INFINIUM

Alpha PM22 Patient Monitor

User’s Manual

V1.0

Infinium Medical Inc.

Introduction

Thank you for choosing Alpha PM22 patient monitor

Before using the product, please read this manual carefully for proper use.

After reading, please properly keep this manual for reference at any time when needed.

Product Name: Patient Monitor

Model Name: Alpha PM22

General Information:

This device is intended to be used for monitoring patient's ECG(Electrocardiogram), Heart Rate (HR), Resparation(Resp), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Respiration Rate (RR), Temperature (Temp), Invasive Blood Pressure (IBP), Cardiac Output (C.O.). End-tidal carbon dioxide (EtCO2), and Bispectral Index (BIS).

Monitoring information can be displayed, reviewed, stored, and printed.

Product Components:

The monitor is a fixed mounting device consisting of a screen, Satellite Module Rack (SMR), Modules, mounting bracket and accessories. Modules include P6, P2, Printer, BIS, AG, CO2; For accessory information, see the accessory list.

Indications for Use:

This device is intended for patient use by trained healthcare professionals in a hospital environment.

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Contents of this manual are subject to changes without prior NOTE.

【Manufacturer Responsibility】

Infinium is responsible for the effects on safety, reliability and performance of this product, only if:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Infinium authorized personnel
- The electrical installation of the relevant room complies with the applicable national and local requirements
- The product is used in accordance with the instructions for use

【Note】

The equipment can't be used at home.

WARNING

- This patient monitor is intended for use only by clinical professionals or at least under their guidance. It must only be used by trained personnel in its use. Anyone unauthorized or untrained must not perform any operation on it.

Preface

【Manual Description】

This manual describes the uses, features, operations and safety messages of the patient monitor. Before using this equipment, observance of the manual is a prerequisite for proper performance and correct operation and ensures patient and user safety.

Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.

【Intended Audience of this Manual】

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices and terminology, as required for the monitoring of all patients.

【Illustrations】

This manual uses illustrations for examples only. Illustrations in this manual may not necessarily reflect all system settings, features, configurations or data display.

Content

1 Safety

1.1 Safety Information

WARNING

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

CAUTION

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

NOTE

- Provides application tips or other useful information to ensure that you get the most from your product.

1.1.1 Warning

WARNING

- — SINGLE PATIENT USE — This equipment is designed for use on one patient at a time.
- To avoid explosion hazard, do not use the equipment in the presence of flammable anesthetics, vapors or liquids.
- Do not use monitoring sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.
- Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.
- Do not touch electrical equipment and the patient at the same time. This may cause an unsafe

electrical shock to the patient.

- Do not come into contact with patients during defibrillation. Otherwise, serious injury or death could occur.
- Do not use the equipment in the presence of flammable anesthetics, vapors or liquids.
- The waveforms, physiological data and alarm messages displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.
- Wrap and secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel.
- Batteries must be taken out when the equipment is not used.
- Do not disassemble the equipment on your own, otherwise electrical shock may occur. Maintenance should be carried out by manufacturer or authorized service personnel.
- The software copyright of the equipment is solely owned by the manufacturer. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.

1.1.2 Caution

CAUTION

- To ensure patient safety, use only parts and accessories specified in this manual.
- Magnetic and electrical fields are capable of interfering with the proper performance of this equipment; Thus, this monitor shouldn't be operated with other High frequency equipment (especially high RF equipment) in the same site. High RF equipment shouldn't stay too close to this monitor, otherwise the normal function of this monitor might be affected.
- Do not lift the monitor by pulling on the sensor cable or power cord, as these cables may be disconnected from the monitor and the equipment may fall and injure the patient.
- Patient monitors are precision medical instruments. Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force. Do not pull, twist, or rub the lead wires.
- Please keep the lead wires and patient monitor dry to avoid the inaccurate measurement result, product damage or any potential risks that might harm the patient. Dry the equipment immediately when it gets wet.
- Some configurations are protected by passwords. If you need to use password to access these functions, please contact associated personnel.

- An indicated potential hazard or unsafe practice that, if not avoided, could result in minor personal injury, product malfunction, damage or property loss.
- Both the monitor and the devices that connected to this equipment, must be grounded together.
- Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g., IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration and all lead wires must meet the requirements of the IEC 60601-1 medical electrical systems standard.
- Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any question, please contact the manufacturer.
- Environment and patient condition must be considered to ensure the precision of measurement. For special safety instructions on these conditions, see chapters of this manual for reference accordingly.
- Chemical leakage from broken LCD is poisonous and adverse health consequences might occur once the leaking liquid enters human body. Please do take care when carrying patient monitors with broken LCD screens.
- Package material may contaminate the environment. Properly dispose of the package material according to applicable waste control regulations and keep it out of children's reach.
- At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.

1.1.3 Note

NOTE

- Put the equipment in a location where you can easily view, operate and maintain it.
- For proper operation, the operator shall stand in front of the equipment.
- Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.

1.2 Electromagnetic Interference

Due to the dramatic increase in the number of radio frequency transmitters or other sources of

electronic interference (such as electronic surgical equipment, cell phones, two-way radar for vehicles, electronic devices, etc.) in medical care settings. The high level of interference caused by the immediate vicinity, or strong transmitter power of the interfering sources may interrupt the normal function of this equipment.

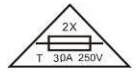
This monitor is designed for use within a specified electromagnetic environment. However, Certain electromagnetic interference may cause blurred or erroneous measurements, even worse, the malfunction of the equipment.

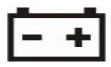
Interference may manifest itself in erratic readings, interruptions in operation or other functional errors. If this occurs, the working environment should be investigated to identify the source of the interference and eliminate it.

- Turn on and off the appliances in the vicinity to find out the interfering appliance.
- Redirect or relocate other receiving devices.
- Keep away from the interfering devices.

This patient monitor may generate or emit the energy of radio frequency, if not used properly according to the manual, it might cause harmful interference with other devices in the vicinity.

1.3 Equipment Symbols

Symbols	**Explanation**
	NOTE! Consult documents accompanying this monitor.
	Power ON/OFF (for a part of the equipment)
	Type CF applied part. Defibrillator-proof protection against electric shock.
	Type BF applied part. Defibrillator-proof protection against electric shock.
	Type BF applied part.
	Rechargeable battery
	Fuse replacement requirements
	Equipotential grounding

	Computer network
	Alternating current (AC)
	Battery indicator
	AC/DC dual-use
SN	Serial number
	Date of manufacture
	Manufacturer
	Fragile, handle with care
	This way up.
	Keep dry. Protect from rain.
	Stacking limit by number: Maximum number is 8 for the symbol in the illustration.

2 Monitor Description

2.1 Intended Use

This device is intended to be used for monitoring and recording multiple physiological parameters of adults, pediatrics, and neonates, to provide key physiological information for medical care. Critical physiological parameters include ECG(Electrocardiogram), Heart Rate (HR), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Respiration Rate (RR), Temperature (Temp), Invasive Blood Pressure (IBP), Cardiac Output (C.O.), End-tidal carbon dioxide (EtCO2), Bispectral Index (BIS), Anesthetics(AG). It can also save, transfer parameter data and generate alarms for patient.

This monitor is intended for use in hospitals, widely used in clinical departments including internal medicine, surgery, operating room, emergency departments, obstetrics and gynecology, etc. It is capable of monitoring the essential physiological parameters of patients regularly, constantly in a prolonged period.

This device provides a wide range of functions, including audio and visual alarms, trend recording and printing, parameter recording and review, alarm event list, pharmacy calculations and C.O. calculations.

WARNING

- This patient monitor is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Operation by patient is not prohibited.

2.2 Operating Principle

Physiological changes are probed via sensor, then amplified, tranformed into electrical information. The electrical information will be acquired by ADC, then forwarded to CPU for calculation, analysis and edition for displaying data on screen. You can also record and print it out as needed. When the measured data exceeds the alarm limit, it will trigger the alarm for action.

The software contains 4 parts: signal acquisition, analog processing, digital processing, information output.

2.3 Contraindications

None

2.4 Components

The monitor is a fixed mounting device consisting of a screen, Satellite Module Rack (SMR), Modules, mounting bracket and accessories. Modules include P6, P2, Printer, BIS, AG, CO2; For accessory information, see the accessory list.

2.5 Main Unit

2.5.1 Display

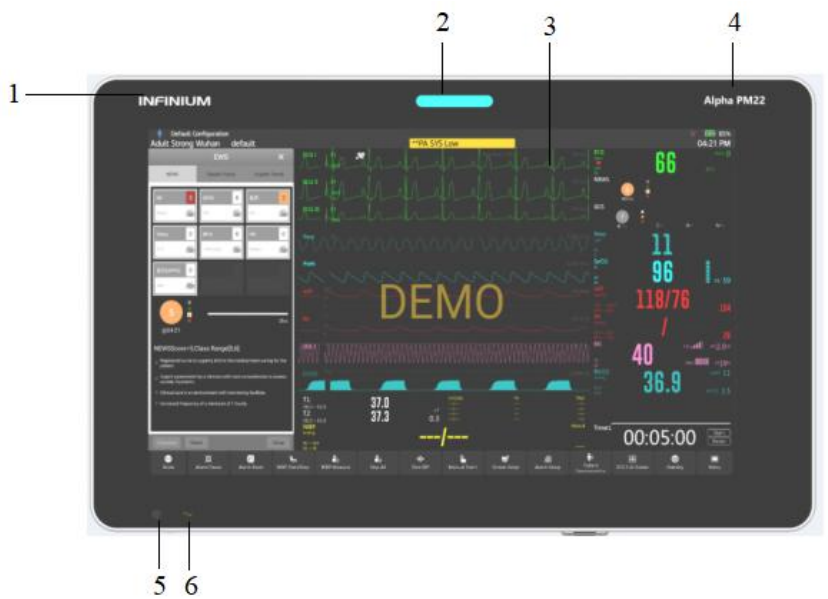


Figure 2-1 Main Unit Display

2.5.2 Main Unit Interface

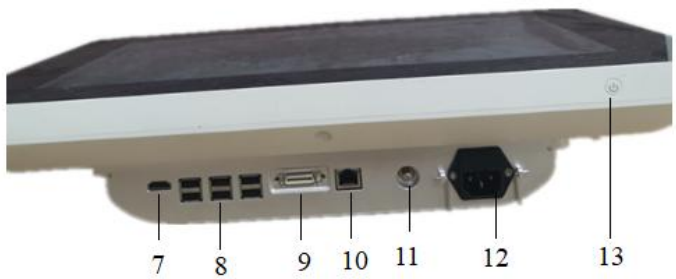


Figure 2-2 Main Unit Interface

Number	Explanation	Symbol
1	LOGO Display	INFINIUM

2	**Alarm Indicator:** Indicate technical alarm level and physiological alarm level with different color and flashing frequency. High level: Red, 2Hz Medium level: Blue, 1Hz Low level: Solid blue	
3	Screen Display Area	
4	Product Model	Alpha PM22
5	**Battery Indicator**: **ON**: when the battery is being charged or already fully charged. **Flash**: when the patient monitor operates on battery power. **OFF**: when no battery is installed or no AC source is connected.	
6	**AC Power indicator**: **ON**: when AC power is connected. **OFF**: when AC power is connected.	
7	HDMI connector	HDMI
8	USB 2.0 port * 6	USB
9	Data cable port	
10	**10/100M Self-Adaptive Network Interface**: It is a standard RJ45 connector that connects the patient monitor to other devices or system to communicate between beds and upgrade system network.	
11	**Equipotential Grounding:** connecting other instruments and equipment with equipotential grounding system to eliminate the ground potential difference between different equipment to ensure safety	
12	**AC Power Input**: 100~240V AC 50/60Hz	100-240V 50/60Hz 1.3-0.5A
13	Power **ON/OFF** (for turning **ON/OFF** the monitor)	

2.6 Satellite Module Rack (SMR)

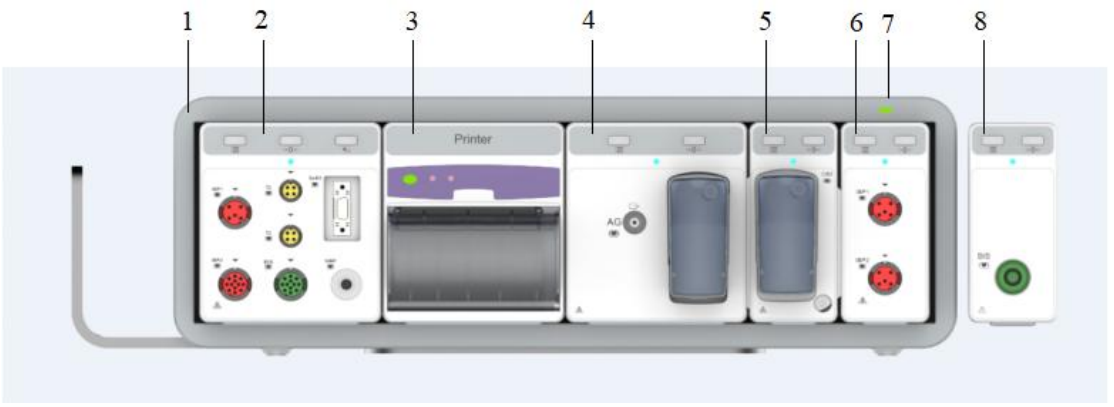


Figure 2-3 Satellite Module Rack (SMR) Front View

Figure 2-4 Satellite Module Rack (SMR) Rear View

Number	Explanation	Symbol
1	Satellite Module Rack (SMR)	
2	P6 Module	
3	Printer Module	
4	AG Module	
5	CO2 Module	
6	P2 Module	
7	Satellite Module Rack (SMR) Power Indicator	
8	BIS Module	
9	Data Cable Port	

2.7 External Modules

2.7.1 P6 Module

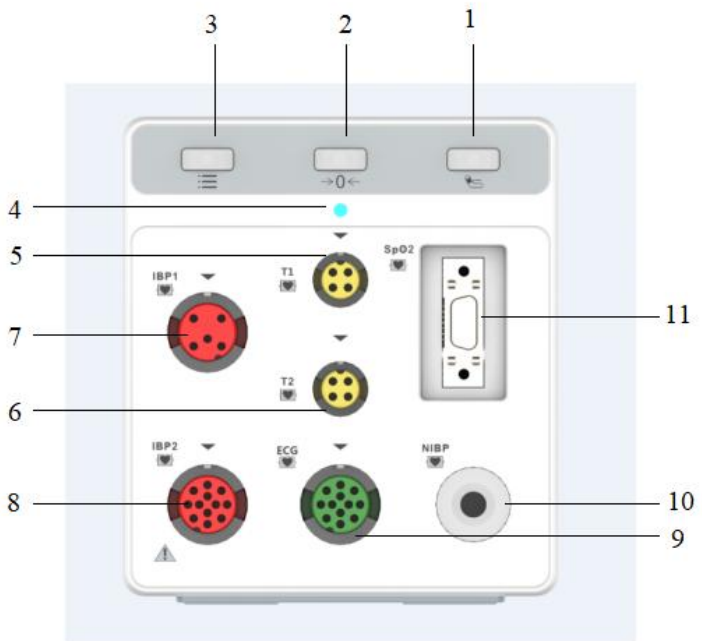


Figure 2-5 P6 Front View

Number	Explanation	Symbol
1	NIBP ON/OFF button	
2	IBP1 and IBP2 zero button	→0←
3	Module setup menu	
4	Module power indicator(Green)	
5&6	T1 and T2 sensor connector (Yellow) Connect with body surface or body cabity temperature probe	
7&8	IBP1 and IBP2 sensor connector (Red) Connect with single IBP extension cable	
9	ECG sensor connector(Green) Connect with ECG lead	

10	NIBP sensor connector Connect with NIBP cuff	
11	SpO2 sensor connector Connect with SpO2 probe	

2.7.2 P2 Module

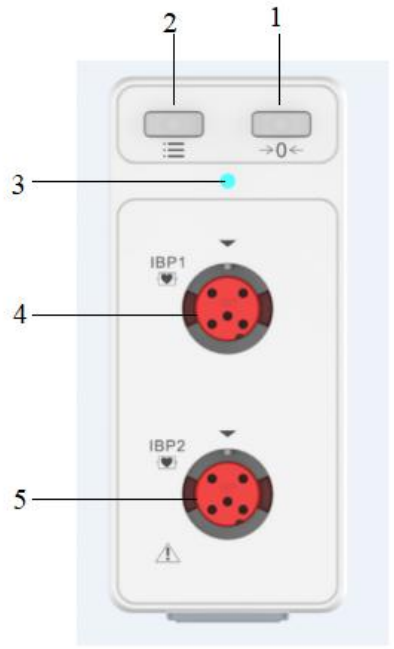


Figure 2-6 P2 Front View

Number	Explanation	Symbol
1	IBP zero button	→0←
2	Module setup menu	
3	Module power indicator(Green)	
4	IBP sensor connector (Red 5P or 10P) Connect with single or dual IBP extension cable IBP1 or IBP1-1/IBP1-2	

5	Config 1: IBP Sensor Connector (Red 5P or 10P) Connect with single or dual IBP extension cableIBP2 or IBP2-1/IBP2-2 Config 2: C.O. Sensor Connector(Green) Connect with C.O. extension cable	

2.7.3 Printer Module

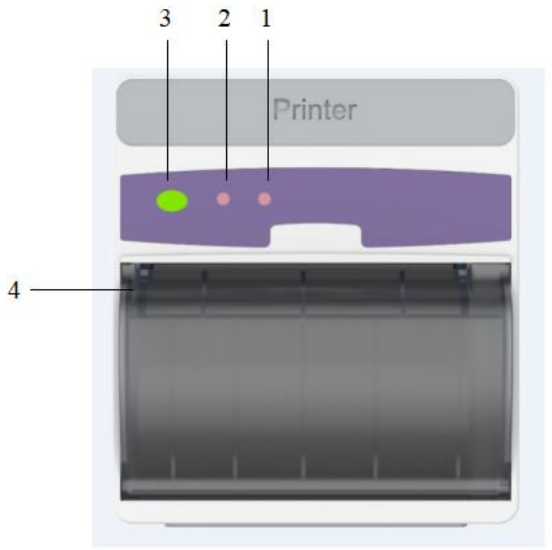


Figure 2-7 Printer Front View

Number	Explanation	Symbol
1	Signal indicator(yellow)	**ERROR**
2	Power indicator(yellow)	**POWER**
3	Paper roll button	**REC/STOP**
4	Thermal paper storage	

2.7.4 CO2 Module

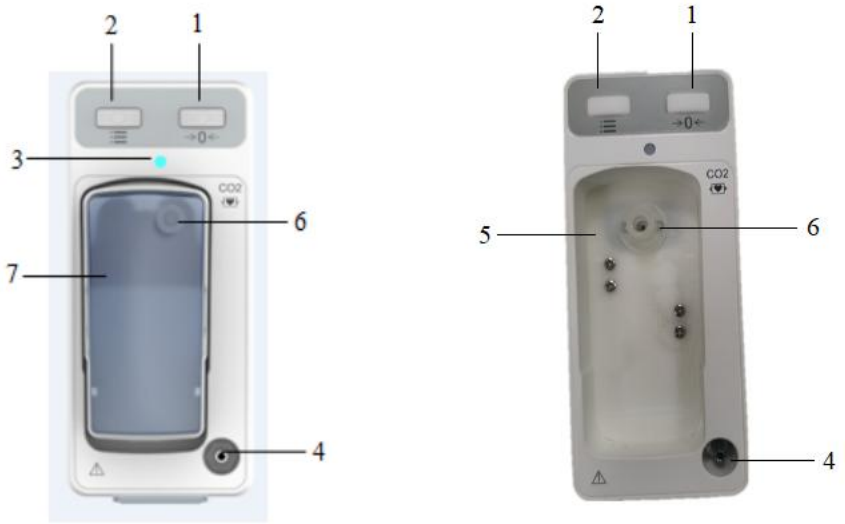


Figure 2-8 CO2 Front View

Number	Explanation	Symbol
1	CO2 zero button	→0←
2	Module setup menu	
3	Module power indicator(green)	
4	Gas outlet	
5	Environmental CO2 concentration acquisition port	
6	Gas in	
7	Dehydration tank	

2.7.5 BIS Module

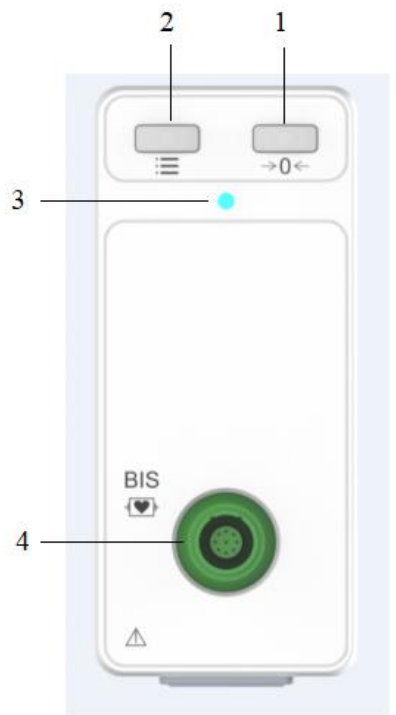


Figure 2-9 BIS Front View

Number	Explanation	Symbol
1	CO2 zero button	→0←
2	Module setup menu	
3	Module power indicator(green)	
4	Bis sensor connector(green)	

2.7.6 AG Module

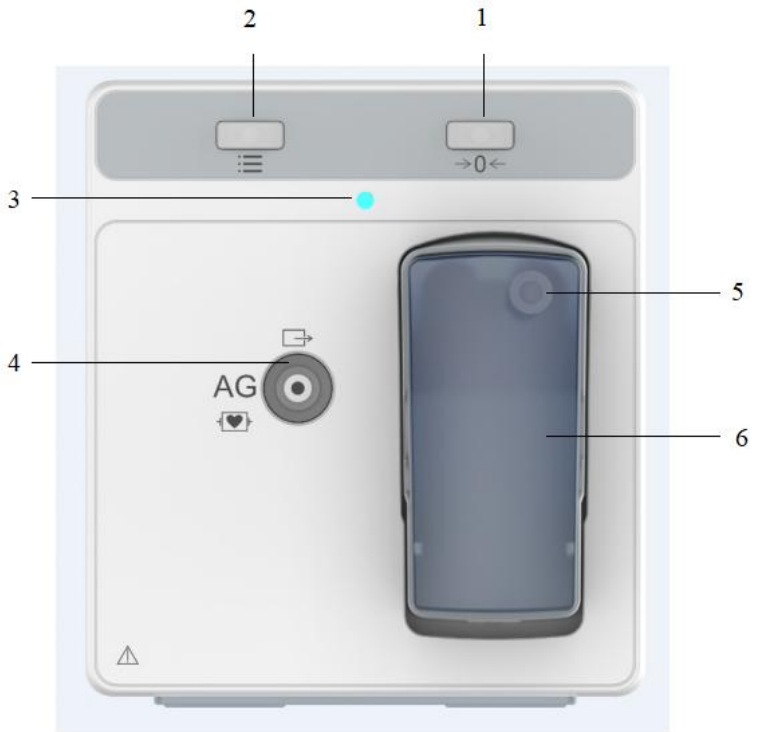


Figure 2-10 AG Front View

Number	Explanation	Symbol
1	CO2 zero button	→0←
2	Module setup menu	
3	Module power indicator(green)	
4	Gas outlet	
5	Air in	
6	Dehydration tank	

2.8 Monitor Mount

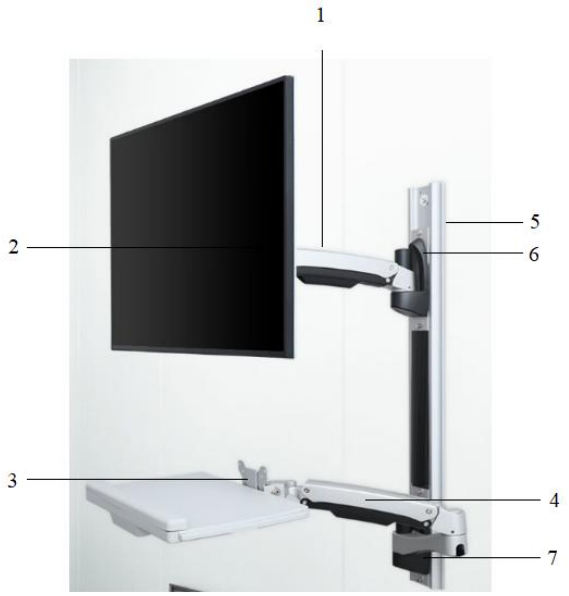


Figure 2-10 Monitor Mount Rendering

Number	Explanation	Symbol
1	Monitor mount arm	
2	Monitor mounting bracket	
3	Module mounting bracket	
4	Module arm	
5	Bracket arm chute	
6	Monitor arm slider	
7	Module arm	

2.9 Input Device

User can input information by touchscreen, keyboard and mouse. You can only use the input device specified by the manufacturer,

2.10 Printing Device

You can output patient information and data using printers or thermal recorders. You have to insert the Module to use thermal recorder module.

This monitor can print patient reports by connecting online printers.

3 Monitor Preparation

3.1 Description

This section describes the preparation work and basic setup of the monitor before it is used.

3.2 Safety Precautions

WARNING

- Please use the installation accessories authorized by us.
- The software copyright of the equipment is solely owned by us. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
- Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g., IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1-1. If you have any question, please contact us.
- If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or else an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.
- ACCURACY - If the accuracy of any value displayed on the monitor, central station, or printed on a graph strip is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly
- The operator should check whether the current alert setting is appropriate for the current patient before using the monitor.

CAUTION

- This device shall be installed by personnels designated by the company.
- Please keep the packaging material out of children's reach. When disposing of it, be sure to observe the applicable waste control regulations.

- The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single-use accessories. In case of any damage, do not apply it to patients.
- Make sure that the operating environment of the equipment meets the specific requirements. Otherwise, unexpected consequences, e.g., damage to the equipment, could result.
- Please read this manual thoroughly to ensure the proper use of the product and safety of both patient and operator.

NOTE

- Put the equipment in a location where you can easily view, operate and maintain it.
- Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.
- Save the packing case and packaging material as they can be used if the equipment must be reshipped.

3.3 Installation

3.3.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or the manufacturer. If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. If you have any question, please contact us.

3.3.2 Environmental Requirements

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

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

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

3.4 Getting Started

Please read this manual carefully before using it to familiarize yourself with the device's performance, operation methods and cautions.

3.4.1 Connecting to AC Power Source

The monitor is powered by AC. Before connecting the AC power source, please make sure that the voltage and frequency of the AC power source are the same as the voltage and frequency marked on the power plug.

Connect to the AC power source by following the steps in below:

1. Plug the power cord into the AC power source.
2. Plug the other end of the power cord into a grounded three-wire power outlet.
3. Check if the AC power status indicator is on to ensure the proper connection with AC power

AC power status indicator is on the right side of **ON/OFF** button. The green LED illuminates when the monitor is receiving AC power. Otherwise, the indicator is off.

WARNING

- Use the power cord provided in the product package for power connection.
- Before connecting to the AC power sources, please ensure the voltage and frequency are the same as marked on the device or meet the requirement of this manual.
- To avoid the risk of electrical shock, Use the battery if the integrity of the protective earth (ground) conductor is in doubt.

3.4.2 Turning On

Before you turn on the monitor, please get ready for monitoring:

1. Check the patient monitor, and Module for any mechanical damage and make sure that cables, modules and accessories are properly connected.
2. Plug the power cord into the AC power source. If you run the patient monitor on battery power, ensure that the battery is sufficiently charged.

Press the Power **ON/OFF** button for 3s to turn on the equipment. The alarm light and the key backlight will illuminate, the welcoming screen will appear with a page indicating '***Loading System ...***' message, after 1-2min, this initialization will start and finish in 20s. When the initialization process is complete, the main screen would appear, then users can operate and start monitoring.

3.4.3 Starting Monitoring

1. Enter the patient data.

2. Connect the required modules, patient cables and sensors.
3. Check that the patient cables and sensors are correctly connected.
4. Check that the patient settings such as [Alarm limit.], [Patient Cat.], [Paced], etc., are appropriate for your patient. Change setting according to your need for measurements.
5. Start Monitoring. Refer to the related sections for parameter measurement and moniroting details.

3.5 Stopping Monitoring or Turning Off

To stop monitoring a parameter for patient:

1. Remove sensors from patient, and disconnect the patient cable from the sensor and module connector.
2. Do not reuse single-use disposable accessories.

If you want to turn off the monitor:

1. Confirm that the patient monitoring is finished.
2. Disconnect the patient cables and sensors from the patient monitor.
3. Press and hold the power **ON/OFF** button for more than 3 seconds and confirm the operation in pop-up shut-down window.

You can unplug the monitor to cut off connection from AC power.

CAUTION

- Although not recommended, you can press and hold the power **ON/OFF** button for 10 seconds to force shutdown if needed. However, this may cause data loss.

3.6 Using Touchscreen

Select screen items by pressing them directly on the patient monitor's screen. You can access nearly all the functions by tapping directly on the screen, and almost every element on the screen is interactive, including parameter measurements, waveforms, quick keys, message areas, alarm areas, menus, etc. Information can be input using the touchscreen.

CAUTION

- Check the touchscreen for any possible damage before use. If it is broken, please to stop using the monitor immediately and contact your service personnel.
- If any sign of screen detachment occurs, please stop using the monitor immediately and contact service personnel.

3.7 Screen Display

This patient monitor uses a high-resolution 21.5 inches LCD to display patient parameters and waveforms. A normal view display is shown below, as indicated in Figure 2-11:

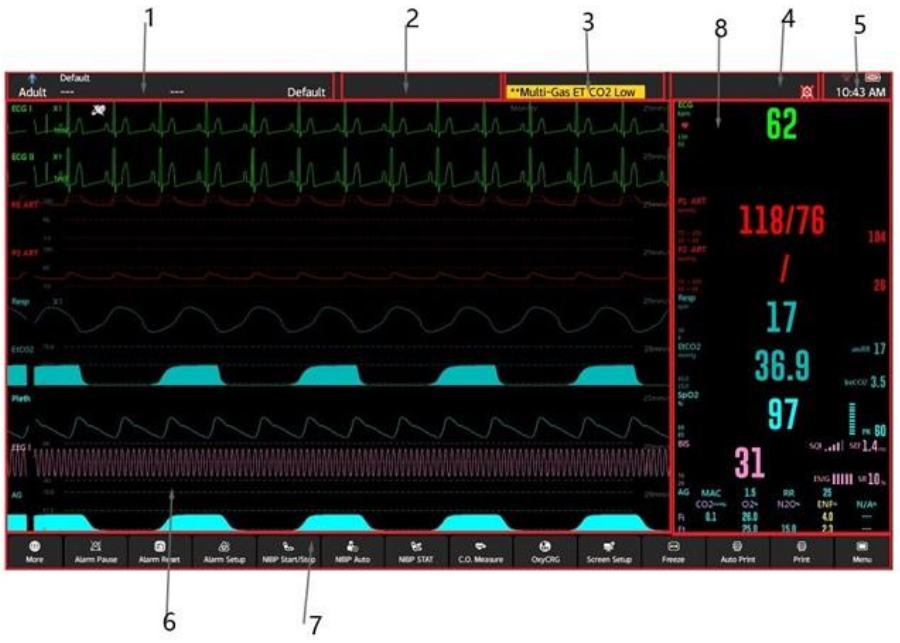


Figure 2-11 Normal Monitor View

Number	Explanation
1	**Patient Information Area** This area shows the patient information such as patient category, name, gender, ID.
2	**Technical Alarm Area** This area shows technical alarm messages and prompt messages. When multiple messages come, they will be displayed circularly. Select this area and the technical alarm list will be displayed.
3	**Physiological Alarm Area** This area shows physiological alarm messages. When multiple alarms occur, they will be displayed circularly. Select this area and the physiological alarm list will be displayed.
4	**Alarm Pause Area:** This area shows alarm pause timer and alarm pause indicator.
5	**System Status Bar**: Indicating time, network and battery status.

6	**Waveform Area** This area shows measurement waveforms. The waveform name is displayed at the left upper corner of the waveform. The waveform position on display can be adjusted. Select this area and the corresponding measurement setup menu will be displayed.
7	**Quick keys Area**: Eight quick keys for quick access: Alarm Pause, Alarm Reset, Freeze, Print, Start/Stop, View Layout, Main Menu, Pause Display.
8	**Parameter Area**: Displaying the real-time measurement value corresponding to each parameter module. Its waveform is displayed in the same row in the waveform area.

3.7.1 Symbols

Symbols	Explanation	Symbols	Explanation
	Adult Patient, male		Adult Patient, female
	Pediatric Patient, male		Pediatric Patient, female
	Neonatal Patient, male		Neonatal Patient, female
	Patient monitor has no network connection		Patient monitor is connected to a wire network successfully.
	Wireless connection is working, the white bar indicates the network signal strength		
	Alarms are turned off.		Alarms are paused.
	Alarm audio is turned off.		Alarms audio is paused.
	Alarm reset		No battery is installed
	Battery failure		Full battery
	Batteries work correctly. The solid portion represents the current charge level of the batteries in proportion to its maximum charge level.		Low battery, needs to be charged

3.7.2 System Status Bar

System status bar is on the upper right and lower right area, as illustrated below:

1) Current time: time format of either 24h or 12h.

2) Network status: display current network status (No connection, wired connection and wireless connection) and network signal strength.

3) Battery status and battery level display: not installed, in charge, failure, work correctly and battery level.

3.7.3 Quick keys

Quick keys refer to the graphical hotkeys located at the bottom of screen, allowing users to easily and quickly access certain features. The quick key area includes 14 quick keys, where the **main menu (Menu)** key is fixed in the lower right corner, and the **More** key is fixed in the lower left corner of the softkey area. Users can click **More** key to display more customized hotkeys. You can customize the hotkeys and define quick keys display order.

Figure 3-1: Quick keys

The bottom part of the monitor display is quick key area, as illustrated in Figure 3-1.

1) More

Find more quick keys.

2) Alarm Pause

Pause the alarm system, and resume the alarm after time limit

3) Alarm Reset

Reset the alarm system

4) Alarm Setup

Input password to change alarm setting for different parameters

5) NIBP Start/Stop

Start/Stop measuring the non-invasive blood pressure

6) NIBP Auto

Select time period for NIBP automatic measurement

7) NIBP STAT

Start/Stop NIBP continuous measurement

8) C.O. Measure

Open C.O. Measure window

9) OxyCRG

Open OxyCRG window

10) **Screen Setup**

Set up the waveform and parameter display layout in main screen

11) **Freeze**: Freeze or unfreeze the waveform display

12) **Auto Print**: Set up time period for auto printing, start/stop auto printing

13) **Print:** Start or stop printing

14) **Menu**: Open the main menu and configure the system parameter

Figure 3-2: More Quick keys Area

Select quick key 

at the bottom of the monitor display to pop up the More Quick keys Area in Figure 3-2.

1) **Calculations**: Calculate drug concentration.

2) **Load Config:** Save or change configuration.

3) **Parameters Setup:** Setup parameters.

4) **Trend Review**: Open tabular trend view window.

5) **History Review**: Open History Review window.

6) **Patient Demographics:** Open Patient information editing window.

7) **Zero IBP:** Open IBP zero window.

8) **Volume:** Open Volume setup window.

9) **ECG Lead/Gain:** Open ECG Lead/Gain setup window.

10) **BIS Trend**: Open BIS Trend window.

11) **Manual Event**: Save the waveform at current time point manually

12) **EWS:** Open EWS window.

13) **GCS:** Open GCS window.

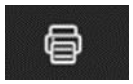
14) **Standby:** Open sleepy mode window.

NOTE

- The monitor automatically loads configuration when it shuts down last time, each time it starts.

3.7.4 Quick keys Lists

Quick keys Symbol	Quick keys Name	Explanation	Quick keys Symbol	Quick keys Name	Explanation
	Menu	Enter main setup menu		Screen Setup	Enter screen layout management window

	Alarm Pause	Pause current alarm		Alarm Off	Turn off the alarm
	Alarm Audio Paused	Pause the alarm sound		Alarm Audio Off	Turn off the alarm audio
	Alarm Reset	Reset the alarm system		NIBP ON/OFF	Start/Stop NIBP
	Freeze	Freeze waveforms		Standby	Enter standby window
	Print	Start/Stop printing		Volume	Open device volume management window
	C.O. Measure	Open Cardiac Output window.		OxyCRG	Open OxyCRG window.
	BIS Trend	Open BIS Trend window.		History Review	Open History Review window.
	Patient Demographics	Open patient information management window		Calculations	Open drug concentration calculation window
	Alarm setting	Open alarm setting menu		Parameters Setup	Open general parameter setup menu
	Zero IBP	Open IBP zero window.		ECG Lead/Gain	Open ECG Lead/Gain setup window
	Manual Event	Save the waveform at current time point manually		EWS	Open EWS window
	GCS	Open GCS window		NIBP Auto	Open auto time period setup window
	NIBP STAT	Start NIBP continuous measurement		Night Mode	Turn on night mode
	Unit	Open unit management window			

3.8 Using Timer

This monitor provides timer to display up to 4 timers at the same time. You can set up each timer respectively. Notification would prompt up when timer is off.

3.8.1 Opening Timer

Use the following method to open timer:

1. Use one of the following method to enter 'Parameters Setup' page:

◆ Select quick key '**Screen Setup**' → Sselect '**Primary Screen**' tab.

◆ Select quick key '**Main Menu'** → Select 'Parameters Setup' from '**Display**' collomn.

2. Click the timer display location in parameter area, and choose **Timer 1** or **Timer 2**

3.8.2 Opearting Timer

Timer operation buttons are:

Start: Timer starts

Pause: Timer pauses

Continue: Timer continues after pause

Reset: Timer resets

Warning

- Do not use timer to for any critical patient treatment.

3.8.3 Settting Timer

You could set up each timer separately:

1. Select timer area to enter **Timer Setup** menu.

2. Set **Timer Type:**

◆ **Normal**:Start timing according to preset **Run Time** and stop timing when Run time is reached.

◆ **Advanced**:Start timing according to preset **Run Time** and continue timing when Run time is reached, display the real-time time out.

◆ **Cycled**: the timer runs continuously with the time interval of preset **Run Time**, when therun time is reach, it will restart timing. An arrow sign in the timer area indicates the number of total timer cycles.

◆ **Unlimited**: Display the passed time.

◆ **Clock**: Display system time

3. Set **Direction**.

4. Set **Run Time**

5. Set Notification Volume. When there is 10 seconds remaining, the monitor starts to make notification sound and the timer flashes in red to alert that the clock is ending.

NOTE

- Timer can not be set while it is running.
- Setup of Timer Direction, Run Time, and Notiification Volume are only valid when Time Type are set as **Normal, Advanced, Cycled**.

3.9 Freezing Waveforms

During patient monitoring, the freeze feature allows you to freeze the currently displayed waveforms on the screen so that you can have a close examination of the patient's status. Besides, you can select any frozen waveform for thermal printing.

3.9.1 Freezing Waveforms

When waveform is not frozen, select '**Freeze**'  quick key to freeze the waveform → Freeze Setup page will pop up after the process is completed, as shown in Figure 3-3.

Figure 3-3 Waveforms Freezing Setup Page

When you freeze waveforms, all the waveforms are frozen, no longer updating or sweeping. Measurement data will update normally in parameter area, real-time alarm messages will continue updating in the alarm area.

Therefore, no alarm will be missed and loss of monitoring data will not happen during the freezing operation.

3.9.2 Viewing Frozen Waveforms

When the moving waveforms are frozen, you can view the first 8 seconds and the last 8 seconds of the continuous waveform at the freeze point. and scroll the progress bar on the freeze setting page, the frozen waveform will scroll left or right accordingly, with a waveform movement step of 1 second. Therefore, you can observe the shape and other details of the entire waveform per second.

3.9.3 Saving Frozen Waveforms

Select '**Save**' in Freeze window to save the current frozen window into file. Also, you can review the saved waveforms in '**Waveform Review**' window under **Trend** page.

3.9.4 Printing Frozen Waveforms

When the moving waveforms are frozen, you can record and print out the frozen waveforms by thermal print. In the **Freeze** menu, select **[Wave 1], [Wave 2]** and **[Wave 3]** drop-down menu respectively and then select your desired waveforms for each **Wave**.

Select the '**Print**' button. The selected waveforms and all numerics at the frozen time are printed out by the thermal printer.

4 Setup

To meet the requirements of different situations, you need to make appropriate settings for the monitor. These settings include general settings, system settings, module parameter settings, alarm settings, display mode settings, screen brightness settings, configuration information settings, factory settings, recorder settings, etc. Since parameter settings, alarm settings are closely interconnected with respective module, they will be introduced separately in other sections.

This section focuses on general settings.

4.1 General

Select '**Menu**'  in the quick keys area → Enter '**Main Menu**', Click 'Parameters Setup'→ Enter 'General Menu', as illustrated in Figure 4-1.

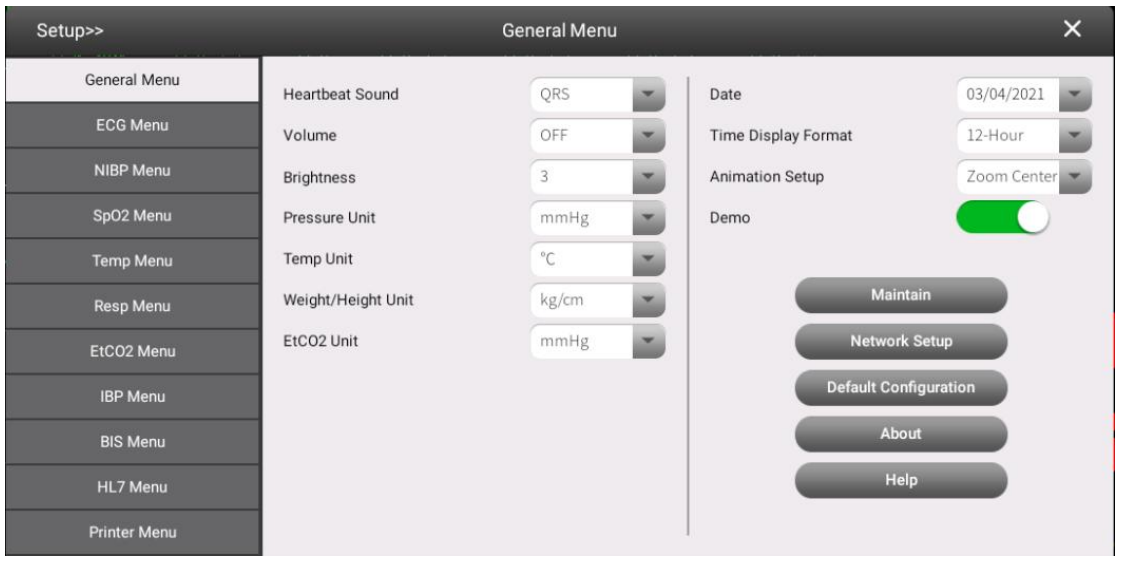


Figure 4-1: General Menu

You can set:

1) Heartbeat Sound

Select "**Heartbeat Sound**" drop-down menu to set the source of the heartbeat sound, choose QRS, Pulse, IBP1, IBP2 and OFF, the default setting is **QRS**, i.e., the heartbeat sound comes from ECG.

