

# **Multi-parameter Patient Monitor**

## **Elegant-3000**

# ***User Manual***

*Version: 2.0*

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**North-Vision Tech. Inc.**



This Manual is written and compiled in accordance with the IEC 60601-1 (Medical electrical equipment Part1: General requirements for safety) . It complies with both international and enterprise standards and is also approved by the Food and Drug Administration, Ministry of Health and Welfare. The Manual is written for the current Elegant-3000 Multi-parameter Patient Monitor.

The Manual describes, in accordance with the Elegant-3000 Multi-parameter Patient Monitor's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

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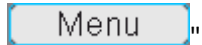
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### Terms used in this User Manual:

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

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

"Button": The operable icon on device screen, which can act as a key function while focused, such as "



"Shortcut Key"(Key): The hard key on device panel for realizing certain function, such as  ".

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

"SpO<sub>2</sub>": Oxygen saturation.

"SpO<sub>2</sub> event": Oxygen desaturation event.

Plugin module: Plug-and-Play module.

Touchscreen operation and key operation are available. Please perform touch screen calibration before starting touchscreen operation.

Notes:

1. The password for system setting is **mnbb**, which will be used when requiring, we will not cover it again.
2. This patient monitor can be customized with different functional modules, therefore, the monitor you purchased may not cover all operation description.

### Caution:

**Federal law restricts this device to sale by or on the order of a physician.**

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# Chapter 1 Safety

## 1.1 Safety Information

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

-  **Warning:** indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.
-  **Caution:** indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
-  **Note:** provides application tips or other useful information to ensure that you get the most from your product.

### 1.1.1 Warnings

-  A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
-  This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
-  Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
-  **WARNING for PACEMAKER PATIENTS:** Although the pacemaker pulse inhibition function is available in this device, the heart rate meter may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.
-  Disconnect the monitor and sensors from the patient before MRI scanning. Using them during MRI could cause burns or adversely affect the MRI image or the monitor's accuracy.
-  If uncertain about the accuracy of any measurement, firstly check the patient's vital signs by any alternative means, and then make sure the monitor is functioning properly.
-  The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
-  Monitor a single person at a time.
-  The monitor is defibrillation-proof. Verify that the accessories can function safely and normally and the monitor is grounded properly before conducting defibrillation.
-  The monitor is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
-  Each time the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.
-  The alarm limit value shall be within the measuring range, or it may disable the alarm system. Please refer to the related chapter for alarm limit range.

- A HAZARD can exist if different alarm presets are used for the same or similar device in a single area.
- Do not silence the audible alarm if patient safety may be compromised.

- The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.
- All the connecting cables and tubes of the applying parts should be kept away from the patient's neck to prevent any possible suffocation of the patient.
- To prevent the risk of the short circuit and to ensure the ECG signal quality, the device must be properly grounded.
- The device should be considered an early warning device as a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition.
- Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.
- Please peruse the relative content about the clinical restrictions and contraindication.
- It is recommended that the clinical operator regularly test the device and accessories. The visual and auditory alarm signal can be checked by disconnect accessories or by setting it at Demo mode to simulate alarm event.
- Do not allow service or maintenance on the device whilst being used on a patient.

### 1.1.2 Cautions


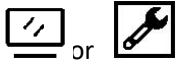




















- 🔔 All the parts of the monitor should NOT be replaced at will, substitution of a component different from that supplied by the manufacturer might result in measurement error. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety, EMC and biocompatibility etc. may be caused. No modification of this device is allowed.
- 🔔 The accessories which can be used repeatedly should be cleaned thoroughly before use on another patient. Please refer to the related chapter for maintenance method.
- 🔔 If the monitor falls off accidentally, please do NOT operate it before its safety and technical indexes have been tested minutely and positive testing results obtained.
- 🔔 Do not immerse the monitor or its accessories in liquid to clean.
- 🔔 The system might not meet its performance specifications if stored or used outside the manufacturer's specified temperature and humidity ranges.






### 1.1.3 Notes

- 👉 All combinations of equipment must be in compliance with the standard IEC 60601-1.
- 👉 The NIBP module of the device was clinically investigated according to the requirements of ISO 81060-2:2013.
- 👉 Please do not position the device so that it is difficult to connect the plug of the power cord.
- 👉 After the life cycle of the monitor and its accessories has been met, disposal should be accomplished following national and/or local requirements.
- 👉 If the user requests more information such as circuit diagrams, parts list and product descriptions, for repairs carried out by qualified technical personnel, please contact us.






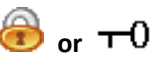






## 1.2 Equipment Symbols








### 1.2.1 Symbol/Icon on the Device

Item	Symbol/Icon	Description
1		Power switch
2		View setting key
3		Alarm reset key
4		Alarm off
5		Freeze/ Unfreeze key
6		Start/Cancel NIBP measurement
7		Print
8		Display view key
9		AC power indicator
10		Working power supply indicator
11		Type CF applied parts with defibrillation-proof
12		Warning --- refer to User Manual
13		Type BF applied parts with defibrillation-proof
14		Equipotential grounding terminal
15	SN	Serial number
16		Battery cover
17		USB connector
18		Network interface
19		Nurse call connector
20		VGA output (optional)
21		Serial port (reserved for future use)
22		ECG Sync output (reserved for future use)
23		Manufacturing date

24		Manufacturer
25	 (optional)	Alarm silence key
26		The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it.
27		This mark means that this device is fully in conformance with the Council Directive Concerning Medical Devices 93/42/EEC.
28		Authorized representative in the European Community





### 1.2.2 Icons List on the Screen

Icon/info.	Description
00000000	Patient ID
	Patient type, there are "Adult", "Pediatric" and "Neonate" for optional
	Arrhythmia symbol (indicates learning or analysis stage for ARR detection)
	Alarm sound is mute/off (only available for the device optioned with "Spot-check Mode")
	Alarm activating status icon/Alarm reset icon
	If the alarm function is disabled for one/some parameter, this icon appear(s) on the corresponding parameter panel(s)
	Keyboard locks up
	Waveform frozen symbol
	Cross cursor for S-T segment measurement
	Heart-beat symbol
	Breath symbol
	AC Power supply and the battery is fully charged.
	The red blinking exclamation mark means battery will run out soon and needs to be charged. Alarm information area will show "Low Battery" message.

	Charging status
	One / two / full grid battery voltage left
	Printer ready. Paper moving means device is printing.
	Printer error. Caused by no paper, uncovered, over-heat and etc.
	Pulse beeper is on
	Pulse beeper is off
	Network connected / disconnected/ established link to remote server (CMS or HL7 client)
S-T +.....	The measured S-T segment level
PI%	Perfusion index percentage
%SpO <sub>2</sub>	Unit of SpO <sub>2</sub> in percentage
mmHg/kPa	Unit of blood pressure
bpm	Unit of heart rate or pulse rate
rpm	Unit of respiration rate
°C/°F	Unit of temperature
mm/s	Unit of waveform sweeping speed

NOTE: some symbols may not appear on your equipment

### 1.2.3 Icons on the Package

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

# Chapter 2 The Basics

## 2.1 Monitor Description

### 2.1.1 Product Name and Model

Product name: Patient Monitor

Product Model: See Label in page I

### 2.1.2 Intended Use and clinical benefit

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult, pediatric and neonate patients. With the functions of real-time recording and displaying parameters, such as ECG, heart rate (HR), non-invasive blood pressure (NIBP), functional oxygen saturation (SpO<sub>2</sub>), respiration (RESP), body temperature (TEMP) and so on, it allows comprehensive analysis of patient's physiological conditions that would be benefit to the patients and doctors.

Note: This patient monitor can be configured with different parameters, the monitor you purchase may not cover all functions described above.

- This instrument is applicable for use in hospitals and clinical institutions. The operation should be performed by qualified professionals or under their guidance. Anyone unauthorized or untrained must not perform any operation on it.
- The physiological waveforms and parameters and the alarm information displayed by the monitor are only for the reference of operators, but cannot be used directly to determine the clinical treatment.

Contraindication: please see each section.

### 2.1.3 Features

This patient monitor can be used to monitor patient's physiological parameters including ECG, heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SpO<sub>2</sub>), Pulse rate (PR), respiration, temperature and so on. It has the following features:

- ✧ Windows style display view, easy to operate;
- ✧ Patient archive management is available;
- ✧ Oxygenation calculation, Ventilation calculation and Renal function calculation is available;
- ✧ Multiple display views are available, which can be easily shifted for different monitoring purpose;



- ✧ Waveform freezing is available with functions of S-T segment measurement and arrhythmia analysis;
- ✧ The compact database can manage the history records effectively;
- ✧ Visual and audible alarm with multiple priority of levels for physiological and technical alarms;
- ✧ Multilingual display for optional;
- ✧ Large capacity storage:
  - Up to 2000 hours of trend data,
  - Up to 12000 groups of NIBP records;
  - 2000 groups of oxygen-desaturation events;
  - 2000 groups of alarm events;
  - Up to 140 hours of ECG waveform;
  - 2000 groups of ARR event data,
- ✧ Touchscreen operation and key operation are available;
- ✧ Protection against defibrillator discharge, resistance against the interference from electro-surgical unit; Cardiac pacemaker pulse detection and inhibition;
- ✧ 12-leads ECG function can be configured for full ECG information (optional);
- ✧ Network capability for central monitoring;
- ✧ Capable to export data to CIS/HIS by HL7 protocol;
- ✧ USB data export function is available (only to the patient monitor with plugin module or extended module)

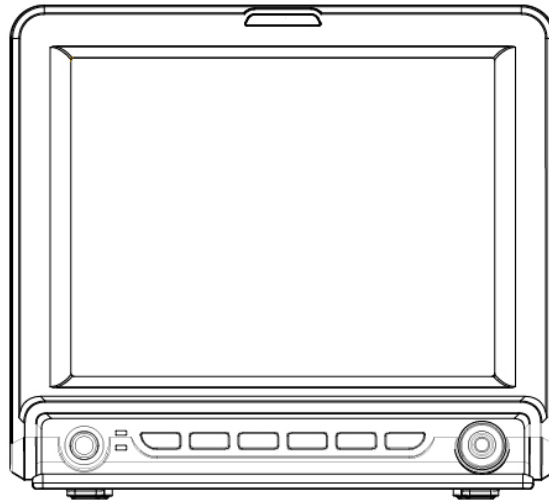
Note: This patient monitor can be configured with different parameters, the monitor you purchase may not cover all functions described above.

## 2.2 Main Unit

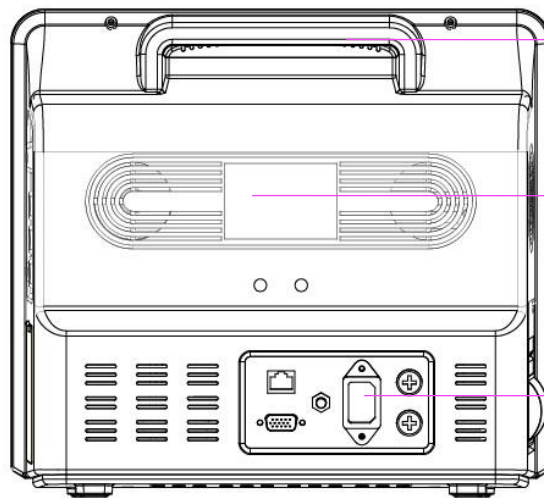
We provide 4 series of monitors for options, and the following figures are for illustration only, please refer to the corresponding figure for the monitor you've purchased.

### ✧ Series I:

11



Front view

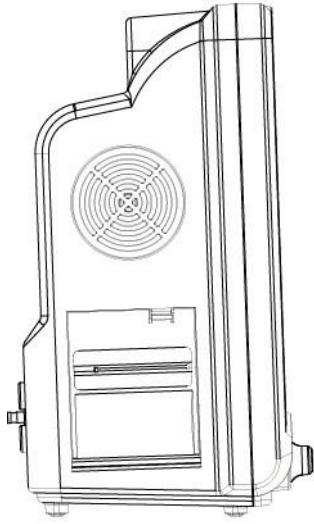


Handle

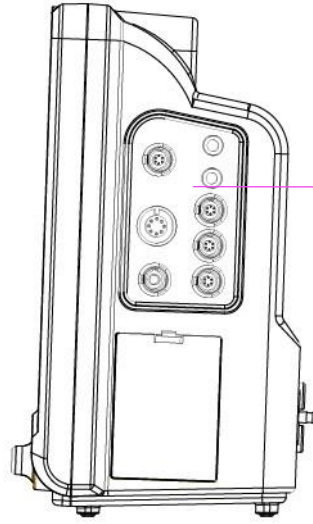
Nameplate

Connector and icon

Rear view



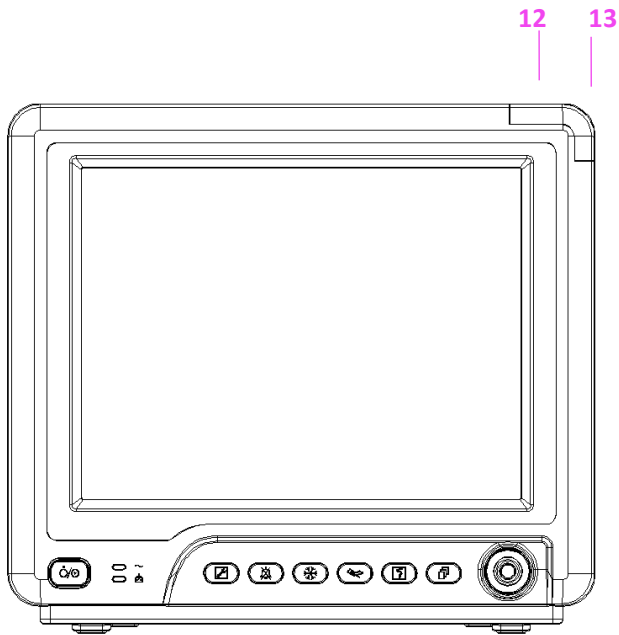
**Left view**



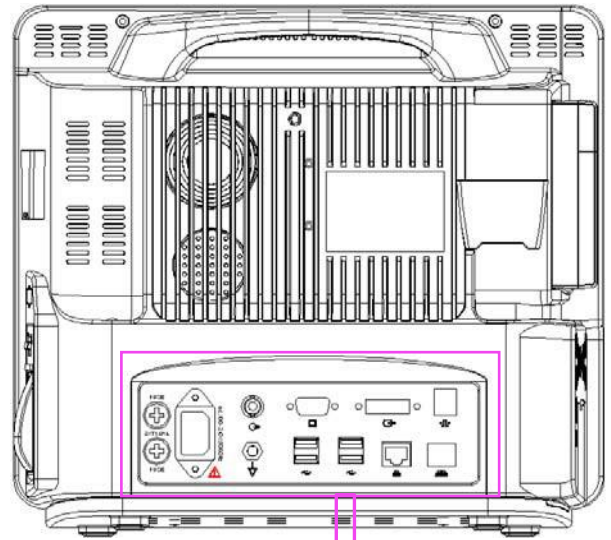
Connector and icon

**Right view**

## Series II

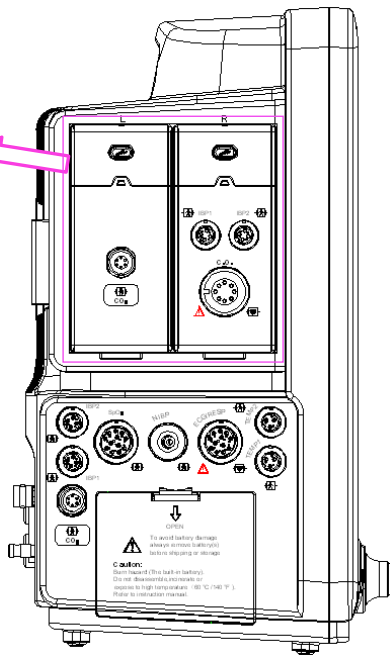


Front view

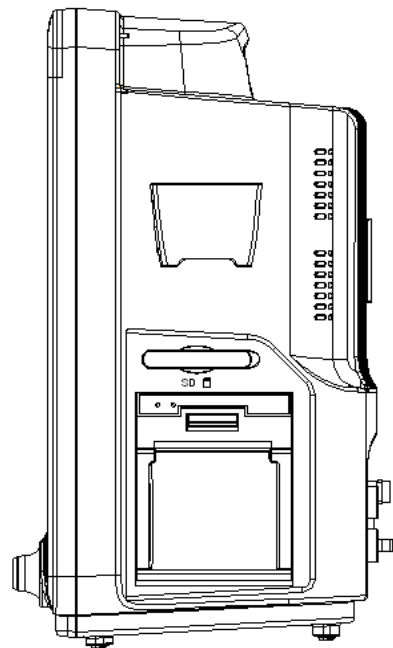


Rear view

Plugin module  
installing location



Left view

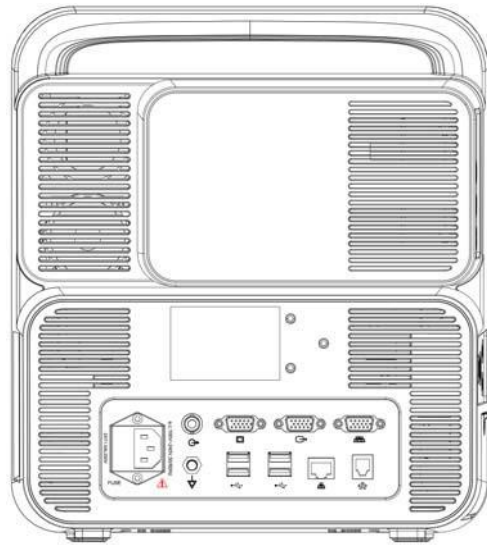


Right view

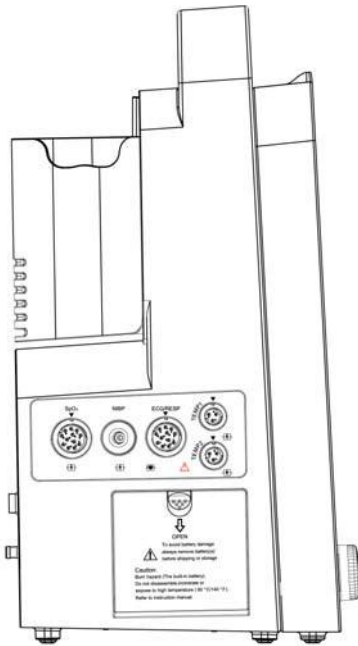
◇ Series III



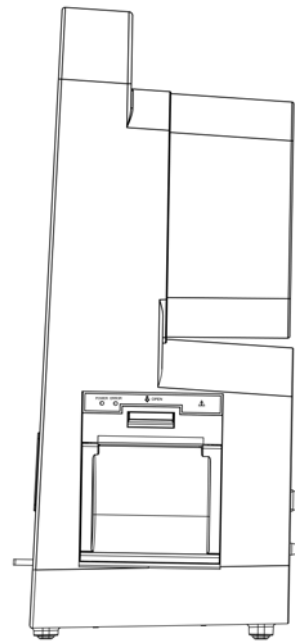
Front view



Rear view

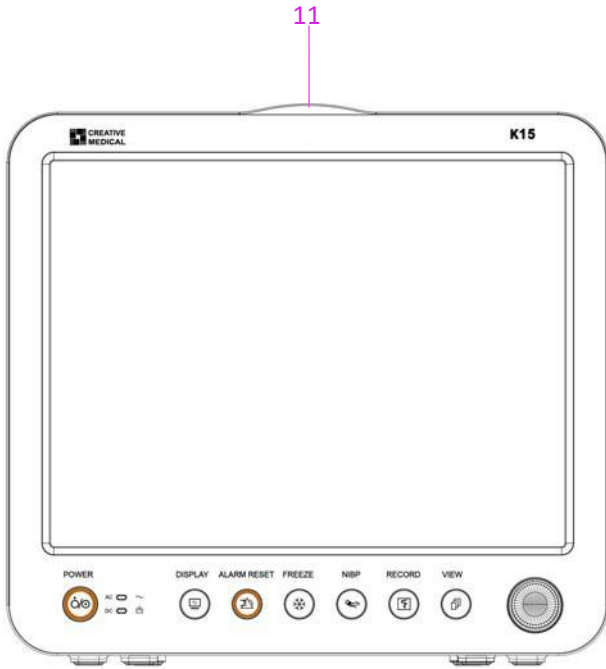


Left view

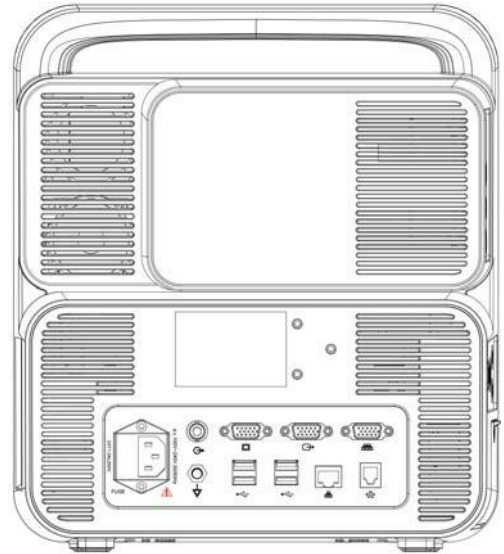


Right view

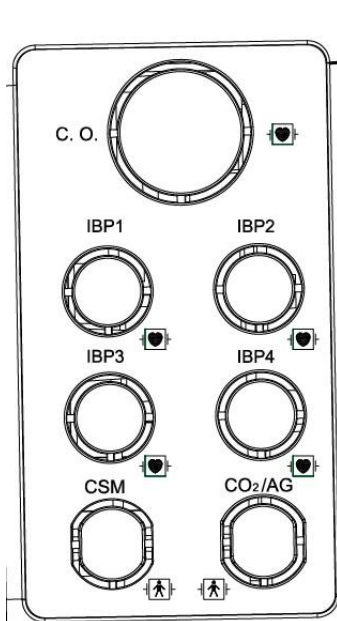
◆ Series IV



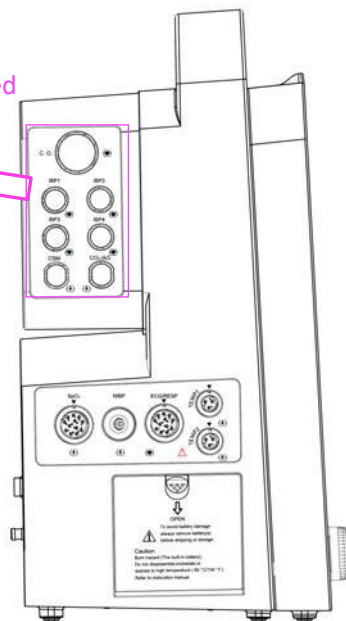
Front view



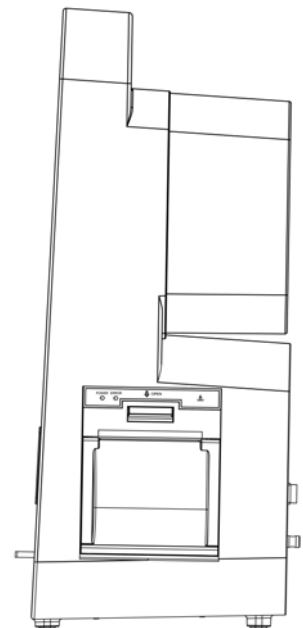
Rear view



Extended Module



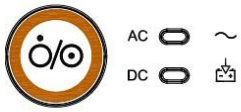
Left view



Right view

◇ Front Panel

POWER



DISPLAY



ALARM RESET



FREEZE



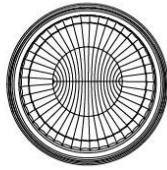
NIBP



RECORD





VIEW




The above icon and its corresponding description is below.

No.	Symbol	Description
1		Power switch
2		AC power indicator
3		Working power supply indicator
4	 or 	View setting key
5	 or 	Alarm reset key / Alarm silence key
6		Freeze key
7		NIBP start/cancel key
8		Record/Print key
9		Display view key
10	 or 	Navigation knob
11	 or 	Alarm lamp

12		Technical alarm status indicator (optional): an auxiliary indicator for “Alarm lamp”. It’s used for indicating whether the system in technical alarm status or not. When the system in technical alarm status, then the indicator in blue, otherwise, it stays off.
13		Physiological alarm indicator (optional)




**Note:** 1. For the software updating reason, the icon for “View setting key” may be  (for the latest version)

or , please refer to the monitor in your hand.

