Biocare

User Manual

Patient Monitor

Model: iM 8

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Shenzhen Biocare Bio-Medical Equipment Co.,Ltd.

About This User Manual

This manual explains for clinical medical staff how to operate this patient monitor.

Due to continuing product innovation, specifications in this manual are subject to change without notice.

The manufacturer will not be responsible for those indirect or accidental injuries due to misusing the manual or errors in the content.

The manufacturer reserves the rights to change specifications or stop provide the product without notice. In addition, the manufacturer will not answer for any sequel because of using the manual.

About Safety

The manufacturer is responsible for the safety, reliability, and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by the manufacturer or the manufacturer's authorized agent.

- The electrical installation of the relevant room complies with the requirements of the appropriate government regulations.

- The instrument must be connected to ground correctly and reliably.

- The instrument is used in accordance with the instructions for use.

About Service

- Contact instrument servicing to the manufacturer or the manufacturer's authorized service personnel only.

- The manufacturer or their authorized agents will provide telephone, email and other communication services.

- In addition to components expanse, payment for service may be required for some kind of services.

- Any unauthorized attempt to repair the instrument under warranty voids that warranty.

- Product's serial number must be provided to the manufacturer for services.

- Under warranty, Damages due to unartificial factors do not need to take any service expense and components expense.

- Under warranty, Damages due to artificialness only need to take components expense and need not take any service expense.

- Outside warranty, Damages due to artificialness need to take service expense and components expense.

- All boards and components that come from repair belong to the manufacture.

- Care should be taken in shipping the defective equipment to the manufacturer or the manufacturer's agent to prevent any damage due to shipment.

- Shenzhen Biocare guarantees the main unit on the material and the technological qualification for this product is within 18 months since purchasing day. For accessories and consumable parts, the warranty period is 6 months. There is no return or exchange in principle.

CE 0123   The CE mark is a protected conformity mark of European
Community. The products herewith comply with the requirements of the
Medical Device Directive 93/42/EEC

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General Warnings for Users

⚠ Caution

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

⚠ Warning

All Users must read following warnings, cautions and guide before operating the Monitors. Our company will not be held responsible nor any warranties will be made by us for any abnormalities or malfunction of the monitor or body injury caused by the violations of the operational guides.

⚠ General Warnings

- The instrument is not a therapeutic instrument.

- This instrument must be operated under the direction of professional medical staff.

- All of the monitoring parameters are used as a reference and should not be used as the clinical diagnosis. For abnormalities, clinical methods should be used to check out the reasons.

- The instrument should not be operated in the circumstance with flammable gas or corrosive gas.

- Prevent ingress of liquid or electrical conductive substance into the instrument.

- The instrument must be grounded correctly, and the power supply must be in accordance with the specified requirement.

- Delete all the previous data when monitoring a new patient. Only one patient should be monitored at once.

- If monitor connects to the other instrument, the leakage current must be tested by qualified technician before use, and must comply with IEC 60601-1.

- Many components may be attached to this monitor, but the entire unit, with accessories must comply with IEC 60601-1.

- The connection must present no danger to the patient. Check cabling prior to attaching to the patient.

- FDA approved ECG defibrillation proof cables must be used with this monitor.

- Checkout the alarm system periodically.

- Do not touch the patient in defibrillation. Otherwise, it may lead to serious injury or death.

- All cables must be kept away from patient's throat to avoid asphyxia.

- When using with a pacemaker or other electric equipment, no parts can be connected with patients, except FDA approved defibrillation ECG cable.

- In order to avoid of burning the patients, high frequency electrical bistoury cannot touch the electrode when used with the monitor.

- Do not place the electrode onto the injured or edematous site to prevent infection.

● Do not measure the blood pressure on the limbs with catheter or infusion. Do not put on the cuff at or near the wounded position.

● Local bleeding may be caused when using the blood pressure monitoring in patients with severe bleeding tendency. Be careful when using on patients with sickle cell disease.

● Do not place the SPO_2 sensor onto the injured skin, edematous or fragile tissues.

● Discomfort or pain may be caused by the continuous use of the clip type SPO_2 sensor especially in patients with microcirculation disorder. Do not place the sensor over 2 hours at the same place.

● $EtCO_2$ cannot be used as the only means of monitoring a patient. It shall always be used in combination with other vital signs monitoring devices and/or professional human judgments of patient condition.

● Non-disposable accessories should be sterilized before used on next patient to prevent cross infection.

● The instrument can only be opened or repaired by authorized personnel by manufacturer.

● Users may not be notified for changes of accessories.

● Please deal with the package waste according to the local regulations.

Warnings and Notes Especially for Neonates

1. **ECG Measurement**

● **Warning:** Keep ECG away from the throats of the neonate to avoid asphyxiation.

● **Caution:** The ECG cables and the electrode must be used correctly because neonate's body is shorter and tender. Check timely and change the electrodes when necessary.

2. **NIBP Measurement**

● **Warning:** The 'neonate mode' must be selected before the measurement of neonates, otherwise the high pressure of the cuff can cause injury to the neonates.

● **Caution:** Select a cuff that fit the size of the neonate before the neonate measurement. Properly set the parameters of the cuff's air pressure and alarm when taking neonate NIBP measurement. Please always pay attention to the neonate parameters if you have to adjust parameters.

3. **SPO_2 Measurement**

● **Caution:** SPO_2 may be not obtained precisely because the neonate moves. To measure precisely, please keep the neonate at rest.

● **Caution:** Use the proper probe to neonate. Do not place the SPO_2 probe on the fingers that have skin injury, edema or fragile. Do not place the probe on the same finger over 2 hours to prevent discomfort of the finger. Check timely and change the fingers when necessary.

4. **TEMP Measurement**

● **Warning:** Do not use oral probe when taking the measurement of neonate's temperature.

5. **$EtCO_2$ Measurement**

● **Warning:** Avoid direct contact between the $EtCO_2$ probe and the infant's body, or an insulation material must be placed between the probe and the body.

Terms for Safety and Symbols

Terms for Safety

In this manual, **Warning, Caution, and Note** are used to describe the level of danger. Please be familiar with their definition and meaning.

Warning: Instructions to avoid potential danger and incorrect operation. Obey the instructions, otherwise death and serious injury may be caused.

Caution: Instructions to avoid potential danger and incorrect operation. Obey the instructions, otherwise injury, equipment failure or data loss may be caused.

Note: Operational instructions or other useful information to help the users to operate the instrument correctly.

Symbols

The followings list of symbols may be used in this instrument.

Symbol	Description
⚠	This symbol means "caution, consult accompanying documents"
CE	CE mark that complies 93/42/EEC as amended by 2007/47/EC medical device directive. It shall be accompanied by the identification number of the notified body beside the right bottom side of CE mark.
SN	Followed by the serial number of theinstrument.
▰	Followed by the manufacturer's name and adress.
EC REP	Followed by the name and address of the authorized representative in the European Community.
⊘	Symbol for "do not reuse", "single use", "use only once".
↕	Symbol for "temperature limitation".
📖	Symbol for "consult instructions for use", "consult user manuals".
☣	Symbol for "biological risks".
❤	Defibrillation-proof type CF applied part, on medical equipment to identify a defibrillation-proof type CF applied part.
⏚	Equipotentiality, to identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential. Not necessarily being the earth (ground) potential. e.g. for local bonding.
♲	The symbol indicating separate collection for electrical and electronic equipment.
⛓	Indicating network interface.

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Chapter 1 General Description

⚠ Note:

- This manual contains information about this Patient Monitor.
- All operators must read and understand this manual before using the monitor.
- All information in this manual, including the illustrations, is based on a monitor with all optional configurations. If your monitor lacks any of these options, some information in this manual may not apply.

⚠ Caution:

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

1.1 Scope

This instrument is a battery or line-powered patient monitor. The patient monitor acquires the physiological signals such as Electrocardiograph (ECG), Respiration (RESP), Non-Invasive Blood Pressure (NIBP), Pulse Oximetry (SPO_2) and End-Tidal CO_2 ($EtCO_2$). The signals are converted into digital data and processed, examines the data for alarm conditions and displays the data. The monitor also provides operating control for the user.

The patient monitor is intended to be used in a hospital clinical area such as intensive care units, cardiac care units, operation room, and emergency department, to provide additional information to the medical and nursing staff about the physiological condition of the patient.

1.2 Models and Configurations

This instrument can be configured with the following physiological parameter monitoring modules: ECG/RESP, NIBP, SPO_2, TEMP and $ETCO_2$. To meet with different application needs, some different combinations of these modules can be selected. The following table shows the selectable model configurations:

Item	Configurations
1	NIBP, SpO_2
2	NIBP, SpO_2, TEMP

1.3 Product Characteristic

- Portable structure;

- LCD+LED display, high resolution, no distortion, high brightness, great view angle LCD;

- Multi-parameter and all-round assistant function;

- Modularized design, and easy for maintenance;

- Monitoring multi-parameters simultaneously, alarm signals will be raised when a parameter overlaps its limit;

- Waves and parameters will be saved when there is an alarm, 3500 groups of alarm data can be saved at most;

- All alarm records can be reviewed afterwards;

- No increased leakage current when some instruments connected together;

- Powered with AC power, internal battery or vehicle DC power supply, the optional high capacity internal Li-ion battery can support 10 hours of normal working;.

- Drop proof design, helpful for first aid medical services;

- Waveforms can be frozen and saved, and SD card can be used for data storage;

- Several different types of temperature probes can be selected.

1.4 Technical Specifications

1.4.1 Physiological parameters

The instrument can be configured with several function modules which supports the monitoring of the following physiological parameters:

Physiological Parameters	
ECG	Electro-Cardio Graph, 3/5 leads selectable
NIBP	Non-Invasive Blood Pressure, Oscillometric method, SYS/DIA/MAP. The manufacturer or SunTech NIBP module is selectable.
SPO_2	Saturation of Pulse Oxygen, Golden standard module supported. The manufacturer or Nellcor or Masimo SPO_2 module is selectable.
RESP	Respiration, thorax impedance method with ECG
TEMP	Temperature, Fast detect module selectable. Conventional temperature probe or infrared Thermometer probe is selectable
$EtCO_2$	End-Tidal CO_2, Mainstream and sidestream method.

Some of the function modules have several options to meet the special requirements of user.

For detailed parameters, please refer to appendix A.

1.4.2 Power and Interface specifications

Power and Interface specifications	
Power Supply	100~240VAC($\pm$10%), 50/60Hz($\pm$3Hz), 2A, 40VA Max.
Internal Battery Input	6.4V~8.4V, 2200mAh, Rechargeable Lithium battery
External DC Input	9V~15V, Vehicle or DC power supply
Display	LED+3.2" TFT LCD (320$\times$240)
Input interface	ECG, RESP, NIBP, SPO$_2$,TEMP and EtCO$_2$
Output interface	Printer port, Network port
Data Storage	Support SD card

For detailed parameters, please refer to appendix A.

