GIMA
PROFESSIONAL MEDICAL PRODUC TS

35306 / K12

GIMA K12 MULTIPARAMETER MONITOR

35307 / K12

GIMA K12 TOUCHSCREEN MULTIPARAMETER MONITOR

35308 / K12

GIMA K12 TOUCHSCREEN MULTIPARAMETER MONITOR - 12 LEADS ECG

35309 / K15

GIMA K15 TOUCHSCREEN MULTIPARAMETER MONITOR

35310 / K15

GIMA K15 TOUCHSCREEN 2 IBP MULTIPARAMETER

35332 / K15

GIMA K15 TOUCHSCREEN MULTIPARAMETER

MONITOR – 10 LEADS ECG

REF
K12 **(GIMA 35306)**
K12 **(GIMA 35307)**
K12 **(GIMA 35308)**
K15 **(GIMA 35309)**
K15 **(GIMA 35310)**
K15 **(GIMA 35332)**

Shenzhen Creative Industry Co., Ltd.
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Made in China

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60°C 106 kPa 95%
-20°C 53 kPa 10%

K10 / K12 / K15
Patient Monitor

Operator's Manual

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.

Manual Information

Part Number: 3502-1510010

Release Date: 2024-04

Revision: V1.2

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

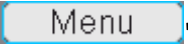Website: www.creative-sz.com

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Terms used in this User Manual

- "Window": The current pop-up operable dialog box on the device screen.

- "View": The screen when there is no pop-up window.

- "Button": An operable icon on the device screen, which acts as a key function while in focus, such as " Menu "

- "Shortcut Key"(Key): The hard-key on device panel for selecting specific functions, such as " ".

- "Long press": The operation pressing shortcut key for over 3 seconds.

- "SpO_2": Oxygen saturation.

- "SpO_2 event": Oxygen desaturation event.

Notes

- The password for the system setting is 8989, which is used as required. The password is only covered here and is not covered again in this manual.

- This patient monitor can be customized with different functional modules. Therefore, the monitor you purchased may not cover all operation description.

Table of Contents

Chapter 1 Safety

1.1 Safety Information

The safety statements presented in this chapter refer to basic safety information that the operator of the monitor must pay attention to and follow. There are additional safety statements in other chapters or sections, which may be the same as or similar to the following, or specific to the operations.

⚠ **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.**

1.1.1 Warnings

⚠ 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 rate meter ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

⚠ 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.

⚠ If uncertain 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.

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

⚠ Monitor a single person at a time.

⚠ The monitor is defibrillation-proof. Verify that the accessories can function safely and normally, and the monitor is grounded correctly before conducting defibrillation.

⚠ The monitor is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

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

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

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

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

⚠ Do not use the monitor to those patients who have a severe hemorrhagic tendency or who have sickle cell disease, for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.

⚠ 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.

⚠ To prevent the risk of a short circuit and to ensure the ECG signal quality, the device must be properly grounded.

⚠ The device should be considered an early warning device as a trend towards patient deoxygenation is indicated; blood samples should be analyzed by a laboratory CO-oximeter to understand the patient's condition completely.

⚠ 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.

⚠ Please peruse the pertinent content regarding clinical restrictions and contraindications.

⚠ The clinical operator should regularly test the device and accessories. A visual and auditory alarm signal can be checked by disconnecting accessories or by setting it in the Demo mode to simulate an alarm event.

⚠ Do not allow service or maintenance on the device while being used on a patient.

1.1.2 Cautions

🛈 DO not replace any of the components in the device with substitute parts. The 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, there may be adverse effects concerning safety and biocompatibility. No modification of this device is allowed.

🛈 Repeatedly used accessories should be cleaned thoroughly before use on another patient. Please refer to the related chapter for the maintenance method.

🛈 If the monitor accidentally falls, please do NOT operate it before testing its safety and technical indexes, with positive testing results obtained.

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

🛈 The system might not meet its performance specifications if stored or used outside the manufacturer's specified temperature and humidity ranges.

1.1.3 Notes

☞ All combinations of equipment must comply with the standard IEC 60601-1.

☞ The device uses a mains plug as a means of electrical isolation from the mains power. DO

NOT locate the device in a place where it would be difficult to access or operate the mains plug.

☞ If the user requests more information such as circuit diagrams, parts list, and product descriptions for repairs carried out by qualified technical personnel, please contact us.
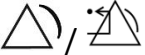
1.2 Equipment Symbols

1.2.1 Symbol/Icon on the Device

Symbol/Icon	Description
	Power switch
	View setting key
	Alarm reset key
	Freeze/ Unfreeze key
	Start/Cancel NIBP measurement
	Print
	Display view key
	AC power indicator
	Working indicator
	Type CF applied parts with defibrillation-proof
	Warning --- refer to User Manual
	Type BF applied parts with defibrillation-proof
	Equipotential grounding terminal
SN	Serial number
	Remove battery cover in this direction.
	ECG Sync output
	Nurse call port
	USB connector
	Network interface.
AUX	Auxiliary output
	Visual graphics output

Symbol/Icon	Description
⚒	Manufacturing date
🏭	Manufacturer
⚠	Caution! Consult accompanying documents
⚠	General warning sign (Background: yellow; Symbol and line: black)
🗑	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it.
C€ 0123	This mark means that this device is entirely in conformance with the Council Directive Concerning Medical Devices 93/42/EEC.
EC REP	Authorized Representative in the European Community

1.2.2 Icons List on the Screen

Icon/info.	Description
00000000	Patient ID
🔲/🔲/🔲	Patient type, there are Adult, Pediatric and Neonate for optional
ARR/ARR	Arrhythmia symbol (indicates learning or analysis stage for ARR detection)
△)/△	Alarm activating status icon/Alarm reset icon
△	If the alarm function is disabled for one/some parameter, this icon appear(s) on the corresponding parameter panel(s)
❤	Heart-beat symbol
🫁	Breath symbol
⌁	AC Power supply and the battery is fully charged.
🔋	The red blinking exclamatory mark means the battery will run out soon and needs to be charged. Alarm information area will show the "Low Battery" message.
🔋	Charging status

Icon/info.	Description
	Battery status can not be indicated.
	One / two / full grid battery voltage left
	Printer ready. Paper moving means the device is printing.
	Printer error. Caused by no paper, uncovered, over-heat
	Pulse beeper is on
	Pulse beeper is off
	Network connected / disconnected/ established link to remote server (CMS or HL7 client)

Note

☞ Some symbols may not appear on your equipment.

1.2.3 Symbol/Icon on the Package

	Fragile articles---It means there are fragile articles in the packaging; thus, they should be handled with care when being carried.
	Up --- It shows that the correct position for handling the packaging is straight up.
	Limit of pile weight--- It shows the maximum weight this parking can bear."XX" stands for the maximum load.
	Limit of pile layers--- It shows the maximum numbers of layers of the same packages. "n" stands for the maximum numbers of layers.
	It indicates that the package should be kept away from rain

Chapter 2 The Basics

2.1 Monitor Description

2.1.1 Product Name and Model

Product name: Patient Monitor

Product Model: K10, K12, K15

	K10	K12	K15
Screen size	10.4"	12.1"	15"
ECG	√	√	√
HR	√	√	√
NIBP	√	√	√
SpO₂	√	√	√
RESP	√	√	√
TEMP	√	√	√
CO₂	Optional	Optional	Optional
IBP	Optional	Optional	Optional
CSM	Optional	Optional	Optional

2.1.2 Intended Use

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult, pediatric and neonatal patients, with the functions of real-time recording and displaying parameters, such as ECG, Heart rate (HR), non-invasive blood pressure, functional oxygen saturation (SpO_2), respiration rate (RESP), body temperature (TEMP), end-tidal CO_2 concentration ($EtCO_2$), invasive blood pressure (IBP) and Cerebral State Index (CSI), it allows comprehensive analysis of patient's physiological conditions.

Note

☞ The CE-certified patient monitors have the functions of recording and displaying parameters in real-time of ECG, heart rate (HR), non-invasive blood pressure (NIBP, age≥ 3 years old), functional oxygen saturation (SpO_2), respiration rate (RESP), body temperature (TEMP), and end-tidal CO_2 concentration ($EtCO_2$) for monitoring the physiological conditions of adult and pediatric patients.

☞ ECG arrhythmia analysis function and S-T segment monitoring have not been CE-certified.

☞ SpO_2 monitoring with Nellcor module and NIBP measurement with SunTech module have not been CE-certified.

Warning

⚠ This equipment is applicable for use in hospitals and clinical institutions. The operation

should be performed by qualified professionals only. Anyone unauthorized or untrained must not perform any operation on it.

⚠ The physiological waveforms and parameters and the alarm information displayed by the monitor are only for the reference of operators, but cannot be used directly to determine the clinical treatment.

Contraindication: Refer to each section.

2.1.3 Features

- Windows-style display view, easy to operate.
- Patient archive management is available.
- Oxygenation calculation, Ventilation calculation and Renal function calculation is available.
- Multiple display views are available, which can easily shift for different monitoring purposes.
- Waveform freezing is available with functions of S-T segment measurement and arrhythmia analysis.
- The compact database can effectively manage history records.
- Visual and audible alarms with multiple priority levels for physiological and technical alarms.
- Intuitive CSM event marking.
- Multilingual display option.
- Large capacity storage:
  - ➢ Up to 2,000 hours of trend data
  - ➢ Up to 12,000 groups of NIBP records
  - ➢ 2,000 groups of oxygen-desaturation events
  - ➢ 2,000 groups of alarm events
  - ➢ Up to 144 hours of ECG waveform
  - ➢ 840 hours of EEG waveform
- Touchscreen operation and key operation are available
- Protection against defibrillator discharge, resistance to interference from the electrosurgical unit; Cardiac pacemaker pulse detection, and inhibition.
- 12-leads ECG function can be configured for full ECG information.
- Network capability for central monitoring.
- Capable to export data to CIS/HIS by HL7 protocol.
- USB data export function is available.

Note

☞ This patient monitor is configurable with different parameters; the monitor you purchase may not cover all the functions described above.

2.2 Main Unit

Front View

Front View (K10)

Front View (K12)

Front View (K15)

Rear View
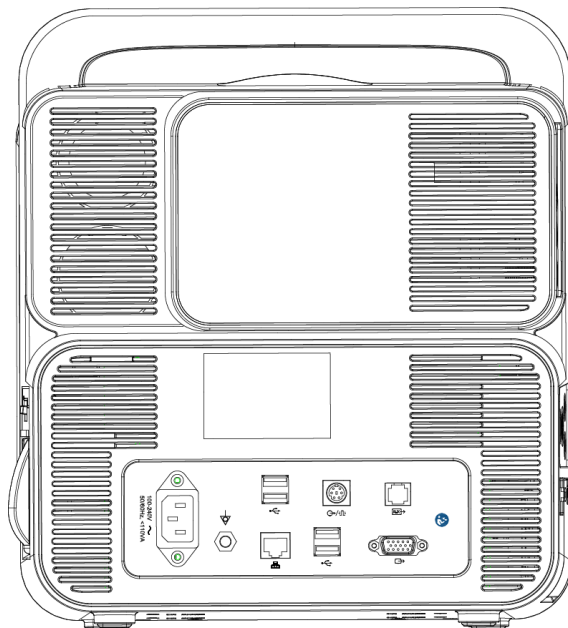
Side View
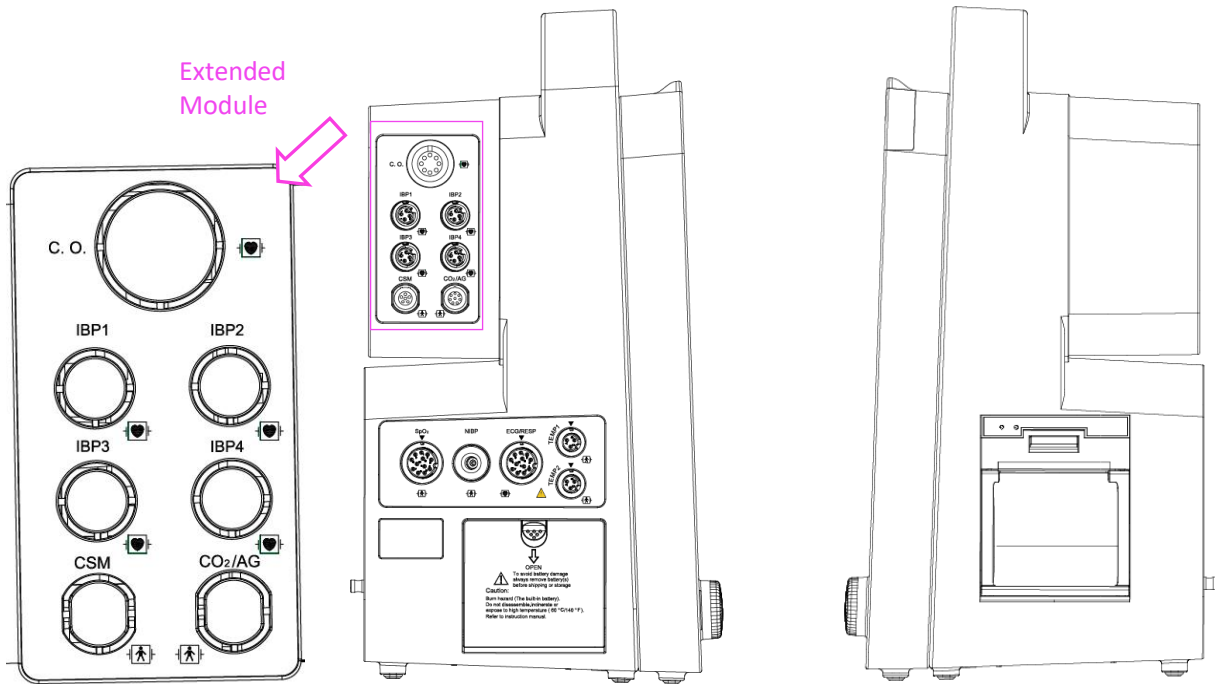
Left view (K10, K12, K15)   **Right view (K10, K12, K15)**

Note

☞ The only difference among K10, K12, and K15 is the display screen size of the monitor.

Front Panel
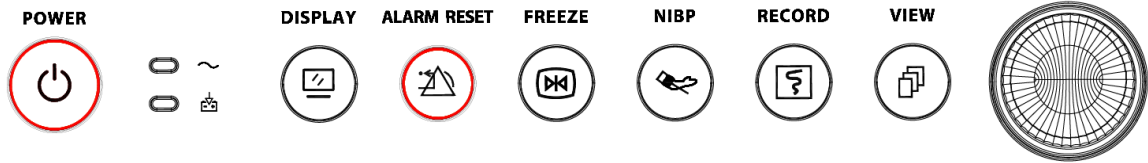
Icon descriptions

No.	Symbol	Description
1		Power switch
2		AC power indicator
3		Working indicator
4		View setting key
5		Alarm reset key
6		Freeze key
7		NIBP start/cancel key
8		Record/Print key
9		Display view key
10		Navigation knob
11		Alarm lamp
12		Technical alarm status indicator: an auxiliary indicator for "Alarm lamp". It's used for indicating whether the system in technical alarm status or not. When the system in technical alarm status, then the indicator in blue; otherwise, it stays off.

Indicator
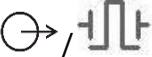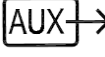
AC power indicator $\sim$:

> ➢ On: The AC power supply powers the monitor.
> ➢ Off: The AC power supply does not power the monitor.

Working indicator ⊡ :

> ➢ On: The monitor is switched on.
> ➢ Off: The monitor is switched off.

Connector

- **TEMP1, TEMP2:** Temperature probe connectors.
- **NIBP:** NIBP cuff connector.
- **SpO₂:** SpO$_2$ sensor connector.
- **ECG/RESP:** ECG cable connector.
- **CO₂:** this connector can be used for external monitoring module such as CO$_2$ measurement (optional).
- **CSM**: this connector can be used as the CSM sensor cable connector (optional).
- **IBP1, IBP2, IBP3, IBP4**: these connectors can be used as the IBP sensor cable connector (optional).
- ▽ **:** Equipotential grounding terminal.
- **100-240V~, 50/60Hz, < 110VA:** Mains power supply socket.
- ⊖→ / ⊣⊓⊢ : Nurse call connectoror connector for ECG sync output.
- ⬚ **:** Network interface.
- AUX→ **:** Auxiliary output connector. Reserved for future use (optional).
- ⊃→ **:** Visual graphics output connector. To connect an external display to synchronize the contents on the monitor screen.
- •←→ : USB connector. Connect the USB drive and export patient monitoring and demographics data.

Symbols

- **S/N:** Serial Number.
- ⊣⟨☆⟩⊢ Type BF applied parts with defibrillation-proof.
- ⊣⟨♥⟩⊢ Type CF applied part with defibrillation-proof.
- 🛈 Warning! Please refer to the manual.

Nameplate

The nameplate includes product name, model, manufacturer information and other information.

Battery slot

 OPEN : Remove the battery cover to install or change the rechargeable battery. Battery specification:

11.1V /4400mAh.

"TO AVOID BATTERY DAMAGE, ALWAYS REMOVE BATTERY(S) BEFORE SHIPPING OR STORAGE"

Printer (Otional)

" ₀₀ "—— printer indicator. One indicator labeled "POWER" will be on (in green) when the printer is powered on. Otherwise, it is off. Another indicator labeled "ERROR" is on (in red) when the printer is malfunction.

2.3 Display Screen

Generally, when there is no pop-up window on the screen, the screen layout of the device includes Message indication area, Waveform area, Parameter area, and Statusbar, as shown in Figure below. The message indication area is on the top of the screen, and Statusbar is on the bottom. The Parameter area is on the right of the screen, and the Waveform area is on the left.

When a window pops up, the new pop-up window is the current operable window displayed on the top layer.

Screen layout (refer to the actual screen)

2.3.1 Message Indication Area

From left to right of the Message indication area, it shows patient information (including gender, patient ID, patient type and name), physiological alarm information, alarm sound status, and current date.

Gender PID Patient type Patient name Physiological alarm information Alarm status

Extended module info
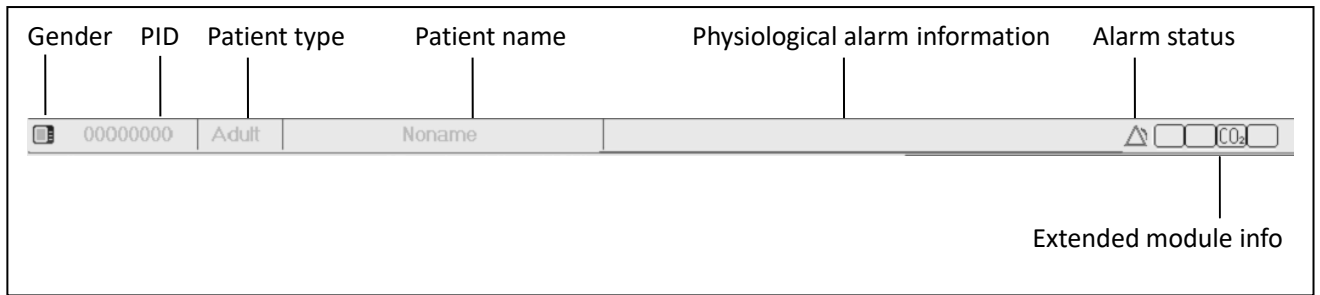
- Patient information area (as shown in the figure above): the patient whose information displayed on the Message indication area is monitored by device currently. Icon " [icon] " means the patient is female, " [icon] " is male and " [icon] " is unknown. The device presets default patient information. When the user does not fill any patient information, the device uses the default patient information. The default patient ID is "00000000", Name is "Noname", the patient type is "Adult". Move the cursor on this information area can shift to "Patient Info." setting window.

- Physiological alarm sources (as shown in the figure above): displays physiological alarm source information.

- Alarm status: See **Chapter 6 Alarms**.

- Extended module info: when the extension modules are identified, the corresponding module icons will appear on the upper right screen, "[CO2]" for CO_2 module, [IBP] for IBP module, and "[CSM]" for CSM module.

Note

☞ If you purchased the monitor with extended module, then the corresponding module icon(s) will also appear on the upper right screen.

2.3.2 Statusbar

From left to right of the status bar, it shows "Menu", "Alarm", and "Review" button, technical alarm event, printer status, pulse beep status, power supply status, current time.

"Menu" button "Alarm" button "Review" button Power supply

Technical alarm event Printer Beep volume System time
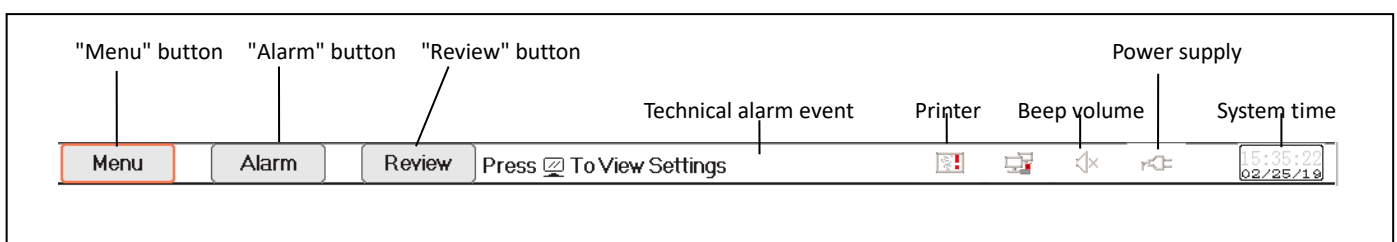
- "Menu" button enters into system menu dialog.

- "Alarm" button: enters into alarm setting dialog.

- "Review" button enters into the data review dialog.

- Technical alarm event: displays the current detected a technical alarm event and detailed technical alarm information. Refer to the **Chapter 6 Alarm** for details.

- Icons of printer status (optional): there are 3 printer status as below:

  ➢ [icon]: it means the printer is ready.

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➤   : it means the printer error caused by no paper or malfunction.

➤   ,   ,   it means that the printer is working in different status.

Move the cursor on this icon can enter into Printer Settings.

Note
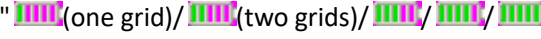
☞ If your monitor is not configured with Printer, the icons do not display.

● Network connection status: there are 3 status

➤ "   " means network connected;

➤ "   " means network disconnected;

➤ "   "(with a moving point) means network is connecting.

If the network connection is lost, then the device will try to connect to the central station every 2 minutes. Move the cursor on this icon can enter into Network Settings.

● Pulse beep status: there are 2 statuses

➤ "   " means pulse beep is enabled;

➤ "   " means pulse beep is disabled.

Move the cursor on this icon can enter into Beep Volume Settings.

● Power supply status

➤ "   " means the battery is charging.

➤ "   (one grid)/   (two grids)/   /   /   " indicates battery voltage;

➤ "   " means the device is powered by AC power supply.

➤ "   " means low battery voltage.

➤ "   " means battery status can not be indicated.

● System time: the current time of the device.

Note

☞ Operating key to move the cursor on status bar and focus on the icon of printer, beep volume, power supply, system time or on the information area, then the corresponding setting window pops up, that's, Printer setting window, Beep volume setting window, power supply setting window, System time setting window.
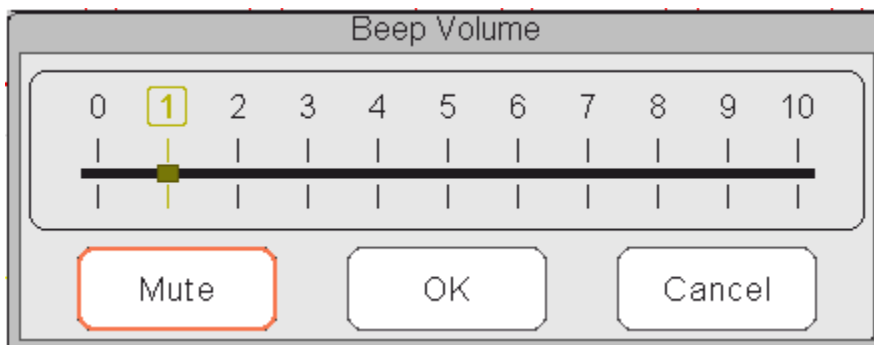
Popup window for Beep Volume setting
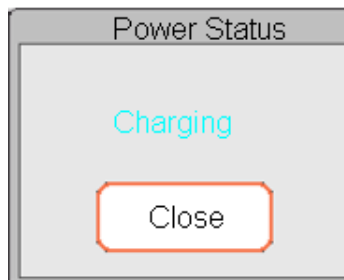
Popup window for Power Status
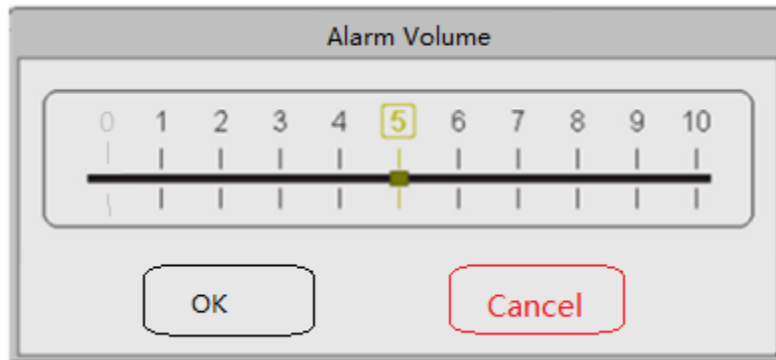
Popup window for Alarm Volume setting

- "Mute": select this option to turn off the beep sound, then the volume indicator stays on "0".

If the customer purchased the monitor with an "Alarm mute for spot check" configuration, please refer to the following description:

⚠ Please be cautious when using this option. It's not recommended to set the alarm sound volume to 0.

"Alarm mute in spot-check mode": Select this option to turn off the alarm sound. In this status, any alarm sound is muted, and the alarm sound does not resume until the user manually sets the alarm volume as non-zero status.

When alarm mute is enabled, the symbol 🔕 will display at the upper right corner of the screen, which means the alarm sound is off.
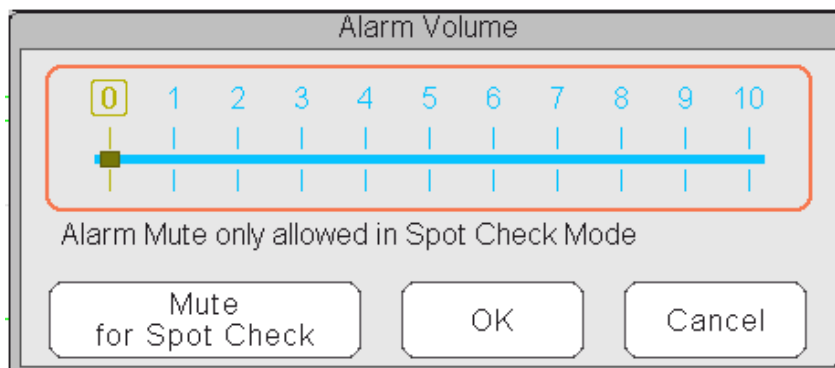
Popup window for Alarm Volume setting---for device optioned with "Alarm Mute" function

2.3.3 Parameter Area and Waveform Area

Parameter Area

Parameter area displays each parameter's value, unit, and icon. Move Navigation Knob to focus on a specific parameter panel, the panel (such as ECG parameter panel shown in below figure) is highlighted. Press the Navigation Knob to enter into the corresponding parameter setting screen.

ECG panel: enter into ECG setting window

SpO$_2$ panel: quick to enter into SpO$_2$ setting window

NIBP panel: quick to enter into NIBP setting window

Respiration panel: quick to enter into RESP setting window

Temperature panel: quick to enter into TEMP setting window

Waveform area

The waveform area in the current view displays the waveform, parameter label, and other information.

2.4 Views Management

Press the "Menu" button and select the "Views" item to enter into the "Views" window.
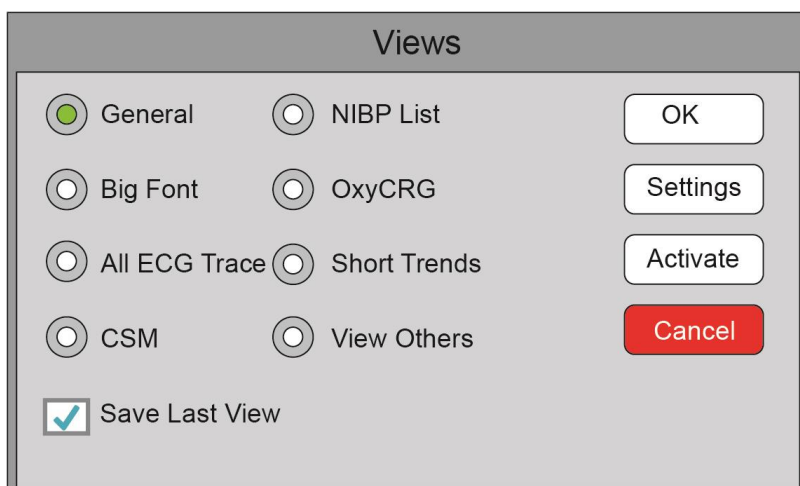
Views selection (refer to the monitor you purchased)

View others: if "View others" option is selected, then this monitor can view the patient information from other bedside monitor via the central monitoring network system.

Save the Last View: Enable or disable the "Save Last View" function. If selected, the Monitor saves the last operating view as the default view when the Monitor is restarted. The factory default is to "enable" this function.
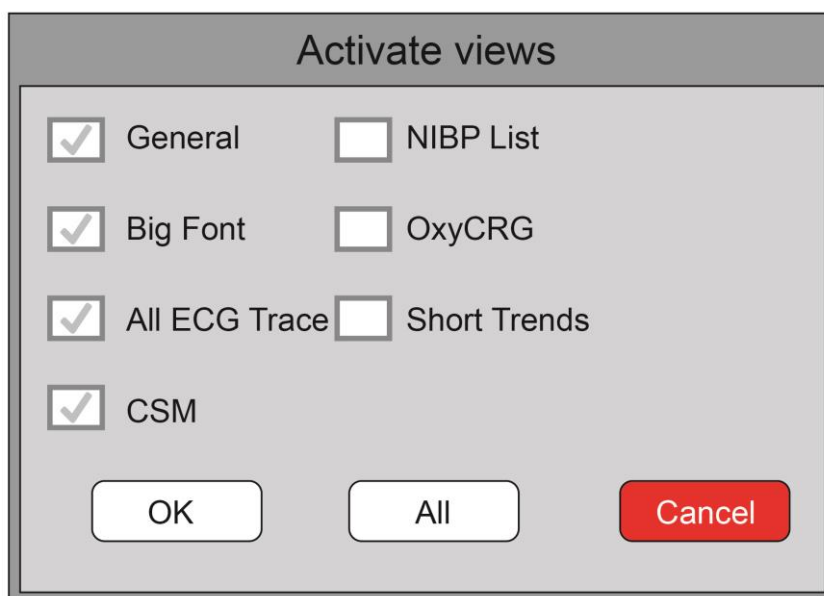
Activate Views (refer to the monitor you purchased)

Description

1) Switch views

Select the view required to be the "Current View", then press the "OK" button to confirm the selection.

2) Views settings

Press the "Settings" button to set up the view selected, where waveforms and parameters are configured as you like.

3) Activate views

- In the "Views" window, press the "Activate" button to enter the "Activate Views" window. Then, the operator can choose the views to activate or not, the optional views (the views can be

activated) are General, Big Font, All ECG Trace, NIBP List, OxyCRG and Short Trends. The inactivated views display in grey.

- Only the activated views can be clockwise shifted by operating Display View Key.

Chapter 3 Operating Instructions

3.1 Installation

Warning

⚠ Devices connected to the equipment must meet the requirements of the applicable IEC standards. The system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance with IEC 60601-1-1. If you have any questions, please contact the manufacturer or your local dealers.

⚠ If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to the summation of leakage currents, please consult the manufacturer or an expert in the field, to ensure the proposed combination does not impair patient safety and all devices concerned.

Caution

⓵ The equipment shall be installed by manufacturer-authorized personnel.

Note

☞ The manufacturer solely owns the software copyright of the equipment. 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.

3.1.1 Unpacking and Checking

1. Open the package, take out the monitor and its accessories from the box and carefully place it in a safe, stable, and easy to watch position.

2. Open the user manual to sort the accessories according to the packing list.

    *   Inspect the accessories for any mechanical damages

    *   Check all the exposed leads and inserted accessories

    *   Check whether any risk or abnormity exists in the device and its accessories before using the monitor. If any abnormity (such as broken cable or crack of the enclosure) is found, do not use it with the device.

Warning

⚠ When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.

⚠ Before use, please verify whether the package is intact, especially for the single use accessories. In case of any damage, do not apply to patients.

Note

☞ Save the packing case and packaging material as they can for reuse if the equipment must is returned.

☞ The user can customize the module configuration by choosing the necessary modules to meet your own needs. Therefore, your monitor may not have all the monitoring functions and accessories.

Please contact the local dealer or our company in case of any problems. We offer the best solution for your satisfaction.

3.1.2 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual. Otherwise, unexpected consequences or equipment damage could result.

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

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

3.2 Getting Started

3.2.1 Connecting to Power Source

Using AC Power Source

The following steps should be followed to install the battery:

1 Make sure that the AC power supply is (100-240) VAC, 50Hz/60Hz.

2 Use the power cable provided by the manufacturer. Insert one end of it to the AC power input of the monitor and the other end to the three-pin outlet of the power source with protected-earth.

3 To eliminate potential differences, the monitor has a separate connection to the equipotential grounding system. Connect one end of the provided ground wire to the equipotential grounding terminal on the rear of the monitor, and connect the other end to one point of the equipotential grounding system.

Caution

⚠ Ensure that the monitor is grounded correctly.

⚠ If you have any doubt about the grounding layout and its performance, you must use the built-in battery to power the monitor.

⚠ After the mains power supply has been interrupted while power switch remains in the "on" status and is restored after for longer than 30 seconds, the monitor runs with the last settings when the monitor restarts.

⚠ The monitor is applicable to connect to the public mains power network.

Using Battery

The following steps should be followed to install the battery:

1 Open the battery cover.

2 Pull out the battery cable and connect it to the battery pack.

3 Push the battery pack into the battery compartment and lock it.

4 Close the battery cover.

Caution

⚠ It's better to recharge the battery after it is used up, and the charging time should be 12 to 15 hours.

⚠ The typical continuous operation time of the battery is no less than 120 minutes in the power-saving mode.

⚠ Recharge the provided monitor battery after transportation or storage. If the monitor is switched on without being connected to the AC power supply, it may not work correctly due to insufficient battery power.

Note

☞ When the device is working, it takes at least 10 hours to charge the battery from empty state to 90% charged.

3.2.2 Turning the Monitor On

The system performs self-test and enters the initial display after the monitor is switched on, and the alarm rings to inform the user that they can begin operating the monitor.

1. Check all the applicable functions to make sure that the monitor works properly.

2. If the built-in battery is applied, please recharge it after using the monitor to ensure sufficient power storage. It takes at least 10 hours to charge the battery from depletion to a 90% charge.

3. Press the Power on/off key on the front panel of the monitor to start the monitor.

Warning

⚠ Do not use this device to monitor the patient if there are indications of damage or reminders of error. Please contact the local dealer or our company.

⚠ The battery-powered monitor continues to run without interruption when the AC mains power is lost.

Caution

⚠ Start the monitor again 1 minute later after it is switched off. When the monitor is switched off, allow one minute before switching it back on so that the monitor powers off correctly.

3.2.3 Starting Monitoring

1 Decide which parameter measurements you want to make.

2   Connect the required modules, patient cables, and sensors.

3   Check that the patient cables and sensors are correctly connected.

4   Check that the patient settings, such as Patient Type, NIBP measuring mode are appropriate to your patient.

Refer to the corresponding Section for details of how to perform the measurements you require.