**For convenient operation, different port is set in different position of the monitor, please refer to the monitor in your hand.**


### Description for connector and icon

#### ✧ Connector


- ✧ **TEMP1, TEMP2:** Temperature probe connectors.
- ✧ **NIBP:** NIBP cuff connector.
- ✧ **SpO<sub>2</sub>:** SpO<sub>2</sub> sensor connector.
- ✧ **ECG/RESP:** ECG cable connector.
- ✧ **AG:** this connector can be used for external monitoring module such as AG (Anaesthesia Gas) measurement (optional).
- ✧ **Net:** Data cable interface. This function is unavailable for most of the monitors, please refer to the monitor in your hand.
- ✧ : Equipotential grounding terminal.
- ✧ : USB data interface. This port is used for data exporting. This function is available for the monitor with plugin module, please refer to the monitor in your hand.
- ✧ **a.c. 100~240V, 50/60Hz:** Mains power supply socket.
- ✧ **FUSE 2 × T1.0AL:** Fuse holder; fuse specification: T1.0AL/250V Φ5 × 20mm.
- ✧ : Nurse call connector. This function is unavailable for most of the monitors, please refer to the monitor in your hand.



✧ **MONITOR:** External display output which will be different depending on the configuration. This function is unavailable for most of the monitors, please refer to the monitor in your hand.


✧  : Network interface. This function is unavailable for most of the monitors, please refer to the monitor in your hand.


✧  : Serial port. Reserved for future use(optional).


✧  : ECG Sync output for defibrillation. Reserved for future use (optional).

## ✧ **Icon**

✧ **S/N:** Serial Number.

✧  Type BF applied parts with defibrillation-proof.

✧  Type CF applied part with defibrillation-proof.

✧  Warning! Please refer to the manual.

## ✧ **Nameplate**

✧ The nameplate includes product name, model, CE mark, and manufacturer information and so on.

## ✧ **Battery slot**



Battery cover: Remove the cover to install or change rechargeable battery. Battery specification:  
11.1V /4400mAh.

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

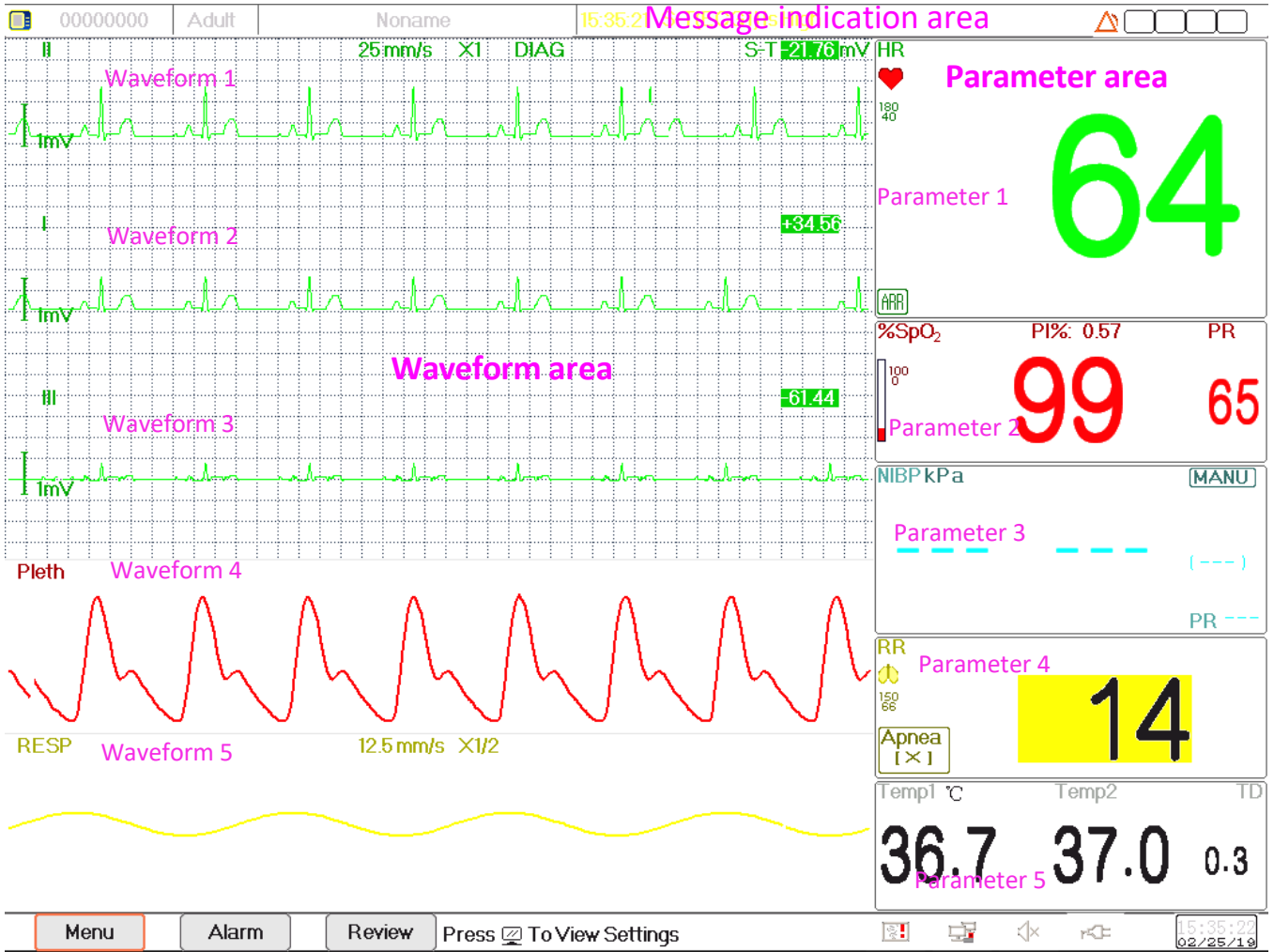
## ✧ **Printer (optional)**

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

## 2.3 Display Screen

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

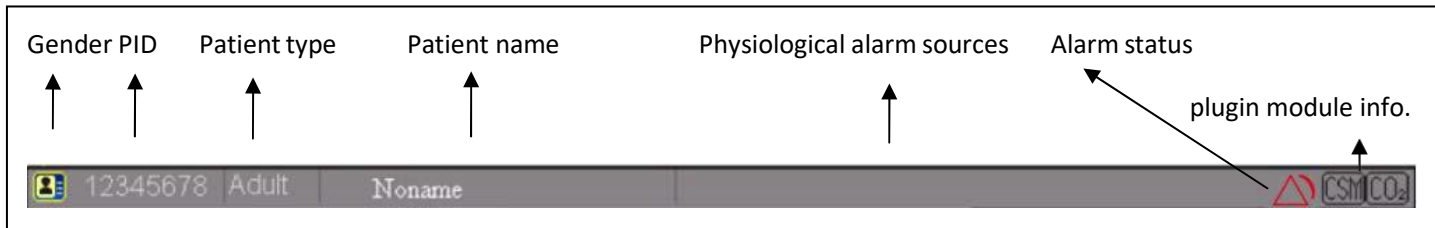
When there is window pops up, the new pop-up window is the current operable window displayed on top layer. We will not cover again.






Screen layout (refer to actual screen)

### 2.3.1 Message Indication Area

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

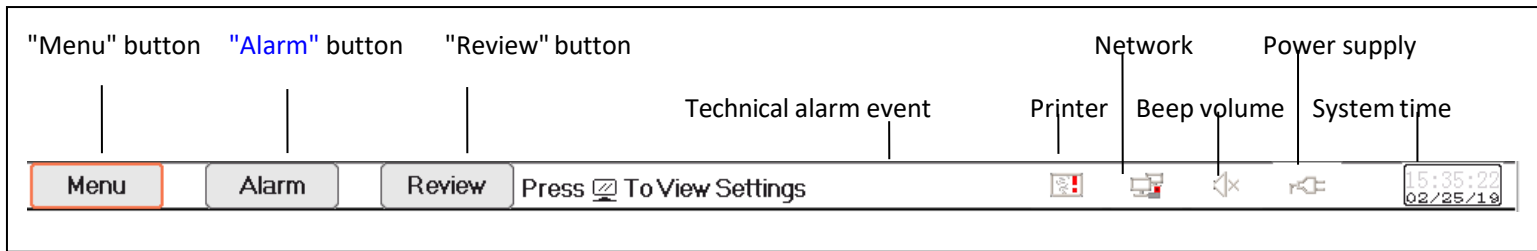


- ✧ Patient information area (as shown in above figure): the patient whose information displayed on Message indication area is monitored by device currently. Icon  means the patient is female,  is male and  is unknown. The device presets a default patient information. When the user does not fill any patient information, the device will use the default patient information. The default patient ID is "00000000", Name is "Noname", patient type is "Adult". Move the cursor on this information area can shift to "Patient Info." setting window.
- ✧ Physiological alarm sources (as shown in above figure): displays physiological alarm source information.
- ✧ Alarm status: See Chapter 6 Alarms.

**Note:** if you purchased the Monitor with extended module, then the corresponding module icon(s) will also appear on the upper right screen.

## 2.3.2 Statusbar

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



- ✧ "Menu" button: enters into system menu dialog.
- ✧ "Alarm" button: enters into alarm setting dialog.
- ✧ "Review" button: enters into data review dialog.
- ✧ Technical alarm event: displays the current detected technical alarm event. Detailed technical alarm information see Section **Alarm**.

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

1. : it means the printer is ready;
2. : it means the printer error caused by no paper or malfunction;
3. During printing, the printer displays status (, , ) showing that the printer is working.

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

**Note:** If your monitor is not configured with Printer, then the icons will not be shown up.

- ✧ Network connection status: there are 3 status --- " means network connected; " means network disconnected; "(with a moving point) means network is connecting, if the network connection is lost, then the device will try to connect to the central station every 2 minutes.

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

- ✧ Pulse beep status: there are 2 status --- " means pulse beep is enabled; " means pulse beep is disabled.

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

- ✧ Power supply status

"" means the battery is being charged;

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

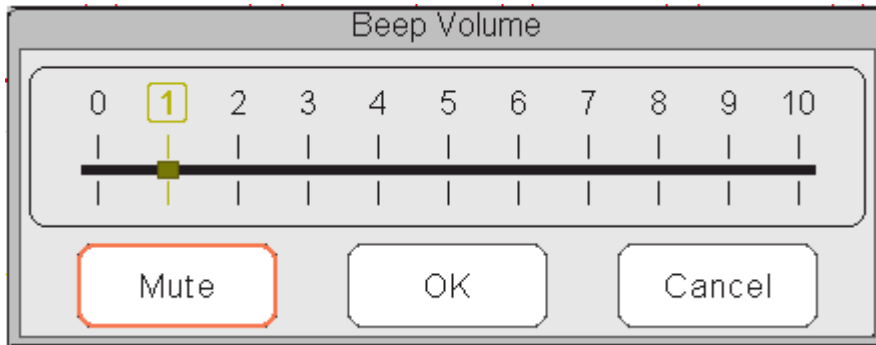
"" means the device is powered by AC power supply.

"" means low battery voltage.

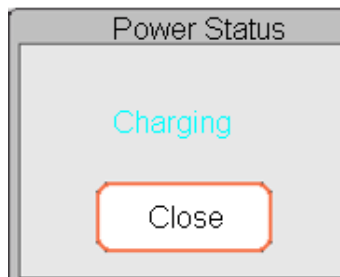
- ✧ System time: the current time running in the device.

Note: operating key to move the cursor on statusbar and focus on the icon of printer, network, beep volume, power

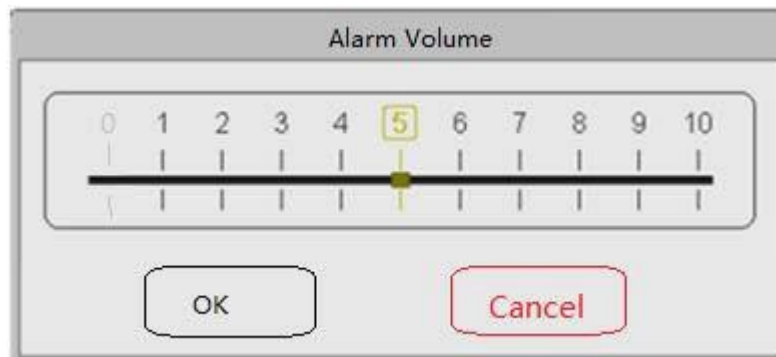
supply, system time or on the information area, then the corresponding setting window pops up, that's, Printer setting window, Network setting window, Beep volume setting window, power supply setting window, System time setting window.



Popup window for Beep Volume setting



Popup window for Power Status

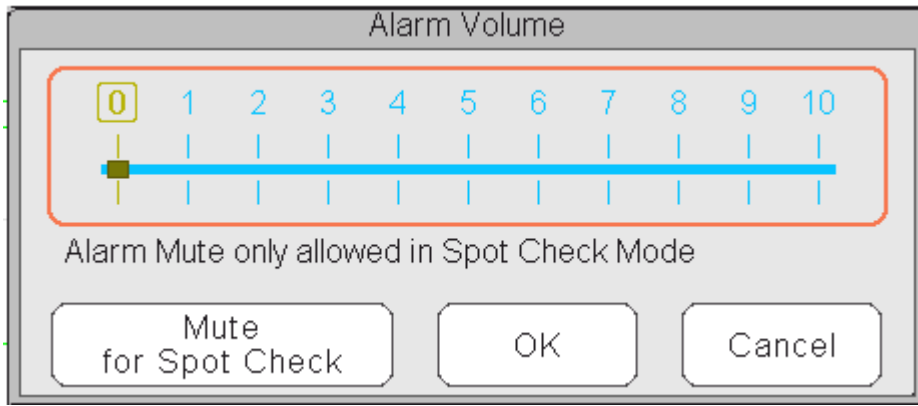


Popup window for Alarm Volume setting

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

Note: if the customer purchased the monitor with configuration of "Alarm mute for spot check", please refer to the following description:

- ✧ "Alarm mute in spot-check mode": select this option to turn off the alarm sound. In this status, any alarm sound will be muted, and the alarm sound will not resume until the user manually set the alarm volume as non-zero status. Note: please be cautious of using this option. It's not recommended to set the alarm sound volume as 0.



Popup window for Alarm Volume setting---for device optioned with “Alarm Mute” function

### 2.3.3 Parameter Area and Waveform Area

#### 1) Parameter Area

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



## 2) Waveform area

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

## 2.4 Views Management

Press "Menu" button, and select "Views" item to enter into "Views" window.

### Views selection (refer to the monitor you purchased)

- ✧ **View others:** if "View others" option is selected, then this monitor can view the patient information from other bedside monitor via the central monitoring network system.
- ✧ **Save Last View:** Enable or disable "Save Last View" function. Select it means enable this function. If selected, then the Monitor will save the last operating view as the default view when re-start the Monitor. The factory default is "enable" this function.



## **Activate Views (refer to the monitor you purchased)**

### **Description:**

#### **1) Switch views**

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

#### **2) Views settings**

- ✧ Press "Settings" button to setup the view selected, where waveforms and parameters can be configured as you like.

#### **3) Activate views**

- ✧ In “Views” window, pressing "Activate" button to enter the "Activate Views" window. Then, the operator can choose the views to be activate or not, the optional views (the views can be activated) are General, Big Font, All ECG Trace, NIBP List, OxyCRG and Short Trends. The inactivated views are display in grey.
- ✧ Only the activated views can be clockwise shifted by operating Display View Key.

# Chapter 3 Operating Instructions

## 3.1 Installation

- ⚠ Devices connected to the equipment must meet the requirements of the applicable IEC standards. The system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance with IEC 60601-1-1. If you have any question, please contact the manufacturer or your local dealers.
- ⚠ If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.
- 🔔 The equipment shall be installed by personnel authorized by manufacturer.
- 👉 The software copyright of the equipment is solely owned by the manufacturer. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.

### 3.1.1 Unpacking and Checking

1. Open the package, take out the monitor and its accessories from the box carefully and place it in a safe, stable and easy to watch position.
  2. Open the user manual to sort the accessories according to the packing list.
    - ✧ Inspect the accessories for any mechanical damages
    - ✧ Check all the exposed leads and inserted accessories
    - ✧ Check whether any risk or abnormality exists in the device and its accessories before using the monitor. If any abnormality (such as broken cable or crack of the enclosure etc.) is found, do not use with the device.
- 🔔 When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.
  - 🔔 Before use, please verify whether package is intact, especially for the single use accessories. In case of any damage, do not apply to patients.
  - 👉 Save the packing case and packaging material as they can be used if the equipment must be reshipped.
  - 👉 The user can customize the module configuration by choosing necessary modules to meet your own needs. Therefore, your monitor may not have all the monitoring functions and accessories.

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

### 3.1.2 Environmental Requirements

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

unexpected consequences, e.g. damage to the equipment, could result.

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

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

## 3.2 Getting Started


### 3.2.1 Connecting to Power Source


#### 1. Using AC Power Source

- ◆ Make sure that the AC power supply is (100-240)VAC, 50Hz/60Hz.
- ◆ Use the power cable provided by the manufacturer. Insert one end of it to the AC power input of the monitor and the other end to the three-pin outlet of the power source with protected-earth.
- ◆ To eliminate potential differences, the monitor has a separate connection to the equipotential grounding system. Connect one end of the provided ground wire to equipotential grounding terminal on the rear of the monitor, and connect the other end to one point of the equipotential grounding system.

**Caution: 1. Ensure that the monitor is grounded correctly.**

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

 After the mains power supply has been interrupted while power switch remains in the “on” status and is restored after a period of time that is longer than 30 seconds, the monitor will run by the last settings when restarting the monitor.

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

#### 2. Using Battery

The following steps should be followed to install the battery:


- Step 1: open the battery cover;
- Step 2: pull out the battery cable and connect it to the battery pack;
- Step 3: push the battery pack into the battery compartment and lock it;
- Step 4: close the battery cover.


**Caution: it's better to recharge the battery after it is used up, and the charging time should be 12~15 hours long.**

**Battery life:** Provided that a battery is new and fully charged, the minimal working time of the monitor with accessories connected is declared in the table below:

Name	Battery life
Patient Monitor	More than 120min

**NOTE:** when the device is working, It takes at least 10 hours to charge battery from empty state to 90% charged.




 The provided battery of the monitor must be recharged after transportation or storage. So if the monitor is switched on without being connected to the AC power supply, it may not work properly due to insufficient battery power.

 : Working power supply indicator and the description is as shown below.

	AC power indicator	Working power supply indicator	Description
Status	On	Off	The monitor is powered by the AC power supply and it is in off status
	Off	On	The monitor is powered by the built-in battery power supply
	On	On	The monitor is powered by the AC power supply and the battery is being charged

### 3.2.2 Turning the Monitor On

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

1. Check all the applicable functions to make sure that the monitor works normally.
  2. If the built-in battery is applied, please recharge it after using the monitor to ensure sufficient power storage. It will take at least 10 hours to charge battery from depletion to 90% charge.
  3. Press the Power on/off key on the front panel of the monitor to start the monitor.
-  Do not use this device to monitor the patient if there are indications of damage or reminders of error. Please contact the local dealer or our company.
  -  The battery powered monitor continues to run without interruption when AC mains power is lost.
  -  Start the monitor again 1 minute later after it is switched off. When the monitor is switched off allow one minute before switching it back on so that the monitor powers off correctly.

### 3.2.3 Starting Monitoring


1. Decide which parameter measurements you want to make.
2. Connect the required modules, patient cables and sensors.
3. Check that the patient cables and sensors are correctly connected.
4. Check that the patient settings, such as Patient Type, NIBP measuring mode, etc, are appropriate to your patient.

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

## 3.3 Turning the Monitor Off

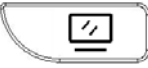

To disconnect the monitor from the power, follow this procedure:


1. Confirm that patient monitoring is complete.
2. Disconnect patient cables and sensors from the patient.
3. Make sure to save or clear the monitoring data as required.
4. Press the Power on/off key on the front panel to turn off the monitor.


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


## 3.4 Using Keys


### 3.4.1 Shortcut Key


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


 **Alarm Reset Key:** when alarm event occurs, press this key to reset this alarm, that means to mute the alarm sound, but the visual alarming is still effective.

(Note: for the device optioned with Alarm Mute function, it is  **Alarm Silence Key:** press this key to pause or resume the alarm sound.)

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



 **NIBP Key:** press this key to start NIBP measurement, and during measurement, pressing this key will pause NIBP measurement.

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

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




Navigation Knob: anticlockwise rotation acts as “Left-arrow” key, clockwise rotation acts as “Right-arrow” key and press-down acts as “OK” key.


Note: for the monitor configured with plugin module, pressing View Setting Key  (or ) can swiftly enter into the corresponding setting window.


### 3.4.2 Buttons and Keyboard

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


#### 1) Buttons in list box:


: previous/next row

: previous/next page of rows

: the last/first row

#### 2) Frame or page moving buttons:



: the first/last page


: the precious/next page



Note: in this monitor, functions of buttons above are similar. The contents will not be repeated in the later chapters.


#### 3) Operation instruction for Soft keyboard

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

✧ Press View Settings key  (or ) to move the cursor to the upper row of the soft keyboard.

✧ "": delete a letter.

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

✧ "": exit without confirmation of the input in this time, i.e. to cancel it.



#### 4) Operation instruction for the often-used key

"Default": press this button can default device settings, but you need choose "OK" on the pop-up screen; choose "Cancel", then the items in setup window will not be changed, and it will keep the settings saved in last time.

"OK": when you setup any items, choose "OK" button and press navigation knob to confirm the settings.

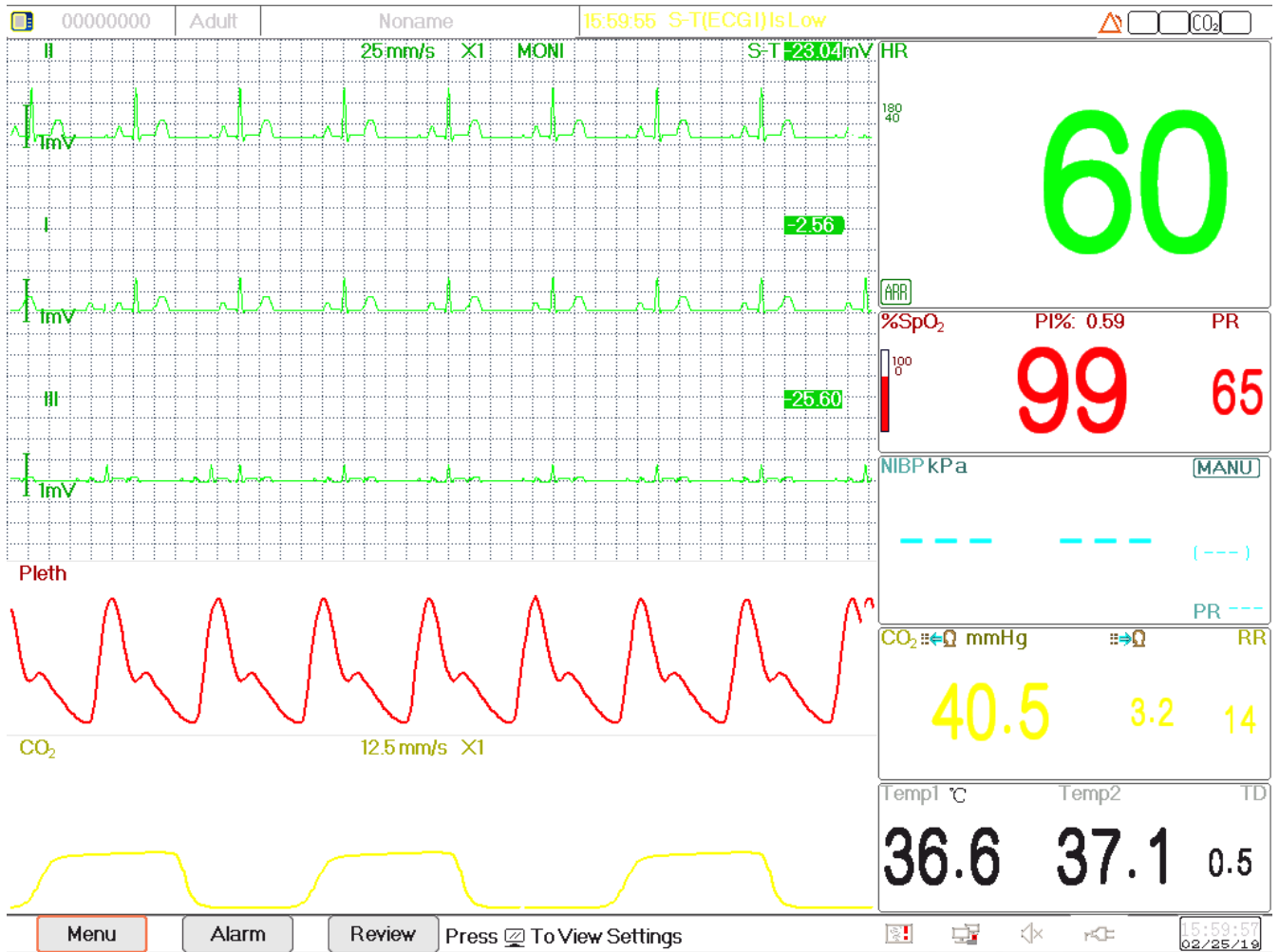
"Cancel": quit the current settings and save it without any changes.