2) Volume

Select "**Volume**" drop-down menu to set the system volume or turn off the sound, there are 6 levels of volume: OFF, 1, 2, 3, 4, 5.

Note

- When the sound volume is set to 0, alarm sound off symbol would appear on screen.

3) Brightness

Select "**Brightness**" drop-down menu to set the screen brightness, there are 6 levels of

brightness: 0 ~ 5, the default setting is **3**.

4) Pressure Unit

Select '**Pressure Unit'** to set the **Pressure Unit** for invasive blood pressure and non-invasive blood pressure, and toggle between [**mmHg**] and [**kPa**] the default setting is **mmHg**.

5) Temp Unit

Select '**Temp Unit**' and toggle between [**ºC**] and [**ºF**]. the default setting is **ºC**.

6) Weight/Height Unit

Select '**Weight/Height Unit**' to set **Weight/Height Unit** and toggle between **kg/cm** and **lb/inch**. The default setting is **kg/cm**.

7) EtCO2 Unit

Select '**EtCO2 Unit**' to set **EtCO2 Unit** and toggle between **mmHg**, **kPa** and **%.** The default setting is **mmHg**.

8) Date

Select '**Date**' to set system date and time.

CAUTION

- Changing date and time will affect the storage of trends and events and may cause data missing.

9) Time Display Format

Select '**Time Display Format**' drop-down menu and select [**24h**] or [**12h**], The default setting is [**12h**].

4.2 Menu

Select '**Menu**'  in the quick keys area → Enter '**Main Menu**', as shown in Figure 4-2:

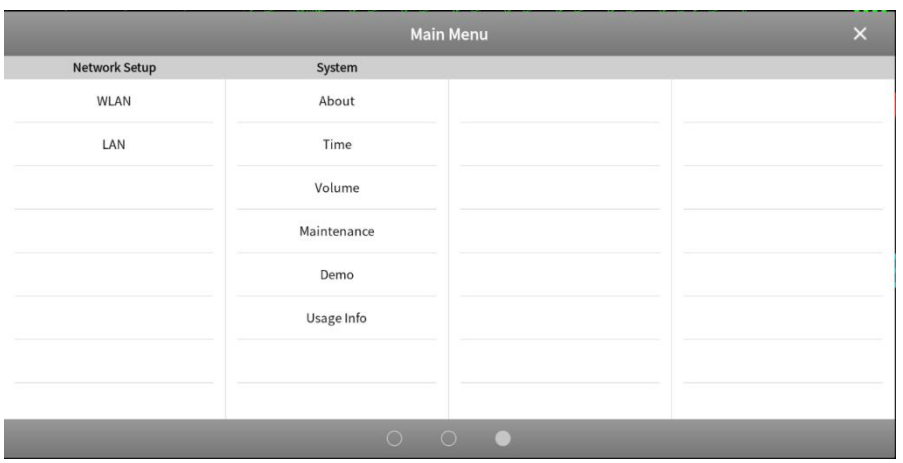


Figure 4-2 Main Menu

1) Demo

Click the **Demo** button, enter password to turn **ON/OFF** the demo.

2) Maintain

Select '**Maintain**' → Enter the maintain password to request for manufacturer maintenance.

3) Network Setup

Select '**Network Setup**' → Configure the wired/wireless connection.

4) Default Configuration

Select '**Default Configuration**' → Configurations of this monitor will be restored to factory default setting.

5) Time

Select '**Date**' to set system time.

Caution

- Changing Date will influence Trend Review and Event Recording, causing data loss.

6) Volume

Select '**Volume**' button to enter volume management manu.

7) Usage Info

Select **Usage Info** button to display device 'CPU', 'memory usage', etc.

8) WLAN

Select **WLAN** button to open WLAN setup page.

9) LAN

Select **LAN** button to open LAN setup page.

10) Drug

Select **Drug** button to open drug calculation page.

11) Oxygenation

Select **Oxygenation** button to open Oxygenation page.

12) Load Config

Select **Load Config** button to open configuration loading page.

13) Default Configuration

Select **Default Configuration** button, enter password to restore default configuration.

14) Parameters Setup

Select **Parameters Setup** button to open parameters setup page.

15) External Data Menu

Select **External Data Menu** button to open external data setup page.

16) Printer Menu

Select **Printer Menu** button to open printer setup page.

17) Primary Screen

Select **Primary Screen** button to open page setup page.

18) Quick Keys

Select **Quick Keys** button to open **quick keys change** page

19) Switch Parameter

Select **Switch Parameter** button to open parameter and waveform display management page

20) Night Mode

Select **Night Mode** button to open Night Mode setup page

21) GCS

Select **GCS** button to open GCS page

22) EWS

Select **EWS** button to open EWS page.

23) Tabular Trends

Select **Tabular Trends** button to open Tabular Trends page.

24) Graphic Trends

Select **Graphic Trends** button to open Graphic Trends page.

25) NIBP Tabular Trends

Select **NIBP Tabular Trends** button to open NIBP Tabular Trends page.

26) Waveform Review

Select **Waveform Review** button to open Waveform Review page.

27) Alarm Limit

Select **Alarm Limit button** to open Alarm Limit setup page.

28) Alarm Setup

Select **Alarm Setup button**, enter password to open alarm setup page.

29) Demographics

Select **Demographics button** to open Patient Demographics page.

30) History Review

Select **History Review button** to open Patient History Review page.

31) Standby

Select **Standby button** to open Standby page.

32) About

Select '**About**' → Check the device basic info and software version, as shown in Figure 4-3.

Figure 4-3: 'About' Window

4.3 External Data Menu

Select the quick key **Menu** from monitor bottom, enter Main Menu and select **External Data Menu** to enter **External Data Menu**, as shown in Figure 4-4

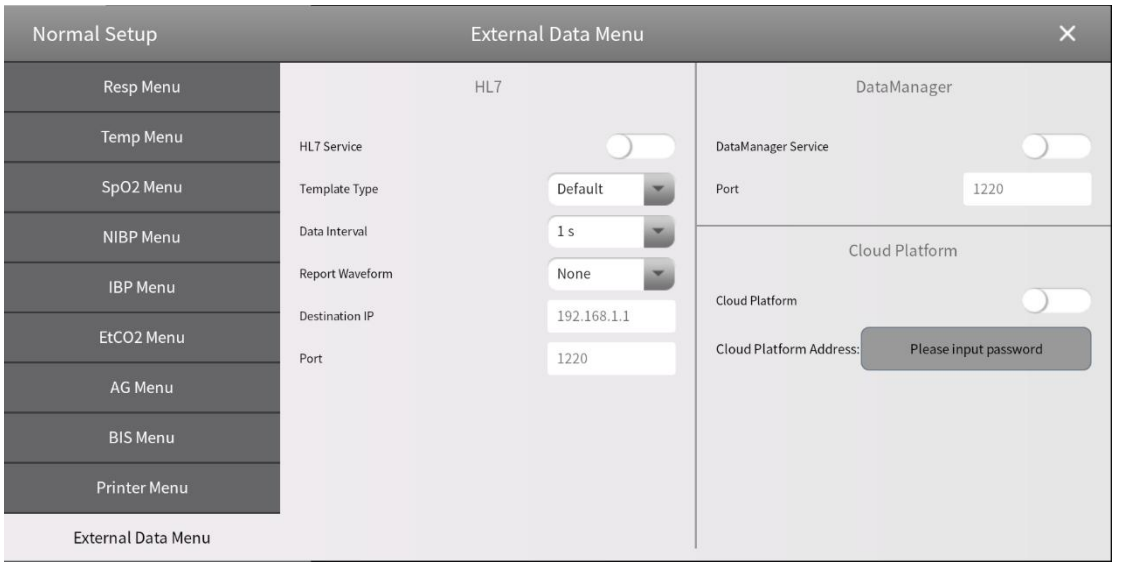


Figure 4-4 External Data Menu

4.3.1 HL7

For data transmission, the following HL7 items needs to be configured:

1) HL7 Service

Click '**HL7 Service**' button to turn **ON/OFF** HL7 Service, the default setting is **OFF**. When HL7 service is **OFF**, you could change HL7 settings. When HL7 service is **ON**, HL7 setting is disabled.

2) Template Type

Select '**Template Type**' to set the Template Type and toggle between '**Default**' and '**EPIC**'. The default type is '**Default**'.

3) Data Interval

Select '**Data Interval**' drop-down menu to set the data interval of HL7 message uploading.

Selections are 1s, 5s, 10s, 15s, 20s, 25s, 30s, 1min. The default setting is **1s**.

4) Report Waveform

Select '**Report Waveform**' drop-down menu to set HL7 waveform type for uploading. In ECG 3-lead mode, no setting is required. In 5-lead mode, Options are None, ECG I, ECG II, ECG III, ECG aVR, ECG aVF, ECG aVL, ECG V, All Leads. The default setting is **None**.

5) Destination IP

The default IP address of remote receiving server for HL7 communication is 192.168.1.1. To communicate successfully, please setup the actual IP address of the remote server.

6) Port

Configure the actual port of remote server. The default port is **1220**.

4.3.2 DataManager

On this setup page, you need to configure the setting items for the DataManager to communicate properly.

1) DataManager Service

Select the **DataManager Service** button to turn on or off the service, by default, the service is off. Users can turn on the service while it is off but can not switch it off while it is on.

2) IP Port

Set the host IP port number, default port: 1220, the user can set the port number accordingly.

4.3.3 Cloud Platform

1) Cloud Platform

Select the Cloud Platform bbutton to turn on or off cloud platform connection, by default, the service is off. Users can modify the cloud platform configuration when the service is off, but can't change and operate while the service is on.

2) Cloud Platform Address

Enter a password to set the IP address and port number based on the remote host IP address and port number.

4.4 Printer Menu

Select '**Main Menu**' → '**Printer Menu**', as shown in Figure 4-5.

Figure 4-5: Printer Menu

You can set:

1) Status

If the monitor is connected to the printer successfully, the status will be '**Connected**'; If connection fails, the status will be '**Disconnected**'.

2) Alarm Print

Select '**Alarm Print**' drop-down menu to turn **ON/OFF** alarm print. If '**Alarm print**' is **ON**, when alarm occurs, the printer would print out the waveform and parameter information for the current state. The function will be disabled when '**Auto Print**' is **OFF**.

3) Auto Print

Select '**Auto Print**' drop-down menu to set the time interval of '**Auto Print**'. Interval options are 5 minutes,10 minutes,20 minutes,30 minutes, 60 minutes and OFF. When auto print interval is set and the time limit is reached, the parameters information will be printed out automatically. The function will be disabled when '**Auto Print**' is **OFF**.

4) Parameters Only

Select '**Parameters Only**' drop-down menu and toggle between **ON/OFF**.

When '**Parameters Only**' is **ON**, Only the parameter information supported by the monitor is printed; if set to **OFF**, print the selected waveform set in **Waveform1 ~ Waveform3** and the information about all parameters.

5) ECG Only

Select 'ECG Only' drop-down menu and toggle ECG Only ON/OFF.

When 'ECG Only' is ON, Only the ECG waveform and parameter are printed; if set to OFF, print all waveform and parameter information set by this monitor.

6) Waveform1 ~ Waveform3

Select '**Waveform 1 ~ 3**' drop-down menu respectively to set the waveform parameter for printing.

4.4 Module Menu

Select '**Main Menu**' → '**Module Menu**' to enter Module Menu window, as illustrated in Figure 4-6.

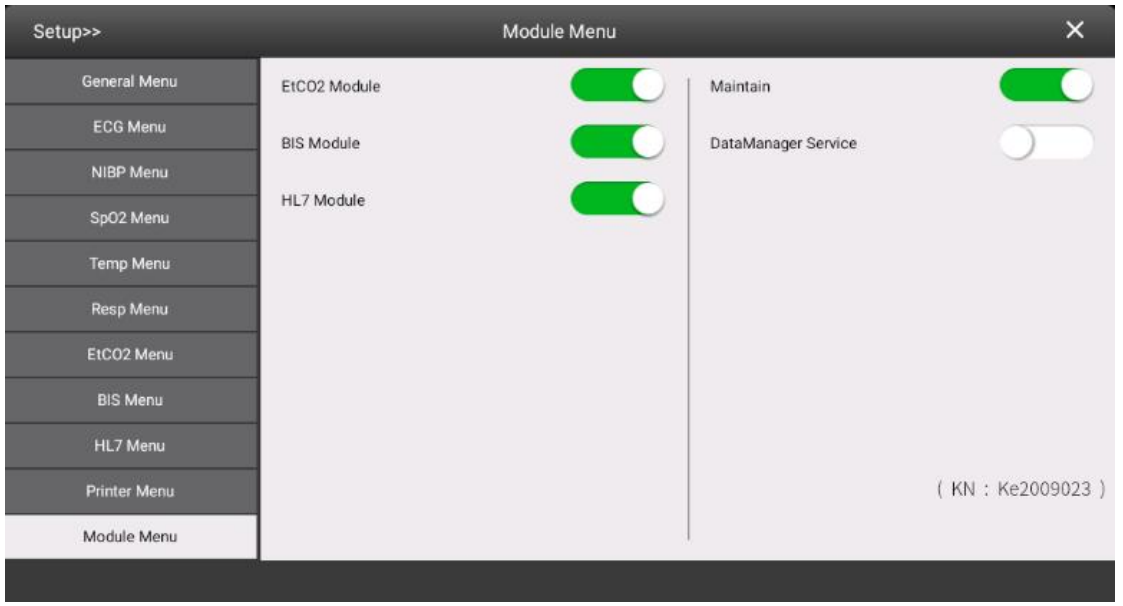


Figure 4-6: Module Menu

To avoid the improper operation of the monitor due to accidentally changed configuration, some configurations require password from authorized personnel. Module Menu settings are:

1) EtCO2 Module

To enable turning **ON/OFF** EtCO2 module, EtCO2 password generated from KN number is required.

2) BIS Module

To enable turning **ON/OFF** BIS module, BIS password generated from KN number is required.

3) HL7 Module

To enable turning **ON/OFF** HL7 module, HL7 password generated from KN number is required.

4) Maintain

Each equipment has only one password. The manufacturer can debug the equipment using manufacturer password, which itself can't be used by any other people.

5) DataManager Service

Installation of our **DataManager** software on PC allows you to view historical patient data stored in different devices within the LAN.

When the **DataManager Service** is enabled on the monitor, your PC can connect to the monitor through the DataManager software and export the history patient data from the device.

4.5 Config Manager

To meet the health care demand for different patient category, you can adjust the settings as required and then save it as a specific Config. Besides the default Config provided by default, you can create new local configurations or save customize local configurations.

To access Configuration Management:

Select the quick key '**Main Menu**' in the quick key area at the bottom of the monitor → Select **Load Config** button to change to configuration management page, as illustrated in Figure 4-6.

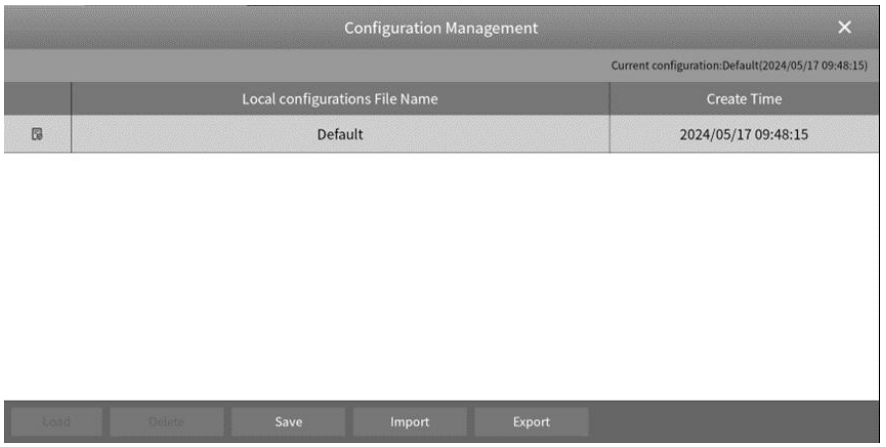


Figure 4-6 Configuration Management

Users need to enter password to gain authorization to enter Config Manage and operate.

Current **Configurations** are all displayed in configuration management window. In the config table, each row represents one configuration storage. Default configuration can only be loaded, operations other than this are all disabled, such as delete, save as, export etc.

1) Delete

Click '**Delete**', the selected configuration will be deleted, deletion will not trigger the configuration reload for current system.

2) Save

Click '**Save**', Enter a name of your configuration in the pop-up window, and the configuration will be saved.

3) Import

Plug the USB drive with the configuration file to the equipment, click "**Import**", and select the configuration file to be imported on the pop-up list. This function is used to share configuration files between devices of the same type.

4) Export

Select the row in configuration list (corresponding to the configuration file), click '**Export'** and the selected configuration will be exported to the specified USB drive.

4.6 Pause Display

Select '**Pause Display**'  in the quick keys area, the monitor will enter the **Pause Display** mode, the '**Pause Display**' window will appear, as illustrated in Figure 4-7.

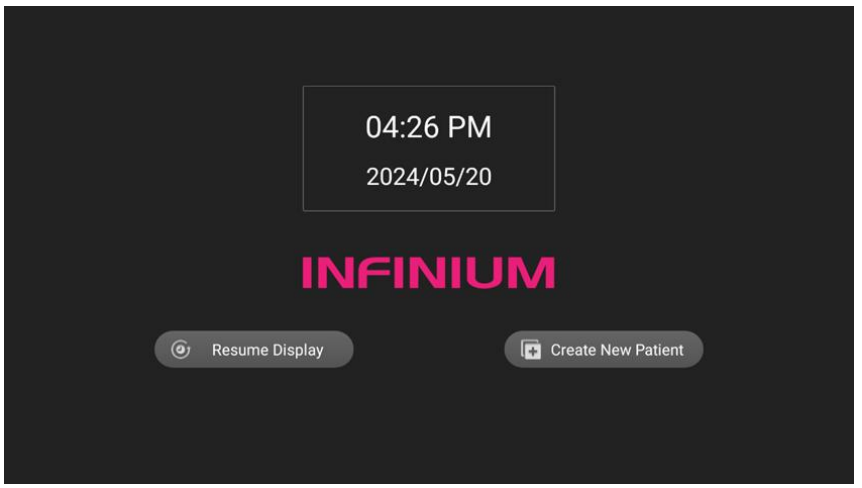


Figure 4-7: Pause Display

In this page, the following functions can be accessed:

1) Resume Display

Click '**Resume Display**' → The monitor will resume the display mode.

2) Create New Patient

Click '**Create New Case**' → The system will exit the current pause display mode. Create new patient profile by enter the patient information, after that the new monitoring procedure will start and monitoring data will be saved.

5 Display Mode

The Alpha PM22 patient monitor includes 7 display modes: **Normal View**, **Big Font View, Minitrend View**, **EWS Monitor, OxyCRG View**, **C.O. Monitor View**, and **BIS Trend View**, the display format of waveforms and parameters differ in different display modes. For more details, see the explanation of each display mode.

5.1 Screen Setup

Select the quick key '**Screen Setup**'  , Enter **Screen Setup** configuration page, as illustrated in Figure 5-1.

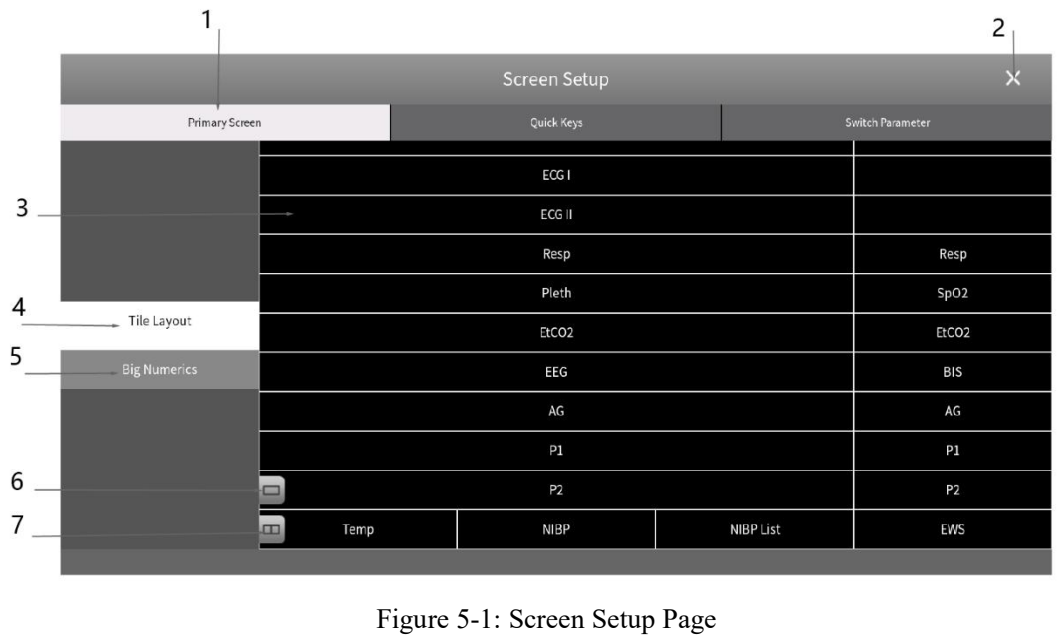


Figure 5-1: Screen Setup Page

5.1.1 Primary Screen

Select Primary Screen tab to enter the Primary Screen setup page. (See Figure 5-1)

Number	Function Explanation
1	**Primary Screen**: Enter primary Screen setup page.
2	**Close**: Close screen setup and refresh the primary screen display.
3	**View/Layout**: Each cell in the table specifies the corresponding area, click the cell to fill in the selected parameters or waveforms for display.
4	**Tile Layout**: Click and enter tile layout setup page.
5	**Big Numerics**: Click and enter big numerics page.
6	**Layout Merge (One cell)**: Indicating that this one-cell waveform area is merged from 2 parameter areas.

7	**Layout Merge (Three cells)**: Click to merge 3 parameter area into one-cell waveform area.

NOTE

- If the measurement module is not in place, corresponding parameters and waveforms can't be displayed.
- After the setup is completed, the system will save the current layout setting to the configuration file and automatically arrange the currently available waveforms and parameters to ensure the best display effect.

5.1.2 Quick Keys

Select '**Quick Keys'** tab to change to '**Quick Keys'** setup page, as shown in Figure 5-2.

Figure 5-2 Quick Keys Setup Page

Number	Function Explanation
1	**Quick Keys:** Category Name, click it to change to quick keys setup page.
2	**Close:** Close setup page and refresh the quick keys at the bottom of screen.
3	**Quick Keys Layout Area**: Layout order in this zone corresponds to the bottom quick key area, which can be modified by selecting buttons.
4	**Set Quick Key Blank:** Click to set the selected quick key as blank.
5	**Select Quick Key:** Click to set the selected quick key
6	**Current:** Click and change the default quick keys at the bottom.

7	**More**: Click and change the extended quick keys at the bottom.

5.1.3 Switch Parameter

Select '**Switch Parameter**' tab to change to 'Switch Parameter' setup page, as shown in Figure 5-3.

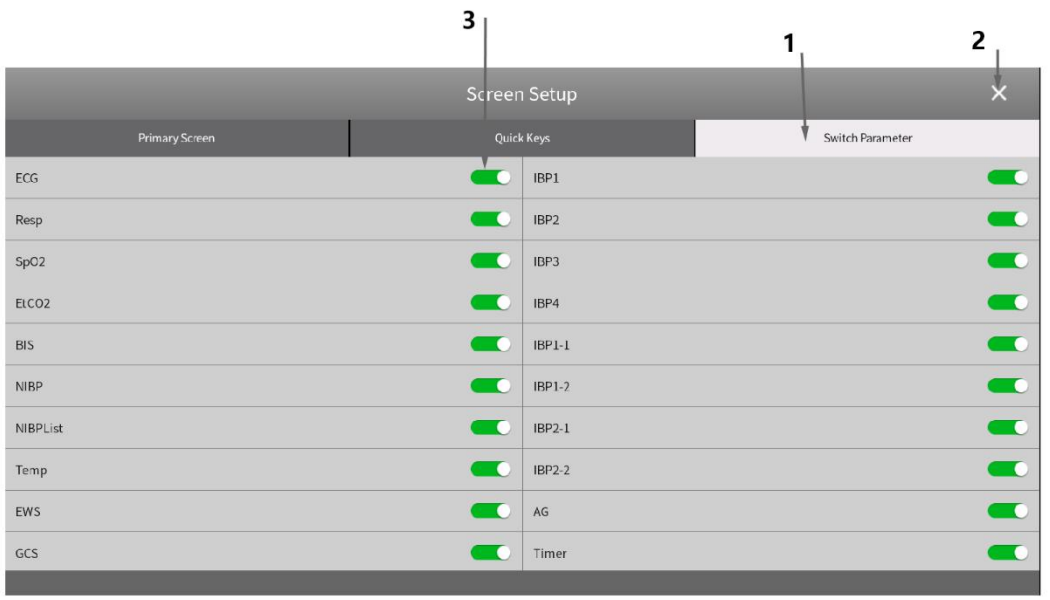


Figure 5-3 Switch Parameter setup page

Number	Function Explanation
1	**Switch Parameter:** Category Name, click it to change to Switch Parameter setup page.
2	**Close:** Close setup page and refresh the parameter and waveform display on primary screen.
3	**Layout Display Switch:** to turn on or turn off corresponding parameter and waveform display on primary screen.

5.2 Normal View

When the monitor is turned on, **Normal View** will be loaded by default, you can use two or more fingers to swipe left and right on the touch screen to switch between the **Normal View** and the **Big Font View**. In Normal View, select "**View/Layout**" to configure the **Normal View Layout**, as shown in Figure 5-4.

Figure 5-4 Normal View

The layout is demonstrated in Figure 5-5:

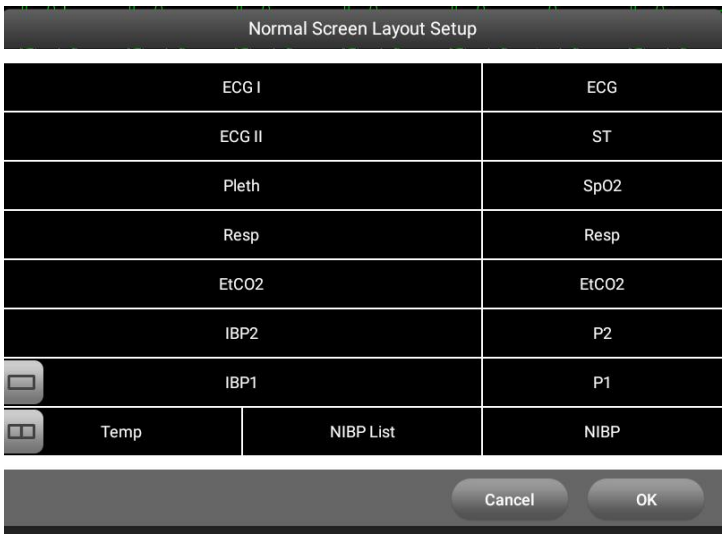


Figure 5-5 Normal View Layout

In this mode, the screen could display 12 waveforms at most on main page simultaneously. And you could select from 20 waveforms: **ECG I, ECG II, ECG III, ECG AVR, ECG AVF, ECG AVL, ECG V, Pleth, Resp, IBP1, IBP2, IBP3, IBP4, IBP1-1, IBP1-2, IBP2-1, IBP2-2, EtCO2, BIS, AG**. Therefore, this mode is suitable for monitoring situations where multiple waveforms are needed for observation at the same time.

You can customize the layout for waveform-parameter combination area:

- Select parameter on the right column, the corresponding waveform will appear in the left cell. Vice versa, select waveform on the left column, the corresponding parameter will appear in the right cell. If the parameter does not have a waveform for display, you could choose ECG waveform for display in the corresponding space or leave it empty.
- The 2 rows and 4 columns at the bottom of the layout table is the mixed waveform-parameter area, which can flexibly meet your layout display demands. The 3 columns on the left can be merged into a waveform area, or the whole merging waveform area split into a 3-column parameter area.

NOTE

- The first row of the waveform-parameter area is set to display the ECG waveform and ECG parameters. (No change can be made)

5.3 Big Font View

Swipe left and right on the touch screen using two or more fingers to switch between the **Normal View** and the **Big Font View**, as illustrated in Figure 5-4.

In Big Font View mode, select '**View/Layout**' → **Big Font View Layout** window will pop up.

Figure 5-6 Big Font View

Figure 5-7 shows the layout setup of **Big Font View**, you could select parameters with or without waveforms to observe in this mode. This mode suits the critical monitoring situation for more convenient observation.

Figure 5-7 Big Font Layout Setup

To customize the **Big Font Layout**:

- No distinction between waveform and parameter areas, and is free to change layout according to needs.
- The screen is divided into 6 display areas.

5.4 Minitrend View

Use two or more fingers to swipe left and right on the touch screen to switch between the Normal View, the Big Font View and Minittrend View. In Minitrend View, select '**Screen Setup**' quick key to configure the Trend View Layout, as shown in Figure 5-8.

Figure 5-8 Trend View Display Page

Minitrend view shares the same layout table with normal view, as shown in Figure 5-9:

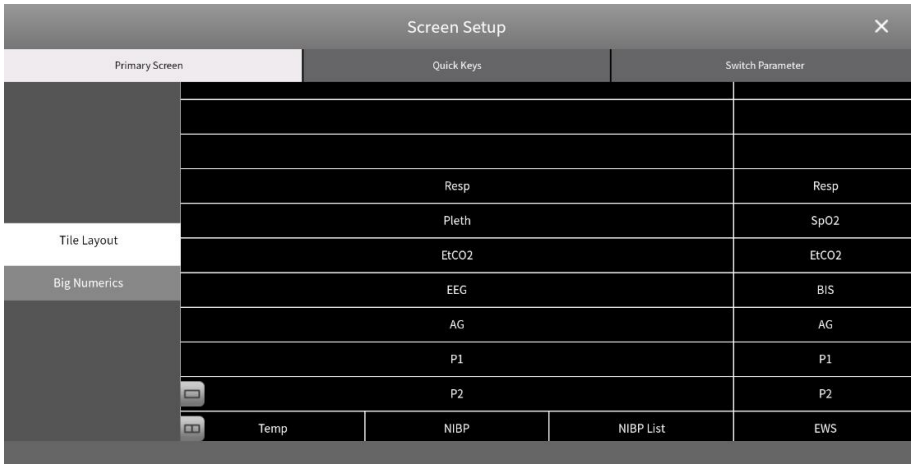


Figure 5-9 Normal View layout table

In this mode, the screen could display 12 waveforms at most on main page simultaneously. And you could select from 20 waveforms: ECG I, ECG II, ECG III, ECG AVR, ECG AVF, ECG AVL, ECG V, Pleth, Resp, IBP1, IBP2, IBP3, IBP4, IBP1-1, IBP1-2, IBP2-1, IBP2-2, EtCO2, BIS, AG. Therefore, this mode is suitable for monitoring situations where multiple waveforms are needed for observation at the same time.

You can customize the layout for waveform-parameter combination area:

- Select parameter on the right column, the corresponding waveform will appear in the left cell. Vice versa, select waveform on the left column, the corresponding parameter will appear in the right cell. If the parameter does not have a waveform for display, you

could choose ECG waveform for display in the corresponding space or leave it empty.

- The 2 rows and 4 columns at the bottom of the layout table is the mixed waveform-parameter area, which can flexibly meet your layout display demands. The 3 columns on the left can be merged into a waveform area, or the whole merging waveform area split into a 3-column parameter area.
- The difference between a minitrend waveform display and a normal waveform display. Due to the minitrend interface, the primary screen is shown in three sections. On the left is the minitrend zone, in the middle is the waveform zone, the right side is the parameter display area. When the three columns of the waveform layout table are all set as parameters, two columns of parameters are displayed at the bottom. The third is automatically displayed on the first column of the penultimate row. For the penultimate row of the layout table, if set as a waveform, it will be overwritten and not displayed. if you set one parameter, it will be displayed in waveform area of primary screen, the second column of the penultimate row. If you set two or three parameters, the second and third parameters will be shown in the antepenultimate row on the waveform area of primary screen. The waveform of the antepenultimate row will be overwritten.

5.4.1 Minitrend Display

The default display order of minitrend follows the parameter layout order on the right. Corresponding parameter data are stored for a certain period for trend display.

5.4.2 Minitrend Setup

Click Minitrend Layout, enter '**Minitrend Setup'**, as shown in Figure 5-10.

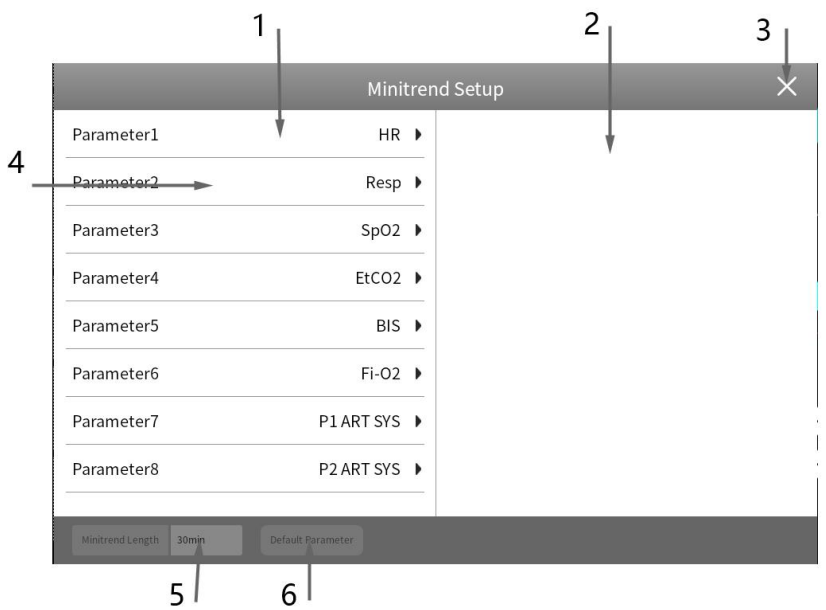


Figure 5-10 Minitrend Setup Page

Number	Function Explanation
1	This area shows the default display order of minitrend on primary screen.
2	The exceeding part of No.1 area would display in this area by order.
3	Close minitrend setup page.
4	Click the drop-down menu, select Change Minitrend Display, and refresh the main screen for Minitrend Display.
5	The default save time is 30min, click the pop-up drop-up menu, select Minitrend Length, and refresh the display of Minitrend on the primary screen.
6	Restore all settings for the default minitrend view and refresh the display on primary screen.

NOTE

- The first row of the waveform-parameter area is set to display the ECG waveform and ECG parameters. (No change can be made)

5.5 OxyCRG View

Select '**OxyCRG**' quick key OxyCRG,→ Enter real-time **OxyCRG View** display page, as shown in Figure 5-11.

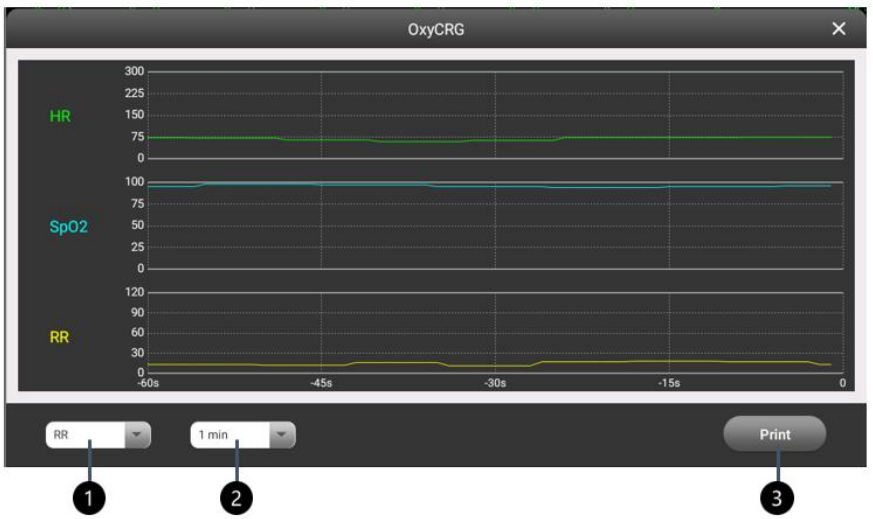


Figure 5-11: OxyCRG View

Number	Explanation
1	**Respiratory Rate (RR)/ Respiratory Waveform (RW) Switch:** Select the drop-down menu to switch between RR and RW display.

2	**Time Interval Setting**: Select the drop-down menu to set the time interval for trend data display. Time Interval lists are: 1min, 2min, 4min, 8min (4 levels in total). For Respiratory Waveform, only 1min time interval can be applied.
3	**Print**: Click '**Print**' to print out OxyCRG trend data or waveform in the current OxyCRG View.

5.6 C.O. Measure View

Select '**C.O. Measure**' quick key → Enter **C.O. Measure View**, as shown in Figure 5-12.

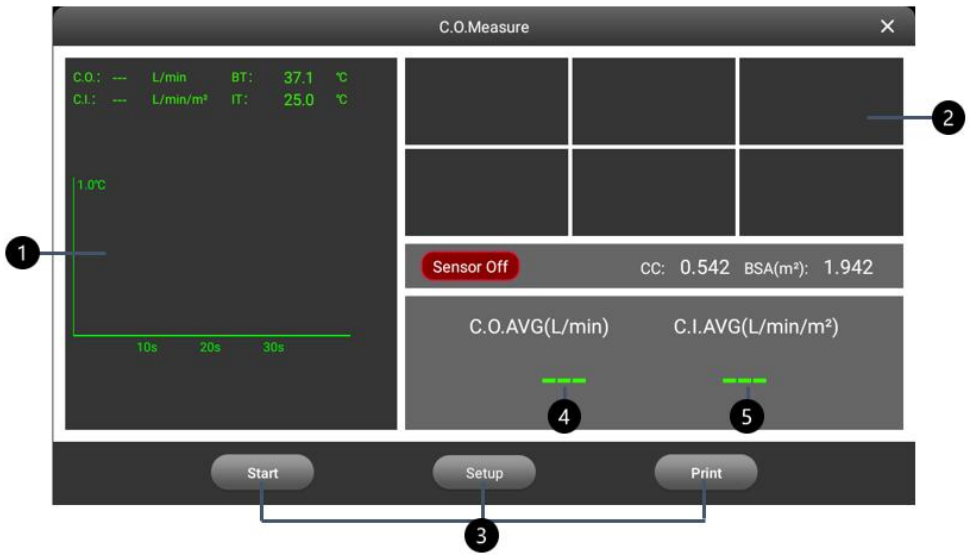


Figure 5-12: C.O. Measure View

Number	Explanation
1	**Real-time Measurement Window**: display the real-time measuring parameter and waveform.
2	**History Measurement Window**: display history measurement data, click to select or unselect the specified history record. If selected, the specified measurement record will be involved for average value calculation. History measurement data is selected by default.
3	**Function Keys**: **Start**: Start measurement **Setup**: Enter the Setup page **Print:** Print current measurement data only, including parameters and waveforms.

4	**C.O. Average**: Calculate automatically the average C.O. value out of the selected measurement data.
5	**C.I. Average**: Calculate automatically the average C.I. value out of the selected measurement data.

5.7 BIS Trend View

Select '**BIS Trend**' 

→ Enter **BIS Trend View**, as shown in Figure 5-13.

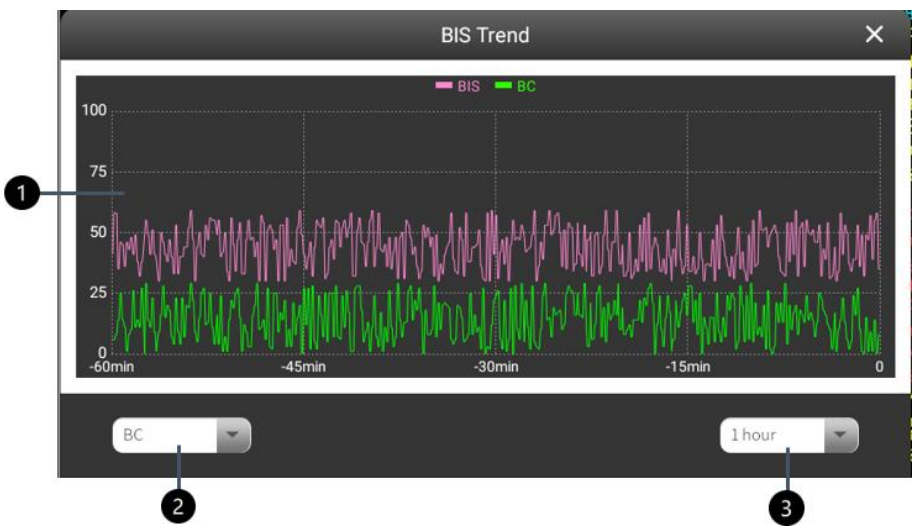


Figure 5-13: BIS Trend View

Number	Explanation
1	**Real-time Trend Field**: Display real-time specified parameter trend in line graph.
2	**Parameter Setting**: Select parameters for display from the drop-down menu. Options are BC, EMG, SQI, SR.
3	**Time Interval Setting**: Select the drop-down menu to set the time interval for trend data display. Time Interval list is: 1 hour, 2 hours, 4 hours (3 levels in total).

NOTE

- In C.O. Monitor View mode, OxyCRG View mode and BIS Trend View mode, you can close the window by clicking white '×' on the top right.

6 Alarm

6.1 Description

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

We'll introduce alarm settings and functions in this chapter.

6.2 Safety Precautions

WARNING

- A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g., an intensive care unit or cardiac operating room.
- Alarm setting may vary in different monitors to suit patient's needs. Before using the monitor, please ensure the previous alarm setting is suitable for this patient. Essential alarm limits should always be turned on.
- Setting alarm limits to extreme values may cause the alarm system to become ineffective.
- When the alarm sound is switched off, the patient monitor will give no audible alarm tones even if a new alarm occurs. Therefore, the user should be very careful about whether to switch off the alarm sound or not.
- Alarms must be set according to the patient's condition for those without continuous health care from medical professionals.
- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Always keep the patient under close surveillance.

6.3 About Alarms

6.3.1 Alarm Categories

The alarms are classified into two categories: physiological alarms and technical alarms.

- **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.

- **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. For example, Lead Wire Disconnection, Battery Too Low, Weak ECG Signal etc.

6.3.2 Alarm Levels

By severity, the patient monitor's alarms can be classified into three categories: high level, medium level and low level:

High level: Indicate that your patient is in a life-threatening situation or a severe device malfunction, an emergency treatment is demanded.

Medium level: Indicate that your patient's vital signs appear abnormal and an immediate treatment is required or a device malfunction. an immediate treatment is required.

Low level: Indicate that you patient's vital signs appear slightly abnormal, a device minor malfunction or an improper operation, an immediate treatment may be required.