3.3 Turning the Monitor Off

To disconnect the monitor from the power, follow this procedure:

1.   Confirm that patient monitoring is complete.

2.   Disconnect patient cables and sensors from the patient.

3.   Make sure to save or clear the monitoring data as required.

4.   Press the Power on/off key on the front panel to turn off the monitor.

Caution

⊙   Although not recommended, you can press and hold the Power on/off key for 10 seconds to forcibly shut down the monitor when it does not follow a normal shut down. Please note that this may result in the loss of data from the monitor.

3.4 Using Keys

3.4.1 Shortcut Key

- **View Settings Key**: in view displaying screen (when there is no pop-up window on the screen), press this key, then the current View Settings window pops up on the screen. On setting a specific parameter, pressing the navigation knob, and pressing View Settings window, then the shortcut keyboard pops up on the screen.

- **Alarm Reset Key:** when alarm event occurs, press this key to reset this alarm that mutes the alarm sound, but the visual alarm is still active.

- **Freeze/Keyboard Lock Key**: Press this key to freeze or unfreeze waveforms. The Display View key and view setting key are disabled when waveforms are frozen. Long press this key can lock or unlock the keyboard. When locking icon displays on the screen, a red lock icon displays on the left of the "Menu" button. At this time, other Shortcut Keys are disabled.

- **NIBP Key**: press this key to start NIBP measurement, and during measurement, pressing this key pauses NIBP measurement.

- **Display View Key**: press this key to shift the main screen when there is no pop-up window on the screen. When a pop-up window is on screen, this key acts as "Exit" (that is the "Cancel" button on the window.

- **Print Key:** press this key to start or stop printing.

- **Navigation Knob**: anticlockwise rotation acts as the "Left-arrow" key, clockwise rotation acts as the "Right-arrow" key, and press-down acts as "OK" key.

3.4.2 Buttons and Keyboard

The followed buttons would be used in a list box or waveform review.

Buttons in the list box

/: previous/next row

/: previous/next page of rows

/: the last/first row

Frame or page moving buttons

/: the first/last page

/: the precious/next page

Note

☞ In this monitor, the button functions noted above are similar.

Operation instruction for Soft keyboard

- If you want to input text in an edit-box, navigate to that edit-box and press the knob, then, a soft keyboard window pops up → navigate to the letter you need, press down the knob to choose it.

- Press View Settings key " " to move the cursor to the upper row of the soft keyboard.

- " ": delete a letter.

- " ": press it or Views Display key " " to exit with confirmation of the input at this time.

- " ": exit without confirmation and cancels the input.

Operation instruction for the often-used key

- "**Default**": press this button sets default device settings. Depress "OK" on the pop-up screen to confirm default settings. Choosing "Cancel" in the setup window restores the current settings.

- "**OK**": when you set up any items, choose the "OK" button and press navigation knob to confirm the settings.

- "**Cancel**": quit the current settings and save it without any changes.

3.5 Using the Touchscreen

We provide an optional Touchscreen function. Therefore, the touchscreen function may not be available for some of the monitors, which should be operated by keys.

3.6 Setting the Screens

Screen layout (refer to the actual screen)

In the General view screen, there are 3 to 7 traces of waveforms in the waveform area, and 2 to 7 parameter panels in the parameter area. Each waveform trace shows specific signal waveform (ECG waveform, plethysmogram, and others); you can also disable this trace. Each parameter panel shows one or one group of parameter values and the corresponding status. The waveform area is located on the left part of the screen. The display order of waveforms in a view is configurable. The default order from up to down is waveform 1, waveform 2, waveform 3, waveform 4, waveform 5, waveform 6, waveform 7 (7 traces at most).

Parameter panels locate at the right part of the screen, the parameter order from up to down is Parameter 1, Parameter 2, Parameter 3, Parameter 4, Parameter 5, Parameter 6, Parameter 7 (displays 7 parameter panels at most); the default order is ECG, SpO_2, NIBP, RESP, TEMP1, and TEMP2.

You can define the positions of the parameter waveforms and panels. The parameters or waveforms not defined are not displayed.

If no corresponding parameter or waveform is displayed, you should perform the following inspections:

- Check the connection between the module and lead, cable, sensor, etc.

- Enter the Setup window for the corresponding display configuration.

3.7 Using the Main Menu

Enter the main menu by selecting the "Menu" button; most of the monitor's operations and access settings through the main menu.

The menu includes parameters setting and the entrances of other functions, such as ECG, SpO_2, RESP/CO_2, TEMP and NIBP parameters setting, and the setting for optional function (e.g., CO_2 setting), "System Settings", "Patient information", "Color Settings" and "Standby".

- Parameters settings window for ECG, SpO_2, RESP, TEMP, and NIBP. Configured optional functions show the corresponding setting window (e.g., CO_2 setting window) automatically on the "Menu" window.

- Functional window for Tourniquet, HEMO (hemodynamic calculation), Nurse Call, Medicine Dosage Calculation, Oxygenation calculation, Ventilation calculation, Renal function and Patient Information;

- Device information window for System Settings, Color Settings, and System Information.

3.8 Changing System Settings

This Section covers general settings, date, time, and Printer setting. Parameter settings and other settings are referenced in their respective sections.

3.8.1 Changing General Settings

Changing Language

1   Select "Menu"→"System Settings"→"General".

2   In the "General" menu, select "Language" and then select the desired language.

3   Enter the required password.

4   Restart the monitor.

> **Note**
>
> ☞ The default required password in the monitor is "8989".
>
> ☞ The selected language is applied after the monitor is restarted.

Adjusting Volume

Alarm Volume

Select "Alarm"→"Others"→"Alarm Volume".

The setting range is "1 - 10", the step is 1. The default range is 5. "10" is the maximum volume.

> **Note**
>
> ☞ If your monitor has the "Spot-check Mode" function option, then the setting options for Alarm Volume is "Spot Check", "0 -10".

Beep Volume

To set the pulse beep sound:

1   Select "Menu"→"System Settings"→"General".

2. In the "General" menu, select "Beep Volume". Its setting range is "OFF", "0 - 10", the step is 1. The default is 5. If you want to set the beep volume as "OFF", you need to enter the password.

   It's not recommended to set it as OFF.

Key Tone

To enable or disable the keystroke sound and the touch-screen sound.

Others

- **Mode:** Monitor working mode selection. See **3.9 Operating Modes**.

- **Freeze type:** Selects waveforms to be frozen on the screen. The options are "All Waves", "EEG" and "ECG Waves". When "ECG Waves" is selected, the system only freezes ECG waveforms. When "EEG" is selected, the system only freezes EEG and EEG waveform. When "All Waves" is selected, the system freezes all waveforms on screen. The default is "ECG Waves". On CSM view, it freezes EEG waveform. And when "All Waves" is selected, the EEG waveform will be priority to be measured.

- **Param font:** Selects parameters' digit font, there are 2 options: Bold and Narrow number.

- **Plethysmogram:** The switch to turn on or off the filled waveform style for plethysmogram display. When it is ON, the monitor displays a filled waveform for plethysmogram; otherwise, it displays in a simple curve style. The default is OFF.

  Note:

  ☞ This function is not available for the ECG waveform.

- **Pitch Tone:** Chooses the style of pitch tone, the pitch tone means the tone of pulse beep (from ECG or Oximetry) changes when the measured SpO_2 value changes, the higher SpO_2 value, the sharper beep sound (high-pitch). Two options: "Mode I" and "Mode II". The difference between Mode I and Mode II is the tone frequency at the same SpO_2 value. The factory default setting is "Mode I".

- **Screen brightness:** Sets the brightness of the LCD backlight, 3 levels (1, 2and 3) for optional. The factory default is level 2. Level 1 is the darkest selection.

- **Key backlight:** Turns on/off the key backlight for the device, the factory default is "On".

- **Beat priority:** to set the priority of the source of beat pulse beep and heartbeat rate display value, there are 2 options: HR and PR. The factory default is "HR".

  ➢ **When the beat priority is selected to be "HR"**, then the ECG panel displays the current measured heart rate value and generates the pulse beep, which is extracted from the ECG signal when the heartbeat is detected. If the heart rate cannot be obtained, or no heartbeat is detected, then the ECG panel shifts to display pulse rate extracted from the oximetry signal, and pulse beep also comes from this source.

  ➢ **When the beat priority is selected to be "PR"**, then the ECG panel displays the current measured pulse rate value and generates the pulse beep, which is extracted from the oximetry signal when the pulse beat is detected. If pulse rate value cannot be obtained and no pulse beat is detected, then the ECG panel shifts to display heart rate extracted from ECG signal, or pulse beep also comes from this source. Even if the pulse rate value is displayed while the priority of PR is set, if the heart rate value, which is not displayed, exceeds the preset high/low alarm limits, the alarm activates and alarm event records.

  The ECG panel shifts to display the high/low alarm limit setting range automatically corresponding to the displayed heart rate or pulse rate value.

- **Use The Last Patient Info When Power On**: Selecting it means that the last patient document will

be used as the Current Patient Document when powered on. Otherwise, the system uses the Default Patient Document (PID: 0000000, No name) as the Current Patient Document when powered on.

- **Touch Screen Calibration:** Enters into touch screen calibration window. There are 5 cross cursors "＋" on the screen, tab the cross point "＋" of the 5 cross cursors with the stylus respectively to finish the calibration.

3.8.2 Setting the Date and Time

Select "Menu"→"System Settings"→"Date/Time".

- Month/Day/Year/Hour/Minute/Second: to set system date and time.

- Date format: Sets the date format of the system. There are 4 options: "YYYY-MM-DD", "YYYY.MM.DD", "MM/DD/YYYY", "DD/MM/YYYY".

- Current time: Refreshes the current system time.

3.8.3 Network Settings

Select "Menu"→"System Settings"→"Network".

- **Server IP Address:** the IP address used to connecting a central monitoring system server (work station) .

- **Port:** the port number to which the monitor will connect to the work station in the central monitoring system. Its setting range is from 6001 to 6064. It can also be used to represent the patient bed number connecting to the work station. For example, the port number means the monitor is assigned to the bed number 2 in the CMS. Our work station can connect to up to 64 bedside monitors, so please set the port between 6001and 6064. Press "OK" to make the new setting effective.

- **HL7 Protocol:** enable or disable the monitor to export data to CIS/HIS by HL7 protocol. Select it means enable HL7 protocol. The default is "enabled" HL7 protocol.

- **Local IP Address:** the local IP address for the device.

- **Subnet Mask:** when the user selects a static IP address, then the subnet mask should be set. The default subnet mask is "255.255.255.0".

- **Gateway:** when the user selects a static IP address, then the gateway should be set. The default gateway is "192.168.168.1".

- **Obtain IP Address Automatically**: (when the remote server supports DHCP service) select it means the IP address can be automatically configured by DHCP service. The device will perform DHCP configuration on every device booting and/or network topology change. If select "Obtain IP Address Automatically", then "Local IP Address", "Subnet Mask" and "Gateway" are in grey and nonadjustable.

Note

☞ If DHCP fails (that's to say, no DHCP server or no network is connected), then the IP address will be changed as "0.0.0.0", and the network icon "🖥" will be displayed on the lower right of the screen. If IP address is automatically configured by DHCP successfully, then the IP address will be displayed and network icon will be changed as "🖥".

☞ If the network is disconnected later after a successful DHCP configuration (for

example, network cable is detached), then the IP address will be changed as "0.0.0.0". When the network connection is recovered, the monitor will obtain IP address automatically again.

- **Disable Network:** enable or disable the network function. Select it means the network is disabled. The default is "disabled" network function.

Notes

☞ Make sure that Central Server and the monitor are located in the same network segment. Every monitor should have its unique Port Number. Otherwise, its network connection will be failed anytime.

☞ The icon "" on the lower right corner of screen displays the network status.

3.8.4 Printer Settings

Select "Menu"→"System Settings"→"Printer".

- **Speed:** the printer sweep speed. Options are 25mm/s and 50mm/s. The default is 25mm/s.

- **Duration:** The duration of printing real-time waveform. Options are: 10, 20, 30, 40, 50, 60 (seconds), and Continuous, the default is "10" seconds. If "Continuous" is selected, then the printer continues to print until the manual stop it by pressing the print key.

- **Wave 1:** print the first channel of waveform. Optional are varied according to the leadwire type. The default is ECG II.

  - **3 leadwire**: If "3-lead wires" is selected, then this item is in grey and nonadjustable. The lead is same as that displayed on the screen. The first channel of waveform displaying on the current ECG window will be the first waveform that the device will print (it can be set by Menu→ECG→Lead).

  - **5 leadwire**: "ECG I", "ECG II", "ECG III", "ECG aVR", "ECG aVL", "ECG aVF" and "ECG V" (that's ECG lead I~V).

  - **10 leadwire**: "ECG I", "ECG II", "ECG III", "ECG aVR", "ECG aVL", "ECG aVF", "ECG V1", "ECG V2", "ECG V3", "ECG V4", "ECG V5" and "ECG V6".

- **Wave 2:** print the second channel of waveform. If "5-lead wires" is selected, then the optional will be: OFF, "ECG I", "ECG II", "ECG III", "ECG aVR", "ECG aVL", "ECG aVF", "ECG V", "SpO_2", "RESP". If "3-lead wires" is selected, then the optional will be: "OFF", "SpO_2" and "RESP". If "10 leadwire" is selected, the option will be OFF, "ECG I", "ECG II", "ECG III", "ECG aVR", "ECG aVL", "ECG aVF", "ECG V1", "ECG V2", "ECG V3", "ECG V4", "ECG V5" and "ECG V6", "SpO_2", "RESP". The default is "SpO_2".

- **Wave 3:** print the third channel of waveform.

  <u>**Note**</u>

  ☞ The setting for Wave 1, Wave 2 and Wave 3 should be different (eg. Wave 2 and Wave 3 can not be set as "ECG III" at the same time). Only 2 ECG waveforms at most can be printed simultaneously.

- **Print ECG Grids:** Switches grids on printed ECG waveform. Select it means the 5x5(mm^2) grid background prints when printing the ECG waveform.

- **Timer:** Switches for the print timer. The default is "OFF". If Print is ON, rotate navigation knob to set on the Timer to enable timed print, and set the value of printing intervals in the cycle category. The setting range is 5~480 minutes; the step is 5 minutes. The default is 60 minutes.

- **CSM:** Select the CSM parameter, options are "EEG" and "Trend" that means the corresponding electroencephalogram and graphic trend will be printed respectively.

3.9 Operating Modes

3.9.1 Real-Time Mode

The "Real-Time" shows the normal work mode with real-time waveform and data.

3.9.2 Demo Mode

The "Demo" mode shows the demo working mode with simulated waveform and data. In the "Demo" mode, all the signals and data are generated by the device to demonstrate and test the monitor (the alarm function can be checked in this mode).

Warning

⚠️ The Demo mode is for demonstration purposes only. To avoid stimulated data being mistaken for a monitored patient's data, you must not change into Demo mode during monitoring. Otherwise, improper monitoring and delayed treatment could result.

3.9.3 Night Mode

You can select night mode to avoid disturbing the patient during monitoring. In the night mode, the pulse beep and key tone are off, alarm volume is set to level 2, and brightness of the screen decreases to level 1 by default.

To enter night mode, select "Menu" → "System Settings" → "General" → "Mode" → "Night Mode".

To exit night mode, select the other desirable mode in "Mode".

Warning

⚠️ Verify the alarm volume and pulse beep volume settings after entering night mode. You can adjust the settings according to your requirements. Pay attention to the potential risk if the setting value is too low.

3.9.4 Privacy Mode

Private mode can be used when the patient information should be protected from visitors and other non-clinical personnel. In privacy mode, the monitor does not display patient information and monitoring data. Only the word "Privacy" displays on the screen. In the private mode, the monitor still monitors the patient, but the monitoring data is only displayed on the central monitoring system.

The monitor has the following features after entering Private Mode:

- No parameters and waveforms are displayed. The screen turns blank.
- All system sounds, including alarm audio, pulse tone are muted.
- The alarm lamp and technical alarm status indicator still can light up for the alarms.
- Monitoring data and alarms are presented only at the central monitoring system.

To enter privacy mode, select "Menu" → "System Settings" → "General" → "Mode" → "Privacy Mode".

To exit privacy mode, press any key except ⏻ , or touch any area on the touchscreen.

Note

☞ You cannot enter the private mode if a low battery alarm occurs.

☞ Private mode is only available when the monitor is connected with the central monitrong system (CMS) and the patient is admitted by the CMS.

3.9.5 Standby Mode

Select "Menu"→"Standby".

In Standby Mode, you can temporarily stop monitoring without turning off the monitor. Click any key to exit from it. If your monitor is configured with touchscreen function, then touch any point of the screen to exit from Standby Mode.

3.10 Connecting to a Central Monitoring System

If your monitor is connected to a Central Monitoring System (CMS):

- All patient information, measurement data and settings on the monitor can be transferred to the CMS.

- All patient information, measurement data and settings can be displayed simultaneously on the monitor and CMS.

- For some functions such as editing patient information, admitting a patient, starting/stopping NIBP measurements, etc., bi-directional control can be achieved between your monitor and the CMS.

For details, refer to the CMS's instructions for use.

Chapter 4 Patient Data Management

Select "Menu"→"Patient Info.".

In the Patient Info. Window, the operator can add, edit, delete, and apply a patient's document as the current document for monitoring.

4.1 Apply an existed patient's document

Select "Menu"→"Patient Info."→"Apply".

If there is an existing patient document for the monitored patient, it is unnecessary to create a new document for the patient. Press the "Apply" button to make the existed document as the "Current Patient's Document".

4.2 Create a new patient's document

Select "Menu,"→"Patient Info."→"Create".

To input characters at an edit-box, press the Navigation Knob (same as "Enter" key), then the soft keyboard pops up immediately.

The following items need to input:

- **PID**: The Patient ID.

- **Group**: 3 types of patients: Adult, Pediatric and Neonate. The default is "Adult".

  - ➢ **Adult**:   age > 12 years
  - ➢ **Pediatric:**   1 month < age ≤ 12 years
  - ➢ **Neonate**:   age $\leq$ 30 days

- **First Name:** patient first name.

- **Last Name:** patient's last name.

- **Gender**: patient gender.

Important notes: When power on the monitor or the patient type is changed (e.g., the patient type changes from Adult to Neonate), then the monitor performs initialization. Therefore, please confirm that the patient type matches the patient to be monitored before monitoring. When "PED" or "NEO" is set to an adult patient, it is difficult to get a valid NIBP measurement value and easy to make false alarms. It's forbidden to use the "Adult" mode on a pediatric or neonate patient, for it may cause serious injury.

4.3 Edit a patient document

Select "Menu"→"Patient Info."→"Edit".

To edit a patient document requires the corresponding password. In the "Patient Info" window, press the "Edit" button, enter the correct password, then the "Edit Patient Info." window pops up on the screen. The item in grey is nonadjustable.

Note

☞ No password is needed to edit the default patient document. In the default patient document, only the patient type can be modified, and other items are not editable.

4.4 Delete a patient document

Select "Menu"→"Patient Info."→"Delete".

To delete a patient document requires the corresponding password.

Note

☞ When a patient document is deleted, all the patient's corresponding records (ECG waveforms, Alarm events, NIBP list, etc.) are deleted and cannot be recovered.

☞ The system does not permit the removal of the default patient and the current patient documents.

Chapter 5 User Screens

5.1 Tailoring/Setting Your Screens

You can tailor your monitor's screens by setting：

- Background theme and color in which each measurement's numerics and waveform display.
- Display Views

5.1.1 Changing the Display Theme

Select "Menu" → "Color Settings".

Press "Details", then the color setting window for each parameter pops up.

- **Principal:** Enters into the setting form for parameter and number. 112 kinds of color for option with code 0~111, one code indicates one color.
- **Theme:** Selects the monitor's color theme, options are Space background, Sky blue, International fashion, and Bamboo lands in China.
- **Param BKG Color A and B:** Sets the background color in parameter panels. The background is set by using color A or color B as the parameter's background color.　The default setting for A and B is 0. The setting range is from 0 to 85; each number indicates one color. If the background color for the first parameter panel is color A, then the second parameter panel is color B, and third is color A. The backgrounds rotate with each selection.

Quick Color Settings

In the drop-down box of "Theme" to select the different theme, to change colors of all items in a view. Options are Space background, Sky blue, International fashion, and Bamboo lands in China.

5.1.2 Changing the Color of Waveforms and Parameter

To set the parameter (ECG, SpO_2, RESP, TEMP, and NIBP) information and the waveform color. Procedures are:

1. Locate the cursor on the color box,

2. Rotate the Navigation Knob, and select the color.

- The ECG color setting for the theme, waveform, and number: the setting range is 0~111; the default is 16.
- The SpO_2 color setting for the theme, waveform, and number: the setting range is 0~111; the default is 2.
- The RESP color setting for the theme, waveform, and number: the setting range is 0~111; the default is 108.
- The TEMP color setting for number: the setting range is 0~111; the default is 111.
- The NIBP color setting for number: the setting range is 0~111; the default is 28.
- The CO_2 color setting for number: the setting range is 0~111; the default is 108.
- The CSI color setting for number: setting range is 0~111, the default is 64.
- The EMG color setting for number: setting range is 0~111, the default is 12.
- The SQI color setting for number: setting range is 0~111, the default is 0.

- The BS color setting for number: setting range is 0~111, the default is 91.

5.2 Display Views

A View can be configured in its Settings Window. To enter into the View Settings window for an individual view, the procedure is: in the default screen, move the Navigation Knob on "Views" button, and select one of the view's label (for example- "Big Font"), press "Settings", then this view setting window (for example- "Big Font View Settings" window) pops up on the screen.

Another way to enter the View Settings window is: when the specified view is the "Current View" on screen, then press the "View Setting key" to enter into the view settings window directly.

Select the "Views" button to enter into the "Views" window.

This monitor provides the following display views

- **General view**: meets most monitoring needs
- **Big Font view**: displays the essential parameters in the big font for remote observation
- **All ECG Trace view**: emphasizes on all ECG waveforms
- **NIBP List view**: emphasizes on NIBP data
- **OxyCRG view**: emphasizes on SpO_2 and Respiration data
- **Short trends view**: displays waveforms and parameters together with a recent 2-hours parameter trend graph.

In a View Settings window, "Wave K" means "Waveform Channel No. K", and "Param K" means "Parameter Panel No. K" (K=1,2,…7), for example, "Wave 2" is "Waveform Channel No. 2", and "Param 3" is "Parameter Panel No. 3".

5.2.1 General View

When powering on the monitor, it enters into the defaulted General View screen. (Please refer to the monitor you purchased) There are 5 traces of waveform in the left view: waveform for ECG lead III, ECG lead I, ECG lead II, SpO$_2$ plethysmogram, and Respiration; And there are 5 panels in the right view: ECG, SpO$_2$, NIBP, RESP, and TEMP.

Description

General View screen shows data and waveforms of main parameters.

- Generally, there are 5 traces of waveform in the waveform area. The default first trace is the waveform for ECG lead II; The second is the waveform for ECG lead III; The third is the waveform for ECG lead I; The fourth is the waveform for SpO$_2$ plethysmogram, And the fifth is the waveform for Respiration. The user can change it as desired.

- Generally, there are 5 parameter panels. The default panel order from up to down is HR, TEMP, NIBP, SpO$_2$, RESP (or CO$_2$).

General View Settings

➢ **Waveform Settings**

Settings of waveform channels and parameter panels can be changed easily. **Wave 1**, **Wave 2**, and **Wave 3** can be set as any ECG lead, or turn off this channel directly.

If "3-lead wires" is selected, it is nonadjustable and fixed to be the current displayed cascaded waveform, it can be set by Menu→ECG→Lead to change the current displayed ECG waveform (we will not cover it again). The default is "ECG II".

Note

☞ If "3-lead wires" is selected, then in all view settings (including general view, big font view, all ECG trace view, NIBP list view and so on), the user can only be set it as the current displayed ECG waveform (that's "ECGII", "ECGI" and "ECGIII").

If the checkbox "Cascaded above" is checked, Wave 1, Wave 2 and Wave 3 displays the same signal channel as the trace in a cascaded way.

Wave 4 and Wave 5 can be set as "OFF", "SpO$_2$", "RESP" and "CO$_2$" and "CSM".

➢ **Parameter Settings**

Parameter 1 and 2 is fixed to be ECG and SpO_2, respectively, which cannot be adjusted. Parameter 3 to 7 settings are OFF, TEMP, NIBP, and RESP.

Note

☞ Waveform 1- 5 and Parameter 1 - 5 are corresponding to the waveform 1- 5 and Parameter 1- 5. Similarly, in other views, the waveform 1- 5 and Parameter 1- 5 corresponds to that in the View settings window.

5.2.2 Big Font View

Description

In this view, the default 3 waveform channels in the waveform area are ECG waveform, SpO_2 plethysmogram, and RESP waveform. Moreover, the default 4 parameter panels in the parameter area are the ECG Panel, SpO_2 Panel, NIBP Panel, and RR panel.

Big Font View Settings

➢ **Waveform Settings**

- Wave 1 can be set as any ECG lead, or turn off this channel directly.

- Wave 2 and Wave 3 can be set as OFF, another ECG wave different from that selected in Wave I, SpO_2, and RESP (or CO_2). If "3-lead wires" is selected, then Wave 2 and Wave 3 can be set as SpO_2, and RESP (or CO_2), or set as the current cascaded ECG waveform (e.g., ECGII).

➢ **Parameter Settings**

- "Param 1", "Param 2," and "Param 4" can be set as OFF, ECG, SpO_2, NIBP, TEMP, and RESP (or CO_2).

- "Param 3" can be set as ECG, TEMP, NIBP, SpO_2, and RESP (or CO_2)

- Cascaded above: select it means all first 3 channels waveform display the waveform set in Waveform 1, and waveform 2 and waveform 3 are the cascaded waveform of Waveform 1. Moreover, at the moment, Wave 2 and Wave 3 are nonadjustable. The default is deselected.

- Close all waveforms: Select it means waveform 1 to waveform 3 does not display on the waveform panel in the big font view, but the information in the parameter panel displays.

5.2.3 All ECG Trace view

Description

In this View, all ECG trace waveforms display on-screen simultaneously. All 7 traces of ECG waveform display on the left and the 5 parameter panels are on the right.

All ECG Trace View Settings

The default 12 waveforms displaying in the view are: ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF, ECG V1, ECG V2, ECG V3, ECG V4, ECG V5, ECG V6, waveform 1~12 are nonadjustable.

The default 7 waveforms displaying in the view are ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF, and ECG V, waveform 1~7 are nonadjustable.

- Parameter 1 and Parameter 2 are nonadjustable; the default settings are ECG and SpO_2, respectively.

- Parameter 3 to Parameter 5 can be set as OFF, TEMP, NIBP, RESP (or CO_2).

- All waves: Select this item and all waveforms (including all ECG waveforms and other waveforms) display on the ECG trace view. The factory default is un-select.

5.2.4 NIBP List view

Description

In this View, 4 waveform channels default to ECG I, ECG II, ECG III, and SpO_2 plethysmogram. Parameter panels in the parameter area default to ECG, SpO_2, NIBP, RESP, and TEMP. At the same view, the NIBP list view displays.

NIBP List View Settings

- Waveform 1 can be set as OFF or one ECG wave.

- Waveform 2 and 3 can be set as OFF, SpO_2, RESP (or CO_2). The default is ECG II for Wave 1, SpO_2 for Waveform 2 and RESP (or CO_2) for Waveform 3.

- Waveform 4 is nonadjustable; the default is NIBP List.

- Parameters 1 and 2 are non-adjustable; the default is ECG and SpO_2, respectively.

- Parameter 3 ~ 5 can be set as OFF, NIBP, RESP, TEMP, CO_2 and CSM.

5.2.5 OxyCRG view

Description

In this View, the upper 3 waveform channels default to ECG II, SpO_2, and RESP. The lower area of the waveform area is Oxycardiorespirogram, which consists of an HR trend graph, SpO_2 trend graph, and Respiration waveform or RR trend graph within a particular time scale. In the "OxyCRG View Settings" window, the time scale and the 3rd graph can be changed as needed (refers to the following section). Settings of the parameter area are similar to that in "General View".

OxyCRG Settings

- Waveform 1 can be set as OFF or one ECG wave.

- Waveform 2 and 3 can be set as OFF, SpO_2, and RESP (or CO_2).

- The time scale for OxyCRG can be set as 1min, 2min, or 4 min. Min is the time unit of "Minute".

- The 3rd graph in OxyCRG can be set as "RR Trend" or "Resp Wave".

- Parameters 1 and 2 are nonadjustable; the default is ECG and SpO_2, respectively.

- Parameter 3 - 5, or Parameter 7, can be set as OFF, TEMP, NIBP, RESP, and CO_2.

5.2.6 Short Trends View

Description

In this view, several waveform channels can be displayed on the waveform area. Trend graphs are in the middle of the screen.

The abscissa of trend graph (-2h -0) means the various trends of every parameter value from now to the previous 2 hours. The panels of HR, SpO_2, TEMP, RESP, and NIBP display on the parameter area.

Short Trends View Settings

- Waveform 1 to 3 can be set as OFF or ECG waves. The three ECG waves, if not set to "Off", should be different from each other.

- Waveform 4 to 5 can be set as OFF, SpO_2, and RESP (or CO_2).

- Trend 1 is nonadjustable; the default is HR.

- Trend 2 ~5 can be set as OFF, TEMP, SpO_2, RR.

- Parameters 1 and 2 are nonadjustable; the default is ECG and SpO_2, respectively.

- Parameter 3~5 can be set as OFF, TEMP, NIBP, and RESP (or CO_2).

5.2.7 CSM View

Description

In this view, the default waveform in the 4th channel is for CSM related. The default in parameter 1, 2 and 5 are ECG, SpO_2 and CSI respectively. Other waveform traces and parameters area can be set by user, refer to the "CSM View Setting" for details.

The EEG waveform, SQI/EMG%/CSI/BS% trend graph and event mark can be displayed on CSM waveform area, the EMG% real-time bar graph will be displayed as well. In above figure, "80" is the amplitude scale for EEG, "-04.00 -03.00 -02.00 -01.00 -00:00" is the time scale for trend graph, and "0 20 40 60 80 100" is the scale for CSI value.

CSM View Settings

- Waveform 1 can be set as OFF or one ECG wave.

- Waveform 2 to 3 can be set as OFF, SpO_2 and RESP (or CO_2) etc. The default is "SpO_2" and "RESP" respectively.

- Waveform 4 is nonadjustable, the default is for EEG waveform and SQI/EMG%/CSI/BS% trend graph.

- Parameter 1, 2 and 5 are nonadjustable, the default is ECG, SpO_2 and CSI (Cerebral State Index) respectively.

- Parameter 3 and 4 can be set as OFF, TEMP, NIBP, RESP (CO_2) etc.

- CSM only: click it to turn on or off the CSM monitoring screen. If you click it to turn on "CSM only" function, then waveform 1~3, and parameter 1~4 are fixed to be "off" and nonadjustable. Waveform 4 and parameter 5 are fixed for CSM related function.

If you turn on "CSM only" function, then, the CSM view only displays EEG waveform, trend graphs and parameters of CSI, EMG%, SQI and BS%, as shown in below figure.
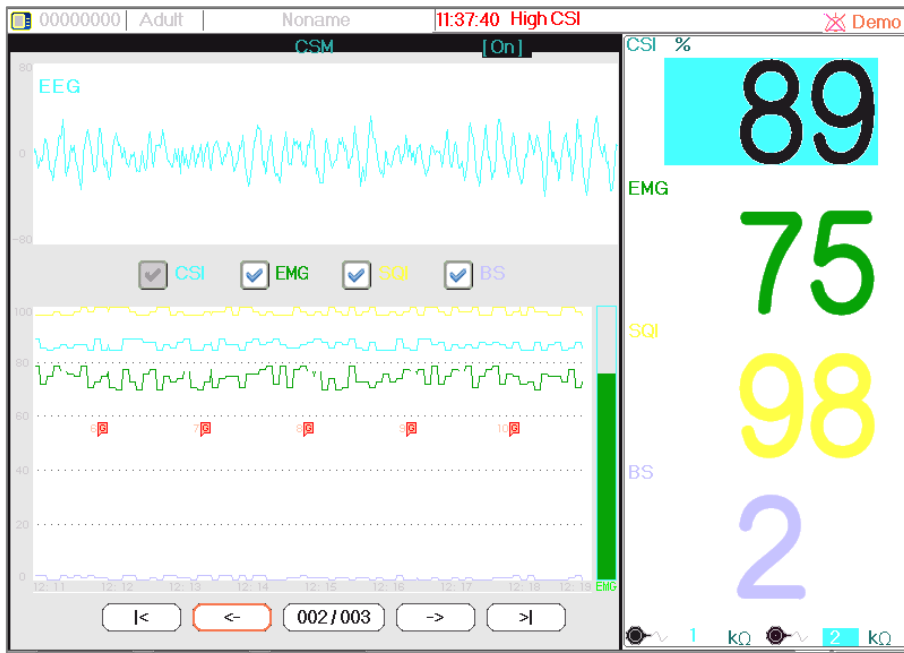
Chapter 6 Alarms

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

<u>Warning</u>

⚠ 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.

⚠ In order to ensure that the operator can accurately identify the alarms, it is recommended that the distance between the operator and 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 meter (there should be no obstacle within the visual effective distance above)

6.1 Alarm Categories

The monitor's alarms are classified into three categories: physiological alarms, technical alarms, and prompt messages.

Physiological alarms

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

Technical alarms

Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems. Technical alarm messages display in the technical alarm area.

Prompt messages

Prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the monitor shows some messages telling the system status or patient status. Messages of this kind are included in the prompt message category and usually displayed in the prompt information area. For some measurements, their related prompt messages display in their respective parameter windows.

6.2 Physiological and Technical Alarms

By severity, the monitor's alarm is classified into three categories: high level, medium level, and low level. Also, the monitor has preset alarm levels about the physiological alarm and technical alarm.

Physiological alarms		
Alarm priority level (Default)	Alarm Source	Alarm Event

High	ECG	Unable to detect HR High HR Low HR
	ECG (Arrhythmia)	Asystole V-Fib/V-Tach Vent Brady Vent Tachy Extreme Tachy Extreme Brady Nonsus V-Tach Vent Rhythm, Run PVCs Pair PVCs R on T Vent Bigeminy Vent Trigeminy PVCs/min Multiform PVC PVC SV Tachy SV Brady A-Fib (HR High) A-Fib A-Fib End Irr Rhythm Irr Rhy End Pause Miss Beat Pauses/min Pacer Not Pacing Pacer Not Capture
	SpO$_2$	Unable to detect SpO$_2$ Low SpO$_2$ High PR Low PR
	Respiration	Apnea, High RR, Low RR
	Temperature	High Temp1/ Temp2 Low Temp1/ Temp2 High TD

	NIBP	High NIBP SYS/ NIBP DIA/ NIBP MAP Low NIBP SYS/ NIBP DIA/ NIBP MAP High NIBP PR Low NIBP PR
	CO_2	High CO_2 RR/ $EtCO_2$/ $FiCO_2$ Low CO_2 RR/ $EtCO_2$/ $FiCO_2$
	CSM	High CSI low CSI
	IBP	IBP1 / IBP2/ IBP3/ IBP4 High SYS/ DIA/ MAP IBP1 / IBP2/ IBP3/ IBP4 Low SYS / DIA/ MAP
Medium	ECG (ST)	High S-T(ECGI) /S-T(ECGII) / S-T (ECGIIII)/ S-T (ECGAVR) / S-T (ECGAVL)/ S-T (ECGAVF)/ S-T (ECGV) Low S-T(ECGI) /S-T(ECGII) / S-T (ECGIIII)/ S-T (ECGAVR) / S-T (ECGAVL)/ S-T (ECGAVF)/ S-T (ECGV)

Technical alarm		
Alarm priority level (Default)	**Alarm source**	**Alarm Events**
High	**System**	Low battery
	SpO$_2$	SpO_2 modular malfunction Unknown error
	CO$_2$	CO_2 sensor failed CO_2 sensor temperature is too high
	IBP	IBP1 / IBP2/ IBP3/ IBP4 no pulse
Medium	**ECG/SpO$_2$**	Lead(s) off SpO_2 Probe off SpO_2 value exceeds measuring range HR exceeds measuring range
	CO$_2$	CO_2 sensor off CO_2 need to perform zero resetting CO_2 over detect value check air adapter check sampling tube, CO_2 zeroing failed.
	IBP	IBP1/ IBP2/ IBP3/ IBP4 Probe off
	CSM	Electrodes off
	Temp	Temp probe off

Low	NIBP	Self-test failed
		System error
		Over time
		Signal weak
		Cuff error
		Air leakage
		Pressure error
		Out of range
		Too much motion
		Overpressure
		Signal saturation
		Detected air leakage
		BP exceeds measuring range
	TEMP	Temperature self-detect failed
		TEMP1/TEMP2 exceed(s) measuring range
	SpO$_2$	No pulsation
	System	AC-DC low voltage

Related to 3 levels of alarm sources, medical and nursing staff should have different responses to deal with potential dangers, the specific demands are as follows:

- **High priority alarm**: medical and nursing staff should respond immediately.