Note: the above buttons' function are similar to that in the following user manual, we will not repeat it in the later chapters.

### 3.5 Using the Touchscreen

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

### 3.6 Setting the Screens



Generally, in general view screen, there are 3 to 7 traces of waveforms in the waveform area, and 2 to 7 parameter panels in the parameter area. Each waveform trace shows specific signal waveform (eg. ECG waveform, plethysmogram and so on), you can also disable this trace. Each parameter panel shows one or one group of parameter value and the corresponding status.

Waveform area locates at the left part of screen. The display order of waveforms in a view is configurable. The default order from up to down is waveform 1, waveform 2, waveform 3, waveform 4, waveform 5... waveform 7 (7 traces at most).

Parameter panels locate at the right part of screen, the parameter order from up to down is Parameter 1, Parameter 2, Parameter 3, Parameter 4... Parameter 7 (displays 7 parameter panels at most); the default order is ECG, SpO<sub>2</sub>, NIBP, RESP and TEMP.

You can allocate the positions of the parameter waveforms and panels. The parameters or waveforms whose positions are not allocated will not be displayed.

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

- ✧ Check the connection between the module and lead, cable, sensor, etc..
- ✧ Enter the Setup window for the corresponding display configuration.

### 3.7 Using the Main Menu



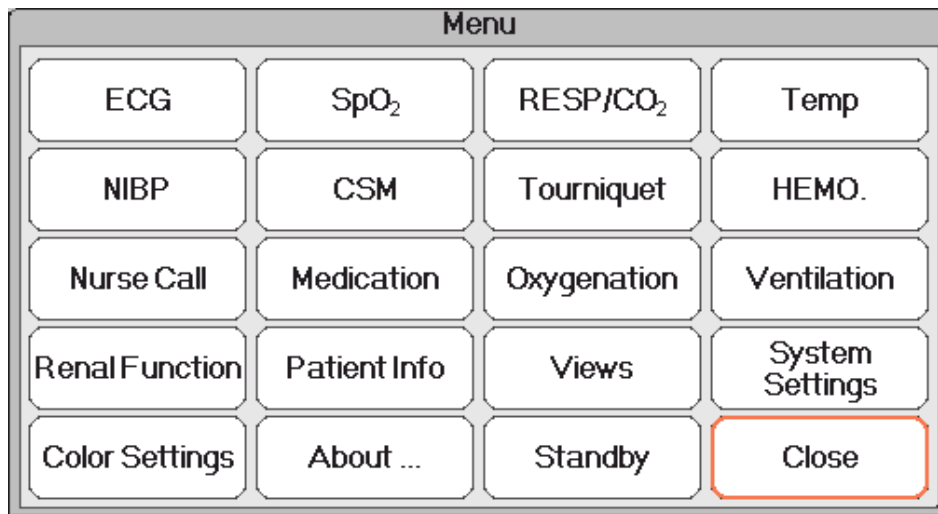
To enter the main menu by selecting the "Menu" button, most of the monitor's operations and settings can be performed through the main menu.

Menu includes parameters setting and the entrances of other functions, such as ECG, SpO<sub>2</sub>, RESP, TEMP and NIBP parameters setting, and the setting for optional function, "Tourniquet", "Medicine Calculation", "Oxygenation", "Ventilation", "Renal Function", "System Settings", "Patient information", "Color Settings" and "Standby" etc..

Parameters settings window for ECG, SpO<sub>2</sub>, RESP, TEMP and NIBP; If some optional function is configured, then the monitor will show the corresponding setting window automatically on the "Menu" window.

Functional window for Nurse Call, Medicine Dosage Calculation, Oxygenation calculation, Ventilation calculation, Renal function and Patient Document;

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



**Note:** some of the above mentioned functions are optional, so your monitor may not cover all functions, please refer to the monitor in your hand.

## 3.8 Changing System Settings

This Section covers only general settings, data and time, Network and Printer setting. Parameter settings and other setting can be referred to in respective sections.

### 3.8.1 Changing General Settings

#### Changing Language

1. Select "Menu" → "System Settings" → "General".
2. In "General" menu, select "Language" and then select the desired language.
3. Enter the required password.
4. Restart the monitor.

Notes:

1. The default required password in the monitor is "8989".
2. The changed language is applied only after the monitor is restarted.

## Adjusting Volume

### 1. Alarm Volume

To set the alarm sound volume.

Step 1: Select "Alarm"→"Others"→"Alarm Volume". Its setting range is "1 ~ 10", the step is 1. The default is 5. "10" is the maximum volume. (Note: if your monitor is optioned "Spot-check Mode" function, then the setting options for Alarm Volume is "Spot Check", "1~10".)

### 2. Beep Volume

To set the pulse beep sound.

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

Step 2: In "General" menu, select "Beep Volume". Its setting range is "OFF", "0 ~ 10", the step is 1. The default is 5. If you want to set the beep volume as "OFF", you need to enter the password. **Attention:** It's not recommended to set it as OFF.

### 3. Key Tone

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

### 4. Others

- ✧ **Mode:** monitor working mode selection. See **Operating Modes**.
- ✧ **Freeze type:** to select waveforms to be frozen on screen. The options are "All Waves", "EEG" and "ECG Waves". When "ECG Waves" is selected, the system only freezes ECG waveforms. When "EEG" is selected, the system only freezes EEG and EEG waveform. When "All Waves" is selected, the system freezes all waveforms on screen. The default is "ECG Waves".
- ✧ **Param font:** to select parameters' digit font, there are 2 options: Bold Digit and Serif Digit.
- ✧ **Plethysmogram:** the switch to turn on or off the filled waveform style for plethysmogram display. When it is ON, the monitor displays filled waveform for plethysmogram, otherwise, displays in simple curve style. The default is OFF.

Note: this function is not available for ECG waveform.

- ✧ **Beep volume:** to set the pulse beep sound. Its setting range is "OFF", "1 ~ 10", the step is 1. The default is 5. Attention: It's not recommended to set it as OFF.
- ✧ **Pitch Tone:** to choose the style of pitch tone, the pitch tone means the tone of pulse beep (from ECG or Oximetry) changes when the measured SpO<sub>2</sub> value changes, the higher SpO<sub>2</sub> value, the sharper beep sound (high-pitch). Two options: "Mode I" and "Mode II". The difference between Mode I and Mode II is the tone frequency at the same SpO<sub>2</sub> value. The factory default setting is "Mode I".

- ✧ **Screen brightness:** to set the brightness of LCD backlight, 3 levels (1, 2 and 3) for optional (note: for some specific module, only 2 levels for optional, that's "1" and "2"), the factory default is level 1. Level 1 is darker. (Note: this function is only available for Series III and Series IV.)
- ✧ **Key backlight:** to turn on/off key backlight for the device, the factory default is "On". (Note: this function is only available for Series III and Series IV.)
- ✧ **Beat priority:** to set the priority of the source of beat pulse beep and heart beat rate display value, there are 2 options: HR and PR. The factory default is "HR".

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

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

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

- ✧ **Use the last patient info. When power on:** tick it means that the patient document of the last time will be used as the Current Patient Document when powered on, i.e. the patient is not changed. Otherwise, system will use the Default Patient Document (PID:0000000, Noname) as the Current Patient Document when powered on.
- ✧ **Touchscreen Calibration (optional):** to enter into touchscreen calibration window. There are 5 cross cursors "+" on the screen, tab the cross point "+" of the 5 cross cursors with the stylus respectively to finish the calibration.

### 3.8.2 Setting the Date and Time

Step 1: Select "Menu" → "System Settings" → "Date/Time".

- ✧ **Month/Day/Year/Hour/Minute/Second:** to set system date and time.
- ✧ **Date format:** to set date format of the system. There are 4 options: "YYYY-MM-DD", "YYYY.MM.DD", "MM/DD/YYYY", "DD/MM/YYYY".
- ✧ **Current time:** to refresh the current system time.

### 3.8.3 Network Settings

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



- ✧ **Server IP Address:** the IP address used to connecting a central monitoring system server (work station).
- ✧ **Port:** the port number to which the monitor will connect to the work station in the central monitoring system. Its setting range is from 6001 to 6064. It can also be used to represent the patient bed number connecting to the work station. Our work station can connect to up to 64 bedside monitors, so please set the port between 6001 and

6064.

Press "OK" to make the new setting effective.

- ✧ **HL7 Protocol:** enable or disable the monitor to export data to CIS/HIS by HL7 protocol. Select it means enable HL7 protocol. The default is "enabled" HL7 protocol.
- ✧ **Local IP Address:** the local IP address for the device.
- ✧ **Subnet Mask:** when the user select a static IP address, then the subnet mask should be set. The default subnet mask is "255.255.255.0".
- ✧ **Gateway:** when the user select a static IP address, then the gateway should be set. The default gateway is "192.168.168.1".
- ✧ **Obtain IP Address Automatically:** (when the remote server supports DHCP service) select it means the IP address can be automatically configured by DHCP service. The device will perform DHCP configuration on every device booting and/or network topology change. If select "Obtain IP Address Automatically", then "Local IP Address", "Subnet Mask" and "Gateway" are in grey and nonadjustable.

#### Notes:

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

2. If the network is disconnected later after a successful DHCP configuration (for example, network cable is detached), then the IP address will be changed as "0.0.0.0". When the network connection is recovered, the monitor will obtain IP address automatically again.

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

#### Notes:

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

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

### 3.8.4 Printer Settings

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

- ✧ **Speed:** the printer sweep speed. Options are 25mm/s and 50mm/s. The default is 25mm/s.
- ✧ **Wave 1:** print the first channel of waveform. Optional are: "ECG I", "ECG II", "ECG III", "ECG aVR", "ECG aVL", "ECG aVF" and "ECG V" (that's ECG lead I~V). The default is ECG II. If "3-lead wires" is selected, then this item is in grey and nonadjustable. The first channel of waveform displaying on the current ECG window will be the first waveform that the device will print (it can be set by Menu → ECG → Lead). The default is ECG lead II.

- ✧ **Wave 2:** print the second channel of waveform. If "5-lead wires" is selected, then the optional will be: OFF, "ECG I", "ECG II", "ECG III", "ECG aVR", "ECG aVL", "ECG aVF", "ECG V". If "3-lead wires" is selected, then the optional will be: "OFF", "PLETH" and "RESP". The default is OFF.
- ✧ **Wave 3:** print the third channel of waveform.
 

Note: the setting for Wave 1, Wave 2 and Wave 3 should be different (eg. Wave 2 and Wave 3 can not be set as "ECG III" at the same time). Only 2 ECG waveforms at most can be printed simultaneously.
- ✧ **ARR Trigger:** ARR triggered printing. "ON" means the printer will print out waveform once an ARR event occurs. The default is "OFF".
- ✧ **Duration:** the duration of printing real-time waveform. Options are: 10, 20, 30, 40, 50, 60 (seconds), and Continuous, the default is "10" seconds. If "Continuous" is selected, then the printer will not stop printing until manual stop it by pressing the print key.
- ✧ **Print ECG Grids:** the switch for grids on printed ECG waveform. Select it means the 5x5(mm<sup>2</sup>) grid background will be printed when printing the ECG waveform.
- ✧ **Timer:** the switch for print timer. The default is "OFF". If Print is ON, rotate navigation knob to set on the Timer to enable timed print, and set the value of printing intervals in the cycle category. The setting range is 5~480 minutes, the step is 5 minutes. The default is 60 minutes.

## 3.9 Operating Modes

### 3.9.1 Real Time Mode

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

### 3.9.2 Demo Mode

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

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

### 3.9.3 Standby Mode

Select "Menu" → "Standby".

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

## Chapter 4 Patient Data Management

Select "Menu" → "Patient Info."

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

### 4.1 Apply an existed patient's document

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

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

### 4.2 Create a new patient's document

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

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

The following items need to input:

- ✧ **PID: the Patient ID.**
- ✧ **Group:** 3 types patient: Adult, Pediatric and Neonate. The default is "Adult".
  - Adult: age  $\geq$  12 years;
  - Pediatric: 1 month  $<$  age  $<$  12 years;
  - Neonate: age  $\leq$  30 days.
- ✧ **First Name:** patient first name.
- ✧ **Last Name:** patient last name.
- ✧ **Gender :** patient gender.

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

### 4.3 Edit a patient document

Select "Menu" → "Patient Info." → "Edit".

To edit a patient document requires the corresponding password, details see Section 3.9. In "Patient Info" window, pressing "Edit" button, and if the password is entered correctly, then "Edit Patient Info." window pops up on the screen. The item in grey is nonadjustable.

**Note:** no password is needed to edit the default patient document. In the default patient document, only the patient type can be modified, and other items are not editable.

## 4.4 Delete a patient document

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

To delete a patient document requires the corresponding password.


### Notes:

- 1 When a patient document is deleted, all his corresponding records (ECG waveforms, ARR events, Alarm events, NIBP list etc.) will be deleted and can not be recovered.
- 2 The system prohibits to remove the default patient and the current patient documents.


## 4.5 Exporting Data


### 4.5.1 Exporting Data from Monitor to a USB Driver

Note: USB data exporting function is available for the monitor with Plug-in module(Series II), Series III and Series IV .

Connect the USB disk (stick memory) to the USB data interface on the rear panel of the patient monitor marked .

Select "Preview" → "Export" to bring up the data exporting window, the plugged USB disk will be identified automatically and displayed on the first line in the pop-up window. (note: if no USB disk is detected, then "Refresh", "Export", and "Unmount" buttons are displayed in grey and unavailable).




- ✧ : Select the USB disk from the drop-down list.
- ✧ **Refresh:** Refresh the USB disk(s) enumeration.
- ✧ **Export:** Export the data and information for the selected patient
- ✧ **Unmount:** Unmount (remove) the selected USB disk from the system.
- ✧ **Exit:** Exit from the current window.

Press the drop-down list  to display all plugged USB disks, select one USB disk you want to export the data, then press "Export" to start exporting. If data is exported successfully, then the window shows "Exported Successfully", and press "Close" to return to disks information displaying window.

### Description:

1.8GB / 1.9GB :indicates the unused memory / total memory. If the USB disk memory is not enough, then the data will fail to be exported.

KRK/20130101\_00000000 : "KRK" indicates the data is exported to a file folder named "KRK" in the USB disk; "20130101" is the time of this exporting; and "00000000" is the patient ID. The data for selected patient will be stored with the file name of "20130101\_00000000" under the file folder "KRK" in the USB disk.

-  Do not unplug the USB disk from the monitor during exporting, or the exported data will be in disorder, and the history record files will be corrupted.
-  Do not unplug the USB disk from the monitor before it is unmounted, or the data in the disk will be corrupted or lost.
-  If you need to review and manage the exported data, you can contact your local sales for address to download the corresponding PC software (Patient Monitor Data Manager) for data management.

## 4.6 Connecting to a Central Monitoring System

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

- All patient information, measurement data and settings on the monitor can be transferred to the CMS.
- All patient information, measurement data and settings can be displayed simultaneously on the monitor and CMS.
- For some functions such as editing patient information, admitting a patient, starting/stopping NIBP measurements, etc., bi-directional control can be achieved between your monitor and the CMS.

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



# Chapter 5 User Screens

## 5.1 Tailoring/Setting Your Screens

You can tailor your monitor's screens by setting:

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

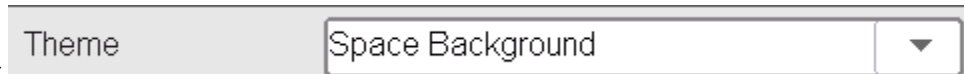
### 5.1.1 Changing the Display Theme

Select "Menu" → "Color Settings".

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

- ✧ **Principal:** to enter into the setting form for parameter and number. 112 kinds of color for option with code 0~111, one code indicates one color.
- ✧ **Theme:** to select the monitor's color theme, options are: Space background, Sky blue, International fashion, and Bamboo lands in China.
- ✧ **Param BKG Color A and B:** set the background color in parameter panels. Using color A and color B as the parameter's background color displayed by turns. The default setting for A and B is 0. The setting range is from 0 to 85, one number indicates one color. If the background color for the first parameter panel is color A, then the second parameter panel will be color B, and third will be color A again, alternately displayed in this way.

#### 1) Quick Color Settings:



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

### 5.1.2 Changing the Color of Waveforms and Parameter

#### 1) Parameter Number Color Settings:

To set the parameter (ECG, S-T, SpO<sub>2</sub>, RESP, TEMP and NIBP etc.) information and the waveform color. Procedures are: Locate the cursor on the color box, rotate the Navigation Knob, and select the color.

The ECG color setting for theme, waveform and number: setting range is 0~111, the default is 16.

The S-T color setting for number: setting range is 0~111, the default is 14.

The SpO<sub>2</sub> color setting for theme, waveform and number: setting range is 0~111, the default is 2.

The RESP color setting for theme, waveform and number: setting range is 0~111, the default is 108.

The TEMP color setting for number: setting range is 0~111, the default is 111.

The NIBP color setting for number: setting range is 0~111, the default is 28.

## 5.2 Display Views

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

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

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

**This monitor provides the following display views:**

- ✧ General view: meets most monitoring needs;
- ✧ Big Font view: displays the important parameters in the big font for remote observation;
- ✧ All ECG Trace view: emphasizes on all ECG waveforms;
- ✧ NIBP List view: emphasizes on NIBP data;
- ✧ RESP-oxy view: emphasizes on SpO<sub>2</sub> and Respiration data;
- ✧ Short trends view: displays waveforms and parameters together with recent 2-hours parameter trend graph.

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

### 5.2.1 General View

When power on the monitor, it enters into the defaulted General View screen. (Please refer to the monitor you purchased) There are 5 traces of waveform in the left view: waveform for ECG lead III, ECG lead I, ECG lead II, SpO<sub>2</sub> plethysmogram and Respiration; And there are 5 panels in the right view: ECG, SpO<sub>2</sub>, NIBP, RESP and TEMP.

#### 1) Description:

- ✧ **General View screen shows data and waveforms of main parameters.**
- ✧ Generally there are 5 traces of waveform in waveform area. The default first trace is the waveform for ECG lead II; The second is the waveform for ECG lead III; The third is the waveform for ECG lead I; The fourth is the waveform for SpO<sub>2</sub> plethysmogram; And the fifth is the waveform for Respiration. The user can change it freely.
- ✧ Generally there are 5 parameter panels. The default panel order from up to down is: HR, TEMP, NIBP, SpO<sub>2</sub>, RESP and so on.

## 2) General View Settings:

### ➤ Waveform Settings:

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

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

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

If check box "Cascaded above" is checked, Wave 1, Wave 2 and Wave 3 will display the same signal channel as the trace in a cascaded way.

**Wave 4 and Wave 5** can be set as "OFF", "SpO<sub>2</sub>", and "RESP".

Waveform Settings		Parameter Settings	
Wave 1	ECG III	Param 1	ECG
<input type="checkbox"/> Cascaded above		Param 2	SpO <sub>2</sub>
Wave 2	ECG I	Param 3	NIBP
Wave 3	ECG II	Param 4	RESP
Wave 4	SpO <sub>2</sub>	Param 5	Temp
Wave 5	RESP		

Buttons: Default, OK, Cancel

### ➤ Parameter Settings:

✧ Parameter 1 and 2 is fixed to be ECG and SpO<sub>2</sub> respectively, which can not be adjusted. Parameter 3 to 7 can be set as OFF, TEMP, NIBP and RESP and so on.

Note: waveform 1~5 and Parameter 1~5 are corresponding to the waveform 1~5 and Parameter 1~5. Similarly, in other views, the waveform 1~5 and Parameter 1~5 corresponds to that in View settings window, we will not cover it later.

## 5.2.2 Big Font View

**1) Description:**

In this view, the default 3 waveform channels in the waveform area are ECG waveform, SpO<sub>2</sub> plethysmogram and RESP waveform. And the default 4 parameter panels in the parameter area are the ECG Panel, SpO<sub>2</sub> Panel, NIBP Panel and RR panel.

**2) Big Font View Settings****➤ Waveform Settings:**

- ✧ Wave 1 can be set as any ECG lead, or turn off this channel directly.
- ✧ Wave 2 and Wave 3 can be set as OFF, ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF, ECG V, SpO<sub>2</sub>, and RESP. If "3-lead wires" is selected, then Wave 2 and Wave 3 can be set as SpO<sub>2</sub>, and RESP, or set as the current cascaded ECG waveform (e.g. ECGII).

**➤ Parameter Settings:**

- ✧ "Param 1", "Param 2" and "Param 4" can be set as OFF, ECG, SpO<sub>2</sub>, NIBP, TEMP and RESP and so on.
- ✧ "Param 3" can be set as ECG, TEMP, NIBP, SpO<sub>2</sub> and RESP and so on.
- ✧ Cascaded above: select it means all first 3 channels waveform display the waveform set in Waveform 1, and waveform 2 and waveform 3 are the cascaded waveform of Waveform 1. And at the moment, Wave 2 and Wave 3 are nonadjustable. The default is deselect it.
- ✧ Close all waveforms: select it means the waveform 1 to waveform 3 will not be displayed on the waveform panel in the big font view, but the information in parameter panel will be displayed.

**5.2.3 All ECG Trace view****1) Description:**

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

**2) All ECG Trace View Settings:**

The default 7 waveforms displaying in the view are: ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF and ECG V, waveform 1~7 are nonadjustable. When "3-lead wires" is selected, then it displays the cascaded waveform, the cascaded waveform is fixed to be "ECG II", "ECG I" or "ECG III".

- ✧ Parameter 1 and Parameter 2 are nonadjustable, the default settings are ECG and SpO<sub>2</sub> respectively.
- ✧ Parameter 3 to Parameter 5 can be set as OFF, TEMP, NIBP, RESP and soon.
- ✧ **All waves:** select this item, then all waveforms (including all ECG waveforms and other waveforms) will be displayed on ECG trace view. The factory default is un-select.

Note: if your monitor is configured with 12-leads ECG function, then in All ECG Trace View Setting window, you can select or un-select "Cabrera". When "Cabrera" is selected, then the waveform sequence of ECG lead will be aVL, I, aVR, II, aVF, III and V1~V6. When un-select "Cabrera", then the waveform sequence of ECG lead will be I, II, III, aVR, aVL, aVF and V1~V6.

## 5.2.4 NIBP List view

### 1) Description:

In this View, 4 waveform channels are default to be ECG I, ECG II, ECG III and SpO<sub>2</sub> plethysmogram. Parameter panels in the parameter area are default to ECG, SpO<sub>2</sub>, NIBP, RESP and TEMP. At the same view, the NIBP list view will be displayed.

### 2) NIBP List View Settings:

- ✧ Waveform 1 can be set as OFF, ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF and ECG V.
- ✧ Waveform 2 and 3 can be set as OFF, SpO<sub>2</sub>, RESP. The default is ECG II for Wave 1, SpO<sub>2</sub> for Waveform 2 and RESP for Waveform 3.
- ✧ Waveform 4 is nonadjustable, the default is NIBP List.
- ✧ Parameter 1 and 2 are nonadjustable, the default is ECG and SpO<sub>2</sub> respectively.
- ✧ Parameter 3 ~ 5 can be set as OFF, NIBP, RESP and TEMP etc..

## 5.2.5 RESP-oxy view

### 1) Description:

In this View, the upper 3 waveform channels are default to ECG II, SpO<sub>2</sub> and RESP. The lower area of the waveform area is Oxycardiorespirogram, which consists of HR trend graph, SpO<sub>2</sub> trend graph and Respiration waveform or RR trend graph within certain time scale. In "OxyCRG View Settings" window, the time scale and the 3rd graph can be changed as needed (refers to the following section). Settings of the parameter area are similar to that in "General View".

### 2) OxyCRG Settings:

- ✧ Waveform 1 can be set as OFF, ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF and ECGV.
- ✧ Waveform 2 and 3 can be set as OFF, SpO<sub>2</sub> and RESP.
- ✧ The time scale for OxyCRG can be set as 1min, 2min or 4 min. Min is the time unit of "Minute"
- ✧ The 3rd graph in OxyCRG can be set as "RR Trend" or "Resp Wave".
- ✧ Parameter 1 and 2 are nonadjustable, the default is ECG and SpO<sub>2</sub> respectively.
- ✧ Parameter 3 ~ 5, or Parameter 7 can be set as OFF, TEMP, NIBP and RESP etc..

