhaust vent.
Warning	Periodically check the CO ₂ /Flow sensor and tubing for excessive moisture or secretion buildup. Do not use them if there is excessive moisture or exterior condensation.
Warning	Prevent electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
Warning	Do not position the sensor cables or tubing in any manner that may cause entanglement or strangulation.
Caution	When changing sampling tube, it is suggested to choose the default sampling tube with dehumidifying function. The sampling tube without dehumidifying function may be easily blocked by excessive moisture (Service life: ordinary sampling tube: 6-12 hours; the sampling tube with dehumidifying function: about 120 hours).
Caution	If the measurement shows an abnormality caused by a sampling tube block, please replace it.
Caution	The total length of the sampling tube and extending airway tube shouldn't be longer than 3 meters. A tube that is too long may cause a measurement abnormality. If using a T connector sampling cannula kit, please insert the sampling tube with the tubes upward to avoid the effects of excessive moisture.
Caution	Cyclic pressure up to 10 kPa (100 cmH ₂ O) can affect the accuracy of measurement.
Caution	The monitor does not have automatic barometric pressure compensation function. Due to the different altitudes in different areas, set the barometric pressure value manually according to the local barometric pressure during CO ₂ monitoring. For more information, see Appendix D Typical Pressures and CO ₂ Readings at Altitudes.
Caution	When CO ₂ monitoring is not required, disconnect the sampling line from

the monitor.

Caution

Do not block the airway. Do not squeeze or bend the sampling line.

Note

The CO₂ sensor is a precision measurement component, please use it correctly and store it properly.

Note

Disposal of the CO₂ Sensor and its accessories should comply with national and/or local requirements.

Note

In the presence of electromagnetic devices (i.e., electrocautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20 V/m will not adversely affect system performance.

Note

Nitrous oxide, elevated levels of oxygen, helium and halogenated hydrocarbons can influence the CO₂ measurement.

Note

Excessive moisture in the CO₂ may affect the accuracy of the flow measurement.

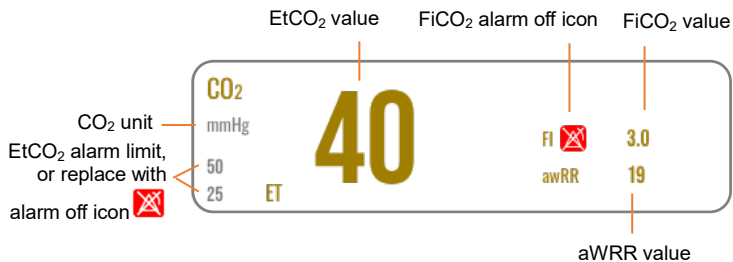
12.2 CO₂ Display

CO₂ waveform area

Label Wave gain



CO₂ parameter area



12.3 Measurement Limitations

The following factors may influence the measurement accuracy:

- Mechanical shock
- Cyclic pressure up to 10 kPa (100 cmH₂O).
- Other sources of interference, if any.

12.4 Zeroing the CO₂ Sensor

In the CO₂ setup screen, select the **[Zero]** button to open a window for CO₂ zeroing. At this time, place the sampling kit of the CO₂ sensor in a drafty place. Then press the **[Zero]** button in the window to perform the zero-resetting. The zeroing status will be displayed in the window. There are three zeroing status: Zeroing, Zero succeeded, Zero failed.

Warning

When perform a zeroing during the measurement, disconnect the sensor from the patient's airway first.

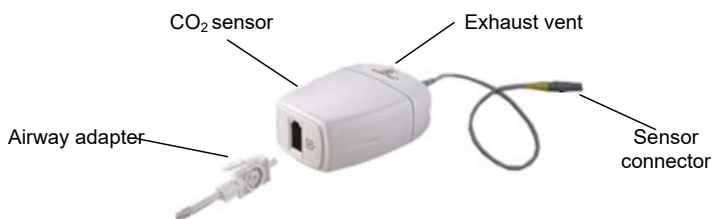
Warning

Please do not rely on the readings during zeroing.

12.5 Connecting CO₂ Sensor

12.5.1 Connecting the Sidestream CO₂ Sensor

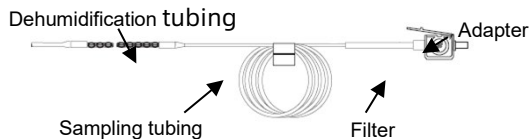
- 1 Insert one end of CO₂ sensor cable into the CO₂ module connector.
- 2 Insert the sampling tubing with adapter into the CO₂ sensor as shown in the figure below:



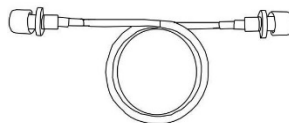
- 3 After finishing sensor connection, make sure that the air inlet of the sampling tube is exposed to room air and away from all sources of CO₂, including the ventilator, the patient's and operator's breathing.
- 4 Wait 2 minutes for the sensor to warm up.

12.5.2 Sidestream Sampling Tube Types

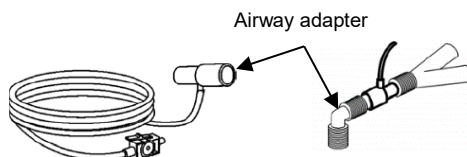
Adapter and sampling tube (single patient use)



Extended airway tube for connecting to sampling tube (Single patient use)



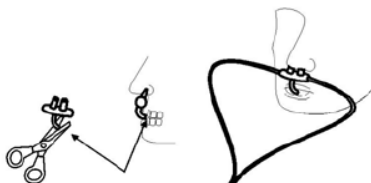
T connector sampling cannula kits



Nasal sidestream cannula kits



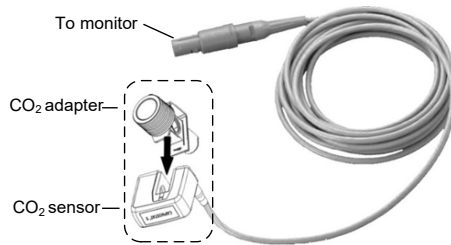
Oral sidestream cannula kits



12.5.3 Connecting the Mainstream CO₂ Sensor

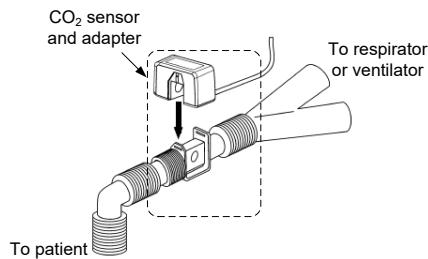
To connect the mainstream CO₂ sensor, follow the steps below:

1. Insert one end of CO₂ sensor cable into the CO₂ module connector, and install the adapter.

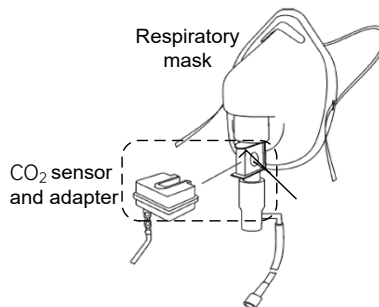


2. Connect the adapter with respiratory device and with patient.

➤ Connection with airway



➤ Connection with respiratory mask



- 3 After finishing sensor connection, make sure that the air inlet of the sampling tube is exposed to room air and away from all sources of CO₂, including the ventilator, the patient's and operator's breathing.
- 4 Wait 2 minutes for the sensor to warm up.

12.6 CO₂ Setup

Access CO₂ setup screen in either of the following ways:

- Select the CO₂ parameter area.
- Select **[Main Menu]** → **[Parameters]** → **[Resp]** tab.

