V9 Patient Monitor

User's Manual

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Product Information

- Product Model: V9
- Product Name: Patient Monitor
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Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

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Statement

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operation, maintenance and service of product, someone else can not publish the manual.

This manual contains exclusive information protected by copyright laws and we reserve its copyright. Without written approval of manufacturer no parts of this manual shall be photocopied, Xeroxed or translated into other languages.

The contents contained in this manual are subject to amendments without notification.

Manufacturer's Responsibility

Only under the following circumstances will manufacturer be responsible for the safety, reliability and performance of the instrument:

All the installation, expansion, readjustment, renovation or repairs are conducted by the personnel certified by manufacturer.

The storage condition, operation condition and electrical status of the instrument conform to the product specification.

The instrument is used in accordance with the user's manual.

About this manual

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

The manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practiced and terminology as required for monitoring patients.

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your product.

Conventions:

Bold Italic text is used in this manual to quote the referenced chapter or sections.

【】is used to enclose screen texts.

→ is used to indicate operational procedures.

Signs in this manual：

Warning: Indicates a potential hazard or unsafe practice that, if not avoided, will 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.

Contents

Chapter 1 General Introduction

1.1 Intended Use

The monitor is intended to be used for monitoring, displaying, reviewing, storing and sending alarms regarding multiple physiological patient parameters, including Pulse Oxygen Saturation (SpO_2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Temperature (Temp) and Carbon dioxide (CO2).

The monitor is intended to be used in outpatient departments, emergency treatment rooms, and low-acuity areas of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.

Warning: The monitor is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operations on it.

1.2 Restrictions for Use

- Do not use the monitor and the SpO2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.
- Operating high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.
- The following factors may influence the accuracy of SPO2 measurements:

✧ Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material);

✧ Electromagnetic interference, such as from an MRI device;

✧ Excessive patient movement;

✧ Intravascular dyes such as indocyanine green or methylene blue;

✧ Significant levels of dysfunctional hemoglobins (such as carboxy hemoglobin or methemoglobin);

✧ Incorrect sensor application or use;

- ✧ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line;
- ✧ Low perfusion;
- ✧ Electrosurgical units.

■ Do not use the SpO_2 sensor on the same limb being used for NIBP measurement. This may result in inaccurate SpO_2 reading due to blocked blood flow during cuff inflation.

■ Do not measure SpO_2 on a finger painted with nail polish. This may result in unreliable measurements.

■ Do not measure NIBP on patients with sickle-cell disease or any condition in which skin damage has occurred or is expected.

■ Use clinical judgment to decide whether to perform frequent Auto BP measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.

■ Use clinical judgment to decide whether to perform Auto BP measurement on patients with thrombasthemia.

■ Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.

■ NIBP Measurement Limitations: Accurate NIBP measurements cannot be taken when the heart rate is extremely low (less than 40 bpm) or extremely high (greater than 240 bpm) or if the patient is on a heart-lung machine. Accurate measurement also cannot be taken when the following conditions exist:

- ✧ Excessive and continuous patient movement such as shivering or convulsions;
- ✧ Difficulty detecting a regular arterial pressure pulse;
- ✧ Cardiac arrhythmias;
- ✧ Rapid blood pressure changes;
- ✧ Severe shock or hypothermia that reduces blood flow to the peripheries;
- ✧ An edematous extremity.

■ MRI may lead to vessel damage.

1.3 Configurations

The monitor consists of main unit, NIBP cuff, SpO2 sensor, CO_2 measuring module and Temperature sensor.

1.4 Main Unit

1.4.1 Front View

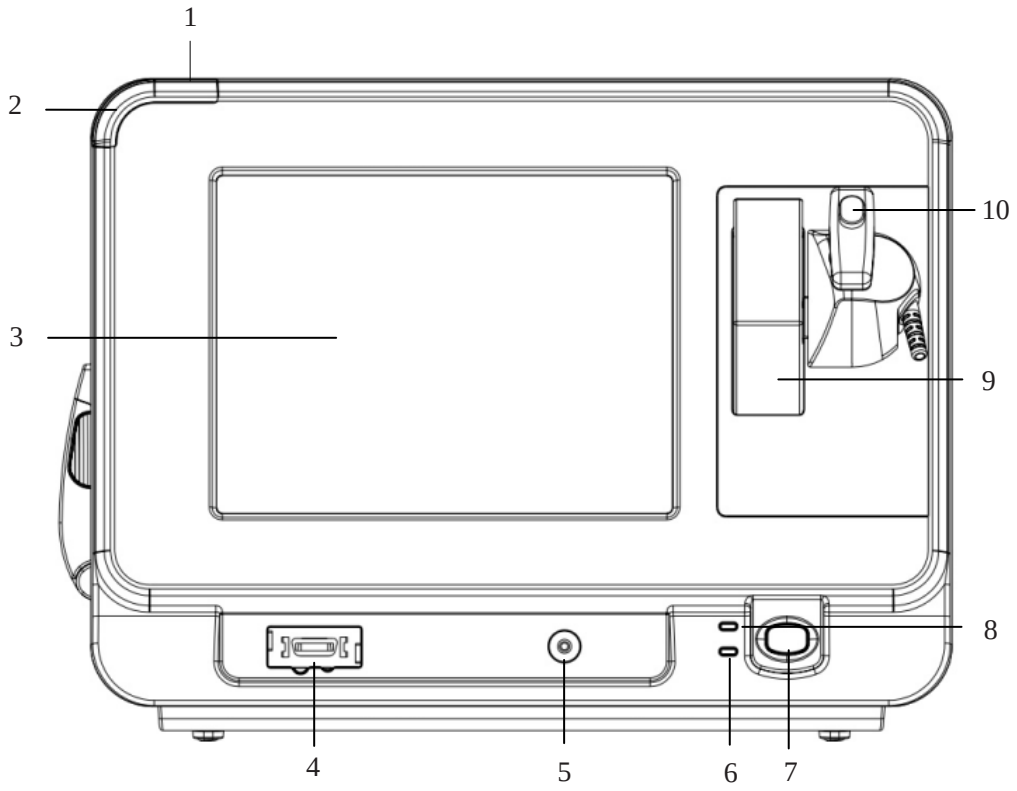


Fig.1-1

1. Physiological alarm visual indicator LED's. When a physiological alarm occurs, this lamp will light up as defined below:
   - High level alarm: the lamp quickly flashes red.
   - Medium level alarm: the lamp slowly flashes yellow.
   - Low level alarm: the lamp lights yellow without flashing.
2. Technical alarm indicating lamp

   When a technical alarm occurs, this lamp will light up as defined below:
   - Medium level alarm: the lamp slowly flashes yellow.
   - Low level alarm: the lamp lights blue without flashing.
3. LCD Touch screen
4. SpO2 connector
5. NIBP connector
6. Battery charging indicating lamp
   - On: When the battery is being charged.
   - Off: When the battery is fully charged or there is no battery in monitor.

7. Power button
   - Press this button to turn on the monitor after AC power is connected or the battery is installed.
   - Press and hold for 3 seconds to turn the monitor off.
8. Power indicator LED. Status of the LED is specified as follows:
   - Green: When the AC mains connected.
   - Orange: When the AC mains not connected and monitor is powered by battery.
   - Off: When the AC mains not connected.
9. Well for 20-count Probe Cover box
10. Covidien Filac 3000 temp probe

1.4.2 Side View

Left side: **Right side:**

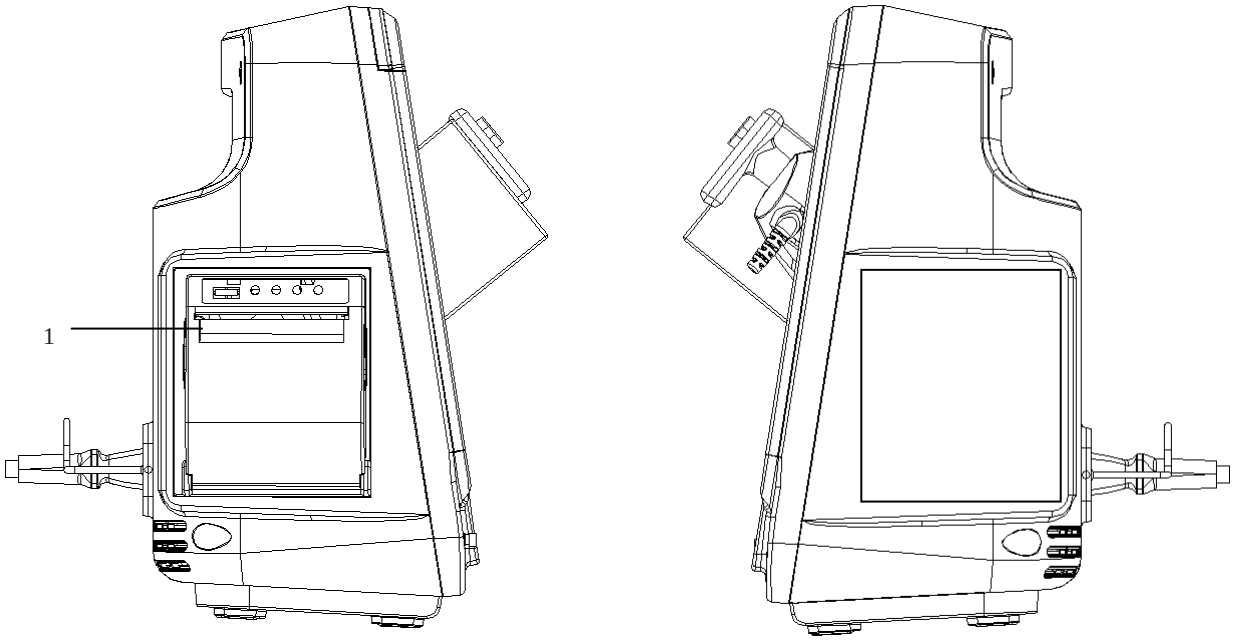


Fig.1-2

1. Print Recorder

1.4.3 Rear View

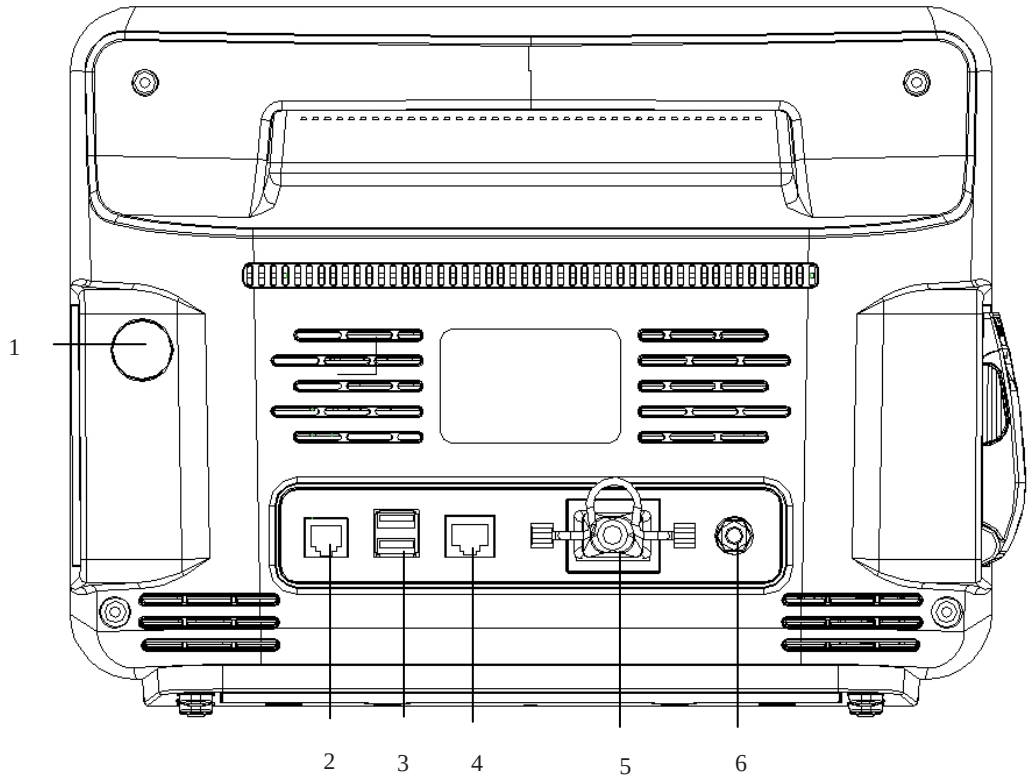


Fig.1-3

1. CO2 Connector
2. Nurse call connector

   Connect to nurse call system in hospital. When an alarm occurs, outputting the nurse call signal to remind nurse.
3. USB socket x 2

Connect to USB device, such as mouse.

4. Wired network connector

   Standard RJ45 socket. It is used for connection with the central monitoring system provided by manufacturer.
5. AC power input connector
6. Equipotentiality terminal

   Base on the requirements of safety and anti-interference, the monitor must be connected with equipotentiality system individual. When connected together, the various parts of an equipment or of a system will be brought to the same potential, not necessarily being the earth (ground) potential.

Warning:

- **Equipment connected to the analog or digital interfaces must comply with the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the current version of the standard for SYSTEMS IEC 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with current version of the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department or your local representative.**
- **The operator could not touch these ports and the patient simultaneously.**

1.4.4 Bottom View

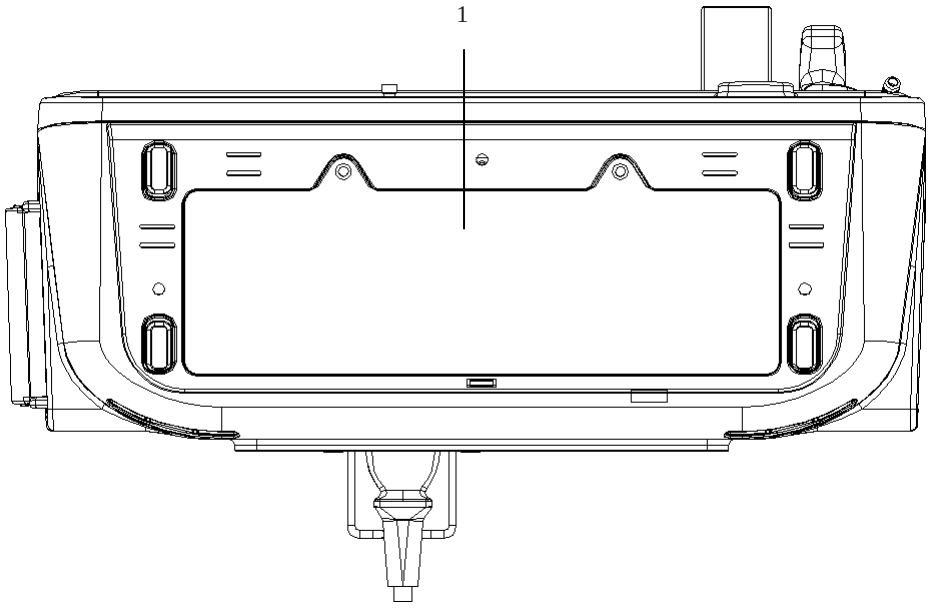


Fig.1-4

1. Battery compartment

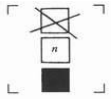
Caution: Clean the battery contacts regularly to ensure optimal electrical contact. Before cleaning, power down the unit and disconnect it from A/C power. To clean the contacts, rub with a cotton swab dampened (not dripping wet) with isopropyl alcohol.