## 5.2.6 Short trends view

### 1) Description:

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

The abscissa of trend graph (-2h -0) means various trend of every parameter value from now on to 2 hours before. The panels of HR, SpO<sub>2</sub>, TEMP, RESP and NIBP are displayed on parameter area.

### 2) Short Trends View Settings

- ✧ Waveform 1 to 3 can be set as OFF, ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF, and ECG V.
- ✧ Waveform 4 to 5 can be set as OFF, SpO<sub>2</sub> and RESP and so on.
- ✧ Trend 1 is nonadjustable, the default is HR.
- ✧ Trend 2 ~5 can be set as OFF, TEMP, SpO<sub>2</sub>, RR and S-T and so on.
- ✧ Parameter 1 and 2 are nonadjustable, the default is ECG and SpO<sub>2</sub> respectively.
- ✧ Parameter 3~5 can be set as OFF, TEMP, NIBP and RESP and soon.



# Chapter 6 Alarms

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

## 6.1 Alarm Categories

By nature, the monitor's alarms can be classified into three categories: physiological alarms, technical alarms and prompt messages.

### 1. Physiological alarms

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

### 2. Technical alarms

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

### 3. Prompt messages

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

## 6.2 Alarm Levels

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

Physiological alarm		
Alarm priority level	Alarm Source	Alarm Event
High	ECG	Unable to detect HR, ECG Arrest, ECG Brady, ECG Tachy, VE RUN,SVE RUN, HR is too high, HR is too low, S-T is too high, S-T is too low, VE Run, ECG VPCEST
	SpO <sub>2</sub>	Unable to detect SpO <sub>2</sub> , SpO <sub>2</sub> too high, SpO <sub>2</sub> too low, PR too high, PR too low
	Respiration	Apnea, RR too high, RR too low
	Temperature	Temp1 too high, Temp1 too low, Temp2 too high, Temp2 too low, TD too high
	NIBP	NIBP SYS too high, NIBP SYS too low, NIBP DIA too high, NIBP DIA too low, NIBP MAP too high, NIBP MAP too low, PR too high, PR too low
Medium	ECG	VE RonT, SVE RonT, S-T1 too high, S-T1 too low, S-T2 too high, S-T2 too low, S-T3 too high, S-T3 too low, S-T4 too high, S-T4 too low, S-T5 too high, S-T5 too low, S-T6 too high, S-T6 too low, S-T7 too high, S-T7 too low
Low	ECG	Miss Beat, VE Early, SVE Early, VE Couplet, SVE Couplet, VE Short Run, SVE Short Run, SVE Run, VE Insert, SVE Insert, VE Bigeminy, SVE Bigeminy, VE Trigeminy, SVE Trigeminy, Multiform Beat
Technical alarm		
Alarm priority level	Alarm source	Alarm Events
High	System	Low battery, SpO <sub>2</sub> modular malfunction, Unknown error
	SpO <sub>2</sub>	when the battery will run out soon and needs to be charged
Medium	ECG/SpO <sub>2</sub>	Lead(s) off, SpO <sub>2</sub> Probe off, SpO <sub>2</sub> value exceeds measuring range, HR exceeds measuring range
Low	NIBP	Self-test failed, System error, Over time, Signal weak, Cuff error, Air leakage, Pressure error, Out of range, Too much motion, Over pressure, Signal saturation, Detected air leakage, BP exceeds measuring range,
	TEMP	Temperature self-detect failed, TEMP1/TEMP2 exceed(s) measuring range
	SpO <sub>2</sub>	Only battery supply the power with cyan LED of battery indicator shown on the panel

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

1. High priority alarm: medical and nursing staff should response immediately.
2. Medium priority alarm: medical and nursing staff should response quickly.
3. Low priority alarm: medical and nursing staff should response as soon as possible.

**NOTE:** Some models may have only Medium and Low alarm priority because of the different configuration.



## 6.3 Alarm Indicators

When an alarm occurs, the monitor will indicate it to the user through visual or audible alarm indications.

### 6.3.1 Alarm lamp

Lamp color	Alarm level	Alarm event
Red flashing	High priority alarm	ECG Brady, ECG Tachy, Low battery, Vital sign alarm
Yellow flashing	Medium priority alarm	Lead off, Probe off, Sensor off, VE RonT,SVE RonT
Yellow	Low priority alarm	Other Arrhythmia event
Green	Normal	
Red flashing	High priority alarm	when the battery will run out soon and needs to be charged
Cyan or yellow	Low priority alarm	Only battery supply the power with cyan LED of battery indicator shown on the panel

### 6.3.2 Alarm message

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

### 6.3.3 Highlighting Numeric

If an alarm triggered by an alarm limit violation occurs, the numeric of the measurement in alarm will be highlighted.

### 6.3.4 Audible Signals

The auditory information signals are distinguishable from those of auditory alarm signals which is define by the following.

#### 6.3.4.1 Information Signal

The auditory information signal in our system includes the heartbeat tones, keystroke tones, and pulse tones in frequency.

#### 6.3.4.2 Alarm Signal


The alarm tones are very solid and can be identified by the alarm levels as following:


- ✧ High priority alarm: beep + beep + double + beep + pause + beep + beep + double + beep
- ✧ Medium priority alarm: triple beep
- ✧ Low priority alarm: single beep
- 🔔 When multiple alarms of different levels occur simultaneously, the monitor will select the alarm of the highest level and give visual and audible alarm indications accordingly.

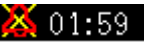
### 6.3.5 Alarm Status Symbols:

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



✧ For the customer purchased the monitor with configuration of “**Alarm pause**”, then this area shows the alarm sound status. There are 3 alarm sound status:


①  means the alarm sound is enabled;

②  “ means the alarm sound is disabled or means the alarm volume is 0 (alarm is mute), at this time the user should pay more attention to the patient;




③  means the alarm sound is paused. Text display area: when the alarm sound is paused, it displays counting-down time, otherwise it displays the date. Move the cursor on this text display area can bring up the edit box of "Alarm volume" setting.

✧ For the customer purchased the monitor with configuration of “**Alarm Reset**”, then this area shows the alarm sound status. There are 2 alarm sound status:

①  means the alarm system keeps on (is on “Alarm activating status”), and when alarm event occurs, it displays icon ”;


② when alarm event occurs, after pressing alarm reset key, then it displays icon ”. Move the cursor on this icon can bring up the edit box of "Alarm volume" setting.

#### Remark:

✧  Alarm reset key: pressing this key can perform alarm reset for the current activated alarm event (that’s to say, the audible alarming will be off, but the visual alarming still keeps effective), then icon ” displays on the upper right corner of the screen. The monitor can response to a new alarm event during the alarm reset status, that’s to say, both visual and audible alarming will be effective when there is a new alarm condition, and the icon ” displays on the upper right corner of the screen at the same time. Alarm reset is not a toggle operation, pressing this key once or more times only makes alarm reset.

✧ The description for technical alarm status indicator and physiological alarm indicator

1) Technical alarm status indicator is an auxiliary indicator for “Alarm lamp”. It’s used for indicating whether the system in technical alarm status or not. When the system in technical alarm status, then the indicator in blue, otherwise, it stays off.

2) When high priority physiological alarm event occurs, the physiological alarm indicator  is flashing with red color; when middle priority physiological alarm event occurs, the indicator is flashing with yellow color; when the low







priority physiological alarm event occurs, the indicator is in constant yellow light; if there is no physiological alarm event, the indicator is in constant blue light.

### 6.3.6 Changing Alarm Volume

To set the alarm sound volume.

Step 1: Select “Alarm”→“Others”.

Step 2: In “Others”, select “Alarm Volume”. Its setting range is "0 ~ 10", the step is 1. The default is 5. “10” is the maximum volume.

-  When the alarm sound is switched off, the monitor will give no audible alarm tones even if a new alarm occurs. Therefore the user should be very careful about whether to switch off the alarm sound or not.
-  Do not rely exclusively on the audible alarm system for monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.
-  Pausing or switching off alarms may result in a hazard to the patient, please be very careful.
-  If occurrence of multiple alarm signal at the same time, the monitor will only show the high priority alarm in the form of audible alarm and alarm lamp. Meanwhile, all alarm signals information including message descriptions and numerical highlight etc. will be shown respectively and simultaneously on the screen.
-  It is suggested that the users should not change the alarm volume lower than the factory default setting if close and constant attention could not be paid to the patient, otherwise the negligence of alarm event might cause irreversible harm to the patient.
-  During the alarm silence period, any new alarm event can activate the audible alarm again and the audible alarm function resumes normal state.

## 6.4 Understanding the Alarm Setting

Select “Alarm” button on Statusbar, and select parameter (such ECG, SpO<sub>2</sub>, NIBP, TEMP, etc.). You can review and set alarm limits, alarm switches, high/low alarm limit, and alarm level for each parameter, as shown in below figure.

GeneralParameter				
	IBP	AG/CSM	ARR	Others
PARAM	Switch	High	Low	Level
HR	On ▼	180	40	High ▼
SpO <sub>2</sub>	On ▼	100	90	High ▼
SpO <sub>2</sub> _PR	On ▼	180	40	High ▼
SYS	On ▼	180	60	High ▼
DIA	On ▼	120	50	High ▼
MAP	On ▼	160	50	High ▼
NIBP_PR	On ▼	180	40	High ▼




Alarm setting window (for full configuration)

- ✧ General parameters: the general parameters include HR, SpO<sub>2</sub>, SpO<sub>2</sub>\_PR, SYS, DIA, MAP, NIBP\_PR, RR, S-T, Temp1, Temp2 and TD.
- ✧ HR: turn on or off over-limits alarms of HR, set the high and low alarm limits, and set the alarm level. Setting range See **below** Section. 3 alarm level for options: high, medium and low.

The operation for other parameters is similar to that of HR, and we will not cover it again.

- ✧ Previous page: click it to turn to previous page.
- ✧ Next page: click it to turn to next page.
- ✧ All on: select it to enable alarm function for all parameters. Password is required for this operation.
- ✧ All off: select it to disable alarm function for all parameters. Password is required for this operation, and it's not recommended to disable the alarm function completely.

**Notes:**

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

2.The high alarm limit for SpO<sub>2</sub> is fixed to be "100" and is nonadjustable.

- ✧ **ARR:** to set the alarm priority level for 5 arrhythmia (ARR) events, which include ECG Brady, ECG Tachy, ECG Arrest, VE Run and SVE Run. 3 priority alarm level for option: high, medium and low. The user can also enable or disable the alarm switch for these 5 ARR events.
- ✧ **Others:** to set the alarm volume and timeout setting for apnea alarm.
- ✧ **Alarm volume:** to set the alarm sound volume for the monitor. The setting range is "1~10" level, and the default is 5. Note: for the monitor optioned with "Mute for Spot Check" function, the setting option is 1~10 and "Spot Check".
- ✧ **Apnea:** to set the timeout setting for apnea alarm (in seconds). The options are: off, 10, 15, 20, 25, 30, 35 and 40. Details see Section "**Changing RESP Settings**".

## 6.4.1 High and Low Alarm Setting Range

Select "Alarm" → "General Parameter".

Parameter	Setting range	
	High limit	Low limit
HR (bpm)	(Low limit+1)~350	0~(High limit-1)
S-T (mV)	(Low limit+0.01)~2.50	-2.5~(High limit-0.01)
SpO <sub>2</sub> (%)	(Low limit+1)~100	0~(High limit-1)
SpO <sub>2</sub> _PR (bpm)	(Low limit+1)~300	0~(High limit-1)
RR (rpm)	(Low limit+1)~150	0~(High limit-1)
TEMP1 (°C)	(Low limit+0.1)~60.0	0~(High limit-0.1)
TEMP2 (°C)	(Low limit+0.1)~60.0	0~(High limit-0.1)
TD (°C)	0.0~5.0	

NIBP (Unit) mmHg		Adult	Pediatric	Neonate
SYS	High limit	(Low limit+1) ~280	(Low limit+1) ~200	(Low limit+1) ~135
	Low limit	29~ (High limit-1)	29~ (High limit-1)	29~ (High limit-1)
MAP	High limit	(Low limit+1) ~242	(Low limit+1) ~165	(Low limit+1) ~110
	Low limit	20~ (High limit-1)	20~ (High limit-1)	20~ (High limit-1)
DIA	High limit	(Low limit+1) ~232	(Low limit+1) ~150	(Low limit+1) ~100
	Low limit	10~ (High limit-1)	10~ (High limit-1)	10~ (High limit-1)
NIBP (Unit) kPa		Adult	Pediatric	Neonate
SYS	High limit	(Low limit+0.1) ~37.3	(Low limit+0.1) ~26.7	(Low limit+0.1) ~18.0
	Low limit	3.9~ (High limit-0.1)	3.9~ (High limit-1)	3.9~ (High limit-0.1)
MAP	High limit	(Low limit+0.1) ~32.3	(Low limit+0.1) ~22.0	(Low limit+0.1) ~14.7
	Low limit	2.7~ (High limit-0.1)	2.7~ (High limit-0.1)	2.7~ (High limit-0.1)
DIA	High limit	(Low limit+0.1) ~30.1	(Low limit+0.1) ~20.0	(Low limit+0.1) ~13.3
	Low limit	1.3~ (High limit-0.1)	1.3~ (High limit-0.1)	1.3~ (High limit-0.1)

Note: The following parameters are optional

- \* Do not set alarm limits to extreme values that can render the alarm system useless.
- \* A potential hazard can exist if different Alarm Pre-sets are used for the same or similar equipment in any single area.
- \* Alarm settings are restored automatically after power is interrupted for  $\leq 30$  s.
- \* Suggest the operator's position away from the equipment about 1 m.
- \* In general, the environment noise cannot be controlled or managed in facilities. However, the volume of alarm system in our device can be adjusted. So, the operators can adjust the volume of the auditory alarm signal tone according to the actual environmental noise in the real environment. So that the alarm signal should be larger than the background noise.

## 6.4.2 Factory Default Alarm Limit Setting Value

Type		Adult	Pediatric	Neonate
Parameter				
HR	High limit	180 bpm	200 bpm	220 bpm
	Low limit	40 bpm	50 bpm	50 bpm
RR	High limit	30 rpm	30 rpm	100 rpm
	Low limit	8 rpm	8 rpm	30 rpm
TEMP	High limit	39 °C	39 °C	39 °C
	Low limit	35 °C	35 °C	35 °C
SYS	High limit	180 mmHg	130 mmHg	110 mmHg
	Low limit	60 mmHg	50 mmHg	50 mmHg
DIA	High limit	120 mmHg	90 mmHg	90 mmHg
	Low limit	50 mmHg	40 mmHg	30 mmHg
MAP	High limit	160 mmHg	110 mmHg	100 mmHg
	Low limit	50 mmHg	40 mmHg	30 mmHg
SpO <sub>2</sub>	High limit	100 %	100 %	100 %
	Low limit	90 %	85 %	85 %
S-T segment	High limit	+1.00mV	+1.00mV	+1.00mV
	Low limit	-1.00mV	-1.00mV	-1.00mV
PR	High limit	180 bpm	200 bpm	220 bpm
	Low limit	40 bpm	50 bpm	50 bpm
TD		2 °C	2 °C	2 °C
ART	High limit	200mmHg	160mmHg	140mmHg
	Low limit	10mmHg	10mmHg	10mmHg
PA	High limit	120mmHg	100mmHg	90mmHg
	Low limit	10mmHg	10mmHg	10mmHg
CVP	High limit	30mmHg	30mmHg	30mmHg
	Low limit	-10mmHg	-10mmHg	-10mmHg



RAP	High limit	30mmHg	30mmHg	30mmHg
	Low limit	-10mmHg	-10mmHg	-10mmHg
LAP	High limit	30mmHg	30mmHg	30mmHg
	Low limit	-10mmHg	-10mmHg	-10mmHg
ICP	High limit	30mmHg	30mmHg	30mmHg
	Low limit	-10mmHg	-10mmHg	-10mmHg
AUXP1	High limit	200mmHg	160mmHg	140mmHg
	Low limit	-30mmHg	-30mmHg	-30mmHg
AUXP2	High limit	200mmHg	160mmHg	140mmHg
	Low limit	-30mmHg	-30mmHg	-30mmHg

1. Except volume of audible alarm can be adjustable, the other properties of the alarm cannot be adjusted by the user, such as alarm priority setting, alarm lamp flashing and so on. In addition, all alarms in this patient monitor are “non-latched” type, that is to say, when the alarm event disappears, the corresponding alarm will automatically stop. The alarm volume range is shown as below:

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

2. Alarm settings are non-volatile, that means the previous settings will still sustain even the patient monitor is powered off including unexpected power failure and manual reboot.

## 6.5 Testing Alarms

When the monitor starts up, a self-test is performed. In this case the alarm lamp will light, and the system gives a beep. This indicates that the visible and audible alarm indicators are functioning correctly.

For further testing of individual measurement alarms, perform the measurement on yourself (for example SpO<sub>2</sub>) or enter Demo Mode, or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.


## 6.6 When an Alarm Occurs

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

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

## 6.7 Sound Pressure Level Range

ALARM CONDITION	Volume level setting	RANGE (dB)
HIGH PRIORITY ALARM CONDITIONS	Maximum "10"	61~70
HIGH PRIORITY ALARM CONDITIONS	MINIMUM "1"	35~44
MEDIUM PRIORITY ALARM CONDITIONS	MAXIMUM "10"	55~64
MEDIUM PRIORITY ALARM CONDITIONS	MINIMUM "1"	29~38
LOW PRIORITY ALARM CONDITIONS	MAXIMUM "10"	52~61
LOW PRIORITY ALARM CONDITIONS	MINIMUM "1"	51~60

-  Auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm conditions and the alarm system provides.

## 6.8 Alarm System Security

In order to restrict the Alarm System from being changed or stored, only the system administrator can enter the system settings to change the default values, but a password must be entered.

# Chapter 7 ECG Monitoring



## 7.1 Introduction

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

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

## 7.2 Safety Information

-  This patient monitor can only be equipped with ECG cable and/or lead wires provided by the manufacturer; using those from other suppliers may cause improper performance or poor protection while using defibrillator.
-  Using the same type of qualified and authorized electrodes which should be within its effective life on the same patient. If any side-effect such as allergic or stimulus skin is found, the measurement should be stopped at once. It is prohibited to apply the electrode to the patient with lesion and body putrescence.
-  To the patient with pacemaker, normally the heart rate meter does not count the pacemaker pulse due to the function of pacemaker pulse inhibition, but for the pacemaker with overshoot pulse, the inhibition function may not be fully effective. So it is important to observe the ECG waveforms carefully and do NOT rely entirely on the heart rate display and alarm system when monitoring the pacemaker patient.
-  The improper connection with electro-surgical unit may not only cause burns, but also damage the monitor or arouse deviations of measurement. You can take some steps to avoid this situation, such as do NOT use small ECG electrodes, choosing the position which is far away from the estimated Hertzian waves route, using larger electro-surgical return electrodes and connecting them with the patient properly.
-  Conductive parts of electrodes, lead wires and cable are forbidden to contact any other conductive parts (including ground).
-  This patient monitor can resist against the discharge of defibrillator and the interference from the electro-surgical unit. Readings may be inaccurate for a short time after or during using defibrillator or electro-surgical unit.
-  Transient caused by cable circuitry blocks while monitoring may cause artifact on ECG signals yielding wrong heart rate reading and even triggering false alarm. If the electrodes and cable are located in proper places according to this manual's instructions for using electrodes, the chance of this transient occurrence will be decreased.
-  ECG cable and/or lead wires may be damaged while using defibrillator. If the cable and/or lead wires are used again, please do the functional check firstly.
-  When the monitor is inoperable due to overload of ECG signal or saturation of any part of the amplifier, it will prompt "Lead(s) off" to remind the operator.

-  The user should ensure that no predictable hazard will be caused by the summation of leakage currents when several items of monitor are interconnected.
-  When plugging or unplugging the ECG cable, be sure to hold the head of the connector and pull it out.

## 7.3 Preparing to Monitor ECG

### 7.3.1 Preparing the Patient and Device

#### 1. Skin preparation

The quality of ECG waveform displayed on the monitor is a direct result of the quality of the electrical signal received at the electrode. Proper skin preparation is necessary for good signal quality at the electrode. A good signal at the electrode provides the monitor with valid information for processing the ECG data. To ensure enough electrolyte material on the skin of patients, you need to moisten the measuring sites with 70% isopropyl Ethanol. This will usually be sufficient for ECG monitoring for a short time (30 to 60 minutes).

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

3. Place the electrode to the patient according to **Section 7.3.2**.

4. Attach the ECG lead wires to the electrode

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

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

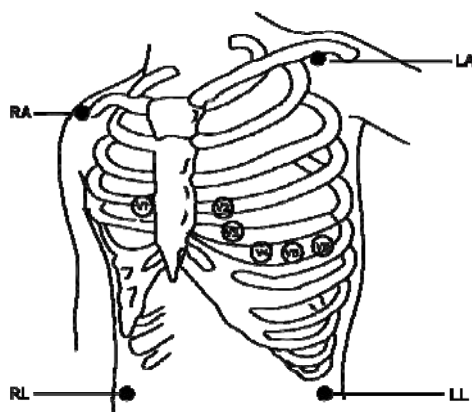
- ✧ It might not display ECG waveform when using ECG cable with 3 lead wires while the setting of "Cable" is set as "5" in the ECG parameter setup menu. Only single channel of ECG signal can be obtained while using 3 lead wires and the "Cable" is set as "3", this ECG signal can be selected between Lead I, Lead II and Lead III.
- ✧ In order to obtain other Leads of the ECG signals, such as aVL, aVR, aVF and V, the ECG cable with 5 lead wires should be used and the "Cable" should be set to "5". At this situation, 7 Leads of ECG signal (lead I, II, III, aVL, aVR, aVF, V) can be obtained and displayed simultaneously.

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



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

### 7.3.2 ECG Electrodes Placement



### Electrode Placement

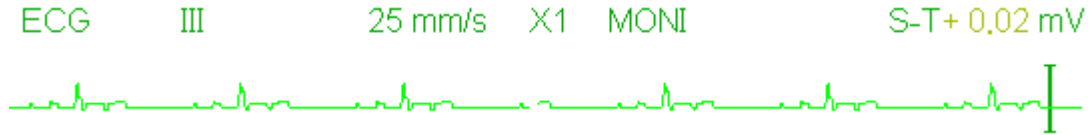
The ECG leads and their corresponding locations are as follows:

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

## 7.4 Understanding the ECG Display

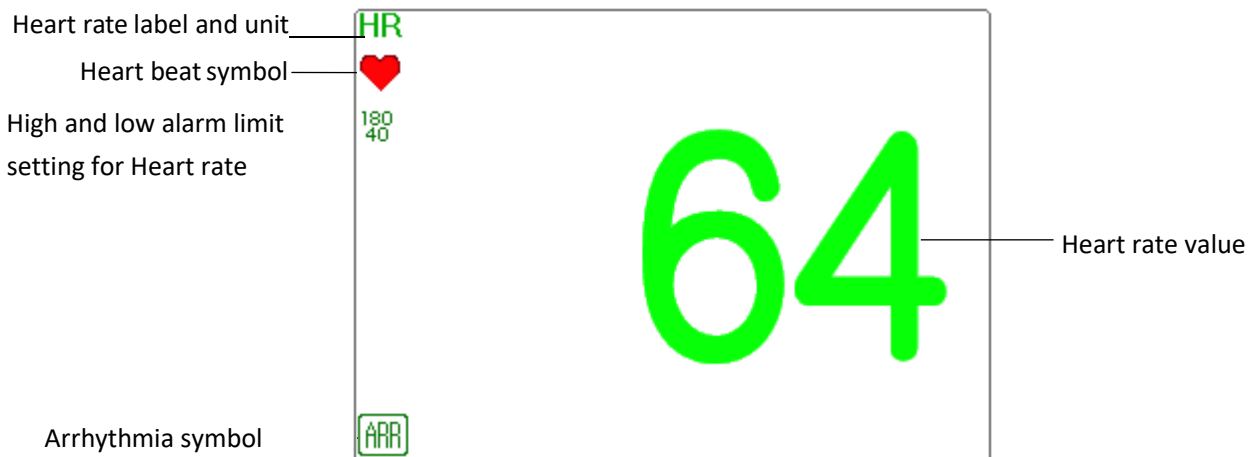
Your display may be configured to look slightly different.



### ECG waveform



- ✧ "ECG": parameter label.
- ✧ "III": ECG lead. III means ECG lead III.
- ✧ "25mm/s": ECG waveform sweeping speed, unit is "mm/s".
- ✧ "X1": ECG waveform gain. "X1" means the waveform scale with base gain.
- ✧ "MONI": ECG filtering mode. There are three types: diagnose, monitoring and operation.
- ✧ "S-T+0.02mV": S-T segment value, here indicates the value is 0.02mV.