Item	Functions	Details
Speed	Set CO ₂ waveform sweeping speed.	The larger the value, the faster the sweeping speed.
Gain	Set CO ₂ waveform amplitude.	The greater the gain, the higher the amplitude of waveform.
Unit	Set CO ₂ unit	Options: %, mmHg, kPa
Work Temp	Set the balance gas temperature in patient's respiration air flow.	Setting range: 0.0°C-50.0°C
CO ₂ Flow	Set the flow rate of the CO ₂ sampling.	Unconfigurable.
Period	Set the calculating cycle of the CO ₂ value.	Options: 1 b (calculate once every respiration cycle) 10 s (calculate once every 10 seconds) 20 s (calculate once every 20 seconds).
Balance Gas	Set the balance gas in patient's respiration air flow.	Options: Air, N ₂ O, He
O ₂ Concentration	Set the amount of oxygen in the balance gas.	Setting range: 1% - 100%.
AG	Set the amount of anaesthetic gas in the balance gas.	Setting range: 0.0% - 20.0%
Atmospheric Pressure	Enter the value of ambient atmospheric pressure.	The pressure unit is mmHg
[CO ₂] alarm tab	Set the alarm properties.	Set the alarm switch, high/low limits, or priority of EtCO ₂ , FiO ₂ , Apnea. Set the Apnea delay time.

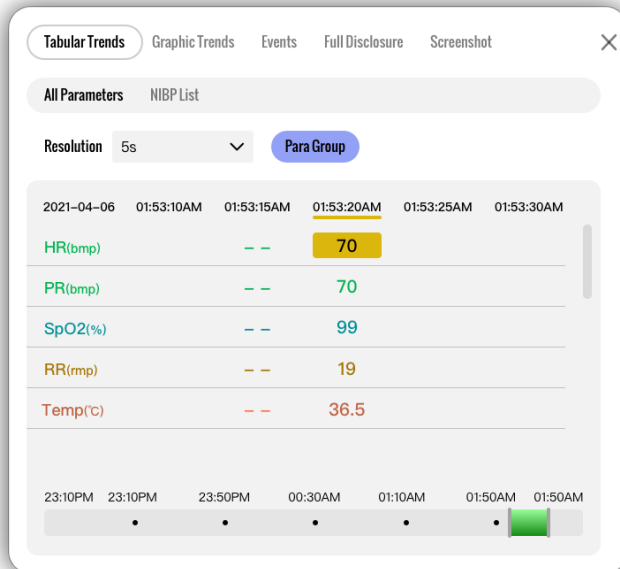
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Chapter 13 Review

Select **[Main Menu]**→**[Review]** to enter the Review screen. You can review trends, events, full disclosure waveforms, and OxyCRG so that you can understand how the patient's condition is developing.

13.1 Tabular Trends

The tabular trends page displays trend data in a tabular form.



In the tabular trends review screen, you can perform the following operations:

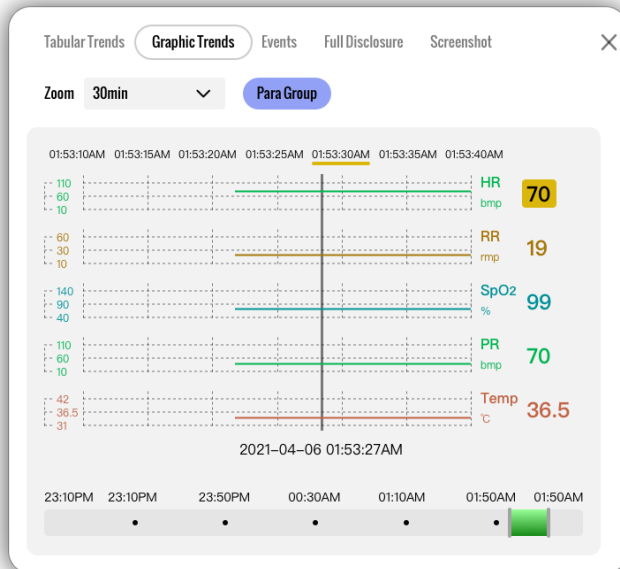
- View trend data in either of the following ways:
 - Drag the slider on the time line left or right, to locate the trend data at a specific time. At the same time, the parameter values displayed in the current screen will be refreshed accordingly.
 - Slide your finger up/down or left/right on the screen to observe other parameters or data.
- Select the parameters in the pop-up menu of **[Para Group]** to set the parameters to be displayed in the trends.

- Set **[Resolution]** to define the interval of displaying trend data displayed on the screen.

A short interval is especially suited for neonatal monitoring, where the clinical situation may change very quickly in a short time. In adult monitoring, where the patient's status typically changes more gradually, a longer interval may be more informative.

13.2 Graphic Trends

The graphic trends review page displays trend data in a visual format.



In the graphic trends review screen, you can perform the following operations:

- View trend data in either of the following ways:
 - Drag the slider on the time line left or right, to locate the trend data at a specific time. At the same time, the parameter values displayed in the current screen will be refreshed accordingly.
 - Slide your finger up/down or left/right on the screen to observe other parameters or data.
- Select the parameters in the pop-up menu of **[Para Group]** to set the parameters to be displayed in the trends.

- Select **[Zoom]** to set the length of trend data displayed on the current screen.

13.3 Events Review

The monitor stores events in real-time. You can view arrhythmia events, physiological alarm events, technical alarm events, and alarm logs in the Events screen.



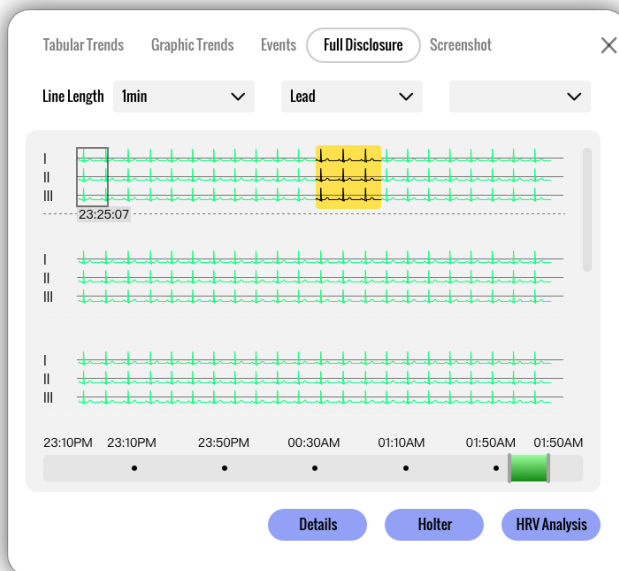
The Events screen displays the event list. Events are displayed in descending chronological order, with the most recent displayed at the top.

Select **[Filter]** to set the filter criterion:

- For arrhythmia events, you can filter the events by their alarm priority.
- For the physiological and technical alarms, you can filter the events by alarm priority and parameters.

13.4 Full Disclosure

In the full disclosure screen, you can view compressed waveforms, full waveforms, and numeric values.



In the Full Disclosure screen, you can perform the following operations:

- View the full disclosure waveforms in either of the following ways:
 - Drag the slider left /right on the time line, to locate the waveform at a specific time.
 - Slide your finger up/ down on the screen to observe the waveforms at other time points.
 - Select a desired location at the waveforms and then a frame appears. Select **[Line Length]** to set the time length of displayed waveforms.
- Select **[Lead]** to set the desired waveforms to be displayed. Up to three channels of waveforms can be displayed.
- Select **[Details]** button to view the all leads, full-size waveforms and parameter values in a new screen. In the new screen, select **[Overview]** to switch back to the compressed waveform screen.

Chapter 14 Cleaning and Disinfection

14.1 Safety Information

- | | |
|----------------|--|
| Warning | Do not immerse the device and accessories in liquid. |
| Warning | Do not pour liquid on the device or accessories. Do not allow the liquid permeate into the device. |
| Warning | Do not use abrasive materials or any strong corrosive solvents for cleaning to avoid scratches or damages to the device. |
| Warning | The parts contacted by the infected or suspected patient should be disinfected. |
| Warning | The manufacturer is not responsible for the effectiveness of the disinfectant or disinfection method used as a means of infection control. Please consult your hospital's infection control director or epidemiologist for advice. |

14.2 Recommended Cleaning and Disinfection Agents

Supported cleaning agents include:

- Water
- Mild soapy water
- Non-corrosive diluted cleaner

Supported disinfection agents include:

- Ethanol (70%~75%)
- Isopropanol (70%)
- Hydrogen peroxide (3%)

Supported cleaning and disinfection tools include cotton ball, soft gauze, soft brush, and soft cloth.

14.3 Cleaning

Clean the exterior surface of the monitor monthly or more frequently if needed.

To clean the monitor, follow the steps below:

- 1 Turn off the monitor and disconnect it from the DC power cable and accessories.
- 2 Clean the surface of the monitor with a clean soft gauze moistened with one of the recommended cleaning agents.