1.4.3 Environment Requirements

Parameters	Specification
Runtime Environment Requirements	
Temperature	5 ~ 40 ℃ (41 ℉ ~ 104 ℉)
Relative humidity	≤95% (non-condensing)
Air pressure	70kPa ~ 106kPa
Other	Drafty and without corrosive gas
Transportation and Storage Environment Requirement	
Temperature	-40 ℃ ~ 55 ℃ (-40 ℉ ~131 ℉)
Relative humidity	≤95% (non-condensing)
Air pressure	16.5kPa ~ 106kPa
Other	Drafty and without corrosive gas

1.4.4 Size and Weight

Instrument	Size	180mm $\times$250mm $\times$180mm
	Weight	2.0 kg (with battery)
Package	Size	310mm $\times$320mm $\times$235mm
	Weight	3.7 kg

1.4.5 Related instrument

● Rollstand: The manufacturer can provide different specifications of rollstand and the patient monitors on the rollstand can be convenient to move.

● Support of ward bed: the support can make the patient monitors can be very good fixed.

1.5 Conformance Information

1.5.1 EMC

The equipment complies with all applicable and required standards for electromagnetic interference.

The safety and efficacy had been certified by the sold monitors. Though standards that the monitors accords with may not accord to the monitors had sold, the safety and efficacy do not be weakened.

For more detailed information about EMC, please refer to appendix B of this user manual.

1.5.2 Harmonized Standards

This Patient Monitor complies with the following harmonized standards:
EN 60601-1, EN 60601-1-2,

EN 60601-1-6, EN 60601-1-8,

EN 60601-2-27, EN 60601-2-30,   EN 60601-2-49,

EN 1060-1,   EN 1060-3,   EN 1060-4,

EN ISO 9919, EN 12470-4,   EN 12470-5,

EN ISO 21647, EN ISO 10993-1,

EN 62304, EN 62366,

EN 980, EN 1041,

AAMI SP10, AAMI EC13,

ASTM E1112, ASTM E1104-03

……

For more information, please contact the manufacturer or the manufacturer's authorized agent.

Chapter 2 Installation

⚠ Warning:

- The instrument must be used under the direction of a professional medical person.

- The instrument can't be used in the environment with flammable or caustic gas.

- Avoid liquid or electric conducting material entering the instrument.

- The instrument use AC110V~240V, user must confirm the power before plugging into the power socket.

- The instrument must be connected to ground correctly and reliably.

- All the non disposable accessories must be sterilized before it is used for the next patient to prevent cross infection.

2.1 Instrument Installation

2.1.1 Unpacking and Checking

Take out the instrument from the package carefully. Check the appearance first. If there are damages due to transportation such as the monitor is damaged, the LCD panel is broken, or there is abnormal sound when shaking the instrument, please do not plug into the power socket or try to open the instrument to examine or repair. Instead, contact with the local dealer or the customer service department of the manufacturer as soon as possible.

2.1.2 Installation of Support of ward bed

If needed, please contact the manufacturer or the manufacturer's authorized agent, the manufacturer will be responsible for installation.

The specific methods of installation please contact the manufacturer or the manufacturer's authorized agent.

2.1.3 Installation of Rollstand

If need, please contact the manufacturer or the manufacturer's authorized agent, the manufacturer will be responsible for installation.

The specific methods of installation please refer to "Instruction for use of rollstand".

2.1.4 Connecting Accessories

If the instrument looks well, put it on the flat desk or fix it on the bracket. Please insert the ECG cable, NIBP cuff, SPO_2 probe, TEMP probe and $EtCO_2$ probe into the corresponding socket on the right panel. If one of the parameters is not wanted, the probe or cable could be taken off from the side panel.

If the monitor is configured with a Recorder, please install the thermal printing paper before use the Recorder.

If the monitor is configured with an external internet communication module, please connect the module to the communication port.

2.1.5 Connecting Power Source

Connect one side of the power wire to the power socket on the backside of the instrument and the other side to the output of AC power supply. Please do remember to confirm that the AC power is suitable for the instrument to avoid damage of the instrument.

If the instrument is configured with an internal battery supply, the instrument can operate on the internal power when it isn't connected to the AC power supply. When the AC power supply is connected, the instrument uses the AC power supply and the internal battery is charged by the AC power.

Now the instrument is ready to be used.
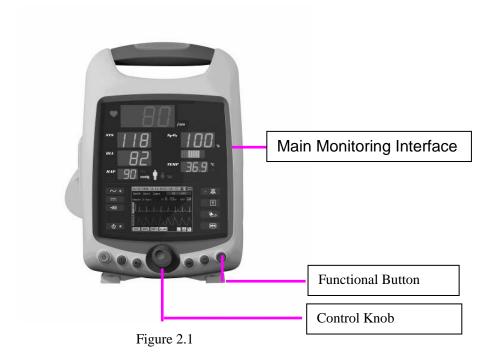
2.2 Description of the Panel

2.2.1 Front Panel

Figure 2.1 shows the front panel which including two parts: LED display area and LCD display area. The LEDs are used to show the values of main physiological parameters, including NIBP (SYS, DIA, MAP), pulse rate / heart rate, temperature, SPO_2 and the type of patient (adult, pediatric or neonate). The LCD is used to display waveform, NIBP data table, $EtCO_2$ data, operating menu, system state etc. Below the panel there are several function buttons: on-off button, printing button, NIBP measuring button, control knob, waveform freeze button, audio control button and multi-function key.

On the left side of the LCD there are four indicators: AC indicator, DC indicator (vehicle power), charging indicator and power on indicator.

On the right side of the LCD there are four other indicators: the alarm indicator, printing indicator and NIBP measuring indicator and freezing indicator.

Figure 2.1

■ **Indicators**

---	DC indicator (blue).	When using DC power, the indicator is lighted.
∿	AC indicator (blue).	When using AC power, the indicator is lighted.
▸◖▥▥▮	Charge indicator (blue)	When the internal battery is been charging, the indicator is lighted, when it is full, the indicator is off.
⏻	Power on indicator (blue)	When the instrument is powered on, the indicator is lighted.
⊠	Alarm indicator (red)	When an alarm is happening, the indicator is lighted.
⸮	Printing indicator (blue)	When the Recorder is printing, the indicator is lighted.
☍	NIBP indicator (blue).	When NIBP is measuring, the indicator is lighted.
▶◀	Freeze indicator (blue)	When the wave is freezing, the indicator is lighted.

■ **Power On/Off**

The instrument can work with AC power, vehicle DC power or the internal Li-battery.

If the internal battery is installed, the instrument can be turned on without outside power supply. When the internal battery is installed while the instrument is connected to AC power, the instrument will work with the AC power and the battery will be charged.

To turn on the instrument, hold the on-off button on the left side for 2~3 seconds till the power indicator is lighted.

To turn off the instrument, hold the on-off button on the left side for 2~3 seconds till the power indicator is off.

This instrument will enter the monitor state automatically after it is turn on. The screen will show the important

physiological parameter values such as NIBP, SPO$_2$ and electrophysiological waveforms such as ECG waveform, pulse waveform and EtCO$_2$ data for medical staff to observe and as a reference.

⚠ Caution:

If the internal battery's capacity is too low for supporting normal work, the instrument will turn off automatically.

■   **Functional Buttons**

There are 6 functional buttons at the bottom side of the front panel, defined as follows:

⏻	**START/STOP**	On –off button
🖋	**RECORDER**	Start or stop recorder printing
🖐	**NIBP**	Start or stop the blood pressure measurement
▶◀	**FREEZE**	Freeze or unfreeze the current waveform
🔕	**MUTE**	Mute or turn on or suspended the alarm sound
▣	**SCREEN**	Multi-function key

■   **Control Knob**

The control knob is located at the middle of the functional buttons. It is used to control the menu to implement each function of the instrument. In different user interfaces different operating methods is defined. Refer the following chapters for more information.

2.2.2 Side Panel

Figure 2.2 shows the side panel located at the right side of the instrument. There are four sockets on the side panel: TEMP socket, SPO$_2$ socket, NIBP socket, ECG socket and EtCO$_2$.

TEMP socket

SPO$_2$ socket

NIBP socket

ECG socket

EtCO$_2$ socket
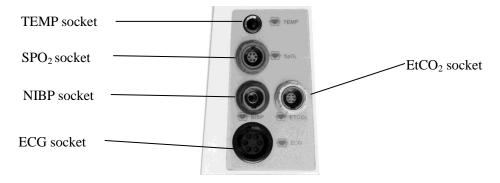
Figure 2.2

2.2.3 Rear Panel

Figure 2.3 shows the rear panel of the monitor.

On the rear panel there is AC power socket, DC power socket, grounding pole, lithium battery socket, network interface. On the left side of the monitor there is an interface for recorder.

Figure 2.3

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Chapter 3 Operation

Please read the information in this chapter carefully so as to operate the instrument more effectively, to get more successful measurement, and to get more accurate results.

3.1 Start to Monitor

3.1.1 Power On

Press the button " " for several seconds, the indicator of the monitor will be lighted. The monitor begins its self-test, as shown in Figure 3.1. It displays product labeling, software version and hardware version.

Alarm light will light, and LED digital tubes will display full dark in the self-test process. After self-test is completed, "beep" will be heard, and all LED digital tubes will light for a moment. Then LED digital tubes will return to normal display status. System enters into patient operation interface.

3.1.2 Main Monitoring Interface

■ **Main interface**

When the monitor finished its self-test, it will display the main interface, as shown in Figure 3.2. It includes four display areas, which are LED display area, LCD display area, on the left side of LCD indicators and on the right side of LCD indicators

Figure 3.2

■ **LED display area**

The information of LED display area is as shown in the Figure 3.3.
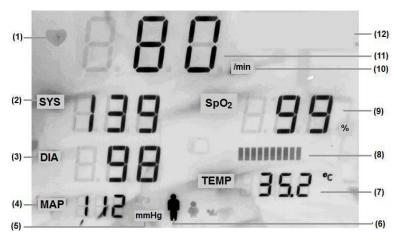
Figure 3.3

Specification:
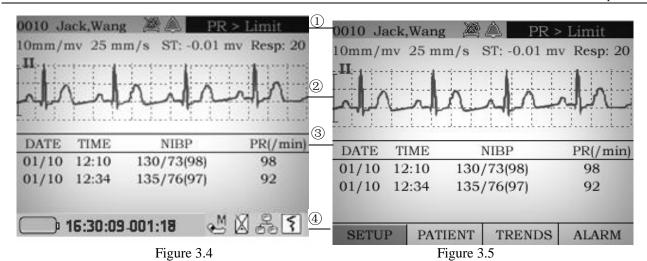
⑴ HR measurement indicator light: when ECG is measured, the indicator will glint;

⑵, ⑶, ⑷ Measurement values of NIBP;

⑸ Display unit of NIBP: kPa or mmHg can be selected;

⑹ Indicator light of NIBP cuff: there are three kinds cuff (Adult, Pediatric and Infant);

⑺ Measurement values and unit of TEMP;

⑻ Indicator light of Pulse strength of SPO$_2$;

⑼ Measurement values and unit of SPO$_2$;

⑽ Display unit of ECG;

⑾ Measurement values of HR/PR;

⑿ The manufacturer's trademark.

Note: The above data in the figure 3.3 is the data of DEMO program.

■ **LCD display area**

The information of LCD display area is as shown in the Figure 3.4 and Figure 3.5.

There are two main status displayed areas and two windows' area.

| Figure 3.4 | Figure 3.5 |

In the Figure 3.4 and Figure 3.5, system menu in the lower state displayed area have two kinds of mode. The mode transformation can be operated by the control knob.