- **Medium priority alarm**: medical and nursing staff should respond quickly.

- **Low priority alarm**: medical and nursing staff should respond as soon as possible.

6.3 Alarm Indicators

When an alarm occurs, the monitor alerts the user through visual or audible alarm indications.

6.3.1 Alarm lamp

Alarm level	Lamp color	Flashing frequency	Duty cycle
High priority alarm	Red flashing	2Hz	50%
Medium priority alarm	Yellow flashing	0.5Hz	50%
Low priority alarm	Yellow	/	100%

6.3.2 Alarm message

When an alarm occurs, an alarm message appears in the technical or physiological alarm area. Moreover, the alarm message is shown in a different color to match the alarm level (high priority alarm in red, medium priority alarm in yellow, and low priority alarm in white).

6.3.3 Highlighting Numeric

If an alarm limit violation triggers an alarm, the numeric measurement in alarm is highlighted.

6.3.4 Audible Alarm Tones

The alarm tone is distinct from the heartbeat tone, keystroke tone, and pulse tone in frequency. The alarm tones identify the alarm levels as follows:

- High priority alarm: beep+beep+double+beep+pause+beep+beep+double+beep

- Medium priority alarm: triple beep

- Low priority alarm: the single beep

Caution

ⓘ When multiple alarms of different levels coincide, the monitor selects the alarm that has the highest level and gives visual and audible alarm indications accordingly.

6.3.5 Alarm Status Symbols

Apart from the alarm mentioned above indicators, the monitor still uses the following symbols telling the alarm status.

For the customer to purchase the monitor with the configuration of "Alarm Reset", then this area shows the alarm sound status. There are two alarm status sounds:

- " ⊠ " means the alarm sound is disabled or means the alarm volume is 0 (alarm is mute), at this time the user should pay more attention to the patient.

- " △ " means the alarm system keeps on (is on "Alarm activating status"), and when an alarm event occurs, or currently active alarms does not meet the alarm conditions any longer, it displays icon " △ ";

- When an alarm event occurs, after pressing the alarm reset key, then it displays icon " △ ". Move the cursor on this icon can bring up the edit box of the "Alarm Volume" setting.

Note

☞ △ Alarm reset key: pressing this key can perform alarm reset for the current activated alarm event (the audible alarm silences, but the visual alarming is active), then the icon " △ " displays on the upper right corner of the screen. The monitor can respond to a new alarm event during the alarm reset status, both visual and audible alarming are active when there is a new alarm condition, and the icon " △ " displays on the upper right corner of the screen at the same time. Alarm reset is not a toggle operation, pressing this key once or more times only makes alarm reset.

Technical alarm status indicator and alarm indicator

- The technical alarm status indicator is an auxiliary indicator for "Alarm lamp". It indicates whether the system is in a technical alarm status or not. When the system is in technical alarm status, then the indicator is blue. Otherwise, it stays off.

- When a high priority physiological alarm event occurs, the alarm indicator flashes red color. When a middle priority physiological alarm event occurs, the indicator flashes yellow. When a low priority physiological alarm event occurs, the indicator is continuous yellow light. If there is no physiological alarm event, the indicator is continuous blue light.

6.3.6 Changing Alarm Volume

Audible alarm volume is adjustable; the user can not adjust the other properties of the alarm. The non-adjustable alarms are alarm priority setting, alarm lamp flashing. Also, all alarms in this patient monitor are "non-latched". When the alarm event disappears, the corresponding alarm automatically stops. The alarm volume range is shown below:

- ➢ **High**: 0dB-80dB (The distance between device front and test instrument is 1m)
- ➢ **Medium**: 0dB-75dB (The distance between device front and test instrument is 1m)
- ➢ **Low**: 0dB-70dB (The distance between device front and test instrument is 1m)

To set the alarm sound volume.

1. Select "Alarm"→"Others".

2. In "Others", select "Alarm Volume". Its setting range is "1 - 10" in standard configuration, and the setting range is "0-10" in spot check configuration, the step is 1. The default is 5. "10" is the maximum volume.

Caution

ⓘ When the alarm sound is switched off, the monitor will give no audible alarm tones even if a new alarm occurs. Therefore, the user should be very careful about whether to switch off the alarm sound or not.

ⓘ 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. Always keep the patient under close surveillance.

ⓘ Switching off alarms may result in a hazard to the patient, please be very careful.

ⓘ If multiple alarms signal at the same time, the monitor shows the high priority alarm with an audible alarm and alarm lamp. All alarm signals information, including message descriptions and numerical highlight show respectively and simultaneously on the screen.

ⓘ Users should not change the alarm volume lower than the factory default setting if close and constant attention cannot be paid to the patient. Otherwise, the negligence of the alarm event might cause harm to the patient.

ⓘ During the alarm reset, any new alarm event can activate the audible alarm again, and the audible alarm function resumes a normal state.

6.4 Understanding the Alarm Setting

Select the "Alarm" button on Statusbar, and select parameter (ECG, SpO$_2$, NIBP, TEMP). You can review and set alarm limits, alarm switches, high/low alarm limits for each parameter, as shown in the below figure.

PARM	Switch	High	Low	Level
HR	On	180	40	High
SpO$_2$	On	100	90	High
SpO$_2$_PR	On	180	40	High
SYS	On	180	60	High
DIA	On	120	50	High
MAP	On	160	50	High
NIBP_PR	On	180	40	High

GeneralParam | CO$_2$ | Others

Previous Page | Next Page | All On | All Off

Default | OK | Cancel

Alarm setting window

- **Previous page**: click it to turn to previous page.

- **Next page**: click it to turn to next page.

- **All On**: select it to enable alarm function for all parameters. Password is required for this operation.

- **All Off**: select it to disable alarm function for all parameters. Password is required for this operation, and it's not recommended to disable the alarm function completely.

- **ARR:** to set the alarm priority level for 5 arrhythmia (ARR) events, which include V-Fib/V-Tach, Asystole, Bradycardia, Tachycardia, and SV Tachy. There are three priority alarm levels for option: high, medium and low. The user can also enable or disable the alarm switch for these 5 ARR events.

- **Others:** to set the alarm volume and timeout setting for Apnea alarm.

Note

☞ If the parameter alarm switch is set to "OFF", then icon "⚠" will be displayed on the corresponding parameter panel. If the parameter panel has two or more related parameters, once one alarm switch for these related parameters set as "OFF", icon "⚠" will be displayed on its parameter panel. For example, there are SYS, DIA and MAP for NIBP parameter panel, if the alarm switch for SYS is set as "OFF", then icon "⚠" will be displayed on the NIBP panel.

☞ The high alarm limit for SpO_2 is fixed to be "100" and is nonadjustable.

☞ For the monitor configured with IBP, CO_2, CSM monitoring, the alarm switch, high/low alarm limits, and alarm level for these parameters can be set here.

☞ Alarm settings are saved when power off, which means the previous settings continue even the patient monitor is powered off. Repower includes unexpected power failure and manual reboot.

6.4.1 High and Low Alarm Setting Range

Select "Alarm"→"Normal Parameter".

Parameter	Setting range	
	High limit	**Low limit**
HR (bpm)	Adult: (Low limit+1) -300 Pediatric/Neonate: (Low limit+1) -350	0 - (High limit-1)
S-T（mV）	(Low limit+0.01) - 2.50	-2.5 - (High limit-0.01)
SpO_2 (%)	100	0 - (High limit-1)
PR (bpm)	(Low limit+1) -300	0 - (High limit-1)
TEMP1 (℃)	(Low limit+0.1) -60.0	0 - (High limit-0.1)
TEMP2 (℃)	(Low limit+0.1) -60.0	0 - (High limit-0.1)
TD (℃)	0.0-5.0	

RR (bpm)	Adult	Pediatric	Neonate
High limit	(Low limit+1) -120	(Low limit+1) -150	(Low limit+1) -150
Low limit	0 - (High limit-1)	0 - (High limit-1)	0 - (High limit-1)

NIBP (Unit: mmHg)		Adult	Pediatric	Neonate
SYS	High limit	(Low limit+1) -290	(Low limit+1) -240	(Low limit+1) -140
	Low limit	25 - (High limit-1)	25 - (High limit-1)	25 - (High limit-1)
MAP	High limit	(Low limit+1) - 260	(Low limit+1) -215	(Low limit+1) - 125
	Low limit	15 - (High limit-1)	15 - (High limit-1)	15 - (High limit-1)
DIA	High limit	(Low limit+1) - 250	(Low limit+1) -200	(Low limit+1) -115
	Low limit	10 - (High limit-1)	10 - (High limit-1)	10 - (High limit-1)
NIBP (Unit: kPa)		Adult	Pediatric	Neonate
SYS	High limit	(Low limit+0.1) – 38.7	(Low limit+0.1) – 32.0	(Low limit+0.1) – 18.7
	Low limit	3.3 - (High limit-0.1)	3.3 - (High limit-1)	3.3 - (High limit-0.1)
MAP	High limit	(Low limit+0.1) – 34.7	(Low limit+0.1)-28.7	(Low limit+0.1) – 16.7
	Low limit	2.0 - (High limit-0.1)	2.0 - (High limit-0.1)	2.0 - (High limit-0.1)
DIA	High limit	(Low limit+0.1) – 33.3	(Low limit+0.1) – 26.7	(Low limit+0.1) – 15.3
	Low limit	1.3 - (High limit-0.1)	1.3 - (High limit-0.1)	1.3 - (High limit-0.1)

Note

☞ The following parameters are optional.

Parameter		Setting range	
		High limit	Low limit
CO_2 (mmHg)	$EtCO_2$	（Low limit+1）-150	0 - （High limit-1）
	$FiCO_2$	（Low limit+1）-50	0 - （High limit-1）
IBP (mmHg)	ART	（Low limit+1）-300	0 - （High limit-1）
	PA	（Low limit+1）-120	-6 - （High limit-1）
	CVP	（Low limit+1）-40	-10 - （High limit-1）

	RAP	（Low limit+1）-40	-10 -（High limit-1）
	LAP	（Low limit+1）-40	-10 -（High limit-1）
	ICP	（Low limit+1）-40	-10 -（High limit-1）
	AUXP1	（Low limit+1）-300	-50 - (High limit-1)
	AUXP2	（Low limit+1）-300	-50 - (High limit-1)
CSI		(Low limit+1)-100	0-(High limit-1)

6.4.2 Factory Default Alarm Limit Setting Value

Parameter \ Type		Adult	Pediatric	Neonate
HR	High limit	180 bpm	200 bpm	220 bpm
	Low limit	40 bpm	50 bpm	50 bpm
RR	High limit	30 rpm	30 rpm	100 rpm
	Low limit	8 rpm	8 rpm	30 rpm
TEMP	High limit	39 ℃	39 ℃	39 ℃
	Low limit	35 ℃	35 ℃	35 ℃
SYS	High limit	180 mmHg	130 mmHg	110 mmHg
	Low limit	60 mmHg	50 mmHg	50 mmHg
DIA	High limit	120 mmHg	90 mmHg	90 mmHg
	Low limit	50 mmHg	40 mmHg	30 mmHg
MAP	High limit	160 mmHg	110 mmHg	100 mmHg
	Low limit	50 mmHg	40 mmHg	30 mmHg
SpO_2	High limit	100 %	100 %	100 %
	Low limit	90 %	85 %	85 %
S-T segment	High limit	+1.00mV	+1.00mV	+1.00mV
	Low limit	-1.00mV	-1.00mV	-1.00mV
$EtCO_2$	High limit	50mmHg	50mmHg	45mmHg
	Low limit	25mmHg	25mmHg	30mmHg
$FiCO_2$	High limit	4mmHg	4mmHg	4mmHg
	Low limit	0	0	0
PR	High limit	180 bpm	200 bpm	220 bpm
	Low limit	40 bpm	50 bpm	50 bpm
TD	/	2 ℃	2 ℃	2 ℃
CSI	High limit	60	60	60

	Low limit	40	40	40
ART	High limit	200mmHg	160mmHg	140mmHg
	Low limit	10mmHg	10mmHg	10mmHg
PA	High limit	120mmHg	100mmHg	90mmHg
	Low limit	10mmHg	10mmHg	10mmHg
CVP	High limit	30mmHg	30mmHg	30mmHg
	Low limit	-10mmHg	-10mmHg	-10mmHg
RAP	High limit	30mmHg	30mmHg	30mmHg
	Low limit	-10mmHg	-10mmHg	-10mmHg
LAP	High limit	30mmHg	30mmHg	30mmHg
	Low limit	-10mmHg	-10mmHg	-10mmHg
ICP	High limit	30mmHg	30mmHg	30mmHg
	Low limit	-10mmHg	-10mmHg	-10mmHg
AUXP1	High limit	200mmHg	160mmHg	140mmHg
	Low limit	-50mmHg	-50 mmHg	-50 mmHg
AUXP2	High limit	200mmHg	160mmHg	140mmHg
	Low limit	-50mmHg	-50 mmHg	-50 mmHg

Warning

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

6.5 Verify Alarm Function

The monitor performs a self-test upon startup. The alarm lamp illuminates, and the system gives a beep. The beep indicates that the visible and audible alarm indicators are functioning correctly.

For further testing of individual measurement alarms, perform the measurement on yourself (for example, SpO_2 or CO_2) or enter Demo Mode or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

6.6 When an Alarm Occurs

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

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

The alarm log will be stored permanently in the monitor, even if the power is down accidental or total loss of power, but the event of accidental powering down will not capture in the log.

The monitor can store 2000 groups of alarm events. When the number of events reaches the maximum storage capacity, the latest event will cover the earliest historical events, that is, the event displayed is the current patient's most recent events.

Chapter 7 ECG Monitoring

7.1 Introduction

The electrocardiogram (ECG) is primarily a tool for evaluating the electrical events within the heart. Electrodes can detect the ECG signals at the surface of the skin; this device connects ECG signals and represents them on the monitor as waveforms and numerical values such as heart rate. The S-T segment measurement and arrhythmia detection can be done as well by the ECG signals.

The ECG electrodes connect the patient, and the lead wires and ECG cable, the lead wires, and cable connect to the monitor. The electrode type selection and the locations of the electrodes are critical to ensure accurate ECG measurement.

7.2 Safety Information

Warning

⚠ This patient monitor can only be equipped with ECG cable and lead wires provided by the manufacturer; using those from other suppliers may cause improper performance or inadequate protection while using a defibrillator.

⚠ Use authorized electrodes on the same patient. DO NOT use the electrodes on other patients, to avoid the potential of contamination. If there are any side-effects such as allergic or stimulus skin, immediately stop the measurement. DO NOT apply the electrode to a patient with a lesion and body putrescence.

⚠ For patients with a pacemaker, the heart rate meter does not count the pacemaker pulse due to the function of pacemaker pulse inhibition, but for the pacemaker with overshoot pulse, the inhibition function may not be fully active. It is vital to observe the ECG waveforms and do NOT rely entirely on the heart rate display and alarm system when monitoring the pacemaker patient.

⚠ 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.

⚠ In operation mode, the monitor can be used with electro-surgical unit. The monitor's operator should ensure the safety of the patients if in use with electro-surgical unit in accordance with the instructions of this manual. After the elimination of high frequency signal and high frequency electromagnetic field, the monitor can be set to the previous operation mode within 10 seconds without losing any stored data.

⚠ Do not use the monitor with electro-surgical unit in non-operation mode, nor with large-scale electrical equipment such as ultrasonic, radiation and magnetic resonance imaging, which may cause electromagnetic interference to the monitor or harm the monitor's operator.

Caution

ⓘ DO not contact any other conductive parts (including ground) with any conductive parts of electrodes, lead wires, and cable.

ⓘ This patient monitor can withstand the discharge of a defibrillator and the interference from the electrosurgical unit. Readings may be inaccurate for a short time after or during using a defibrillator or electro-surgical unit.

ⓘ Transients caused by cable circuitry blocks while monitoring may cause an artifact on ECG signals yielding wrong heart rate reading and even triggering a false alarm. Accurately locate the electrodes and cable according to this manual's instructions for using electrodes. Proper placement decreases the chance of these transients.

ⓘ ECG cable and lead wires may be damaged while using a defibrillator. Perform a function check on the cable and lead wires before reuse.

ⓘ When the monitor is inoperable due to an overload of ECG signal or saturation of any part of the amplifier, it prompts "Lead(s) off" to remind the operator.

ⓘ The user should eliminate any potential predictable hazards caused by the summation of leakage currents when several items are interconnected.

ⓘ When plugging or unplugging the ECG cable, be sure to hold the head of the connector and pull it out.

ⓘ Checking for the shelf life of the electrodes, and do not use the expired electrodes.

7.3 Preparing to Monitor ECG

7.3.1 Preparing the Patient and Device

1. Skin preparation

Clean and scrap skin to ensure low sensor impedance if necessary. Mild soap and water are recommended as a skin cleanser. Scraping the skin gently with a dry washcloth, gauze, for skin preparation is helpful to remove the non-conductive skin layer.

Note

☞ If alcohol is used as a cleanser, it is recommended to have a 30-second drying time for a better connection.

2. Connect the cable to the connector marked with the "ECG" icon on the signal input panel.

3. Place the electrode to the patient according to **Section 7.3.2 ECG Electrodes Placement.**

4. Attach the ECG lead wires to the electrode

5. Make sure the monitor is turned on and is ready for monitoring.

6. After starting the monitor, if the electrodes become loose or disconnected during monitoring, the system displays "*LEAD OFF*" on the screen to alarm the operator.

   - It might not display ECG waveform when using ECG cable with 3 lead wires while the setting of "Wires" is set as "5-leadwire" in the ECG parameter setup menu. Only single channel of ECG signal can be obtained while using 3 lead wires and the "Wire" is set as "3-leadwire", this ECG signal can

be selected between Lead I, Lead II and Lead III.

- In order to obtain other Leads of the ECG signals, such as aVL, aVR, aVF and V, the ECG cable with 5 lead wires should be used and the "Wires" should be set to "5-leadwire". At this situation, 7 Leads of ECG signal (lead I, II, III, aVL, aVR, aVF, V) can be obtained and displayed simultaneously.

Note

☞ If any side-effect such as allergic or itchy reaction is noted, remove the electrodes from the patient immediately.

☞   The symbol indicates that the cable and accessories are "CF" type levels for protection against electric shocks and with defibrillation-proof capability.

7.3.2 ECG Electrodes Placement
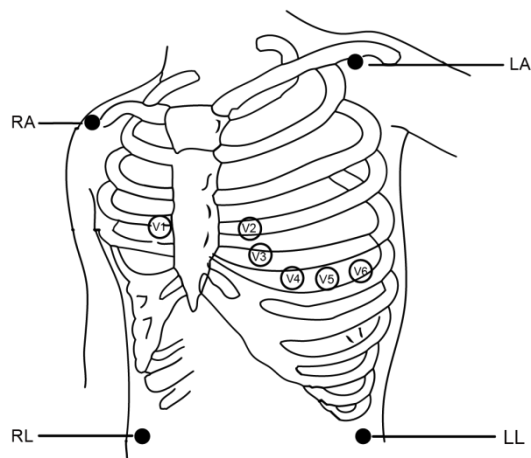
Electrode Placement

The ECG leads, and their corresponding locations are as follows:

Electrode connection 1 (IEC Standard)		Electrode connection 2 (AHA Standard)		Electrode position on body surface
Color code	Label on lead wire	Color code	Label on lead wire	
Red	R	White	RA	Right Arm: The intersection between the centerline of the right clavicle and Rib 2
Yellow	L	Black	LA	Left Arm: The intersection between the centerline of the left clavicle and Rib 2
Green	F	Red	LL	Left Leg: Left part of the upper abdomen
Black	N/RF	Green	RL	Right Leg: Right part of the upper abdomen
White	C	Brown	V	Any of the following location (C1-C6 or V1-V6) on chest
White/Red	C1	Brown	V1	4th Intercostal (IC) space at the right border of the sternum
White/Yellow	C2	Brown/Yellow	V2	4th IC space at the left border of the sternum
White/Green	C3	Brown/Green	V3	Midway between V2 and V4
White/Brown (Blue)	C4	Brown/Blue	V4	5th IC space on left midclavicular line
White/Black	C5	Brown/Red	V5	Left anterior axillary line at the horizontal level of V4
White/Purple	C6	Brown/Purple	V6	The left midaxillary line at the horizontal level of V4

7.4 Understanding the ECG Display

Your display may be configured to look slightly different.

ECG waveform
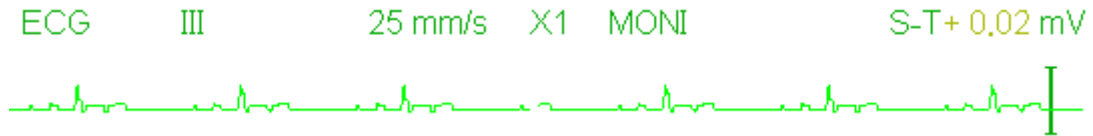
- "ECG": parameter label.

- "III": ECG lead. III means ECG lead III.

- "25mm/s": ECG waveform sweeping speed, unit is "mm/s".

- "X1": ECG waveform gain. "X1" means the waveform scale with base gain.

- "MONI": ECG filtering mode. There are three types: diagnose, monitoring, and operation.

- "S-T+0.02mV": S-T segment value, here indicates the value is 0.02mV.

Heart Rate Panel
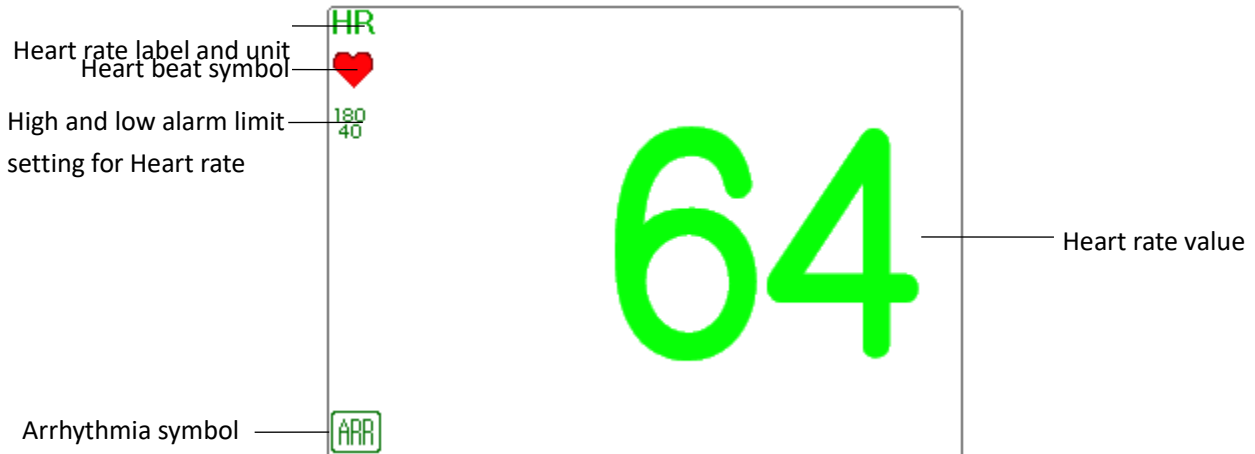
- "HR": heart rate. The 64 on the right is the heart rate measured.

- "bpm": the unit of heart rate, it means "beats per minute".

- " ": the heart-beat symbol, blinks corresponding to the R wave of ECG waveform.

- "180/40": high and low alarm limit setting for heart rate.

- " ": Arrhythmia symbol. If the ARR function is set as ON, then this symbol will be displayed.

7.5 Changing ECG Settings

Select "Menu" → "ECG" to enter into ECG related settings.

- **Speed**: The ECG waveform sweeping speed, 4 options: 6.25mm/s, 12.5mm/s, 25mm/s and 50mm/s. The factory default is 25 mm/s.

- **Filter**: ECG filtering mode, 3 options: MONI, DIAG, OPER and ST. The default mode is "MONI".

  - ➢ **DIAG**: Extended bandwidth to provide the ECG waveforms with the quality of diagnosis level.
  - ➢ **MONI**: Normal bandwidth to provide noise-free ECG waveforms for effective monitoring.
  - ➢ **OPER**: Narrow bandwidth to suppress interference from the electrosurgical unit during operation.
  - ➢ **ST**:Use this mode in ST monitoring.

- **Gain:** The ECG gain, 7 options: x1/8, x1/4, x 1/2, x 1, x 2, x 4 and Auto. The "Auto" is for automatic gain control. The default is "x1".

  - ➢ Auto: auto gain control;
  - ➢ x1/4: 1/4 of the base gain;
  - ➢ x1/2: 1/2 of the base gain;
  - ➢ x1: the base gain;
  - ➢ x2: twice of the base gain;
  - ➢ x4: 4 times of the base gain;
  - ➢ x1/8: 1/8 of the base gain.
  - ➢ The base gain is 10 mm/mV.

- **Wires**: The default is "5-leadwire", it is necessary to select ECG Lead with a "5-leadwire" setting to obtain all ECG signals, including Lead I, II, III, aVR, aVL, aVF, and V. The user can also choose "3-leadwire" setting. When "3-leadwire" is chosen, only electrodes of R/RA, L/LA, and F/LL are used for detecting ECG signals, and the user can only select ECG signal of Lead I, or II, or III, the default Lead selection is Lead "II".

- **Cal 1mV**: Generate the 1mV calibration signal internally. This signal is used to self-test the signal amplitude of the monitor. It must be unselected during normal operation. The default is unselected.

- **Notch:** only in "DIAG" filtering mode, the notch filter can be chosen. 3 options: OFF, 50Hz, 60Hz. The factory default is 60Hz.

- **Grid:** The display switch of the grid lines on the background of the ECG waveform. The default is OFF.

- **Pacer:** Enable the cardiac pacemaker pulse detection; the default is unselected. When the "Pacer" is selected, the function of pacemaker pulse detection operates. A mark " ≣ " will be overlapped on the ECG waveform (as shown in the following figure.) if the pacemaker pulse is detected while the patient wears a cardiac pacemaker.
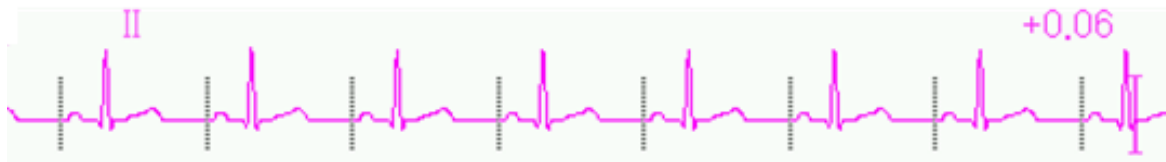
Note

☞ Pacemaker pulse inhibition function operates for Heart Rate calculation whether you enable or disable the function of cardiac pacemaker pulse detection or not.

7.6 About Arrhythmia Detection and Template Learning

7.6.1 ECG arrhythmia analysis

- **ARR switch:** the switch of ECG arrhythmia detection. The default is ON. This switch does not affect the alarm function for 5 ARR events (Bradycardia, Tachycardia, Asystole, V-Fib/V-Tach, SV Tachy). That's to say, the detection and alarm for 5 ARR events is fixed to be ON, and nonadjustable.

- **Extra ARR Learning:** indication of ARR learning status or activating ARR learning manually. When ARR is set to "ON", the device will start to learn the regular ECG signal automatically for ARR detection and icon " 🔲 " will be displayed. The device will finish the learning after a certain period, and the icon will become " 🔲 ". The detected arrhythmia waveform will be displayed on the third or the last ECG waveform display channel; if there is only one ECG waveform display channel, then the detected arrhythmia waveform will be re-displayed and frozen on this channel for 8 seconds. The arrhythmia waveform will be re-displayed on the cascaded waveform channel if there is a single Lead of ECG signal displayed with cascaded waveform channels.

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.

☞ When the device is restarted, the Arrhythmia detection is reset to its default status.

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

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

☞ 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.

Caution

⚠ The arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect atrial or supraventricular arrhythmias. It may incorrectly identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information with other clinical findings.

⚠ Take care to initiate template relearning only during periods of normal rhythm and when the ECG signal is relatively noise-free. If template learning takes place during ventricular rhythm, the ectopics may be incorrectly learned as the normal QRS complex. This may result in missed detection of subsequent events of V-Tach and V-Fib.

7.6.2 Understand the ARR Type

No.	Abbreviation	Full name/Description
1	Asystole	Asystole
2	V-Fib/V-Tach	Ventricular fibrillation/ventricular tachycardia
3	Vent Tachy	Ventricular tachycarida
4	Vent Brady	Ventricular bradycardia
5	Nonsus V-tach	Non-sustained ventricular tachycardia
6	Vent rhythm	Ventricular rhythm
7	Run PVCs	More than two consecutive Premature Ventricular Contractions
8	Pair PVCs	A Pair of Premature Ventricular Contractions
9	R on T	R wave interrupting T Waves
10	Vent bigeminy	Ventricular bigeminy
11	Vent trigeminy	Ventricular trigeminy
12	PVCs/min	Premature ventricualr contractions per minute
13	Multiform PVC	Multiform premature ventricualr contraction
14	PVC	Premature ventricualr contraction
15	Extreme Tachy	Extreme tachycardia
16	Extreme Brady	Extreme bradycardia
17	SV Tachy	Supraventricular tachycardia
18	SV Brady	Supraventricular bradycardia
19	A-Fib	Atrial fibrillation

20	A-Fib (HR High)	Atrial fibrillation (high heart rate)
21	A-Fib end	Atrial fibrillation end
22	Irr Rhythm	Irregular rhythm
23	Irr Rhy End	Irregular rhythm end
24	Pause	Heartbeat pause
25	Pauses/min	Heartbeat pauses per minute
26	Miss beat	Missed beat
27	Pacer Not Pacing	Pacemaker not pacing
28	Pacer Not Capture	Pacemaker not capture

7.7 About S-T Segment Monitoring

The operator can use the Navigation Knob to do the S-T segment measurement manually, the value is displayed with "S-T +0.xxx mV". There are 2 cross cursors on screen. The red cross is the activated one. The

arrows (←→and ↕) on the red cross indicate the directions that the cross cursor moves when rotating the Navigation Knob. Press the Navigation Knob can change directions of the cross cursor or change the activating status of the cross cursor.

The measured S-T value will be accurate only in Diagnosis mode, while the S-T value is less meaningful in other modes. In Diagnosis mode, when ARR event is detected, the S-T value is only for reference.
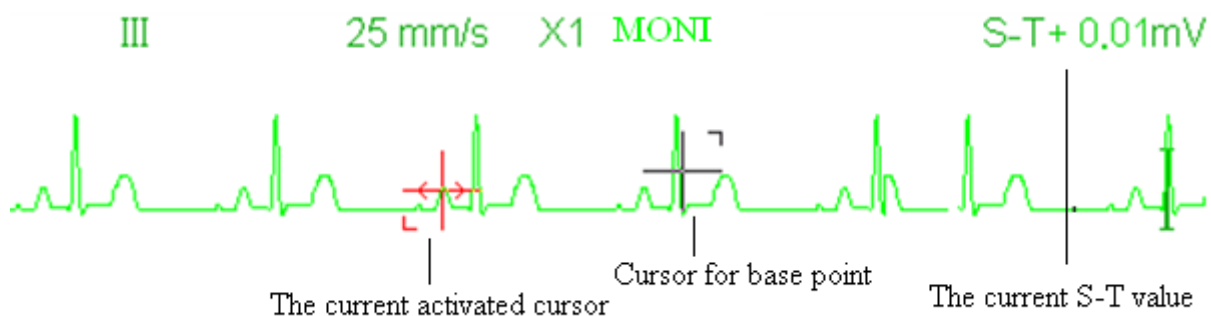
Caution

ⓘ   The S-T segment measuring algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.

7.8 Freezing Waveform

When there are waveforms displayed on the screen, press the Freeze key to enter into the waveform freezing screen. During freezing, the frozen symbol "❄" and frozen time displays on the upper right corner of the waveform area.

There are 2 Freeze types: "ECG waves" and "All waves", which can be set in the System Settings window.

7.9 Factors Affecting ECG signal

- Interference from Electro-surgical Unit

- Doesn't set the filter mode properly

- Poor grounding

- Electrodes are not appropriately placed

- Use expired electrode or use disposable electrode repeatedly

- The skin placed electrode is unclean or poor contract caused by scurf and hair

7.10 Acquire 12-lead ECG for Analysis

This function is available in some model of the monitors.

The monitor can acquire 12-lead ECG waves of a defined duration and send them to the artificial intelligence powered AI-ECG system for ECG analysis. You can view the analysis result in the AI-ECG system.

You can acquire 12-lead ECG data by the following way:

1   Make sure that the **Wires** is set to **10-Leadwire** in **ECG Settings** diaglog box.

2   Select **Menu** – **Views**.

3   Select **All ECG Trace**, and exit the window. The current screen is in **All ECG Trace** view.

4   Select **Menu** – **ECG Analyzer**.

5   In the pop-up ECG Analyzer window, select the acquire time among 10 sec, 20 sec, 30 sec, 1 min.

6   Select **Start**. The ECG acquisition starts and ECG data is automatically uploaded to the AI-ECG system when acquisition is over.

   Note

   ☞ The 12-lead ECG acquisition can only be conducted in the All ECG Trace view.

   ☞ Once the ECG is acquired, the ECG data automatically stored in the review records. If the monitor fails to upload the ECG data to the AI-ECG system due to network connection, you can upload it again by selecting the records in Review – ECG Report.

AI-ECG System Setup

To make the ECG analysis done, you need configure the monitor to establish the connection between monitor and AI-ECG system before upload the ECG data:

1   Select **Menu** – **System Settings**.

2   Select **AI-ECG** tab.

3   Configure the Operator account, device ID, AI-ECG server IP, etc.

Chapter 8 Monitoring Respiration (RESP)

8.1 Introduction

Respiration is monitored by measuring the impedance across the thorax via electrodes placed on the chest. When the patient is breathing or ventilated, the volume of air changes in the lungs, resulting in impedance changes between the electrodes. The device applies a safe high-frequency current through ECG electrodes into the body and measures the change of voltage between the electrodes to reflect the thoracic impedance while ECG monitoring is not affected. Respiration rate (RR) is calculated from these impedance changes, and the respiration waveform is displayed on the monitor screen.

8.2 Safety Information

Warning

⚠ When monitoring the patient's respiration, it is recommended to use the so-called "non-OR" ECG cable which has no built-in resistors to prevent the energy loss of defibrillator discharge. Otherwise, the performance of respiration monitoring is degraded.

⚠ The respiration measurement does not recognize the cause of Apnea. It only indicates an alarm if Apnea is detected when a preset time has elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purposes.