6.3.3 Alarm Indicators

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

<table>
<tr><th colspan="2">Alarm Indicator</th><th>High Level</th><th>Medium Level</th><th>Low Level</th><th>Reminder</th><th>Explanation</th></tr>
<tr><td colspan="2">Alarm Lamp</td><td>Flashing Red
Frequency: 2Hz
Duty Ratio: 50%</td><td>Flashing Yellow
Frequency: 0.5Hz
Duty Ratio: 50%</td><td>Solid Blue
Duty Ratio: 100%</td><td>/</td><td>/</td></tr>
<tr><td rowspan="2">Audible Alarm Tones</td><td>ISO</td><td>Triple + Double + Triple + Double Beep.</td><td>Triple Beep.</td><td>Single Beep.</td><td>/</td><td rowspan="2">Alarm tone is set to be distinct from heartbeat and pulse sound for easy identification.</td></tr>
<tr><td>Infinium</td><td></td><td></td><td></td><td>/</td></tr>
<tr><td colspan="2">Alarm Message</td><td>Black Text with Red Background</td><td>Black Text with Yellow Background</td><td>Black Text with Blue Background</td><td>White Text</td><td>Alarm message appears on the top of the screen. You can click the area to view the alarm message list.
The reminder appears at the bottom.</td></tr>
<tr><td colspan="2">Alarm Level Symbol</td><td>***</td><td>**</td><td>*</td><td>/</td><td>The symbol will appear before the alarm message appear</td></tr>
<tr><td colspan="2">Alarm Parameter</td><td colspan="3">Flashing</td><td>/</td><td>/</td></tr>
</table>

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.
- When multiple alarms of different levels occur simultaneously in the same area, only **high-level alarm** will be displayed.
- When multiple alarms of same levels occur simultaneously in the same area, the patient monitor give visual and audible alarm indications circularly.

6.3.4 Alarm Status Symbols

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

 indicates alarm sound is silenced.

 indicates alarm sound is paused.

 indicates alarms are turned off.

 indicates alarms are paused.

 indicates alarm has been received, alarm is reset.

6.4 Check Alarm List

6.4.1 Check Technical Alarm List

In Normal View, to check technical alarm list:

1)Click **'Alarm List** 'window;

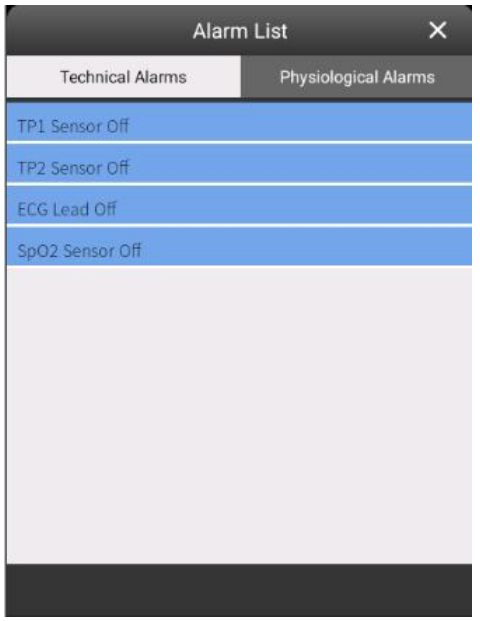
2)Select '**Technical Alarms**' Tab.

6.4.2 Check Physiological Alarm List

In Normal View, to check physiological alarm list:

1)Click **'Alarm list** 'window;

2)Select '**Physiological Alarms**' Tab.



igure 6-1: Alarm List

6.5 Alarm Setup

Select '**Alarm Setup**' in the extended quick key area → Enter **Alarm Setup** Menu

Users need to enter password to gain authorization to enter Alarm Setup and operate.

6.5.1 Set Alarm Properties for All Parameters

There are 3 ways to set alarm properties for the specified parameter:

1)Select '**Alarm Setup**' → '**XXX Alarm Menu**', This patient monitor can also give alarms of these measured parameters.

In parameter specific menu, you must set **alarm ON/OFF**, **alarm limits**, **alarm level**, and **alarm record** separately on this monitor.

2)Select '**Main Menu**' → '**XXX Menu**' → '**Alarm Setup**', in the alarm menu of the specified parameter, you could turn **ON/OFF** alarm or alarm recording, set the alarm level, high alarm limit, and low alarm limit.

3)Select the **parameter** on the screen → In the pop-up setup menu of the parameter, select '**Alarm Setup**', in the alarm menu of the specified parameter, you could turn **ON/OFF** the alarm or alarm event saving, set the alarm level, High alarm limit, and Low alarm limit.

6.5.2 Alarm General Setup

Select '**Alarm Setup**' in the extended quick keys area → Select '**General Alarm Menu**', You can set:

1）**Pause**: Select the drop-down menu to specify the pause mode for the quick key. You can toggle between '**Alarm Pause**' and '**Audio Pause**', the default setting is '**Alarm Pause**'.

2）**Pause Time**: Set the alarm pause time as desired. Select drop-down menu to choose: **1min**, **2min**, **3min**, **infinite**, The default alarm pause time is **2 minutes**.

3）**Alarm Sound**: Set the alarm sound type. Select the drop-down menu and toggle between '**ISO**' and '**Default**', the default setting is '**ISO**'.

4）**High Alarm Interval**: Set the interval for high alarm lamps and alarm tones. Input interval value manually as you desired, valid input range is 3s~15s, the default setting is **10s**.

5）**Med Alarm Interval**: Set the interval for med alarm lamps and alarm tones. Input interval value manually as you desired, valid input range is 10s~20s, the default setting is **20s**.

6）**Low Alarm Interval**: Set the interval for low alarm lamps and alarm tones. Input interval value manually as you desired, valid input range is 20s~30s, the default setting is **20s**.

NOTE

- Alarm sound volume can't exceed the system sound volume. When the system sound is switched off, the patient monitor will give no audible alarm tones even if a new alarm occurs, thus the user should be cautious for setting the system sound.

6.6 Pause Alarm and Pause Audio Alarm

6.6.1 Set the Pause Function

You can pause the alarm or pause the alarm sound according to your Pause setting. To set the pause function:

1）Select '**Alarm Setup**' in the extended quick key area → Click '**General Alarm Menu**' tab → Choose '**Alarm Pause'** or **'Audio Pause'.** The default setting is '**Alarm Pause'.**

2）Set '**Pause**' to '**Alarm Pause**' or '**Audio Pause'**, the default setting is '**Alarm Pause**'.

6.6.2 Alarm Pause

If the Pause quick key is set to '**Alarm Pause**', you can select the button to pause alarm:

- All alarms are paused during the set alarm pause time.
- The remaining pause time and the alarm pause symbol will be displayed in the system status bar.

When the alarm pause session expires, the alarm paused status is automatically canceled and the alarm tone will sound. And you can cancel the '**Alarm Pause**' manually by reselecting the '**Alarm Pause**' quick key. The quick key's name and symbol vary with the pre-defined pause function. (Alarm Pause or Audio Pause)

6.6.2.1 Set Alarm Pause Time

You can select 1min, 2min, 3min or Infinite, the default alarm pause time is **2 min**. To set the alarm pause time:

1）Select '**Alarm Setup**' in the extended quick keys area → Select '**General Alarm Menu**' tab.

2）Select '**Pause Time**' as you desired.

6.6.2.2 Turn Off the Alarms

If the '**Pause Time**' is set '**Infinite**' (For more details, please refer to the 6*.6.2.1 Set alarm pause time*), Selecting '**Alarm Pause**' quick key will turn off all the alarms:

- No alarm lamps flash and no alarms are sounded.
- No alarm messages are shown.
- The '***alarm off***' message and **alarm off red symbol** are displayed in the system status bar.

You can cancel the '**Alarm Pause**' manually by reselecting the '**Alarm Pause**' quick key.

WARNING

- Alarm Pause and Alarm OFF may cause a potential hazard to patients. Please use the function

with careful consideration.

6.6.3 Silencing the Alarm Sound

If the pause function is set to '**Audio Pause**', selecting '**Audio Pause**' will silence the alarm sound. When the alarm sound is muted:

- Both physiological alarms and technical alarms are off during the set alarm pause time.
- The remaining pause time and the alarm pause symbol will be displayed in the system status bar.

When the muted session expires, the alarm sound paused status will be automatically canceled and the alarm tone will sound. And you can cancel the '**Alarm Pause**' manually by reselecting the '**Alarm Pause**' quick key.

6.6.3.1 Set Alarm Sound Pause Time

You can select 1min, 2min, 3min or Infinite. The default alarm sound pause time is fixed to be **2 min**.

To set the alarm sound pause time: please refer to *the 6.6.2.1*, setting steps are the same.

6.6.3.2 Turn Off the Alarm Sound

If '**Pause**' is set to '**Infinite**', Selecting '**Audio Pause**' quick key will turn off all alarm sounds:

- Both physiological and technical alarm sounds are off during the set alarm pause time.
- The '**Alarm Sound Off**' message and the **alarm sound pause red symbol** will be displayed in the system status bar.

To exit the '**Audio Pause**' status, please retap the '**Alarm Sound Off**' quick key.

WARNING

- Pausing or turning off alarm sound may cause a potential hazard to patients. Please use the function with careful consideration.

6.7 Alarm Reset

Select '**Alarm Reset**' quick key → Reset the alarm system. When the alarm system is reset successfully, the **Alarm Reset** symbol will appear in the system status bar.

NOTE

- When monitor is in **Alarm Reset** state, if a new alarm occurs, the Alarm Reset symbol will disappear, alarm light and sound will be generated normally.

After alarm is reset:

- Current alarm sound and lamp will be blocked.
- '√' appears before the alarm message to indicate that this alarm has been received.
- Numerics stop flashing.

6.8 Testing Alarms

When the monitor starts up, a self-check is performed. In the meantime, alarm lamp is lit in red, yellow and blue respectively. This indicates that the alarm lamps indicators are working properly.

For further testing of a certain parameter measurement alarm, perform the measurement with a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

6.9 Responding to an Alarm

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

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

For troubleshooting specific alarms, see appendix ***Alarm Messages***.

7 ECG, ST Segment, Arrhythmia Analysis

7.1 ECG Description

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the patient monitor as a waveform and a numeric. The monitor provides 3-lead/5-lead monitoring, ST segment and arrhythmia analysis.

Figure 7-1: ECG Display

7.2 ECG Safety

WARNING

- Direct cardiac contact with this monitor is prohibited.
- When connecting electrodes and/or patient cables, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are attached to the patient.
- Use defibrillation-proof ECG cables during defibrillation.
- Do not touch the patient, or table, or instruments during defibrillation.
- When using high-frequency electrosurgical units (ESU), never place ECG electrodes near between the surgical site and the negative plate of ESU to avoid burns to patients.
- To avoid burns to patients during high-frequency surgery, monitor cables, sensors must avoid contact with high-frequency electrosurgical equipment.
- Plug the ECG sensor into the ECG connector on the front panel of the monitor; Remember to align the protruding part of the sensor with the small slot of the connector when plugging it.

CAUTION

- Use only ECG electrodes and cables specified by this manual under its instruction. All warnings and notes must be followed.
- Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.
- Interference from a non-grounded instrument near the patient and electrosurgery interference can cause problems with the waveform.

7.3 ECG Display

ECG waveform display area and parameter display area are shown in Figure 7-2.

Figure 7-2: ECG Display

Number	Explanation	Number	Explanation
1	ECG Lead Label	9	PVCs Label
2	ECG Gain	10	PVCs Value
3	ECG Filter Label	11	ECG 1mV Calibration Bar
4	ECG Sweep Speed	12	ECG Waveform
5	ECG Name	13	ECG Alarm Limit
6	HR Unit	14	ST Parameter Label
7	Heart Beat Symbol	15	ST Value
8	HR Value		

NOTE

- For leads of different types and settings, the display of ECG parameter area and waveform area may vary.

7.4 Preparing to Monitor ECG

7.4.1 Prepare the Patient's Skin

Skin condition of the patient directly impact the ECG signal strength and the accuracy of the collected data. To properly prepare the skin, avoid bleeding or broken skin and choose flat, non-muscular areas for electrodes placement. Follow this procedure:

1. If necessary, shave hair from skin at chosen sites.
2. Gently rub skin surface at application sites to remove dead skin cells.
3. Thoroughly cleanse the site with a mild soap and water solution. We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.
4. Dry the skin completely before applying the electrodes.

7.4.2 Electrode Placement

Please place the electrodes following the steps below:

1. Check whether the electrode package is intact within the expiration date. Tear off the protective paper on the back of the electrode sheet. Make sure the electrode gel is moist. Attach the clips or snaps to the electrodes before placing them.
2. Place the electrodes on the prepared skin. Squeeze out the air between the electrode and the patient's skin.
3. Attach the lead wires to the ECG trunk cable.
4. Plug the trunk cable into the equipment's ECG connector.

NOTE

- Please store the electrodes in ambient temperature.
- Check that the patient cable or lead-wires are not damaged. Change them if necessary.
- Use the electrodes immediately once the conducting gel is unpacked.
- Use electrodes of the same brand. Using different brands with dissimilar composition can hinder an accurate ECG trace.
- When placing electrodes, choose a flat, non-muscular site where the signal will not be interfered with by either movement or bones. If you place electrodes in major muscle site, for example, the chest area, false Arrhythmia Alarm might be triggered due to the excessive muscle motion.

7.4.3 Color and Letter Coding

There are two color coding standards for leads (IEC and AHA):

Position On Body Surface	IEC		AHA	
	Inscription	Color	Inscription	Color
Right Arm	R	Red	RA	White
Left Arm	L	Yellow	LA	Black
Right Leg (Neutral)	N or RF	Black	RL	Green
Left Leg	F	Green	LL	Red
Chest 1	C1	White/Red	V1	Brown /Red
Chest 2	C2	White/Yellow	V2	Brown /Yellow
Chest 3	C3	White/Green	V3	Brown /Green

Chest 4	C4	White/Brown	V4	Brown /Blue
Chest 5	C5	White/Black	V5	Brown/Orange
Chest 6	C6	White/Purple	V6	Brown /Purple

7.4.4 ECG Lead Placements

The electrode placement illustrations in this chapter adopt the AHA standard:

1) 3-Leadwire Electrode Placement

Following is an electrode configuration when using 3 lead-wires:

- White Electrode (right arm)RA placement: directly below the clavicle and near the right shoulder.
- Black Electrode (left arm)LA placement: directly below the clavicle and near the left shoulder.
- Red Electrode (left leg)LL placement: on the left lower abdomen.

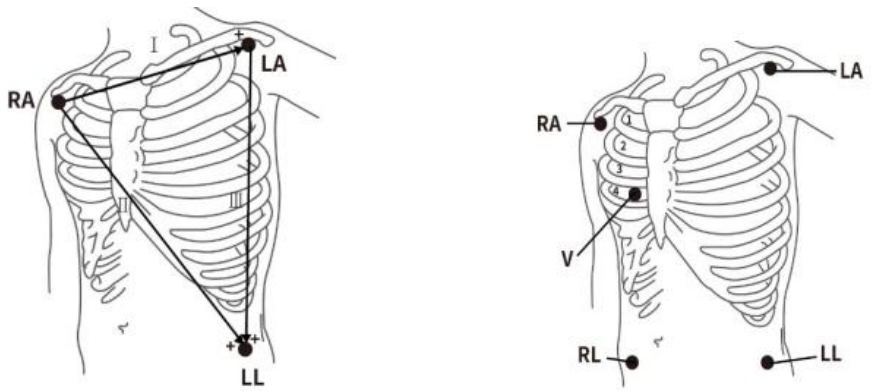


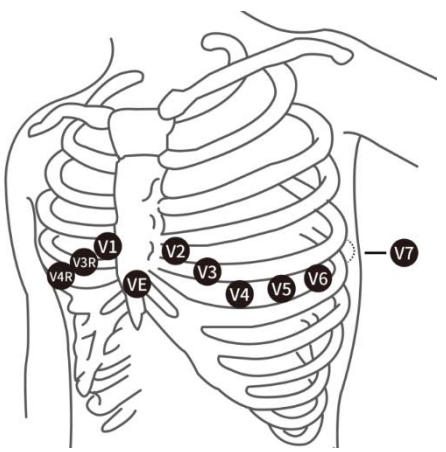
Figure 7-3: ECG Lead Placements

2) 5-Leadwire Electrode Placement

Following is an electrode configuration when using 5 lead-wires:

- White Electrode (right arm)RA placement: directly below the clavicle and near the right shoulder.
- Black Electrode (left arm)LA placement: directly below the clavicle and near the left shoulder.
- Green Electrode (reference)RL placement: on the right lower abdomen.
- Red Electrode (left leg)LL placement: on the left lower abdomen.
- Brown Electrode (chest)V or C placement: on the chest.

The chest (V or C) electrode can be placed on one of the following positions:



- V1 placement: on the fourth intercostal space at the right sternal border.
- V2 placement: on the fourth intercostal space at the left sternal border.
- V3 placement: midway between the V2 and V4 electrode positions.
- V4 placement: on the fifth intercostal space at the left midclavicular line.
- V5 placement: on the left anterior axillary line, horizontal with the V4 electrode position.
- V6 placement: on the left midaxillary line, horizontal with the V4 electrode position.
- V3R-V6R placement: on the right side of the chest in positions corresponding to those on the left.
- VE placement: over the xiphoid process.
- V7 placement: on posterior chest at the left posterior axillary line in the fifth intercostal space.
- V7R placement: on posterior chest at the right posterior axillary line in the fifth intercostal space.

Lead Placement for Surgical Patients:

The surgical site should be taken into consideration when placing electrodes on a surgical patient. e.g., for open-chest surgery, the chest electrodes can be placed on the lateral chest or back. To reduce artifacts and interference from electrosurgical units, you can place the limb electrodes close to the shoulders and lower abdomen and the chest electrodes on the left side of the mid-chest. Do not place the electrodes on the upper arm. Otherwise, the ECG waveform will be very small.

WARNING

- When using electrosurgical units (ESU), patient leads should be placed in a position that is equal distance from the electrosurgery electrotome and the grounding plate to avoid burns to the patient.
- Never entangle the ESU cable and the ECG cable together.
- When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.

7.4.5 Choosing ECG Lead Set

To select ECG lead set:

1. Select ECG parameter area or waveform area → '**ECG Menu**'.
2. Select '**Normal Setup**'.
3. Set '**Lead Set**' according to the applied electrodes., the default type is '**5-lead**'.

7.4.6 Checking Paced Status

It is important to set the paced status correctly when you start monitoring ECG. The paced symbol  is displayed when the '**Pace Detection**' is set to **ON**. The pace pulse markers '|' are

shown on the ECG wave when the patient has a paced signal.

The paced symbol  will not be displayed when the '**Pace Detection**' is set to **OFF**

To change the paced status:

1. Select ECG parameter area or waveform area→ Enter '**ECG Menu**'.
2. Select '**Normal Setup**' tab.
3. Set '**Pace Detection**' to [**Yes**] or [**No**] according to patient's need.

WARNING

- For paced patients, you must set '**Pace Detection**' to [**Yes**]. Otherwise, the patient monitor could mistake a pace pulse for a QRS and fail to alarm when the ECG signal is too weak. For paced patients, Ventricular tachycardia may not always be detected
- Some heart pacemakers may cause false alarm on low heart rate or cardiac arrest due to pacemaker artifacts, for example, pacemaker overshoot may override the real QRS wave.
- Do not rely entirely on rate meter alarms when monitoring patients with pacemakers. Always keep these patients under close surveillance.
- For non-paced patients, you must set '**Pace Detection**' to [**No**].

7.5 Changing ECG Settings

Select ECG parameter window or waveform area → Enter '**ECG Menu**' page, as shown in Figure 7-4.

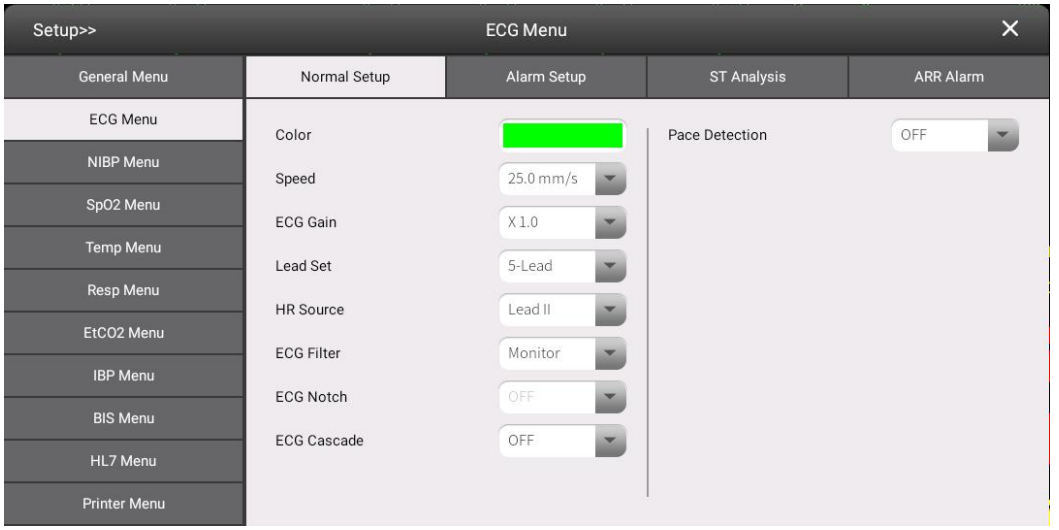


Figure 7-4: ECG Menu

7.5.1 ECG Normal Setup

In '**ECG Menu**' page, select '**Normal Setup**' tab to set:

1) Color:

Select the drop-down menu of '**Color**' to set ECG waveform and parameter color. 32 colors are available, as shown in Figure 7-5. The default color is **Green**.

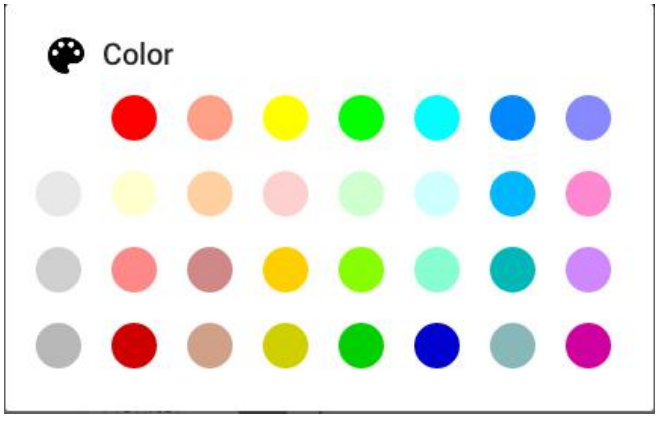


Figure 7-5: ECG Color Menu

2) Speed

Select '**Speed**' drop-down menu, you can choose **12.5 mm/s**,**25mm/s** or **50mm/s**. The default speed is **25mm/s**. The larger the value, the faster the wave sweeps.

3) ECG Gain

Select '**ECG Gain**' drop-down menu, you can choose **×0.25, ×0.5**, **×1.0**, **×2.0**. ECG Gain change will adjust the waveform scale and waveform size. Higher ECG gain represents larger waveform size. The default Gain is **×1.0.**

4) Lead Set

Select '**Lead Set**' drop-down menu, and toggle between **3 Leads** and **5 Leads** mode. The default setting is **5 Leads**.

5) HR Source

Select '**HR Source**' drop-down menu, when lead set is **3 Leads**, you can choose **Lead I, Lead II** or **Lead III**. The default setting is **Lead II**.

When lead set is **5 Leads**, you can choose **Lead I, Lead II, Lead V**. The default setting is **Lead II**.

6) ECG Filter

Select '**ECG Filter**' drop-down menu, you can choose **Monitor**, **Diagnose** or **Surgery**. The default setting is **Monitor**.

The ECG filter setting defines how ECG waves are smoothed:

- **[Monitor]:** Use under normal measurement conditions.
- **[Diagnostic]:** Use when diagnostic quality is required. The unfiltered ECG wave is displayed so that changes such as R-wave notching or discrete elevation or depression of the ST segment are visible.
- **[Surgery]:** Use when the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to wandering or rough baseline. In the operating room, the surgery filter reduces artifacts and interference from electrosurgical units. Under normal measurement conditions, selecting [**Surgery**] may suppress the QRS complexes too much and then interfere with ECG analysis.

NOTE

- The [**Diagnostic**] filter is recommended when monitoring a patient in an environment with slight interference only.

7) ECG Notch

Select '**ECG Notch**' drop-down menu to set Notch Freq. and then select **50Hz,60H or OFF** according to the power line frequency. The default '**Notch'** is **50Hz**.

NOTE

- When ECG Notch is set to **Diagnose** or **Surgeri**es Notch setting is disabled with OFF shown on the button. Only when ECG Notch is set to **Monitor,** ECG Notch setting is allowed

8) ECG Cascade

Select '**ECG Cascade**' drop-down menu and toggle between **ON/OFF**. When '**ECG Cascade**' is **ON,** A cascaded waveform is displayed in two waveform positions.

NOTE

- **ECG Cascade** only supports the first row of ECG waveforms.

9) Pace Detection

Select '**Pace Detection**' drop-down menu and toggle between **ON** and **OFF.** The default setting is **OFF**. When '**Pace Detection**' is **ON**, the pace pulse markers '|' are shown on the ECG wave when a paced signal has been detected. As shown in Figure 7-6, for more details, please refer to 7.4.6.

Figure 7-6: Pace Detection

7.5.2 ECG Alarm Setup

In '**ECG Menu**' page, select '**Alarm Setup**' tab, as shown in Figure 7-7.

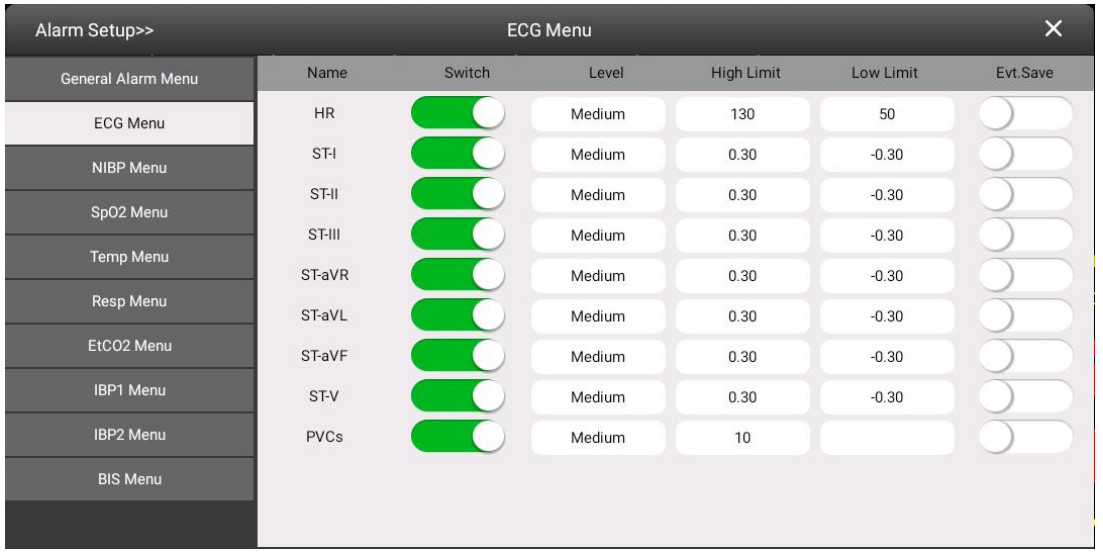


Figure 7-7: ECG Alarm Setup Menu

You can configure the alarm setting for ECG parameters, including HR, ST-X (X represents the following: I/II/II/aVR/aVL/aVF/V)and PVCS according to your needs.

7.6 ST Monitoring

The ST segment is an interval between ventricular depolarization and ventricular repolarization. It is identified as the end of the QRS complex to the beginning of the T wave. ST monitoring is intended to monitor the patient's oxygen supply and myocardial function. ST segment analysis calculates ST segment elevations and depressions for a given lead. As shown in Figure 7-8: As shown in the Figure below, the ST measured for each beat complex is the vertical difference between two measurement points with the R-wave peak as the baseline for the measurement.

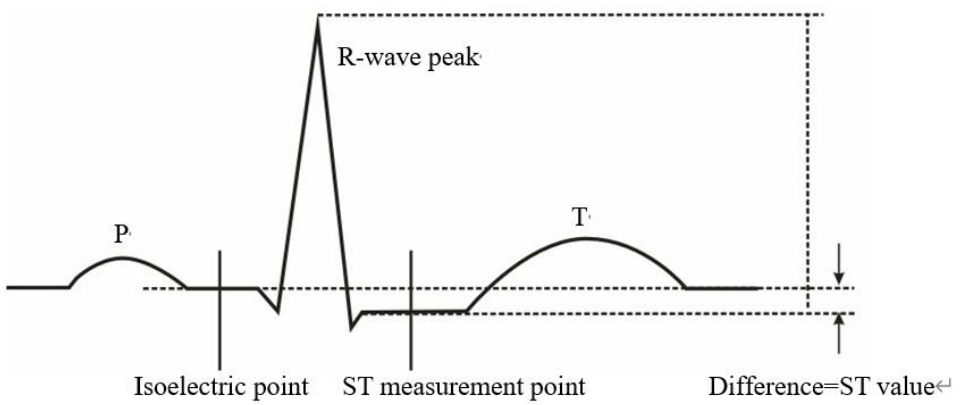


Figure 7-8: ST Segment

7.6.1 ST Security Information

WARNING

- Factors such as medications, metabolic or conduction disturbances may affect ST values.
- Since ST is calculated from a fixed delay after the J-point, it may be affected by heart rate variability.
- The data accuracy of the ST algorithm has been tested and its clinical significance should be determined by the physician.
- This monitor provides information on ST segment changes and the clinical significance of this information should be determined by the physician.

7.6.2 ST Display

Figure 7-9 shows ST numerics.

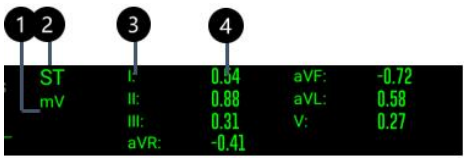


Figure 7-9: ST Numerics

Number	Explanation	Number	Explanation
1	ST Unit	3	Lead Name
2	ST Label	4	ST Value

ST parameters displayed in the ECG parameter area varies with the operating '**Lead Set**':

When 3-lead is used for monitoring, only one ST parameter value is displayed in ECG parameter area, No ST parameter area will appear;

When 3-lead is used for monitoring, 7 ST parameters' values are displayed in ST parameter area, they are: **ST-I**, **ST-II**, **ST-III**, **ST-aVR**, **ST-aVL**, **ST-aVF**, **ST-V**.

7.6.3 ST Setting

Select ECG waveform area or ECG parameter area on monitoring screen → Enter '**ECG Menu**' → Select '**ST Analysis**' tab, as shown in Figure 7-10.

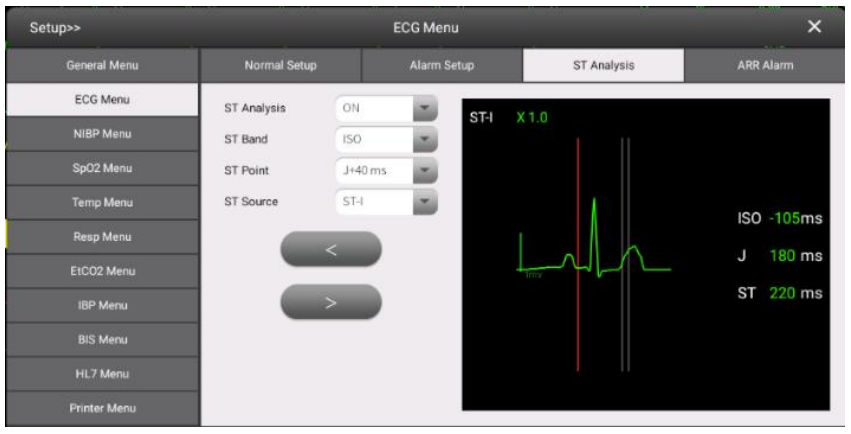


Figure 7-10: ST Setting

1) Switching ST Analysis ON/OFF

Select '**ST Analysis**' drop-down menu and toggle between **OFF** and **ON**, by default, '**ST Analysis**' is **OFF**. When ST analysis is switched on, the measured ST numerics will be displayed in ECG parameter area. Also, history ST numerics can be accessed in graphical trend or tabular trend.

2) ST Point

Select '**ST Band**' drop-down menu and toggle between '**ISO**', '**J**' and '**ST**', as shown in Figure 7-10: three vertical lines represent the ISO, J and ST point positions respectively. You can adjust the point position by using the touchscreen.

- **ISO (Reference Point)**: Set the baseline. Adjustment range is -500ms～0ms, default setting is -105ms, indicating the reference point is located 105ms before the R-wave peak.
- **J or ST (Measurement Point)**: Specify the measurement point. Adjustment range is +460ms～+0ms, default setting is +180ms, indicating the reference point is located 180ms after the R-wave peak.

3) ST Source

Select '**ST Source**' drop-down menu to set ST Source.

When Lead Set is **3 Leads**, Options are **Lead I, Lead II** and **Lead III**. The default setting is **Lead II**.

When Lead Set is **5 Leads**, Options are **Lead I, Lead II, Lead III, Lead AVL, Lead AVR, Lead AVF, Lead V**. The default setting is **Lead II**.

7.6.4 Additional Information

Exceptional QRS complex will not be considered in ST analysis. In some clinical situations where reliable ST monitoring can hardly be ensured, ST analysis should be switched off.

Possible situations are:

- You are unable to get a lead that is not noisy.
- Arrhythmias such as atrial fib/flutter cause irregular baseline.
- The patient is continuously ventricularly paced.
- The patient has left bundle branch block.

7.6.5 Adjusting ST Measurement Points

The ST measurement (i.e., ST segment offset), refers to the vertical distance between the iso-location (ISO) and the ST point. The isotropic line is located between the end point of the P wave and the start point of the QRS complexes and provides the baseline for ST measurement. The ST point is located in the middle of the ST segment and the J point is the end point of the QRS complexes. Since the distance between the J point and the ST power is fixed, it can help to position ST point accurately.

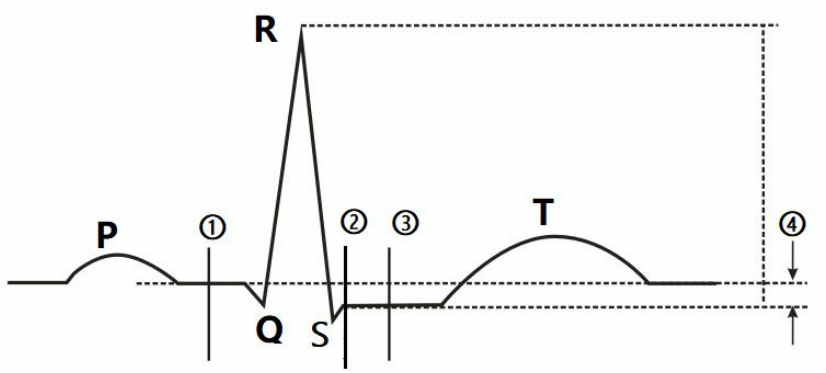


Figure 7-12: ST Measurement Adjustment

Number	Explanation	Number	Explanation
1	ISO Point	3	ST Point
2	J Point	4	ST Value

To adjust the ST measurement points:

1. In '**ECG Menu**', Select '**ST Analysis**' tab;
2. Select corresponding setting page and then use the touchscreen to adjust the position of each point;

- The ISO-point cursor (1) positions the isoelectric point relative to the R-wave peak. Position the ISO-point in the middle of the flattest part of the baseline (between the P and Q waves or in front of the P wave).
- The J-point cursor (2) positions the J-point relative to the R-wave peak. It helps you to correctly position the ST-point. Position the J-point at the end of the QRS complex and the beginning of the ST segment.
- The ST-point is positioned a fixed distance from the J-point. Move the J-point to position the ST-point at the midpoint of the ST segment. You can select the following positions: J+40, J+60, J+80 or J+60/80. If the heart rate is greater than or equal to 120 bpm, it is recommended that the ST point is set to J + 60 ms. If the heart rate is less than 120 bpm, t it is recommended that the ST point is set to J + 80 ms.

As shown in Figure 7-11 below:

Figure 7-11: ST Measurement Points

CAUTION

- If using ST analysis, the ST measurement points need to be adjusted when you start monitoring and if the patient's heart rate or ECG morphology changes significantly, as this may affect the size of the QT interval and thus the placement of the ST point. Artifactual ST segment depression or elevation may occur if the isoelectric point or the ST point is incorrectly set.
- Always ensure that ST measurement points are appropriate for your patient.

7.7 Arrhythmia Analysis

Arrhythmia analysis is intended for adults, pediatrics and neonates. It can be used for both paced patient and non-paced patient monitor.

Arrhythmia analysis provides information on your patient's condition, including heart rate, PVC rate, rhythm, and ectopics. Healthcare professionals can use the analysis for patient treatment.

7.7.1 Safety Information

WARNING

- Arrhythmia may impact the Heart Rate. When patient with Arrhythmia is monitored, do not rely exclusively on the alarm messages based on HR value. Always keep the patient under close surveillance.
- Arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect atrial or supraventricular arrhythmias. It may incorrectly identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information with other clinical findings.

CAUTION

- The sensitivity and specificity of the arrhythmia algorithm cannot reach 100%. Sometimes false alarms or missed alarms may occur, which is especially obvious when ECG signal is severely interfered.
- ECG waveform amplitude and QRS threshold settings can affect the sensitivity of arrhythmia detection and heart rate calculation.
- If the QRS amplitude is too low, the monitor may not be able to calculate heart rate or may detect false arrests.

7.7.2 Arrhythmia Events

This monitor can detect 13 Arrhythmia events.

Number	Arrhythmia	Explanation
1	ASY	Asystole
2	FIB	Fibrillation
3	VTA	Ventricular Tachyarrhythmia
4	ROT	R_ON_T (R on T is detected)
5	RUN	VT>2 More than 2 consecutive PVCs within the last minute.

6	TPT	Irr. Rhythm Consistently irregular rhythm
7	CPT	Ventricular Couplet
8	PVC	Ventricular Premature Beats
9	BGM	Bigeminy
10	TGM	Trigeminy
11	TAC	Tachycardia
12	BRD	Bradycardia
13	MIS	Missed Beats

7.7.3 Changing Arrhythmia Alarm Settings

To change arrhythmia alarm settings, click '**ECG Menu**'→ select '**ARR Alarm**' tab → Set the arrhythmia alarm for every arrhythmia condition according to your needs, as shown in Figure 7-12:

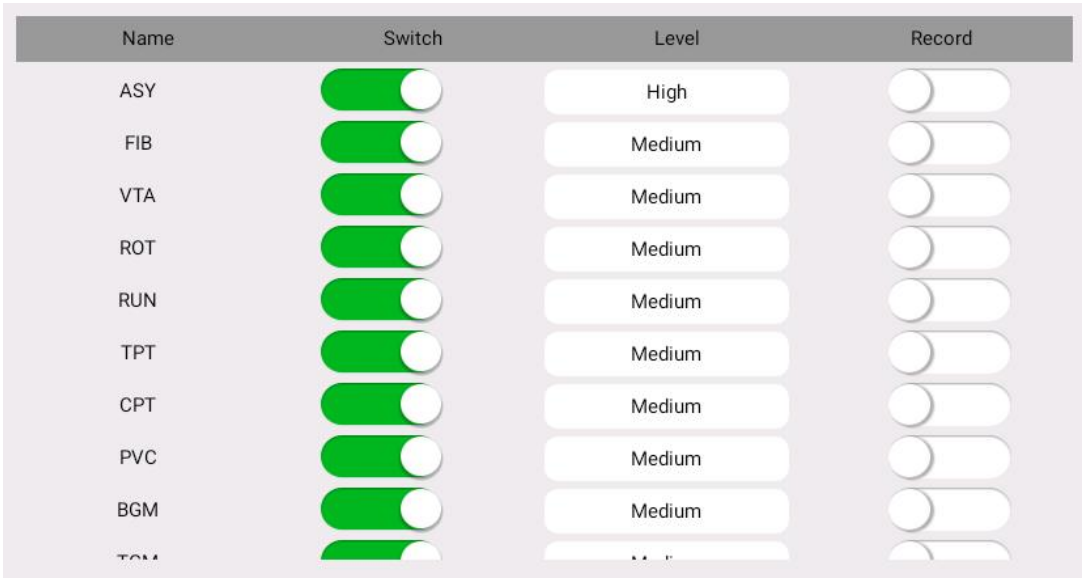


Figure 7-12: Arrhythmia Alarm Setup Menu

7.8 ECG Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

Problem	Corrective Action
ECG Artifact	1.Check that electrodes are not detached or dry. Replace with fresh and moist electrodes if necessary. 2.Check that leadwires are not defective. Replace leadwires if necessary. 3.Check that patient cable or leadwires are routed too close to other electrical devices. Move the patient cable or leadwires away from electrical devices.
Excessive Electrosurgical Interference	Use ESU-proof ECG cables.
Muscle Noise	Inadequate skin preparation, tremors, tense subject, and/or poor electrode placement. 1.Perform skin preparation again and re-place the electrodes. For more information, refer to 8.4 Preparing to Monitor ECG. 2.Apply fresh, moist electrodes. Avoid muscular areas.
Intermittent Signal	1.Check that cables are properly connected. 2.Check that electrodes are not detached or dry. Perform skin preparation again as described in 8.4 Preparing to Monitor ECG. 3.Check that the patient cable or leadwires are not damaged. Change them if necessary.
Excessive Alarms: heart rate, lead fault etc.	1. Check that electrodes are not dry. Perform skin preparation again and replace the electrodes. For more information, refer to 8.4 Preparing to Monitor ECG. 2.Check for excessive patient movement or muscle tremor. Reposition the electrodes. Replace with fresh and moist electrodes if necessary.

Low Amplitude ECG Signal	1.Check that the ECG gain is not set too low. Adjust the gain as required. 2.Perform skin preparation again and re-place the electrodes. 3.Check electrode application sites. Avoid bone or muscular area. 4.Check that electrodes are not dry or used for a prolonged time. Replace with fresh and moist electrodes if necessary.
No ECG Waveform	1. Check that the ECG gain is not set too low. Adjust the gain as required. 2. Check that the leadwires and patient cables are properly connected. Change cable and lead wires. 3. Check that the patient cable or leadwires are not damaged. Change them if necessary.
Base Line Wander	1.Check for excessive patient movement or muscle tremor. Secure leadwires and cable. 2.Check that electrodes are not detached or dry and replace with fresh and moist electrodes if necessary. 3. Check for ECG filter setting. Set ECG Filter mode to [**Monitor**].

NOTE

- For the physiological and technical alarm messages, refer to *Appendix C Alarm messages*

8 Resp

8.1 Description

Respiration is measured by thoracic impedance method. When the patient is breathing or ventilated, the volume of air changes in the lungs, resulting in impedance changes between the electrodes. Respiration rate (RR) is calculated from these impedance changes, and a respiration waveform appears on the patient monitor screen.

8.2 Resp Safety Information

WARNING

- When monitoring the patient's respiration, do not use ESU-proof ECG cables.
- The respiration measurement does not recognize the cause of apneas. It only indicates an alarm if no breath is detected when a pre-adjusted time has elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purpose.
- If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3V/m), field strengths above 1V/m may cause erroneous measurements at various frequencies. Therefore, it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.
- When using the electrosurgery unit, ensure that the ESU return electrode is near the operating area. Also don't place ESU return electrode between the surgical area of the patient and the negative plate of the electrosurgery equipment to avoid burns at measurement sites.