Specification:

① The upper state displayed area:

- "0010": Bed ID of the patient;

- "Jack, Wang": Name of the patient;

- "⚠": Alarm signal. When alarm is on, the alarm signal is red. When alarm is disable, the alarm signal is gray and has a red fork on it;

- "🔔": Speaker signal. When speaker is on, the signal is red. When speaker is off, the signal is gray;

- "PR>Limit": Current alarm information.

② The upper windows' area: ECG windows, can display real-time measurement data of ECG.

- "10mm/mv", "25mm/s" : The set value of "Gain" and "Sweep speed" of ECG wave;

- "ST:-0.01mv", "Resp: 20": The measurement real-time data of ST and Respiration parameters;

- " Ⅱ ": ECG lead of channel;

- "〰": One measurement real-time waveform.

③ The lower windows' area: Blood pressure table, can most display the latest four blood pressure values at the same time.

- "DATE": The date of real-time measurement;

- "TIME": The time of real-time measurement;

- "NIBP": "SYS/DIA (MAP)" data of NIBP real-time measurement;

- "PR": The pulse rate value of NIBP measurement.

④ The lower state displayed area: system menu.

- " ▰▱ ": Battery Indicator. When the internal battery is been charging, the indicator is lighted, when it is full, the indicator is off. If the symbol is " ⊠ ", No battery is installed in the battery slot;

- "16:30:09-001:18": Current Time and Monitor Time;

- " ": Start or stop the blood pressure measurement;

- " ": SD card information;

- " ": Network information;

- " ": When the Recorder is printing, the indicator is lighted;

- "Setup": Setup the detection module, including system setup, alarm setup, range, NIBP setup, other and ECG setup(if ECG function is available);

- "Patient": Modify the current patient information, including patient information and hospital information;

- "Trend": Start the function of history review;

- "Alarm": Enter the alarm history trend.

■ **LCD indicators**

The LCD indicators are as shown in the Figure 3.2.

① On the left side of LCD indicators:

- " ": DC indicator (blue). When using DC power, the indicator is lighted;

- " ": AC indicator (blue). When using AC power, the indicator is lighted;

- " ": Charge indicator (blue) When the internal battery is been charging, the indicator is lighted, when it is full, the indicator is off;

- " ": Power on indicator (blue). When the instrument is powered on, the indicator is lighted.

② On the right side of LCD indicators:

- " ": Alarm indicator (red).When an alarm is happening, the indicator is lighted.

- " ": Printing indicator (blue). When the Recorder is printing, the indicator is lighted.

- " ": NIBP indicator (blue). When NIBP is measuring, the indicator is lighted.

- " ": Freeze indicator (blue). When the wave is freezing, the indicator is lighted.

3.2 Patient Login

A moment after startup, the monitor will enter into login interface.

➢ The monitor is firstly used after the monitor is out of factory or system has been upgraded. Then the interface is shown in Figure 3.6. Select **"New Patient"** by Control Knob, and press it to edit information. Doctors select **"Hospital"** and press it to edit information. Finally, doctors respectively select **"Save Change"** to save these information, as shown in Figure 3.7. After logging in the new patient, **"No Data Saved"** information will be disappeared and enter into monitoring main interface. If doctors want to cancel the operation, they can select **"Cancel"**.

⚠**Caution:**

The "Continue Patient" is invalid in this case. Users can only select "New Patient" or "Demo" in the condition.
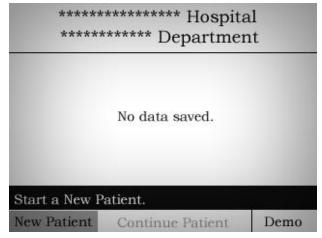
Figure 3.6

Figure 3.7

➢ When monitor has logged patients, it will display the name and number information of last patient, the interface is shown in figure 3.8. If doctors login new patient, please select **"New Patient"** by Control Knob, and press it to edit information. Doctors select **"Hospital"** and press it to edit information. Finally, doctors respectively select **"Save Change"** to save these information, as shown in figure 3.9. After logging in the new patient, the monitor will enter into monitoring main interface. If doctors want to cancel the operation, they can select **"Cancel"**.
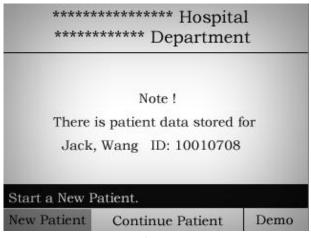
Figure 3.8   Figure 3.9

Name	Function
New Patient	Create a new patient information, and enter into editing interface of patient information.
Continue Patient	Load information of the last patient, and continue to monitor.
Demo	Enter into demo working mode.

3.2.1 New Patient

Press **"New Patient"** by Control Knob, and press it to edit information. Doctors select **"Hospital"** and **"Patient Info"**, and press it.

➢ **After enter into "New Patient" interface,** the interface is as shown in figure 3.10.

Operation is as following:

1) Enter into editing interface;

2) Edit content by Control Knob;

3) After edition has been completed, select **"Save Change"** by turning Control Knob. Press Control Knob to save modified content, and return to main monitor interface.

Figure 3.10

Users can set patient information through the setting interface:

Menu Item	Function Description	Value Range
CHECK ID	The detected number of patient, the monitor provide automatically.	Users can not set it.
Patient ID	Set patient case number.	8 bit digits, 0~9
NAME	Set patient name.	13 bit characters, A~Z,'.',' '
SEX	Set patient sex.	Male / Female / Unknown
AGE	Set patient age.	0~149
BED ID	Set patient bed number.	4 bit digits, 0~9
Save Patient	Save modified content and exit the interface.	Button operation item
Hospital Info	Enter into editing interface of hospital information.	Button operation item
Cancel	Do not save modified content, and exit the interface.	Button operation item

➢ **After enter into "Hospital" interface, the interface is as shown in figure 3.11.**

Operation is as following:

1) Enter into editing interface

2) Edit content by Control Knob.

3) After edition has been completed, select "Save Change" by turning Control Knob. Press Control Knob to save modified content, and return to main monitor interface.
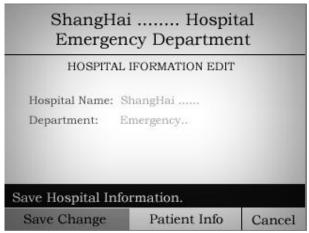
Figure 3.11

Users can set hospital name and department name through the setting interface.

Menu Item	Function Description	Value Range
Hospital Name	Set English name of hospital.	16 bit digits, A~Z,'.',' '
Department	Set English name of department.	12 bit digits, A~Z,'.',' '
Save Change	Save modified content, and exit the interface.	Button operation item
Patient Info	Enter into editing interface of patient information.	Button operation item
Cancel	Do not save modified content, and exit the interface.	Button operation item

3.2.2 Continue Patient

If doctors want to login the last patient, please select **"Continue Patient"** by Control Knob, and press it, as shown in figure 3.12. Then the monitor will enter into monitoring main interface.
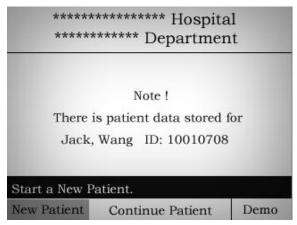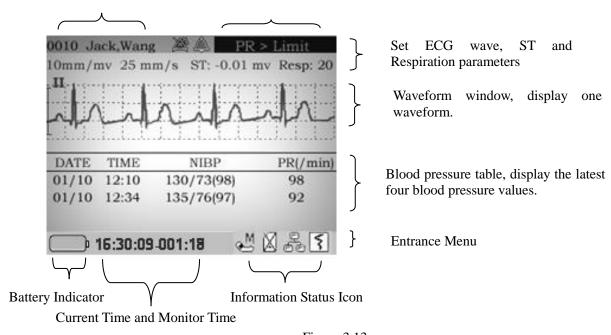
Figure 3.12

3.2.3 Demo

Doctors select **"Demo"** to enter into monitoring main interface of demo, as shown in figure 3.13,

Bed ID + Patient Name   Current Alarm Information

Set ECG wave, ST and Respiration parameters

Waveform window, display one waveform.

Blood pressure table, display the latest four blood pressure values.

Entrance Menu

Battery Indicator

Information Status Icon

Current Time and Monitor Time

Figure 3.13

3.3 Function Buttons

3.3.1 Function Buttons

There are 6 functional buttons and a control knob at the underside of the front panel, as shown in figure 2.1, the 6 function buttons and there functions are defined as follows:

Function Buttons	Descriptions
(START/STOP)	On –off button
(RECORDER)	Start or stop recorder printing
(NIBP)	Start or stop the blood pressure measurement
(FREEZE)	Freeze or unfreeze the current waveform
(MUTE)	Mute or turn on or suspended the alarm sound
(SCREEN)	Multi-function key

3.3.2 Control Knob

The control knob is located at the middle of the functional buttons. It is used to control the menu to implement each function of the instrument. In different user interfaces different operating methods is defined.

3.3.3 Multi-function key

■ **Return to Main Interface Immediately**

Press " 🔲 ", the monitor will return main interface immediately in these following operation interface.

1) Patient information setting interface.

2) Hospital information setting interface.

3) Trend chart reviewing interface.

4) Alarm record reviewing interface.(No record or no ECG module)

■ **Turn Page Function**
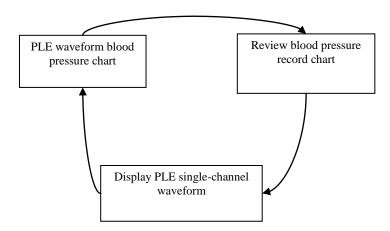
Press " 🔲 ", the monitor will turn page in these following operation interface.

1) Parameters setting interface (Circulate turning page).

2) Trend graph reviewing interface.

3) Alarm record reviewing interface (ECG module). Enter into ECG wave interface that is recorded when the monitor alarms.
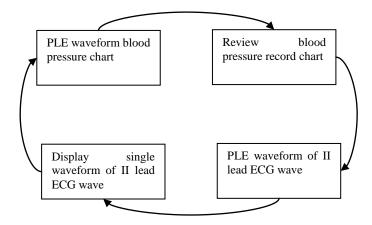
■ **Switch Interface Style**

Switch interface style in the main monitor interface or blood pressure chart reviewing interface.

Case 1: NO ECG Module

Case 2: With ECG module

3.4 Quick Reference Table

Main Menu

Menu	Description
SETUP	Setup the detection module, including system setup, alarm setup, range, NIBP setup, other and ECG setup(if ECG function is available)
PATIENT	Modify the current patient information, including patient information and hospital information.
TRENDS	Start the function of history review.
ALARM	Enter the alarm history trend.

3.4.1 Setup

Menu	Description
SYSTEM	Setup DATE, TIME, VOLUME, OPT EYE, ALARM CTRL, PAUSE TIME, BEAT TUNE, LANGUAGE, TREND SCALE, VERSION, TECH ALARM and Export Data.
ALARM	Setup parameters PROJECT SELECT, HR/ PR LIMIT, SPO$_2$ LIMIT, SYS LIMIT, DIA LIMIT, TEMP LIMIT, RESP LIMIT and ST LIMIT.
NIBP	Setup NIBP parameters PATIENT, NIBP MEHTOD, NIBP UNIT, TIME SEGMENT1 and TIME SEGMENT2.
ECG	Setup parameters SWEEP SPEED, TRACE GAIN, LEAD TYPE, WAVE WIN-1, WAVE WIN-2, ECG MODE, RESP LEAD and PACE.
OTHER	Setup parameters TEMP UNIT, ALARM PRINT, TIMER PRINT, REPORT RORM, NET ID, NET WORK, NET MODE and NURSE CALL.
RESET	The parameters on the current page turn to default.
SAVE	Confirm to the parameters amendment on this page.
NEXT	Turn to next interface that includes "Setup" include "System", "NIBP", "ALARM" and "OTHER".
EXIT	Exit the system setup.