⚠ If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3V/m), field strengths above 1V/m may cause erroneous measurements at various frequencies. Therefore, it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.

8.3 Understanding the RESP Display

RESP waveform

RESP   12.5 mm/s X1/2

Respiration Panel

Label and unit of respiration
Respiratory Sync mark
The high and low alarm limit setting of RR
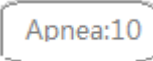
Respiration rate

- "RR": the label of Respiration. "**rpm**" is the unit of the Respiration Rate (respiration per minute). The big font "14" is the value of Respiration rate.

- "⬙": Breath symbol. The blinking frequency is the same as the Respiration Rate.

- "150/66": the high and low alarm limit setting for Respiration Rate.

- Apnea (X): the apnea alarm status in RESP alarm setting, refer to the following Section for details.

8.4 Changing RESP Settings

Select "Menu" → "RESP" to enter into RESP related setting.

- **Gain:** Respiration amplification/gain times, 4 options: X1/2, X1, X2, X4. The default is X1 for adult and pediatric patients, and X2 for neonate patient.

  - X1/2: half-scale size of the base gain
  - X1: waveform scale with base gain
  - X2: twice scale size of the base gain
  - X4: four times scale size of the base gain

- **Speed:** Respiration waveform sweep speed of, 2 options: 6.25mm/s and 12.5 mm/s. The default is 12.5 mm/s.

- **Apnea:** The timeout setting for apnea alarm (in second). It can be set as any number from 5 to 120 seconds, the step is 1 second. Icon "Apnea:10" displays on the lower left corner of Respiration Panel; When the device has not detected any breathing signal for the specified time, the "Apnea" alarm prompts on, and alarm sound will be activated. If it is set as OFF, the icon "Apnea (X)" displays on lower left corner of the Respiration Panel.

  Note

  ☞ When "Wires" is set as "10-leadwire" in ECG related settings, then "Apnea" can be set as off, 10, 15, 20, 25, 30, 35 and 40.

- **Source:** Respiration signal source. This item is fixed to be "CO_2" if the CO_2 monitoring function is selected. Otherwise, the source is obtained by measuring the thoracic impedance via ECG electrodes, the signal source can come from the ECG electrodes defined by "ECG Lead I" and "ECG Lead II".

- **PARM:** to enter into RR alarm setting. See Section 6.4 **"Understanding the Alarm Setting".**

- **Zero:** press it to perform CO_2 zeroing.

- **Default:** resume to the factory default value.

Note

☞ In RESP settings window, CO$_2$ Settings are entered if your monitor is configured with CO$_2$ monitoring.

☑ Start CO$_2$ Monitoring : click it to turn on or off CO$_2$ Monitoring. When the CO$_2$ monitoring is selected, then all items setting as "RESP" shifts to "CO$_2$". **See Chapter Monitoring Carbon Dioxide (CO$_2$)**.

Chapter 9 Monitoring NIBP

9.1 Introduction

9.1.1 The Oscillometric Blood Pressure Measurement

This device applies the typical non-invasive blood pressure measurement with the oscillometric method. A cuff is used to occlude the artery by inflating it above the patient's systolic pressure, and the device measures 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 a systolic pressure (SYS), and the cuff pressure at the pulse amplitude forward reduced according to proper proportion is defined as diastolic pressure (DIA)

9.1.2 The Oscillometric method vs. the Korotkoff Sound Method

Blood pressure measurements by the oscillometric method and Korotkoff sound method have a reasonable correlation with the invasive blood pressure measurement. Notwithstanding, any of the non-invasive blood pressure measurements has its one-sidedness when it is compared to the invasive measurement. Studies show that the oscillometric method has its advantages over the Korotkoff sound method in less error, higher reliability, and stability, especially in critical cases such as arrhythmia, vasoconstriction, hypertension, shock.

9.2 Safety Information

Warnings

⚠ When taking the blood pressure measurement on a neonate patient. DO NOT operate in the Adult mode. The high inflation pressure may cause lesion or even body putrescence. Even though the monitor can identify the cuff type so it will stop inflation and indicate "Cuff error" when taking the blood pressure measurement for a neonate in the "Adult" patient type setting. The user (doctor or nurse) should pay more attention to select the correct patient type.

⚠ It is recommended to take the blood pressure measurement manually

⚠ Do not perform NIBP to patients who have a severe hemorrhagic tendency or with sickle cell disease. Otherwise, partial bleeding appears.

⚠ Do not wrap the cuff on limbs with a transfusion tube or intubations or on a skin lesion area. Otherwise, there may be an injury to the limbs.

⚠ If the patient is moving or trembling, hyperkinesia, or arrhythmia, it may cause the inflation time of inflatable balloon to run longer, which may not only prolong the measurement time but also result in the cuff wrapped area to suffer purpura, hypoxemia, or neuralgia because of the friction.

⚠ Before the measurement is carried out, select an appropriate measuring mode depending on the patient type.

⚠ The air-hose, which connects the cuff and monitor, should be straight and untangled.

Cautions

ⓘ When an adult patient is monitored, the device may fail in giving the blood pressure measurement if the pediatric patient type is selected.

ⓘ Before use of the cuff, empty the cuff until there is no residual air inside it to ensure accurate measurement.

ⓘ Do not twist the air tube or put heavy things on it. This may cause inaccurate blood pressure values.

ⓘ When unplugging the air tube, hold the head of the connector and pull it out.

ⓘ The NIBP measurement is affected when the monitor is connected to the patient on whom the electro-surgical unit and defibrillator are used.

ⓘ The appearance of arrhythmia in an irregular heartbeat may affect the accuracy of NIBP measurement. It is recommended to retake the measurement in this case.

ⓘ 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.

ⓘ The monitor can be used on the patients who are pregnant or pre-eclamptic, but close attention should be paid to such patients.

ⓘ The performance of the NIBP function can be affected by the extremes of temperature, humidity, and altitude; please use it within the appropriate working environment.

ⓘ Do not apply the cuff and its pressure on the arm at the side of mastectomy or lymph node clearance.

ⓘ The cuff pressure may temporarily cause loss of function of simultaneously used monitoring medical device on the same limb.

ⓘ The NIBP module of the device was clinically investigated according to the requirements of ISO 81060-2:2013.

9.3 Measurement Limitations

- Serious angiospasm, vasoconstriction, or too weak pulse limit measurement accuracy.

- Measurements are inaccurate when extremely low or high heart rate or severe arrhythmia of the patient occurs. Auricular fibrillation leads to unreliable or impossible measurements.

- Do not take the measurement when the patient is connected with an artificial heart-lung machine.

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

- When the patient is suffering from significant hemorrhage, hypovolemic shock, and other conditions with rapid blood pressure change or when the patient has too low body temperature, the reading will not be reliable. Reduced peripheral blood flow leads to reduced arterial pulsation.

- Measurements are not accurate on a patient with hyperadiposis.

9.4 Measurement Mode

There are four measuring modes for NIBP measurement:

- **Manual:** Measurement on demand.

- **Auto:** Continually repeated measurements at set intervals.

- **STAT:** Continually rapid series of measurements over a five-minute period, then return to the previous mode.

- **Customized Multi-Cycle:** Continually perform the NIBP measurement according to the pre-defined phases which each have specific lasting period and repeats.

9.5 Setting Up the NIBP Measurement

9.5.1 Preparing to Measure NIBP

1. Power on the monitor.

2. Check the patient information area on the screen. Set a correct patient type, select a correct cuff size.

3. Connect the tube with the cuff to the connector marked with the "NIBP" icon on the signal input panel.

4. Select a cuff with the correct size, then unfold the cuff and wrap it around the patient's upper arm as follows:

   ➢ Determine the patient's limb circumference.

   ➢ Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% of the limb circumference or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb. When putting on the cuff, unfold and wrap it around the upper arm evenly to appropriate tightness.

   ➢ Remember to empty the residual air in the cuff before the measurement starts.

   ➢ Locate the cuff, so the artery mark " ϕ " is at a location where the clearest pulsation of the brachial artery is observed.

   ➢ The cuff should be tightened to a degree where a finger can be inserted.

   ➢ The lower end of the cuff should be 2cm above the elbow joint.
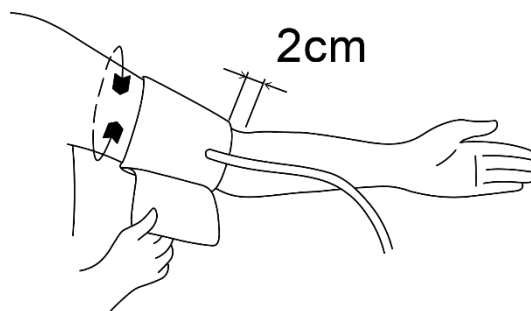
9.5.2 Starting and Stopping Measurements

Starting and Stopping NIBP Measurements by pressing NIBP measure key " ".

Warning

⚠ Too frequently, blood pressure measurements may cause purpura, ischemia, and

neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth, and sensitivity. If any abnormity occurs, move the cuff to another site or stop the blood pressure measurements immediately.

Note

☞ You can not start NIBP measurement if the NIBP parameter area is not displayed.

9.5.3 Factors Affecting NIBP Measurement

Improper operation may cause inaccurate or blank results or misunderstanding of the measured information when the oscillometric method is used to take the blood pressure measurement. The following points mitigate these problems.

- Requirements of the cuff:
  - ➢ The appropriate cuff should be selected according to the age of the patient.
  - ➢ Remember to empty the residual air in the cuff before the measurement begins.
  - ➢ 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 be tightened to a degree where the insertion of one finger is allowed.
  - ➢ The lower end of the cuff should be 2cm above the elbow joint.
- The patient should lie on their back so that the cuff and the heart are in a horizontal position, to achieve the most accurate measurement. Other postures may lead to inaccurate measurements.
- Do not speak or move before or during the measurement. Care should be taken so that the cuff does not hit or touch other objects. The air tube which connects the cuff and monitor should be straight and tangle-free.
- The measurement should be taken at appropriate intervals. Continuous measurement at extremely short intervals may lead to pressed arm, reduced blood flow and lower blood pressure, and resulting in an inaccurate measurement of blood pressure. To ensure proper measurement, take measurements at intervals of more than two minutes.
- The operating steps needed to obtain accurate routine resting BLOOD PRESSURE measurements for the condition hypertension including:
  - ➢ Patient position in normal use, including comfortably seated, legs uncrossed, feet flat on the floor, back and arm supported, middle of the cuff at the level of the right atrium of the heart.
  - ➢ The patient should be relaxas much as possible and should not talk during the measurement procedure.
  - ➢ 5 minutes should elapse before the first reading is taken.
  - ➢ Operator position in normal use.
- With the oscillometric method, when blood pressure is measured, the inflation pressure of the cuff will be automatically adjusted according to the previous measurement. Generally, the initial inflation pressure is 150mmHg (for the adult mode) or 120mmHg (for pediatric) or 70 mmHg (for neonate) when it is powered on. Following that, 28mmHg (for adult) or 25mmHg (for pediatric) or 25mmHg (for the neonate) will be added on the basis of the last measurement of systolic pressure. In this way, when the blood pressure rises or the patient is changed, the device may fail in giving the result after the first-time inflation. This device will automatically adjust the inflation pressure until the measurement is taken, after that, up to four times retry will be allowed.
- When an adult patient is monitored, the device may fail in giving the blood pressure measurement if the Pediatric or neonate patient type is selected.

- When taking NIBP measurement on pediatric or neonatal patients, the operator must select correct patient type depending on different patients (refer to NIBP menu setup) and do NOT operate with the adult patient type setting. The high inflation pressure for adult is not suitable for pediatric patients.

9.6 Understanding the NIBP Numerics

NIBP Panel

NIBP label and unit ⎯⎯ NIBPkPa · MANU ⎯⎯ NIBP measurement mode

⎯⎯ Diastolic pressure value

Systolic pressure value ⎯⎯ 123 80

PR 62 ⎯⎯ Pulse rate value
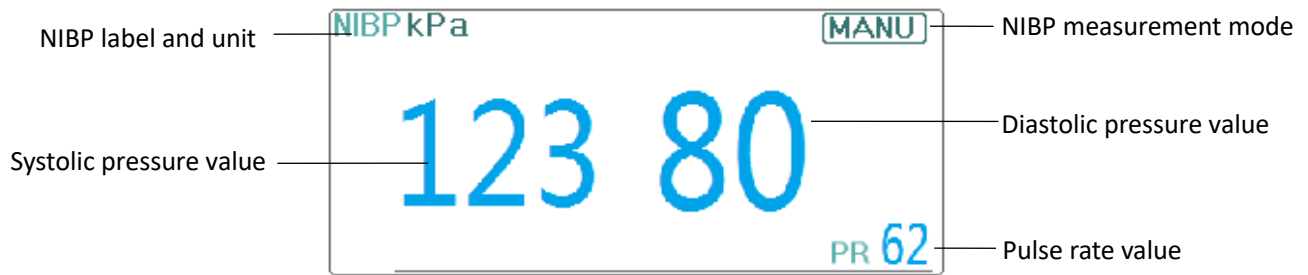
- **"NIBP" :** The blood pressure label. "123" is the systolic pressure value, "80" is the diastolic pressure value.

- **"mmHg":** The unit of blood pressure value, 1kPa = 7.5mmHg.

- **"PR 62":** Pulse rate value when taking blood pressure measurement.

- **"Manu"**: the NIBP icon measurement mode. There are 4 modes: "Manual", "Auto" , "STAT" and "customized multi-cycle". When in "AUTO" mode, a count-down timer is displayed as well.

9.7 Changing NIBP Settings

Select "Menu" → "NIBP" to enter into NIBP related settings.

Mode

"MANU", "AUTO", "STAT" and "Customized Multi-cycle" can be selected. The default is "MANU".

- In "**MANU**" mode, press the NIBP measure key " 🖐 " manually can start or stop NIBP measurement.

- In the "**AUTO**" mode, the device repeats NIBP measurement automatically with the set time interval. In this mode, manual interference still works.

- In "**STAT**" mode (only used for an adult), press the NIBP measure key " 🖐 ", the device does NIBP measurement again and again. The device will not stop measuring until the measuring time is over 5 minutes, or the operator stops it manually.

- **Customized Multi-cycle**: move the cursor on "Customized Multi-cycle" and click "OK" to enable this function. The user can customize the related parameters: Phase, time cycle (the time interval between two measurements), and repeats. There are 5 phases: A, B, C, and E. The user can set the time cycle and repeats for Phase A to Phase E.

  - ✓ **Cycle**: 1min, 2min, 3min, 4min, 5min, 6min, 7min, 8min, 9min, 10min, 15min, 20min, 25min, 30min, 35min, 40min, 45min, 50min, 55min, 1h, 1.5h, 2h, 2.5h, 3h, 3.5h, 4h, 4.5h, 5h, 5.5h, 6h, 6.5h, 7h, 7.5h, 8h for optional.

  - ✓ **Repeats**: OFF, 1, 2, ...9 and 10 for optional.

  For example, first, the monitor enters into Phase A (making NIBP measurement once every 5 minutes, and repeat once only); Secondly, entering into Phase B (making NIBP measurement once every 10 minutes, and repeat once only); Thirdly, entering into Phase C (making NIBP measurement once every 20 minutes, and repeat 2 times); Fourthly, entering into Phase D (making

NIBP measurement once every 30 minutes, and repeat 5 times); Lastly, entering into Phase E (making NIBP measurement once every 60 minutes, and repeat once only). In 30 minutes, if the NIBP measurement is less than 6 times, and NIBP measurement mode is not changed, then the monitor starts to make NIBP measurement from Phase A to E automatically.

Caution

⚠ STAT mode can only be used for an adult.

Note:

☞ When changing the patient, the default NIBP measuring mode is "Manual".

☞ For "Adult", if the NIBP measuring mode is set as "STAT", then the monitor does not save this setting when you shut down the monitor. When re-starting the monitor, the NIBP measuring mode for Adults is "Manual".

☞ For all patient types, if the NIBP measuring mode is set as "Manual", or "Auto", or "Customized Multi-cycle", the monitor saves this setting when you shut down the monitor.

Cycle

it can be set only in the "AUTO" mode. Cycle means the time interval between measurements when the measuring mode is set to Auto. The Cycle options are: 1min, 2min, 3min, 4min, 5min, 6min, 7min, 8min, 9min, 10min, 15min, 20min, 25min, 30min, 35min, 40min, 45min, 50min, 55min, 1h, 1.5h, 2h, 2.5h, 3h, 3.5h, 4h, 4.5h, 5h, 5.5h, 6h, 6.5h, 7h, 7.5h and 8h. That's, the range is from 1 minute to 10 minutes, step is 1 minute; for range from 10minutes-1hour, step is 5 minutes; for range from 1 hour-8 hours, step is 0.5 hour.

When in AUTO mode and this item is set, the operator must manually press NIBP measure key " " for the first time, then the device starts time counting down. The device starts taking the next blood pressure measurement automatically after finishing counting down.

Unit

the pressure unit. "mmHg" and "kPa" can be selected. 1 kPa =7.5 mmHg.

Init. Pressure

Initial cuff pressure. The range is different depending on patient type.

for adult: 80, 100, 120, 140, 150, 160, 180, 200, 220, 240, 260, 280 mmHg;

for pediatric : 80, 100, 120, 140, 160, 180, 200, 210 mmHg;

for neonate: 60-140 mmHg.

Note

☞ if your monitor is configured with SunTech NIBP module, then the initial cuff pressure range for adult is 120-200mmHg, the initial cuff pressure range for pediatric is 80- 200 mmHg, the initial cuff pressure range for neonate is 60 – 80 mmHg.

PARM

to enter into NIBP (SYS, DIA, MAP,) alarm setting. See Section **6.4 "Understanding the Alarm Setting".**

Verification

To verify the NIBP pneumatic system, it is used to verify the pressure accuracy and check the air leakage of the pneumatic system, which should be conducted by technicians in the specified environment. It includes "Verification A", "Verification B," and "Leakage Check".

> **Verification A & Verification B**: The 2 kinds of verification of the pressure accuracy. Press the relevant button to start Verification A or B. When completed, it is necessary to stop the verification manually by pressing the "Stop" button. The system stops the verification when the "Exit" button pressed.

> **Leakage Check:** it is used by technicians to perform a leakage inspection for NIBP pneumatic system.

Note

☞ **Verification A:** The monitor will auto inflate to the preset pressure value (depending on the patient type) by the pump, then it closes the deflating valve. Comparing the pressure value on the device with that on standard pressure manometer, and verify whether the pressure accuracy exceeds the rated tolerance range.

The auto inflating pressure value for Adult: 250 mmHg (33.3 kPa)

The auto inflating pressure value for Pediatric: 200 mmHg (26.7 kPa)

The auto inflating pressure value for Neonate: 125 mmHg (16.7kPa)

Verification B: The monitor closes the valve; the pressure should be inflated manually. Comparing the pressure value on the device with that on standard pressure manometer, and verify whether the pressure accuracy exceeds the rated tolerance range.

☞ If the verification window pops up during verification, you can press the "Close" button to exit from it only, but DO NOT from by Verification B by pressing "Display View Key".

Chapter 10 Monitoring Oxygen Saturation (SpO₂)

10.1 Introduction

The functional oxygen saturation (SpO$_2$) - a percentage of the hemoglobin that can transport oxygen, is monitored by this device via a non-invasive optical technique. Based on the principle that oxygenated hemoglobin (HbO$_2$) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light, the device measures the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into electrical signals by the photo-detector in the probe. The SpO$_2$ module processes the electrical signals and gives out waveform data and digital values for SpO$_2$ and pulse rate displayed on the screen.

10.2 Safety Information

Warning

⚠ Continuous use of fingertip SpO$_2$ sensors may result in discomfort or pain, especially for those patients with microcirculatory problems. The sensor should NOT be applied to the same site for over two hours, please inspect the monitoring site every 1-2 hours for skin integrity, and change the measuring site periodically if necessary.

⚠ Check the SpO$_2$ probe application site periodically (every 30 minutes) to determine circulation, positioning, and skin sensitivity.

⚠ The SpO$_2$ measuring site must be examined more carefully for some unique patients. Do NOT place the SpO$_2$ sensor on the finger with edema or fragile tissue.

⚠ Avoid placing the SpO$_2$ sensor on the same extremity with an arterial catheter, blood pressure cuff, or intravascular infusion line, otherwise the blood flow could be interrupted by the cuff or the circulatory condition could make low blood perfusion so that would result in no pulse found or loss of pulse during SpO$_2$ monitoring and further cause false alarm.

⚠ The SpO$_2$ measurement of this monitor may not work effectively for all kinds of patients; for those with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of a vascular contracting drug, the measurement is more sensitive to interference. If stable readings cannot be obtained at any time, discontinue the use of the SpO$_2$ 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 determination by this monitor may be inaccurate.

⚠ Drugs such as dopamine, procaine, prilocaine, lidocaine, and butacaine may also cause erroneous SpO$_2$ measurements.

⚠ Excessive ambient light may also affect the measurements. The light sources include fluorescent lamps, dual ruby light, infrared heater, and direct sunlight.

⚠ As the SpO$_2$ value serves as a reference value for judgment of anemic anoxia and toxic anoxia, the measurement result of some patients with acute anemia may also present as good SpO$_2$ value.

⚠ Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate oxygen saturation measurements.

⚠ Vigorous movement of the patient, intense ambient light, or extreme electro-surgical interference may also affect the SpO$_2$ measuring accuracy.

⚠ Do not stare at the SpO$_2$ light sensor (infrared is invisible) when the device is on. Infrared light can the eye.

⚠ The information, such as the range of the peak wavelengths and maximum optical output power of the light by the SpO$_2$ sensor, can be especially useful to clinicians.

⚠ Always observe the plethysmogram (waveform), which is auto-scaled (normalized). When the measured signal is inadequate, the waveform is irregular or does not have a smooth appearance. The SpO$_2$ reading is most likely inaccurate or displays "--". If in doubt, rely on your clinical judgment, rather than the monitor readout.

⚠ Do not use the SpO$_2$ sensor and the monitor while performing MRI imaging, as the faradism may cause a burn.

<u>Caution</u>

① Dispose of the SpO$_2$ sensor if the sterile packaging is damaged.

① Check the SpO$_2$ sensor and cable before use. Do NOT use the damaged SpO$_2$ sensor.

① Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl Ethanol. If low-level disinfection is required, use a 1:10 bleach solution.

① DO not use the SpO$_2$ sensor anymore if the temperature sensor readings are abnormal.

① Please do not allow the cable to be twisted or bent.

① Please do not use nail polisher or other cosmetic product on the nail.

① The fingernail should be of reasonable length.

① The SpO$_2$ sensor cannot be immersed into water, liquor, or cleanser completely, because the sensor is susceptible to the ingress of liquid.

① Do not disinfect any SpO$_2$ sensor by irradiation, steaming, or ethylene oxide.

① Carefully route cables to reduce the possibility of patient entanglement or strangulation.

☞ A clinical study for SpO$_2$ measurement accuracy was completed on human subjects according to Standard ISO 80601-2-61.

☞ A functional tester or SpO$_2$ simulator cannot be used to assess the accuracy of the oximeter or a SpO$_2$ 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 ask the manufacturer which calibration curve to use. If necessary, request the manufacturer for its dedicated calibration curve and download it into the tester.

10.3 Apply the Sensor

1. Select an appropriate sensor and probe according to the module type and patient category.

2. Apply the sensor to the proper site of the patient.

3. Select an appropriate adapter cable according to the connector type and plug this cable into the SpO$_2$ connector.

4. Connect the sensor cable to the adapter cable.

10.4 Using Probe and Sensor

When selecting a SpO$_2$ probe or sensor, do consider the patient's category, adequacy of perfusion, availability of probe site, and anticipated monitoring duration. Use only SpO$_2$ probes provided by our company with this monitor.

Type 1: SpO$_2$ Finger Clip Sensor

Insert the patient's index finger (middle finger or ring finger with proper nail length can be used as well) into the sensor, as shown in the figure below.
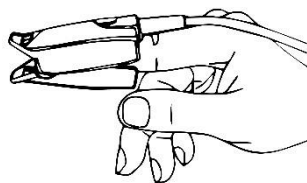
Type 2: SpO$_2$ Finger Rubber Sensor

Hold the sensor with its opening towards the patient's finger, the sensor should be oriented in such a way that the sensor side with a fingertip sign is positioned on the top.

Insert the patient's finger into the sensor until the fingernail tip rests against the stop at the end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor. Direct the cable along the top of the patient's hand. Apply adhesive tape to secure the cable if necessary.
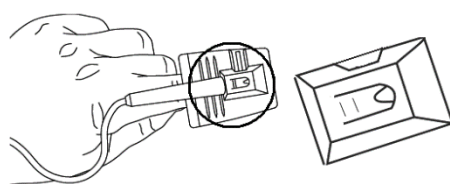
Type 3: SpO$_2$ Ear Clip Sensor

Clip the sensor on the patient's earlobe, refer to the following figure:
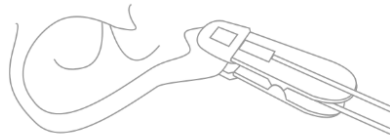
Type 4: SpO₂ Sensor with L-type Wrapper

Refer to the following connection method:

L type sensor → Neonate foot wrapper

Self-adhesive tape →
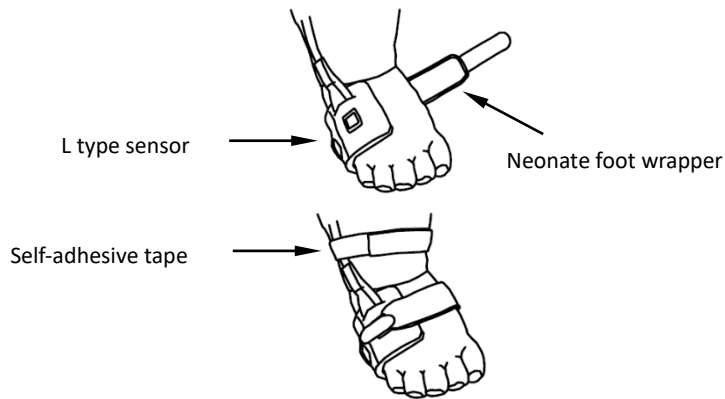
10.5 Understanding the SpO2 and PR Display

Plethysmogram
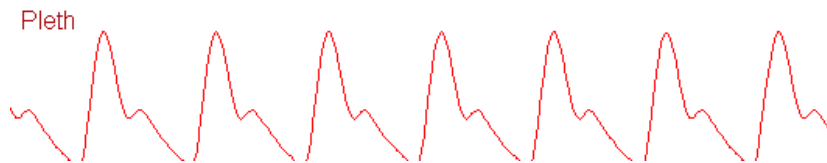
Pleth

- **Pleth**:A label for the abbreviation of plethysmogram.

SpO₂ Panel

SpO₂ label — %SpO₂   PI%: 0.59   PR — Label of pulse rate

Pulse intensity bar graph — 99   65 — Pulse rate value

High and low alarm limit for SpO₂ — SpO₂ value
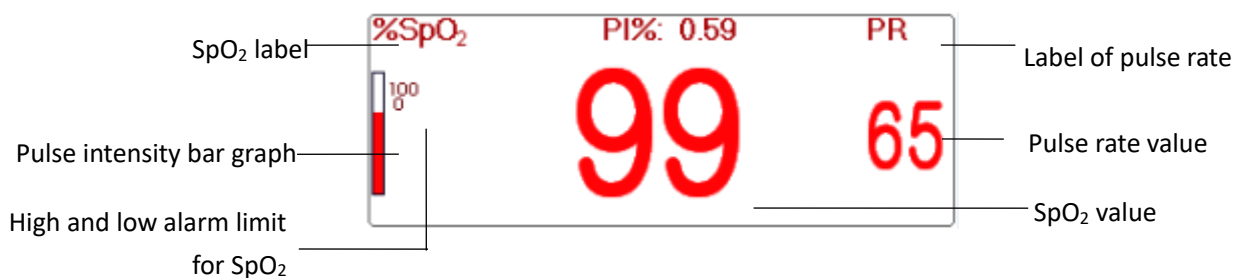
- **"SpO₂":** SpO₂ label. "99" is the current SpO₂ value.

- **"PR":** The Pulse Rate label. "65" is the current Pulse Rate value.

- "PI": The Pulse Rate label.

- " ": The high and low alarm limit setting for SpO₂.

- " ": Pulse intensity bar graph.

10.6 Changing SpO$_2$ and PR Settings

Select "Menu" → "SpO$_2$" to enter into the SpO$_2$ related setting.

- **SE Threshold (%):** set the threshold of oxygen desaturation event (%), the value range is from 1 to 12, step is 1. The default is 3(%).

- **Beep Volume**: to set the pulse beep sound volume. Its setting range is "0 - 10" level. The default is 5. If you set the beep volume as "0", it means the pulse beep sound is off. It's not recommended to set it as "0".

- **PARM**: to enter into SpO2 alarm setting. See Section **6.4 "Understanding the Alarm Setting"**.

The conditions to trigger SpO$_2$ Event (SE):

Condition 1:

If the value difference between current SpO$_2$ value and the average value of the last 1 minute is larger than the set threshold, and it keeps this value for at least 8 seconds, then an SE is generated.

Condition 2:

When the current SpO$_2$ value is between 90% and 100%, and the value difference between current SpO$_2$ value and the average value in the previous second is larger than the set threshold, then a SE is generated too.

10.1 Nellcor SpO$_2$ Module

Note

☞ The SpO$_2$ monitoring with Nellcor module is not CE-certified.

☞ If your monitor is configured with Nellcor SpO$_2$ Module, then the SpO$_2$ related setting window is as shown in below figure.
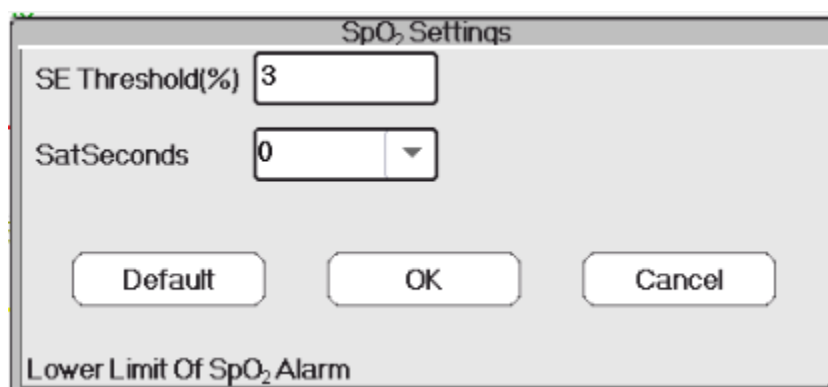
- **SE Threshold(%)**: set the threshold of oxygen desaturation event (%), the value range is from 1 to 12, step is 1. The default is 3(%).

- **SatSeconds**: SatSeconds sensitivity setting, to set the max buffering time of activating SpO$_2$ alarm. Options are "0", "10", "20", "50" and "100". If you set SatSeconds as "0", it means to turn off the SatSeconds alarm management function. The over-limit points multiplied over-limit seconds makes SatSeconds.

SpO$_2$ panel for Nellcor SpO$_2$ module

SatSeconds icon and sensitivity setting
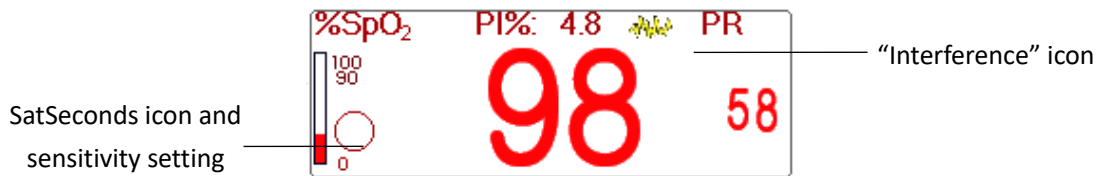
"Interference" icon

Notes

☞ When inserting finger into the probe cushion, then searching pulse icon "" appears on the upper side of the SpO₂ panel. However, once the SpO₂ /PR readings appear, or probe/ finger is off, then icon "" will disappear.

☞ When interference (caused by e.g., shaking finger) appears, then icon "" appears on the upper middle side of the SpO₂ panel. However, once the interference disappears, or probe / finger is off, then icon "" will disappear.

☞ The alarm will be triggered if the SpO₂ measurements exceeds the limits totally three times in one minute despite the Sat-seconds limit is not reached yet.

Below is the related alarm information for Nellcor SpO₂ module.

No.	Event	Alarm level	Remark
1	SpO₂ INOP	High priority alarm	Such alarm will not display on alarm information area, but it will be recorded as alarm event which can be reviewed on "Alarm event". these events are mostly unrecoverable faults.
2	SpO₂ firmware error		
3	Communication error		
4	SpO₂ faulty sensor		
5	SpO₂ hardware error		
6	SpO₂ module error		
7	SpO₂ sensor error		It means the SpO₂ sensor identifications fails.
8	SpO₂ sensor disconnected	Medium priority alarm	The sensor cable or extension cable is not connected to the monitor.
9	SpO₂ probe off		It means the sensor cable is connected, but the probe is out of the measuring site.

Chapter 11 Monitoring Temperature

11.1 Introduction

Body temperature is monitored by direct measuring mode with a thermistor type temperature sensor. A small amount of constant current is applied to the temperature sensor to avoid self-heating. The voltage across the thermistor is measured and converted to the temperature reading according to the temperature-resistance characteristic for a specific type of thermistor. The temperature measuring circuit performs self-testing periodically to prevent false reading when there is a failure in hardware.

You can simultaneously monitor two temperature sites using the device for a specific model; only one channel temperature is available.

11.2 Safety Information

Warning

⚠ Verify that the probe detecting function works correctly before monitoring. Unplug the temperature probe cable from the T1 or T2 connector, and the monitor displays the message [T1 Sensor Off] or [T2 Sensor Off] and gives alarm tones.

⚠ Make the correct choice in the setup menu for "KRK" series of temperature sensors used. The sensors have different temperature-resistance characteristics (KRK thermistor has 10.000K ohms @25°C). Mismatching causes erroneous temperature readings or even an out-of-range reading.

11.3 Making a TEMP Measurement

Please follow the methods defined below to take temperature measurements according to the temperature transducer you selected.

Connecting the thermal temperature sensor

The temperature sensor is thermo-resistor type and needs time to respond to the temperature change, so the accurate temperature value takes a display of the results. The temperature sensor equipped may have a different shape for measuring body surface temperature or cavity temperature.

Note

☞ For body surface temperature probe, attach the TEMP sensor to the patient. If the TEMP sensor does not directly contact the skin, the measured value becomes lower. For patients that need temperature monitoring, add a pad to the sensor and fix it with adhesive tape to ensure close contact.

☞ Pediatric patients are generally more active, pay close attention when affixing the sensor.

☞ The TEMP sensor is designed for use with the specific patient monitor, which cannot be used as applied part to other products.

☞ The operator is responsible for checking the compatibility of the patient monitor and sensor type, including cable before use.

☞ Incompatible components can result in degraded performance.

Operation Procedures for thermal temperature transducer

1. Securely attach the transducer to the patient;

2. Connect the cable to the TEMP probe connector marked "TEMP" in the panel.

3. Check that the menu setting is matching the used temperature sensor type.

4. Check that the alarm settings are appropriate for this patient.

Note

☞ When unplugging the probe, be sure to hold the head of the connector and pull it out.