CAUTION

- Use only the accessories specified by this manual and follow the guidance for operation. Adhere to all WARNING, CAUTION and NOTES.
- Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.

8.3 Resp Display

Resp waveform area and parameter area are shown as below in Figure 8-1.

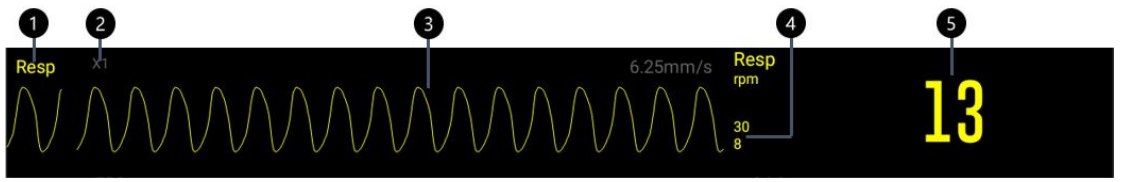


Figure 8-1: Resp Parameter and Waveform Display

Number	Explanation	Number	Explanation
1	Resp Label	4	Alarm Limit
2	Resp Gain	5	Resp Rate (RR)
3	Resp Waveform		

NOTE

- If ESU-proof ECG cables are used, the Resp waveform area will display the message 'Check Leads. Please replace the ECG cables if necessary.

8.4 Preparing to Monitor Resp

8.4.1 Skin Preparation

Before monitoring Resp, prepare skin by the following steps:

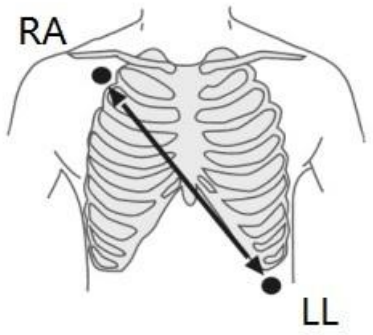
- Shave hair from skin at chosen sites.
- Gently rub skin surface at sites to remove dead skin cells.
- Thoroughly cleanse the site with a mild soap and water solution. We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.
- Dry the skin completely before applying the electrodes.

CAUTION

- As the skin is a poor conductor of electricity, preparing the skin is necessary to capture effective respiration signals.

8.4.2 Placing Resp Electrodes

As the Respiration measurement adopts the standard ECG electrode placement, you can use different ECG cables (3-lead, 5-lead). No additional electrodes are needed after ECG measurement. But the optimizing lead placement for Resp is essential. In clinical applications, some patients (especially neonates) expand their chests laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two respiration electrodes in the right midaxillary and the left lateral chest areas at the patient's maximum point of the breathing movement to optimize the respiratory waveform, as shown in below Figure.



CAUTION

- Avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes. This is particularly important for neonates.
- Some patients with restricted movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.
- In clinical applications, some patients (especially neonates) expand their chests laterally, causing a negative intrathoracic pressure. In these cases, it is best to place the two respiratory electrodes in the right midaxillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave
- To optimize the respiration waveform, place the RA and LL electrodes diagonally when using ECG Lead II.
- Periodically inspect the sensor application site, if skin irritations or lacerations occur, change the application site regularly.

NOTE

- Please store the electrodes in ambient temperature.
- Check whether the electrode package is intact and use the electrode before expiration date.

Don't use it if electrode conducting gel has dried out.

8.5 Setting Resp

Select Resp parameter area or waveform area → '**Resp Menu**' will pop up, as shown in Figure 8-2:

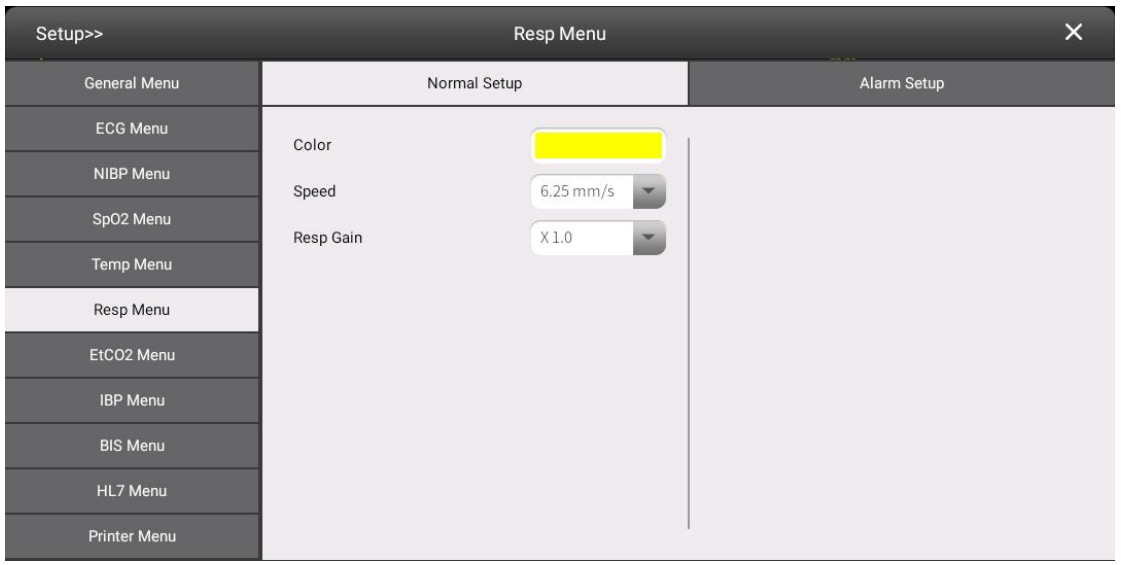


Figure 8-2: Resp Setup Menu

8.5.1 Resp Normal Setup

In '**Resp Menu**', select '**Normal Setup**' tab, you can set:

1) Resp waveform and parameter color (Color)

Select '**Color**' → Color setting window will pop up → 32 colors are available to choose. The default color is **Cyan**.

2) Resp Waveform Speed

Select '**Speed**' drop-down menu → You can set speed to **6.25 mm/s**, **12.5 mm/s**, **25mm/s**. The default speed is **6.25mm/s**.

3) Resp Gain

Select '**Resp Gain**' drop-down menu→ You can set Resp Gain to **×0.25, ×0.5**, **×1.0**, **×2.0**. Resp Gain change will change the waveform size. The default Gain is **×1.0**.

8.5.2 Resp Alarm Setup

Select '**Resp Menu**' → Select '**Alarm Setup**' tab, you can set alarm properties according to your need, the setup window is shown in Figure 8-3.

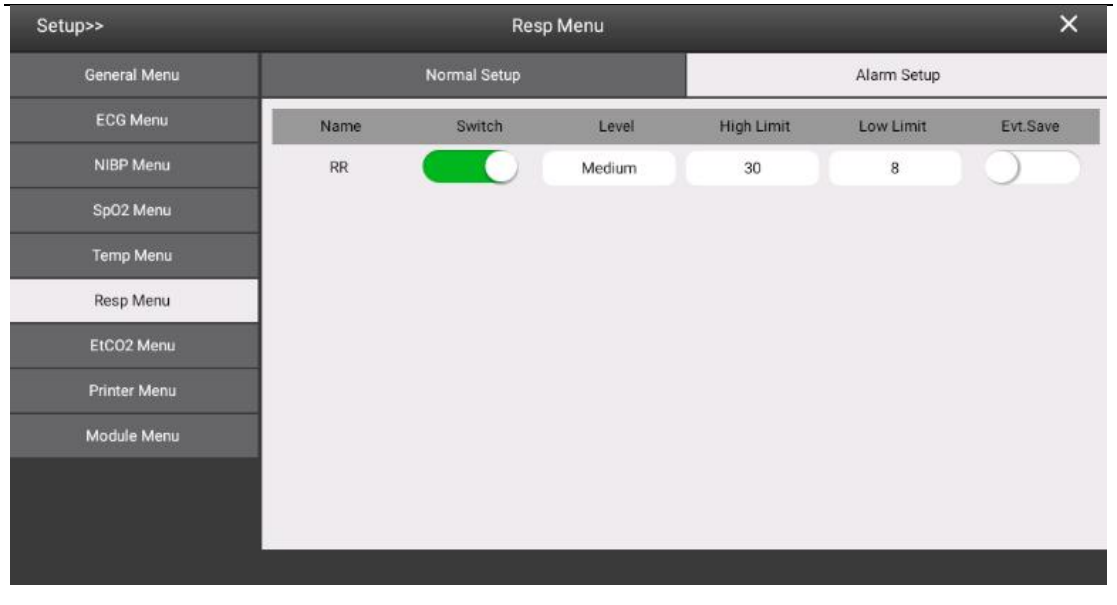


Figure 8-3 Resp Alarm Setup

NOTE

- Apnea Alarm is set to ON by default. Change to apnea alarm is disabled.

8.6 Resp Troubleshooting

Please refer to *Appendix C alarm messages* for detailed information.

9 SpO2

9.1 SpO2 Description

SpO2(Oxygen saturation) is the percentage of saturated hemoglobin compared to total hemoglobin measured by a two-wavelength pulse oximeter (also called functional or In Vivo oxygen saturation). The SpO2 value is measured by light absorption technique: Red and infrared light is emitted from the emitter side of the sensor. The light is partly absorbed when it passes through the monitored tissue. The amount of transmitted light is detected in the detector side of the sensor. When the pulsative part of the light signal is examined, the amount of light absorbed by arterial hemoglobin is discovered and the saturation level can be calculated.

The SpO2 module processes the electrical signal and displays a 'Pleth' waveform and digital values for SpO2 and pulse rate.

SpO2 measurement is applicable to adults, pediatrics and neonates.

This monitor supports Infinium SpO2 module, Nellcor SpO2 module and Masimo SpO2 module.

Infinium SpO2: No logo on the module;

Nellcor SpO2: Nellcor logo on the module;

Masimo SpO2: Masimo logo on the module.

NOTE

- Each SpO2 sensor connector can only be connected to the same type of extension cable. For example, Masimo SpO2 connector can only be connected to Masimo SpO2 extension cable.
- Functional testing equipment or SpO2 emulator can be used to evaluate the accuracy of PR (pulse rate) measurement.
- A functional tester or SpO2 emulator cannot be used to assess the accuracy of SpO2 sensor and pulse oximeter for monitor. They must be verified with clinical data.
- This monitor, and the SpO2 sensor, probe extension cable bundled with this equipment are all verified in compliance with ISO80601-2-61.

9.2 SpO2 Safety Information

WARNING

- When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by blood gas analyzer to completely understand the patient's condition.

- Do not use SpO2 sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- Setting alarm limits to extreme values may cause the alarm system to become ineffective. For example, High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off.

CAUTION

- Use only the SpO2 sensors and other accessories specified in this manual. Follow this manual's instructions for use and adhere to all warnings and cautions.

9.3 SpO2 Measurement Influencing Factors

Many factors may cause inaccurate measurement:

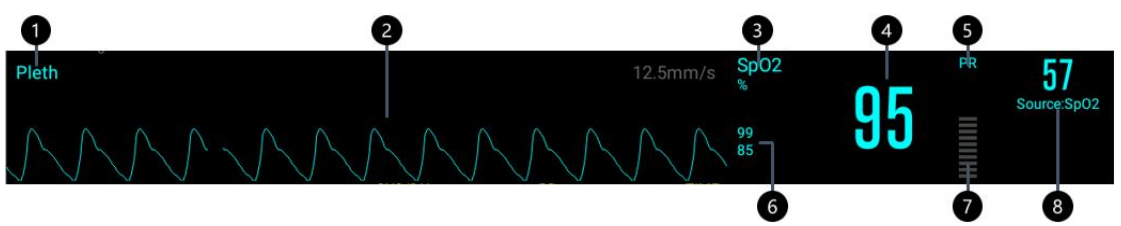
- Physiological characteristics that may interfere:
  - Cardiac arrest
  - Hypotension
  - Shock
  - Severe vasoconstriction
  - Severe anemia
  - Hypothermia
  - Venous pulsations
  - Darkly pigmented skin
  - Ventricular septal defects (VSDs)
  - Low perfusion
- Interfering substances:
  - Intravascular dyes (such as indocyanine green, methylene blue, etc.)
  - Dysfunctional haemoglobin, such as carboxyhemoglobin (COHb)and methemoglobin (MetHb)

- Presence of certain dyes on the measured site, such as methylene and indigo carmine

- Environmental conditions:
  - Excessive ambient light
  - Electrical interference
  - Electrosurgery
  - Defibrillation - May cause inaccurate reading for a short amount of time.
  - Excessive patient/sensor motion.
- Others
  - Incorrect sensor placement or incorrect SpO2 sensor is used.
  - Blood pressure cuff or other measuring sensor on the same limb as the SpO2 sensor

9.4 SpO2 Display

The SpO2 waveform area and parameter area as shown in Figure 9-1.



Number	Explanation	Number	Explanation
1	Pleth Label	5	PR Label
2	Pleth Waveform	6	SpO2 Alarm Range
3	SpO2 Label	7	Perfusion Indicator: the pulsatile portion of the measured signal caused by arterial pulsation.
4	SpO2 Value	8	Pulse Source: Options are SpO2, HR and IBP.

Figure 9-1: SpO2 Display

9.5 SpO2 Measurement Preparation

To prepare:

1. Select an appropriate sensor according to the module type, patient category and weight.
2. Cleanse the surface of reusable sensor.
3. Remove colored nail polish from the application site.
4. Apply the sensor to the patient following 'SpO2 placement' guidelines.
5. Select an appropriate adapter cable according to the connector type and plug this cable into the SpO2 connector.
6. Connect the sensor cable to the adapter cable.

CAUTION

- Choose a sensor that matches the selected measurement site, too loose a sensor may cause light leakage, too tight a sensor may cause pulsation of the vein and make the measurement value inaccurate.
- In case of high ambient temperature, special attention should be paid to the selected measurement site with poor perfusion. High ambient temperatures can cause skin damage where the sensor placement positions for prolonged monitoring.
- Do not place sensor on a limb with the NIBP cuff, an intravenous infusion or arterial catheter in place.
- For neonatal patients, make sure that all sensor connectors and adapter cable connectors are outside the incubator. The humid atmosphere inside can cause inaccurate measurements.
- Plug the SpO2 sensor into the socket/connector marked "SpO2" on the monitor panel. Remember to align the protruding part of the sensor plug with the small slot on the connector when plugging or removing it, otherwise it will cause unreliable measurements or damage to the sensor connector.
- Place the finger probe on the finger and align the finger with the direction of the finger indicated on the sensor.

9.6 Changing SPO2 Setting

Select SpO2 waveform area or parameter area → '**SpO2 Menu**', as shown in Figure 9-2.

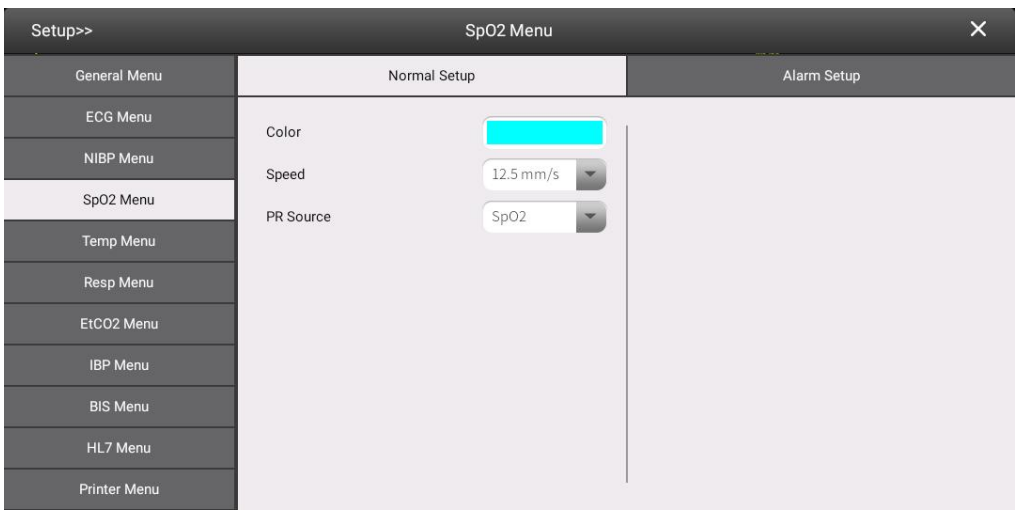


Figure 9-2: SpO2 Menu

9.6.1 SpO2 Normal Setup

Select '**SpO2 Menu**' page → select '**Normal Setup**' tab, to set:

1) Color

Select the drop-down menu for '**Color**', 2 colors are available, as shown in Figure 9-2. The default color is **Cyan**.

2) Speed

Select '**Speed**' drop-down menu, you can choose 12.5 mm/s,25mm/s or 50mm/s. The default speed is **25mm/s**. The larger the value is, the faster the wave sweep speed.

3) Pulse Source

Select '**PR Source**' drop-down menu, you can choose SpO2, IBP1 or IBP2.

4) FastSAT

You can set FastSat only when Masimo SpO2 module is used. Select '**FastSAT**' drop-down menu, and toggle between ON and OFF. The default setting is **OFF**.

5) Sensitivity Mode

You can set '**Sensitivity Mode**' only when Masimo SpO2 module is used. Select '**Sensitivity Mode**' drop-down menu → Select Masimo mode, Normal mode or APOD mode. The default setting is **Normal mode**.

Masimo mode is used for critically ill patients that are difficult to obtain parameter values; Normal **mode** is suitable for most patients, and **APOD** (Adaptive Probe Dislodgement Detection) mode applies for cases where the probe contact with the patient is intermittent.

6) Averaging Time

7) You can set **Averaging Time** only when Masimo SpO2 module is used. Select '**Averaging Time**' drop-down menu to set the **Averaging Time**, you can choose: 2-4s, 5-6s, 8s, 10s, 12s, 14s, 16s.

9.6.2 SpO2 Alarm Setup

Select '**SpO2 Menu**' → Select '**Alarm Setup**' tab, as shown in Figure 9-3.

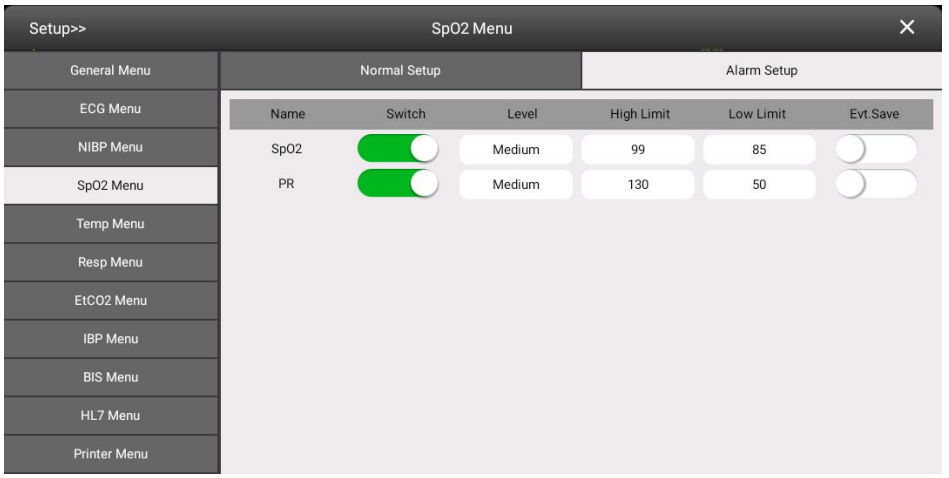


Figure 9-3: SpO2 Alarm Setup Menu

You can set the following alarm parameters for SpO2 module: SpO2, PR, PI, (PI setting is enabled only when Masimo SpO2 module is used. Set the alarm according to your needs)

9.7 SpO2 Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

The following message may appear in '**Pleth**' waveform area:

Message	Explanation
'Long searching time'	SpO2 searching time is too long
'Searching pulse…'	This monitor is searching the pulse signal
'SpO2 sensor off'	The SpO_2 sensor has become detached from the patient or the module
'SpO2 communication error'	There is a communication problem with the SpO_2 measurement board

Problem	Corrective Action
No SpO2 parameter window and waveform area are displayed	1、Check if SpO2 module is plugged properly; 2、Check if the SpO2 parameter and waveform display is turned ON in 'View Layout'. 3、Make sure SpO2 module and Main Unit of the monitor are connected.
'---' appears in SpO2 value	1、Check if the SpO2 sensor and adapter cable are connected tightly. Replace the SpO2 sensor or cable if necessary. 2、Check "SpO2 sensor off" alarm occurs, reconnect the sensor.

Pleth waveform size too low	1、NIBP cuff on the same limb as the SpO2 sensor. Change measured site if necessary. 2、PI value too low. Adjust the sensor position and connect to site with better perfusion. 3、Check sensor condition and sensor placement.
Inaccurate measurement	4、Check patient vital signs. 5、check for conditions that may cause inaccurate SpO2 readings. 6、check the monitor and the SpO2 module, cable, or sensor for proper functioning

NOTE

- For physiological and technical alarm message, please refer to *Appedix C Alarm messages*.

10 Temp

10.1 Temp Description

Temperature of the human body is measured by the sensor that turns the temperature into an electrical signal, which is amplified and processed. Temp module can measure patient temperature in prolonged period. Continuous temperature measurement uses thermistor method, based on the principle that the resistance of a thermistor changes with temperature. The thermistor measures the amount of change in resistance and thus calculates the temperature value.

This monitor can be used to measure patient's surface and cavity temperature. This monitor supports two-channel temperature measurements to display both channels of body temperature (T1 and T2) and to calculate and display the difference between two channels of temperature (△T).

Temp measurement is intended to use for adults, pediatrics and neonates.

10.2 Temp Display

Temp waveform area and parameter area are shown in Figure 10-1.

Figure 10-1: Temp Display

Number	Explanation	Number	Explanation
1	Temp Label	4	Temp Alarm Range
2	Temp Unit	5	ΔT Value: displaying the difference between two temperature values
3	T1&T2 Value		

10.3 Temp Measurement Preparation

Prepare for a Temp measurement by the following steps:

1) Select an appropriate probe according to patient type and measurement site.

2) Plug the Temp sensor into the ‘**T1**’ or ‘**T2**’ connector socket on the monitor panel.

3) Follow the manufacturer's instructions for probe application and instructions.

10.4 Temp Setting

Select Temp parameter area→ '**Temp Menu**' will pop up, as shown in Figure 10-2.

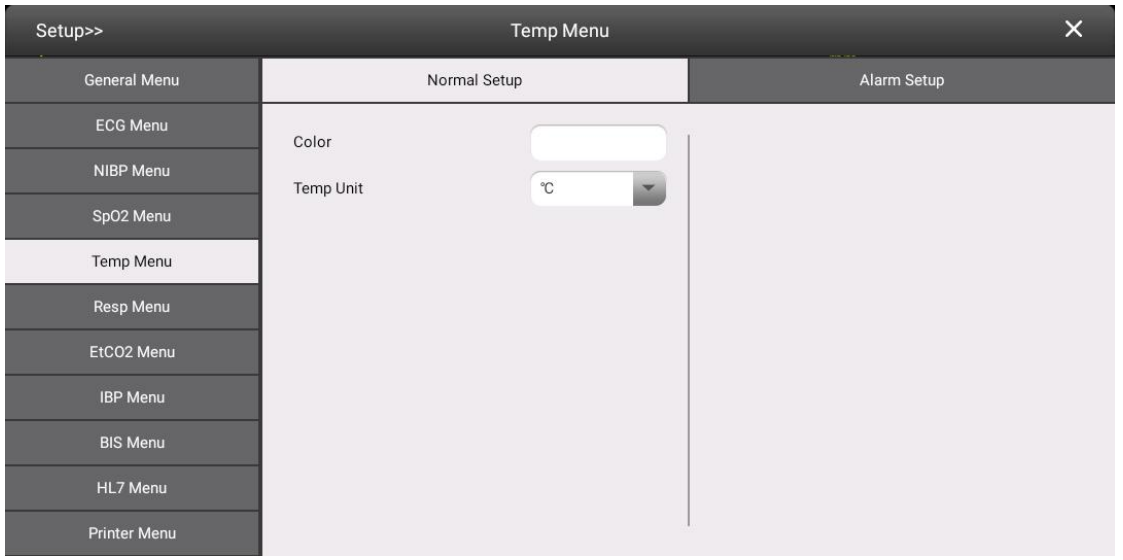


Figure 10-2: Temp Menu

10.4.1 Temp Normal Setup

In '**Temp Menu**' → Select '**Normal Setup**' tab:

1) Color

Select '**Color**' → Color setting window will pop up → 32 colors are available to choose. The default color is **White**.

2) Temp Unit

Select '**Temp Unit**' drop-down menu to set **Temp unit** and toggle between **℃** and **℉**. The default temp is **℃;**

10.4.2 Temp Alarm Setup

Select '**Temp Menu**' → Select '**Alarm Setup**' tab, as shown in Figure 10-3.

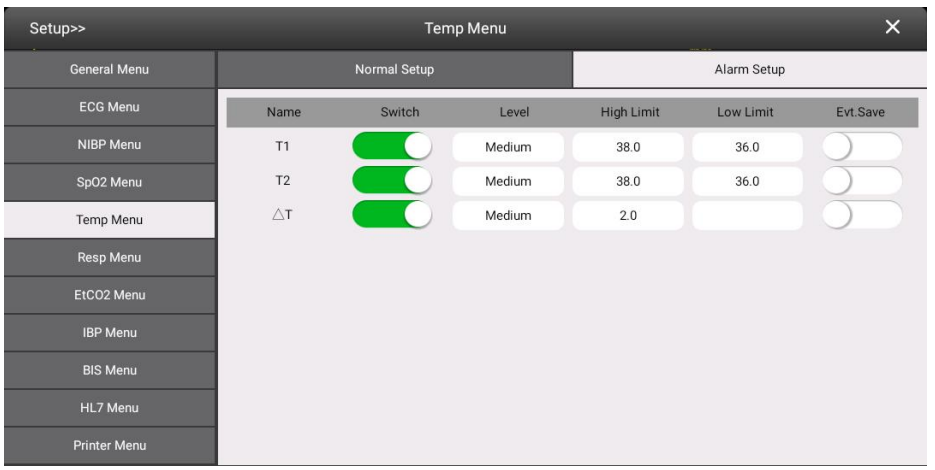


Figure 10-3: Temp Alarm Setup Menu

Temp alarm parameters are: T1, T2 and △T. Set T1, T2 and △T parameter according to your

needs.

10.5 Temp Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

Problem	Corrective Method
No Temp parameter area is display.	Check if Temp parameter is set to ON in 'View Layout'
Measurement failure or '---' shown in Temp value	1、If you are using a disposable probe, check whether the connection between the probe to the temperature cable is tight and secure. 2、If any physical damage occurs on the probe, replace it with an intact one.

NOTE

- For physiological and technical alarm message, please refer to *Appendix C Alarm Message*.

11 NIBP

11.1 NIBP Description

This monitor uses the oscillometric method for measuring the non-invasive blood pressure (NIBP). It is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. Oscillometric devices use a blood pressure cuff to sense these oscillations that appear as tiny pulsations in cuff pressure. By measuring and analyzing at various cuff pressures, the amplitude (which changes based on the pressure within the cuff) and the frequency of these pulsations (which is dependent on the patient's heart rate), oscillometric devices can non-invasively determine blood pressure. Once the mean pressure is determined, the systolic and diastolic pressures are calculated with reference to the mean.

This measurement can be used for adults, pediatrics and neonates.

NOTE

- Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the deviations specified by IEC 60601-2-30.
- NIBP measurement can be performed during electro-surgery and discharge of defibrillator.

11.2 NIBP Safety Information

WARNING

- Be sure to select the correct patient category setting for your patient before measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise, it may present a safety hazard.
- Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
  - Use clinical judgement to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
  - Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.
- Avoid applying the cuff on the side of the mastectomy.

- Kinked or otherwise restricted tubing can lead to a continuous cuff pressure, causing blood flow interference and potentially resulting in injury to the patient.
- The measurement site, patient's position (standing, sitting, lying down), exercise, or physiologic condition can all affect the NIBP readings. If you doubt the NIBP readings, determines the patient's vital signs by alternative means and then verify that the monitor is working correctly
- Continuous non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. More frequent checks are required when performing automatic or continuous measurements. If any abnormity occurs, move the cuff to another site or stop the blood pressure measurements immediately. The 1 and 2-minute intervals are not recommended for extended periods of time.
- NIBP diagnostic significance must be decided by the doctor who performs the measurement.

CAUTION

- Use only the modules and accessories specified in this manual. Follow this manual's instructions for use and adhere to all warnings and cautions.
- Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and choose the proper size cuff.

11.3 NIBP Measurement Influencing Factors

Measurements are impossible with heart rate extremes of less than 30bpm or greater than 300bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

- If a regular arterial pressure pulse is hard to detect
- With excessive and continuous patient movement such as shivering or convulsions
- With cardiac arrhythmias
- Rapid blood pressure changes
- Severe shock or hypothermia that reduces blood flow to the peripheries
- Obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery
- On an edematous extremity

NOTE

- The NIBP feature is not validated for pregnant, including preeclamptic patients use.

11.4 Measurement Methods

There are three methods of measuring NIBP:

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

11.5 Understanding the NIBP Numerics

The NIBP display shows numeric only as below. Your display may be configured to look slightly different. We'll explain NIBP numerics on manual mode for illustration, as shown in Figure 11-1.

Figure 11-1: NIBP Numerics

Number	Explanation
1	**Unit of Pressure**: mmHg or kPa, the default unit is mmHg.
2	**Systolic / Diastolic Pressure**: if the real-time pressure value has risen above the high alarm limit or fallen below the low alarm limit, the numerics will flash.
3	**Measurement Method**: Indicating methods for current measurement. Methods are **Manual, Auto, STAT**
4	**Alarm Limits**: The upper digits are systolic alarm range; the bottom digits are diastolic alarm range.
5	**Mean Pressure**: Mean pressure obtained after the measurement and the real-time cuff pressure obtained during the measurement**.**

11.6 NIBP Measurement Preparation

11.6.1 NIBP Patient Preparation

When taking routine resting blood pressure, ensure that:

- The patient is comfortably seated, with their legs uncrossed and feet flat on the floor.
- The patient's arms and back are supported.
- The middle of the cuff is at the level of the right atrium of the patient's heart.

NOTE

- Ensure that the patient is relaxed and does not talk during the measurement.
- Allow 5 minutes to pass before taking the first measurement
- Other factors that cause high blood pressure measurements include dyspnea, bladder fullness, pain, etc.

11.6.2 NIBP Patient Connection

To place NIBP cuff:

1. Be sure to select the correct patient category setting for your patient before measurement. Verify the patient category and replace the cuff.
2. Connect the NIBP cuff hose to the module's NIBP connector.
3. Choose the appropriate cuff and make sure that the cuff has been completely deflated. Position the NIBP cuff on the patient:
   a. Determine the patient's limb circumference.
   b. Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb.
   c. Apply the cuff to an upper arm or leg of the patient and make sure the Φ marking on the cuff matches the artery location. Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities. Make sure that the cuff edge falls within the marked range. If it does not, use a larger or smaller cuff that will fit better.
   d. Ensure that cuffed limb is supported to maintain the cuff at level of patient's heart. Correcting the Measurement if Limb is not at Heart Level:
      - Add 0.9 mmHg (0.12 kPa) for each centimeter higher, or
      - Deduct 0.9 mmHg (0.12 kPa) for each centimeter lower.alarm

CAUTION

- Improper NIBP cuff size or compression of the cuff may lead to measurement inaccuracy.
- Avoid touching or squeezing the cuff and air tubing, otherwise the measurement may be inaccurate.
- Please be cautious about the accuracy when measuring other physiological parameters with NIBP cuff placement on the limb.

11.7 Starting/ Stopping NIBP Measurement

Task	Steps
Starting or Stopping a Single NIBP Measurement	1、Set NIBP measurement method to '**Manual**' 2、Start the measurement by selecting NIBP '**Start**'. 3、Stop the measurement by selecting NIBP '**Stop**'. 4、Measurement ends When the procedure is completed or measurement anomalies occur. You could also select 'Stop' terminate the NIBP measurement manually.
Starting / Stopping NIBP Auto Measurement	1、Set NIBP measurement method to '**Auto**' and set the required interval. 2、Select NIBP '**Start**' → Start NIBP Auto measurement. 3、Start a measurement manually. The monitor will then automatically repeat NIBP measurements at the set time interval. 4、During the measurement, Select NIBP '**Stop**' at any time to terminate measurement procedure, and the count-down timer will be reset.
Starting / Stopping NIBP STAT Measurement	1、Set NIBP measurement method to '**STAT**'; 2、Select NIBP '**Start**' 3、In STAT mode, when the first measurement is complete, it will continue the 2nd measurement. The automatic NIBP measurement process will stop after 5 measurements. 4、During the measurement, Select NIBP '**Stop**' at any time to terminate measurement process.

11.8 Changing NIBP Settings

Select the NIBP parameter area → '**NIBP Menu**' will pop up, as shown in Figure 11-2.

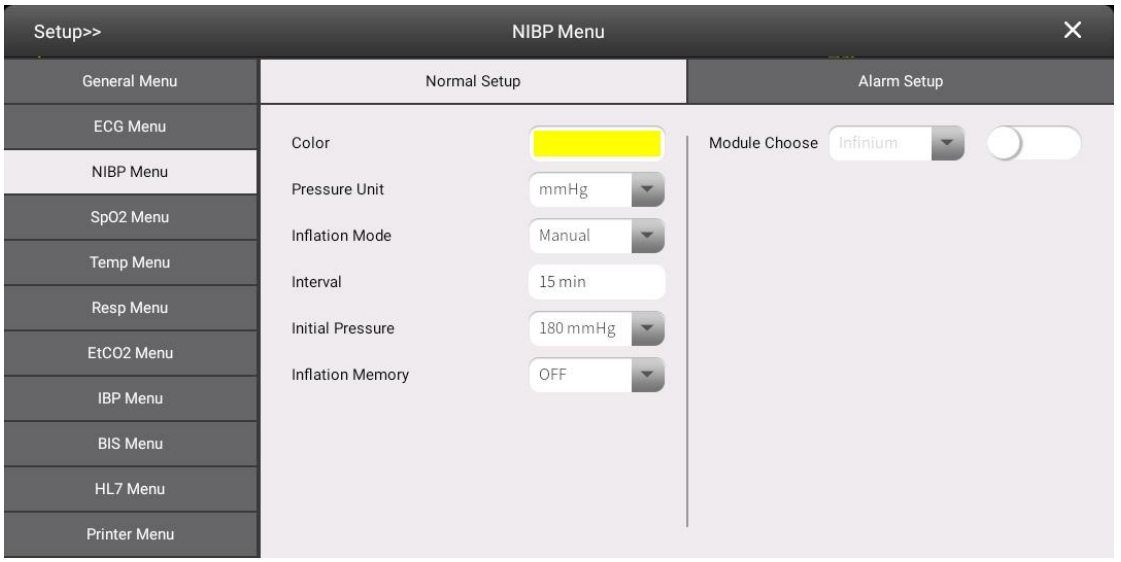


Figure 11-2: NIBP Setup Menu

11.8.1 NIBP Normal Setup

Select '**NIBP Menu**'→ Select '**Normal Setup**' tab to set:

1) Color

Select '**Color**' → Color setting window will pop up → 32 colors are available to choose. The default color is **Yellow**.

2) Pressure Unit

Select '**Pressure Unit**' drop-down menu and toggle between **mmHg** and **kPa**. The default unit is **mmHg**.

3) Inflation Mode

Select '**Inflation Mode**' drop-down menu → Set **Inflation Mode** for measurement method, you can select: Manual, Auto, STAT**.** The default '**Inflation Mode**' is **Manual**.

4) Interval

When inflation mode is set to **Auto**, '**Interval**' setting will be enabled. Select '**Interval**' and then select a desired time interval. The interval range is 1 min — 4 hrs. The default Interval is **5 min**.

5) Initial Pressure

Select '**Initial Pressure**' drop-down menu → Set the initial cuff inflation pressure manually, setting options may vary with the patient category.

- **Adult**:

Represents Adult Mode, during the initial measurement, the cuff is inflated to 180 mmHg, and if the blood pressure hasn't been captured, a second inflation, which is no more than 297mmHg, will start.

- **Pediatric**:

Represents Pediatrics Mode, during the initial measurement, the cuff is inflated to 170 mmHg, and if the blood pressure hasn't been captured, a second inflation, which is no more than 297mmHg, will start.

- **Neonate**:

Represents Neonates Mode, during the initial measurement, the cuff is inflated to 100 mmHg, and if the blood pressure hasn't been captured, a second inflation, which is no more than 147mmHg, will start.

6) Inflation Memory

Select '**Inflation Memory**' drop-down menu → Turn **ON/OFF** '**Inflation Memory**', When '**Inflation Memory**' is turned **ON**, the monitor will save the inflation pressure as baseline and set the inflation pressure as baseline + 30mmHg for next measurement automatically in order to reduce the measurement duration by decreasing the number of inflations. When '**Inflation Memory**' is turned **OFF**, then the monitor sets the inflation pressure automatically according to the previous measurement.

7) NIBP Module Choose

Select '**NIBP Module Choose**' → Enter password (e.g., nbp…) to enable the drop-down menu → choose NIBP module type: **Infinium, SunTech Human** or **SunTech Animal**, the default setting is **Infinium**.

11.8.2 NIBP Alarm Setup

In '**NIBP Menu**' window → Select '**Alarm Setup**' tab, as shown in Figure 11-3.

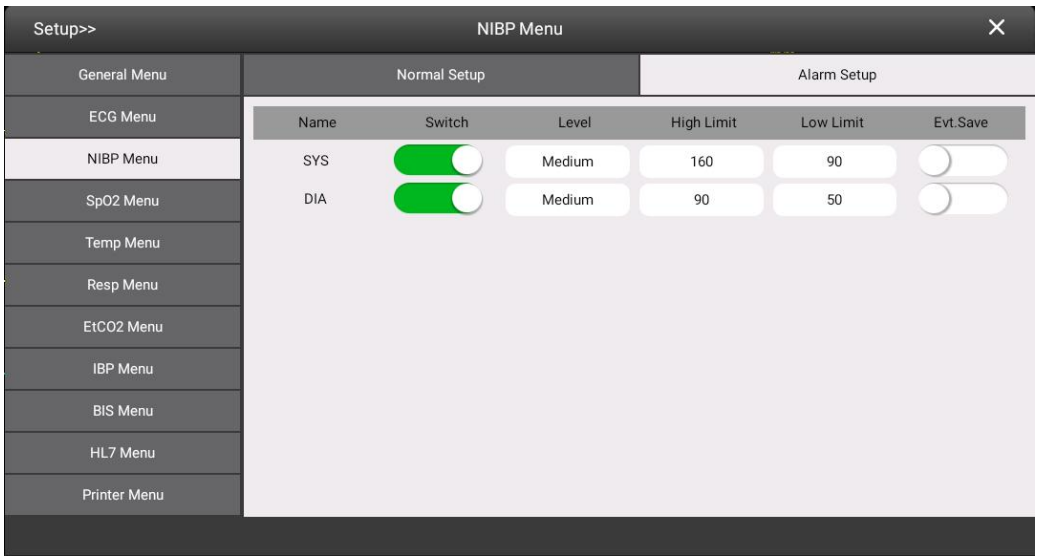


Figure 11-3: NIBP Alarm Setup Menu

You can set NIBP parameters: SYS and DIA alarm limits according to patient category

Range / Patient Category	SYS High alarm limit (mmHg)	SYS Low alarm limit (mmHg)	DIA High alarm limit (mmHg)	DIA Low alarm limit (mmHg)
Adult	40~270 Factory Default Setting: 150	40~270 Factory default setting: 100	10~210 Factory default setting: 90	10~210 Factory default setting: 50
Pediatric	40~230 Factory default setting: 90	40~230 Factory default setting: 40	10~150 Factory default setting: 60	10~150 Factory default setting: 20
Neonatal	40~135 Factory default setting: 120	40~135 Factory default setting: 70	10~95 Factory default setting: 70	10~95 Factory default setting: 40

11.9 NIBP List

You can set **'NIBP List'** to be displayed in **View Layout** Menu. Then, multiple sets of most recent NIBP measurements will be displayed. And PR displayed is derived from NIBP.

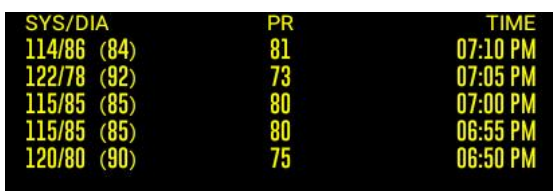


Figure 11-4: NIBP List Display

Due to the screen size limit, The NIBP List displays only the most recent few NIBP measurements. The device can store a maximum 86,400 blood pressure measurement sets in its storage for NIBP List. To see more measurements, select the NIBP List display area → Enter the '**NIBP Tabular Trends**' Tab, as shown in Figure 11-4. Check the data by scrolling the data list, and you can manually set the number of viewable items on the current page by clicking the button to the right of "Number" according to your needs.

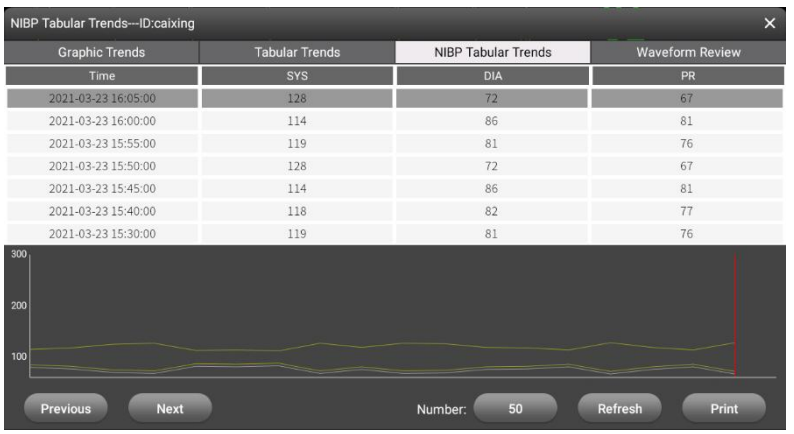


Figure 11-5: NIBP Tabular Trends

11.10 NIBP Maintenance

11.10.1 NIBP Leakage Test

The NIBP leakage test checks the integrity of the system and of the valve. It is required at least once every two years or when you doubt the measured NIBP. Leakage Test must be performed by your service personnel.

11.10.2 Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure transducers must be verified and calibrated once every two years by a qualified service professional. Contact your service personnel when a calibration is necessary.

11.11 NIBP Troubleshooting

Refer to *Appendix C alarm messages*

12 IBP

12.1 IBP Description

IBP is performed when real-time monitoring of blood pressure changes is required in critically ill patients such as shock patients, some cardiac surgeries and other major procedures. Invasive blood pressure (IBP) is generally monitored for: arterial blood pressure (ABP), central venous pressure (CVP), pulmonary artery pressure (PAP), left atrial pressure (LAP), and intracranial pressure (ICP).

