



OMEGA12 Patient Monitor

User's Manual

Infinium Medical Inc.

Introduction

Thank you for choosing Omega 12 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: Omega 12

General Information:

This device is intended to be used for monitoring, and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. 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.). Additionally, End-tidal carbon dioxide (EtCO₂), and Bispectral Index (BIS) can be monitored through plug-in module, the measurement can be displayed, reviewed, stored, and printed.

Product Components:

Portable and all-in-one integrated, the Omega 12 contains the main unit and accessories (temperature sensor, pulse oximetry sensor, disposable electrodes, ECG lead, blood pressure cuff and tubings).

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.

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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 Notes



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.

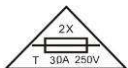
This monitor is designed for use within a specified electromagnetic environment. However, Certain electromagnetic interference may cause blurred or erroneous measurements, even worse, the malfunction of the equipment.

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

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	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 of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. 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.). Additionally, End-tidal carbon dioxide (EtCO₂), and Bispectral Index (BIS) can be monitored through plug-in module, the measurement can be displayed, reviewed, stored, and printed.

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 features audio and visual alarms, Trend recording and printing, NIBP recording and review, alarm event system, 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

The monitor operates based on the principle that various physiological changes are probed through sensor, amplified through signal booster, and ultimately turned into electrical information for analysis. The monitor software will calculate, analyze and edit the data, and display it in parameter area. 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

This patient monitor contains a main unit, display, battery, measurement modules, SpO₂

sensor, NIBP cuff, IBP cables, C.O. cables, Temp sensor etc.

2.5 Main Unit

2.5.1 Front View



Figure 2-1 Front View

Number	Explanation	Symbol
1	HDMI connector	HDMI
2&3	USB connectors: upgrade firmware or importing/exporting configuration.	USB
4	Thermal printing: Infinium STR-80 thermal printing is recommended	
5	Non-Invasive Blood Pressure connector	NIBP
6	Connector for Temp probe 1	T1
7	Connector for Temp probe 2	T2
8	AAMI ECG cable connector	ECG
9	* SpO2 sensor connector (sensor connector varies with SpO2 modules)	SpO2

10	Alarm Status Symbols: LED indicators tell the priority of the technical and physiological alarm High: Red with quick flashes, 2 flashes per second Medium: Yellow with slow flashes, 1 flash per second Low: Solid blue without flashes	
11	Speaker	
12	AC Power indicator: ON: when AC power is connected. OFF: when AC power is connected.	~
13	Power ON/OFF (for turning ON/OFF the monitor)	⏻/⏻
14	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.	⎓

2.5.2 Rear View

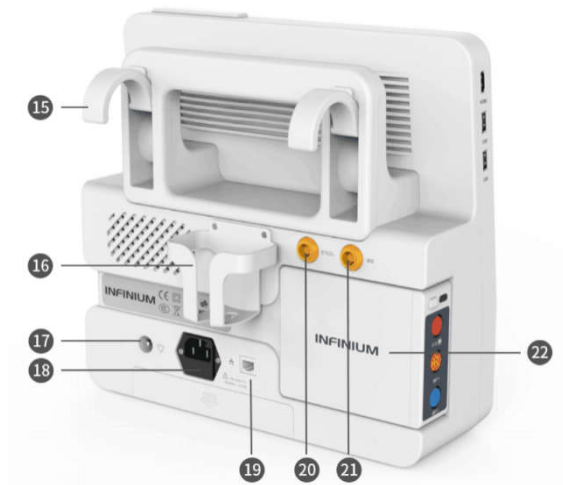


Figure2-2 Rear View

Number	Explanation	Symbol
15	Mounting Hook: hanging the monitor onto the wall or besides the patient bed.	

16	EtCO2 Bracket: installing EtCO2 module	
17	Equipotential Grounding: connecting other instruments and equipment with equipotential grounding system to eliminate the ground potential difference between different equipment to ensure safety	
18	AC Power Input: 100~240VAC50/60Hz	100-240V 50/60Hz 1.3-0.5A
19	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.	
20	EtCO2 Sensor Connector: connecting external EtCO2 sensor module	EtCO2
21	BIS Sensor Connector: connecting external BISx sensor module	BIS
22	IBP/C.O. Plug-In Modules: Connecting and removing multifunctional IBP/C.O. plug-in modules. Allowing for module connections like CO+IBP×2, IBP ×4. Plug-in modules contain IBP connector and C.O. connector.	

2.6 Display Screen

This patient monitor uses a high-resolution 12.5 inches LCD to display patient parameters and waveforms. A typical display screen is shown below.

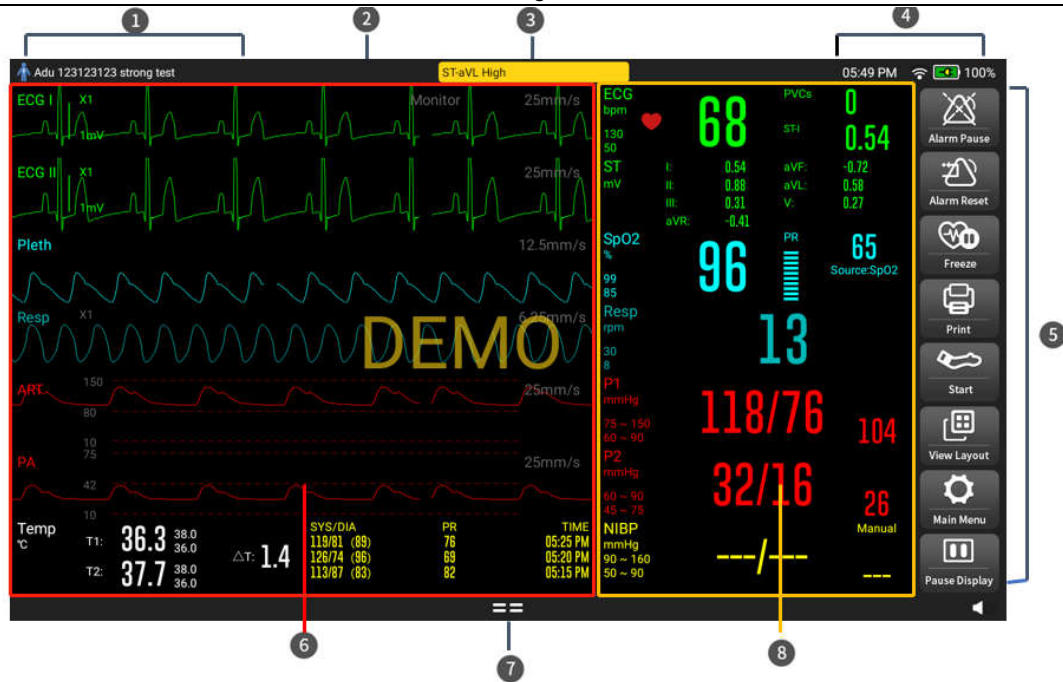
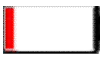


Figure 2-3 Normal Monitor View

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	System Status Bar: Indicating time, network and battery status.
5	Soft Keys Area: Eight soft keys for quick function access: Alarm Pause, Alarm Reset, Freeze, Print, Start/Stop, View Layout, Main Menu, Pause Display.
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	Extended Soft Keys Area: Click this button, and extended soft keys area will pop up for quick function access.
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.

2.6.1 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

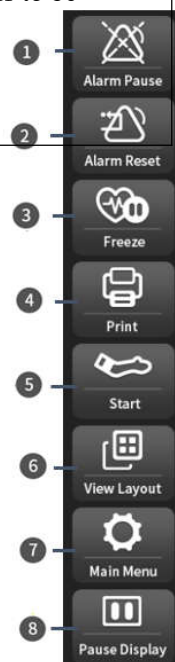
2.6.2 Soft Keys

Soft Keys column is on the right of the screen, as illustrated in the right Figure.

1) Alarm Pause:

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

2) Alarm Reset:



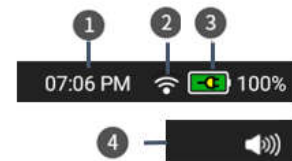
Reset the alarm system

- 3) **Freeze:** Freeze or unfreeze the waveform display
- 4) **Print:** Start or stop the printing procedure.
- 5) **Start/Stop:** Start/Stop measuring the non-invasive blood pressure
- 6) **View Layout:**
Set up the waveform in main display and parameter display layout.
- 7) **Main Menu:** Configure the system parameter.
- 8) **Pause Display:** Pause the monitor and close the monitor display

2.6.3 System Status Bar

System status bar is on the upper right and on the lower right, as illustrated in the right Figure.

- 1) Current time: shown 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.
- 4) Speaker volume: adjust the speaker volume in general setting.



2.6.4 Extended Soft Keys Area:

Click the **Extended Soft Keys Area** at the bottom of the display , the following **Extended Soft Keys Area** as illustrated in Figure3-4 will pop up.



Figure 3-4: Extended Soft Keys Area

- 1) **ViewBed:** Check other patients in network.
- 2) **C.O.Measure:** Enter C.O. window.
- 3) **OxyCRG:** Enter OxyCRG window.
- 4) **BISTrend:** Enter BISTrend window.
- 5) **History Review:** Enter History Review window.
- 6) **Trend Review:** View the physiological trend data in graphic trend or tabular trend view.
- 7) **Pharmacy Calculator:** Calculate drug concentration.
- 8) **Alarm Setup:** Set alarm properties for all parameters and set general alarm limits
- 9) **Config Manage:**
Import/Export or save user configuration.

10) Night Mode:

Switching between "night mode" and "day mode".

11) UsageInfo:

A new window will pop-up to show the current status of the monitor, including CPU usage, memory usage and runtime etc.



NOTE

- When turned on, this monitor will load automatically the latest configuration when it shut down last time.

2.6.5 Soft Keys Lists

Soft Keys Symbol	Soft Keys Name	Explanation	Soft Keys Symbol	Soft Keys Name	Explanation
	Setting	Enter setting menu		View Layout	Enter layout menu
	Alarm Paused	Pausecurrent 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		Display Paused	Pause current display
	Print	Start/Stop printing		ViewBed	View the monitoring information of other patients whose monitor is connected in LAN.
	C.O. Measure	Open Cardiac Output window.		OxyCRG	Enter OxyCRG window.
	BISTrend	Enter BISTrend window.		History Review	Enter History Review window.

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	Trend Review	Open trend review window for current patient.		Pharmacy Calculator	Open drug concentration calculation window
	Alarm setting	Open alarm setting menu		Config Manager	Open configuration management menu
	Night Mode	Turn on night mode			

3 Basic Operations

3.1 Description

The following section describes the basic operations 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
-
-



CAUTION

- 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

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 Power On

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

1. Check the patient monitor, and plug-in modules 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 “**LoadingSystem ...**” message, after 1-2min, the initialization of monitoring will begin after the with the **monitoring LOGO** on screen. Around 20s later, the initialization will be completed and the monitor enters the main screen. Now we could 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 appropriate measurement section for details of how to perform the measurements you require.

3.5 Stopping Monitoring or Turning Off the Power

To stop monitoring patient on a certain parameter:

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 above 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 the 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, soft 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.
-

4 Setup

To meet the patient needs in different clinical settings, you can set up the monitor accordingly in **General Menu**, **Printer Menu**, **Module Menu**, **Config Manager**. For specific parameter measurement, the related alarm setting is complex, thus we'll introduce its setup in separate chapters. This chapter introduces only the monitor setup you need before use.

4.1 General Menu

Select "**Main Menu**"  in the soft keys area → Enter "**General Menu**", as illustrated in Figure4-1.

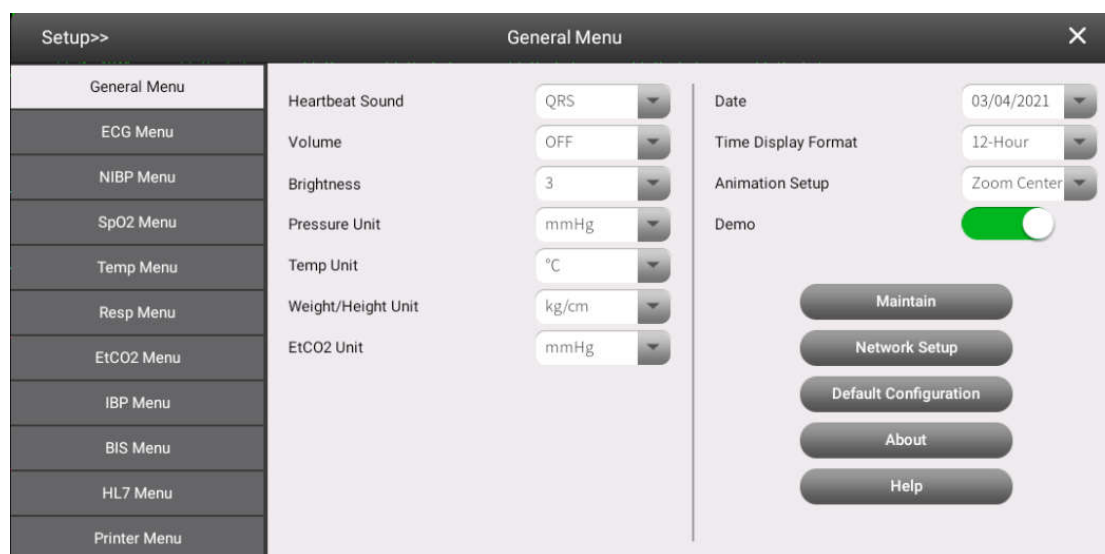


Figure 4-1: General Menu

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.

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) PressureUnit

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) TempUnit

Select “**Temp Unit**” and toggle between [°C] and [°F]. the default setting is °C.

6) Weight/HeightUnit

Select “**Weight/HeightUnit**” 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 causedata missing.
-

9) TimeDisplayFormat

Select “**TimeDisplayFormat**” drop-down menu and toggle between [24h] and [12h]. The default setting is [12h].

10) AnimationSetup

Select “**AnimationSetup**” drop-down menu and toggle between **ON** and **OFF**, the default setting is **OFF**.

11) Demo

Enter password to turn **ON/OFF** the demo.

12) Maintain

Select “**Maintain**” → Enter the corresponding key to request for manufacturer maintenance.

13) NetworkSetup

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

14) DefaultConfiguration

Select “**DefaultConfiguration**” → Configurations of this monitor will be restored to factory default setting.

15) About

Select “**About**” → Enter the basic information window of device and software, you can also upgrade software in this window, as shown in Figure 4-2.



Figure 4-2: “About” Window

To upgrade the firmware: Select “**Upgrade**” → Enter password as required to choose upgrade mode.

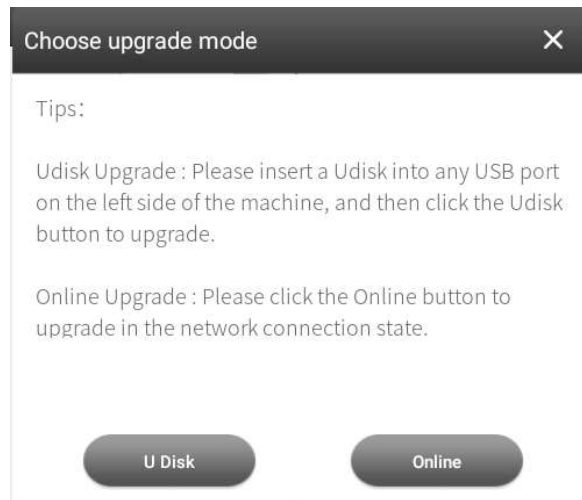


Figure 4-3: “Upgrade” Window

16) Help

Click “**Help**” → Download the video online to USB drive → Click and play the video.

4.2 HL7 Menu

Select “Main Menu”  → “HL7 Menu” to enter HL7 Menu, as illustrated in Figure 4-4.

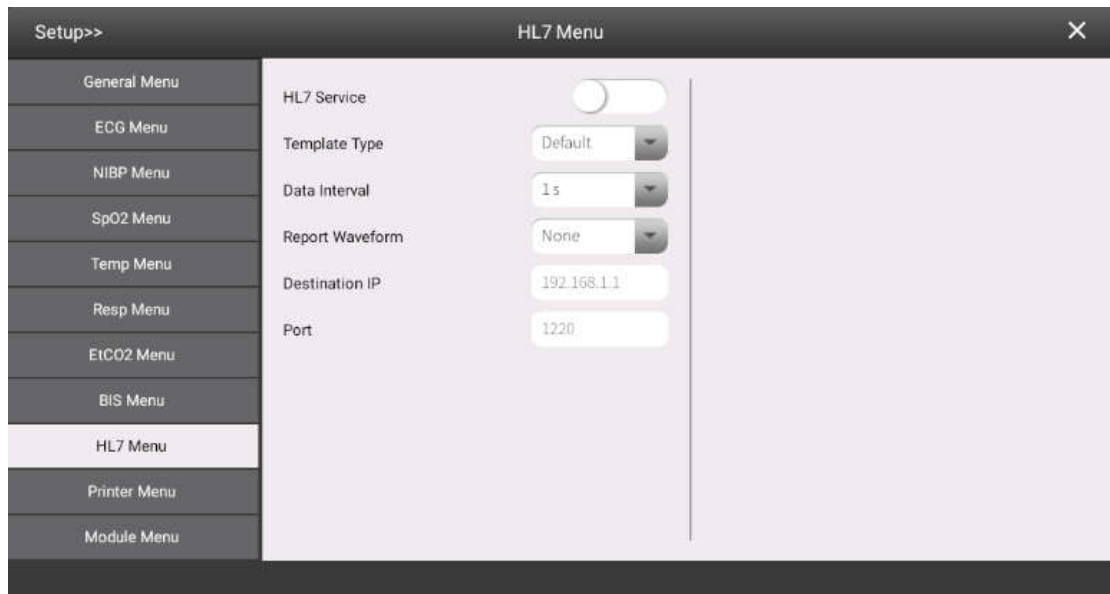


Figure 4-4: HL7 Menu

For patient data transmission, HL7 needs to be configured:

1) HL7 EnableService

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) TemplateType

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) DestinationIP

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 Printer Menu

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

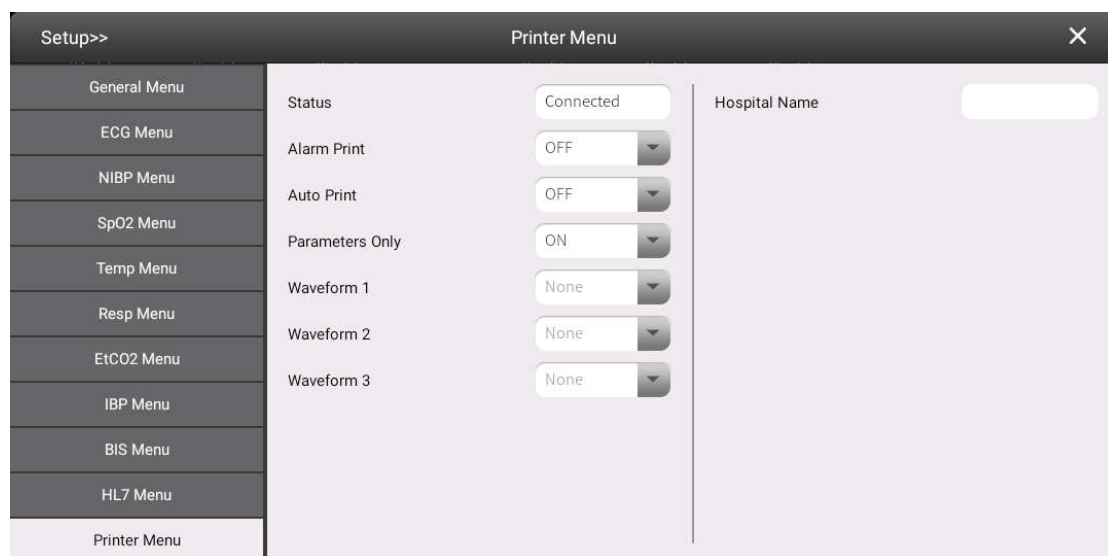


Figure 4-5: Printer Menu

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) Waveform1 ~ Waveform3

Select “**Waveform 1 ~ 3**” drop-down menu respectively to set the waveform parameter for

display.

4.4 Module Menu

Select “Main Menu”  → “Module Menu” to enter ModuleMenu window, as illustrated in Figure 4-6.

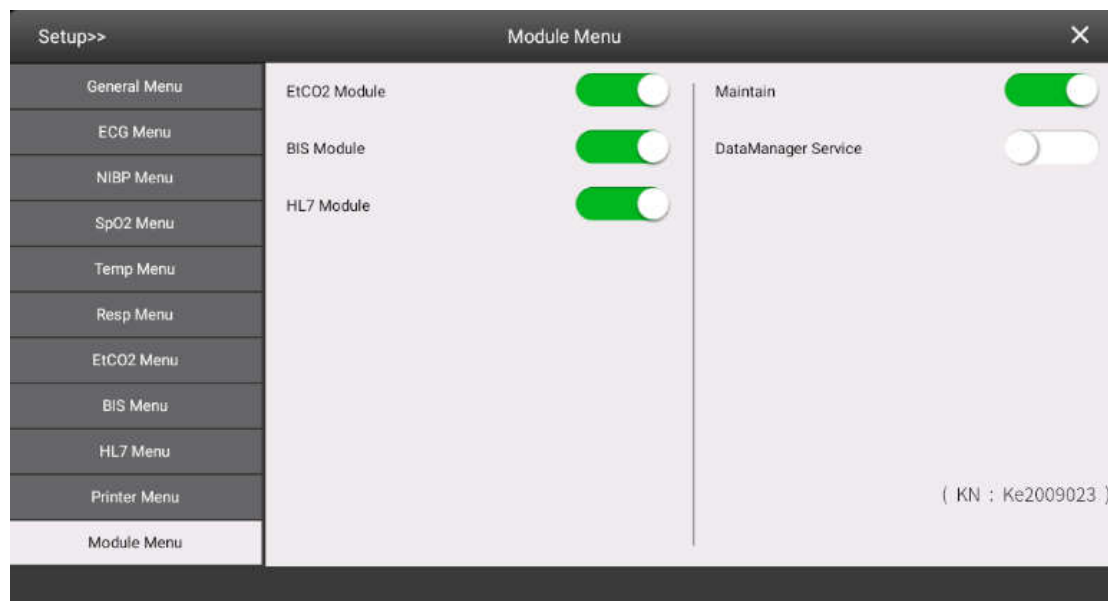


Figure 4-6: Module Menu

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 customize local configurations.

To access Configuration Management:

Select “**Config Manage**” in the extended softkeys area → **Configuration Management** window will appear, as illustrated in Figure 4-7.



Figure 4-7: Configuration Management

Current **Configurations** are all displayed in configuration management window. In the Figure, data of each row are stored in corresponding configuration file. Default configuration can only be loaded, operations other than this are all disabled, such as delete, save as, export etc.

1) Load

Click “**Load**”, the selected configuration will be loaded and take effect immediately.

2) Delete

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

3) Save

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

4) 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.

5) 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 softkeys area, the monitor will enter the **Pause Display** mode, the **“Pause Display”** window will appear, as illustrated in Figure 4-8.

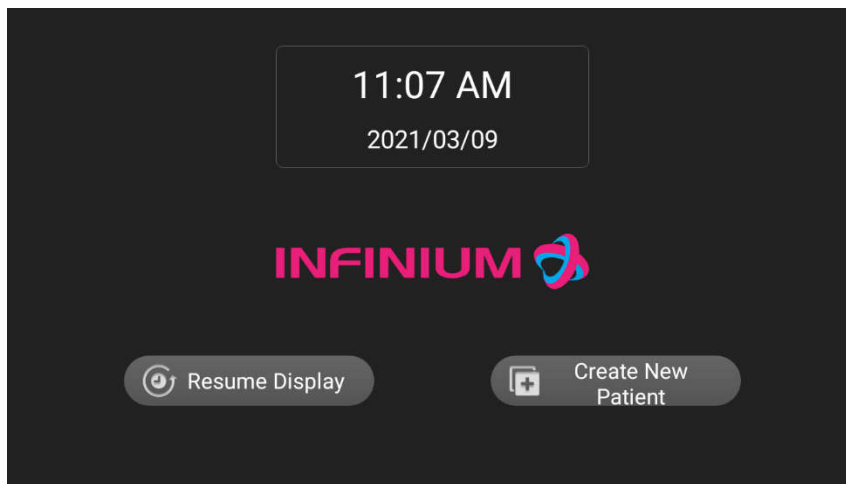


Figure 4-8: Pause Display

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 Omega12 patient monitor has five display modes: **Normal View**, **Big Font View**, **OxyCRG View**, **C.O. View**, and **BIS Real-time Trending View**, the display format of waveforms and parameters are different from each other in different display modes. For more details, see the explanation of each display mode.

5.1 Layout Setup

Click “**View/Layout**” , Enter **View/Layout** configuration window, as illustrated in Figure 5-1.

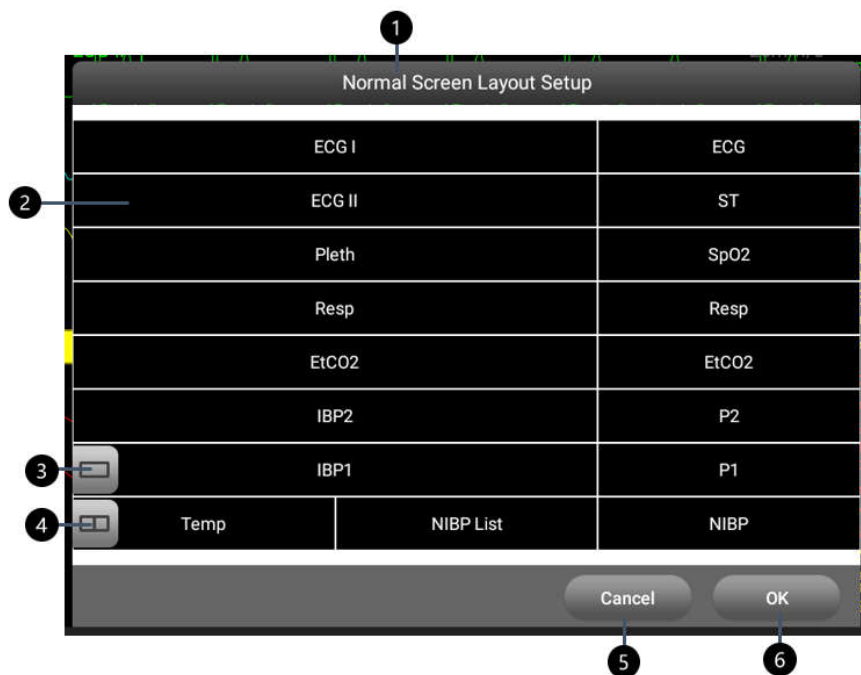


Figure 5-1: View/Layout

Number	Function Explanation
1	Normal Screen Layout: Display current layout: Normal View or Big Font View
2	View/Layout: Each cell in the table specifies the corresponding area, click the cell to fill in the selected parameters or waveforms for display.
3	Layout Merge (One cell) : Indicating that this one-cell waveform area is merged from 2 parameter areas.
4	Layout Merge (Two cells) : Click to merge 2 parameter area into one-cell waveform area.
5	Cancel: Click the button to cancel configuration changes and close the window

6	OK: Click the button, settings will be saved into configuration file and applied to monitor immediately, Normal Screen Layout will update.
---	---

**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.

5.2 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 5-2.

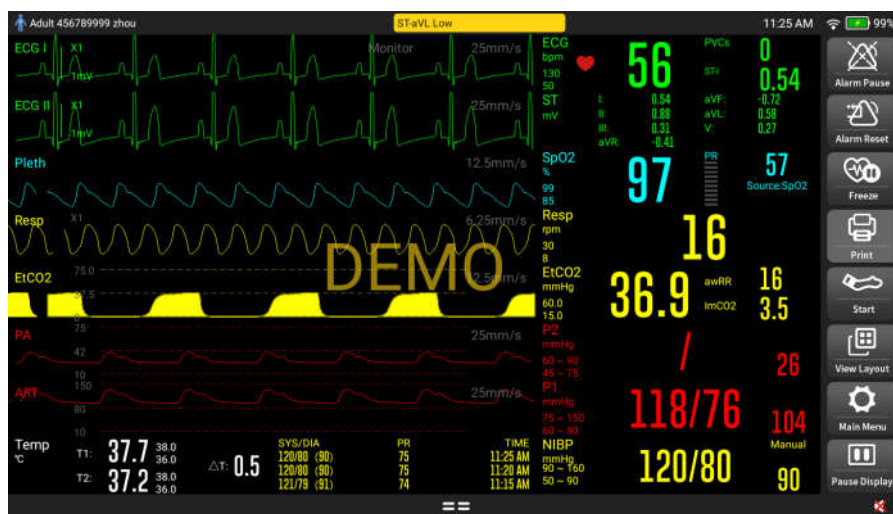


Figure 5-2: Normal View

The layout is demonstrated in Figure 5-3:

Normal Screen Layout Setup		
ECG I		ECG
ECG II		ST
Pleth		SpO2
Resp		Resp
EtCO2		EtCO2
IBP2		P2
IBP1		P1
Temp	NIBP List	NIBP
Cancel OK		

Figure 5-3: Normal View Layout

In this mode, the screen could display 8 waveforms at most on main page simultaneously. And you could select from 13 waveforms: **ECG I, ECG II, ECG III, ECG AVR, ECG AVF, ECG AVL, ECG V, Pleth, Resp, IBP1, IBP2, EtCO2, BIS**. Therefore, this mode is suitable for monitoring situations where multiple waveforms are needed for observation at the same time.

You can customize the layout in left bottom side of the last 2 rows by merging 2 parameter areas to form a one-cell waveform 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 3 columns at the bottom of the layout table is the mixed waveform-parameter area, which can flexibly meet your layout display demands. The 2 columns on the left can be merged into a waveform area, or the whole merging waveform area split into a 2-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.

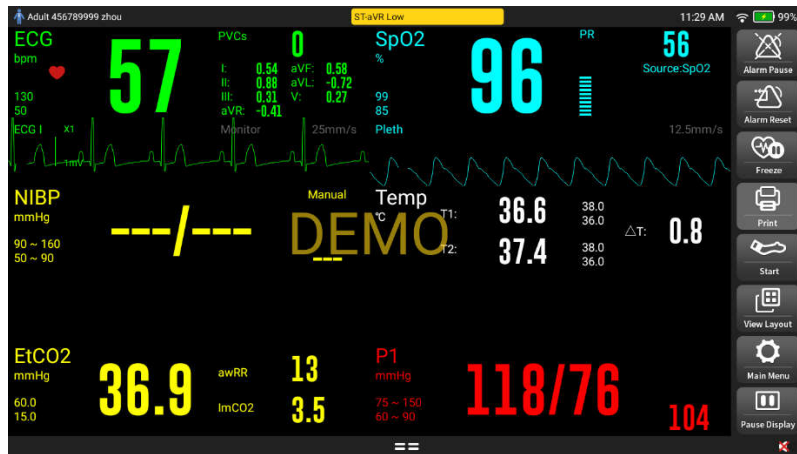


Figure 5-4: Big Font View

Figure 5-5 shows the layout setup of **Big Font View**, you could select 4 parameters with waveforms and 2 parameters without waveforms in **Big Font View** mode. This mode suits the critical monitoring situation for more convenient observation.

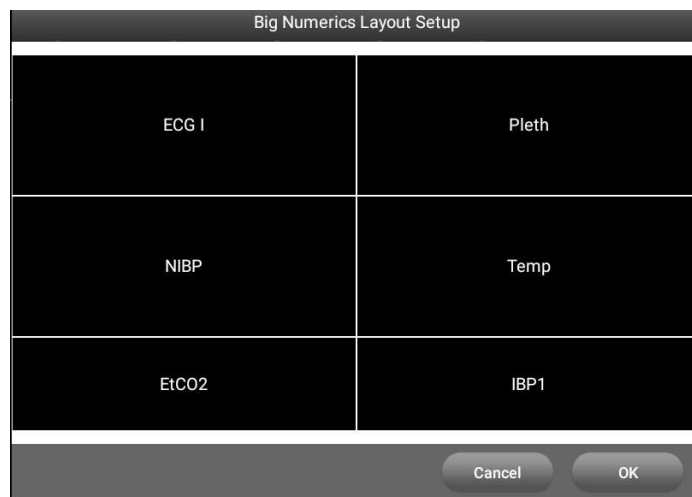


Figure 5-5: Big Font Layout Setup

To customize the **Big Font Layout**:

- Cells in the first 2 rows and the first 2 columns in the layout table can display parameters and its waveform simultaneously. Cells in the last row could only display parameters.
- There are 6 display areas in screen.

5.4 OxyCRG View

Select “OxyCRG” soft key , → Enter real-time OxyCRG View display page, as shown in Figure 5-6.

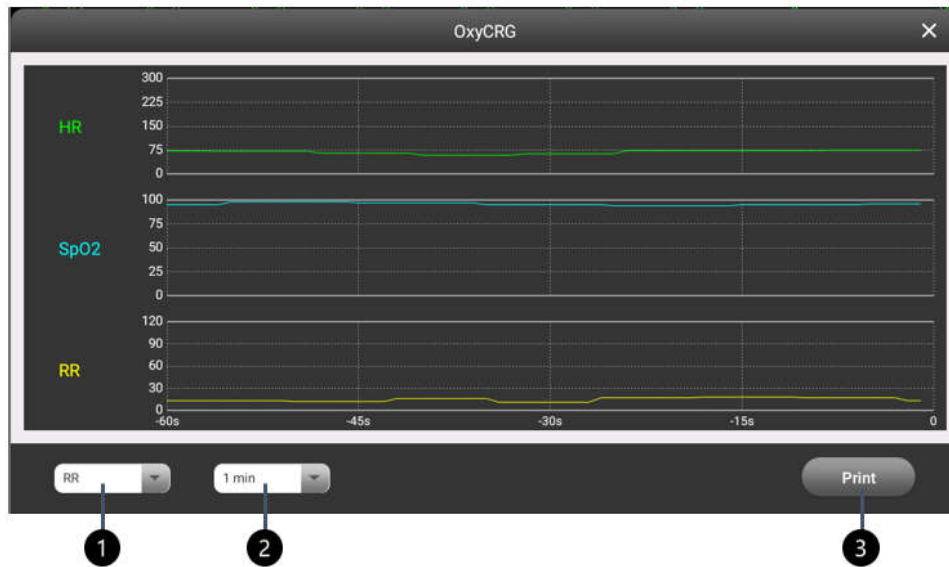


Figure 5-6: OxyCRG View

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 RespiratoryWaveform, only 1min time interval can be applied.
3	Print: Click “Print” to print out OxyCRG trend data or waveform in the current OxyCRG View.

5.5 C.O. Measure View

Select “C.O. Measure” soft key  → Enter **C.O. Measure View**, as shown in Figure 5-7.

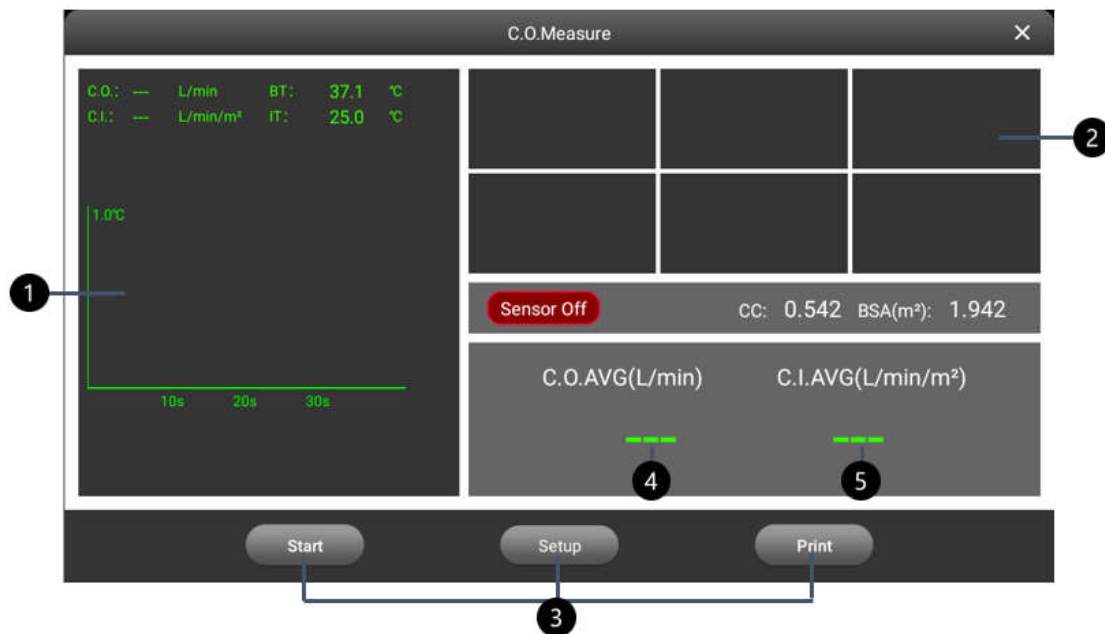


Figure 5-7: C.O. Measure View

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.

5.6 BIS Trend View

Select “BIS Trend”  → Enter **BIS Trend View**, as shown in Figure 5-8.



Figure 5-8: 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:

Alarm Indicator		High Level	Medium Level	Low Level	Reminder	Explanation
Alarm Lamp		Flashing Red Frequency: 2Hz Duty Ratio: 50%	Flashing Yellow Frequency: 0.5Hz Duty Ratio: 50%	Solid Blue Duty Ratio: 100%	/	/
Audible Alarm Tones	ISO	Triple + Double + Triple + Double Beep.	Triple Beep.	Single Beep.	/	Alarm tone is set to be distinct from heartbeat and pulse sound for easy identification.
	Infinium				/	
Alarm Message		Black Text with Red Background	Black Text with Yellow Background	Black Text with Blue Background	White Text	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.
Alarm Level Symbol		***	**	*	/	The symbol will appear before the alarm message appear
Alarm Parameter		Flashing			/	/

**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.

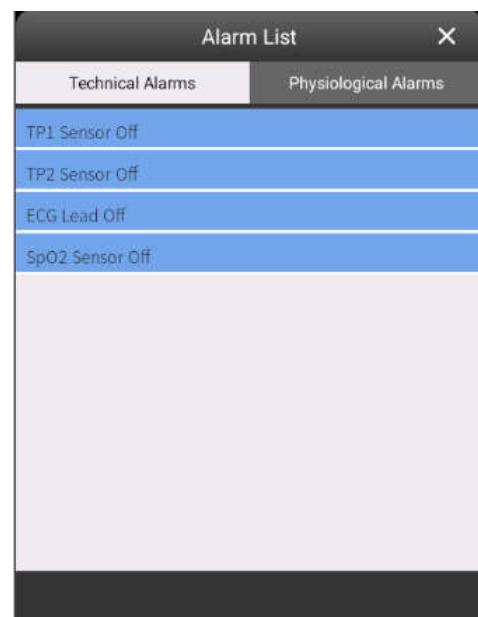


Figure 6-1: Alarm List

6.5 Alarm Setup

Select “**Alarm Setup**” in the extended softkey area → Enter **Alarm Setup** Menu

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 **alarmON/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 softkeys area → Select “**General Alarm Menu**”, You can set:

1) **Pause**: Select the drop-down menu to specify the pause mode for the softkey. 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 softkey 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 soft 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”** softkey. The softkey'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 softkeys 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”** softkey 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”** softkey.



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**” softkey.

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**” soft 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**” soft 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**” soft 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

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.

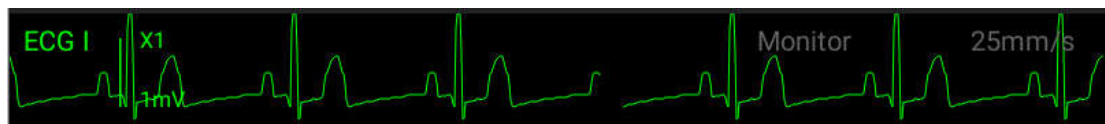


Figure 7-1: ECG Display

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.
- 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.

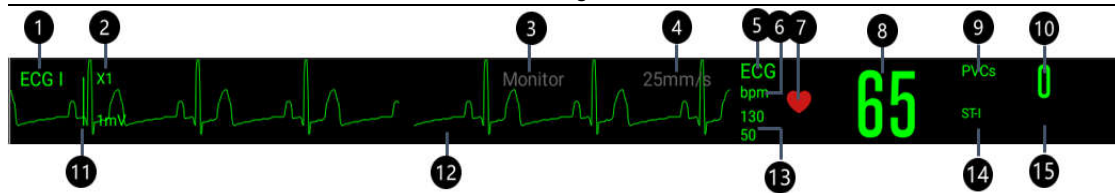


Figure 7-2: ECG Display

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:

- If necessary, shave hair from skin at chosen sites.
- Gently rub skin surface at application 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.

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.

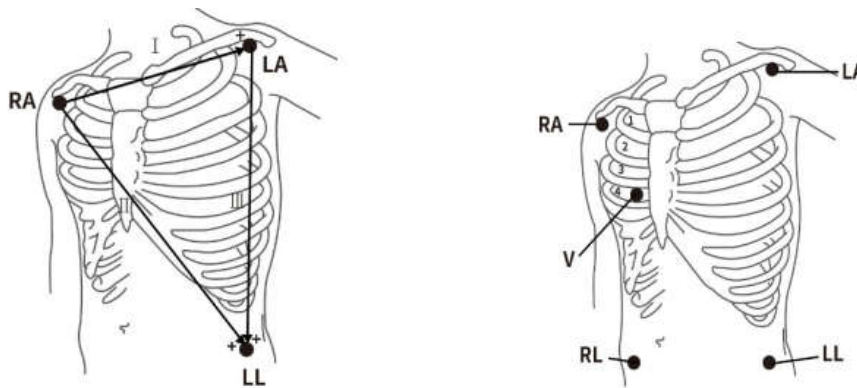


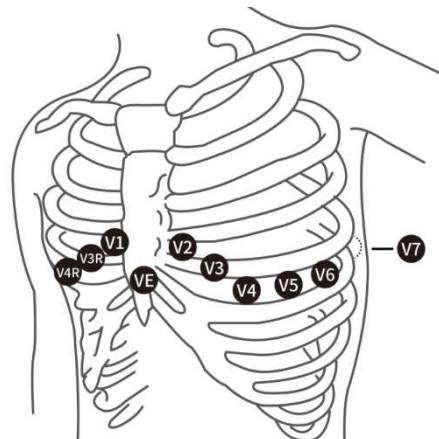
Figure 7-3: ECG Lead Placements

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.

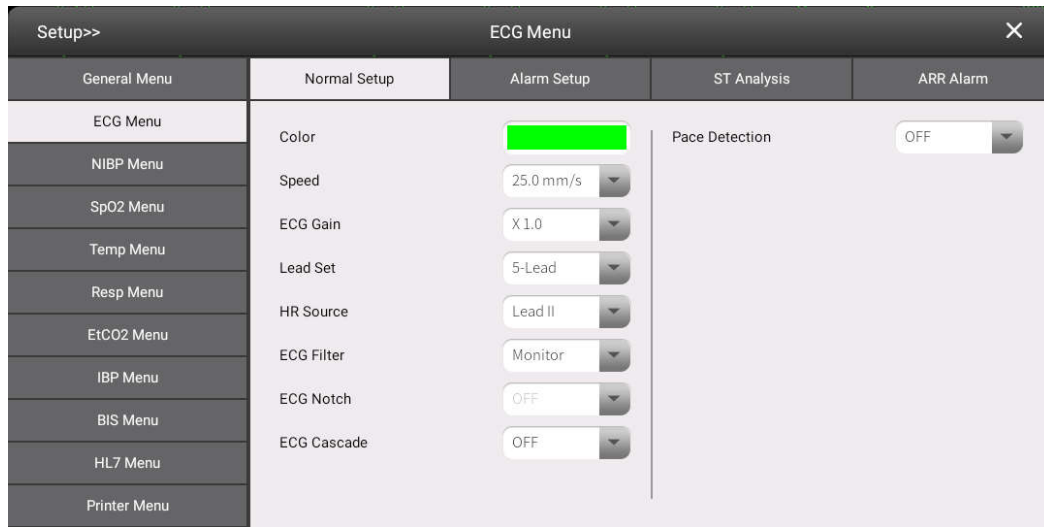


Figure 7-4: ECG Menu

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**.

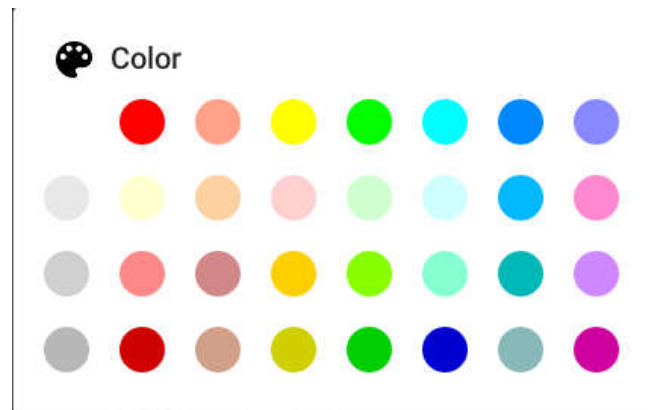


Figure 7-5: ECG Color Menu

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) ECGGain

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) HRSource

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

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- 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 **Surgeries** 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.

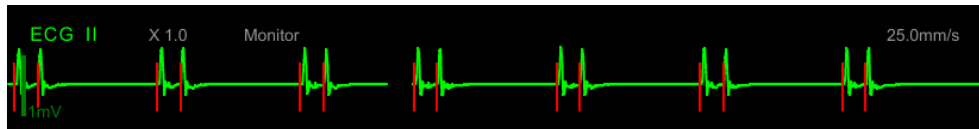


Figure 7-6: Pace Detection

7.5.2 ECG Alarm Setup

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

Alarm Setup>>		ECG Menu					×
General Alarm Menu	Name	Switch	Level	High Limit	Low Limit	Evt.Save	
ECG Menu	HR	☒	Medium	130	50	☐	
NIBP Menu	ST-I	☒	Medium	0.30	-0.30	☐	
SpO2 Menu	ST-II	☒	Medium	0.30	-0.30	☐	
Temp Menu	ST-III	☒	Medium	0.30	-0.30	☐	
Resp Menu	ST-aVR	☒	Medium	0.30	-0.30	☐	
EtCO2 Menu	ST-aVL	☒	Medium	0.30	-0.30	☐	
IBP1 Menu	ST-aVF	☒	Medium	0.30	-0.30	☐	
IBP2 Menu	ST-V	☒	Medium	0.30	-0.30	☐	
BIS Menu	PVCs	☒	Medium	10		☐	

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/III/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.

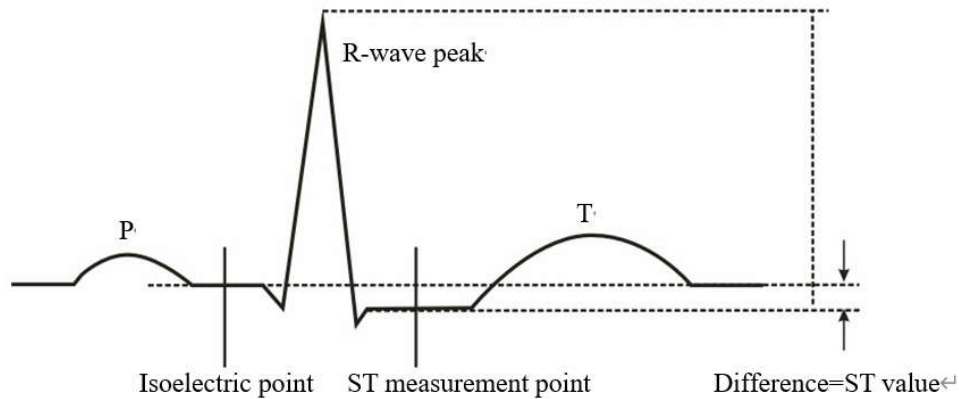


Figure 7-8: ST Segment

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.

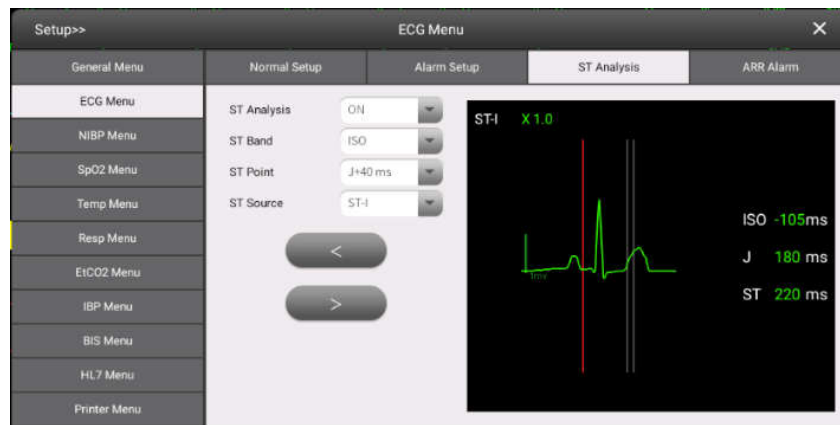


Figure 7-10: ST Setting

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.

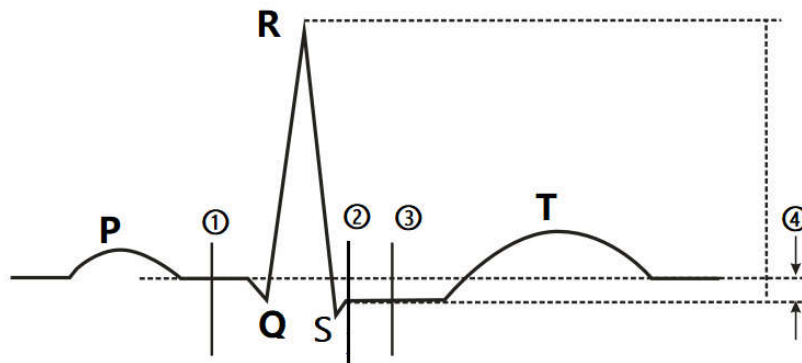


Figure 7-12: ST Measurement Adjustment

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, it is recommended that the ST point is set to J + 80 ms.

As shown in Figure 7-11 below:

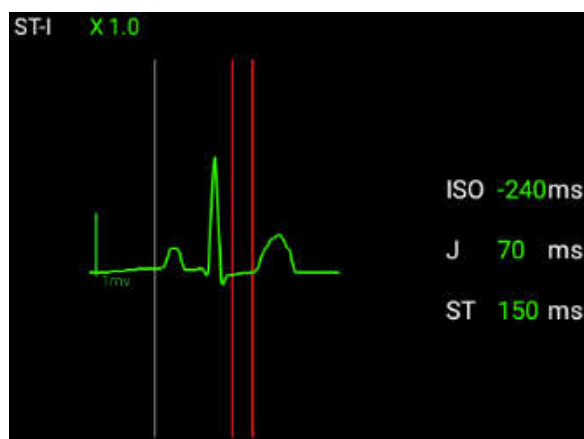


Figure 7-11: ST Measurement Points



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 “**ARRAlarm**” tab → Set the arrhythmia alarm for every arrhythmia condition according to your needs, as shown in Figure 7-12:

Name	Switch	Level	Record
ASY	☒	High	☐
FIB	☒	Medium	☐
VTA	☒	Medium	☐
ROT	☒	Medium	☐
RUN	☒	Medium	☐
TPT	☒	Medium	☐
CPT	☒	Medium	☐
PVC	☒	Medium	☐
BGM	☒	Medium	☐
TGM	☒	Medium	☐

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

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- 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.

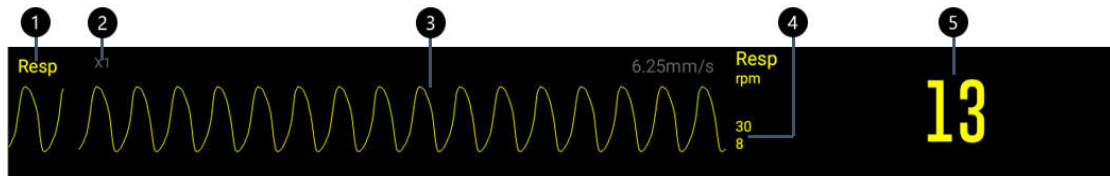


Figure 8-1: Resp Parameter and Waveform Display

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.

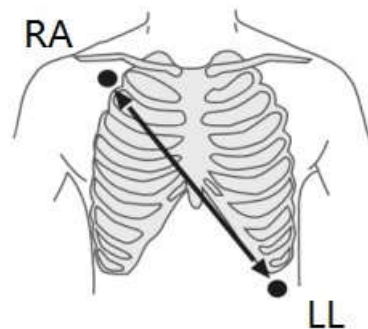


CAUTION

- 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:

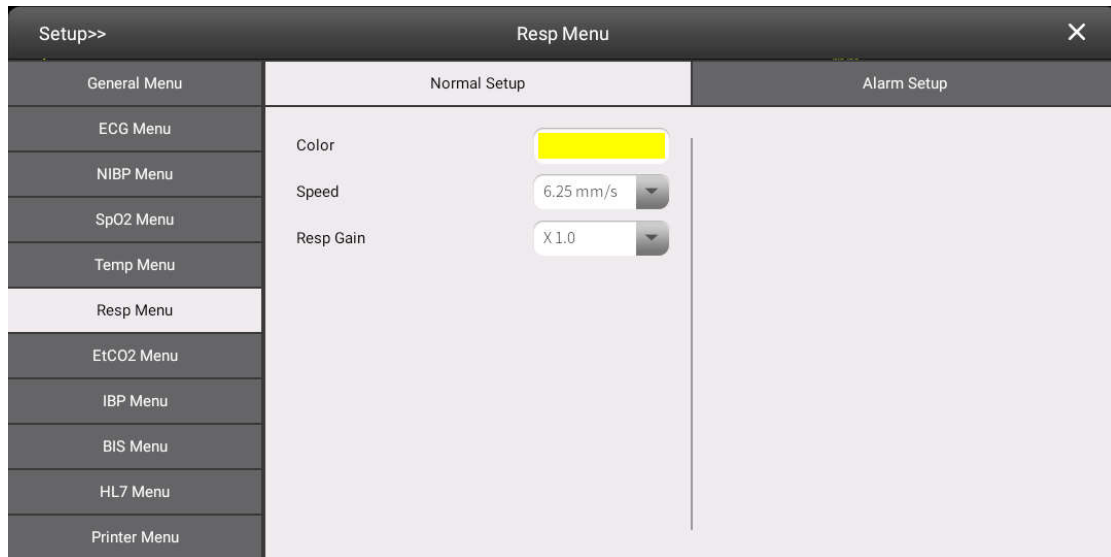


Figure 8-2: Resp Setup Menu

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 $\times 0.25$, $\times 0.5$, $\times 1.0$, $\times 2.0$. Resp Gain change will change the waveform size. The default Gain is $\times 1.0$.

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.

Name	Switch	Level	High Limit	Low Limit	Evt. Save
RR	☒	Medium	30	8	☐

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.

This device is calibrated to display functional oxygen saturation.

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.
 - Each pulse oxygen probe and extension line used with the monitor are specially designed for the monitor.
 - Before use, the responsible party or operator shall check the compatibility of the monitor with the probe and extension cable, otherwise it may cause patient injury.
-

 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

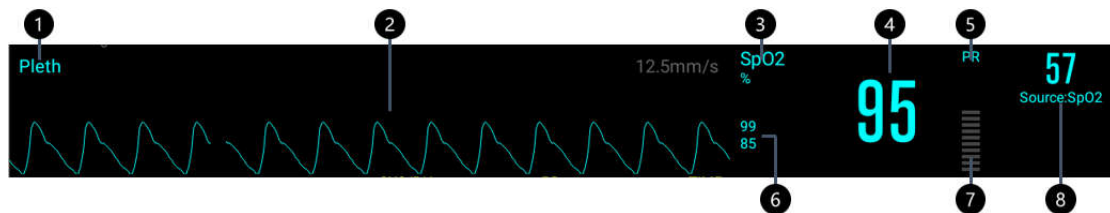
Many factors may cause inaccurate measurement:

- 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

Note:

(1) The amplitude of pleth waveform can directly reflect the strength of the patient's pulse signal. Pleth waveform is not normalized.

(2) The bar graph is directly proportional to the pulse intensity and can reflect the filling state of blood. As an indication of signal integrity, there are 15 grids in total. When it is less than 3 grids, the signal is weak and the measurement result may be inaccurate.

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.

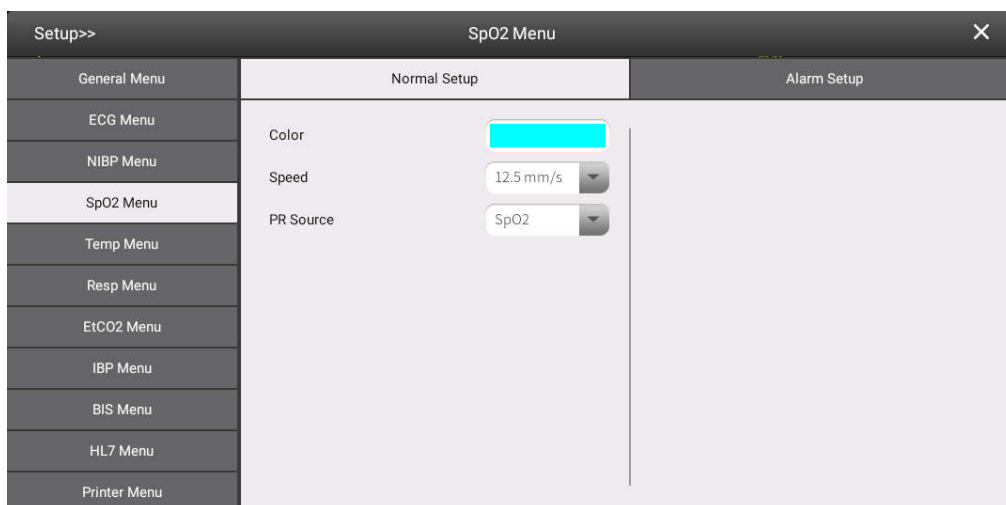


Figure 9-2: SpO2 Menu

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.

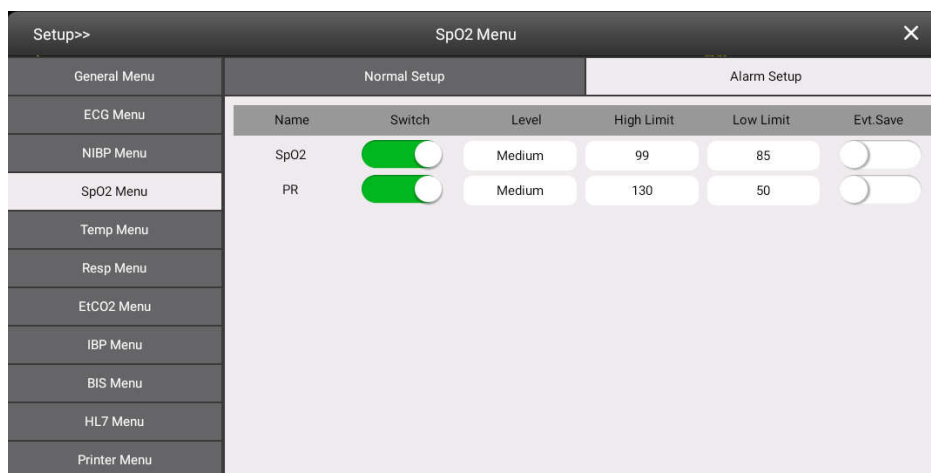


Figure 9-3: SpO2 Alarm Setup Menu

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 SpO2 sensor has become detached from the patient or the module
“SpO2 communication error”	There is a communication problem with the SpO2 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 *Appendix C Alarm messages*.

9.8 Manufacturer Information

This monitor supports 3 SpO2 module: BCI, Nellcor and Masimo module. For more information, please contact technical support or after-sales service personnel.

9.8.1 Masimo Information



- **Masimo Patents:**

For more information, please refer to Masimo website: <http://www.masimo.com/patents.html>.

- **No Implied License:**

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

9.8.2 Nellcor Information



- **Nellcor Patents:**

This device is covered under one or more the following U.S. Patents: 4,802,486; 4,869,254; 4,928,692; 4,934,372; 5,078,136; 5,351,685; 5,485,847; 5,533,507; 5,577,500; 5,803,910; 5,853,364; 5,865,736; 6,083,172; 6,463,310; 6,591,123; 6,708,049; Re.35,122 and international equivalents. U.S.A international patents pending.

- **No Implied License**

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

10 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. 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.

The monitor can be used to measure the temperature of the patient's surface and cavity. This monitor supports 2 channel temperature measurement, the temperature of 2 channels (T1 and T2) can be displayed at the same time, and the temperature difference between two channels (ΔT) can be calculated and displayed.

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.

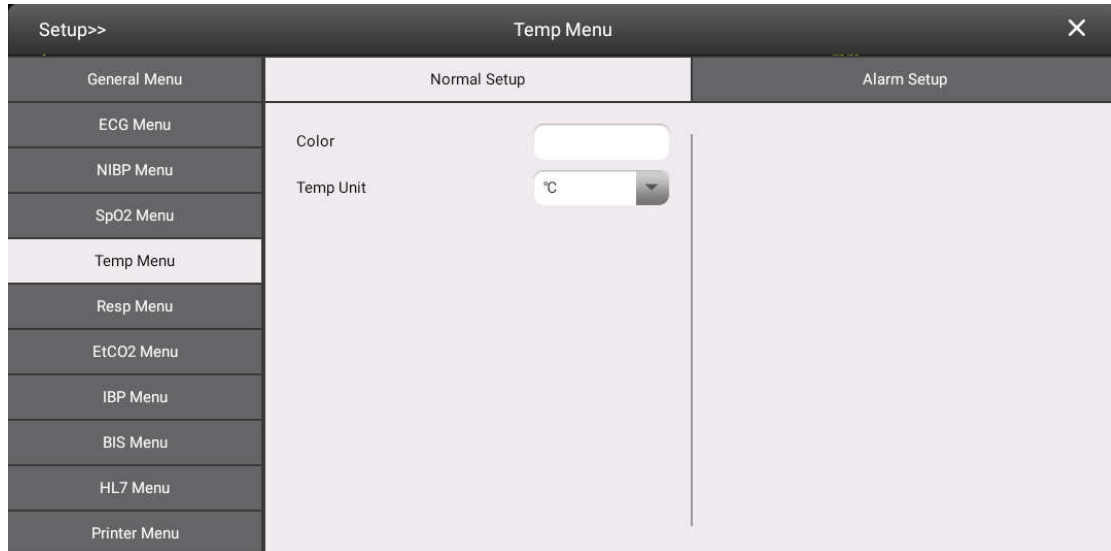


Figure 10-2: Temp Menu

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 °C and °F. The default temp is °C;

10.4.2 Temp Alarm Setup

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

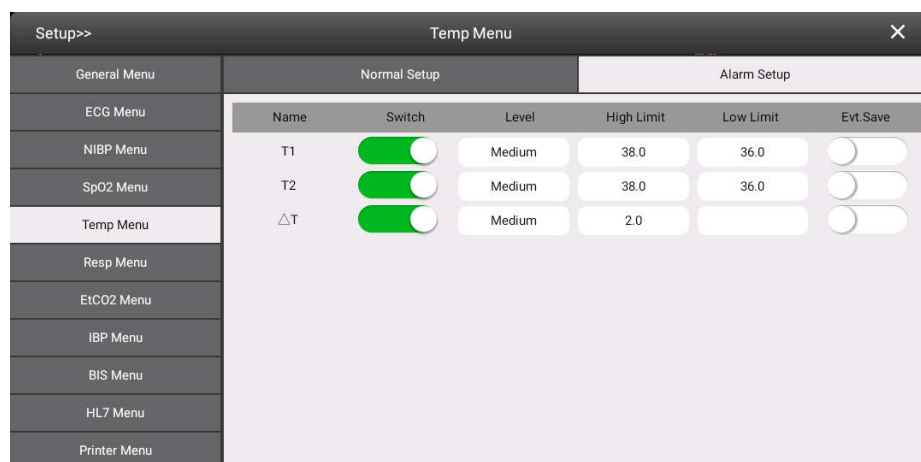


Figure 10-3: Temp Alarm Setup Menu

Temp alarm parameters are: T1, T2 and ΔT . Set T1, T2 and ΔT 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.
 - **Do not wear the cuff on the wound, otherwise it will cause further injury.**
-
-

- Avoid applying the cuff on the side of the mastectomy.
 - Cuff pressurization may cause temporary loss of the function of monitoring equipment used simultaneously on the same limb.
 - 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, determine 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 abnormality 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.

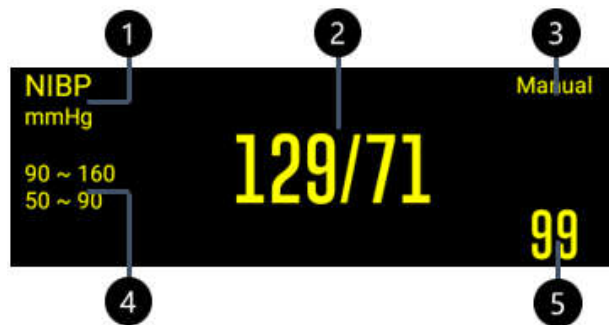


Figure 11-1: NIBP Numerics

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.



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.

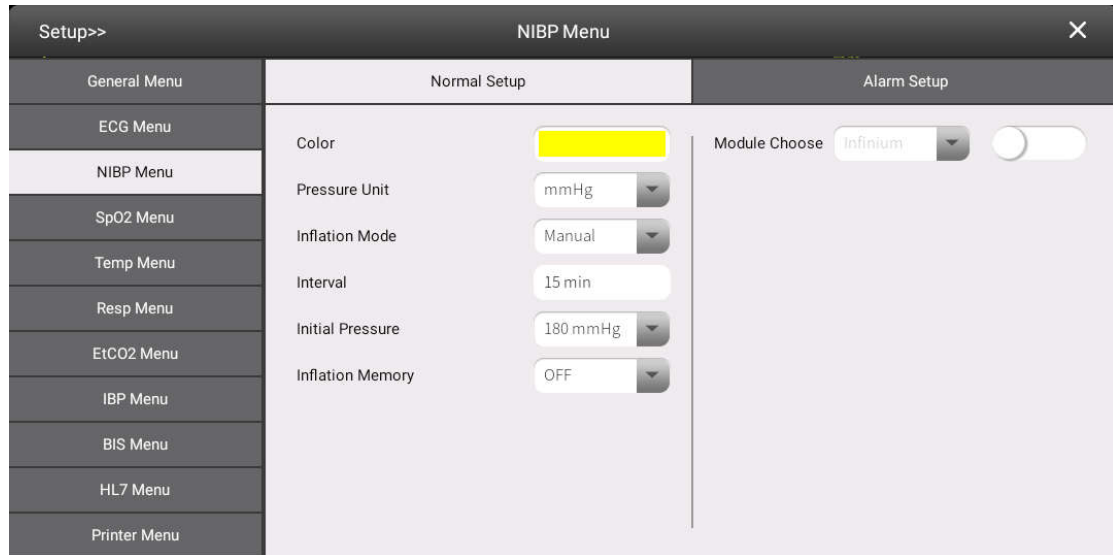


Figure 11-2: NIBP Setup Menu

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**, **SunTechHuman** or **SunTechAnimal**, 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.

Name	Switch	Level	High Limit	Low Limit	Evt. Save
SYS	☒	Medium	160	90	☐
DIA	☒	Medium	90	50	☐

Figure 11-3: NIBP Alarm Setup Menu

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

Patient Category \ Range	SYS High alarm limit (mmHg)	SYS Low alarm limit (mmHg)	DIA High alarm limit (mmHg)	DIA Low alarm limit (mmHg)
Adult	30~240 Factory Default Setting: 150	30~240 Factory default setting: 100	15~180 Factory default setting: 90	15~180 Factory default setting: 50
Neonatal	30~240 Factory default setting: 90	30~240 Factory default setting: 40	15~180 Factory default setting: 60	15~180 Factory default setting: 20
Pediatric	30~240 Factory default setting: 120	30~240 Factory default setting: 70	15~180 Factory default setting: 70	15~180 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.

SYS/DIA	PR	TIME
114/86 (84)	81	07:10 PM
122/78 (92)	73	07:05 PM
115/85 (85)	80	07:00 PM
115/85 (85)	80	06:55 PM
120/80 (90)	75	06:50 PM

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.



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

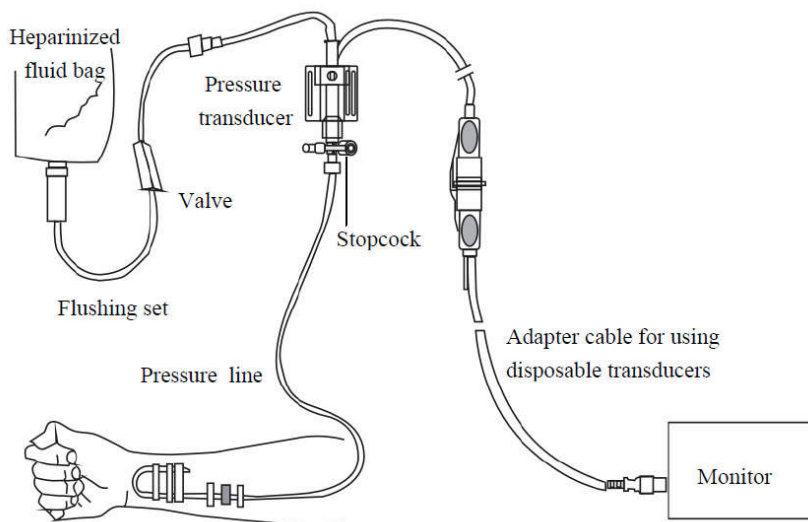


Figure 12-1: IBP Device Connection Diagram

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.

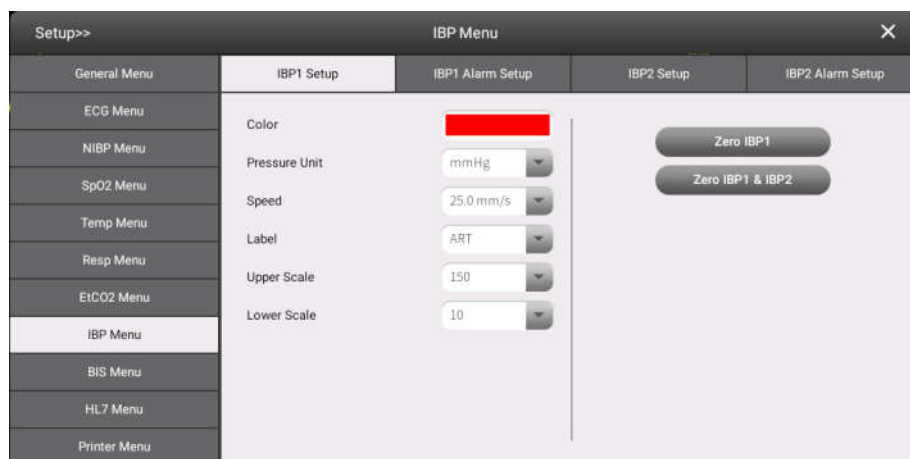


Figure 12-3: IBP Menu

12.5.1 IBP1/IBP2 Setup

In “**IBP Menu**” page → Select “**IBP1/IBP2 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 “**UpperScale**” drop-down menu to set waveform Upper Scale for display, options are 180,150,120,100,75. The default **UpperScale** is **150**.

6) LowerScale

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

7) Zero IBP1 or IBP2

Select “Zero IBP1/IBP2” → You can zero one channel at a time with selection Zero IBP1 or Zero IBP2.

8) Zero IBP1 & IBP2 Simultaneously

Select “Zero IBP1& IBP2” to zero both of them.

12.5.2 IBP1/IBP2 Alarm Setup

In “IBP Menu” window → Select “IBP1/IBP2 Setup” tab, as shown in Figure 12-3.

Name	Switch	Level	High Limit	Low Limit	Evt.Save
ART SYS	☒	Medium	150	75	☐
ART DIA	☒	Medium	90	60	☐
PA SYS	☒	Medium	90	60	☐
PA DIA	☒	Medium	75	45	☐
CVP MAP	☒	Medium	30	10	☐
RAP MAP	☒	Medium	30	10	☐
LAP MAP	☒	Medium	30	10	☐
ICP MAP	☒	Medium	30	10	☐

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 IBPTroubleshooting

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).

There are two methods for measuring CO₂ in the patient's airway:

1. Mainstream measurement uses a CO₂ sensor attached to an airway adapter directly inserted into the patient's breathing system.
2. Sidestream/Microstream 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.
-
-



CAUTION

- Disconnect the airway adapter during nebulization of medications.
 - EtCO₂ values may differ from blood gas readings.
 - Mechanical Shock must be avoided when using sidestream CO₂ with paramagnetic oxygen.
-
-



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.

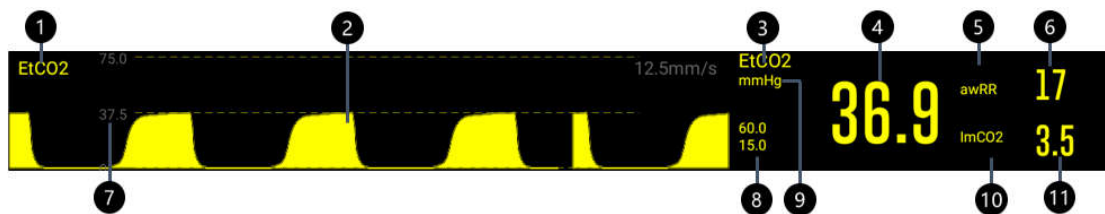


Figure 13-1: EtCO₂ Waveform and Parameter Display

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

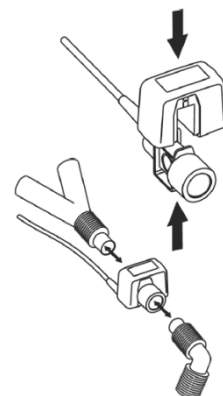
13.5 EtCO₂ Sensor Preparation

13.5.1 Preparing to Measure Mainstream CO₂

You must perform a zero as described in this procedure each time you use a new airway adapter.

1. Attach the sensor connector to the CO₂ connector on the MMS extension, or on the X2 (when the optional CO₂ measurement is integrated).

2. Wait 2 minutes, allowing the sensor to reach its operating



temperature and a stable thermal condition.

3. Choose the appropriate airway adapter and connect it to the sensor head. The airway adapter clicks into place when seated correctly.

4. 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.

5. Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y section.

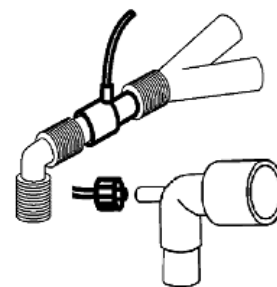
13.5.2 Preparing to Measure Sidestream CO₂

When ambient temperature change exceeds over 10°C (like, equipment transferring), Rezeroing must be performed with the instructions specified by this manual.

1. Plug the sensor cable into the monitor's CO₂ input connector. Allow the sensor two minutes warm up time.

2. Connect the cannula, airway adapter, or sample line as appropriate to the sensor. It will click into place when seated correctly.

3. Please follow 13.5.1 Step 3, 4, 5.



WARNING

- 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.



NOTE

- Be sure to set the barometric pressure properly before using the mainstream CO₂ module. Improper settings will result in erroneous CO₂ reading.
- 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.
- EtCO2 sensors are external module, thus please strictly adhere to the module manual for measurement operation.

13.6 EtCO2 Setup

Select EtCO2 waveform area parameter area on monitoring screen → Enter “**EtCO2 Menu**”, as shown in Figure 14-2.

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) WaveformType

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) WaveformScale

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 **1 Breath**, **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 Compens.** 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°C~50°C (50°F~122°F), the default gas temp is **35.0°C**.

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.
 - Be sure to set the barometric pressure properly before using the mainstream CO2 module. Improper settings will result in erroneous CO2 reading.
-
-

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.

Name	Switch	Level	High Limit	Low Limit	Evt. Save
EtCO2	☒	Medium	60	15	☐
awRR	☒	Medium	30	8	☐

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. For mainstream CO2 modules, no calibration is required. If calibration is needed, please contact the service personnel.



NOTE

- When Calibrating EtCO2 module, the sample gas must be connected to a scavenging system.

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 BIS

14.1 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.

14.2 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.

14.3 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 $\leq$ 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 BCParameter is valid only when SQI $\geq$ 15% and SR $\geq$ 5%.

14.4 BIS Display

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

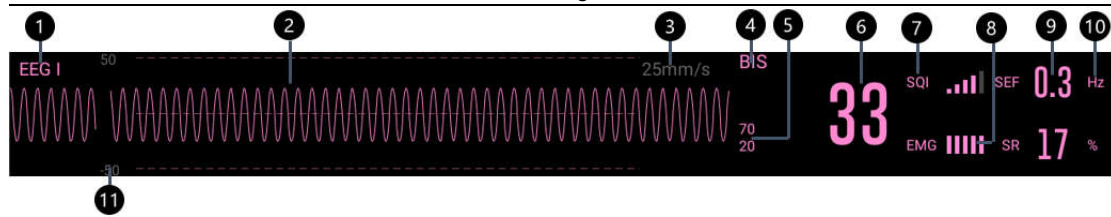


Figure 14-1: EEG Waveform Area and Parameter Area

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		

14.5 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.

14.6 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 14-2:

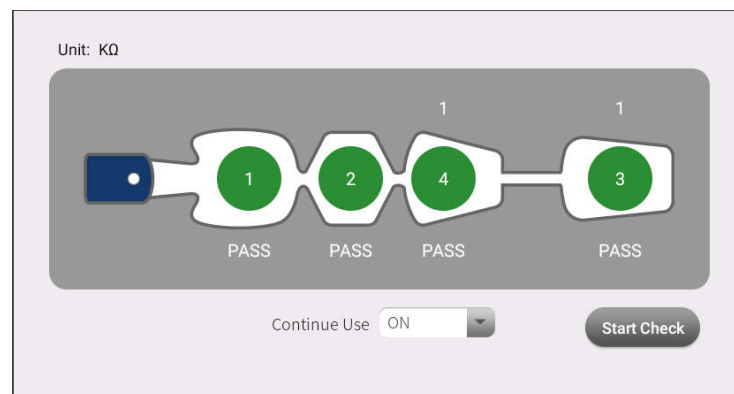


Figure 14-2: BIS Sensor Check

1) Unit

BIS impedancecheck unit: $K\Omega$ (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) StartCheck

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

the function by selecting **“StartCheck”**.



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.

14.7 BIS Setup

Select EEG waveform area or BIS area → Enter **“BIS Menu”**, as shown in Figure 14-3.

Figure 14-3: BIS Setup Menu

14.7.1 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 WaveformScale

WaveformScale is shown in the form of gridlines, corresponding to the magnitude of the scale line. Select “**WaveformScale**” drop-down menu to choose 50µV, 100µV, 200µV or 500µV.

8) SmoothingRate

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**.

14.7.2 BIS Alarm Setup

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

14.8 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*

15 C.O.

15.1 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.

15.2 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.
-

15.3 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°C lower than blood temperature.
- Inject solution rapidly and smoothly.
- Inject within four to five seconds.
- Inject at end expiration.

15.4 C.O. Display

Please refer to Chapter 5.5

15.5 C.O. Measurement

15.5.1 C.O. Equipment to Patient Connection

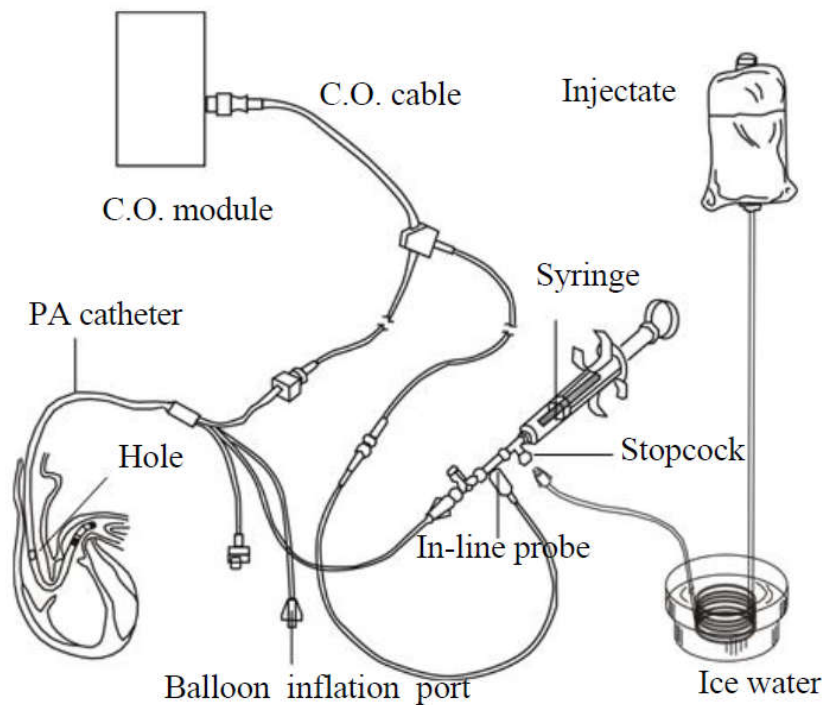


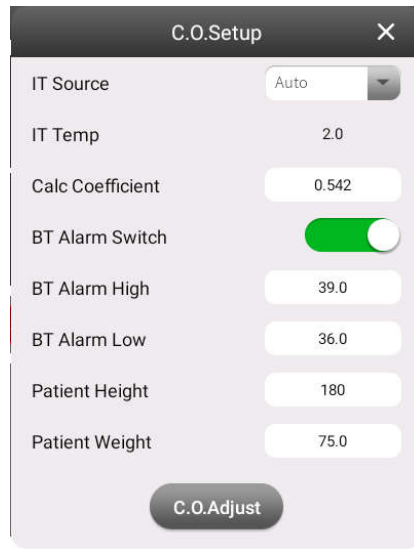
Figure 15-1: C.O. Equipment for Connection

15.5.2 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.

15.6 C.O. Setup

In “C.O. Measure” window → Select “Setup” → Enter “C.O. Setup”, as shown in Figure 15-2. You can set:



The screenshot shows the 'C.O. Setup' window with the following settings:

Parameter	Value
IT Source	Auto
IT Temp	2.0
Calc Coefficient	0.542
BT Alarm Switch	ON (Green)
BT Alarm High	39.0
BT Alarm Low	36.0
Patient Height	180
Patient Weight	75.0

At the bottom of the screen is a button labeled 'C.O.Adjust'.

Figure 15-2: 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°C. The default setting is **39.0°C**.

5) BT Alarm Low

Select “BT Alarm Low” menu → Enter **Alarm Low** value, valid range for input is 23.0 ~ 37.0°C, The default setting is **36.0°C**.

6) PatientHeight

Select “PatientHeight” menu → Enter **Height** value, valid range for input is 30~255cm.

7) PatientWeight

Select “PatientWeight” menu → Enter **Weight** value, valid range for input is 0.1~200.0kg.

15.7 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*.

16 Managing Patients

16.1 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 **defaultpatient**. 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 16-1.

Figure 16-1: Patient Information

You can set:

1) Department

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

2) BedNO.

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 LastName (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**.

16.2 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 soft 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**.
-
-

16.3 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.

16.4 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 softkeys 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"**.

17 Trends

17.1 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.

17.2 View Graphic Trends

Select “**Trend Review**” in the extended soft keys area → Select “**GraphicTrends**” tab, the graphic trends are shown in Figure 17-1.

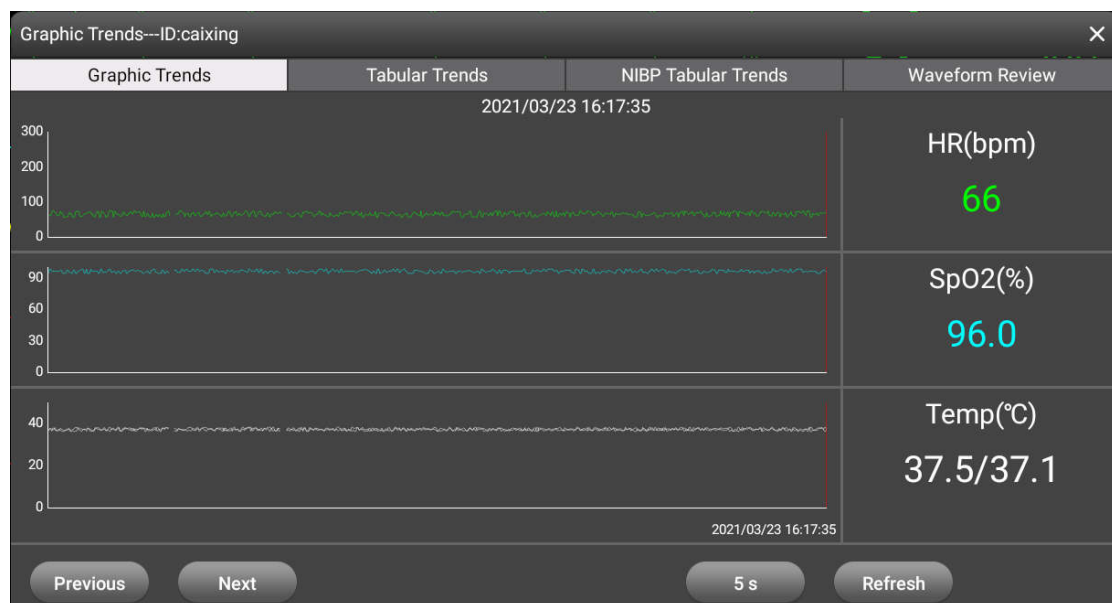


Figure 17-1: Graphic Trends

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.

17.3 View Tabular Trends

Select “**Trend Review**” in the extended soft 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.

Tabular Trends---ID:caixing										
Graphic Trends		Tabular Trends			NIBP Tabular Trends			Waveform Review		
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 “**TrendGroup**” 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.

17.4 View NIBP Tabular Trends

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

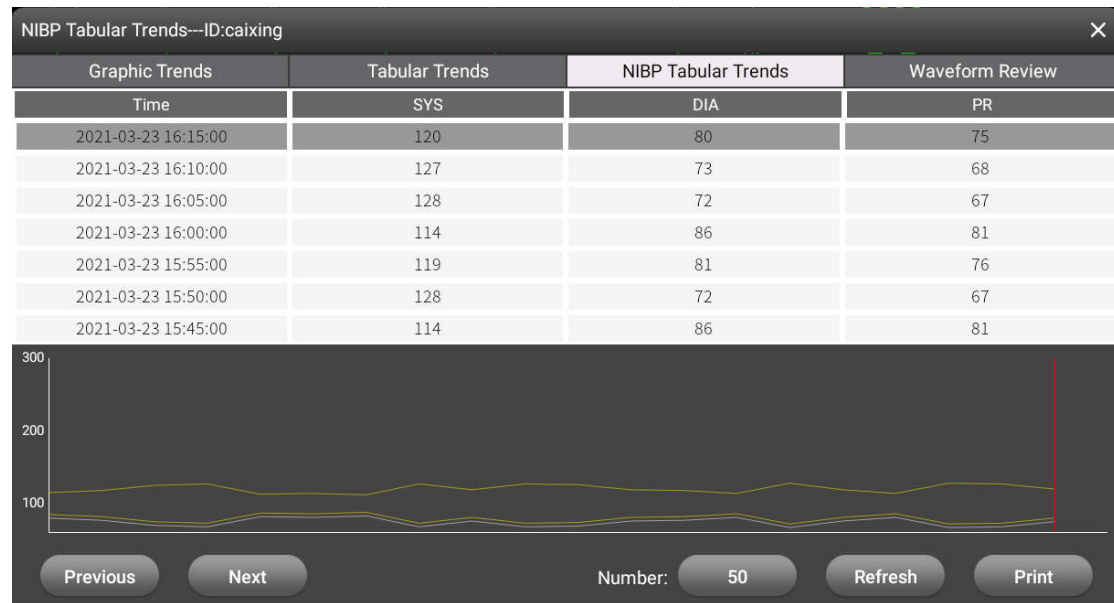


Figure17-3: NIBP Tabular Trends

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.

17.5 Waveform Review

Select “**Trend Review**” in the extended soft 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.

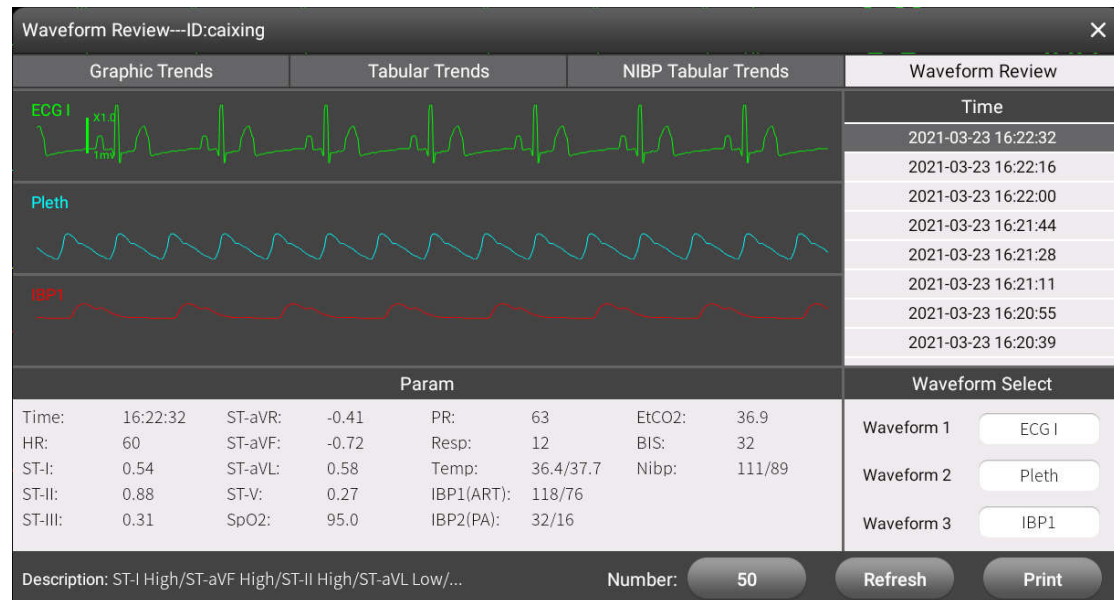


Figure 17-4: Waveform Review

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.

18 Patient History Data

18.1 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 **GraphicTrends**, **Tabular Trends** or **Waveform Review**, and export the historical data for analysis.

18.2 History Data

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

History Review			
History Data			
Type	Information	Time	Update Time
	ID: default	2021-02-05 14:56:07	2021-03-01 14:20:35
	ID: qwessrdserrg	2021-03-01 14:21:25	2021-03-03 16:03:20
	ID: 123123123	2021-03-03 16:07:02	2021-03-05 11:11:25
	ID: 456789999	2021-03-05 11:26:16	2021-03-10 16:23:35
ID: 123123123 Age: 23 Start DateTime: 2021-03-03 16:07:02 FN: strong Height: 180 Waveform Record: 0 Group LN: test Weight: 75.0 I.C.O Graphics: 0 Group Gender: Male			
 Delete  Lock  Export  Open			

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) Lock/Unlock

Select “**Lock/Unlock**” to lock/unlock the selected patient history data. Once locked, the selected data can neither be overwritten nor be deleted.

3) Export

Select “**Export**” to export data. You can export the selected history data to the plugged USB

drive.

4) 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 17 Trend Review*.

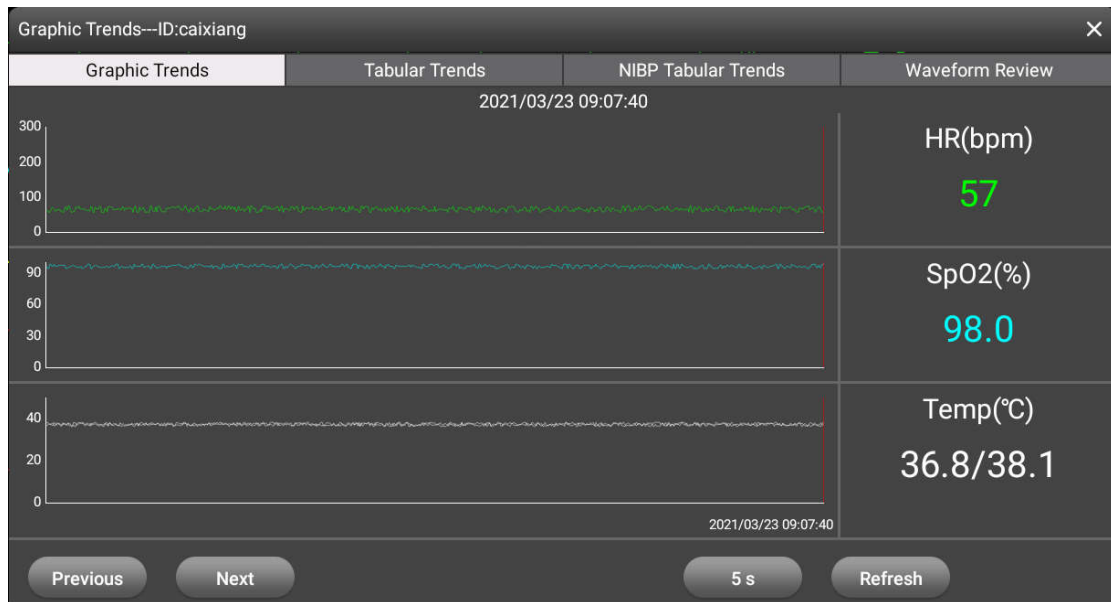


Figure 18-2: History Trend Review

19 Freezing Waveforms

19.1 Description

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.

19.2 Freezing Waveforms

When waveform is not frozen, select “Freeze”  soft keys to enter freezing process → Freeze window will pop up after the process is completed, as shown in Figure 19-1.

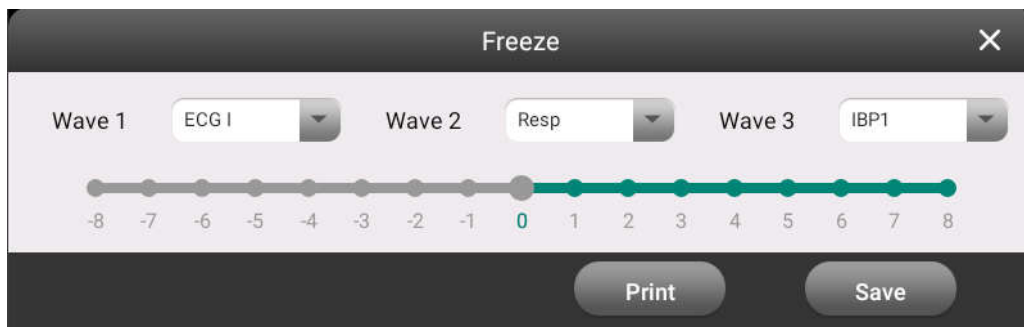


Figure 19-1: Freezing Waveforms

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.

19.3 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.

19.4 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.

19.5 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.

20 Pharmacy Calculations

20.1 Description

This monitor provides **PharmacyCalculation** 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 soft 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 soft 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	Amount = Dosage × Infusion Time
Amount (Weight-dependent)	unit series: unit, KU, MU mEq series: mEq	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 soft 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**” Soft 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, SpO₂, NIBP SYS /DIA, Resp, Temp, ST segment and hospital name, etc.

Printing example is shown in Figure 21-1. (For illustration only)

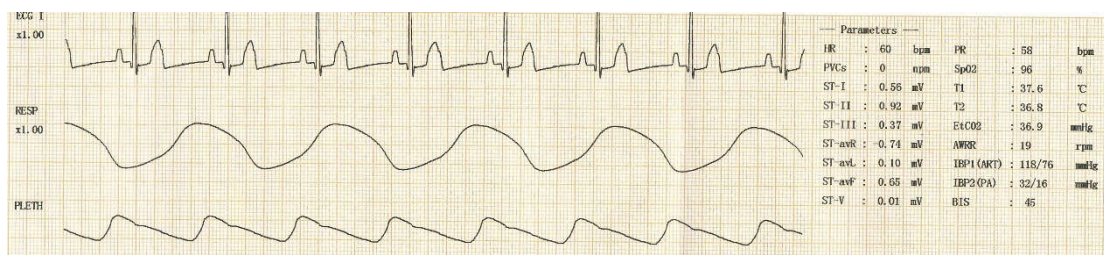


Figure 21-1: Real-time Waveform Printing Report

21.4.2 Printing Procedure

Select **“Print”** in soft keys area to start printing → Text on the soft key will change to **“StopPrinting”** → After printing is completed, you can get the report.

If you want to stop the printing → Select **“StopPrinting”** → Printing stops immediately → Text on the soft 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 08:42:23	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 08:33:13	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 08:19:37	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 soft keys area → Enter Trend Review page.
2. Select **“TabularTrend”** 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:

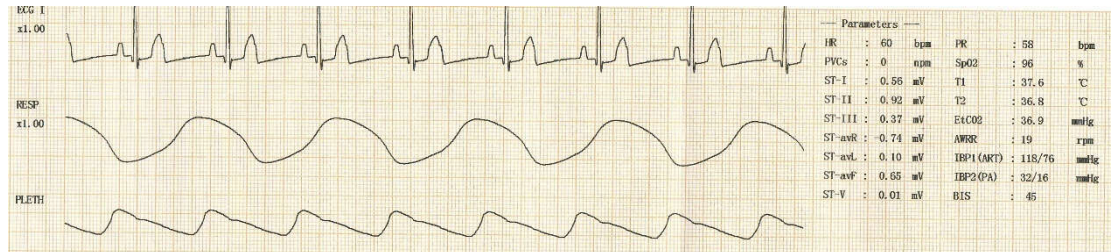


Figure 21-3: Alarm Event Printing Report

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.

Patient Information		NIBP List (Unit : mmHg)		
		Date/Time	SYS/DIA	PR
Dept.	: 23123	2021-03-10 15:30:00	122/78	73
Bed No.	: 33	2021-03-10 15:25:00	116/84	79
ID	: 456789999	2021-03-10 15:20:00	124/76	71
Name	: will	2021-03-10 15:15:00	114/86	81
Gender	: Male	2021-03-10 15:10:00	121/79	74
Age	: 22	2021-03-10 15:05:00	125/75	70
Height	: 180 cm	2021-03-10 15:00:00	122/78	73
Weight	: 75.0 kg	2021-03-10 14:55:00	115/85	80
.....		2021-03-10 14:50:00	119/81	76
NIBP Type	: Adult	2021-03-10 14:45:00	124/76	71
.....		2021-03-10 14:40:00	122/78	73
Hospital	:			

Figure 21-4: NIBP List Printing Report

21.7.2 Printing Procedure

1. Select “Trend Review”  in extended soft keys area → Enter **Trend Review** page.
2. Select “NIBP TabularTrend” 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

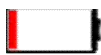
Battery Power Indicators, On-screen battery symbols and battery alarm message indicate the current status of the battery.

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 Check 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 battery 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°C~35°C. 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 Care, Cleaning and Maintenance

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 Disinfecting

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 Maintenance

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 abnormality, do not use the patient monitor. Contact the hospital's biomedical engineers or your service personnel immediately.

24 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.

24.1 ECG Accessories

Name	Model	explain	Type	Remark	Manufacturer

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24.2 SpO2 Accessories

Name	Model	Type	Remark	Manufacturer

Wavelength emitted by pulse oximetry probe is 600 ~ 1000nm, The maximum photic output consumption of the sensor is less than 18 mW.

The information about the wavelength range and maximum photic output consumption can be especially useful to clinicians, for example, clinicians performing photodynamic therapy.

A Specifications

A.1 Safety Specifications

A.1.1 Classifications

The patient monitor is classified, according to IEC60601-1:

Type of protection against electrical shock	I
Degree of protection against electrical shock	CF: ECG、NIBP、TEMP、IBP、C.O. BF: SpO2、ETCO2、BIS
Mode of operation	Continuous
Degree of protection against harmful ingress of water	IPX2

A.1.2 Environmental Specifications

Item	Temperature (°C)	Relative humidity	Barometric (kPa)
Operating conditions	5°C~40°C	15%~95%	80kPa~105kPa
Storage conditions	-20°C~55°C	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	10.89V DC
Volume	5200 mAh
Run Time	More than 2h in continuous operation (For new, fully-charge battery, with ambient temperature: 25°C)
Charge Time	Monitor ON or OFF: Charge 90% within 4 hours and full within 5 hours

A.3 Hardware Specification

A.3.1 Display Specification

Screen Type	TFT-LCD
Screen Size	12.5 inch
Resolution	1366x768 @ 60hz (24bit Colors)

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

Power	1 AC power connector
Ethernet Port	1 1000M Ethernet port
USB	2 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.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 ● BISTrend View ● C.OMeasure View ● View Bed
InternalStorage	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/DDHH:MM 12H: YYYY/MM/DDH:MM AM/PM Turn on automatic synchronization, when the monitor is connected to WLAN. Time is automatically synchronized with network time.
USB Extension	USBKeyboard USBMouse USB Flash Disk ● USBCode 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 FlashDisk 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	ECGmodule Resp module Temp module NIBPmodule *EtCO2module (External) *BISmodule (External)
Dynamic Module	SpO2module IBPmodule C.Omodule
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 PatientMonitor $\longleftrightarrow$ PatientMonitor
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 ($\times 0.25$), 5mm/mV ($\times 0.5$), 10mm/mV ($\times 1$), 20mm/mV ($\times 2$); error $\leq \pm 10\%$
Speed	12.5 mm/s, 25 mm/s, 50 mm/s; error $\leq \pm 5\%$
Mode	Diagnostic mode Monitor mode Surgical mode

User's Manual for Omega 12 Patient Monitor

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	$\geq 5\text{M}\Omega$
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	$\leq \pm 300\text{mV}$
Lead-off Detection Current	Measuring electrode: <0.1uA Drive electrode: <1uA
Baseline Recovery Time	<5s
Patient Leakage Current	<10uA
Calibration Signal	1mV (peak-to-peak value) $\pm 10\%$
ESU Protection	Cut mode: 300W Coagulate mode: 100W Recovery time: $\leq 10\text{s}$
PACE Pulse	
Pace Pulse Markers	Pace pulses meeting the following conditions are labeled with a PACE marker: Amplitude: ± 2 to $\pm 700\text{ mV}$ 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 $\pm 700\text{ mV}$ Width: 0.1 to 2ms Risettime: 10 to 100 μs
Pacemaker Pulse Rejection of Fast ECG Signals	25V/s $\pm 15\%$ RTI
HR	
Measurement Range	15bpm~300bpm
Resolution	1bpm
Accuracy	$\pm 1\text{ bpm}$ or $\pm 1\%$, whichever is greater.

HR Averaging Method	In compliance with the requirements in Clause 4.1.2.1 d) of ANSI/AAMI EC13-2002, the following method is used: the 4 most recent RR intervals are averaged to compute the HR. The HR value displayed on the monitor screen is updated every 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	≤ 12 s
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	$\pm 15\%$ or ± 0.05 mV 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

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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	15~ (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: $\leq \pm 2$ rpm 0rpm~6rpm: Not specified
Speed	6.25mm/s, 12.5mm/s, 25.0mm/s
Display Gain	$\times 0.25$, $\times 0.5$, $\times 1.0$, $\times 2.0$
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	
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 accuratemeasurement	Body surface: <100 s Body cavity: <80 s	
Refreshing rate	1s	
TempDifference 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
Speed	12.5mm/s, 25.0mm/s
Module Type	Infinium module, Nellcor module, Masimo module
Alarm Limit	Range
SpO ₂ Alarm High	(Low limit + 1) ~ 100% Infinium/Nellcor module: Default value: 99% Masimo module: Default value: 99.9%
SpO ₂ Alarm Low	0 ~ (high limit - 1) % Infinium/Nellcor module: Default value: 85% Masimo module: Default value: 85.0%
PR Alarm High	(High limit + 2) ~ 300bpm
PR Alarm Low	15 ~ (low limit - 2) bpm
PI Alarm High (Masimo)	(Low limit + 0.2) ~ 20.0% Default value: 20.0%
PI Alarm Low (Masimo)	0.0% ~ (high limit - 0.2) % Default value: 0.3%
SpO₂ Alarm Response Time	≤ 12s
Infinium Module	
Measurement Range	0% ~ 100%
Resolution	1%
Accuracy	70% ~ 100%: ≤ ±2% 0% ~ 69%: Not specified
Refreshing rate	1s
Low Perfusion Conditions	0.3% ~ 20%
Pulse Rate	
Measurement Range	30bpm ~ 250bpm
Resolution	1bpm
Accuracy	≤ ±2 bpm (measured without motion) ≤ ±3 bpm (measured with motion)
Nellcor Module	
Measurement Range	0% ~ 100%
Resolution	1%
Accuracy	Adult/Pediatric: 70% ~ 100%: ≤ ±2% Neonate: 70% ~ 100%: ≤ ±3% 0% ~ 69%: Not specified

Refreshing rate	1s
Low Perfusion Conditions	NA
Pulse Rate	
Measurement Range	20bpm~250bpm
Resolution	1bpm
Accuracy	20bpm~250bpm: ± 3 bpm
Masimo Module	
Measurement Range	0%~100%
Resolution	0.1%
Accuracy	Adult/Pediatric 70%~100%: $\leq \pm 2\%$ Neonate 70%~100%: $\leq \pm 3\%$ 1%~69%: Not specified
Refreshing rate	1s
Low Perfusion Conditions	0.02%~20%
Pulse Rate	
Measurement Range	20bpm~250bpm
Resolution	1bpm
Accuracy	20bpm~250bpm: ± 3 bpm

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	Pediatric options: 80mmHg 100mmHg 120mmHg 140mmHg	Neonate options: 60mmHg 70mmHg 80mmHg 100mmHg

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	150mmHg 160mmHg 180mmHg (Default) 200mmHg 220mmHg 240mmHg	(Default) 160mmHg 180mmHg 200mmHg 220mmHg 240mmHg	(Default) 120mmHg
Inflation Memory Mode	Yes		
Alarm Limit	Range		
Sys High	Adult: (low limit + 5) ~270mmHg Pediatric: (low limit + 5) ~200mmHg 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)		
Dia 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)		

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	90s (Neonate)
Static Pressure Measurement Range	0~300mmHg
Accuracy	±3mmHg
Dynamic Pressure Measurement Range	Adult: SYS: 40mmHg~270mmHg DIA: 10mmHg~210mmHg Pediatric: SYS: 40mmHg~200mmHg 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/Pediatric: 297mmHg±3mmHg Neonate: 147mmHg±3mmHg
PR Measurement Range	40~240bpm
PR Accuracy	2% or ±3bpm, whichever is greater
SunTechModule (Human)	
Standard	ISO80601-2-30:2019
Measurement Method	Upper arm oscillometry
Mode Of Operation	Manual, Auto and STAT
Max Measurement Time	130s (Adult/Pediatric) 75s (Neonate)
Static Pressure Measurement Range	0~300mmHg
Static Pressure Accuracy	±3mmHg
Dynamic Pressure Measurement Range	Adult: SYS: 40 mmHg~260mmHg DIA: 20mmHg~200mmHg Pediatric: SYS: 40 mmHg~160mmHg DIA: 20mmHg~120mmHg Neonate: SYS: 40mmHg~130mmHg

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	DIA: 20mmHg~100mmHg
Dynamic Pressure Accuracy	±3mmHg
Resolution	1mmHg
Software Overpressure Protection	Adult/Pediatric: 300mmHg±10mmHg Neonate: 150mmHg±10mmHg
PR Measurement Range	30~220bpm
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	5VDC, ±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 Alarm High	(Low limit + 2) ~60mmHg 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°C~43°C IT: 0°C~27°C
Resolution	C.O.: 0.1L/min BT/IT: 0.1°C
Accuracy	C.O.: $\pm 5\%$ or $\leq \pm 0.1\text{L/min}$, whichever is greater BT/IT: $\leq \pm 0.1^\circ\text{C}$
C.O. Graphical Trends Capacity	256 sets
Alarm Limit	Range
BT Alarm High	(Low limit + 1) ~43.0°C Default value: 39.0°C
BT Alarm Low	23.0~ (high limit - 1) °C Default value: 36.0°C

A.5.8 EtCO₂

General Specification	
Standard	ISO 80601-2-55:2018
Measurement Method	Using nondispersive infrared sensor
Initialization Time	At temperature of 25°C, the waveform is produced within 20s and all data are given within two min
Measurement Range	0 - 150mmHg 0 - 19.7% 0 - 20kPa (Barometric is set by main unit)
Calculation Method	Body temperature and pressure saturation (BTPS)
Response Time	<3s, the response time is the sum of the rise time and the delay time

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Co2 Resolution	在 0 - 69mmHg: 0.1mmHg 在 70 - 150mmHg: 0.25mmHg
Accuracy*	0 - 40mmHg: ± 2 mmHg 41 - 70mmHg: $\pm 5\%$ 71 - 100mmHg: $\pm 8\%$ 101 - 150mmHg: $\pm 10\%$ respiration rate > 80/min: $\pm 12\%$ *NOTE: the above data is based on gas temperature of 25°C.
Accuracy Drift	Short-term drift: < 0.8mmHg in 4-hour operation Long-term drift: Meet the requirement for measurement accuracy within 120 hours
Noise	At 5% CO2 concentration, the Root Mean Square (RMS) of sensor noise is not greater than 0.25 mmHg.
Frequency	100Hz
awRR Measurement Range	2 - 150/min (rpm)
awRR Measurement Precision	± 1 rpm
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 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 FilterCut-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		ON	
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°C	
	Alarm Low	36°C	
	Alarm Level	Medium	
	Alarm Record	OFF	
ΔT	Alarm ON/OFF	ON	
	Alarm High	2.0°C	
	Alarm Level	Medium	
	Alarm Record	OFF	
Color		White	
Temperature Unit		°C	

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°C
	Alarm Low	36.0°C
	Alarm Level	Medium
C.O. Coefficient		0.542
Automatic Measurement		ON
AutoIT		2.0°C

B.8 EtCO₂ Setup

Item		Factory Default Settings	
EtCO ₂	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		N ₂ O	
Anesthetic		0.0%	
Barometric Pressure		760mmHg	
Gas Temp		35°C	

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 respire 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

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	ECG Lead LA Off	Low	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 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.

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	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: 15~300bpm 3-lead: I,II,III 5-lead: I,II,III, V, aVR,aVF,aVL Input Signal Range: $\pm 5\text{mV}$
SpO ₂	Measurement Range: 0~100%
NIBP	Measurement Range: Adult/Pediatric: SYS (40~250) mmHg DIA (15~200) mmHg Neonate: SYS (40~135) mmHg DIA (10~100) mmHg Mode of operation: Auto, Manual, STAT

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Resp	Measurement Range: 0~120rpm
Temp	Measurement Range: 0~50°C
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 (50/60 Hz) magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at level typical location in a commercial or hospital 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.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to 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. 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 observe 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	IEEE 802.11b/g/n(HT20): 2412MHz to 2462MHz IEEE 802.11n(HT40): 2422MHz to 2452MHz
Modulation	IEEE for 802.11b: DSSS(CCK, DQPSK, DBPSK) IEEE for 802.11g :OFDM(64QAM, 16QAM, QPSK, BPSK) IEEE for 802.11n(HT20 and HT40) : OFDM (64QAM, 16QAM, QPSK,BPSK)
Effective Radiation Power (dBm)	<20dBm (Average value) <30dBm (Peak)

FCC



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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