11.4 Understanding the TEMP Display
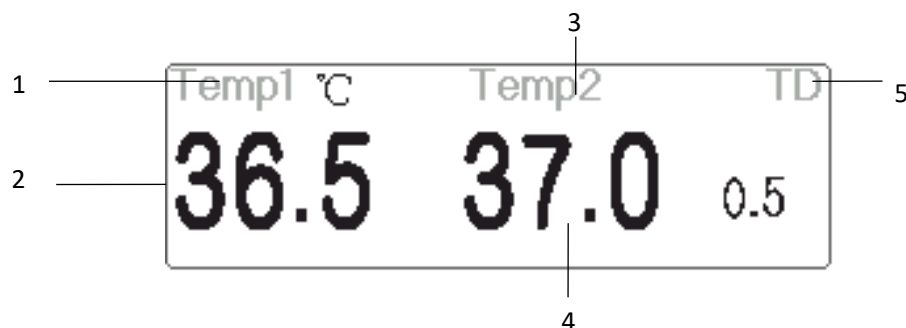
1 "TEMP1 ℃" : Temperature 1 mark and unit. Temperature unit: ℃ or ℉。

2 "36.5": displays the temperature measured at temperature channel 1.

3 "TEMP 2": Temperature channel 2.

4 "37.0": displays the temperature measured at temperature channel 2.

5 "TD 0.5": Temperature difference, namely the difference between temperature 1 and temperature 2.

11.5 Changing TEMP Settings

Select "Menu" → "TEMP" to enter into TEMP related setting.

- **Temp Unit：** Temperature unit. The default is ℃ (Celsius) and can be set as ℉ (Fahrenheit). The default is "℃".

- **Probe type:** KRK can be selected. If the user type and the set type are different, then the measured value is invalid.

- **TD**: the absolute temperature difference. When the temperature difference is higher than the preset value, then the device activates an alarm. If there is only one temperature, the TD shows "——".

- **PARM:** to enter into RESP alarm setting. See Section **6.4 "Understanding the Alarm Setting".**

Chapter 12 Monitoring IBP

12.1 Introduction

Invasive Blood Pressure (IBP) is a direct measurement of the patient's arterial or venous blood pressure. A catheter is used and inserted directly into a vein, artery or other pressure access areas, and is connected to a pressure transducer for measuring systolic, diastolic and mean blood pressures. The device can choose to monitor 2 or 4 (for specific model) channels IBP depending on the configuration. The device can display the systolic, diastolic and mean blood pressures and a waveform for each pressure channel.

12.2 Safety Information

<u>Warning</u>

⚠ The pressure tube which connects the catheter and the pressure transducer should be straightway without any tangle.

⚠ Use the pressure transducer kit specified in this manual. Never reuse disposable pressure transducers.

⚠ Make sure that the applied parts never contact other conductive parts.

⚠ To reduce the hazard of burns during high-frequency surgical procedures, ensure that the monitor's cables and transducers never come into contact with the high-frequency surgical units.

⚠ When using accessories, their operating temperature should be taken into consideration. For details, refer to instructions for use of accessories.

⚠ Use the accessories specified by the manufacturer, when a defibrillator is used.

⚠ Improper use of a defibrillator may cause injury to the patient. The user should determine whether to perform defibrillation or not according to the patient's condition.

⚠ Before defibrillation, the user must ensure both defibrillator and monitor have passed the system test and can be safely used jointly.

⚠ Do Not use the damaged pressure tube and transducer.

⚠ If air bubble appears in pressure tube, please fill the tube with saline solution again. Air bubble may cause inaccurate reading.

⚠ When doing ICP measurement to the patient who is sitting, please keep the pressure transducer and the top of patient's ear at the same level, or it may lead to error reading.

⚠ When unplugging the cable from the monitor, be sure to hold the head of the connector and pull it out.

⚠ Each time when connecting transducer kit or using a new transducer kit, zero calibration to the IBP transducer must be carried out.

⚠ Before using the tube, cable and/or transducer, make sure that all accessories meet the

performance requirements which is not changed by aging or environmental conditions.

12.3 Setting Up the IBP Measurement

If your monitor is configured with internal IBP Module, then the IBP icon appears on the upper right side of the screen.

12.3.1 Understanding IBP Icon

"IBP X" (X stands for number 1-4) marked on the device is the icons for IBP cuff connector of the internal IBP module. The internal IBP module will be shown as like "IBP1" in software and operation.

12.3.2 IBP Transducer Kit Connection

1. On the signal input panel of the patient monitor, there are 2 (or 4) connectors with label "IBP1" and "IBP2" (or label "IBP1", "IBP2" , "IBP3", and "IBP4") depending on your monitor configuration, which are used to connect the IBP transducer kit. If you want to use IBP monitoring function, please connect the IBP transducer kits into the IBP connectors on the panel of the patient monitor. Please make sure the cables of the transducer kits are not folded or twisted.

2. Prepare the pressure tube and transducer by filling the pressure tube with saline solution, and make sure that the pressure tube is free from any air bubble.

3. Connect the pressure catheter coming from the patient to the pressure tube of the transducer kit, and ensure there is no air present in the pressure tube, pressure transducer or pressure catheter.

4. The pressure transducer must be placed at the same level with the patient's heart.

5. Check if the correct label name is chosen, see below table.

Label	Description	Label	Description
ART	Artery pressure	LAP	Left atrium pressure
CVP	Central vain pressure	RAP	Right atrium pressure
ICP	Intracranial pressure	PA	Pulmonary pressure
AUXP1	Auxiliary pressure 1	AUXP2	Auxiliary pressure 2

6. Zero the transducer.
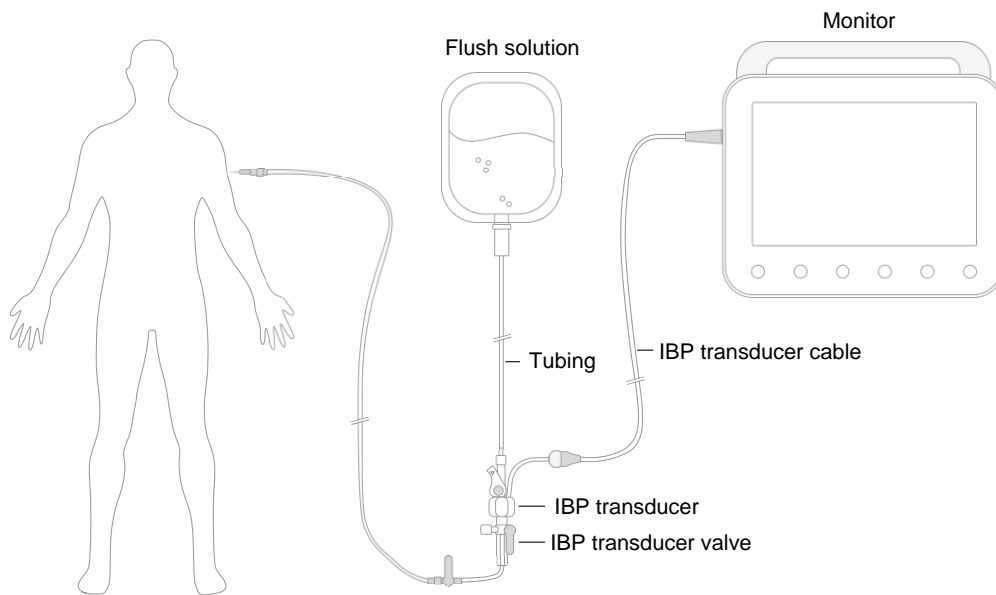
IBP transducer kit with disposable pressure sensor

12.4 Understanding the IBP Display

IBP Waveform

- "IBP1": Parameter label.
- [0   300]: IBP coordinates scale.

Note

☞ For K10 and K12 monitors, it only show 2 channels of waveforms.

☞ For K15 monitor, it shows 4 channels of waveforms.

IBP Panel
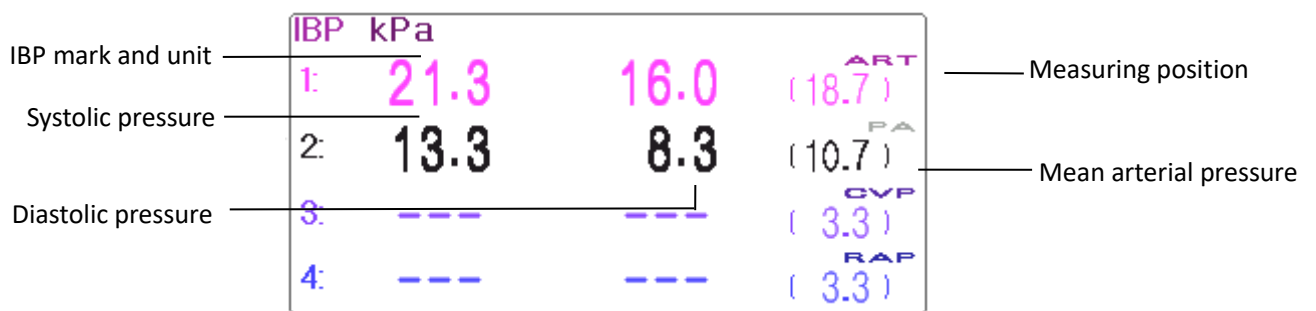
IBP Alarm information

- The IBP alarm information will be displayed on the alarm information area.

- Technical alarm: "IBP1 Probe off" and so on.

- Physiological alarm: "IBP1 Low SYS " and so on.

12.5 Changing IBP Settings

Select "Menu" → "IBP" to enter into IBP related setting.

- **Label:** the name of blood pressure to be measured. It has the following options:
  - ➢ ART---artery pressure
  - ➢ PA---pulmonary pressure
  - ➢ CVP---central vain pressure
  - ➢ RAP---right atrium pressure
  - ➢ LAP---left atrium pressure
  - ➢ ICP---intracranial pressure
  - ➢ AUXP1---auxiliary pressure 1
  - ➢ AUXP2---auxiliary pressure 2

- **AUXP** -- auxiliary pressure: AUXP1/2 can be chosen if the actual measuring pressure is not in the list of ART, PA, CVP, RAP, LAP, and ICP. The operator can choose the Calculating Mode according to the type of blood pressure. If artery pressure is monitored, please choose "dynamic", then the reading out will include Systolic, Diastolic and MAP. If vein pressure is monitored, please choose "static", then only the MAP will be displayed.

- **Calc. Mode**: when the Label is AUXP1 or AUXP2, the calculate mode can be "static" or "dynamic".

- **Filter:** there are two options for the pressure waveform filtering ---12.5Hz and 40Hz, the factory is 12.5Hz.

- **Avg. time:** the time period for averaging to calculate Mean Pressure. Setting range from 1s to 12s, the factory is 8s.

- **Unit:** pressure unit. 2 options: mmHg and kPa.

- **Zero**: perform zero calibration for pressure transducer. Press "Zero" button, then zero calibration dialog pops up on the screen, then press "Zero" to start calibration. (Note: before performing zero calibration, please make sure that the transducer is well connected, or the zero calibration will not work.)

- **PARM:** to enter into IBP alarm setting. See Section **"Understanding the Alarm Setting".**

Chapter 13 Monitoring Carbon Dioxide (CO$_2$)

13.1 Introduction

CO$_2$ Measuring Principle

The principle is based on the fact that CO$_2$ molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO$_2$ concentration. When an IR light beam is passed through a gas sample containing CO$_2$, the electronic signal from a photodetector (which measures the remaining light energy), can be obtained. This signal is then compared to the energy of the IR source, and calibrated to reflect CO$_2$ concentration in the sample accurately. To calibrate, the photodetector's response to a known concentration of CO$_2$ is stored in the monitor's memory.

The monitor determines CO$_2$ concentration in the breathing gases by measuring the amount of light absorbed by these gases. EtCO$_2$ displays a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). Also, a CO$_2$ waveform (capnogram) may be displayed, which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube placement. Respiration rate is calculated by measuring the time interval between detected breaths.

Mainstream vs. Sidestream Sampling

Mainstream CO$_2$ sensors are placed at the airway of an intubated patient, allowing the inspired and expired gas to pass directly across the IR light path. The major advantages of mainstream sensors are fast response time and elimination of water traps.

Sidestream CO$_2$ sensors are located away from the airway, requiring a gas sample to be continuously aspirated from the breathing circuit and transported to the sensor through a pump. This type of system is needed for non-intubated patients.

When using mainstream CO$_2$ sensors, check the window for the patient secretions pooled on periodically. That condition may affect the accuracy of the measurement or even make the sensor not work.

When using sidestream CO$_2$ sensors, there is a water trap or a part of the sampling tube with a dehumidifying function. Please periodically check the flow sensor and tubing for excessive moisture or secretion buildup.

13.2 Safety Information

Warning

⚠ CO$_2$ Sensor is a precision measuring part, please use it correctly and store it properly;

⚠ Precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.

⚠ Failure of Operation: If the CO$_2$ Sensor fails to respond as described in this user manual, DO NOT use it until approved for use by qualified personnel.

⚠ Do not position the sensor cables or tubing in any manner that may cause entanglement or strangulation.

⚠ Support the airway adapter to prevent stress on the ET tube.

⚠ 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.

⚠ Inspect the sidestream on-airway adapters and sidestream sampling kits for damage before use. DO NOT use the sidestream on-airway adapters and sidestream sampling kits if they appear to be damaged or broken.

⚠ If the CO_2 waveform (Capnogram) appears abnormal, inspect the CO_2 airway adapters and replace it if needed.

⚠ Periodically check the CO_2/Flow sensor and tubing for excessive moisture or secretion buildup. Do not use the sensor or tubing if there is excessive moisture or exterior condensation.

⚠ Electric Shock Hazard: The CO_2 Sensor contains no user-serviceable parts.

⚠ Refer service to qualified service personnel. Do not open the sensor cabinet at will, as electric shock hazard may occur.

⚠ Place the exhaust vent of the CO_2 Sensor in drafty ambient and do not let anything block the exhaust vent.

⚠ Always disconnect the CO_2 Sensor before cleaning. Do NOT use it if it appears to have been damaged. Refer servicing to qualified service personnel.

⚠ Do not sterilize or immerse the CO_2 Sensor in liquids.

⚠ Replace the sidestream on-airway adapters and sidestream sampling kits if excessive secretions are observed.

⚠ Do not operate the CO_2 Sensor when it is wet or has exterior condensation.

⚠ Monitor the CO_2 waveform (Capnogram). If you see changes or abnormal appearance, check the patient and the sampling line. Replace the line if needed.

⚠ Do not use the device on patients that cannot tolerate the withdrawal of 50 ml/min +/- 10 ml/min from the airway or patients that cannot tolerate the added dead space to the airway.

⚠ Do not apply excessive tension to any sensor cable or pneumatic tubing.

⚠ Explosion Hazard: Do not use in the presence of flammable anesthetics or other flammable gasses. The use of the CO_2 Sensor in an environment may present an explosion hazard.

⚠ Electrical Shock Hazard: Always disconnect the CO_2 Sensor before cleaning. Do NOT use it if it appears to have been damaged. Refer servicing to qualified service personnel.

Caution

⚠ The power voltage over monitor working voltage may cause damage to the CO_2 sensor. Likewise, too low power voltage may affect the CO_2 measuring accuracy or even make the CO_2 sensor not work.

(I) When changing the sampling tube, it is suggested to choose the default sampling tube with a dehumidifying function. The sampling tube without dehumidifying function may be easily blocked by excessive moisture. (Use life: ordinary sampling tube: 6-12 hours; the sampling tube with dehumidifying function: about 120 hours.)

(I) If the measurement shows an abnormality caused by sampling tube block, replace the sampling tube block.

(I) The total length of the sampling tube and extending the airway tube shouldn't be longer than 3 meters. If the tube is too long, measurement errors may occur. If using T connector sampling cannula kits, insert the sampling tube with the tubes upward to avoid the effects of excessive moisture.

(I) Altitudes vary for different locations. Set the Barometric Pressure setting value to the ambient barometric pressure for the location of use.

(I) Use the manufacturer-approved accessories only.

(I) While using the CO_2 sensor, a system leak, that may be caused by an uncuffed endotracheal tube or a damaged CO_2 sensor may significantly affect flow-related readings. These readings include flow, volume, pressure, and other respiratory parameters.

(I) When stopping the CO_2 monitor, please disconnect the CO_2 sensor from the patient monitor.

(I) Connect the gas outlet to the scavenging system when using sidestream CO_2 module to measure CO_2.

Note

☞ Disposal of the CO_2 Sensor and its accessories should comply with national and local.

☞ 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.

☞ Nitrous oxide, elevated levels of oxygen, helium, and halogenated hydrocarbons can influence the CO_2 measurement.

☞ Excessive moisture in the CO_2 may affect the accuracy of the flow measurement.

13.3 CO$_2$ Sensor Connection

13.3.1 Sidestream CO$_2$ Sensor Connection
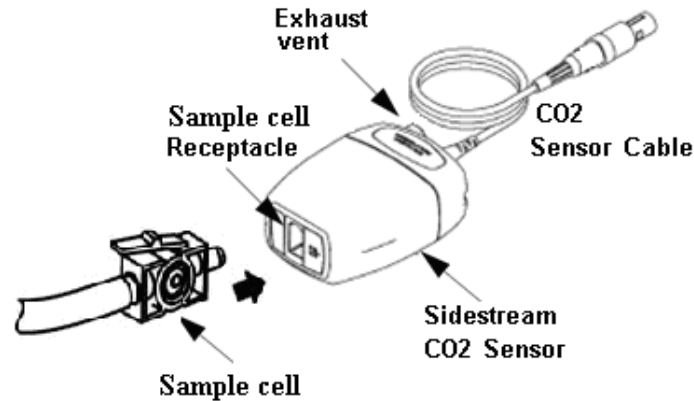
Demonstration for Sidestream CO$_2$ Sensor Connection

1. Take out the CO$_2$ Sensor and insert the CO$_2$ Sensor Cable into the connector labeled "CO$_2$" on the connector panel of the monitor;

2. The sample cell of the sampling cannula must be inserted into the sample cell receptacle of the CO$_2$ Sensor. A "click" sounds when the sample cell is inserted correctly, then connect to the airway tube. After finishing sensor connection, and make sure that the air input end is exposed to room air and away from all sources of CO$_2$, including the ventilator, the patient's breath, and your own. Next, turn on the CO$_2$ switch at CO$_2$ Setup Screen and then wait 2 minutes for the sensor warm-up.

3. Default Tubing Configuration
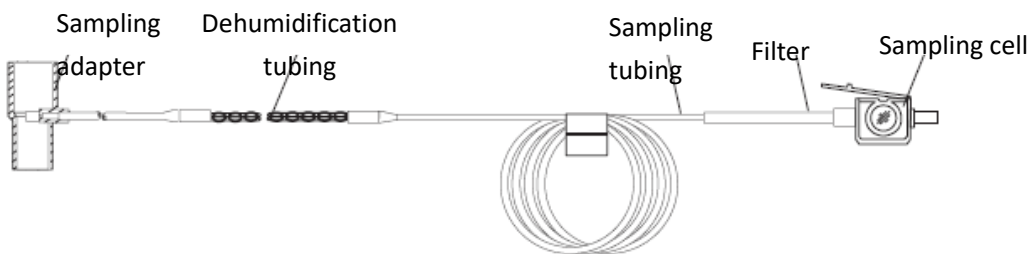
Adapter and Sampling tube (Single patient use)
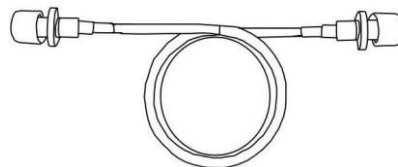
Extending the airway tube for connecting to sampling tube (Single patient use)
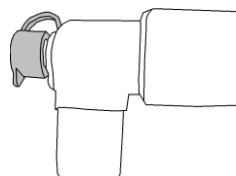
Wye Connector

4. Optional sampling cannula kits

(1) T connector sampling cannula kits

On-air Connector

Adapter
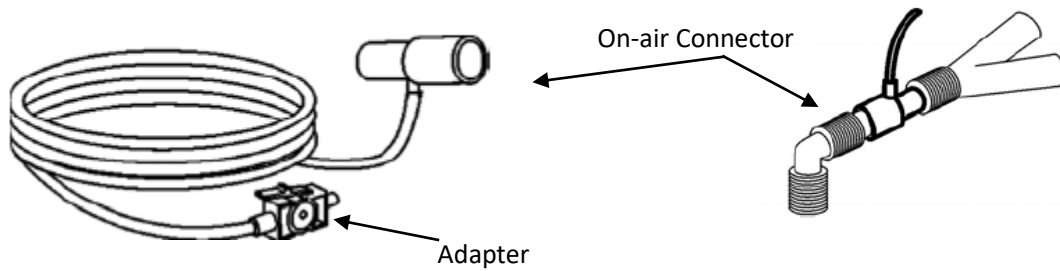
(2) Nasal Sidestream Cannula Kits
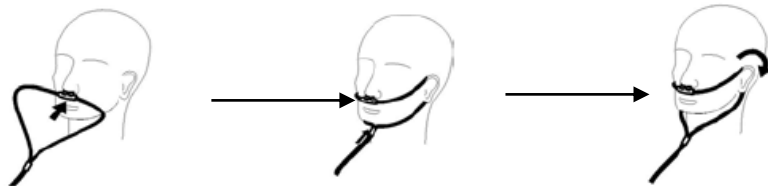
(3) Oral Sidestream Cannula Kits

13.3.2 Mainstream CO_2 Sensor Connection

Sensor cable
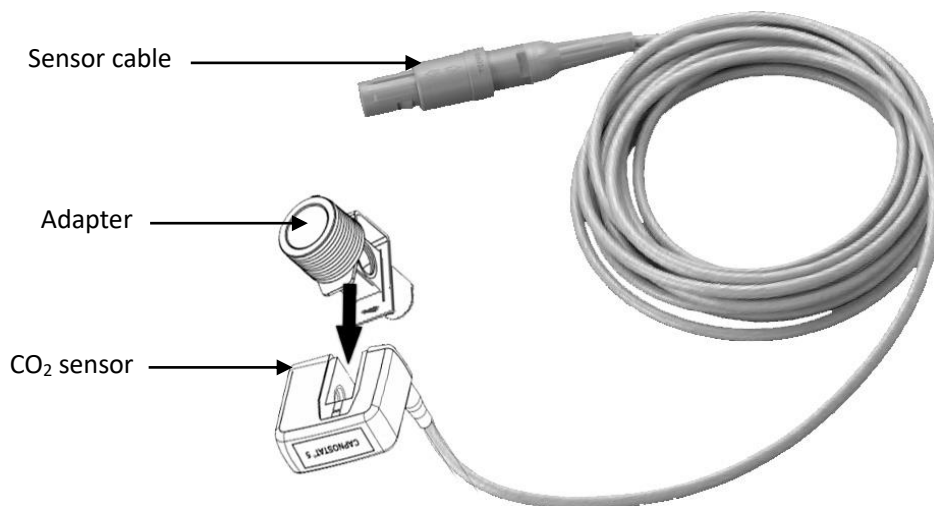
Adapter

CO_2 sensor

13.3.3 Demonstration for Mainstream CO_2 Sensor Connection

1. Take out the CO_2 Sensor and insert the CO_2 Sensor Cable into the connector labeled "CO_2" on the connector panel of the monitor;

2. Snap the CO_2 sensor onto the airway adapter. A "click" sounds when the airway adapter is inserted

correctly.

3. Position the airway adapter in the patient's respiratory circuit (as close to the patient as possible) between the endotracheal tube and the ventilator circuit. Next, turn on the CO_2 switch at CO_2 Setup Screen and then wait 2 minutes for the sensor warm-up.
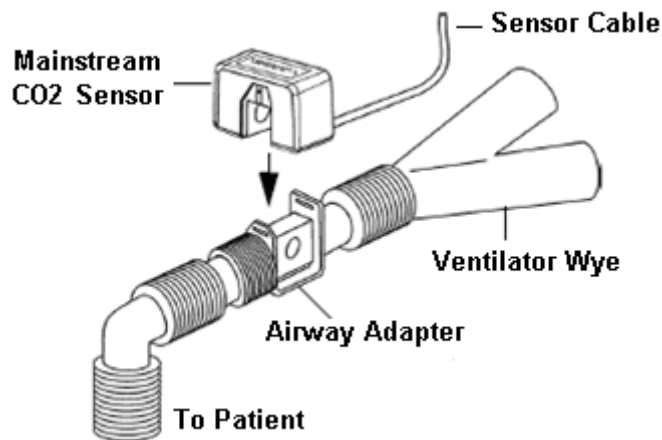
Note

☞ Always position the sensor with the adapter in an upright position to avoid a collection of fluids on the windows of the adapter. Large concentrations of fluids at this point obstruct gas analysis.

13.4 Measurement Limitations

The following factors may influence the accuracy of measurement:

- Leaks or internal venting of the sampled gas
- Mechanical shock
- Cyclic pressure up to 10 kPa (100 cmH$_2$O)
- Other sources of interference, if any.

13.5 Troubleshooting the Sidestream CO$_2$ Sampling System

When the sampling system of the sidestream CO_2 module works incorrectly, check if the sampling line is kinked. If not, remove it from the water trap. If the monitor gives a message indicating the airway still works incorrectly, it indicates that the water trap must is blocked, and you should replace it with a new one. Otherwise, you can determine that the sampling line is blocked. Replace with a new sampling line.

13.6 Understanding the CO_2 Display

CO_2 panel
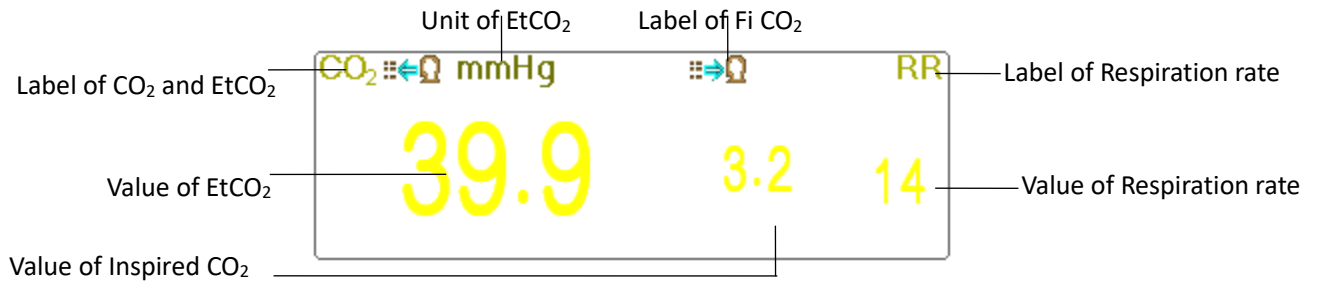
- $\blacksquare\Leftarrow\Omega$ mmHg: the label and unit of EtCO$_2$

- $\blacksquare\Rightarrow\Omega$: the label of FiCO$_2$

- mmHg: the unit of EtCO$_2$ and FiCO$_2$

- rpm: the unit of Respiration rate

- "39.9   3.3   14": the value of EtCO$_2$, FiCO$_2$ and respiration rate

13.7 Changing CO_2 Settings

When CO_2 Monitoring is selected, the respiration parameter is by the CO_2 module. The respiration waveform area shifts to the CO_2 waveform area, respiration parameter area shifts to the CO_2 parameter area.

Select "Menu" → "CO_2" to enter into CO_2 related setting.

In the RESP settings window, CO_2 Settings can be entered if your monitor is configured with CO_2 monitoring.
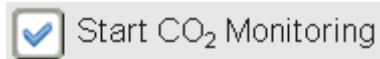
✔ Start CO₂ Monitoring : Click it to turn on or off CO_2 Monitoring. When the CO_2 monitoring is selected, then all items setting as "RESP" shift to "CO_2". **See Chapter Monitoring Carbon Dioxide (CO_2)**.
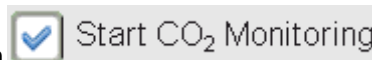
On RESP Settings screen, there is CO_2 Monitoring Switch ✔ Start CO₂ Monitoring : click it to turn on or off CO_2 Monitoring. Turn on the switch when there is a need to monitor the CO_2 parameter. Selecting this mode reduces the power consumption and also extends the life of the CO_2 measurement module.

In order to maintain the monitor, please set the CO_2 switch at OFF state in system setup when the CO_2 function is not used.

- **Gain:** the CO_2 waveform gain. 4 options: X1/2, X1, X2, and X4. The default is X1 for adult and pediatric patients, and X2 for neonate patient.

  X1/2: half-scale size of the base gain

  X1: waveform scale with base gain

  X2: twice scale size of the base gain

  X4: four times scale size of the base gain

- **Speed:** Respiration waveform sweep speed of, 2 options 6.25mm/s and 12.5 mm/s. The default is 12.5 mm/s.

- **Apnea:** The timeout setting for Apnea alarm (in second).

  (1) When CO_2 monitoring is on:

It can be set as any number from 10 to 60 seconds; the step is 1 second. Icon displays on the upper right corner of the Respiration Panel. When the device has not detected any breathing signal for the specified time, the "Apnea" alarm activates, and an alarm sounds off. If it is set to OFF, the icon displays on the lower left corner of the Respiration Panel. The default is 20s.

(2) When CO$_2$ monitoring is off: refer to Section **8.4 Changing RESP setting**.

- **Source:** Respiration signal source. This item is fixed to be "CO$_2$" if the CO$_2$ monitoring function is selected. Otherwise, the source is obtained from a thoracic impedance measurement from the ECG module.

- **Zero:** Press it to perform zero reset.

- **Default:** resume to the factory default value.

- **Unit:** It can be set up as "%", "kPa" and "mmHg". If the unit is changed, then the parameter value changes and refreshes immediately. The unit displays the parameter area. The default is "mmHg".

- **Period:** When setting the calculating cycle of the EtCO$_2$ value, there are three selectable options: "1b", "10s" and "20s". The default is "10s". "1b" means the EtCO$_2$ value is calculated once every respiration cycle. "10s" means the EtCO$_2$ value is calculated once every 10 seconds, and the maximum EtCO$_2$ value measured during these 10s is displayed on the data area. "20s" means the EtCO$_2$ value is calculated once every 20 seconds, and the maximum EtCO$_2$ value measured during this 20s is displayed on the data area.

- **Balance:** When setting the balance gas in a patient's respiration airflow, there are three kinds of selectable balance gas: "Air", "N$_2$O" and "He" (nitrous oxide, and helium). If no specific balance gas is given, the balance gas can be set as "Air".

- **O$_2$ Comp.:** If adjusting the concentration of the compensating gas in a patient's respiration airflow, the compensating gas is Oxygen. This can be called oxygen compensation concentration. The unit: %; Setting range: 1-100%. Default value: 16.

- **TEMP:** When setting the temperature value of the current measured airflow, the temperature is at 37℃, when measuring the patient's respiration by airflow. However, if the airflow to be measured is the reference gas, the temperature is set at 25℃. The setting range: 0.0 - 50.0; Unit: ℃; Default value: 35.0℃.

- **Agent:** This setting adds anesthetic gas to the patient's respiration airflow and the concentration of anesthetic gas. The setting range is 0.0%-20.0%; the default status is: not adding anesthetic gas, the concentration is 0.0%.

- **Flow (CO$_2$ flow):** This is the flow rate of CO$_2$ sampling. Its default value is 50 ml/min.

- **Barometric (Barometric pressure):** Set ambient atmospheric pressure. It can be determined by the barometer or the ambient altitude. Altitude can be used to determine the typical barometric pressure if a barometer is not available, refer to Appendix Typical Pressures and CO$_2$ Readings at Altitudes for details.

- **Zero:** Press it to perform Zero Reset, then the following figure pops up on the window. Please note that the sample unit of the CO$_2$ sensor must be placed in a well-ventilated area. Then press on the "Start Zero" button to perform zero-resetting, then the screen shows the current calibration status.

There are three calibration statuses: 1. Zeroing   2. Zero success   3. Zero fail

Caution:

⚠ The information prompts during Zero calibration, but there is no audible and visual alarm.

⚠ When performing a zero calibration during normal patient measurement operations,

disconnect the transducer from the patient's airway first.

⚠ DO not rely on the measurement readings taken during zeroing.

Chapter 14 **Monitoring CSM**

14.1 Introduction

The Cerebral State Monitoring (CSM) is intended for use in monitoring the hypnotic state of the brain by data acquisition of EEG signals of the anaesthetized or sedated patient in all areas of the hospital. CSM is a non-invasive measurement tool to be used by a trained professional to measure the level of consciousness during general anaesthesia and sedation by use of variations in the frequency content of the spontaneous EEG. It analyses the frequency shifts that take place in the EEG signal as the level of consciousness changes. Based on this principle, the device calculates the Cerebral State Index (CSI), which is used to estimate the level of consciousness of the patient.

14.2 Safety Information

Warning

⚠ If used with High Frequency (HF) surgery please pay attention to the positioning of CSM electrodes. In order to reduce the hazard of burns, the electrodes should not be located between the surgical site and the electro-surgical unit return sensor.

⚠ The conductive parts of sensors and their connectors, including the neutral sensor, should not contact other conductive parts including earth and ground.

⚠ The monitor will not render accurate reading when used on patients with severe neurological disorders and patients under 2 years old.

⚠ The use of pacemakers might cause either long periods of artefacts or elevated CSI values.

⚠ If skin rash or other unusual symptoms are developed, remove sensors from patient.

⚠ Ethanol is not recommended as a skin cleanser, for it leaves a film layer that may cause high sensor impedance.

⚠ If used with High Frequency surgery during CSM monitoring, then artefacts or elevated CSI value may be caused.

14.3 Understanding CSM Parameters

CSI

The performance of the CSM is based on the analysis of the frequency content of the EEG signal.

The energy of the EEG is evaluated in specific frequency bands. These are used to define two energy ratios called alpha (α) and beta (β). Both of these show a shift in energy content from a higher to the lower frequencies during anaesthesia. The relationship between these quantities is also analysed as a separate parameter (β-α).

$$\alpha_{ratio} = \ln\left(E_{30-42.5Hz} / E_{6-12Hz}\right)$$

$$\beta_{ratio} = \ln\left(E_{30-42.5Hz} / E_{11-21Hz}\right)$$

The monitor also on-line evaluates the amount of instantaneous burst suppression (BS) in each thirty-second period of the EEG. This measurement quantifies the amount of "silent" or "flat" EEG period characteristic of the deepest levels of hypnosis.

These four parameters are used as input to a fuzzy logic classifier system that calculated the Cerebral State Index.
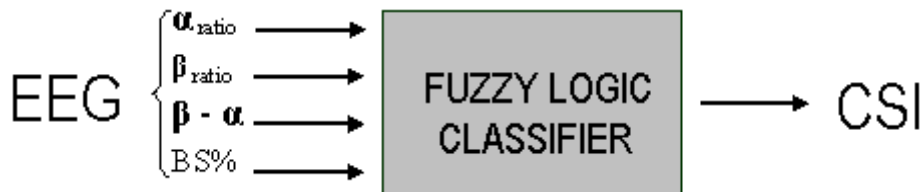
CSI Scale

The CSI is a unit-less scale from 0 to 100, where 0 indicates a flat EEG and 100 indicates EEG activity corresponding to the awake state. The range of adequate anaesthesia is designed to be between 40 and 60. All values in the table are approximate values based on the mean values of the patient behaviour.

CSI	State
100	Awake
	Sedated
80	
	Light anaesthesia
60	
	Surgical anaesthesia
40	
	Deep anaesthesia
0	Flat line EEG

EMG

Facial EMG may increase the CSI under certain conditions. The monitor incorporates an EMG filter that removes most of the potential interfering EMG activity. The EMG% bar shows the energy of the EMG level in the 75-85 Hz frequency band (0-100 logarithmic). The bar is located on the right side of the display.

EMG activity is expected to be present when the patient is awake. When the patient is asleep, EMG activity can increase due to:

- Reflex reactions to painful stimuli during surgery.

- Lack of muscular relaxation.

- Muscular rigidity caused by some opioids (analgesics).

- Presence of large external electrical fields, e.g., diathermy.

The EMG bar should be checked frequently, especially in case of a sudden increase in the CSI. If the increase in CSI is accompanied by an increase in muscular activity, there is a risk that EMG is causing interference. When this happens, attention must be paid to the stimuli receive by the patient during surgery. In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent will cause the CSI to decrease. Since patients receiving neuromuscular blocking agents cannot exhibit movement as a sign

of arousal, the CSI is a valuable tool in their anaesthetic management.