The measurement principle is: First, the catheter is placed inside the blood vessel at the measured site by inserting a cannula needle in a suitable artery, and the outer end of the catheter is directly connected to the pressure transducer, due to pressure transmission effect of fluid, the blood pressure will be transmitted to the external pressure transducer through the fluid inside the catheter, so that a patient's blood pressure is constantly monitored beat-by-beat and the dynamic waveform of real-time blood pressure can be displayed. Through specific calculation methods, the systolic pressure, diastolic pressure and mean arterial pressure can be obtained.

You can measure and monitor two invasive blood pressures at the same time using a dual invasive blood pressure cable.

IBP measurement is suitable to use for adults, pediatrics, and neonates.

12.2 IBP Safety Information

WARNING

- Use only pressure transducers specified in this manual. Never reuse disposable pressure transducers.
- Make sure that the applied parts never come into contact with other electric devices.
- To reduce the hazard of burns during high-frequency surgical procedure, ensure that the monitor's cables and transducers never come into contact with the high-frequency surgical units.
- When using accessories, their operating temperature should be taken into consideration. For details, refer to instructions for use of accessories.
- All invasive procedures involve risks to the patient. Use aseptic technique. Follow catheter manufacturer's instructions.
- Mechanical shock to the invasive blood pressure transducer may cause severe shifts in zero balance and calibration, and cause erroneous readings.
- For physiological and technical alarm message, please refer to *Appendix C Alarm messages.*

12.3 IBP Measurement

12.3.1 IBP Device Connection

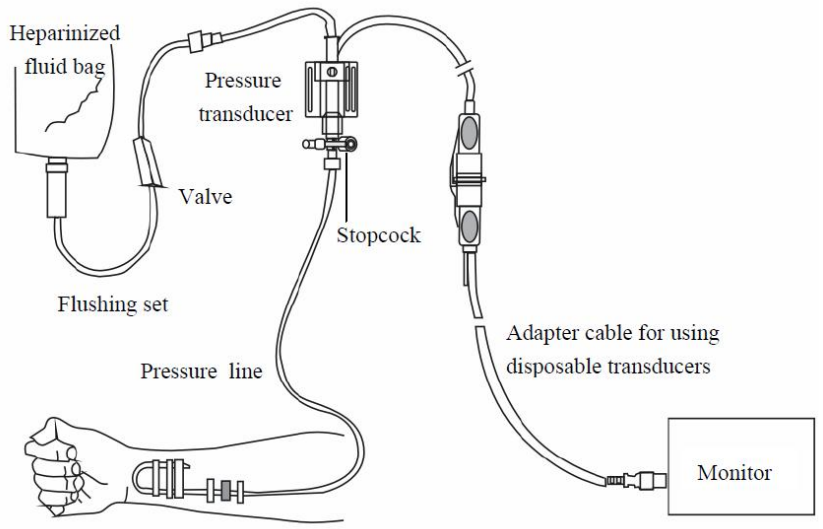


Figure 12-1: IBP Device Connection Diagram

12.3.2 Setting up IBP Measurement.

1. Plug the pressure cable into the IBP connector.
2. Plug the other side of the pressure cable into the IBP module.
3. Flush the system to exhaust all air from the tubing according to the IBP manufacturer's instructions. Ensure that the transducer and stopcocks are free of air bubbles.
4. Position the transducer so that it is level with the heart, approximately at the level of the midaxillary line.
5. Select the appropriate pressure label for measurement.
6. Zero the transducer. After a successful zeroing, turn off the stopcock to the atmosphere and turn on the stopcock to the patient.

CAUTION

- Before IBP measurement, make sure that all the transducers are zeroed correctly
- Ensure that the transducer and stopcocks are free of air bubbles. Air bubble may lead to wrong pressure reading.
- If measuring intracranial pressure (ICP) with a sitting patient, level the transducer with the top of the patient's ear. Incorrect leveling may give incorrect values.

12.3.3 Zeroing IBP Sensor

To avoid inaccurate pressure readings, the monitor requires a valid zero. Zero the transducer in accordance with your hospital policy (at least once per day). Zero whenever:

- A new transducer or adapter cable is used.

- You reconnect the transducer cable to the monitor.
- The monitor restarts.
- You doubt the readings.

Follow the below procedure to Zero the transducer:

1. Connect the pressure module with the transducer, and plug it into the monitor,
2. Turn off the stopcock to the patient and open the venting stopcock to air.
3. Select IBP waveform window or parameter area on screen → Enter '**IBP Menu**' → Select '**IBP1/IBP2 Setup**' tab → Select '**Zero IBP1/IBP2**'.
4. After the zero calibration is completed, close the stopcock to the air and open the stopcock to the patient.

Zeroing failure may occur when pressure fluctuates or exceeds the valid range of zeroing pressure. If zeroing fails, try the following methods:

1. Check the stopcock position to make it is vented to air.
2. Rezero the transducer and don't move the transducer and tubing to avoid motion artifacts.

12.4 IBP Display

The IBP measurement is displayed on the monitor as a waveform and numeric pressures. For ART pressure, Systolic, diastolic and mean pressure values of invasive blood pressures are displayed. For intravenous pressure, only mean blood pressure is displayed.

The Figure below shows the waveform and numerics for the ART pressure.

Figure 12-2: IBP Waveform and Parameter Display

Number	Explanation	Number	Explanation
1	IBP Label	5	P1 Label
2	IBP Waveform Scale	6	IBP Value (SYS/AID)
3	IBP Waveform	7	IBP Alarm Range
4	IBP Sweep Speed	8	IBP Value (MAP)

12.5 IBP Setting

Select IBP waveform window or parameter area → '**IBP Menu**' pops up, as shown in Figure 12-3.

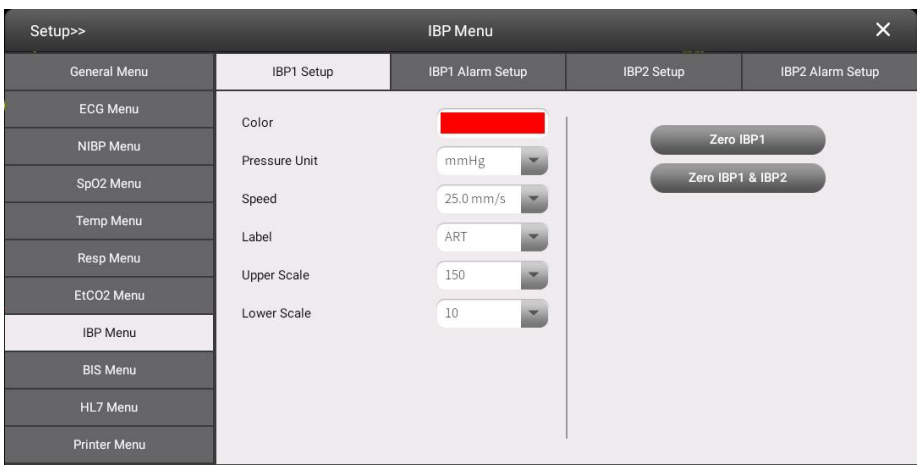


Figure 12-3: IBP Menu

12.5.1 Normal Setup

In '**IBP Menu**' page → Select '**Normal Setup**' tab to set:

1） Color

Select '**Color**' → Color setting window will pop up → 32 colors are available to choose. The default color is **Red**.

2） Pressure Unit

Select '**Pressure Unit**' drop-down menu to set Pressure Unit and toggle between **mmHg** and **kPa**. The default unit is **mmHg**.

3） Speed

Select '**Speed**' drop-down menu to set speed: **12.5 mm/s**, **25 .0mm/s**. The default speed is **25.0mm/s**. The larger the speed value is, The faster the wave sweeps.

4） Label

Select '**Label**' drop-down menu and then select your desired label from the list, IBP labels are Arterial blood pressure (**ART**), Pulmonary artery pressure (**PA**), Right atrial pressure (**RAP**), Central venous pressure (**CVP**), cranial pulse pressure (**ICP**) and left atrial pressure (**LAP**). The default is **ART**.

5） Upper Scale

Select '**Upper Scale**' drop-down menu to set waveform Upper Scale for display, options are 180,150,120,100,75. The default **Upper Scale** is **150**.

6） Lower Scale

Select '**Lower Scale**' drop-down menu to set waveform Lower Scale for display, options are 10, 0, -10, -20, -30. The default **Lower Scale** is **10**.

7） Zero

Select '**Zero**' → You can zero corresponding IBP.

12.5.2 NORMAL Alarm Setup

In '**IBP Menu**' window → Select '**Alarm Setup**' tab, as shown in Figure 12-4.

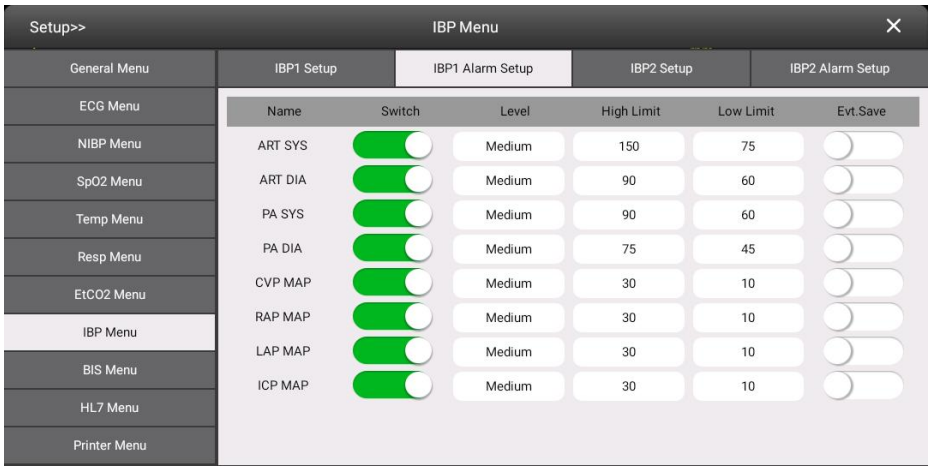


Figure 12-4 IBP Alarm Setup Menu

In this menu, you can set SYS, DIA and MAP properties for different pressure categories (ART, PA, CVP, RAP, LAP, ICP). Configure the alarm switch, alarm levels, high alarm limit and low alarm limit and alarm event recording for each parameter according to your needs.

12.6 IBP Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

Problem	Corrective Method
No IBP parameter window and waveform area on screen	1、Check if the IBP parameter and waveform display is turned ON in 'View Layout'. 2、Make sure the IBP module and monitor are connected.
Invasive pressure readings seem unstable.	1、Make sure there are no air bubbles in the transducer systems. 2、Check if the transducer is fixed. 3、Flush and zero. 4、Replace the transducer.
Zeroing failure	1、Make sure that the transducer is vented to air, not to the patient, and try again. 2、Rezero the transducer and don't move the transducer and tubing when zeroing. 3、Replace the transducer if the rezeroing still fails.

13 EtCO2

13.1 EtCO2 Description

End-tidal CO2 or partial pressure (EtCO2) reflects pulmonary ventilation and also pulmonary blood flow. When no significant cardiopulmonary disease exists and V/Q ratio is normal, EtCO2 reflects PaCO2 (arterial blood carbon dioxide), with a normal EtCO2 value of 5% corresponding to 5KPa (38mmHg).

This monitor uses the following methods to measure carbon dioxide in the patient's airway:

Sidestream measurement samples expired patient gas at a constant sample flow from the patient's airway and analyzes it with a CO2 sensor built into the CO2 module.

CO2 measurement is suitable to use for adults, pediatric and neonates.

13.2 EtCO2 Safety Information

WARNING

- EtCO2 monitoring is an external function of the patient monitor, please read thoroughly the manual that comes with the EtCO2 sensor before use.
- Route all tubing away from the patient's throat to avoid strangulation.
- If the sampled gas is returned to the respiratory system, there is a risk of cross infection among patients.

CAUTION

- Remove the airway sample line from the patient's airway while nebulized medications are being delivered. Measuring CO2 during nebulization may lead to inaccurate CO2 readings.
- EtCO2 values measured from the CO2 module may differ from those from the blood gas analysis.
- Avoid mechanical shock to the sidestream CO2 module.
- Shaking the CO2 module during O2 measurement may lead to a distorted O2 waveform or inaccurate O2 measurement.

NOTE

- When monitoring patient with EtCO2 module, please make sure the proper connection between the patient and module.
- Explosion Hazard: Do not use in the presence of flammable anesthetics or gases, such as a flammable anesthetic mixture with air, oxygen or nitrous oxide. Use of the devices in such an environment may present an explosion hazard.
- Failure of operation: if the measurement or a sensor fails to respond as described, do not use it until the situation has been corrected by qualified personnel.

13.3 Measurement Influencing Factors

The following factors may influence the accuracy of measurement:

- Leaks or internal venting of sampled gas
- Mechanical shock
- Cyclic pressure up to 10 kPa (100 cmH2O)
- Other sources of interference, if any

13.4 EtCO2 Display

EtCO2 waveform display area and parameter display area are shown in Figure 13-1.

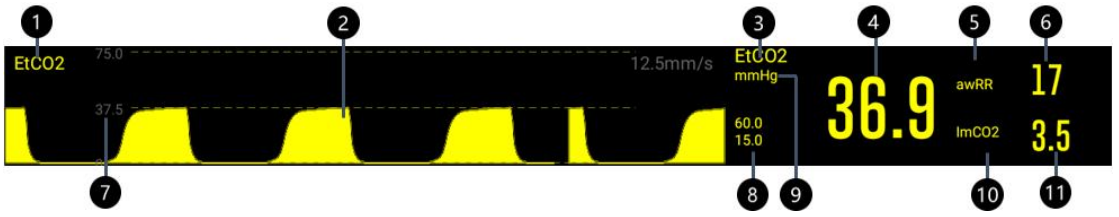


Figure 13-1: EtCO2 Waveform and Parameter Display

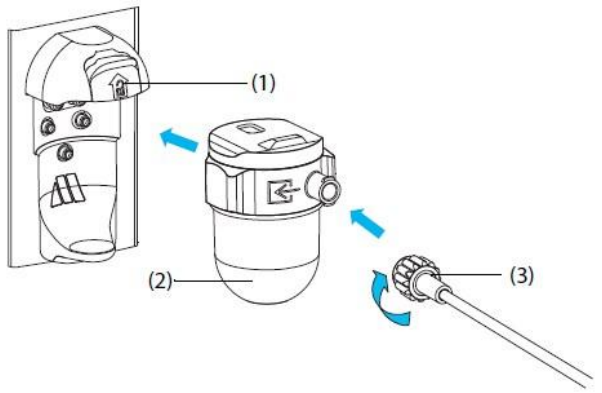
Number	Explanation	Number	Explanation
1	EtCO2 Waveform Label	7	EtCO2 Waveform Scale
2	EtCO2 Waveform	8	EtCO2 Alarm Range
3	EtCO2 Label	9	EtCO2 Unit
4	EtCO2 Value	10	ImCO2 Label
5	awRR Label	11	ImCO2 Value
6	awRR Value		

13.5 EtCO2 Sensor Preparation

Preparing to Measure Sidestream CO2

1. Select the appropriate gas sample line and watertrap according to the patient category.

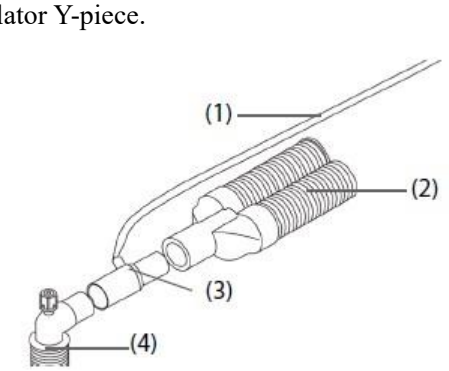
2. Connect the watertrap to the CO2 module, and connect the gas sample line to the watertrap.



(1) Watertrap receptacle (2) Watertrap (3) Gas sample line

3. Connect the other end of the gas sample line to the patient.

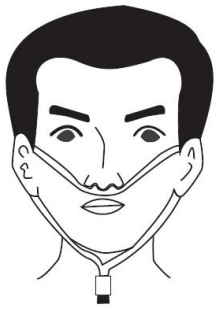
◆ For intubated patients requiring an airway adapter, install the airway adapter between the patient circuit and the ventilator Y-piece.



(1) Sample line (2) Connection to the ventilator

(3)Airway adapter (4) Connection to the patient

◆ For non-intubated patients, place the nasal cannula onto the patient.



4. Connect the gas outlet to the scavenging system using an exhaust tube.

5. To zero the sensor:

– Expose the sensor to room air and keep it away from all sources of CO2 including the ventilator, the patient's breath and your own.

– In the setup menu for the CO2, select **Zero**.

– After clicking the "zero" button, the prompt message '**zero calibration in progress**' will appear on screen. When it disappears, the zero calibration has been completed and you can start monitoring.

WARNING

- Do not use the adult or pediatric watertrap with a neonate patient. Otherwise, patient injury could result.
- Connect the gas outlet to the scavenging system when measuring CO2 using the sidestream CO2 module.
- When perform a zero calibration during the measurement, disconnect the transducer from the patient's airway first.
- Do not rely on the gas readings when zeroing.

CAUTION

- Leakage in the breathing or sampling system may cause the displayed EtCO2 values to be significantly low. Always make sure that all components are securely connected.
- Inspect the airway adapter for a tight connection and proper operation before attaching it to the patient.
- Squeezing or bending the sample line during sidestream CO2 measurement may cause inaccurate CO2 readings or no reading.
- To avoid blocking the airway, empty the watertrap container whenever half full. Replacing the watertrap once a month is recommended. Dispose of accumulated fluids in accordance with hospital policy or your local regulations.
- The watertrap has a filter preventing bacterium, water and secretions from entering the module. Extended use could destroy the filter in watertrap and fail to stop the bacterium, water and secretions entering the module, result in damaging the gas module and having infection risk.

NOTE

- To extend the lifetime of the watertrap and module, disconnect the watertrap from the module and set the operating mode to Standby mode when CO2 monitoring is not required.

- The emptying interval of the watertrap is 30 hours @ 50 ~ 250 ml/min, sample gas of 37 ° C, room temperature of 23 ° C, and 100% RH.
- Always position the sensor with the adapter in an upright position to avoid collection of fluids on the windows of the adapter. Large concentrations of fluids at this point will obstruct gas analysis.
- Place the sensor and adapter close to the patient to avoid blockage in airway.

13.6 EtCO2 Setup

Select EtCO2 waveform area parameter area on monitoring screen → Enter '**EtCO2 Menu**', as shown in Figure 13-2.

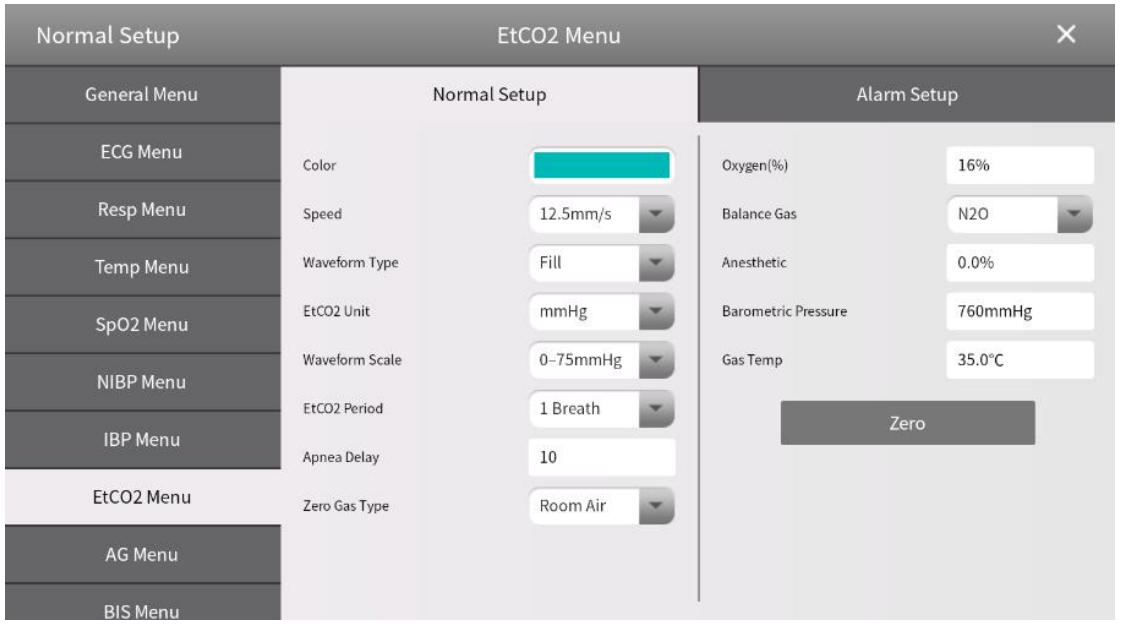


Figure 13-2 EtCO2 Menu

13.6.1 EtCO2 Normal Setup

In '**EtCO2 Menu**' page, select '**Normal Setup**' tab:

1) Color

Select '**Color**' drop-down menu to set ECG waveform and parameter color. 32 colors are available, as shown in Figure 13-2. The default color is **Yellow**.

2) EtCO2 Unit

Select '**EtCO2 Unit**' drop-down menu to set EtCO2 unit, there are 3 options: **mmHg**, **kPa** and **%**. The default unit is **mmHg**.

3) Speed

Select '**Speed**' drop-down menu, you can choose **6.25 mm/s, 12.5 mm/s, 25mm/s.** The default speed is **12.5mm/s**. The larger the value is, the faster the wave sweeps.

4) Waveform Type

Select '**Waveform Type**' drop-down menu → Toggle between [**Draw**] and [**Fill**]:

- [**Draw**]: The CO2 wave is displayed as a curved line.
- [**Fill**]: The CO2 wave is displayed as a filled area.

The default wave type is **Fill**.

5) Waveform Scale

Select '**Waveform Scale**' drop-down menu to change the size of the CO2 waveform. →You can choose '**0-75mmHg**' or '**0-150mmHg**'.

6) EtCO2 Period

Select '**EtCO2 Period**' drop-down menu to set EtCO2 Period for calculation and toggle between **1Breath**,**10s** and **20s**. The default Period is **1 Breath**.

7) Apnea Delay

Select '**Apnea Delay**' → Manually enter parameter value of 10-60s, the monitor will alarm if the patient has stopped breathing for longer than the preset apnea time. The default setting is **10s**.

8) Zero Gas Type

Select '**Zero Gas Type**' drop-down menu → Toggle between **Room Air** and **N2**. The default setting is **Room Air**.

9) Oxygen %

Select '**Oxygen**' → Enter the concentration value for **Oxygen Compen**. For relevant setting, follow instructions specified by the module manual. The default setting is **16%**.

10) Balance Gas

Select '**Balance Gas**' drop-down menu to set Gas Type and toggle between **Room Air**, **Nitrogen** and **Helium**. The default balance gas is **N2O**.

11) Anesthetic %

Select '**Anesthetic**' menu to set concentration value → Enter the parameter value manually. The default setting is **0.0%**.

12) Barometric Pressure

Select '**Barometric Pressure**' menu to set current Barometric Pressure value to which the patient monitor is exposed to → Enter the parameter value, the default barometric pressure is **760 mmHg**.

13) Gas Temp

Select '**Gas Temp**' menu → Enter the parameter value of 10℃～50℃ (50℉～122℉), the default gas temp is **35.0℃**.

14) Zero Setup

Select 'Zero Setup' → Zero the EtCO2 parameters.

WARNING

- Make sure that the appropriate compensations are used based on real scenarios. Inappropriate compensations may cause inaccurate measurement values and result in misdiagnosis.

13.6.2 EtCO2 Alarm Setup

In '**EtCO2 Menu**' Page, select '**Alarm Setup**' tab, as shown in Figure 13-3. Set EtCO2 and awRR alarm value as you desired.

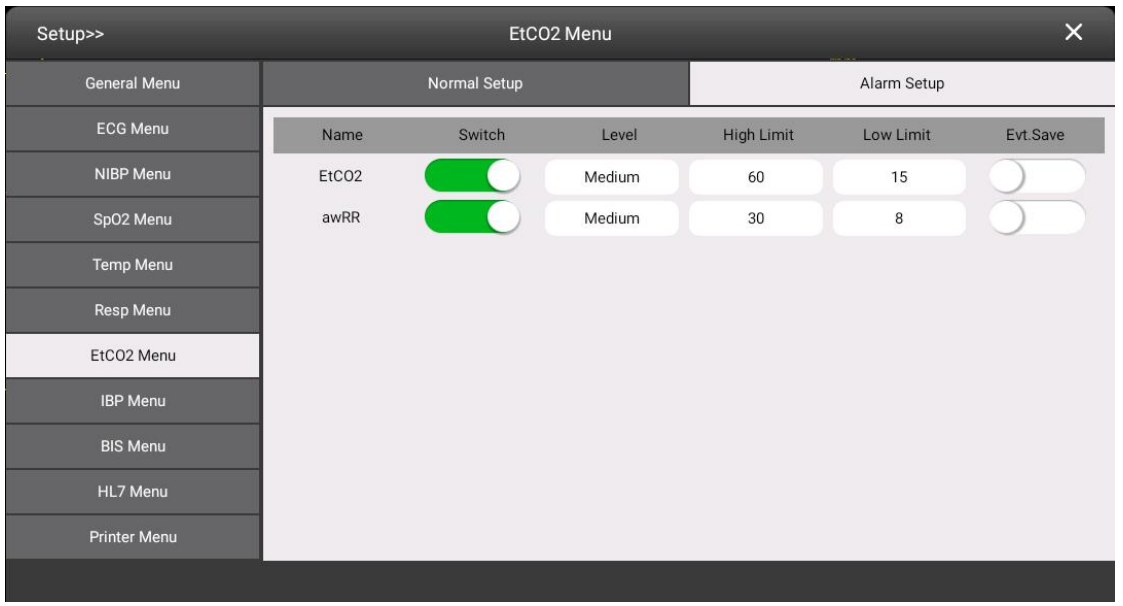


Figure 13-3 EtCO2 Alarm Setup Menu

13.7 Calibrating EtCO2 Sensor

For sidestream CO2 modules, a calibration should be performed once every year or when the readings go far beyond the range. If calibration is needed, please contact the service personnel.

NOTE

- Connect the gas outlet to the scavenging system when calibrating the CO2 module.

13.8 CO2 Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

Problem	Corrective Method
EtCO2 measurement values are too low	1、Check whether the CO2 concentration of the measurement site. If the environmental concentration is a bit high, measured value tends to be lower than expected. In the worst scenario, the too high concentration may lead to zeroing failure. Please ventilate the environment. 2、Check the sampling line and connectors for leakage. 3、Check the patient status
Elevated baseline	1、Check the patient status. 2、Check the sensor.

NOTE

- For the physiological and technical alarm messages, refer to *Appendix C Alarm messages*

14 AG

14.1 AG Description

The Anaesthetic Gas (AG) module measures anaesthesia and respiratory gas in patients.

The AG module measures gas concentration based on the principle of gas absorption properties of infrared. The gas that can be measured by the AG module absorbs infrared light and each gas has different absorption characteristics. The gas is transmitted into a sampling chamber and the infrared filter emits light with a particular frequency through the gas. When several gases are measured, there are several infrared filters. In a given volume, the higher the gas concentration, the more infrared light is absorbed, the less infrared light is transmitted through the gas. The gas concentration can be calculated by measuring the transmission of infrared light.

AG measurements are suitable for adults, pediatrics and neonates.

14.2 AG Safety Information

WARNING

- Can not use flammable anaesthetic such as ether and cyclopropane to prevent explosion.
- Use of high frequency electrical surgical equipment can lead to burn hazards and can not use anti-static or conductive respiratory ducts.
- When installing pipes such as sampling tubes, it should be prevented not to suffocate the patient's throat.

CAUTION

- Perform AG monitoring in a well-ventilated environment.
- EtCO2 values measured with the AG module may differ from the CO2 partial pressure values measured with blood gas analysis.

NOTE

- The AG module has automatic alarm suppression function, and the AG module produces physiological alarms only after the respiratory wave is monitored. When using the AG module to monitor the patient, make sure the device is properly connected to the patient

14.3 AG Measurement Influencing Factors

The following factors may affect measurement accuracy:

■ Leakage or internal sampling gas leakage

■ Mechanical shock

■ Circulating pressure greater than 10 kPa (100 cmH2O)

■ Other sources of interference, if any.

14.4 AG Display

AG waveform display area and parameter display area are shown in Figure 14-1.

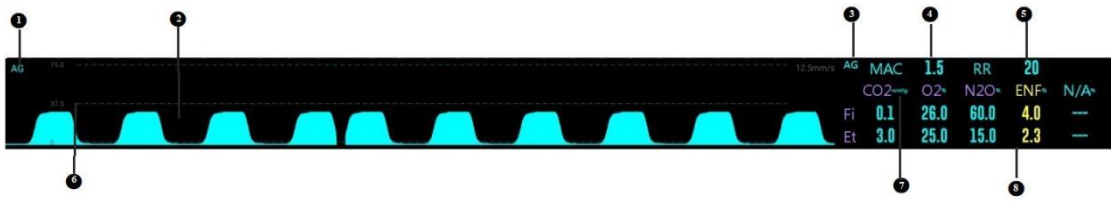


Figure 14-1 AG waveform and parameter display

Number	Explanation	Number	Explanation
1	AG Waveform Label	5	RR Parameter Value
2	AG Waveform	6	AG Waveform Scale
3	AG Label	7	Unit
4	MAC Value	8	AG Parameter Value

The AG module displays all measured waveforms and parameters on the monitor screen, including:

■ CO2 waveform.

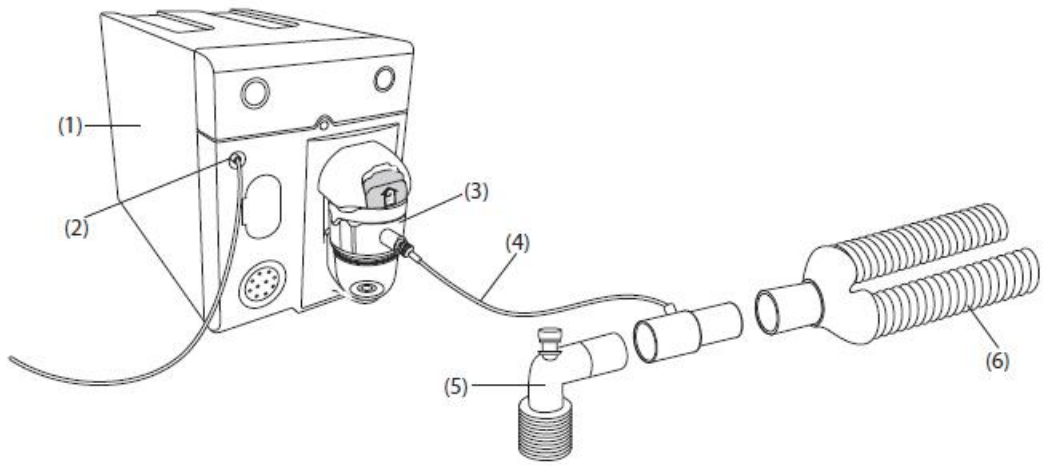
■ awRR: Airway respiration rate.

■ MAC: Minimum alveolar effective concentration.

■ Values of CO2, O2, N2O and AA exhalation end (Et) and inhalation (Fi).

AA represents one of the five anesthetic gases Des (deflurane), Iso (isflurane), Enf (anfluoride), Sev (sevoflurane) and Hal (fluorane).

14.5 AG Device Connection



Number	Explanation	Number	Explanation
1	AG Module	4	Gas Samplle Line
2	Gas Outlet	5	Airway Adapter (connected to patient)
3	Watertrap	6	Y-Piece (connected to the anesthesia machine)

14.6 AG Measurement Preparation

Refer to the following steps to prepare an AG measurement:

1. Select suitable sampling tubes and watertraps according to patient type.

2. Install the watertrap into the watertrap fixture and attach one end of the sampling tube to the watertrap.

3. Connect the other end of the sampling tube through the airway adapter to the patient.

4. The sample gas is discharged into the exhaust gas treatment system using a single exhaust pipe connected to the exhaust hole on the module.

5. Check that the airway is tightly connected.

The AG module is set in measurement mode by default, and when the AG module is inserted into the module Module, the monitor prompts [AG is starting]. Measurements can be made once the startup is complete.

WARNING

- Don't use adult watertrap and sampling tubes on neonates, otherwise, damage to patient may occur.
- When using the AG module, the exhaust holes on the module must be connected to the

exhaust gas treatment system.

- Ensure that all connections are secure and reliable. Any leakage causes ambient air to blend into the patient's breathing gas, resulting in incorrect readings.
- Ensure that the airway adapter is tightly connected to other components and works properly before connecting it to the patient.
- When making measurements, be careful not to squeeze or bend the sampling tube; Otherwise, it may cause the module to have no readings or incorrect readings.

CAUTION

- The end of the gas sampling tube connected to the airway adapter should be pointed upwards. This prevents condensed water from passing into the gas sample line and causing an occlusion.
- Watertrap is used to collect condensed water droplets from the sampled airways to prevent the entry into the module. When the water collected in the watertrap reaches a certain amount, the water must be emptied before it continues to be used to avoid airway blockage.
- Dispose of waste fluid in accordance with hospital regulations or local regulations.
- Watertrap contains filtration material to prevent bacteria, water vapor and patient secretions from entering the module. After long-term use, dust or other foreign objects can lead to reduced air permeability of the filter material in the watertrap, which can cause airway clogging in severe cases. In this case, the watertrap must be replaced. Also, it is recommended to replace the watertrap every month.

NOTE

- When not using AG monitoring, it is best not to connect to the watertrap and set the AG module to standby mode to improve the service life of the watertrap and module.
- DRYLINE II adult/pediatric watertrap emptying time is 26h@120 ml/min, 37℃, 100% RH
- DRYLINE II neonate watertrap emptying time is 35h@90 ml/min, 37℃, 100% RH

14.7 MAC Value

MAC, the lowest alveolar concentration, is a basic indicator of the depth of anesthesia in response to inhalation. Standard ISO 80601-2-55 defines MAC as the alveolar concentration of an inhaled anaesthetic which prevents 50% of patients from developing limb movement under a standard surgical stimulus when no other anaesthetic is present and equilibrium is achieved,

The 1 MAC concentration values for various inhalation anaesthetics are shown in the

following table:

Anesthetic	DES	ISO	ENF	SEV	HAL	**N2O**
1 MAC	6%	1.15%	1.7%	2.1%	0.77%	105%*

*: The N2O concentration of 1 MAC can only be achieved in a high-pressure chamber.

NOTE

- The above data are from ISO 80601-2-55, a 40-year-old healthy male patient case published by the Food and Drug Administration.
- In practical applications, consideration should be given to factors such as age and weight that may affect the effects of inhalation of anaesthetics.

The formula for calculating MAC:

$$MAC = \sum_{i=0}^{N-1} \frac{EtAgent_i}{AgentVol_{\text{age}^i}}$$

N indicates the type of anaesthetic (including N2O) that can be measured by the AG module; EtAgenti indicates the end-of-breath concentration of each inhaled anesthetic; AgentVolagei represents the 1 MAC concentration value for each inhaled anesthetic, which corrects the age factor.

The formula used to calculate the age-modified 1MAC concentration value is:

$$MAC_{age} = MAC_{40} \times 10^{(-0.00269 \times (age - 40))}$$

For example, 1MAC concentration value of 60-year-old patients inhaled DES：6% × $10^{(-0.00269\times(60-40)} = 6\% \times 0.88$. Then, if the AG module measures a 60-year-old patient with 4% DES, 0.5% HAL, and 50% N2O in the gas at the end of the breath, the MAC value is:

$$MAC = \frac{4.0\%}{6\%\times0.88} + \frac{0.5\%}{0.77\%\times0.88} + \frac{50\%}{105\%\times0.88} = 2.04$$

NOTE

- The above formula is only applicable to patients over the age of one. If the patient is less than one year old, the system uses 1 year for age correction.

14.8 AG Setup

14.8.1 Normal Setup

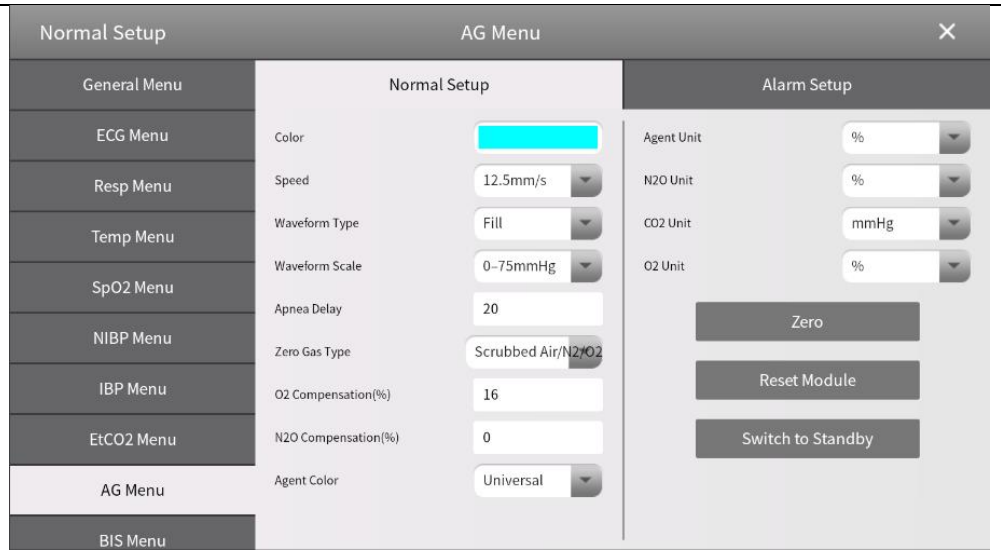


Figure 14-2 AG Normal Setup Page

In '**AG Menu',** select '**Normal Setup'** tab to setup:

1) Color

Select 'Color' drop-down menu to set AG waveform and parameter color. 32 colors are available, the default color is blue.

2) Speed

Select 'Speed' drop-down menu, you can choose 6.25 mm/s, 12.5 mm/s, 25mm/s. The default speed is 12.5mm/s. The larger the value is, the faster the wave sweeps.

3) Waveform Type

Select 'Waveform Scale' drop-down menu to choose whether to Fill the waveform. Select **Draw** as linear waveform, Select **Fill** as filled waveform. The default waveform type is FILL.

4) Waveform Scale

Select '**Waveform Scale**' drop-down menu to change the size of the CO2 waveform. You can choose '**0-75mmHg**' or '**0-150mmHg**'.

5) Apnea Delay

Select 'Apnea Delay' → Manually enter parameter value of 10-60s, the monitor will alarm if the patient has stopped breathing for longer than the preset apnea time. The default setting is 20s.

6) Zero Gas Type

Select 'Zero Gas Type' drop-down menu to configure zero gas type, select **Scrubbed Air/N2/O, Room Air, 100% O2.** The default setting is Room Air.

7) O2 Compensation %

Select '**O2 Compensation'** to enter O2 compensation %. For relevant setting, follow instructions specified by the module manual. The default setting is 16%.

8) N2O Compensation %

Select **N2O Compensation** Menu to enter N2O Compensation %. For relevant setting, follow instructions specified by the module manual. The default setting is 16%.

9) Agent Color

Select **Agent Color** drop-down menu to configure Agent color, can choose '**Universal**', '**No Color**'. The default color is **Universal**

10) Agent Unit

Select 'Agent Unit' drop-down menu to set Agent unit, there are 3 options: mmHg, kPa and %. The default unit is %.

11) N2O Unit

Select 'N2O Unit' drop-down menu to set N2O unit, there are 3 options: mmHg, kPa and %. The default unit is %.

12) CO2 Unit

Select 'CO2 Unit' drop-down menu to set CO2 unit, there are 3 options: mmHg, kPa and %. The default unit is mmHg.

13) O2 Unit

Select 'O2 Unit' drop-down menu to set O2 unit, there are 3 options: mmHg, kPa and %. The default unit is %.

14) Zero

Click 'Zero' button to zero EtCO2.

15) Reset Module

Click '**Reset Module'** button to reset AG module.

16) Switch to Standby/Normal

Click the **Switch to Standby/Normal** button to switch module mode.

You can select the operating mode based on the actual situations:

■ Normal mode: When using the AG module for measurement, you need to select normal mode.

■ Standby mode: When you are not using AG modules for monitoring, it is recommended to set AG modules to standby mode to increase the service life of AG modules.

14.8.2 Alarm Setup

In '**AG Menu'**, select '**Alarm Setup'**, the page is shown in Figure 14-3. Set up AG alarm in this page.

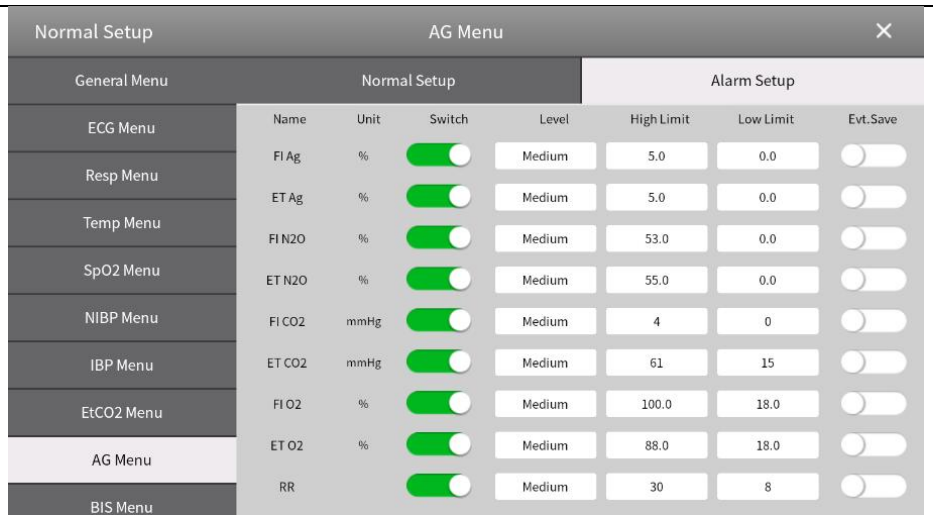


Figure 14-3 AG Alarm Setup Page

14.9 Changing AG

If the anaesthetic used on the patient changes, the mixture of the two gases can be detected by modules during the transition. However, the time required to complete the anaesthetic exchange depends on the type of anaesthetic (low or high flow) and the characteristics of the anaesthetic used (drug metabolic dynamics). During the swap, the MAC values displayed may be inaccurate.

The anesthesia module automatically identifies two anesthetics. When there is a large change in the composition of the primary and secondary anaesthetic gases, the monitor determines the dominant anaesthetic based on the contribution to the MAC value, replacing the displayed anaesthetic label and data.

14.10 Calibrating AG Module

The AG module needs to be calibrated annually or in case of suspected improper measurements. For calibration, contact your maintenance staff.

CAUTION

- When calibrating the AG module, the calibrated gas must be connected to the exhaust gas treatment system.