- 3 Wipe off all the cleaning agent residue with a clean dry cloth. Dry your monitor in a ventilated, cool place.

Caution Keep the cleaning agent away from the connectors of the monitor and accessories while cleaning the device housing.

Caution Use non-aggressive cleaning agent to clean the surface of the monitor and the display screen.

Caution Most cleaning agents must be diluted before usage.

14.4 Disinfection

Disinfect the monitor in accordance with the disinfection procedures of your hospital. Clean the monitor before disinfection.

Warning Ethanol is flammable. Please keep away from fire while using the ethanol disinfectant.

Warning People allergic to ethanol are forbidden to use the ethanol disinfectant.

Caution Rubber and plastic products will harden after prolonged contact with alcohol disinfectants, hence the residual disinfectant should be removed in time after disinfection.

Caution Do not use radiation or steam for disinfection.

Caution Please avoid contact with the metal parts when user disinfects the device with peroxide or chlorine-containing disinfectants.

14.5 Sterilization

It is not allowed to sterilize the monitor and related accessories unless stated in their operation instructions.

14.6 Cleaning the Thermal Print Head

If the thermal printer has been used for a long time, deposits of paper debris may collect on the print head, which may affect the print quality and shorten the lifetime of the roller.

Caution The thermal head may be hot after completing the recording task. Do not clean the thermal head of the recorder immediately.

Follow this procedure to clean the thermal print head:

- 1 Take measures against the static electricity such as Disposable Wrist Strap for the work.
- 2 Open the printer door and take out the paper.
- 3 Gently wipe around the print head using cotton swabs dampened with Ethanol.

- 4 After the Ethanol has completely been dried, reload the paper and close the printer door.

14.7 Cleaning, Disinfection and Sterilization of Accessories

For the cleaning, disinfection and sterilization methods of reusable accessories, refer to the instructions for use that accompany the accessories. If the accessories have no user manual accompanied, refer to this chapter for instructions on cleaning, disinfection, and sterilization of the monitor.

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Chapter 15 Care and Maintenance

In order to ensure the normal operation of the monitor and maintain its service life, please pay attention to the maintenance of the monitor.

15.1 Safety Information

Warning	No modification of this device is allowed.
Warning	This device contains no user serviceable parts.
Warning	The safety checks or maintenance involving any disassembly of the device should be performed by professional service personnel. Otherwise, undue device failure and possible health hazards could result.
Warning	A comprehensive inspection for the monitor (including functions and safety inspections) should be carried out by qualified personnel every year or after each maintenance.
Warning	Do not open the device housings. All servicing and future upgrades must be carried out by trained and authorized personnel.
Caution	If the user does not regularly check or maintain the monitor, it may affect its performance and safety.
Caution	If the user cannot implement a satisfactory maintenance plan, it may disable the monitor functions and endanger human health.
Caution	If you discover a problem with any of the device, contact your service personnel or our company.
Caution	Use and store the device within the specified temperature, humidity, and altitude ranges.
Caution	When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of the reach of children.
Caution	At the end of its service life, the device, as well as its accessories, must be disposed of in compliance with the local regulations regarding the disposal of such products. If you have any questions concerning disposal of the device, please contact our company.
Caution	The device and accessories shall not be serviced or maintained while in use on a patient.
Note	Upon request, the manufacturer may provide necessary circuit diagrams, component part lists, and other technical information to assist qualified service personnel in parts repair.

15.2 Routine Inspections

Before using the monitor, the checks below should be carried out:

- Check the monitor for any mechanical damages.
- Inspect the exposed parts and the inserted parts of all the cables and the accessories.
- Examine all the functions of the monitor that are likely to be used for patient monitoring, and ensure that it is in good working condition.
- Make sure that the monitor is grounded properly.

15.3 Regular Inspections

The monitor is designed with a service life of 10 years.

It is strongly recommended to use the product within its life cycle, or it may cause inaccurate measurement. During the long-term use, it is recommended that the user check and calibrate the monitor once a year to ensure the measurement accuracy. Due to the high risk of product aging in the last year of the service life, please pay close attention to the inspection results. Dispose of the monitor and its accessories when their service life is reached.

The inspection items mainly include:

- Check whether the safety signs are damaged.
- Check the main unit and accessories for mechanical and functional damages.
- Carry out the protective grounding impedance, leakage current and insulation resistance test according to the requirements of IEC60601-1.
- Verify the functions of the device according to the operator's manual.

The test and results recording should be carried out by trained and qualified personnel with the safety test knowledge. Please maintain the monitor if any problem is detected in the above tests.

15.4 Battery Maintenance

The performance of the battery deteriorates over time. It is recommended to check and condition the battery every three months.

Caution

Do not condition the monitor battery while a patient is under monitoring.

Caution

If the battery conditioning has not been conducted for a long time, the battery capacity display may be inaccurate, causing the incorrect judgment of remaining battery runtime.

Caution

The operating time of the battery reflects its performance directly. If the operating time of a battery is noticeably shorter than that stated in the specifications, the battery may have reached its service life or be malfunctioning.

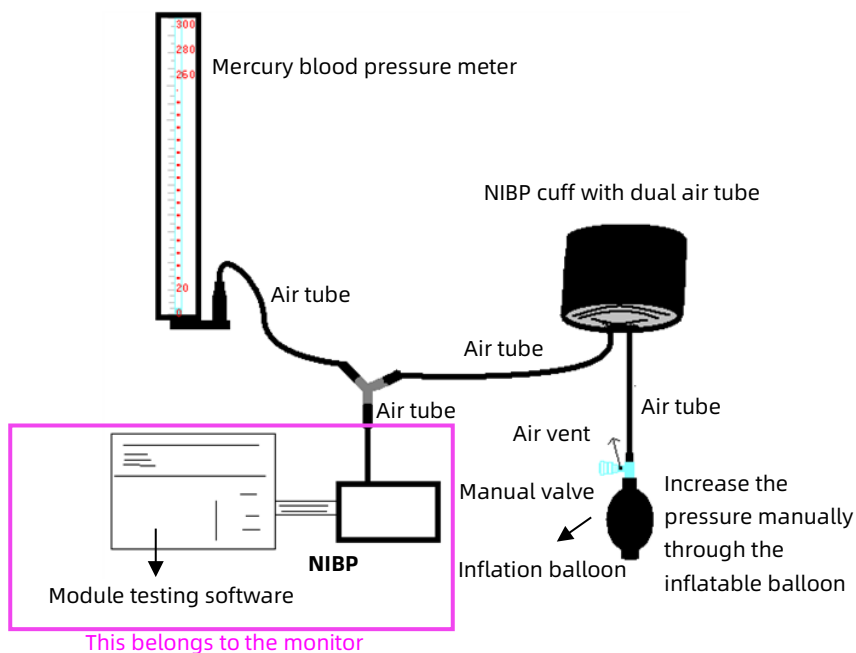
Perform battery conditioning as follows:

- 1 Disconnect the monitor from the patient and stop all monitoring and measurements.
- 2 Allow the battery to be charged uninterruptedly until it is fully charged.
- 3 Allow the monitor to run on the battery until the battery is completely depleted and the monitor automatically shuts down.
- 4 Fully recharge the battery for use or charge it to 40%-60% for storage.

15.5 NIBP Pressure Accuracy Verification

NIBP pressure accuracy verification is a function to inspect the accuracy of pressure measurement by the NIBP module inside the device. A technician or device manager should perform pressure accuracy verification every six months or a year in order to check if the pressure measurement still conforms to the requirement of product performance. If the deviation is beyond the declared specification, it is permitted to return it to factory for repair or calibration.

Before verification, please connect the monitor to a precision pressure meter as the reference equipment like a mercury pressure meter.



Mode 1: Automatic inflation for the pressure accuracy verification

In this mode, the monitor can activate the inflation, so the pressure will increase automatically until it exceeds the limit value specified in the table below. This pressure limit value depends on the patient type selection as shown in the table below:

Patient Type	Mode 1 (Maximum pressure value)	Mode 2 (Over-pressure protection pressure value)
Adult	240 mmHg	300 mmHg
Pediatric	200 mmHg	240 mmHg

During the inflation, the monitor will close the deflating valve, and the pressure value will be shown during the process. If there is no manual deflation operation, the pressure will persist until deflation by manual operation, so it is necessary to use a manual valve for doing adequate deflation in several steps to verify the pressure accuracy in the full scale of measurement range.