### Heart Rate Panel:



- ✧ "**HR**": heart rate. The 64 on the right is the heart rate measured.
- ✧ "**bpm**": the unit of heart rate, it means "beats per minute".
- ✧ "": the heart-beat symbol, blinks corresponding to the R wave of ECG waveform.
- ✧ "**180/40**": high and low alarm limit setting for heart rate.
- ✧ "": Arrhythmia symbol. If the ARR function is set as ON, then this symbol will be displayed.

## 7.5 Changing ECG Settings

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

Note: according to the different function configuration, the ECG parameter setting window may be different, please

refer to the monitor in your hand.

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

✧ **Filter:** ECG filtering mode, 3 options: MONI, DIAG, and OPER.

**DIAG:** extended bandwidth to provide the ECG waveforms with the quality of diagnosis level.

**MONI:** normal bandwidth to provide noise free ECG waveforms for effective monitoring purpose.

**OPER:** narrow bandwidth to deeply suppress the interference from electro-surgical unit during operation.

The default mode is "MONI".

**Notes:**

1. For different ECG related setting window, and when the ECG filtering mode is set as "OPER", then items like "Notch", "Wires", "Lead" and "Pacer" are in grey and nonadjustable. The "Notch" shows the lasting setting, the "Wires" is fixed to be "3 lead wires", the "Lead" is fixed to be lead "II", and the "Pacer" is fixed to be unselectable.

2. if the amplitude of an ECG waveform is too large, the peak of the waveform might not be displayed. In this case, you should change the waveform gain properly.

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

x1/8: 1/8 of the base gain;

x1/4: 1/4 of the base gain;

x1/2: 1/2 of the base gain;

x1: the base gain;

x2: twice of the base gain;

x4: 4 times of the base gain;

Auto: auto gain control;

The base gain is 10 mm/mV.


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

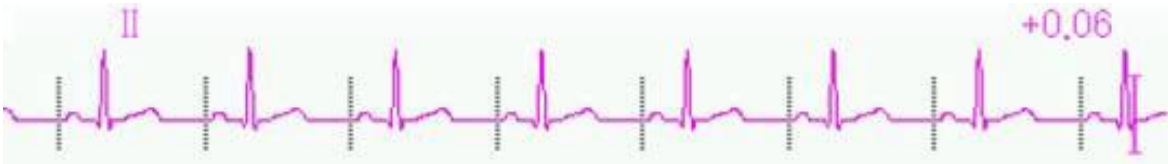
✧ **Wires:** The default is "5-lead", it is necessary to select ECG Lead with "5-lead" setting to obtain all ECG signals including Lead I, II, III, aVR, aVL, aVF, and V. The user can also choose "3-lead" setting. When "3-lead" is chosen, only electrodes of R/RA, L/LA, and F/LL are used for detecting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

Note: if your monitor is configured with 12-lead ECG function, then you can set "Wires" as "5-lead" or "12-lead" to obtain ECG signals. When "12-lead" is chosen, then the waveform of lead I, II, III, aVR, aVL, aVF, V1~V6 will be displayed on the All ECG Trace view.

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

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

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



Note: pacemaker pulse inhibition function is always effective for Heart Rate calculation whether you enable or disable the function of cardiac pacemaker pulse detection or not.

- ✧ **PARM:** to enter into HR alarm setting. See Section “Understanding the Alarm Setting”.


## 7.6 About Arrhythmia Detection and Template Learning


- ✧ **ARR:** ECG arrhythmia analysis

**ARR switch:** the switch of ECG arrhythmia detection. The default is ON. This switch does not effect the alarm function for 5 ARR events (ECG Brady, ECG Tachy, ECG Arrest, VE Run and SVE Run). That’s to say, the detection and alarm for 5 ARR events is fixed to be ON, and nonadjustable.

**Extra ARR Learning:** indication of ARR learning status or activating ARR learning manually.

When ARR is set to "ON", the device will start to learn the regular ECG signal automatically for ARR detection and

icon  will be displayed. The device will finish the learning after a certain period, and the icon will become

"". The detected arrhythmia waveform will be displayed on the third or the last ECG waveform display channel; if there is only one ECG waveform display channel, then the detected arrhythmia waveform will be re-displayed and frozen on this channel for 8 seconds. The arrhythmia waveform will be re-displayed on the cascaded waveform channel if there is a single Lead of ECG signal displayed with cascaded waveform channels.

Note: Because Arrhythmia detection needs a template ECG waveform as reference which is a piece of normal ECG waveform with regular rhythm and stable amplitude, it is necessary to re-activate the template learning when the patient is changed, or the Arrhythmia detection is incorrect. For stronger Arrhythmia detection, it is recommended to wait for a clean and stable ECG waveform before starting ARR detection during the monitoring.

Note: when the device is restarted, the Arrhythmia detection is reset to its default status.

- ✎ During Arrhythmia detection, incorrect detection might occur if the non-ECG waveforms (e.g. square or triangle waveform) appear.
- ✎ Before starting the 1mV calibration signal, please turn off the Arrhythmia detection.
- ✎ During Arrhythmia detection, the template learning is very important. The device requires a group of stable QRS complex waveforms to build up this template. If the system detects Arrhythmia incorrectly, please re-activate the template learning and obtain the correct template.

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

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





V-Fib.

### 7.6.1 Understand the ARR Type

Type	Abbreviation	Full name
1	ECG TACHY	Tachycardia
2	ECG BRADY	Bradycardia
3	ECG ARREST	Cardiac Arrest
4	MISS BEAT	Missing Beat
5	VE EARLY	Ventricular Premature Contraction (VPC)
6	SVE EARLY	Supra-ventricular Premature Contraction (SVPC)
7	VE COUPLET	Ventricular Couplet
8	SVE COUPLET	Supra-ventricular Couplet
9	VE RUN	Ventricular Run
10	SVE RUN	Supra-ventricular Run
11	VE SHORT RUN	Ventricular Short Run
12	SVE SHORT RUN	Supra-ventricular Short Run
13	VE BIGEMINY	Ventricular Bigeminy
14	SVE BIGEMINY	Supra-ventricular Bigeminy
15	VE TRIGEMINY	Ventricular Trigeminy
16	SVE TRIGEMINY	Supra-ventricular Trigeminy
17	VE INSERT	Ventricular Insert
18	SVE INSERT	Supra-ventricular Insert
19	VE RONT	Ventricular RonT
20	SVE RONT	Supra-ventricular RonT

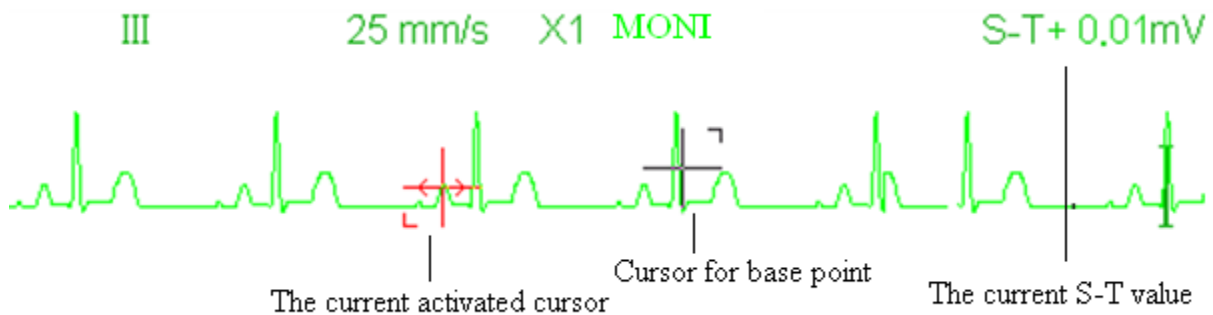
## 7.7 About S-T Segment Monitoring

### Manual S-T segment measurement operation:

The operator can use the Navigation Knob to do the S-T segment measurement manually, the value is displayed as "ST+0.xxx mV". There are 2 cross cursors on screen. The red cross is the activated one. The arrows (  and  ) on the red cross indicate the directions that the cross cursor moves when rotating the Navigation Knob. Press the

Navigation Knob can change directions of the cross cursor or change the activating status of the cross cursor.

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



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

## 7.8 Freezing Waveform

When there are waveforms displayed on screen, press the Freeze key to enter into waveform freezing screen. During freezing, the frozen symbol ❄ " and frozen time will be displayed on the upper right corner of the waveform area. At the moment, the operator can do S-T measurement, and get the real-time value of S-T segment

There are 2 Freeze types: "ECG waves", "EEG" (if optional) and "All waves", which can be set in System Settings window.

## 7.9 Factors Affecting ECG signal

- ❖ Interference from Electro-surgical Unit;
- ❖ Doesn't set the filter mode properly;
- ❖ Poor grounding;
- ❖ Electrodes are not placed properly;
- ❖ Use expired electrode or use disposable electrode repeatedly;
- ❖ The skin placed electrode is unclean or poor contact caused by scurf and hair;

# Chapter 8 Monitoring Respiration (RESP)

## 8.1 Introduction

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

## 8.2 Safety Information

- When monitoring the patient's respiration, it is recommended to use the so-called "non-OR" ECG cable which has no built-in resistors to prevent the energy loss of defibrillator discharge. Otherwise the performance of respiration monitoring is degraded.
- The respiration measurement does not recognize the cause of apneas. It only indicates an alarm if no breath is detected when a preset time has elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purpose.
- If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3V/m), field strengths above 1V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.

## 8.3 Understanding the RESP Display

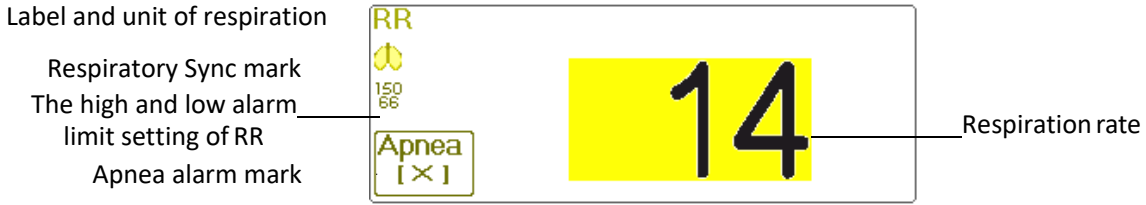
RESP waveform:

RESP

12.5 mm/s X1/2



**Respiration Panel:**



- ✧ "RR": the label of Respiration. "rpm" is the unit of the Respiration Rate (respiration per minute). The big font "14" is the value of Respiration rate.
- ✧ "👤": Breath symbol. The blinking frequency is the same as the Respiration Rate.
- ✧ "150 66": the high and low alarm limit setting for Respiration Rate.
- ✧ "Apnea (X)": the apnea alarm status in RESP alarm setting, refer to the following Section for details.

**8.4 Changing RESP Settings**

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

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

X1	waveform scale with base gain	X1/2	half scale size of the base gain
X2	twice scale size of the base gain	X4	four times scale size of the base gain
  - ✧ **Speed:** Respiration waveform sweeping speed of, 2 options: 6.25mm/s and 12.5 mm/s. The default is 12.5 mm/s.
  - ✧ **Apnea:** The timeout setting for apnea alarm (in second). It can be set as any number from 5 to 120 seconds, the step is 1 second. Icon "Apnea:10" displays on the lower left corner of Respiration Panel; When the device has not detected any breathing signal for the specified time, the "Apnea" alarm prompts on, and alarm sound will be activated. If it is set as OFF, the icon "Apnea (X)" displays on lower left corner of the Respiration Panel.
- Note: when "Wires" is set as "12-lead" in ECG related settings, then "Apnea" can be set as off, 10, 15, 20, 25, 30, 35 and 40.
- ✧ **Source:** Respiration signal source. This item is fixed to be "CO<sub>2</sub>" if CO<sub>2</sub> monitoring function is selected. Otherwise, the source will be obtained by measuring the thoracic impedance via ECG electrodes, the signal source can come from the ECG electrodes defined by "ECG Lead I" and "ECG Lead II". (Note: WHEN "12-lead" is selected, then the "Source" is fixed to be "ECG Lead II" and nonadjustable.)
  - ✧ **PARAM:** to enter into RR alarm setting. See Section "Understanding the Alarm Setting".

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

# Chapter 9 Monitoring NIBP

## 9.1 Introduction









### 9.1.1 The Oscillometric Blood Pressure Measurement

This device applies the typical non-invasive blood pressure measurement with the oscillometric method. A cuff is used to occlude the artery by inflating it above the patient's systolic pressure, the device measures the amplitude of pressure changes with pulsation in the cuff as the cuff pressure decreases. The pulsations increase in amplitude, and reach a maximum, then diminish along with the decrement of cuff pressure. The cuff pressure corresponding to the maximal pulse amplitude approximates to the mean artery pressure (MAP), the cuff pressure at the pulse amplitude backward reduced according to proper proportion is defined as systolic pressure (SYS), and the cuff pressure at the pulse amplitude forward reduced according to proper proportion is defined as diastolic pressure (DIA)









### 9.1.2 The Oscilometric method vs. the Korotkoff Sound Method

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

## 9.2 Safety Information

-  When taking the blood pressure measurement on a neonate patient. DO NOT operate in the Adult mode. The high inflation pressure may cause lesion or even body putrescence. Even though the monitor can identify the cuff type so it will stop inflation and indicate "Cuff error" when taking the blood pressure measurement for a neonate in the "Adult" patient type setting. The user (doctor or nurse) should pay more attention to select the correct patient type.
-  It is recommended to take the blood pressure measurement manually
-  NIBP monitoring is prohibited to those who have severe hemorrhagic tendency or with sickle cell disease, otherwise, partial bleeding will appear.
-  DO NOT wrap the cuff on limbs with transfusion tube or intubations or skin lesion area, otherwise, injury may be caused to the limbs.
-  If the patient is moving or suffering tremble, hyperkinesia or arrhythmia, it may cause the inflation time of inflatable balloon endures longer, which may not only prolong the measurement time, but also result in the body wrapped by the cuff is troubled by purpura, hypoxemia and neuralgia because of the friction.
-  Before the measurement is carried out, select an appropriate measuring mode depending on the patient type (adult, pediatric or neonate).
-  The air-hose which connects the cuff and monitor should be straightway without any tangle.
-  When an adult patient is monitored, the device may fail in giving the blood pressure measurement if

The pediatric patient type is selected.

-  Prior to use of the cuff, empty the cuff until there is no residual air inside it to ensure accurate measurement.
-  DO NOT twist the air tube or put heavy things on it.
-  When unplugging the air tube, hold the head of the connector and pull it out.
-  The NIBP measurement will not be affected when the monitor is connected to the patient on whom the electro-surgical unit and defibrillator is being used.
-  The appearance of arrhythmia results in irregular heart beat which may affect the accuracy of NIBP measurement. It is recommended to take the measurement again at this situation.
-  The blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, manual, electronic, or automated sphygmomanometers.
-  The monitor can be used on the patients who are pregnant or pre-eclamptic, but close attention should be paid to such patients.
-  The performance of NIBP function can be affected by the extremes of temperature, humidity and altitude, please use it within the appropriate working environment.

### 9.3 Measurement Limitations

1. Serious angiospasm, vasoconstriction, or too weak pulse.
2. When extremely low or high heart rate or serious arrhythmia of the patient occurs. Especially auricular fibrillation will lead to unreliable or impossible measurement.
3. Do not take the measurement when the patient is connected with an artificial heart-lung machine.
4. Do not take the measurement when the patient uses diuresis or vasodilator.
5. When the patient is suffering from major hemorrhage, hypovolemic shock and other conditions with rapid blood pressure change or when the patient has too low body temperature, the reading will not be reliable, for reduced peripheral blood flow will lead to reduced arterial pulsation.
6. Patient with hyperadiposis;

### 9.4 Measurement Mode

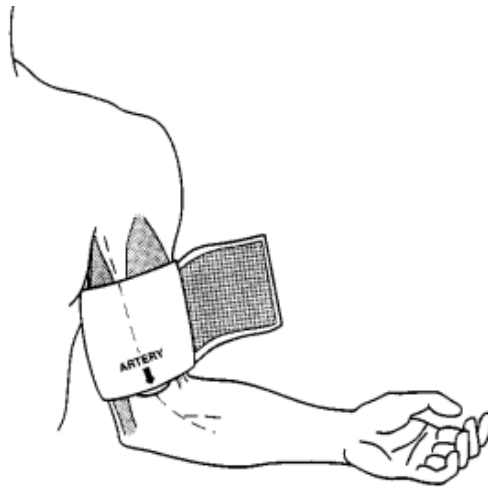
There are three measuring mode for NIBP measurement:

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


### 9.5 Setting Up the NIBP Measurement

### 9.5.1 Preparing to Measure NIBP

1. Power on the monitor.
2. Check the patient information area on the screen. Set a correct patient type, select a correct cuff size.
3. Connect the tube with cuff to the connector marked with "NIBP" icon on the signal input panel.
4. Select a cuff with correct size, then unfold the cuff and wrap it around the patient's upper arm as follows:
  - ✧ Determine the patient's limb circumference.
  - ✧ Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% of the limb circumference, or  $\frac{2}{3}$  of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb. When putting on the cuff, unfold and wrap it around the upper arm evenly to appropriate tightness.
  - ✧ Remember to empty the residual air in the cuff before the measurement is commenced.
  - ✧ Locate the cuff in such a way that the artery mark "↓" is at a location where the clearest pulsation of brachial artery is observed.
  - ✧ The cuff should be tightened to a degree where insertion of one finger is allowed.
  - ✧ The lower end of the cuff should be 2cm above the elbow joint.



### 9.5.2 Starting and Stopping Measurements

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


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

### 9.5.3 Factors Affecting NIBP Measurement



Like common non-invasive blood pressure measurement, improper operation may cause inaccurate or blank result or misunderstanding of the measuring information when the oscillometric method is used to take the blood pressure measurement. These points need particular attention of the operators.

1. Requirements of the cuff:

- 1) Appropriate cuff should be selected according to the age of the patient.
- 2) Remember to empty the residual air in the cuff before the measurement is commenced.
- 3) Locate the cuff in such a way that the artery mark “” is at a location where the clearest pulsation of brachial artery is observed.
- 4) The cuff should be tightened to a degree where insertion of one finger is allowed.
- 5) The lower end of the cuff should be 2cm above the elbow joint.

2. The patient should lie on the back so that the cuff and the heart are in a horizontal position and the most accurate measurement is taken. Other postures may lead to inaccurate measurement.

3. Do not speak or move before or during the measurement. Care should be taken so that the cuff will not be hit or touched by other objects. The air tube which connects the cuff and monitor should be straightway without any tangle.

4. The measurement should be taken at appropriate intervals. Continuous measurement at too short intervals may lead to pressed arm, reduced blood flow and lower blood pressure, and resulting inaccurate measurement of blood pressure. It is recommended the measurement be taken at intervals of more than two minutes.

5. With the oscillometric method, when blood pressure is measured, the inflation pressure of the cuff will be automatically adjusted according to the previous measurement. Generally, the initial inflation pressure is 150mmHg (for the adult mode) or 120mmHg (for pediatric) or 70 mmHg (for neonate) when it is powered on. Following that, 28mmHg (for adult) or 25mmHg (for pediatric) or 25mmHg (for the neonate) will be added on the basis of the last measurement of systolic pressure. In this way, when the blood pressure rises or the patient is changed, the device may fail in giving the result after the first-time inflation. This device will automatically adjust the inflation pressure until the measurement is taken, after that, up to four times retry will be allowed.

6. When an adult patient is monitored, the device may fail in giving the blood pressure measurement if the Pediatric or neonate patient type is selected.

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

## 9.6 Understanding the NIBP Numerics



### NIBP Panel:



- ✧ **"NIBP"**: the label of blood pressure. "123" is the systolic pressure value, "80" is the diastolic pressure value, and "95" is the mean arterial pressure.
- ✧ **"mmHg"**: the unit of blood pressure value, 1kPa = 7.5mmHg.
- ✧ **"PR 62"**: pulse rate value when taking blood pressure measurement.
- ✧ **"Manu"**: the icon of NIBP measurement mode. There are 3 modes: "Manual", "Auto" and "STAT". When in "AUTO" mode, a count-down timer is displayed as well.

## 9.7 Changing NIBP Settings

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

- ✧ **Mode:** "MANU", "AUTO", "STAT" and "Customized Multi-cycle" can be selected. The default is "MANU".
  - In "MANU" mode, press the NIBP measure key  manually can start or stop NIBP measurement.
  - In "AUTO" mode, the device repeats NIBP measurement automatically with the set time interval. In this mode, the manual interference still works.
  - In "STAT" mode (only used for adult), press the NIBP measure key , the device will do NIBP measurement again and again. The device will not stop making measurement until the measuring time is over 5 minutes or the operator stops it manually.
- ✧ **Customized Multi-cycle:** move the cursor on "Customized Multi-cycle" and click "OK" to enable this function. The user can customize the related parameters: Phase, time cycle (the time interval between two measurements) and repeats. There are 5 phases: A, B, C, D and E. The user can set the time cycle and repeats for Phase A to Phase E.
- ✧ **Time cycle:** 1min, 2min, 3min, 4min, 5min, 10min, 15min, 20min, 25min, 30min, 35min, 40min, 45min, 50min, 55min, 1h, 1.5h, 2h, 2.5h, 3h, 3.5h and 4h for optional.
- ✧ **Repeats:** OFF, 1, 2, ...9 and 10 for optional.

For example, firstly, the monitor enter into Phase A (making NIBP measurement once every 5 minutes, and repeat once only); Secondly, entering into Phase B (making NIBP measurement once every 10 minutes, and repeat once only); Thirdly, entering into Phase C (making NIBP measurement once every 20 minutes, and repeat 2 times); Fourthly, entering into Phase D (making NIBP measurement once every 30 minutes, and repeat 5 times); Lastly, entering into Phase E (making NIBP measurement once every 60 minutes, and repeat once only). In the period of 30 minutes, if the NIBP measurement is less than 6 times and NIBP measurement mode is not changed, then the monitor will start to make NIBP measurement from Phase A to E automatically.

**Caution:** STAT mode can only be used for adult.


Notes:

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

For "Adult", if the NIBP measuring mode is set as "STAT", then the monitor will not save this setting when you shutdown the monitor. That's to say, when re-starting the monitor, the NIBP measuring mode for Adult is "Manual".

For all patient types, if the NIBP measuring mode is set as "Manual", or "Auto", or "Customized Multi-cycle", then the monitor will save this setting when you shutdown the monitor.

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

and this item is set, the operator must manually press NIBP measure key  for the first time, then the device will start time counting down. The device will start taking the next blood pressure measurement automatically after finishing counting down.

- ✧ **Unit:** the pressure unit. "mmHg" and "kPa" can be selected. 1 kPa = 7.5 mmHg.
- ✧ **Init. Pressure:** Cuff pressure to be inflated initially. Its range is different depending on patient type.

**for adult:** 80, 100, 120, 140, 150, 160, 180, 200 mmHg;

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

**for neonate:** 60, 70, 80 mmHg.

Note: if your monitor is configured with SunTech NIBP module, then the initial cuff pressure range for adult is 120~220mmHg.

- ✧ **PARM:** to enter into NIBP (SYS, DIA, MAP,) alarm setting. See Section "Understanding the Alarm Setting".
- ✧ **Verification:** to verify the NIBP pneumatic system, is used to verify the pressure accuracy and check the air leakage of the pneumatic system, which should be conducted by technicians in the specified environment. It includes "Verification A", "Verification B" and "Leakage Check".
- **Verification A & Verification B:** the 2 kinds of verification of the pressure accuracy. Press the relevant button to start Verification A or B. When completed, it is necessary to stop the verification manually by pressing "Stop" button. System will also stop the verification when "Exit" button pressed.
- **Leakage Check:** it is used by technicians to perform a leakage inspection for NIBP pneumatic system..

**Important:**

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

The auto inflating pressure value for Adult: >190mmHg (25.3kPa)

The auto inflating pressure value for Pediatric: >160mmHg (21.3kPa)

The auto inflating pressure value for Neonate: >80mmHg (10.7kPa)

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

Note: if the verification window pops up during verification, you can press "Close" button to exit from it only, but it is forbidden to exit from by pressing "Display View Key".