1.5 Equipment Symbols

Symbol	Symbol Note
	Defibrillation-proof Type CF applied part
	Defibrillation-proof Type BF applied part
	Refer to instruction manual/booklet.
	Non-ionizing radiation
	Dangerous voltage
	Equipotential grounding
	USB socket
	Network connector
	Nurse call connector
	Manufacture date
	Manufacturer
	Catalog Number
	Batch or Lot Code
	Serial number
	Temperature limitation
	Humidity limitation
	Pressure limitation

Symbol	Symbol Note
IPX1	Degree of protection against ingress of liquid
SpO_2	Pulse Oxygen Saturation
NIBP	Non-Invasive Blood Pressure
CO_2	Short for "Carbon dioxide"
Temp	Temperature
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.

1.6 Packaging Symbols

Symbol	Symbol Note
	Fragile. Handle with care.
	This Side Up.
	Keep dry.
	Stacking layer limit, where 'n' represents the maximum permissible number of layers. (N = 6).

Chapter 2 Safety

2.1 Safety Information

Warning:

- **Before putting the system into operation, verify that the monitor, connecting cables and accessories are in correct working order and operating condition.**
- **Please connect the monitor to a socket with protective earth. If the socket does not have protective earth conductor, please do not use the socket and use battery to provide power to the monitor.**
- **The function and network connector of the device are just connected with the match accessory and network. When use the connector improperly, there may be damage to the device and patient.**
- **Do not use device if any electrical connections become damaged, bent, or mis-aligned.**
- **To avoid explosion hazard, do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.**
- **Do not open the monitor housings; electric shock hazard may exist. All servicing must be performed by personnel authorized by the manufacturer only.**
- **When using the monitor with electrosurgical units (ESU), make sure the patient is safe. And the ESU must not contact with patient cable.**
- **Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.**
- **Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**
- **The physiological data and alarm messages displayed on the monitor are for reference only and cannot be directly used for diagnostic interpretation.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patient or personnel.**

- **To avoid risk of electric shock, this equipment must only be connected to a grounded power supply.**
- **No modification of this equipment is allowed. Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.**
- **There will be significant risks of reciprocal interference when the device is used in specific investigations or treatments.**
- **The device's connector (including USB, network and so on) can only be connected to the matched accessories and network server. The misuse of them may cause damage to the device.**
- **Operating high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements. When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided conductive connection to the HF equipment to protect against burns to the patient.**

Caution:

- **To ensure patient safety, use only parts and accessories specified in this manual.**
- **At the end of its service life, the monitor, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the monitor, please contact the manufacturer.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the monitor. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Before connecting the monitor to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the monitor's label or in this manual.**

- **Always install or carry the monitor properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**

Note:

- **Put the monitor in a location where you can easily see the screen and access the operating controls.**
- **Keep this manual in the vicinity of the monitor so that it can be obtained conveniently when needed.**
- **The software was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.**
- **This manual describes all features and options. Your monitor may not have all of them.**

2.2 General Safety

Warning: This monitor is neither a therapeutic instrument nor a device that can be used at home.

1. Safety precautions for installation
   - Connect the power cord to a properly grounded socket. Only connect device to A/C power sockets designated for use by medical equipment.
   - Avoid putting the monitor in a location where it easily shakes or wobbles.
   - Enough space shall be left around the monitor so as to guarantee normal ventilation.
   - Make sure the ambient temperature and humidity are stable and avoid the occurrence of condensation in the operation process of the monitor.

Warning: Never install the monitor in an environment where flammable anesthetic gas is present.

2. Monitor conforms to the safety requirements of IEC 60601-1. This monitor is protected against defibrillation effects.

3. Notes on symbols related to safety

Type CF applied part, defibrillation protected

The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof. The type CF applied parts provide a higher degree of protection against electric shock than that provided by type BF applied parts.

Attention! Please refer to the documents accompanying this monitor, such as the instruction manual.

4. When a defibrillator is applied on a patient, the monitor may have some disruption in its display of waveforms.

Warning: When conducting defibrillation, do not come into contact with the patient, the bed or the monitor. Otherwise serious injury or death could result.

5. To guarantee the safe operation of the monitor, the monitor is provided with various replaceable parts, accessories and consumables. Please use the products provided or designated by the manufacturer.

6. Safety and accuracy are assured only by the device and accessories provided or designated by the manufacturer. If the monitor is connected to other undesignated electrical equipment or devices, safety hazards and/or excessive leakage current may occur.

7. To guarantee the normal and safe operation of the monitor, a preventive check and maintenance should be conducted of the monitor and its parts every 6-12 months (including performance and safety check) to verify that the instrument can be operated safely, properly, and accurately.

Caution: The monitor does not contain any user-serviceable parts. The repair of the instrument must be conducted by technical personnel authorized by the manufacturer.

2.3 Important Notes for Safety

- **Patient Number**

  The monitor can only be applied to one patient at one time.

- **Interference**

Do not use a mobile phone in the vicinity of the monitor. High level of electromagnetic radiation emitted from such devices may result in strong interference with the monitor performance.

- **Protection against ingress of liquid**

To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered the device, take it out of service and have it checked by a service technician before it is used again.

- **Accuracy**

If the accuracy of any value displayed on the monitor or printed on a printout paper is questionable, determine the patient's vital signs by alternative means. Verify that the equipment is working correctly.

- **Alarm**

Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance and correct operation of monitor.

The functions of the alarm system for monitoring the patient must be verified at regular intervals.

- **Before Use**

Before putting the system into operation, please visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately.

Before using the system, the operator must verify that it is in correct working order and operating condition.

Periodically, and whenever the integrity of the product is in doubt, test all functions.

- **Cables**

Route all cables away from patient's throat to avoid possible strangulation.

- **Disposal of package**

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

- **Explosion hazard**

Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.

- **Leakage current test**

When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.

- **Battery**

The device is equipped with a battery. The battery discharges even when the device is not in use. Store the device with a fully charged battery and take out the battery, so that the service life of the battery will not be shortened.

- **Disposal of accessories and device**

Disposable accessories are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

The service life of this monitor is 5 years. At the end of its service life, the monitor, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact manufacturer or its representatives.

- **EMC**

Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason, make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Also, keep mobile phones or other telecommunication equipment away from the monitor.

- **Instruction for use**

For continuous safe use of the monitor, it is necessary that listed instructions were followed. However, instructions listed in this manual in no way can supersede established medical practices concerning patient care.

- **Loss of data**

Should the monitor at any time temporarily lose patient data, close patient observation or alternative monitoring devices should be used until monitor function is restored.

When the AC power supply has been interrupted of the monitor, the monitor can change to use the battery supply power.

When the monitor lost of power and has been powered off, if the monitor does not automatically resume operation within 60s, restart the monitor using the power

switch. Once monitoring is restored, you should verify correct monitoring state and alarm function.

- **Intended for use in conjunction with other medical devices**

The monitor can be used together with high-frequency electrosurgical units and defibrillators.

2.4 Safe Operation Conditions

Methods of sterilization or disinfection recommended by the manufacturer	Sterilization: not applicable Disinfection: Refer to ***Maintenance and Cleaning*** Chapter
Electromagnetic interference	Not in proximity with mobile phones
Electrosurgical interference damage	No damage
Diathermy instruments influence	Displayed values and prints may be disturbed or erroneous during diathermy
Defibrillation shocks	The monitor specifications fulfill the requirements of IEC 60601-1, IEC 60601-2-49

Chapter 3 Operations

3.1 Unpacking and Checking Contents

1. Unpacking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier. If the packing case is intact, open the package.

2. Remove the monitor and accessories carefully.

3. Keep all the packaging materials for future use in transportation or storage.

4. Check the monitor and accessories

Check the monitor and its accessories one by one in accordance with the packing list. Check to see if the parts have any mechanical damages. In case of problems, please contact us or our agent.

Warning:

- **Keep the packing materials out of children's reach. Disposal of the packing materials should observer the applicable waste control regulations.**
- **The monitor might be contaminated during storage and transport. Before use, please verify whether the packages, especially the package of disposable accessories, are intact. In case of any damage, do not apply it to the patient.**

Caution: Please put a monitor onto a horizontal and stable supporting plane. Avoid putting the monitor in the locations where it easily shakes or wobbles. Enough space shall be left around the monitor so as to guarantee normal ventilation.

Warning: Please ensure the monitor is working under specified conditions; otherwise, the technical specifications mentioned in this manual will not be met, thus possibly leading to damage of equipment and other unexpected results.

3.2 Getting Started

3.2.1 Inspecting the Monitor

1. Before you start to make measurements, carry out the following checks on the monitor including all connected modules.

——Check for any mechanical damage;

——Check for any incorrect connection of all the external cables and accessories.

2. Plug the power cord into the AC power source. If you are using battery power, ensure that the battery has sufficient power for monitoring. When you use a battery for the first time, you must charge it, following the instructions given in ***Battery*** chapter.

3.2.2 Starting the Monitor

1. Press the power switch, physiology alarm lamp lights up in yellow, the technical alarm lamp will light up in cyan in turn, and goes out, afterwards the startup screen will display.

2. After the startup screen disappears, the system clanks and enters main screen and meanwhile the technical alarm lamp goes out.

Warning: If the monitor is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient. Contact your service personnel.

Caution:

- **The monitor does not have mains switch. The monitor is switched completely only by unplugging the power cable from the AC power source. Please always make the pulg easily to operate.**
- **For measurements in or near the heart we recommend connecting the monitor to the equipotential grounding system. Use the green/yellow equipotential grounding cable and connect it to the terminal labeled with the symbol**  **.**

3.3 Starting Monitoring

1. Decide what parameters should be monitored or measured.
2. Install required modules or sensors.
3. Check whether the installation of modules or sensors is correct.
4. Check whether all kinds of settings are correct.
5. Start monitoring on a patient. Detailed information refers to the related chapters.

3.4 Shutting off the Monitor

There are two ways to shut off the monitor:

1. Press and hold the power switch for more than 1 second. A message box will appear asking for verification that power down is desired. Press 'Ok' to power down the device.

2. Press the power switch and hold it for 5seconds to turn off the monitor without additional prompts.

3.5 Operation Profiles

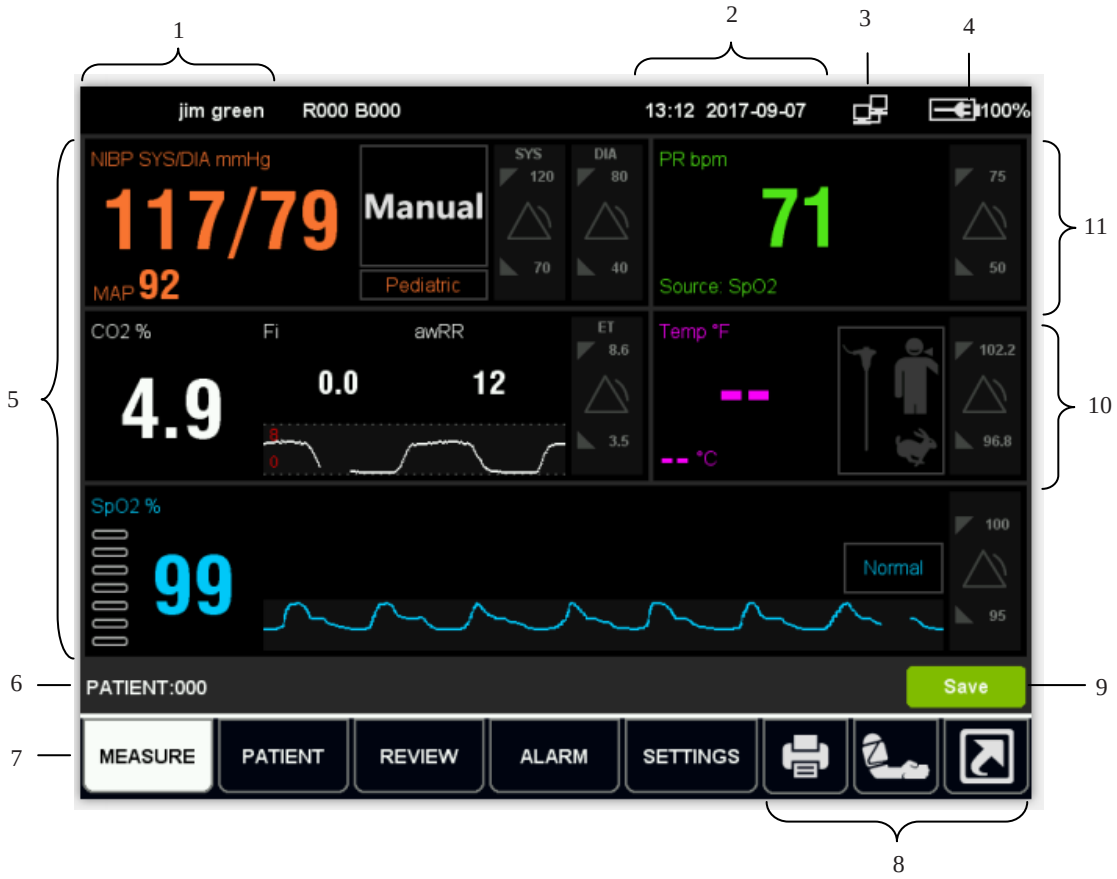
The device has three Operation Profiles for different clinical applications:

- **Monitor Profile:** This profile is designed for monitoring patients over time, and includes physiological and technical alarms.
- **Spot Check Profile:** This profile is designed for taking a single set of vital signs measurements on a patient. Patient information can be entered and managed, and while technical alarms are still available, physiological alarms are disabled. Here is an example of the home screen in Spot Check profile:
- **Triage profile:** This profile is designed for rapidly taking vital signs measurements on many patients. Patient information is disabled, in addition to physiological alarms. Here is an example of the home screen in Triage profile:

  If you want to change the work mode, you can select **【SETTINGS】→【Profile】** to select the work mode you want.

3.6 Screen Display

Measurement numerics, waveforms, patient info, time and date, clinician information, alarm information and menu can be displayed on the screen. Standard screen is shown as follows:



1. **Clinician Information Area**

   a) Displays the clinician's Full Name, Department, and ID.

   b) Press anywhere in this area to open the Clinician Settings. Clinician Settings can also be accessed from the Settings tab: **【SETTING】→【Clinician】**

2. **System Date and Time Area**

   a) Displays the current system date and time.

   b) Press anywhere in this area to enter the Device Settings window where time and date can be set. Time and Date Settings can also be accessed from the Settings tab: **【SETTING】→【Device】→【Time】**.

   c) Press anywhere in this area to enter the brightness adjust menu, you can adjust the brightness of the screen.

   d) Press anywhere in this area to enter the auto standby, you can select **【on】** or **【off】** to set the auto standby.

3. **Network Status Area**

   Display the current network status of the system.

4. **Battery Status Area**

Displays the current charge status of the battery and whether or not the unit is connected to A/C power. See ***Chapter 9*** for more details.

5. **Measurement Display and Alarm Area**

- **Measurement Display Area**

a) Displays information about each vital signs parameter, including measurement values, and upper and lower alarm limits.

b) Pressing on a measurement value will enlarge the information for that parameter. Pressing on the measurement again will shrink it. Pressing on an alarm limit box will enter the Alarm Setting window for that parameter, where the alarm limits can be adjusted. This window can also be accessed from the Alarm tab: **【ALARM】→【NIBP】/ 【PR】/ 【SpO2】/ 【Temp】/【CO2】.**

- **Alarm Message Area**:

Entire area displays alarm messages when physiological and technical alarms are activated. If more than one alarm occurs, the highest level alarm will be displayed. Alarm settings can be changed by pressing the alarm areas in each measurement display window, or from the Alarm tab: **【ALARM】**

6. **Patient Information Area**

Display patient information such as Name, Location, and ID.