Mode 2: Manual inflation for the pressure accuracy verification

In this mode, the pressure should be increased manually by a pumping balloon, and the verification can be done by applying different pressure value manually. If the increased pressure exceeds the given limit as shown in the table above, the monitor will deflate automatically because of over-pressure protection.

To perform the NIBP pressure accuracy verification, follow the steps below:

- 1 Press **[Main Menu]** → **[Maint.]** → input password → press **[Enter]**.
- 2 Select the **[Module]** tab.
- 3 Select **[Auto Pressure Test]** to perform automatic inflation for the pressure accuracy verification. Or select **[Manual Pressure Test]** to perform manual inflation for the pressure accuracy verification.

Warning

Pressure accuracy verification must be operated by technician or device manager. Physicians and nurses are not allowed to do the verification, it is very dangerous especially when the pressure cuff is still on patients.

Caution

After the verification, do press the button again to return to normal working mode, then continue other operation, or the NIBP measurement key will be invalid.

15.6 Storage, Packaging and Transportation

If the monitor will not be used for a long time, wipe it clean and keep it in the packaging, which shall be kept in a dry and well ventilated room free from dust and corrosive gases.

The monitor is packed in high quality corrugated cartons with foam inside to protect the monitor against damage during transportation.

The outer packaging box is marked with gross weight and dimension.

The monitor should be transported by land (vehicle or railway) or air in accordance with the contractual terms. Do not hit or drop it with force during transportation.

15.7 Viewing System Version

When performing maintenance for the monitor, you may need to check the system and module information.

Select **[Main Menu] → [System] → [Version]**, you can view the system software version, hardware version, module version, firmware version, and other version information.

Chapter 16 Troubleshooting

Status	Possible Causes	Handling Measures
Battery cannot be recharged and/or fully charged	Battery is defective	Contact the service personnel and replace the battery.
	Main board is defective	Contact the service personnel and replace the main board.
Alarm lamp does not light	Mainboard is defective	Contact the service personnel and replace the main board.
No alarm sound	Audible alarm is disabled	Check if  is displayed. If yes, the audible alarm is disabled.
	Speaker is defective	Contact the service personnel and replace the speaker.
	Mainboard is defective	Contact the service personnel and replace the main board.
Excessive ECG signal interferences, or thick baseline	Check that the electrodes are properly located	Adjust the electrode placement
	Check that valid electrodes are being used	Replace the electrode
	Check if lead wires are properly inserted	Properly connect the cable
	Check that the mains outlet has standard grounding wire.	Replace the outlet with protective grounding wire.
No SpO ₂ readings	Check that the SpO ₂ sensor is properly connected to the SpO ₂ connector.	Properly connect the cable
	Check that the indicator of the pulse oxygen sensor flashes	The SpO ₂ sensor is defective. Replace the sensor.
No NIBP readings	Check that the blood pressure cuff is properly wrapped around the arm	Properly wrap the cuff.

Status	Possible Causes	Handling Measures
	according to the instructions.	
	Check that cuff is leaking	If there is leakage, replace the cuff.
	Check that inlet is firmly connected to the NIBP jack.	Properly connect the cable
No CO ₂ readings	The temperature of the sensor is greater than 40°C	Repair or replace CO ₂ sensor
	Sensor faulty	Repair or replace CO ₂ sensor
Recorder produces unusual sounds	Check for a paper jam	Take out the paper and tear off the draped part. Reload the paper.

Chapter 17 Accessories

The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the monitor. The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1. For details about the accessories, refer to the instructions for use provided with the accessory.

Warning Use accessories specified in this chapter. Using other accessories may cause damage to the patient monitor or not meet the claimed specifications in this manual.

Warning Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do not apply to those who have anaphylaxis.

Warning Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.

Warning Reuse of disposable accessories may cause a risk of contamination and affect the measurement accuracy.

Warning Although the accessory material that contacts patients has been evaluated biologically and the biological safety meets the requirements of ISO 10993-1, very few people may have allergic reaction, and those with allergic reaction should stop using it!

Caution The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.

Caution Use the accessories before the expiration date if an expiration date is indicated.

Caution Do not use expired accessories.

Caution Discard disposable accessories according to your local regulations or hospital regulations.

Caution The accessories which can be used repeatedly should be cleaned thoroughly before use on another patient. Please refer to the related chapter for maintenance method.

Note Part No. is subject to change without prior notice, please refer to the label of parts or the supplied package list.

Note This manual describes all the accessories that are validated for use. Not all accessories are available in every market. Please check availability with your local supplier.

Note

For the replacement cycle and replacement method of the accessories, refer to the instructions for use provided with the accessory.

17.1 ECG Accessories

No.	Accessories	Model/Part No.	Description	Applicable Patient
1	ECG lead wire	KE-DGB031	3-electrode, snap, defibrillation-proof, reusable	Adult/ Pediatric/ Neonate
2	ECG lead wire	KE-DGB051	5-electrode, snap, defibrillation-proof, reusable	

17.2 SpO₂ Accessories

No.	Accessories	Model/Part No.	Description	Applicable Patient
1	SpO ₂ sensor	KS-AE01	Ear-clip, reusable	Adult
2	SpO ₂ sensor	KS-AC01	Finger-clip, reusable	Adult
3	SpO ₂ sensor	KS-AR01	Large finger-cot, reusable	Adult
4	SpO ₂ sensor	KS-AR02	Small finger-cot, reusable	Adult/ Pediatric
5	SpO ₂ sensor	KS-ALW02	L-type, with wraps, reusable	Neonate
7	SpO ₂ sensor	L-type, with wraps, disposable, non-sterile	L-type, with wraps, disposable, non-sterile	Neonate

17.3 Temp Accessories

No.	Accessories	Model/Part No.	Applicable Patient
1	Temp adapter	I5080006	Adult/ Pediatric/Neonate
2	Temp probe	KT-S00, surface	Adult/ Pediatric/Neonate
3	Temp probe	KT-A00, cavity	Adult/ Pediatric/Neonate

17.4 NIBP Accessories

No.	Accessories	Model/Part No.	Description	Applicable Patient
1	Cuff	KN-231	10 cm-19 cm, reusable	Adult/ Pediatric
2	Cuff	KN-233	18 cm-26 cm, reusable	
3	Cuff	KN-241	25 cm-35 cm, reusable	
4	Cuff	KN-243	33 cm-47 cm, reusable	
5	Cuff	KN-114	7.1 cm - 13.1 cm, disposable	
6	Cuff	KN-115	8 cm - 15 cm, disposable	

17.5 CO₂ Accessories

No.	Accessories	Model/Part No.	Description	Applicable Patient
Respironics CO ₂				
1	CO ₂ sensor (Sidestream)	LoFlo	Sidestream	Adult/ Pediatric/ Neonate
2	Sampling cannula	#3475-00	Disposable, non-sterile	
3	CO ₂ sensor (Mainstream)	CAPNOSTAT 5	Mainstream	
4	Sampling adapter	#606300	Disposable, non-sterile	Adult/ Pediatric
Kingst CO ₂				
5	CO ₂ sensor (Sidestream)	Capnograph_S	Sidestream	Adult/ Pediatric/ Neonate
6	CO ₂ sampling line	15100121	240cm- ϕ 2.5*16, two male heads	
7	Filter	2500-0000218	T4F, T3	
8	CO ₂ sensor (Mainstream)	Capnograph_M	Mainstream	

No.	Accessories	Model/Part No.	Description	Applicable Patient
9	Airway adapter	2301-0000034	V9/ Mainstream	Adult/ Pediatric

17.6 Other Accessories

No.	Accessories	Specification/Model
1	Multi-functional adapter (VX)	150I0070
2	DC power adapter	LXCP40-01233
3	Monitor base	V-Base

Appendix A Technical Specifications

A.1 Overall Specifications

Classifications

Anti electric-shock type	Class I and internally powered device
Anti electric-shock degree	Type CF with defibrillation protection
Degree of protection against harmful ingress of water	Main unit: IPX2 Main unit + base: IPX1
Disinfection/sterilization method	Refer to <i>Chapter 14 Cleaning and Disinfection</i> .
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The device is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Operation mode	Continuous
Installation method	Non-permanent installation device
Electromagnetic compatibility	Group I, Class A