(1) System

Menu	Description	Value Range
DATE	Modify system date.	YYYY-MM-DD
TIME	Modify system time.	HH-MM-SS
VOLUME	Setup speaker volume.	--
OPT EYE	Set optical eye.	AUTO/ LEVEL=1~5
LANGUAGE	Display system language	Chinese / English / Spanish / Portuguese / French
TREND SCALE	Set the scale of trend figure.	4/ 8/ 12 Hours
BEAT TUNE	Set heart beat rhythm sound from pulse pitch tune.	Off / Pitch Tune / Frequency
VERSION	Display current version and release date of software.	
ALARM CTRL	Ensure the functional definition of mute.	DISABLE / PAUSE
PAUSE TIME	Set the interval time of alarm sound.	30s～120s
TECH ALARM	Control response switch of technology alarm.	ON / OFF
EXPORT DATA	Export function trigger switch of historical data.	Start / Stop

(2) Alarm

Menu	Description	Value Range
Project select	Select default program of module.	Project1 / Project2 / Project3
HR/PR Upper Limit	Pulse rate upper limit alarm	20~350
HR/PR Lower Limit	Pulse rate lower limit alarm	20~350
HR/PR Alarm Switch	Alarm switch of pulse rate	ON/ OFF
SPO$_2$ Upper Limit	SPO$_2$ upper limit alarm	40~100
SPO$_2$ Lower Limit	SPO$_2$ lower limit alarm	40~100
SPO$_2$ Alarm Switch	Alarm switch of SPO$_2$	ON/ OFF
SYS Upper Limit	SYS upper limit alarm	40~255
SYS Lower Limit	SYS lower limit alarm	40~255
SYS Alarm Switch	Alarm switch of SYS	ON/OFF
DIA Upper Limit	DIA upper limit alarm	10~195 mmHg
DIA Upper Limit	DIA lower limit alarm	10~195 mmHg
DIA Alarm Switch	Alarm switch of DIA	ON/OFF
TEMP Upper Limit	TEMP upper limit alarm	0~50℃
TEMP Lower Limit	TEMP lower limit alarm	0~50℃
TEMP Alarm Switch	Alarm switch of TEMP	ON/ OFF
RESP Upper Limit	RESP upper limit alarm	0~120
RESP Lower Limit	RESP lower limit alarm	0~120

RESP Alarm Switch	Alarm Switch of RESP	ON/ OFF
ST Upper Limit	ST upper limit alarm	-1.00~1.00
ST Lower Limit	ST lower limit alarm	-1.00~1.00
ST Alarm Switch	Alarm Switch of ST	ON/ OFF

(3) NIBP

Menu	Description	Value Range
PATIENT	Set the patient type.	ADULT / CHILD / NEONATAL
NIBP METHOD	Set the NIBP measurement method.	MANUAL / AUTO / SERIES / BPG
NIBP UNIT	Set the unit of NIBP.	mmHg / KPa
TIME SEGMENT1	Set the first begin time of data reviews and interval (or close)	The interval of 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15minutes, 30 minutes, 45 minutes, 60 minutes, 90 minutes, 2hours, 4 hours, 6 hours, 8 hours or off.
TIME SEGMENT2	Set the second begin time of data reviews and interval (or close),	The interval of 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 90 minutes, 2 hours, 4 hours, 6 hours, 8 hours, or off.

(4) ECG (Option)

Menu	Description	Value Range
SWEEP SPEED	Set sweep speed of ECG wave.	12.5/25/50 mm/s
TRACE GAIN	Set trace gain of ECG wave.	5mm/mv,10mm/mv
LEAD TYPE	Set electrode connection.	3-LEADS/ 5-LEADS
WAVE WIN-1	Set wave content of wave window1.	PLE/REP/I/II/III/avR/avL/ avF/V
WAVE WIN-2	Set wave content of wave window2.	NIBP/OFF/PLE/REP/I/II/ III/avR/avL/avF/v
ECG MODE	Set filtering mode of ECG wave.	MODE1 / MODE2 / MODE3 / MODE4
RESP LEAD	Set respiration analysis lead.	I / II / III
PACE	Set switch of pacemaker analysis function.	OFF/ ON

(5) OTHER

Menu	Description	Value Range
TEMP UNIT	Set the unit of temperature measurement.	℃ / ℉
ALARM PRINT	Enable or disable the alarm print function.	ON/OFF
TIMER PRINT	Enable or disable the timer print function.	OFF, 5mins, 15mins, 30mins, 1hour, 2hours, 5hours
REPROT FORM	Set the print content.	DATA ONLY / DATA+TRACE
NET ID	Set the monitor ID of net for connecting the remote of internet central station	001~255
NET WORK	Enable or disable the networking function	ON LINE / OFF LINE
NURSE CALL	The switch to setup nurse call function	ENABLE / DISABLE

3.4.2 Patient

Name	Function
New Patient	Create a new patient information, and enter into editing interface of patient information.
Continue Patient	Load information of the last patient, and continue to monitor.
Demo	Enter into demo working mode.

New Patient

Menu Item	Function Description	Value Range
CHECK ID	The detected number of patient, the monitor provide automatically.	Users can not set it.
Patient ID	Set patient case number.	8 bit digits, 0~9
NAME	Set patient name.	13 bit characters, A~Z,'.',' '
SEX	Set patient sex.	Male / Female / Unknown
AGE	Set patient age.	0~149
BED ID	Set patient bed number.	4 bit digits, 0~9
Save Patient	Save modified content and exit the interface.	Button operation item
Hospital Info	Enter into editing interface of hospital information.	Button operation item
Cancel	Do not save modified content, and exit the interface.	Button operation item

Hospital Info

Menu Item	Function Description	Value Range
Hospital Name	Set English name of hospital.	16 bit digits, A~Z,'.',' '
Department	Set English name of department.	12 bit digits, A~Z,'.',' '
Save Change	Save modified content, and exit the interface.	Button operation item
Patient Info	Enter into editing interface of patient information.	Button operation item
Cancel	Do not save modified content, and exit the interface.	Button operation item

3.4.3 Alarm

Menu Item	Function Description	Value Range
Project select	Select default program of module	Project1 / Project2 / Project3
HR/PR Upper Limit	Pulse rate upper limit alarm	20~350
HR/PR Lower Limit	Pulse rate lower limit alarm	20~350
HR/PR Alarm Switch	Alarm switch of pulse rate	ON/ OFF
SPO_2 Upper Limit	SPO_2 upper limit alarm	40~100
SPO_2 Lower Limit	SPO_2 lower limit alarm	40~100
SPO_2 Alarm Switch	Alarm switch of SPO_2	ON/ OFF
SYS Upper Limit	SYS upper limit alarm	20~290 mmHg
SYS Lower Limit	SYS lower limit alarm	20~290 mmHg
SYS Alarm Switch	Alarm switch of SYS	ON/OFF
DIA Upper Limit	DIA upper limit alarm	10~250 mmHg
DIA Lower Limit	DIA lower limit alarm	10~250 mmHg
DIA Alarm Switch	Alarm switch of DIA	ON/OFF
TEMP Upper Limit	TEMP upper limit alarm	0~50℃
TEMP Lower Limit	TEMP lower limit alarm	0~50℃
TEMP Alarm Switch	Alarm switch of TEMP	ON/ OFF
RESP Upper Limit	RESP upper limit alarm	0~120
RESP Lower Limit	RESP lower limit alarm	0~120
RESP Alarm Switch	Alarm Switch of RESP	ON/ OFF
ST Upper Limit	ST upper limit alarm	-1.00~1.00
ST Lower Limit	ST lower limit alarm	-1.00~1.00
ST Alarm Switch	Alarm Switch of ST	ON/ OFF

3.5 System Parameter Defaults

Module parameters setup	Default	Module Parameters Setup	Default
OPT EYE	AUTO	TREND SCALE	4H
BEAT TUNE	PITCHTUNE	VERSION	V3.0.0 II-B May.10.2010
ALARM CTRL	PAUSE	PAUSE TIME	50s
TECH ALARM	OFF	Export Data	STOP
PROJECT SELECT	PROJECT 3	HR Upper LIMIT	100 ON
HR Lower LIMIT	60 ON	SPO$_2$ Upper LIMIT	100 ON
SPO$_2$ Lower LIMIT	92 ON	SYS Upper LIMIT	160 ON
SYS Lower LIMIT	80 ON	DIA Upper LIMIT	110 ON
DIA Lower LIMIT	50 ON	TEMP Upper LIMIT	38.0 OFF
TEMP Lower LIMIT	36.0 OFF	RESP Upper LIMIT	60 OFF
RESP Lower LIMIT	10 OFF	ST Upper LIMIT	0.30 OFF
ST Upper LIMIT	-0.30 OFF	PATIENT	ADULT
NIBP METHOD	MANUAL	NIBP UNIT	mmHg
TIME SEGEMENT 1	6:00 30 min	TIME SEGEMENT 2	20:00 60 min
TEMP UNIT	℃	ALARM PRINT	OFF
TIMER PRINT	OFF	REPORT FORM	DATA ONLY
NET ID	001	NET WORK	ON LINE
NET MODE	CIS3000	NURSE CALL	DISABLE
SWEEP SPEED	25mm/ s	TRACE GAIN	10mm/ mv
LEAD TYPE	5-LEADS	WAVE WIN-1	PLE
WAVE WIN-2	NIBP	ECG MODE	MODE 3
RESP LEAD	I	PACE	OFF

Chapter 4 Working Status Setup

This instrument provides many parameters setup for users. It can be used to change the status to a special one which users need.

4.1 System Parameters Setup

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface, as shown in figure 4.1.

The default first page of **"SETUP"** interface is **"SYSTEM"** interface. Select **"NEXT"** button or use " " to switch page.
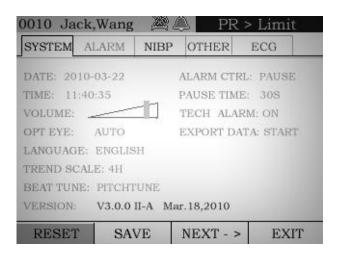
Figure 4.1

System parameters setup as follows: (Change the content of each item, and finally save the content by the Control Knob.)