7. **Menu Tabs Area**: Used to access and navigate through the device Menu.

a) **MEASURE**: The MEASURE tab is the default Home screen used to display vital sign parameter information.

b) **PATIENT**: Used to enter, modify, and select patient information, review the patient list, and transmit patient information. *NOTE: This tab does not appear in Triage Profile*.

c) **REVIEW**: Used to quickly review and delete historical patient measurement information. *NOTE: This tab does not appear in Triage profile.*

d) **ALARM**: Used to adjust alarm limits for each parameter, change alarm volume settings, and review historical alarms. *NOTE: This tab does not appear in either Spot Check profile or Triage profile.*

e) **SETTINGS**: Used to adjust special settings for each vital sign parameter, enter and manage clinician information, and manage general device settings. General device settings include Date/Time, and selection of Operation Profile.

Advanced settings are also accessed from the SETTINGS tab and include language settings, nurse call settings, and data / network setup and maintenance. *NOTE: A password is required to access Advanced settings*.

8. **Shortcut Icons**: Used to perform specific functions on the device.
   a)  Shortcut key to print ;
   b)  Shortcut key to start/stop NIBP measurement;
   c)  Shortcut key to enter more menu;
   d)  The alarm is suspended.

9. **Save button**

   Press to save the current measurement data for the current patient.

10. **Alarm limits**

3.7 Clinician Management

To enter information for a clinician:

1. Select【**SETTINGS**】→【**Clinician**】to set the clinician【**ID**】,【**First name**】, 【**Last name**】,【**Department**】
2. Select【**SETTINGS**】→【**ADVANCED**】→【**DATA**】→【**Clinician Set**】to choose the clinician information as follows that can be displayed :【**Clinician ID**】, 【**Clinician name**】,【**Clinician Icon**】

Note: * means this item must be input related information, or the settings will not be effective.

3.8 Advance Setup

3.8.1 General Setting

3.8.1.1 Setting the Languages

1. Select【**SETTINGS**】→【**ADVANCED**】→【**Language**】 to access the language list.
2. Select the desired Language and press【**OK**】save the language setting.

3.8.1.2 Setting the Date and Time

- **Setting the current time:**

1. Select【**SETTINGS**】→【**DEVICE**】→【**Settings**】→【**Time**】.
2. Set【**Year**】,【**Month**】,【**Day**】,【**Hour**】,【**Minute**】to the desired value.
3. Select 【**OK**】to save settings.

- **Setting the date/time format:**

1. Select【**SETTINGS**】→【**ADVANCED**】→【**GENERAL**】→【**DATE/TIME**】
2. Set the 【**Date Format**】to **yyyy-mm-dd**, **mm-dd-yyyy** or **dd-mm-yyyy**;
3. Set the 【**Time Zone**】to be **GMT**, **GMT+1**, **GMT+2**, **GMT+3**, etc.

3.8.1.3 Alarm Setup

Select【**SETTINGS**】→【**ADVANCED**】→【**GENERAL**】→【**ALARM**】 to enter the alarm setting. You can set the Alarm control, Minimum alarm volume, Nurse call threshold, Nurse call relay type, Nurse call trigger mode, remind signal interval. For more details about alarm, please refer ***Chapter6 Alarm***.

3.8.1.4 DEMO Modes

1. Select【**SETTINGS**】→【**ADVANCED**】→【**GENERAL**】→【**DEMO**】to select demo type. There are three demo modes to choose from: Monitor profile demo, Spot check profile demo, or Triage profile demo.
2. Select【**Start**】to begin the demo.

3.8.1.5 General Device Options

1. Select【**SETTING**】→【**ADVANCED**】→【**GENERAL**】→【**OPTIONAL**】 to view the list of options available.
2. Choose the desired options.
3. Select 【**OK**】to save settings.

3.8.2 Parameters Settings

1. Select【**SETTING**】→【**ADVANCED**】→【**PARAMETERS**】to enter the parameters setting interface.
2. You can set the following parameters of NIBP, PR, SpO2, Temp and CO2 as below:

- NIBP: Select the default patient type, BP unit, alarm limit status.
- PR: Set the PR source, alarm limit status.
- SpO2: Set the Default response time, Sweep speed and alarm limit status.
- Temp: Set the unit and alarm limit status.
- CO2: Set the Sweep speed, CO2 units, Wave range, ETCO2 Time Period and alarm limit status.

  For more details about parameters setting, please refer ***Chapter 4 Patient Manage.***

3.8.3 Data Options

1. Select【**SETTINGS**】→【**ADVANCED**】→【**DATA**】to choose whether or not the full name or abbreviation is displayed for both the Patient and the Clinician. You can also choose to automatically send clinical information to the EMR when saving manually, and whether or not to delete the displayed readings after the data is sent to the EMR successfully.
2. Select【**OK**】to save settings.

3.8.4 Network Settings

With the network function that supports IHE protocol and connects with the HIS system of hospital to realize data sharing:

- With the PDQ strategy, the patient information of monitor is in synchronism with the HIS system.
- With the PCD strategy, the monitor sends the measuring results of patient to the HIS system.

Note: Data that transmits between the monitor and HIS system use the SSL to encrypt and only provide the certificate by the HIS.

Set the network as following:

1. Select【**SETTINGS**】→【**ADVANCED**】→【**NETWORK**】to set the network to be【**Wired LAN Network**】or【**Wireless WLAN Network**】.
2. Select【**SETTING**】→【**ADVANCED**】→【**NETWORK**】→【**IHE Setting**】, in this interface set the network server to be【**PCD Server**】/【**PDQ Server**】.
3. Select【**OK**】to save settings.

3.8.5 Service settings

1. Select【**SETTINGS**】→【**ADVANCED**】→【**SERVICE**】 to reset factory default settings (not recommended), import and export the configure files by USB, or import configuration settings from a USB drive. In the 【**SERVICE**】 menu, you can also see the device logs and other information about the device.

3.8.6 Other settings

1. Select【**SETTINGS**】→【**ADVANCED**】→【**PARAM**】→【**HT./WT.**】to set the【**Height Unit**】and the【**Weight Unit**】.
2. Select【**OK**】to save settings.

Chapter 4 Patient Management

4.1 Adding a Patient

To add a patient,

1. Select 【**PATIENT**】→【**Add**】. The patient information window will pop up.

2. Enter or select the patient information:

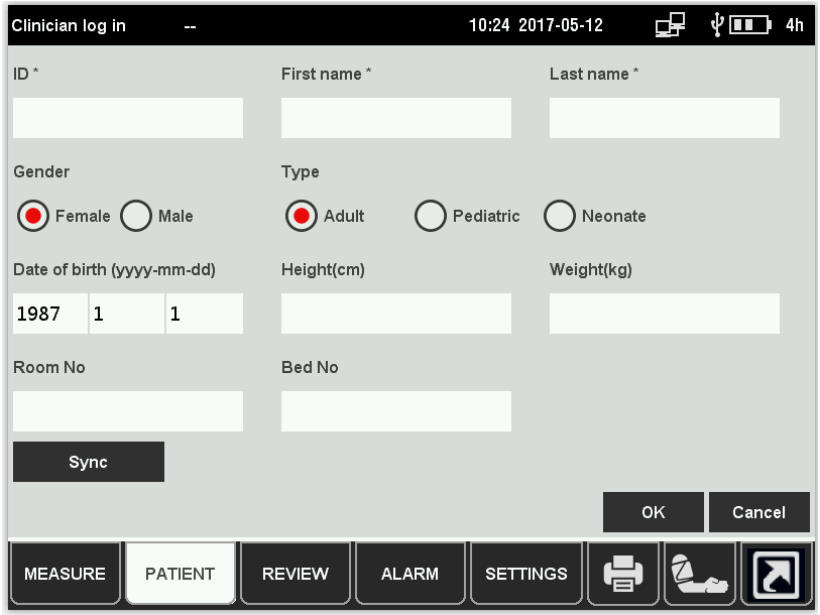


Fig 4-1

——**Patient ID**: The system can automatically produce an ID for the patient. The ID can also be manually entered.

——**First Name**: Enter the patient's first name.

——**Last Name**: Enter the patient's last name (family name).

——**Gender**: Choose 【**Male**】 or 【**Female**】.

——**Patient Type**: Choose the patient category, either【**Adult**】, 【**Pediatric**】 or 【**Neonate**】.

——**Date of birth**: Enter the patient's birthday.

——**Height**: Enter the patient's height.

——**Weight**: Enter the patient's weight.

——**Room No.**: Enter the patient's room number.

——**Bed No.**: Enter the patient's bed number.

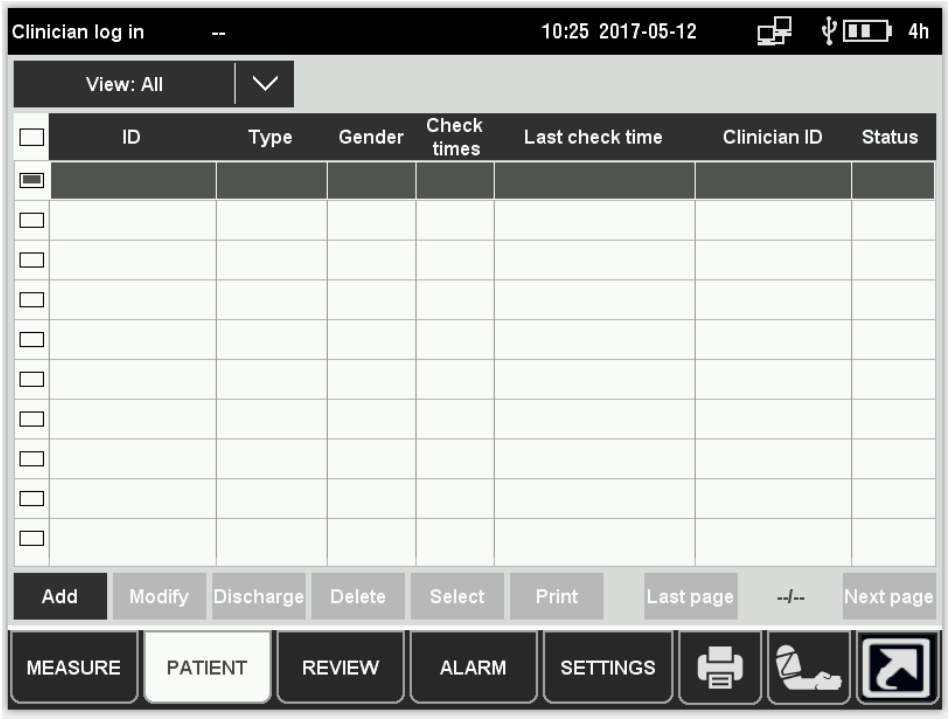
Select 【**OK**】 to add the new patient.

Caution: The patient type determines which measurement algorithms, safety limits, and alarm limits the device will use during operation.

Caution: The number of patients who can be entered depends on the device's storage space.

4.2 Patient Management

When the patient is added, the patient information will automatically populate the patient interface (see the following picture):



And you can conduct any of the following operations:

1. Select **【View All】:**Can view the last 1 day, last 7 days, or all the patients. Even you can choose the keyword search to find the exact one you need.
2. Select **【Modify】:**Select one piece of patient information to modify it（except the patient ID）.
3. Select **【Discharge】:** Can discharge the current patient.
4. Select **【Delete】:** Select one or more pieces of patient information to delete it.
5. Select **【Select】:** Select one piece of patient information. The system automatically will go to the home screen. Monitoring of the selected patient will begin immediately.

6. Select 【**Print**】: Can print the patient information and measurement data about the selected one;
7. Select 【**Last page**】: Can check the patient information of the last page;
8. Select 【**Next page**】: Can check the patient information of the next page.

Caution: Do not attempt to delete or modify that patient that is currently being monitoring.

Chapter 5 Measurement

5.1 SpO2 Measurement

5.1.1 Introduction

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, or SpO_2) adopts the principles of light spectra and volume tracing. The LED emits lights with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.

$$SpO_2\ \% = \frac{\text{Oxygenated hemoglobin}}{\text{Oxyhemoglobin + deoxyhemoglobin}} \times 100\%$$

Wavelengths of the light emitted by the pulse oximeter probe are nominally 660nm for red LED and 940nm for infrared LED. The total optical output power of the sensor LEDs is less than 15 mW.

5.1.2 Safety Information

Warnings:

- **Use only SpO2 sensors specified in this manual. Follow the SpO2 sensor's instructions for use and adhere to all warnings and cautions.**
- **When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's conditions.**
- **Do not use the monitor and the SpO2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.**
- **Prolonged continuous monitoring may increase the risk of unexpected changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.**

- **Check the SpO2 sensor and its package for any sign of damage before use. Do not use the sensor if any damage is detected. Contact the manufacturer.**
- **Use only SpO2 sensors and extension cables approved for use with this monitor. Do not use damaged sensors or cables. Incompatible or damaged sensors or cables could pose patient burn risk.**
- **Do not soak the sensor in water. Avoid contact with moisture to prevent damage.**
- **When disposing of any SpO2 probes, please observe all local, state, and federal regulations that relate to the disposal of this product or similar products.**
- **Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis.**

Caution: If it is necessary to clip the SpO2 device to the patient, always clip the cable, not the sensor itself. Never use force to pull the sensor cable.

Note:

- **During SpO2 measurement, SpO2 wave will show in the SpO2 display area. This wave does not equal the intensity of the PR signal.**
- **The production divergence and drive current of LED influence the range of the peak wavelength of the emitted light by the oxygen probe.**
- **The monitor does not provide automatic self-examination alarm signal. The operator must use a SpO2 simulator for self-test of the device.**
- **Functional test can not be used to assess the accuracy of the monitor.**
- **When the displayed SpO2 or pulse rate value is potentially incorrect, the system will show a "？" in the value position.**

5.1.3 SpO2 Monitoring Procedure

1. Selecting SpO2 Sensor: Select SpO_2 sensor that is appropriate for the patient category, weight and application site.

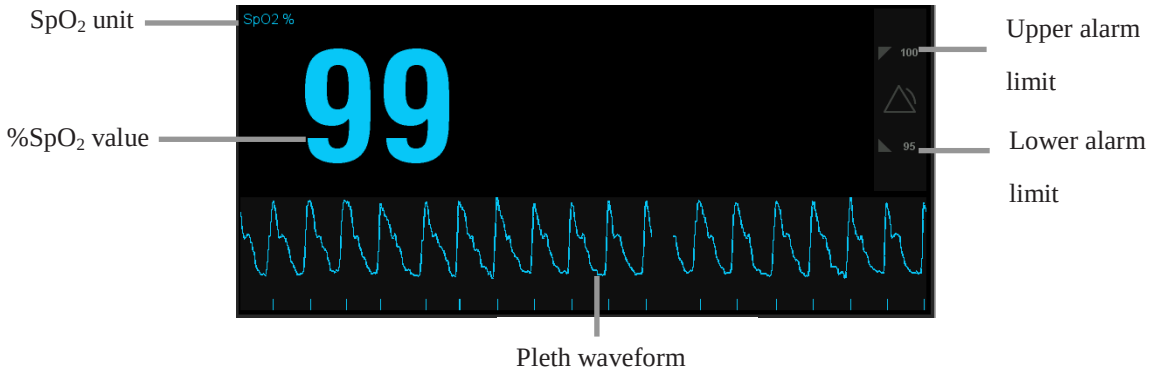
2. Connecting SpO2 Sensor: Plug the SpO_2 sensor cable into the SpO_2 connector on the device. (See device diagram in ***Chapter 1.4***.)

3. Applying SpO2 Sensor: Clean the application site, removing any colored nail polish, and apply the sensor to the patient. Typically, the sensor should be used on the index, middle or ring finger. The fingernail should face the side with the red light.