Environmental Specifications

Main unit

Environment	Temperature	Relative Humidity (Non-condensing)	Atmospheric pressure
Operating	0°C - 40°C	15% - 95%	57.0 kPa -107.4 kPa
Transport & Storage	-20°C - +60°C	10% - 95%	50.0 kPa-107.4 kPa

CO₂ Module (Sidestream)

Environment	Temperature	Relative Humidity (Non-condensing)	Atmospheric pressure
Operating	0°C - 40°C	10% - 90%	53.0 kPa -106 kPa
Transport & Storage	-20°C - +60°C	10% - 90%	53.0 kPa -106 kPa

CO₂ Module (Sidestream)

Environment	Temperature	Relative Humidity (Non-condensing)	Atmospheric pressure
Operating	0°C - 40°C	10% - 90%	50 kPa-106 kPa
Transport & Storage	-20°C - +60°C	< 90%	50 kPa-106 kPa

Power Supply Specifications

External power supply	
Input voltage	AC 100 - 240 V
Input power	0.6 A-0.2 A
Frequency	50 Hz/60 Hz
Battery	
Type	Built-in lithium-ion rechargeable battery
Rated voltage	DC 7.4 V
Battery capacity	5000 mAh

Run Time	≥ 360 min (standard operating mode) Standard operating mode: With a fully charged battery, NIBP measurement every 15 minutes, ECG, SpO₂, and temperature monitoring in continuous operation.
Charging Time	• When charged by external power supply, after the device is turned off, the charging time is as follows: Time of charging to 90% is less than 4 hours. Time of charging to 100% is less than 5 hours. • When charged by external power supply, after the device is turned on, the charging time is as follows: Time of charging to 90% is less than 10 hours. Time of charging to 100% is less than 13 hours.
Low-Battery Alarm	With a new battery, NIBP measurement every 15 minutes, ECG, SpO₂, and temperature monitoring in continuous operation, the lowest screen brightness. At least 20 minutes since the first low battery alarm. At least 5 minutes since the battery depleted alarm.
Data protection from power failure	This monitor protects your data from shutdown due to battery depletion. The monitored information will be automatically saved. Upon recharging or reconnecting to external power, the monitor will return to its pre-shutdown state.

Physical Specifications

Main unit size	254 mm×185 mm×28 mm
Weight	Main unit: 1.4 kg Base: 1.2 kg
Display screen	10.1 inches, 1280×800, color LCD screen with multi-touch capacitive touch panel.
Main Unit Indicators	Power/switch indicator: 1 (green, yellow and white) Alarm indicator: 1 (red, yellow and cyan)
Speaker	Support alarm tones (45 db to 85 db), key tone, QRS tone and system prompt tone. Support pitch tone and multi-level tone modulation. The standard alarm tones comply with IEC 60601-1-8
Main unit connectors	Multifunction adapter connector:1 NIBP cuff connector:1 CO₂ module connector: 1 Power adapter connector:1 PogoPin connector:1

	USB connector:1
Camera	Color CMOS camera, 8M pixels, 3264*2448
Base connectors	USB connector:3 PogoPin connector: 1 (for communication with main unit)
Thermal recorder	Recorder Indicator: 1 power indicator (Green); 1 error indicator (Red) Horizontal resolution: 8 dots/mm Vertical resolution: 8 dots/mm Paper width: 50 mm±1mm Paper speed: 25 mm/s, 50 mm/s

Signal Outputs Specifications

Alarm Output	
Alarm Delay	The delay time from alarm triggering to alarm indication is ≤ 6 s
Inherent alarm condition delay	The delay time to indicate the determined alarm condition ≤ 1 s

Data Storage

Patients	≤ 100
Trend Data	≤ 240 hours per patient
Full-disclosure waveforms	≤ 140 hours per patient
NIBP measurements	≤ 2000 sets per patient
Alarm events	≤ 1000 sets per patient

Wi-Fi Module

Frequency	2.4 G/5 G dual-band WLAN communication
Standard compliance	802.11 a/b/g/n and 802.11 ac
Transmission rate	≥ 2 MB/s

Network Security

Network condition	The monitor is connected to LAN through a wireless module and TCP/IP protocol, and can be connected to the central monitoring system produced by our company through LAN.	
Security software	The monitor is of an independent embedded software with communication protocol and verification, and does not support the use of other security software.	
Data and device interface	• USB interface: With USB 2.0 protocol, it supports batch export of discharged patient data through USB drive, including patient information, trend review, events, full-disclosure waveform data. The data storage format is dat and pdf. Support the use of USB drive for system upgrade. • Wireless network: The device uses Wi-Fi, and TCP/IP standard protocol for updating software and connecting to central monitoring system.	
Network security measures	Functions provided by the monitor through the network	Security measures
	The monitor uploads patient information, measurement data and alarms to the central monitoring system.	The communication protocol is a customized, private protocol based on TCP/IP. The communication port is the non-universal port agreed by both parties.
	The monitor send patient information, measurement data through network.	The communication protocol is a customized, private protocol based on TCP/IP. The communication port is the non-universal port agreed by both parties.
	The general network service function is not provided on the monitor, and the general network service port is closed.	
User access control mechanism	User types: medical staff, hospital equipment maintenance personnel, manufacturer maintenance personnel. User permissions: • Permission of medical staff: No password. The monitor automatically enter the monitoring screen after starting up, and can be set according to requirements, for example, all the modules can be accessed and set except setting unconfigurable alarms and maintenance functions. • Permission of hospital equipment maintenance personnel: Enter the maintenance password by inputting the hospital maintenance password, and then can set the configurable alarm, some of the maintenance functions (except version information,	

	original data collection and other functions). • Permission of manufacturer's maintenance personnel: Enter the maintenance menu by inputting the manufacturer's maintenance password. In addition to the permissions of the hospital equipment maintenance personnel, you can also export the original data collection and upgrade the software and parameter board.
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A.2 ECG Specifications

ECG	
Compliant standards	IEC 60601-2-27: 2011 and IEC 60601-2-25: 2011
Lead	Support monitor 3-electrode, 5-electrode ECG • 3-electrode lead: I, II, III • 5-electrode lead: I, II, III, aVR, aVL, aVF, V
Waveform sweeping speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error $\leq \pm 5\%$
Frequency response	Expand (Diagnostic) mode: 0.05 Hz-150 Hz Monitor mode: 0.5 Hz-40 Hz Surgery mode: 1 Hz-20 Hz
Display sensitivity	1.25 mm/mV($\times 0.125$), 2.5 mm/mV($\times 0.25$) 5 mm/mV($\times 0.5$), 10 mm/mV($\times 1$) 20 mm/mV($\times 2$), 40 mm/mV($\times 4$) Error $\leq \pm 5\%$
Common mode rejection ratio (CMRR)	Expand (Diagnostic) mode >90 dB Other modes >105 dB
Input impedance	≥ 10 M Ω
Input signal range	-10.0 mV to +10.0 mV (peak-to-peak value)
Electrode polarization voltage range	± 800 mV
Input offset current	≤ 0.1 μ A
Patient leakage current	50 μ A