Menu Item	Function Description	Value Range
DATE	Modify system date.	YYYY-MM-DD
TIME	Modify system time.	HH-MM-SS
VOLUME	Set system speaker volume.	Adjust range from 0 to 32.
OPT EYE	Set whether start optical eye.	Auto /1~5(No function)
LANGUAGE	Set language environment of system operation.	Chinese / English / Spanish / Portuguese / French
TREND SCALE	Set the displaying length time of trend chart- screen.	4H / 8H / 12H
BEAT TUNE	Control oxygen pulse modulation. sound.	Adjust SPO2 / Fixed Frequency / Close

ALARM CTRL	Determine mute function.	PAUSE/ DISABLE
PAUSE TIME	Set the interval time of mute time.	30s~120s
TECH ALARM	Control response switch of technology alarm.	ON/ OFF
EXPORT DATA	Export function trigger switch of historical data.	Start/ Stop
VERSION	Display version number and release date of system software.	Cannot adjust it.
RESET	Load default parameters.	Button operation item.
SAVE	Save modified parameters to Flash.	Button operation item.
NEXT	Cancel modification operation, and enter into the next page.	Button operation item.
EXIT	Exit system parameters setting interface, and return to main interface.	Button operation item.

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**" ,"**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item.(Before exit please ensure all settings have been saved.)

4.2 ECG Parameters Setup (Optional function)

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

The default first page of "**SETUP**" interface is "**SYSTEM**" interface. Select "**NEXT**" button or press " " into the "**ECG**" page, as shown in figure 4.2.

Figure 4.2

⚠ **Caution:**
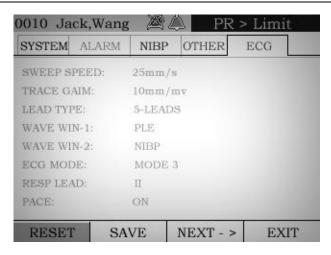
There is no ECG setting interface of without ECG module.

Menu	Description	Value Range
SWEEP SPEED	Set sweep speed of ECG wave	12.5/25/50 mm/s
TRACE GAIN	Set trace gain of ECG wave	5mm/mv,10mm/mv
LEAD TYPE	Set electrode connection.	3-LEADS/ 5-LEADS
WAVE WIN-1	Set wave content of wave window1	3-LEADS:PLE/REP/ I/ II/ III/ 5-LEADS: PLE/REP/
WAVE WIN -2	Set wave content of wave window2	3-LEADS: NIBP/OFF/PLE/REP/I/II/III/ 5-LEADS: NIBP / OFF / PLE / REP / I / II / III / aVR / aVL / aVF / V
ECG MODE	Set filtering mode of ECG wave	MODE1/ MODE2/ MODE3/ MODE4
RESP LEAD	Set respiration analysis lead	I / II / III
PACE	Set switch of pacemaker analysis function.	OFF/ ON

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item.(Before exit please ensure all settings have been saved.)

4.3 NIBP Parameters Setup

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

The default first page of "**SETUP**" interface is "**SYSTEM**" interface. Select "**NEXT**" button or press " ▣ " into the "**NIBP**" page, as shown in figure 4.3.

```
0000 .......          ▲▲    ------------
SYSTEM  ALARM   NIBP   OTHER

PATIENT:         ADULT
NIBP MODE:       MANUAL
NIBP UNIT:       mmHg
TIME SEGMENT1:   06:00   30mins
TIME SEGMENT2:   20:00   60mins
─────────────────SPO2─────────────────
SWEEP SPEED:     25mm/s


  RESET  │  SAVE  │  NEXT->  │  EXIT
```

Figure 4.3

Menu	Description	Value Range
PATIENT	Set the patient type.	ADULT/ CHILD/ NEONATAL
NIBP METHOD	Set the NIBP measurement method.	MANUAL/ AUT/ SERIES/ BPG
NIBP UNIT	Set the unit of NIBP.	mmHg/ KPa
TIME SEGMENT1	Set the first begin time of data reviews and interval (or close)	The interval of 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15minutes, 30 minutes, 45 minutes, 60 minutes, 90 minutes, 2 hours, 4 hours, 6 hours, 8 hours or off
TIME SEGMENT2	Set the second begin time of data reviews and interval (or close),	The interval of 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 90 minutes, 2 hours, 4 hours, 6 hours, 8 hours, or off

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item.(Before exit please ensure all settings have been saved.)

4.4 SPO$_2$ Parameters Setup

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

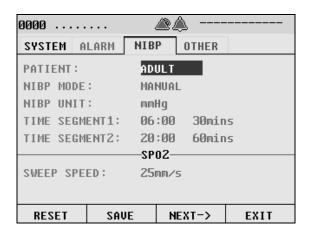The default first page of "**SETUP**" interface is "**SYSTEM**" interface. Select "**NEXT**" button or press " ▣ " into the "**NIBP**" page, the lower windows' area is the setup menu of SPO$_2$, as shown in figure 4.4.


```
0000 ........          🔔🔔  -------------
┌────────┬───────┬──────┬────────┐
│ SYSTEM │ ALARM │ NIBP │ OTHER  │
PATIENT:          ▐ADULT▌
NIBP MODE:          MANUAL
NIBP UNIT:          mmHg
TIME SEGMENT1:      06:00   30mins
TIME SEGMENT2:      20:00   60mins
                  ─SPO2─
SWEEP SPEED:        25mm/s

┌─────────┬──────┬────────┬──────┐
│  RESET  │ SAVE │ NEXT-> │ EXIT │
└─────────┴──────┴────────┴──────┘
```

Figure 4.4

Menu	Description	Value Range
SWEEP SPEED	Set the sweep speed	12.5mm/s, 25mm/s, 50mm/s

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item.(Before exit please ensure all settings have been saved.)

4.5 EtCO$_2$ Parameters Setup (Optional)

Use " ⬛ " to enter into "**EtCO$_2$ SETUP**" setting interface after insetting the EtCO$_2$ probe, in the main monitor interface, as shown in Figure 4.4.

Figure 4.4

Menu	Description	Value Range
PERFORM ZERO	Choose ON the module will perform zero	ON / OFF
SCALE	Setup the range of the waveform display	0~10%(0-76mmHg), 0~15 %(0-114 mmHg)
NO BRE TIMEOUT	Non breath overtime setup	20, 40, 60 secs.
UINT	Unit choose	% or mmHg
Set O$_2$	O$_2$ supply	low (0%) and (50%)

OPERATION MODE	Set the working mode	measurement, self test, sleep
Set N_2O	N_2O supply	low (0%) and (50%)
$EtCO_2$ upper limit:	Set the upper limit of $EtCO_2$ alarm	0~12
$EtCO_2$ lower limit:	Set the lower limit of $EtCO_2$ alarm	0~12
ALARM switch	ALARM switch	On or disable
$FiCO_2$ upper Limit	Set the upper limit of $FiCO_2$ alarm	0~1
$FiCO_2$ lower Limit	Set the lower limit of $FiCO_2$ alarm	0~1
$FiCO_2$ alarm switch	$FiCO_2$ alarm switch	ON or disable
AwRR upper limi	Set the upper limit of AwRR alarm	0~100
AwRR lower limit	Set the lower limit of AwRR alarm	0~100
AwRR alarm switch	AwRR alarm switch	ON or disable

The operation of function setup:

1) Rotating the knob to select the item which will displayed with yellow background.

2) Push the knob to change the content of the item. The item will become yellow font and red background. Rotating the knob can change the content and push it again to save it.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next page.

EXIT: Select it and press the control knob to exit this functional item.(Before exit please ensure all settings have been saved.)

4.6 Other Parameters Setup

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

The default first page of "**SETUP**" interface is "**SYSTEM**" interface. Select "**NEXT**" button or press " " into the "**OTHER**" page, as shown in figure 4.5.
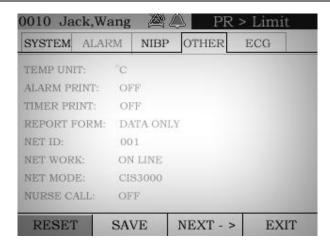
Figure 4.5

Set temperature module, print module, and network module parameters;

Menu	Description	Value Range
TEMP UNIT	Set the unit of temperature measurement	℃ / ℉
ALARM PRINT	Enable or disable the alarm print function	ON/OFF
TIMER PRINT	Enable or disable the timer print function	Off, 5mins, 15mins, 30mins, 1hour, 2hours, 5hours
REPROT FORM	Set the print content.	DATA ONLY/ DATA+TRACE
NET ID	Set the monitor ID of net for connecting the remote of internet central station	001~255
NET WORK	Enable or disable the networking function	ON LINE/ OFF LINE
NET MODE	Select net mode.	CIS3000/ CIS-120
NURSE CALL	The switch to setup nurse call function	ENABLE/ DISABLE

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item. (Before exit please ensure all settings have been saved.)

Chapter 5 Alarm

The alarm system of the instrument is classified into two classes: Technical Alarm (TA) and Physiological Alarm (PA).

TA is a signal that indicates the instrument or parts of the monitor, which is not capable of accurately monitoring the patient's condition, such as SPO_2 probe off, blood pressure measure failure, etc.

PA is a signal, which indicates the patient's physiological parameters abnormal. Such as rhythm of the heart overflow, SPO_2 overflow, premature, etc. And it also indicates that a monitored physiological function is out of specified limits or indicates an abnormal patient condition, such as rhythm of SPO_2 overflow, etc.

5.1 Alarm Parameters Setup

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

Select **"NEXT"** button or press " ⬛ " into the **ALARM** page, as shown in figure 5.1.

Physiological parameters are detected by ECG module, which are not displayed in the "ALARM" interface of without ECG module
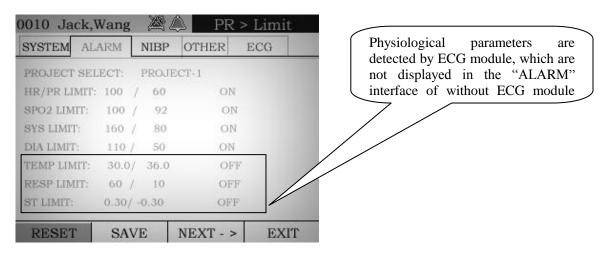
Figure 5.1

Additionally, the setup or start status of the module are displayed as screen indicate, such as SPO2 module off or recorder off. They do not belong to TA to keep the normal run of the monitor.

Menu Item	Function Description	Value Range
Project select	Select default program of module	Project1 / Project2 / Project3
HR/PR Upper Limit	Pulse rate upper limit alarm	20~350
HR/PR Lower Limit	Pulse rate lower limit alarm	20~350
HR/PR Alarm Switch	Alarm switch of pulse rate	ON/ OFF
SPO2 Upper Limit	SPO2 upper limit alarm	40~100

SPO2 Lower Limit	SPO2 lower limit alarm	40~100
SPO2 Alarm Switch	Alarm switch of SPO2	ON/ OFF
SYS Upper Limit	SYS upper limit alarm	20~290 mmHg
SYS Lower Limit	SYS lower limit alarm	20~290 mmHg
SYS Alarm Switch	Alarm switch of SYS	ON/OFF
DIA Upper Limit	DIA upper limit alarm	10~250 mmHg
DIA Lower Limit	DIA lower limit alarm	10~250 mmHg
DIA Alarm Switch	Alarm switch of DIA	ON/OFF
TEMP Upper Limit	TEMP upper limit alarm	0~50℃
TEMP Lower Limit	TEMP lower limit alarm	0~50℃
TEMP Alarm Switch	Alarm switch of TEMP	ON/ OFF
RESP Upper Limit	RESP upper limit alarm	0~120
RESP Lower Limit	RESP lower limit alarm	0~120
RESP Alarm Switch	Alarm Switch of RESP	ON/ OFF
ST Upper Limit	ST upper limit alarm	-1.00~1.00
ST Lower Limit	ST lower limit alarm	-1.00~1.00
ST Alarm Switch	Alarm Switch of ST	ON/ OFF

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and " **ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item. (Before exit please ensure all settings have been saved.)

5.2 Alarm Indicators

When alarm occurs, the instrument will indicate users by visual and auditory alarm. There are three types of alarm indicates.

Auditory: Alarm speaker send audio alert. The volume can be adjusted. In accordance with different audio frequency and duration, users can distinguish whether the alarm is PA or TA.

Visual: The alarm signal and parameter will display on relevant area. In PA, the related parameter will glitter to increase the marked degree.

Assistant visual: Alarm lights. There is a alarm light on the top of the instrument. When PA occurs, they will glitter to arouse attention.

Auditory and assistant visual alarm indicates can be turned off by pushing the MUTE and **PAUSE/ DISABLE** alarm button.

(1) Technical Alarm (TA)

Alarm Type	Alarm Class	Description	Alarm Light	Word Color	Indicate Info and Position
Technical Alarm	low	Lead off	-	Yellow	Lead off
	low	Lead saturated	-	Yellow	Lead saturated
	low	SPO$_2$ probe fall off	-	Yellow	SPO$_2$ probe fall off (in the wave window of PLE)
	low	Battery capacity low	-	Yellow	Signal of battery empty glitter
	low	NIBP measure fail	-	Systolic, diastolic, no display, and MAP shows 7	00: no error 06: cuff error 07: leakage 08: air pressure error 09: weak signal 10: exceed the range 11: excess movement 12: over pressure 13: signal saturation 19: overtime

(2) Physiological Alarm (PA)

Alarm Type	Alarm Class	Description	Alarm Light	Word Color	Indicate Info and Position
Physical alarm	High	HR exceeds limit	Glitter	Red	Alarm information position: HR exceeds limit, and light Glitters
	High	SPO$_2$ exceeds limit	Glitter	Red	Alarm information position: SPO$_2$ exceeds limit, and light Glitters
	High	NIBP DIA exceeds limit	Glitter	Red	Alarm information position: DIA exceeds limit, and indicate light Glitters
	High	NIBP SYS exceeds limit	Glitter	Red	Alarm information position: SYS exceeds limit, and indicate light Glitters
	High	TEMP exceeds limit	Glitter	Red	Alarm information position: TEMP exceeds limit, and indicate light Glitters
	High	RESP exceeds limit	Glitter	Red	Alarm information position: RESP exceeds limit, and indicate light Glitters

(3) Module installation (Not belong to alarm)

State	Alarm Light	Word Color	Indicate Info and Position
No Recorder	-	Red	Gray Recorder sign is signed red "X"
No Battery	-	Red	Gray battery sign is signed red "X"

5.3 Alarm Control

The instrument provides with mute function which can temporarily inhibit the auditory alarm.

The instrument provides with **PAUSE/ DISABLE** alarm way which can temporarily or enduringly inhibit all auditory and assistant visual alarm indicators and lights. It can NOT inhibit the visual alarm.

The instrument provides with ways to inhibit single alarm. They can enduringly inhibit the specified PA indicates.

All alarms in the instrument are non-latched alarms.

There are two signals on the top right corner of the screen, they are " ⌓ " and " ◁ ". They separately identifies whether the MUTE and PAUSE/ DISABLE function is turning on.

When speaker is on, " ⌓ " is yellow. When speaker is off, " ⌓ " is gray.

When alarm is on, the alarm signal is yellow. When alarm is paused, " ◁ " is gray.

When alarm is disable, "⌂" is gray and has a red fork on it.

The time of alarm of **PAUSE/ DISABLE** can be set in the **"System Parameters"** menu. (This time is the paused time.)
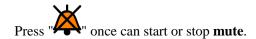
The **PAUSE/ DISABLE** function can only be single selected one time in the **"System Parameters"** menu.

"ALARM CTRL" is used to select the time of the **PAUSE/ DISABLE**. The range is between 30-120 sec.

"PAUSE TIME" is used to set the time of pause time and mute time. The range is between 30-120 sec.

Methods of setting **mute** and **PAUSE/ DISABLE** as follows:

There is a functional button " " on the instrument, as shown in figure 2.1, which can control the **mute** and **PAUSE/ DISABLE** function.

Press " " once can start or stop **mute**.

Quickly press " " twice (within 0.5 sec) can enter into **PASUE/ DISABLE** status.

Bell and alarm signals can change to indicator the current status on the top of corner of the screen.

The alarm states shows as follows:

Type	Duration	TA	PA
Normal	Permanent	Voice slow, no alarm light. Have indicate info, but no glitter Frequency:500Hz Size:40mm×20mm Sound: 69dB Alarm interval:3s	Voice fast, with glitter light Red words glitter in the alarm information district Frequency:1500Hz Size:40mm×20mm Sound: 69dB Alarm interval:2.253s Light glitter frequency:60Hz
Mute	temporary (30~120s)	Voice off, no alarm light. Have indicate info, but no glitter	Sound off, light off Red words glitter in the alarm information district
Suspend	temporary (30~120s)	Voice off, no alarm light Have indicate info, but no glitter	Sound off, light off Red words glitter in the alarm information district
Inhibition	permanent	Voice off, no alarm light Have indicate info, but no glitter	Sound off, light off Red words glitter in the alarm information district

5.4 Alarm record and history

Alarm record and history is one important function of patient monitor. When there is special alarm, this instrument will inform the doctor or others in time by sound, light and display. Besides, the monitor will record the whole information when the alarm happens. These alarm record can be reviewed at any time.

The alarm situation is saved by the monitor when some physiological parameter value exceeds the limit.

Select **"ALARM"** to enter into setting interface by turning Control Knob in the main monitor interface.

The saved alarm information can be reviewed as shown in figure 5.2

Figure 5.2

Four functional items, **"ITEM"**, **"PAGE"**, **"WAVE>"**, **"EXIT"**, compose the alarm control menu, as shown in Figure 5.1. The description of the control menu as follows:

(1) Select **"ITEM"** and press the knob. The knob can operate the items of the alarm table. Rotate the knob, the item will roll one by one to select the needed item. At the same time, the relevant data will be shown on the right shows. Press the knob again to return to the control menu.

(2) Select **"PAGE"** and press the knob. The knob can operate the alarm record as page moving function.

(3) Select **"WAVE"** and press the knob. The screen can show the wave of the selected item in alarm situation.

(4) Select **"EXIT"**, press the knob to leave the alarm page and return to the main monitor page.

The alarm table lists the alarm items before present time. Every alarm item shows the order, alarm and happening time. The selected alarm item is in yellow ground and the item in white ground is not selected.

The alarm parameters table shows PR, SPO_2, TEMP, SYS, DIA, MAP, REP, $EtCO_2$.

Chapter 6 Patient Monitoring

6.1 ECG and RESP Monitoring (Optional)

⚠ **Warning:**

● One-channel standard ECG monitoring system. Isolated and floaty electrical amplifier is used in ECG system for safety.

● Capable of displaying the ECG signal in the presence of pacemaker pulses with amplitudes 2mV.

● The monitor has taken a protection to the ECG defibrillator, and the ECG module is of "defibrillator CF type".

6.1.1 Preparation

The ECG cable of this monitor can be 3-lead cable or 5-lead cable.

The color set of AHA or IEC standard is defined as follows:

AHA standard:

Mark	Color	Location
LA	Black	'Left Arm': Cross point of the left midclavicular line and the 2nd intercostals space
RA	White	'Right Arm': Cross point of the right midclavicular line and the 2nd intercostals space
LL	Red	'Left Leg': Costal margin of the left anterior axillary line
RL	Green	'Right Leg': Costal margin of the right anterior axillary line
C	Brown	C1: The 4th intercostals space of the right sternal margin
		C2: The 4th intercostals space of the left sternal margin
		C3: Mid point between C2 and C4
		C4: The 5th intercostals space of the left midclavicular line
		C5: Left anterior axillary line and C4 horizontal position
		C6: Left midaxillary line and C4,C5 horizontal position

IEC standard:

Mark	Color	Location
L	Yellow	'Left Arm': Cross point of the left midclavicular line and the 2nd intercostals space
R	Red	'Right Arm': Cross point of the right midclavicular line and the 2nd intercostals space
F	Green	'Left Leg': Costal margin of the left anterior axillary line
N	Black	'Right Leg': Costal margin of the right anterior axillary line
C	White	C1: The 4th intercostals space of the right sternal margin
		C2: The 4th intercostals space of the left sternal margin

		C3: Mid point between C2 and C4
		C4: The 5th intercostals space of the left midclavicular line
		C5: Left anterior axillary line and C4 horizontal position
		C6: Left midaxillary line and C4,C5 horizontal position

Before ECG monitoring, please ensure that:

● The instrument is suitable for cardiac monitoring for the patient.

● Use only ECG cables supplied to or suitable for this monitor.

● Check the ECG cables, if it is worn out or broken, do not use it.

● Keep The ECG cable away from the patient's throat to avoid asphyxia.

● Before the electrode being placed onto the patient, the skin should be cleaned by alcohol, polish the skin with the abrasive paper attached with the electrodes when necessary to remove the oil on the patient's skin to ensure fine contact of the electrodes. Do not place electrodes on wounded or edematous position to prevent infection.

● Place the electrodes to the correct position. Please refer to Figure 6.1

● The conductive part of the electrode should not touch other conductive parts. Otherwise, the protection of isolation will lose its effect.

● For better monitoring performance, use only high quality ECG cables and electrodes which accord with CE rules.

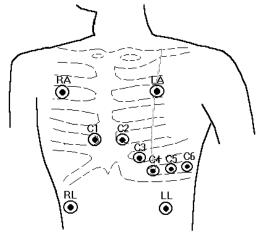● The potential equalization conductor must be connected to the earth for safety.

Figure 6.1

⚠ WARNING:

To avoid burn, use the defibrillation ECG cable and the electrodes supplied by The manufacturer when the monitor is used with the defibrillator.

⚠ WARNING — PACEMAKER PATIENTS.

Monitor may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon monitor ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of page 1-2 of this instrument.

Although better anti-interference and base line floating depressing technique were used in the instrument, to obtain high quality electrocardiograph and precise heart rate (HR) value, please pay attention to the followings:

● First, the hospital should be equipped with standard uniphase power supply system with good grounding. If no suitable grounding is available, please connect one end of the special grounding wire to the grounding pole of the monitor, and another end to the water piping or heating pipes.

● The electrodes used for the monitors are very easy to lose efficacy. Usually the valid time is only one month after the package is opened. If the expired electrodes are used to obtain the electrocardiograph, the base line of electrocardiograph will become unstable duo to the interference caused by the increased skin contact resistance and the electrode polarization voltage. So It is important to use the unexpired electrodes.

● Please refer to Figure 3.1 for the correct position of the electrodes, pay attention to the relationships between the lead color and the position, and do not confuse. Do not paste the electrodes to wrong positions.

⚠ Caution:

Do not place electrodes on wounded skin or edematous site to prevent infection or incorrect measurements.

● The heart rate calculation in this instrument is obtained by the computer according to the character of the electrocardiograph, so the quality of the electrocardiograph will directly influence the calculation of the heart rate. After the instrument starts to monitor or re-start the ECG module, there will be a process (which lasting for about 10s) to establish the template for Printing the basic information of the patient electrocardial signal. This template will be use as the basis for the later heart rate calculation. To enhance the reliability of the calculation and the analysis, the establishment of the electrocardial template is real-time and dynamic.

● After the instrument begins to monitor, it will establish the template according to the electrocardial waveform, and display the electrocardiograph at the optimal position. The "study key" also has a similar function, press this key when the electrocardial waveform changes greatly or the heart rate is not detectable.

● If the electrocardial monitoring is not wanted in the process of monitoring, then the ECG module can be 'turned off'. After the electrocardial module being closed, the electrocardiograph will not be displayed, the heart rate value of this time is obtained from the pulse rate (if the blood oxygen module is not closed).

6.1.2 Display interface

■ **ECG Parameter**

In the main interface the upper, ECG parameter is displayed, as shown as Figure 6.2.
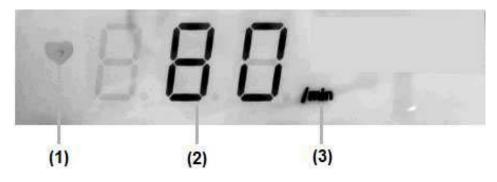

Figure 6.2

Specification:

(1) Heartbeat (HR) measurement indicator light: when ECG is measured, the indicator will glint;

(2) Measurement values of HR/PR;

(3) Display unit of ECG.

■ **ECG Wave**

In the upper windows' area of LCD display area, if one of "I / II / III / aVR / aVL / aVF / V" channel wave of ECG is set in the WAVE WIN-1, ECG wave can be displayed, as shown as Figure 6.3.
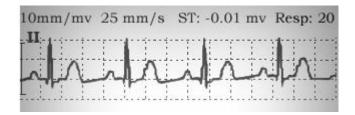
Figure 6.3

Specification:

- "10mm/mv": The set value of "Gain" of ECG wave. "5mm/mv" and "10mm/mv" can be selected;

- "25mm/s": The set value of "Sweep speed" of ECG wave. "12.5mm/s", "25mm/s" "50mm/s" can be selected;

- "ST:-0.01mv": The measurement real-time data of ST parameter;

- "Resp: 20": The measurement real-time data of Respiration parameter;

- "Ⅱ": ECG lead of channel. The channel of Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, Ⅴ can be selected.

- " ": One measurement real-time waveform.

⚠ **Note**

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

6.1.3 Setup menu

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

The default first page of "**SETUP**" interface is "**SYSTEM**" interface. Select "**NEXT**" button or press " ▣ " into the "**ECG**" page, as shown in figure 6.4.

⚠ **Caution:**

There is no ECG setting interface of without ECG module.

Figure 6.4

Menu	Description	Value Range
SWEEP SPEED	Set sweep speed of ECG wave	12.5/25/50 mm/s
TRACE GAIN	Set trace gain of ECG wave	5mm/mv,10mm/mv
LEAD TYPE	Set electrode connection.	3-LEADS/ 5-LEADS
WAVE WIN-1	Set wave content of wave window1	3-LEADS:PLE/REP/ I/ II/ III/ 5-LEADS: PLE/REP/
WAVE WIN -2	Set wave content of wave window2	3-LEADS: NIBP/OFF/PLE/REP/I/II/III/ 5-LEADS: NIBP / OFF / PLE / REP / I / II / III / aVR / aVL / aVF / V
ECG MODE	Set filtering mode of ECG wave	MODE1/ MODE2/ MODE3/ MODE4
RESP LEAD	Set respiration analysis lead	I / II / III
PACE	Set switch of pacemaker analysis function.	OFF/ ON

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into

yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item. (Before exit please ensure all settings have been saved.)

⚠ Caution:

- Only one of "I / II / III / aVR / aVL / aVF / V" channel wave of ECG can be set in the "WAVE WIN-1" and "WAVE WIN-2", "NIBP / OFF / PLE / REP" only can be set another "WAVE WIN".
- If one of "I / II / III / aVR / aVL / aVF / V" channel wave of ECG is set in the WAVE WIN-1, ECG wave can be displayed in the upper windows' area of LCD display area, as shown as Figure 6.3.
- If one of "I / II / III / aVR / aVL / aVF / V" channel wave of ECG is set in the WAVE WIN-2, ECG wave can be displayed in the lower windows' area through pressing " ▣ " twice, as shown as Figure 6.5.

Figure 6.5

In the figure 6.5, the ECG setup is:

- SWEEP SPEED: 10mm/mv;
- TRACE GAIN: 25mm/s;
- LEAD TYPE: 5-LEADS;
- WAVE WIN-1: REP;
- WAVE WIN-2: II;
- ECG MODE: MODE 3;

- RESP LEAD: I;
- PACE: OFF.

6.1.4 RESP Monitoring (Optional)

■ **Measuring Method**

The monitoring of respiration is done together with the ECG electrodes.

To obtain better respiratory waveform (RESP) and more precise respiratory rate (RESP), following points should be noticed:

⚠ CAUTION:

- The respiratory measurement of this instrument adopted the thorax impedance method, and the respiratory signal is also gained by the cardio-electrode, so the electrode pacing way correct or not will affect the measurement of the respiration directly. For correctly placing the electrode, please to refer "For electrocardiogram measurement".
- Since the calculation of the respiratory rate is obtained by the way of the instrument measuring the respiratory waveform, so the quality of the respiratory wave and the interference extent will affect the precision of the respiratory rate directly. For obtaining the better waveform, it's better to keep the patient quiet and relax, not to turn the body frequently, no arm motion to prevent the electromyo-signals.
- The respiratory waveform gain should be automatically regulated periodically by the instrument to display the optimal respiratory waveform in window.

■ **Interface and setup of RESP**

The RESP wave and parameter data can refer to figure 6.5.

RESP wave can be set in the WAVE WIN-1 or WAVE WIN-2. Please refer to 6.1.3.

6.2 NIBP Monitoring (Standard)

6.2.1 Preparation

■ **NIBP Module Information**

Standard NIBP Configuration: The Biocare NIBP module

Standard NIBP Configuration of this instrument is the Biocare NIBP module.

The Non-invasive Blood Pressure (NIBP) measurement module is designed by the manufacturer.

The Module meets all relevant parts of the following Safety Standards:

- • IEC60601-1:2005

- • IEC/EN60601-2-30:1999/2000

- • AAMI SP10:1992/2002

- • EN1060-1:1995+A2:2009

- • EN1060-3:1997+A2:2009

Optional Configuration: SunTech NIBP module

Optional NIBP Configuration of the instrument is SunTech NIBP module.

The Non-invasive Blood Pressure (NIBP) measurement module is designed by SunTech.

Since 1982, SunTech has been producing automated Blood Pressure monitoring technology that provides the highest level of clinical accuracy and reliability. Because we live in an increasingly mobile world, SunTech focuses on providing product solutions for clinical applications where:

- • Manual BP results are often questionable or simply not possible.

- • Other automated BP products perform poorly or not at all.

The Suntech NIBP measurement module has been certified by CE and FDA.

The Module meets all relevant parts of the following Safety Standards:

- • IEC60601-1:1997

- • IEC/EN60601-2-30:1999/2000

- • AAMI SP10:1992/2002

- • EN1060-1:1995

- • EN1060-3:1997

■ **Measuring Method**

The traditional blood pressure method is the Korotkoff-souna Method, while the present automatic instrument adopted the oscillometric method. Oscillometric and the Korotkoff-souna method are very well interrelated, and have their own advantages and disadvantages. Compared to the Korotkoff-souna method, the oscillometric method has minor error, stronger objectivity, better reliability and higher stability. Besides, the oscillometric based automatic blood pressure measurement system is well developed, and is more suitable for NIBP measurement in patient monitor.

The NIBP module of our patient monitors adopted the oscillometric method to measure the blood pressure. In the process of measuring the blood pressure, the module records all the measuring process, analyzes the data one

point by one point on the basis of the relative value of the pulse amplitude. Special anti-interference circuit is used to improve the precision, consistency, adaptability of the measurement.

■ **Cuff Selection and Placement**

● Please use the cuff provided by the manufacturer or authorized party of the manufacturer.

● Make sure the cuff is empty before wrapping it.

● Wrap the cuff onto the arm, be sure that the gas tube is stretched out without twisting and to avoid compression or restriction of pressure tubes. After wrapping the cuff, the lower end of the cuff should be1~2 cm higher than the elbow joint. It is better for the tightness that it can be inserted for one or two fingers. Too loose may lead to high pressure result. Too tight may lead to low pressure result and make the patient feel uncomfortable, the resume of arm blood pressure may also be affected in this case. The air pipe of the cuff should be placed on the brachial artery and on the extension line of the middle finger.(Refer to Figure 6.6)
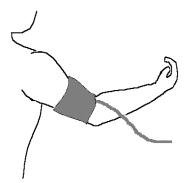

Figure 6.6

● Do not pull the gas tube hardly to avoid damage to the tube.

● The sign on the cuff should be pointed to the position of the artery.

● The width of the cuff should be 40% of perimeter of the arm (50% for neonates), or 2/3 of the length of the upper arm. The filling part of the cuff should be long enough to wrap 50-80% of the wrapped limb. The following table is a reference.

Arm	perimeter of the arm	Size of the cuff
Upper arm of Neonates	<8 cm	7.2×13 cm
Upper Arm of Pediatrics	17~35 cm	9.8×18 cm
Upper Arm of Adults	35~55 cm	16.5×32 cm

Please choose the right cuff for your patient.

⚠ **Other warning and attentions:**

● The measurement should be done on patient's left arm.

● Roll up the sleeves. Thick clothes lead to lower accuracy.

● Put the arm on the desktop and at the same height with the heart, the patient should keep quiet and avoid

moving when inflating and deflating.

● The palm should be upside.

● Do not measure the blood pressure on the limbs with catheter or infusion. Do not put on the cuff at or near the wounded position.

● Generally speaking, the first measurement result can only be used as a reference.

● When used with the high frequency surgical equipment, the HF surgical equipment cannot contact the electric interface of NIBP of the monitor.

● The monitor can protect against the effects of the discharge of a defibrillator. The cuff is dielectric, and the interface of the NIBP is isolated.

● Do not contact the electric interface of NIBP of the monitor when the defibrillation discharge, and must use the cuff provided by the manufacturer.

■ **Warning and caution**

To precisely and safely measure the blood pressure, please pay attention to the following points:

● Different cuff should be chosen for adults, pediatrics and neonates. Drive away the air residue in the cuff before measurement. Put the sign (Φ) on the cuff at the point where the brachial artery pulse is the most obvious. It is better for the tightness that it can be inserted for one finger. The lower end of the cuff should be 2 cm higher than the elbow joint. (for details, please refer to Figure 6.6)

⚠ **Cautions:**

Do not measure blood pressure on the limb with infusion or catheter, neither on the injured site or tie the cuff near it.

● The person being measured should be in supine position, and the cuff should be at the same level of the patient's heart.

● In the process of pumping in or releasing out the air (especially in the air releasing process), the person being measured should not speak or move, neither the cuff being collided.

● The interval between two measurements should not be too short (generally should be more than 2 minutes). Too short interval will cause the arm being pressed to have less blood flow and cause the blood pressure lower.