# Chapter 10 Monitoring Oxygen Saturation (SpO<sub>2</sub>)


















## 10.1 Introduction

The functional oxygen saturation (SpO<sub>2</sub>) - a percentage of the hemoglobin that can transport oxygen, is monitored by this device via a non-invasive optical technique. Based on the principle that oxygenated hemoglobin (HbO<sub>2</sub>) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light, the device measures the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into electrical signals by the photo-detector in the probe. The SpO<sub>2</sub> module processes the electrical signals and gives out waveform data and digital values for SpO<sub>2</sub> and pulse rate displayed on the screen.

## 10.2 Safety Information

- Continuous use of fingertip SpO<sub>2</sub> sensor may result in discomfort or pain, especially for those patients with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same site for over two hours, please inspect the monitoring site every 1~2 hours for skin integrity, and change the measuring site periodically if necessary.
- Check SpO<sub>2</sub> probe application site periodically (every 30 minutes) to determine circulation, positioning and skin sensitivity.
- SpO<sub>2</sub> measuring site must be examined more carefully for some special patient. Do NOT place the SpO<sub>2</sub> sensor on the finger with edema or fragile tissue.
- Avoid placing the SpO<sub>2</sub> sensor on the same extremity with an arterial catheter, blood pressure cuff, or intravascular infusion line, otherwise the blood flow could be interrupted by the cuff or the circulatory condition could make low blood perfusion so that would result in no pulse found or loss of pulse during SpO<sub>2</sub> monitoring and further cause false alarm.
- The SpO<sub>2</sub> measurement of this monitor may not work effectively for all kinds of patients, for whose with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the measurement will be more sensitive to interference, if stable readings cannot be obtained at any time, discontinue use of SpO<sub>2</sub> monitoring function.
- For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO<sub>2</sub> determination by this monitor may be inaccurate.
- The drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO<sub>2</sub> measurements.
- Excessive ambient light may affect the measuring result, it includes fluorescent lamp, dual ruby light, infrared heater, and direct sunlight etc.
- As the SpO<sub>2</sub> value serves as a reference value for judgment of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO<sub>2</sub> value.
- Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate

oxygen saturation measurements.

-  Vigorous movement of the patient, strong ambient light, or extreme electro-surgical interference may also affect the SpO<sub>2</sub> measuring accuracy.
-  DO NOT stare at the light of SpO<sub>2</sub> sensor (infrared is invisible) when switch it on, for the infrared may do harm to the eye.
-  The information, such as the range of the peak wavelengths and maximum optical output power of the light by the SpO<sub>2</sub> sensor can be especially useful to clinicians.
-  Always observe the plethysmogram (waveform), which is auto-scaled (normalized). When the measured signal is inadequate, the waveform will be not smooth or irregular, the SpO<sub>2</sub> reading may be unlikely true or displayed with "--", and even a technical alarm will be generated. If in doubt, rely on your clinical judgement, rather than the monitor readout.
-  Please do not use the SpO<sub>2</sub> sensor and the monitor when doing the MRI imaging, or burn may be caused by faradism.
-  For disposal SpO<sub>2</sub> sensor, if the sterile packaging is damaged, do not use it any more.
-  Check the SpO<sub>2</sub> sensor and cable before use. Do NOT use the damaged SpO<sub>2</sub> sensor.
-  Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl Ethanol. If low-level disinfection is required, use a 1:10 bleach solution.
-  When the temperature of SpO<sub>2</sub> sensor is abnormal, do not use it any more.
-  Please do not allow the cable to be twisted or bent.
-  Please do not use nail polisher or other cosmetic product on the nail.
-  The fingernail should be of normal length.
-  The SpO<sub>2</sub> sensor cannot be immersed into water, liquor or cleanser completely, because the sensor has no capability to resist the harmful ingress liquid.
-  Do not disinfect any SpO<sub>2</sub> sensor by irradiation, steaming, or ethylene oxide.
-  Carefully route cables to reduce the possibility of patient entanglement or strangulation.
-  The clinical study for SpO<sub>2</sub> measurement accuracy was done on human subjects according to Standard ISO 80601-2-61.
-  A functional tester or SpO<sub>2</sub> simulator cannot be used to assess the accuracy of the oximeter or a SpO<sub>2</sub> sensor. However, it can be used to check how accurately a particular oximeter is reproducing the given calibration curve. Before testing the oximeter by a functional tester, please firstly ask the manufacturer which calibration curve is used.

## 10.3 Apply the Sensor

1. Select an appropriate sensor and probe according to the module type and patient category..
2. Apply the sensor to the proper site of the patient.

3. Select an appropriate adapter cable according to the connector type and plug this cable into the SpO<sub>2</sub> connector.
4. Connect the sensor cable to the adapter cable.

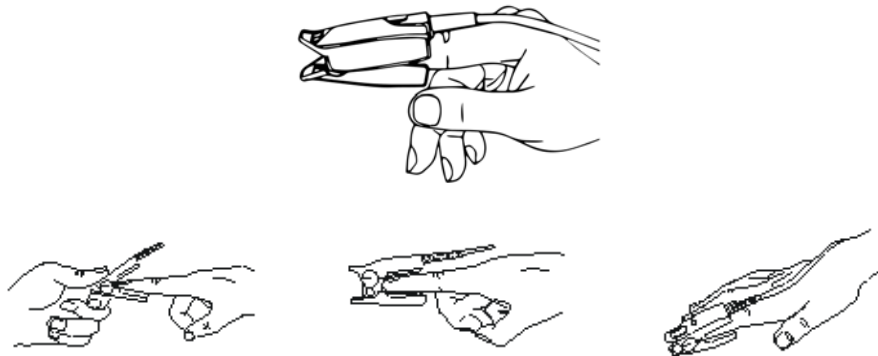
## 10.4 Using Probe and Sensor

When selecting a SpO<sub>2</sub> probe or sensor, do consider the patient's category, adequacy of perfusion, availability of probe site and anticipated monitoring duration. Use only SpO<sub>2</sub> probes provided by our company with this monitor.

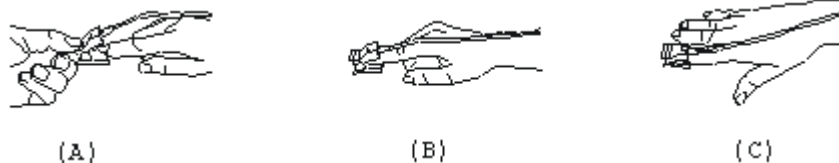
**We provide several probes for optional, please refer to the following description according to the probe/sensor you've purchased.**

### Type 1: Adult SpO<sub>2</sub> Finger Clip Sensor

Insert one finger (index finger is preferred, but middle or ring finger with proper nail length is possible as well) into the probe according to the finger mark on the probe, shown as below.

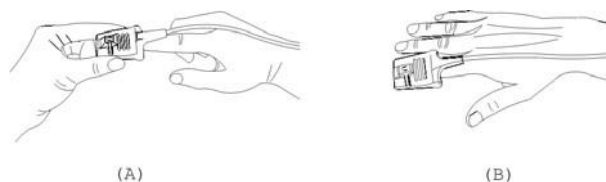


### Type 2: Pediatric SpO<sub>2</sub> Finger Clip Sensor



- (A) With the upper and lower jaws open, place a finger evenly on the base of the clip. Push the fingertip against the stop so that it is over the sensor window.
- (B) Spread open the rear tabs of the sensor to provide even force over the length of the pads.
- (C) The sensor should be oriented in such a way that the cable is positioned along the top of the hand.

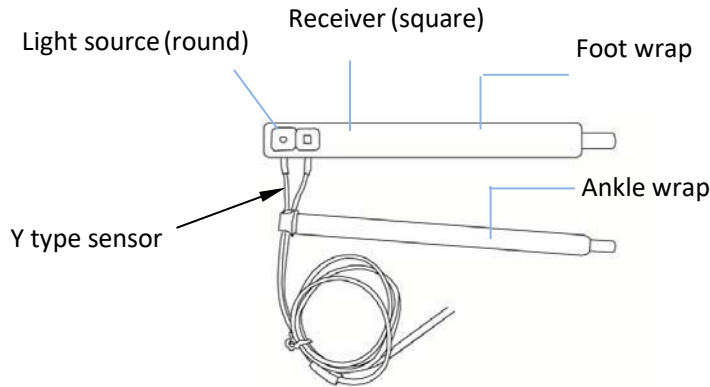
### Type 3: Adult/Pediatric SpO<sub>2</sub> Finger Rubber Sensor



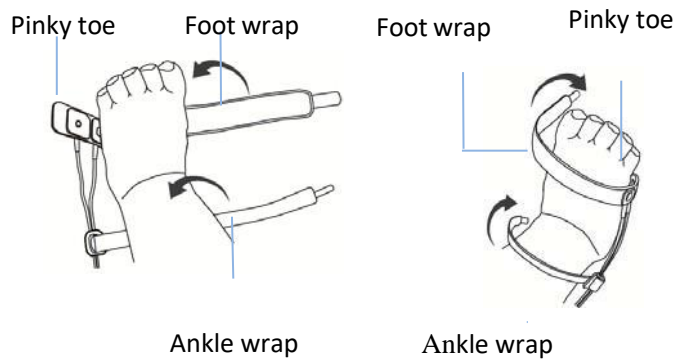
- (A) Hold the sensor with its opening towards the patient's finger, the sensor should be oriented in such a way that the sensor side with a fingertip sign is positioned on the top.

(B) Insert the patient's finger into the sensor until the fingernail tip rests against end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor. Direct the cable along the top of the patient's hand. Apply adhesive tape to secure the cable if necessary.

**Type 4: Y type Neonate SpO<sub>2</sub> sensor**



① For correct placement on foot, place the sensors on the outside of the foot behind the pinky toe. Make sure the sensor touches the skin closely, then secure the foot wrap with Velcro. Do not over-tighten.



Left foot (wrap goes under the foot)

Right foot(wrap goes from top of the foot)

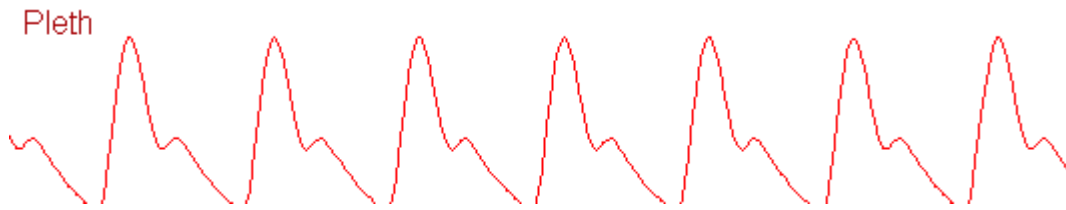
② Use the ankle wrap to secure the sensor cable on the ankle or leg. Do not over-tighten.





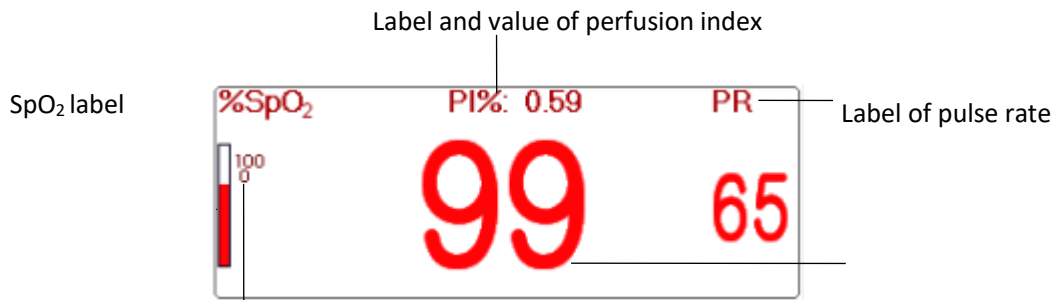
## 10.5 Understanding the SpO<sub>2</sub> and PR Display



### Plethysmogram:



✧ "Pleth": label for abbreviation of plethysmogram.

### SpO<sub>2</sub> Panel:



- |   |  |
|---|--|
| Pulse intensity bar graph                     |  Pulse rate value |
| High and low alarm limit for SpO <sub>2</sub> | SpO <sub>2</sub> value   |
- ✧ "SpO<sub>2</sub>": SpO<sub>2</sub> label. "99" is the current SpO<sub>2</sub> value.
  - ✧ "PR": the label of Pulse Rate. "65" is the current Pulse Rate value.
  - ✧ "PI%": the label of Perfusion Index, "0.59" is the Perfusion Index.
  - ✧ "PR": Label of pulse rate.
  - ✧ "100": the high and low alarm limit setting for SpO<sub>2</sub>.
  - ✧ : pulse intensity bar graph.

## 10.6 Changing SpO<sub>2</sub> and PR Settings

Select "Menu" → "SpO<sub>2</sub>" to enter into SpO<sub>2</sub> related setting.

- ✧ **SE Threshold (%)**: set the threshold of oxygen desaturation event (%), the value range is from 1 to 12, step is 1. The default is 3(%).
- ✧ **Beep Volume**: to set the pulse beep sound volume. Its setting range is "0 ~ 10" level. The default is 5. If you set the beep volume as "0", it means the pulse beep sound is off. It's not recommended to set it as "0".
- ✧ **PARM**: to enter into SpO<sub>2</sub> alarm setting. See Section "Understanding the Alarm Setting".

### The conditions to trigger SpO<sub>2</sub> Event (SE):

#### Condition 1:

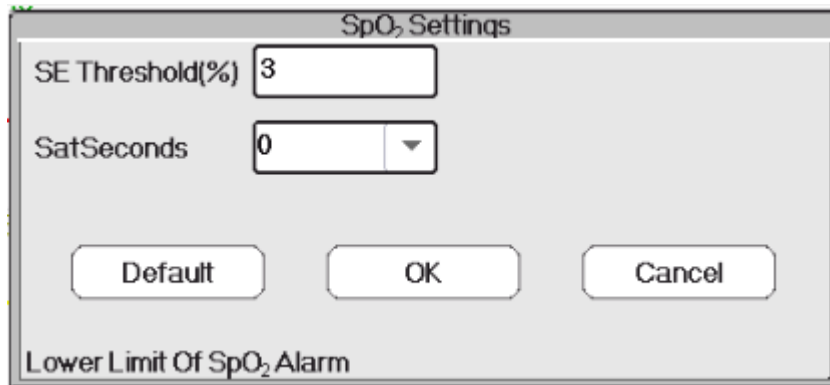
If the value difference between current SpO<sub>2</sub> value and the average value in the latest 1 minute is larger than the set threshold, and it keeps true for at least 8 seconds, then a SE is generated.

#### Condition 2:

When the current SpO<sub>2</sub> value is between 90% and 100%, and the value difference between current SpO<sub>2</sub> value and the average value in previous second is larger than the set threshold, then a SE is generated too.

## 10.7 Nellcor SpO<sub>2</sub> Module (Optional)

- ✧ If your monitor is configured with Nellcor SpO<sub>2</sub> Module, then the SpO<sub>2</sub> related setting window is as shown in below figure.

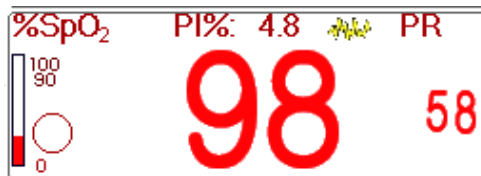


- ✧ **SE Threshold(%)**: set the threshold of oxygen desaturation event (%), the value range is from 1 to 12, step is 1. The default is 3(%).
- ✧ **SatSeconds**: SatSeconds sensitivity setting, to set the max buffering time of activating SpO<sub>2</sub> alarm. Options are “0”, “10”, “20”, “50” and “100”. If you set SatSeconds as “0”, it means to turn off the SatSeconds alarm management function.

The over-limit points multiplied over-limit seconds makes SatSeconds.





**SpO<sub>2</sub> panel for Nellcor SpO<sub>2</sub> module:**

SatSeconds icon and sensitivity setting



“Interference” icon

**Notes:**

1. When inserting finger into the probe cushion, then searching pulse icon  appears on the upper side of the SpO<sub>2</sub> panel. However, once the SpO<sub>2</sub>/PR readings appear, or probe/ finger is off, then icon  will disappear.
2. When interference (caused by e.g. shaking finger) appears, then icon  appears on the upper middle side of the SpO<sub>2</sub> panel. However, once the interference disappears, or probe / finger is off, then icon  will disappear.

**Below is the related alarm information for Nellcor SpO<sub>2</sub> module.**

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

# Chapter 11 Monitoring Temperature

## 11.1 Introduction

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

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

## 11.2 Safety Information

- 🔧 Verify that the probe detecting function works correctly before monitoring. Unplug the temperature probe cable from the T1 or T2 connector, and the monitor can display the message [T1 Sensor Off] or [T2 Sensor Off] and give alarm tones correctly.
- 🔧 Select temperature sensor as “KRK” in setup menu. KRK thermistor has 10.000K ohms @25°C.

## 11.3 Making a TEMP Measurement

Please follow the corresponding methods to make temperature measurement according to the temperature transducer you selected.

### ✧ Connecting the thermal temperature sensor:

The temperature sensor is thermo-resistor type it needs time to respond the temperature change, so the accurate temperature value displays after a while. The temperature sensor equipped may have different shape for measuring body surface temperature or cavity temperature respectively.

Normal value for body surface: 36.5°C ~37°C;

Notes:

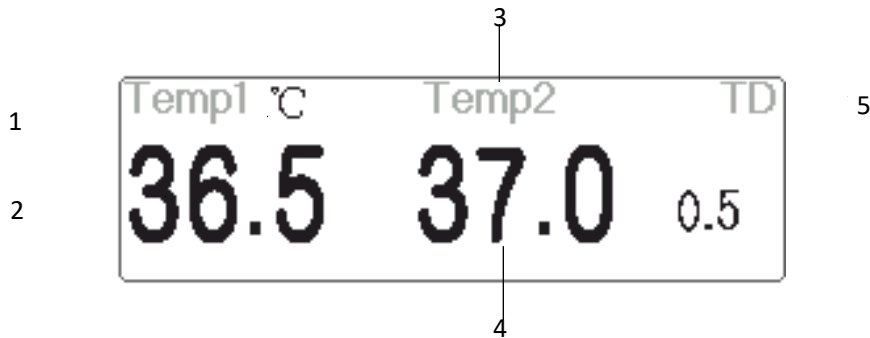
- For body surface temperature probe, attach the TEMP sensor to the patient, generally if the TEMP sensor and skin doesn't contact closely, the measured value becomes lower, so for those who have requirement for temperature monitoring, add a proper pad to the sensor and fix it with adhesive tape to make them contact firmly.
- Especially for pediatric patient, they have more activities, pay more attention to the sensor fixing.
- The TEMP sensor is designed for use with the specific patient monitor, which cannot be used as applied part to other products.
- The operator is responsible for checking the compatibility of the patient monitor and sensor type including cable before use.
- Incompatible components can result in degraded performance.

#### ✧ Operation Procedures for thermal temperature transducer:

1. Securely attach the transducer to the patient;
2. Connect the cable to TEMP probe connector marked "TEMP" in the panel.
3. Check that the menu setting is matching the used temperature sensor type.
4. Check that the alarm settings are appropriate for this patient.

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

## 11.4 Understanding the TEMP Display



1. TEMP1 °C: Temperature 1 mark and unit. Temperature unit: °C or °F。
2. 36.5: displays the temperature measured at temperature channel 1.
3. TEMP 2: Temperature channel 2.
4. 37.0: displays the temperature measured at temperature channel 2.
5. TD 0.5: Temperature difference, namely the difference between temperature 1 and temperature 2.

## 11.5 Changing TEMP Settings

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

- ✧ **Temp Unit:** Temperature unit. The default is °C (Celsius) and can be set as °F (Fahrenheit), the default is "°C".
- ✧ **Probe type:** Please select KRK type.
- ✧ **TD:** the absolute temperature difference. When the temperature difference is higher than preset value, then the device will activate alarm. If there is only one temperature , the TD shows "— —".
- ✧ **PARM:** to enter into RESP alarm setting. See Section "Understanding the Alarm Setting".

## Chapter 12 Review

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



Refer to the actual window

In "Review" window, select the patient record you want to review, the following data record can be viewed: Arrhythmia (ARR) event, Trend graphs, NIBP List, ECG Waveforms, Alarm events and SpO<sub>2</sub> events.

Select one of the patient list on the left window, and press the related button to review the corresponding information.

**Patient list:** including PID (Patient ID), name, birth date, group.

**Data Review button:** including ARR Event, Trend Graph, NIBP List, ECG Wave, Alarm Event and SpO<sub>2</sub> Event.

### 12.1 ARR Events

**"Search" button:** search the ARR Event records in the specified date.

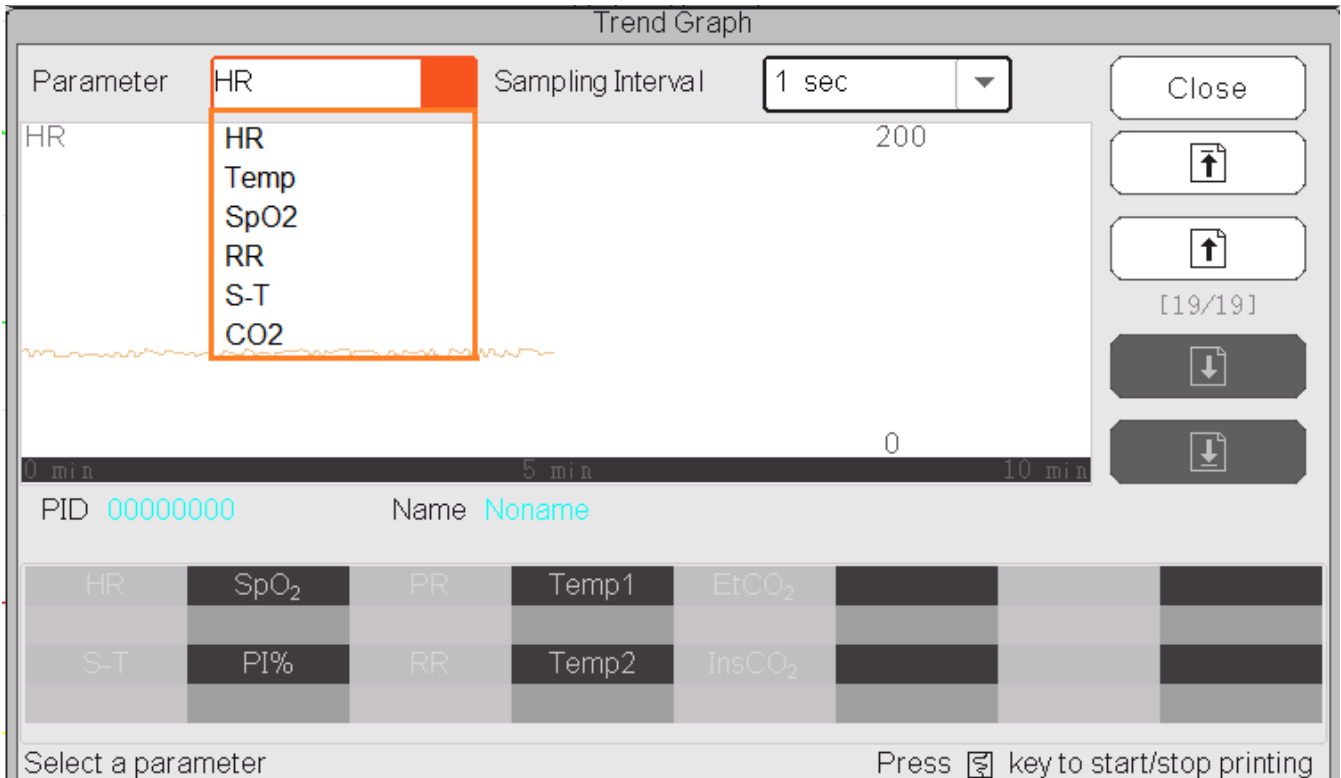
In the numeric box of "Month", "Day" and "Year", select the specified date, and press "Search" button to review the event list in specified date.

The numeric box "Day" can be set as "All", it means all the month. The numeric box "Month" can also be set as "All", it means all the year.

Note: all event list can be searched by date, we will not cover it later again.

## 12.2 Trend Graph

The "Trend Graph" window is as shown in following Figure.



**Trend Graph window**

**Parameter:** select a parameter to review its graph, options are: HR, SpO<sub>2</sub>, RR, S-T, TEMP and so on

**Sampling interval:** sample time interval of the trend graph, 7 options: 1 second, 5 seconds, 10 seconds, 30 seconds, 1 minute, 5 minutes and 10 minutes.

**Positioning:** positioning mark is a data point that the cursor line (a blue vertical line) locates on the trend graph. And the table on the lower window shows the detailed information (date, time, HR, SpO<sub>2</sub>, and etc.) of the time point where the Positioning Mark located.

