Remote Patient Monitoring & Diagnostics System

USER MANUAL

MP802

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Contents

Copyright Statement

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Definitions of Symbols

	Caution		Alarm Off
	Operating instructions		Waveform Freeze
	Adult Male		Heart Rate
	Adult Female		Patient wearing a pacemaker
	No Alarm		The patient did not wear a pacemaker
	Alarm silence		System Setup
	Alarm Paused		Help
	Battery indicator		Patient Management
	Bluetooth Connection Status		Alarm Setting
	Wi-fi connection status Wi-fi		Parameters Setup
	Reserved		Advanced Setup
	No littering		CF medical device CF
	Keep dry		Manufacturer
	Authorised representative in the European community		Date of manufacture
	Catalogue number		Serial number

⚠Cautions

- The use of the system is restricted to one patient at a time.
- The system cannot be used with high-frequency surgical equipment, otherwise it may cause burns to the patient.
- The system should be used by professional clinical staff or under the guidance of professional clinical staff. Personnel using the monitoring system should receive adequate training. Anyone who is not authorized or who is not trained may not perform any operations.
- The system should be installed by a trained installer.
- The alarm volume and alarm limit should be set according to the actual situation of the patient. It is not possible to rely solely on an audible alarm system to monitor a patient. Adjusting the alarm sound to a small volume may result in patient risk. The actual clinical condition of the patient should be closely monitored.
- The physiological parameters and alarm information displayed by this system are for medical reference only and cannot be directly used as the basis for clinical treatment.
- When performing patient monitoring, the monitoring system should be continuously powered.
- Before use, the user must check the equipment, cables and accessories to ensure that they work properly and safely.

- Do not open the outer casing of the system equipment, otherwise there is a danger of electric shock. Repair, installation or upgrade of the equipment may only be carried out by maintenance personnel trained and authorized by the company.
- Do not use the device in an oxygen-rich environment or in an environment where flammable or explosive materials such as anesthesia are placed to avoid fire or explosion.
- This system is only suitable for adults and not for children and newborns.
- Do not wear the vital patch when charging.
- The conductive parts of electrodes should not contact any other conductive parts including earth.
- WARNING—PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter ALARM SIGNALS. Keep pacemaker PATIENTS under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.
- After the system expires, you cannot continue to use it, otherwise it may cause harm to users or patients.
- After the system expires, it should be disposed of in accordance with local regulations to avoid environmental pollution.
- This system is for non-living support and cannot be used for life support! The monitor data is for reference only and should not be used as a

treatment basis!

1. General Discriptions

1.1 Intended Use

The Raiing Remote Patient Monitoring & Diagnostics System is a wireless remote monitoring system intended to be used by healthcare professionals for continuous monitoring, collecting and analysing physiological data in home and professional healthcare settings, which includes heart rate, electrocardiography (ECG), SpO2, non-invasive blood pressure, respiratory rate, body temperature. The system is intended for using as a patient monitor and diagnostic system for general and intensive care patients. The system has no defibrillation function.

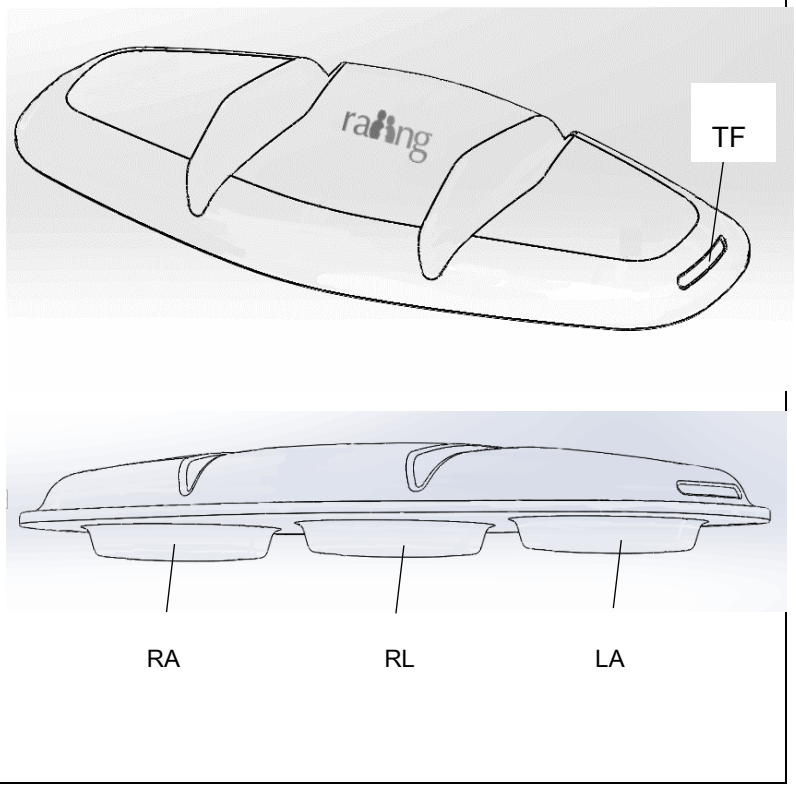
1.2 Contraindications

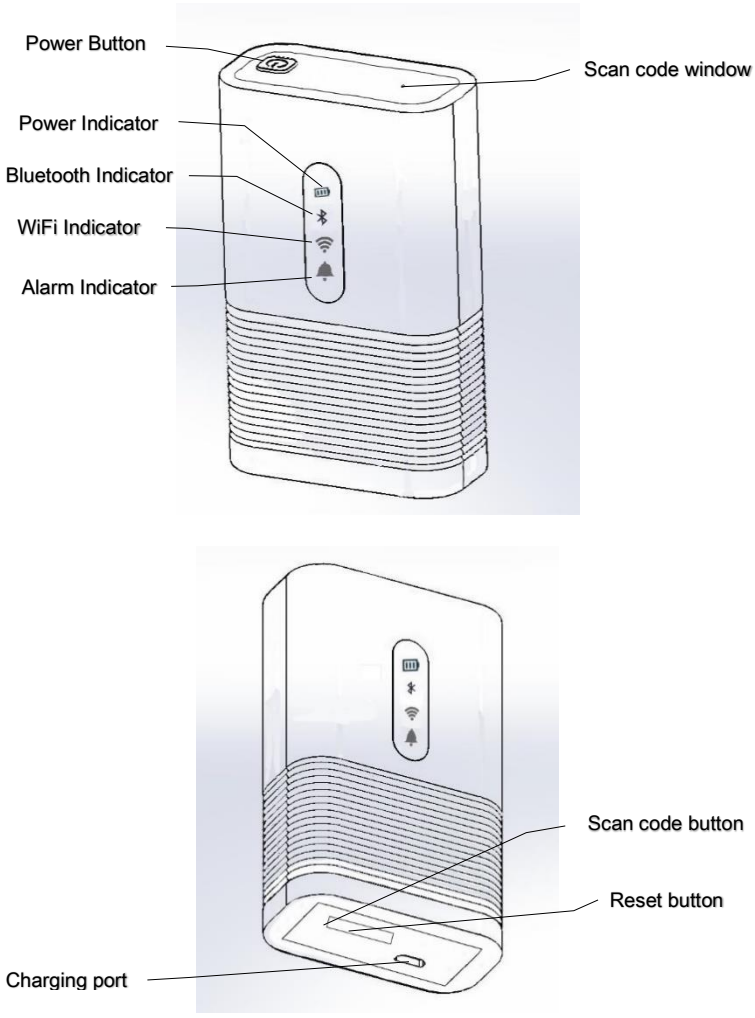
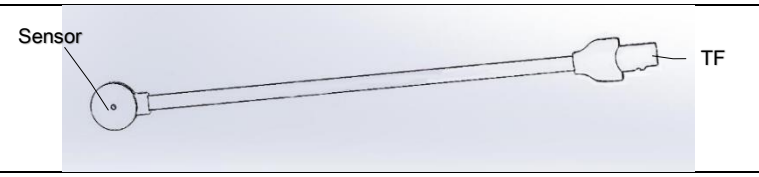
No.

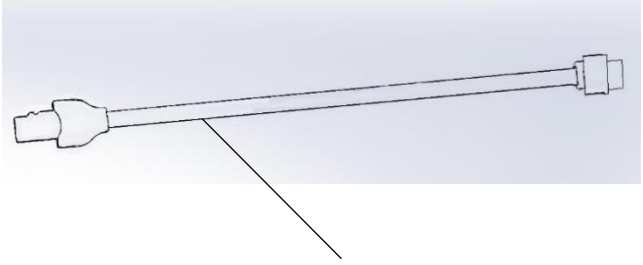
1.3 Product composition

The Raiing Remote Patient Monitoring & Diagnostics System includes Raiing multi-parameter vital patch, Raiing cHUB, pulse oximeter, blood pressure monitor, data aggregating & streaming device, display unit and other accessories. The Raiing multi-parameter vital patch is designed to be applied onto patient's skin for collecting physiological data which will be transmitted to

the cHUB via Bluetooth. The Raiing cHUB is a dedicated equipment for aggregating all physiological data and navigating it into display unit via data aggregating & streaming device. Accessories include charger, charging cables.

No.	Accessories Name	Sketch
1	Raiing multi-parameter vital patch	

2	Raiing cHUB	
3	Temperature Sensor	
4	Pulse Oximeter	
5	Blood Pressure Monitor	

4	Data aggregating & streaming device	
5	Display unit	
6	Mouse	
7	Charger	
8	Charging cables	 cHUB Charging cables  multi-parameter vital patch Charging cables

1.4 Installation

The data aggregating & streaming device, display unit and mouse are installed in the non-patient environment, and the Raiing multi-parameter vital patch, Raiing cHUB, temperature sensor, pulse oximeter and blood pressure monitor are installed in the patient environment. The data aggregating & streaming device and the Raiing cHUB communicate via wireless LAN.

Configuring WLAN

1) Connect the Raiing cHUB to the WLAN

The information of the WLAN to be accessed by the company's operation and maintenance personnel, including the network name, password and IP address, is wirelessly written into the Raiing cHUB via Bluetooth.

2) Connect the data aggregating & streaming device

According to the data aggregating & streaming device manual, set the wireless network information, including the pre-accessed wireless network name, password and IP address.

Installation of a non-patient environment

1) Place the data aggregating & streaming device in a place 1m away from the bed, then connect the power cord, and the device will automatically power on;
2) Turn on the power of the display;

3) Connect the display to the HDMI interface of the data aggregating & streaming device;

4) Press the attached file of the mouse to connect the mouse to the USB interface of the data aggregating & streaming device;

5) Press the display key to enter the interface of the data aggregating & streaming device;

6) Click the icon to start the system and enter the main interface of the system.

Note: When the client network power is cut off for more than 30s, the system settings will be restored to the last saved state.

Raiing cHUB Installation

1) Turn on the device

Press and hold the On/Off button of the Raiing cHUB until all four LEDs are lit, and place the device within 1m of the patient's bed to be used.

cHUB Indicator status table

		LED1	LED2	LED3	LED4
Status		Battery indicator	Bluetooth Connection Status	Wi-fi connection status Wi-fi	Coordinate
Color	Constantly	Normal	Bluetooth	Wi-fi	/

	bright	battery	connection status is normal.	connection is normal. Wi-fi	
	Flashing 闪烁	Low battery	Bluetooth disconnec	Wi-fi disconnect Wi-fi	/
	Flashing alternately	Charging in the off state.			
	Flashing simultaneously	Charging completed in the off state.			

2) Turn off the device

After use, press and hold the on/off button of the Raiing cHUB until all the lights are off, that is, the device is turned off.

3) Charging

When the display shows that the cHUB is low battery and the LED1 of the cHUB is flashing, the cHUB is low battery and should be charged immediately, otherwise it will affect the use.

The cHUB can be charged when it is turned on or off. When charging, plug one end of the USB charging cable into the charging port of the repeater and the other end into the charger connected to the network power supply.

When the Chub is charging in the power-on state, the battery indicator LED1 flashes; when the battery indicator is always on, charging is complete.

When the cHUB is charged in the off state, the four LED indicators flash in turn; when the four LEDs flash simultaneously, the charging is completed.

⚠ Note: 1) Only use the charger provided by the company. Otherwise, the unmatched charger may cause damage to the product or pose a safety hazard.

2)) When the low battery prompt appears, the cHUB should be charged in time to avoid affecting the use and battery life.

3) Keep it in a dry and ventilated place when charging.

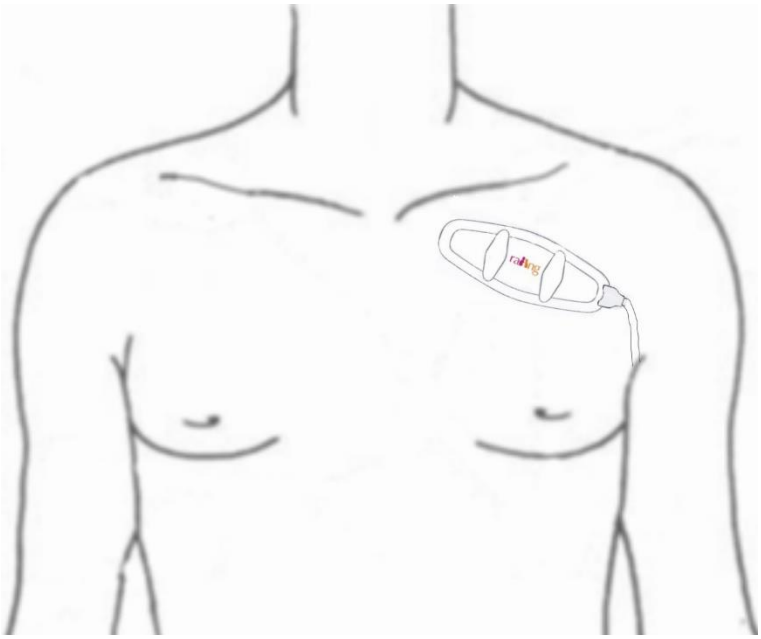
4) Unplug the charger when the charger is not in use.

Wearing Raiing multi-parameter Vital Patch

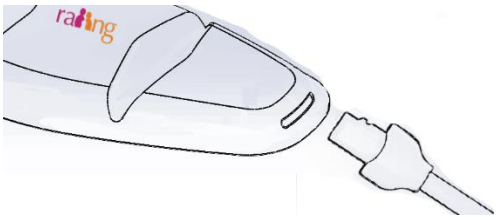
1) Wearing Raiing multi-parameter Vital Patch

- Skin preparation. Select a flat, less muscular area as the place to place the electrode and treat the skin as follows:
  - Remove the body hair at the electrode placement;
  - Gently rub the skin on the electrode to remove dead skin cells;
  - Wash skin thoroughly with soapy water (do not use alcohol or pure alcohol as this will increase the impedance of the skin and lead to inaccurate monitoring of physiological parameters)
  - Make sure the skin is completely dry before placing the electrode.
- Attach the electrode pads to the three electrodes of the multi-parameter vital patch and attach them to the chest position of the human body. The

company logo is facing up.



- Insert the temperature sensor cable into the TF card interface of the multi-parameter vital patch. The direction is as shown in the figure. If you hear a click, it will be inserted into place. Then use a medical tape to attach the temperature sensor to the underarm of the human body.



Multi-parameter vital patch indicator status table

Color	Status
Flashing green light	Power on
Not bright	Power off
Flashing red light	Low battery

Yellow light is always on	Charging
Green light is always on	Charging is complete.

Note: The used temperature sensors are not multiplexed. The disposable temperature sensor with adhesive tape must be used immediately, otherwise it cannot be reused, so as not to be confused with the used temperature sensor.

2) Power on/off

Power on: Continuously tapping the vital patch housing twice, the green light flashes, that is, the boot is successful;

Power off: Remove the vital patch from the patient and tap twice. The green light will no longer flash to complete the shutdown. Or remove the vital patch from the patient. After 30 minutes, the green light will no longer flash and the system will automatically shut down.

3) Charging

When the display shows that the vital patch is low battery and the red light on the vital patch is flashing, it indicates that the vital patch is low battery and should be charged immediately.

Turn off the vital patch. In the non-patient environment, insert one end of the charging cable into the TF card interface of the vital patch, and the other end into the USB port of the charger connected to the network power supply. The yellow light indicates that the charging is completed, and the green light

constant is charged.

⚠ Note: 1) Only use the charger provided by the company, otherwise the unmatched charger may cause damage to the product.

2) Do not wear when the vital patch is charging.

3) When the low battery prompt appears, the vital patch should be charged in time to avoid affecting the use and battery life.

4) Keep it in a dry and ventilated place when charging.

5) Unplug the charger when the charger is not in use.

Wearing the blood pressure monitor

Please refer to the attached file of the blood pressure monitor.

Wearing the pulse oximeter

Please refer to the attached file of the pulse oximeter.

1.5 Main interface

When entering the following interface, the system starts successfully.

Main interface

Patieng information area

Display patient related information: patient type, bed number, name, patient id, date of birth (age).

Alarm Indicator

When an alarm occurs, the alarm indicator will flash different color prompts depending on the level of the alarm:

Alarm indicator status table

Alarm priority and status	Alarm indication
No alam	Alarm Indicator
Low priority alarm	Alarm Indicator

Medium priority alarm	
High priority alarm	

Alarm silence button

When an alarm is occurs, click this button to mute the alarm sound.

This button can’t be clicked when there is no alarm.

Alarm paused button

Whether or not an alarm is occurs, you can click this button to pause the alarm. The pause time can be set (see chapter 3.5 for the setting method). The default pause time is 2min. After the pause time arrives, the alarm will be automatically restored. You can click the resume pause again.

Alarm information area

When an alarm occurs, the details of the alarm appear in this area:

he upper part is the technical alarm area: the background corresponds to different alarm levels, and different alarm colors appear: red means advanced alarm, yellow means intermediate alarm, blue means low level alarm; when there is more information, the information is cyclically displayed. You can click on this area to open the [Alarm List] screen to view all the alarms that are occurring.

Below is the physiological alarm zone: the background corresponds to different alarm levels, and different alarm colors appear: red for advanced alarm, yellow for intermediate alarm, blue for low-level alarm; when there are multiple messages, the information is displayed cyclically. You can click on this area to open the [Alarm List] screen to view all the alarms that are occurring.

Function button area

[Patient Management]: Information on receiving patients and managing patients, see Chapter 2 for details.

[Alarm Setting]: For the setting of the upper and lower limits of the alarm, see section 3.4 for details.

[Parameter setup]: Set the display parameters of the waveform. For details, see ECG, RESP, TEMP,SPO2,NIBP.

[Advanced Setup]: Set the alarm lock. For details, see section 3.8 .

[System Setup]: Set the system parameters. See section 7 for details.

Waveform freeze

During the monitoring of the patient, you can freeze the waveform on the screen and review it to see the patient's condition during this time.

Enter the frozen state

1 In the non-freeze state, press the [Waveform Freeze] button.

2 The system will freeze the waveform of ECG and breathing on the

interface, and the waveform will not refresh or scroll. The data in the parameter area is refreshed normally.

Waveform review

In the frozen state, you can click on the pop-up control in the ECG area to browse the waveform: click the left and right arrows to slide the waveform to the left and right.

Two ways to unfreeze:

- Click the [Waveform Freeze] button again.
- Execution will open the operation of other interfaces

Heart rate parameter area

This area contains the display of two data: ECG and heart rate parameters.

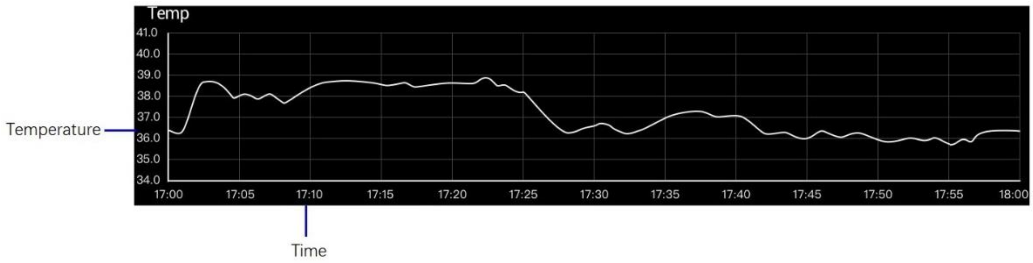
Respiratory rate parameter area

This area contains the display of two data: the respiratory map and the respiratory rate parameter.

Body temperature parameter area

This area contains two data displays: body temperature curve and body temperature parameter.

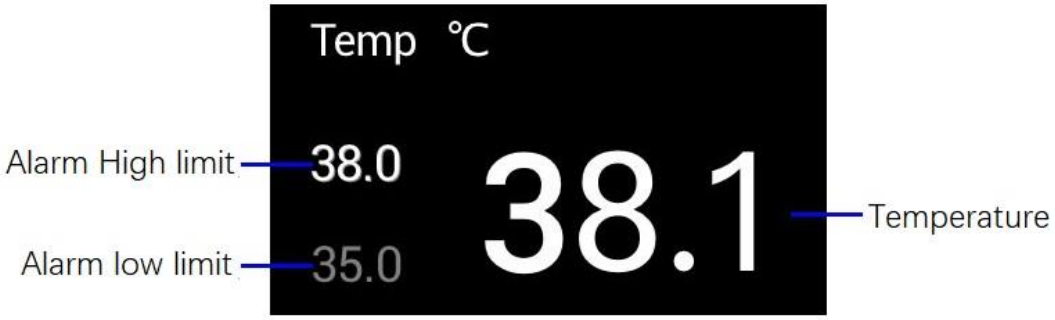
Body temperature curve



Temperature: The temperature scale of the current body temperature curve; you can set the upper and lower limits of the temperature scale by modifying the [body temperature curve upper limit] and [body temperature curve lower limit] in [Parameter Setup] - [TEMP Setup].

Time: The time scale of the current body temperature curve; you can set the upper and lower limits of the time scale by modifying the [Time Length] in [Parameter Setup] - [TEMP Setup].

Body temperature parameter

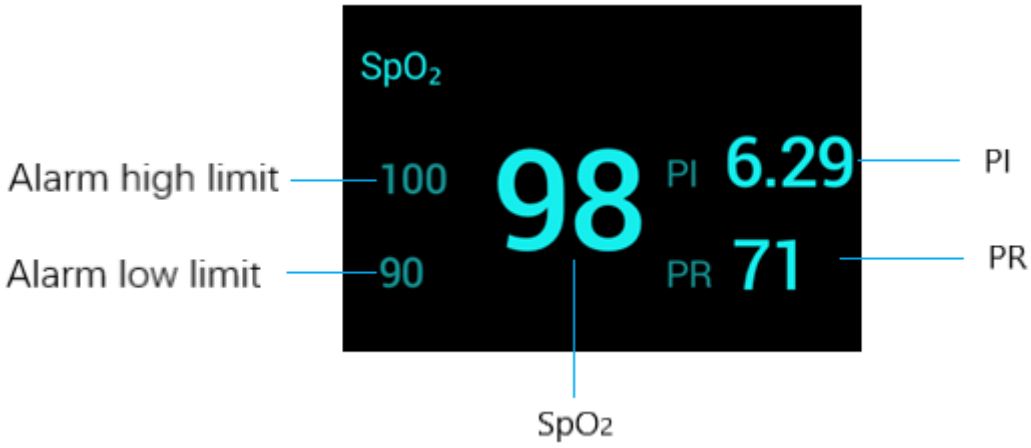


Body temperature alarm high limit: The high limit value of the monitoring body temperature, when the body temperature is higher than this value, the system will issue an alarm; you can modify the [Alarm Setting] - [TEMP Alarm Setting] interface of the [Alarm High Limit] field value. Adjust the high limit.

Body temperature alarm low limit: the lower limit of the body temperature, when the body temperature is lower than this value, the system will issue an alarm; you can modify the [Alarm Low] field of the [Alarm Settings] - [TEMP Alarm Settings] interface. Adjust the low limit.

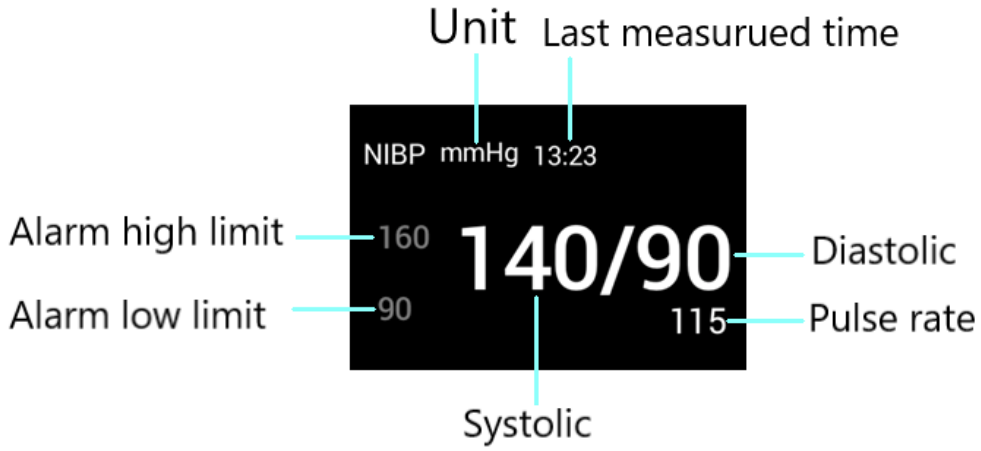
SpO_2 parameter area

This area contains the display of two data: ECG and heart rate parameters.



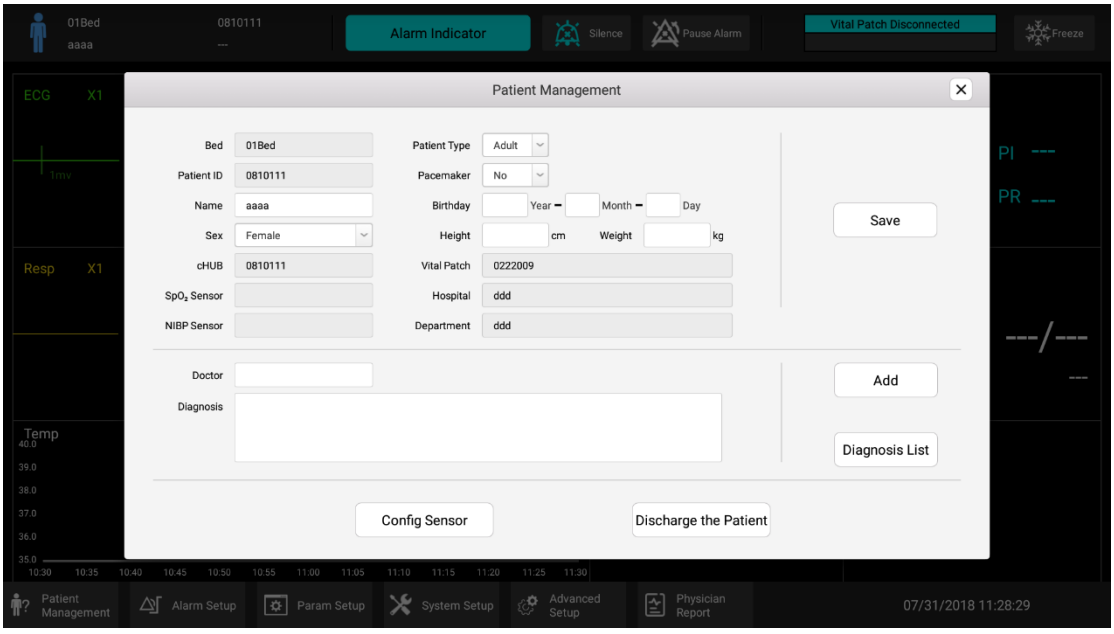
NIBP parameter area

This area contains the display of two data: ECG and heart rate parameters.



2. Patient Management

Click [Patient Management] to enter the [Patient Management] interface. The patient management function provides the ability to receive patient, patient information, and discharge the patient.



2.1 Receive Patient

Click [Patient Management] to enter the [Receive Patient] interface。

1) Fill in the patient's bed number, patient ID number, name, gender and patient type, and whether to pacing.
2) After the input is completed, click [Save] to complete the patient reception.
3) After receiving the patient successfully, it will automatically enter the [Patient Management] interface.

Note: The patient ID number must be entered in English when it is entered.

After receiving the patient, the patient information can be improved in the [Patient Management] interface, and the collector configuration operation is performed on the patient.

For patients who are already under supervision, this page can modify patient information, manage diagnostic results, [configure the vital patch] and [release the patient] multiple operations.

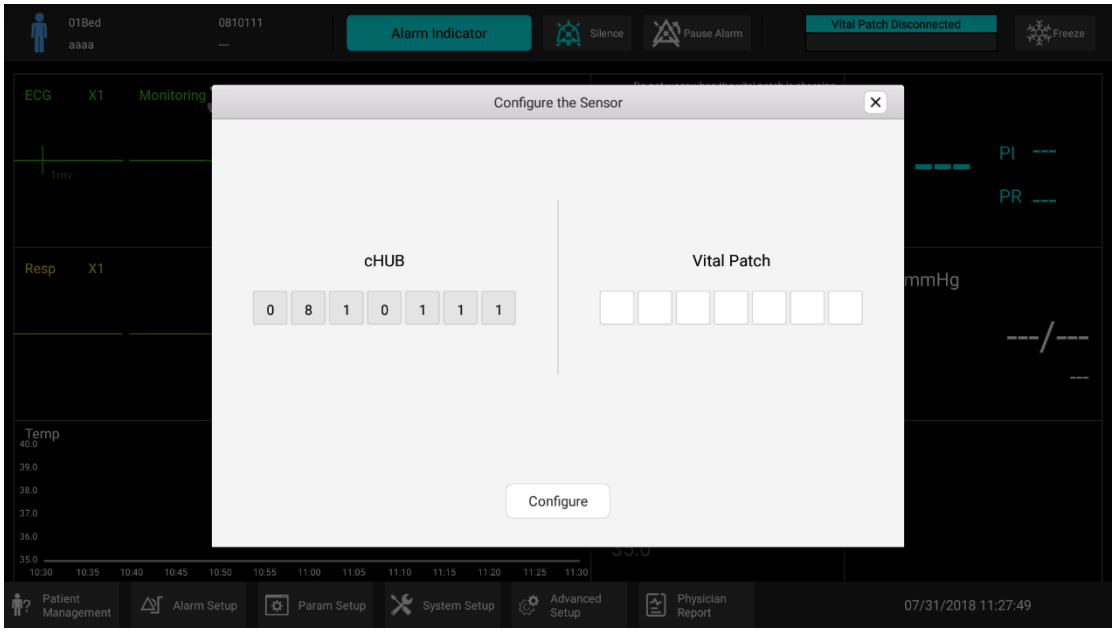
2.2 Managing patient information

1) Click the [Patient Management] button from the main interface to enter the [Patient Management] interface to modify the patient information.

2) After the modification is completed, click the save button on the right side of the patient information to save the information.

2.3 Configure the vital patch

Click the [Config Sensor] button on the [Patient Management] interface to enter the configuration vital patch interface to configure the vital patch for the patient.

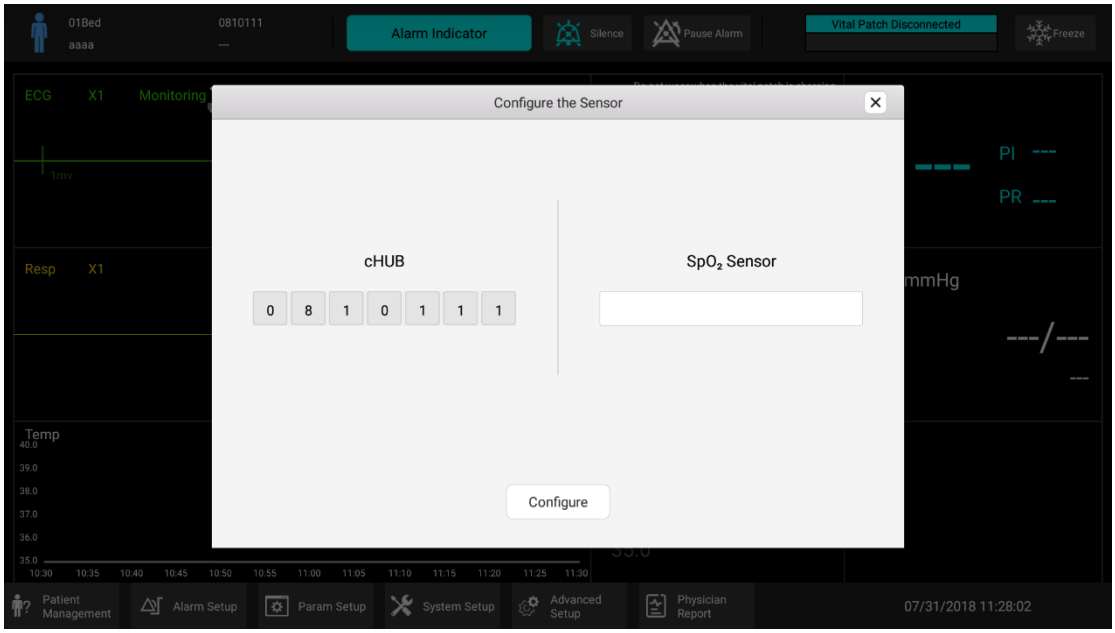


2. Enter the serial number of the vital patch to be worn by the patient, then click [Configure]

3. The system automatically completes the configuration of the vital patch worn by the patient.

2.4 Configure the pulse oximeter

Click the [Config Sensor] button on the [Patient Management] interface to enter the configuration SpO_2 Sensor interface to configure the pulse oximeter for the patient.

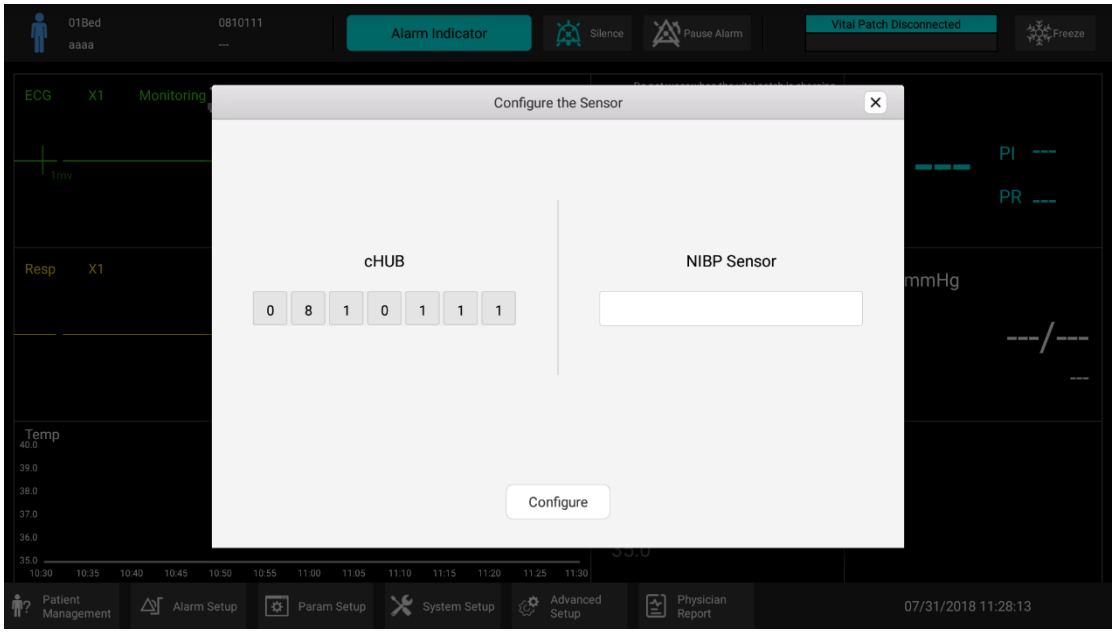


2. Enter the serial number of the pulse oximeter to be worn by the patient, then click [Configure]

3. The system automatically completes the configuration of the pulse oximeter worn by the patient.

2.5 Configure the blood pressure monitor

Click the [Config Sensor] button on the [Patient Management] interface to enter the configuration NIBP Sensor interface to configure the blood pressure monitor for the patient.



2. Enter the serial number of the blood pressure monitor to be worn by the patient, then click [Configure]

3. The system automatically completes the configuration of the blood pressure monitor worn by the patient.

2.6 Managing Diagnostic Results

The [Patient Management] interface provides a module for medical staff to quickly record the patient's condition. You can edit it in the following ways:

1) In the lower part of the [Patient Management] screen, fill in the doctor's name and diagnosis.
2) Click the [Add] button on the right to save the information to the system.
3) Click [Historical Diagnostic Results] under the [Add] button to enter the [Historical Diagnostic Results] screen to view all the saved diagnostic results.

2.7 Discharge the Patient

The feature application will clear the patient's personal data and restore the bed's information to its default value.

If you want to perform the [Discharge the Patient] operation, you can:

1. Click the [Discharge Patient] button on the [Patient Management] screen to enter the [Discharge Patient] screen.
2. Click the [OK] button to prompt the patient to complete the patient's data will be restored to the default value.

3. Alarm system

The alarm refers to the prompts made by the monitoring system to the medical staff through auditory and visual means when the patient being monitored is abnormally changed in vital signs, or the monitoring system itself fails to cause the patient's monitoring to be performed smoothly.

3.1 Alarm condition

According to the source of the alarm, the alarm can be divided into physiological alarm and technical alarm.

3.1.1 Physiological Alarm

The physiological alarm is usually caused by the physiological parameter

of the patient exceeding the upper and lower limits of the alarm set by the system, and the physiological alarm information is displayed in the physiological alarm area.

3.1.2 technical alarm

A technical alarm is an alarm that is triggered by a misoperation or a malfunction of the monitoring system due to improper operation or system failure. Technical alarm information is displayed in the technical alarm area.

3.2 Alarm priority

1) Low priority alarm: In the physiological alarm part, the patient's physiological signs are abnormal, and it may be necessary to take corresponding measures or treatment; in the technical alarm part, due to machine failure or improper operation, some monitoring functions may not operate normally, but the patient safety will not be threatened.
2) Medium priority alarm: n the physiological alarm part, if the patient's physiological signs are abnormal, the corresponding measures should be taken immediately for treatment; in the technical alarm part, some machine failures or misoperations may not threaten the patient's safety, but it will also affect the normal monitoring of key physiological parameters.
3) High priority alarm: In the physiological alarm part, the patient is in a crisis state and may be in danger of life; the technical alarm part, serious

machine failure or misoperation may not be able to monitor the patient's crisis state, making it life-threatening.

3.3 Alarm mode

When an alarm occurs, the system will prompt the user with the following alarm signal:

- Alarm information
- Parameter flashing
- Auditory alarm signals

The above methods are all issued by the display.

3.3.1. Alarm information

When an alarm occurs, the physiological alarm area and the technical alarm area of the display will prompt the corresponding alarm information. For physiological alarms, the following flags are used in front of the alarm message to distinguish the level of the alarm:

- High priority alarm：***
- Medium priority alarm：**
- Low priority alarm：*

The system also uses different background colors to distinguish between levels of physiological and technical alarms:

- High priority alarm: red

- Medium priority alarm: yellow
- Low priority alarm: blue

3.3.2. Parameter flashing

When the physiological parameter of the patient is alarmed, the corresponding parameter in the parameter area of the main interface of the display will flash at a frequency of once per second; the alarm high or low limit of the parameter will also flash at the same frequency, indicating that the parameter exceeds Upper or lower limit.

3.3.3. Auditory alarm signals

When an alarm occurs, the display unit uses different sound effects to prompt different levels of alarms.

Characteristics of auditory alarm signals

Alarm priority	Characteristics of auditory alarm signals
Low	Beep-Beep; Repeat after 20s interval
Medium	Beep-beep-beep; Repeat after 20s interval
High	Beep-beep-beep--beep-beep-----beep-beep-beep--beep-beep; Repeat after 10s interval

Note: When multiple alarms of different levels occur simultaneously, the system will sound an alarm according to the highest level of all current alarms.

The alarm sound is sent by the local display or the central station; when it is not connected to the central station, it is sent by the local display; when the monitor is connected to the central station, the audible alarm is given by the central station.

3.3.4. Alarm signal states

The system will display the following alarm signal on the screen to indicate the status of the alarm

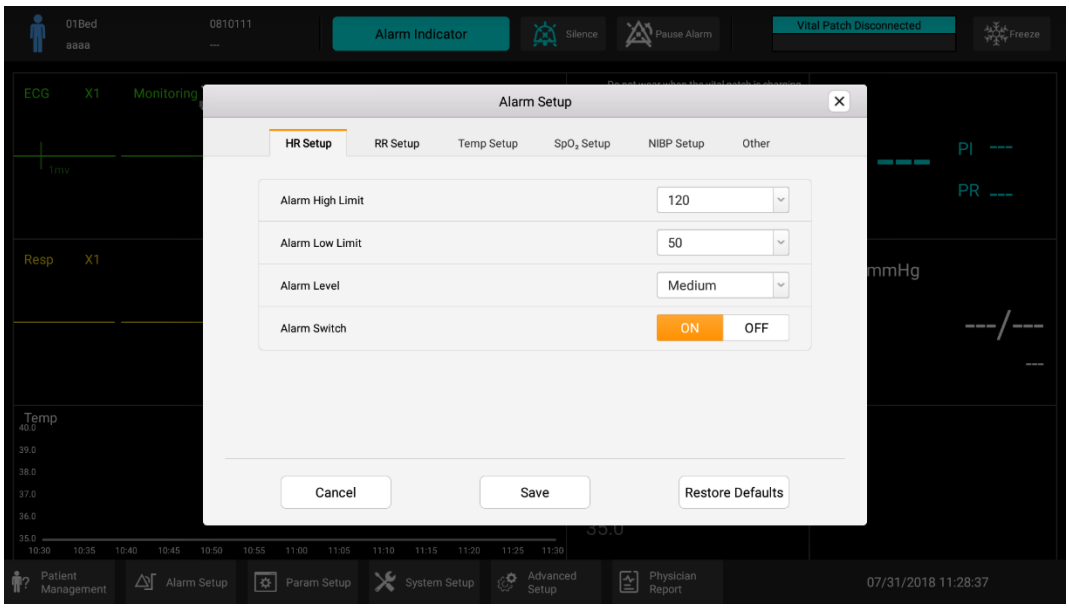
Alarm signal states

Alarm signal	Characteristics of alarm signals states
	All alarm were paused(Technical alarm information will continue to scroll and be unaffected)
	The alarm pause was set to permanent. When it appears next to the physiological parameter, it indicates that the physiological alarm was turned off.

3.4 Alarm Setting

Select [Alarm Setting] in the main interface to open the [Alarm Setting]

interface:



In this interface you can:

- Set the alarm attribute of HR;
- Set the alarm attribute of RR;
- Set the alarm attribute of TEMP;
- Set the alarm attribute of SpO_2;
- Set the alarm attribute of NIBP;
- Set other alarm properties.

3.4.1. HR alarm settings

You can modify the upper and lower limits of the HR alarm:

1) Click the alarm limit you want to modify, and the drop-down box will pop up.

2) Select the desired alarm value.

3) Click Save to save the changes.

You can modify the switch of the HR alarm, select the alarm [ON] or [OFF], after the selection is completed, click Save to save the operation. When the alarm is selected off, the icon  is displayed in the parameter display area.

Note: When the alarm is set to off, the system will not generate an alarm even if the HR exceeds the alarm limit.

3.4.2. RR alarm settings

You can modify the upper and lower limits of the RR alarm:

1) Click the alarm limit you want to modify, and the drop-down box will pop up.

2) Select the desired alarm value.

3) Click Save to save the changes.

You can set the switch of the HR alarm, select the alarm [ON] or [OFF], after the selection is completed, click [Save] to save the operation. When the selection is tuned off, the symbol  is displayed in the parameter display area.

Note: When the alarm is set to off, the system will not generate an alarm even if the HR exceeds the alarm limit.

3.4.3. TEMP alarm settings

You can modify the upper and lower limits of the TEMP alarm:

1) Click the alarm limit you want to modify, and the drop-down box will pop up.

2) Select the desired alarm value.

3) Click Save to save the changes.

You can modify the switch of the HR alarm, select the alarm [ON] or [OFF], after the selection is completed, click Save to save the operation. When the alarm is selected off, the icon  is displayed in the parameter display area.

Note: When the alarm is set to off, the system will not generate an alarm even if the HR exceeds the alarm limit.

3.4.4. Setting other alarms

You can set the following alarms:

- Time of asphyxia delay;
- On or off of Asystole detection.

When you modify the time of asphyxia delay, the system delays the occurrence of the suffocation alarm according to the set time.

When you set the cardiac stop to off, the system no longer alerts you to asystole.

3.5 Alarm paused

In the main monitoring interface, click the [Alarm Pause] button to temporarily pause the following status:

- The visual and auditory of physiological alarm
- The auditory of technical alarm
- The flashing of physiological parameters and alarm limits

When the alarm is paused, a symbol  will appear in the alarm information area, indicating that the alarm is paused, and the remaining time of the pause will be displayed next to the alarm pause button. If you click the [Alarm Pause] button again, the alarm pause state will be canceled.

The default time for pause is 2min, if you need to modify the time the alarm is paused, you can:

1. Click the [Advanced Settings] button and enter the password to enter the [Advanced Settings] interface.
2. In the [Advanced Settings] interface, select the [Alarm Settings] icon and modify the [Alarm Pause Time] (see Chapter 9: Alarm Specifications for the setting range).

3.6 Alarm inhibition

When [Alarm Pause Time] is set to [Permanent], press [Alarm Pause] and the system will enter the alarm inhibition state:

- The visual and auditory of the physiological alarms is turned off.
- The auditory of technical alarms are turned off.
- The flashing of physiological parameters and alarm limits are turned off.

This state can only be canceled by clicking the [Alarm Pause] button again.

3.7 Alarm silence

When an alarm occurs, you can click the [Alarm Mute] button to mute the alarm that is occurring.

When the alarm is muted:

- The auditory for physiological and technical alarms will be turned off.
- In front of the text of the physiological and technical alarm information, it will be confirmed by the symbol √.

3.8 Latched alarm and non-latched alarm

Physiological alarms can be set to [latched] and [non-lached]

Latched：

Even if the condition that caused the physiological alarm disappears, the alarm signal will still be [locked], but the way of the alarm will change as follows:

- Physiological parameters and upper or lower alarm limits are no longer flashing.

- The time when the alarm was last triggered is displayed after the alarm information in the alarm information area.

Non-latched：

When the condition that caused the physiological alarm disappears, the alarm signal will also disappear.

Set the latched or non-latched state of the physiological alarm:

1. Click the [Advanced Settings] button and enter the password to enter the [Advanced Settings] interface.
2. In the [Advanced Settings] interface, select the [Alarm Lock] tab and change the status of the alarm lock to [On] or [Off].

Tip: The implementer will provide a password during the installation process. Tip: The implementer will provide a password during the installation process.

3.9 Alarm response measures

When the system has an alarm, please follow the steps below to take the appropriate action:

1. Confirm the type of parameter and alarm that is being alerted.
2. Identify the cause of the alarm.
3. Check the condition of the patient.
4. Release the cause of the alarm.
5. Confirm if the alarm is cleared.

For details on the alarm, please click [Alarm Information Area] to enter the [Alarm List] for detailed inspection.

4. ECG

An electrocardiogram (ECG) measures the electrical activity of the heart and displays the ECG waveforms and parameters on the screen.

4.1. Check if the pacemaker is wearing

Before setting up ECG monitoring, it is very important to set the patient's pacing state correctly. When the pacing is used, the icon  is displayed in the ECG waveform area. When the pacing signal is detected, the ECG waveform is marked at the baseline, and the color of the symbol is different from that of the waveform. When you set to no, display the icon  in the ECG waveform area.

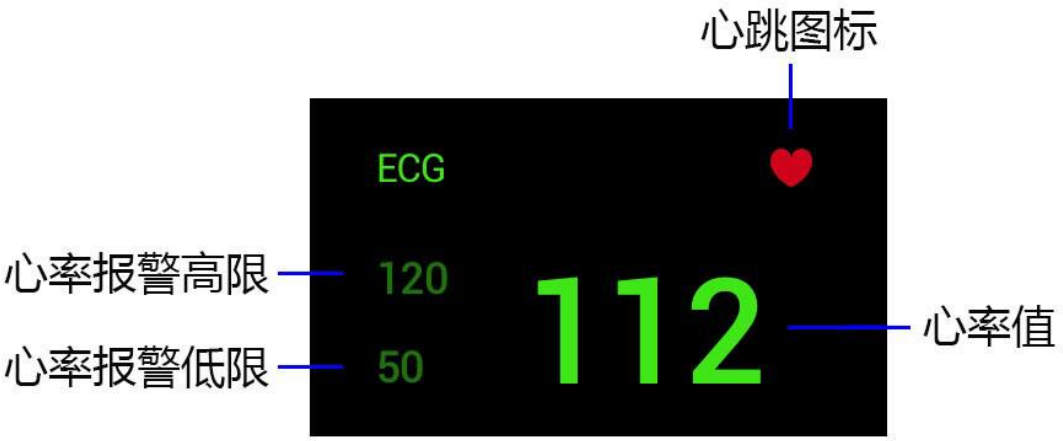
You can modify the pacing state in this way.

- Enter [parameter settings] - [ECG settings] interface.
- Select [pacing] button to modify pacing state.

4.2. ECG display ECG

Waveform

Parameters



4.3. Setting ECG

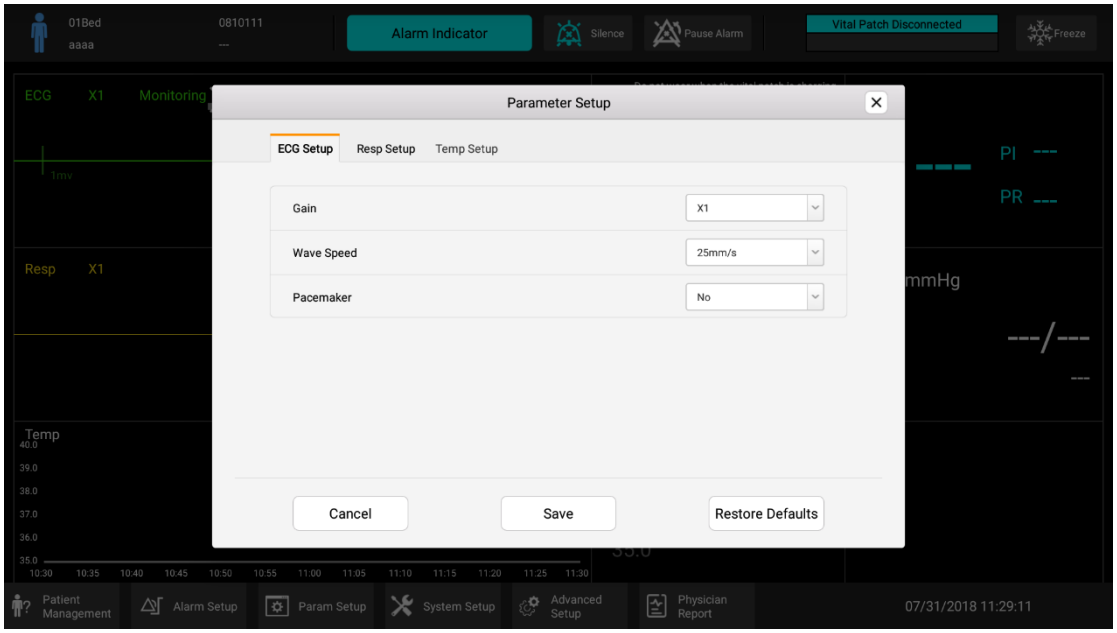
4.3.1. Setting Waveform Parameters

Enter [Parameter Setting] - [ECG Setting] interface to set the display parameters of the waveform:

Gain: You can set the magnification of the waveform: X0.5 X1 X2 X4;

Sweep speed: You can set the width of the waveform display. The higher the speed, the wider the waveform.

Pacing: You can set whether the patient wears a pacemaker.

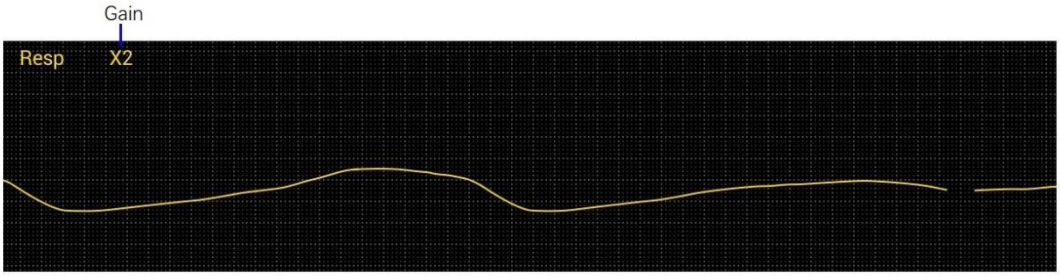


5. RESP

Breathing measurements were performed using the thoracic impedance method. When the patient breathes, the thoracic activity causes a change in the thoracic impedance between the two ECG electrodes, and the system displays a respiratory wave on the screen by measuring the change in impedance. The system follows the waveform period to calculate the respiratory rate (RR).

5.1. RESP display RESP

Waveform



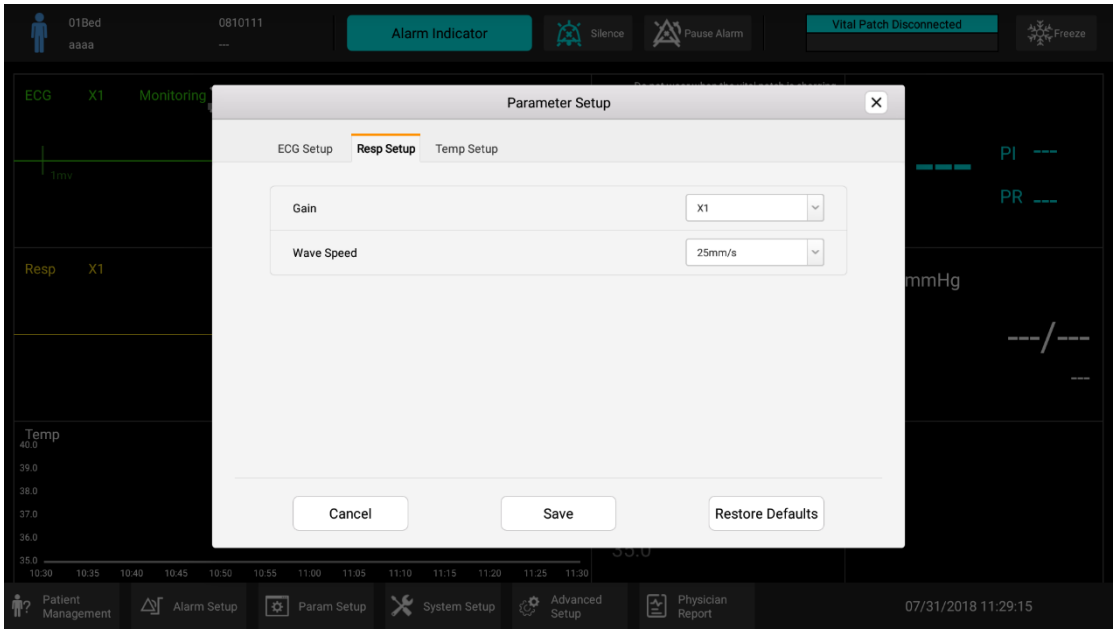
Parameters

5.2. Setting Waveform Parameters

Enter [Parameter Setting] - [RESP Settings] interface to set the display parameters of the waveform:

Gain: You can set the magnification of the waveform: X0.5 X1 X2 X4

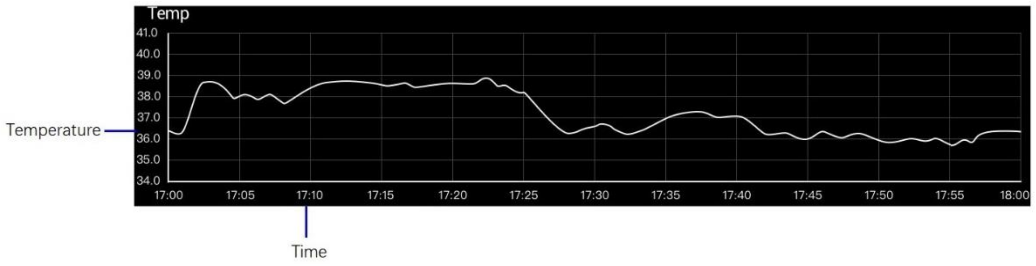
Sweep speed: You can set the width of the waveform display. The higher the speed, the wider the waveform.



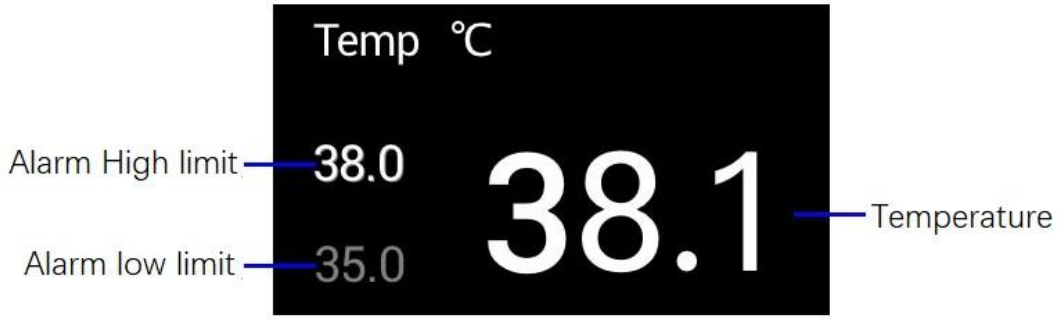
6. TEMP

6.1. TEMP display TEMP

Body temperature curve



Body temperature parameters

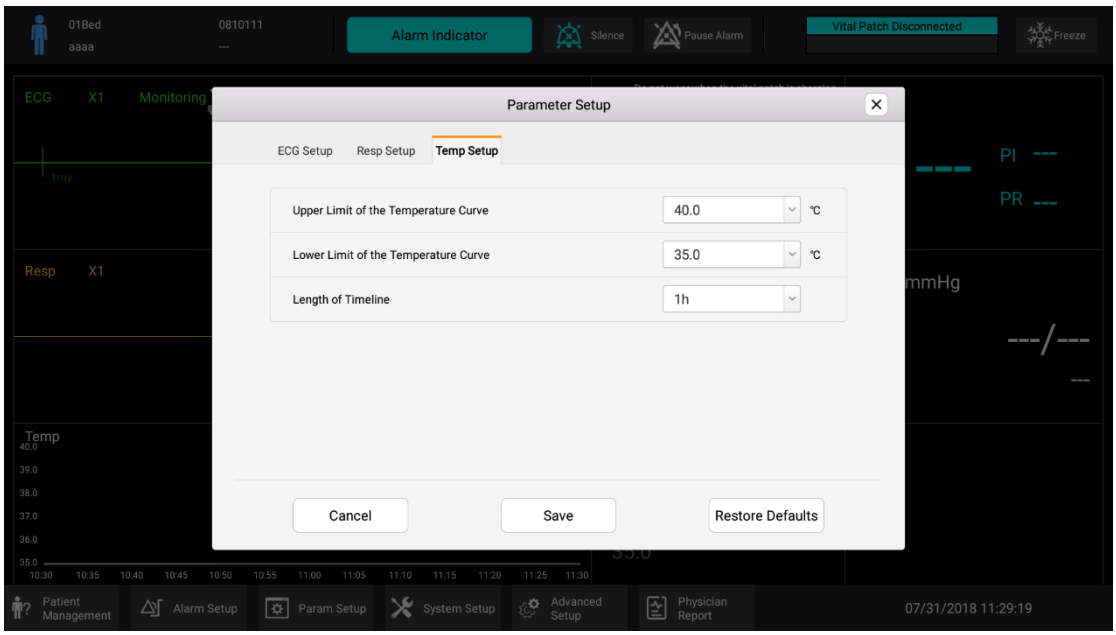


6.2. Setting waveform parameters

Enter [Parameter Settings] - TEMP Settings interface to set the display parameters of the waveform:

Temperature: The temperature scale of the current body temperature curve; you can set the upper and lower limits of the temperature scale by modifying the [body temperature curve upper limit] and [body temperature curve lower limit] in [Parameter Setting] - [TEMP Settings].

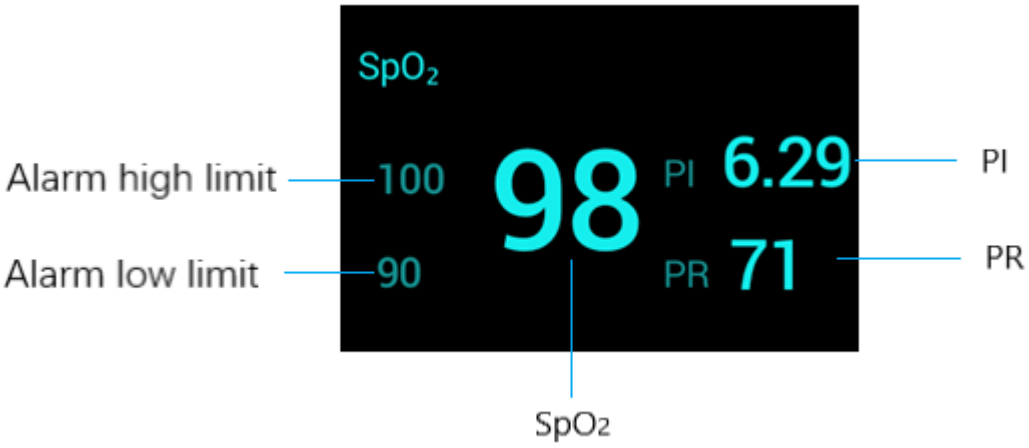
Time: The time scale of the current body temperature curve; you can set the upper and lower limits of the time scale by modifying the [Time Length] in [Parameter Settings] - [TEMP Settings].



7. SpO_2

7.1. SpO_2 display

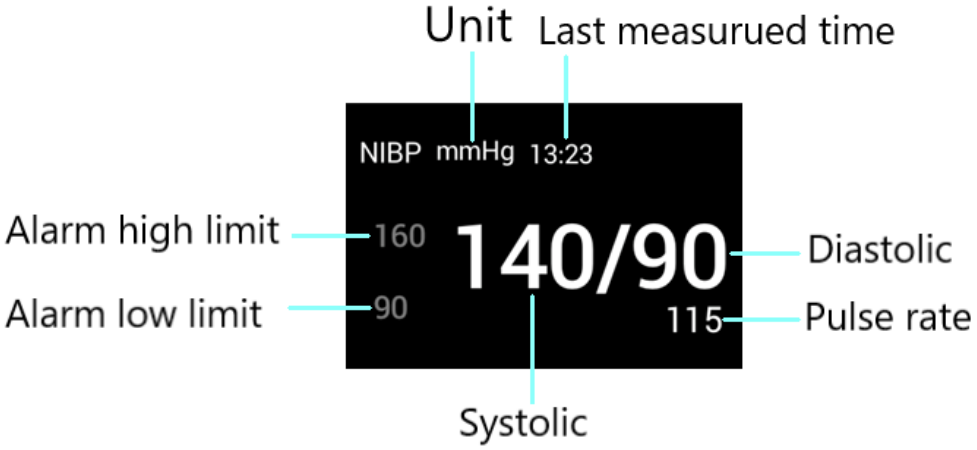
SpO_2 parameters



8. NIBP

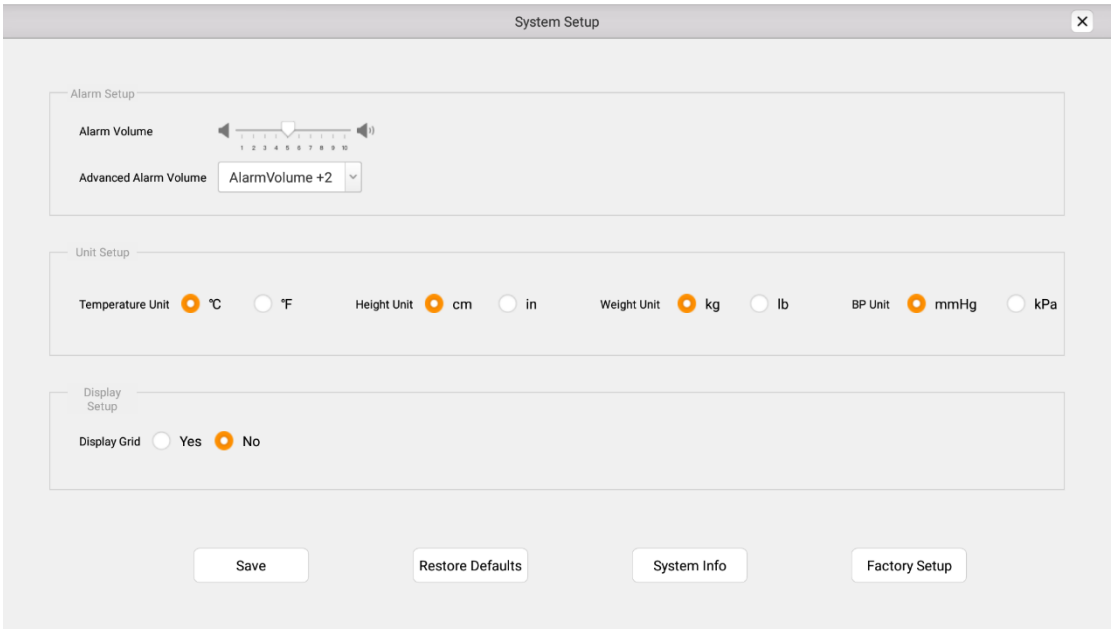
8.1. NIBP display

NIBP parameters



9. System setup

Click the button  in the lower left corner of the main interface to enter the system settings interface:



Some system level parameters can be set in the system settings interface:

- The size of the alarm sound
- Units of body temperature, height and weight
- Display the status of the grid

Note: If the setting sound is too small, it may cause people to ignore the alarm information.

It also provides access to other features:

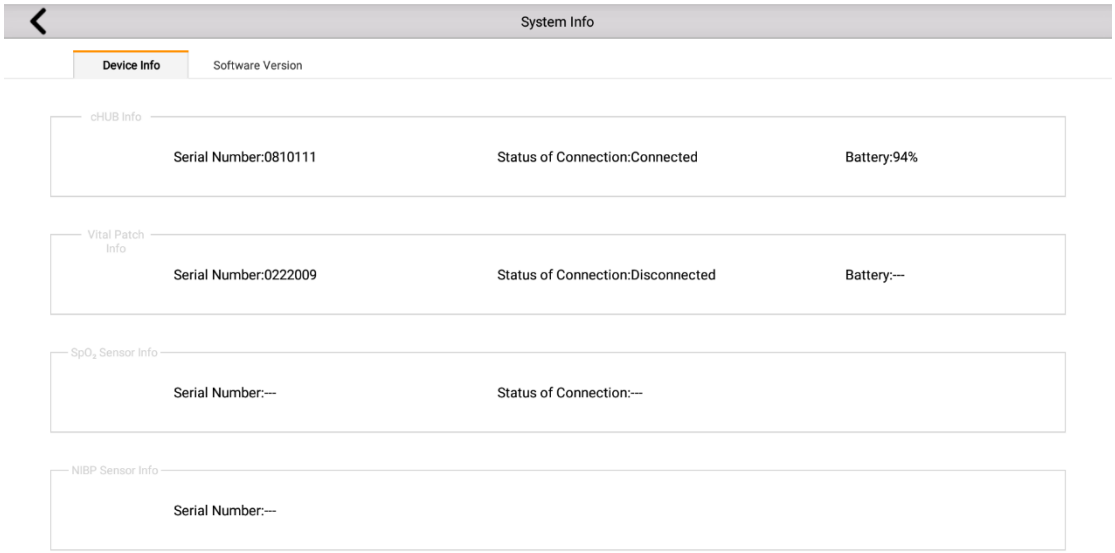
- System information
- Factory setting

9.1 System information

To enter the [System Information] interface, you must enter a password for authentication. After [System Information] is entered, the [Device Information] and [Software Version] screens are displayed.

Tip: The implementer will provide a password during the installation process.

9.1.1 Device information

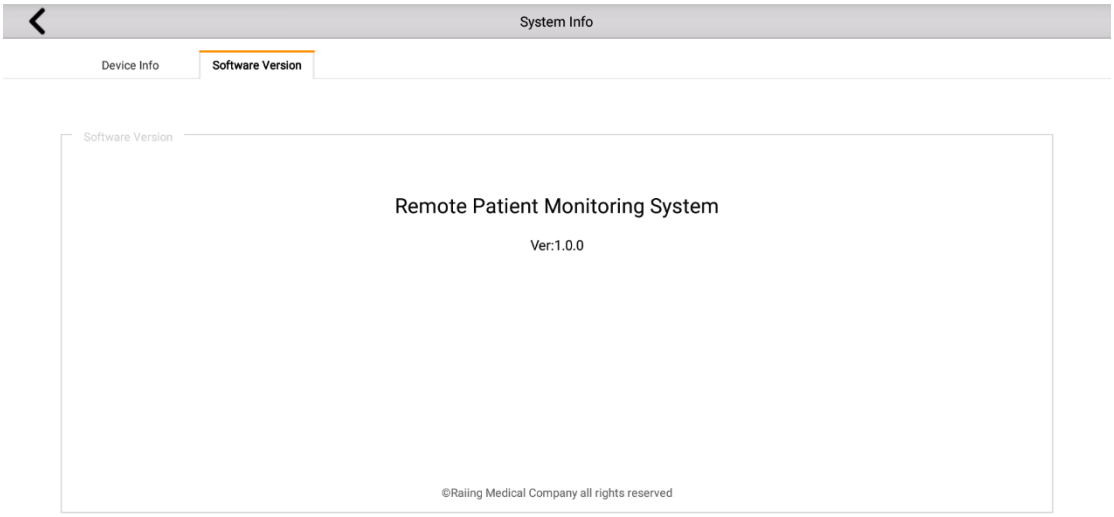


In this interface you can:

- View the running information of the repeater.
- View the running information of the collector.
- View the running information of the SpO_2 sensor.

- View the running information of the NIBP sensor.

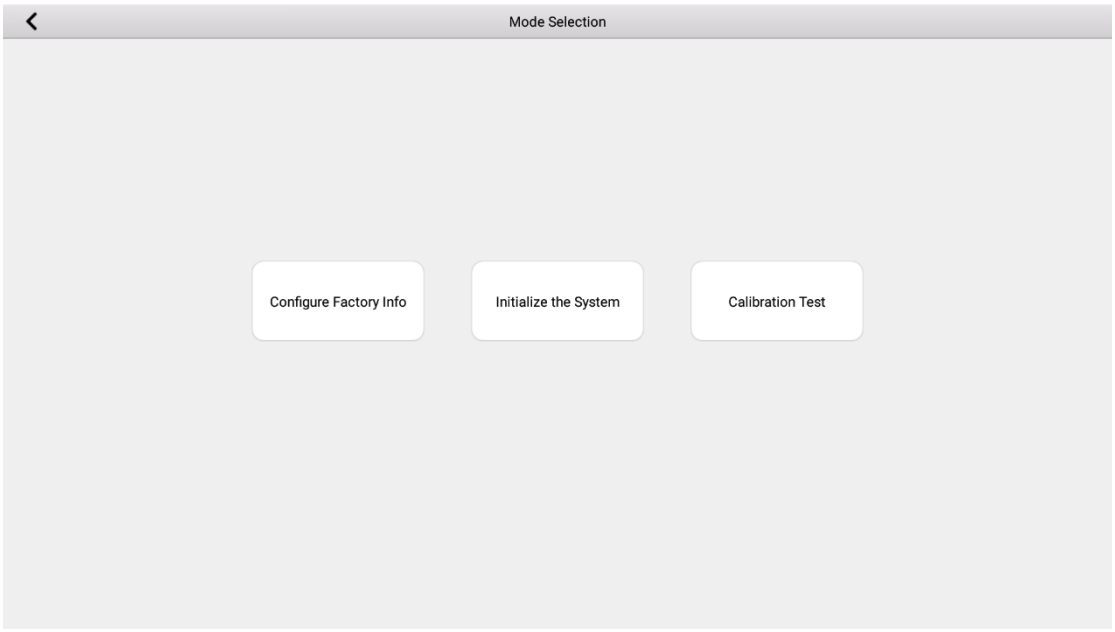
9.1.2 Software version



9.2 Factory setting

Enter the [factory settings] interface must enter the user name and password for authentication, after entering the [factory settings], you can choose three modes:

- Configure factory information
- Initialize the system
- Calibration test

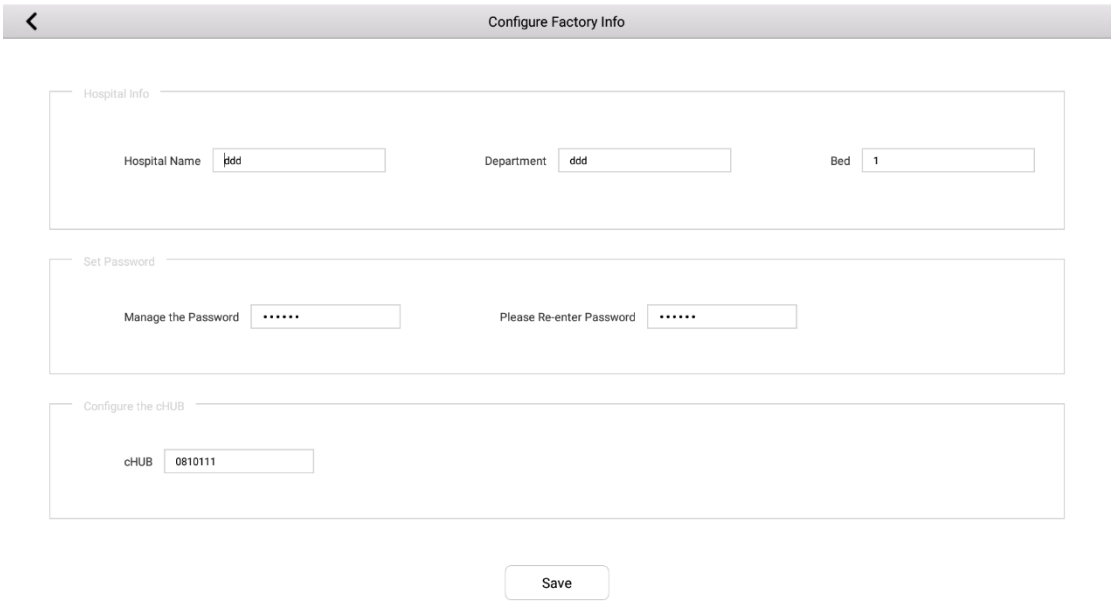


Tip: The implementer will provide a password during the installation process.

8.2.1 Configure factory information

Click [Configure Factory Information] to enter the configuration factory information interface, you can set the hospital information, set the password and configure the cHUB.

- Hospital Information: You can enter or modify [Hospital Name], [Department Name] and [Bed No.].
- Set password: You can set the [Management Settings Password] and [Re-enter Password] to change the password.
- Configure the repeater: You can enter the repeater device number to configure the repeater. For the repeater device number, check the SN number on the cHUB label.



8.2.2 initializing system

Click [Initialize System] to enter the initialization system interface.

Notice: After initializing the system, all settings of the system will be restored to the default values, please be cautious.

8.2.3 Calibration test

Click [Calibration Test] to enter the calibration test interface. Calibration tests are used for ECG calibration.

10. ECG analysis

Click the [ECG Analysis] button to enter the physician report interface and report any abnormal events that the system can detect.

11. Product specifications

11.1 Environmental Specifications

Item	Temperature	Relative humidity	Atmospheric pressure
Operating environment	5℃ ~ 40℃	15% ~ 85%	86kPa ~ 106kPa
Storage and transportation environment	-20℃ ~ 50℃	10% ~ 85%	86kPa ~ 106kPa

11.2 Power Specifications

Non-patient environment equipment		
	Display unit	Data aggregating & streaming device
Input voltage	AC100~240V	AC100~240V
Frequency	50~60Hz	50~60Hz
Input current	1.5A	0.5A
Protection against electric shock	/	Class II equipment

	Multi-parameter vital patch		cHUB	
Power supply type	Mains voltage	Rechargeable lithium battery	Mains voltage	Rechargeable lithium battery
Voltage/ Frequency	AC100~240/ 50~60Hz	DC3.7V	AC100~240/ 50~60Hz	DC3.7V
Capacity	/	150mAh	/	1250mAh
Power input	0.4A	5V/0.1A max	0.4A	5V/0.5A max
Protection against electric shock	Class II	Internally powered equipment	Class II	Internally powered equipment
Applied part	Type CF		No	

Caution: Users cannot replace the battery

Tips: 1) In normal use and battery conditioning, the vital patch battery charge is depleted to 90% of the charge time is 1.3h.

In normal use and battery conditioning, the cHUB battery charge is depleted to 90% of the charge time is 4h.

2) The minimum operating time of the vital patch is 40h, if the battery is new and fully charged.

The minimum operating time of the cHUB is 5h, if the battery is new and fully charged.

11.3 Hardware Specifications(Minimum configuration)

Display unit	With a stereo, the resolution is 1920*1080 and the screen size is 23 inches.
Data aggregating & streaming device	6 core 64 bit CPU, 2GB memory, 8GB flash memory; Andriod5.1 system
Mouse	USB2.0

11.4 Body temperature specifications Temp

Measuring method	Thermistor method	
Measuring range	25℃~45℃	
Resolution	0.1℃	
Accuracy	±0.1 ℃	
Alarm limit specification	Range	Adjustment step

Alarm high limit	（Alarm low limit+1）℃ ~40℃	0.1℃
Alarm low limit	25℃~（Alarm high limit-1）℃	
Alarm level	Low/Medium/high	
Alarm switch	ON/OFF	

11.5 ECG specifications ECG

ECG	
Standards compliant	IEC60601-2-27: 2006、IEC60601-2-47: 2012
Lead type	I
Gain	5mm/mV(×0.5)、10mm/mV(×1)、20mm/mV(×2)、40mm/mV(×4)
Sweep speed	6.25mm/s、12.5mm/s、25mm/s、50mm/s
Aspect ratio	6.4，3.2，1.6，0.8，0.4，0.2，0.1
Electrosurgical protection announced	No protection
The current to the patient for the purpose of respiration sensing, leads-off sensing or	<0.1μA

active noise suppression	
Time to alarm for tachycardia.	No alarm.
Electrode polarization	Only the recommended electrodes can be used. Other electrodes cannot be connected externally, otherwise there will be a large potential shift due to polarization.
Pace pulse	
Rejection of pacemaker pulses	Comply with the requirements of IEC60601-2-27 201.12.1.101.13, suppress the pacemaker pulse without overshoot that meets the following conditions; Amplitudes : ± 2 mV~± 700 mV Pulse widths : 2ms Rise time : 10μs~100 μs Can't suppress the pacemaker pulse with overshoot.
Pacemaker pulse rejection disabling	Pulse width is 0.1ms, Amplitude is less than 50mV; Pulse width is 0.2ms, Amplitude is less than

	14mV; Pulse width is 0.5ms, Amplitude is less than 6mV; Pulse width is 1ms, Amplitude is less than 4mV; Pulse width is 1.5ms, Amplitude is less than 2mV; Above pacing pulse failure.
HR	
Heart rate range	30bpm~200bpm
Accuracy	±10% or ±5 1/min, whichever is greater.
QRS detection range	0,5 mV to 5 mV for durations of the QRS wave between 70ms and 120ms
Resolution	1bpm
Heart rate averaging	Meets the requirements of IEC60601-2-27, 201.7.9.2.9.101b) 3). The heart rate average is calculated by the following method: if the last three consecutive RR intervals are greater than 1200 ms, the heart rate is calculated by averaging the four nearest RR intervals; otherwise, taking the 12 most recent RR intervals, subtracting the maximum and minimum Then take the average to

	calculate the heart rate. The heart rate value displayed on the screen is refreshed every second.
Response to irregular rhythm	Comply the requirements of IEC60601-2-27, 201.7.9.2.9.101b) 4). The heart rate value displayed after a 20s stabilization period has passed: A1： 80±1bpm A2： 60±1bpm A3： 120±1bpm A4： 90±2bpm
Response time of heart rate meter to change in heart rate	Comply the requirements of IEC60601-2-27, 201.7.9.2.9.101b) 5) Heart rate increased from 80bpm to 120bpm: less than 11s Heart rate reduced from 80bpm to 40bpm: less than 11s
Tall T-wave rejection capability	When tested in accordance with IEC 60601-2-27, section 201.7.9.2.9.101b) 2), the heart rate monitor suppresses all T waves with amplitudes less than 1.2 mV, 100ms and Q-T intervals of 350ms.

Alarm limits specification	Range（bpm）	Adjustment step（bpm）
Alarm high limit	(Alarm low limit+2) ~200	1
Alarm low limit	30~(Alarm high limit-2)	
Alarm level	Medium/High	
Alarm switch	ON/OFF	
Asystole	ON/OFF	

Note：Electrodes cannot use different metal materials.

11.6 Resp specifications RESP

RR	
Measuring range	0brpm~120brpm
Resolution	1brpm
Accuracy	±2brpm or ±2%, which is greater.
Alarm limit specification	
Alarm high limit	（Alarm low limit+2）~100
Alarm low limit	0-（Alarm high limit-2）
Alarm level	Medium/High
Alarm switch	ON/OFF
Asphyxia Delay	10-40s，Adjustment step is 5

11.7 SpO_2 specifications SpO_2

SPO2	
Display range	0%~100%
Measurement range	70%~100%
Resolution	1%
Accuracy	70%~100% ±2; 0%~69% no definition
Pulse Rate	
Display range	0bpm~250bpm
Measure range	30bpm~250bpm
Accuracy	30bpm~99bpm, ±2bpm; 100bpm~235bpm, ±2%
Resolution	1bpm
PI	
Measure range	0.2%~20.0%
Accuracy	0.2%~1.0%,±0.2digits; 1.1%~20.0%,±20%
Resolution	0.1%
Alarm limit specification	
Alarm high limit SpO2	（Low limit +2）%~100%

Alarm low limit SpO2	0%- (high limit -2) %
Alarm level	Medium/High
Alarm switch	ON/OFF
Desat alarm limit	0~98%
Desat alarm level	High
Desat alarm switch	ON/OFF

11.8 NIBP specification NIBP

NIBP	
Measurement range	Cuff pressure: 0~300mmHg Systolic: 60~260mmHg Diastolic:40~199mmHg Pulse rate: 40~180 beats/minute
Resolution	1brpm
Accuracy	Pressure: ±3mmHg Pulse rate: ±5%
Alarm specification	
NIBP-S alarm high limit	(Low limit +1) kPa ~ 35kPa
NIBP-S alarm low limit	5kPa ~(High limit -1)kPa
NIBP-S alarm level	Medium/High

NIBP-S alarm switch	ON/OFF
NIBP-D alarm high limit	(Low limit +1) kPa ~ 27kPa
NIBP-D alarm low limit	1kPa ~(High limit -1)kPa
NIBP-D alarm level	Medium/High
NIBP-D alarm switch	ON/OFF
NIBP-M alarm high limit	(Low limit +1) kPa ~ 30kPa
NIBP-M alarm low limit	3kPa ~(High limit -1)kPa
NIBP-M alarm level	Medium/High
NIBP-M alarm switch	ON/OFF

11.9 Alarm specifications

Alarm specification	
Asphyxia Delay	10s~40s, step is 5s
Asystole	ON/OFF

12. Default settings

12.1 Alarm setup

HR setup	
Item	Default setting
Alarm high limit	120
Alarm low limit	50
Alarm priority	Medium
Alarm switch	ON
Resp setup	
Item	Default setting
Alarm high limit	30
Alarm low limit	8
Alarm priority	Medium
Alarm switch	ON
Temp setup	
Item	Default setting
Alarm high limit (℃)	38.0
Alarm low limit (℃)	35.0

Alarm priority	Medium
Alarm switch	ON
SpO_2 setup	
Item	Default setting
Alarm high limit	100
Alarm low limit	90
Alarm level	Medium
Alarm switch	ON
Desat alarm limit	80
Desat alarm level	High
Desat alarm switch	ON
NIBP setup	
Item	Default setting
NIBP-S alarm high limit	21
NIBP-S alarm low limit	12
NIBP-S alarm level	Medium
NIBP-S alarm switch	ON
NIBP-D alarm high limit	12

NIBP-D alarm low limit	7
NIBP-D alarm level	Medium
NIBP-D alarm switch	ON
NIBP-M alarm high limit	15
NIBP-M alarm low limit	8
NIBP-M alarm level	Medium
NIBP-M alarm switch	ON
Other	
Item	Default setting
Asphyxia Delay	20
Asystole	ON

12.2 Parameters setup

HR setup	
Item	Default setting
Gain	X1
Sweep speed	25mm/s
Pacemaker	No

Resp setup	
Item	Default setting
Gain	X1
Sweep speed	25mm/s
Temp setup	
Item	Default setting
Upper limit of the temperature curve	40
lower limit of the temperature curve	35
Length of timeline	1h

12.3 System setup

Item	Default setting
Alarm Volume	5
Adanced alarm volume	Alarm Volume +2
Temperature unit	℃
Height unit	cm
Weight unit	kg
BP unit	mmHg

Display grid	No

12.4 Advanced setup

Item 名称	Default settings
Alarm Pause Time	2min
Alarm Lock	ON
Power frequency notch	ON

13. Alarm List

13.1 Physiological alarm conditions

Source	Alarm information	Priority	Causes and measures
ECG	*** Asystole	High	The patient's heart rate is monitored as 0. Please check the patient's condition, electrodes and wearing conditions.

	** HR> xxx	Medium/High	The HR value is higher than the alarm high limit or lower than the alarm low limit. Check the patient's physiological condition, confirm the patient type and the alarm limit settings for the patient.
	** HR< xxx	Medium/High	
Resp	*** Asphyxia	High	The patient's breathing signal is too weak for the system to analyze. Check the patient's condition, electrodes, cables and wearing conditions.
	** RR >xxx	Medium/High	The RR value is higher than the alarm high limit or lower than the alarm low limit. Check the patient's physiological condition, confirm the patient type and the alarm limit settings for the patient.
	** RR <xxx	Medium/High	
Temp	** Temp> xxx	Low/medium/High	The Temp value is higher than the alarm high limit or lower

	** Temp<xxx	Low/medium/High	than the alarm low limit. Check the patient's physiological condition, confirm the patient type and the alarm limit settings for the patient.

13.2 Technical alarm conditions

Source	Alarm information	Priority	Causes and measures
ECG	Heart rate measurement.	Low	The measured value of the heart rate exceeds the measurement range that can be performed to detect whether the connection is normal or the device is abnormal.
Resp	Respiratory rate measurement.	Low	The measured value of the breath exceeds the measurement range that can be performed to detect whether the connection is normal or the device is abnormal.
Temp	Body temperature sensor off	Medium	Check that the temperature sensor is connected and that any of the electrodes are not

			misaligned. If this INOP still exists, wipe the skin and prepare to reposition the temperature sensor.
	Body temperature measurement.	Low	The measured value of body temperature exceeds the measurement range that can be performed. Please check if the device is in normal use or replace the body temperature sensor for the patient.
	Unconnected body temperature sensor.	Low	The temperature sensor is not connected and is checked for unconnected or intentional disconnection.
Vital patch	The vital patch has low battery.	Medium	Please charge the vital patch as soon as possible.
	The vita patch’s battery is seriously insufficient	High	Please charge the patch, otherwise it will automatically shut down, affecting normal monitoring.

	ECG lead off.	Medium	Please check the wearer's condition and see if the electrode is loose or falling off.
	Vital patch disconnected.	Medium	Please check if the Vital patch is turned off or if it exceeds the repeatable range of the cHUB.
cHUB	The cHUB has low battery.	Medium	The cHUB battery is low, please charge it as soon as possible.
	The cHUB's battery power is seriously insufficient.	High	Please charge cHUB, otherwise it will shut down automatically and affect normal monitoring.
	The cHUB disconnect.	Low	Please check if the cHUB is shut down or if the network is working properly and if the cHUB is over the network coverage area, and remove the problem.

14. Accessories

⚠ Warning: Appendices specified by the Company must be used, otherwise they may not match, display inaccurate values, or cause harm to the patient.

Accessories list

Name	Model	Period of use
Vital patch	THR101	300 charge and discharge(For single patient)
cHUB	BT101	300 charge and discharge(For single patient use)
Charger	LXCP12-005100XFG	5 years
Temperature sensor	CW2000	Once for single patient

⚠ Note: Use the product strictly according to the period of use of the above table, otherwise it may cause cross infection or other injury to the patient!

Expired parts should be properly disposed of in accordance with hospital management regulations.

In addition to the above accessories, the patient monitor has a service life of 5 years.

15. Product maintenance

If you find any problems with the system, please contact our operation and maintenance personnel.

If you accidentally pour liquid on the system or accessories, please contact our operation and maintenance personnel.

a) Inspection

Before the system is used, repaired or upgraded, a comprehensive inspection should be carried out by trained maintenance personnel to ensure the normal operation and operation of the system. Items examined include:

- Environment and power supply meet the requirements
- There is no mechanical damage to the components and accessories.
- The power cord has no wear and good insulation performance.
- Use the specified attachment.
- The function of the alarm system is normal.
- Each function is in good working condition.

If any damage or abnormality is found, please do not use the system and immediately contact the hospital maintenance personnel or the company's operation and maintenance personnel.

b) Maintenance plan

The following tasks, except visual inspection and start-up testing, can only be done by professional maintenance personnel. When you need to perform the following repairs, please contact the maintenance personnel in time. The monitor must be cleaned and disinfected prior to testing or maintenance.

Inspection/maintenance project	Recommended frequency
Visual inspection	First time installation, or after each reinstallation
ECG performance test	When the user suspects that the measured value is not accurate.
Resp performance test	
Temp performance test	
SpO2 performance test	
NIBP performance test	
Boot detection	1. First time installation, or after each reinstallation. 2. After each repair or replacement of parts. 3. After each upgrade of the software.

16. Maintenance and cleaning

Use only the materials and methods listed in this section to clean or disinfect the system. The company does not provide any guarantee for damage or accident caused by the use of other materials or methods.

The company is not responsible for the effectiveness of the listed chemicals or methods as a means of controlling infection. For information on how to control infection, please consult the hospital's infection prevention department or epidemiologist.

16.1 General

Please keep all parts of your system and accessories free of dust. In order to prevent damage to equipment, please comply with the following requirements:

- Please use detergents and disinfectants according to the instructions of this instruction, otherwise the product life may be reduced.
- No part of the system can be immersed in liquid.
- No liquid should be dumped on the system or accessories.
- Do not allow liquids to enter the system and accessories.
- No abrasive material (such as steel wool or silver polishing agent) or any strong solvent (such as acetone or detergent containing acetone) shall be used.

Be careful:

1) Before cleaning, please disconnect all the power cord from the socket.
2) If you accidentally dump the liquid on the system or accessories, please contact the maintenance personnel or our company immediately.

16.2 Cleanliness

Display unit, data aggregating & streaming device, cHUB and chargers should be cleaned weekly. Frequencies of cleanliness should be increased in areas with serious environmental pollution or heavy wind and sand. The pulse oximeter and blood pressure monitor are cleaned and sterilized according to the requirements attached to them.

When cleaning:

1. Turn off all power and disconnect the power cord.
2. Use soft cloth, soak in soapy water or diluted non-corrosive detergent solution, wipe the surface of equipment other than the display screen.
3. When necessary, use dry cloth to wipe away excess detergent.
4. Place it in a cool and ventilated environment.

16.3 Disinfection

Disinfection operations can cause a degree of damage to the equipment. It is recommended that disinfection be performed only if it is deemed necessary in your hospital maintenance plan. Clean the display unit, cHUB,

data aggregating & streaming device and charger before disinfecting.

The recommended disinfectant is: 75% ethanol.

Do not use gas (EtO) or formaldehyde for disinfection.

16.4 Cleaning of accessories

Before each use, wipe the vital patch and the surface of the temperature sensor with a cotton ball with a concentration of 75% medical alcohol for 2 minutes, and let it dry naturally.

Warning:

- Cleaning agents other than alcohol may damage the temperature sensor and vital patch, shortening their service life or causing safety risks.
- Do not immerse the vita patch and temperature sensor in any liquid.
- The product may not be sterilized or autoclaved.
- If you find any damage to the product, stop using it immediately.

16.5 Cleaning the display unit

Since dust, fingerprints, and the like can affect the use of the display unit, regular (weekly) cleaning is required.

To clean the monitor screen, use a lint-free cloth or microfiber cloth, soak the monitor with a liquid crystal screen cleaner.

⚠ To avoid damage to the device:

- Never use abrasive materials to wipe the screen, as it will scratch the screen.
- Never use alcohol (methanol, ethanol or isopropanol) or other potent solvents.
- Do not spray cleaner directly onto the display case, which may cause detergent to enter the display.
- Do not press hard on the screen or wipe it hard during the cleaning process, which may damage the screen.
- Wait for the monitor to dry completely before turning it on.

17. Electromagnetic compatibility

⚠ Warning

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.

Portable and mobile RF communications equipment can affect MEDICAL

ELECTRICAL EQUIPMENT.

ME EQUIPMENT or ME SYSTEM should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the ME

EQUIPMENT or ME SYSTEM should be observed to verify normal operation in the configuration in which it will be used.

Note - The information provided by the EMC form and other guide notes is important to the customer or user. This information can help determine the applicability of a device or system application in an electromagnetic environment, and manage the application of the device or system in an electromagnetic environment so that it does not interfere with other devices, systems, or non-medical electrical devices during operation.

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

The list of all cables

No.	Name	Length	Block	Connection	Removable
1	Temperature sensor connection line	200mm	No	From temperature sensor to vial patch.	No
2	Charger cable	200mm	No	From changer to vital patch.	No

3	Charger cable	1.5m	No	From charger to cHUB.	No

Basic performance

1) Heart rate range:30bpm~200bpm
2) Accuracy:±10% or ±5 1/min, whichever is greater.
3) QRS detection range:0,5 mV to 5 mV for durations of the QRS wave between 70ms and 120ms

Guidance and manufacturer's declaration – electromagnetic emissions		
The Remote Patient Monitoring & Diagnostics System MP802 is intended for use in the electromagnetic environment specified below. The customer or the user of The Remote Patient Monitoring & Diagnostics System MP802 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Remote Patient Monitoring & Diagnostics System MP802 uses RF energy only for its internal function. Therefore, its RF emissions are very low and

		are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Remote Patient Monitoring & Diagnostics System MP802 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Remote Patient Monitoring & Diagnostics System MP802 Image Intensifier is intended for use in the electromagnetic environment specified below. The customer or the user of The Remote Patient Monitoring & Diagnostics System MP802 Image Intensifier should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance

Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT	Mains power quality should be that of a typical commercial or hospital environment. If the user of The Remote

input lines IEC 61000-4-11	(60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	(60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Patient Monitoring & Diagnostics System MP802 image intensifier requires continued operation during power mains interruptions, it is recommended that The Remote Patient Monitoring & Diagnostics System MP802 Image Intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position The Remote Patient Monitoring & Diagnostics System MP802 image intensifier further from sources of

			power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Remote Patient Monitoring & Diagnostics System MP802 is intended for use in the electromagnetic environment specified below. The customer or the user of The Remote Patient Monitoring & Diagnostics System MP802 should assure that it is used in such an electromagnetic environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to

Radiated RF IEC 61000-4-3	outside ISM bandsa 3 V/m 80 MHz-2.5 GHz	3 V/m	any part of The Remote Patient Monitoring & Diagnostics System MP802, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 3,5 P d = 12 P d = 1,2 P 80 MHz to 800 MHz d = 2,3 P 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation

			distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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.			
The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause			

interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which The Remote Patient Monitoring & Diagnostics System MP802 is used exceeds the applicable RF compliance level above, The Remote Patient Monitoring & Diagnostics System MP802 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The Remote Patient Monitoring & Diagnostics System MP802.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and The Remote Patient Monitoring & Diagnostics System MP802

The Remote Patient Monitoring & Diagnostics System MP802 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of The Remote Patient Monitoring & Diagnostics System MP802 can help prevent lectromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The Remote Patient Monitoring & Diagnostics System MP802 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz outside ISM bands d = 3,5 $\sqrt{P}$	150 kHz to 80 MHz in ISM bands d = 12 $\sqrt{P}$	80 MHz to 800 MHz d = 1,2 $\sqrt{P}$	800 MHz to 2,5 GHz d = 2,3 $\sqrt{P}$
0.01	0.35	1.2	0.12	0.23
0.1	1.1	3.8	0.38	0.73
1	3.5	12	1.2	2.3
10	11	38	3.8	7.3

100	35	120	12	23

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

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

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

18. FCC Notice

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference. (2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

---Reorient or relocate the receiving antenna.

---Increase the separation between the equipment and receiver.

---Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

---Consult the dealer or an experienced radio/TV technician for help.

WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

RF Exposure

The equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This device should be installed and operated with more than distance 20cm between the radiator & your body.