14.11 AG Troubleshooting

When the AG module channel is blocked, there is a "AG airway blocking" prompt on the screen. There are several clogging situations for AG troubleshooting. The methods of removing such blockages are:

1. Check the airway adapter for blocking and replace the airway adapter if blocking.
2. Check that the tube is blocked or tangled and, if necessary, replace the tube.

3. Check the watertrap for excessive or clogged water, and replace the watertrap if the watertrap is still clogged.

4. Check the air outlet and exhaust pipe for blockages.

If the blocking information continues to appear, it is likely that the module will fail. At this point, contact the maintenance staff.

NOTE

- For physiological and technical alarms, See *C Alarm Messages*.z

15 BIS

15.1 Description

Bispectral Index monitoring helps to monitor the level of consciousness of a patient under general anesthesia or sedation in the OR and ICU. By measuring the ECG signal, use of BIS monitors the patient's brain activity to help reduce the incidence of awareness with recall during general anesthesia or sedation.

The patient's brain function is monitored by measuring the spontaneous, rhythmic electrical activity of brain cell populations.

This monitor uses the BISx module for hemispheric BIS monitoring.

EEG monitoring is suitable to use for adults and pediatrics.

15.2 BIS Safety Information

WARNING

- BIS monitoring is an external function of the patient monitor, please read thoroughly the manual that comes with the BIS sensor before use.
- BIS monitoring should not be performed on neonates.
- The conductive parts of sensors and connectors should not come into contact with other conductive parts, including earth.
- To reduce the hazard of burns in the high-frequency surgical neutral electrode connection, the BIS sensor should not be located between the surgical site and the electro-surgical unit return electrode.
- When using brain stimulation devices such that transcranial electrical stimulation motor evoked potentials occur, the stimulation electrodes should be placed as far away from the BIS sensor as possible and ensure that the electrodes and sensor are placed according to the instructions specified on the package to avoid burns.
- The BIS sensor must not be located between defibrillator pads when a defibrillator is used on a patient connected to the patient monitor.
- The clinical utility, risk/benefit and application of the BIS component have not undergone full evaluation in the pediatric population.
- Due to limited clinical experience in the following applications, BIS values should be interpreted cautiously in patients with known neurological disorders, those taking psychoactive medications, and in children below the age of 1.

- The Bispectral Index is a complex technology, intended for use only as an adjunct to clinical judgment and training.
- Clinical judgment should always be used when interpreting BIS in conjunction with other available clinical signs. Reliance on BIS alone for intraoperative anesthetic management is not recommended.
- Misinterpretation of BIS can result in incorrect administration of anesthetic agents and/or other potential complications of anesthesia or sedation.
- Be cautious in interpreting BIS values when using certain anesthetic combinations when using benzodiazepines, nitrous oxide or ketamine as anesthetics.

CAUTION

- Ensure that the BISx does not come into prolonged contact with your patient's skin, as it may generate heat and cause discomfort.
- Do not use the BIS sensor if the sensor gel is dry. To avoid dryout, do not open the pack until you are ready to use the sensor.
- When Electroconvulsive (EsCT) is performed during BIS monitoring, it should be NOTED that ECT electrodes should be placed as far away from the BIS sensors as possible to minimize interference, some ECT devices may interfere with the normal function of BIS monitoring and the ECT device compatibility with the BIS sensors should be checked.
- The BIS measurement based on measuring the EEG signal is inherently very sensitive. Do not use electrical radiating equipment close to the BISx or DSC.
- Use only the accessories specified by this manual and follow the guidance for operation. Adhere to all WARNING, CAUTION and NOTES.
- Artifact may lead to inappropriate BIS values. Potential artifact may be caused by unusual or excessive electrical interference or high EMG activity like shivering, muscle activity or rigidity, sustained eye movements, head and body motion. Also, improper sensor placement and poor skin contact (high impedance) may cause artifact and interfere with the measurement.
- External radiating devices may disturb the measurement.
- Poor signal quality may lead to inappropriate BIS values

NOTE

- This monitor uses a component modular device in deriving the Bispectral index (BIS) purchased from Covidien. It is important to recognize this index is derived using solely that company's proprietary technology. It is recommended that clinicians have reviewed applicable information on its utility and/or risks in published articles and literature/web site information from Covidien (www.covidien.com) or contact that company itself if they have clinical-based BIS questions relating to this module portion of the patient monitor.
- The BISx equipment is a 2-channel EEG signal monitoring device for unilateral cerebral hemisphere BIS monitoring.
- The BISx equipment must be used under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use.

15.3 BIS Parameters

Unilateral cerebral hemisphere BIS monitoring measures the following parameters:

Parameter	Explanation
BIS	The BIS numeric reflects the patient's level of consciousness. It ranges from 100 (fully awake) to 0 (suppression; no electrical brain activity). The higher the value, the more conscious the patient is; the lower the value, the deeper the anesthesia. During surgery, the BIS value of a patient under general anesthesia is usually between 40 and 60. 100: The patient is widely awake. 70: The patient is underdosed but still unlikely to become aware. 60: The patient is under general anesthesia and loses consciousness. 40: The patient is overdosed and in deep hypnosis. 0: The EEG waveform is displayed as a flat line, and the patient has no electrical brain activity.
SQI	The SQI numeric reflects signal quality and provides information about the reliability of the BIS, SEF, TP, and SR numerics during the last minute. It ranges from 0-100%. The higher the value, the better the signal; the lower the value, the worse the signal. If the signal strength is too weak to calculate the

	BIS value, it may cause the BIS value or other Parameter not being displayed.
EMG	The EMG numeric reflects the electrical power of muscle activity and high frequency artifacts. The larger the value, the greater the EMG interference: EMG > 55 dB: Too high to lose medical reference value. EMG < 55 dB: this is an acceptable EMG EMG ≤ 30 dB: this is an optimal EMG (Note that the minimum possible EMG is approximately 25 dB).
SR	The SR is the percentage of time over the last 63-second period during which the EEG is considered to be in a suppressed state SR. For example, SR=10 indicates that a suppressed state SR accounted for 10% of the time over the past 63s, that is, the signal was inhibited for 6s. When SR=100%, the EEG signal is displayed as a flat line. It is valuable in medical applications to brain injury, coma, hypoxia, hypothermia, prematurity, and anesthesia.
SEF	The SEF is a frequency below which 95% of the total power is measured. The useful range is 0 ~ 30.0Hz.
TP	TP numeric which only monitors the state of the brain indicates the power in the frequency band 0.5-30Hz. The useful range is 40-100db.
BC	A burst means a period (at least 0.5 second) of EEG activity followed and preceded by inactivity. The BC numeric helps you quantify suppression by measuring the number of EEG bursts per minute. This parameter is intended for the BIS module with the Extend Sensor only. The BC Parameter is valid only when SQI ≥ 15% and SR ≥ 5%.

15.4 BIS Display

BIS waveform area and parameter area are shown in Figure 15-1.

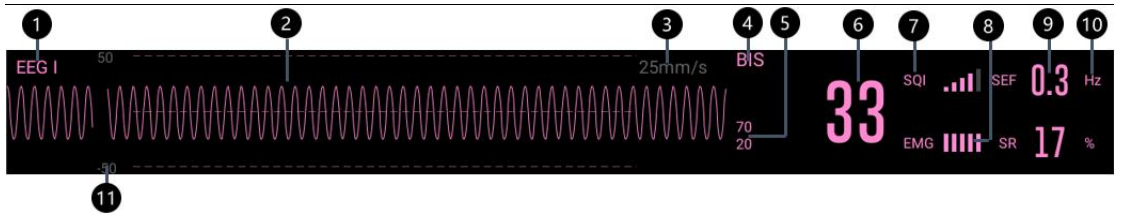


Figure 15-1: EEG Waveform Area and Parameter Area

Number	Explanation	Number	Explanation
1	EEG Lead Label	7	SQI Signal Strength Bar Graph
2	BIS Waveform Display	8	EMG Strength Bar Graph
3	EEG Sweep Speed	9	Related Parameter Value
4	BIS Label	10	Related Parameter Unit
5	BIS Alarm Limits	11	EEG Waveform Scale
6	BIS Value		

15.5 BIS Monitoring

BIS monitoring procedure is:

1. Connect the digital signal processing unit (BISx) cable to the BIS connector of the monitor.
2. Connect the patient interface cable to the BISx.
3. Secure the BISx to a convenient location, preferably close to the patient's head.
4. Clean the application site with alcohol and let dry.
5. Place the BIS sensor on the patient; see sensor package for instructions.
6. Connect the sensor to the patient interface cable.
7. Observe the results of the automatic sensor check in the parameter window. The measurement starts automatically after the sensor has passed the check.

WARNING

- Securing Cables: To minimize the risk of patient strangulation, the patient interface cable (PIC) must be carefully placed and secured.

NOTE

- Make sure the patient's skin is dry. A wet sensor or a salt bridge could result in erroneous BIS and impedance values.
- Do not use the BIS sensor if the sensor gel is dry. To avoid dryout, do not open the pack until you are ready to use the sensor.
- Since the BIS sensor is in close contact with the skin, Reuse may cause a risk of contamination. If a skin rash or other abnormalities appear, stop the measurement and remove the sensor immediately.
- BIS sensors are external module, thus please strictly adhere to the module manual for measurement operation.

15.6 BIS Sensor Check

Use the clip on the rear of the BISx to affix it in a position convenient for your patient, not above the patient's head. Connect the BISx adapter cable to the BIS module connector. Attach the BIS sensor to the patient's head following the instructions supplied with the sensor.

Select '**BIS Menu**' → Switch to '**Sensor Check**' tab → Check impedance status of sensors to ensure all electrodes should be in [Pass] status. This measures the exact impedance of each individual electrode to ensure the quality of EEG signal. It causes a disturbed EEG wave. During the monitoring process, BIS Sensor Check continues. If the electrode malfunction occurs, the alarm message will be shown on the monitor screen.

BIS Sensor Check window is shown in Figure 15-2:

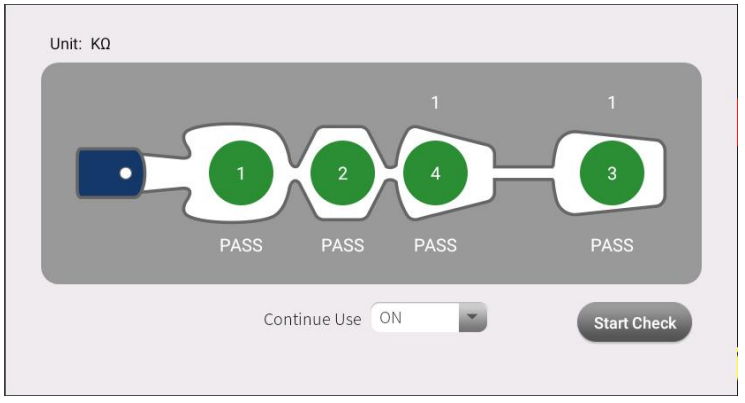


Figure 15-2: BIS Sensor Check

1) Unit

BIS impedance check unit: KΩ (ohm).

2) Sensor Type

The monitor can automatically identify the type of sensor you are using. The BISx device supports 3 sensors in below:

Category	**Explanation**	**Sample**

Quatro	Normal dual channel sensor for adults	
Extend	Extended sensor for adults requiring long-term monitoring of brain activity	
Pediatric	Sensors for pediatrics	
Demo	Sample demonstration	
Simulator	Simulation demonstration	

3) BIS Sensor Status

The monitor can automatically identify the Sensor Status:

Status	**Explanation**	**Action**
PASS	The impedance is within valid range	No action necessary.
NOISE	The EEG signal is too noisy. Impedance cannot be measured	Check the sensor-to-skin contact. If necessary, clean and dry skin.
HIGH	The impedance is above the limit	Check the ground electrode connection and check if the electrolyte solution expires.
LEAD OFF	Electrode falls off and has no skin contact	Reconnect electrode, or check the sensor-to-skin contact. If necessary, clean and dry skin.

4) Continual Use

When the sensor has expired, '**Expired Sensor**' notification will be displayed in the '**Sensor State'** and Waveform area, please evaluate whether the performance of the expired sensor declined. Then select "**Continual Use**" and toggle between "**YES**" and "**NO**" to confirm the continual use of the Expired Sensor.

5) Start Check

The system will automatically check the BIS sensor status. You can also manually perform

the function by selecting '**Start Check**'.

NOTE

- Make sure the patient's skin is dry. A wet sensor or a salt bridge could result in erroneous BIS and impedance values.
- Ensure that the BISx does not come into prolonged contact with your patient's skin, as it may generate heat and cause discomfort.
- When connecting the sensor, please check each individual electrode's status in Sensor Check page. If some of the electrodes do not pass the test, please manually select "Start Check" in the setup menu. The BISx will start monitoring only after the impedance check status of all electrodes are "PASS".
- If unsupported sensors are used, 'Unsupport' message will appear in Sensor State and waveform area, please replace with compatible sensors. Be cautious to use expired sensors as their performance may decline.

15.7 BIS Setup

Select EEG waveform area or BIS area → Enter '**BIS Menu**', as shown in Figure 15-3.

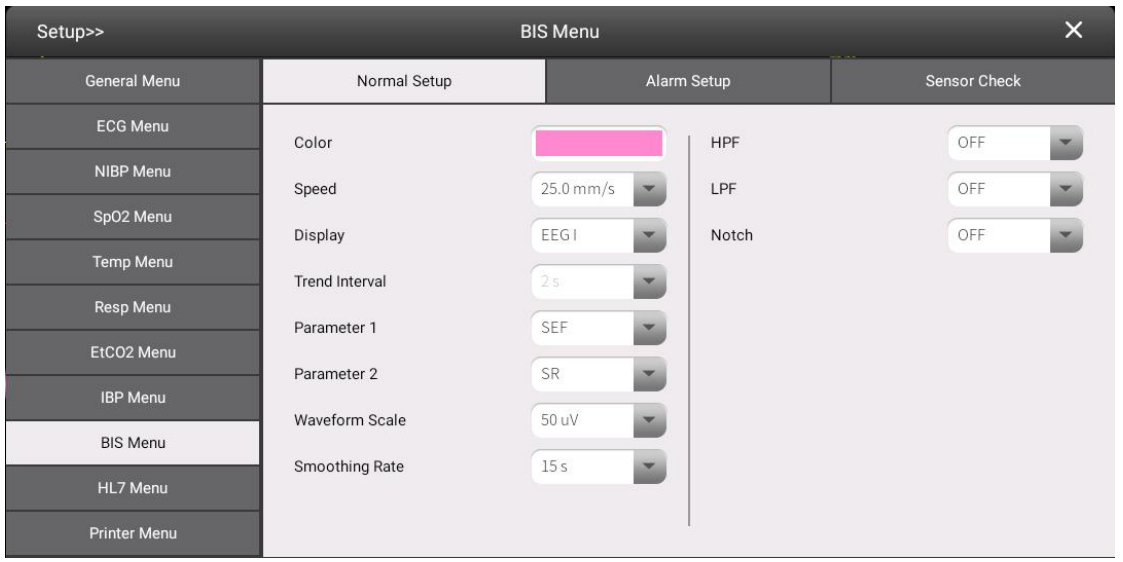


Figure 15-3: BIS Setup Menu

15.7.1 BIS Normal Setup

In '**BIS Menu**' → Select '**Normal Setup**' tab to set:

1) Color

Select '**Color**' drop-down menu to set waveform and parameter color. 32 colors are available. The default color is **Pink**.

2) Speed

Select '**Speed**' drop-down menu, you can choose **6.25 mm/s,12.5 mm/s,25mm/s.** The default speed is **12.5mm/s**. The larger the value, the faster the wave sweeps.

3) Display

Select '**Display**' drop-down menu to set BIS waveform type for display. BISx is a dual-channel EEG signal monitoring device for unilateral cerebral hemisphere BIS monitoring. Waveform display options are **EEG I**, **EEG II**, and **Trend**. When you select **EEG I** or **EEG II**, **EEG I** or **II** waveforms are displayed in the BIS waveform area; When you select Trend, BIS real-time trends are displayed in the BIS waveform area.

4) Trend Interval

Select '**Trend Interval**' drop-down menu to set Trend time interval for display. You can select 2s, 6s, 12s and 24s. The default setting is **2s**. You can set the **Trend Interval** only when the **Display** is **Trend**.

5) Parameter1

Select '**Parameter1**' drop-down menu to set **Parameter1** for display in BIS parameter area. You can choose: SR, TP, SEF or BC. **BC** is only visible when Extended sensor is used.

6) Parameter2

Select '**Parameter2**' drop-down menu to set **Parameter2** for display in BIS parameter area. You can choose: SR, TP, SEF or BC. **BC** is only visible when Extended sensor is used.

7) EEG Waveform Scale

Waveform Scale is shown in the form of gridlines, corresponding to the magnitude of the scale line. Select '**Waveform Scale**' drop-down menu to chooses 50μV, 100μV,200μV or 500μV.

8) Smoothing Rate

Select '**Smoothing Rate**' drop-down menu → Select 15s, 30s, 60s or 10s. The default smoothing rate is **15s**.

The smoothing rate defines how the monitor averages the BIS value. With the smoothing rate becoming smaller, the monitor provides increased response to changes in the patient's state. Contrarily, the monitor provides a smoother BIS trend with decreased variability and sensitivity to artifacts.

9) High-pass filtering (HPF)

With BIS filters you can filter out disturbances from the EEG signal and improve the signal quality. Select '**HPF**' drop-down menu to set **High-pass filtering** frequency → Select: OFF, 30Hz, 50Hz, 70Hz, the default setting is **OFF**.

10) Low-pass filtering (LPF)

With BIS filters you can filter out disturbances from the EEG signal and improve the signal quality. Select '**LPF**' drop-down menu to set **Low-pass filtering** frequency → Select: OFF, 0.25Hz, 1.0Hz, 2.0Hz, the default setting is **OFF**.

11) Notch filtering (Notch)

With BIS filters you can filter out disturbances from the EEG signal and improve the

signal quality. Select '**Notch**' drop-down menu → Select: OFF, 50Hz, 60Hz, 50&60Hz, the default notch filtering is **OFF**.

15.7.2 BIS Alarm Setup

In '**BIS Menu**' page → Select '**Alarm Setup**' tab to set BIS alarm according to your needs.

Figure 15-4 BIS Alarm Setup Menu

15.8 BIS Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

Problem	Corrective Method
No EEG waveform even with tight electrode and cable connection.	1. Check whether EEG waveform is selected in Layout Setup. 2. Check the BIS module function is enabled.
'---' Displayed in EEG parameter area	The patient has high muscle activity in the head area, or noise from some interfering equipment is coupling to electrode cables. Relax the patient and remove the source of noise.
Measurement does not start	1. Check sensor attachment to the patient and the sensor placement. And check the sensor's contact with skin. 2. Check the sensor type. 3. Check all cable connections.

Notifying 'Invalid Sensor'	Replace the invalid sensor
Notifying 'Too Many Uses'	Replace the sensor
Notifying 'Sensor Expired'	Expired Sensor, determine whether to continue using the sensor.

NOTE

- For the physiological and technical alarm messages, refer to *Appendix C Alarm messages*

16 C.O.

16.1 C.O. Description

The Cardiac Output (C.O.) measurement invasively measures cardiac output and other hemodynamic parameters using a technique called thermodilution. This can be used to determine the flow rate of a system by introducing a cold solution into the system and measuring the resulting drop in temperature at a downstream site. The temperature change is displayed as a curve in the C.O. procedure window. As it indicates the heart condition and calculates relevant hemodynamic parameters, the C.O. measurement is given vital importance in modern medical practice, especially for high-risk surgical and critically ill patients.

As cardiac output varies continuously, a series of measurements must be carried out to achieve a reliable C.O. average value. This monitor saves the last 6 sets of thermodilution measurements. And users can calculate the average by selecting the measurement results as desired for therapy decisions.

16.2 C.O. Safety Information

WARNING

- C.O. monitoring is an external function of the patient monitor, please read thoroughly the manual that comes with the C.O. sensor before use.
- The cardiac output measurement results may be erroneous during electrosurgery.
- All invasive procedures involve risks to the patient. Use aseptic technique. Incorrect use of the catheter can lead to vessel perforation. Follow catheter manufacturer's instructions.
- Use only the accessories specified by this manual. Also, the conductive parts of sensors and connectors should not come into contact with other conductive parts.

16.3 C.O. Measurement Influencing Factors

The following factors can impact the measurement accuracy:

- Temperature of the injectate solution.
- Volume of the injectate solution.
- Patient’s baseline blood temperature.
- Patient’s inspiratory/expiratory cycle.
- Placement of catheter with relation to proximity of lung field.
- The pulmonary artery catheter itself.
- The patient’s rhythm and hemodynamic status.
- Any other rapid IV solutions which are infused while the cardiac output is being

performed.

The following are suggestions about technique that can help obtain accurate cardiac output:

- The temperature of the injectate should always be 10℃ lower than blood temperature.
- Inject solution rapidly and smoothly.
- Inject within four to five seconds.
- Inject at end expiration.

16.4 C.O. Display

Please refer to Chapter 5.5

16.5 C.O. Measurement

16.5.1 C.O. Equipment to Patient Connection

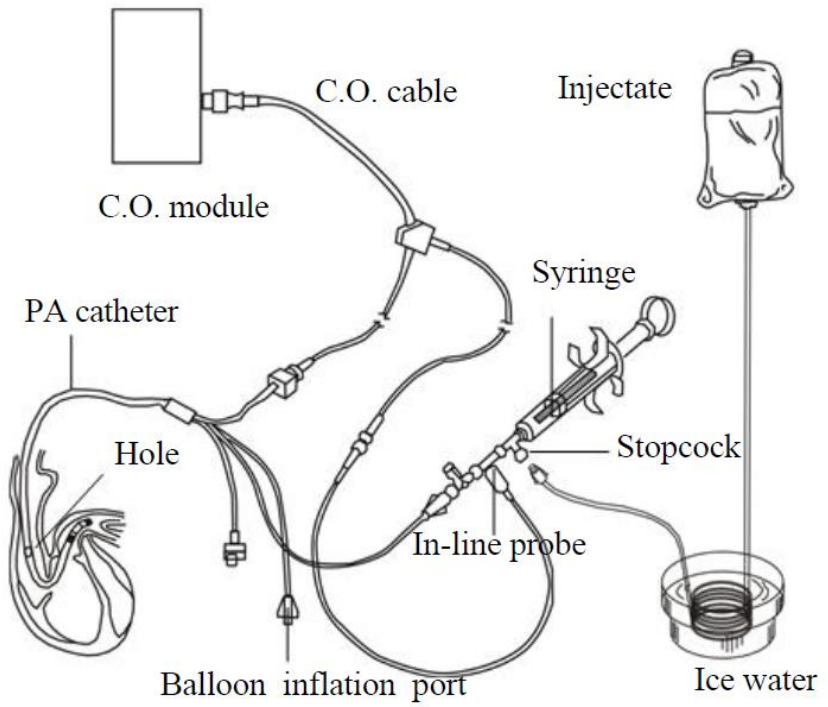


Figure 16-1: C.O. Equipment for Connection

16.5.2 Preparing the C.O. Measurement

1. Connect the C.O. cable to the acquisition module, thermistor, and injectate temperature port.
2. Follow your care unit's policy and procedures for positioning the patient for the C.O. measurement.
3. Follow the catheter manufacturer's instructions to set up the in-line or bath probe patient cables.
4. Check that the connected accessories are functioning properly.

16.6 C.O. Setup

In '**C.O. Measure**' window→ Select '**Setup**'→ Enter '**C.O. Setup**',

as shown in Figure 16-2. You can set:

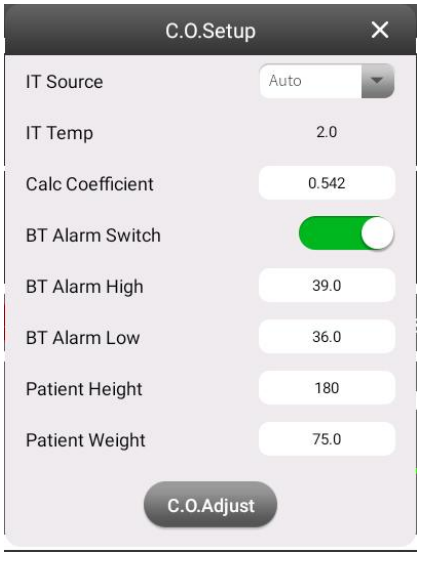


Figure 16-2: C.O. Setup

1) IT Source

Select '**IT Source**' drop-down menu and toggle between **Auto** and **Manual**. The default setting is **Auto**.

2) Calc Coefficient

Select '**Calc Coefficient**' menu → Enter **Coefficient** value, valid range for input is 0.001～0.999.

3) BT Alarm Switch

Select the button to switch **ON/OFF** BT alarm.

4) BT Alarm High

Select '**BT Alarm High**' menu → Enter **Alarm High** value, valid range for input is 37.0～43.0℃. The default setting is **39.0℃**.

5) BT Alarm Low

Select '**BT Alarm Low**' menu → Enter **Alarm Low** value, valid range for input is 23.0～37.0℃, The default setting is **36.0℃.**

6) Patient Height

Select '**Patient Height**' menu → Enter **Height** value, valid range for input is 30~255cm.

7) Patient Weight

Select '**Patient Weight**' menu → Enter **Weight** value, valid range for input is 0.1~200.0kg.

16.7 C.O. Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor or accessories, check the table below for troubleshooting. If the problem persists, contact your service personnel.

Problem	Corrective Method
C.O. measurement window fail to appear	Check if the C.O. module is correctly plugged into the monitor.
Inaccurate measurement	1. Make sure the position of the Catheter is correct 2. Catheter constant - Make sure that the catheter constant for the measurement is appropriate to the injectate volume, injectate temperature and catheter type used. 3. Inject solution rapidly and smoothly. 4. Inject within four to five seconds. 5. Add the volume of injectate or cool the injectate. 6. Check if the patient height and weight are set correct.
C.O. measurement failure	1. Add the volume of injectate or cool the injectate 2. Inject smoothly and within 4 to 5 seconds. 3. Check the connection between C.O. cable, catheter and injectate sensor.

NOTE

- For physiological and technical alarm message, please refer to *Appendix C Alarm messages*.

17 Managing Patients

17.1 Patient Information Setup

When you turn on the monitor and enters the normal screen, a prompt window will appear.

Select "**Create New Patient**" → Enter the patient information according to instructions shown on screen. When input is complete, click "**OK**" and the new patient is created.

If you select "**Continue Monitoring**", then this monitor will keep monitor the previous patient; Select "**Do Not Save** ", then the patient is monitored as the **default patient**. During the monitoring process, touch the patient information area in the upper left corner of the main screen to view and modify the patient information, as shown in Figure 17-1.

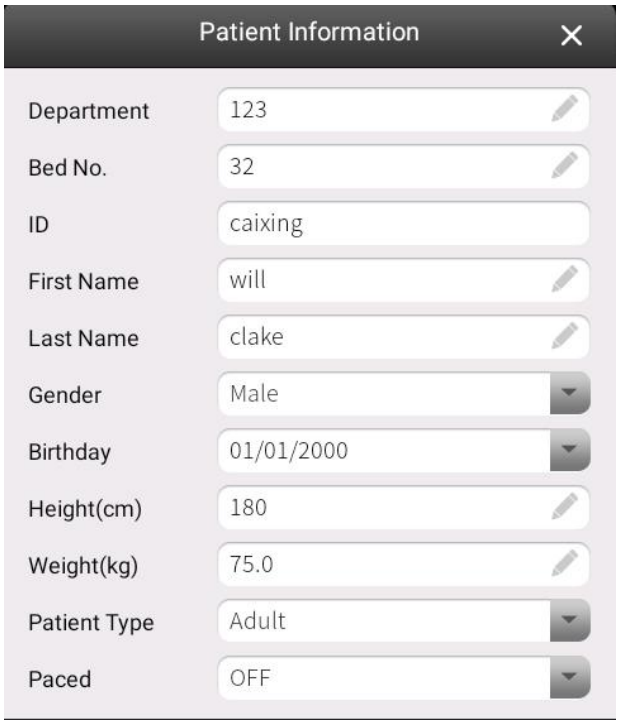


Figure 17-1: Patient Information

You can set:

1) Department

Enter the patient department. User can enter a maximum of 18 characters.

2) Bed NO.

Enter the patient number. User can enter a maximum of 18 characters.

3) Patient ID

Enter the patient ID. User can enter a maximum of 18 characters, the patient ID cannot be empty and cannot be modified once the input is confirmed.

4) Name

Patient name include First Name (Required)and Last Name (Optional). User can enter a maximum of 18 characters.

5) Gender

Set patient gender. The default setting is **Male**

6) Birthday

Set patient birthday. The default setting is 01/01/2020.

7) Height cm

Set patient height, the input range is 50～250cm.

8) Weight kg

Set patient weight, the input range is 1～300kg.

9) Patient Type

Set patient type: adult, pediatric or neonatal. The default setting is **adult**.

10) Paced

Choose **ON** or **OFF**, the default setting is **OFF**.

17.2 Create New Patient

There are 2 methods to create new patient:

- Turn on the monitor, the '**Patient Management**' dialog window will pop up→ Select '**Create New Patient**'.
- Select '**Pause Display**' in extended quick keys area → In the pop-up page, select '**Create New Patient**'.

WARNING

- If you do not erase data from the previous patient, the new patient's data will be saved into the data of the previous patient. The monitor makes no distinction between the old and the new patient data.
- For paced patients, you must set '**Paced**' to **ON**. If it is incorrectly set to **NO**, the patient monitor could mistake a pace pulse for a QRS and fail to alarm when the ECG signal is too weak.
- For non-paced patients, you must set '**Paced**' to **OFF**.

17.3 Editing Patient Information

To edit the patient information:

Select the patient information area on the screen → '**Patient Information**' window will pop up, and you can make the required changes. Besides **Patient ID**, you can modify all the other information.

17.4 Deleting Patient Information

This monitor can save up to 20 patients’ information. When trying to save more than 20 patients’ information, message will appear: ‘**Full Patients, please go to the History Review to delete it from list, then you can create new patient’!**

To delete:

Select the "**History Review**" in the extended quick keys area → enter the "**History Review**" page and select the patient ID you want to delete in the history patient list → Delete it.

If the patient ID is locked, you need to "**Unlock**" it first, then "**Delete**".

18 Trends

This section introduces the patient history review and trends review.

18.1 History Review

18.1.1 Description

Patient History Data refers to the monitoring data of previous sessions when a new monitoring session starts. This monitor can save the data of the last 8 monitoring sessions at most, and you can select to view each session in the form of Graphic Trends, Tabular Trends or Waveform Review, and export the historical data for analysis.

18.1.2 Managing History Reivew

Select '**History Review**' in the extended quick keys area to enter '**History Data**' page, as shown in Figure 18-1.

Figure 18-1: History Data

You can:

1) Delete

Select '**Delete**' to delete the selected patient history data (When the data is locked, you are unable to delete it)

2) Export

Select '**Export**' to export data. You can export the selected history data to the plugged USB drive.

3) Open

Select '**Open**' in the bottom of the page → The selected data will be loaded into **Trend Review** display, as shown in Figure 18-2. For the page operations, please refer to *Chapter 18 Trend Review*.

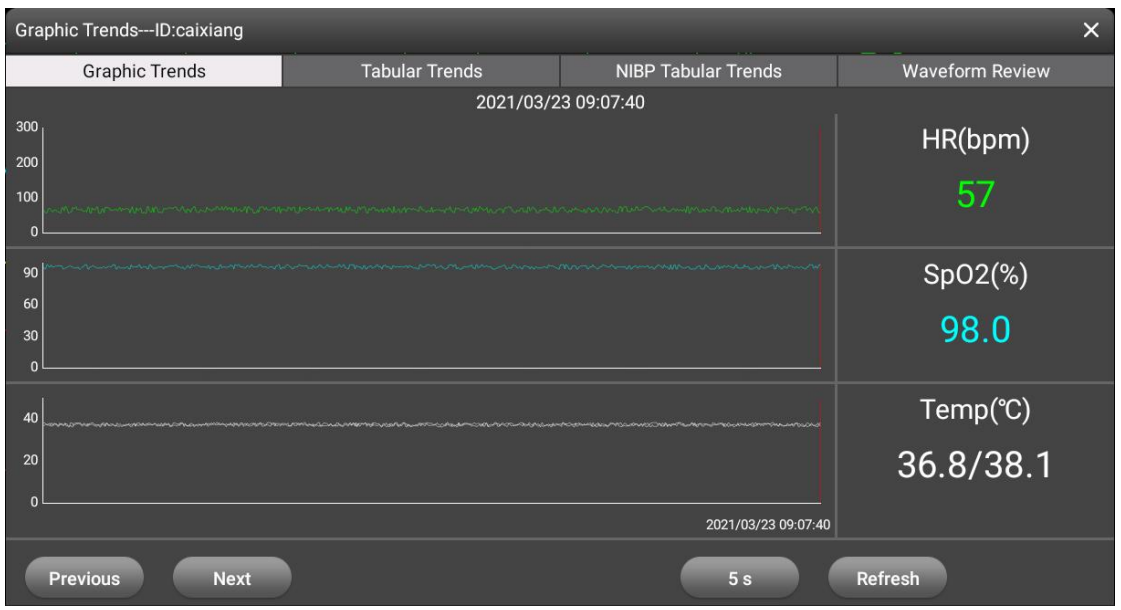


Figure 18-2: History Trend Review

18.2 Trend Review

18.2.1 Description

During the patient monitoring process, the monitor will periodically collect current measurement data of each parameter and save it on the internal memory for data review, to help understand the patient's condition and health trend over a period of time. This monitor can save up to 120 hours (5 days, 24 hours per day) of monitoring data for a single patient, and display trend in graphic or tabular form to give you a picture of how your patient's condition is developing. You can export the saved monitoring data from the USB port.

The trend review page includes 4 tabs: **Graphic Trends**, **Tabular Trends**, **NIBP Tabular Trends**, and **Waveform Review**. They demonstrate the patient trend figure in different forms.

18.2.2 View Graphic Trends

Select '**Trend Review**' in the extended quick keys area → Select '**Graphic Trends**' tab, the graphic trends are shown in Figure 17-1.

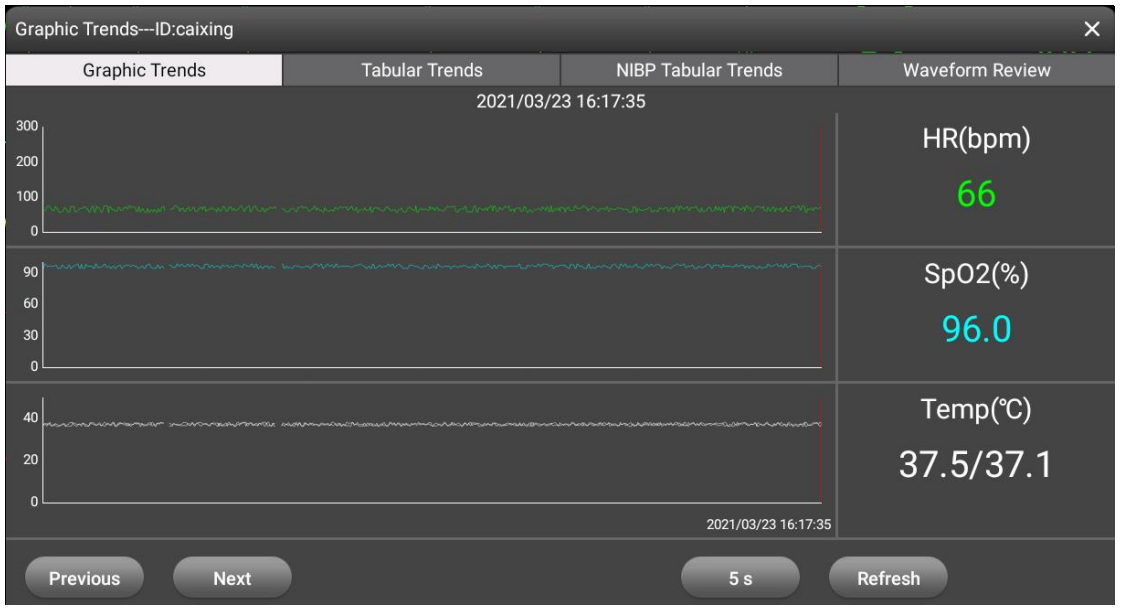


Figure 17-1: Graphic Trends

Graphic trends page contains 3 fields for separate parameter graphic display. On the right side, value of each parameter, in correspondence to the cursor indicated timepoint (the red time line), is displayed.

Setting Up Trends:

1) Timeline

Select '**Previous**' or '**Next**' to move the red timeline, you can position the timeline cursor in small and accurate step → Then you can simultaneously view 3 measurement value corresponding to the cursor position.

2) Choose Parameters

Touch and select the parameter area on the right side of the screen → In the pop-up window, choose parameters for monitor display as you required.

3) Trend Interval

Select the **Time Interval (**'5s' button in Figure 17-1**)** in the bottom of the page → Set the **Time Interval** in the pop-up window as you required, there are 12 options: 5s, 10s, 20s, 30s, 40s, 50s, 1min, 2min, 4min, 6min, 8min, 10min.

4) Trend Refresh

Select '**Refresh**' in the bottom of the page to refresh the graphic curve and parameter value.

18.2.3 View Tabular Trends

Select '**Trend Review**' in the extended quick keys area to enter the Trend review page → Select '**Tabular Trends**' tab to switch to the Tabular Trends window, as shown in Figure 17-3.

Date/Time	HR	ST-I	ST-II	ST-III	ST-aVR	ST-aVF	ST-aVL	ST-V	SpO2	PR
2021/03/23 16:17:35	66	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	96.0	73
2021/03/23 16:17:30	69	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	96.0	73
2021/03/23 16:17:25	69	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	97.0	63
2021/03/23 16:17:20	66	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	97.0	63
2021/03/23 16:17:15	66	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	96.0	73
2021/03/23 16:17:10	70	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	96.0	73
2021/03/23 16:17:05	67	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	94.0	58
2021/03/23 16:17:00	67	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	94.0	58
2021/03/23 16:16:55	60	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	94.0	69
2021/03/23 16:16:50	67	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	94.0	69
2021/03/23 16:16:45	67	0.54	0.88	0.31	-0.41	-0.72	0.58	0.27	96.0	62

Figure 17-2: Tabular Trends

Tabular Trends supports thermal printing.

1) Set Parameter

Select '**Trend Group**' drop-down menu → Select Parameters that you want to display by module or Select '**Custom**' to customize the parameters for Tabular Trends view.

2) Trend Interval

Select the **time interval** for trend ('5s' in Figure) in the bottom of the page → Set the required interval in the pop-up window, there are 12 options: 5s, 10s, 20s, 30s, 40s, 50s, 1min, 2mins, 4mins, 6mins, 8mins, 10mins.

3) Trend Refresh

Select '**Refresh**' in the bottom of the page to refresh data in tabular trend.

4) Browse Data

Each page displays 30 groups measurement data. You can view the all the data by scrolling the pages. There are 24 pages in total, you can Select ◀ ▶ on the bottom to scroll left or right to navigate through the trend database.

5) Print/ Record

By selecting the **Print** button, you can print out the currently displayed tabular trends.

18.2.4 View NIBP Tabular Trends

Select '**Trend Review**' in the extended quick keys area to enter the Trend review page → Select '**NIBP Tabular Trends**' tab to switch to the Tabular Trends page, as shown in Figure 17-3.

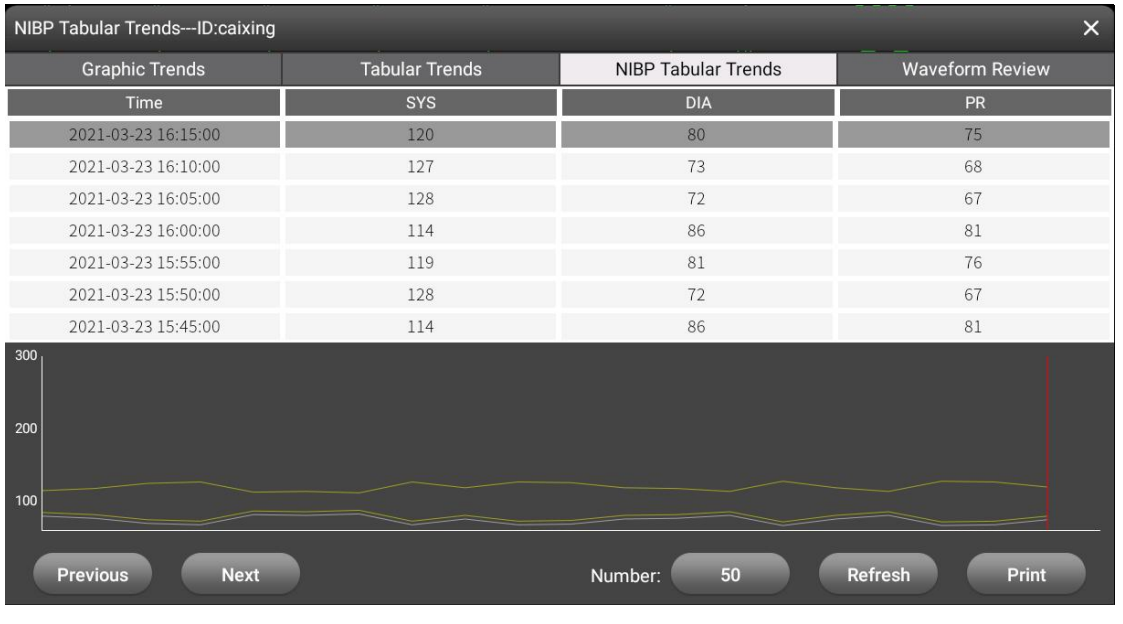


Figure17-3: NIBP Tabular Trends

NIBP measurements over a certain period of time are displayed in the form of a Graphic Trend and Tabular Trend simultaneously. Since the NIBP measurement data is not recorded and saved periodically, the NIBP trend curve is different from the other parameters' trend curves. Select a row of data in the NIBP tabular list, the red time line will navigate to the corresponding time point. Conversely, select a certain time by positioning the cursor (red time line) in the graphic trend, the corresponding row in the NIBP tabular list will be selected with gray background. By selecting the "Previous" or "Next" button at the bottom of the page, you can scroll the red time line left or right, and the row of the corresponding time point in the NIBP tabular list will be selected.

1) Trend Refresh

Select '**Refresh**' in the bottom of the page to refresh NIBP data in tabular list and graphic trend.

2)Maximum Number of Records from List for Display

Select the **number value** (to the right of '**Number**' label) → Set the maximum number of NIBP history records displayed on the current page.

3)Print/ Record

By selecting the '**Print'** button, you can print out the currently displayed data in NIBP tabular list.

18.2.5 Waveform Review

Select '**Trend Review**' in the extended quick keys area to enter the Trend review page → Select '**Waveform Review**' tab to switch to the waveform review page, as shown in Figure 17-4.