Warnings:

- **Do not use the SpO2 sensor on the same limb being used for NIBP measurement. This may result in inaccurate SpO2 reading due to blocked blood flow during cuff inflation.**
- **Do not measureSpO2 on a finger painted with nail polish. This may result in unreliable measurements.**
- **When using a finger sensor, make sure the fingernail faces the red light.**
- **If "Weak Signal" is indicated, check the patient's condition and move the probe to another position to try to obtain a better signal.**

5.1.4 SpO2 Display



5.1.5 Setting SpO2

1. Select 【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**SPO2**】→【**Default response**】to choose the response to be【**Normal : 16 seconds**】or【**Fast : 4 seconds**】.
2. Select 【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**SPO2**】→【**Alarm limits status**】 to setup the alarm limits to be【**On**】or【**Off**】.
3. Select 【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**SPO2**】→【**Sweep speed**】 to setup the speed to be【**6.25mm/s**】or【**25 mm/s**】.

5.1.6 SpO2 Measurement Limitations

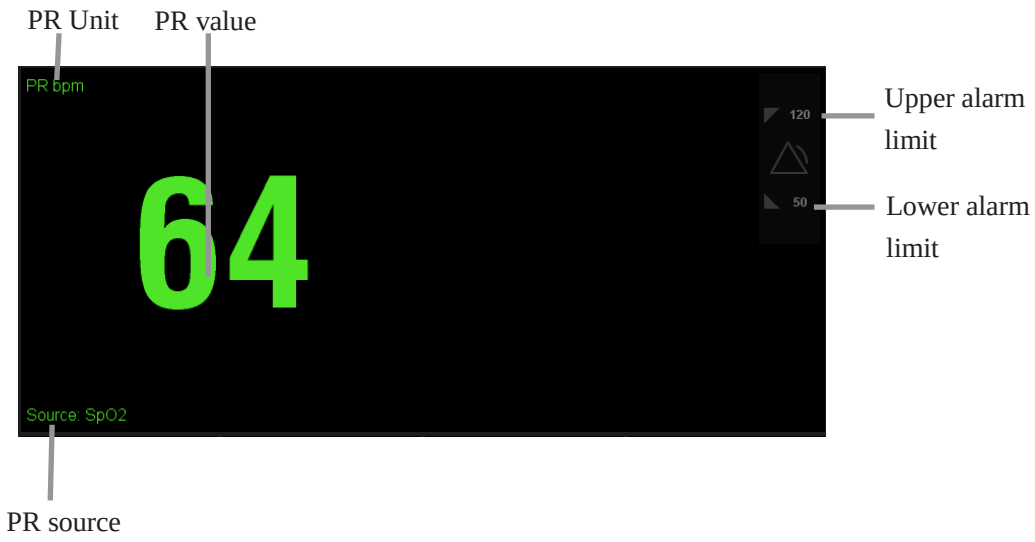
If you doubt the SpO_2 measurements, check the patient and move the probe to a different finger. The following factors may influence the accuracy of measurements:

- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material);
- Electromagnetic interference, such as from an MRI device;
- Excessive patient movement;
- Intravascular dyes such as indocyanine green or methylene blue;
- Significant levels of dysfunctional hemoglobins (such as carboxy hemoglobin or methemoglobin);
- Incorrect sensor application or use;
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line;
- Low perfusion;
- Electrosurgical units.

The monitor can be used during defibrillation, but the readings may be inaccurate for a short time.

5.2 PR Measurement

5.2.1 PR display



5.2.2 Selecting PR Source

Select 【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**PR**】→【**Source**】: SpO_2 or NIBP.

5.3 NIBP Measurement

The monitor uses the oscillometric method for measuring NIBP. It is applicable for adult, pediatric and neonatal patients. It is not applicable for pregnant or pre-eclamptic patients.

The oscillometric method indirectly estimates the systolic and diastolic pressures within the blood vessels by measuring pressure change within the blood pressure cuff. The device senses pressure waves in the artery when occluded by pressure in the cuff and calculates the average pressure.

NIBP measurement is suitable for use during electrosurgery and during the discharge of a cardiac defibrillator according to IEC 80601-2-30.

A physician must determine the clinical significance of the NIBP measurement.

5.3.1 Safety Information

Warnings:

- **Check the patient category before monitoring. Incorrect settings may result in some risk for patient safety. For example, higher alarm-level settings for adults are not suitable for pediatric and neonatal patients.**
- **Do not measure NIBP on patients with sickle-cell disease or any condition in which skin damage has occurred or is expected.**
- **Use clinical judgment to decide whether to perform frequent Auto BP measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
- **Use clinical judgment to decide whether to perform Auto BP measurement on patients with thrombasthemia.**
- **Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.**
- **If you doubt the NIBP measurements, check the patient's vital signs using another device, and then check the monitor.**
- **The NIBP measurement function must be calibrated regularly for safe use.**
- **The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.**

- **Avoid compression or restriction of the connection tubing, or the measurement result will be wrong, which may mislead the doctor to make wrong diagnosis, patient may be hurt.**
- **When the patients can not take care of themselves, there must be an operator stand by during auto mode measurement.**
- **The environmental or operational factors which can affect the performance of the NIBP module and its BP reading :**
  - ✧ **Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.**
  - ✧ **The bladder of the cuff is not folded or twisted.**
  - ✧ **A wrong cuff size, and a folded or twisted bladder, can cause inaccurate measurements**
  - ✧ **Do not wrap the cuff too tightly around the limb.**
- **The continuous cuff pressure due to connection tubing kinking may cause the effect of blood flow interference and resulting harmful injury to the patient.**
- **Do not use the cuff over a wound, as this can cause further injury.**
- **Do not use the NIBP cuff on the arm of a mastectomy patient, we suggest measuring blood pressure on their legs.**
- **Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb.**
- **The application of the cuff and its pressurization on any limb where intravascular access or therapy, or an arterio-venous(A-V) shunt is present, temporary interference to blood flow and could result in injury to the patient.**
- **Check the operation of the automated sphygmomanometer regularly to make sure that it does not result in prolonged impairment of the circulation of the blood of the patient.**

5.3.2 NIBP Measurement Limitations

Accurate NIBP measurements cannot be taken when the heart rate is extremely low (less than 40 bpm) or extremely high (greater than 240 bpm) or if the patient is on a heart-lung machine.

Accurate measurement also cannot be taken when the following conditions exist:

- excessive and continuous patient movement such as shivering or convulsions;

- difficulty detecting a regular arterial pressure pulse;
- cardiac arrhythmias;
- rapid blood pressure changes;
- severe shock or hypothermia that reduces blood flow to the peripheries;
- an edematous extremity.

5.3.3 NIBP Measurement Modes

There are four modes of measuring NIBP:

- **Manual**: a single measurement on demand.
- **Auto:** continuous repeated measurements with a set interval.
- **STAT:** rapid series of measurements over a five-minute period. For use only on supervised patients.
- **Averaging:** a set number of measurements taken and averaged.

Fig 5-1

Note:

- **Averaging measurement mode is intended only for the conscious adults.**

5.3.4 NIBP Monitoring Procedure

5.3.4.1 Preparing to Measure NIBP

1. Encourage the patient to be still and quiet.
2. Check the patient category. If you want to change the patient category, select to enter the 【**Patient Info**】 menu. Select the desired patient category.
3. Select the appropriate cuff according to patient size.

- Check the limb circumference of patient. (Use the upper arm or thigh.)
- Select the appropriate cuff. (The applicable limb circumference for the cuff is marked on the cuff.) The width of the cuff should be about 40% of the limb circumference (50% for neonates), or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle 50% to 80% of the limb.

Note:

- **BP measurement accuracy depends on a properly fitted cuff.**
- **The following steps should be taken to obtain accurate routine resting blood pressure measurements for the condition of hypertension , including:**
  1) Comfortably seated
  2) Legs uncrossed
  3) Feet flat on the floor
  4) Back and arm supported
  5) Middle of the cuff at the level of the right atrium of the heart.
  6) The patient should relax as much as possible and not talk during the measurement procedure.
  7) 5min should elapse before the first reading is taken;
  8) The operator is suggested standing on the right side of the monitor in normal use.

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4. Confirm the cuff has been entirely deflated.
5. Connect one end of the BP cable to the cuff air tube and the other end to the monitor's NIBP connector. Gently push the tip of the BP cable over each socket to click the cable securely in place.

6. Wrap the cuff snugly around the upper arm or thigh of the patient. On the arm, the bottom of the cuff should be approximately 1 inch above the elbow joint. Ensure the Artery Marker "Φ" on the cuff is positioned above artery and that there are no knots in the BP cable. When wrapped around the patient's arm, the Cuff Index Line should fall within the Range Markers ⟺ printed on the cuff. If not, select another cuff size. The monitor is designed for use with standard neonatal, pediatric and adult cuffs (including arm and thigh cuffs).

Note:

- **The cuff should be at heart level to avoid measurement errors. If you cannot position the cuff on a limb at heart level, you may need to make manual adjustments to measurements as follows:**
- **If the limb/cuff position is higher than heart level, the BP reading will be lower. Add 0.75mmHg (0.1kPa) to the measurement result for each centimeter of distance between the limb/cuff and the heart.**
- **If the limb/cuff position is lower than heart level, the BP reading will be higher. Subtract 0.75mmHg (0.1kPa) for each centimeter of distance between the limb/cuff and the heart.**

5.3.4.2 Starting/Stopping Measuring

Press  on the device display to start NIBP measurement. Press  again to stop measurement.

5.3.4.3 Measurement Mode Setting

- **Auto Measurement**
  1. Select【**SETTING**】→【**NIBP Mode**】→【**Long-Term Automatic**】 to start an automatic measurement cycle.
  2. Select【**Minute**】to set the duration of time you want to automatically measure BP. Select a time period from 【**5min**】 to【**240 min**】.
  3. Select  to begin the cycle.

Warning: Prolonged NIBP measurement in Auto Measurement mode can be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. Wshen monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, please stop NIBP measurement immediately.

- **STAT Measurement**

1. Select 【**SETTINGS**】→【**NIBP**】→【**STAT**】 to start a quick measurement cycle. BP measurements will be taken for about 5 minutes.
2. Select  to begin the cycle.

Note: STAT measurement mode will return to manual mode when one STAT measurement is finished.

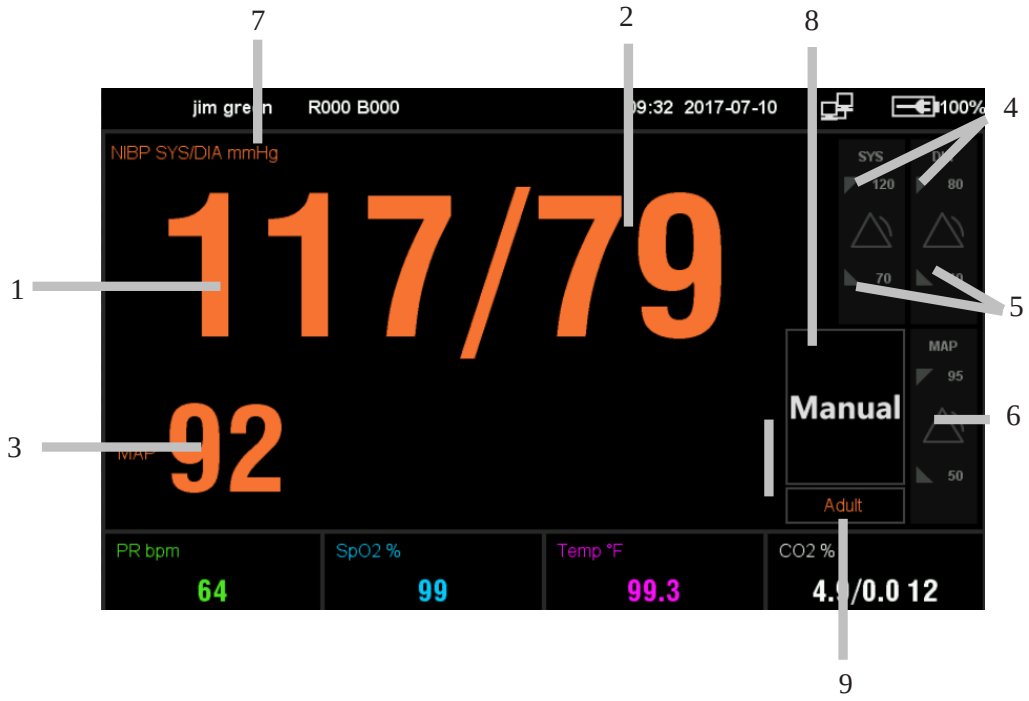
- **Averaging Mode**

1. Select 【**SETTINGS**】→【**NIBP Mode**】→【**Averaging**】 to start an averaging mode measurement cycle.
2. To include the first measurement in the average, check the box beside "Include the first measurement in averaging calculation." If you do not wish to include the first measurement in the average, and the box is checked, touch the check box to uncheck it.
3. Select the total number of measurements to be taken and averaged. Select between 2 and 5 measurements.
4. Select the number of minutes before the first measurement begins. Select between 0 minutes and 5 minutes. If you select 0, measurement will begin immediately after you begin the cycle by touching  . If you select 1, measurement will begin 1 minute after you touch  , etc.
5. Select the number of seconds between each discreet measurement. Select an interval between 15 seconds and 120 seconds.
6. Select OK to apply your settings and then select  to begin the cycle.

Warning: Operator is in continual attendance during the series of determinations.

5.3.5 NIBP Display

There is no waveform displayed for NIBP measurement. NIBP readings are displayed in the BP section of the measurement display. The following figure shows the NIBP display screen. The display on your monitor may look slightly different.



1. Systolic blood pressure
2. Diastolic blood pressure
3. Mean arterial blood pressure
4. Upper alarm limits
5. Lower alarm limits
6. Alarm switch
7. Pressure unit
8. Measurement mode
9. Patient type

Note: In Triage profile, click the patient type area (see the above picture area 9) can change the patient type. In monitor and spot check Profile, the patient type just display in this area.

5.3.6 Setting NIBP

You can setup the NIBP measurement information as follows:

1. Select【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**NIBP**】→【**Default patient type**】 to choose the patient category. Choose either 【**Adult**】, 【**Pediatric**】 or 【**Neonate**】.
2. Select 【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**NIBP**】 to set the 【**Unit**】 to 【**mmHg**】 or 【**kPa**】.

5.3.7 NIBP Maintenance

Maintenance of NIBP should be done every two years and calibrate once, if you need the maintenance, please contact the professionals or the specified personnel of the manufacturer. Please read the ***Service Manual*** for more details.

5.4 CO2 Measurement

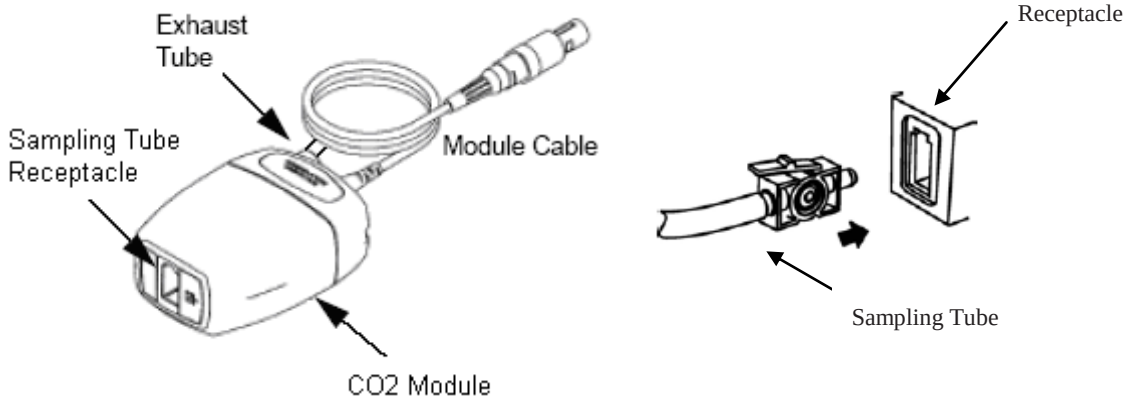
5.4.1 Introduction

The monitor adopts infrared absorption technology to measure the carbon dioxide (CO_2) concentration in the breathing airway of patient. Because CO_2 molecule can absorb infrared light of special wavelength, and the amount of absorbed infrared light directly relates to the concentration of CO_2, therefore while the infrared light radiated from the infrared light source passing through the gas sample containing CO_2, part of energy will be absorbed by CO_2 in the gas. At another side of infrared light source, a photo detector is used to measure the remaining infrared energy and convert it to electric signal, which will be compared with the energy of infrared light source and adjusted so as to correctly reflect the CO_2 concentration in the gas sample.