BS% Indicator

The monitor includes a Burst Suppression indicator to show periods when the EEG is iso-electric or "flat". The indication appears in the upper left-hand side of the graph window in the display and shows the percentage of burst suppression over the last 30 seconds of the EEG signal. A BS% = 20 readouts means that the EEG has been iso-electric during 20% of the last 30 seconds.

Signal Quality Indicator (SQI%)

SQI% measures the quality of the acquired EEG signal. The calculation is based on a number of artifacts during the last minute. The quality is displayed numerically as a percentage (0-100%, 100%equals best signal quality) in Display Mode A.

Sensor Impedance

The impedance of the white and black sensors is continuously measured and displayed in Display Mode C. Low sensor impedance values (typically between 1 and 3 kΩ) are essential for good monitor operation. A "<1 kΩ" readout means that sensor impedance is optimal.

Sensor Alarm

The Sensor Alarm signals the interruption of reliable CSI calculation due to corrupted or interrupted EEG. This is usually caused by the use of diathermia or a faulty sensor connection (high sensor impedance or disconnection of sensor leads). Should any o these situations occur, the RED Error light (2) will turn on. The CSI is not calculated during these periods.

14.4 CSM Processes

Step 1: Clean and prepare skin

It's recommended that the skin-electrode impedance should be less than 2k ohm in order to obtain good signal quality. Before placing the sensors, the user should clean the skin with mild soap, and prepare the skin to remove the non-conductive layer of the skin by filing off it with the sandpaper on the provided electrode.

Different skin conditions need different preparations:

- Case (1): for the female with make-up

  Smear the cleanser on the skin and wipe out the make-up at first, then wait for its evaporation. After that, rubbing the skin 2 or 3 times with the sandpaper on the provided electrode, and clean up the rest substance with cotton or gauze. Lastly, placing the electrodes.

- Case (2): for those with oily skin

  Smear the Ethanol on the skin and wipe out the oily substance at first, then wait for its evaporation. After that, rubbing the skin 2 or 3 times with the sandpaper on the provided electrode, and clean up the rest substance with cotton or gauze. Lastly, placing the electrodes.

- Case (3): for pediatric patient

  Smear the clear water on the skin at first, then clean the skin with cotton or gauze. Lastly placing the electrodes.

Step 2: Place the electrodes

The placement of three electrodes is shown below. The advanced signal processing technique ensures that the distance between electrodes can be as close as 2 cm (0.78 in) to get correct CSI value. However, it is recommended to place the electrodes on the skull area with few muscle fibrils in order to obtain better signal quality.

Middle of forehead
Left side of forehead
Mastoid left side
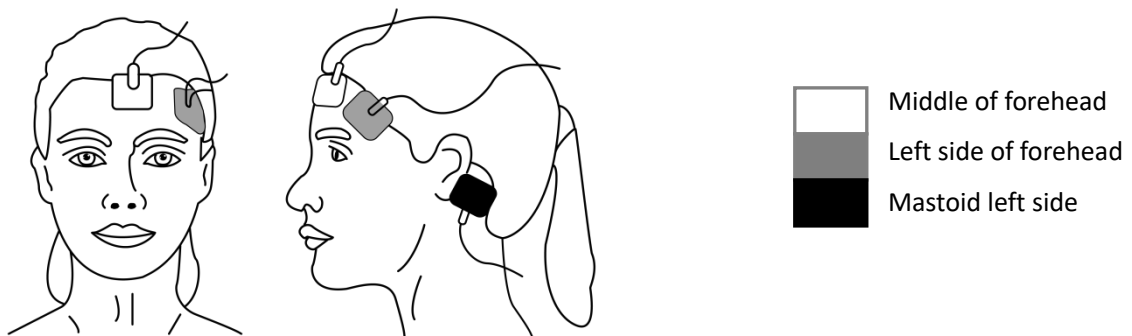
Note

☞ Once the electrodes have been secured on the skin, attach the color-coded wires on the patient cable to appropriate electrode.

☞ Shown above is a left sided setup; right sided is also acceptable.

☞ Place electrodes at the side farthest from the surgical area.

Step 3: Connect lead wires to CSM module connector

Make sure that the lead wires of CSM is well connected. Connecting one end to the electrode and another end to CSM connector.

14.5 Changing CSM Settings

Select "Menu" → "CSM" to enter into CSM related setting.

Mark Event

- **The latest event:** the latest event can be "General", "Intubation", "Surgery", "Note", "Movement", "Induction", "Maintenance", "Injection" and "End Maintenance".

- **Renumber:** renumber the current selected event type.

- **EEG Range:** set the EEG amplitude range, the range is 20, 40, 80 and 160, the default is 80.

- PARM: to enter into CSI alarm setting. See Section **6.4 "Understanding the Alarm Setting".**

Chapter 15 Review

Press the "Review" button on the status bar to enter into the History Records window, including waveform information, trend data, and event list, as shown in the following Figure.
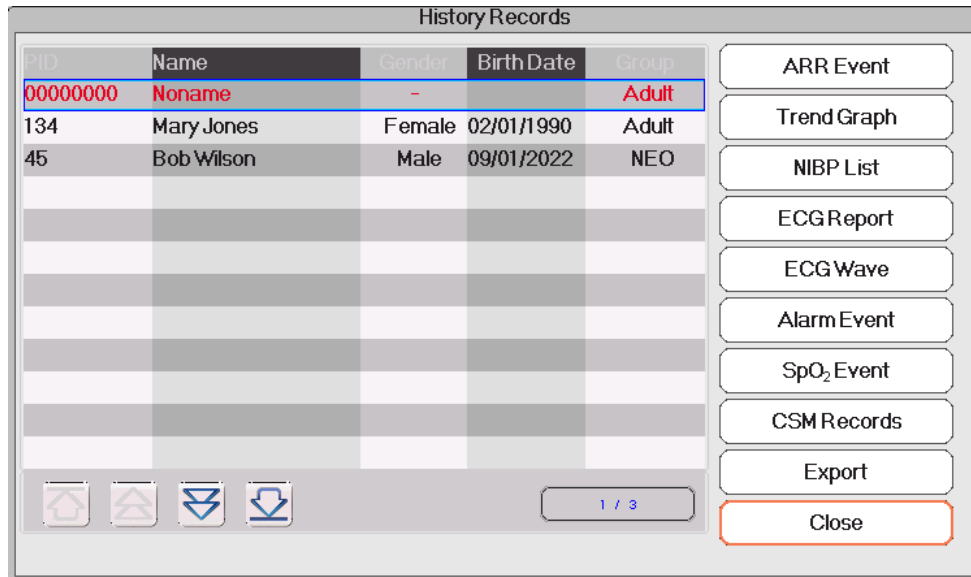
Refer to the actual window

In "Review" window, select the patient record you want to review, the following data record can be viewed: Arrhythmia (ARR) event, Trend graphs, NIBP List, ECG Waveforms, Alarm events, SpO$_2$ events and CSM Records.

Select one of the patient lists on the left window, and press the related button to preview the corresponding information.

- **Patient list:** Shows PID (Patient ID), name, birth date, group.
- **Data Review button:** Shows Trend Graph, NIBP List, ECG Wave, Alarm Event, and SpO$_2$ Event.

15.1 ARR Events

"Search" button: search the ARR Event records in the specified date.

In the numeric box of "Month", "Day" and "Year", select the specified date, and press "Search" button to review the event list in specified date.

The numeric box "Day" can be set as "All", it means all the month. The numeric box "Month" can also be set as "All", it means all the year.

Note

☞ All event list can be searched by date, we will not cover it later again.

15.2 Trend Graph

The "Trend Graph" window is as shown in the following Figure.
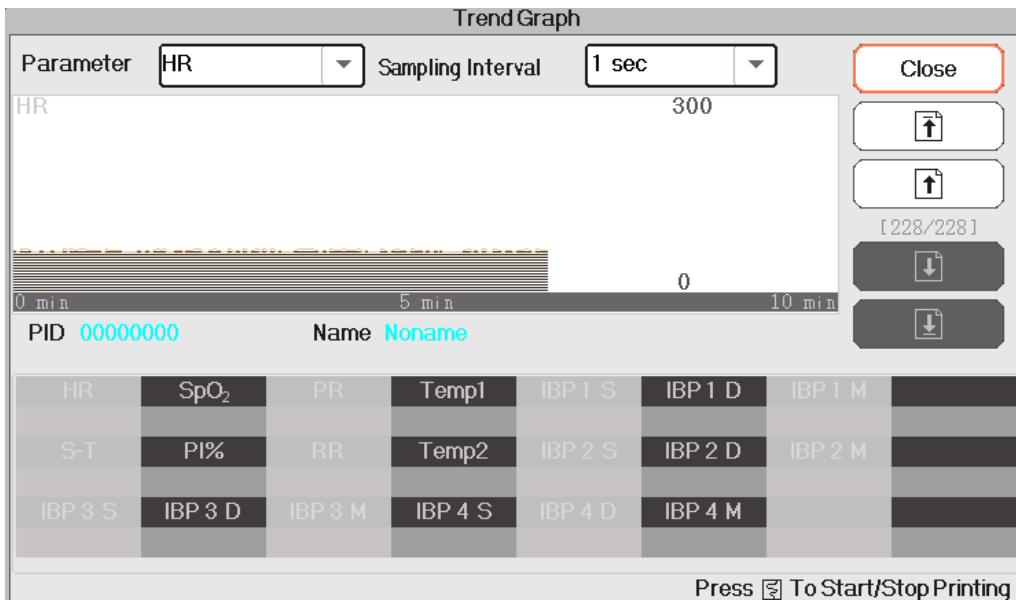
Trend Graph window

- **Parameter:** Select a parameter to review a graph, options are: HR, SpO_2, RR, TEMP, CO_2

- **Sampling interval**: Sample time interval of the trend graph, 7 options: 1 second, 5 seconds, 10 seconds, 30 seconds, 1 minute, 5 minutes, and 10 minutes.

- **Positioning**: The positioning mark is a data point that the cursor line (a blue vertical line) locates on the trend graph. Moreover, the table on the lower window shows the detailed information (date, time, HR, SpO_2) of the time point where the Positioning Mark located.

- **The operation for the Cursor line:** Move the cursor line to the left and right. The step is 1 pixel initially, but it increases to 8 pixels by rotating of Navigation Knob in one direction more than 30 steps. If the step is 8 pixels, rotating of Navigation Knob in the opposite direction steps to 1 pixel. Press down Navigation Knob to exit from the "Positioning" mode.

Note

☞ On the Short Trends view, the general waveform is on the left of the waveform area and the short trend view on the right.

15.3 NIBP List

An NIBP record not only consists of blood pressure data, i.e., SYS (systolic pressure), DIA (diastolic pressure), but it also includes data of PR, RR, SpO_2, Temp1, Temp2 a, stored at the measurement time.

- "Search" button: search the NIBP records on the specified date.

- "Trend graph" check-box: makes the trend graph of NIBP records visible or invisible, as shown in the following Figure.
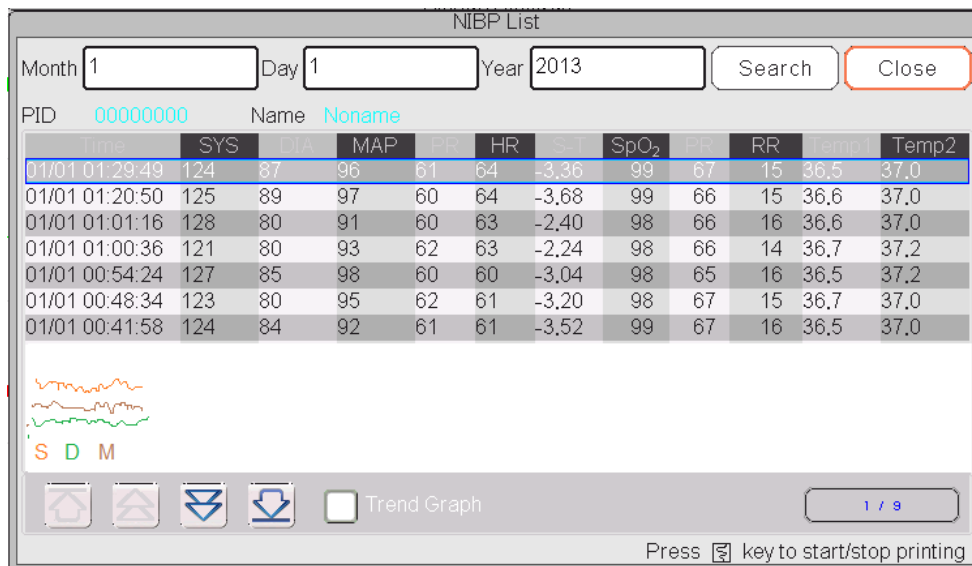
NIBP trend graph window

"S", "D", "M,": is the abbreviation for Systolic pressure and Diastolic pressure. The letter color is the same as its waveform color.

xx/yy: the current record number/ total records.

15.4 ECG Waveforms

The device can store the latest ECG Waveforms Records for more than 72 hours. All ECG Waveforms Records are listed on the left part of the window. The selected ECG waveform Record (in the blue frame) display on the right.

Selecting from the drop-down box " [ECG I ▼] " can change the ECG lead. The ECG leads options are ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF, and ECGV.

There may be several pages for an ECG waveform record (10 seconds for one page). Use page-turn buttons [↑] [↓] [↓] [↑] to review pages

"xx/xx" means "Page No. / total pages".

15.5 Alarm Event

Each Alarm Event record consists of Time (the time when an alarm occurs), Level (alarm level), Param (the parameter activates alarm), Value (the value of the parameter when an alarm occurs), the preset high and low alarm limit setting value.

There are 2 alarm categories: Parameter Alarm and Technical Alarm (refer to **Chapter 6 alarm** for details).

There are 3 alarm Levels: High priority, Medium priority, and Low priority corresponding to high risk, medium risk, and low risk, respectively.

15.6 SpO$_2$ Event

If the patient's SpO$_2$ value decreased by a specific value in a short time, it is defined as an SpO$_2$ Event.

A SpO$_2$ Event record includes the Time (the time when the event occurs), Minute-average, SpO$_2$ value (the current SpO$_2$ value), HR, PR, and RR.

15.7 CSM Records

CSM records can be reviewed by "Trends" and "Events".

The default "CSM Records" reviewing window is by "Trends". All CSM records (including CSI, SQI, EMG% and BS%) and EEG of the current patient can be reviewed.
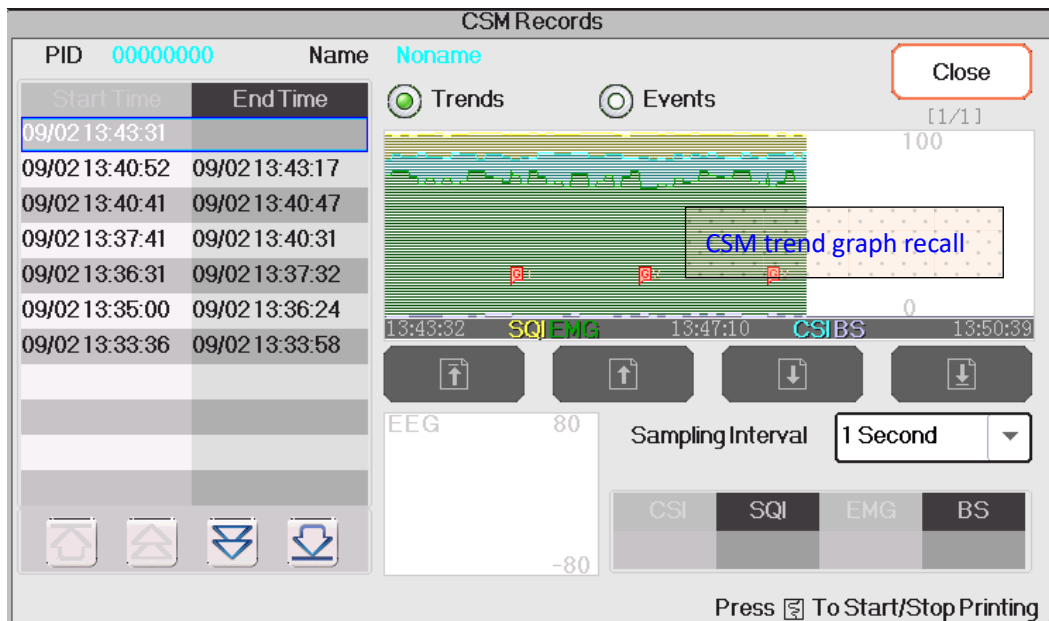
CSM record---by Trends

In the window as shown in above Figure, the positioning measurement of the CSM trend graph can be entered. The measured value that the cursor line indicates will be displayed on the lower right side, for

example, "", and the EEG waveform will be displayed on the
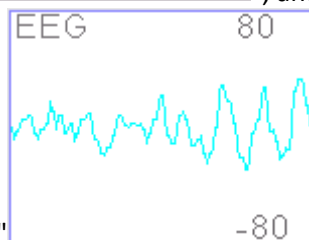
lower middle side, for example, "". That's the positioning measurement for CSI, SQI, EMG%, BS% and EEG.

- " ": The event mark. The number is the event No., the letter is the event type. The event type description is as below:
  - ➢ G: General
  - ➢ U: Intubation
  - ➢ S: Surgery
  - ➢ N: Note
  - ➢ M: Movement
  - ➢ I: Induction
  - ➢ C: Maintenance
  - ➢ J: Injection
  - ➢ E: End Maintenance
- **Sampling Interval:** sample time interval of the trend graph, 6 options: 1 second, 5 seconds, 10 seconds, 30 seconds, 1 minute and 5 minutes.

The current event records can be reviewed by "Events"
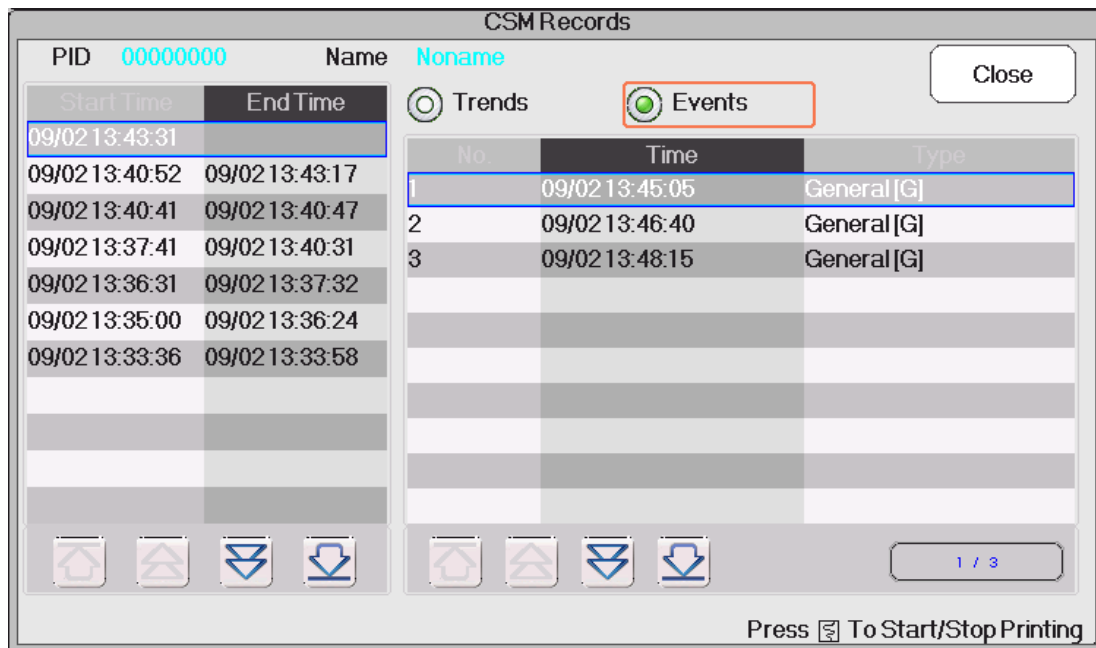
CSM record---by Events

If reviewed the CSM records by Events, then the event No., event time and event type will be listed on the "CSM Records" window.

15.8 Exporting Data

15.8.1 Exporting Data from Monitor to a USB Driver

Connect the USB disk to the USB data interface on the rear panel of the patient monitor marked "⟶".

Select "Review"→"Export" to bring up the data exporting window, the plugged USB disk will be identified automatically and displayed on the first line in the pop-up window.

☞ If no USB disk is detected, then "Refresh", "Export", and "Unmount" buttons are displayed in grey and unavailable.

● ⬚⯆ : Select the USB disk from the drop-down list.

● **Refresh:** Refresh the USB disk(s) enumeration.

● **Export:** Export the data and information for the selected patient

● **Unmount:** Unmount (remove) the selected USB disk from the system.

● **Exit:** Exit from the current window.

Press the drop-down list "⬚⯆" to display all plugged USB disks, select one USB disk you want to export the data, then press "Export" to start exporting. If data is exported successfully, then the window shows "Exported Successfully", and press "Close" to return to disks information displaying window.

Description

1.8GB / 1.9GB : indicates the unused memory / total memory. If the USB disk memory is not enough, then the data will fail to be exported.

KRK/20130101_00000000 : "KRK" indicates the data is exported to a file folder named "KRK" in the USB disk; "20130101" is the time of this exporting; and "00000000" is the patient ID. The data for selected patient will be stored with the file name of "20130101_00000000" under the file folder "KRK" in the USB disk.

Caution

⚠ Do not unplug the USB disk from the monitor during exporting, or the exported data will be in disorder, and the history record files will be corrupted.

⚠ Do not unplug the USB disk from the monitor before it is unmounted, or the data in the disk will be corrupted or lost.

Note

☞ If you need to review and manage the exported data, you can contact your local sales for address to download the corresponding PC software (Patient Monitor Data Manager) for data management.

Chapter 16 Calculations

16.1 Introduction

The calculation feature is available with your monitor. The calculated values, which are not directly measured, are computed based on the values you provide.

You can perform the following calculations:

- Medicine Dose calculations
- Oxygenation calculations
- Ventilation calculations
- Hemodynamic calculations
- Renal calculations

16.2 Safety Information

Warning

⚠️ After the calculation is finished, verify the entered values are correct and the calculated values are appropriate. We assume no responsibility for any consequences caused by wrong entries and improper operations.

⚠️ The calculation feature is independent of other monitoring functions and can be therefore used for patients being monitored by other monitors. Any operation in a calculation window does not affect the monitoring by the local monitor.

16.3 Medication Calculation (Medicine Dosage Calculation)

In "Menu" window, the Medication Calculation window can be entered.

Medication Calculation -- Adult

Medicine	AMINOPHYLLINE ▼			
Weight	70.00 kg	D/kg/m	14.29	mcg
Gross	500.00 mg	D/kg/h	857.14	mcg
Cubage	500.00 ml	TS	60.00	ml/hr
MC	1.00 mg/ml	DS	20.00	GTT/min
D/m	1.00 mg	Drop	20.00	GTT/ml
D/h	60.00 mg	Duration	8.33	hr

Please check all inputed items
and assure them correct!

Titration>>   Close

Medicine Dosage Calculation window

This monitor provides the dosage calculation for 10 kinds of medicine, including: AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, ADRENALINE, HEPARIN, ISUPREL, LIDOCAINE, NIPREL, NITROGLYCERIN and PITOCIN.

Medicine Dosage Calculation applies the following Formulas:

MC = Gross ÷ Cubage

(D/m) = (D/h) ÷ 60

(D/Kg/m) = (D/m) ÷ Weight

(D/Kg/h0 = (D/h) ÷ Weight

DS = TS ÷ (Cubage/drop)

Duration = Gross ÷ (D/h)

Items definitions:

MC: medicine consistency;

(D/m): dosage per minute;

(D/h): dosage per hour;

(D/Kg/m): dosage per kilogram per minute;

DS: drop speed;

TS: titration speed

(D/Kg/h): dosage per kilogram per hour;

Gross: medicine gross;

Description

All items in formulas above are consistent with those in the Medicine Calculation Window.

In the Medicine Calculation Window, only "Medicine" and "Weight" are input items, all others are output items.

- **Medicine:** to select a medicine type.

- **Weight:** to set the weight of a patient for calculation, the patient here is not the current patient being monitored right now. The weight can be set from 0.5kg to 300kg. Its interval is 0.5kg. The defaults are 70kg for Adult, 20kg for Pediatric, 3.0Kkg for Neonate.

- **Other output items:** except "Medicine" and "Weight" items, all other items are outputs. Generally, they are not needed to be adjusted after calculation. However, they can be fine-tuned practically. All other items results will be updated accordingly when an item fine-tuned.

- **Operation steps**:

  1   Select a "Medicine", e.g., AMINOPHYLLINE;

  2   Set a "Weight", e.g., 70.00 kg;

  3   Any change in "Medicine" or "Weight" will cause the system to calculate all output items and display them on screen automatically.

Because each output item has its own valid range, it will be displayed as "…" when the calculating result exceeds its range.

- **Medicine:** select one of the medicines: AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHERINE, HEPARIN, ISUPREL, LIDOCAINE, NIPREL, NITROGLYCERIN and PITOCIN. The default is AMINOPHYLLINE.

- **Weight:** when entering into medicine calculating window, the operator should enter patient's weight; the weight is used for MC calculation only; weight: 0.5Kg to 300Kg selectable; step: 0.5Kg; default: 70 Kg for adult; 20Kg for pediatric; 3.0 Kg for neonate.

Caution

ⓘ The medicine applies the fixed unit, or a fixed family of units. The operator must select the appropriate unit according to doctor's advices. In a unit family, the carry between 2 adjacent units performs automatically along with the current inputs. When the space on screen for an item is not enough to display all digits of the item in a certain unit, it will be displayed as "…".

ⓘ In neonate mode, "DS" and "Drop" items are ignored.

Note

☞ The patient here has nothing to do with the current patient monitoring right now, and only for Medicine Calculation.

Titration

When the concentration calculation of a medicine is OK in the first tab, the Titration Table in the second tab ("Titration") can be browsed. The Titration is a "Dose - Drop Speed" or a "Dose - Titration Speed" cross-reference list.

Titration -- AMINOPHYLLINE					
Gross	500.00 mg		Cubage	500.00 ml	
D/h	60.00 mg		TS	60.00 ml/hr	
Weight	70.00 kg		DS	20.00 GTT/min	

Dose	TS	Dose	TS	Dose	TS
0.00	0.00	8.00	480.00	16.00	960.00
1.00	60.00	9.00	540.00	17.00	---
2.00	120.00	10.00	600.00	18.00	---
3.00	180.00	11.00	660.00	19.00	---
4.00	240.00	12.00	720.00	20.00	---
5.00	300.00	13.00	780.00	21.00	---
6.00	360.00	14.00	840.00	22.00	---
7.00	420.00	15.00	900.00	23.00	---

Reference: Dose
Step length: 1
Dose Type: /min

<<Medication   Close

Titration window

There are 3 editable boxes on the lower left of the window for retrieve of **Titration Table in details.**

- **Reference:** to make item as the independent variable, other items will be dependent variables. There are 3 options: "Dose", "DS-Drop Speed" and "TS-Titration Speed";

- **Step length:** the gap between two adjacent values, its range is 1-10, step is 1;

- **Dose Type:** choose the type of dose 4 options: /h, /m, /Kg/h, /Kg/m. The changing of unit will cause the re-calculation of Drop Speed and Titration Speed according to formulas mentioned in the above section

- "**[1/1]**": the number on the lower part is the current page/total pages.

16.4 Oxygenation Calculation

From "Menu" window, the "Oxygenation Calculation" window can be brought up.

Oxygenation calculation window

The input items include C.O.(Cardiac output), FiO$_2$ (Fraction of inspired oxygen), PaO$_2$ (oxygen partial pressure), PaCO$_2$ (carbon dioxide partial pressure), Hb (Hemoglobin), CaO$_2$(oxygen content of arterial blood), CvO$_2$ (oxygen content of mixed blood), VO$_2$ (oxygen consumption), RQ (Respiratory quotient), ATMP (Atmospheric pressure), Height and Weight.

Refer to the following table for the detailed definition, unit and adjustable range of the input items.

Input item	Unit	Definition	Adjustable range
C.O	L/min	Cardiac output	0.1-20.0
FiO$_2$	%	Fraction of inspired oxygen	18%-100%
PaO$_2$	mmHg	Oxygen partial pressure	10-800
PaCO$_2$	mmHg	Arterial carbon dioxide tension	0-200
Hb	g/L	Hemoglobin	50-200
CaO$_2$	ml/L	Oxygen content of arterial blood	10-400
CvO$_2$	ml/L	Oxygen content of mixed blood	10-400
VO$_2$	ml/min	Oxygen consumption	50-1000
RQ	__	Respiratory quotient	0.1-1.5
ATMP	mmHg	Atmospheric pressure	300-1200
H	cm	Height	20-300
W	kg	Weight	1.0-250.0

Oxygenation calculation function can perform calculation for 14 parameters (i.e. Output items): BSA (body surface area), VO$_2$ calc (oxygen consumption), C(a- v)O$_2$ (oxygen content difference between artery and vein), O$_2$ER (oxygen extraction rate), DO$_2$ (oxygen delivery), PAO$_2$ (oxygen pressure in alveolar), AaDO$_2$ (oxygen pressure difference between alveolar and artery), CcO$_2$ (pulmonary capillary oxygen content),

Qs/Qt (intra-pulmonary shunt rate), C.O.calc (calculated cardiac output), PaO_2 / FiO_2 (oxygenation index), AaO_2 / PaO_2 (Ratio of alveolar-arterial oxygen partial pressure difference to oxygen partial pressure), DO_2l (oxygen delivery index) and VO_2l (oxygen consumption index).

Refer to the following table for the detailed definition, unit and adjustable range of the output items.

Parameters	Definition	Calculation formula	Unit	Range
BSA	Body surface area	$W^{0.425} * H^{0.725} * 0.007184$	m^2	—
VO_2 calc	Oxygen consumption	$C(a-v)O_2 * 13.4 * Hb * C.O.$	ml/min	—
$C(a-v)O_2$	Oxygen content difference between artery and vein	$CaO_2 - CvO_2$	ml/L	42-59
O_2ER	Oxygen extraction rate	$VO_2(CaO2-CvO2)*100$	%	24-28
DO_2	Oxygen delivery	$CaO_2 * C.O.$	ml/min	950-1150
PAO_2	Oxygen pressure in alveolar	$(FiO_2)*(ATMP - 47) - (PaCO_2 / RQ)$	mmHg	—
$AaDO_2$	Oxygen pressure difference between alveolar and artery	$(FiO_2)*(ATMP - 47) - (PaCO_2 / RQ) - PaO_2$	mmHg	10-15
CcO_2	Pulmonary capillary oxygen content	$(Hb*1.34)+(((FiO_2)*(ATMP - 47) - (PaCO_2 / RQ))* 0.0031)$	ml/L	—
Qs/Qt	Intra-pulmonary shunt rate	$\{[(Hb*1.34)+(((FiO_2)*(ATMP-47)-(PaCO_2/RQ))* 0.0031)] - CaO_2) / \{ [(Hb*1.34)+(((FiO_2)*(ATMP-47)-(PaCO_2/RQ))* 0.0031)] - CvO_2 \}*100$	%	3.0-5.0
C.O.calc	Calculated cardiac output	$VO_2 / (CaO_2-CvO_2)$	L/min	0.1-20.0
PaO_2 / FiO_2	Oxygenation index	$PaO_2 / (FiO_2)$	mmHg	—
AaO_2 / PaO_2	Ratio of alveolar-arterial oxygen partial pressure difference to oxygen partial pressure	$[(FiO_2)*(ATMP - 47) - (PaCO_2 / RQ) - PaO_2] / PaO_2$	—	—
DO_2l	Oxygen delivery index	$(CaO_2 * C.O.)/BSA$	$ml/min/m^2$	—
VO_2l	Oxygen consumption index	$(CaO_2 - CvO_2)*C.O. /BSA$	$ml/min/m^2$	—

Operations

Entering the value for each input item, and click "Calculate", and the monitor will calculate the parameter according to the calculate formula, the result will be displayed on the screen. then click "Range" to view the range for each parameter.

Note

☞ The result for each parameter will be shown as "---" before click "Calculate" button.

☞ The calculation result will be shown in yellow if the result is beyond the reference range.

Oxygenation calculation---Calculate result

Oxygenation calculation---Reference range

16.5 Ventilation Calculation

From "Menu" window, the "Ventilation Calculation" window can be brought up.

Ventilation calculation window

The input items include FiO_2 (fraction of inspired oxygen), RR (respiratory rate), $PeCO_2$ (end-tidal CO_2 pressure), $PaCO_2$ (carbon dioxide partial pressure), PaO_2 (oxygen arterial pressure), TV (tidal volume), RQ (respiratory quotient), ATMP (atmospheric pressure).

Refer to the following table for the detailed definition, unit and adjustable range of the input items.

Input item	Unit	Definition	Adjustable range
FiO_2	%	Fraction of inspired oxygen	18% -100%
RR	rpm	Respiratory rate	4-120
$PeCO_2$	mmHg	End-tidal CO_2 pressure	0-114
$PaCO_2$	mmHg	Carbon dioxide partial pressure	1-200
PaO_2	mmHg	Oxygen partial pressure	10-800
TV	ml	Tidal volume	15-2000
RQ	/	Respiratory quotient	0.1-1.5
ATMP	mmHg	Atmospheric pressure	300-1200

Ventilation calculation function can perform calculation for 9 parameters (i.e. Output items): PAO_2 (oxygen pressure in alveolar), $AaDO_2$ (oxygen pressure difference between alveolar and artery), PaO_2 / FiO_2 (ratio of expired oxygen pressure to inspired oxygen pressure), Pa/AO_2 (ratio of oxygen pressure in artery to alveolar), $AaDO_2 / PaO_2$ (respiratory index), MV (minute ventilation), Vd (dead space ventilation), Vd/Vt (physiological dead cavity) and VA (alveolar ventilation).

Refer to the following table for the detailed definition, unit and adjustable range of the output items.

Parameters	Definition	Calculation formula	Unit	Range
PAO_2	Oxygen pressure in alveolar	$FiO_2*(ATMP - 47) - (PaCO_2 / RQ)$	mmHg	—

Parameters	Definition	Calculation formula	Unit	Range
$AaDO_2$	Oxygen pressure difference between alveolar and artery	$FiO_2 * (ATMP - 47) - (PaCO_2 / RQ) - PaO_2$	mmHg	—
PaO_2 / FiO_2	Ratio of expired oxygen pressure to inspired oxygen pressure	PaO_2 / FiO_2	mmHg	—
Pa / AO_2	Ratio of oxygen pressure in artery to alveolar	$PaO_2 / (FiO_2 * (ATMP - 47) - (PaCO_2 / RQ))$	%	—
$AaDO_2 / PaO_2$	Respiratory index	$(FiO_2 * (ATMP - 47) - (PaCO_2 / RQ) - PaO_2) / PaO_2$	—	—
MV	Minute ventilation	$TV * RR / 1000$	L/min	—
Vd	Dead space ventilation	$((PaCO_2 - PeCO_2) / PaCO_2) * TV$	ml	145-155
Vd/Vt	Ratio of dead-space ventilation to tidal ventilation (Physiological dead cavity)	$((PaCO_2 - PeCO_2) / PaCO_2) * 100\%$	%	25-40
VA	Alveotar ventilation	$(TV - ((PaCO_2 - PeCO_2) / PaCO_2) * TV) * RR / 1000$	L/min	—

Operations

Entering the value for each input item, and click "Calculate", and the monitor will calculate the parameter according to the calculate formula, the result will be displayed on the screen. then click "Range" to view the range for each parameter.

Note

☞ The result for each parameter will be shown as "---" before click "Calculate" button.

☞ The calculate result will be shown in yellow if the result is beyond the reference range.