Time constant	Monitor mode ≥ 0.3 s Expand (Diagnostic) mode ≥ 3.2 s
System noise	≤ 30 μ V (p-v RTI)
ESU protection	ESU cutting power: 300 W ESU coagulating power: 100 W Recovery time ≤ 10 s Heart rate change under ESU interference $\leq \pm 10\%$
Defibrillation protection	Withstands 5000 V (360 J) defibrillation discharge without data loss or damage Defibrillation energy absorption $\leq 10\%$ (100 Ω load)
Pacemaker pulse	
Pulse indication	It can mark pacemaker pulses with an amplitude of ± 2 mV - ± 700 mV and a pulse duration of 0.1 ms-2 ms.
Pulse rejection	It can suppress non-overshoot pacing pulses with an amplitude of ± 2 mV - ± 700 mV and a pulse width of 0.1 ms-2 ms. And it can also suppress the pacing pulses in IEC 60601-2-27-2011, including the presence of atrial and ventricular pacing pulses. The minimum input slew rate is 2.5 V/s $\pm 15\%$ RTI
Gain indicator	1mV, error: $\pm 5\%$
HR	
Measurement range and error	Adult: 15 bpm-300 bpm Pediatric/Neonate: 15 bpm-350 bpm Error: $\pm 1\%$ or ± 1 bpm, whichever is greater
Alarm limit range	Adult high limit: 16 bpm-300 bpm Adult low limit: 15 bpm-300 bpm Pediatric/Neonate high limit: 16 bpm-350 bpm Pediatric/Neonate low limit: 15 bpm-350 bpm
Alarm limit error	± 1 bpm
Tall T-wave rejection capability	For T wave with QRS wave of 100 ms, QT interval of 350 ms, duration of 180 ms and amplitude lower than 1.2 mV, the heart rate calculation is not affected.
Minute heart rate averaging algorithm	The latest 8 RR intervals are all in a certain range of average heartbeats.
Time of response to heart rate	From 80 bpm to 120 bpm ≤ 10 s From 80 bpm to 40 bpm ≤ 10 s

change	
Accuracy of heart rate meter and its response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (waveform A1): 80 bpm, error: ± 1 bpm Slow alternating ventricular bigeminy (waveform A2): 60 bpm, error: ± 1 bpm Rapid alternating ventricular bigeminy (waveform A3): 120 bpm, error: ± 1 bpm Bidirectional systoles (waveform A4): 90 bpm, error: ± 1 bpm
Time to alarm for tachycardia	<10 s (applicable to all clauses of IEC 60601-2-27)
Time to alarm for cardiac arrest	<10 s

A.3 Resp Specifications

Respiration excitation waveform	<300 μ A RMS, 64 kHz ($\pm 10\%$)		
RR measurement range	Adult: 0 rpm-120 rpm Pediatric/Neonate: 0 rpm-150 rpm		
RR measurement accuracy	Adult: 7-120 rpm: ± 2 rpm or $\pm 2\%$, whichever is greater Pediatric/neonate: 7-150 rpm: ± 2 rpm or $\pm 2\%$, whichever is greater Other range: not defined		
Alarm limit range		Adult	Pediatric/Neonate
	High limit	1 rpm-120 rpm	1 rpm-150 rpm
	Low limit	0 rpm-119 rpm	0rpm-149 rpm
Alarm error	± 1 rpm		
Apnea alarm delay range	5 s-120 s		
Waveform gain	$\times 0.125$, $\times 0.25$, $\times 0.5$, $\times 1$, $\times 2$, $\times 4$		
Waveform speed	50 mm/s, 25 mm/s, 12.5 mm/s, 6.25 mm/s		

A.4 SpO₂ Specifications

Compliant standards	ISO 80601-2-61: 2017
Measurement range	0%-100%
Display range	0%-100%
Measurement accuracy	70%-100%: $\pm 2\%$ 50%-69%: $\pm 3\%$ 0%-49%: not defined
Sensor	Wavelength: Red light: 660 nm, Infrared light: 905 nm Maximum optical output power ≤ 2 mW Note: The accuracy of the measurement may be affected when clinicians operate devices involving peak wavelengths (such as: photodynamic therapy devices).
Data update cycle	SpO ₂ <30 s
SpO ₂ accuracy test	The SpO ₂ measurements are statistically distributed, only about 2/3 of SpO ₂ measurements can be expected to fall within $\pm$ Arms of the value measured by a CO-Oximeter.
Refresh time	1 s
Perfusion index (PI) measurement range	0.1%- 20%
Alarm limit range	High limit: 1%-100%, Low limit: 0%-99% Alarm accuracy: 70%-100%, error $\pm 1\%$
Arms (%)	70%-100%, Arms accuracy < 3%

A.5 PR Specifications

Alarm limit range and error	High limit: 1 bpm-250 bpm Low limit: 0 bpm-249 bpm Alarm accuracy: $\pm 1\%$ or ± 1 bpm, whichever is greater
Data update cycle	PR <30 s
Refresh time	1 s
Display range	30 bpm-250 bpm
PR from NIBP module	

Measurement range and accuracy	30 bpm-250 bpm, error ± 3 bpm or $\pm 3\%$, whichever is greater
PR from SpO₂ module	
Measurement range and accuracy	30 bpm-250 bpm, error ± 2 bpm or $\pm 2\%$, whichever is greater

A.6 Temp Specifications

Compliant standards	ISO 80601-2-56: 2017
Measurement mode	Direct mode
Measurement range	0.0°C - 50.0°C
Measurement accuracy	0°C - 50°C, error $\pm 0.1^\circ\text{C}$ (without probe) 25.0°C - 45.0°C, error $\pm 0.2^\circ\text{C}$ Other Measurement range, error $\pm 0.4^\circ\text{C}$
System response time	$<150\text{s}$
Minimum time for accurate measurement	Body surface $<100\text{ s}$ Body cavity $<80\text{ s}$
Refresh time	1 s
Probe power provided by monitor	$<50\text{ }\mu\text{W}$
Alarm limit range and accuracy	High limit: 0.1 °C-50.0 °C, Low limit: 0.0 °C-49.9 °C Alarm accuracy: $\pm 0.1^\circ\text{C}$

A.7 NIBP Specifications

Compliant standards	IEC 80601-2-30: 2018
Mode	Manual, Auto, STAT, Sequence, ABPM
Automatic measurement mode repetition intervals	1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 h, 1.5 h, 2 h, 3 h, 4 h, 8 h, Clock 30 min, Clock 1 h

A.8 EtCO₂ Specifications

Compliant standards	ISO 80601-2-55: 2018	
Measurement mode	Sidestream and mainstream	
Measurement range	0 mmHg-150 mmHg (0.0 kPa-20.0 kPa)	
Measurement accuracy	0 mmHg - 40 mmHg (0 kPa - 5.3 kPa), Error: ± 2 mmHg (± 0.27 kPa) 41 mmHg - 70 mmHg (5.5 kPa - 9.3 kPa), Error: $\pm 5\%$ 71 mmHg - 100 mmHg (9.4 kPa - 13.3 kPa), Error: 8% 101 mmHg - 150 mmHg (13.4 kPa - 20.0 kPa), Error: $\pm 10\%$	
Alarm limit range and accuracy	High limit: 1 mmHg - 150 mmHg (0.13 kPa - 20 kPa) Low limit: 0 mmHg - 149 mmHg (0 kPa - 19.8 kPa) Alarm accuracy: ± 1 mmHg (± 0.13 kPa)	
Waveform gain	$\times 1/4$, $\times 1/2$, $\times 1$, $\times 2$, $\times 4$	
Waveform speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s.	
Gas Compensation	1%- 100%	
RR test method	Measure RR with respiratory simulator and I/E ratio as 1:1 according to EN ISO 80601-2-55 fig 201.101	
EtCO ₂ inaccuracy factor	The EtCO ₂ measurement accuracy is affected by the respiration rate. High RR causes a slight decrease in EtCO ₂ measurement accuracy.	
	EtCO ₂ (mmHg)	Respiration Rate (rpm)
	0-40	0-79
		± 2 mmHg
	41-70	≥ 80
		$\pm 12\%$
	70-100	0-79
		$\pm 5\%$
	≥ 100	≥ 80
		$\pm 12\%$
	0-79	$\pm 8\%$
		$\pm 12\%$
	≥ 80	$\pm 10\%$
		$\pm 12\%$
	Respironics CO ₂ Module	Kingst CO ₂ Module
Drift of measurement accuracy	The module works for more than 4 hours, and the maximum drift does not exceed 0.8 mmHg.	The module works for more than 4 hours, and the maximum drift does not exceed 1 mmHg.