The method to measure carbon dioxide in the patient's airway for this monitor is microstream. That is taking a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with the CO2 sensor.

5.4.2 Monitoring Procedure

1. Attaching the CO_2Module Cable
   Plug the cable into the CO_2 connector on the monitor.
2. Attaching the Sampling Tube
   Insert the sampling tube into the sampling tube receptacle. Shown as follows:



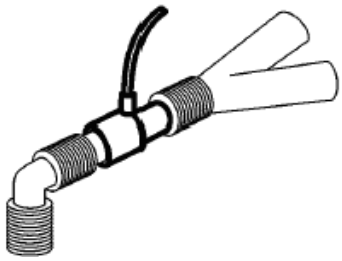
Note:

- **Inserting the sampling tube into the receptacle automatically starts the sampling pump. Removal of the sampling tube turns the sample pump off.**

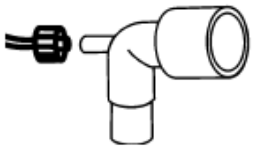
■ **To remove the sampling tube from the sampling tube receptacle, press down on the locking tab and pull the sampling tube from the receptacle.**

3. If the sampling pump fails to turn on, or runs intermittently, perform a "Zero" procedure.
4. Ensure that the CO_2 module exhaust tube vents gases away from the module environment.
5. Wait for the CO_2 module to warm up.The monitor will display the**"**Sensor Warm Up**"**message for approximately 1minute while the module warms up to operating temperature. The message disappears when the module is ready for use.
6. Apply Microstream airway adapter or cannula.

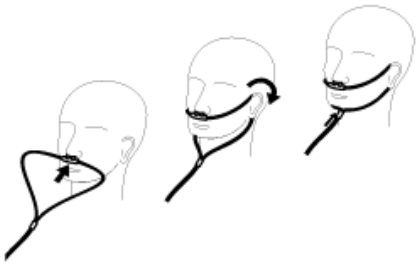
1）For intubated patients requiring an airway adapter: Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y section. Shown as follows:



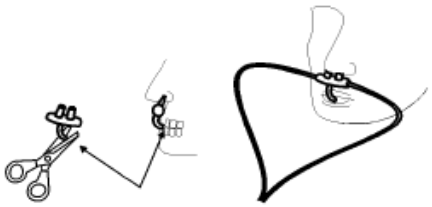
2）For intubated patients with an integrated airway adapter in the breathing circuit: Connect the male connector on the straight sample line to the female port on the airway adapter. Shown as follows:



3）For non-intubated patients: Place the nasal cannula onto the patient. Shown as follows:



4）For patients prone to mouth breathing use an oral-nasal cannula. Trim the oral sampling tip if necessary to fit the patient. It should extend down past the teeth and be positioned in the mouth opening. Remove the cannula from the patient if the tip needs to be trimmed. Shown as follows:



5）For nasal or oral-nasal cannulas with oxygen delivery, place the cannula on the patient as shown then attach the oxygen supply tubing to the oxygen delivery system and set the prescribed oxygen flow.

Caution:

- **Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.**
- **Always disconnect the cannula, airway adapter or sampling tube from the CO2 sensor when not in use.**
- **Do not insert the things other than sampling tube into receptacle of sampling tube.**
- **Only use the CO2 sampling tubes specified by our company.**
- **The sampling tubes are disposable. Please keep the sampling tube clean, and prevent the tube from clogging by dust. It is advised to replace the sampling tube every 12h (up to 120h of use with filter tip), the sampling tube leaks or has been damaged and contaminated.**
- **If the sampling tube is clogging and result in reducing flow, alarms will display in the screen.**

5.4.3 CO_2 Display

1. Unit of CO_2
2. End-tidal CO2 value (EtCO2)
3. CO_2 waveform
4. Inspired minimum CO_2 ($FiCO_2$)
5. Airway respiration rate (awRR)
6. Upper alarm limit
7. Lower alarm limit

5.4.4 Setting CO_2

5.4.4.1 Entering CO_2 Menu

Select **【SETTINGS】→【ADVANCED】→【PARAMETERS】→【CO2】** to enter the CO2 setup menu.

5.4.4.2 Setting Sweep Speed

- **CO_2 Sweep Speed**

1. EnterCO_2 Setup menu.
2. Set **【Sweep Speed】**to**【6.25 mm/s】**,**【12.5 mm/s】**or**【25 mm/s】**.

5.4.4.3 Setting Unit

1. Enter CO2 Setup menu.
2. Set【CO2 **Unit】** to **【mmHg】**, **【kPa】** and**【%】**.

5.4.4.4 Setting Wave Range

1. Enter CO2 Setup menu.
2. Set 【**WaveRange**】 to【**8%**】,【**10%**】, 【**12%**】and【**14%**】.

5.4.4.5 Setting ETCO2 Time Period

1. Enter CO2 Setup menu.
2. Set 【**Setting ETCO2 Time Period**】 to【**One Breathe**】,【**10s**】and 【**20s**】.

5.4.4.6 Setting Alarm Limit Status

1. Enter CO2 Setup menu.
2. Set【**Alarm Limit Status**】to【**on**】or【**off**】.

5.4.4.7 Setting the Atmospheric Pressure

1. Enter CO2 Setup menu.
2. The monitor equipped with automatic barometric pressure compensation, you can set the atmospheric pressure according to different altitude, default atmospheric pressure is 760 mmHg.

5.4.5 Zeroing

Zeroing allows the CO_2 module to adjust to the optical characteristics, in order to obtain accurate readings. While zeroing is recommended the first time a CO_2 module is connected to the monitor, it is only absolutely necessary when the message "Zero Required" is displayed.

Follow these steps:

1. Ensure that the nasal cannula or airway adapter is not connected to the patient or close to any source of CO_2 (including the patient's, your own, exhaled breath and ventilator exhaust valves).
2. Select【**Zero**】in the CO_2 parameter setting menu, this will start zeroing. The monitor zeroes the module and displays the message "Zero In Progress" for about 15-20s on the screen. The message disappears upon completion of the zeroing.

Caution:

- **Always ensure that the sampling tube is properly connected to the microstream CO2 module before zeroing.**
- **Do not attempt zeroing for 20s after removing the adapter or cannula from the patient's airway. This time allows any CO2 remaining in the adapter or cannula to dissipate before zeroing.**
- **Do not attempt to zero the module while the adapter or cannula is in the patient's airway.**
- **Do not attempt zeroing if the temperature is not stable.**
- **Zeroing with CO2 in the adapter or cannula can lead to inaccurate measurements or other error conditions. If you attempt zeroing while CO2 remains in the adapter or cannula, the time required to zero the module may be increased.**

5.4.6 Calibrating

The monitor has been calibrated before leaving factory. You can use the monitor directly except the following three situations. When one of the following situations happens, please calibrate the CO_2 module.

——The CO_2 module has been used for half a year or a whole year.

——The therapeutist doubt about the reading of measurement.

——The atmospheric pressure or height above sea level has changed a lot after last calibrating.

Caution：Please calibrate the monitor under the direction of the technician authorized by manufacturer. Incorrect calibrating process should lead incorrect reading.

5.4.7 Removing Exhaust Gases

Warning: When using the microstream CO2 measurement on patients who are receiving or have recently received anesthetics, connect the

outlet to a scavenging system, or to the anesthesia machine/ventilator, to avoid exposing medical staff to anesthetics.

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the outlet connector of microstreamCO_2 module.

5.4.8 Adverse Effects On Performance

——quantitative effects of gas sample humidity or condensate

——leaks or internal venting of sampled gas;

——cyclical pressure of up to 10 kPa (100 cmH2O);

——other sources of interference.

5.5 Temperature Measurement

5.5.1 Introduction

This monitor is equipped with fast temperature measurement capability. Fast temperature measurement uses a pre-heating mode to reach the patient's body temperature rapidly. It then converts the temperature into electrical signals, which are processed by the monitor and quickly displayed as measurements.

5.5.2 Temperature Monitoring Procedure

1. Select the appropriate measurement sites. Choose between Oral, Axillary or Rectal.

2. Select the measurement mode. Choose between quick, Cold , or Monitor. For Oral site measurement, only Quick or Cold modes are available. For Axillary or Rectal site measurement, all three modes are available.

Note:

- **Quick mode is suitable for patients whose body temperature is expected to be in the normal range of between 96.8 degrees F to 100.4 degrees F(36 degrees C to 38 degrees C).**
- **Cold Preheat mode is suitable for patients whose temperature is expected to be lower than normal (i.e., 91.4 degrees F, or 33 degrees C), such as those coming out of surgery.**
- **Monitor mode is suitable for continuous temperature monitoring. The minimum measuring time of this mode is recommend 60s.**

3. Remove the temp probe rapidly from the probe well on the front of the monitor. This temp probe symbol will begin flashing as a reminder to apply a probe cover.

4. Place the disposable probe cover and position the probe on the patient (see guidance below on proper positioning). The temperature timer symbol will flash while the measurement is completed.

If using Direct mode, real-time measurement data will appear on the screen continuously.

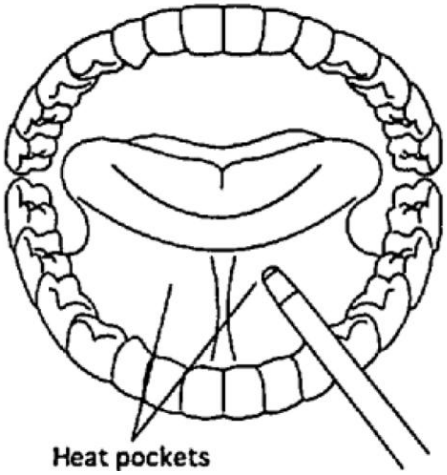
5. When the measurement is completed, this probe symbol will flash as a reminder to eject the used disposable probe cover. Eject the probe cover and insert the probe back into the probe well.

Warnings: If measure without the probe cover, the measurement result may be inaccurate.

Proper Temperature Probe Positioning

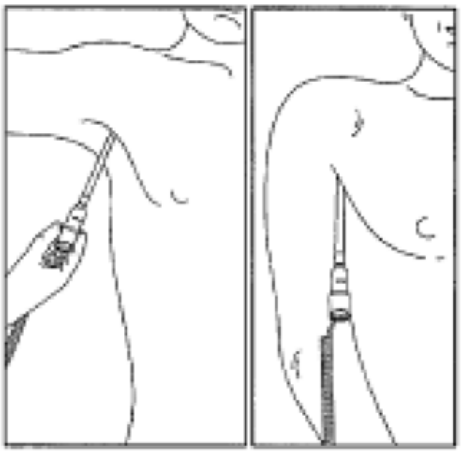
Oral Temperature Taking

Insert the probe tip under the tongue on one side or the other. Ask the patient to close his mouth. Hold the probe in place until there is a long beep and the temperature reading displays.



Axillary Temperature Taking

With the patient's arm uplifted, place the probe tip into the patient's armpit, directly on the skin. Ask the patient to lower his arm and hold still. Hold the probe perpendicular to the arm until there is a long beep and the temperature reading displays.

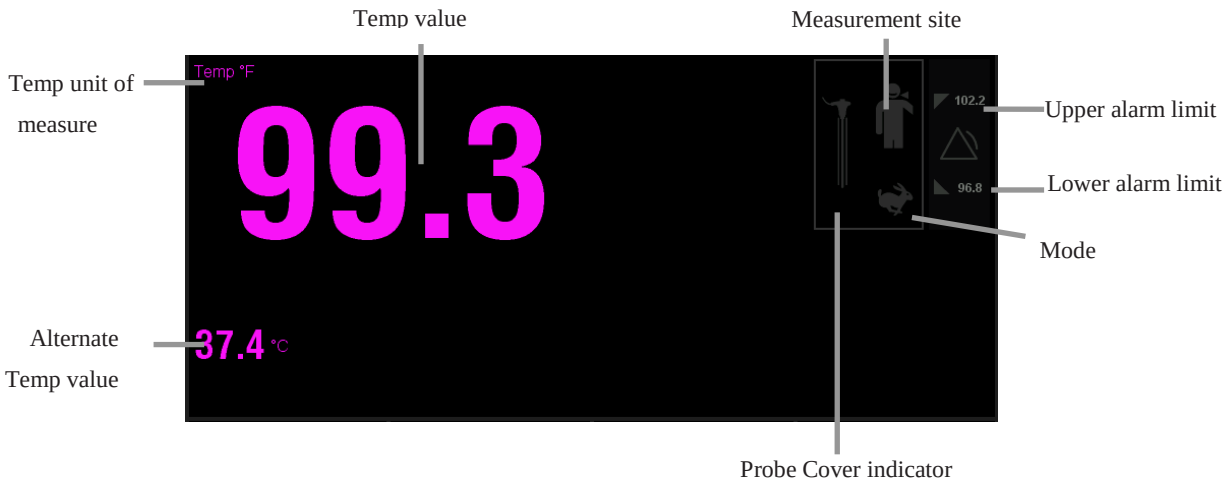


Rectal Temperature Taking

Apply lubricant to the probe cover and insert it gently into the patient's rectum only one-half inch to three-fourth inch (12 mm to 19 mm) for adults or one-fourth to one-half inch (6 mm to 13 mm) for children. Hold the probe still until there is a long beep and the temperature reading displays.

Caution: If the monitor cannot take the temperature in quick temp mode, it will automatically change modes and output the results. The temperature measurement site and mode can only be changed when the probe is stored in its holding receptacle on the monitor. These settings cannot be changed when the probe is out.

5.5.3 Temperature Display



5.5.4 Temperature Settings

1.Select 【SETTINGS】→【ADVANCED】→【PARAMETERS】→【Temp】 to enter the temperature setup menu.

2. Set 【Unit】 to 【Celsius】 or 【Farhenheit】. The selected measurement unit will be effective during the next measurement.

5.5.5 Safety Information

Warning:

- **Calibrate the device's temperature measurement function every six months to one year or according to your facility's regulations.**

- **If the temperature exceeds the measurement range, the alarm will be activated. Check whether the temperature probe is placed on the patient's appropriate site.**
- **Damaged or outdated probes should be repaired or replaced immediately.**
- **The probe cover is intended for single use, it may do harm to patient if re-used it. A new probe cover shall be used for each output temperature measurement.**
- **Use only accessories specified in this manual, incompatible components can result in degraded performance.**

5.6 Nurse Call

The Nurse Call function will send a signal to the nurse call system when a patient's vital signs exceed a pre-set alarm limit. To activate this function, the monitor must be connected to the hospital's nurse call system. Please use the provided the nurse-call connection cable.

The Nurse Call function will only operate under these concurrent conditions:

- The Nurse Call function is active;
- An alarm condition is occurring; and
- Alarms have not been paused or silenced.