Ventilation calculation---Calculate result

Ventilation calculation---Reference range

16.6 Renal Function Calculation

From "Menu" window, the "Renal Function Calculation" window can be brought up.

Renal function calculation window

The input items include URK (urine kalium), URNa (urine natrium), Urine (24 hours urine), Posm (plasma osmotic pressure), Uosm (urine osmotic pressure), SerNa (serum natrium), SCr (serum creatinine), UCr (urine creatinine), BUN(blood urea nitrogen), Height and Weight.

Refer to the following table for the detailed definition, unit and adjustable range of the input items.

Input item	Definition	Adjustable range	Unit
URK	Urine Kalium	1-9999	mmol/L
URNa	Urine Natrium	0-9999	mmol/L
Urine	24 hours Urine	0-5000	ml/24h
Posm	Plasma osmotic pressure	100-500	mOsm/kgH$_2$O
Uosm	Urine osmotic pressure	200-2000	mOsm/kgH$_2$O
SerNa	Serum Natrium	50-300	mmol/L
SCr	Serum Creatinine	45-90	umol/L
UCr	Urine creatinine	100-50000	umol/L
BUN	Blood urea nitrogen	0-10	mmol/L
Weight	Patient's weight	20-300	cm
Height	Patient's height	1-250	kg

Rental function can perform calculation for 11 parameters (i.e. Output items): URNaEx (urine natrium excretion), URKEx (urine nalium excretion), Na/K (excretion ratio of urine sodium and kalium), CNa (natrium clearance), Clcr (creatinine clearance), FENa (fractional excretion of sodium), Cosm (osmolar clearance), CH2O (free water clearance), U/Posm (ratio of Urine to Plasma osmotic pressure), BUN/Scr (ratio of blood urea nitrogen to serum creatinine), and U/SCr (ratio of urine creatinine to serum creatinine) .

Refer to the following table for the detailed definition, unit and adjustable range of the output items.

Parameter	Definition	Formula	Unit	Range

Parameter	Definition	Formula	Unit	Range
URNaEx	Urine Natrium excretion	URNa *Urine/1000ml	mmol/24h	51-102
URKEx	Urine Kalium excretion	URK * Urine /1000ml	mmol/24h	130-260
Na/K	Excretion ratio of Urine Sodium and Kalium	URNa / URK * 100%	%	—
CNa	sodium clearance	(URNa * Urine)/SerNa	ml/24h	—
Clcr	Creatinine clearance	(Urine * UCr)/(SCr * 1440)	ml/min	80-120
FENa	Fractional excretion of sodium	(URNa * Scr) / (SerNa * UCr) * 100%	%	—
Cosm	Osmolar clearance	(Uosm * Urine/24/60)/Posm	ml/min	2-3
CH2O	Free water clearance	Urine*(1-uosm/posm)/24	ml/h	-120- - 25
U/Posm	Ratio of Urine to Plasma osmotic pressure	Uosm / Posm	—	3.0-4.5
BUN/Scr	Ratio of blood urea nitrogen to Serum Creatinine	BUN / Scr	—	—
U/SCr	Ratio of Urine creatinine to Serum Creatinine	Ucr / Scr	—	—

Operations

Entering the value for each input item, and click "Calculate", and the monitor will calculate the parameter according to the calculate formula, the result will be displayed on the screen. then click "Range" to view the range for each parameter.

Note

☞ The result for each parameter will be shown as "---" before click "Calculate" button.

☞ The calculate result will be shown in yellow if the result is beyond the reference range.

Renal function calculation---Calculate result

Renal function calculation---Reference range

16.7 HEMO.(Hemodynamic Calculation)

Select "Menu"→ "Hemo." to enter into hemodynamic calculation window, as shown in below figure. Hemodynamic calculation to derive CI, SV, SVR etc. based on the weight, height, HR etc..

Hemodynamics Setting

Hemodynamics Setting

Parameters to be set for hemodynamics calculation:

- **C.O.:** cardiac output.

- **Height:** patient's height.

- **Weight**: patient's weight.

- **HR:** heart rate.

- **LVD:** left ventricle diameter.

- **MAP:** mean artery pressure.

- **MVP:** mean vein pressure.

- **PAW:** pulmonary artery wedge pressure

- **CVP:** central vein pressure.

Description of hemodynamics calculation result and their formulas:

Result	Description	Formula	Unit
CI	Cardiac function Index	C.O. / BSA	liters/min/m^2
SV	Stroke Volume	1000*C.O. / HR	ml
SVI	Stroke Volume Index	SV / BSA	ml/m^2
SVR	Systemic Vascular Resistance	79.96 *(MAP - CVP)/C.O.	DS/cm^{-5}
SVRI	Systemic Vascular Resistance Index	SVR*BSA	DS•m^2/cm^5
PVR	Pulmonary Vascular Resistance	79.96 *(paMAP - PAWP)/C.O.	DS/cm^{-5}
PVRI	Pulmonary Vascular Resistance Index	PVR*BSA	DS•m^2/cm^5

Result	Description	Formula	Unit
LCW	Left Cardiac Work	0.0136*MAP*C.O.	kg-m
LCWI	Left Cardiac Work Index	LCW/BSA	kg-m/m^2
LVSW	Left Ventricle Stroke Work	0.0136*MAP*SV	g·m
LVSWI	Left Ventricle Stroke Work Index	LVSW/BSA	g·m/m^2
RCW	Right Cardiac Work	0.0136 * paMAP * C.O.	kg-m
RCWI	Right Cardiac Work Index	RCW/BSA	kg-m/m^2
RVSW	Right Ventricle Stroke Work	0.0136*paMAP*SV	g·m
RVSWI	Right Ventricle Stroke Work Index	RVSW/BSA	g·m/m^2
EF	Ejection Fraction	(SV/t)*100	%

Note：BSA (Body Surface Area) = 0.006*height+0.0128*weight-0.1529

t = (7.0 / (2.4 + lv_d/10)) * lv_d * lv_d * lv_d / 1000   (lv_d：left ventricle diameter)

Chapter 17 Tourniquet

Select "Menu" → "Tourniquet" to enter into Tourniquet window.

Tourniquet Settings	Count-down
Tourniquet Pressure 140 mmHg Duration 40 Deflation Count-down 5 Cuff Pressure --- Start Close	Tourniquet Pressure 140 mmHg Duration 40 Deflation Count-down 5 Cuff Pressure 116 Stop Close Swtich of Tourniquet

- **Pressure:** the upper limit of the cuff pressure during inflation. The monitor will stop inflating if the cuff pressure exceeds this value. The step is 10mmHg (1.3kPa) ranges and defaults for different patient age group are listed in the table below:

Group	Pressure range	Default
Adult	20mmHg(2.7 kPa)-120mmHg(16 kPa)	80mmHg(10.7 kPa)
Pediatric	20mmHg(2.7 kPa)-80mmHg(10.7 kPa)	60mmHg(8 kPa)
Neonate	20mmHg(2.7 kPa)-50mmHg(6.7 kPa)	40mmHg(5.3 kPa)

- **Duration:** the lasted time that cuff pressure maintained with the specified value.

- **Deflation Count-down:** the initial value of the count-down timer of cuff deflation. The cuff will deflate immediately when the count-down comes to zero.

- **"Start/Stop" button:** Start / stop tourniquet function. The cuff pressure value will be displayed during inflating. Note: once enter into the window, then pressing "NIBP Measure key" cannot perform NIBP measurement.

Note

☞ The lasted time that cuff pressure maintained with the specified value for adult and pediatric is fixed to be 170s and nonadjustable, and for neonate is fixed to be 85s and nonadjustable. The count-down timer of cuff deflation will not be displayed on the screen, and it begins to counting down once the cuff starts inflating.

☞ The unit of cuff pressure is same as the unit of NIBP.

Chapter 18 Printing

18.1 Using a Printer

The thermal Printer can be used to print patient information, measurement numerics, up to three waveforms.

Note

☞ The built-in printer may be used due to the configuration.

Printer operation instruction

- **Power indicator**: The green light shows the power is on. While the monitor is out of power, the green light is off.

- **Error indicator**: red light is constant, which shows the printer is out of paper, or the printing paper is not installed correctly. When the printing paper is loaded correctly, the red light is off.

18.2 Loading Printing Paper

This description is for loading paper for the built-in printer.

Operating procedures:

1. Press both "OPEN" notches with force on printer shield with two thumbs to open it.

2. Move the tab of rubber roller lock at the left 90°upwards to unlock it.

3. Cut one end of the paper into triangle, and load the paper from the underside of the rubber roller.

4. Turn the roller clockwise to get the paper rolled, and put the paper roll into the compartment.

5. Pull the paper out of paper slot on the shield.

6. Move the tab of the rubber roller lock 90° downwards to lock it.

7. Put the shield back in position and secure it.

Roller lock
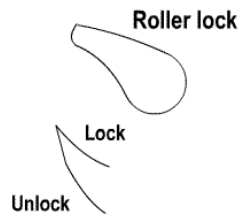
Lock

Unlock

Unloading printing paper

1   Press both "OPEN" notches vertically with force on printer shield with two fingers to open it.

2   Move the tab of roller lock at the left 90° upwards to unlock it.

3   Roll the loading roller anti-clockwise and pull the paper out.

4   Roll the loading roller clockwise to get the paper rolled, and put it into the compartment.

5   Pull the paper out of paper slot on the shield.

Loading roller

Unloading

Loading
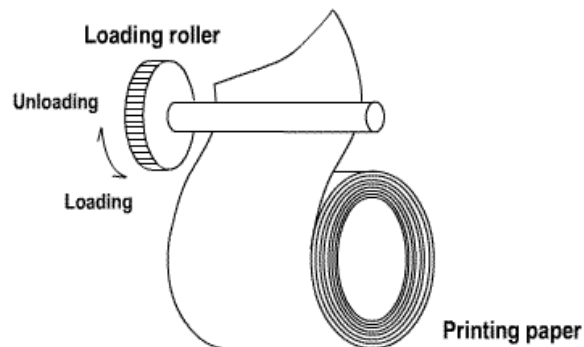
Printing paper

Loading printing paper

1   press and hold down the cartridge button to open the paper cartridge;

2   Install the paper to the printer properly, pull the paper out of the printer for 2 cm.

3   Close the printer cover along the direction of arrow.

Printing paper

18.3 Attentions

<u>**Caution**</u>

- ⓘ Use only specified thermal paper. Otherwise, it may cause damage to the recorder's print head, the recorder may be unable to print, or poor print quality may result.

- ⓘ Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.

- ⓘ Do not leave the recorder door open unless you reload paper or remove troubles.

- ⓘ Do not use anything that may destroy the thermal element.

- ⓘ Do not add unnecessary force to the thermal head.

18.4 Performing Printing

The device printing function consists of manual printing. The medical staff can press the Print key " 🗲 " to perform printing, and the device can make cycle printing.

Start or stop printing by pressing Print Key " 🗲 " located in the front panel.

The content for printing consists of real-time data printing and review record printing. In different views and windows, pressing the Print key can print that shows in the following Tables.

18.4.1 Print Real-Time Data

Current view/window	Contents	
	Header information	Waveform/Text information
General view	Data identifier: "==Real time==";	Print the real-time waveform of 10 seconds:
	Patient info.: PID, name, gender, patient group, weight, height and birth date;	The 1st trace: ECG waveform
Big font view	Time: the current date and time when printing;	The 2nd trace: ECG/SpO$_2$/RESP waveform
	Real-time parameter: speed, HR, SpO$_2$, PR, RR, TEMP1/2, and pressure value.	The 3rd trace: nothing/RESP/SpO$_2$ waveform
All ECG Trace view		Note: on the top of the printed waveform area, the 10s waveform's time shows within 2 intervals.
Short trends view		
NIBP list view	Data identifier: "==NIBP List==";	Print the 11 groups of NIBP list
	Item in the list: time, PID, name, SYS, DIA, PR, HR and SpO$_2$	
OxyCRG view	Data identifier: "==OxyCRG==";	Print the trend graph of OxyCRG
	Patient info.: PID, name, gender, patient group, weight, height and birth date;	
	Time: the current date and time when printing;	
	The start time and end time of the OxyCRG graph.	
Menu, settings window and functional window	Data identifier: "==Real time==";	Print the real-time waveform of 10 seconds:
	Patient info.: PID, name, gender, patient group, weight, height and birth date;	The 1st trace: ECG waveform
	Time: the current date and time when printing;	The 2nd trace: ECG/SpO$_2$/RESP waveform
	Real-time parameter: speed, HR, SpO$_2$, PR, RR, TEMP1/2, and pressure value.	The 3rd trace: nothing/RESP/SpO$_2$ waveform
		Note: on the top of the printed waveform area, the 10swaveform's time shows within 2 intervals.
View's activating Window and settings window	Data identifier: "==Real time==";	Print the real-time waveform of 10 seconds:
	Patient info.: PID, name, gender, patient group, weight, height and birth date;	The 1st trace: ECG waveform
	Time: the current date and time when printing;	The 2nd trace: ECG/SpO$_2$/RESP waveform
	Real-time parameter: speed, HR, SpO$_2$, PR, RR, TEMP1/2, and pressure value.	The 3rd trace: nothing/RESP/SpO$_2$ waveform
		Note: on the top of the printed waveform area, the 10s waveform's time shows within 2 intervals.
The main screen of data	Data identifier: "==Real time==";	Print the real-time waveform of 10

Current view/window	Contents	
	Header information	Waveform/Text information
reviewing (before entering each history records window)	Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Real-time parameter: speed, HR, SpO$_2$, PR, RR, TEMP1/2, and pressure value.	seconds: The 1st trace: ECG waveform The 2nd trace: ECG/SpO$_2$/RESP waveform The 3rd trace: nothing/RESP/SpO$_2$ waveform Note: on the top of the printed waveform area, the 10s waveform's time shows within 2 intervals.
Trigger real time printing when ARR event occurs	Data identifier: "==ARR=="; Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Real-time parameter: speed, HR, SpO$_2$, PR, RR, TEMP1/2 and pressure value.	Print the waveform of the current ARR event

18.4.2 Print History Records

Data review window	Contents	
	Header information	Waveform/text information
ARR event window	Data identifier: "==ARR=="; Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing;	Print the 6 items in ARR event list, including time, ARR type, lead, gain, filter and HR.
The operating status in ARR event, and setting item "Print the current record only" is selected.	Data identifier: "==ARR=="; Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; ARR info.: the time, ARR type, lead, gain, filter and HR of the current reviewed ARR event.	Print the waveform of the current reviewed ARR event.
The operating status in ECG Wave	Data identifier: "==ECG Wave=="; Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; ECG Wave information: ECG lead, speed, gain, HR, filter, Start time, and end time.	Print the current reviewed ECG waveform information.

Data review window	Contents	
	Header information	Waveform/text information
The operating status in the Trend Graph	Data identifier: "==Trend Graph=="; Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Trend graph info.: parameter label, sampling interval, start time, and end time.	Print the trend graph of a specific parameter displayed on the current window.
The operating status in NIBP List	Data identifier: "==NIBP List=="; Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Items in the list: time, SYS, DIA, PR, HR, SpO_2/HR, and TEMP1	Print the 12 groups NIBP lists displayed on the current window.
The operating status in Alarm Event	Data identifier: "==Alarm Event=="; Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Items in the list: time, event name, level, parameter, alarm value, the preset high/low alarm value.	Print the 11 group alarm events displayed on the current window.
The operating status in SpO_2 Event	Data identifier: "==SpO_2 Event=="; Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Items in the list: time, PID, Minute-average, SpO_2, PR, HR, and RR.	Print the 11 groups SpO_2 events displayed on the current window.

18.5 Cleaning the Printing Head of Printer

If the printer has in use for a long time, deposits of paper debris may collect on the printing head, compromising the print quality and shortening the lifetime of the roller. Follow this procedure to clean the printing head:

1. Take measures against 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 printhead using cotton swabs dampened with Ethanol.

4. After the Ethanol has entirely dried, reload the paper and close the printer door.

Chapter 19 Other Functions

19.1 System Information

Select "Menu" → "About…", then the "System Info" window can be entered, which including release version, software version, hardware version, power version and product ID.

Product ID: set by the manufacturer for traceability.

Embedded Module: other extended modules except the built-in module (ECG/ SpO$_2$/ NIBP/ RESP/TEMP), such as CSM and CO$_2$ module.

The current installed module information will also be displayed, for example, "Plug-and-Play modules 1: CSM-IoC 2: EtCO$_2$".

19.2 Nurse Call Settings

- **Output level:** the output level from nurse call connector, "High level" and "Low level" for option.

- **Duration:** two output modes for optional: "Continuous" and "Pulse". The continuous mode of output means the nurse call signal will keep until the alarm disappears. The pulse mode means the output nurse call signal lasts for one second.

- **Trigger Condition:** 3 kinds of alarm sources can trig the nurse call: high level alarm, medium level alarm and low level alarm.

Caution

⚠ Do not rely exclusively on the nurse call system for alarm notification. Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient's clinical condition.

Chapter 20 Battery

20.1 Overview

The monitor has a built-in chargeable battery. When the monitor is disconnected from the external AC power supply, it is powered by the built-in battery. When the monitor is supplied by external AC power, then the battery is charged. It's unnecessary to maintain the battery when using under normal working conditions.

When the monitor is powered by the built-in battery, and the battery is in low voltage, then the technical alarm is triggered, and a message "Low battery" pops up. Now the user should immediately connect the external power to make sure the monitor continues working.

On-screen battery symbols indicate battery status as follows:

	AC Power supply and the battery is fully charged.
	The blinking red exclamatory mark means that the battery voltage is low and needs to charge. The alarm information area shows the "Low Battery" message.
	Battery status cannot be indicated.
	Charging status
	One / two/ full grid battery voltage left

The capacity of the internal battery is limited. If the battery voltage is too low, a technical alarm triggers and a message displayed. Immediately connect the AC mains power to the monitor. Otherwise, the monitor powers off automatically before the battery is depleted.

20.2 Battery Maintenance

Warning

⚠ Please pay attention to the battery polarities. Do not insert it into the battery compartment with reversed polarities.

⚠ Do not use the batteries manufactured by other companies. Using batteries other than those recommended may damage the device.

⚠ To avoid damaging the battery, Do not use any other power supply than the power supplied with the monitor.

⚠ After battery ageing phenomenon occurs, do not throw the battery into fire to avoid explosion risk.

⚠ Do not hit or strike it with force.

⚠ Do not use this battery on other devices.

⚠ Do not use this battery below -10°C or above 40°C.

⚠ Dispose of the battery in accordance with local law.

⚠ To avoid battery damage always remove battery(s) before shipping or storage.

Caution

ⓘ To maintain battery supply time and prolong battery life, please charge the battery every one or two months if the battery is not used for an extended period. Charge battery at least 12-15 hours every time. Before charging, run down the internal battery until the monitor turns off automatically to minimize memory effects. Charging time is the same, no matter whether the monitor is working or not. Charge the battery fully before putting the monitor into storage.

ⓘ When the battery is stored with the battery power being 50% of the total power, the shelf life of a lithium battery is about 6 months. In 6 months, the battery power must be depleted before the lithium battery is fully charged. When its battery power becomes 50% of the total power, take out the battery from the monitor and store it.

ⓘ The battery should be charged even when the device is still sitting on the shelf of the factory, as all batteries will self-discharge, resulting in a low battery voltage if not recharged periodically.

ⓘ Using a monitor powered solely by an internal battery that has low power charge power causes the monitor to turn off automatically when the battery is depleted.

ⓘ Do not use batteries manufactured by other companies, which may cause damage to the device. If battery is damaged, please replace with same type and specification battery marked by "CCC" or "CE" in time, or contact the company directly.

ⓘ Keep the battery out of the reach of children.

ⓘ Do not disassemble battery.

ⓘ Do not dispose of them in fire.

ⓘ Do not cause them to short circuit.

20.3 Battery Recycling

When a battery has visual signs of damage or no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly. To dispose of the batteries, follow local laws for proper disposal.

Chapter 21 **Cleaning and Disinfection**

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

Recommended cleaning agents are:

- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- 75% Ethanol
- 70% Isopropanol

To clean your device, follow these rules:

- Switch off the monitor and disconnect the power cable before cleaning.
  - ➢ Kept the monitor from dust.
  - ➢ It is recommended to clean the outer shell and screen of the monitor to keep it clean. Only non-corrosive cleanser such as clear water is permitted.
  - ➢ Wipe the surface of the monitor and transducers with an Ethanol impregnated wipe, and dry it with a dry and clean wipe or simply air-dry.
  - ➢ This monitor can be disinfected. Prior to disinfection, clean the monitor.
- Do not let the liquid cleanser flow into the connector jack of the monitor to avoid damage.
- Clean the exterior of the connector only.
  - ➢ Dilute the cleanser.
  - ➢ Do not use abrasive materials.
  - ➢ Do not let any liquid flow into the shell or any parts of the monitor.
  - ➢ Do not let cleanser and disinfectant stay on its surface.
  - ➢ Do not perform high-pressure sterilization to the monitor.
  - ➢ Do not put any parts of the monitor or its accessories in liquid.
  - ➢ Do not pour disinfectant on its surface while disinfecting.
  - ➢ If the monitor accidentally gets wet, thoroughly dry the monitor before use. The rear cover can be removed by a qualified service technician to verify the absence of water.
  - ➢ Never use this machine in an environment with inflammable gas.
  - ➢ Avoid being hit by lightning. Plug the power cable into an outlet with a grounding wire. Do not use an outlet in poor condition. If possible, use a power supply system with a regulator.
  - ➢ It must be used in a clean environment protected against shock. Keep it away from corrosive substances, explosive substances, high temperature, and dampness.
  - ➢ If it is installed in a cabinet, make sure the installation allows for adequate ventilation, and easy maintenance, observation, and operation.

21.1 Disinfecting the Device and Accessories

Disinfection may cause damage to the device and is therefore not recommended for this monitor unless otherwise indicated in your hospital's servicing schedule. Cleaning device before disinfecting is recommended.

The recommended disinfects include:

- 75% Ethanol

- 70% Isopropanol

<u>Caution</u>

ⓘ Do not use damaged accessories.

ⓘ Accessories cannot be entirely immerged into water, liquor or cleanser.

ⓘ Do not use radiation, steam or EO to disinfect accessories.

ⓘ Do wipe off the remained Ethanol or isopropanol on the accessories after disinfection, for good maintenance can extend the life of accessories.

ⓘ Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.

Chapter 22 **Maintenance**

In case of trouble with this device while it is in service, first follow the instructions below to eliminate the problem. If the attempt fails, refer to the dealer in your local area or the manufacturer. Refer to the detailed provisions in the contract for the warranty period of the main unit and the accessories of this monitor.

22.1 Daily Examination

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

- Check the monitor for any mechanical damage;

- 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 correctly.

- Pay close attention to local power supply voltage fluctuations. A power voltage regulator is recommended when necessary.

In case any indication of damage to the function of the monitor is detected and proven, DO NOT apply it to the patient for any monitoring. Please contact the local dealer or our company, and we are to offer the best solution as soon as possible for your satisfaction.

22.2 Alarm System Examination

The monitor will perform an automatic check of the alarm sound and light every time it is started up. To start the monitor, press the power button for approximately three seconds. The monitor will emit a "beep" sound and activate the physiological and technical alarm lights, indicating that the sound and light alarm function is working correctly.

If you need to verify that a specific parameter alarm is working correctly, you can use the corresponding simulator or enter the demonstration mode to adjust the alarm limit settings and verify that the correct alarm signal is triggered.

22.3 Routine Maintenance

At each routinely maintenance or the yearly maintenance, the monitor can be thoroughly inspected by qualified personnel, including performance and safety examinations. This monitor is designed with life cycle of 5 years. It is strongly recommended to use the product which is still within its life cycle, or it may cause inaccurate measurement. In order to ensure its long service life, please pay attention to the maintenance.

Warning

⚠ If the hospital fails to carry out a satisfactory maintenance program with the monitor, the monitor may not function properly and present the potential to jeopardize the patient's safety and health.

⚠ Perform protective grounding impedance, leakage current and insulation resistance test.

⚠ In case of ECG cable/lead wires damage or aging, please replace the cable or lead wires.

⚠ If there is any indication of cable and transducer damage or they deteriorate, CEASE TO

USE the cable and transducer.

⚠ The Monitor is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. Any patient simulators should not be used to validate the accuracy of blood pressure and oxygen saturation measurement, they can only be used as functional testers to verify its precision.

Caution

🛈 The accuracy of ECG signal amplification can be verified by the built-in 1mV calibration signal.

🛈 The accuracy of pressure measurement and air leakage in pneumatic system can be verified by means of the built-in pressure verification function and a precision pressure meter, please refer to the related chapter of the operator's manual for detail operation.

🛈 The SpO_2 simulator cannot be used to verify the SpO_2 measuring accuracy, which should be supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark-skinned subjects in an independent research laboratory. However, it is necessary for the user to use SpO_2 simulator for routine verification of precision.

🛈 Please note that the specific calibration curve (R-curve) should be selected for the use of the SpO_2 simulator. For Index 2 series SpO_2 simulator from Fluke Biomedical Corporation, please set "Make" to "DownLoadMake: KRK", then the user can use this particular R-curve to test the SpO_2 function of the patient monitor with Creative oximetry technology. If the SpO_2 simulator does not contain the specific R-curve, please ask the manufacturer to help to download the given R-curve into the SpO_2 simulator.

🛈 The adjustable units within the monitor such as potentiometers are not allowed to adjust without permission to avoid unnecessary failures that affect normal application.

🛈 It is recommended to use the battery once a month to ensure its power capability and maximize the service life. Recharge the battery after it has run to its minimum operating capacity.

22.4 ECG Verification

The ECG signal may be inaccurate due to hardware or software problems. As a result, the ECG wave amplitude becomes greater or smaller.

You can print out the square wave and wave scale and then measure the difference between them if necessary. If the difference exceeds 5%, contact your service personnel.

22.5 Pressure Accuracy Verification

Pressure Accuracy Verification is a function to inspect the accuracy of pressure measurement by the NIBP module inside the device. A technician or equipment manager should do pressure accuracy verification every half-year or year 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 the 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

Mercury blood pressure meter

NIBP cuff with dual air tube

Air tube

Air tube

Air tube

Air tube

Air tube

Air vent

Manual valve

Increase the pressure manually through the inflatable balloon

Inflation balloon

Module testing software

NIBP module

This belongs to the monitor
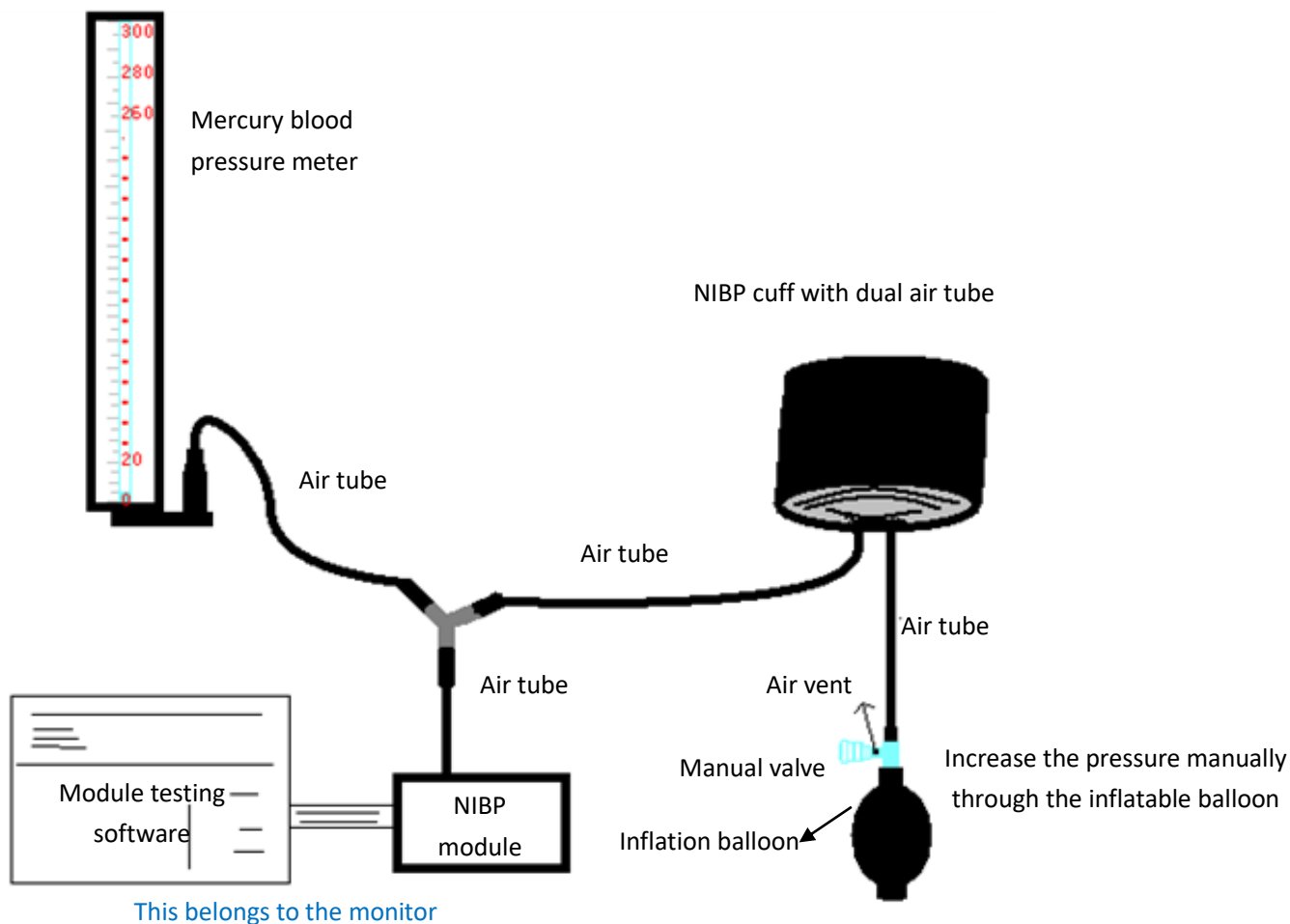
Mode 1: Automatic inflation for the pressure accuracy verification

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

Adult	240mmHg
Pediatric	200mmHg
Neonate	120mmHg

Table A

During inflation, the Monitor closes the deflating valve, and the pressure value shows during the process. If there is no manual deflation operation, the pressure remains until deflation by manual operation. It is necessary to use a manual valve to complete adequate deflation in several steps to verify the pressure accuracy in the full scale of the measurement range.

Mode 2: Manual inflation for pressure accuracy verification.

In mode, the pressure is increased manually by a pumping balloon, and the verification is done by applying different pressure values manually. If the increased pressure exceeds the given limit, as shown in table B, the Monitor deflates automatically because of over-pressure protection.

Adult	300mmHg
Pediatric	240mmHg
Neonate	140mmHg

Table B

Caution

☞ After the verification, press the button again to return to the normal working mode to continue other operations, or the NIBP key is invalid.

☞ Pressure accuracy verification must be performed by a technician or equipment manager. Doctors and nurses are not qualified to perform the verification. Accuracy verification performed while the pressure cuff is still on the patient may cause patient injury.

Air Leakage Check

To avoid significant error of blood pressure measurement or even a no measurement result caused by air leakage in the pneumatic system, including the cuff during measuring, check if there is a leak in the pneumatic system as well.

Note

☞ Remove the cuff from the patient while performing the leakage check.

22.6 IBP Calibration

This section is for professional technician only.

Each time connecting transducer or selecting another measuring label, then prompt displays on the screen. There is two methods for calibration: zero calibration and pressure value calibration.

Calibration procedure

1 On calibration window, press "Zero" button to perform zero calibration, then "Zeroing OK" will display on the window.

   The following message may appear on the window during calibration:

   • Probe off, unable to zero

   • Probe off, unable to calibrate

   • Unstable zero base pressure

   • Pressure out of range

   • Zeroing OK

2 Expulse all the air from the tube, then adjust the transfusion tube and stopcock ("Off" to the transfusion tube). Open the dust cap, and ensure the dome touch the air.

3   Zero calibration is required, zero calibration must be done before IBP monitoring, or the IBP readings will not be accurate.

4   It is recommended that "0 calibration" must be carried out each time before measuring, and at least performing once a day (zero calibration should be performed every time you connecting the plug to the IBP socket on the monitor), or the inaccuracy will be caused. If using a new IBP transducer, please perform pressure calibration.

22.7 CO_2 Test

For sidestream CO_2 modules, a calibration is needed every year or when the measured values have a significant deviation. No calibration is required for the mainstream CO_2 module. Contact your service personnel to calibrate CO_2.

Chapter 23 Accessories

The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the patient 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.

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

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

⚠   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.

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

☞   Do not use expired accessories.

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

Note

ⓘ   Part number is subject to change without prior notice, please refer to the label of parts or the supplied package list.

ⓘ   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.