**Operation for the Cursor line:** move the cursor line to the left and right. The step is 1 pixel initially, but it will be increased to 8 pixels by rotating of Navigation Knob in one direction more than 30 steps. If the step is 8 pixels, rotating of Navigation Knob in opposite direction will make step to 1 pixel. Press down Navigation Knob to exit from "Positioning" mode.

Note: on Short Trends view, the general waveform is on the left of waveform area and the short trend view on the right.

## 12.3 NIBP List

A NIBP record not only consists of the blood pressure data, i.e. SYS(systolic pressure), DIA(diastolic pressure), MAP( mean arterial pressure), but it also includes data of PR, RR, S-T, SpO<sub>2</sub>, Temp1, Temp2 and etc., stored at the measurement time.

"Search" button: search the NIBP records in the specified date.

"Trend graph" check-box: makes the trend graph of NIBP records visible or invisible as shown in following Figure.

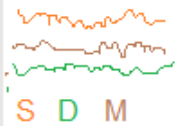


NIBP List


Month  Day  Year

PID 00000000 Name Noname

Time	SYS	DIA	MAP	PR	HR	S-T	SpO <sub>2</sub>	PR	RR	Temp1	Temp2
01/01 01:29:49	124	87	96	61	64	-3,36	99	67	15	36,5	37,0
01/01 01:20:50	125	89	97	60	64	-3,68	99	66	15	36,6	37,0
01/01 01:01:16	128	80	91	60	63	-2,40	98	66	16	36,6	37,0
01/01 01:00:36	121	80	93	62	63	-2,24	98	66	14	36,7	37,2
01/01 00:54:24	127	85	98	60	60	-3,04	98	65	16	36,5	37,2
01/01 00:48:34	123	80	95	62	61	-3,20	98	67	15	36,7	37,0
01/01 00:41:58	124	84	92	61	61	-3,52	99	67	16	36,5	37,0



Trend Graph 1 / 9

Press  key to start/stop printing

### NIBP trend graph window



"S", "D", "M": is the abbreviation for Systolic pressure, Diastolic pressure and Mean arterial pressure. The letter color is the same as the its waveform color.



xx/yy: the current record number/ total records.

## 12.4 ECG Waveforms

The device can store the latest ECG Waveforms Records more than 72 hours. All ECG Waveforms Records are listed on the left part of the window. The selected ECG waveform Record (in the blue frame) are displayed on the right.

Selecting from drop-down box  can change the ECG lead. The ECG leads options are ECG I, ECG II, ECG III, ECG aVR, ECG aVL, ECG aVF and ECGV.

There may be several pages for an ECG waveform record (10 seconds for one page). Use page-turn buttons  

  to review pages

"xx/xx" means "Page No. / total pages".

## 12.5 Alarm Event

Each Alarm Event record consists of Time (the time when alarm occurs ), Level (alarm level), Param (the parameter activates alarm), Value (the value of the parameter when alarm occurs), the preset high and low alarm limit setting value.

**There are 2 alarm categories:** Parameter Alarm and Technical Alarm (refer to alarm section for details in Section

Alarm).

**There are 3 alarm Levels:** High priority, Medium priority and Low priority corresponding to high risk, medium risk and low risk respectively.

## 12.6 SpO<sub>2</sub> Event

If the patient's SpO<sub>2</sub> value decreased by certain value in a short time, it will be defined as a SpO<sub>2</sub> Event.

A SpO<sub>2</sub> Event record includes the Time (the time when the event occurs), Minute-average, SpO<sub>2</sub> value (the current SpO<sub>2</sub> value), HR, PR and RR.

## Chapter 13 Printing

### 13.1 Using a Printer

The thermal Printer can be used to print patient information, measurement numerics, up to three waveforms, etc

**Built-in printer may be used due to the different configuration.**

#### Printer operation instruction:

Power indicator: The green light shows the power is on. While the monitor is out of power, the green light is off.

Error indicator: red light is constant which shows the printer is out of paper, or the printing paper is not installed properly. When the printing paper is loaded correctly, the red light is off.

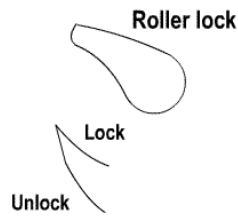


### 13.2 Loading Printing Paper

This description is for loading paper for the built-in printer.

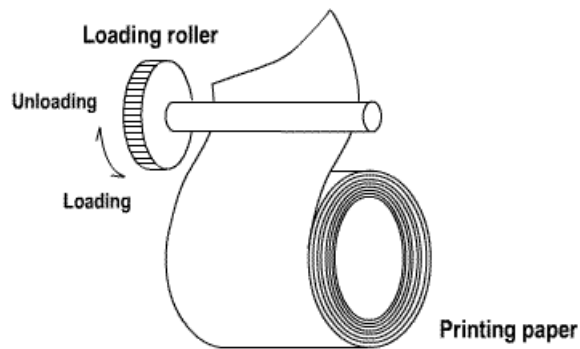
#### Operating procedures:

1. Press both "OPEN" notches with force on printer shield with two thumbs to open it.
2. Move the tab of rubber roller lock at the left 90° upwards to unlock it.
3. Cut one end of the paper into triangle, and load the paper from the underside of the rubber roller.
4. Turn the roller clockwise to get the paper rolled, and put the paper roll into the compartment.
5. Pull the paper out of paper slot on the shield.
6. Move the tab of the rubber roller lock 90° downwards to lock it.
7. Put the shield back in position and secure it.



**Unloading printing paper**

1. Press both "OPEN" notches vertically with force on printer shield with two fingers to open it.
2. Move the tab of roller lock at the left 90° upwards to unlock it.
3. Roll the loading roller anti-clockwise and pull the paper out.
4. Roll the loading roller clockwise to get the paper rolled, and put it into the compartment.
5. Pull the paper out of paper slot on the shield.








**Loading printing paper:**

- 1: press and hold down the cartridge button to open the paper cartridge;
  - 2: Install the paper to the printer properly, pull the paper out of the printer for 2 cm. 3:
- Close the printer cover along the direction of arrow.




**Printing paper**

### 13.3 Attentions

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

### 13.4 Performing Printing

The device printing function consists of manual printing and auto trigger printing. The medical staffs can press the Print key  to perform printing, and the device can make cycle printing and auto trigger to print ARR event.

Start or stop printing by pressing Print Key  located in the front panel.

The content for printing consists of real time data printing and review record printing. In different views and windows, pressing Print key can print that shows in the following Tables.

#### 13.4.1 Print Real Time Data

Current view/window	Contents	
	Header information	Waveform/Text information
General view	Data identifier: "=="Real time==";	Print the real time waveform of 10 seconds:  The 1st trace: ECG waveform  The 2nd trace: ECG/SpO <sub>2</sub> /RESP waveform  The 3rd trace: nothing/RESP/SpO <sub>2</sub> waveform  Note: on the top of the printed waveform area, the 10s waveform's time will be shown within 2 interval.
Big font view	Patient info.: PID, name, gender, patient group, weight, height and birth date;	
All ECG view	Time: the current date and time when printing;	
Short trends view	Real-time parameter: speed, HR, SpO <sub>2</sub> , PR, RR, TEMP1/2 and pressure value.	
NIBP list view	Data identifier: "=="NIBP List==";	Print the 11 groups of NIBP list
	Item in the list: time, PID, name, SYS, DIA, MAP, PR, HR and SpO <sub>2</sub>	

RESP-Oxy view	Data identifier: "=="RESP-Oxy==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; The start time and end time of the	Print the trend graph of RESP-Oxy
Menu, settings window and functional window	Data identifier: "=="Real time==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Real-time parameter: speed, HR, SpO <sub>2</sub> , PR, RR, TEMP1/2 and pressure value.	Print the real time waveform of 10 seconds: The 1st trace: ECG waveform The 2nd trace: ECG/SpO <sub>2</sub> /RESP waveform The 3rd trace: nothing/RESP/SpO <sub>2</sub> waveform Note: on the top of the printed waveform area, the 10s waveform's time will be shown within 2 interval.
View's activating window and settings window	Data identifier: "=="Real time==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Real-time parameter: speed, HR, SpO <sub>2</sub> , PR, RR, TEMP1/2 and pressure value.	Print the real time waveform of 10 seconds: The 1st trace: ECG waveform The 2nd trace: ECG/SpO <sub>2</sub> /RESP waveform The 3rd trace: nothing/RESP/SpO <sub>2</sub> waveform Note: on the top of the printed waveform area, the 10s waveform's time will be shown within 2 interval.
Main screen of data reviewing(before entering each history records window)	Data identifier: "=="Real time==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Real-time parameter: speed, HR, SpO <sub>2</sub> , PR, RR, TEMP1/2 and pressure value.	Print the real time waveform of 10 seconds: The 1st trace: ECG waveform The 2nd trace: ECG/SpO <sub>2</sub> /RESP waveform The 3rd trace: nothing/RESP/SpO <sub>2</sub> waveform Note: on the top of the printed waveform area, the 10s waveform's time will be shown within 2 interval.

Trigger real time printing when ARR event occurs	Data identifier: "=="ARR==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Real-time parameter: speed, HR, SpO <sub>2</sub> , PR, RR, TEMP1/2 and pressure value.	Print the waveform of the current ARR event
--	--	---

### 13.4.2 Print History Records

Data review window	Contents	
	Header information	Waveform/text information
ARR event window	Data identifier: "=="ARR==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing;	Print the 6 items in ARR event list, including time, ARR type, lead, gain, filter and HR.
The operating status in ARR event, and setting item "Print the current record only" is selected.	Data identifier: "=="ARR==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; ARR info.: the time, ARR type, lead, gain, filter and HR of the current reviewed ARR event.	Print the waveform of the current reviewed ARR event.
The operating status in ECG Wave	Data identifier: "=="ECG Wave==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; ECG Wave information: ECG lead, speed, gain, HR, filter, Start time and end time.	Print the current reviewed ECG waveform information.
The operating status in Trend Graph	Data identifier: "=="Trend Graph==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Trend graph info.: parameter label, sampling interval, start time and end time.	Print the trend graph of a certain parameter displayed on the current window.

The operating status in NIBP List	Data identifier: "=="NIBP List==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Items in the list: time, SYS, DIA, MAP, PR, HR, SpO <sub>2</sub> /HR and TEMP1.....	Print the 12 groups NIBP lists displayed on the current window.
The operating status in Alarm Event	Data identifier: "=="Alarm Event==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Items in the list: time, event name, level, parameter, alarm value, the preset high/low alarm value.	Print the 11 groups alarm events displayed on the current window.
The operating status in SpO <sub>2</sub> Event	Data identifier: "=="SpO <sub>2</sub> Event==" Patient info.: PID, name, gender, patient group, weight, height and birth date; Time: the current date and time when printing; Items in the list: time, PID, Minute-average, SpO <sub>2</sub> , PR, HR and RR.	Print the 11 groups SpO <sub>2</sub> events displayed on the current window.

### 13.5 Cleaning the Printing Head of Printer

If the printer has been used for a long time, deposits of paper debris may collect on the printing head compromising the print quality and shortening the lifetime of the roller. Follow this procedure to clean the printing head:

1. Take measures against the static electricity such as Disposable Wrist Strap for the work.
2. Open the printer door and take out the paper.
3. Gently wipe around the printhead using cotton swabs dampened with Ethanol.
4. After the Ethanol has completely been dried, reload the paper and close the printer door.



# Chapter 14 Other Functions

## 14.1 System Information

Select "Menu" → "System Info", then the "System Info" window can be entered, which including release version, software version, hardware version and product ID.

**Product ID:** set by manufacturer for traceability.

**For some monitors, it may also show embedded module information:**

## 14.2 Nurse Call Settings (Optional)

- ✧ **Output level:** the output level from nurse call connector , "High level" and "Low level" for option.
- ✧ **Duration:** two output modes for optional: "Continuous" and "Pulse". The continuous mode of output means the nurse call signal will keep until the alarm disappears. The pulse mode means the output nurse call signal lasts for one second.
- ✧ **Trigger Condition:** 3 kinds of alarm sources can trig the nurse call: high level alarm, medium level alarm and low level alarm.
- 🔔 Do not rely exclusively on the nurse call system for alarm notification. Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient's clinical condition.





# Chapter 15 Battery

## 15.1 Overview

The monitor has built-in chargeable battery, when the monitor is disconnected from the external AC power supply, then it will be powered by the built-in battery. When the monitor is supplied by external AC power, then the battery will be charged. Generally, it's unnecessary to maintain the battery when using under normal working condition.










When the monitor is powered by built-in battery, and battery is in low voltage, then technical alarm will be triggered, and message "Low battery" pops up. At this moment, the user should connect the external power immediately to make sure the monitor continue working.

On-screen battery symbols indicate the battery status as follows:

	AC Power supply and the battery is fully charged.
	The red exclamation mark blinks means battery voltage will be used out and needs to be charged. Alarm information area will show "Low Battery" message.
	Charging status
	One / two/ full grid battery voltage left

The capacity of the internal battery is limited. If the battery voltage is too low, a technical alarm will be triggered and the message displayed. At this moment, connect AC mains power to the monitor. Otherwise, the monitor will power off automatically before the battery is completely depleted.

## 15.2 Battery Maintenance

-  Please pay attention to the polarity of battery, do NOT insert it into battery compartment with reversed polarities;
  -  Do NOT use the batteries manufactured by other companies, if being inserted, the device will may be damaged;
  -  In order to avoid damaging the battery, do NOT use other power supply device to charge the battery;
  -  After battery ageing phenomenon occurs, do NOT throw the battery into fire to avoid explosion risk.
  -  Do not hit or strike it with force;
  -  Do not use this battery on other devices;
  -  Do not use this battery below -10°C or above 40°C;
  -  Dispose of the battery, the local law should be followed.
-  In order to maintain battery supply time and prolong battery lifetime, please charge the battery every one or two months if don't use battery for a long time. Charge battery at least 12-15 hours every time. Before charging, run down the internal battery until the monitor turn off automatically to minimize memory effects. Charging time will be the same no matter whether the monitor is working or not. Charge fully before putting

the monitor into storage.

- 🔔 Using a monitor powered solely by an internal battery which has short charge power will cause the monitor to turn off automatically when the battery is depleted.
- 🔔 Do not use batteries manufactured by other companies, which may cause damage to the device. If battery is damaged, please replace with same type and specification battery marked by “CCC” or “CE” in time, or contact the company directly.



**Warning:**

1. To avoid battery damage always remove battery(s) before shipping or storage.
2. It is recommended to use the battery specified by the manufacturer.
3. Life expectancy of a battery depends on how frequently and how long it is used. For a properly maintained and stored lead-acid or lithium battery, its life expectancy is about 2 or 3 years respectively. For more aggressive use mode, life expectancy can be less. We recommend replacing lead acid battery every 2 years and lithium battery every 3 years.

**Caution:**

- 🔔 Keep the battery out of the reach of children.
- 🔔 Do not disassemble battery.

## 15.3 Battery Recycling

When a battery has visual signs of damage, or no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly. To dispose of the batteries, follow local laws for proper disposal.

# Chapter 16 Cleaning and Disinfection

## 16.1 Cleaning the Device and Accessories

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

Recommended cleaning agents are:

- ✧ Sodium hypochlorite bleach (diluted)
- ✧ Hydrogen peroxide (3%)
- ✧ 75% Ethanol
- ✧ 70% Isopropanol

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

- **Switch off the monitor and disconnect the power cable before cleaning.**
  - ✧ Kept the monitor from dust.
  - ✧ It is recommended to clean the outer shell and screen of the monitor to keep it clean. Only non-corrosive cleanser such as clear water is permitted.
  - ✧ Wipe the surface of the monitor and transducers with an Ethanol impregnated wipe, and dry it with dry and clean wipe or simply air-dry.
  - ✧ This monitor can be disinfected, please clean the monitor firstly.
- **Do not let the liquid cleanser flow into the connector jack of the monitor to avoid damage.**
- **Clean the exterior of the connector only.**
  - ✧ Dilute the cleanser.
  - ✧ Do not use abrasive materials.
  - ✧ Do not let any liquid flow into the shell or any parts of the monitor.
  - ✧ Do not let the cleanser and disinfectant stay on its surface.
  - ✧ Do not perform high pressure sterilization to the monitor.
  - ✧ Do not put any parts of the monitor or its accessories in the liquid.
  - ✧ Do not pour the disinfectant on its surface while disinfectant.
  - ✧ If the monitor is accidentally wet, it should be thoroughly dried before use. The rear cover can be removed by qualified service technician to verify absence of water.
  - ✧ Never use this machine in an environment with inflammable gas.
  - ✧ Avoid being hit by lightning. The power cable should be plugged into an outlet with grounding wire. Do not use an outlet with poor condition. If possible, use power supply system with regulator.






- ✧ It must be used in a clean environment protected against shock. Keep it away from corrosive substances, explosive substances, high temperature and dampness.
- ✧ If it is installed in a cabinet, make sure the installation allows for good ventilation, and easy maintenance, observation and operation.

## 16.2 Disinfecting the Device and Accessories

Disinfection may cause damage to the device and is therefore not recommended for this monitor unless otherwise indicated in your hospital's servicing schedule. Cleaning device before disinfecting is recommended.

The recommended disinfectants include:

- 75% Ethanol
- 70% Isopropanol

-  Do not use damaged accessories.
-  Accessories cannot be entirely immersed into water, liquor or cleanser.
-  Do not use radiation, steam or EO to disinfect accessories.
-  Do wipe off the remained Ethanol or isopropanol on the accessories after disinfection, for good maintenance can extend the life of accessories.
-  Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.

# Chapter 17 Maintenance

In case of trouble of this machine in the service, follow the instructions below to eliminate the problem first. If the attempt fails, refer to the dealer in your local area or the manufacturer. Refer to the detailed provisions in contract for the warranty period of the main unit and the accessories of this monitor.

## 17.1 Daily Examination

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

- ✧ Check the monitor for any mechanical damage;
- ✧ Inspect the exposed parts and the inserted parts of all the cables and the accessories;
- ✧ Examine all the functions of the monitor that are likely to be used for patient monitoring, and ensure that it is in good working condition;
- ✧ Make sure that the monitor is grounded properly.
- ✧ Pay close attention to the fluctuation of the local power supply voltage. A power voltage regulator is recommended when necessary.

In case any indication of damage about the function of the monitor is detected and proven, it is not allowed to apply it to the patient for any monitoring. Please contact the local dealer or our company, and we are to offer the best solution as soon as possible for your satisfaction.

## 17.2 Routine Maintenance

At each routinely maintenance or the yearly maintenance, the monitor can be thoroughly inspected by qualified personnel, including performance and safety examinations. This monitor is designed with life cycle of 5 years. It is strongly recommended to use the product which is still within its life cycle, or it may cause inaccurate measurement. In order to ensure its long service life, please pay attention to the maintenance.

- 🔧 If the hospital fails to carry out a satisfactory maintenance program about the monitor, it may get disabled and harm the patient's safety and health.
- 🔧 In case of ECG cable/lead wires damage or aging, please replace the cable or lead wires.
- 🔧 If there is any indication of cable and transducer damage or they deteriorate, they are prohibited from any further use.
- 🔧 The Monitor is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. Any patient simulators should not be used to validate the accuracy of blood pressure and oxygen saturation measurement, they can only be used as functional testers to verify its precision.
- 🔧 The accuracy of ECG signal amplification can be verified by the built-in 1mV calibration signal.
- 🔧 The accuracy of pressure measurement and air leakage in pneumatic system can be verified by means of the built-in pressure verification function and a precision pressure meter, please refer to the related chapter in Part 2 of the user manual for detail operation.
- 🔧 The SpO<sub>2</sub> simulator cannot be used to verify the SpO<sub>2</sub> measuring accuracy, which should be supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark-skinned subjects in an independent research laboratory. However it is necessary for the user to use SpO<sub>2</sub> simulator for routine

verification of precision.

- 🔔 Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO<sub>2</sub> simulator, e.g. for Index 2 series SpO<sub>2</sub> simulator from Fluke Biomedical Corporation, please set "Make" to "DownLoadMake: KRK", then the user can use this particular R-curve to test the SpO<sub>2</sub> function of the patient monitor. If the SpO<sub>2</sub> simulator does not contain the specific R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO<sub>2</sub> simulator.
- 🔔 The adjustable units within the monitor such as potentiometers are not allowed to adjust without permission to avoid unnecessary failures that affect normal application.
- 🔔 It is recommended to use the battery once a month to ensure its power capability and long service life, and recharge it after run out of its power capacity.

### **17.3 ECG Verification**

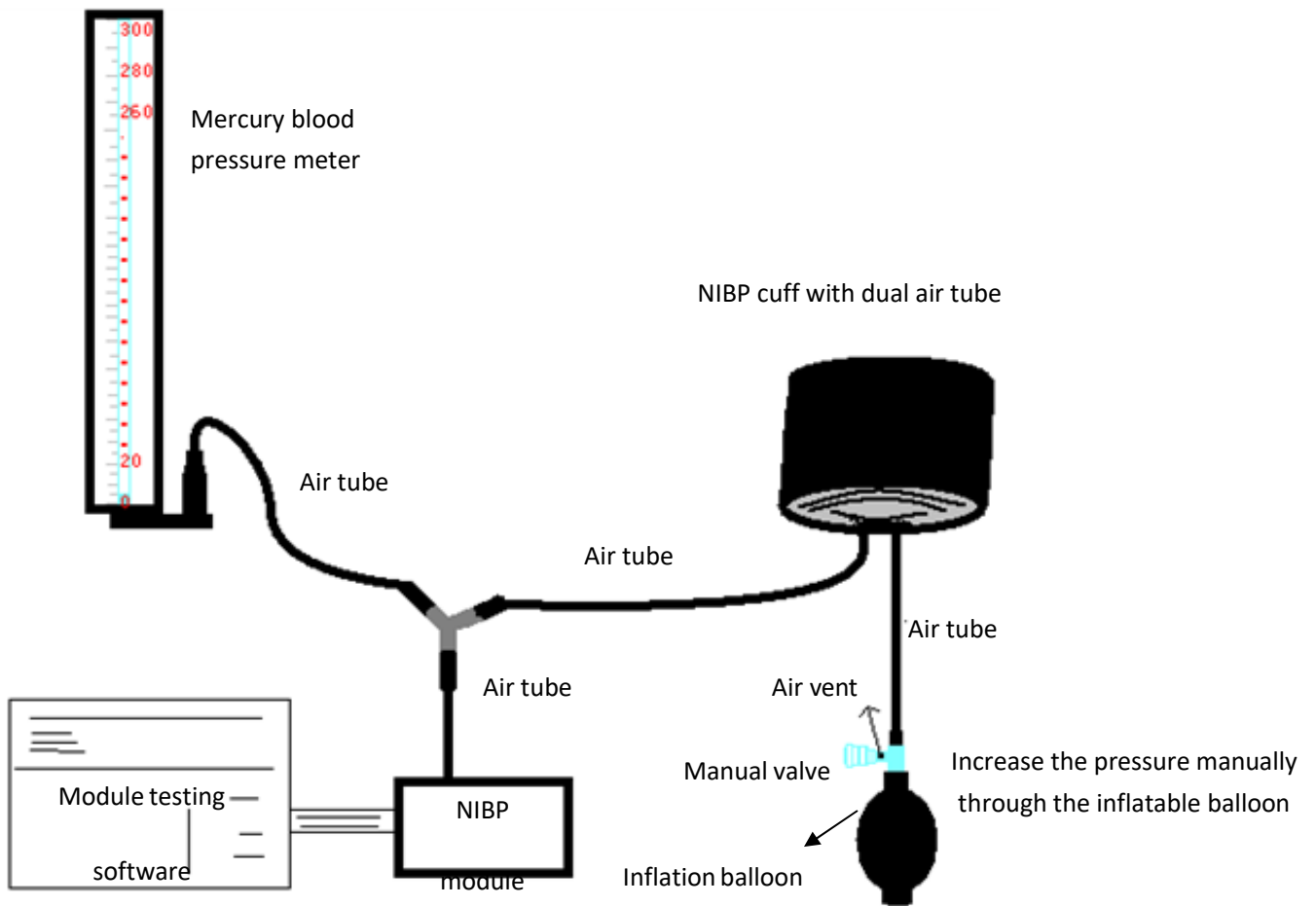
The ECG signal may be inaccurate due to hardware or software problems. As a result, the ECG wave amplitude becomes greater or smaller.

You can print out the square wave and wave scale and then measure the difference between them if necessary. If the difference exceeds 5%, contact your service personnel.

### **17.4 Pressure Accuracy Verification**

Pressure Accuracy Verification is a function to inspect the accuracy of pressure measurement by the NIBP module inside the device. Technician or equipment manager should do pressure accuracy verification every half year or year in order to check if the pressure measurement still conforms to the requirement of product performance. If the deviation is beyond the declared specification, it is permitted to return it to factory for repair or calibration.