To set up Nurse Call:

1. Select【**SETTINGS**】→【**ADVANCED**】→【**GENERAL**】→【**OPTIONAL**】and then【**Enable Nurse Call**】

2. Select【**SETTINGS**】→【**ADVANCED**】→【**GENERAL**】→【**ALARM**】→【**Nurse Call threshold**】to set the alarm level at which the nurse will be called (i.e., low, middle or high).

3. Select【**SETTINGS**】→【**ADVANCED**】→【**GENERAL**】→【**ALARM**】→【**Nurse Call relay type**】 to set the relay type to be【**Normally close**】or【**Normally open**】.

4. Select【**SETTINGS**】→【**ADVANCED**】→【**GENERAL**】→【**ALARM**】→【**Nurse Call trigger mode**】 to set the trigger mode to be 【**continual**】or【**1s pause**】.

5. Select【**SETTINGS**】→【**ADVANCED**】→【**GENERAL**】→【**ALARM**】→【**Remind signal interval**】 to set the interval to be **30, 60, 90 and 120sec**.

Warning: The Nurse Call function should not be used as the primary means of patient monitoring. The care team should evaluate alarms in combination with observations of the patient's symptoms and overall physiological condition.

Chapter 6 Alarms

Alarms are prompts given by the monitor for medical personnel through visual, audible and other means when either a vital sign appears to be abnormal or a technical problem occurs.

Note:

- **The monitor generates all audible and visual alarms through a speaker, LED lights and the display. When the monitor powers on, the alarm LEDs will light once and the speaker will beep, which indicates that the alarm system is working properly.**
- **Alarm settings are saved in real time, once a setting is finished, it has been saved simultaneously. So after a loss of power, the alarm settings prior to the power loss will recover automatically when restart the monitor.**

Warning:

- **Do not set the alarm limits to extreme values that can render the alarm system useless. Vital signs alarm limits are pre-set by the manufacturer, but be sure to choose clinically appropriate limits for the patient. Only when the selected patient's type is different from the last one, the alarm limits will return to factory defaults.**

6.1 Alarm Categories

The monitor's alarms can be classified into three categories: physiologic alarms, technical alarms and prompt messages.

Physiologic alarms: Physiologic alarms are triggered by a monitored parameter value (i.e., the DIA blood pressure value) that violates set alarm limits. Physiologic alarm messages are displayed in the physiologic alarm area.

Technical alarms: Technical alarms are triggered by a device malfunction due to improper operation or system problems. The problems may result in system abnormal operation. Technical alarm messages are displayed in the technical alarm area.

Prompt messages: As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the monitor will show some message to indicate the system status.

6.2 Alarm Levels

The monitor's physiologic alarms are classified into three categories according to the severity of the alarm issue.

High level alarms: Indicate that the patient is in a life-threatening situation and an emergency treatment is necessary. This is the highest level alarm.

Medium level alarms: Indicate that the patient's vital signs appear abnormal and an immediate treatment is required.

Low level alarms: Indicate that the patient's vital signs appear abnormal and an immediate treatment may be required.

The monitor's technical alarms are classified into three categories: high level, medium level and low level. Technical alarm levels are predefined at the factory and can't be changed by users.

6.3 Alarm Indicators

When an alarm occurs, the monitor will indicate it through the following means:

Alarm tone: According to the alarm level, alarm sounds in different tones will emit from the speaker.

Alarm Light: According to the alarm level, the alarm LED light on the monitor will flash in a different color and speed.

Alarm message: Alarm messages will be displayed on the screen.

Flashing numeric: The numeric of parameter in alarm flashes.

Caution: The concrete presentation of each alarm prompt is related to the alarm level.

6.3.1 Alarm Tones

The device will make the following sounds for different level alarms:

Alarm level	Audible prompt
High	"DO-DO-DO------DO-DO, DO-DO-DO------DO-DO"
Medium	"DO-DO-DO"

Low	"DO-"

6.3.2 Alarm Lamp

The device has two alarm lamp, one flashes as red/yellow, the other flashes as cyan.When a physiologic alarm occurs, the alarm levels are indicated in the following visual ways:

Alarm level	Visual prompt
High	Alarm lamp flashes in red at 2 Hz intervals.
Medium	Alarm lamp flashes in yellow with 0.5 Hz intervals.
Low	Alarm lamp lights on in yellow without flashing.

When a technical alarm occurs, the alarm levels are indicated in following visual ways:

Alarm level	Visual prompt
High	Alarm lamp flashes in red at 2 Hz intervals.
Medium	Alarm lamp flashes in yellow with 0.5 Hz intervals.
Low	Alarm lamp lights on in cyan without flashing.

Caution: When multiple alarms of different levels occur at the same time, the monitor will issue visual and audible alarm indicators for the highest-level issues. When the low level alarm of technical alarm and physiologic alarm occur at the same time, the two alarm lamps will be light simultaneously, one flashes yellow, one is cyan.

6.3.3 Alarm Messages

◆ **Physiological alarm**

1) Physiological alarm messages are displayed in the physiological alarm area.

2）The "*" symbol before the alarm message match the alarm level as follows:

High level alarms: ***

Medium level alarms: **

Low level alarms: *

3）The system uses different background colors for the alarm message to match the alarm level:

High level alarms: red

Medium level alarms: yellow

Low level alarms: yellow

◆ **Technical alarm**

1) Technical alarm messages are displayed in the technical alarm area.

2）The "*" symbol before the alarm message match the alarm level as follows:

Medium level alarms: **

Low level alarms: *

3）The background color for the alarm message is blue.

◆ **Prompt messages**

1) Prompt messages are displayed in technical alarm area or the corresponding parameter area.

2) Prompt messages have no color and visual and audible alarm indication.

◆ When multiple alarms occur at the same time, the alarm messages will be displayed in the alarm area in turn.

Caution: If several alarms occur, the highest-level alarm message will be displayed first. The latest alarm message will display first when the alarm level of two alarm message is same .You can manually change the display message in this area to see other alarm message.

6.4 Alarm Icons

 The alarm is off.

 The alarm is active.

 The alarm sound is off.

 The alarm is paused

6.5 Setting Alarm Volume

1. Select【**Alarm**】→【**General**】.

2. Select 【**Alarm Volume**】 and choose a desired value from 【**Low**】,【**Medium**】, 【**High**】;

At the same time , you can select【**SETTINGS**】→【**ADANCED**】→【**General**】 →【**Alarm**】to set the Minimum Alarm Volume to be 【**Low**】,【**Medium**】,【**High**】.

Warning:

- **Auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm conditions and the alarm system.**
- **When adjust the alarm volume, the volume should be louder than the environment noise.**

6.6 Alarm Parameters

All alarm limits are adjustable. When the physical measurement value exceeds the alarm limit value, the alarm will be triggered.

6.6.1 Alarm Switches

To turn alarm limits on or off, select【**SETTINGS**】→【**ADANCED**】→ 【**PARAMETERS**】→【**Alarm limits status**】and then choose the measurement type (i.e., NIBP, PR, SpO2 or Temp). to set the alarm to be【**Alarm limits on**】or 【**Alarm limits off**】. When you select 【**Alarm limits off**】, the symbol  will display in the status bar of the related parameter.

6.6.2 Setting Alarm Limits

1. Select 【**Settings**】→【**Profile**】 and select 【**Monitor**】 to make sure the device is in this profile. This profile must be selected in order to access alarms settings and set alarm limits.

2. From the main measurement display, press anywhere in the Alarm Settings Area to access alarm limit settings. Then you can set the upper and lower alarm limits.

3. The alarm limits can also be set up by selecting 【**Alarm**】 on the main measurement display and then selecting the tab for the alarm limits you wish to set (i.e., alarm limits for NIBP, PR, etc.).

Warning: Medical personnel should set alarm limits based on industry protocols, the clinical environment and their clinical experience. Before monitoring, please confirm whether alarm settings are suitable for the monitored patient.

6.7 Pausing Alarms

Press the button on the front panel of monitor to temporarily suspend all alarm indicators. The suspend time will occur in the status area, after 30s, the alarm suspend will be cancel automatically; or press the button again to exit alarm pause status manually. When you pausing alarms, the following will occur:

- All the physiological alarms will be closed.
- Only alarm messages in the technical alarm area will still be displayed. The lamp and volume of the technical alarm will be closed.
- A 30-second countdown for the alarm pause period will appear at top right in a red bar across the top of the screen.

After the alarm pause time has elapsed, the monitor will automatically cancel the alarm pause and return to normal status. If alarm conditions remain active, alarms will be active. To manually cancel the alarm pause at any time, select .

6.8 Acknowledging Alarms

By selecting on the front panel of the monitor; you can acknowledge active physiological and technical alarms one by one. After you take this action, the following occurs:

- Visual alarms are open, but audible alarms are shut off.
- "Acknowledged" will appear in front of the acknowledged physiologic alarm message.
- Other remaining physiological and technical alarms will remain.

If a new technical or physiological alarm occurs, the acknowledged alarms will not be influenced, and the system will produce audible alarm according to the level of the new alarms.

6.9 Alarm Reset

Press the button on the front panel of the monitor, you can reset all active physiological and technical alarms:

- The auditory alarms are all shut off.
- The visual alarm signals for any existing alarm conditions will continue as long as those alarm conditions exist.
- The technical alarm about lead-off/sensor-off will be deleted.
- After reset the alarms, if a new technical alarm or physiological alarm occurs, the monitor will enable the audible alarm once again.

6.10 Alarm Volume Off and On

Only when the following setting steps are performed, function of the alarm volume off or on can be achieved.

Select **【SETTINGS】→【ADVANCED】**, input the correct password to enter the alarm control interface. In this interface, select **【Allow control alarm audio】**. Then go back to the main interface, select→**【ALARM】** to choose **【Alarm audio on 】**or **【Alarm audio off】.**

Note: After select 【Alarm audio off】, the icon of will occur in the interface.

6.11 Reminder Signal

When active alarm audio on, the alarm system would provide a periodical audible reminder signal sound like "Ding, Ding, Ding". **【 SETTINGS 】→ 【ADVANCED】**, input the correct password to enter the alarm control interface. In this interface, you can select or deselect**【Active reminder signal】** to open or close the reminder signal. You also can adjust the intervals between the reminder signal to be 30s, 60s, 90s, 120s in this interface.

6.12 Resetting Alarm Limit

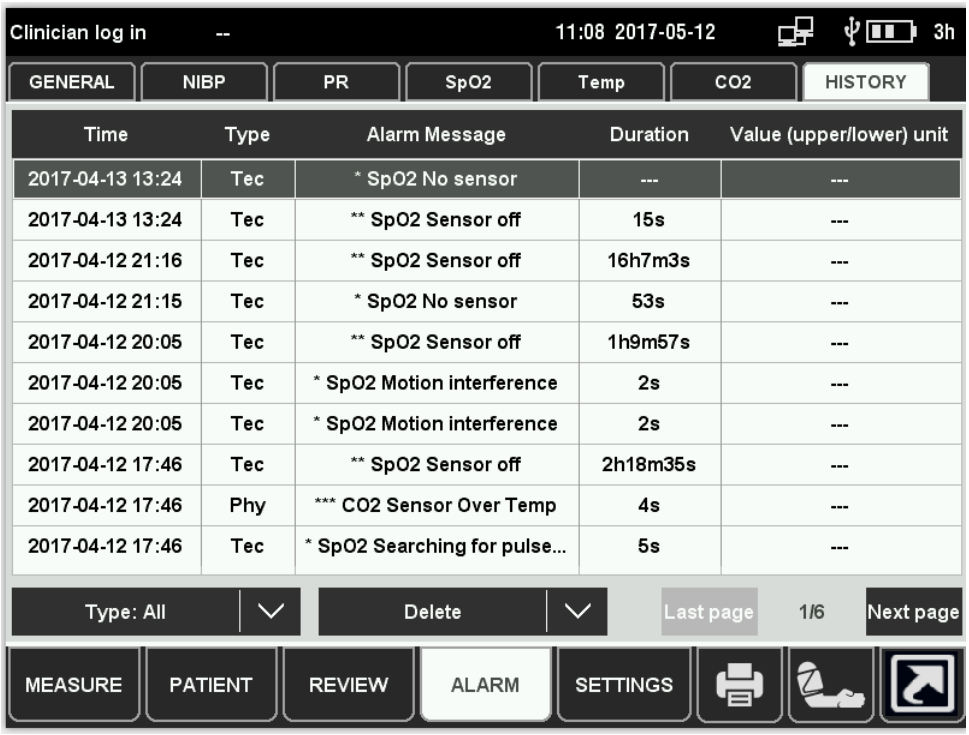
To reset all alarm limits to factory default levels, select 【**Alarm**】→【**General**】→【**Reset alarm limits**】. Limits will be reset to the following defaults:

Parameter			**Upper limit**	**Lower limit**
NIBP (mmHg)	Adult	SYS	160	90
		DIA	150	50
		MAP	110	60
	Pediatric	SYS	120	70
		DIA	70	40
		MAP	90	50
	Neonatal	SYS	90	40
		DIA	60	25
		MAP	70	35
SpO2			100	95
PR			120	50
TEMP（℃）			39	36
CO2	EtCO2		65	26
	FiCO2		4	0
	awRR		30	8

Warnings: A potential hazard can exist if different alarm pre-sets are used for the same or similar equipment in any single area.

6.13 Alarm History

Select the 【**ALARM**】 on main measurement display and then select the 【**HISTORY**】 tab to see all the alarm time, alarm level ,alarm message, alarm duration time and so on as the following picture shows:



Note:

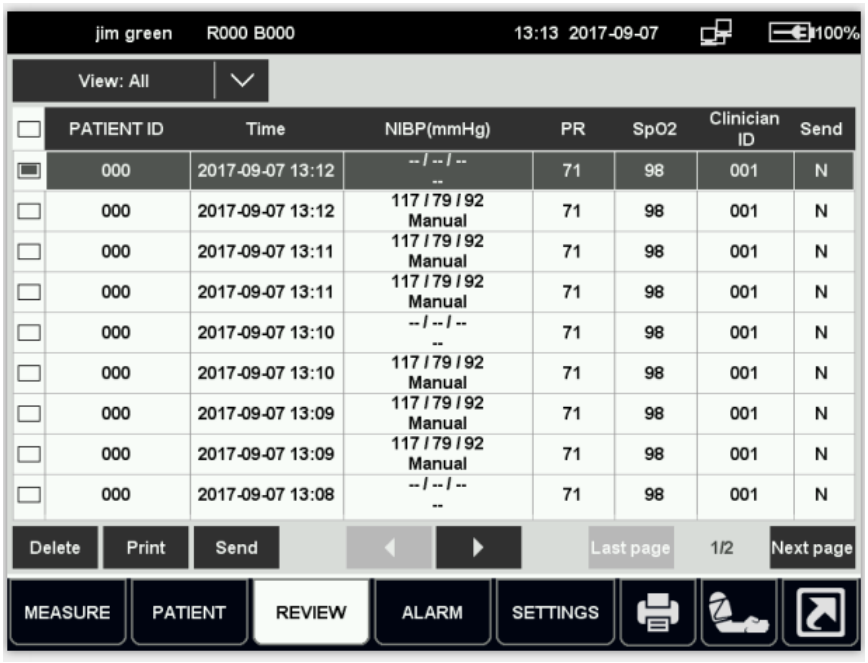
- **The record number of the alarm log depends on the storage space.**
- **The alarm system generates a technical alarm condition when the storage space is insufficient. When the storage space is less than 10M, the low level technical alarm occurs, and prompt information will pop up as "Insufficient storage space"; when the storage space is less than 5M, the other low level technical alarm occurs, and a prompt information will pop up as "Critical shortage of storage space".**
- **When the alarm system is powered down, the log is maintained, but the time of powering down will not be captured in the log.**
- **The contents of the log are maintained after the alarm system has experienced a total loss of power (supply mains and internal electrical power source) for a finite duration.**
- **When the log reaches capacity, the system will automatically delete the earliest log.**

Chapter 7 Reviewing

You can use the Review feature to access any patient information saved by the monitor.