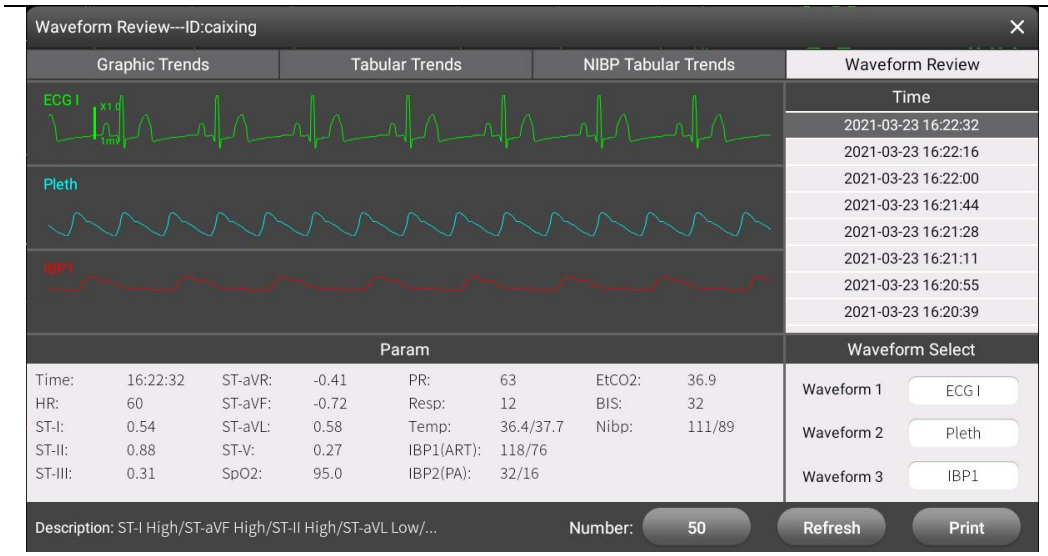


Figure 17-4: Waveform Review

This page shows the waveform and parameter values at a certain time point. The waveform and parameter data are indexed by the time points on the following:

- Waveforms freeze operation.
- Alarm event trigger.

1) Time

Select the record in '**Time**' list to load the saved data into waveform area and parameter area for display

2) Waveform

This page can display 3 waveforms simultaneously. To select the parameters whose waveforms you want to view, you can select **'Waveform Select'** in the bottom right side of the page → set '**Waveform1 Waveform2 Waveform3**'.

3) View Event Description

The '**Description**' in the bottom left side of the page indicates the trigger for current selected waveform and parameter recording.

4) Full Waveform

The waveform area shows the continuous waveforms 8s respectively before and after the currently selected time point, and you can scroll left or right to view the whole 16s waveform.

5) Refresh Data

Select '**Refresh**' in the bottom of the page to refresh waveform review list.

6) Maximum Number of Records for Display

Select the **number value** (on the right of '**Number**' label) → Set the maximum number of Waveform records displayed on the current page.

7) Print/ Record

By selecting the Print button in the bottom, you can print out the waveform, parameter value and event description corresponding to the selected time point.

19 Clinical Decision Support

Clinical decision support is a comprehensive analysis and centralized presentation based on existing monitor measurements and serves as a digital tool of commonly used clinical guidelines and tools.

The primary purpose of clinical decision support is to improve doctor efficiency, it is not used for diagnosis, can not be a substitute for medical personnel to make decisions.

19.1 Early Warning Score (EWS)

Early warning scores can help identify early signs of deterioration and are an early warning indicator of critical or potentially critical illness.

Early Warning Scoring System obtains the corresponding score by monitoring and observing the patient's vital signs and status, and clinical responses are provided according to the results of the score.

This monitor provides the following scoring systems:

■ Modified Early Warning Score (MEWS)

■ National Early Warning Score (NEWS)

There are two kinds of scoring systems: total scoring and individual parameter scoring (IPS)

■ Total Scoring: Rate each parameter you select and calculate an aggregate score. Each parameter is scored with a color mark indicating the appropriate severity level. Clinical responses are provided when the total score exceeds the limit. MEWS and NEWS are total scoring systems.

■ Individual Parameter Scoring (IPS): Score individual parameters and clinical responses are provided when the any parameter score exceeds the limit.

Customized scoring systems are based on parameters selected by users. Custom scoring systems can be either total scoring system or IPS.

Customized scoring systems are only available for adults.

WARNING

- Early warning score results and medical actions provided are for reference only and cannot be used directly as a basis for clinical treatment.
- Early warning score results and treatment recommendations must be used in conjunction with the patient's clinical symptoms and signs.
- Early warning scores are not available for pregnant women, people with COPD (chronic obstructive pulmonary disease) and people under 16.

19.1.1 Scoring Parameters

Different scoring systems utilize different scoring parameters, see the following table:

Modified Early Warning Score (MEWS)	National Early Warning Score (NEWS)	Individual Parameter Scoring (IPS)	Customized Total Scoring
RR, Temp, NIBP-SYS, PR/HR, AVPU	RR, SpO2, Oxygen saturations, Temp, NIBP-SYS, PR/HR, AVPU	RR, SpO2, Oxygen saturations, Temp, NIBP-SYS, PR/HR, AVPU Real scoring parameters are defined by Clinical Grading System Configuration Tool	RR, SpO2, Oxygen saturations, Temp, NIBP-SYS, PR/HR, AVPU, blood sugar, urine volume, urinary conduction, pain score, pain, EtCO2, inhalation oxygen concentration, airways, users can select up to 3 parameters for customization. Real scoring parameters are defined by Clinical Grading System Configuration Tool

19.1.2 Display EWS Parameter Area

Select **Screen Setup** Quick key to open **Screen Setup**, to display EWS on screen. EWS parameter example is shown as Figure 19-1.

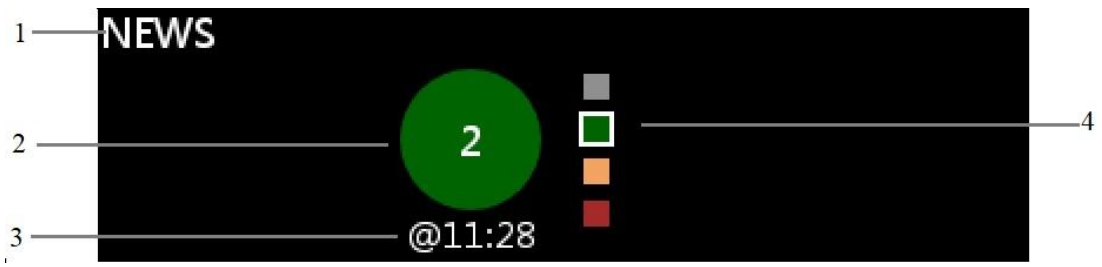


Figure 19-1 EWS Parameter Area

Number	Function Explanation
1	Early Warning Score System Name
2	Total Score, Circle color represents current score level.
3	Current Scoring Time
4	Score Level Indicators: Increase in the order of warning hazards from top to bottom. The box shows the current level.

19.1.3 Enter EWS Page

Besides EWS parameter area, This monitor also provides a separate EWS display page.

可以Select one of the following ways to enter EWS Page:

- Select **'EWS'** Parameter Area
- Select **'EWS'** Quick key
- Select '**Main Menu'** Quick key and select **'EWS'** from CAA column.

EWS display example is shown in Figure 19-2. Real page display varies according to select score system and setting.

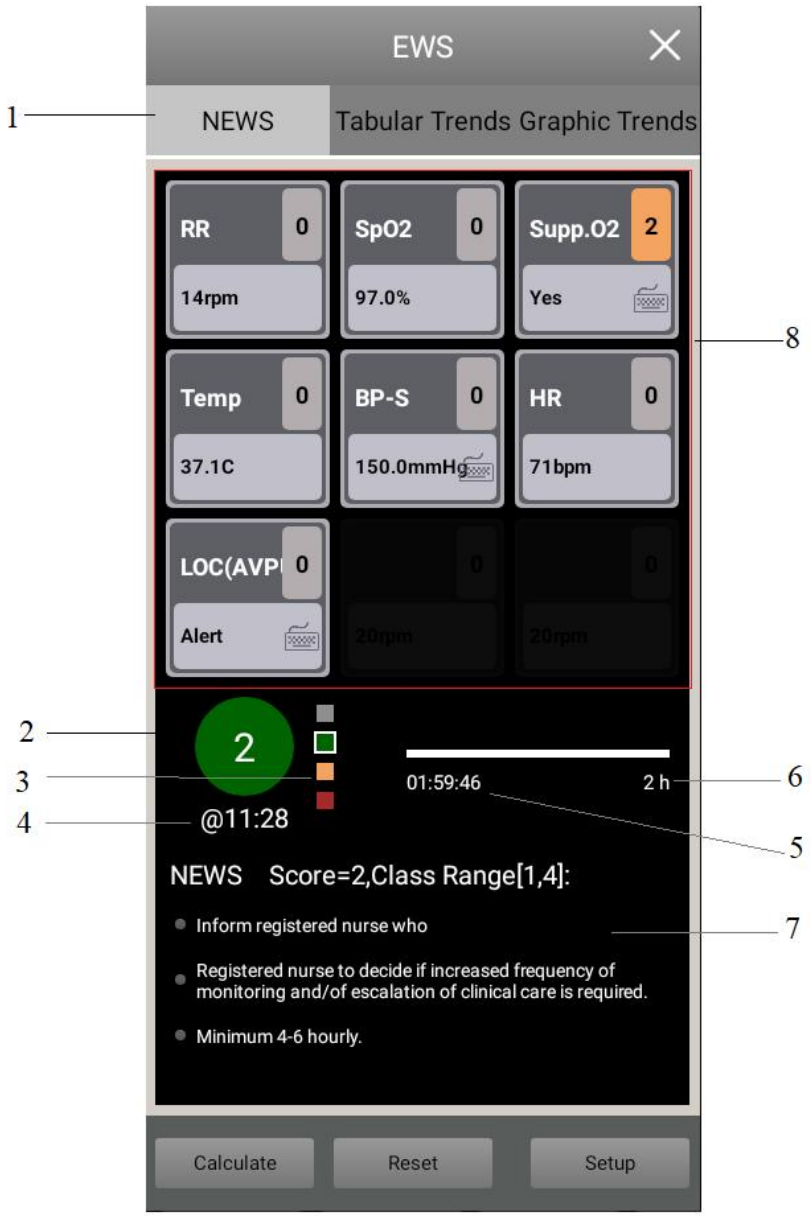


Figure 19-2 EWS Page

Number	Function Explanation
1	Score System Name

2	Total Score, Circle color represents current score level.
3	Score Level Indicators: Increase in the order of warning hazards from top to bottom. The box shows the current level.
4	Current Scoring Time
5	Next Score Timer
6	Score Interval
7	Recommended Medical Response
8	Parameter Area: Displays the parameter value and score for a single parameter, and the keyboard icon indicates that the parameter value is from manual input.

19.1.4 Calculate Score

Calculate the score as follows:

1. Select 'Reset' to clears the last score and refreshes the parameter values, parameter score automatically in this monitor.

2. Measure or manually enter parameter values for other parameters

3. Select "Calculate" to get the score result.

NOTE

- Before each scoring, select '**Reset**' to clear the last score.
- The keyboard symbol on the right side of the parameter value indicates that the parameter value is entered manually.
- You can calculate the score only if the parameter values of all the parameters involved in the calculation are valid.

19.1.5 Automatic Scoring

To set up automatic scoring:

1. Select '**Setup**' in EWS scoring page

2. In the Auto Scoring area, check as needed:

- Interval mode: The guardian automatically calculates the score at a set time interval
- NIBP: The monitor automatically calculates the score after each NIBP measurement is complete
- Alarm: The score parameter is automatically calculated after the physiological alarm occurs.

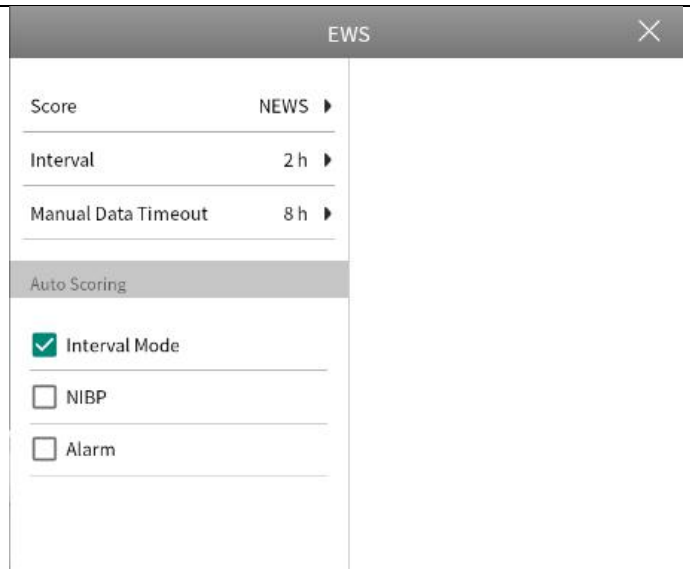


Figure 19-3 EWS Setup Page

19.1.6 EWS Setup

Select **Setup** in EWS Page**,** to open EWS setup Page, as shown in Figure 19-3.

19.1.6.1 Select Score System

The monitor is configured with a default scoring system, and you can select other scoring systems as needed, as follows:

1. Select '**Setup'** in EWS Page
2. Select **'Score'**

19.1.6.2 Set the Scoring Interval

1. Select '**Setup'** in EWS Page
2. Set '**Interval**'
   - ◆ Sets the countdown interval for manual scoring when the interval mode for the automatic scoring area is not checked.
   - ◆ Sets automatic scoring interval for manual scoring when the interval mode for the automatic scoring area is checked.

19.1.6.3 Set Manual Data Timeout

For manually entered parameter, you can set Manual Data Timeout for them:

1. Select '**Setup'** in EWS Page
2. Set **'Manual Data Timeout'**

NOTE

- Monitors offer MEWS and NEWS scoring systems by default and they are not allowed to be

removed.

19.1.7 Score Review

In EWS Page, Select '**Tabular Trends**' or '**Graphic Trends'** tab to check all measured parameters', input parameters' values and scores.

19.2 Glasgow Coma Index (GCS)

Glasgow Coma Index (1974_Lancet_ Teasdale Assessment of Comaand Impaired Consciousness-A Practical Scale) can be used to objectively express the AVPU status of patients in coma caused by various causes. The GCS score consists of three aspects: eye response, verbal response, and motor response.

The GCS score is suitable for adults and pediatrics.

CAUTION

- The results of the GCG score are for reference only, please use other clinical evidence for diagnosis.
- GCS is not suitable for patients with sedation or myosone, artificial airways, drunkenness and epilepsy.
- GCS is not available for people with language impairment, deafmutism and mental disorders.
- When GCS is used in unresponsive older people under 5 years of age, it is prone to produce low scores.

19.2.1 Display GCS Parameter Area

Select '**Screen Setup'** Quick key, to enter '**Screen Setup**' page and select GCS to display on primary screen. GSC parameters will appear on primary screen. GCS parameter example is shown as below:(Display varies according to settings)

Figure 19-4 GCS Parameter Area

Number	Function Explanation
1	Score System Name

2	Total Score (Glasgow Coma Index)
3	Current Scoring Time
4	Single Item Score E: Eye Response V: Verbal Response M: Motor Response

19.2.2 Enter GCS Page

Select one of the following ways to enter GCS Page:

- Select '**GCS'** Parameter Area
- Select '**GCS**' Quick key
- Select '**Main Menu**' Quick key, Select '**GCS**' from CAA column.

Figure 19-5 GCS Page

Number	Function Explanation
1	Single Item Score
2	Total Score (GCS)

19.2.3 Calculate GCS

Calculate the score as follows:

1. In the '**GCS**' menu, select an option that corresponds to the patient's status from the

eye response, verbal response, and motor response.

2. Select '**Calculate**'

The following table lists the default range and colors for each rating level:

Level	Score Range	Background Color	说明
Mild	12 ~ 15	White	Normal or mild brain impairment
Moderate	5 ~ 11	Yellow	Moderate to severe impairment of brain function
Severe	3 ~ 4	Red	Dead brain or vegetative state

19.2.4 Set GCS Interval

Select '**Interval'** in GCS menu to set GCS interval. If the set scoring interval is reached without new scoring, the original score is invalid and is shown in hollow text.

20 Pharmacy Calculations

20.1 Description

This monitor provides **Pharmacy Calculation** function for patients, which produces the calculation result based on the input data and measurements. The calculation is independent of the other functions of the monitor and can be performed on other patient which is not monitored by this equipment. Calculation operations do not affect its monitoring process.

20.2 Safety Information

WARNING

- Decisions on the choice and dosage of drugs administered to patients must always be made by the physician in charge.
- Always cautiously check the input correctness and calculation plausibility. Infinium Medical Inc. is not liable for any consequences out of input and operation errors.

20.2 Performing Calculations

The general intravenous drip method can hardly ensure the accuracy and constancy of the dose. The monitor provides a Drug Calculator for concentration calculation to aid medical care. Therefore, reference drug doses can be obtained through Drug Calculator before its use.

20.2.1 Calculation Procedure

The procedure is as below:

1. Select '**Pharmacy Calculator**'  in the extended quick keys area → Enter **Pharmacy Calculator** window → Select '**Calculator**' tab, as shown in Figure 20-1.
2. Set '**Pharmacy**' and '**Patient Type**'. Enter the patient weight if the selected drug calculations are affected by weight.
3. Input values for Dose, Amount and Volume of this drug
4. Calculation starts automatically after input.

NOTE

- When the **Pharmacy Calculator** is accessed for the first time, the patient category and weight from the Patient Information setting will be loaded automatically in the **Pharmacy Calculator** window. You can manually change the patient category and weight, and this will not change what are stored in the patient information

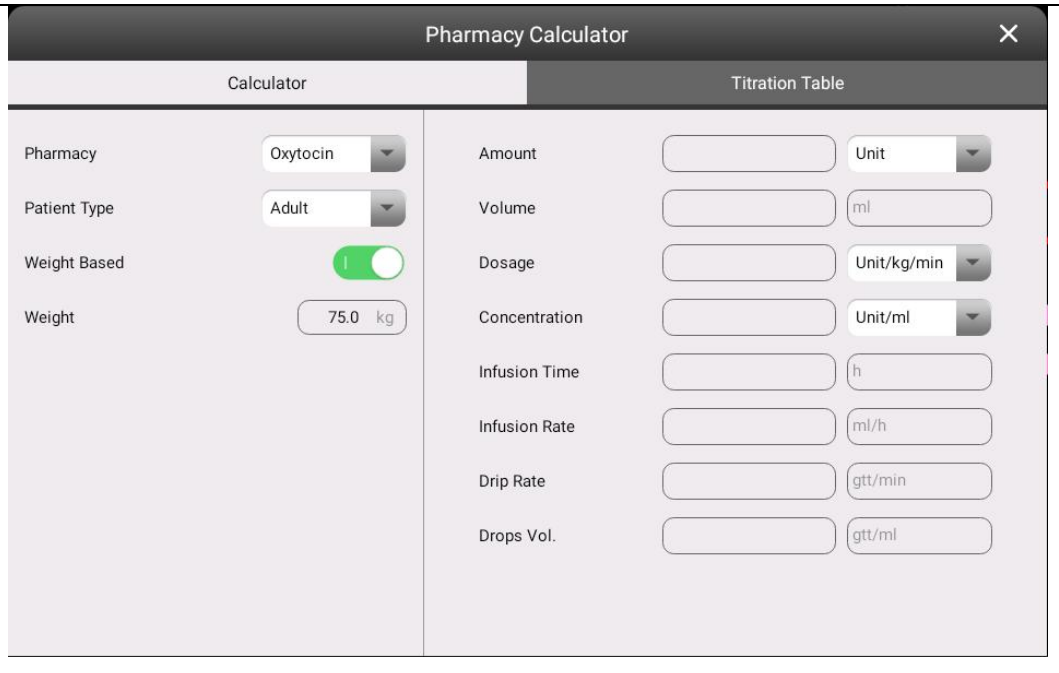


Figure 20-1: Pharmacy Calculator Window

20.2.2 Using the Titration Table

Titration table indicates the information regarding current drugs in use. Use the Titration Table to see at a glance what dose your patient would receive of a drug at different infusion rates.

To see the Titration Table:

1. Select '**Pharmacy Calculator**'  in the extended quick keys area → Enter **Pharmacy Calculator** window → Select '**Titration Table**' tab, Titration Table window is as shown in Figure 20-2.
2. In titration table menu, user can modify reference, interval and dose type, when changes are made, the titrated values change accordingly.
3. Select '**Print**' print a report of the current titration Table.

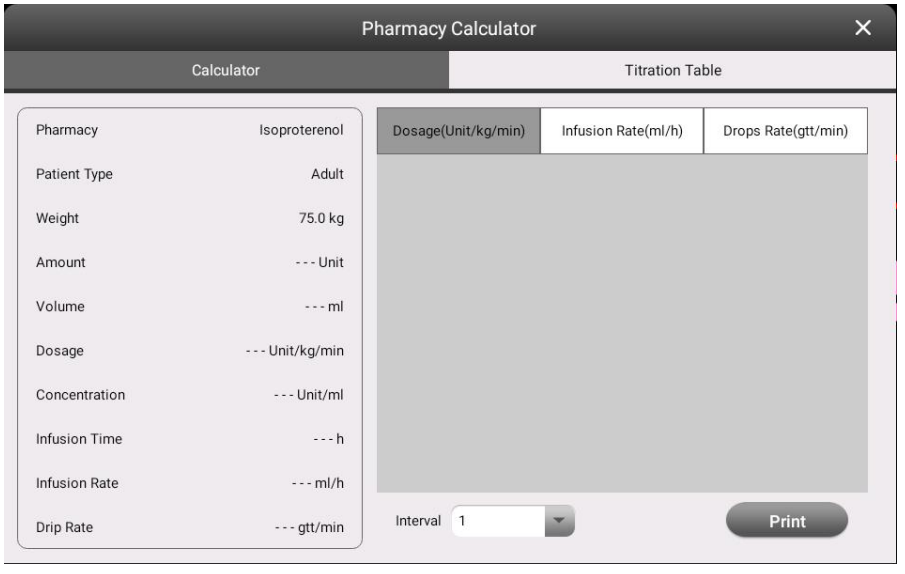


Figure 20-2: Titration Table

20.2.3 Drug Name

You can select 15 drugs as you desired. Among them, you can customize drug name of A, B, C, D, E.

- Oxytocin
- Nitroglycerin
- Nipride
- Lidocaine
- Isoproterenol
- Heparin
- Adrenaline
- Dopamine
- Dobutamine
- Aminophylline
- Drug A, B, C, D

20.2.4 Pharmacy Calculation Formula

Item	Unit	Formula
Amount (Amount)	g series: mcg, mg, g unit series: unit, KU, MU mEq series: mEq	Amount = Dosage × Infusion Time
Amount (Weight-dependent)		Amount (Weight-dependent) = Dosage × Infusion Time × Weight
Volume (Volume)	ml	Volume = Infusion Rate × Infusion Time
Dosage (Dosage)	Dosage/h Dosage/min	Dosage = Infusion Rate × Concentration
Dosage (Weight-dependent)	Dosage/kg/h Dosage/kg/min	Dosage (Weight-dependent) = Infusion Rate × Concentration/Weight
Concentration (Concentration)	mcg/ml mg/ml g/ml Unit/ml KU/ml MU/ml	Concentration = Amount/Volume

	mEq/ml	
Infusion Time	h	Infusion Time = Amount / Dosage
Infusion Time (Weight-dependent)	h	Infusion Time (Weight-dependent) = Amount / (Dosage × Weight)
Infusion Rate	ml/h	Infusion Rate = Dosage / Concentration
Infusion Rate (Weight-dependent)	ml/h	Infusion Rate = Dosage × Weight / Concentration

20.2.5 Titration Table Calculation Formula

Item	Unit	Formula
Infusion Rate	ml/h	Infusion Rate = Dosage/Concentration
Infusion Rate (Weight-dependent)	ml/h	Infusion Rate = Dosage × Weight /Concentration
Dosage	Dosage/h Dosage/min	Dosage = Infusion Rate ×Concentration
Dosage (Weight-dependent)	Dosage/kg/h Dosage/kg/min	Dosage (Weight-dependent) = Infusion Rate × Concentration / Weight

21 Printing

21.1 Use a Recorder

This monitor uses the thermal recorder to print patient information, measurement numerics, waveforms (Up to 3 waveforms per printing) etc.

21.2 Start Printing

You can manually start a recording or automatic recording will be triggered in certain conditions.

21.2.1 Start Printing Manually

To manually start a recording, you can either:

- Select '**Print**' in quick keys area.
- Select '**Print**' button from the current menu or window.

21.2.2 Automatic Printing

You can set automatic recordings in the following conditions:

- Timed recordings will start automatically at preset intervals.
- If the **Alarm** is set on, an alarm recording will be triggered automatically as alarms occur.

21.3 Stop Printing

You can manually stop a recording or recording stop automatically.

21.3.1 Stop Printing Manually

To manually stop a recording, you can either:

- Select '**Stop Printing**' Quick keys to stop printing.

21.3.2 Printings Stop Automatically

Recordings stop automatically when:

- The runtime is over.
- The recorder runs out of paper.
- When the recorder has an alarm condition or technical issue.

21.4 Real-time Waveform and Parameter Printing

21.4.1 Printing Content

- Print out 8-second waveforms (up to 3 waveforms at a time) from the current moment.
- Print out Parameter Report:

The report contains the following parameters: Name, Patient ID, Printing time, HR, SpO_2, NIBP SYS /DIA, Resp, Temp, ST segment and hospital name, etc.

Printing example is shown in Figure 21-1. (For illustration only)

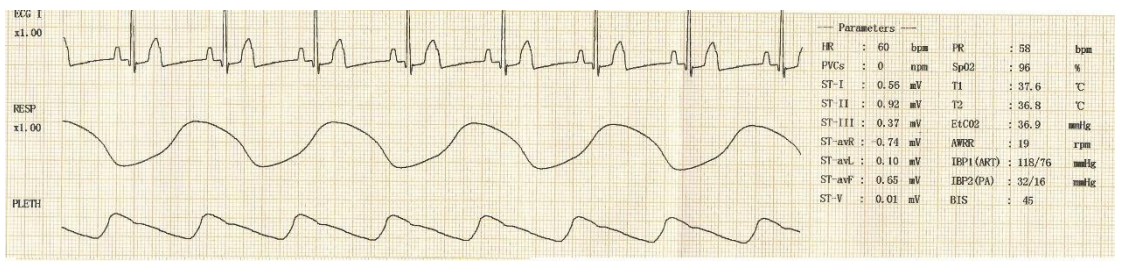


Figure 21-1: Real-time Waveform Printing Report

21.4.2 Printing Procedure

Select '**Print**' in quick keys area to start printing → Text on the quick key will change to '**Stop Printing**' → After printing is completed, you can get the report.

If you want to stop the printing → Select '**Stop Printing**' → Printing stops immediately → Text on the quick key will be reset to '**Print**'.

21.5 Trend List Printing

21.5.1 Printing Content

16 sets of parameter records for the current page will be printed, including: Patient Name, Patient ID, Date, Time, NIBP (SYS/DIA), SpO2, HR, PR, Resp, Temp, ST segment, etc. Parameter.

Printing example is shown in Figure 21-2. (For illustration only)

Date/Time	HR	ST-I	ST-II	ST-III	ST-aVR	ST-aVF	ST-aVL	ST-V
2019/01/23 08:51:32	63	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:46:57	62	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:42:22	72	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:37:47	56	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:33:12	56	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:28:37	72	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:24:02	68	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:19:27	59	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:14:52	72	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:10:17	71	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:05:42	73	0.56	0.92	0.37	-0.74	0.65	0.10	0.01
2019/01/23 08:01:07	56	0.56	0.92	0.37	-0.74	0.65	0.10	0.01

Figure 21-2: Trend List Printing Report

21.5.2 Printing Procedure

1. Select '**Trend Review**' 

in extended quick keys area → Enter Trend Review page.
2. Select '**Tabular Trend**' tab → Enter Tabular Trend page.
3. Select '**Print**' → Initiate the printing process of history data for all parameters in current page.
4. After printing is completed, you can get the report.

21.6 Alarm Event Printing

21.6.1 Printing Content

Alarm records printing is the waveform and parameter printout for the first 4 seconds and the last 4 seconds (8 seconds in total) of the alarm event.

The printing content includes information such as patient name, patient ID, alarm time, heart rate (HR), blood oxygen (SpO2), pulse rate (PR), NIBP (systolic blood pressure (SYS)/diastolic blood pressure (DIA)), respiratory rate (Resp), temperature (Temp), ST segment, alarm type, and hospital name. Printing example is shown in Figure 21-3:

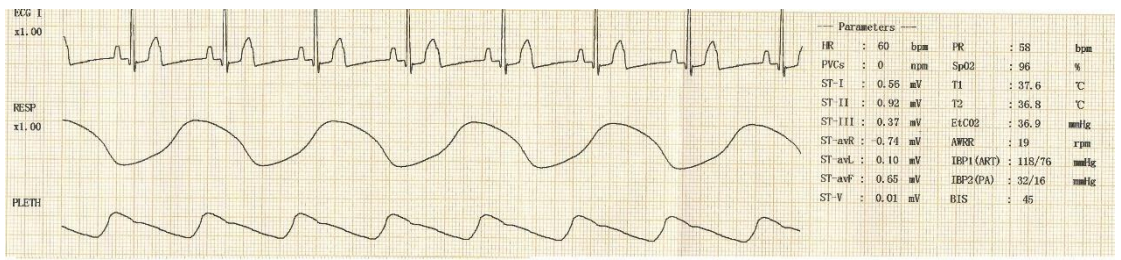


Figure 21-3: Alarm Event Printing Report

21.6.2 Automatic Alarm Printing

In '**Main Menu**' → Select '**Printer Menu**' → Set '**Alarm Print**' **ON**. The automatic alarm printing is turned **ON**. For automatic printing alarm setting, please refer to *4.3 Printer Menu*.

21.7 NIBP List Printing

21.7.1 Printing Content

NIBP list printing will print out the last 11 NIBP measurement time and result. Printing example is shown in Figure 21-4.

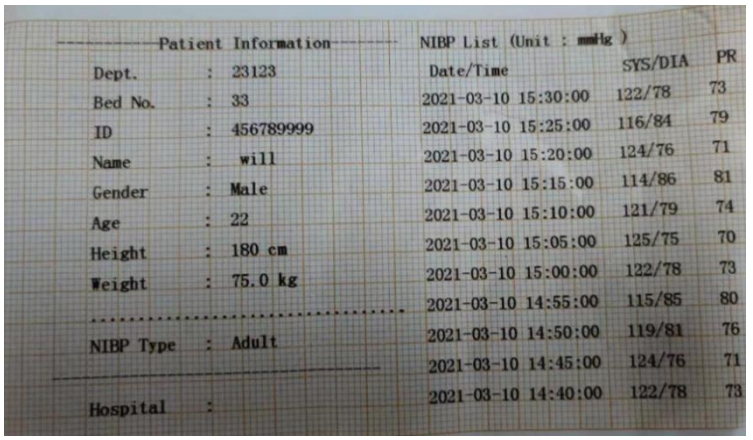


Figure 21-4: NIBP List Printing Report

21.7.2 Printing Procedure

1. Select '**Trend Review**' 

in extended quick keys area →Enter **Trend Review** page.
2. Select '**NIBP Tabular Trend**' tab → Enter **NIBP Tabular Trend** page.
3. Select '**Print**' → Start printing out the last 11 NIBP measurement data and time.
4. After printing is completed, you can get the report.

21.8 Loading Paper

1. Press the door latch to open the recorder door. Remove the paper core. Place a new paper roll between the tabs of the paper holder.
2. Make sure the paper unrolls from underneath the paper roll. Close the recorder door, make sure the new paper roll fits snugly into its housing and the paper end is feeding from the top. Otherwise, it would be hard to feed the paper under the roller.

NOTE

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

21.9 Removing Paper Jam

If the recorder works incorrectly or produces unusual sounds, check if there is a paper jam first. If a paper jam is detected, follow this procedure to remove it:

1. Open the recorder door.
2. Take out the paper and tear off the draped part.
3. Reload the paper and close the recorder door.

22 Internal Batteries

22.1 Description

The number of Lithium battery charge and discharge is more than 300 times (300-500 times, depending on the use of the situation). Battery lifespan depends on how frequent and how long it is use. If the battery is properly maintained and stored, its lifespan is about 3 years. If the battery is used improperly, its lifespan may decrease. When the battery is used frequently, replacing the lithium battery every 2 years is recommended; when it is not used frequently, it is recommended to replace the battery every 3 years.

The monitor is designed to operate on rechargeable Lithium-ion battery to ensure the normal operation of the monitor even when the AC power supply is interrupted. The patient monitor will prioritize the external AC as power source when available. If the AC power is cut off, the patient monitor will automatically run power from the internal batteries.

22.2 Safety Information

WARNING

- Keep the battery out of children's reach.
- Use only batteries specified in the chapter on 'Accessories'. Use of a different battery may present a risk of fire or explosion.
- Keep batteries in their original package until you are ready to use them.
- Do not expose batteries to liquids.
- Do not crush, drop or puncture batteries - mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally. If a battery has been dropped or banged against a hard surface, whether damage is visible externally or not: discontinue use
- If the battery is damaged or leaking, replace it immediately.
- Extremely high ambient temperatures may cause the battery to overheat, resulting in interruption of power to the monitor.
- The lifespan of a lithium battery is two years. Replace the battery when its lifetime is expired. Failure to replace the battery on schedule may cause the battery to overheat during the monitoring process and cause serious damage to the device.
- Please install the battery into the equipment for charging before first use. When inserting the battery, Load the batteries in the chamber as indicated by the polarity symbols (+/ -) marked inside, inserting the battery backward is not allowed.

- Do not open batteries, heat above 60°C (140°F), incinerate batteries, or cause them to short circuit. They may ignite, explode, leak or heat up, causing personal injury.

CAUTION

- Take out the battery before the monitor is transported or will not be used for a long time.
- When using battery power, if the too many measurement modules are connected to the equipment for measurement, the monitor may automatically shut down due to excessive load.

22.3 Battery Installation

Batteries are not installed by default. Battery installation and replacement must be performed by our trained and authorized service personnel.

22.4 Battery Status

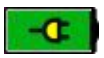
Battery Power Indicators, On-screen battery symbols and battery alarm message indicate the current status of the battery.

22.4.1 Battery Power Indicators

- Solid Green: Indicates that the batteries are charging.
- Green, Flashing: when the patient monitor operates on battery power.
- No light: when no battery is installed or no AC source is connected.

22.4.2 On-screen Battery Symbols

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

-  Indicates that no batteries are installed
-  Indicates that batteries work correctly. The solid portion represents the current charge level of the batteries in proportion to its maximum charge level.
-  Indicates that the batteries have low charge level and need to be charged.
-  Indicates that the batteries are charging.
-  Indicates that the batteries are fully charged.
-  Indicates that the batteries malfunction.

22.4.3 Battery Alarm

If the battery capacity is too low, a technical alarm will be triggered and the [**Battery Too Low**] message displayed. At this moment, apply AC power to the patient monitor. Otherwise, the patient monitor will power off automatically in 15s.

22.5 Charging a Battery

The battery is charged whenever the patient monitor is connected to an AC power source regardless of whether or not the patient monitor is currently on.

22.6 Conditioning a Battery

22.6.1 Optimizing Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery performance check is recommended to be performed every 3 months. If the battery is not optimized for a long time, it may cause the inaccuracy of battery indicator, resulting in a wrong judgment of the remaining battery operating time.

A battery needs at least two conditioning cycles when it is put into use for the first time. A battery conditioning cycle is one complete, uninterrupted charge of the battery, followed by an uninterrupted discharge of the battery. Batteries should be conditioned regularly to maintain their useful life.

NOTE

- Do not monitor patients when the batteries are conditioned.
- Do not stop charging or discharging cycle when batteries during conditioning.

22.6.2 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery performance check must be performed every 3 months.

If you doubt that there is a battery malfunction, Check batter performance immediately.

The operating time of the battery reflects its performance directly. If the discharging time of a battery is noticeably shorter than that indicated in the specifications, replace the battery or contact your service personnel.

If the battery condition is normal, Reconnect the monitor to mains power and charge the battery until it is full for use or charge to 40~60% for storage.

NOTE

- The operating time depends on the configuration and operation. For example, Screen brightness too high or monitoring NIBP repeatedly will all shorten the operating time of the batteries.

22.7 Storing a Battery

When storing the battery, make sure the electrodes of the battery are not in contact with metal objects. If the battery needs to be stored for prolonged period, it should be placed in a cool environment and charged to 40%-60%.

Stored batteries should also be conditioned periodically.

NOTE

- Remove the battery from the monitor when it is not used for a longer period of time, to avoid potential damage caused by battery leakage.
- Storing batteries in high temperatures for long periods of time will significantly reduce the battery lifespan.
- The temperature range for battery storage is -5℃~35℃. Storing the battery in a cool environment can slow down the battery aging. Ideally, batteries should be stored at 15°C.

22.8 Disposing of Used Batteries

Replace the used batteries and dispose them when:

- There is clear damage.
- There is a malfunction.
- Battery ages or the discharging time of a battery is noticeably shorter than that indicated in the specifications.
- Battery lifespan has expired.

Dispose of used batteries promptly and follow local government regulations in an environmentally responsible manner.

23 Cleaning and Disinfection

23.1 Description

In this chapter we only describe cleaning and disinfection of the main unit. For the cleaning and disinfection of reusable accessories, refer to instructions for use of corresponding accessories.

23.2 Safety Information

WARNING

- Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.
- Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.
- We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.
- The responsible hospital or institution shall carry out all cleaning and disinfection procedure specified in this chapter.

CAUTION

- Do not immerse part of the equipment into liquid.
- Any contact of disinfectant solutions with metal parts may cause corrosion.
- Do not allow liquid to enter the case.
- If you spill liquid on the equipment or accessories, please disconnect from power, erase the liquid and contact us or your service personnel immediately.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).
- Dilute and use cleaning and disinfecting agents following instructions specified in product manual.
- After cleaning and disinfection, check the equipment carefully. Do not use if you see signs of deterioration or damage.

23.3 Cleaning

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

Recommended **cleaning agents** are:

- Mild soap (diluted)
- Ammonia (diluted)
- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

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

1. Shut down the patient monitor and disconnect it from the power line.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated, cool place.

23.4 Disinfection

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

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants

NOTE

- Never use EtO or formaldehyde for disinfection.

23.5 Consequences of Improper Cleaning

Using a non-recommended cleaning agent or method may result in the following consequences:

- Discoloration of device surface
- Corrosion of metal components
- Cable, port, equipment housing cracking, deformation;
- Cable, lead wire life shortened
- System performance reduced
- Device failure.

24 Maintenance

24.1 Description

Regular maintenance of equipment and accessories is essential to ensuring the proper operation of the equipment. This chapter describes the inspection and testing methods of the equipment.

24.2 Safety Information

WARNING

- Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure, possible health hazards, and may endanger personal safety.
- The safety checks or maintenance involving any disassembly of the equipment should be performed by professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.
- Personnel that is responsible for maintain this equipment must be qualified and familiar with the operation of the product.
- Do not disassemble the battery, store it in an environment above 60°C, incinerate it or short-circuit it, as these may cause battery burning, explosion, leakage or overheating, and serious injury or death could result.
- No changes should be made to this device itself.

NOTE

- Maintenance and conditioning of the monitor are not allowed when the patient is monitored.
- If you discover a problem with any of the equipment, contact your service personnel or us.
- Do not use or store equipment outside the specified temperature, humidity, or altitude ranges.
- Disposal of packaging materials must comply with local regulations or the hospital's waste disposal policy.
- When the equipment and its accessories have reached the expiration date, they must be disposed of in accordance with local regulations. If you have any questions regarding the disposal, please contact our company.

Before every use, after your patient monitor has been used for 6 to 12 months, or whenever your patient monitor is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect all power cords for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Inspect if the alarm system functions correctly.
- Make sure that the recorder functions correctly and the recorder paper meets the requirements.
- Make sure that the batteries meet the performance requirements.
- Make sure that the patient monitor is in good working condition.
- Make sure that the grounding resistance and leakage current meet the requirement.

In case of any damage or abnormity, do not use the patient monitor. Contact the hospital's biomedical engineers or your service personnel immediately.

24.3 Maintenance Plan

Ensure that maintenance tasks are performed in accordance with maintenance plans or local regulations. Equipment must be cleaned and disinfected prior to testing and maintenance. Test and maintenance items and recommended frequency as follows:

Test / Maintenance Items	Recommended Frequency
Performance Test	
Visual Inspection	Before everyday use
Parameter Module Performance Test and Calibration	1. When the user suspects that the measurement value is inaccurate 2. Repair or replacement of relevant modules 3. CO2 and AG modules should be tested and calibrated at least once a year 4. Other modules should be tested and calibrated at least every two years.
Safety Test	
Selected items based on IEC60601-1	1. When battery module is repaired or replaced. 2. When monitor falls over. 3. At least every two years or based on demands.
Other Tests	
Power On Test	Before every use
Recorder Test	1. Before first usage. 2. After recorder repairment or replacement.

Network Printer Test		1. First installation. 2. After network printer repairment or replacement.
Device Integration Test		1. During first installation. 2. After integrated device is repaired or replaced.
Battery Check	Function Test	1. During first installation. 2. After battery replacement.
	Performance Test	Every 3 months or when battery running time shortens significantly

24.4 Maintenance Method and Procedures

In addition to the following maintenance tasks, all testing and maintenance can only be performed by our accredited professional maintenance staff.

- Routine checks, including Visual Inspection and power-on inspection
- Printer and Recorder Testing
- Battery Check

When additional testing and maintenance is required, contact the maintenance staff in time.

1. Visual Inspection

The appearance of the device should be checked before everyday use. If equipment, accessories are found to be damaged or malfunctioned, stop using it immediately and contact the hospital's equipment engineer or our maintenance staff.

Visual inspection includes:

- Environment and power supply meet the requirements
- Device shell is free of stains, the panel and display is not broken or damaged
- Power supply without wear, good insulation performance
- Port, plugs and cables are not damaged and intangled.
- Cables are connected firmly with the device and modules.

2. Power On Inspection

Implement self-test after the monitor is on. Self test items include:

- Equipment can power up properly
- Alarm system works properly
- The device displays normally

3. Recorder Test

Follow these steps to check that the recorder is working properly.

- Turn on recorder to print waveform and parameters
- Check that the recorder paper runs properly
- Check that the waveform and text are clear with no leaks.

4. Network Printer Test

Follow these steps to check that the network printer is working properly.

- Turn on network printer to print waveform and parameters.
- Check that the printer runs properly.
- Check that the printed waveform and text are clear.

5. Battery Check

See *22.6.2 Check Battery Performance*

24.5 Disposal of Monitor

When the equipment reaches the service life, please dispose of the monitor and accessories according to local regulations.

WARNING

- Dispose of components and accessories following hospital waste regulations if there is no corresponding regulations.

25 Accessories

All accessories listed in this chapter meet the requirements of IEC 60601-1-2 when used with a monitor. Accessory materials in contact with the patient have been tested for biocompatibility and verified to meet the requirements of ISO 10993-1. Detailed information on accessories can be found in the relevant accessory manual.

WARNING

- Use accessories specified in this chapter. Using other accessories may cause damage to the patient monitor or not meet the claimed specifications.
- The accessories should be used with this monitor only. It is the responsibility of the user to read this manual carefully (including accessories) or contact us to confirm the compatibility of the accessories with the device prior to use. Failure to do so may cause injury to patient.
- Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.

NOTE

- If accessories are used or stored outside of the specified temperature or humidity range, its performance may not reach the specifications claimed by this manual.
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
- Do not use the expired accessories.
- Disposal of single-use accessories must comply with local regulations or hospital waste disposal policy.

See the accessory identification label for accessory information. If you need to buy, please contact the sales agent.

25.1 ECG Accessories

Name	Model	Patient Type	Note	Manufacturer
Disposable Electrode	YY-W55	Adult	/	Qingdao Bright Medical Manufacturing Co., Ltd.

Name	Model	Type	Patient Type	Note	Length	Manufacturer
ECG Leads	M0202233	Clip Reusable	Adult	Separable 3 Leads	3.6m	Qingdao Bright Medical Manufacturing Co., Ltd.
	M0202232		Adult	Separable 5 Leads		
	M0202221	Snap Reusable	Adult	Integrative 5 Leads		
	M0202227		Neonate	Separable 3 Leads		
	M0202222		Adult	Integrative 3 Leads		

25.2 SpO_2 Accessories

Name	Model	Type	Patient Type	Note	Manufacturer
SpO2 Extension Cable	M0511027	Reusable	Adult、Pediatric、Neonate	Length: 3m	Qingdao Bright Medical Manufacturing Co., Ltd.

Name	Model	Type	Patient Type	Note	Manufacturer
SpO2 Probe	DP400N/A-090103	Disposable	Adult/Neonate	Applicable to BCI Module Length: 1.6m	Beijing Rongrui-Century Scie. & Tech. Co., Ltd.
	RSJ001DA	Reusable	Adult		
	RSY001DN		Neonate		

The SpO2 probe has a emission wavelength of 600 ~ 1000 nm and a maximum optical output of less than 18 mW.

Information on wavelength range and maximum optical output power is particularly useful for clinicians, for example, for photodynamic therapy.

25.3 NIBP Accessories

Name	Model	Type	Patient Type	Note	Manufacturer
NIBP Extension Pipe	L340	Reusable	Adult 、Pediatric 、Neonate	3.4m	Infinium Medical Inc.

Name	Model	Type	Patient Type	Note	Manufacturer
NIBP Cuff	LF1101S	Reusable	Neonate	/	Shenzhen Lifemed Co., Ltd.
	LF1102S		Pediatric		
	LF1103S		Adult		

25.4 Temp Accessories

Name	Model	Type	Patient	Note	Name	Manufacturer
Temp Probe	A-MR-01	Reusable	Adult	Body cavity	3m	Shenhen Anpukang Co., Ltd.
	A-MR-03		Adult	Body surface		

25.5 IBP Accessories

Name	Model	Type	Patient	Note	Manufacturer
IBP Cable	M0511023	Reusable	Adult	Applicable to abott disposable ibp sensor	Qingdao Bright Medical Manufacturing Co., Ltd.
IBP Sensor	SCW-Y-01	Disposable	Adult	/	SCW Medical LTD.

25.6 C.O. Accessories

Name	Model	Type	Patient	Note	Manufacturer
C.O. Cable	M0511022	Reusable	Adult	/	Qingdao Bright Medical Manufacturing Co., Ltd.

25.7 CO2 Accessories

Name	Model	Type	Note	Manufacturer
Gas Conduit	YSK-CYG-M	Disposable	/	USCON
Sampling Cannula	DM-4100-AF	Disposable	/	Dispo-Med

25.8 Other Accessories

Name	Model	Type	Patient	Note	Manufacturer
Lithium battery	XHL 18650-2S2P	Reusable	/	/	ShenZhen New Light Energy Technology Co. , Ltd

A Specifications

A.1. Safety Specifications

A.1.1 Product Category

According to the classification of the National Drug Administration of China, this monitor is Class III equipment.

This monitor is classified according to IEC60601-1 as follows:

Type of protection against electrical shock	Class I, with internal power
Degree of protection against electrical shock	Type CF defibrillation proof for ECG, RESP, SpO2, NIBP, TEMP, IBP, C.O., ETCO2, BIS, AG
Mode of operation	Continuous
Degree of protection against harmful ingress of water	IPX1
Portability type	Fixed

A.1.2 Environmental Specifications

Item	Temperature (℃)	Relative Humidity(non-condensing)	Barometric (kPa)
Operating conditions	5℃～40℃	15%～95%	80kPa～105kPa
Storage conditions	-20℃～55℃	10%～95%	80kPa～105kPa

WARNING

- Operation within the specified environmental specifications is a must. Otherwise, it may cause damage to the patient monitor or not meet the claimed specifications. If aging or any performance change that results from the environment condition, please contact the service personnel.

NOTE

- Unspecified modules' environment specifications are the same with the main unit's.

A.2 Power Supply Specifications

A.2.1 External AC Power

Input Voltage	100 ~ 240V
Input Current	1.3 ~ 0.5A
Input Line Frequency	50/60 Hz

A.2.2 Battery

W ×D × H	145mm × 64mm × 21.5mm
Weight	340g
Type	Lithium-ion battery, rechargeable
Rated Voltage	11.1V DC
Volume	5200 mAh
Run Time	More than 1h in continuous operation (For new, fully-charge battery, with ambient temperature: 25℃)
Charge Time	Monitor OFF: 0-90%: < 4h 0-100%: < 5h Monitor ON: 0-90%: < 8h 0-100%: < 10h

A.3 Hardware Specification

A.3.1 Display Specification

Screen Type	TFT-LCD
Screen Size	21.5 inch
Resolution	1920x1080 @ 60hz
Touch-Screen Type	Multi-Touch Capacitive Screen

A.3.2 Thermal Printer Specification

Type	Thermal dot array
Paper Width	80mm
Paper Speed	25mm/s

Number of Waveform Channels	1, 2 or 3
Tabular Printing	Yes
Graphic Printing	Yes
Out of Paper/ Printers Door Open Detection	Yes

A.3.3 LEDs on Main Units

Alarm Lamp	1 (3 colors: red, yellow, blue)
AC Power Indicator	1 (green)
Battery Status Indicator	1 (green)

A.3.4 Interface Specifications

Power	1 AC power connector
Ethernet Port	1 1000M Ethernet port
USB	6 USB2.0 port
HDMI Port	1 HDMI 1.4 port
Equipotential End	1
WIFI Standard	IEEE 802.11 a/b/g/n
Bluetooth Standard	BT2.0 & BLE

A.3.5 Signal Outputs Specifications

Alarm output	
Alarm signal sound pressure level range	40 dB(A) to 80 dB(A) within a range of one meter

A.4 Software Specifications

General Specifications	
Channel	Up to 8 Channels are displayed.
Layout	1) Up to 12 physiological parameters supported 2) Waveform parameter customization 3) Waveform area dynamic setup 4) 32 sets of colors 5) 6 display modes: ● Normal View ● Big Font View ● OxyCRG View ● BIS Trend View

	● C.O Measure View ● View Bed
Internal Storage	8 GB storage, usable size is 4.5GB
External File System	USB Flash Disk, FAT32 and NTFS format supported
Brightness	6 levels. Adjustable range is 0~5, 0 is the darkest, 5 is the brightest. Default setting is 3. Night mode brightness level is 0.
Sound Volume	6 levels. Adjustable range is OFF and 1~5, choose OFF to silence the audio, level 5 is the highest volume. Default setting is 2.
System Time	24H/12H format supported: 24H: YYYY/MM/DD HH:MM 12H: YYYY/MM/DD H:MM AM/PM Turn on automatic synchronization, when the monitor is connected to WLAN. Time is automatically synchronized with network time.
USB Extension	USB Keyboard USB Mouse USB Flash Disk ● USB Code Scanner ● USB Hub (supported, connection with too many devices is not recommended)
Patient Information Management	
Patient Setup	Supported, indexed with patient ID.
Trend Data Saving	● 5×24h Parameter data saving ● Waveform recording (ECG, SpO2, IBP, RESP etc.), 16s duration per waveform.
Patient Review	Patient information display supported Sorting by time supported
Data Export	USB Flash Disk exportation supported Exportation through DataManager application within WLAN connection supported
Data Protection/ Deletion	● Data protection supported to avoid accidental deletion or overwritten ● Deletion confirmation window to avoid accidental deletion.
Management Capacity	20 patient information sets at most
Module Setup Management	

General Module	ECG Module Resp Module Temp Module NIBP Module SpO2 Module CO2 Module IBP Module C.O Module BIS Module AG Module
Dynamic Module	ECG Module Resp Module Temp Module NIBP Module SpO2 Module CO2 Module IBP Module C.O Module BIS Module AG Module
Config Manager	Up to 30 configurations supported.
Configuration Export/Import	Yes
Ethernet Setup	IPv4 address supported, DHCP and Static IP supported. The system default is DHCP.
WIFI	1) WIFI SSID Scanning 2) WIFI non-encryption/encryption connection supported, security certificates are: ● WPA-PSK (recommended) ● WPA2-PSK recommended) ● WEP **Once connected, the system will save the password and connect to the WIFI automatically.**
WIFI Setup	IPv4 address supported, the system default is DHCP.
Alarm Management	
Alarm Levels	Classified into 3 levels: ● High: Flashing red with 2Hz frequency (twice per second) ● Medium: Flashing yellow with 1Hz frequency (once per second) ● Low: Solid blue You can set alarm sound type and alarm interval
Physiological Parameters	HR, PVCs, ST, ARR, RR, TP, SpO2, PR, PI(Masimo), NIBP-SYS, NIBP-DIA, IBP-ART-SYS, IBP-ART-DIA, IBP-PA-SYS, IBP-PA-DIA, IBP-CVP-MAP, IBP-RAP-MAP, IBP-LAP-MAP, IBP-ICP-MAP, B.T(C.O.), EtCO2, AWRR, BIS

Physiological Alarm Events Recordings	Physiological Alarm can trigger the recording the waveform when the alarm event occurs. You can turn off the trigger function. Event recordings are: 1. 16s waveform data (8s respectively before and after the alarm event occurring moment) 2. Physiological measurement data
Physiological Alarm List	Summary of current physiological alarms for review. Summary of history alarms for a specific parameter in Alarm Review, capacity: 100 sets.
Physiological Alarm	Sensor Off, Low Battery, Hardware malfunction, Module Disconnection, Signal out of range
Technical Alarm List	Current technical alarm list for review. History alarm list for technical alarms in Alarm Review, **Capacity**: 100 sets.
Data Communication	
View Other Monitored Patients	Searching and remote view patient monitors within the same network are supported Patient Monitor ←→ Patient Monitor
Health Level 7 Standards	1、 HL7 two-way communication supported 2、 HL7 patient management supported 3、 HL7 view report For more information about the HL7 standards process, please refer to the HL7 standards process document that we provide
Data Transmission	Data export/import mode through network supported Exportation content: Patient data and config Importation content: Config
History Patient Data Export	Installation of our DataManager software on PC allows you to view historical patient data stored in different devices within the LAN. When the DataManager Service is enabled on the monitor, your PC can connect to the monitor through the DataManager software and export the history patient data from the device, including measurement data and alarm recordings.
Smart Upgrade	
System Firmware Upgrade	Yes
Automated Upgrade by Network	Yes

A.5 Measurement Specifications

A.5.1 ECG

ECG	
Standards	ANSI-AAMI EC13, IEC 6061-2-27:2011
Lead Set	3-lead: I, II, III 5-lead: I, II, III, AVR, AVF, AVL, V
ECG Standard	IEC
Display Sensitivity	Gain: 2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2); error ≤ ±10%
Speed	12.5 mm/s, 25 mm/s, 50 mm/s; error ≤ ±5%
Mode	Diagnostic mode Monitor mode Surgical mode
Common Mode Rejection Ratio (With Notch Off)	>90dB
Notch	Diagnostic mode: Notch is 50/60Hz, nonadjustable Monitor and surgical mode: 50Hz/60 Hz/OFF, manual adjustment
Differential Input Impedance	≥5MΩ
Accuracy of Reappearing Input Signal	Use A and B methods based on EC13 or IEC60601-2-27 to determine system total error and frequency response.
Electrode Offset Potential Tolerance	≤±300mV
Lead Off Detection Current	Measuring electrodes: < 0.1uA Drive electrode: < 1uA
Baseline Recovery Time	<5s
Patient Leakage Current	<10uA
Calibration Signal	1mV (peak-to-peak value)±10%
ESU Protection	Cut mode: 300W Coagulate mode: 100W Recovery time: ≤10s
PACE Pulse	
Pace Pulse Markers	Pace pulses meeting the following conditions are labeled with a PACE marker: Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms

	Rise time: 10 to 100 μs
Pace Pulse Rejection	When tested in accordance with the ANSI/AAMI EC13-2002: Sections 4.1.4.1 and 4.1.4.3, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 μs
Pacemarker Pulse Rejection of Fast ECG Signals	25V/s±15%RTI
HR	
Measurement Range	30bpm~300bpm
Resolution	1bpm
Accuracy	±1 bpm or ±1%, whichever is greater.
Average HR	Meets ANSI/AAMI EC13-2002 requirements. Calculate average HR by: The heart rate is calculated by averaging the adjacent four RR waves. The heart rate displayed on the screen refreshes once per second.
Response to Irregular Rhythm	In compliance with the requirements in Clause 4.1.2.1 e) of ANSI/AAMI EC13-2002, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (3a): -80±1 bpm Slow alternating ventricular bigeminy (3b): -60±1 bpm Rapid alternating ventricular bigeminy (3c): -120±1 bpm Bidirectional systoles (3d): -90±2 bpm
Response Time to Heart Rate Change	From 80 to 120bpm: less than 12 s From 80 to 40bpm: less than 12s
Response to Tachycardia	≤12s
Tall T-Wave Rejection Capability	When the test is performed based on part 4.1.2.1 c) of ANSI/AAMI EC 13-2002, the heart rate meter will reject all 100 ms QRS complexes with less than 0.8 mV of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.
ST Segment Analysis	

Measurement Range	-2.00mV ~ +2.00mV
Resolution	0.01mV
Accuracy	±15% or ±0.05mV whichever is greater
Arrhythmia	
Asystole (ASY)	Yes
Fibrillation (FIB)	Yes
Ventricular Tachycardia (VTA)	Yes
R On T (ROT)	Yes
Ventricular Run (RUN)	Yes
Ventricular Triplet (TPT)	Yes
Ventricular Couplet (CPT)	Yes
Ventricular Premature Beat (VPB)	Yes
Bigeminy (BGM)	Yes
Trigeminy (TGM)	Yes
Tachycardia (TAC)	Yes
Bradycardia (BRD)	Yes
Missed Beat (MIS)	Yes
Alarm Limit	**Range**
HR Alarm High	(Low limit + 2) ~300 bpm Default value: 130 bpm (Adult) 160bpm (Pediatric) 200bpm (Neonate)
HR Alarm Low	30~ (high limit - 2) bpm Default value: 50bpm (Adult) 75bpm (Pediatric) 100 bpm (Neonate)
ST Alarm High	(Low limit - 0.20) ~ 2.00mV Default value: 0.30mV
ST Alarm Low	-2.00~ (high limit - 0.20) mV Default value: -0.30mV

A.5.2 Resp

Resp	
Technique	Trans-thoracic impedance
Lead	Lead II
Resp Measurement Range	0rpm~120rpm
Resolution	1rpm
Accuracy	7rpm~120rpm: ≤±2rpm 0rpm~6rpm: Not specified
Speed	6.25mm/s,12.5mm/s,25.0mm/s
Display Gain	×0.25, ×0.5, ×1.0, ×2.0
Apnea Alarm Delay	10s~ 60s, Default value: 20s
Alarm Limit	**Range**
RR High	(Low limit + 2) ~120 rpm Default value: 30rpm
RR Low	0~ (high limit -2) rpm Default value: 6rpm

A.5.3 Temp

Temp		
Standard	ISO 80601-2-56:2018	
Measurement method	Thermal Resistance	
Operating mode	Direct mode	
Measurement range	0℃~50℃ (32℉~122℉)	
Resolution	0.1℃	
Unit	℃/℉	
Error	Temp range	Error
	0℃～34.9℃	±0.2℃
	35.0℃～39.9℃	±0.1℃
	40.0℃～44.9℃	±0.2℃
	45.0℃～50.0℃	±0.3℃
Channel	2 channels	
Minimum Time for Accurate Measurement	Body Surface: < 100s Body cavity: < 80s	
Refreshing rate	≤2s	
Temp Difference Calculation	Yes	

Alarm Limit	
T1/T2 Alarm High	(Low limit + 1) ~50℃ Default value: 38.0℃
T1/T2 Alarm Low	0~ (high limit - 1) ℃ Default value: 36.0℃
△T High	0~50℃ Default value: 2.0℃

A.5.4 SpO2

General Specification	
Standard	ISO 80601-2-61:2017
*Measurement accuracy verification: The SpO2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.	
SpO2	
Measurement Range	0%~100%
Resolution	1%
Accuracy	70%~100%: ≤±2% (measured without motion) 0%~69%: Not specified
Waveform Speed	12.5mm/s, 25.0mm/s
Refreshing Period	1s
Response time	⩽30 s (normal perfusion, no disturbance, SpO2 value sudden change within 70% – 100%)
Low Perfusion Conditions	0.3%~20%
Pulse Rate	
Measurement Range	30bpm~250bpm
Resolution	1bpm
Accuracy	≤±2 bpm
Alarm Limit	**Range**
SpO2 Alarm High	(Low limit + 1) ~100% Default value: 99.9%
SpO2 Alarm Low	0~ (high limit - 1) % Default value: 85%
PR Alarm High	(Low limit + 2) ~300bpm
PR Alarm Low	30~ (High limit - 2) bpm

SpO2 Alarm Response Time	≤12s

A.5.5 NIBP

General Specification			
Standard	ISO 80601-2-30:2019		
Measurement Method	Oscillometry		
Mode of Operation	Manual, Auto and STAT		
Auto Mode Repetition Intervals	2min~240min		
Number of STAT Mode Cycle	5		
Total Number of NIBP Listings	1024		
Measurement Type	Adult, Pediatric, Neonate		
Initial Cuff Inflation Pressure	Adult options: 80mmHg 100mmHg 120mmHg 140mmHg 150mmHg 160mmHg **180mmHg** **(Default)** 200mmHg 220mmHg 240mmHg	Pediatric options: 80mmHg 100mmHg 120mmHg **140mmHg** **(Default)** 160mmHg 180mmHg 200mmHg 220mmHg 240mmHg	Neonate options: 60mmHg 70mmHg 80mmHg **100mmHg** **(Default)** 120mmHg
Inflation Memory Mode	Yes		
Alarm Limit	**Range**		
Sys High	Adult: (low limit + 5) ~270mmHg Pediatric: (low limit + 5) ~230mmHg Neonate: (low limit + 5) ~135mmHg Default value: 160mmHg (Adult) 120mmHg (Pediatric) 90mmHg (Neonate)		
Sys Low	40~ (high limit - 5) mmHg Default value:		

	90mmHg (Adult) 70mmHg (Pediatric) 40mmHg (Neonate)
Día High	Adult: (low limit + 5) ~210mmHg Pediatric: (low limit + 5) ~150mmHg Neonate: (low limit + 5) ~95mmHg Default value: 90mmHg (Adult) 70mmHg (Pediatric) 60mmHg (Neonate)
Dia Low	10~ (high limit - 5) mmHg Default value: 50mmHg (Adult) 40mmHg (Pediatric) 20mmHg (Neonate)
Infinium Module	
Standard	ISO80601-2-30:2019
Measurement Method	Upper arm, Oscillometry
Mode of Operation	Manual, Auto and STAT
Max Measurement Time	180s (Adult/Pediatric) 90s (Neonate)
Static Pressure Measurement Range	0~300mmHg
Accuracy	±3mmHg
Dynamic Pressure Measurement Range	**Adult:** SYS: 40mmHg~270mmHg DIA: 10mmHg~210mmHg **Pediatric:** SYS: 40mmHg~230mmHg DIA: 10mmHg~150mmHg **Neonate:** SYS: 40mmHg~135mmHg DIA: 10mmHg~95mmHg
Dynamic Pressure Accuracy	Max mean error: ±5mmHg Max standard deviation: 8mmHg
Resolution	1mmHg
Software Overpressure Protection	Adult: 297mmHg±3mmHg Pediatric: 237mmHg±3mmHg

	Neonate: 147mmHg±3mmHg
PR Measurement Range	40~240bpm
PR Accuracy	2% or ±3bpm, whichever is greater

A.5.6 IBP

General Specification	
Standard	IEC 60601-2-34:2011
Measurement Method	Direct invasive measurement
Measurement Range	-30mmHg~300mmHg
Resolution	1mmHg
Accuracy	≥-10mmHg: ±1mmHg or 2%, whichever is greater < -10mmHg: ±3mmHg or 4%, whichever is greater
Number Of Channels	2Channels
Zeroing Range	≤120mmHg
Excitement Voltage	5V DC, ±2%
Sensitivity	5uV/V/mmHg
Impedance Range	300Ω~3KΩ
Sweep Speed	12.5mm/s, 25.0mm/s
Waveform Scale	-30mmHg~300mmHg, manual input required
Waveform Optimization Mode	Manual / Auto (In manual mode, optimization varies with waveform scale)
Pressure Label	ART (Arterial Blood Pressure) PA (Pulmonary Artery Pressure) CVP (Central Venous Pressure) RAP (Right Arterial Pressure) LAP (Left Arterial Pressure) ICP (Intracranial Pressure)
Alarm Limit	**Range**
ART Alarm High	(Low limit + 2) ~300mmHg Default value: 150mmHg
ART Alarm Low	0~ (high - 2) mmHg Default value: 75mmHg
PA Alarm High	(Low limit + 2) ~200mmHg Default value: 90mmHg
PA Alarm Low	-30~ (high limit - 2) mmHg Default value: 60mmHg
CVP/RAP/LAP/ICP	(Low limit + 2) ~60mmHg

Alarm High	Default value: 30mmHg
CVP/RAP/LAP/ICP Alarm Low	-30~ (high limit - 2) mmHg Default value: 10mmHg

A.5.7 C.O.

General Specification	
Measurement Method	Thermodilution method
Measurement Range	C.O.: 0.1L/min~20L/min BT: 23℃~43℃ IT: 0℃~27℃
Resolution	C.O.: 0.1L/min BT/IT: 0.1℃
Accuracy	C.O.: ±5% or ≤±0.1L/min, whichever is greater BT/IT: ≤±0.1℃
C.O. Graphical Trends Capacity	256 sets
Alarm Limit	**Range**
BT Alarm High	(Low limit + 1) ～43.0℃ Default value: 39.0℃
BT Alarm Low	23.0～ (high limit - 1) ℃ Default value: 36.0℃

A.5.8 EtCO2

General Specification C200		
Standard	ISO 80601-2-55:2018	
Measurement Range	0 - 20% Volume ratio (0-152mmHg@BTPS)	
Accuracy*	0-5% CO2(ATPS): ±2mmHg 5%-20% CO2(ATPS): < 10%	
Response Time	5s	
Flow Control	100ml/min	
Flow Control Accuracy	±15% or ±15 ml/min, whichever is greater.	
Warm-up Time	10s	
Rise time	≤ 200ms	
awRR		
Measurement Range	2 rpm~150 rpm	
Measurement Accuracy	1%±1rpm	
Resolution	1 rpm	
Effect of interference gases on CO2 measurements		
Gas	Concentration	Quantitative effect*
N2O	≤ 60 %	±1 mmHg
HAL	≤ 4 %	

SEV	≤ 5 %	
ISO	≤ 5 %	
ENF	≤ 5 %	
He	≤ 50 %	
Xe	≤ 100 %	
DES	≤ 15 %	±2 mmHg
*: means an extra error should be added in case of gas interference when CO2 measurements are performed between 0 to 40 mmHg.Inaccuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15 bpm and I:E ratio smaller than 1:1 relative to the gas readings without breath.		

Alarm Limit	**Range**
EtCO2 Alarm High	(Low limit + 2) ~150mmHg manual input required Default value: 60mmHg
EtCO2 Alarm Low	0~ (high limit - 2) mmHg manual input required Default value: 15mmHg
awRR Alarm High	(Low limit + 2) ~150rpm manual input required Default value: 30rpm (Adult) 100rpm (Neonate)
awRR Alarm Low	0~ (high limit - 2) rpm manual input required Default value: 5rpm (Adult) 30rpm (Neonate)

A.5.9 AG

ANESTHETICS(DRÄGER)	
Standard	ISO 21647
Measurement Method	Infreared Absorption
Gas Type	Fluorane, Isoflurane, Anflurane, Sevoflurane, Deflurane, CO2, N2O, O2(Optinoal)
Zeroing Interval	1 / day (first zeroing 35 minutes after power on, then once every 24 hours)
Zeroing Time	< 15 s
Working temperature	+10℃～+50℃
Start Time	< 4 minutes
Accuracy	CO2: ± (0.43vol% + 8 % rel.) N2O: ± (2 vol% + 8% rel.) Agents: ± (0.15vol% + 15 % rel.) O2: ± (2.5vol% + 2.5 % rel.)
Sampling Gas Flow Rate	200 mL/min
Rise Time	CO2<= 350 ms N2O<= 350 ms Agents <= 350 ms O2<= 500 ms

删除[Xingwei Peng]:

HR	0～80 bpm
Power Supply Voltage	10.5～62 V
Measurement Range	Halothane, Isoflurane: 0～8.5% Enflurane, Sevoflurane: 0～10% Desflurane: 0～20% CO2: 0～10% N2O: 0～100% O2:0～100%

A.5.10 BISx2

EEG General Specification		
Standard	IEC 60601-2-26:2012	
Patient Leakage Current	<=10μA (AC: 110V)	
Calibration Signal	1mV (peak to peak value)	
Differential Input Impedance	>15MΩ @ 10 Hz	
Max. DC Input Offset Voltage	±320 mV	
Input Protection	Against defibrillation (5kV) and electrosurgery	
Common Mode Rejection Ratio	> 105dB @ 5kΩ imbalance and 60 Hz	
Noise	<0.4μV RMS (1 ~ 30 Hz)	
Electromagnetic Sensitivity	< 10μV (peak to peak) @ 3 V/m, 26-1000 MHz	
Electrode Impedance Measurement	0 ~ 30kΩ, ±1kΩ	
Bandwidth	0.25 - 100Hz (-3dB)	
High Filter Cut-Off Frequencies	15 Hz (65 dB/ octave) 30 Hz (75 dB/ octave) 50 Hz (85 dB/ octave)	
Low Filter Cut-Off Frequencies	0.5,1.0,2.0 and 5.0 Hz (12 dB/ octave)	
Measurement Parameter	**Measurement Range**	**Error**
BIS	0 - 100	Not specified
SQI	0 – 100%	
EMG	0 - 100dB	
SR	0 - 100%	
SEF	0.5 - 30.0Hz	
TP	0 - 100dB	
Burst Counts (BC)	0 – 30/min	
Noise	<0.3μV RMS (2.0μV peak to peak)	
Waveform Scale	50μV, 100μV, 200μV, 500μV	
Refresh Rate (BIS Value)	2048ms	

Bandwidth	0.25 - 100Hz (-3dB)
High Pass Filter	0.25Hz, 1Hz, 2Hz (-3 dB)
Low Pass Filter	30Hz, 50Hz, 70Hz, 100Hz (-3 dB)
Notch Filter (Frequency)	50Hz, 60Hz
Impedance Range	0 ~ 999kΩ
Alarm Limit	**Range**
BIS Alarm High	(Low limit + 2) ~100 Default value: 70
BIS Alarm Low	0 ~ (high limit - 2) Default value: 20

B Factory Defaults

B.1 ECG, Arrhythmia, ST Factory Default Settings

B.1.1 ECG Setup

ECG Setup		Factory Default Settings	
HR	Alarm **ON/OFF**	ON	
	Alarm High	Adult	130bpm
		Pediatric	160bpm
		Neonate	200bpm
	Alarm Low	Adult	50bpm
		Pediatric	75bpm
		Neonate	100bpm
	Alarm Level	Medium	
	Alarm Record	OFF	
	Alarm Source	HR	
Color			
Speed		25.0 mm/s	
ECG Gain		×1.0	
Lead Set		5-lead	
ECG Filter		Monitor	
ECG Notch		50Hz/60Hz	
ECG Cascade		OFF	
Paced		OFF	

B.1.2 Arrhythmia Alarm Setup

Item	Alarm ON/OFF	Alarm Level	Alarm Record
ASY	ON	High	ON
FIB	ON	Medium	OFF
VTA	ON	Medium	OFF
ROT	ON	Medium	OFF
RUN	ON	Medium	OFF
TPT	ON	Medium	OFF
CPT	ON	Medium	OFF
PVC	ON	Medium	OFF
BGM	ON	Medium	OFF
TGM	ON	Medium	OFF

TAC	ON	Medium	OFF
BRD	ON	Medium	OFF
MIS	ON	Medium	OFF

B.1.3 ST Segment Setup

Item		Factory Default Settings
ST Alarm Mode		Real-time
ST-I, ST-II, ST-III, ST-aVR ST-aVL, ST-aVF, ST-V	Alarm ON/OFF	ON
	Alarm High	0.30mV
	Alarm Low	-0.30mV
	Alarm Level	Medium
	Alarm Record	OFF
ST Analysis		ON
ST Segment		Auto
ST Point		J+40ms
ST Point adjustment		ON
ISO Point		-105ms
J Point		180ms

B.2 Resp Setup

Item		Factory Default Settings	
RR	Alarm ON/OFF	ON	
	Alarm High	Adult	30rpm
		Pediatric	30rpm
		Neonate	100rpm
	Alarm Low	Adult	8rpm
		Pediatric	8rpm
		Neonate	30rpm
	Alarm Level	Medium	
	Alarm Record	OFF	
Apnea	Alarm **ON/OFF**	ON (Cannot be set)	
	Alarm Level	High (Cannot be set)	
	Alarm Record	ON (Cannot be set)	
RR Source		Resp	
Color			
Speed		6.25mm/s	

Gain	×1.0

B.3 SpO2 Setup

Item			Factory Default Settings
SpO2	Alarm ON/OFF		ON
	Alarm High		99%
	Alarm Low		85%
	Alarm Level		Medium
	Alarm Record		OFF
PR	Alarm ON/OFF		ON
	Alarm High	Adult	130bpm
		Pediatric	160bpm
		Neonate	200bpm
	Alarm Low	Adult	50bpm
		Pediatric	75bpm
		Neonate	100bpm
	Alarm Level		Medium
	Alarm Record		OFF
Color			
Speed			12.5mm/s
PR Source			SpO2

B.4 Temp Setup

Item		Factory Default Settings
T1/T2	Alarm ON/OFF	ON
	Alarm High	38℃
	Alarm Low	36℃
	Alarm Level	Medium
	Alarm Record	OFF
△T	Alarm ON/OFF	ON
	Alarm High	2.0℃
	Alarm Level	Medium
	Alarm Record	OFF
Color		White
Temperature Unit		℃

B.5 NIBP Setup

Item		Factory Default Settings	
NIBP-SYS	Alarm ON/OFF	ON	
	Alarm High	Adult	160mmHg
		Pediatric	120mmHg
		Neonate	90mmHg
	Alarm Low	Adult	90mmHg
		Pediatric	70mmHg
		Neonate	40mmHg
	Alarm Level	Medium	
	Alarm Record	OFF	
NIBP-DIA	Alarm ON/OFF	ON	
	Alarm High	Adult	90mmHg
		Pediatric	70mmHg
		Neonate	60mmHg
	Alarm Low	Adult	50mmHg
		Pediatric	40mmHg
		Neonate	20mmHg
	Alarm Level	Medium	
	Alarm Record	OFF	
Color			
Pressure Unit		mmHg	
Mode of Operation		Manual	
Initial Pressure		Adult	180mmHg
		Pediatric	140mmHg
		Neonate	100mmHg

B.6 IBP Setup

Item			Factory Default Settings
IBP-SYS	Alarm ON/OFF		ON
	ART	Alarm High	150mmHg
		Alarm Low	75mmHg
	PA	Alarm High	90mmHg
		Alarm Low	60mmHg
	Alarm Level		Medium
	Alarm Record		OFF

IBP-DIA	Alarm ON/OFF		ON
	ART	Alarm High	90 mmHg
		Alarm Low	60 mmHg
	PA	Alarm High	75 mmHg
		Alarm Low	45 mmHg
	Alarm Level		Medium
	Alarm Record		OFF
IBP-MAP	Alarm ON/OFF		ON
	CVP, RAP LAP, ICP	Alarm High	30 mmHg
		Alarm Low	10 mmHg
	Alarm Level		Medium
	Alarm Record		OFF
Color			
Pressure Unit			mmHg
Speed			25.0mm/s
Parameter Label			IBP1 — ART IBP2 — PA
Parameter Ruler			IBP1 — 10~150mmHg IBP2 — 10~75mmHg

B.7 C.O. Setup

Item		Factory Default Settings
BT	Alarm ON/OFF	ON
	Alarm High	39.0℃
	Alarm Low	36.0℃
	Alarm Level	Medium
C.O. Coefficient		0.542
Automatic Measurement		ON
Auto IT		2.0℃

B.8 EtCO2 Setup

Item		Factory Default Settings	
EtCO2	Alarm ON/OFF	ON	
	Alarm High	60	
	Alarm Low	15	
	Alarm Level	Medium	
	Alarm Record	OFF	
awRR	Alarm ON/OFF	ON	
	Alarm High	Adult	30
		Pediatric	30
		Neonate	100
	Alarm Low	Adult	8
		Pediatric	8
		Neonate	30
	Alarm Level	Medium	
	Alarm Record	OFF	
Color			
Unit		mmHg	
Speed		12.5mm/s	
Waveform Type		Fill	
Waveform Scale		0~75mmHg	
Apnea Delay		10s	
Zero Gas Type		Room air	
Oxygen (%)		16%	
Balance Gas		N2O	
Anesthetic		0.0%	
Barometric Pressure		760mmHg	
Gas Temp		35℃	

B.9 BIS Setup

Item		Factory Default Settings
BIS	Alarm ON/OFF	ON
	Alarm High	70
	Alarm Low	20
	Alarm Level	Medium
	Alarm Record	OFF
Color		
Speed		25mm/s
Display		EEG1
Parameter1		SEF
Parameter2		SR
Scale		50μV
Smoothing Rate		15s
Filter		OFF
Auto Impedance Inspection		ON

C Alarm Messages

C.1 Physiological Alarm Messages

General Physiological Alarm

Alarm Messages	Default Level	Cause and Solution
XXX Too High	Medium	XX value has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct.
XXX Too Low	Medium	
Resp Apnea	High	Patient can't respirate or the respiration signal was so weak that the monitor cannot perform respiration analysis. Check the patient's Condition, electrode placement and the Resp connections.

Note: XXX represents Physiological parameter, like HR, ST, RR, SpO2, PR, EtCO2, ART-SYS, ART-DIA etc.

Arrhythmia Alarm messages

Alarm Messages	Default Level
Asystole	High
V-Fib/V-Tach	Medium
V-Tach	Medium
R on T	Medium
RUN	Medium
Vent Rhythm	Medium
Couplet	Medium
PVC	Medium
Bigeminy	Medium
Trigeminy	Medium
Tachy	Medium
Brady	Medium
Missed Beats	Medium

C.2 Technical Alarm Messages

Module	Alarm Messages	Default Level	Cause and Solution
ECG	ECG Lead Off	Low	The electrode has become detached from the patient or the lead wire has become disconnected from the adapter cable. Check the connections of the electrodes and leadwires.
	ECG Lead LA Off	Low	
	ECG Lead RA Off	Low	
	ECG Lead LL Off	Low	
	ECG Lead V Off	Low	
	ECG Lead V2 Off	Low	
	ECG Lead V3 Off	Low	
	ECG Lead V4 Off	Low	
	ECG Lead V5 Off	Low	
	ECG Lead V6 Off	Low	
	ECG Invalid Signal	Medium	Electrode-to-Skin Impedance too high, and reposition the electrode.
	HR Overrange	Medium	If HR>300bpm, Check patient's condition.
SpO2	SpO2 Sensor Off	Low	The SpO2 sensor has become detached from the patient or the module, check the connection. If the alarm persists, replace it with a new sensor.
	SpO2 Sensor Fault	Low	Troubleshoot the problem with instructions specified by the manual that comes with Masimo SpO2 module.
	SpO2 No Sensor	Low	
	SpO2 Unrecognized Sensor	Low	
	SpO2 Sensor Incompatible	Low	
	SpO2 Too Much Ambient Light	Low	
	SpO2 Low Signal	Low	
	SpO2 Weak Signal	Low	
	SpO2 Weak Pulse	Low	
	SpO2 Interference	Low	
	SpO2 Board Fault	Low	
Temp	TP1 Sensor Off	Low	Check the sensor connections. Reconnect the sensor.
	TP2 Sensor Off	Low	
NIBP	NIBP Self-check Error	Low	Check NIBP module or replace it.
	NIBP Cuff Off	Low	Reconnect the cuff.

	NIBP Loose Cuff or Pneumatic Leak	Low	Check the leakage in cuff or airway.
	NIBP Weak Signal	Low	The patient’s pulse is weak or the cuff is loose. Check the patient’s condition and change the cuff application site.
	NIBP Overrange	Low	The measured NIBP value is not within the specified range. Check the patient’s condition.
	NIBP Excessive Motion	Low	Please keep quiet and remeasure.
	NIBP Overpressure	Low	The NIBP airway may be occluded. Check the airway and measure again. If the alarm persists, replace it with a new sensor.
	NIBP Signal Saturated	Low	The NIBP signal is saturated due to excess motion or other sources.
	NIBP Air Leak	Low	Check the NIBP cuff and pump for leakages.
	NIBP System Error	Low	Re-plug the module or restart the monitor.
	NIBP Timeout	Low	An error occurred during NIBP measurement and therefore the monitor cannot perform analysis correctly. Check the patient’s condition and NIBP connections, or replace the cuff.
IBP	IBP1 Sensor Off	Low	Check the sensor connection and reconnect the sensor.
	IBP2 Sensor Off	Low	
	IBP3 Sensor Off	Low	
	IBP4 Sensor Off	Low	
EtCO2	EtCO2 Error	Low	Re-plug the module or restart the monitor.
	EtCO2 Sensor High Temp	Low	High ambient temperature or module malfunction. 1、Lower the ambient

			temperature. 2、Reconnect the module. 3、If the alarm persists, please contact the service personnel.
	EtCO2 Zero Failed	Low	Check the CO2 connections. After the sensor's temperature becomes stabilized, perform a zero calibration again.
	EtCO2 Overrange	Low	
	EtCO2 Airway Adapter Error	Low	Check, clean or replace the adapter.
	EtCO2 Pump Life Expired	Low	Replace the pump.
BIS	BIS Sensor Expired	Low	Replace the sensor.
	BIS Sensor Off	Low	Check the sensor connection and reconnect the sensor. If the alarm persists, replace it with a new sensor.
	BIS Error	Low	Check or replace the sensor.
	BIS REF Node Off	Low	Check electrode placement, reposition the electrode if necessary.
	BIS GND Node Off	Low	
	BIS CH1 Node Off	Low	
	BIS CH2 Node Off	Low	
C.O.	TB Sensor Off	Low	Check the sensor connection and reconnect the sensor.
	TI Sensor Off	Low	
Battery	Battery Low	Low	Battery Low, please charge the battery.
	Battery Too Low	High	Battery Too Low, please charge it immediately, otherwise, the monitor will shut down automatically.

D EMC and Radio Regulatory Compliance

The product is in radio-interference protection class A in accordance with EN55011. The product complies with the requirement of standard EN60601-1-2:2007 'Electromagnetic Compatibility – Medical Electrical Equipment'.

NOTE

- Using accessories, transducers and cables other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the patient monitoring equipment.
- The device or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or its components should be observed to verify normal operation in the configuration in which it will be used.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may affect this monitor even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication devices can affect their performance.
- Other devices containing RF emission may affect this device (e. g., mobile phone, PAD, computer with wireless functionality).

Monitor Performance Specifications:

Item	Performance Specifications
ECG	HR Range: 30~300bpm 3-lead: I, II, III 5-lead: I, II, III, V, aVR, aVF, aVL Input Signal Range: ±5mV
SpO_2	Measurement Range: 0~100%
NIBP	Measurement Range: Adult: SYS (40~270) mmHg DIA (10~210) mmHg Pediatric: SYS (40~230) mmHg DIA (10~150) mmHg

	Neonate: SYS (40~135) mmHg DIA (10~90) mmHg Mode of operation: Auto, Manual, STAT
Resp	Measurement Range: 0~120rpm
Temp	Measurement Range: 0~50℃
PR	Measurement Range: 30~250bpm
Display	12.5-inch multi-colored display, Resolution: 1366*768
Operation method	Use touchscreen
Alarm Indicator	Audio alarm, Lamp alarm
Data Communication	Ethernet supported
Power Supply	AC power: 100~220V, 50/60Hz, 1.3~0.5A DC power: Battery power supplied 10.89V/5200mAh Lithium chargeable battery

Guidance and Declaration - Electromagnetic Emissions		
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic Environment - Guidance**
Radio frequency (RF) emissions CISPR 11	1 Group	The device 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 device is suitable for use in all establishments other than domestic and those indirectly 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	Complies	

WARNING

- This equipment is expected to be operated by medical professionals, as it may cause electromagnetic interference or interfere with other devices in the vicinity. If abnormal

performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment or shielding the relevant electromagnetic site.

Guidance and Declaration - Electromagnetic Immunity			
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential Mode ±2 kV differential Mode	±1 kV differential Mode ±2 kV differential Mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	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 (50/60Hz) magnetic Field	3 A/m	3 A/m	Power frequency magnetic fields should be at level typical location in a commercial or hospital

Guidance and Declaration - Electromagnetic Immunity			
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
IEC 61000-4-8			environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance, which can be calculated using the formula applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The formulas for calculating the recommended separation distance are as follows: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80%AM@2Hz 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Only ISA CO2 is tested at 20 V/m	20 V/m 80%AM@1kHz 80 MHz to 2.5 GHz	20 V/m	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: 

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

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

a). Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio and TV broadcasters cannot be accurately predicted theoretically. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be conducted. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level, verify that the device works normally. If you observer abnormal performance, you may need to reorient or relocating the device.

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the device

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

Rated Maximum Output power of Transmitter Watts (W)	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23

0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: From 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

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

Radio Management Compliance

RF Parameter

Project	**IEEE 802.11b/g/n (2.4G)**
Operating Frequency (GHz)	ETSI:2.4GHz~2.483GHz FCC:2.4GHz~2.483GHz MIC:2.4GHz~2.495GHz KC:2.4GHz~2.483GHz
Modulation	802.11b: DSSS(DBPSK/DQPSK/CCK) 802.11g/n: OFDM(BPSK/QPSK/16QAM/64QAM)
Effective Radiation Power (dBm)	<20 dBm (Average value) <30 dBm (Peak)

FCC WARNING

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

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

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

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

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

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

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

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