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



This belongs to the monitor

**Mode 1: Automatic inflation for the pressure accuracy verification**

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

Adult	240mmHg
Pediatric	200mmHg
Neonate	120mmHg

Table A

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



**Mode 2: Manual inflation for the pressure accuracy verification.**

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



Adult	300mmHg
Pediatric	240mmHg
Neonate	140mmHg

Table B

-  After the verification, do press the button again to return to normal working mode, then continue other operation, or the NIBP key will be invalid.
-  Pressure accuracy verification must be operated by technician or equipment manager. Doctors and nurses are not allowed to do the verification, it is very dangerous especially when the pressure cuff is still on patients.

➤ **Air Leakage Check**

In order to avoid significant error of blood pressure measurement or even no measurement result caused by air leakage in the pneumatic system including the cuff during measuring, it is recommended to check if there is leak in the pneumatic system as well.





**Please remove the cuff from patient while performing the leakage check.**

## 18 Accessories

 Check the accessories and their package for any signs of damage. Do not use them if any damage is detected.

Part Name		Lengths	Photos
ECG cable		2900mm; 630mm	
ECG electrode		350mm	
SpO <sub>2</sub> Sensor	Adult SpO <sub>2</sub> Finger Clip Sensor (15040077)	930mm	
	Adult SpO <sub>2</sub> Finger Stall Sensor (15040099) Optional	870mm	
	Pediatric SpO <sub>2</sub> Finger Clip Sensor (15040097) Optional	910mm	
	Pediatric SpO <sub>2</sub> Finger Stall Sensor (15040098) Optional	950mm	
	Y type Neonate SpO <sub>2</sub> sensor (15040078) Optional	950mm	
SpO <sub>2</sub> sensor cable extender (2909-0000034)		2000mm	
Cuff	Adult NIBP cuff	475mm x135mm	
	Small-sized Pediatric NIBP Cuff (Optional)		
	Middle-sized Pediatric NIBP Cuff (Optional)		
	Large-sized Pediatric NIBP (Optional)		

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TEMP probe	Body TEMP probe	2970mm	
Power cord		3000mm	
Net wire			
Printing paper (Optional)			

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

**Warning:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. For more information regarding the accessories, please contact your local sales representative or the manufacturer.

# 19 Technical Specifications

## 19.1 ECG

1. Input dynamic range:  $\pm(0.5\text{mVp} \sim 5\text{mVp})$
2. Heart rate display range: 15 bpm  $\sim$  350 bpm ( for Adult and Pediatric)
3. Heart rate display accuracy:  $\pm 1\%$  or  $\pm 2\text{bpm}$ , whichever is greater.
4. Heart rate averaging: Averages the recent eight beats having RR intervals falling within the acceptable limits.
5. Defibrillation recovery time:  $\leq 10\text{ sec}$
6. Alarm signal (for any alarm source) generation delay time:  $< 1\text{ sec}$   
Heart rate alarm condition delay time:  $\leq 10\text{ sec}$
7. Response time to change in heart rate:  
Change from 80bpm to 120bpm:  $< 8\text{ sec}$   
Change from 80bpm to 40bpm:  $< 8\text{ sec}$
8. Tall T-wave rejection: Rejects all T-wave less than or equal to 120% of 1mV QRS.
9. Pacemaker pulse rejection:  
Rejects all pulses of amplitude  $\pm 2\text{mV}$  to  $\pm 700\text{mV}$  and duration 0.1 to 2 ms without overshoot;
10. Sensitivity selection:  $\times 1/8, \times 1/4, \times 1/2, \times 1, \times 2, \times 4$  and AUTO  
 $\times 1/2, 5\text{mm/mV}$  tolerance:  $\pm 5\%$   
 $\times 1, 10\text{mm/mV}$  tolerance:  $\pm 5\%$   
 $\times 2, 20\text{mm/mv}$  tolerance:  $\pm 5\%$
11. Sweeping speed: 6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s tolerance:  $\pm 10\%$
12. ECG noise level:  $\leq 30\mu\text{V}_{\text{p.p.}}$
13. ECG input loop current:  $\leq 0.1\mu\text{A}$
14. Differential input impedance:  $\geq 5\text{M}\Omega$
15. Common-mode rejection ratio (CMRR):  
In Diagnostic mode:  $\geq 90\text{dB}$  In Operation and Monitoring mode:  $\geq 105\text{dB}$
16. Time constant:  
Monitoring mode:  $\geq 0.3\text{s}$  Diagnostic mode:  $\geq 3.2\text{s}$
17. Frequency response:  
Operation mode: 1 Hz  $\sim$  20Hz  $\begin{matrix} + 0.4 \text{ dB} \\ (- 3.0 \text{ dB}) \end{matrix}$   
Monitoring mode: 0.67 Hz  $\sim$  40Hz  $\begin{matrix} + 0.4 \text{ dB} \\ (- 3.0 \text{ dB}) \end{matrix}$   
Diagnositc mode: 0.05 Hz  $\sim$  150Hz  $\begin{matrix} + 0.4 \text{ dB} \\ (- 3.0 \text{ dB}) \end{matrix}$

## 19.2 RESP

1. RESP rate measuring range: 0rpm~120rpm
2. RESP rate accuracy:  $\pm 5\%$  or  $\pm 2$  rpm, whichever is greater
3. RESP rate alarm limit setting range: High: 1rpm~150rpm; Low: 0rpm~149rpm.
4. Alarm tolerance:  $\pm 1$ rpm

## 19.3 TEMP

1. TEMP measuring range: 21.0°C~50.0 °C
2. TEMP measuring accuracy:  $\pm 0.2$  °C for the range from 25°C to 45°C, 0.4 °C for other ranges.
3. TEMP responding time:  $\leq 150$ s
4. TEMP minimum measuring time:  $\geq 130$ s
5. Measuring site: bodysurface
6. Mode of operation: direct mode
7. Unit: °C and °F
8. TEMP alarm limit setting range: High: 0°C~60°C; Low: 0°C~59.9°C.
9. Tolerance:  $\pm 0.1$ °C

## 19.4 NIBP

1. Measuring method: Oscillometric Technique
2. Pneumatic pressure measuring range: -50mmHg~300mmHg
3. Accuracy of pressure measurement:  $\pm 3$  mmHg
4. Typical measurement time: <30 seconds (adult cuff)
5. Measurement time on the average: < 90 seconds
6. Air release time while the measurement is canceled: <2 seconds (typical adult cuff)
7. Initial cuff inflation pressure  
Adult:  $\leq 200$ mmHg; Pediatric:  $\leq 200$ mmHg; Neonate:  $\leq 80$  mmHg Tolerance:  $\pm 5$  mmHg
8. Overpressure protection limit  
Adult:  $\leq 300$  mmHg; Pediatric:  $\leq 240$ mmHg; Neonate:  $\leq 150$  mmHg
9. NIBP measurement range:

Pressure (unit)		Adult	Pediatric	Neonate
SYS	mmHg	25~290	25~230	25~140
	kPa	3.3~38.7	3.3~30.7	3.3~18.7
MAP	mmHg	15~260	15~167	15~125
	kPa	2.0~34.7	2.0~22.3	2.0~16.7
DIA	mmHg	10~250	10~149	10~115
	kPa	1.3~33.3	1.3~19.9	1.3~15.3

10. NIBP accuracy:
  - Maximum mean difference:  $\pm 5$  mmHg
  - Maximum Standard deviation: 8 mmHg
11. Measurement mode: Manual, Auto, STAT, Customized Multi-cycle
12. NIBP Alarm setting range: **see Section Alarms**

## 19.5 SpO<sub>2</sub>

1. Transducer: dual-wavelength LED
  - Wavelength: Red light: 663 nm, Infrared light: 890 nm.
  - (Note: for Series III and Series IV, Red light: 660 nm, Infrared light: 905 nm)
  - Maximal optical output power: less than 2mW maximum average
2. SpO<sub>2</sub> measuring range: 0%~100%
3. SpO<sub>2</sub> measuring accuracy: Arms\* is not greater than 2% for SpO<sub>2</sub> range from 70% to 100%
 

\*NOTE: Arms is the accuracy defined as root-mean-square value of deviation according to ISO 80601-2-61.
4. Alarm range: High: 1%~100%;      Low: 0%~99%
5. Low perfusion performance: the declared accuracy is sustained when the pulse amplitude modulation ratio is as low as 0.3%

### Data averaging and update:

The displayed SpO<sub>2</sub> and Pulse Rate values are the average of data collected within a specific time. The SpO<sub>2</sub> is calculated every second by the data collected in recent 5 seconds, the Pulse Rate is calculated for every beat. The averaging method depends on the pulse rate value, for pulse rates below 50bpm, the SpO<sub>2</sub> is averaged by 16-second sliding average, the Pulse Rate is averaged by 4-beat sliding average; for pulse rates between 50bpm and 120bpm, the SpO<sub>2</sub> is averaged by 8-second sliding average, the Pulse Rate is averaged by 8-beat sliding average; for pulse rates above 120bpm, the SpO<sub>2</sub> is averaged by 4-second sliding average, the Pulse Rate is averaged by 16-beat sliding average.

The screen display of SpO<sub>2</sub> and Pulse Rate are updated every second with the most recent value, if the signal is noisy or missing, the display will hold the last value for at most 15 seconds before showing dashes.

The over-limit alarm is triggered once the SpO<sub>2</sub> or Pulse Rate exceeds the preset limits, the alarm signal generation delay is small (less than 1 second) compared with the alarm condition delay, which is caused by the data average as described above.

## 19.6 Pulse Rate

1. Pulse rate measuring range: 0bpm~300bpm
2. Pulse rate measurement accuracy:  $\pm 2$ bpm or  $\pm 2\%$ , whichever is greater.
3. Alarm range: High: (1~300) bpm;      Low: (0~299) bpm
4. Pulse rate alarm tolerance:  $\pm 2$ bpm within (30~250) bpm

Note: The pulse rate ACCURACY is tested by an electronic pulse simulator.

## 19.7 S-T Segment

1. Measuring range:  $-2.0\text{mV}\sim+2.0\text{mV}$
2. Tolerance:  $-0.8\text{mV}\sim+0.8\text{mV}$      $\pm 0.02\text{mV}$  or  $\pm 10\%$  (which is greater)

## 19.8 Data Recording

1. Sensitivity selection tolerance:  $\pm 5\%$
2. Recording speed:  $25\text{mm/s}$
3. Recording speed accuracy:  $\pm 10\%$
4. Hysteresis:  $\leq 0.5\text{mm}$
5. Frequency response:  
Monitoring mode:  $0.5\sim 40\text{Hz}$     Diagnostic mode:  $0.05\sim 75\text{Hz}$
6. Time constant:  
Monitoring mode:  $\geq 0.3\text{s}$     Diagnostic mode:  $\geq 3.2\text{s}$

## 19.9 Other Technical Specifications

1. Power supply: AC100V-240V, 50/60Hz, 60VA; Internal power supply: DC 11.1V
2. Mode of operation: Continuous
3. Applied Part: ECG lead wire, SpO<sub>2</sub> sensor, TEMP sensor and Cuff
4. Display mode: TFT color LCD
5. Alarm mode: audible & visible alarm
6. Communication: Net port

## 19.10 Classification

<b>Safety standard:</b>	<b>IEC 60601-1</b>
The type of protection against electric shock	Class I and Internally powered equipment
The degree of protection against electric shock	Defibrillation-proof BF and Defibrillation-proof CF applied parts
Electro-Magnetic Compatibility:	Group I, Class A
The protection against harmful ingress of liquid or particulate matter	IPX2

The device is not intended for use in an oxygen rich environment.

The surface of the device can be cleaned and disinfected with 75% Ethanol, no need to sterilize.

## 19.11 Operating Environment

1. Ambient temperature range: 10°C~40°C

Relative humidity range: 30% ~ 80%

Atmospheric pressure: 86kPa ~106kPa

Power Voltage: (100-240)VAC

Power frequency: 50Hz/60Hz

Intended use: Professional healthcare

2. This equipment should be situated in a place protected against direct sunlight, so as to prevent overheating inside the equipment.

3. The device should be stored and used within specified temperature, humidity and atmospheric pressure range, or it may cause damage to the device or inaccurate measurement result.

4. If the device gets wet by accident, the operator should NOT power it on directly until it has been air-dry enough to avoid any damage to it.

5. Do not use this equipment in an environment with toxic or inflammable gas.

6. This equipment should be placed on a stand or flat platforms, so as to prevent possible shock.

7. Do not use this equipment in combination with any equipment other than those expressly permitted in the manual.

8. The monitor is defibrillator discharge proof and can be used with electrosurgical unit. But when the device is used together with defibrillator or electrosurgical equipment, the user (doctor or nurse) should keep the patient under close surveillance for his/her safety. Refer to the following function description for specific protective measures or notes.

9. Make sure that the equipotential grounding terminal is grounded correctly.

10. Do not use mobile phone nearby, so as to avoid strong radiant field interference.

## 19.12 Storage

If the equipment will not be used for long period of time, wipe it clean and keep it in the packaging, which shall be kept in a dry and good ventilation place free from dust and corrosive gases

Storage environment: ambient temperature: -20~55°C

relative humidity: 10% ~ 95%

atmospheric pressure: 50kPa~106kPa

## 19.13 Transportation

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

Transportation environment: ambient temperature: -20~55°C

relative humidity: 10% ~ 95%



## 19.14 Packaging

The product is packed in high quality corrugated cartons with foam inside to protect the apparatus against damage in the handling process.

Gross weight: Details see the indication on the outer package

Dimension: Details see the indication on the outer package

## 19.15 Summary of Safety and Clinical Performance

Device Name: Multi-parameter Patient Monitor

Model Name: Elegant-3000

Basic UDI-DI: 471988303PMEG3000Y9

SRN: TW-MF-00000147

Intended Use: This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult, pediatric and neonate patients. With the functions of real-time recording and displaying parameters, such as ECG, heart rate (HR), non-invasive blood pressure (NIBP), functional oxygen saturation (SpO<sub>2</sub>), respiration (RESP), body temperature (TEMP) and so on, it allows comprehensive analysis of patient's physiological conditions that would be benefit to the patients and doctors.

For the evaluation regarding the **Class IIb** product safety aspects, the following **harmonized standards** are applied:

- **EN ISO 14971:2019** – Application of risk Management to medical devices
- **EN ISO 15223-1:2021** - Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- **EN ISO 10993-1:2021** - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- **EN 60601-1:2006+A12:2014** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **EN 60601-1-2:2015/IEC 60601-1-2:2014** - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
- **IEC 80601-2-49:2018** Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
- **IEC 60601-2-27:2011** Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- **IEC 80601-2-30:2018** Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- **ISO 80601-2-61:2017** Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- **EN 60601-1-8:2007+A11:2017** Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- **IEC 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices

- **EN ISO 80601-2-56:2017/A1:2018** Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- **EN 60601-1-4:1996** Medical electrical equipment - Part 1-4: General requirements for the safety - Collateral standard: Programmable electrical medical systems
- **EN 62304:2006** Medical device software - Software life-cycle processes
- **DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (**RoHS 2.0**)
- **Common Specification: N/A**

Suggested profile and training for users: Manufacturer shall provide the users the training course before use.

### Warnings

- 🔥 To the patient with pacemaker, due to that this device has been designed to provide resistance to pacemaker signal interference, generally the pacemaker pulse is not counted in heart rate measurement and calculation, but when the cycle time of pacemaker pulse is over 2ms, it may be counted. In order to reduce this possibility, observe the ECG waveforms on the screen carefully and do NOT rely entirely on the heart rate display and alarm system of this monitor when monitoring this kind of patients.
- 🔥 Besides the improper connection with electrosurgical unit may cause burns, the monitor may be damaged or arouse deviations of measurement. You can take some steps to avoid this situation, do NOT use small ECG electrodes, choosing the position which is far away from the estimated Hertzian waves route, using larger electrosurgical return electrodes and connecting with the patient properly.
- 🔥 When taking the measure of an pediatric's (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.
- 🔥 It is recommended to take the blood pressure measurement manually. Automatic measurement should be used at the presence of a doctor/nurse.
- 🔥 NIBP monitoring is prohibited to those who have severe hemorrhagic tendency or with sickle cell disease, or partial bleeding will appear.
- 🔥 Do NOT bind NIBP cuff on limbs with transfusion tube or intubations or skin lesion area, otherwise, damages may be caused to the limbs.
- 🔥 Pay attention to the color and sensitivity of the limb when measuring NIBP; make sure the blood circulation is not blocked. If blocked, the limb will discolor, please stop measuring or remove the cuff to other positions. Doctor should examine this timely.

### Precautions

- 🔥 Do NOT operate this monitor in the circumstance where flammable gas or explosion factor exists.
- 🔥 Please shut down the monitor and remove sensors while during MRI scanning, or else induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of monitor measurements.

### Contraindications



- 🔥 It is contraindicated for use on active patients or for prolonged use.

### Adverse Reaction

- 🔥 Continuous use of fingertip SpO2 sensor may result in discomfort or pain, especially for those patients with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same finger for over two hours.
- 🔥 It is contraindicated for use on active patients or for prolonged use.

# Chapter 20 Troubleshooting

**Note:** In case of trouble of this machine in service, follow the instructions below to eliminate the problem first. If the attempt fails, contact the dealer in your local area or the manufacturer.

-  **Do NOT open the monitor cabinet without permission**
  
-  **During operation, if the system error and the prompt pops up on the screen, then the system will shutdown, and it restarts within 5 seconds and resume to factory default settings.**

## 20.1 No Display on the Screen

Shut down the machine and unplug the power cable. Use a universal meter to check if the outlet has proper voltage, check the power cable is in good condition, and that it has been properly connected to the monitor and outlet. Remove the fuse from the back cover of this machine, and make sure it is in good condition. If all of above is in good condition, there may be an issue with display screen.

## 20.2 Excessive ECG Signal Interference or too Thick Baseline

1. Check if the plate electrodes are properly located, and if valid plate electrodes are used.
2. Check whether the lead wires are properly inserted. If no ECG curve displayed, check if the ECG lead wires are broken.
3. Make sure the mains outlet has standard grounding wire.
4. Check if the grounding wire of the apparatus properly grounded.


## 20.3 No Blood Pressure and Pulse Oxygen Measures

1. Check if the blood pressure cuff is properly wrapped around the arm according to the operating instructions, if the cuff leaks, and if the inlet is closely connected with the NIBP jack on the side panel. Check if the indicator of the pulse oxygen sensor flashes and if the pulse oxygen probe is properly connected to the SpO<sub>2</sub> jack on the side panel.
2. If the problems still exist, please contact the manufacturer.

## 20.4 System Alarm

1. When the parameter value is higher or lower than the alarm limits, the alarm will ring. Please check whether the alarm limit value is proper or the condition of the patient.
2. Leads off. Please check the connection of the leads.
3. Probe off. Please check the connection of the probes.

## 20.5 Alarm Problems

Symptoms	Possible cause	Correction action
The alarm LED does not light	Main board is defective	Replace the main board
No alarm sound is issued	Audible alarm is disabled	Check is the  ” is displayed, if yes, the audible alarm is disabled.
	Speaker is defective	Replace the speaker
	Main board is defective	Replace the main board

## 20.6 Power Supply Failure

Symptoms	Possible cause	Correction action
Battery cannot be recharged and/or fully charged	Battery is defective	Replace the battery
	Main board is failure	Replace the main board

## A Alarm Information

Alarm Information	Descriptions
Over HR limit	The related parameter value exceeds the preset high/low alarm limits.
Over RR limit	
Over TEMP limit	
Over SpO <sub>2</sub> limit	
Over PR limit	
Over NIBP SYS limit	
Over NIBP DIA limit	
Over NIBP PR limit	
Unable to detect HR	ECG cable and leads are connected to monitor and patient well, but HR is unable to be detected. It may be caused by poor integrity of ECG signals.
Unable to detect SpO <sub>2</sub>	SpO <sub>2</sub> probe is connected to monitor and patient well, but SpO <sub>2</sub> is unable to be determined. It may be caused by poor plethysmogram signals.
The battery capacity will exhaust	Low battery voltage
Lead Off	The ECG electrodes or cable fell off
Probe Off	SpO <sub>2</sub> probe fell off

## **B Status/Error during NIBP Monitoring**

“Cuff error”	—cuff is not wrapped correctly, or is not connected
“Air leak”	—Air moving part, tube or the cuff leak air.
“Pressure error”	—Unstable cuff pressure or tangled cuff tubing
“Signal weak”	—Very weak signal because of the cuff, or the patient has very weak pulse
“Over extent”	—The measurement range exceeds 255 mmHg (Pediatric patient over 135 mmHg)
“Over motion”	—The repeated measurement due to moving, excessive noise during the stepping inflation and measuring pressure and pulse, e.g. during patient shaking motion
“Signal overflow”	—Blood pressure amplifier overflow due to excessive movement
“Leak in gas run”	—Leaking during the pneumatic device testing
“System error”	—Abnormal condition of CPU, such as register overflow, divided by zero
“Adult”	—The blood pressure measuring now is in adult mode. In this case, it is not allowed to monitoring Pediatric or neonatal patient. Otherwise, there may be serious danger to the Pediatric monitored.
“Pediatric”	—The blood pressure module is now worked in Pediatric measuring mode.
“PROBE OFF”	—SpO <sub>2</sub> probe fell off
“LEADS OFF”	—The ECG electrodes or cable fell off
“LEARNING”	—Learning arrhythmia for 15 seconds
“DEMO”	—The monitor is displaying the demo waveforms, which are generated by the monitor itself.

## C EMC Compliance

**Table 1**

**Guidance and manufacturer's declaration-electromagnetic emission-  
for all EQUIPMENT AND SYSTEMS**

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The product is not an RF electromagnetic energy medical product. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.  If you have any questions, please contact the dealers or manufacturer.
Harmonic emissions IEC61000-3-2	Class A *1	
Voltage fluctuations/flicker emissions IEC61000-3-3	*2	

\*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A.  
For the regions where the rated voltage is 127 V or less, this standard is not applicable.

\*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard.  
For the regions where the rated voltage is 127 V or less, this standard is not applicable.

**Table 2**  
**Guidance and manufacturer's declaration-electromagnetic immunity**  
**for all EQUIPMENT AND SYSTEMS**


The device is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment -guidance</b>
Electrostatic discharge(ESD) <b>IEC61000-4-2</b>	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst <b>IEC61000-4-4</b>	±2kV for power Supply lines ±1 kV for input/output lines	±2kV for power Supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge <b>IEC 61000-4-5</b>	±0.5, 1 kV line(s) to line(s) ±0.5, 1, 2 kV line(s) to ground	±0.5, 1 kV line(s) to line(s) ±0.5, 1, 2 kV line(s) to ground	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 <b>IEC61000-4-11</b>	0% Ur for 0.5 cycle (1 phase) 0% Ur for 1 cycle 70% Ur for 25/30 cycles (50/60Hz) 0% Ur for 250/300 cycles (50/60Hz)	0% Ur for 0.5 cycle (1 phase) 0% Ur for 1 cycle 70% Ur for 25/30 cycles (50/60Hz) 0% Ur for 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency(50Hz/60Hz) magnetic field <b>IEC61000-4-8</b>	30A/m (50 or 60 Hz)	30A/m (50 or 60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.			



**Table 3**

**Guidance and manufacturer’s declaration – electromagnetic immunity-  
for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING**

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

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms at 0.15 – 80MHz & 6V at ISM Frequency	3 Vrms at 0.15 – 80MHz & 6V at ISM Frequency	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b>  $E = \frac{6}{d} \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol.  

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

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

a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Patient Monitor is used exceeds the applicable RF compliance level above 3V/m, Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Patient Monitor.

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

**Table 4**  
**Test specifications for enclosure port immunity to RF wireless communications equipment**

Test frequency (MHz)	Band <sup>a</sup> (MHz)	Service <sup>a</sup>	Modulation <sup>b</sup>	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation <sup>b</sup> 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM <sup>c</sup> ± 5 kHz deviation	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation <sup>b</sup> 217 Hz	0.2	0.3	9
745						
780						

Test frequency (MHz)	Band <sup>a</sup> (MHz)	Service <sup>a</sup>	Modulation <sup>b</sup>	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation <sup>b</sup> 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation <sup>b</sup> 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation <sup>b</sup> 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse Modulation <sup>b</sup> 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- c) 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.



WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. The minimum separation distance for higher immunity test levels shall be calculated using the following equation:  $E = \frac{6}{d} \sqrt{P}$ , where P is the maximum power in watts

$$E = \frac{6}{d} \sqrt{P}$$

(W), d is the minimum separation distance in meters(m), and F is the immunity test level in V/m.

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