7.1 Reviewing Patient Measurements

Select 【**REVIEW**】 on the home screen to access saved patient measurement data.



7.2 Deleting Patient Data

Select the blank box ☐ to the left of the Patient ID and then select【**Delete**】 to delete the patient's measurement data.

7.3 Print Patient Data

Select the blank box ☐ to the left of the Patient ID and then select 【**Print**】 to print the selected patient's measurement data.

7.4 Send Patient Data

Select the blank box ☐ to the left of the Patient ID and then select 【**Send**】 to send the selected patient's measurement data to the hospital information system (HIS). As soon as the data send to the HIS, there is the symbol 'Y' in the line of "**Send**"

Chapter 8 Battery

8.1 Introduction

The monitor can be fitted with a rechargeable battery to ensure continuous operation in the event of a power outage. The battery requires no special maintenance under normal conditions. While the monitor is connected to an external power source, the battery will charge, regardless of whether the device is turn on. In the case of a sudden power outage, the monitor will automatically switch to battery power without interruption of measurement.

Battery status can be found at the top right corner of the touch screen.

 Indicates the battery is fully charged.

 Indicates the battery is depleted and needs recharging.

 Indicates the battery is recharging.

 Indicates the battery is abnormal.

Battery power lasts for a limited time. When battery power is very low, the monitor will issue a monitor technical alarm. The user should immediately connect the device to a power supply to charge the battery.

Caution: If the monitor is unlikely to be used for an extended time period, remove the batteries prior to shipping or storage.

Warnings:

- **Use only batteries specified in this manual.**
- **Keep the batteries out of children's reach.**
- **Check the battery regularly to guarantee its normal function.**
- **Replace the battery at the end of its service life.**
- **The battery can only be replaced, maintained by professional personnel specified by the manufacturer or the device may not be started up.**

8.2 Installing a Battery

The battery compartment is located on the bottom of the monitor. Follow these steps when installing the batteries.

1. Turn off the monitor and disconnect the power cable and other connected wires and cables.
2. Open the battery door in the direction indicated on the door label.
3. Take out the old battery.
4. Insert the new battery in the direction indicated.
5. Close the battery door.

8.3 Optimizing Battery Performance

A battery needs at least two optimizing cycles when it is put into use for the first time. A battery cycle is one complete, uninterrupted charge of the battery, followed by a complete, uninterrupted discharge of the battery. A battery should be conditioned in this way regularly to maintain its useful life. In addition to initial use, ideal times to condition a battery are when it is used or stored for two months or when its run time becomes noticeably shorter.

To optimize a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the battery in need of optimizing into the battery compartment.
3. Place the monitor in the charger stand and connect it to AC power supply. Allow the battery to charge uninterrupted for at least 6 hours.
4. Disconnect the monitor from the AC power supply and allow the monitor to run on battery power until the battery is depleted and the device shuts off.
5. Return the monitor to the charger stand and connect it to the AC power supply. Allow the battery to charge uninterrupted for at least 6 hours.

8.4 Checking Battery Performance

The performance of a battery may deteriorate over time. To check battery performance, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the monitor in the charger stand and connect it to an AC power supply. Allow the battery to charge uninterrupted for at least 6 hours.

3. Disconnect AC power and allow the monitor to run on battery power until it shuts off.
4. Make note of the monitor operating time on battery power. Operating time is a direct indicator of battery performance. If you notice declining battery operating time span, you may need to run it through an optimizing cycle or replace it.

Caution: Battery operating time depends on the configuration and operation of the monitor. For example, continuous monitoring of NIBP and SpO2 will deplete the battery faster than occasional vital signs spot checks.

8.5 Disposing of Battery

Batteries that are damaged or depleted should be replaced and discarded properly. Dispose of used batteries according to local regulations.

Caution: Battery service life depends on how often the monitor is used and how many features are used. The battery typically can be charged and discharged 300 times.

Warning: Do not disassemble batteries or dispose of them in fire, or cause them to short circuit. They may ignite, explode or leak, causing personal injury.

Chapter 9 Maintenance and Cleaning

9.1 Introduction

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

1. Always dilute cleaners according the manufacturer's lowest-possible concentration.
2. Do not immerse any part of the equipment in liquid.
3. Do not pour liquid onto the equipment or accessories.
4. Do not allow liquid to enter the case.
5. Never use abrasive materials (such as steel wool or silver polish) or erosive cleaners (such as acetone or acetone-based cleaners).

Warning: For optimal performance, product service should be performed only by qualified service personnel.

Note: To ensure equipment performance and safety, the monitor should be evaluated by a qualified service technician after 1 year of use. Contact the device manufacturer to schedule a service appointment.

9.2 Cleaning the Monitor

1. Common detergents and non-corrosive disinfectants commonly used in hospitals can be applied to clean the monitor. Many of these cleaners must be diluted prior to use. Please use them according to the instructions of the detergent manufacturer.
2. Avoid the use of alcohols, amino or acetonyl detergents.
3. The monitor's enclosure casing and touch screen should be kept free of dust. They can be wiped with a lint-free soft cloth or moistened sponge. While cleaning, be careful and do not spill liquid onto the monitor. Be especially careful to keep water and liquid out of all cable outlets and USB ports.
4. Do not use abrasive materials, including wire brushes or metal brighteners, during cleaning. They will damage the panel and monitor screen.
5. Do not submerge the monitor in liquid.

6. If a cable or other attachment accidentally gets wet with cleanser, please rinse it with distilled water or deionized water and dry it at a room temperature 40 degrees C to 80 degrees C for at least one hour.

9.3 Cleaning and Disinfection of Accessories

9.3.1 SpO2 Sensor

Isopropyl alcohol 70% or 10% bleach solution can be used for sterilization. Do not use undiluted bleach (5% ～ 5.25% sodium hypochlorite) or other non-recommended disinfectants to avoid damaging the sensor.

Caution:

- **Do not sterilize the sensor by radiation, steam or ethylene oxide (EtO_2).**
- **Do not directly submerge sensor in liquid.**
- **To avoid long-time harm to sensor, sterilization should only be conducted when necessary according to your facility's regulations.**

9.3.2 NIBP Cuff

a) Please regularly clean the product;
b) Remove cuff from connector and pull out airbag from sheath;
c) Submerge clean and soft medical gauze pad or other soft cleaning tools into fresh water or neutral soapy water, and wring out surplus water from the submerged gauze then wipe airbag and pipe;
d) Wash the cuff sheath in the clean neutral soapy water;
e) After the sheath and airbag intensive drying, enclose airbag with cuff sheath and put into operation.

Caution:

- **Excessive or frequent cleaning may damage cuff.**
- **Do not dry cuff at high temperatures.**
- **If a high level of sterilization is required, please choose a disposable cuff.**
- **Disposable cuff only use by one patient.**
- **Be careful to keep water and cleaning solutions out of the connecting parts of the cuff and monitor.**

9.3.3 Temp probe

Dampen a cloth or sponge with a 10:1 water/bleach mixture or 70% isopropyl alcohol. Use this to wipe the sensor occasionally. During cleaning, shake the probe handle to drain out any excess liquid thoroughly.

Caution: Probe covers are only for single use. Reuse may cause damage and contamination.

9.3.4 CO2 Sensor and Reusable Airway Adapter

- The outside of the module or sensor may be cleaned and disinfected by wiping with 70% isopropyl alcohol, a 10% bleach solution, or mild soap. After cleaning, wipe with a clean, water-dampened cloth to rinse. Dry before use.
- Reusable airway adapters may be cleaned by rinsing in a warm soapy solution, followed by soaking in a liquid disinfectant such as 70% isopropyl alcohol, a 10% bleach solution, Cidex® or System 1® (refer to the disinfectant manufacturer's instructions for use). Adapters should then be rinsed with sterile water and dried.
- Reusable airway adapters may also be pasteurized or autoclaved. Autoclave at 121℃ (250℉) for 20 minutes, unwrapped.
- Before reusing the adapter, ensure the windows are dry and residue-free, and that the adapter has not been damaged during handling or by the cleaning process.

9.4 Maintenance and Replace of the Accessories

The device should be checked and maintained regularly by professional personnel to identify whether it is operating properly. Do not use the device if it is operating abnormally.

Caution: Always unplug the device from the power source before changing any accessories. Service personnel should use caution when repairing broken power cables.

Note: The device's electric schematic and element list should only be supplied to an eligible service center or qualified personnel.

Chapter 10 Accessories

Warning:

- **Use only accessories specified in this manual. Using other accessories may cause damage to the monitor.**
- **Disposable accessories are designed for single-patient use only. Reuse of them may cause a risk of contamination and affect measurement accuracy.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**

10.1 SpO2

- **Nellcor SpO2 sensor**

Type	Model	Patient category
Disposable	MAX-A	Adult finger (patient size>30kg)
	MAX-P	Pediatric foot/hand (patient size 10-50kg)
	MAX-I	Infant foot/hand (patient size 3-20kg)
	MAX-N	Adult finger or neonatal foot/hand (patient size >40 kg or <3 kg)
Reusable	DS-100A	Adult
	OXI-A/N	Adult / neonatal
	OXI-P/I	Pediatric / infant

- **Nellcor SpO2 Extension cable**

Accessories	Model / PN
Extension cable	15-100-0144

- **BLT SpO2 sensor**

Type	Patient category	PN
Reusable	Adult	15-100-0013
	Pediatric	15-100-0014
	Neonatal	15-100-0015

- **SpO_2 Extension cable**

Accessories	PN
Extension cable	15-031-0007

- **Masimo SpO_2 Sensor**

Type	Model / PN	Patient category
Reusable	M-LNCS DCI	Adult finger
	M-LNCS DCIP	Pediatric finger
	M-LNCS YI	Neonatal
Disposable	M-LNCS Neo	Neonatal foot
	M-LNCS Inf	Infant toe

- **Masimo SpO2 Extension cable**

Accessories	Model / PN
Extension cable	15-100-0186

10.2 NIBP

- **Disposable cuffs**

Patient category	Model	Limb circumference (cm)
Neonatal	M5541-1#	3-5.5
	M5541-2#	4-8
	M5541-3#	6-11
	M5541-4#	7-13

- **Reusable cuffs**

Patient category	Model	Limb circumference (cm)
Adult	RNC0001A	27~35
Small adult	RNC0002X	18~26
Pediatric	RNC0003I	13~20
Infant	RNC0004E	13~20
Neonatal	RNC0005N	9~16
Neonatal	M5121	6~11
Pediatric	M5123	18~26
Adult	M5124	25~35
Large adult	M5125	33~47

Adult thigh	M5126	44~53

10.3 CO2 (LoFlo)

Accessories	PN
LoFlo CO_2 sensor	16-100-0016
CO_2 nasal cannula (adult)	15-100-0044
CO_2 nasal cannule (pediatric)	15-100-0048
CO_2 nasal cannule (infant)	15-100-0049

10.4 Temp

F3000 Fast Temp

Accessories	Model
F3000 fast temp probe(Red)	500037
F3000 fast temp probe (blue)	500027
Fast temp probe cover	500500

Appendix A Product Specifications

A.1 Safety Specifications

According to the MDD 93/42/EEC, the monitor is Type Ⅱb equipment.

Classified according to the IEC60601-1 is as follows:

Parts	**Classification of protection against electric shock**	**Degree of protection against electric shock**	**Degree of protection against ingress of liquid**	**Degree of protection against hazards of explosion**	**Mode of operation**
Mainframe	I	No mark	IPX1	Not suitable	Continuous
Temp Module	NA	Type CF applied part defibrillation proof			
NIBP Module					
SpO_2 Module					
CO2 Module		Type BF applied part			

Note:

I: Class I, internally and externally powered equipment.

When you doubt about the protecting earth integrality or protecting earth lead of the equipment, you'd better change the equipment to internally powered equipment..

NA: Not applicable.

CF: Type CF applied part.

BF: Type BF applied part.

Not suitable: Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

A.2 Environmental Specifications

Operating temperature	+5℃ to +40℃
Operating humidity	15% to 85%（non condensing）
Operating atmospheric pressure	700hPa to 1060hPa
Transportation and	-20℃ to +55℃

storage temperature	
Transportation and storage humidity	10% to 93%（non condensing）
Transportation and storage atmospheric pressure	500hPa to 1060hPa

A.3 Physical Specifications

Model	Weight（kg）	Size(W×H×D)(mm)	Remarks
V9	<4kg	308mm ×233mm × 125mm	Including screen, stationary parameter module, a lithium battery, printer, without accessories.

A.4 Power Specifications

Input voltage	100V-240V AC
Frequency	50Hz/60Hz
Earth leakage current	<0.3 mA
Input current	1.5A-0.7A
Standard requirement	According to IEC 60601-1 and IEC 60601-1-2
Fuse	T 2A/250V, integrated in the power module

A.5 Hardware Specifications

A.5.1 Display

Mainframe display	
Type	Color TFT LCD
Size （diagonal）	8 inch
Resolution	800×600 pixels

A.5.2Printer

Model	BTR50

Type	Thermal dot array
Horizontal resolution	16 dots/mm（at25 mm/s paper speed）
Vertical resolution	8 dots/mm
Paper width	48 mm
Paper length	15 m
Recording speed	12.5 mm/s, 25 mm/s, 50 mm/s
Recording waveform	1 track, 2 track
Recording way	Real-time recording, periodic recording, alarm recording

A.5.3 Battery

Type	Rechargeable lithium ion battery
Model	DVAUS-BLT-001
Size	200mm×57mm×24mm
Weight	<360 g
Quantity	1
Rated voltage	10.8 VDC
Capability	6600 mAh
Operating time	Over 10 hours; One new and fully charged battery at 25℃ ambient temperature, using SpO_2, Temp, and NIBP on AUTO mode for 15 minute interval.
Charge time	6h to 100%（Standby）
Turn off delay	5 min -15 min after the low battery alarm first occurs.
Indicator of battery capability	With

A.5.4 Mainframe LED

Physiologic alarm	1 (Yellow/Red)
Technical alarm	1 (Cyan)
Power indication LED	1 (Green/Orange) When supply by AC power, power indication LED

	displays in green at the time power on or power off the monitor. When supply by internal battery, power indication LED displays in orange at the time power on the monitor, there is no LED display when power off.
Battery charging	1 (Orange)

A.5.5 Audio indicating

Speaker	Gives audible alarm(sounds as DO, DO,DO) Supports Pitch Tone(sounds as DE, DE,DE) Alarm tones meet the requirement of IEC 60601-1-8.
Alarm pressure	45 dB to 85 dB. Test distance is 1 meter from the tone.

A.5.6 Input device

Keys	
Key Numbers	1 power button
Touch screen	
Touch screen input	With
Others	
Mouse input	Support
Keyboard input	Support

A.5.7 Connectors

Power	1 x AC power inlet
Wired network	1 x standard RJ45 interfaces.10-100 BASE-TX, IEEE 802.3
USB	2 x standard USB socket (for the connections to peripherals)
Equipotential grounding point	1
Nurse call	1 x RJ11 connector for nurse call

A.5.8 Signal Output

Nurse call output

Drive mode	Relay
Electric specification	≤60W, ≤2A, ≤36VDC, ≤25VAC
Isolated voltage	1500 VAC
Signal type	N.C., N.O.

A.5.9 Data Storage

Patient numbers	＞1000
Parameter measurement event	＞5000 items
alarm event	＞100000items
Log event	＞10000 items

A.6 Measurement Specifications

A.6.1 SpO2

BLT SpO_2

SpO_2	
Measurement technique	BLT SpO_2 technique
Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2% 0% to 69%: unspecified
Update Period	1s
Average time	8s
Recovery time after defibrillation	<5s
PR modulation tone （Pitch Tone）	with
Alarm range	0% to 100%, high/low limit can be adjusted continuously.
PR	
Reference method for	Electronic pulse simulator

the computation of PR accuracy	
Measurement range	20bpm to 250 bpm
Resolution	1 bpm
Accuracy	±1% or ±1 bpm, whichever is the greater
Alarm range	0bpm～300bpm, high/low limit can be adjusted continuously.

Nellcor SpO_2

SpO_2	
Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2%（adult/pediatric） 70% to 100%: ±3%（neonate） 0% to 69%, unspecified
Alarm range	0% to 100%, high/low limit can be adjusted continuously.
Update Period	1s
Recovery time after defibrillation	<5s
PR	
Reference method for the computation of PR accuracy	Electronic pulse simulator
Measurement range	20 bpm to 300 bpm
Accuracy	20 bpm to 250 bpm: ±3 bpm 251 bpm to 300 bpm: unspecified
Resolution	1 bpm
Alarm range	0bpm～300bpm, high/low limit can be adjusted continuously.

Masimo SpO_2

SpO_2	
Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2%（adult/pediatric, non-motion conditions） 70% to 100%: ±3%（neonate, non-motion conditions） 70% to 100%: ±3%（motion conditions） 0% to 69%,unspecified
Average time	2-4s, 4-6s, 8s, 10s, 12s, 14s, 16s
Recovery time after defibrillation	<5s
PR	
Reference method for the computation of PR accuracy	Electronic pulse simulator
Measurement range	25 bpm to 240 bpm
Accuracy	±3 bpm（non-motion conditions） ±5 bpm（motion conditions）
Resolution	1 bpm
PI	
Measurement range	0.05% to 20%

Note 1: The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

A.6.2 NIBP

Standard	IEC 80601-2-30		
Measurement way	Automatic oscillometry		
Measurement kinds	Sys, Dia, Map,PR		
Measurement range	Adult	Sys	30~270 mmHg

（mmHg）		Dia	10~220 mmHg
		Map	20~235 mmHg
	Pediatric	Sys	30~235 mmHg
		Dia	10~220 mmHg
		Map	20~225 mmHg
	Neonatal	Sys	30~135 mmHg
		Dia	10~110 mmHg
		Map	20~125 mmHg
Cuff pressure range	0 mmHg to 300 mmHg		
Resolution	1 mmHg		
Pressure accuracy Static: Clinic:	±3 mmHg Average error: ±5 mmHg, standard deviation: ≤8 mmHg		
Unit	mmHg, kPa		
Automatic pressure zero	Automatic zero after power on.		
Cuff auto deflation	The cuff will deflate automatically when power is off or time of measurement is beyond 120 seconds (90 seconds for neonate) or the cuff pressure is beyond the overpressure protection set by software and hardware.		
Aerate time of cuff	Less than 40s every time (for standard cuff of adult).		
Measurement time	Normally, it is 20s to 45s (depending on HR and moving interference typically)		
Software overpressure protection	Adult: (297±3) mmHg Pediatric: (252±3) mmHg Neonatal: (147±3) mmHg		
Intervals for periodic measurement time	5 min~240min, continuously adjustable.		
Recovery time after defibrillation	<5s		
Alarm range	Sys	0 mmHg to 300 mmHg, high/low limit can be	

		adjusted continuously.
	Dia	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
	Map	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
Alarm Indication	Blinking display of the data and parameters, text prompts, Three levels of alarming: sound-light alarming, alarming with blinked data and parameters, and that with text prompts.	
Work mode	Adult	Single, Cycle, STAT, Averaging
	Pediatric	Single, Cycle, STAT, Averaging
	Neonatal	Single, Cycle
PR		
PR range	40bpm to 240 bpm	
Resolution	1 bpm	
Accuracy	±3 bpm or 3%, whichever is the greater	

A.6.3 CO2

- **LoFlo CO_2 module**

Warm up time	Capnogram displayed in less than 20 s, At an ambient temperature of 25℃, full specifications within 2 minutes.
Measurement range	0% to 19.7 %（0 mmHg to 150 mmHg）
Resolution	0.1% or 1 mmHg
Stability	Accuracy specification will be maintained over a 6 hour period.
Unit	%, mmHg, kPa
Accuracy (760mmHg， temperature is 25℃)	0 mmHg to 40 mmHg, ±2 mmHg 41 mmHg to 70 mmHg, ±5% of reading 71 mmHg to 100 mmHg, ±8% of reading 101 mmHg to 150 mmHg, ±10% of reading (when RR ＞80 rpm, all the range is ±12% of reading) Gas temperature at 25℃
Total time of system	＜3s

response	
Recovery time after defibrillation	＜5s
Sampling frequency and accuracy of gas	Sampling frequency: 50mL/min Accuracy: -7.5mL/min～+15mL/min

- **awRR**

Measurement range	0 rpm~150 rpm
Measurement accuracy	0 rpm～70 rpm: ±1 rpm; 71 rpm～120 rpm: ±2 rpm; 121 rpm～150 rpm: ±3 rpm.
Alarm range and accuracy	Range: 0rpm~150rpm，high/low limit can be adjusted continuously. Accuracy: ±1 rpm

A.6.4 Fast Temp

F3000 Fast Temp

Sensor type	Thermosensitive sensor
Measurement range	30.0°C~43.0°C
Measurement part	Oral, Axillary, Rectal
Measurement modes	Direct mode: Monitor modes Adjusted mode: Quick modes and Cold modes
Unit	℃, ℉
Resolution	0.1℃
Accuracy	Accuracy of Laboratory(Constant temperature water tank): ±0.1 ℃ (±0.2 ℉)
Measurement time	Adjusted mode: Oral 6-10 seconds Axillary Mode10-14 seconds Rectal Mode14-18 seconds Direct Mode (All Sites): 60-120 seconds
Update time	Every 1s
Recovery time after defibrillation	＜5s
Preheat time	About 800ms
Self-checking	Every 3s
Alarm range	30.0~43.0℃, high/low limit can be adjusted continuously.
Alarm indication	Three levels of alarms: sound-light alarms, color change in alarm limits area; and alarms with text prompts.

Appendix B Factory Defaults

This chapter is about factory defaults setup. The user can't change the factory defaults. Qualified personnel must input a password through【**SETTINGS**】→【**ADVANCED**】to change the factory defaults.

B.1 Date /Time

Date /Time general setting	**Factory Defaults**
Date type	yyyy/mm/dd
Time zone	GMT 8

B.2 Alarm

Alarm setup	**Factory defaults**
Minimum alarm volume	Low
Allow control alarm audio	No selection
Active reminder signal	√
Alarm paused time	30s
Nurse call threshold	Low
Nurse call relay type	Normally close
Nurse call trigger mode	Continual
Remind signal interval	30sec

B.3 Optional

Item	**Factory defaults**
Measure SpO2	√
Measure temperature	√
Measure CO2	√
Allow use of USB devices	√
Allow user to select device profile	√
Enable nurse call	√

B.4 PR

PR setup	Factory defaults
Source	SpO2
Alarm limit status	Alarm limits on

B.5 SpO2

SpO2 setup	Factory defaults
SPO2 display	SPO2value
Response time	Normal:16s
Sweep Speed	25mm/s
Alarm limit status	Alarm limits on

B.6 NIBP

NIBP setup	Factory defaults
Default patient type	Adult
Unit	mmHg
Alarm limit status	Alarm limits on

B.7 CO2

CO2 setup	Factory defaults
Sweep Speed	12.5mm/s
Unit	%, mmHg, kPa
Wave range	8%
ETCO2 time period	10s
Alarm limit status	Alarm limits on

B.8 Temp

Temp setup	Factory defaults
Unit	℃
Alarm limit status	Alarm limits on

B.9 Other

Other setup	Factory defaults
Height U/M	Cm
Weight U/M	kg

B.10 Data

Data setup	Factory defaults
Patient name format	Patient ID
Clinician name format	Full name
Automatically send data to EMR on manual save	√
Delete measurement data after successful send	√
Clinician info display	Clinician name

B.11Network

Network setup	Factory defaults
Network type	Wired LAN network

Appendix C Alarm Messages

The alarm levels are as follows:

Physiological alarm	**Alarm level**
SpO_2 lower alarm limit exceeded	High
NIBP SYS high /low	Medium
NIBP DIA high /low	Medium
NIBP MAP high /low	Medium
PR high /low	Medium
SpO_2high /low	High
TEMP high /low	Low
Search timeout	High
$EtCO_2$ high/ low	Medium, User can select Medium or High
$FiCO_2$ high	
CO_2Apnea	High

Technical alarm	**Alarm level**
Battery Low	High
NIBP	
Self-Test Error	Low
System Failure	Low
Loose Cuff	Low
Air Leak	Low
Air Pressure Error	Low
Weak Signal	Low
Range Exceeded	Low
Excessive Motion	Low
Overpressure Detected	Low
Signal Saturated	Low
Time Out	Low
Cuff Type Error	Low
Zero Calibration Error	Low
Calibration Failure	Low

Hardware overpressure: Zero Calibration Error	Low
Hardware overpressure: Calibration Failure	Low
SpO_2	
Sensor off	Medium
SpO2 Searching for pulse...	Low
TEMP	
Upper alarm limit exceeded	Low
Lower alarm limit exceeded	Low
TEMP Module Failure	Low
CO2	
CO_2 sensor off	Low
Check airway adapter	Low
CO_2 measurement over range	Low
CO_2 sensor error	Low
CO_2 communication error	Medium
Sensor Over Temp	Low
Check CO_2 Sampling Line	Low
Zero Required	Low
Sensor no initialized	Low

All the alarm levels including physiologic alarms and technical alarms can not be changed by users.

Appendix D Guidance and Manufacturer's Declaration of EMC

Guidance and manufacturer's declaration – electromagnetic emissions

-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

–for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV 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	±0.5kV, ±1 kV line(s) to lines ±0.5kV, ±1 kV, ±2 kV line(s) to earth	±0.5kV, ±1 kV line(s) to lines ±0.5kV, ±1 kV, ±2 kV line(s) to earth	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 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 cycles	0 % UT; 0.5 cycle 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 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

–for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of monitor should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V
0.15 MHz to 80 MHz

6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz</td><td>3 V
0.15 MHz to 80 MHz

6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of V9, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ 150 KHz to 80 MHz
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 80 MHz to 2.7 GHz
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).
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.
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>10V/m
80 MHz to 2.7 GHz</td><td>10V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones</td></tr>
</table>

and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor

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

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

Recommended separation distances between portable and mobile RF communications equipment and the monitor			
The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be 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.			

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

declaration - IMMUNITY to proximity fields from RF wireless communications equipment						
The monitor is intended for use in an electromagnetic environment in which RF wireless communications equipment are controlled.						
Immunity test	IEC60601 test level				Compliance level	Electromagnetic environment - guidance
	Test frequency	Modulation	Maximum power	Immunity level		
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m	
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m	
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m	
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
Note * - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.						

Warning:

- **This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. This unit can be affected by portable and mobile RF communications equipment.**

- **Do not use a mobile phone or other devices that emit electromagnetic fields near the unit. This may result in incorrect operation of the unit.**

Caution:

- **This unit has been thoroughly tested and inspected to assure proper performance and operation.**
- **This machine should not be used adjacent to or stacked with other equipment. If such positioning is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.**

Appendix E Troubleshooting

E.1Normal Trouble

Possible Trouble	Possible Reason	Trouble Shooting
Startup failure	1. The device is not turned on 2.External power supply failure 3. No battery or the power wire is not connected 4.The battery charge is not strong enough to power the device	1. Open the device 2. Make sure the external power supply system works normally. 3.Connect the power wire or install the battery 4.Connect the device to AC power supply, recharge the battery
Blank screen	1.The device is not turned on 2.The device is in standby mode	1.Turn on the device 2.Press any button on the device to illuminate the screen
Printer doesn't work	1.The paper is not loaded 2. The printer door is not fully closed. 3. The printer is too hot.	1.Load paper according to the user's manual 2. Ensure the printer door is fully closed. 3. Start the operation again after the printer as a chance to cool.
Printer paper does not fit	1.Specified paper is not used 2. The paper is installed improperly. 3. Software failure	1.Use the correct paper 2. Install the paper according to the user's manual or product diagram. 3.Turn off the device then start it again
Printer paper jam	1. Specified paper is not used 2. The paper is installed	1. Use the correct paper 2. Install the paper according to the user's manual or product

Possible Trouble	Possible Reason	Trouble Shooting
	improperly	diagram..
The scanner doesn't work	1. The scanner is not connected to the device or they have poor contact. 2. Scanner breakdown	1. Connect the scanner to the main USB port. Ensure the connection is secure. 2.Change the scanner to one that functions properly
The device automatically shutdown	The battery charge is not strong enough to power the device.	Connect the device to AC power supply to recharge the battery.

E.2Prompt Information

Prompt Information	Possible Reason
Printer Out of Paper	Printer paper is not installed or paper is used up
Battery Low	Medium level alarm means the battery life is less than 30min; high level alarm means the battery life is less than 5min.
DEMO	The system is in demonstration mode.
Insufficient storage space	The space of the storage medium is less than 10MB
Critical shortage of storage space	The space of the storage medium is less than 5MB
There are too many log entries.	Over 5000 items have been logged.
Critical shortage of space for log entries.	Over 7000 items have been logged.
SpO2 Sensor off	The SPO2 sensor is off from the finger or it is not placed rightly.
SpO2 No sensor	There is no SPO2 sensor on the device.
SpO2 Searching for pulse...	The SPO2 module is searching for pulse

Prompt Information	Possible Reason
SpO2 Replace Cable	The cable of the Masimo SPO2 module must be changed
SpO2IncompatibleCable	The cable of the Masimo SPO2 module is incompatible
SpO2 Unrecognized Cable	The cable of the Masimo SPO2 module can't be recognized
SpO2 No Sensor	The sensor of the Masimo SPO2 module can't be detected
SpO2 Invalid Sensor	Thesensor of the Masimo SPO2 module is invalid
SpO2 Replace Sensor	The sensor of the Masimo SPO2 module needs to be changed
SpO2 Calibrate Sensor	The Masimo SPO2 module is calibrating
SpO2 Motion Interference	The patient's fingeris moving toomuch during SPO2 measurement
SpO2 Low perfusion	The signal of the patient's finger is too low during SPO2 measurement
NIBP Cuff Type Error	The cuff type is wrong
NIBP Air Leak Or Loose Cuff	An internal valve, air hose, or the cuff is leaking air. The cuff is not wrapped properly around the patient's limb. An adult cuff is used in neonate mode
NIBP Air Pressure Error	The system can't maintain a stable air pressure.
NIBP Weak Signal	The cuff is wrapped too loosely, leading to a low patient signal. The pulse of the patient is very weak.
NIBP Range Exceeded	The NIBP value exceeds the measurement range (275mmHg)
NIBP Excessive Motion	The patient is moving too much. The signal noise is too loud when use deflation to detect the patient's pulse pressure. The patient's pulse is random.
NIBP Overpressure	There is too much cuff pressure. Pressure exceeds the set

Prompt Information	Possible Reason
Detected	safe range (adult mode is 325mmHg，neonate mode is 165mmHg)
NIBP Signal Saturated	Too much patient movement has impacted the NIBP signal amplifier.
NIBP Time Out	The time exceeds 120s in adult mode; The time exceeds 90s in neonate mode;
TEMP No Probe	The fast temp probe is not connected.
TEMP too high/ too low	The temp value exceeds the measurement range

Product name: Patient Monitor

Product model:V9

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