Total system response time	<4 s	
Warm-up time	The time of reaching the specified working performance after the CO ₂ module is switched on: Mainstream: Parameters can be displayed within 15 s, and the ambient temperature is 25°C, and it takes 2 minutes to reach the specified working performance standard. Sidestream: Parameters can be displayed within 20 s, and the ambient temperature is 25°C, and it takes 2 minutes to reach the specified working performance standard.	
Maximum time interval of intervention	When the sampling gas temperature is 37°C, the indoor temperature is 23°C, and the sampling relative humidity is 100%, the maximum time interval for the operator to intervene in the water and gas treatment system is 120 hours.	
Airway respiration rate (awRR)		
	Respironics CO ₂ Module	Kingst CO ₂ Module
Measurement range and accuracy	Sidestream: 2 rpm- 150 rpm Mainstream: 0 rpm - 150 rpm Error: ±1 rpm	3 rpm-150 rpm Error: ±1 rpm
Alarm limit range and accuracy	High limit: 1 rpm-150 rpm Low limit: 0 rpm-149 rpm Alarm error: ±1 rpm	

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Appendix B Alarm Messages

B.1 Physiological Alarms

Alarm	Alarm Messages	Default Priority
General	XX High	Medium
	XX Low	Medium
ECG	Extreme Tachy	High
	Extreme Brady	High
Resp	Apnea	High
SpO ₂	SpO ₂ Desat	High
	SpO ₂ Event	Low
PR	Pulse not found	High
CO ₂	FiO ₂ shortage	Medium

B.2 Technical Alarms

Technical Alarms (ECG)

Alarm Messages	Priority	Causes
ECG lead off	High/ medium/low adjustable	All ECG leads fall off or ECG cable is not connected.
ECG xx lead off	High/ medium/low adjustable	The electrode is not firmly connected with the patient or falls off, resulting in the corresponding ECG lead falling off.

Technical Alarms (SpO₂)

Alarm Messages	Priority	Causes
SpO ₂ sensor off	Low, adjustable	The SpO ₂ sensor detaches from the patient.
SpO ₂ sensor disconnected	Low	The SpO ₂ main cable is disconnected from the multifunctional adapter, or the SpO ₂ sensor is disconnected from the

Alarm Messages	Priority	Causes
		main cable.
SpO ₂ no pulse	Low	The PR from SpO ₂ module cannot be detected.
SpO ₂ sensor error	Low	The SpO ₂ sensor is faulty.
SpO ₂ search pulse	Prompt	The monitor is searching for SpO ₂ pulse.
SpO ₂ low perfusion	Prompt	The SpO ₂ sensor is placed incorrectly or the patient's perfusion index is too low. Position SpO ₂ sensor correctly or replace the measuring site.

Technical Alarms (Temp)

Alarm Messages	Priority	Causes
Temp module error	Low	Temperature module self-test fails.
Temp X probe off	Low	Temperature probe detaches from the patient or multifunctional adapter.

Technical Alarms (NIBP)

Alarm Messages	Priority	Causes
NIBP too loose or disconnected	Low	Please check the cuff and air tubing for air leakage.
NIBP cuff or tubing leakage	Low	Please check the cuff and air tubing for air leakage.
NIBP signal too weak	Low	The patient's pulse is too weak or the cuff is too loose.
NIBP overrange	Low	The patient's blood pressure may exceed the measurement range.
NIBP excessive motion	Low	The patient's arm is not still.
NIBP overpressure protection	Low	The cuff may be squeezed or the module may be faulty.
NIBP measurement timeout	Low	If the measurement time is over 120 seconds in adult or pediatric mode and over 90 seconds in neonatal mode. The blood pressure cannot be obtained.
Cuff and patient	Low	The cuff used does not match the preset

Alarm Messages	Priority	Causes
type mismatch		patient type: use neonatal cuff in adult mode.
NIBP airway leak	Low	Air moving part, tube or the cuff leak air.
NIBP airway occlusion	Low	• Check whether the air tube is bent or squeezed • Check whether the patient is lying on the cuff • Check whether the cuff is wrapped in the correct position • Check whether the valve is open normally
NIBP measurement failed	Low	• At the beginning of the measurement, the cuff pressure is greater than 15 mmHg and does not drop below 15 mmHg within 5 s • Failed or incomplete extraction of blood pressure parameters • Other
NIBP module error	Low	• Sensor or A/D sampling error • EEPROM error • Not calibrated • Auto zeroing failed

Technical Alarms (CO₂)

Alarm Messages	Priority	Causes
CO ₂ sensor off	Low	The CO ₂ module cable is disconnected from the monitor
CO ₂ sensor temperature too high	Low	CO ₂ sensor temperature too high
CO ₂ sensor fault	Low	• Module current failure • EEPROM verification failed • Hardware error, etc.
CO ₂ zero required	Low	• The CO₂ sensor needs to be zeroed • Zero error • Check if the airway adapter needs to be cleaned, or zeroed
CO ₂ zeroing	Prompt	Sensor is zeroing

Alarm Messages	Priority	Causes
CO ₂ zero failed	Prompt	Sensor zeroing failed
Check CO ₂ sampling tube	Low	Airway pressure outside expected range. Check sampling line for blockage or kinks
Check CO ₂ adapter	Low	• The airway adapter is removed from the module • Optical blockage of the airway adapter window • Failed to perform zeroing when changing the adapter type • The calculated CO₂ is less than 0 for a period of time
CO ₂ over range	Low	The calculated value is greater than the upper limit of the CO ₂ parameter. if the error still exists after adjustment, please perform zeroing.

Technical Alarms (Power Supply)

Alarm Messages	Priority	Causes
Low battery	Medium	Low battery (after the first alarm of low battery, it supports no less than 20 minutes of work)
Battery depleted	High	Too low battery (The battery power is seriously low, it supports no less than 5 minutes of monitoring)
Battery error	High	Battery temperature is too high or voltage is too high
Power supply error	High	The AC voltage is too high/low, the voltage of the system power is too high/low

Other Technical Alarms

Alarm Messages	Priority	Causes
Recorder error!	Prompt	Recorder initialization error, communication error, or recorder unavailable

Alarm Messages	Priority	Causes
Recorder out of paper	Prompt	Recorder runs out of paper, or recorder door not closed.
Recorder not exist	Prompt	Recorder not connected
Central station disconnected	Prompt/High, Decided by distributed alarms switch	Monitor disconnected with central station
Obtaining wireless IP failed	Low	Can not obtain wireless IP address
Parameter board communication error	High	Communication error with parameter board

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Appendix C Default Settings

This chapter lists only the most important default settings of your monitor as it is delivered from the factory.

C.1 Alarm Defaults

Patient Type Parameter		Adult	Pediatric	Neonate
HR	Switch	On	On	On
	High	120 bpm	160 bpm	200 bpm
	Low	50 bpm	75 bpm	100 bpm
	Priority	Medium	Medium	Medium
Extreme Tachy	High	160 bpm	180 bpm	220 bpm
	Priority	High	High	High
Extreme Tachy	Low	35 bpm	50 bpm	60 bpm
	Priority	High	High	High
Arrhythmia	Asystole	Switch	On	On
		Priority	High	High
	V-Fib/V-Tachy	Switch	On	On
		Priority	High	High
	Vent Tachy	Switch	On	On
		Priority	High	High
	Vent Brady	Switch	On	On
		Priority	High	High
	Extreme Tachy	Switch	On	On
		Priority	High	High
	Extreme Brady	Switch	On	On
		Priority	High	High
	Nonsus V-Tachy	Switch	On	On
		Priority	Medium	Medium

Patient Type Parameter			Adult	Pediatric	Neonate
	Vent Rhythm	Switch	On	On	On
		Priority	Medium	Medium	Medium
	Run PVCs	Switch	On	On	On
		Priority	Medium	Medium	Medium
	PVCs Couplet	Switch	On	On	On
		Priority	Medium	Medium	Medium
	R on T	Switch	On	On	On
		Priority	Medium	Medium	Medium
	Vent Bigeminy	Switch	On	On	On
		Priority	Medium	Medium	Medium
	Vent Trigeminy	Switch	On	On	On
		Priority	Medium	Medium	Medium
	PVCs/min	Switch	On	On	On
		Priority	Medium	Medium	Medium
	Multiform PVC	Switch	On	On	On
		Priority	Medium	Medium	Medium
	PVC	Switch	On	On	On
		Priority	Medium	Medium	Medium
	Tachy	Switch	On	On	On
		Priority	Medium	Medium	Medium
	Brady	Switch	On	On	On
		Priority	Medium	Medium	Medium
	A-Fib (HR High)	Switch	On	On	On
		Priority	Medium	Medium	Medium
	A-Fib	Switch	On	On	On
		Priority	Medium	Medium	Medium
	A-Fib End	Switch	On	On	On