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

23.1 ECG Accessories

No.	Accessories	Model/ Part No.	Description	Applicable Patient
1	ECG cable and electrode	KE-IGB031/15010028	3-leadwire, snap, defibrillation-proof, reusable	Adult/ Pediatric/ Neonate
2	ECG cable and electrode	KE-IGB051/15010020	5-leadwire, snap, defibrillation-proof	
3	ECG cable and electrode	KE-IGB101/15010030	10-leadwire, snap, defibrillation-proof	

23.2 Temp Accessories

No.	Accessories	Model/ Part No.	Description	Applicable Patient
1	Temp probe	KT-S00	10K skin surface	Adult/ Pediatric/ Neonate
2	Temp probe	KT-A00	10K cavity	

23.3 SpO$_2$ Accessories

No.	Accessories	Model/ Part No.	Description	Applicable Patient
1	Nellcor SpO$_2$ sensor	DS100A	Finger-clip, reusable	Adult/Pediatric
2	Nellcor SpO$_2$ sensor	D-YS	Y-type, reusable	Neonate
3	Nellcor SpO$_2$ sensor extension cable	DOC-10	Reusable	Adult/Pediatric/Neonate
4	SpO$_2$ sensor	KS-AE01	Ear-clip, reusable	Adult
5	SpO$_2$ sensor	KS-AC01	Finger-clip, reusable	Adult
6	SpO$_2$ sensor	KS-AR01	Large soft finger-cot, reusable	Adult
7	SpO$_2$ sensor	KS-AR02	Soft finger-cot, reusable	Pediatric
8	SpO$_2$ sensor	KS-ALW02	L-type, with wraps, reusable	Pediatric/Neonate
9	SpO$_2$ sensor	KS-ALW02S	L-type, with wraps, disposable, non-sterile	Neonate
10	SpO$_2$ sensor extension cable	KS-AExt01	Reusable	Adult/Pediatric/Neonate

23.4 NIBP Accessories

No.	Accessories	Model/ Part No.	Description	Applicable Patient
1	Cuff	98-0084-95	12cm-19cm, reusable	Child
2	Cuff	98-0084-96	17cm-25cm, reusable	Small adult
3	Cuff	98-0084-97	23cm-33cm, reusable	Adult
4	Cuff	98-0084-98	31cm-40cm, reusable	Adult
5	Cuff	98-0400-99	3cm-6cm, disposable	Neonate
6	Cuff	98-0400-96	4cm-8cm, disposable	Neonate
7	Cuff	98-0400-97	6cm-11cm, disposable	Neonate
8	Cuff	98-0400-98	7cm-13cm, disposable	Neonate
9	Cuff	98-0400-90	8cm-15cm, disposable	Neonate
10	Cuff	KN-221	6cm – 11 cm, reusable	Neonate
11	Cuff	KN-231	10cm-19cm, reusable	Infant
12	Cuff	KN-233	18cm-26cm, reusable	Child
13	Cuff	KN-241	25cm-35cm, reusable	Adult
14	Cuff	KN-243	33cm-47cm, reusable	Large adult
15	Cuff	KN-111	3.1cm-5.7cm, disposable	Neonate
16	Cuff	KN-112	4.3cm-8.0cm, disposable	Neonate
17	Cuff	KN-113	5.8cm-10.9cm, disposable	Neonate
18	Cuff	KN-114	7.1cm-13.1cm, disposable	Neonate
19	Cuff	KN-115	8cm-15cm, disposable	Neonate

23.5 CO_2 Accessories

No.	Accessories	Model/ Part No.	Description	Applicable Patient
1	CO_2 module (sidestream)	LoFlo	Sidestream	Adult/Pediatric/Neonate
2	Sampling cannula	#3475-00	Disposable, non-sterile	Adult/Pediatric/Neonate
3	CO_2 module (mainstream)	CAPONSTAT 5	Mainstream	
4	Sampling adapter	#606300	Disposable, non-sterile	Adult

No.	Accessories	Model/ Part No.	Description	Applicable Patient
5	CO_2 module (sidestream)	Capnograph_S	Sidestream	Adult/Pediatric/Neonate
6	CO_2 sampling line	15100121	240cm-φ2.5*1.6, two male heads	
7	Filter	2500-0000218	T4F/T3	
8	CO_2 module (mainstream)	Capnograph_M	Mainstream	
9	Airway adapter	2301-0000034	V9 / mainstream	Adult

23.6 IBP Accessories

No.	Accessories	Model/ Part No.	Description	Applicable Patient
1	IBP transducer	MMBPTSA20	Disposable	Adult/Pediatric/Neonate
2	IBP cable	15039057	4 pin, plastic, reusable	

23.7 CSM Accessories

No.	Accessories	Model/ Part No.	Description	Applicable Patient
1	CSM cable	CSM-C-02	Reusable	Adult/Pediatric/Neonate
2	Electrode patch	5101-0108310	Disposable	

23.8 Other Accessories

No.	Accessories	Model/ Part No.	Description
1	Rechargeable battery	2302-0000006	11.1V/4400mAH

Chapter 24 Technical Specifications

24.1 ECG

ECG	
Compliant standards	IEC 60601-2-27: 2011 and IEC 60601-2-25: 2011
Lead type	• 3 leadwire: I, II or III • 5 leadwire: I, II, III, aVR, aVL, aVF, V • 10 leadwire: I, II, III, aVR, aVL, aVF, V1 to V6
Sampling rate	2000Hz
Skew between channels	≤100μs
Bandwidth	0.05 Hz-150 Hz
Amplitude quantisation	4.9 μV/LSB
Waveform sweeping speed	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s Error: ≤ ±5%
Frequency response	• Diagnostic mode: 0.05 Hz-150 Hz • Monitor mode: 0.5 Hz-40 Hz • Surgery mode: 1 Hz-20 Hz • ST mode: 0.05 Hz-40 Hz Use A and E methods based on IEC 60601-2-25 to determine frequency response.
Time constant	• Monitoring mode: ≥0.3s • Diagnostic mode: ≥3.2s
Display sensitivity	1.25mm/mV (×1/8), 2.5mm/mV (×1/4), 5mm/mV (×1/2), 10mm/mV (×1), 20mm/mV (×2), 40 mm/mV (×4), Auto. Error: ±5%
Common mode rejection ratio	Surgery mode, monitor mode, ST mode > 105dB Diagnostic mode > 90dB
Input impedance	≥10 MΩ
Input signal range	-10.0mV - +10.0mV (peak-to-peak value)
Electrode polarization voltage range	±800 mV
Input offset current	≤0.1μA
Baseline recovery time	<5 s after defibrillation
Patient leakage current	10μA
System noise	≤30 μV (p-v RTI)
Calibration voltage	1mV, error range ±5%

ESU protection	ESU cutting power: 300 W
	ESU coagulating power: 100 W
	Recovery time: <10 s
	Heart rate change under ESU interference: <±10%
Defibrillation protection	Recovery time of electrode polarization <10 s
Timing accuracy	Total error within 24 hours: ≤30 s
Pace Pulse	
Pulse marking	It can mark pacing pulses with an amplitude of ±2mV - ±700mV and a pulse width of 0.1 ms-2 ms.
Pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions.
	Amplitude: ±2mV to ±700mV;
	Width: 0.1ms to 2ms
	No overshoot
	Minimum input slew rate: 5.5V/s RTI
HR	
Measurement range	• Adult: 15 bpm-300 bpm
	• Pediatric: 15 bpm-350 bpm
	• Neonate: 15 bpm-350 bpm
Resolution	1 bpm
Measurement accuracy	±1% or ±1 bpm, whichever is greater
Alarm limit setting resolution	1 bpm
Alarm limit accuracy	±1 bpm
Tall T-wave rejection capability	For T wave with QRS wave of 100ms, QT interval of 350ms, duration of 180ms and amplitude lower than 1.2mV, the heart rate calculation is not affected.
Minute heart rate averaging algorithm	The lastest 8 RR intervals are all in a certain range of average heart beats.
	Display refresh rate: 1 beat/s
Response time to heart rate changes	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5).
	• From 80 bpm to 120 bpm: less than 8 s
	• From 80 bpm to 40 bpm: less than 9 s
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
	• Slow alternating ventricular bigeminy (waveform A2): 60 bpm
	• Rapid alternating ventricular bigeminy (waveform A3): 120 bpm
	• Bidirectional systoles (waveform A4): 90 bpm
Time to alarm for tachycardia	<11s (applicable to all clauses of IEC 60601-2-27)
ST Segment Analysis	

Measurement range	-2.0 mV - +2.0 mV
Measurement accuracy	-0.8 mV-0.8 mV: ±0.02 mV or ±10%, whichever is greater. Beyond this range: not defined.
Resolution	0.01 mV

24.2 RESP

Respiration excitation waveform	<300 μA RMS, 52 kHz (±10%)
Respiration rate measurement range	• Adult: 0 rpm-120 rpm • Pediatric and neonate: 0 rpm-150 rpm
Respiration rate measurement accuracy	Adult: 7-120 rpm: ±2 rpm or ±2%, whichever is greater Pediatric/neonate: 7-150 rpm: ±2 rpm or ±2%, whichever is greater 0-6 rpm: not defined
Alarm accuracy	±1 rpm
Apnea alarm delay setting range	5 s-120 s

24.3 TEMP

Compliant standards	ISO 80601-2-56: 2017
Measurement range	0℃-50℃ (32°F-122°F)
Measurement accuracy	**Without Probe:** In the range of 0℃-50℃, error is ±0.1℃ **With Probe:** In the range of 25℃-45.0℃, error is ±0.2℃ In other ranges, error is ±0.4℃
Minimum time for accurate measurement	Body surface: <100 s Body cavity: <80 s
System response time	<150 s
Alarm accuracy	±0.1℃

24.4 NIBP

Compliant standards	IEC 80601-2-30: 2018
Measurement mode	Manual, Auto, NIBP STAT, Customized multi-cycle
Automatic measurement mode repetition intervals	1min, 2min, 3min, 4min, 5min, 6min, 7min, 8min, 9min, 10min, 15min, 20min, 25min, 30min, 35min, 40min, 45min, 50min, 55min, 1h, 1.5h, 2h, 2.5h, 3h, 3.5h, 4h, 4.5h, 5h, 5.5h, 6h, 6.5h, 7h, 7.5h and 8h
Continuous measurement mode time	5 min

Maximum single measurement time	• Adult and pediatric: no more than 180s • Neonate: no more than 90s			
Static pressure measurement range	0 mmHg-300 mmHg (0.0 kPa-40.0 kPa)			
Static pressure measurement accuracy	±3 mmHg (±0.4 kPa)			
Initial inflating pressure setting range	**NIBP(KRK) Module** • Adult: 80 mmHg-280 mmHg (10.6 kPa-37.2 kPa) • Pediatric: 80 mmHg-210 mmHg (10.6 kPa-27.9 kPa) • Neonate: 60 mmHg-140 mmHg (7.8 kPa-18.2 kPa) **NIBP (SunTech) Module** • Adult: 120 mmHg-200 mmHg (16.0 kPa-26.7 kPa) • Pediatric: 80 mmHg-200 mmHg (10.7 kPa-26.7 kPa) • Neonate: 60 mmHg-80 mmHg (8.0 kPa-10.7 kPa)			
Default value of initial inflating pressure	• Adult: 160 mmHg (21.3 kPa) • Pediatric: 140 mmHg (18.6 kPa) • Neonate: 90 mmHg (12.0 kPa)			
Overvoltage protection	**NIBP(KRK) Module** • Adult: ≤297 mmHg (39.5kPa) ±3 mmHg (±0.4kPa) • Pediatric: ≤247 mmHg (32.9kPa) ±3 mmHg (±0.4kPa) • Neonate: ≤147 mmHg (19.6kPa) ±3 mmHg (±0.4kPa) **NIBP (SunTech) Module** • Adult/Pediatric: 297 mmHg (39.5kPa) ±3 mmHg (±0.4kPa)			
Measurement range	**NIBP(KRK) Module**			
	Blood pressure (unit)	Adult	Pediatric	Neonate
	SYS mmHg	25-290	25-240	25-140
	SYS kPa	3.3-38.6	3.3-31.9	3.3-18.6
	MAP mmHg	15-260	15-215	15-125
	MAP kPa	2.0-34.6	2.0-28.6	2.0-16.6
	DIA mmHg	10-250	10-200	10-115
	DIA kPa	1.3-33.3	1.3-26.6	1.3-15.3
	NIBP (SunTech) Module			
	Blood pressure (unit)	Adult	Pediatric	Neonate
	SYS mmHg	40-260	40-230	40-130
	SYS kPa	5.3-34.6	5.3-30.7	5.3-17.3
	MAP mmHg	26-220	26-183	26-110
	MAP kPa	3.5-29.3	3.5-24.4	3.5-14.7

		DIA	mmHg	20-200	20-160	20-100
			kPa	2.7-26.7	2.7-21.3	2.7-13.3
Measurement accuracy	Average deviation ≤±5mmHg (±0.67 kPa)					
	Standard deviation ≤8mmHg (1.067 kPa)					

24.5 SpO₂

SpO₂ from KRK Module

Compliant standards	ISO 80601-2-61: 2011
Measurement range	0%-100%
Measurement accuracy	• 70%-100%: ±2%
	• 50%-69%: ±3%
	• 0%-49%: not defined
Sensor	Wavelength: Red light: 660nm, Infrared light: 905nm
	Maximum optical output power: ≤2mW
Data update cycle	≤8s
Perfusion index (PI) measurement range	0.1%-20%, the measurement accuracy is not defined
Alarm accuracy	70%-100%: ±1%

SpO₂ from Nellcor Module

Compliant standards	ISO 80601-2-61: 2011
Measurement range	0%-100%
Measurement accuracy	• Adult/Pediatric: 70%-100%: ±2%
	• Neonate: 70%-100%: ±3%
	• 0%-69%: not defined
Sensor	Wavelength: Red light: 660nm, Infrared light: 900nm
	Maximum optical output power: ≤15mW
Data update cycle	≤8s
Perfusion index (PI) measurement range	0.1%-20%, the measurement accuracy is not defined
Alarm accuracy	70%-100%: ±1%

Accuracy of SpO₂ Sensors

No.	Model/Part No.	Applicable patient	Accuracy Arms (%)
1	Sensor: DS100A	Adult/Pediatric	±2

	Extension cable: DOC-10 Module: Ne111-SR		
2	Sensor: D-YS Extension cable: DOC-10 Module: Ne111-SR	Neonate	±3
3	Sensor: KS-AE01 Extension cable: KS-AExt01 Module: KM-SPO-03	Adult	±2
4	Sensor: KS-AC01 Extension cable: KS-AExt01 Module: KM-SPO-03	Adult	±2
5	Sensor: KS-AR01 Extension cable: KS-AExt01 Module: KM-SPO-03	Adult	±2
6	Sensor type: KS-AR02 Extension cable: KS-AExt01 Module: KM-SPO-03	Adult, pediatric	±3
7	Sensor type: KS-ALW02 Extension cable: KS-AExt01 Module: KM-SPO-03	Neonate	±3
8	Sensor type: KS-ALW02S Extension cable: KS-AExt01 Module: KM-SPO-03	Neonate	±3

NOTES

☞ Arms is the accuracy defined as the root-mean-square value of deviation according to ISO 80601-2-61.

☞ Because PULSE OXIMETER EQUIPMENT measurements are statistically distributed, only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.

Data averaging and update

The displayed SpO_2 and Pulse Rate values are the average of data collected within a specific time. The SpO_2 is calculated every second by the data collected in recent 5 seconds, the Pulse Rate is calculated for every beat. The averaging method depends on the pulse rate value, for pulse rates below 50bpm, the SpO_2 is averaged by 16-second sliding average, the Pulse Rate is averaged by 4-beat sliding average; for pulse rates between 50bpm and 120bpm, the SpO_2 is averaged by 8-second sliding average, the Pulse Rate is averaged by 8-beat sliding average; for pulse rates above 120bpm, the SpO_2 is averaged by 4-second sliding average, the Pulse Rate is averaged by 16-beat sliding average.

The screen display of SpO_2 and Pulse Rate are updated every second with the most recent value, if the signal is noisy or missing, the display will hold the last value for at most 15 seconds before showing dashes.

The over-limit alarm is triggered once the SpO_2 or Pulse Rate exceeds the preset limits, the alarm signal generation delay is small (less than 1 second) compared with the alarm condition delay, which is caused by

the data average as described above.

24.6 Pulse Rate

Alarm accuracy	±1% or ±1bpm, whichever is greater
PR from NIBP (KRK) module	
Measurement range	30 bpm-250 bpm
Measurement accuracy	±3bpm or ±3%, whichever is greater
PR from NIBP (Suntech) module	
Measurement range	30 bpm-220 bpm
Measurement accuracy	±3bpm or ±2%, whichever is greater
PR from SpO$_2$ (KRK) module	
Measurement range	30 bpm-250 bpm
Measurement accuracy	±2bpm or ±2%, whichever is greater
PR from SpO$_2$ (Nellcor) module	
Measurement range	20 bpm-250 bpm
Measurement accuracy	±3bpm
PR from IBP module	
Measurement range	20 bpm-250bpm
Measurement accuracy	±1 bpm or ±1%, whichever is greater

Note

☞ The pulse rate ACCURACY is tested by an electronic pulse simulator.

24.7 CO$_2$

Compliant standards	ISO 80601-2-55: 2018
Measurement mode	Sidestream and mainstream
Measurement range	0 mmHg-150 mmHg (0 kPa-20.0 kPa)
Measurement accuracy	• 0 mmHg-40 mmHg (0 kPa-5.3 kPa), the error is ±2 mmHg (±0.27 kPa) • 41 mmHg-70 mmHg (5.5 kPa-9.3 kPa), the error is ±5% • 71 mmHg-100 mmHg (9.4 kPa-13.3 kPa), the error is ±8% • 101 mmHg-150 mmHg (13.4 kPa-20.0 kPa), the error is ±10%
Alarm accuracy	±1 mmHg (±0.1 kPa)
Sampling rate (sidestream)	50 ml/min or 100 ml/min (flow rate adjustable)

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)	Accuracy
	0-40	0-79	±2 mmHg
		>80	±12%
	41-70	0-79	±5%
		>80	±12%
	70-100	0-79	±8%
		>80	±12%
	>100	0-79	±10%
		>80	±12%
Response time and rise time	For Kingst CO$_2$ module: • Sidestream: Rise time < 250 ms (t 10%-90%), total system response time < 4 s when use a 2.4 m sampling line. • Mainstream: Rise time is approximately 70 ms (t 10%-90%), total system response time < 1 s.		
Drift of measurement accuracy	• Short-term: The module works for more than 4 hours, and the maximum drift does not exceed 0.8 mmHg. • Long-term: The module works for more than 120 hours and still meets the specified performance standards.		
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.		
Apnea			
Measurement range	• Sidestream: 2 rpm-150 rpm • Mainstream: 0 rpm-150 rpm		
Measurement accuracy	±2 rpm		
Apnea alarm delay	0-60 s		

24.8 CSM

EEG sensitivity	±400 µV
Noise level	<2 µVp-p, <0.4 µV RMS, 1 Hz-250 Hz
CMRR	>140 dB
Input impedance	>50 Mohm
Sample rate	2000 samples/sec. (14 bits equivalent)
CSI and update	0-100. Filter 6-42 Hz, 1sec. update
EMG	0-100 logarithmic. Filter 75-85 Hz, 1 sec. update
BS%	0-100%. Filter 2-42 Hz, 1sec. update

24.9 IBP

Compliant standards	IEC 60601-2-34:2011
Measurement range	-50 mmHg-300 mmHg (-6.7kPa-40.0 kPa)
Measurement accuracy	±1 mmHg (±0.1 kPa) or ±2%, whichever is greater (main unit)
Resolution	1 mmHg (0.1 kPa)
Alarm accuracy	±1 mmHg (±0.1 kPa)
Pressure transducer	
Sensitivity	5V/Volt/mmHg
Impedance range	300 Ω to 3000 Ω
Volume output	<0.02 mm³/100 mmHg

24.10 Wi-Fi Specifications

Protocol	IEEE 802.11 a/b/g/n (2.4 GHz & 5 GHz)
Operating frequency	2412 MHz – 2484 MHz 4.9 GHz – 5.975 GHz
Modulation mode	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM, 802.11b with CCK and DSSS
Wireless security features	WPA/WPA2-Personal WPA/WPA2 Enterprise for Client EAP-TLS EAP-FAST EAP-TTLS PEAP-MSCHAP-v2
Data security	AES128/256, SHA256/384/512, RSA, ECC, ECDH, RNG, CRC
Average output power	< 20 dBm (2.5 GHz) < 23 dBm (5 GHz)
Compliance	The radio device used in this product is in compliance with the restrictions in Article 10 (10) of Directive 2014/53/EU,applicable to the market of Belgium (BE), Bulgaria (BG), the Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL),Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands(NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE), the United Kingdom (UK), Turkey(TR), Norway (NO), Switzerland (CH), Iceland (IS), and Liechtenstein (LI). The WLAN function for this device is restricted to indoor use only when operating in the 5150 to 5350 MHz frequency range.

24.11 Signal Outputs Specifications

Auxiliary output	
Standard	Meets the requirements of IEC 60601-1 for short-circuit protection and leakage current
ECG analog output	
Bandwidth (-3dB; reference frequency: 10Hz)	0.5 Hz-40 Hz
QRS delay	< 25ms(non-paced)
Output sensitivity	0.4 V/mV5%
Baseline level	2.20 ± 0.2 V
Output impedance	≤ 100 Ω
Duration of short-circuit	Short circuit to ground for 1 minute, no fault after disconnection.
Nurse call signal output	

Amplitude	10 V-15 V
Maximum load current	350 mA
Duration of short-circuit	Lasting short-circuits is allowable, and it can return to normal automatically.

24.12 Classification

Safety standard	IEC 60601-1
The type of protection against electric shock	Class I and Internally powered equipment
The degree of protection against electric shock	Defibrillation-proof BF (for CO_2 module) and Defibrillation-proof CF (for ECG, RESP, TEMP, SpO_2, NIBP) applied parts
Electro-Magnetic Compatibility	Group I, Class A
Mode of operation	Continuous

The device is not intended for use in an oxygen-rich environment.

The surface of the device can be cleaned and disinfected, no need to sterilize.

24.13 Operating Environment

- Ambient temperature range: 5 °C- 40 °C

  Relative humidity: 30%-80%, non-condensing

  Atmospheric pressure: 70kPa - 106.0kPa

- This equipment should be situated in a place protected against direct sunlight, to prevent overheating inside the equipment.

- The device should be stored and used within the specified temperature, humidity, and atmospheric pressure range, or it may cause damage to the device or inaccurate measurement result.

- If the device gets wet by accident, the operator should NOT power it directly until it has been air-dried enough to avoid any damage to it.

- Do not use this equipment in an environment with toxic or inflammable gas.

- This equipment should be placed on a stand or flat platforms, to prevent possible shock.

- Do not use this equipment in combination with any equipment other than those expressly permitted in the manual.

- The monitor is defibrillator discharge proof and can be used with an electrosurgical unit. When the device is used in conjunction together with a defibrillator or electrosurgical equipment, the user (doctor or nurse) should keep the patient under close surveillance for his/her safety. Refer to the following function description for specific protective measures or notes.

- Make sure that the equipotential grounding terminal is grounded correctly.

- Do not use a mobile phone nearby, to avoid strong, radiant field interference.

24.14 Storage

If the equipment is used for long periods of time, wipe it clean and keep it in the packaging. The equipment should be stored in a dry and good ventilation place free from dust and corrosive gases

Storage environment:

- Ambient temperature: -20°C - 60°C
- Relative humidity: 10% - 95%
- Atmospheric pressure: 53kPa -106kPa

24.15 Transportation

This monitor should be transported by land (vehicle or railway) or air per the contractual terms. Do not hit or drop it with force.

Transportation environment:

- Ambient temperature: -20 - 60°C
- Relative humidity: 10% - 95%
- Atmospheric pressure: 53kPa - 106kPa

24.16 Packaging

The product is packed in high-quality corrugated cartons with foam inside to protect the apparatus against damage in the handling process.

Gross weight:

- K10:4.5kg
- K12: 5.2kg
- K15: 5.7kg

Dimension:

- K10: 295mm(L)x178mm(D) x334mm(H)
- K12: 313mm(L)x178mm(D) x334mm(H)
- K15: 357mm(L)x178mm(D) x334mm(H)

24.17 Other Technical Specifications

- Power supply: AC100V-240V, 50/60Hz, 0.45A~1A; Internal power supply: DC 11.1V
- Applied Part: ECG lead wire, SpO_2 sensor, TEMP sensor, Cuff and CO_2 module
- Display mode: TFT color LCD
- Alarm mode: audible & visible alarm
- System alarm delay time

  The delay time from the measurements triggering the alarm on the monitor to the alarm indicated on the remote device ≤ 10 seconds, in the condition of normal network transmission.

Chapter 25 Troubleshooting

Caution：

◑ Do not open the monitor cabinet without permission.

Note

⚠ In case of problems while this device is in service, follow the instructions below to eliminate the problem first. If the attempt fails, contact the dealer in your local area or the manufacturer.

25.1 Alarm or Prompt Troubleshooting

The monitor prompts messages to indicate the current system status. Follow the instructions in the table below to eliminate the problems.

NIBP

Status / Error	Description	Corrective Actions
Self-test failed	NIBP module self-test failed during power on, sensor or other hardware errors.	Module abnormal or faulty, it is recommended to power on again. If this symptom cannot be eliminated, it is recommended to replace the NIBP module or return to the factory for repair.
System error	Abnormal condition of CPU, such as register overflow, divided by zero.	Module abnormal or faulty, it is recommended to power on again. If this symptom cannot be eliminated, it is recommended to replace the NIBP module or return to the factory for repair.
Weak signal	Very weak signal because of the cuff, or the patient has very weak pulse.	Normal module operating report, not error or fault.
Cuff error	Cuff is not wrapped correctly, or is not connected.	Normal module operating report, not error or fault.
Air leak	Air moving part, tube or the cuff leak air.	Check the cuff for air leakage. Check the tightness of the module airway. Recondition the module pneumatic components.
Pressure error	Unstable cuff pressure or tangled cuff tubing.	Check the airway, especially the hose, for kinks. Recondition the module.
Overof range	Very weak signal because of the cuff, or the patient has very weak pulse.	Normal module operating report, not error or fault.
Over motion	The repeated measurement due to moving, excessive noise during the stepping inflation and	Normal module operating report, not error or fault.

Status / Error	Description	Corrective Actions
	measuring pressure and pulse, e.g., during patient shaking motion.	
Overpressure detected	The blood pressure amplifier is saturated by excessive motion disturbance.	Check whether the airway or air tubing is blocked. Recondition the module.
Exceed measurement range	When any measured value of systolic blood pressure, diastolic blood pressure or mean artery pressure exceeds the nominal measurement range, this technical alarm will be triggered.	Normal application software report, not an error or fault.
Timeout	Indicates that the operation has timed out.	Remeasure

Temp

Status / Error	Description	Corrective Actions
Temperature self-test failed	Power on hardware self-test of temp module failed.	Module abnormal or faulty, it is recommended to power on again. If this symptom cannot be eliminated, it is recommended to replace the Temp module or return to the factory for repair.

ECG

Status / Error	Corrective Actions
Lead(s) off	Normal module operating report, not error or fault.

SpO$_2$

Status / Error	Corrective Actions
Probe off	Normal module operating report, not error or fault.

IBP

Status / Error	Description	Corrective Actions
Probe off	IBP cable connector not connected.	Normal prompt message, not an error or fault.

CO$_2$

Status / Error	Description	Corrective Actions
Sensor over temp	When the temperature of the sensor is higher than 40℃, the	Module hardware error or module failure, please return to the factory for repair or replace the

Status / Error	Description	Corrective Actions
	module will send out the information automatically.	sensor.
Sensor faulty	Hardware error, EEPROM checksum error or module failure.	Module hardware error or module failure, please return to the factory for repair or replace the sensor.
No parameter	Barometric pressure and/or gas compensations have not been set since power on. For CO_2 to be calculated with the stated accuracy, these values should be set whenever the sensor is plugged in.	Wait for the module to complete the setting of barometric pressure and gas compensation. If the information still exists after more than 20 seconds, consider the following reasons: the module barometric pressure and gas compensation settings are wrong, and the application software fails to issue the setting command.
Module in sleep mode	The sensor is currently in standby state.	Normal module operating report, not error or fault. If this prompt appears during the normal monitoring, it is recommended to start the monitoring operation again for the sensor.
Sensor warm up	After power on, the module has a preheating process, mainly to detect the temperature of the sensor.	Normal module operating report, not error or fault.
Zero required	When the module's auto zero error occurs.	It is suggested to reset the sensor to zero at this time. If the zero operation fails for more than three times or the request is still reported, it indicates that the sensor is faulty. Please return to the factory for repair or replace the sensor.
CO_2 out of range	The value being calculated is greater than the upper CO_2 limit (150mmHg). The maximum value output is the upper CO_2 limit.	It is recommended to perform sensor zeroing at this time. If the zeroing operation fails for more than three times or the error is still reported, the sensor is faulty. Please return to the factory for repair or replace the sensor.
Check airway adapter	Usually caused when the airway adapter is removed from the sensor or when there is an optical blockage on the windows of the airway adapter. May also be caused by failure to perform sensor zero when adapter type is changed.	Correctly connect the adapter to eliminate the error. Check if the round transparent window of the adapter is blocked or damaged. It is recommended to replace the adapter.
Check sampling line	When the sampling line is blocked or kinked, the pneumatic pressure is outside	Check for blockage in the sampling line. Check whether the sampling line is tangled. The error can be eliminated when the airway is

Status / Error	Description	Corrective Actions
	the expected range.	unblocked.
Sensor off	When the software system fails to receive any CO_2 data for more than 2 seconds, it is considered that the sensor is off at this time.	Monitoring application software setting status, not reported by the module itself, not an error or fault.
Sensor not ready	When setting the zero operation, the sensor status is not ready. Possible reasons include: Breaths detected The preheating is not completed, and the sensor temperature is not stable The sensor is still in sleep mode Sensor barometric pressure and gas compensation settings are not completed	Normal report during zero operation, not error or fault.
Zero in progress	The status information returned by the module during the zero operation.	Normal report during zero operation, not error or fault.
Zero failed and breaths detected	Breathing is detected within 20 seconds of the zero operation.	It is recommended to ensure that there is no breathing gas for at least 20 seconds before the zeroing operation, and perform the zero operation under the condition of clear air to avoid operation failure or zero deviation.

Battery

Status / Error	Corrective Actions
Low battery	Charge the battery in time

25.2 Common Faults

Check the solutions below before requesting service, if you encounter the problems when using the monitor or accessories. If the problem persists, contact your service personnel.

Display Troubleshooting

When there is no display on the screen, follow the steps below:

- Shut down the device and unplug the power cable.
- Use a universal meter to check if the outlet has proper voltage.

- Check the power cable is in good condition, and that it has been properly connected to the monitor and outlet.

- Remove the fuse from the back cover of this device, and make sure it is in good condition.

- If all of the above is in good condition, there may be an issue with display screen.

Power Supply Troubleshooting

Symptoms	Possible Causes	Corrective Actions
Battery cannot be recharged and/or fully charged	Battery is defective	Replace the battery
	Main board is defective	Replace the main board

Alarm Troubleshooting

Alarm lamp & alarm sound

Symptoms	Possible Causes	Corrective Actions
The alarm LED does not light	Mainboard is defective	Replace the main board
No alarm sound is issued	Audible alarm is disabled	Check if " " is displayed. If yes, the audible alarm is disabled.
	Speaker is defective	Replace the speaker
	Mainboard is defective	Replace the main board

System alarm

- When the parameter value is higher or lower than the alarm limits, the alarm will issue. Please check whether the alarm limit value is proper or the condition of the patient.

- In case of ECG alarm, check the patient's current condition and check whether the connection of electrode and lead wire is normal.

- Lead(s) off. Please check the connection of the leads.

- Probe off. Please check the connection of the probes.

ECG Troubleshooting

If there are excessive ECG signal interferences or the baseline is too thick, always check the following:

- Check if the plate electrodes are properly located, and if valid plate electrodes are used.

- Check whether the lead wires are properly inserted. If no ECG waveform displayed, check if the ECG lead wires are broken.

- Make sure the mains outlet has standard grounding wire.

- Check if the grounding wire of the apparatus is properly grounded.

SpO$_2$ and NIBP Troubleshooting

If there is no blood pressure and pulse oxygen measurement results, always check the following:

- Check if the blood pressure cuff is properly wrapped around the arm according to the operating instructions, if the cuff leaks, and if the inlet is closely connected with the NIBP jack on the side panel.
- Check if the indicator of the pulse oxygen sensor flashes (do not look directly at the lamp in the pulse oximetry sensor) and if the pulse oxygen sensor is properly connected to the SpO_2 connector on the side panel.

IBP Troubleshooting

Symptoms	Possible Causes	Corrective Actions
Unable to calibrate	Device malfunction	The pressure hardware may be faulty. Contact the manufacturer or your local distributor.
	Out of range	Confirm that you have selected the value for calibration value that you applying to the transducer, and repeat the calibration.
	No transducer is detected	Check that the transducer is connected and try again.
	Unstable signal is measured	Confirm that there is no disturbance to transducer, and repeat the calibration.
	Perform zero first	No valid zero. Zero the transducer first.
Unable to zero	Device malfunction	The pressure hardware may be faulty. Contact the manufacturer or your local distributor.
	Excessive offset	Confirm that the transducer is vented to air and try again. If this fails, the hardware may be faulty, please change a new adapter cable and try again. If it fails, change a new transducer and try again. If it still fails, please contact the manufacturer or your local distributor.
	Unstable signal is measured	
	No transducer is detected	Check that the transducer is connected and try again. If this fails, exchange the adapter cable and try again. If this fails, exchange the transducer.
	Plusatile pressure	Confirm that the transducer is vented to air, not to the patient, and try again.

CO_2 Troubleshooting

No CO_2 readings

Symptoms	Error Type	Description	Corrective Actions
Sensor temperature is too high	Hardware error	The temperature of the sensor is greater than 40℃.	Repair or replace CO_2 sensor
Sensor faulty	Hardware error	Hardware error, EEPROM check error, or module failure	Repair or replace CO_2 sensor

Troubleshooting the sidestream CO_2 sampling

When the sampling system of the sidestream CO_2 module works incorrectly, always check the following:
- Check if the sampling line is kinked.
- If not, remove it from the water trap.

- If the monitor gives a message indicating the airway still works incorrectly, it indicates that the water trap must have been blocked, and you should replace with a new one. Otherwise, you can determine that the sampling line must have been blocked. Replace with a new sampling line.

CSM Troubleshooting

CSM does not turn on when power key is pressed?

Change to a new battery or fully recharged battery.

If changing the battery does not help, send the CSM for service.

CSM has blanked index- why?

- Sensor impedance too high

- If sensor impedance is >5kΩ the CSI, BS AND EMG will be blanked.

- Check that sensors are not dry.

- Check that the skin has been cleaned properly.

- Clean skin and attach new sensors.

CSI rises along with EMG

High levels of facial muscular or electromyographic (EMG) activity can elevate the CSI under certain circumstances. When this happens, attention must be paid to the stimuli received by the patient during surgery. When the patient is asleep, EMG activity can increase due to reflex reactions to painful stimuli during surgery, lack of muscular relaxation or muscular rigidity caused by some opioids (analgesics). In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent may cause the CSI to decrease.

Note

☞ Facial muscles will recover sooner than skeletal muscles.

☞ When these artifacts are present, the CSI should be interpreted with caution.

A Typical Pressures and CO₂ Readings at Altitudes

Altitude	Barometric Pressure(mmHg)	EtCO₂ Reading	
		(%)	(mmHg)
0m	760	5	38.0
70m	754	5	37.7
100m	751	5	37.5
200m	743	5	37.1
1500m	641	5	32.0
3000m	537	5	26.8
5000m	420	5	21.0

B EMC Compliance

Essential Performance

The monitor has the following essential performance in an environment of electromagnetic environment specified below:

- Operating mode
- Accuracy
- Function
- Alarm

Warning

⚠ Use of the monitor adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the monitor could result in increased electromagnetic emissions or decreased electromagnetic immunity of the monitor and result in improper operation.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of the monitor could result.

⚠ In operation mode, the monitor can be used with electro-surgical unit. The monitor's operator should ensure the safety of the patients if in use with electro-surgical unit in accordance with the instructions of this manual. After the elimination of high frequency signal and high frequency electromagnetic field, the monitor waveform and parameter can recover within 10 seconds without losing any stored data.

⚠ Do not use the monitor with electro-surgical unit in non-operation mode, nor with large-scale electrical equipment such as ultrasonic, radiation and magnetic resonance imaging, which may cause electromagnetic interference to the monitor or harm the monitor's operator.

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 equipment should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	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 IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

<u>Note</u>

☞ The EMISSIONS characteristics of the monitor make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), the monitor might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocation or re-orienting the monitor.

☞ If the electromagnetic field strength in the location where monitor is used within 1.5 km from the AM, PM, TV broadcast exceeds the applicable RF compliance level (listed in Table 3), the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Monitor.

Table 2

Guidance and manufacturer's declaration-electromagnetic immunity

for all EQUIPMENT AND SYSTEMS

Patient Monitor 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 ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC61000-4-4	±2kV for power Supply lines ±1 kV for input/output lines	±2kV for power Supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line (s) to line(s) ±2kV line(s) to earth	±1kV differential mode ±2kV 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 Patient Monitor (K10, K12, K15) requires continued operation during power mains interruptions, it is recommended that the Patient Monitor (K10, K12, K15) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of an ideal location in a typical commercial or hospital environment.

NOTE: UT is the a. c. Mains voltage before application of the test level.

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity-for EQUIPMENT and SYSTEM that is not LIFE-SUPPORTING

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	Portable and mobile RF communications equipment should be used no closer to any part of the **Patient Monitor** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[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:

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

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

a   The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b   Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM, and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Patient Monitor (K10, K12, K15) is used exceeds the applicable RF compliance level above, the Patient Monitor (K10, K12, K15) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the patient Monitor (K10, K12, K15).

c   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 SYSTEMS that are not LIFE-SUPPORTING

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

Rated maximum output of the transmitter W	Separation distance according to the frequency of the transmitter			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

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

NOTE 1 At 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.

Symbols

	Date of manufacture	**REF**	Product code
	Manufacturer	**LOT**	Lot number
	Defibrillation-proof type BF applied part		Defibrillation-proof type CF applied part
	Caution: read instructions (warnings) carefully		Humidity limit
$C\epsilon$	Medical Device complies with Directive 93/42/EEC		Atmospheric pressure limit
	Follow instructions for use		Temperature limit
EC REP	Authorized representative in the European community		Keep in a cool, dry place
	WEEE disposal		Keep away from sunlight

__Disposal:__ The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies