Patient Monitor

Operation Manual

Preface

Manual Purpose

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

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

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

Intended Audience

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

Illustrations

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

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1 Overview

1.1 Intended Use

The monitor is intended to be used for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in health care facilities. The devices are to be used in health care facilities by trained health care professionals. They are not intended for home use. This device is restricted to be used by or on the order of a physician.

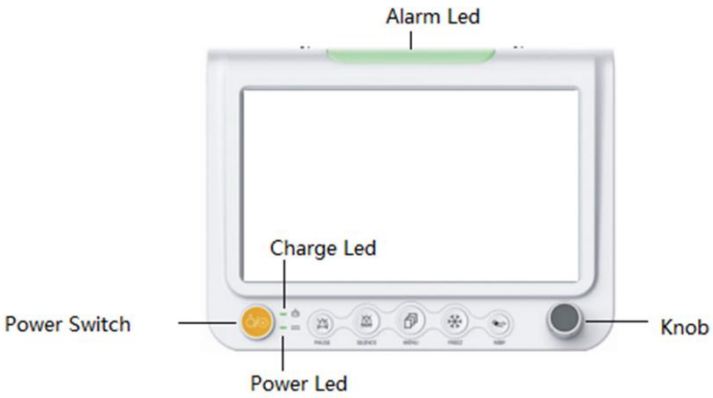
⚠ **WARNING** ⚠

- **This is not a therapeutic device.**

1.2 Appearance

1.2.1 7-inch

■Front Panel



■Rear Panel

■Side Panel

1.2.2 8-inch

■Front Panel

■Side Panel

■Rear Panel

1.2.3 12.1-inch Type A

■Front Panel

■Side Panel

■Rear Panel

1.2.4 12.1-inch Type B

■Front Panel

■Side Panel

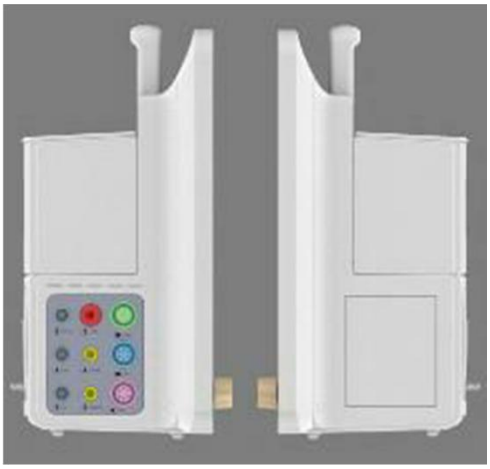
■Rear Panel

15-inch

1.2.5 12.1-inch Type A

■Front Panel

■Side Panel



■Rear Panel

1.2.6 Buttons

Power switch: Press this button to turn On/Off the monitor.
Alarm silence: Press this button to silence the alarms.
Alarm pause: Press this button to pause the alarms.
Waveform freeze: Press this button to freeze the waveform on the screen.
NIBP start/stop: Press this button to start/stop NIBP monitoring.
Record (Print) start/stop: Press this button to start/stop recording.
Main menu: Press this button back to the upper level menu.
Encoder knob: Turn this button left/right to select the menu. Press this button to enter the window of setting or confirm the selection.

1.2.7 LED Indicator

Alarm LED: Flash when alarms happen.
Charging LED: It turns green when the external power is connected with the monitor.
Power On/Off LED: It turns green when the monitor turns on.

1.2.8 Connector

Temp (1/2) probe connector: Link to the temperature probe.
(Masimo) SpO2 sensor (mini) connector: Link to the SpO2 sensor.
ECG cable (mini) connector: Link to the ECG cable.
NIBP cuff connector: Link to the NIBP cuff.
IBP (1/2) connector: Link to the IBP "cuff".
CO2 sensor connector: Link to the SpO2 sensor.
Network connector: Link to internet for updating the software of the monitor.
USB connector: Link to PC for updating the software of the monitor.
External power input connector: Link to the external power.

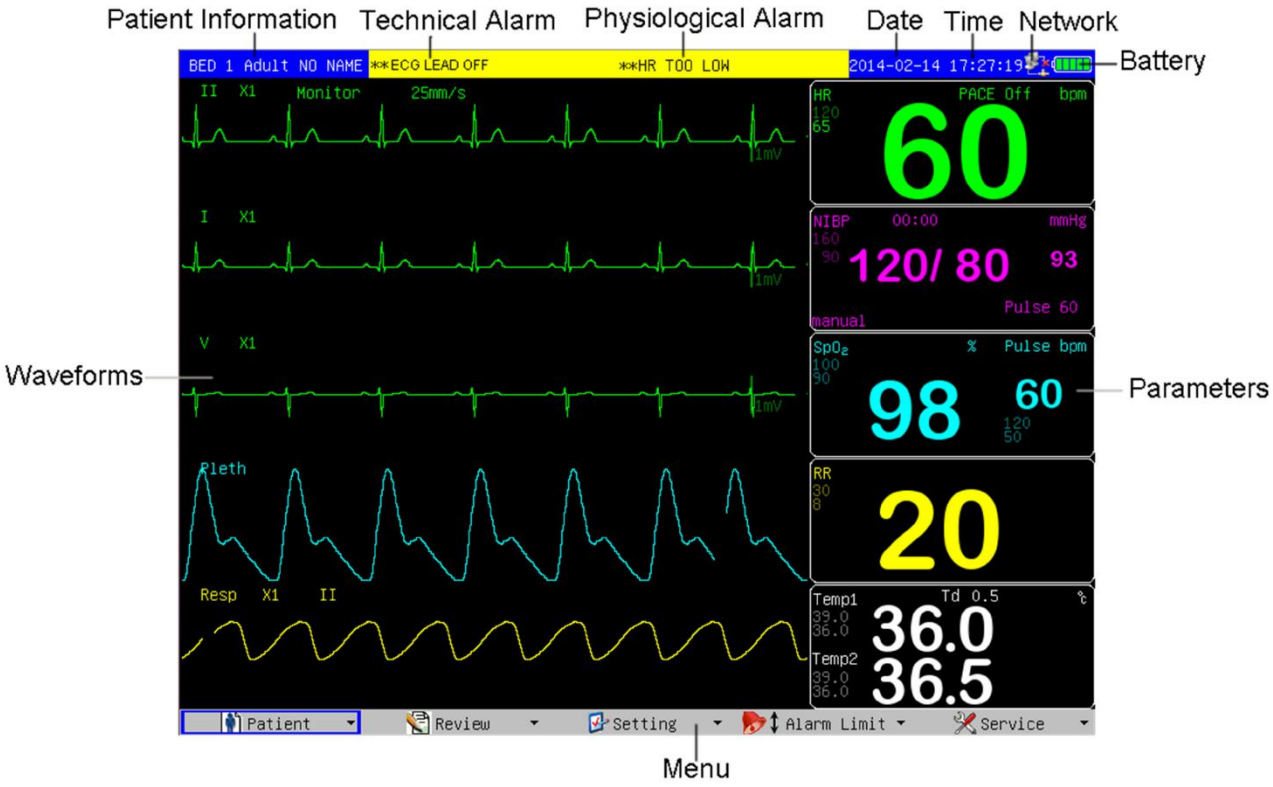
1.2.9 Others

Handle: Portable design.
Mounting holes for hanging bracket (1/2): Reserve for hanging bracket.
Support bracket: Adjust it to achieve different angle of the monitor.
Speaker holes (1/2): Alarms voice.
Nameplate place: The place for the nameplate.
Battery place: The place for battery.
Recorder place: The place for recorder.
Fuse: Safety.
Equipotential Grounding System: Safety.

⚠ **WARNING** ⚠

● Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

1.3 Display



Patient Information: Bed No., Patient type, Patient name
Technical Alarm: Technical alarm information
Physiological Alarm: Physiological alarm information
Date: Current date
Time: Current time
Network: Network state
Battery: Battery state
Waveforms: Waveforms monitoring
Parameters: Parameters monitoring
Menu: Patient, Review, Setting, Alarm Limit, Service

1.4 Battery

Patient monitor is equipped with a built-in rechargeable battery. In the top right corner of the screen exists a symbol "  ", indicating the status of the battery capacity, of which the green part denoting electric quantity of the battery. When the battery is charged, the charging condition is expressed with animation. After the battery is full-charged, the symbol will show as "  ". When this monitor has not been installed the built-in battery, the symbol shows as "  " indicating no battery.

When the monitor runs with the power supplied from battery, the monitor detects the volume of the battery, and alarms when the battery is insufficient, and prompts in the information area: "**BAT LOW". At this moment, external power should be connected in, and immediately charge battery in time. If battery is running with the power supplied from battery, the monitor will power off automatically when the battery exhausted.

⚠ **WARNING** ⚠

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

1.5 Network

The network port of the monitor is the standard RJ45 network interface, may communicate with the central monitoring station through the Ethernet cable to achieve the function of remote monitoring. In the top right corner of the screen, there is a network icon indicating the current network status. If the network cable is disconnected, the icon shows as "  "; When the monitor has established connection with the central monitoring station, the icon shows as "  "; If the monitor communicates successfully with the central monitoring system, the icon shows as "  ".

2 Installation

⚠ **WARNING** ⚠

● The installation of the monitor must be carried out by personnel authorized by us. The software copyright of the monitor is solely owned by our company. Any action to change, copy or exchange the software copyright by any organization or person is regarded as copyright infringement and is not allowed.
● Accessory equipment connected to this patient monitor must be certified according to the respective IEC standards (e.g. IEC 60950 for information technology equipment and IEC 60601-1 for medical electrical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input or signal output is responsible to ensure the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, contact our company or customer service.
● If the monitor is connected to another electrical instrument and the instrument specifications cannot tell whether the instrument combination is hazardous (e.g. due to summation of leakage currents), you should consult us or experts in the field to ensure the required safety of all instruments concerned.

⚠ **NOTE** ⚠

● The operations in this section are not all required. User-customized installation by authorized personnel is provided.

2.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or our company.
If the packing case is intact, open the package and remove the instrument and accessories carefully. Check all materials against the packing list and check for any mechanical damage.
Contact our Customer Service Department in case of any problem.

⚠ **NOTE** ⚠

● Please save the packing case and packaging material for future transport and storage.

⚠ **WARNING** ⚠

● Be sure to keep the packaging materials from children's reach.
● Disposal of the packaging materials shall comply with your local requirements.
● The equipment might be contaminated in storage, transport or when used. Verify the package and the single use accessories are intact. In case of any damage, do not apply it to patients.

2.2 Environmental Requirements

The operating environment of the monitor must meet the requirements specified in this manual.

The environment where this monitor is to be used should be free from noise, vibration, dust, and corrosive or explosive and inflammable substances. For a cabinet mounted installation, allow sufficient room at the front and the rear of the cabinet for operation, maintenance and servicing. Besides, allow at least 2 inches clearance around the instrument for proper air circulation.

Condensation can form when the monitor is moved from one location to another, and being exposed to differences in humidity or temperature. Make sure that during operation the instrument is free from condensation.

2.3 Power Source Requirements

The power applied to the monitor must meet the requirements specified in this manual.

⚠ WARNING ⚠

● Make sure that the operating environment and the power applied to the patient monitor complies with the specified requirements. Otherwise its performance might not meet the specifications claimed in this manual, and unexpected results, such as damages to the patient monitor, may be incurred.
● The monitor shall be powered according to the requirement for the system power voltage. Otherwise, serious damage might be caused to the system.

2.4 Installation Method

2.4.1 Connecting to Power Supply

1. Use the original three-wire external power cord.
2. Connect the power cord to the receptacle for external power cord on the rear panel of the monitor.
3. Connect the other end of the power cord to a compatible 3-prong hospital grade external power outlet.

⚠WARNING⚠

● Connect the power line to the jack special for hospital usage.

2.4.2 Connecting Patient Sensors and Probes

Connect the necessary patient sensors or probes to the monitor. For details, see the chapters for specific parameter monitoring in the following pages, or corresponding instructions for sensors and probes.

2.4.3 Connecting the Network Cable

The network connector of the monitor is a standard RJ45 connector. It connects the monitor with the central monitoring system, or with a PC for online upgrading or data output.

1. Connect one end of the network cable with the network connector of the monitor.

2. Connect the other end of the network cable with the hub or switch of the central monitoring system, or with the network connector of a PC.

⚠ **NOTE** ⚠

● Different network cable may be used for different connections. Please consult our customer service personnel for details.

● The system upgrading through the network connector is to be executed by our authorized personnel only.

2.4.4 Connecting to VGA Monitor (optional)

This monitor can be connected with a standard color VGA monitor. The VGA monitor will display the patient waveforms and parameters measured by the patient monitor. To connect the patient monitor with the VGA monitor, follow the steps as below.

1. Power off the patient monitor.
2. Connect the signal cable of the VGA monitor to the VGA connector on the rear panel of the patient monitor.
3. Power on the VGA monitor and then the patient monitor.

⚠ **NOTE** ⚠

● The VGA monitor should be installed at a distance of more than 1.5 m from the patient.

2.4.5 Equipotential Grounding

When other equipments are used together with the monitor, a grounding cable should be used to connect the equipotential grounding connectors of the monitor and of other equipments. This helps to reduce the potential differences between different pieces of equipment, and ensure the safety of the operator and patient.

⚠**WARNING**⚠

● If the grounding system is in doubt, the monitor must be supplied from its internal battery.

2.5 Powering on the Monitor

After installing the monitor, please follow the procedures described below to power on the monitor:

1. Before using the monitor, please carry out corresponding safety inspection.
2. Press the Power Switch on the control panel.
3. The system begins self-testing and “Staring up” will be displayed on the screen.
4. Several seconds later, the system finishes the self-test and displays the main screen.
5. The system will initiate every module, and display alarm information in the top part of the screen.
6. At this time, you can operate the monitor using the control panel and press SILENCE key. Alarm information will disappear a few seconds later.

⚠ **WARNING** ⚠

● If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or manufacturer Customer Service Center immediately.

⚠ **NOTE** ⚠

● During initialization process, alarms of every module detected by the system are useless, and thereby are disabled.

⚠ **NOTE** ⚠

● If the monitor finds any fatal error during self-test, it will alarm.

⚠ **NOTE** ⚠

● Check all the functions that may be used to monitor and make sure that the monitor is in good status.

⚠ **NOTE** ⚠

● The battery must be recharged to the full electricity after each use to ensure adequate electricity reserve.

⚠ **NOTE** ⚠

● The interval between twice press of POWER should be more than 1 minute.

2.6 Powering off the Monitor

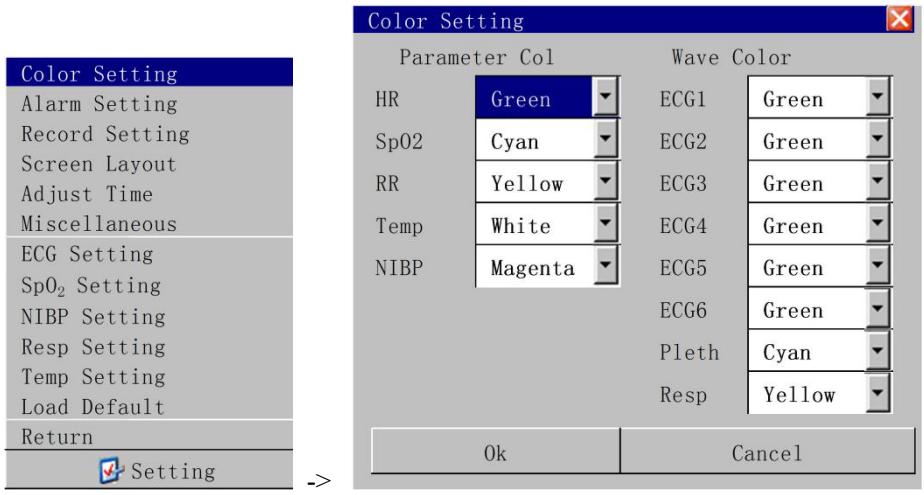
To power off the monitor, please follow the procedures below:

1. Confirm the patient monitoring is to be finished.
2. Disconnect the cables and sensors between the monitor and the patient.
3. Confirm whether to store or clear the patient monitoring data.
4. Press the Power Switch for more than 2 seconds, and the monitor will be powered off.

3 General Setting

3.1 Color Setting

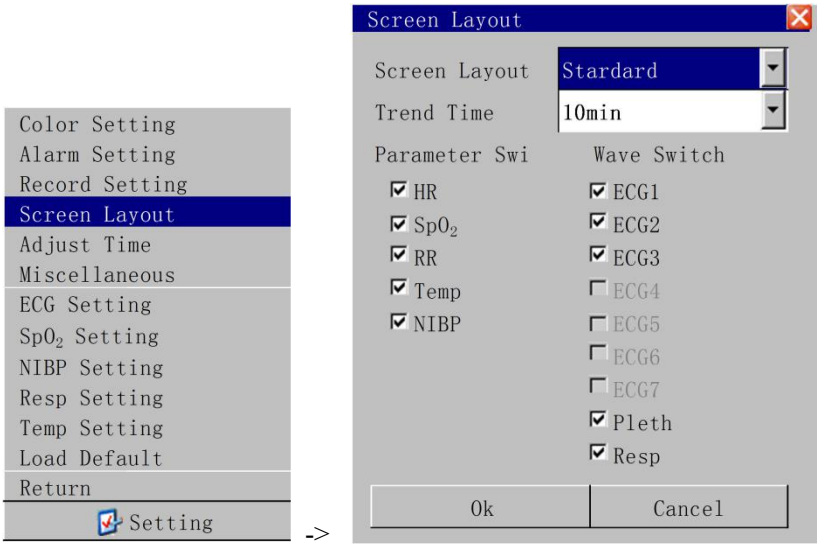
1. Rotate the knob to select “Color Setting” in “Setting” menu.
2. Press the knob to enter the window of “Color Setting”.
3. Select colors from the lists of corresponding parameters or corresponding waves. And confirm by “Ok”.



Color Setting	
Color Range	White, Red, Green, Blue, Cyan, Yellow, Magenta, Sky Blue, Orange, Purple, Sapphire

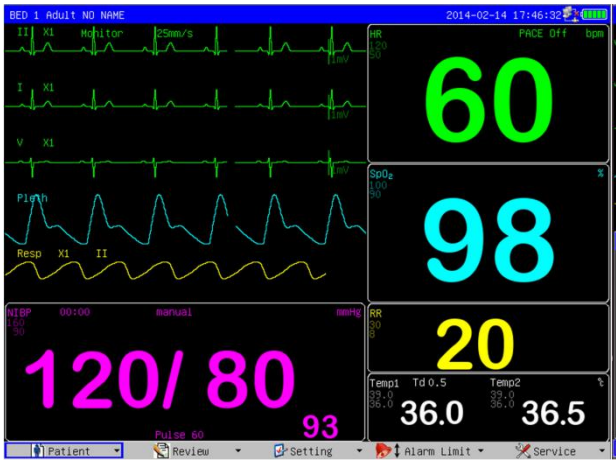
3.2 Screen Layout

1. Rotate the knob to select “Screen Layout” in “Setting” menu.
2. Press the knob to enter the window of “Screen Layout”.
3. Select screen type from the list of “Screen Layout”. Select trend time from the list of “Trend Time”. Select the parameters that need to display on the screen.



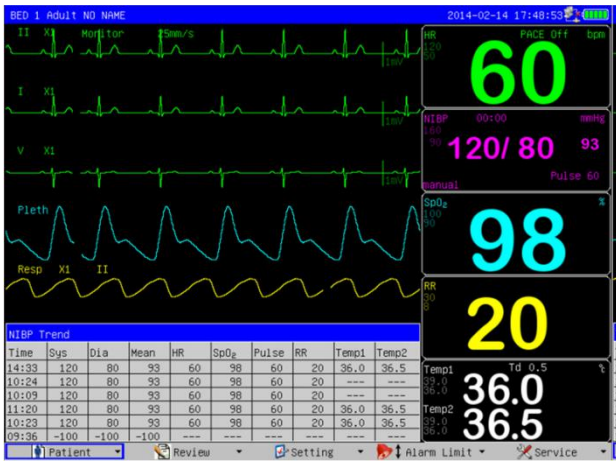
Screen Layout	
Screen Layout	Standard, Big Font, OxyCRG, NIBP Trend, Trend Table, Ecg Full Lead
Trend Time	1min, 3min, 5min, 7min, 10min, 15min, 20min, 30min, 40min, 50min, 60min
Parameter Switch	HR, SPO_2, RR, Temp, NIBP
Wave Switch	ECG1, ECG2, ECG3, ECG4, ECG5, ECG6, ECG7, Pleth, Resp

Big Font



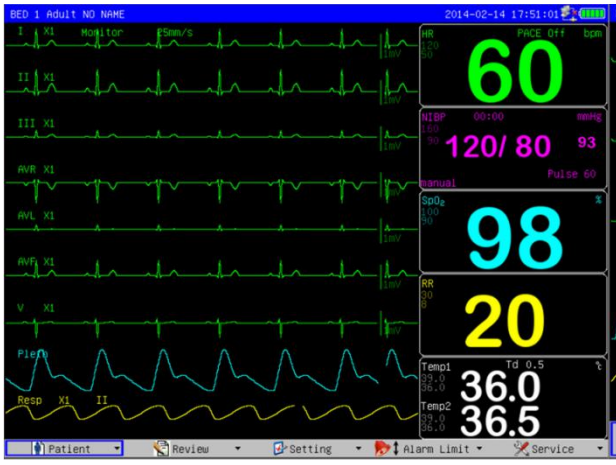
OxyCRG

NIBP Trend

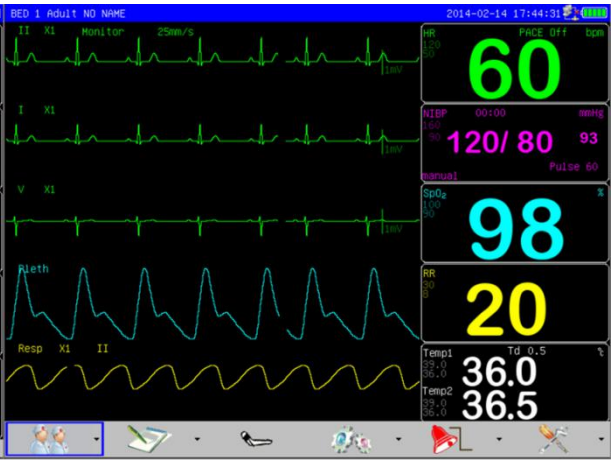


Trend Table

ECG Full Lead

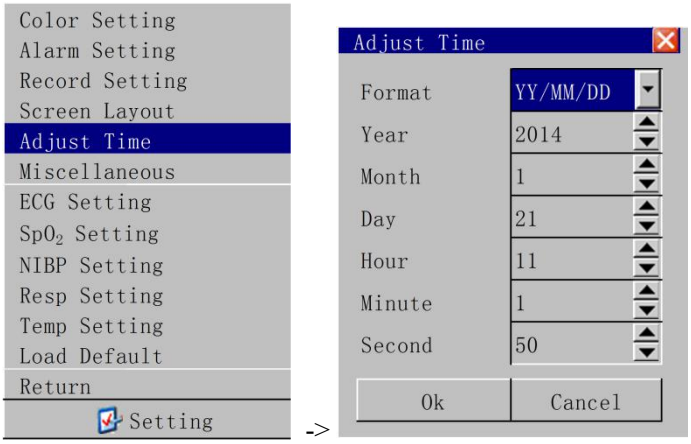


Touch Screen (optional)



3.3 Adjust Time

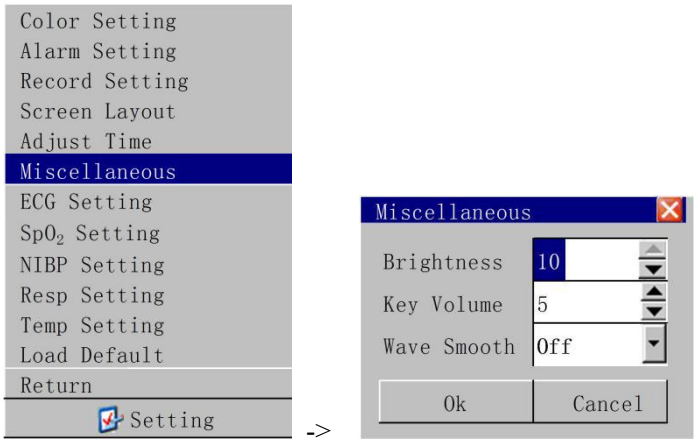
1. Rotate the knob to select “Adjust Time” in “Setting” menu.
2. Press the knob to enter the window of “Adjust Time”.



Adjust Time	
Format	YY/MM/DD, DD/MM/YY, MM/DD/YY
Year	2005~2100

3.4 Miscellaneous

1. Rotate the knob to select “Miscellaneous” in “Setting” menu.
2. Press the knob to enter the window of “Miscellaneous”.



Miscellaneous	
Brightness	1 ~ 10
Key Volume	0 ~ 10
Wave Smooth	Off / On

Brightness: Screen brightness (not available in 7-inch)

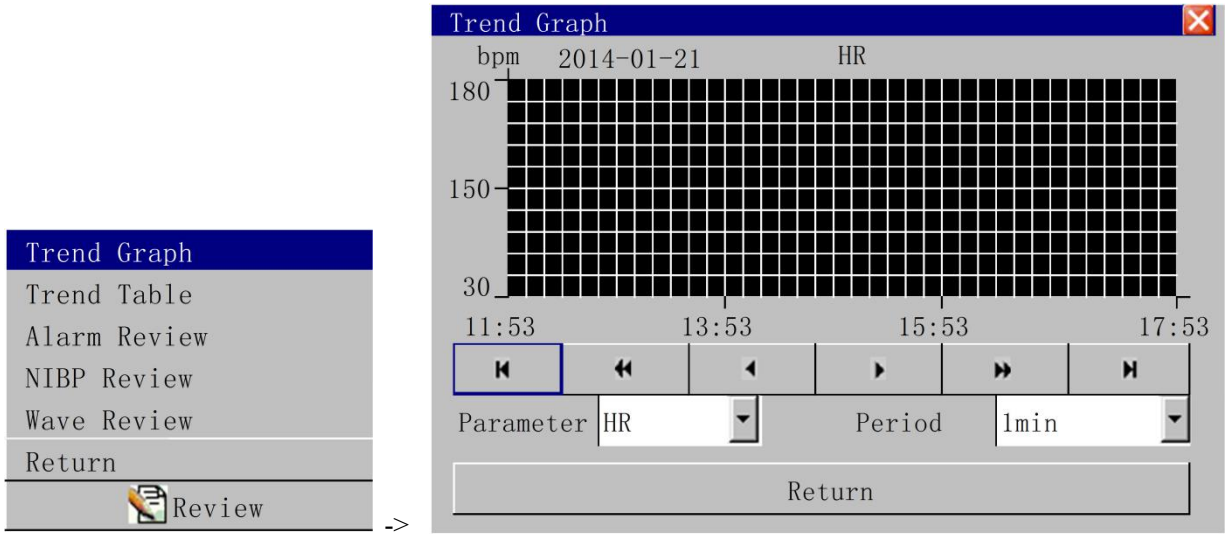
Key Volume: The volume of pressing buttons on the control panel.

Wave Smooth: If “Off” is selected, waves will display normally; if “On” is selected, waves will display without jaggies.

4 Review

4.1 Trend Graph

1. Rotate the knob to select “Trend Graph” in “Review” menu.
2. Press the knob to enter the window of “Trend Graph”.



Trend Graph	
Parameter	HR, RR, SpO_2, PR, Temp
Period	1s, 5s, 1min, 5min, 10min

3. Press “ ” and “ ” to review the trend graph **step by step**; press” ” and “ ” to review the trend graph **page by page**; press “ ” to review the trend graph **720 hours before** and press “ ” to review the trend graph of **the current time**.

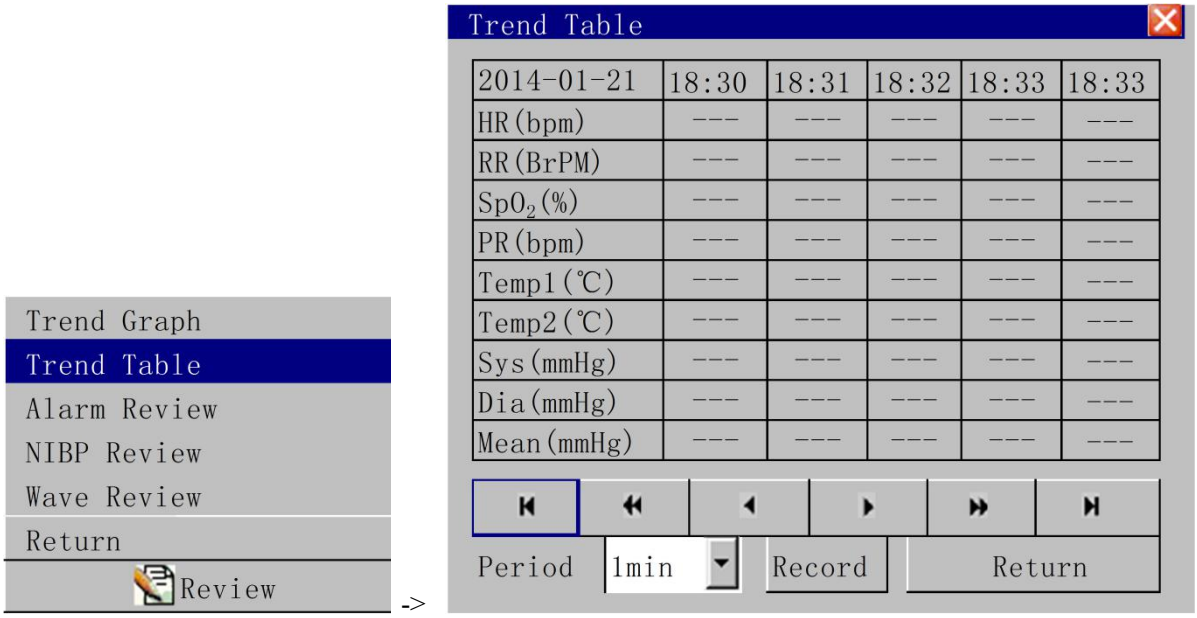
4. Select a parameter type from the list of “Parameter” to review the trend graph of different parameter. Select a time interval from the list of “Period” to review the trend graph by different time interval.

⚠ **NOTE** ⚠

- **The monitor can store Max. 720 hours of trend data.**

4.2 Trend Table

1. Rotate the knob to select “Trend Table” in “Review” menu.
2. Press the knob to enter the window of “Trend Table”.



Trend Table	
Period	1min, 2min, 3min, 4min, 5min, 10min, 15min, 30min, 60min

3. Press “ ” and “ ” to review the trend table **step by step**; press " ” and “ ” to view the trend table **page by page**; press “ ” to view the trend table **720 hours before** and press “ ” to view the trend table of **the current time**.

4. Select a time interval from the list of “Period” to review the trend graph by different time interval.

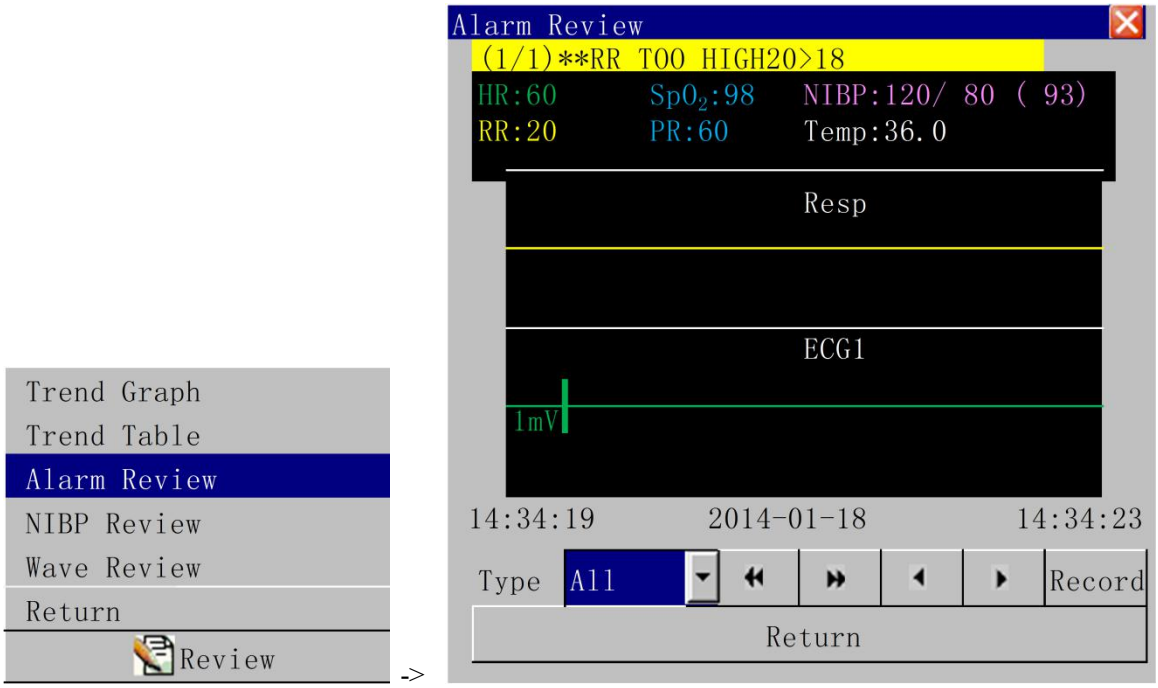
5. Press “Record” to print the currently displayed data of trend table by recorder (if the monitor has a built-in recorder).

⚠ **NOTE** ⚠

- **The monitor can store Max. 720 hours of trend data.**

4.3 Alarm Review

1. Rotate the knob to select “Alarm Review” in “Review” menu.
2. Press the knob to enter the window of “Alarm Review”.



Alarm Review	
Type	All, ECG, SpO_2, NIBP, RESP, TEMP

3. Select a parameter type from the list of “Type” to review the alarm history by different parametertype.

4. Press “ ” and “ ” to review the alarm history **step by step**; press” ” and “ ” to review the alarm history **page by page**; press “ ” to review **the first page** of alarm history and press “ ” to review **the last page** of alarm history.

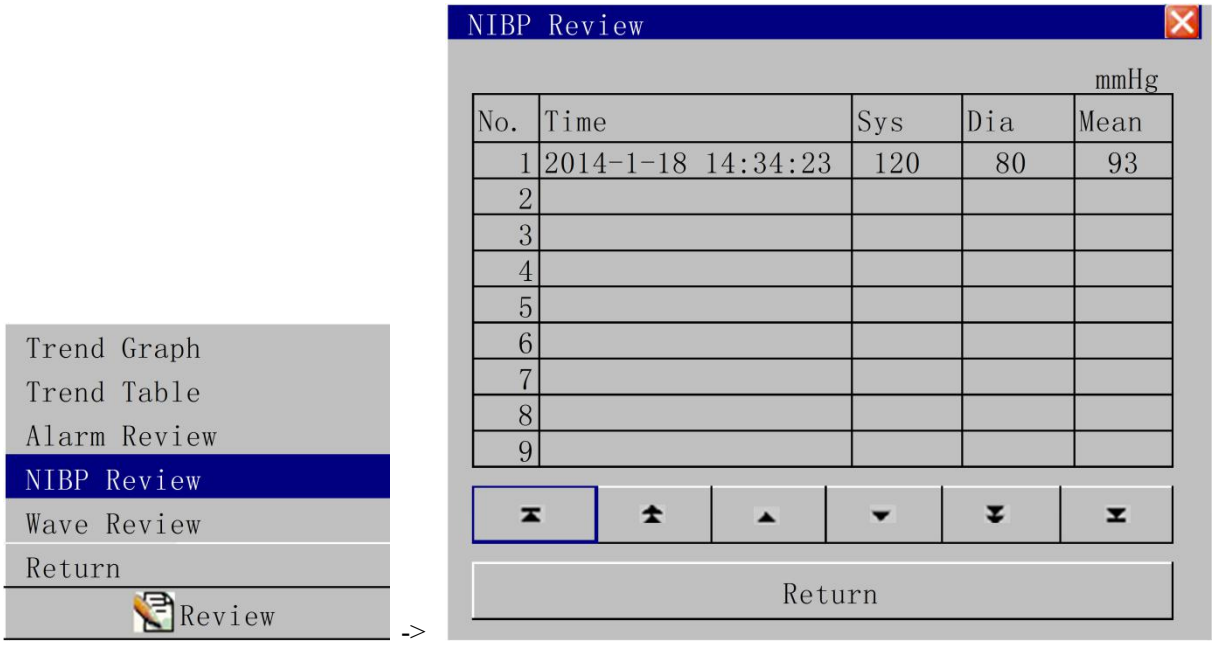
5. Press “Record” to print the currently displayed data of alarm history by recorder (if the monitor has a built-in recorder).

⚠ **NOTE** ⚠

- **The monitor store Max. 200 groups of alarm history data.**

4.4 NIBP Review

1. Rotate the knob to select “NIBP Review” in “Review” menu.
2. Press the knob to enter the window of “NIBP Review”.



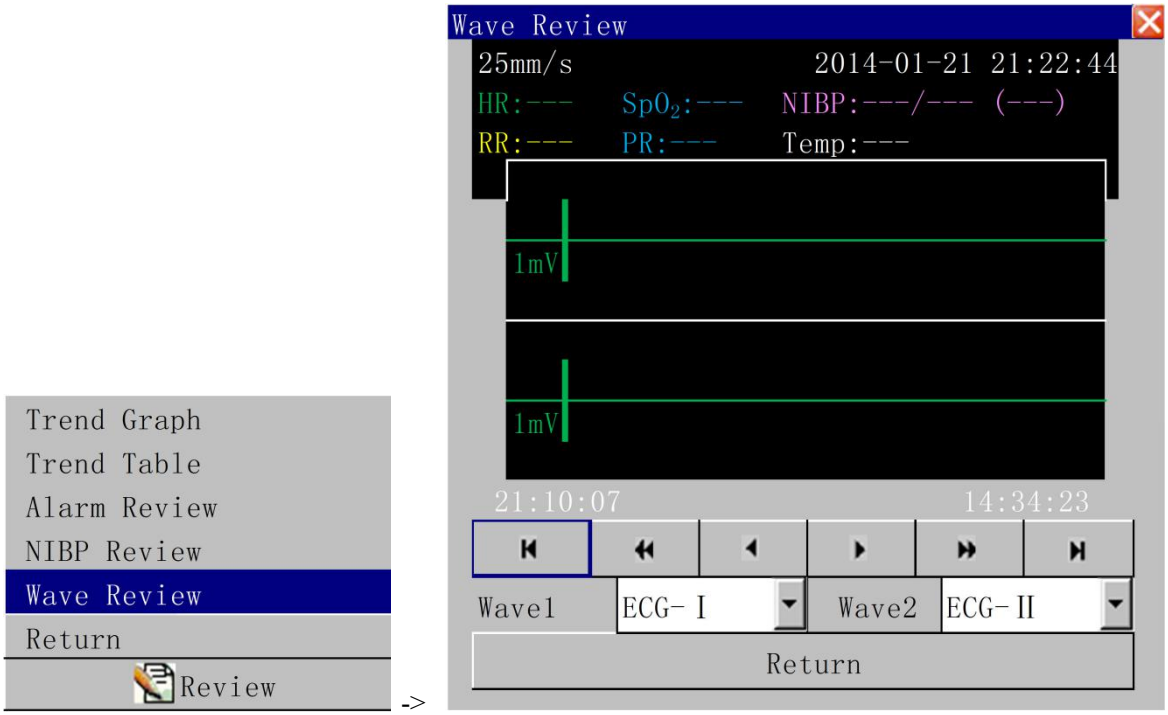
3. Press “ ” and “ ” to review the NIBP monitoring data **step by step**; press” ” and “ ” to review the NIBP monitoring data **page by page**; press “ ” to review **the first page** of NIBP monitoring data and press “ ” to review **the last page** of NIBP monitoring data.

⚠ **NOTE** ⚠

● **The monitor can store Max. 1000 groups of NIBP monitoring data.**

4.5 Wave Review

1. Rotate the knob to select “Wave Review” in “Review” menu.
2. Press the knob to enter the window of “Wave Review”.



Wave Review	
Wave1	ECG-Ⅰ, ECG-Ⅱ, ECG-Ⅴ, Pleth, Resp
Wave2	ECG-Ⅰ, ECG-Ⅱ, ECG-Ⅴ, Pleth, Resp

3. Press “ ” and “ ” to review the wave history **step by step**; press” ” and “ ” to review the wave history **page by page**; press “ ” to review the wave history **12 hours before** and press “ ” to review the wave history of **the current time.**

4. Select wave types from the list of “Wave1” and “Wave2” to review the wave history of different wave types.

⚠ **NOTE** ⚠

● The monitor can store Max. 12 hours wave history data.

● The trend data can be preserved for 720 hours after the turning off of the monitor. If the monitor is turned on after 720 hours’ power-off, the trend data would be eliminated.

● The waveform review data can be preserved for 2 hour after the turning off of the monitor. If the monitor is turned on after 2 hour’s power-off, the waveform review data would be deleted.

5 Alarm

5.1 Alarm Overview

The monitor gives audible or visual alarms to indicate the medical staff, when a vital sign of the patient appears abnormal, or mechanical or electrical problems occur to the monitor.
Upon turning on the monitor, the alarm indicator will flash once in yellow and red. Then, a beep will be heard. This is used to verify the audible and visual alarm function of the monitor. If no beep is heard, or the alarm indicator doesn't flash normally, please do not use the monitor, and contact our customer service.

5.1.1 Alarm Categories

The patient monitor's alarms can be classified into two categories: technical alarms and physiological alarms.
1. 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.
2. 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.

5.1.2 Alarm Levels

The patient monitor's alarms can be classified into three levels: high level, medium level and low level.

Alarm Levels		
	Physiological alarms	**Technical alarms**
High level	Indicate that your patient is in a life threatening situation and an emergency treatment is demanded.	Indicate a severe device malfunction or an improper operation, which could make it possible that the monitor cannot detect critical patient status and thus threaten the patient's life.
Medium level	Indicate that your patient's vital signs appear abnormal and an immediate treatment is required.	Indicate a device malfunction or an improper operation which may not threaten the patient's life but may compromise the monitoring of vital physiological parameters.
Low level	Indicate that you patient's vital signs appear abnormal and an immediate treatment may be required.	Indicate a device malfunction or an improper operation, which may compromise a certain monitoring function but will not threaten the patient's life.

⚠ **NOTE** ⚠

● The levels of all technical alarms and some physiological alarms are not user-adjustable, because they have been fixed when the monitor is produced. However, you can change the levels of some physiological alarms in the corresponding parameter setup menus.

5.1.3 Alarm Modes

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

1. Alarm LED: If an alarm occurs, the alarm LED will flash.
2. Alarm message: When an alarm occurs, an alarm message will appear in the technical or physiological alarm information area.
3. Numeric color: If an alarm triggered by an alarm limit violation occurs, the color of numeric in parameter area will change from dark color to bright color.
4. Audible alarm tones: The patient monitor uses different alarm tone patterns to match the alarm levels.
5. Reminder tones: When alarms are turned off or alarm tones are paused or turned off, the patient monitor will give a single beep as the reminder tone in case of an active alarm condition.

Alarm Modes					
	Alarm LED	**Alarm Message Symbols**	**Alarm Message Background Color**	**Numeric Color**	**Audible Alarm Tones**
High Level	flashes quickly in red	***	red	dark colors become bright colors	DO-DO-DO--DO-DO---DO-DO-DO---DO-DO, 1 time/8sec
Medium Level	flashes slowly in yellow	**	yellow		DO-DO-DO, 1 time/25sec
Low Level	turns yellow without flashing	*	yellow		DO, 1 time/25sec

⚠ **NOTE** ⚠

● When multiple alarms of different levels occur simultaneously, the patient monitor will select the alarm of the highest level and give visual and audible alarm indications accordingly.

5.2 Alarm States

5.2.1 Alarm Silencing

1. Press “SILENCE” button on the control panel. The alarm voices including audible alarm tones, reminder tones and human voice will be disabled. Press “SILENCE” button again. The alarm voices will be reactivated.

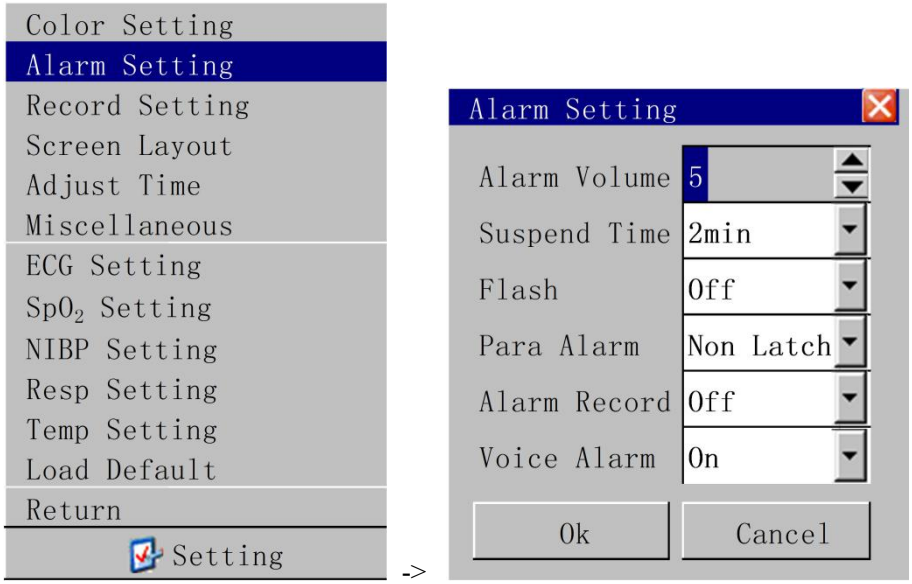
2. If the alarm still exists under the condition of the silence state, then the alarm information area display this alarm information. If there is no alarm exists under the condition of the silence status, then all the alarm information will be eliminated.

⚠ **NOTE** ⚠

● When the system is under the “SILENCE” condition, any newly triggered alarm will terminate the silence condition, and then makes the system to restore to the normal alarm condition.

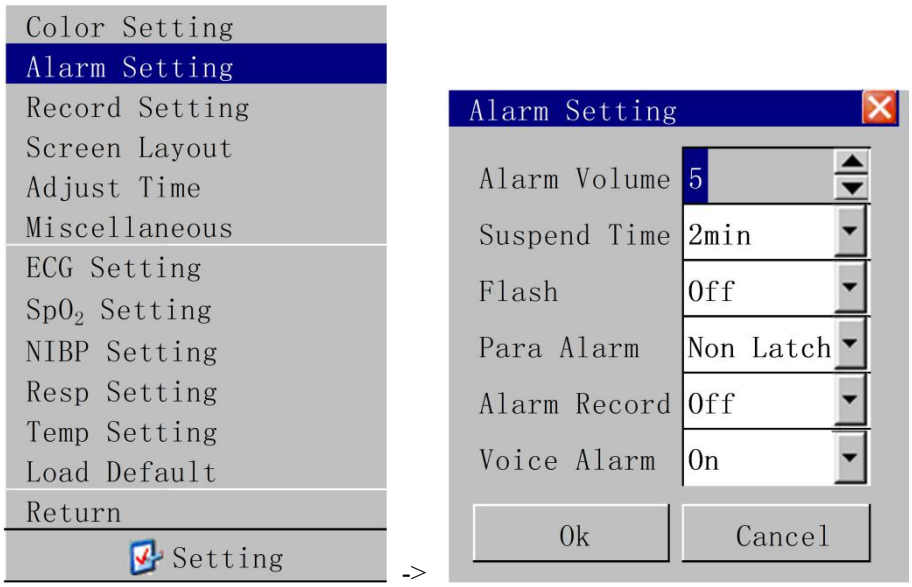
5.2.2 Alarm Pausing

1. Press “PAUSE” button on the control panel. All alarms will be disabled. “ALARM PAUSE” and countdown will display in technical alarm area. Press “PAUSE” button again. All alarms will be reactivated.
2. The suspend time of alarm pausing can be set in the window of “Alarm Setting” in “Setting” menu.



5.3 Alarm Setting

1. Rotate the knob to select “Alarm Setting” in “Setting” menu.
2. Press the knob to enter the window of “Alarm Setting”.



Alarm Setting	
Alarm Volume	0~10
Suspend Time	1min, 2min
Flash	Off / On
Para Alarm	Non Latch, Latch

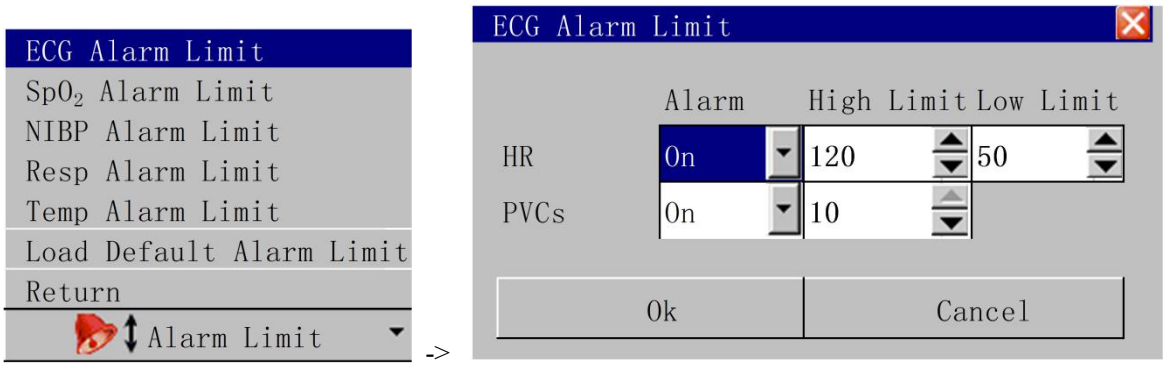
Alarm Record	Off / On
Voice Alarm	Off / On

Alarm Volume: The volume of audible alarm tones and reminder tones
Suspend Time: The duration of alarm pausing when "PAUSE" button is pressed.
Flash: If "On" is selected, displayed parameters will flash when physiological alarms happen; if "Off" is selected, displayed parameters will not flash when physiological alarms happen.
Parameter Alarm: If "Non Latch" is selected and alarms happen, alarms will stop once physiological or technical situation become normal; if "Latch" is selected and alarms happen, alarms will not stop unless alarms are discharged by human (for example, press "SILENCE" button).
Alarm Record: If "On" is selected, alarms will be recorded by recorder when alarms happen (if the monitor has a built-in recorder).
Voice Alarm: If "On" is selected, audible alarm tones and reminder tones will be trigged when alarms happen; if "Off" is selected, voice alarms are disable.

5.4 Alarm Limit

5.4.1 ECG Alarm Limit

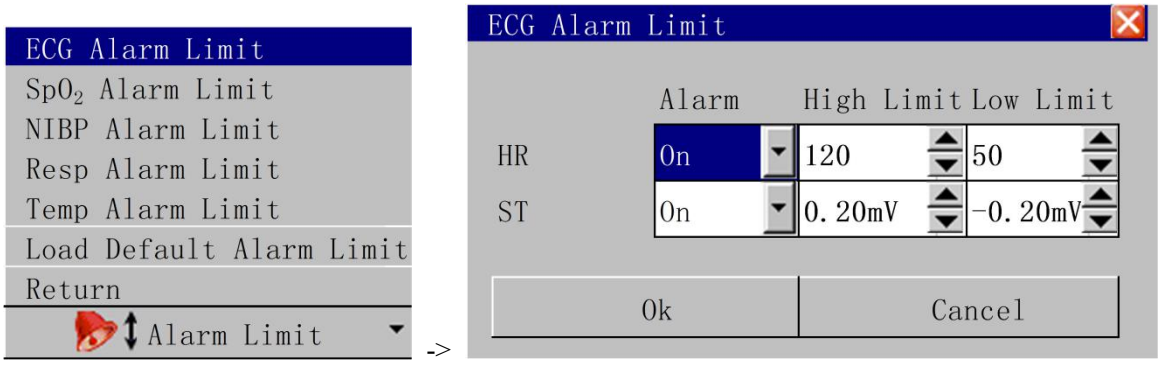
1. Rotate the knob to select "ECG Alarm Limit" in "Alarm Limit" menu.
2. Press the knob to enter the window of "ECG Alarm Limit".



ECG Alarm Limit	
HR Alarm	On / Off
HR High Limit	17 ~ 300
HR Low Limit	15 ~ 298

5.4.2 ST Alarm Limit

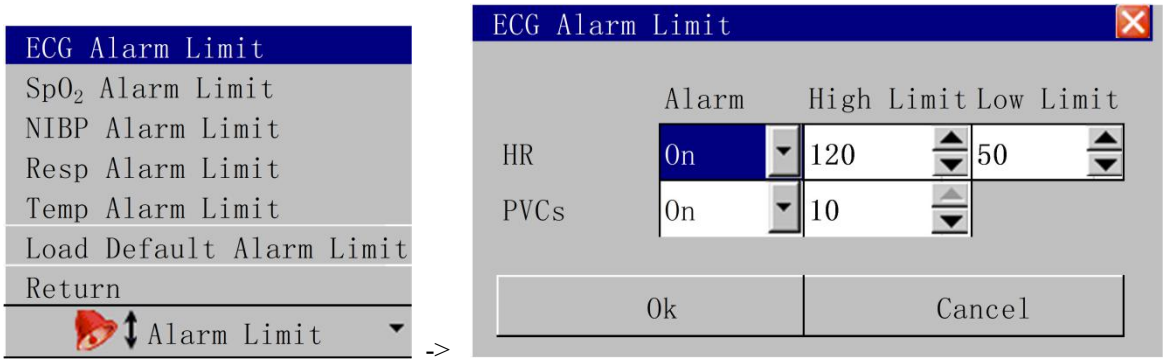
1. Rotate the knob to select "ECG Alarm Limit" in "Alarm Limit" menu.
2. Press the knob to enter the window of "ECG Alarm Limit".



ST Alarm Limit	
ST	On / Off
High Limit	2.00 ~ -2.00mV
Low Limit	-2.00 ~ 2.00mV

5.4.3 ARR Alarm Limit

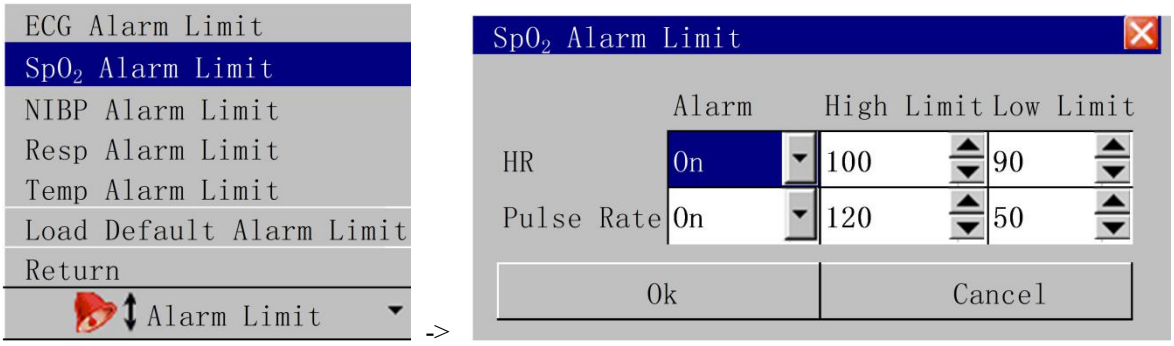
1. Rotate the knob to select “ECG Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “ECG Alarm Limit”.



ARR Alarm Limit	
PVCs	On / Off
High Limit	0 ~ 10

5.4.4 SpO₂ Alarm Limit

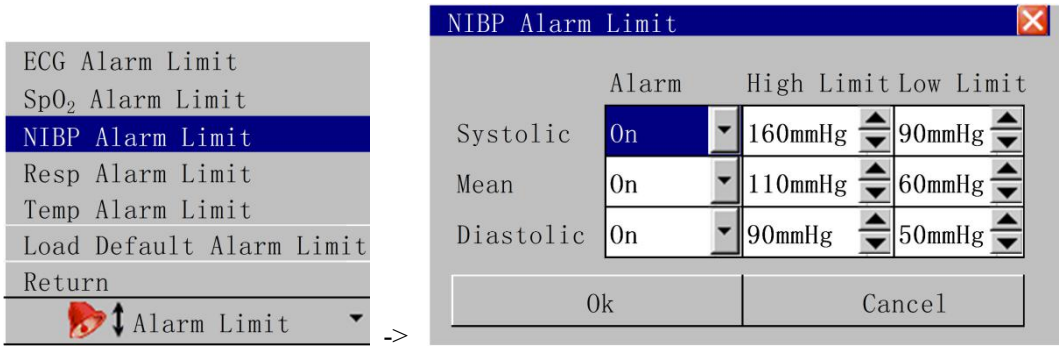
1. Rotate the knob to select “SpO2 Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “SpO2 Alarm Limit”.



SpO_2 Alarm Limit	
SpO_2 Alarm	On / Off
SpO_2 High Limit	1 ~ 100
SpO_2 Low Limit	0 ~ 99
Pulse Rate Alarm	On / Off
Pulse Rate High Limit	21 ~ 240
Pulse Rate Low Limit	20 ~ 239

5.4.5 NIBP Alarm Limit

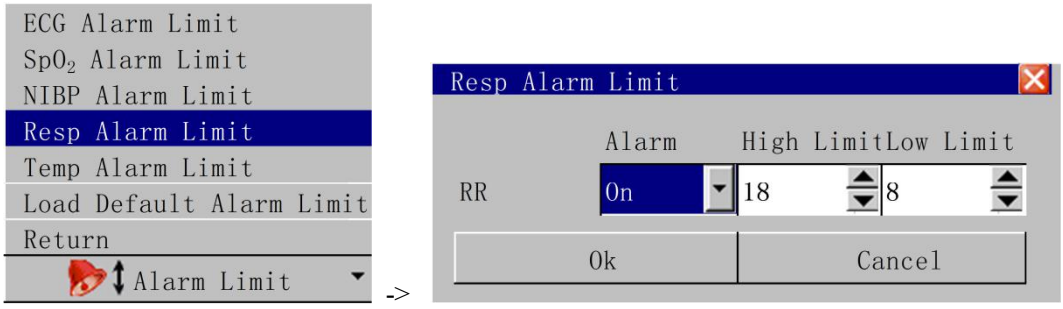
1. Rotate the knob to select “NIBP Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “NIBP Alarm Limit”.



NIBP Alarm Limit			
Patient Type	**Adult**	**Pediatric**	**Neonate**
Systolic Alarm	On / Off	On / Off	On / Off
Systolic High Limit	32 ~ 280mmHg	32 ~ 220mmHg	32 ~ 135mmHg
Systolic Low Limit	30 ~ 278mmHg	30 ~ 218mmHg	30 ~ 133mmHg
Mean Alarm	On / Off	On / Off	On / Off
Mean High Limit	22 ~ 240mmHg	22 ~ 170mmHg	22 ~ 110mmHg
Mean Low Limit	20 ~ 238mmHg	20 ~ 168mmHg	20 ~ 108mmHg
Diastolic Alarm	On / Off	On / Off	On / Off
Diastolic High Limit	12 ~ 220mmHg	12 ~ 160mmHg	12 ~ 100mmHg
Diastolic Low Limit	10 ~ 218mmHg	10 ~ 158mmHg	10 ~ 98mmHg

5.4.6 Resp Alarm Limit

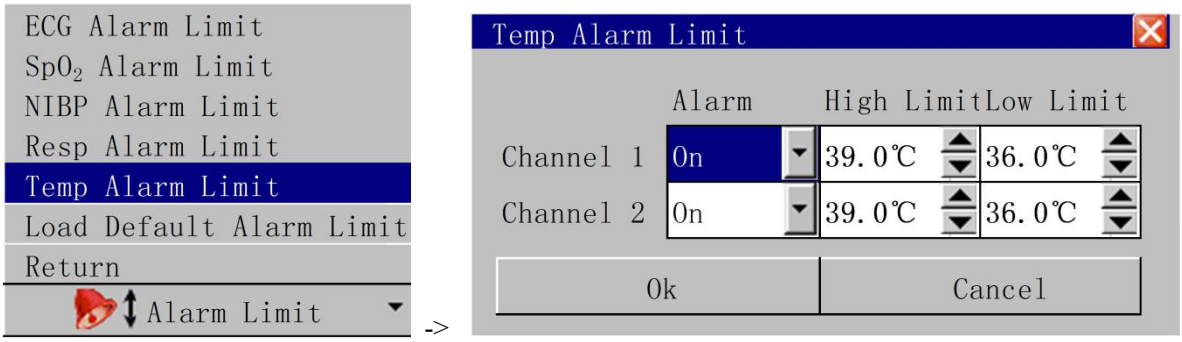
1. Rotate the knob to select “Resp Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “Resp Alarm Limit”.



Resp Alarm Limit	
RR Alarm	On / Off
RR High Limit	2 ~ 125
RR Low Limit	0 ~ 123

5.4.7 Temp Alarm Limit

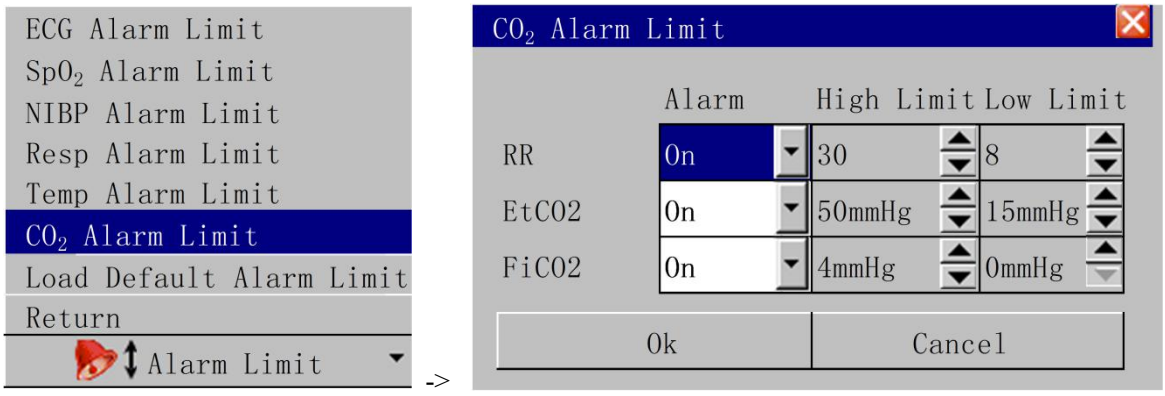
1. Rotate the knob to select “Temp Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “Temp Alarm Limit”.



Temp Alarm Limit	
Channel 1 Alarm	On / Off
Channel 1 High Limit	0.2 ~ 50.0℃ (32.36 ~ 122.0℉)
Channel 1 Low Limit	0.0 ~ 49.8℃ (0.0 ~ 121.64℉)
Channel 2 Alarm	On / Off
Channel 2 High Limit	0.2 ~ 50.0℃ (32.36 ~ 122.0℉)
Channel 2 Low Limit	0.0 ~ 49.8℃ (0.0 ~ 121.64℉)

5.4.8 CO2 Alarm Limit

1. Rotate the knob to select “CO2 Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “CO2 Alarm Limit”.

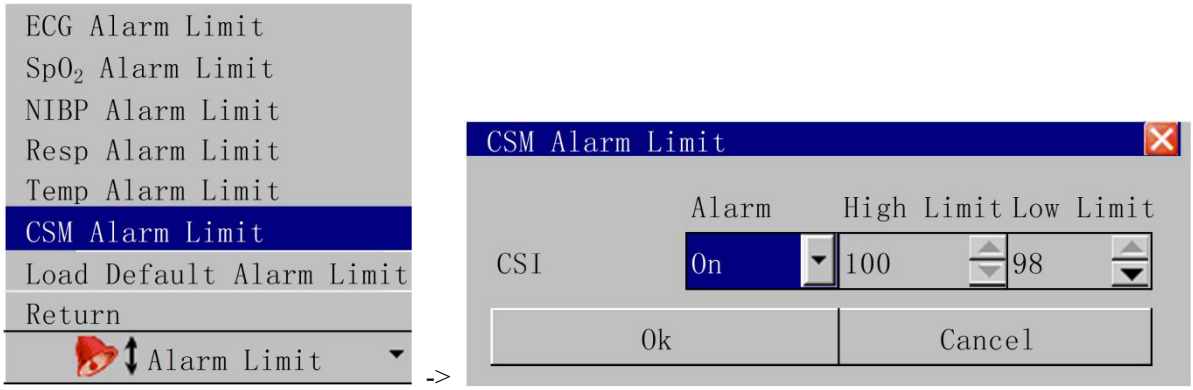


CO_2 Alarm Limit	
RR Alarm	On / Off
RR High Limit	0 ~ 120
RR Low Limit	0 ~ 120
$EtCO_2$ Alarm	On / Off

$EtCO_2$ High Limit	2 ~ 100mmHg
$EtCO_2$ Low Limit	0 ~ 98mmHg
$FiCO_2$ Alarm	On / Off
$FiCO_2$ High Limit	2 ~ 100mmHg
$FiCO_2$ Low Limit	0 ~ 98mmHg

5.4.9 CSM Alarm Limit

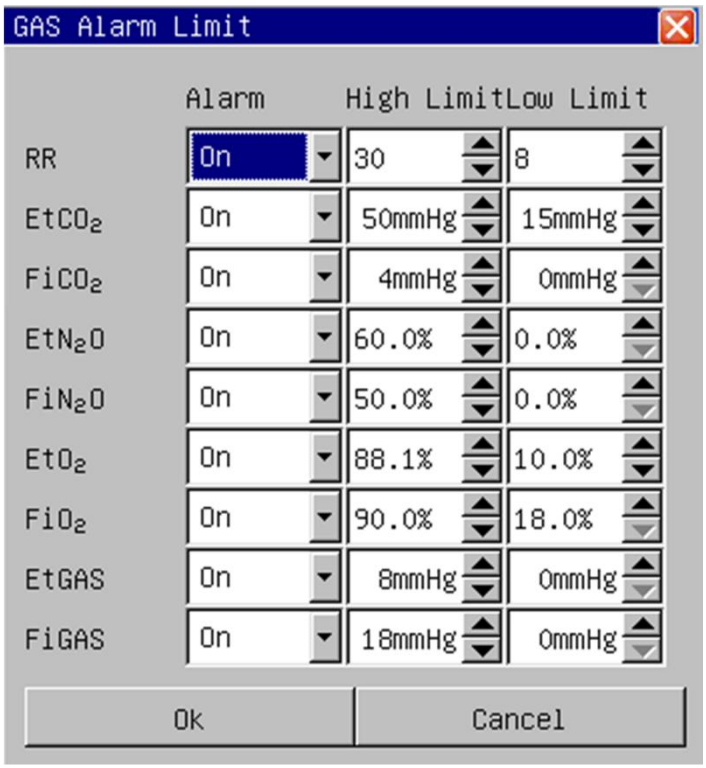
1. Rotate the knob to select “CSM Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “CSM Alarm Limit”.



CSM Alarm Limit	
CSI Alarm	On / Off
CSI High Limit	2 ~ 100
CSI Low Limit	0 ~ 98

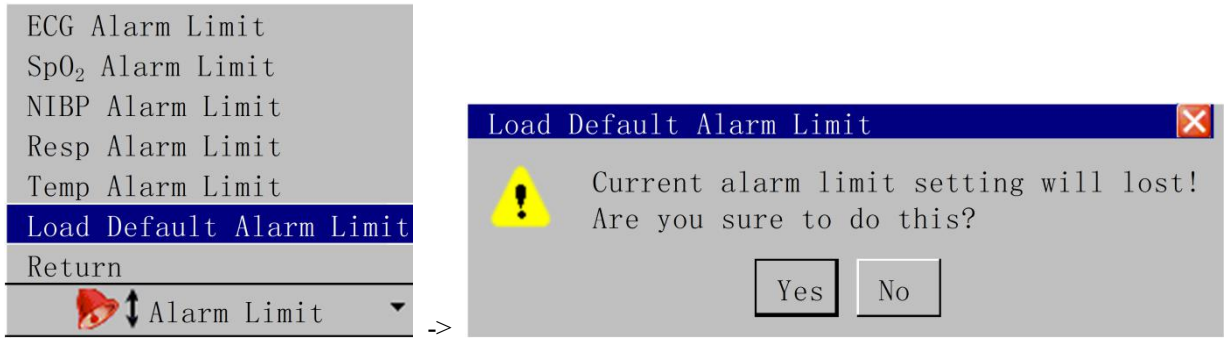
5.4.10 GAS

1. Rotate the knob to select “GAS Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “GAS Alarm Limit”.



5.4.11 Load Default Alarm Limit

1. Rotate the knob to select “Load Default Alarm Limit” in “Alarm Limit” menu.
2. Press the knob to enter the window of “Load Default Alarm Limit”.
3. Select “Yes” and press the knob, the current alarm limit settings will be deleted.



5.5 Alarm Messages

5.5.1 Technical Alarm Messages

Alarm Information	Trigger Condition	Process Method
**ECG LEAD OFF	RL or more than 2 ECG leads falls off	Check the ECG lead connection
**ECG LEAD RA OFF	RA lead fall off	Check the ECG lead connection
**ECG LEAD LA OFF	LA lead fall off	Check the ECG lead connection
**ECG LEAD LL OFF	LL lead fall off	Check the ECG lead connection
**ECG LEAD V OFF	V lead fall off	Check the ECG lead connection
**MODULE INIT ERR	Module self-checking mistake	Restart the machine, if error still existed, contact the factory service
***MODULE COMM STOP	The module and the main engine communication have problems	Restart the machine, if error still existed, contact the factory service
**MODULE COMM ERR	The module and the main engine communication have problems	Restart the machine, if error still existed, contact the factory service
**PARA ALARM LMT ERR	The parameter of the alarm limit is modified by the accident	contact the factory service
**RANGE EXEED	The parameter observed value has exceed the measurement scope which the system can carry on	contact the factory service
**SpO_2 SENSOR OFF	SpO_2 sensor does not connected	Check SpO_2 sensor connection
**SpO_2 FINGER OFF	The finger fall off from SpO_2 sensor	Check SpO_2 sensor connecting with the finger
SEARCHING PULSE...	SpO_2 sensor connects badly or the patient move the arm	Check SpO_2 sensor connection situation and patient's current condition
**Temp1 SENSOR OFF	The body temperature channel 1 sensor do not connect	Check temperature sensor connection
**Temp2 SENSOR OFF	The body temperature channel 2 sensor do not connect	Check temperature sensor connection
**WATCHDOG ERR	Main engine watch-dog self-checking defeat	Restart the machine, if wrong still existed, contact the factory service
**SYSTEM TIME LOST	The system clock has not set	Change the system time as the current time, if error still existed, related the factory to carry on the service
**12V HIGH	The 12V voltage examination exceeds the normal voltage scope	Restart the machine, if error still existed, contact the factory service
**12V LOW	The 12V voltage examination is lower than the normal voltage scope	Restart the machine, if error still existed, contact the factory service
**3.3V HIGH	The 3.3V voltage examination exceeds the normal voltage scope	Restart the machine, if error still existed, contact the factory service
**3.3V LOW	The 3.3V voltage examination is	Restart the machine, if error still

	lower than the normal voltage scope	existed, contact the factory service
**BAT HIGH	The battery voltage examination exceeds the normal voltage scope	Restart the machine, if error still existed, contact the factory service
**BAT LOW	The battery capacity is insufficient	Meets the alternating current to carry on the charge immediately to the battery
*NIBP LOOSE CUFF	The cuff has not connected	Reconnects the blood pressure cuff
*NIBP AIR LEAK	The cuff has not connected good or the air course leaks air	check the pipe connection situation or replace cuff, if the breakdown still existed, please contact the factory service
*NIBP DEFLATE ERR	When blood pressure measurement deflates has the problem	check the tube connection or replace cuff, if the error still existed, please contact the factory service
*NIBP WEAK SIGNAL	When blood pressure measurement the pulse signal too weak, is unable to calculate the blood pressure	Examined the patient type set whether correctly, check the tube connection or replace cuff, if the error still existed, please contact the factory service
*NIBP OUT OF RANGE	When blood pressure measurement the blood pressure or the pulse signal exceeds the normal range, is unable to carry on the measurement	check he tube connection or replace cuff, if the error still existed, please contact the factory service
*NIBP MOVEMENT	Patient arm move	Check the patient situation or replace cuff, if the error still existed, please contact the factory service
**NIBP OVER PRESSURE	The pressure value exceeds the measurement scope	check the pipe connection situation or replace cuff, if the error still existed, please contact the factory service
*NIBP SATURATE	When blood pressure measurement the pulse signal exceeds the normal range, is unable to carry on the measurement	Check the patient situation or replace cuff, if the error still existed, please contact the factory service
*NIBP PNEUMATIC FAIL	The cuff has not connected good or the air course leaks air	check the pipe connection situation or replace cuff, if the error still existed, please contact the factory service
**NIBP SYSTEM ERR	Blood pressure system self-check defeat	Restart the machine, if the error still existed, please contact the factory service
**NIBP TIME OUT	Blood pressure measurement overtime	Restart the machine, if the error still existed, please contact the

		factory service
**NIBP CUFF TYPE WRONG	Patient type for adult when has used the neonate cuff	Check the patient type or replace cuff, if the error still existed, please contact the factory service
**NIBP MEASURE FAIL	This blood pressure measurement has not been able to calculate the blood pressure	Check the patient situation or replace cuff, if the error still existed, please contact the factory service
**NIBP RESET ERR	When blood pressure measurement exceptionally reset	Restart the machine, if the error still existed, please contact the factory service
**CO_2 STANDBY	CO_2 is on standby mode	Set CO_2 to run mode
***CO_2 COMM STOP	CO_2module and the main engine communication have the problem	Restart the machine, if error still existed, contact the factory service
**CSI COMM STOP	CSI module and the main engine communication have the problem	Restart the machine, if error still existed, contact the factory service
**CSI SENSOR OFF	CSI sensor does not connected	Check CSI sensor connection
CSI SQI LOW	CSI sensor does not connected or skin dirty	Check CSI sensor connection
**AwRR TOO HIGH	AwRR exceeds the high limit	**AwRR TOO HIGH
**AwRR TOO LOW	AwRR is lower than the low limit	**AwRR TOO LOW

5.5.2 Physiological Alarm Messages

Alarm Information	**Trigger Condition**
***ASYSTOLE	Over 4 seconds non- palpitations signals
***APNEA	In a setting time without breath signal
***NO PULSE	Over 15 seconds without pulse signals
**HR TOO HIGH	The heart rate exceeds the alarm high limit
**HR TOO LOW	The heart rate is lower than the alarm low limit
**ST-I TO HIGH	the ST value correlate with I surpass the upper alarm limit
**ST-I TOO LOW	the ST value correlate with I surpass the lower alarm limit
**ST-II TO HIGH	the ST value correlate with II surpass the upper alarm limit
**ST-II TOO LOW	the ST value correlate with II surpass the lower alarm limit
**ST-III TO HIGH	the ST value correlate with III surpass the upper alarm limit
**ST-III TOO LOW	the ST value correlate with III surpass the lower alarm limit
**ST-AVR TOO HIGH	the ST value correlate with AVR surpass the upper alarm limit
**ST-AVR TOO LOW	the ST value correlate with AVR surpass the lower alarm limit
**ST-AVL TOO HIGH	the ST value correlate with AVL surpass the upper alarm limit
**ST-AVL TOO LOW	the ST value correlate with AVL surpass the lower alarm limit
**ST-AVF TOO HIGH	the ST value correlate with AVF surpass the upper alarm limit
**ST-AVF TOO LOW	the ST value correlate with AVF surpass the lower alarm limit
**ST-V TOO HIGH	the ST value correlate with V surpass the upper alarm limit
**ST-V TOO LOW	the ST value correlate with V surpass the lower alarm limit
**PVCs TOO HIGH	The PVCs value exceeds the alarm high limit
**SPO_2 TOO HIGH	The oxygen saturation exceeds the alarm high limit

**SPO_2 TOO LOW	The oxygen saturation is lower than the alarm low limit
**Pulse rate TOO HIGH	The Pulse rate surpass the alarm high limit
**Pulse rate TOO LOW	The Pulse rate are lower than the alarm low limit
**NIBP SYS TOO HIGH	NIBP systolic pressure exceeds the alarm high limit
**NIBP SYS TOO LOW	NIBP systolic pressure is lower than the lower alarm limit
**NIBP MEAN TOO HIGH	NIBP mean pressure exceeds the alarm high limit
**NIBP MEAN TOO LOW	NIBP mean pressure is lower than the alarm low limit
**NIBP DIA TOO HIGH	NIBP diastolic pressure exceeds the alarm high limit
**NIBP DIA TOO HIGH	NIBP diastolic pressure is lower than the alarm low limit
**RR TOO HIGH	The Breath rate exceeds the alarm high limit
**RR TOO LOW	The Breath rate is lower than the alarm low limit
**TEMP1 TOO HIGH	The body temperature channel 1 exceeds the alarm high limit
**TEMP1 TOO LOW	The body temperature channel 1 is lower than the alarm low limit
**TEMP2 TOO HIGH	The body temperature channel 2 exceeds the alarm high limit
**TEMP2 TOO LOW	The body temperature channel 2 is lower than the alarm low limit
**$EtCO_2$TOO HIGH	$EtCO_2$exceeds the high limit
**$EtCO_2$ TOO LOW	$EtCO_2$ is lower than the low limit
**$FiCO_2$ TOO HIGH	$FiCO_2$exceeds the high limit
**$FiCO_2$ TOO LOW	$FiCO_2$ is lower than the low limit
**AwRR TOO HIGH	AwRR exceeds the high limit
**AwRR TOO LOW	AwRR is lower than the low limit
**CSI TOO HIGH	CSI is higher than the low limit
**CSI TOO LOW	CSI is lower than the low limit

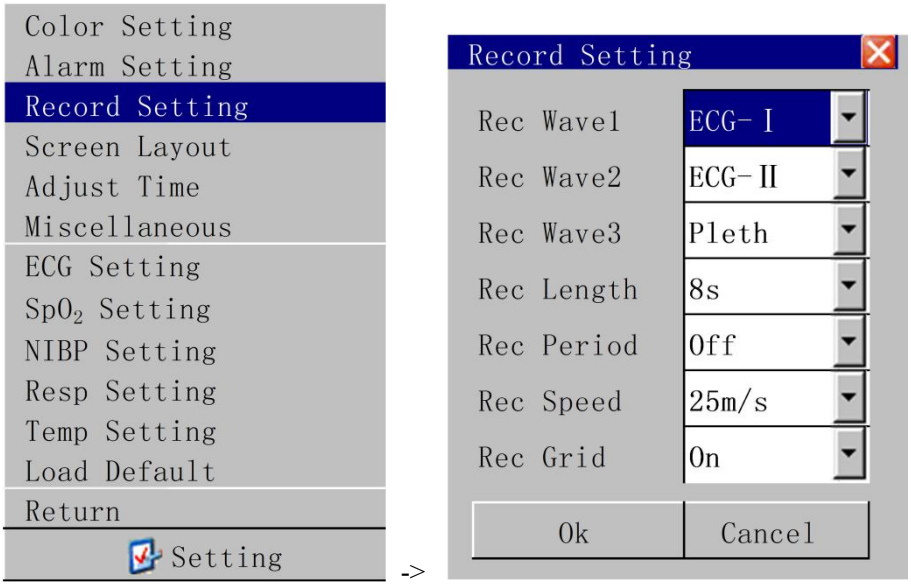
⚠ **NOTE** ⚠

- **When different level of alarm simultaneously exists, the sound of the alarm is the highest level alarm.**
- **In alarm suspend condition, Monitoring will not process any alarm information.**

6 Recording

6.1 Record Setting

1. Rotate the knob to select “Record Setting” in “Setting” menu.
2. Press the knob to enter the window of “Record Setting”.



Record Setting	
Rec Wave1	Off, ECG-Ⅰ,ECG-Ⅱ,ECG-III,ECG-AVR,ECG-AVL,ECG-AVF,ECG-Ⅴ, Pleth, Resp
Rec Wave2	Off, ECG-Ⅰ,ECG-Ⅱ,ECG-III,ECG-AVR,ECG-AVL,ECG-AVF,ECG-Ⅴ, Pleth, Resp
Rec Wave3	Off, ECG-Ⅰ,ECG-Ⅱ,ECG-III,ECG-AVR,ECG-AVL,ECG-AVF,ECG-Ⅴ, Pleth, Resp
Rec Length	8s, Continuous
Rec Period	Off, 10min, 20min, 30min, 40min, 50min, 60min, 2hour, 3hour, 4hour
Rec Speed	12.5mm/s, 25mm/s, 50mm/s
Rec Grid	Off / On

■ **Record Wave 1~3:** The parameter waves that need to be recorded, the user can decide to record one of them, two of them or three of them.

■ **Record Length:** Recording length, if “8s” is selected, when “RECORD” button is pressed, the recorder will record 8s of parameter waves each time; if “Continuous” is selected, when “RECORD” button is pressed, the recorder will keep recording the parameter waves until “RECORD” button is pressed again or recording function is closed.

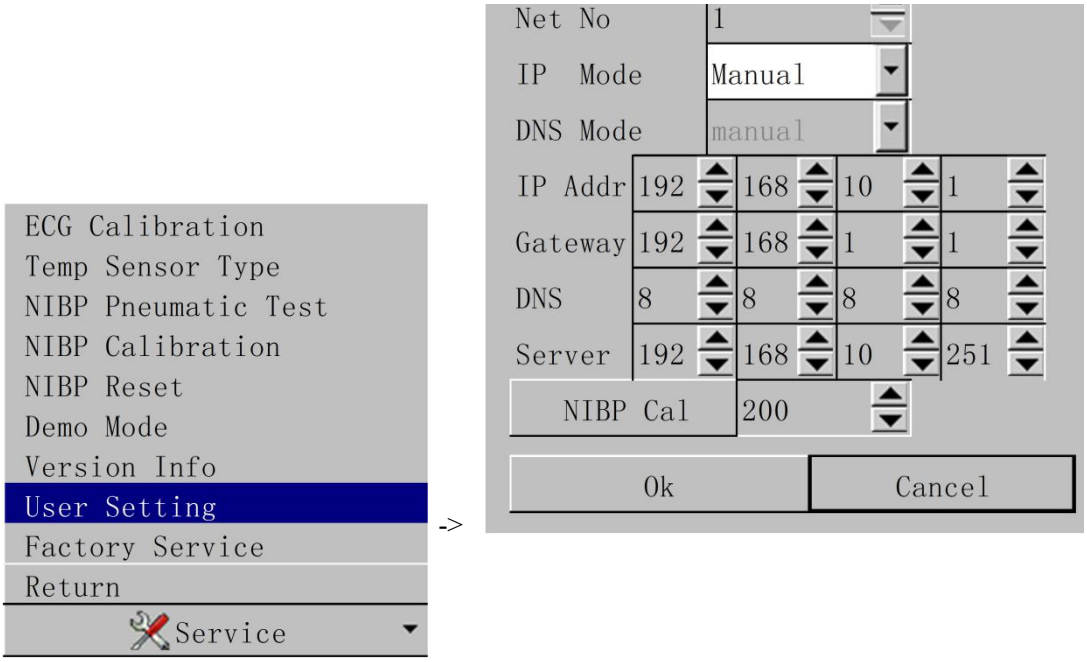
■ **Record Period:** The time interval between recording outputs.

■ **Record Speed:** Recording speed

■ **Record Grid:** If “On” is selected, the background grid will output; if “Off” is selected, the background grid will not output.

6.2 Recorder On / Off

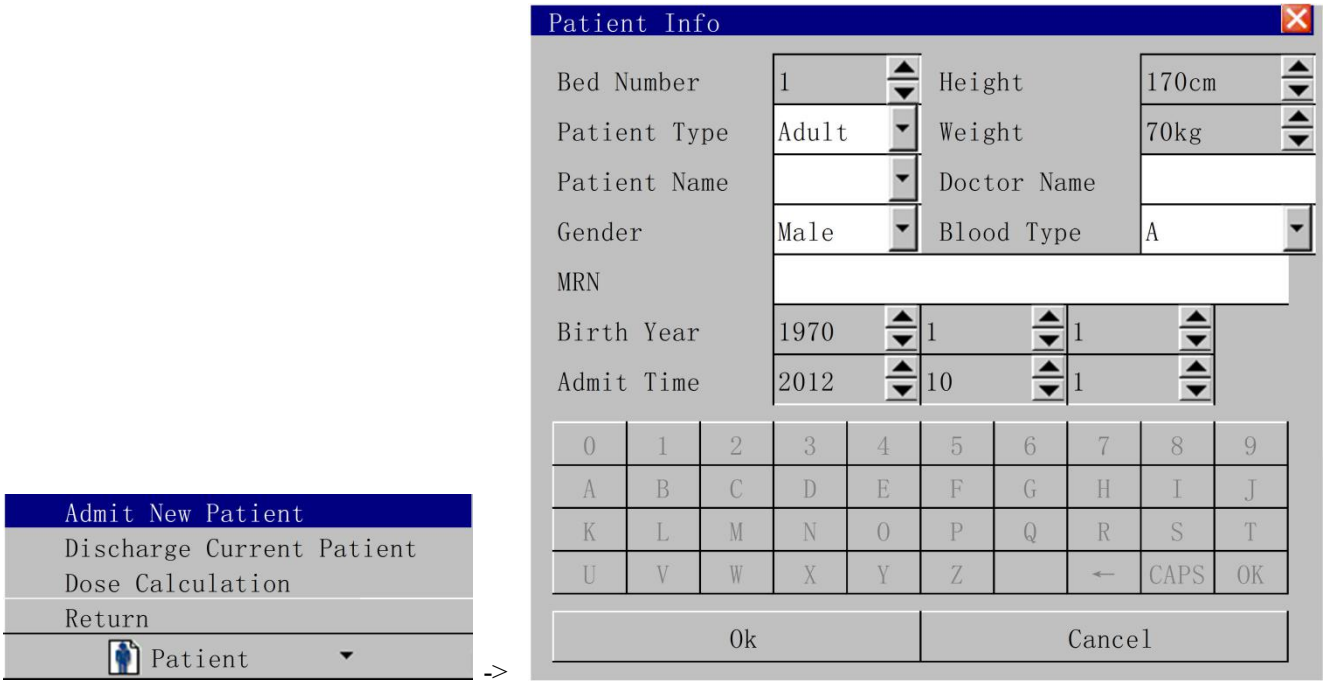
1. Rotate the knob to select “User Setting” in “Service” menu.
2. Press the knob to enter the window of “User Setting”.
3. If “On” is selected from the list of “Recorder”, the recorder will be available. If “Off” is selected from the list of Recorder, the recorder will be disabled.



7 Patient Managing

7.1 Admit Patient

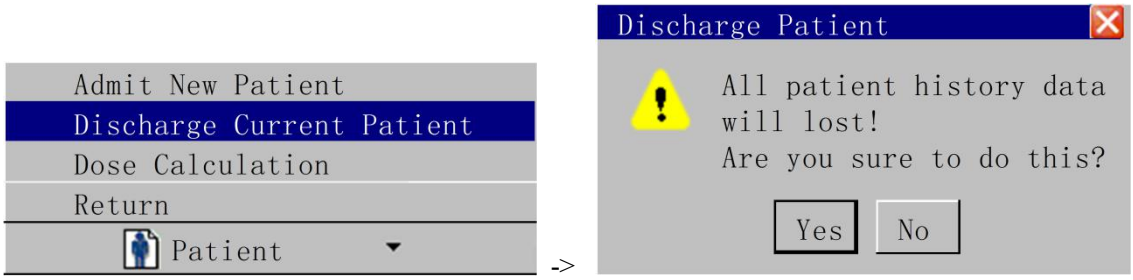
1. Rotate the knob to select “Admit New Patient” in “Patient” menu.
2. Press the knob to enter the window of “Patient Info”.
3. Input the patient’s information and confirm by “Ok”. The patient will be admitted.



Admit Patient	
Bed Number	1 ~ 100
Patient Type	Adult, Pediatric, Neonate
Patient Name	Supports inputting by letter and number
Gender	Male, Female
Height	20 ~ 250 cm
Weight	2 ~ 250 kg
Doctor Name	Supports inputting by letter and number
Blood Type	A, B, O, AB, NA
MRN	Supports inputting by letter and number
Birth Year	1900/1/1 ~ 2099/12/31
Admit Year	1900/1/1 ~ 2099/12/31

7.2 Discharge Current Patient

1. Rotate the knob to select “Discharge Current Patient” in “Patient” menu.
2. Press the knob to enter the window of “Discharge Current Patient”.
3. Select “Yes” and press the knob. The current patient’s information will be deleted.



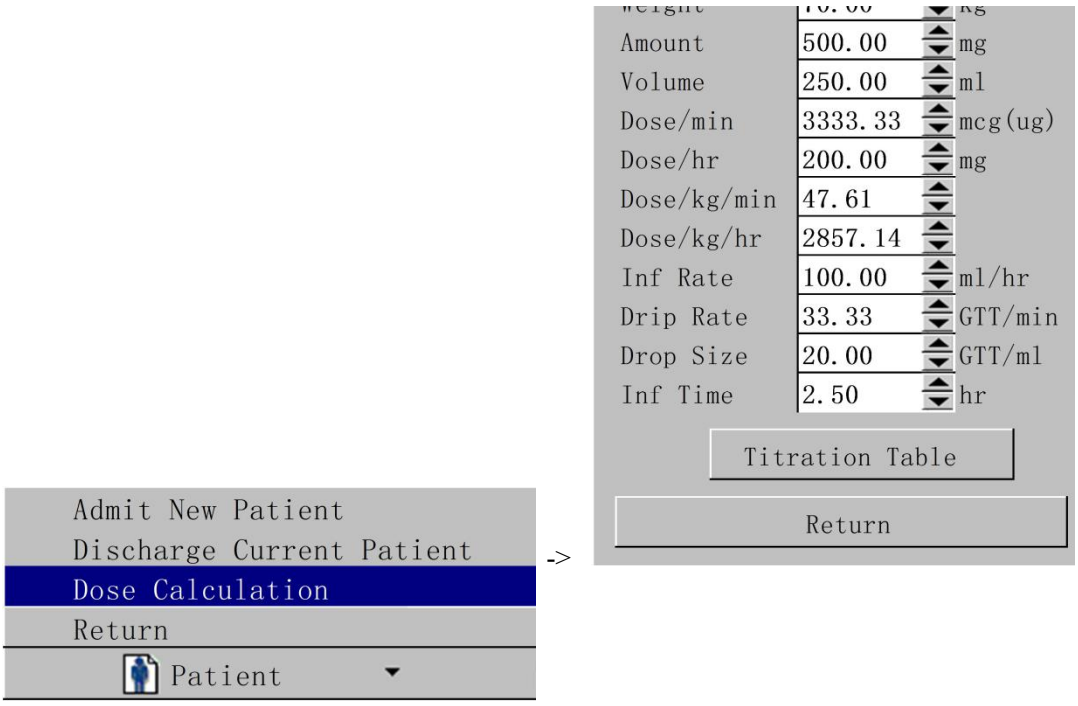
⚠ NOTE ⚠

● **If do not relieve the patient firstly before receive new patient, new patient’s measurement data would be save in the preceding patient's data. The monitor can not distinguish the new patient data from the old one.**

7.3 Dose Calculation

7.3.1 Dose Calculation Procedure

1. Rotate the knob to select “Dose Calculation” in “Patient” menu.
2. Press the knob to enter the window of “Dose Calculation”.
3. Select a drug name from the list of “Drug Name”. Input the patient’s “Weight” and other known values. The corresponding values will be calculated and displayed.



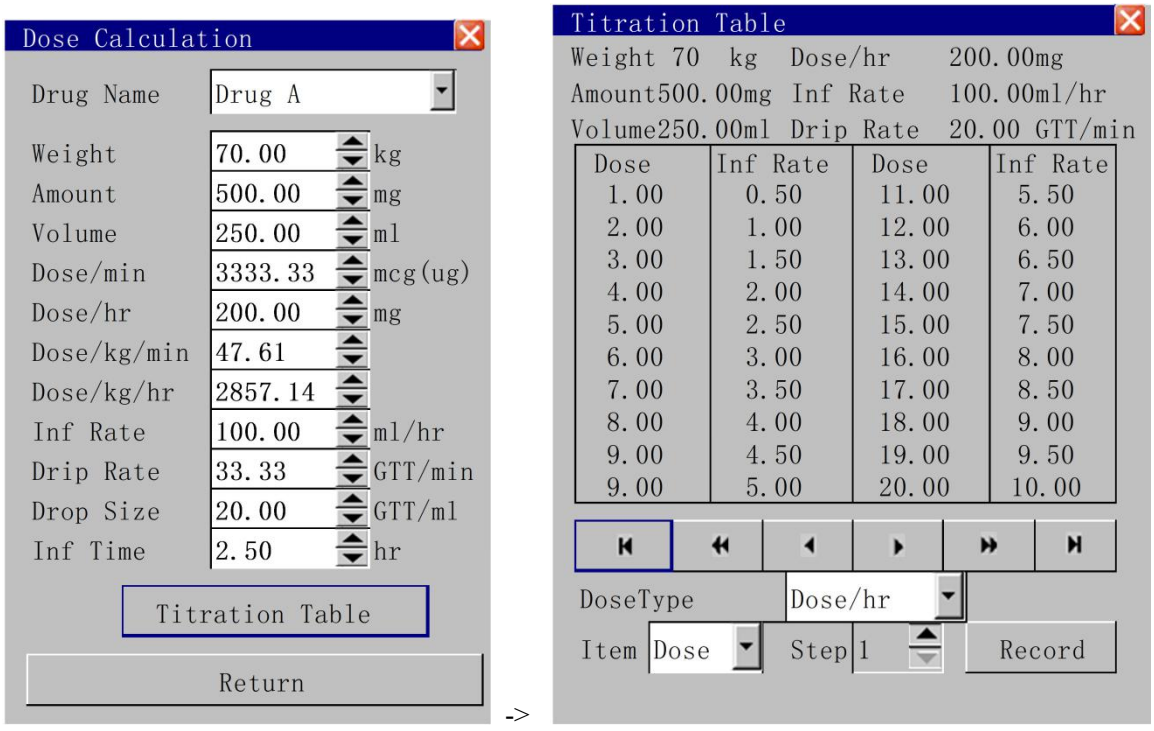
Drug Name	Drug A, Drug B, Drug C, Drug D, Drug E, Aminophylline, Dobutamine, Dopamine, Epinephrine, Heparin, Inocor, Insulin, Isuprel, Lidocaine, Nipride, Nitroglycerin, Norepinephrine, Pitocin, Procainamide, Vasopressin
Weight	0.50 ~ 250.00 kg
Amount	0.00 ~ 9999.00 mg
Volume	0.00 ~ 9999.00 ml
Dose/min	0.00 ~ 9999.00 mcg(ug)
Dose/hr	0.00 ~ 9999.00 mg
Dose/kg/min	0.00 ~ 9999.00 mcg(ug)
Dose/kg/hr	0.00 ~ 9999.00 mcg(ug)
Inf Rate	0.10 ~ 4999.50 ml/hr
Drip Rate	0.10 ~ 999.98 GTT/hr
Drop Size	0.10 ~ 999.97 GTT/ml
Inf Time	0.10 ~ 999.98 hr

7.3.2 Drug Unit

Drug Unit Table	
Drug	**Unit**
Drug A, Drug B, Drug C, Aminophylline, Dobutamine, Dopamine, Epinephrine, Inocor, Isuprel, Lidocaine, Nipride, Nitroglycerin, Norepinephrine, Procainamide	mg, mcg (ug)
Drug D, Heparin Insulin, Pitocin, Vasopressin	UNIT, m UNIT
Drug E	mEq, uEq

7.3.3 Titration Table

1. Select “Titration Table” in the window of “Dose Calculation”.
2. Press the knob to enter the window of “Titration Table”.



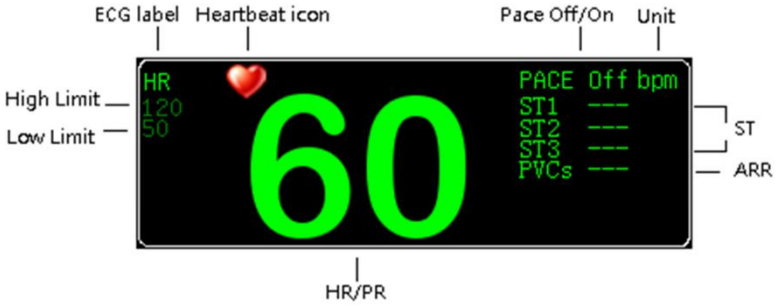
2. Press “  ” and “  ” to view the titration table **step by step**; press”  ” and “  ” to view the titration table **page by page**; press “  ” to view **the first page** of titration table and press “  ” to view **the last page** of titration table.

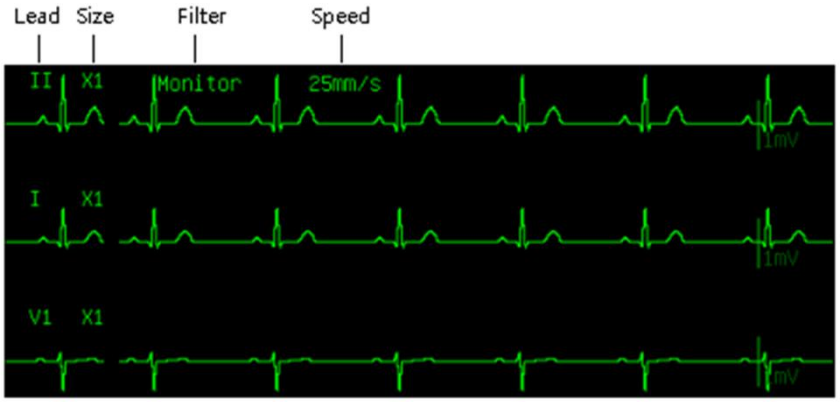
3. Charge the values of “Dose Type”, “Item” or “Step”. The corresponding values will change in the titration table.

4. Press “Record” to print the currently displayed data of titration table by recorder (if the monitor has a built-in recorder).

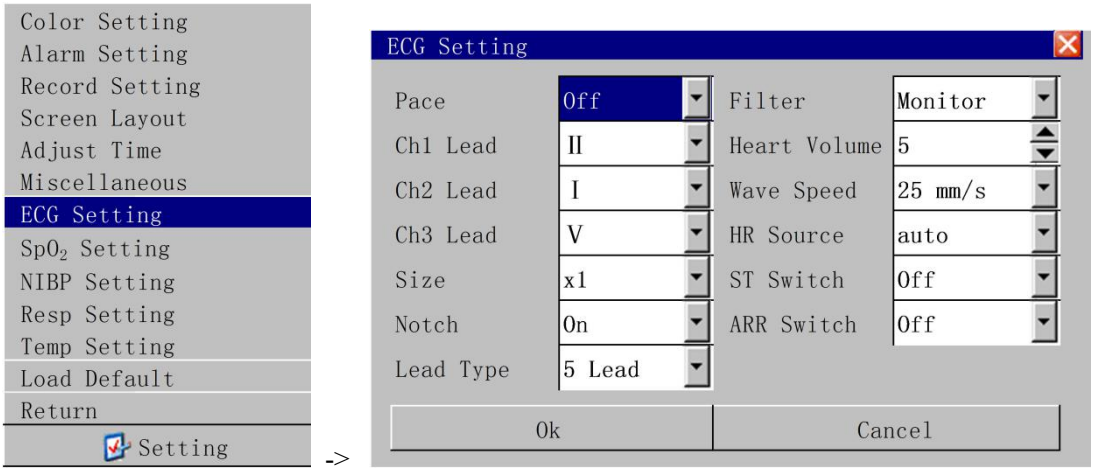
8 ECG Monitoring

8.1 ECG Display



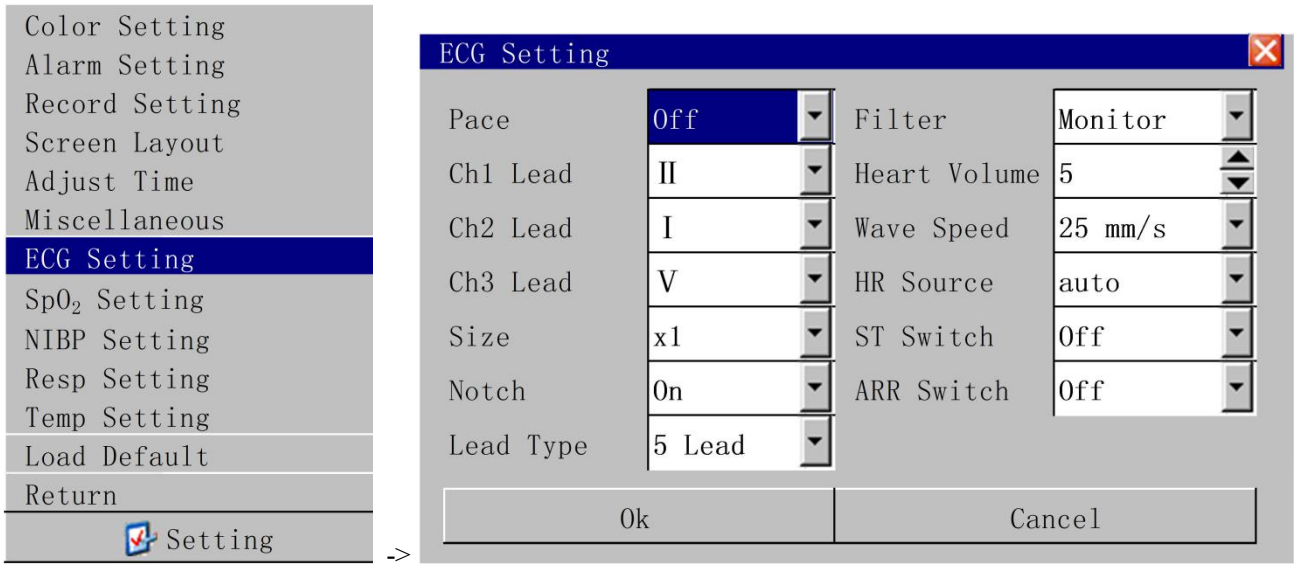


1. The heartbeat icon flashes in the same rate with the patient's heartbeat or pulse.
2. ST1, ST2 and ST3 display only when ST Switch is "On"; PVCs displays only when ARR Switch is "On".



8.2 ECG Setting

1. Rotate the knob to select “ECG Setting” in “Setting” menu. Press the knob to enter the window of “ECG Setting”.



ECG Setting	
Pace	Off / On
Ch1 Lead	Ⅰ, Ⅱ, Ⅲ, AVR, AVL, AVF, V
Ch2 Lead	Ⅰ, Ⅱ, Ⅲ, AVR, AVL, AVF, V
Ch3 Lead	Ⅰ, Ⅱ, Ⅲ, AVR, AVL, AVF, V
Size	x0.25, x0.5, x1, x2
Notch	Off / On
Lead Type	3 Lead, 5 Lead
Filter	Diagnostic, Monitor, Surgery
Heart Volume	0~10
Wave Speed	12.5mm/s, 25mm/s, 50mm/s
HR Source	ECG, SpO_2, auto
ST Switch	Off / On
ARR Switch	Off / On

■ Pace

♦ On: When “On” is selected, a detected pacemaker signal is indicated by a "|" symbol above the ECG waveform.

♦ Off: When “Off” is selected, the pacemaker analysis is disabled.

■ Ch1~3 Lead

Lead type.

■ Size

Adjust the amplitude of the ECG waveforms. A “1mV” scale is displayed at the right side of each ECG waveform, the height of the 1mV bar is directly proportional to the ECG waveform amplitude.

■ Notch

Determines whether filter or not.

♦ On: When “On” is selected, the monitor protects the signals from the noise generated by the power line.

♦ Off: When “Off” is selected, there is no filtering for outside signals.

■ Lead Type

■ Filter

The filtering enables clearer and more detailed waveforms. There are three filter methods for selection.

♦ Diagnostic: The monitor displays the ECG waveforms without filter;

♦ Monitor: It effectively filters the artifacts that might cause false alarms;

♦ Surgery: This filter is used to reduce the artifacts and interference from electrosurgery equipment.

The selected filter is applied to both channels, but the filter label is merely displayed above the first ECG waveform.

■ Heart Volume

■ Wave Speed

■ HR Source

HR comes from "ECG", "SpO_2", "Auto".

♦ ECG: HR is always calculated from ECG.

♦ SpO2: If the ECG signal is seriously interfered, you can select SpO2, which means PR will be derived from PLETH waveform.

♦ Auto: The monitor determines the heart rate source depending on the signal quality. The priorities for heart rate calculation are: ECG, SpO2.

■ ST Switch

The function of ST analysis is optional. In the factory configuration, ST analysis is disabled.

■ ARR Switch

Arrhythmia Analysis. In the factory configuration, ST analysis is disabled.

⚠ **WARNING** ⚠

● Don't touch the patient or the monitor in the period of defibrillating.

● In order to ensure the patient safety, all leads must be connected to the patient

● When the electricity surgical (ES) equipment is used, lay the ECG-lead in the middle of both the ES ground plate and ES to avoid burning. The cable of the electricity surgical equipment cannot twist with the ECG-cable.

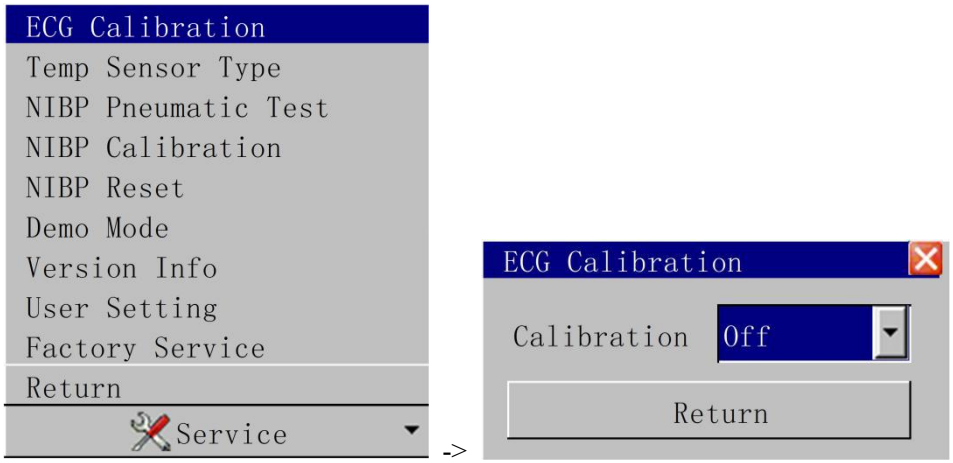
● When the electricity surgical (ES) equipment is used, don't place the electrode on the ground plate near the electricity surgical equipment. Otherwise, the ECG-signal will be disturbed.

● If monitoring a patient with the pacemaker, set "PACE" to On. If monitoring a patient without pacemaker, set "PACE" to Off.

● Regarding the pacemaker patient, the pacing switch must be "On", otherwise, it is possibly to consider the pacing pulse as the normal QRS.

8.3 ECG Calibration

Rotate the knob to select "ECG Calibration" in "Service" menu. Press the knob to enter the window of "ECG Calibration". If "On" is selected, the monitor will have a self-calibration for ECG waves. If "Off" is selected, self-calibration will stop.



ECG Calibration	
Calibrate	Off / On

8.4 ECG Monitoring Procedure

8.4.1 Preparation

1. Skin preparation

The quality of ECG information 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. Choose flat area to place electrodes. Following is a suggested guideline for skin preparation:

a. Shave hair from skin at chosen sites.

b. Gently rub skin surfaces at sites to remove dead skin cells.

c. Thoroughly cleanse the site with a mild soap and water solution (do not use ether or pure alcohol because they will increase skin impedance).

d. Dry the skin completely before applying the electrodes.

2. Attach the ECG lead wire to the electrodes.

3. Place the electrodes on the patient. (conductive ointment can be applied to the electrodes to improve the skin conductance if it is necessary)

4. Connect the ECG lead wire to the ECG connector of the monitor.

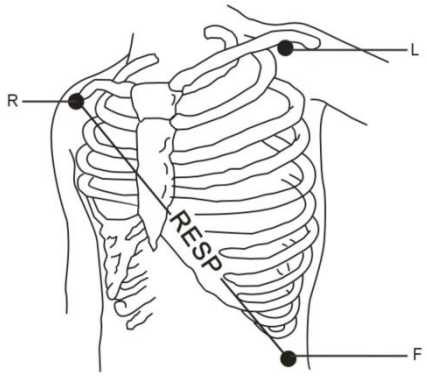
5. Make sure the monitor is turned on and is ready for monitoring.

6. Make sure the monitor have a proper ECG setting.

8.4.2 Electrode Placement

8.4.2.1 3-Leadwire Electrode Placement

3-Leadwire electrode placement is showed by European standard as follow:

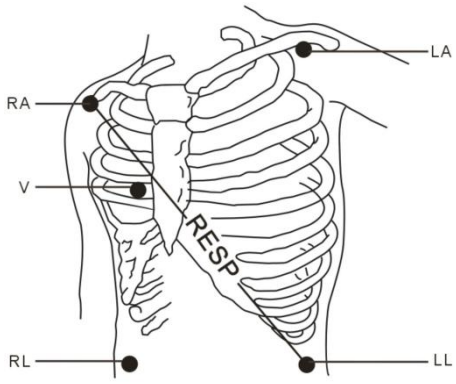


■ R (right arm) electrode: near the right shoulder, directly below the clavicle.
■ L (left arm) electrode: near the left shoulder, directly below the clavicle.
■ F (left leg) electrode: on the left hypogastrium.

American Standard (AHA)		European Standard (IEC)	
Label	**Color**	**Label**	**Color**
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green

8.4.2.2 5-Leadwire Electrode Placement

5-Leadwire electrode placement is showed by American standard as follow:



■ RA (right arm) electrode: near the right shoulder, directly below the clavicle.
■ LA (left arm) electrode: near the left shoulder, directly below the clavicle.
■ RL (right leg) electrode: on the right hypogastrium.
■ LL (left leg) electrode: on the left hypogastrium.
■ V (precordial) electrode: on the chest.

American Standard (AHA)		European Standard (IEC)	
Label	**Color**	**Label**	**Color**
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White

⚠ **WARNING** ⚠

● When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient.

⚠ **WARNING** ⚠

● Verify lead fault detection before start of monitoring. Unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm is activated.

⚠ **WARNING** ⚠

● Use five lead wires. Use only silver - silver chloride (Ag-AgCl) ECG electrodes and cables that meets AAMI standards.

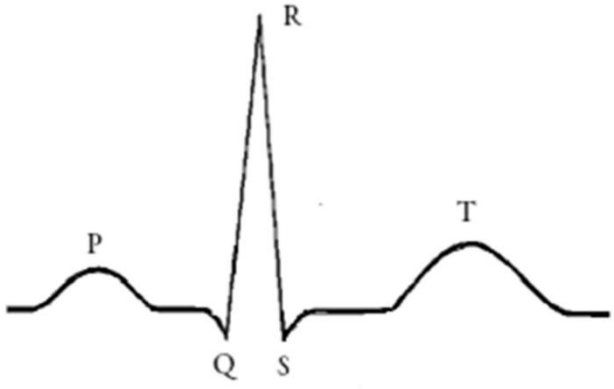
⚠ **WARNING** ⚠

● Set out the following table are standard in Europe and the United States the name of the lead.

8.4.2.3 Electrode Placement for Surgical Patients

Electrode placement during surgery is dependent on the type of surgery being performed. For example, with open chest surgery, the electrodes might be placed laterally on the chest or on the back. In the operating room, artifact can sometimes affect the ECG waveform due to the use of electrosurgery equipment. To help reduce this, place the electrodes on the right and left shoulders, the right and left sides near the stomach, and place the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms. This will cause the ECG waveform to be too small.

A good characteristic of the ECG-waveform:
The QRS wave height is great and narrow with no notches.
The R wave height is big and located completely above the baseline or under.
The amplitude of the P wave and the T wave is smaller than 0.2mV.



⚠ **WARNING** ⚠

● Do not touch the patient, table nearby, or the equipment during defibrillation.

⚠ **WARNING** ⚠

● When apply the ECG cable with no resistances to patient monitor or other patient monitors which themselves with no current limit resistance, it can't be applied to defibrillation.

⚠ NOTE ⚠

● Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

⚠ WARNING ⚠

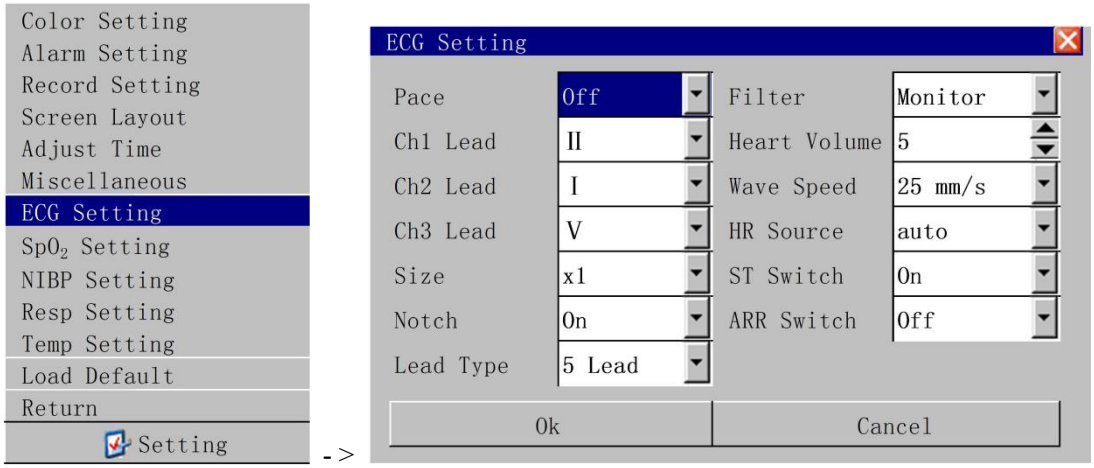
● When using ESU equipment, leads should be placed in a position in equal distance from ESU electrotome and the grounding plate to avoid cautery. ESU equipment wire and ECG cable must not be tangled up.

8.5 ST Analysis

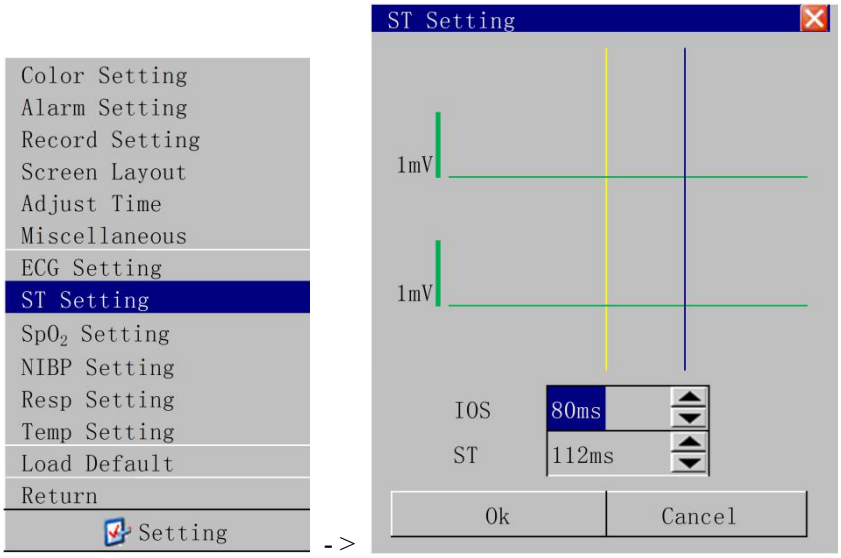
8.5.1 ST Display

8.5.2 ST Setting

1. Rotate the knob to select “ECG Setting” in “Setting” menu.
2. Press the knob to enter the window of “ECG Setting”.

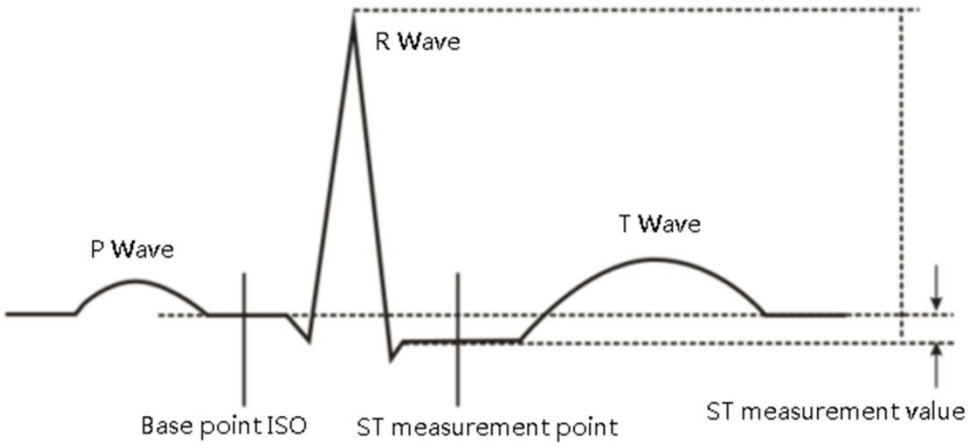


3. Select “On” from the list of “ST Switch” and confirm by “Ok”. ST Setting will appear in “Setting” menu.
4. Select “ST Setting” and press the knob to enter the window of “ST Setting”.



■ ISO: The isoelectric point provides the baseline for the measurement.
■ ST: The ST point provides the other measurement point.

ST Setting	
ISO	0 ~ 500ms
ST	0 ~ 500ms



The ST measurement for each beat complex is the vertical difference between two measurement points.

⚠ **WARNING** ⚠

● ST analysis is not intended for neonatal patients.
● The ST 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.

⚠ **NOTE** ⚠

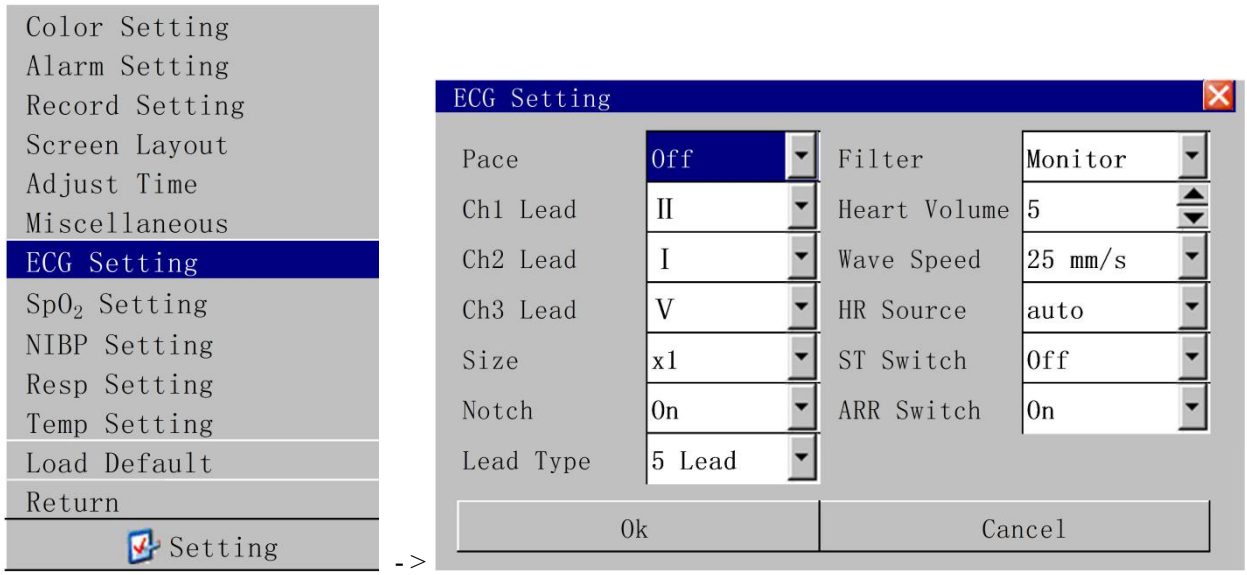
● The function of ST analysis is optional. In the factory configuration, ST analysis is disabled.
● The ST measurement points need to be adjusted when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly.
● Artifactual ST segment depression or elevation may occur if the ISO or the ST point is incorrectly set.
● Abnormal QRS complex is not considered in ST analysis.

8.6 Arrhythmia Monitoring

8.6.1 ARR Display

8.6.2 ARR Setting

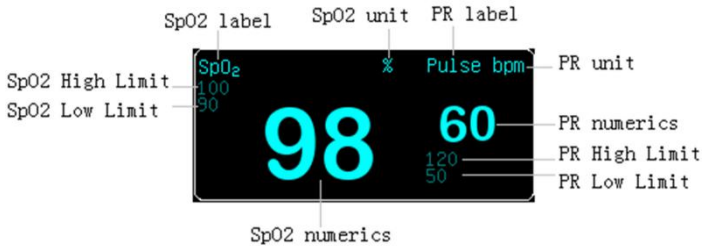
1. Rotate the knob to select “ECG Setting” in “Setting” menu.
2. Press the knob to enter the window of “ECG Setting”.
3. Select “On” from the list of “ARR Switch” and confirm by “Ok”. Arrhythmia monitoring is activated.

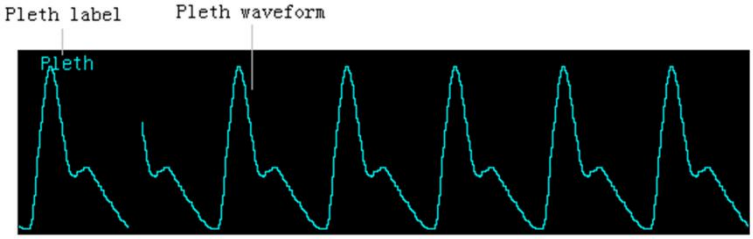


9 SpO2 Monitoring

9.1 SpO2 Display

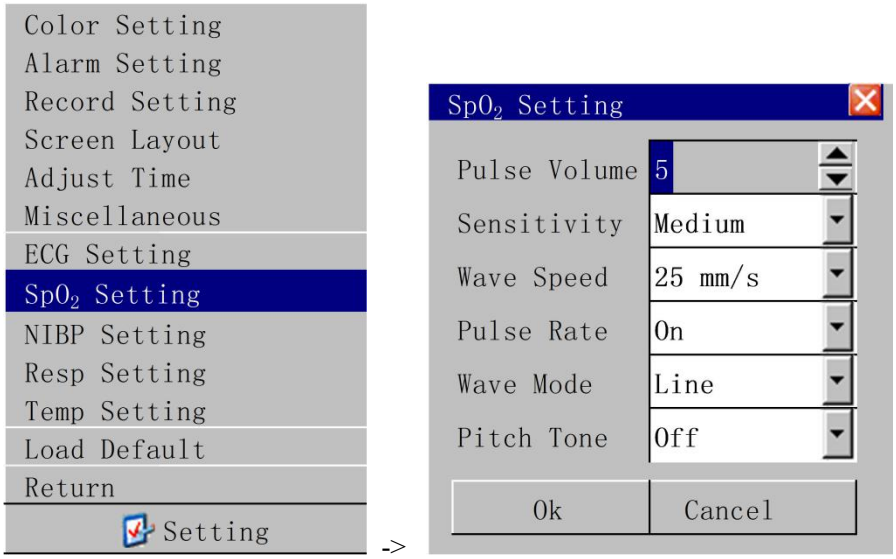
The Oxygen Saturation (SpO_2) parameter measurement the artery blood oxygen saturation, it is the percentage of the oxygen gathers hemoglobin .For example, if in the artery blood red blood cell, 97% hemoglobin combine with the oxygen, then this blood has 97% oxygen saturation, the value reading on the monitor should be 97%, this value demonstrated the percent of the carry oxygen hemoglobin molecule which forms the oxygen gathers hemoglobin.





9.2 SpO2 Setting

1. Rotate the knob to select “SpO2 Setting” in “Setting” menu.
2. Press the knob to enter the window of “SpO2 Setting”.



SpO₂ Setting	
Pulse Volume	0~10
Sensitivity	High, Medium, Low
Wave Speed	12.5mm/s, 25mm/s

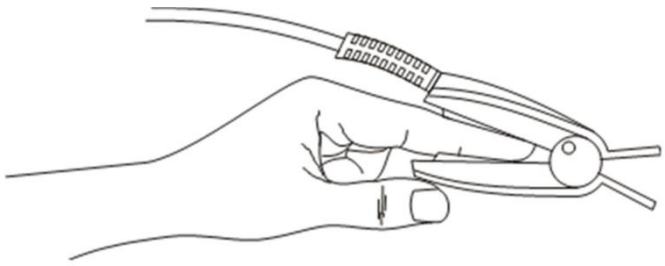
Pulse Rate	Off / On
Wave Mode	Line, Fill
Pitch Tone	Off / On

⚠ **WARNING** ⚠

● If it has the carbon oxygen hemoglobin, metahemoglobin or dye dilution chemicals, then the oxygen saturation value can have the deviation;
● Electricity surgical department equipment electric cable cannot twine with the sensor cable in the same place;
● Do not place the sensor at the body has the ductus arteriosus or the vein syringe;
● Guarantees the nail to block the lights. Sensor should at the back of hand;
● Do not place SpO_2 or the blood pressure oversleeve blood pressure measurement on the same body, because in the blood pressure measurement process the blood stream unenlightened can affect the oxygen saturation reading;
● Continually, the excessively long time monitor possibly can increase do not hope danger that the skin characteristic change occurs, for example exceptionally sensitive, changes red, bubbles or pressure necrosis, specially in the neonate or has pour barrier as well as the change or juvenility skin kind sickness person;
● In the long time continuous monitoring process, about every 2 hours inspects the measurement SpO_2 the end circulation situation and the skin situation, if discovered changes not good, should change the measurement SpO_2 promptly, simultaneously should periodical inspection the sensor fastness situation, avoids the sensor fastness situation change caused by the moving and so on the factors affect the accuracy of the measurement;
● If the test SpO_2 and the sensor cannot locate accurately, possibly causes the oxygen saturation reading inaccurate, even unable to search the pulse wave result in unable to carry on the blood oxygen monitor, this time should relocate;
● Measurement SpO_2 move excessively possibly creates measurements inaccurate, this time should cause the patient peaceful or the replacement measurement SpO_2, reduces the influence of moves excessively to the measurement.

9.3 SpO2 Monitoring Procedure

9.3.1 Finger Sensor Placement



1. Power on the monitor.
2. Select the proper sensor according to patient type.
3. Attach the sensor to the proper site on the patient.
4. Plug the connector of the sensor extension cable into the SpO2 connector on monitor.

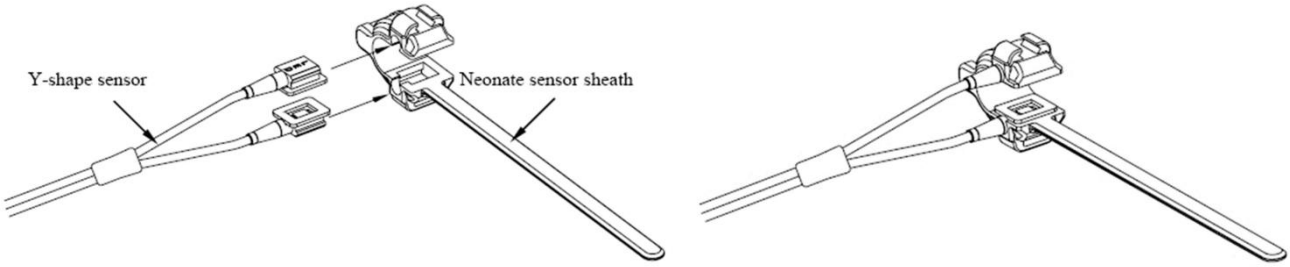
⚠ **NOTE** ⚠

● Place the SpO2 sensor cable at the backside of the patient hand. Make sure the fingernail is just opposite to the light emitted from the sensor.

9.3.2 Neonate SpO2 Plethysmography Measurement

Neonate SpO2 sensor consists of a Y-shape SpO2 sensor and its sheath. Insert the LED and PD ends of the Y-shape SpO2 sensor respectively into the upper and lower grooves on the sheath (Figure 7-2). The Figure 7-3 shows us the neonate SpO2 sensor after insertion.

(1) **(2)**



9.3.3 Neonatal Oxygen Probe Placement

Wind the SpO2 sensor around a hand or foot of a neonate patient. Hold the sensor, pull the belt and fit one of its sides with “V” edge into the “V” groove on the corresponding side of the sheath. Appropriately elongate the belt to about 20mm, and fit the “V” edge of the other side of the belt into the “V” groove of the other side of the sheath. Then, loosen the belt. After the “V” edges of the two sides of the belt fit well into the “V” grooves on the two sides of the sheath, put the belt into the first lock bar to fasten the belt. If the belt is too long, you may put it into the second lock bar. You must position the SpO2 sensor in this way so as to make the photoelectric component face the correct position. Besides, note not to elongate the belt too much, which may lead to inaccurate measurement and block the blood circulation severely.

⚠ **NOTE** ⚠

● No calibration curve for the pulse oximeter.
● No normalization for the waveform.
● If the sensor cannot be positioned accurately to the part to be measured, it may result in inaccurate SpO2 reading, or even that the SpO2 cannot be measured because no pulse is detected. If this is true, you must position the sensor again.
● The excessive patient movement may result in inaccurate reading. In this situation, you must keep the patient quiet or change the part for monitoring to reduce the adverse influence of excessive movement.
● Function tester cannot evaluate the accuracy of the probe and the patient monitor.

Special use for the probe:

Patient Type	**Adult**	**Pediatric**	**Neonate**
Age	≧18years	1month-12years	≦28days
Weight	>30 kg	10-50 kg	2.5-4 kg

Type of the probe	Finger type for adult	Finger type for Pediatric	Tied type for neonate
Sensor position	Finger	Finger	Palm or leg
Application condition	Normal temperature，check the peripheral circulation and the skin every 2 hours, keep the patient quiet.	Normal temperature，check the peripheral circulation and the skin every 2 hours, keep the patient quiet.	Normal temperature，check the peripheral circulation and the skin every 2 hours, keep the patient quiet.

⚠ **WARNING** ⚠

● The probe should be non-poisonous.

● In the process of extended and continuous monitoring, you should check the peripheral circulation and the skin every 2 hours. If any unfavorable changes take place, you should change the measured position in time.

● In the process of extended and continuous monitoring, you should periodically check the position of the sensor. In case that the position of the sensor moves during monitoring, the measurement accuracy may be affected.

The temperature of the probe should be less than 41℃, otherwise the patient will be burned.

9.4 Measurement Restrictions

In the operating process, following factors may affect the accuracy of the oxygen saturation measurement:

1) High-frequency electrical jam, such as the disturbance which is produced by monitor system oneself or comes from such as the electricity surgery instrument disturbance which connected with the system;

2) In magnetic resonance image formation scanning (MRI) period do not use the blood oxymeter and the blood oxygen sensor, the induced current possibly can cause the burn;

3) In vein dye;

4) Patient too frequently migration;

5) Outside ray radiation;

6) Sensor installment inappropriate or contact the improper position with the object;

7) Body temperature (best body temperature should in 28℃- 42℃);

8) Lay aside the sensor in the body has the blood pressure cuff, in the ductus

9) Arteriosus or the cavity on the pipeline body;

10) The density of the non- function hemoglobin like carbon oxygen hemoglobin (COHb) and blood and iron hemoglobin (MetHb) and so on;

11) Oxygen saturation lowly;

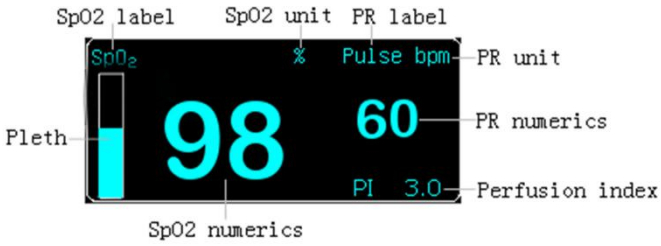
To be circular poured is not good at the test part;

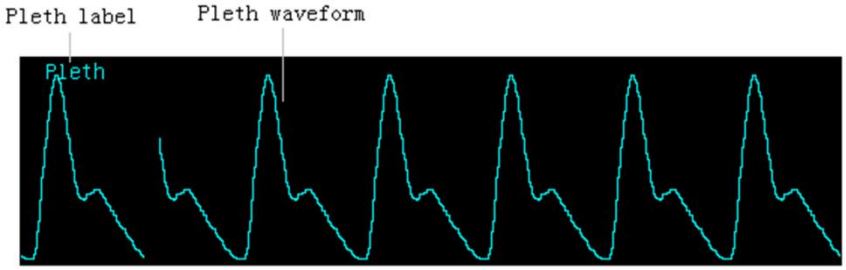
Shock, anemia, the low temperature and applies the vasoconstriction medicine and so on all possibly cause the artery blood stream to be reduced to the level which was unable to measurement;

12) Measurement is also decided on the oxygen gathers hemoglobin and the absorption situation of the return oxygen gathers hemoglobin to the special wave length light. If other substances which absorb the same wave length light exist, they can cause the measurement to appear pseudo or the low oxygen saturation value. For example: Carbonizes the hemoglobin, the blood and iron hemoglobin, the methylene blue, indigo carmine.

9.5 Masimo SpO2 Monitoring (optional)

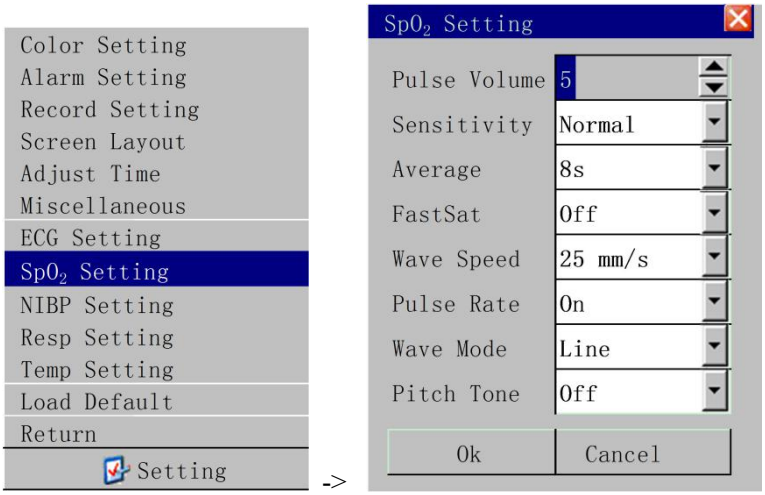
9.5.1 Masimo SpO2 Display





9.5.2 Masimo SpO2 Setting

1. Rotate the knob to select “SpO2 Setting” in “Setting” menu.
2. Press the knob to enter the window of “SpO2 Setting”.



Masimo SpO2 Setting	
Pulse Volume	0~10
Sensitivity	Max, Normal, APOD
Average	2-4s, 4-6s, 8s, 10s, 12s, 14s, 16s
FastSat	Off / On
Wave Speed	12.5mm/s, 25mm/s
Pulse Rate	Off / On
Wave Mode	Line, Fill
Pitch Tone	Off / On

■ **Pulse Volume**

■ **Sensitivity**

Max: the patient monitor is more sensitive to minor signals. When monitoring critically ill patients whose pulsations are very weak, it is strongly recommended that the sensitivity is set to “Maximum”.

Normal: When monitoring neonatal or non-critically ill patients who tends to move a lot, noise or invalid signals may be caused. In this case, it is recommended that the sensitivity is set to “Normal” so that the interference caused by movement can be filtered and therefore the measurement stability can be ensured.

APOD: Masimo Adaptive Probe-Off Detection Technology

■ **Average**

Determines the average SpO2 calculation time.

■ **FastSat**

FastSat enables rapid tracking of arterial oxygen saturation changes, making Masimo SET the highest fidelity pulse oximetry available today.

Rapid changes in arterial oxygen saturation are typically 'smoothed-out' by pulse oximeter averaging algorithms, yielding blunted readings. FastSat captures and reports these rapid oxygen saturation changes.

■ **Wave Speed**

Waveform speed

■ **Pulse Rate**

■ **Wave Mode**

■ **Pitch Tone**

SpO2 and PR alarm limits

Parameter	Max. upper limit	Min. lower limit	Step
SpO2	100	0	1
PR	240	25	1

The default SpO2 and PR alarm limits

Parameter	Patient type	Upper limit	Lower limit
SpO2	Adult	100	90
	Pediatric	100	90
	Neonate	95	80
PR	Adult	120	50
	Pediatric	160	75
	Neonate	200	100

⚠ **WARNING** ⚠

● Setting the SpO2 upper alarm limit to 100% will disable the upper alarm limit. High oxygen levels may predispose a premature infant to retrolental fibroplasia. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accordance with the commonly accepted clinical practices.

9.5.3 Masimo SpO2 Monitoring Procedure

⚠ **NOTE** ⚠

● **This section is only applicable to the monitor equipped with a Masimo SpO2 module.**

9.5.3.1 Principle of Operation

The Masimo SET® MS board pulse oximeter is based on three principles:
1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
2. The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).
3. Arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse.

The Masimo SET MS board pulse oximeter as well as traditional pulse oximetry determines SpO2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 905 nm:

$$S(660) = AC(660)/DC(660)$$
$$S(905) = AC(905)/DC(905)$$

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

$$R = S(660)/S(905)$$

This value of R is used to find the saturation SpO2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The Masimo SET MS board pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. MS board decomposes S(660) and S(905) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

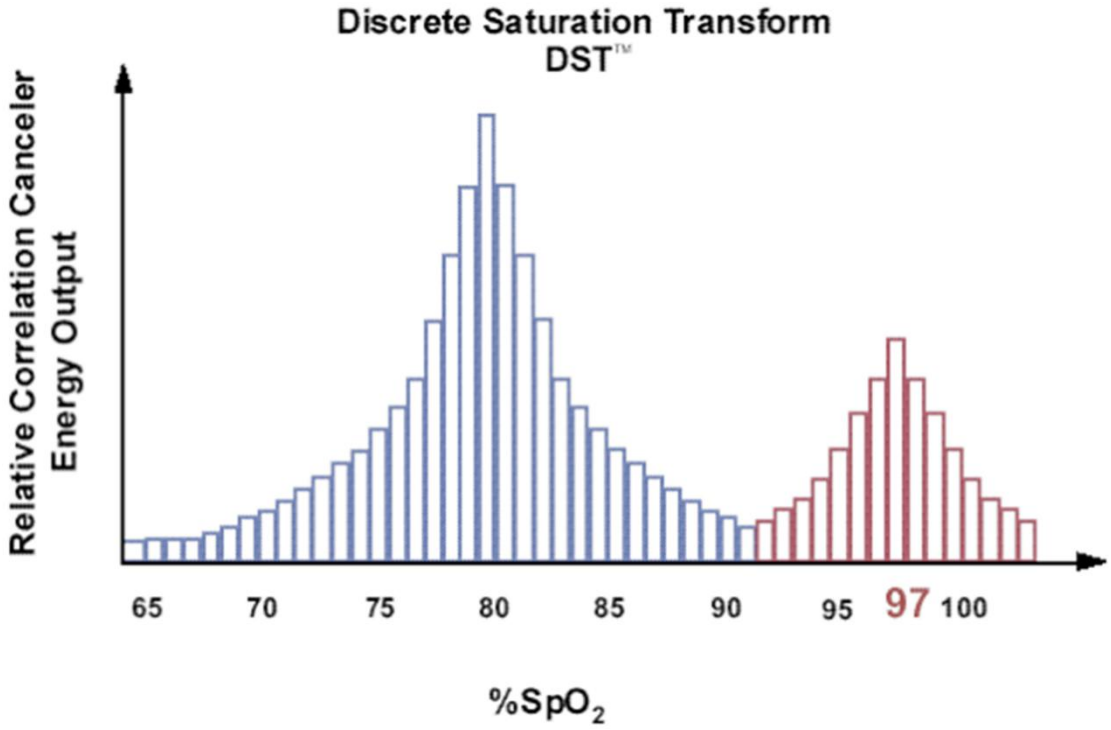
$$S(660) = S1 + N1$$
$$S(905) = S2 + N2$$
$$R = S1/S2$$

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The above equations are combined and a noise reference (N') is determined:

$$N' = S(660) - S(905) \times R$$

If there is no noise N' = 0: then S(660) = S(905) x R which is the same relationship for the traditional pulse oximeter. The equation for the noise reference is based on the value of R, the value being seeked to determine the SpO2. The MS board software sweeps through possible values of R that correspond to SpO2 values between 1% and 100% and generates an N' value for each of these R-values. The S(660) and S(905) signals are processed with each possible N' noise reference through an adaptive correlation canceler (ACC) which yields an output power for each possible value of R (i.e., each possible SpO2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possible SpO2 value as shown in the following figure where R corresponds to SpO2 = 97%:



The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The SpO2 value therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

9.5.3.2 Precautions

⚠ **WARNING** ⚠

● The pulse oxymeter should NOT be used as an apnea monitor.
● 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.
● If an alarm condition (other than exceptions listed herein) occurs in the Alarms Silenced status, the monitor only gives visual alarm symbols.
● Measure the monitor's leakage current whenever an external device is connected to the serial port. Leakage current must not exceed 100 microamperes.
● To ensure patient electrical isolation, connect only to other equipment with electronically isolated circuits.
● Do not connect to an electrical outlet controlled by a wall switch or dimmer.
● Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
● Interfering Substances: Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.
● Do not use this instrument and the sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
● The SpO2 value might be overestimated in the presence of Hb-CO, Met-Hb or dye dilution chemicals.
● Verify sensor cable fault detection before beginning monitoring. Unplug the SpO2 sensor cable from the connector. The screen displays the prompt information "SPO2 SENSOR OFF" and the audible alarm is activated.

● Do not use the supplied sterile SpO2 sensors if the packaging or the sensor is damaged. Return them to the distributor or manufacturer.
● Do not perform SpO2 and NIBP measurements on the same limb simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO2 value.
● Prolonged and continuous monitoring may increase the risk of burns at the site of the sensor. It is especially important to check the sensor placement, and ensure proper attachment on neonates and patients of poor perfusion or skin sensitive to light. Check the sensor location every 2–3 hours and move to another location if the skin deteriorates. More frequent examinations may be required for different patients.

⚠ **NOTE** ⚠

● Place the SpO2 sensor cable at the backside of the patient hand. Make sure the patient nail is just opposite to the light emitted from the sensor.

9.5.3.3 Basic Steps

1. Power on the monitor.
2. Attach the sensor to the proper site on the patient.
3. Plug the connector of the sensor extension cable into the SpO2 connector on monitor.

The process of SpO2 plethysmogram measurement is generally the same. But the SpO2 sensor selection and placement depend on the patient type. When choosing a site for a sensor, refer to the directions for that sensor.

9.5.4 Measurement Limitations

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by an alternate method. Then check the instrument for proper function. Inaccurate measurements may be caused by:
■ Incorrect sensor application or use;
■ Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methemoglobin);
■ Intravascular dyes such as indocyanine green or methylene blue;
■ Exposure to excessive illumination, such as surgical lamps (especially ones
■ With a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark material);
■ Excessive patient motion;
■ Venous pulsations;
■ Placement of a sensor on the same extremity with a blood pressure cuff, arterial catheter, or intravascular line;
■ The monitor can be used during defibrillation. However, the readings may take a short period of time to return to normal.

Loss of pulse signal can occur in the following situations:
■ The sensor is too tight;
■ There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight;
■ A blood pressure cuff is inflated on the same extremity as the one with a SpO2 sensor attached;
■ The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
■ There is arterial occlusion proximal to the sensor;
■ The patient is in cardiac arrest or is in shock.

9.5.5 Sensors and Accessories

If your monitor is equipped with a Masimo SpO2 module, use only Masimo oximetry sensors for SpO2 measurements. Other sensors may cause improper pulse oximeter performance. Before use, carefully read the directions for the LNOP sensor. Tissue damage can be caused by incorrect application or use of a sensor. An example is wrapping the sensor too tightly. Inspect the sensor site as specified in the directions to ensure skin integrity, correct positioning, and adhesion of the sensor.

⚠ **CAUTION** ⚠

● Do not use damaged sensors. Do not use a sensor with exposed optical components. Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide.

● Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide.

9.5.5.1 Selecting a Masimo sensor

When selecting a sensor, consider, the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. For more information refer to the following table or contact Masimo. Use only Masimo sensors and sensor cables. Select an appropriate sensor, apply as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with dark, opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

Sensor	**Usage**	**Patient weight (W)**
LNOP ADT	Disposable	Adult W>30 kg
LNOP PDT	Disposable	Adult 10kg<W<50kg
LNOP NEO	Disposable	Neonate W<10kg
LNOP NEO PT	Disposable	Neonate W<1kg or patient with poor skin integrity
LNOP DCI	Reusable	Adult and pediatric W>30kg
LNOP DCIP	Reusable	Pediatric 10kg<W<50kg
LNOP DCSC	Reusable	Adult and pediatric W>30kg
LNOP EAR	Reusable	Adult and pediatric W>30kg
LNOP YI Multisite	Reusable	Adult, pediatric, infant and neonate W>1 kg

9.5.5.2 Selecting Masimo Sensor Cables

Only use Masimo oximetry patient cables for SpO2 measurements. Other patient cables may cause improper pulse oximeter performance.

Reusable patient cables of various lengths are available. All cables that marked by the Masimo SET logo are designed to work with any Masimo LNOP sensor, and with any pulse oximeter or multi-parameter instrument marked by the Masimo SET logo.

⚠ **NOTE** ⚠

● Carefully route patient cables to reduce the possibility of patient entanglement or strangulation.
● If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.

9.5.5.3 Cleaning and Reusing a Masimo LNOP Sensor

Reusable sensors can be cleaned per the following procedure:
1. Remove the sensor from the patient.
2. Disconnect the sensor from the monitor.
3. Wipe the entire sensor with a 70% isopropyl alcohol pad, and clean with a dry cloth.
4. Allow the sensor to air-dry before returning it to operation.

This method can be used to clean emitting and receiving parts too. The cables should be cleaned with a 3% Hydrogen peroxide, a 70% isopropyl alcohol or other solutions. Keep the cleaning solution away from the sensor connections.

Reattaching a Disposable Adhesive Sensor:
■ LNOP single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin;
■ The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol wipe and allowing the sensor to thoroughly air-dry prior to replacement on the patient.

⚠ **WARNING** ⚠

● To avoid cross contamination only use Masimo LNOP disposable sensors on the same patient.
● Before cleaning the monitor or the sensor, make sure the equipment is switched off and disconnected from AC power.

⚠ **CAUTION** ⚠

● Do not reuse Masimo LNOP disposable sensors.
● Do not soak or immerse patient cables in any liquid solution. Do not sterilize patient cables by irradiation steam or ethylene oxide. See the cleaning instructions for use for reusable Masimo patient cables.

9.5.6 Masimo Information

The MASIMO SET® Product

1. Masimo Patents

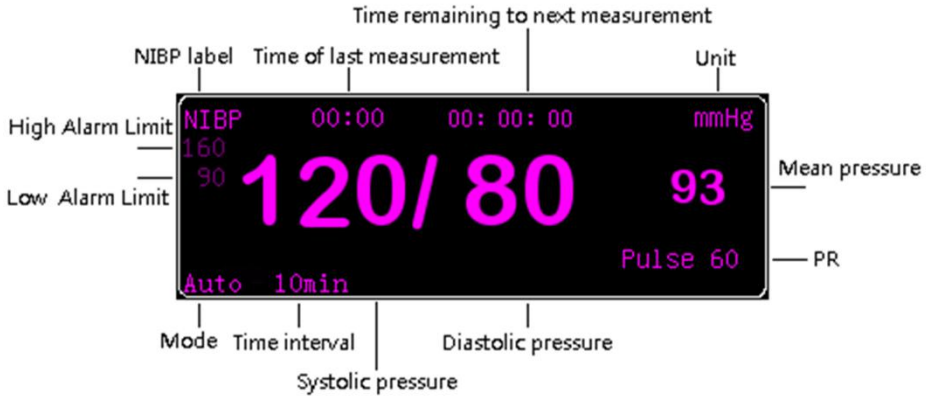
Patents: www.masimo.com/patents.htm

2. No Implied License

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

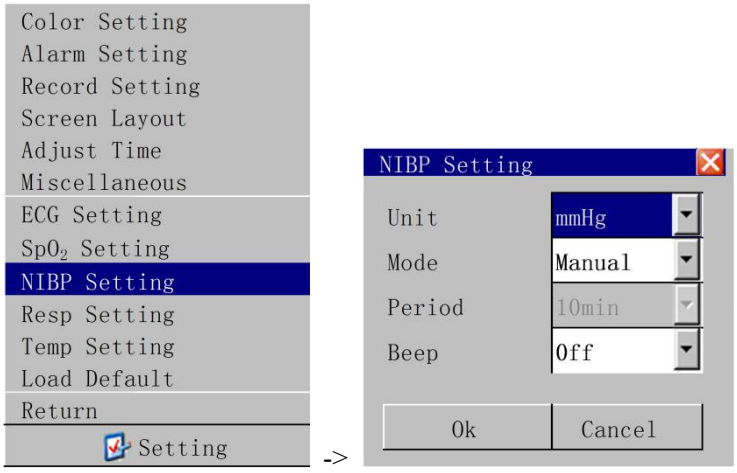
10 NIBP Monitoring

10.1 NIBP Display



10.2 NIBP Setting

1. Rotate the knob to select “NIBP Setting” in “Setting” menu.
2. Press the knob to enter the window of “NIBP Setting”.



■ Unit: Blood pressure unit

■ Mode

Manual: Measurement on demand; Auto: Continually repeated measurements at set intervals; Stat: A continuous measurement for five minutes.

■ Period

Period is adjustable only when mode is “Auto”. Different time intervals can be selected to determine the interval between automatic measurements.

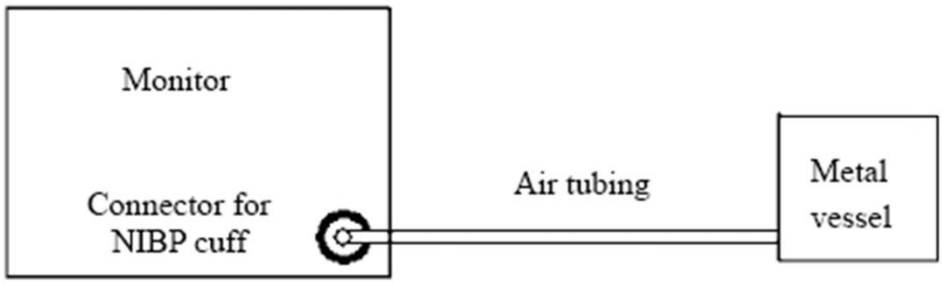
■ Beep

On: The monitor will have a beep “DO” when NIBP monitoring is finished; Off: The monitor will not have a beep “DO” when NIBP monitoring is finished.

NIBP Setting	
Unit	mmHg, kPa

Mode	Aanual, Auto, Stat
Period	Off, 1min, 2min, 3min, 4min, 5min, 10min, 15min, 30min, 60min, 90min, 2hour, 3hour, 4hour, 8hour
Beep	Off / On

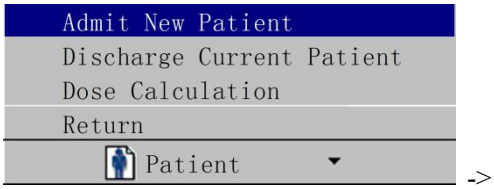
10.3 NIBP Pneumatic Test



1. Set Patient Type to Adult.

a. Rotate the knob to select “Admit New Patient” in “Patient” menu.

b. Press the knob to enter the window of “Patient Info”. Select “Adult” from the list of “Patient Type” and confirm by “Ok”



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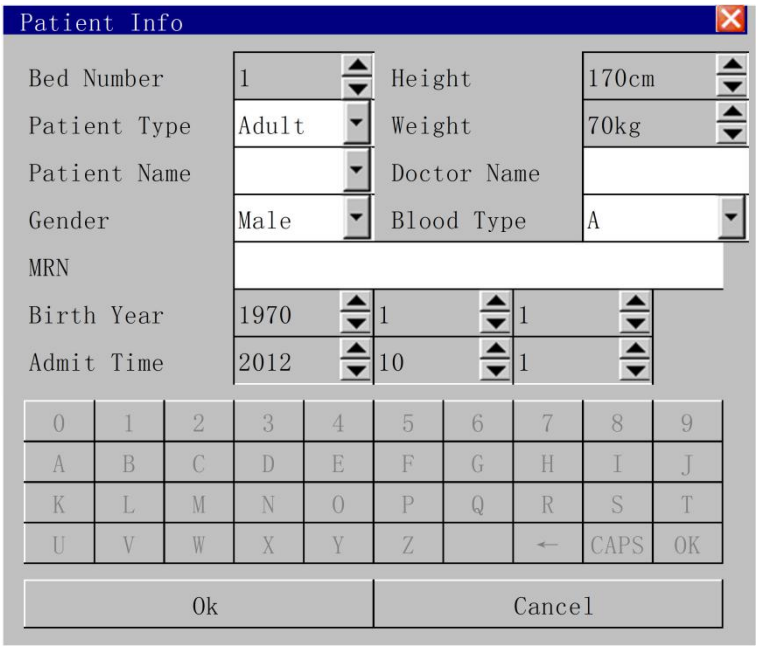
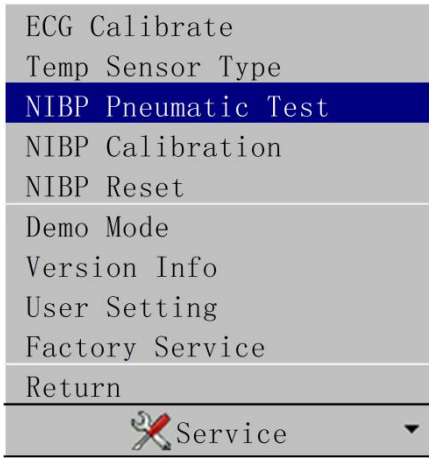
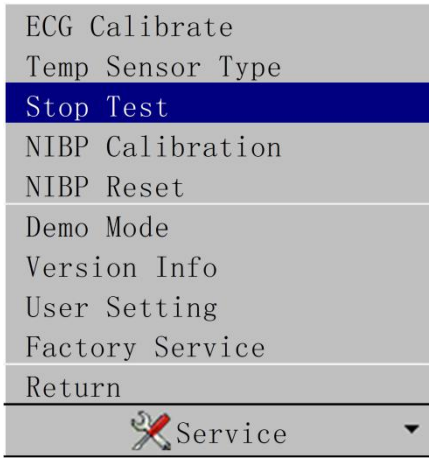


2. Connect a rigid metal container or vessel (with a capacity of 500 ml ± 5%) to the NIBP cuff connector of the monitor.

3. Rotate the knob to select “NIBP Pneumatic Test” in “Service” menu. Press the knob. The monitor begin to have a NIBP Pneumatic Test. After approximately 20 seconds, the monitor will automatically open the deflate valve, ending the test. If there is a failure, contact our Customer Service.



4. Rotate the knob to select “Stop Test” in “Service” menu. Press the knob. The monitor will stop the NIBP Pneumatic Test. Or press the “NIBP” button on the control panel. The monitor will stop the NIBP Pneumatic Test.



⚠ **WARNING** ⚠

● Can’t carry on the noninvasive blood pressure on the patient who have the sickle cell anemia or have the skin disrepair or will have damage.

● To the patient who has the serious hemoglutination machine-made barrier, must according to the clinically appraise decided whether carries on the automatic blood pressure measurement, because the place where the body and the cuff friction will has have the haematoma danger.

● Before start the measurement, you must confirm the patient type is correct(adult, pediatric, neonate).

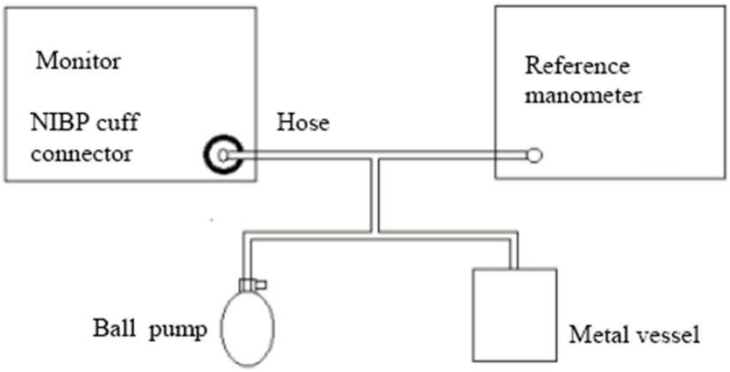
● Do not enwind the cuff to the body have the venous transfusion or inserted the drive pipe, while cuff charging period, when the transfusion reduces speed or stops up, possibly causes damage around the drive pipe.

● If the time of the automatic pattern noninvasive blood pressure measurement pull too long, then the body connected with the cuff possibly have the purpura, lack the blood and the neuralgia. When guarding patient, must inspect the luster, the warmth and the sensitivity of the body far-end frequently. Once observes any exception, please immediately stop the blood pressure measurement.

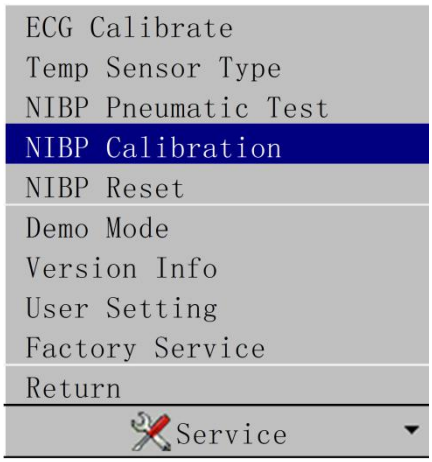
● The calibration of the noninvasive blood pressure measurement is supposed to be carried on one time every year. (Or according to the maintenance regulation of your hospital).

● The cuff width should be 40% size of the body perimeter. (Neonate is 50%), or the 2/3 of the upper arm length. The length of the cuff charging part should long enough surround 50~80% of the body, the inappropriate size cuff can have the wrong reading. If the cuff size has the question, should use the bigger cuff to reduce the mistake.

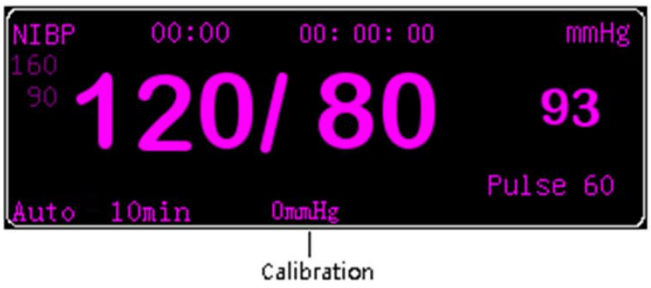
10.4 NIBP Calibration



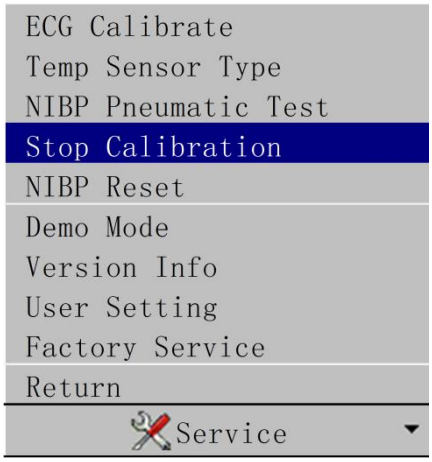
1. Connect a rigid metal container or vessel (with a capacity of 500 ml ± 5%) to the NIBP cuff connector of the monitor.
2. Connect a calibrated reference manometer (with an error less than 1mmHg) and a ball pump using “T” connectors as shown.
3. Rotate the knob to select “NIBP Calibration” in “Service” menu and press the knob.



5. The indicated pressure of the monitor will appear in the NIBP parameters displayed area on the screen.



4. Inflate the metal container by using the ball pump until the reference manometer reads 0, then 50, and finally 200 mmHg.
5. The difference between the indicated pressure of the reference manometer and the indicated pressure of the monitor will not exceed 3 mmHg. Contact our Customer Service if these values are not met.
6. Rotate the knob to select “Stop Calibration” in “Service” menu. Press the knob. The monitor will stop the NIBP calibration. Or press the “NIBP” button on the control panel. The monitor will stop the NIBP calibration.

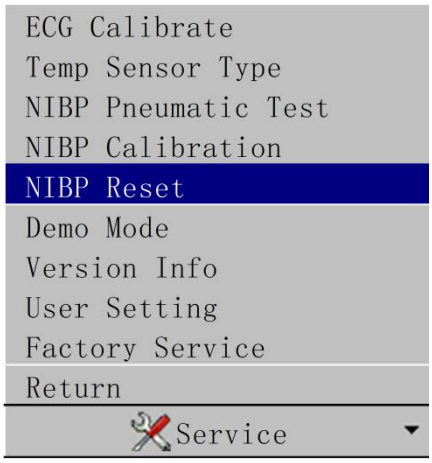


⚠ **NOTE** ⚠

● The calibration of the NIBP measurement should be performed every two years or performed according to the Hospital Procedure.

10.5 NIBP Reset

1. If the monitor fails to give a visual indication when the pressure pump is working improperly, have a NIBP Reset to activate a self-test procedure, and restore the monitor to normal performance.
2. Rotate the knob to select “NIBP Reset” in “Service” menu. Press the knob. The monitor will restore the initial settings of the pressure pump.



10.6 NIBP Monitoring Procedure

⚠ **WARNING** ⚠

● Use accessories specified by manufacturer only, otherwise; the device may not function normally.

⚠ **WARNING** ⚠

● Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric or neonate.)
● Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

⚠ **WARNING** ⚠

● Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.

⚠ **NOTE** ⚠

● The blood pressure of the patient as the basis for establishing therapy may be obtained by using other method such as the cuff/stethoscope auscultation method. Accordingly, the clinical doctor must note that the values obtained by using other method and UN-8000S may be different.

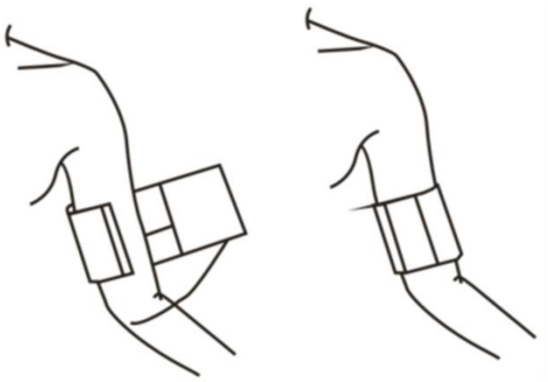
⚠ **NOTE** ⚠

● NIBP monitoring uses the oscillometric method of measurement. Blood pressure determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method and an intra-arterial blood pressure measurement device, within the limits prescribed by the ANSI/AAMI SP10.
The initial air inflation is 160mmHg for adult, 120 mmHg for pediatric and 70 mmHg for neonate.

⚠ **NOTE** ⚠

● This equipment is suitable for use in the presence of electro-surgery.

1) Insert the gas tube into the blood pressure socket of the monitor;
2) Tie the blood pressure cuff on the patient upper arm or the thigh;
3) Use the suitable size cuff for the patient, guaranteed the symbol Φ is located above to the suitable artery.
Guarantee the cuff to twine the body is not too tight, otherwise possibly causes the body far-end to change color even lacks the blood;
4) Inspects the edge of the cuff to fall in the range signed <->.If it is not this, exchange a more appropriate cuff;
5) Confirm the cuff deflated completely;
6) Cuff and gaseous tube coupling. The body which will be measured should put in the same horizontal position with the patient heart. If it is unable to achieve, must use the following adjustment method to make the revision to the measurement result
If the cuff is higher than the heart horizontal position, each centimeter disparity should add 0.75mmHg(0.10kPa) in the value.
If the cuff is lower than the heart horizontal position, each centimeter disparity should reduce 0.75mmHg(0.10kPa) in the value.
7) Confirm the patient type whether correct (patient type shows in the block of information on the monitor, the right side of bed number), if needs to change the patient type, please enter “the patient information” window, change “the patient type”;
8) Press down the blood pressure measurement button on the front panel, start to measures the blood pressure.



⚠ **NOTE** ⚠

● The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, then use a larger cuff.

⚠ **NOTE** ⚠

● For Neonate measurement, the maximum pressure of the cuff is 147mmHg. The maximum pressure is 140mmHg when the cuff is used normally. The initial inflating pressure of the cuff is 70mmHg during measurement.

Size of reusable cuff for neonate/children/adult

Patient Type	Limb perimeter	Cuff width	Hose
Neonate	10 ~19 cm	8 cm	1.5 m or 3 m
Pediatric	18 ~ 26 cm	10.6 cm	
Adult 1	25 ~ 35 cm	14 cm	
Adult 2	33 ~ 47 cm	17 cm	
Thigh	46 ~ 66 cm	21 cm	

Size of disposable cuff for neonate/children/adult

Size No.	Limb perimeter	Cuff width	Hose
1	3.1 ~ 5.7 cm	2.5 cm	1.5 m or 3 m
2	4.3 ~ 8.0 cm	3.2 cm	
3	5.8 ~ 10.9 cm	4.3 cm	
4	7.1 ~ 13.1 cm	5.1 cm	

10.7 NIBP Measurement Limits

This machine NIBP measuring technique is the vibration mothod, this kind of measuring technique basis has the certain limit according to difference metrical object. The user should realize at following several situations, the observed value changes unreliable, or the time measured press increases or the measurement is unable to carry on.

1) Patient movement: If the patient is moving, trembles or the convulsion;

2) Arrhythmia: the irregular heart beat caused by the arrhythmia;

3) Heart-lung machine: such as the patient uses the heart-lung machine connection;

4) Pressure variation: such as while in blood pressure measurement the patient blood pressure rapid change;

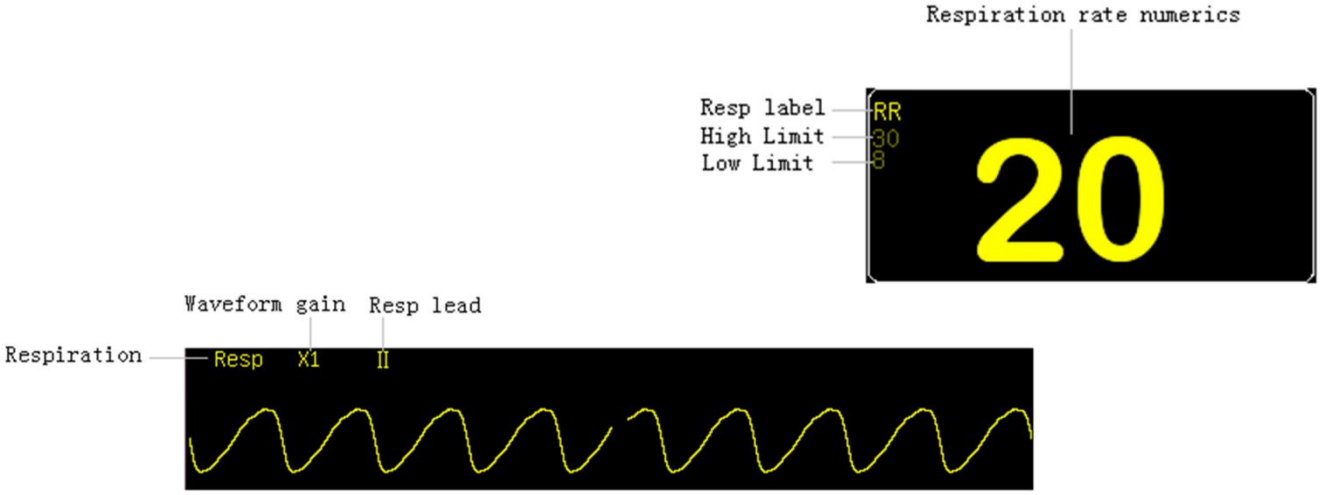
5) Serious shock: such as the patient is being in the serious shock or the hypothermia;

6) The heart rate exorbitant or lower: The heart rate is lower than 40bpm (heart beat/minute) and is higher than 240bpm (heart beat/minute), cannot carry on the blood pressure measurement;

7) Obese patient: The excessively thick fat stratum can reduce the accuracy of the measurement, because the fat can cause the artery pulse signal cannot arrive the cuff.

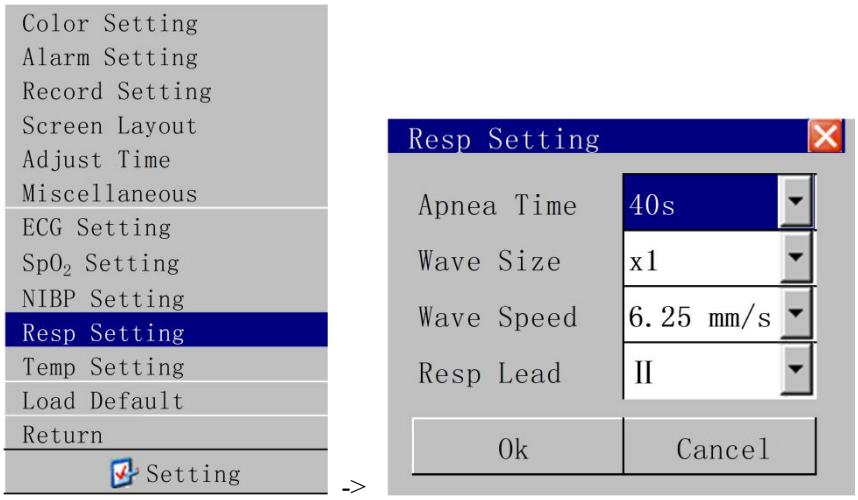
11 Resp Monitoring

11.1 Resp Display



11.2 Resp Setting

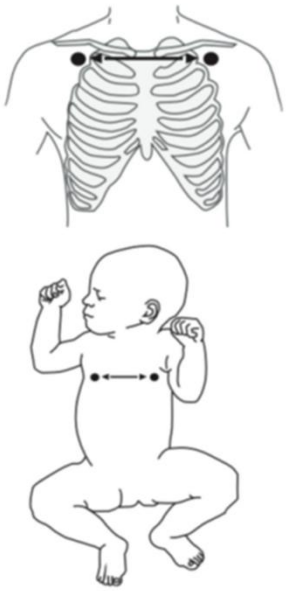
1. Rotate the knob to select “Resp Setting” in “Setting” menu.
2. Press the knob to enter the window of “Resp Setting”.



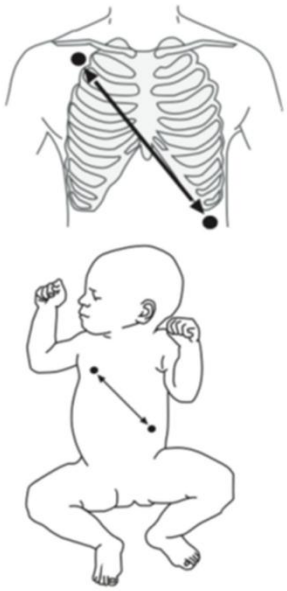
Resp Setting	
Apnea Time	Off, 10s, 15s, 20s, 25s, 30s, 35s, 40s
Wave Size	x0.25, x0.5, x1, x2, x4
Wave Speed	6.25 mm/s, 12.5 mm/s, 25 mm/s
Resp Lead	Ⅰ, Ⅱ

■ Apnea Time Determines whether the patient’s cessation of breath is an apnea event.
■ Wave Size Waveform gain.
■ Wave Speed Wave speed.
■ Resp Lead Respiration lead type.

11.3 Electrode Placement



Electrode Placement of ECG Lead I



Electrode Placement of ECG Lead II

⚠ **NOTE** ⚠

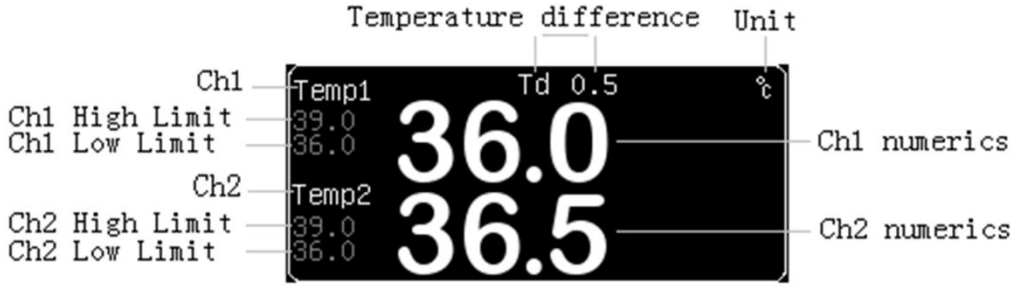
● Resp monitoring is not recommended on patient who moves a lot, because this possibly causes wrong alarm.

⚠ **NOTE** ⚠

● Place the RA and the LL electrode in the patient opposite angle of the body in order to obtain the best breath wave. Should avoid the liver area and the ventricle at the breath electrode's lines, this may avoid the false difference to be caused by the heart beat or pulsing blood stream, this is especially important to the neonate.

12 Temp Monitoring

12.1 Temp Display

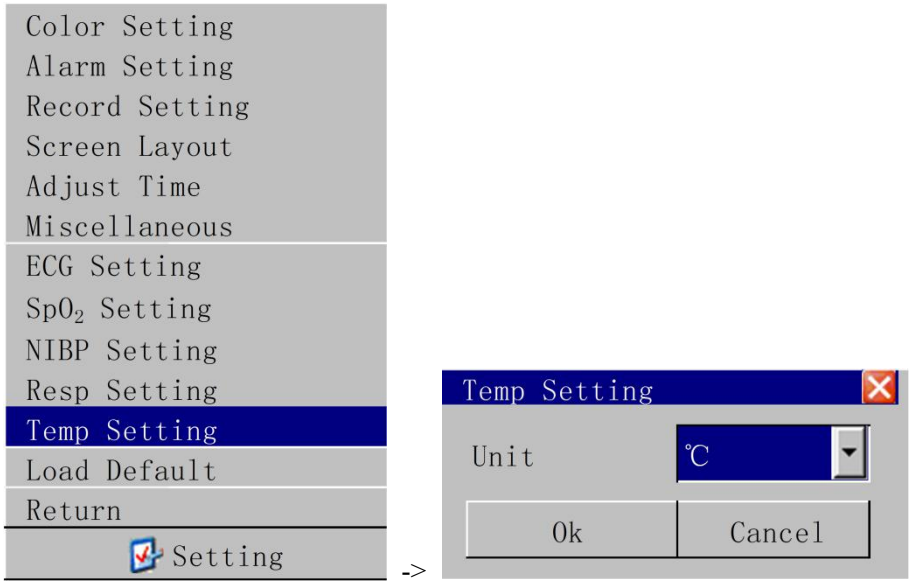


⚠ NOTE ⚠

● 7-inch and 10-inch have one channel temperature monitoring only.

12.2 Temp Setting

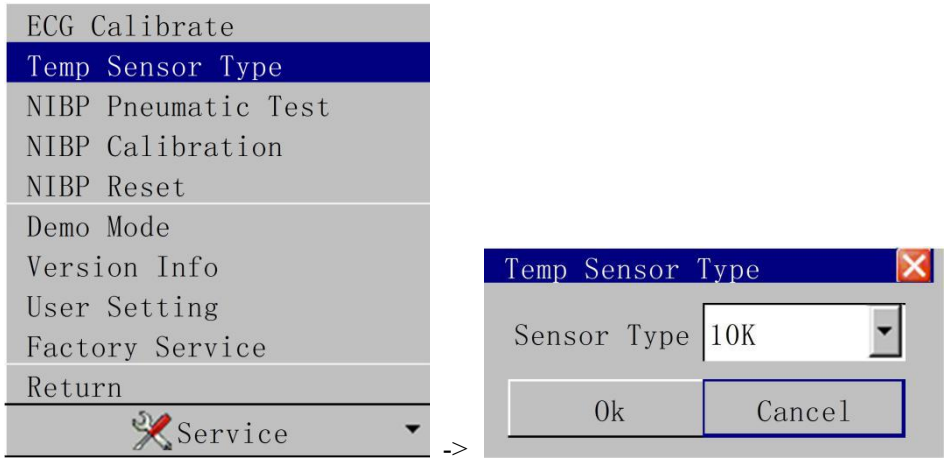
1. Rotate the knob to select “Temp Setting” in “Setting” menu.
2. Press the knob to enter the window of “Temp Setting”.



Temp Setting	
Unit	℃, ℉

12.3 Temp Sensor Type

1. Rotate the knob to select “Temp Sensor Type” in “Service” menu.
2. Press the knob to enter the window of “Temp Sensor Type”. Select the temperature sensor type from the list of “Sensor Type” and confirm by “Ok”.



Temp Sensor Type	
Sensor Type	2.25K, 10K

12.4 Measurement Procedure

1. Select an appropriate probe for your patient.
2. Plug the temperature cable to the temperature connector of the monitor. (If a disposable probe is used, connect the probe to the temperature cable. Then plug the temperature cable to the temperature connector of the monitor.)
3. Attach the probe to the patient correctly.
4. Power on the monitor.
5. Check that the temperature alarm settings are appropriate for your patient.

⚠ NOTE ⚠

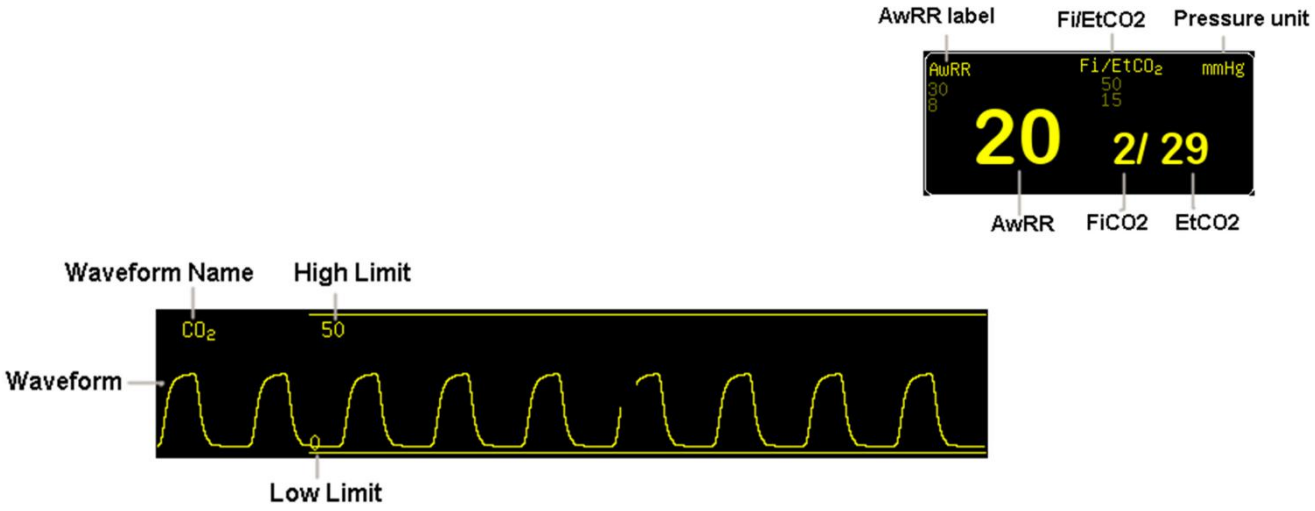
● The battery and single-use temperature probe should be recycled or destroyed according to regular rules.
● The measurement range is 0 to 50℃, the maximum permissible errors is ±0.1℃ (not including the probe) and ±0.2℃ (including the probe).
● The minimum time to get an accurate data is 150 seconds.

⚠ WARNING ⚠

● Before start to use the temperature measuring, please examine whether the sensor cable is normal. Unplug the temperature sensor cable from the socket, the screen will display the error message “Temp sensor off” and sends out the sound alarm.

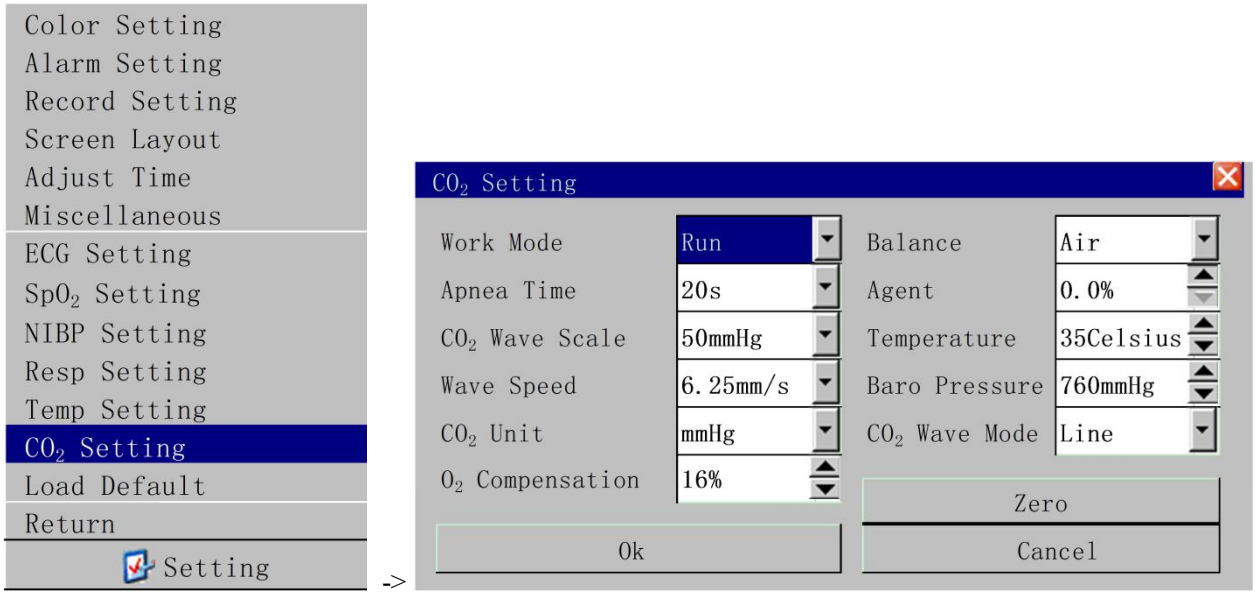
13 CO2 Monitoring (optional)

13.1 CO2 Display



13.2 CO2 Setting

1. Rotate the knob to select “CO2 Setting” in “Setting” menu.
2. Press the knob to enter the window of “CO2 Setting”.

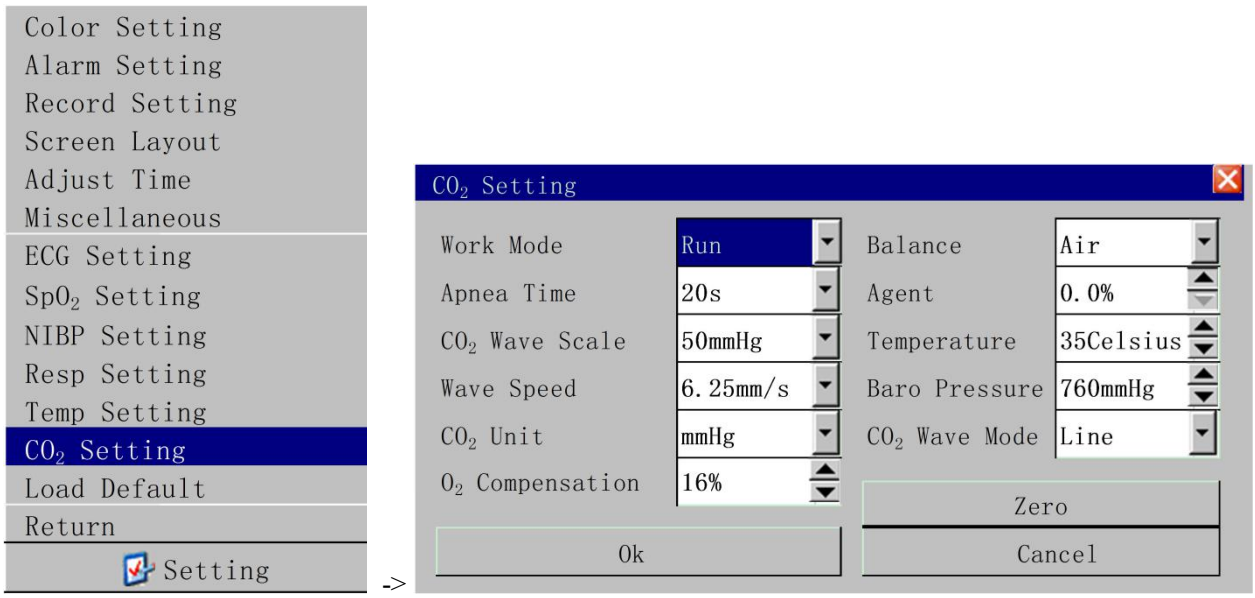


CO2 Setting	
Work Mode	Run, Stanby
Apnea Time	Off, 10s, 15s, 20s, 25s, 30s, 35s, 40s
CO2 Wave Scale	30mmHg, 40mmHg, 50mmHg, 60mmHg, 70mmHg, 80mmHg, 90mmHg, 100mmHg, 110mmHg, 120mmHg, 130mmHg, 140mmHg, 150mmHg
Wave Speed	6.25mm/s, 12.5mm/s, 25mm/s

CO_2 Unit	mmHg, kPa, %
O_2 Compensation	0% ~ 100%
Balance	Air, N_2O, Helium
Agent	0.0% ~ 20.0%
Temperature	0Celsius ~ 50Celsius
Baro Pressure	400mmHg ~ 850mmHg
CO_2 Wave Mode	Line, Fill

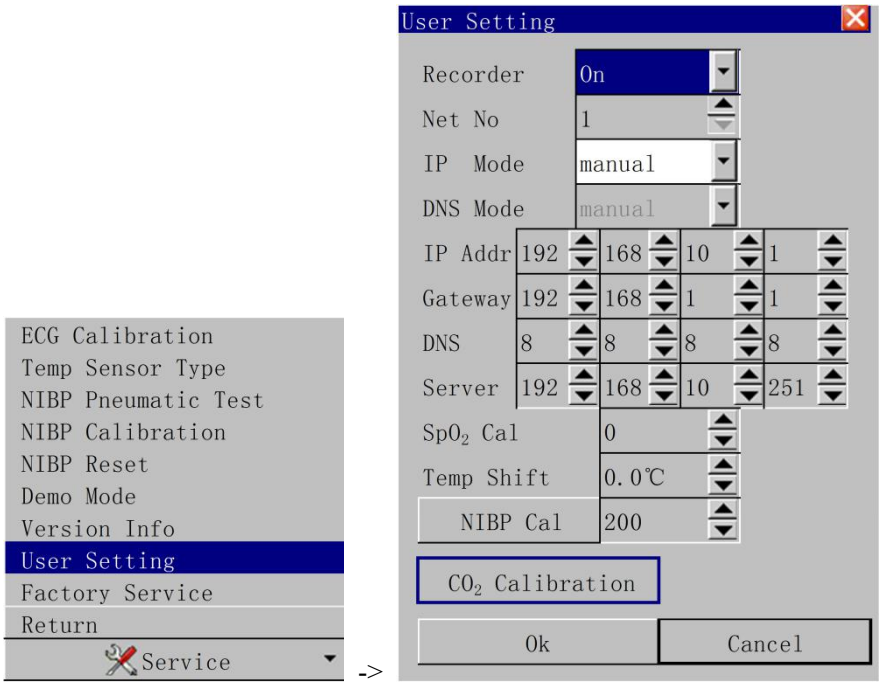
13.3 CO2 Zero

1. Rotate the knob to select “CO2 Setting” in “Setting” menu.
2. Press the knob to enter the window of “CO2 Setting”.
3. Select “Zero” and press the knob to activate a CO2 zero procedure.

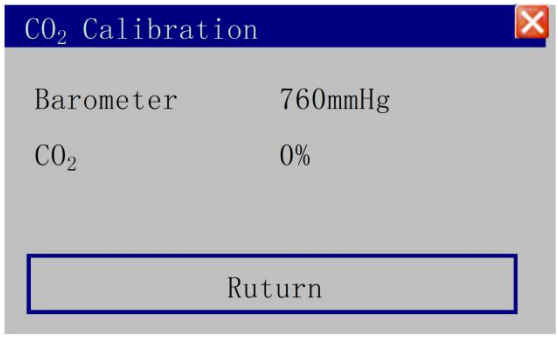


13.4 CO2 Calibration

1. Rotate the knob to select “User Setting” in “Service” menu.
2. Press the knob to enter the window of “User Setting”.

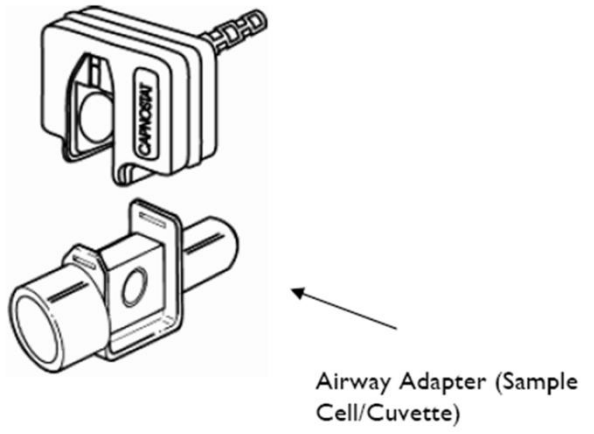


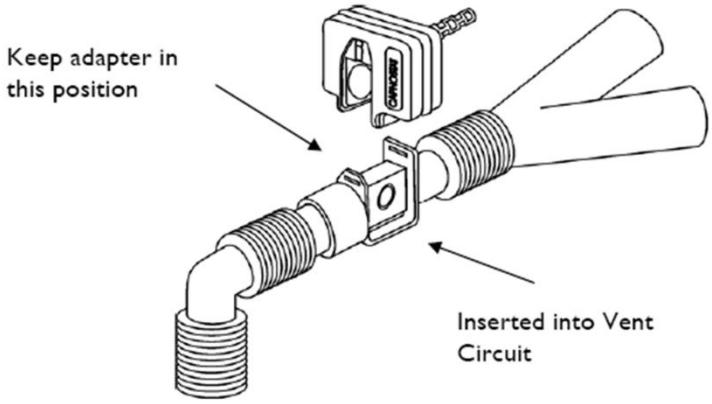
3. Select “CO2 Calibration”. Press the knob to activate a CO2 zero procedure or a CO2 calibration procedure.

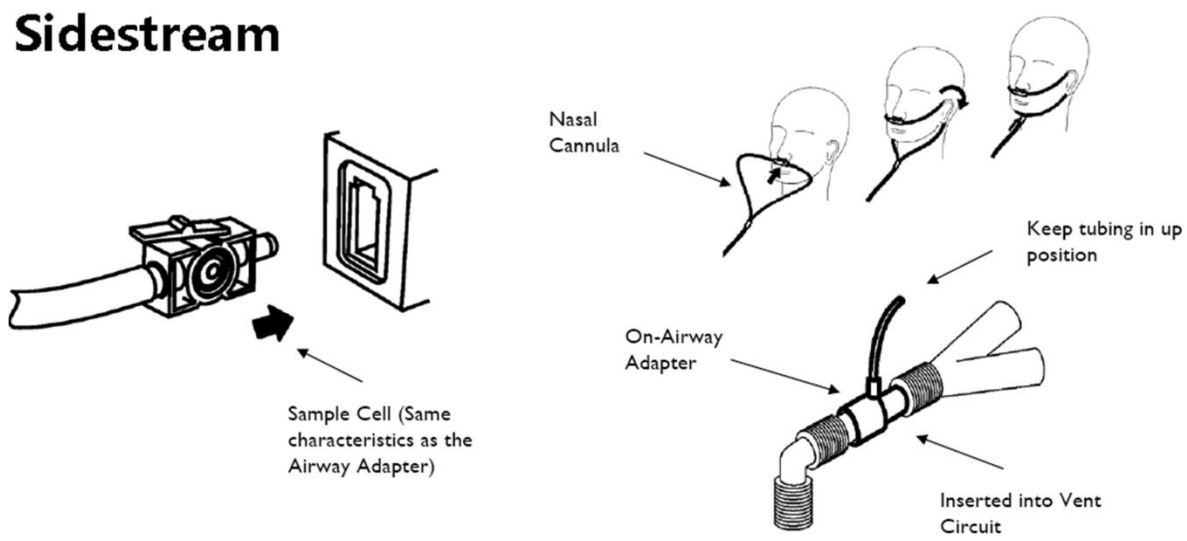


13.5 Measurement Procedure

Mainstream



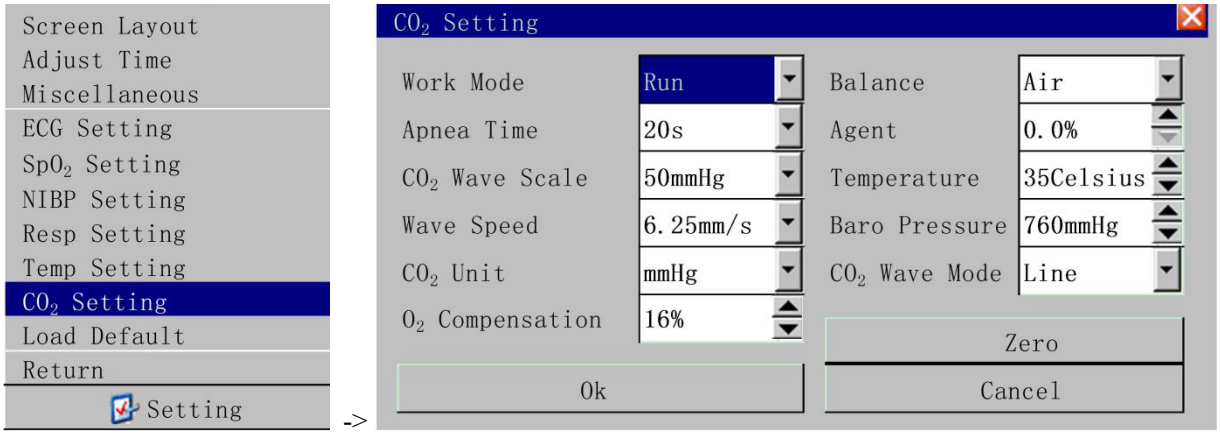




1. Plug the water trap into its receptacle before the measurement.
2. Set CO2 “Work Mode” to “Run” in the window of “CO2 Setting” in “Setting” menu.

a. Rotate the knob to select “CO2 Setting” in “Setting” menu.

b. Press the knob to enter the window of “CO2 Setting”. Select “Run” in the list of “Work Mode” and confirm by “Ok”.



⚠ WARNING ⚠

● Use the monitor under proper temperature and humidity. Otherwise, the tube connecting to patient may be blocked under high humidity or condensation. It may lead to that the patient can’t have spontaneous breathing and the monitor can’t monitor the CO2 concentration.

● Do not use the monitor under high CO2 concentration(＞0.5%). It may lead to inaccurate measurement.

● Avoid the collision and shacking of CO2 module.

● Use the monitor under a stable power supply system to avoid voltage fluctuation.

● Use the monitor under a proper environment to avoid the interferences of gases, vapor and other sources of interference.

● CO2 calibration should be operated by manufacturer and should be operated according to related regulations.

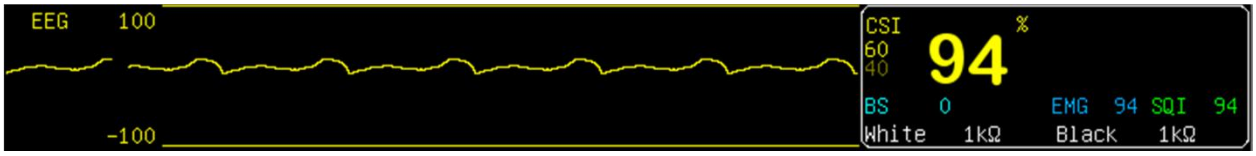
● Test the monitor and the CO2 module before using them.

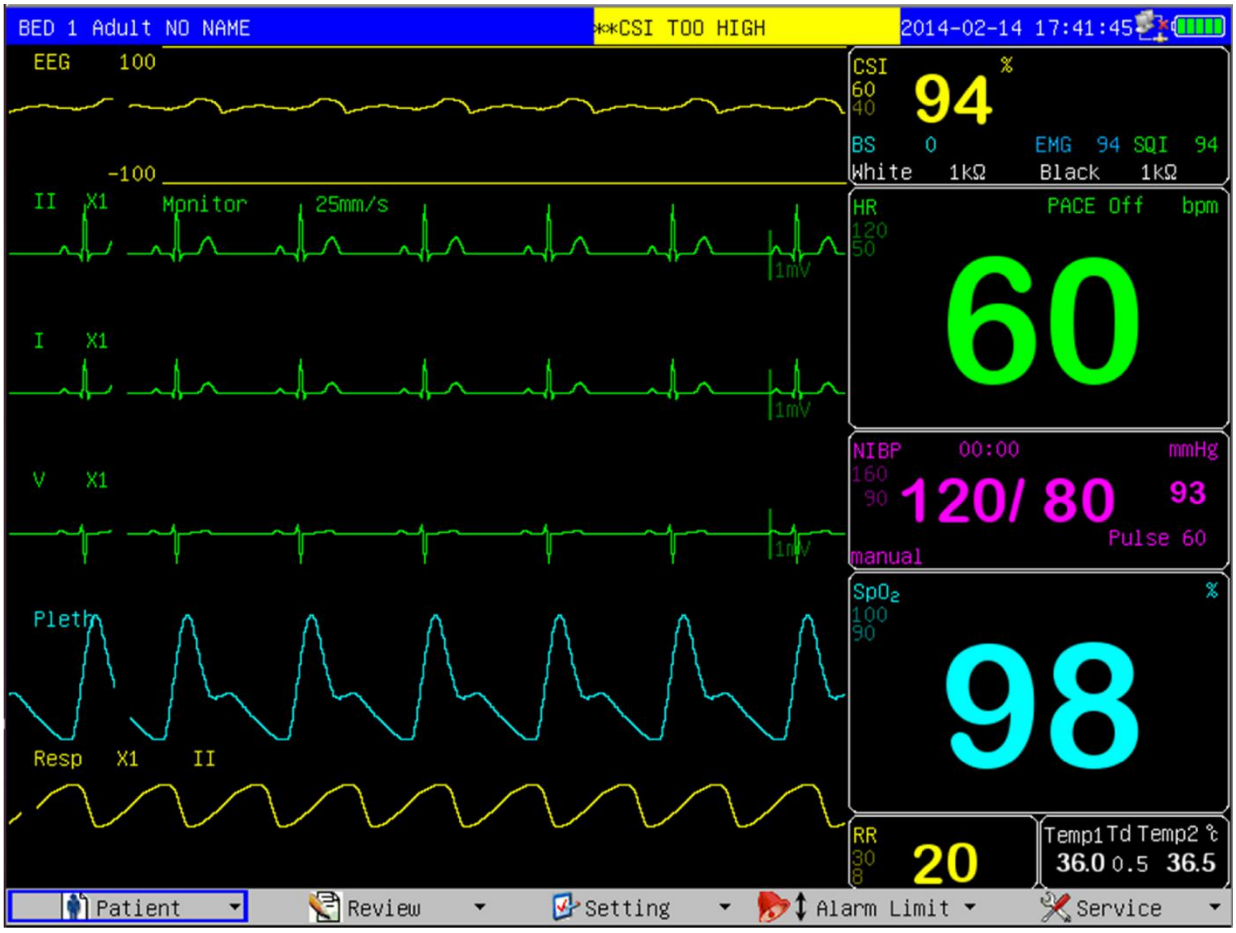
● Sidestream CO2 module do not need daily calibration. But the calibration should be operated once a year. And the calibration should be operated when the values of CO2 are not in a normal level.

● Deal with the discarded components or accessories according to related regulations.

14 CSM Monitoring (optional)

14.1 CSM Display





The Cerebral State Index (CSI) has been designed to be used in the monitoring of the level of consciousness of a person during the application of general anaesthesia or in intensive care. This is accomplished by registering the electroencephalographic signal (EEG) by means of surface electrodes which is then analyzed by a digital process. As a result of the applied calculation, an index “CSI” is obtained, which serves as guidance to the experts who use it to determine the level of consciousness of the patient during surgery.

Cerebral State Index (CSI)	
CSI	**Clinical State**
90-100	Awake
80-90	Drowsy
60-80	Light anaesthesia

40-60	Range consider as adequate for surgical anaesthesia
10-40	Deep anaesthesia, in most cases accompanied by BS (Burst Suppression)
0-10	Close to coma. BS greater than 75. When CSI is below 3, the EEG is practically is o-electric

⚠ WARNING ⚠

● Not to be used in the presence of flammable gases; explosion risk.

● When used with High Frequency(HF) surgery please note the positioning of the sensors. In order to reduce the hazard of burns the sensors should not be located between the surgical site and the electro-surgical unit return sensor.

● Pay attention if the monitor is connected to a patient connected to other equipment. The total of leakage current may exceed the allowable limit and cause a possible hazard to the patient.

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

● The monitor will not accurate readings when used on patients with severe neurological disorders and patients under 2 years of age.

● The use of pacemakers might cause either long periods of artifacts or elevated CSM values.

⚠ CAUTION ⚠

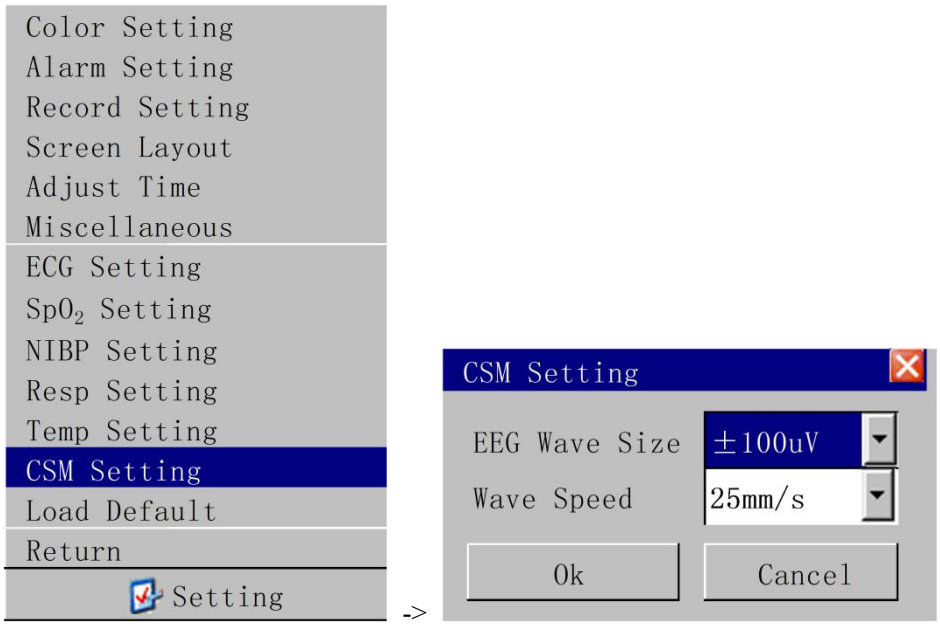
● The monitor should be used in conjuction with other patient monitoring parameters and clinical signs. This will ensure the optimum balance of the anaesthesia/sedation administration.

● Do not use CSM monitor when cardiac defibrillator is used.

● Patient cable are not protected against defibrillation.

14.2 CSM Setting

1. Rotate the knob to select “CSM Setting” in “Setting” menu.
2. Press the knob to enter the window of “CSM Setting”.



CSM Setting

EEG Wave Size	±10uV, ±20uV, ±40uV, ±80uV, ±150uV, ±200uV,
Wave Speed	6.25mm/s, 12.5mm/s, 25mm/s

14.3 CSM Monitoring Procedure

14.3.1 Skin Preparation

TO insure low sensor impedance, cleanse skin using mild soap and water.

⚠ **NOTE** ⚠

● Alcohol is not recommended as skin cleanser; it leaves a film layer that may cause high sensor impedance. If alcohol is used, ensure 30 seconds drying time.

14.3.2 Electrode Placement

The CSM Procedure Pack contains a skin preparation product and 3 neuro sensors.

⚠ **NOTE** ⚠

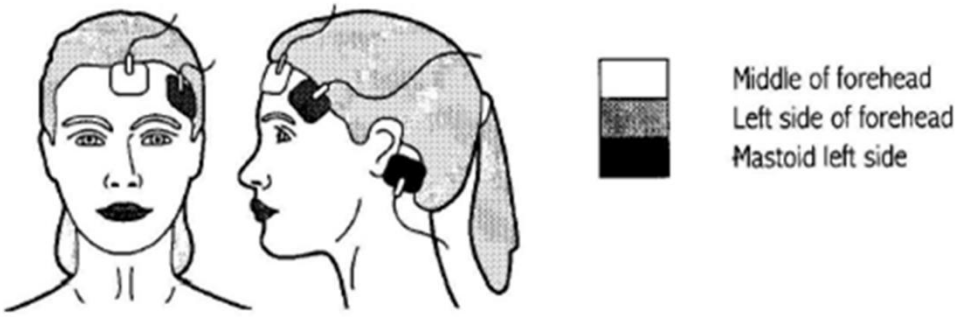
● The performance of the CSM is only guaranteed by the manufacturer when the CSM Procedure Pack is used.

Dry-abrade the skin gently using the skin prep product or with a dry wash cloth or gauze, to remove the non-conductive skin layer. See diagram below.

⚠ **CAUTION** ⚠

● Make sure no part of the sensor is in contact with any other conductive parts including earth/ground.
● If skin rash or other unusual symptoms develop, remove sensors from patient.
● Change sensors every 24 hours to check skin integrity.

Position the three sensors from your CSM Procedure Pack according to the diagram below:



The diagram above shows a left-side setup; right-side is also acceptable. Place sensor at the side furthest from the surgical area.

The advanced signal processing of the monitor ensures that a deviation in the positioning of the sensors up to 2 cm (0.78 in) has no significant influence on the index. However, it is recommended to place the sensors on an area of the skull where only a few muscle fibers are present in order to achieve the best quality signal.

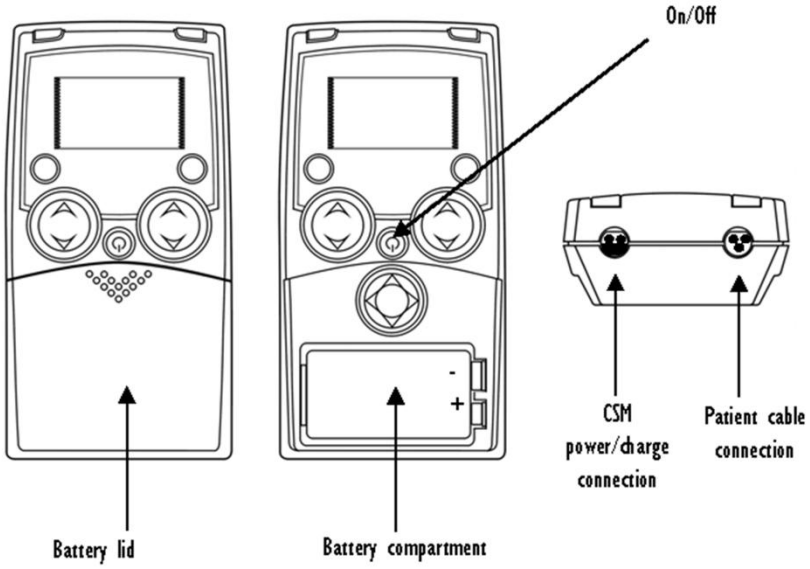
⚠ **NOTE** ⚠

● Once the sensors have been secured to the skin, attach the color-coded wires on the patient cable to the appropriate sensor.

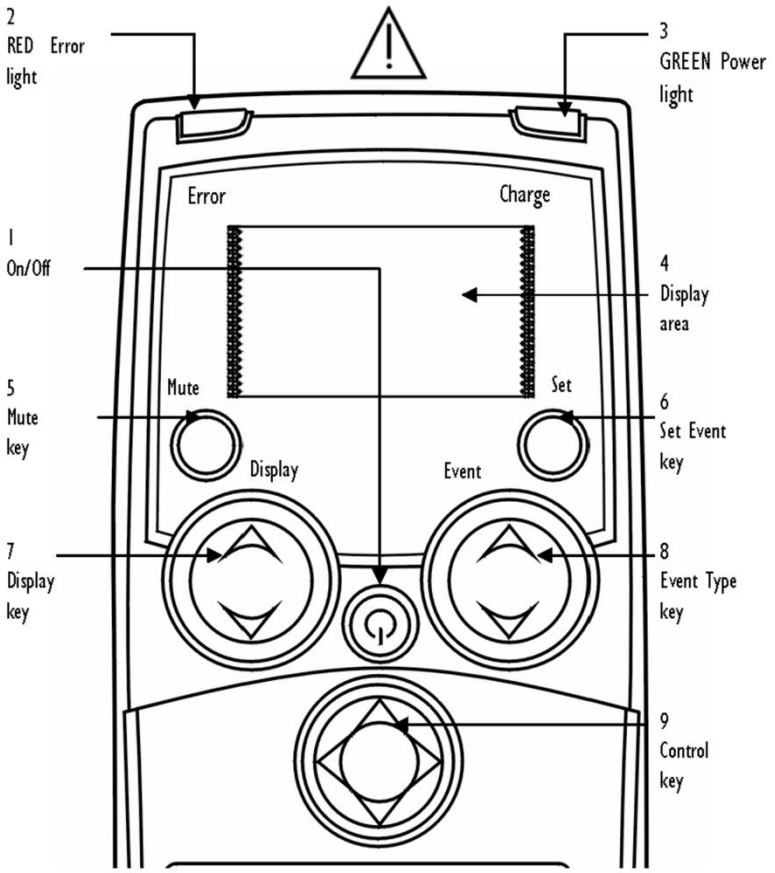
14.4 Device Description

14.4.1 Device Appearance

Overview



Keys



Key Description

1 Power On
Press once

1 Power Off
Press and hold until "Power Off" bar disappears

1 Wireless Link connection, disconnection or reconnection
Press twice within 1 second

5 Mute key
Mutes alarms

6 Set Event key / Set link (accessory)

7 Display key
Changes between graphical and information screen

7a - For immediate impedance update

8 Event key
Select event type / Select link (accessory)

9 Control key
Used for menu selection of parameter settings

9a - Use the Control key to scroll in the menus or set values

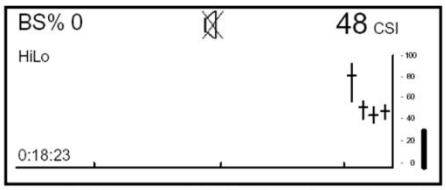
9b - Select a submenu or function

9c - Go back one menu level

14.4.2 Display and Modes

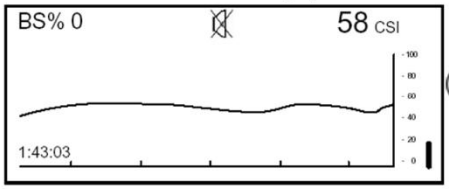
The CSM always starts up with display A.
Switch between displays A, B, C, D and E by pressing the Display key (7).

Mode D



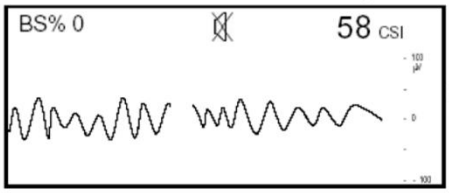
CSI trend histogram with 5-minute interval showing average, lowest and highest CSI values within the interval. EMG% is displayed as a bar in the right panel.

Mode C



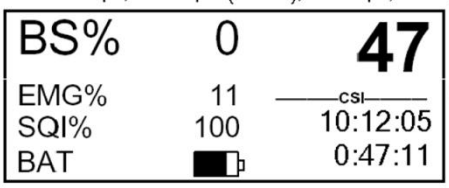
CSI trend curve with event markers and BS curve. EMG% is displayed as a bar in the right panel. Operation time and numeric value of the actual CSI and BS%. The time scale for the trend curve is 5.27 minutes and each tag is 60 seconds.

Mode B



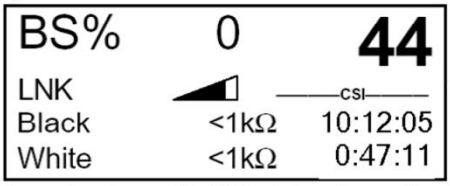
Displays 3 seconds of EEG waveform. Use Event key (8) to scale up and down. EEG scales are ±200µV, ±100µV (default), ±50µV, ±20µV and ±10µV.

Mode A



Main information window with CSI, BS%, EMG%, SQI%, clock, operation time and battery operation.

Mode E



Sensor impedance, CSI, BS%, clock and operation time. When display E is active, the sensor impedance is updated every 60 seconds. Press Display key (7a) firmly for immediate impedance update.

15 Anesthesia Gas Monitoring

15.1 Overview

The anesthesia gas monitoring can be used for measuring the anesthesia gas and respiration gas of the patient in the anesthetic status. This monitor can configure IRMA AX+ gas module. Gas module provides the numerics of the gases mentioned below.

- Carbon dioxide (CO_2): The measured numeric is $EtCO_2$ (Max. exhaling value: Max. exhaling numeric detected during the respiration);
- Nitrous oxide (N_2O): Laughing gas;
- Oxygen (O_2);
- Anesthetic (AA): Refers to the monitored anesthetic (DES, ISO, ENF, SEV or HAL);
- Airway respiration rate (AwRR): respiration per minute (BrPM).

The patient monitor can display simultaneously a maximum of 4 waveforms, including the CO_2 waveform (default waveform), N_2O waveform, O_2 waveform and the anesthetic (ENF: Enflurane) waveform.

In addition, the patient monitor can display parameters, including CO_2, N_2O, O_2 and AA (Which refers to the monitored anesthetic: DES, ISO, ENF, SEV or HAL). It also displays the inhaling and exhaling numerics as well as MAC (Minimum Alveolar Concentration)/MAL (balance gas) and AwRR.

Parameters include: CO_2 (Carbon dioxide), N_2O (Nitrous oxide, laughing gas), O_2 (Oxygen), AwRR (Airway respiration rate, respiration per minute, BrPM), HAL: Halothame, ISO: Isoflurane, ENF: Enflurane, SEV: Sevoflurane, DES : Desflurane.

15.2 MAC (Minimum Alveolar Concentration) Calculation

The MAC value may be calculated and displayed by using end-tidal (ET) gas concentrations according to the following formula:

MAC = %ET(AA1)/X(AA1) + %ET(AA2)/X(AA2) + %ET(N2O)/100

X(AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

Note: The altitude and the patient age as well as other individual factors are not taken into account in the above described formula. ET gas concentrations for secondary agent (AA2) is only available for IRMA AX+/OR+ probes.

15.3 Measurement Principles and Procedure

The gas concentration is measured based on the rationale that the gas have the property of absorbing the infrared.

The gas module can measure gases that have various properties of absorbing the infrared. To measure the concentration of a gas, send it to the sampling room, select the infrared of a specific wavelength with an optical infrared filter, and transmit it through the gas. For a given volume of gas, the higher its concentration is, the more the

infrared that will be absorbed by the gas is, and the less the infrared that will be transmitted through the gas is. The concentration of the measured gas is in inverse proportion to the volume of the infrared that is transmitted through the gas. Therefore, the gas concentration can be obtained by calculating the infrared. For the gas module that implements the measurements of multiple gases, multiple infrared filters are necessary.

The oxygen (O_2) does not absorb the infrared within the above-mentioned wavebands, so the oxygen is measured based on its paramagnetism. Inside the sensor of the O_2 module, there are two crystal balls full of nitrogen. They are suspended in the symmetrical magnetic field, and they are designed to point to the strongest outgoing part of the magnetic field. Outside the balls is the paramagnetic oxygen. Therefore, the balls are forced, by the relatively stronger paramagnetic oxygen, out of the magnetic field. The moment of the force acting on the balls is proportional to the paramagnetic strength as well as to the concentration of the oxygen.

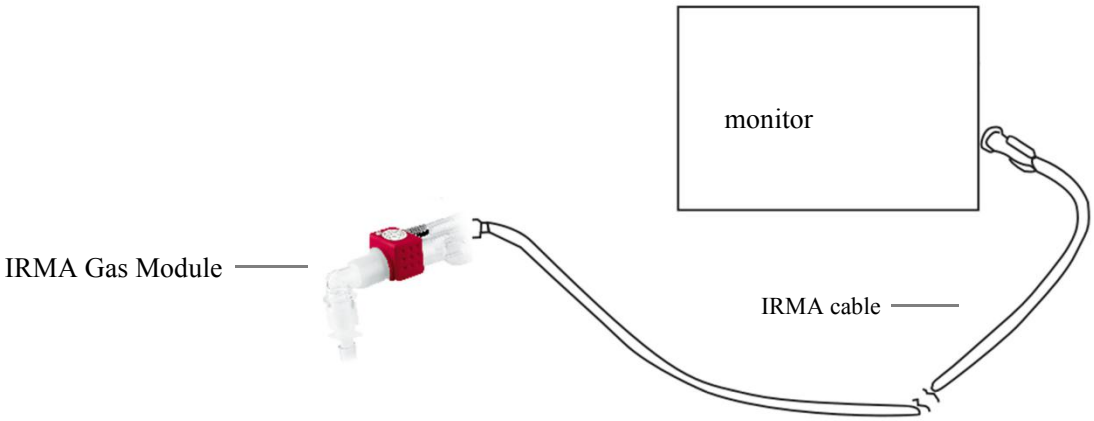


Figure 15-1 IRMA gas module connection

15.4 Measurement Procedure

1) Plug IRMA gas module into the airway and connect IRMA cable to the “GAS” socket on the patient monitor;
2) If there are “IRMA Stand by” prompt on the screen, set “work mode” to “Run” in the “Gas Setting” dialog;
3) Co2, N2O, O2 and gas waveform and value will be displayed on the screen after gas module starts up.

15.5 Gas Setting

Enter “Gas Setting” dialog by select “Gas setting” menu:

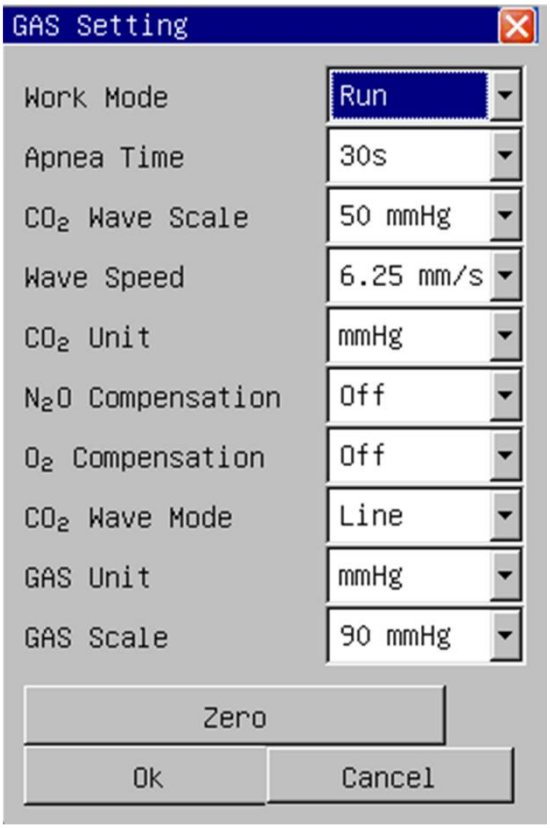


Figure 15-1 Gas Setting

1) Work Mode：when “Standby” is selected, gas IR source will be closed to lower the power consumption and extend the lifetime of gas module;
2) Apnea Time：set delay time of apnea detection, from 10 seconds to 40 seconds. If the settings off, indicate the apnea alarm is closed.
3) Wave Scale：wave scale is 30~100mmHg;
4) Wave Speed：6.25mm/s,12.5mm/s, 25.0mm/s;
5) Unit：mmHg, kPa, %, the formula of unit list below：
   CO （mmHg）= CO （%）×Pbaro（mmHg）/100
   CO （kPa）= CO （mmHg）/7.5
   PCO : CO pressure; Pbaro: barometer pressure,standard barometer is 760mmHg.

1) Wave mode： “line” or “fill” mode can be selected；
2) Gas ID：set the anesthesia gas type: (DES, ISO, ENF, SEV or HAL). This selection is only enabled when using manual ID gas module.
3) Gas unit：mmHg、kPa、% can be selected；
4) Gas gain：wave scale is 30mmHg~150mmHg.

15.5.1 Gas zeroing procedure

1) Power on the patient monitor for at least 30 minutes;
2) Input gas without CO and other anesthesia gases ;
3) Select “Zero” in “Gas Setting ” dialog;
4) “Zero OK” will be displayed on the screen when zero done.

16 Maintenance

⚠ **WARNING** ⚠

● Failure on the part of the responsible hospital or institution employing the use of the monitoring equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazard.
● The safety inspection or maintenance, which requires opening the monitor housing, must be performed by trained and authorize personnel only.
● Otherwise, equipment failure and possible health hazard may be caused.

16.1 Inspection and Maintenance

Make sure the qualified service personnel have implemented a complete inspection before putting the monitor into operation, after monitor servicing or system upgrading, or after the monitor has been used for 6-12 consecutive months. This is to ensure the normal operation of the system.

Follow these guidelines when inspecting the equipment:
The environment and the power supply meet the specified requirements.
Inspect the keys, control knob, connectors and accessories for damage.
Inspect the power cords for fraying or other damage and check the insulation.
The grounding cables are correctly connected.
Only specified accessories like electrodes, sensors and probes are applied.
The monitor clock is correct.
The audible and visual alarms functions normally.
The recorder functions normally and the recorder paper meets the requirement. (optional)
Batteries are in good status and can operate normally.

The defibrillator synchronization function must be verified according to your hospital regulations, and be checked by a qualified technician once every 3 months.
In case of any damage or exception, do not use the monitor. Contact the technician in your hospital or our Customer Service immediately.

⚠ **WARNING** ⚠

● If the hospital or agency that is responding to using the monitor does not follow a satisfactory maintenance schedule, the monitor may become invalid, and the human health may be endangered.

16.2 Cleaning

⚠ **WARNING** ⚠

● Turn off the power and disconnect the line power before cleaning the monitor or the sensor/probe.

● The Multi-Parameter Patient Monitor must be kept dust-free.

● It is recommended that you should clean the outside surface of the monitor enclosure and the display screen regularly. Only use non-caustic detergents such as soap and water to clean the monitor enclosure.

⚠ **CAUTION** ⚠

● Pay special attention to avoid damaging monitor:

1. Avoid using ammonia-based or acetone-based cleaners such as acetone.

2. Most cleaning agents must be diluted before use. Dilute the cleaning agent as per the manufacturer's direction.

3. Do not use the grinding material, such as steel wool etc.

4. Do not let the cleaning agent enter the monitor. Do not immerse any part of the system into liquid.

5. Do not leave the cleaning agents at any part of the equipment.

Except the solutions specified in the above Caution, you can use any of the solutions listed below as the cleaning agent.

- Diluted Ammonia Water
- Diluted Sodium Hyoichlo (Bleaching agent).

⚠ **NOTE** ⚠

The diluted sodium hyoichlo from 500ppm (1:100 diluted bleaching agent) to 5000ppm (1:10 bleaching agents) is very effective. The concentration of the diluted sodium hyocihlo depends on how many organisms (blood, mucus) are left on the surface of the enclosure.

- **Diluted Formaldehyde 35% -- 37%**
- **Hydrogen Peroxide 3%**
- **Alcohol**
- **Isopropanol**

⚠ **NOTE** ⚠

You can use hospital-grade ethanol to clean UN-8000S monitor and its sensor/probe and leave it to dry naturally or use clean cloth to dry it.

⚠ **NOTE** ⚠

Manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

16.3 Disinfection and Sterilization

Sterilization or disinfection may cause damage to the equipment. We recommend the sterilization and disinfection are contained in the hospital's servicing schedule only when necessary. The equipment should be cleaned prior to sterilization and disinfection.

Recommended sterilization material: Alcohol based (Ethanol 70%, Isopropanol 70%), and aldehyde based.

⚠ **CAUTION** ⚠

- **Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible concentration.**
- **Do not let liquid enter the monitor.**
- **Do not immerse any part of the monitor into liquid.**
- **Do not pour liquid onto the monitor during sterilization.**
- **Use a moistened cloth to wipe off any agent remained on the monitor.**
- **Do not use EtO gas or formaldehyde to disinfect the monitor.**

17 Accessories

⚠ **WARNING** ⚠

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

The operating and storage conditions of the patient monitor should meet the specifications claimed by respective accessories. For environmental specifications of each accessory, refer to instructions for use of respective accessories.

Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.

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

Type	Model	Supplier
NIBP Cuff	Y000T1	xxxxxxxxxx
ECG cable	3 meter	
SpO2 Sensor	S0044B-S	
Temp Sensor	W0001A	

Masimo SpO2 Accessories

6Pin SpO_2 Cable
LNCS NeoPt Neonatal SpO_2 Adhesive Disposable Sensor
LNCS Neo Neonatal SpO_2 Adhesive Disposable Sensor
LNCS Inf Infant SpO_2 Adhesive Disposable Sensor
LNCS Pdt Pediatric SpO_2 Adhesive Disposable Sensor
LNCS Adt Adult SpO_2 Adhesive Disposable Sensor
LNCS DC-I Pediatric Resuable Sensor

18 Appendix A - Safety

18.1 Safety Information

⚠ WARNING ⚠	**Points to be noted to avoid injury to the patient and the operator.**
⚠ CAUTION ⚠	**Points to be noted to avoid damage to the equipment.**
⚠ NOTE ⚠	**Points to be noted to avoid injury to the patient and the operator.**

⚠ WARNING ⚠

● Do not rely only on audible alarm system to monitor patient. When monitoring adjusting the volume to very low or completely muting the sound may result in the disaster to the patient. The most reliable way of monitoring the patient is at the same time of using monitoring equipment correctly, manual monitoring should be carried out.

● This multi-parameter patient monitor is intended for use only by medical professionals in health care institutions.

● To avoid electrical shock, you shall not open any cover by yourself. Service must be carried out by qualified personnel.

● Use of this device may affect ultrasonic imaging system in the presence of the interfering signal on the screen of ultrasonic imaging system. Keep the distance between the monitor and the ultrasonic imaging system as far as possible.

● It is dangerous to expose electrical contact or applicant coupler to normal saline, other liquid or conductive adhesive. Electrical contact and coupler such as cable connector, power supply and parameter module socket-inlet and frame must be kept clean and dry. Once being polluted by liquid, they must be thoroughly dried. If to further remove the pollution, please contact your biomedical department or Factory.

⚠ WARNING ⚠

● Monitor can only monitoring one patient at a time.

⚠ WARNING ⚠

● There could be hazard of electrical shock by opening the monitor casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by Factory.

⚠ WARNING ⚠

● You must verify if the device and accessories can function safely and normally before use.

⚠ WARNING ⚠

● Possible explosion hazard if used in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

⚠ WARNING ⚠

● You must customize the alarm setups according to individual patient situation and make sure that alarm sound can be activated when alarm occurs.

⚠ WARNING ⚠

● Do not touch the patient, table, or the device during defibrillation.

⚠ WARNING ⚠

● Do not use cellular phone in the vicinity of this device. High level electromagnetic radiation emitted from such devices may greatly affect the monitor performance.

⚠ WARNING ⚠

● Devices connected to the monitor shall form an equipotential system (protectively earthed).
● Connect the grounding wire to the equipotential grounding terminal on the main system. If it is not evident from the instrument specifications whether a particular instrument ombination is hazardous or not, for example due to summation of leakage currents, the user should consult the manufacturers concerned or else an expert in the field, to ensure that the necessary safety of all instruments concerned will not be impaired by the proposed combination.

⚠ WARNING ⚠

● When used with Electro-surgery equipment, you (doctor or nurse) must give top priority to the patient safety.

⚠ WARNING ⚠

● Do not place the monitor or external power supply in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient cable, use only the handle on the monitor.

⚠ WARNING ⚠

● Consult IEC-601-1-1 for system interconnection guidance. The specific requirements for system interconnection are dependent upon the device connected to the monitor and the relative locations of each device from the patient, and the relative location of the connected device to the medically used room containing the monitor. In all circumstance the monitor must be connected to a grounded AC power supply. The monitor is referred to as an IEC 601/F device in the summary of situations table contained in IEC 601-1-1.

⚠ WARNING ⚠

● Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.

⚠ WARNING ⚠

● Grounding:
Connect the monitor only to a three-wire, grounded, hospital-grade receptacle. The three-conductor plug must be inserted into a properly wired three-wire receptacle; if a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code.
Do not under any circumstances remove the grounding conductor from the power plug.
Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
If there is any doubt about the integrity of the protective earth conductor arrangement, operate the monitor on internal battery power until the AC power supply protective conductor is fully functional.

⚠ **WARNING** ⚠

● For continued safe use of this equipment, it is necessary that the listed instructions be followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

⚠ **WARNING** ⚠

● It is important for the hospital or organization that employs this equipment to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.

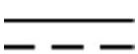
⚠ **CAUTION** ⚠

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

18.2 Equipment Symbols

⚠ **NOTE** ⚠

Some symbols may not appear on your equipment.

	Power On/Off key
	Power On/Off (key)
	Battery indicator
	External power indicator
	SILENCE alarm key
	FREEZE waveforms key
	NIBP start/stop key
	RECORD key
	MENU main screen Key
	This symbol indicates that the instrument is IEC 60601-1 Type BF equipment.
	TYPE BF applied part. Defibrillator-proof protection against electrical shock.
	Connector has special protection against electric shocks and is defibrillator proof.
	External power connector
	Network connector

	USB connector
	Equipotential grounding
	Video output connector
	Refer to accompanying documents
	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive.

18.3 Patient Safety

The Patient Monitor is designed to comply with the International National Safety requirements for medical electrical equipment, IEC60601-1, EN60601-2-27 and EN60601-2-30. This device has floating inputs and is protected against the effects of defibrillation and electrosurgery. If the correct electrodes are used and applied in accordance with the manufacturer instructions (see Chapter ECG/RESP Monitoring), the system can restore screen display within 10 seconds after defibrillation.

This symbol indicates that the instrument is IEC60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.

⚠ **WARNING** ⚠

● Do not come into contact with patients, bed or the monitor during defibrillation.

Environment

Follow the instructions below to ensure complete and safe electrical installation. The environment where the PM-5000 Multi-Parameter Patient Monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.
The Patient Monitor operates within specifications at ambient temperatures between 0℃ and 40℃. Ambient temperatures that exceed these limits may affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5cm) clearance around the instrument for proper air circulation.

Power Requirements

See Chapter 14 Appendix - Specifications.

Grounding

To protect the patient and hospital personnel, the enclosure of the Patient Monitor must be grounded. Accordingly, the Patient Monitor is equipped with a detachable 3-wire cable which grounds the instrument to the power line

ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician.

⚠ **WARNING** ⚠

● **Do not use a 3-wire to 2-wire adapter with this instrument.**

The ground equipment and other potential associated to the ground terminal. From the instrument specifications confused whether a particular combination of dangerous equipment, such as leakage current caused by the accumulation of dangerous, the user should consult the manufacturers or other experts in this field to ensure that all instruments which necessary security will not be damaged by the proposed combination.

Equipotent grounding

When other devices used in conjunction with the monitor, you should also use the wire to the rear panel monitors and other potential ground terminal and other equipment such as potential ground terminal connected to different equipment to eliminate potential difference between the grounds and ensure safety.

Condensation

In the work, to ensure no condensation apparatus, when the equipment from one room to another room to go, it may form a condensation. This is because the equipment exposed to humid air and the temperature difference among the reasons.

⚠ **WARNING** ⚠

● **If there are places where flammable anesthetics used, there will be a risk of explosion.**

19 Appendix B - EMC

The monitor meets the requirements of IEC 60601-1-2:2001

⚠ **Caution** ⚠

The use of unapproved accessories may diminish the monitor performance.

⚠ **Note** ⚠

The monitor should not be used adjacent to or stacked with other equipment. If adjacent or tacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.

⚠ **Note** ⚠

The monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

⚠ **Note** ⚠

Portable and mobile RF communications equipment can affect this monitor. See tables 1,2,3, and 4 below.

TABLE 1

Guidance and declaration — electromagnetic emissions

The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment — guidance**
RF emissions CISPR 11	Group1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic Emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	

TABLE 2

Guidance and declaration — electromagnetic immunity

The monitor is intended for use in the electromagnetic environment specified below.
The customer or the user of the monitor should assure that it is used in such 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 (>3m).	±2 kV for power supply lines ±1 kV for input/output lines (>3m).	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV different mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product 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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

UT is the A.C. mains voltage prior to application of the test level.

TABLE 3

Guidance and declaration — electromagnetic immunity

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment — guidance

Conduced RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). **Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,** [a] **should be less than the compliance level in each frequency range** [b] **Interference may occur in the vicinity of equipment marked with the following symbol:** 
Radiated RF IEC 61000-4-3	**3 V/m 80MHz to 2.5 GHz**	3V/m	

Note — At 80 MHz and 800 MHz, the higher frequency range applies.

Note — 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 the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.

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

TABLE 4

Recommended separation distances between portable and mobile RF communication and the monitor

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

Rated Maximum Output power of Transmitter W (Watts)	Separation Distance According to Frequency of Transmitter M (Meters)		
	150kHz -2MHz	80MHz -800MHz	800MHz -2.5GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (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 — At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

20 Appendix C - Product Specifications

⚠ **WARNING** ⚠

The patient monitor may not meet its performance specification if stored or used outside the manufacturer's specified temperature and humidity range.

20.1 Safety Classifications

Item	Specification
MDD classification	Class IIb
Anti-electroshock degree	Class I equipment with internal power supply
Anti-electroshock degree	TEMP/SpO2/NIBP: BF ECG/RESP: CF
Explosion proof level	Ordinary equipment，without explosion proof
Harmful liquid proof degree	IPX1
Working system	Continuous running equipment
Equipment type	Portable

20.2 Applicable Standards

Medical Device Directive 93/42/EEC	
EN60601-1:2005 or IEC60601-1:2005	Medical Electrical Equipment, Part 1: General Requirements for Safety
EN60601-1-1 or IEC60601-1-1	Medical Electrical Equipment, Part 1-1: General Requirements for Safety, Collateral Standard: Safety Requirements for Medical Electrical Systems
IEC60601-1-4	Medical Electrical Equipment, Part 1-4: General Requirements for Safety, Collateral Standard: Programmable Electrical Medical Systems
IEC60601-2-49	Medical Electrical Equipment, Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment
IEC 60601-1-2:2007	Electromagnetic Compatibility, Medical Electrical Equipment
ISO 21647:2009	Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors

20.3 Environment

Temperature

Working 0 ~ 40 ℃

Storage -20 ~ 50 ℃

Humidity

Working 15 % ~ 90 %

Storage 15 % ~ 90 % (no coagulation)

Atmospheric pressure

Working 86.0 kPa ~ 106.0kPa;

Storage 86.0 kPa ~ 106.0kPa

20.4 Size and Weight

Model	Color TFT LCD	Size	Weight
7-inch	7-inch, 800×480 pixels	192×148×91 mm	1.2 Kg
8-inch	8-inch, 800×600 pixels	212×172×80 mm	1.5Kg
12.1-inch	12.1-inch, 800×600 pixels	312×287×175 mm	3.4Kg
15-inch	15-inch, 1024×768 pixels	353×324×176 mm	4.4Kg

20.5 Power Supply

Model	External power required	Input power	Fuse
7-inch	DC 16.8V, 1.5A	Pmax=32VA	No fuse
8-inch	AC 100V~240V, 50Hz/60Hz	Pmax=90VA	T 1.5A, 250V
12.1-inch	AC 100V~240V, 50Hz/60Hz	Pmax=90VA	T 1.5A, 250V
15-inch			

20.6 Battery

Model	Battery capacity	Battery operating time
7-inch	2200 mAh 14.8V rechargeable lithium battery	5.5 hours
8-inch		4 hours
12.1-inch		3.5 hours
15-inch		2 hours

⚠ **NOTE** ⚠

- **Operating time after the first alarm of low battery will be about 5 minutes.**
- **Maximum charging time is less than 6 hours.**

20.7 Data Storage

Trend graph and table	720 hours
Alarm review	200 events
NIBP review	1000 groups
Wave review	2 hours

⚠ NOTE ⚠

● **All storage data are Non-Volatile.**

20.8 Signal Output Specifications

Network connector	Standard RJ45 connector

20.9 Wireless Network (optional)

Standards	IEEE 802.11g, Wi-Fi compatible

20.10 Recorder Specifications (optional)

Paper width	48 mm
Speed	25/50 mm/s
Wave channel	3 channels

⚠ NOTE ⚠

No recorder for 7 inch patient monitor, available for other models

20.11 ECG Specifications

20.11.1 Heart rate calculation method

The average of the last 4 R-to-R intervals, when last 3 R-to-R intervals > 1200msec. Otherwise, the average of the last 12 R-to-R intervals, minus the maximum and minimum values. The update rate of the Heart Rate on the display is once per second.

20.11.2 Heart rate meter accuracy and arrhythmia response

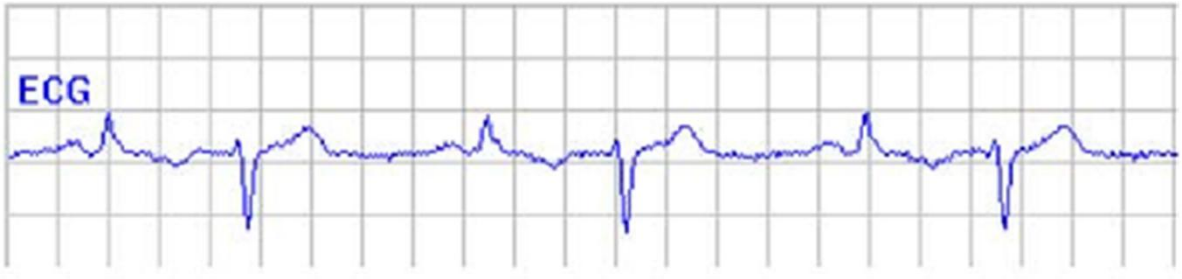
After 20s stable time, the monitor will display

a): heart rate display 40bpm ± 5bpm;

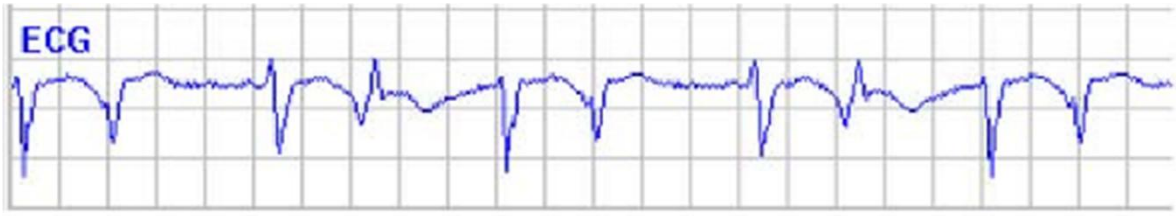
b): heart rate display 30bpm ±5bpm;

c): heart rate display 120bpm±5bpm;
d): heart rate display 45bpm±5bpm.

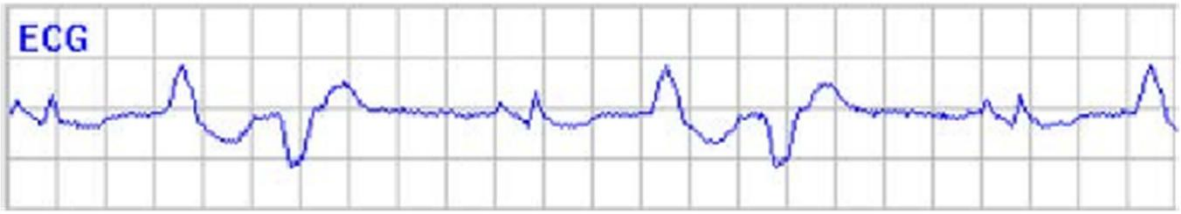
a) Couplet rhythm — two waves of duration is 1500ms; if calculate all the QRS complex, heart rate is 80bpm, if only calculate large R wave or S-wave, the heart rate is 40bpm.



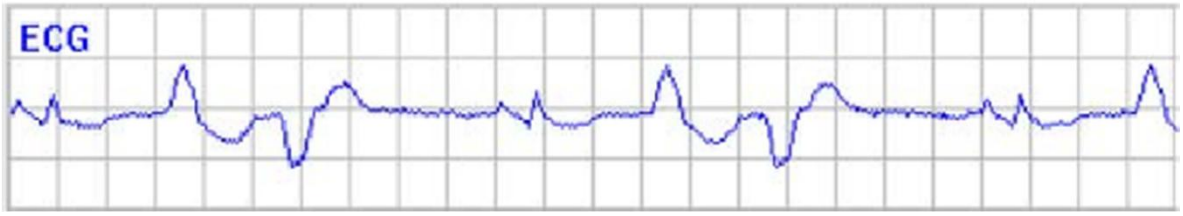
b) Slow change couple rhythm — if calculate all the QRS complex, heart rate is 60bpm, if onlycalculate large waves, heart rate is 30bpm.



c) Fast couple rhythm — if the calculate all the QRS complex, heart rate is 120bpm.



d) bi-directional contraction — if calculate all the QRS complex, heart rate is 90bpm, if only large waves, heart rate is 45bpm.



20.11.3 Lead mode

5 Leads: RA、LA、LL、RL、V; Lead mode: I, II, III, AVR, AVL, AVF, V

20.11.4 Gain

×2.5mm/mV, ×5.0mm/mV, ×10mm/mV, ×20mm/mV

20.11.5 Sweep speed

12.5mm/s, 25mm/s, 50mm/s

20.11.6 Heart rate

Measure range

Adult	15 ~ 300 bpm
Neonatal/Pediatric	15 ~ 350 bpm
Accuracy	±1%
Resolution	1 bpm

20.11.7 Sensitivity

> 200 μV P-P

20.11.8 Differential Input Impedance

> 5 M ohm

20.11.9 Bandwidth

Surgery	1 ~ 20 Hz
Monitor	0.5 ~ 40 Hz
Diagnostic	0.05 ~ 130 Hz

20.11.10 CMRR

Diagnostic Mode	>90 dB
Monitor Mode	>110 dB
Surgery Mode	>110 dB

20.11.11 Electrode offset potential

300mV

20.11.12 Input dynamic range

The device shall be capable of responding to and displaying differential voltages of ±5 mV varying at a rate up to 320 mV/s from a dc offset voltage in the range of .300 mV to +300 mV, when applied to any lead. The time-varying output signal amplitude shall not change by more than ±10 percent over the specified range of dc offset.

20.11.13 Pace pulse suppression

When the pace switch is “On”, the patient monitor can inhibit pace pulse without affect heart rate calculation: ± 2 mV ~ ± 700mV, width: 0.1ms ~ 2ms, rise time: 10us ~ 100μs normal QRS wave single pulse without overshoot pacing pulse.

When the pace switch is “On”, the patient monitor can inhibit pace pulse without affect heart rate calculation: ± 2 mV ~ ± 5mV, width: 0.5ms ~ 2ms, rise time: 10us ~ 100μs single pulse overshoot normal QRS waves of pacing pulses. Overshoot (a0) range should 0.025ap to 0.25ap range, independent of the choice of time constant, but not more than 2mV;

When the pace switch is “On”, pace pulse inhibition of rapid ECG signal to 1V / s RTI minimum input slew rate.

20.11.14 QRS wave amplitude and period range between

The minimum range of QRS amplitude (ar + as) is 0.5 mV to 5 mV, and the duration of the QRS wave is between 70 ms and 120 ms (40 ms and 120 ms for neonatal/pediatric monitors). For monitors set for adult patients, the heart rate meter shall not respond to signals having a QRS amplitude of 0.15 mV or less, or a duration of 10 ms or less with an amplitude of 1 mV. Response to either or both of these types of signals is permitted in monitors set for neonatal/pediatric patients.

20.11.15 Line frequency voltage tolerance

The maximum line frequency peak-to-valley sinusoidal voltage amplitude that can be superimposed on a train of QRS signals without exceeding the error limits of ±10% for indicated heart rate accuracy shall be no less than 100 μV p-v. The QRS signal shall have an amplitude of 0.5 mV, a duration of 100 ms, and a repetition rate of 80 bpm.

20.11.16 Drift tolerance

The monitor shall indicate the heart rate within the error limits of 80bpm ± 8bpm when a 0.1 Hz triangular wave of 4 mV p-v amplitude is superimposed on a train of QRS signals of 0.5 mV amplitude, 100 ms duration, and 80 bpm repetition rate.

20.11.17 Baseline stability

Reset: reset recovery time is not greater than the 3s;
Baseline Stability: After boot, 10s baseline drift in the output rate should not exceed 10μV / s RTI; After boot, 1h, total drift should not exceed 500μV / s RTI;
Working temperature should not exceed 50μV / ℃

20.11.18 System noise

No more than 30μV (p-v RTI)

20.11.19 Multi-channel crosstalk

Any input signal limited in amplitude and rate of change as per 14.7.12, applied to any one lead of a multi-channel monitor, and with all unused inputs connected to patient reference through a 51 kilohm resistor in parallel with a 47 nF capacitor, shall not produce an unwanted output greater than 5% of the applied signals (multiplied by the gain) in those channels where no signal is applied.

20.11.20 Electro surgery interference suppression

The heart rate shall not change by more than ±10 percent of the rate before electrosurgical interference was activated while the interference is applied for less than 10s.

20.11.21 Pace pulse display capabilities

An indication of the pacemaker pulse shall be visible on the display with an amplitude of no less than 0.2 mV RTI.

20.11.22 Heart rate response time

The maximum response time is less than 10 s, for step change of heart rate from 80bpm to 120bpm;
The maximum response time is less than 10 s, for step change of heart rate from 80bpm to 40bpm;

20.11.23 Baseline Recovery

< 3 s After defibrillation.

20.11.24 Signal Range

±8 mV p-p

20.11.25 Calibration Signal

1 mV p-p, ±5% accuracy

20.12 SpO2 Specifications

20.12.1 Measurement Range

0 ~ 100 %

20.12.2 Resolution

1 %

20.12.3 Accuracy

70% ~ 100% ±2 %
<69% unspecified

20.12.4 Pulse Rate

Measure and Alarm Range	20~250bpm
Resolution	1bpm
Accuracy	±3bpm

20.13 Masimo SpO2 Specifications

20.13.1 SpO2

Measurement range	1 to 100%
Resolution	1%
Accuracy	70 to 100%: ±2% (measured without motion in adult/pediatric mode)
	70 to 100%: ±3% (measured with motion in neonate mode)
	70 to 100%: ±3% (measured with motion)
	0% to 69%: Not specified.
Refreshing rate	1 s
Updated period	8 s, 16 s

20.13.2 PR

Measurement range	25 to 240 bpm
Resolution	1 bpm
Accuracy	±3 bpm (measured without motion)
	±5 bpm (measured with motion)
Refreshing rate	1 s
Updated period	8 s, 16 s

20.13.3 Low Perfusion

Conditions	Pulse amplitude: >0.02%
	Light penetration: >5%
SpO2 accuracy	±2%
PR accuracy	±3 bpm

20.14 NIBP Specifications

20.14.1 Method

Oscillometry

20.14.2 Measure mode

Manual, Auto, STAT

20.14.3 Measure Interval in AUTO Mode

1,2,3,4,5,10,15,30,60,90,120,180,240,480 min

20.14.4 Measure Period in STAT Mode

5 min

20.14.5 Pulse Rate Range

40 ~ 240 bpm

20.14.6 Measure and Alarm Range

Adult Mode

SYS	40 ~ 280 mmHg
DIA	10 ~ 220 mmHg
MEAN	20 ~ 240 mmHg

Pediatric Mode

SYS	40 ~ 220 mmHg
DIA	10 ~ 160 mmHg
MEAN	20 ~ 170 mmHg

Neonatal Mode

SYS	40 ~ 135 mmHg
DIA	10 ~ 100 mmHg
MEAN	20 ~ 110 mmHg

20.14.7 Static pressure accuracy

± 3 mmHg

20.14.8 Resolution

1mmHg

20.14.9 Accuracy

Maximum Mean error	±5mmHg
Maximum Standard deviation	8mmHg

20.14.10 Overpressure Protection

Adult	300 mmHg
Pediatric	240 mmHg
Neonatal	150 mmHg

20.15 Resp Specifications

20.15.1 Method

Impedance between RA-LL

20.15.2 Respiration Impedance Range

0.3~3Ω

20.15.3 Base Impedance Range

200Ω-4000Ω

20.15.4 Bandwidth

0.3 ~ 2.5 Hz

20.15.5 Gain

×0.25, ×0.50, ×1, ×2, ×4

20.15.6 Respiration Rate

Measurement Range

Adult	0 ~ 120 BrPM
Neonatal / Pediatric	0 ~ 150 BrPM
Resolution	1 BrPM
Accuracy	0～6 BrPM: unspecified
	7～150 BrPM: ±2 BrPM

20.15.7 Apnea Alarm

10 ~ 40 s

20.16 Temp Specifications

Sensor Type	10K series，2.25K series
Channel	DK-8000M、DK-8000 and DK-8000N are one, others are two
Measure and Alarm Range	0 ~ 50 ℃
Resolution	0.1 ℃
Accuracy(no sensor)	± 0.1 ℃ (0℃ – 50℃)

20.17 CO_2 Specifications (LoFlo)

Transducer Type	Sidestream CO2 Sensor
Sample Rate	50 mL/min. ±10 mL/min
CO2 Measurement Range	0 to 100 mm Hg
CO2 Resolution	1 mm Hg
CO2 Accuracy	±2 mm Hg (0 – 40 mm Hg)
	±5% of reading (41 – 70 mm Hg)

	±8% of reading (71 – 100 mm Hg)
Respiratory Rate Range	2 to 150 Breaths Per Minute (BPM)
Respiratory Rate Accuracy	±1 BrPM
CO2 Stability	Short Term Drift: Drift over four hours shall not exceed 0.8 mm Hg max; Long Term Drift: Accuracy specification will be maintained over a 120-hour period

20.18 CSM Specifications (optional)

EEG sensitivity	±475 uV
CMRR	> 100 dB
Input Impedance	> 50 Mohm
CSI	0-100
ESR	0-100%
EMG	0-100

20.19 Default Settings

Patient Information

Patient Type	Adult
Bed number	1
Gender	Male

Alarm Setting

Alarm Volume	5
Flicker	Off
Parameter Alarm	None bolt-lock
Alarm Record	Off
Voice Alarm	On

Record Setting

Record Waveform 1	ECG1
Record Waveform 1	ECG2
Record Length	8S
Inter-record Gap	Off
Record Speed	25mm/s
Record Grid	On

ECG Setting

Pacemaker	Off
Channel 1 Lead	II
Channel 1 Amplitude	X1
Channel 2 Lead	I
Channel 2 Amplitude	X1
Notch	On

Filter	Monitor
Heartbeat Volume	5
Waveform Speed	25mm/s
HR Source	Auto

Resp Setting

Apnea Time	40s
Waveform Size	X2
Waveform Speed	6.25 mm/s

SpO2 Setting

Pulse Volume	5
Sensitivity	Medium
Waveform Speed	25mm/s
PR	Off
Waveform Mode	Line

NIBP Setting

Unit	mmHg
Mode	Auto
Period	10 minutes

Temp Setting

Unit	℃

CO_2 Setting

Work Mode	Run
Apnea Time	20s
CO_2 Wave Scale	50 mmHg
Wave Speed	6.25 mm/s
CO_2 Unit	mmHg
CO_2 Compensation	16%
Balance	Air
Agent	0.0%
Temperature	35℃
Baro Pressure	760 mmHg
CO_2Wave Mode	Line

CSM Setting

EEG Wave Size	±100uv
Wave Speed	25 mm/s

Alarm Limits Setting

Parameters	Adult	Pediatric	Neonate	Unit
HR High Alarm Limit	120	160	200	bpm
HR Low Alarm Limit	50	75	100	bpm
Resp High Alarm Limit	30	30	100	brpm

Resp Low Alarm Limit	8	8	30	brpm
SpO2 High Alarm Limit	100	100	95	%
SpO2 Low Alarm Limit	90	90	80	%
PR High Alarm Limit	20	160	200	bpm
PR Low Alarm Limit	50	75	100	bpm
Sys High Alarm Limit	160	120	90	mmHg
Sys Low Alarm Limit	90	70	40	mmHg
Mean High Alarm Limit	110	90	70	mmHg
Mean Low Alarm Limit	60	50	25	mmHg
Dia High Alarm Limit	90	70	60	mmHg
Dia Low Alarm Limit	50	40	20	mmHg
Temp High Alarm Limit	39.0	39.0	39.0	℃
Temp Low Alarm Limit	36.0	36.0	36.0	℃
CO_2 High Alarm Limit(RR)	30	30	30	brpm
CO_2 Low Alarm Limit(RR)	8	8	8	brpm
Et CO_2 High Alarm Limit	50	50	50	mmHg
Et CO_2 Low Alarm Limit	15	15	15	mmHg
Fi CO_2 High Alarm Limit	4	4	4	mmHg
Fi CO_2 Low Alarm Limit	0	0	0	mmHg
CSM High Alarm Limit	60	60	60	%
CSM Low Alarm Limit	40	40	40	%