Patient Type Parameter			Adult	Pediatric	Neonate
		Priority	Medium	Medium	Medium
		Switch	On	On	On
	Irr Rhythm	Priority	Medium	Medium	Medium
		Switch	On	On	On
	Irr Rhy End	Priority	Medium	Medium	Medium
		Switch	On	On	On
	Pause	Priority	Medium	Medium	Medium
		Switch	On	On	On
	Pauses/min	Priority	Medium	Medium	Medium
		Switch	On	On	On
	Missed Beats	Priority	Medium	Medium	Medium
		Switch	On	On	On
	Pacer Not Pacing	Priority	Medium	Medium	Medium
		Switch	On	On	On
	Pacer Not Capture	Priority	Medium	Medium	Medium
		Switch	On	On	On
	PAC	Priority	Medium	Medium	Medium
		Switch	On	On	On
	PACs Couplet	Priority	Medium	Medium	Medium
		Switch	On	On	On
	SV Bigeminy	Priority	Medium	Medium	Medium
		Switch	On	On	On
	SV Trigeminy	Priority	Medium	Medium	Medium
		Switch	On	On	On
	2nd Degree A-V Block	Priority	Medium	Medium	Medium
		Switch	On	On	On
	1st Degree A-V Block	Priority	Medium	Medium	Medium
		Switch	On	On	On

Patient Type Parameter		Adult	Pediatric	Neonate
RR	Switch	On	On	On
	High	30 rpm	30 rpm	100 rpm
	Low	8 rpm	8 rpm	30 rpm
	Priority	Medium	Medium	Medium
Apnea	Switch	On	On	On
	Priority	High	High	High
	Apnea delay	20 s	20 s	15 s
Temp1/ Temp2	High	38.0°C	38.0°C	38.0°C
	Low	35.0°C	35.0°C	35.0°C
	Priority	Medium	Medium	Medium
ΔT	Switch	On	On	On
	High	2.0	2.0	2.0
	Priority	Medium	Medium	Medium
SpO ₂	Switch	On	On	On
	High	100%	100%	95%
	Low	90%	90%	90%
	Priority	Medium	Medium	Medium
SpO ₂ Desat	Switch	On	On	On
	Low	80%	80%	80%
	Priority	High	High	High
SpO ₂ Event	Switch	On	On	On
	High	3%	3%	3%
	Priority	Low	Low	Low
PR	Switch	On	On	On
	High	120 bpm	160 bpm	200 bpm

Patient Type Parameter		Adult	Pediatric	Neonate
	Low	50 bpm	75 bpm	100 bpm
	Priority	Medium	Medium	Medium
NIBP-S	Switch	On	On	/
	High	160 mmHg	120 mmHg	/
	Low	90 mmHg	70 mmHg	/
	Priority	Medium	Medium	/
NIBP-D	Switch	On	On	/
	High	90 mmHg	70 mmHg	/
	Low	50 mmHg	40 mmHg	/
	Priority	Medium	Medium	/
NIBP-M	Switch	On	On	/
	High	110 mmHg	90 mmHg	/
	Low	60 mmHg	50 mmHg	/
	Priority	Medium	Medium	/
EtCO ₂	Switch	On	On	On
	High	50 mmHg	50 mmHg	45 mmHg
	Low	25 mmHg	25 mmHg	30 mmHg
	Priority	Medium	Medium	Medium
FiCO ₂	Switch	On	On	On
	High	4 mmHg	4 mmHg	4 mmHg
	Priority	Medium	Medium	Medium

C.2 System Default Settings

Screen	Item	Default Setting
ECG Setup	Lead Type	5 leads
	ECG1	II
	ECG2	V
	Speed	25 mm/s
	Gain	Auto
	Filter	Diagnosis
	Notch Filter	On
	Grid	Off
Resp Setup	Speed	6.25 mm/s
	Gain	×2
	Apnea Delay	Adult/Pediatric: 20 s Neonate: 15 s
	RR Source	Auto
	Resp Lead	Adult/Pediatric: Auto Neonate: II
SpO ₂ Setup	Speed	25 mm/s
	Display PI	On
	PR Source	Auto
	NIBP Simul.	Off
Temp Setup	Temp1 Label	Temp1
	Temp2 Label	Temp2
	Unit	°C
NIBP Setup	Measurement mode	Manual
	Limb	Left Arm
	Interval	15 min
	Unit	mmHg

Screen	Item	Default Setting		
	Initial Pressure	Adult: 160; Pediatric: 140		
	Venipuncture	Auto		
	Sequence	Phase	Duration	Interval
		A	1 h	10 min
		B	12 h	15 min
		C	8 h	30 min
		D	4 h	15 min
		E	Off	/
		F	Off	/
		G	Off	/
	ABPM	Time Type	Duration	Interval
		Adaption	1 h	10 min
		Day	6:00 - 22:00	15 min
		Night	22:00 - 6:00	30 min
CO ₂ Setup	Speed	6.25 mm/s		
	Gain	Adult/Pediatric: ×1; Neonate: ×2		
	Concentration Unit	mmHg		
	Work Temp(°C)	35.0		
	Flow	50 ml/min		
	Calculation Period	10 s		
	Balance Gas	Air		
	Gas Compensation(%)	16		
	AG(%)	0.0		
	Atmospheric Pressure	760 mmHg		

Screen	Item	Default Setting
System Setup	Key Volume	On
	QRS Volume	6
	Alarm Volume	6
	Brightness	6
	QRS	Mode 2
	Date Format	YYYY-MM-DD
	Time Mode	24 hours
Patient Info	Patient Type	Adult
	Gender	Unknown
	Height	cm
	Weight	kg
	Paced	No
Maintenance - Alarm	Physio. Alarm Latch	Off
	Alarm Audio Mode	ISO
	Alarm Audio Paused Time	2 min
	High Alarm Audio Interval(s)	10
	Med Alarm Audio Interval(s)	20
	Low Alarm Audio Interval(s)	20
	Reminder of Alarm Audio Off	Enable
	V-Tachy/V-Fib Off	Disable
	Apnea Off	Disable
	ECG Lead Off	Low

Screen	Item	Default Setting
	SpO ₂ Sensor Off	Low
	Distributed Alarm	Disable
	Permission Password	Enable

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Appendix D Typical Pressures and CO₂ Readings at Altitudes

Altitude	Atmospheric Pressure (mmHg)	EtCO ₂ Reading	
		(%)	(mmHg)
0 m	760	5	38.0
70 m	754	5	37.7
100 m	751	5	37.5
200 m	743	5	37.1
1500 m	641	5	32.0
3000 m	537	5	26.8
5000 m	420	5	21.0

Appendix E Quick Keys

The monitor is pre-configured with the following quick keys:

- Alarm Setup
- Patient Info
- Freeze Wave
- Stop All
- NIBP STAT
- Venipuncture
- Parameters
- Minitrends
- OxyCRG
- ECG Full-Screen
- EWS
- Discharge
- Review
- Screens
- Alarm Audio Pause
- Standby
- Volume
- Screenshot
- Alarm Reset
- Lock Screen
- Print Record
- Start NIBP
- Other

Appendix F EMC Compliance

Table 1

Guidance and manufacturer's declaration-electromagnetic emission for all EQUIPMENT and SYSTEMS		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group I	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A	

Table 2

Guidance and manufacturer's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material,

			the relative humidity should be at least 30%.
Electrostatic transient / burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment or system requires continued operation during power mains interruptions, it is recommended that the equipment or system be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of Patient Monitor should assure that it is used in such an electromagnetic environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz-80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P} \quad 80 \text{ MHz}-800 \text{ MHz}$ $d=2.3\sqrt{P} \quad 800 \text{ MHz}-2.5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz-2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
 NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio 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 Patient Monitor is used exceeds the applicable RF compliance level above, the Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Patient Monitor.
- b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the equipment or system for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

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

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-2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

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Shenzhen Creative Industry Co., Ltd.

Manufacturer address: Floor 5, BLD 9, BaiWangXin High-Tech Industrial
Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Tel: +86-755-26431658

Fax: +86-755-26430930

Website: www.creative-sz.com

Email: info@creative-sz.com