● When measuring the blood pressure, the initial inflation pressure of the cuff is adjusted according to the last measurement result. The initial value after monitor startup is 21.33kpa (160mmHg) for adults, 16kPa (120mmHg) for pediatric and 9.33kPa (70mmHg) for neonates. The later inflation pressure is plus 6.67kPa (50mmHg) for adults, 5.33kPa (40mmHg) for pediatrics and plus 4kPa (30mmHg) for neonates on the basis of the last detected systolic pressure. In cases such as the patient's blood pressure goes up suddenly or the patient is been changed to another one, the blood pressure measurement may fail after the first inflation. In this case, the monitor will adjust the inflation pressure and make another measurement until the pressure is get

or failed 3 times. If the measurement is failed 3 times, the monitor will stop the measurement for this time and will show the error code for the doctor to check.

⚠ Warnings:

Choose different mode for different people. Never use the 'adult mode' to measure the blood pressure for neonates, otherwise the high pressure of the cuff can cause injury to the neonates. Although there is no risk to use 'neonatal mode' upon adults, it will cause the blood pressure undetectable, or the result of the measurement has no meaning, so the correct mode must be selected.

⚠ Cautions:

In following cases, be cautious to measure the blood pressure:

1. Severe spasm of the blood vessel, blood vessel contraction, and pulse beat too weak.

2. Patient heart rate too low or too high or too severe arrhythmia especially in patients with atriafibrillation, the value will be not reliable or undetectable.

3. Do not use this machine when the patient is connected with the artificial heart-lung machine.

4. After the patient taking the diuretic or vessel dilator.

5. In the condition of hematorrhea, hypovolemia, shock or low temperature, the blood pressure of the patient will change too fast and the body temperature too low, the value will be unreliable for the peripheral blood volume too low and the artery beat too weak.

6. The value will be incorrect on too fat patient.

7. On patients with Parkinson's disease.

● It is illustrated by the statistical principles that, in the process of the measurement, some abnormal value may appear. It is objective to any kind of scientific experiment. This may be caused by some obvious reason or unknown reason. Experience can help to identify the abnormal values and get rid of them. Sometimes obviously unreasonable results may appear when measuring Blood Pressure with oscillometric method, and they can be eliminated by the doctor according to his/her experience.

⚠ Cautions:

1. The accuracy of the blood pressure measurement depends on appropriate cuff. Measure the perimeter of the arm to select suitable cuff.

2. Do not push or pull the cuff during measurement. External pressure may lead to low accuracy.

6.2.2 Display interface

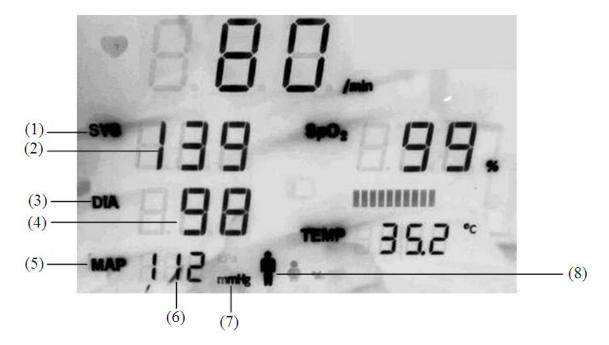In the main interface, NIBP parameters are displayed, as shown as Figure 3.2. The definition can refer to 6.7.

Figure 6.7

Specification:

    (1) Abbreviation of the systolic pressure;

    (2) Measurement values of the systolic pressure;

    (3) Abbreviation of the diastolic pressure;

    (4) Measurement values of the diastolic pressure;

    (5) Abbreviation of the mean pressure;

    (6) Measurement values of the mean pressure;

    (7) Display unit of NIBP: kPa or mmHg can be selected;

    (8) Indicator light of NIBP cuff: there are three kinds cuff (Adult, Pediatric and Infant);

6.2.3 Setup menu

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

The default first page of "**SETUP**" interface is "**SYSTEM**" interface. Select "**NEXT**" button or press " 🔲 " into the "**NIBP**" page, as shown in figure 6.8.
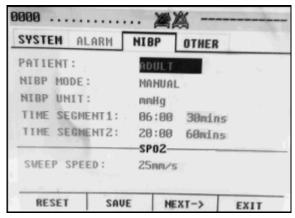
Figure 6.8

Menu	Description	Value Range
PATIENT	Set the patient type.	ADULT/ CHILD/ NEONATAL
NIBP METHOD	Set the NIBP measurement method.	MANUAL/ AUT/ SERIES/ BPG
NIBP UNIT	Set the unit of NIBP.	mmHg/ KPa
TIME SEGMENT1	Set the first begin time of data reviews and interval (or close)	The interval of 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15minutes, 30 minutes, 45 minutes, 60 minutes, 90 minutes, 2 hours, 4 hours, 6 hours, 8 hours or off
TIME SEGMENT2	Set the second begin time of data reviews and interval (or close),	The interval of 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 90 minutes, 2 hours, 4 hours, 6 hours, 8 hours, or off

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item.(Before exit please ensure all settings have been saved.)

6.2.4 Calibration

Making "NIBP METHOD" to BPG in the figure 6.8, and save it. The monitor is set the NIBP calibration mode.

Calibrate the cuff pressure reading with a calibrated reference manometer (or mercury manometer) with accuracy higher than 1mmHg. To perform the calibration, follow the procedure shown below:

1. Remove the blood pressure cuff from the monitor;

2. Connect a calibrated reference manometer (with an error less than 1mmHg) and a ball pump using "T" connectors.

3. Inflate the metal container using the ball pump until the reference manometer reads 0, then 50, and finally 200 mmHg.

4. The difference between the indicated pressure of the reference manometer and the DIA indicated pressure of the monitor will not exceed 3 mmHg.

5. Contact our Customer Service if these values are not met.

6.3 SPO$_2$ Monitoring (Standard)

6.3.1 Preparation

■ **SPO$_2$ Module Information**

Standard SPO$_2$ Configuration: The Biocare SPO$_2$ module

Standard SPO$_2$ Configuration of the instrument is the Biocare SPO$_2$ module.

The Module meets all relevant parts of the following Safety Standards:

  • IEC60601-1:2005

  • EN ISO9919:2009

The first optional Configuration: Nellcor SPO$_2$ module

The first optional SPO$_2$ Configuration of the instrument is Nellcor SPO$_2$ module.

SPO$_2$ Blood Oxygen measurement module is designed by Nellcor Puritan Bennett Division.

If Nellcor SPO$_2$ module is installed, the "Nellcor" label will appear on the side panel, as shown as Figure 6.9.
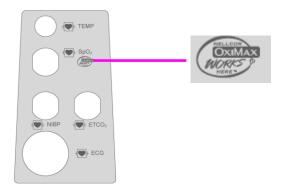
Figure 6.9

(1) Accessories

Using the sensor of Nellcor Company when the monitor which is configured with Nellcor SPO_2 module measuring SPO_2. Other kinds' sensors may cause incorrect measurement. Please read the user manual of the sensor carefully before operating it (including all warnings, cautions and usages). When choosing the sensor, please consider the patient's weight and activity amount, the extent of blood supply, the position of the sensor and sterilization.

Nellcor sensor has finished the biocompatibility test. This test is finished according the first part of ISO100993-1 medical equipment biology measurement.

Before cleaning the sensor, please read the instruction of the sensor carefully. Each kind of the sensor has special cleaning instruction.

⚠ **Warnings:**

When using SPO_2 sensor, musculature injury may be caused by wrong method. According the usage of the sensor, watch the position which the sensor touches carefully.

(2) Nellcor Patent

This equipment is protected by follow American patents: 4802486, 4869254, 4928692, 4934372, 5078136, 5351685, 5485847, 5533507, 5577500, 5803910, 5853364, 5865736, 6083172, 6463310, 6591123, 6708049, Re.35122. International patents are universal.

(3) No Implicit Admission

Own or purchase this equipment doesn't mean that one or some parts of the equipment can be replaced, nor having some patents of this equipment.

The second optional Configuration: Masimo SPO_2 module

The second optional SPO_2 Configuration of this patient monitor is Masimo SPO_2 module.

SPO_2 Blood Oxygen measurement module is designed by Masimo Corporation.

The module and accessories have been certified by CE.

If Masimo SPO_2 module is installed, the "Masimo" label will appear on the side panel, as shown as Figure 6.10.
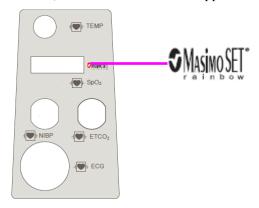

Figure 6.10

■ **Measuring Method**

Monitoring SPO_2 is an invasive technology. SPO_2 and pulse rate is measured by the measurement of absorbability of wave with special wavelength. The led of the probe emits light through the tissue, and the light is detected by the sensor that changes it to electrical signal. The monitor disposes the signal and displays the pulse wave, SPO_2 and pulse rate on the main interface.

Normally, there is relation between oxygen parameter value and pulse waveform. Typically good SPO_2 wave as follows. (Figure 6.11)

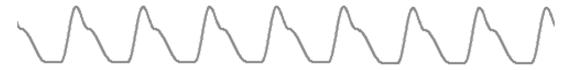Figure 6.11

For obtaining precise blood oxygen value (SPO_2) and the true pulse wave (PLE), following "warning and caution" should be noticed:

■ **Probe Placement**

1) The manufacturer or Nellcor probe placement instructions

The clip should be placed on the finger correctly, do not reverse the placement (see Figure 6.12), otherwise the measurement result will be incorrect.
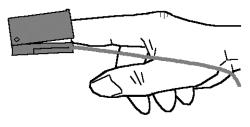
Figure 6.12

2) Masimo probe placement instructions

a) Site Selection

Choose a site that is well perfused and least restricts a conscious patient's movements. The ring or middle finger of the non-dominate hand is preferred.

Alternatively, the other digits on the non-dominate hand may be used. Always choose a site that will completely cover the sensor's detector window. The great toe or long toe (next to the great toe) may be used on restrained patients or patients whose hands are unavailable.

Site should be cleaned of debris and dry prior to sensor placement.

b) Attaching the sensor to the patient

Open the sensor by pressing on hinge tabs. Place the selected digit over the sensor window of the sensor. The fleshiest part of the digit should be covering the detector window in the lower half of the sensor. The top half of the sensor is identified by the cable. The tip of the finger should touch the raised digit stop inside the sensor. If the fingernail is long, it may extend over and pass the finger stop.

- The hinged tabs of the sensor should open to evenly distribute the grip of the sensor along the length of the finger. Check position of sensor to verify correct positioning. Complete coverage of the detector window is needed to ensure accurate data.

- Orient the sensor so that the cable will be running towards the top of the patient's hand. Connect the sensor connector to a patient cable or directly to the device.

  NOTE: With smaller digits, in order to completely cover the detector window, the digit might not need to be pushed all the way to the stop. The sensor is not intended for use on the thumb or across a child's hand or foot.

c) Disconnecting the Sensor from the Patient Cable

- Place thumb and index finger on gray buttons on either side of the patient cable connector.

- Press firmly on the gray buttons and pull to remove the sensor.

■ **Warning and caution**

1) To the manufacturer's SPO$_2$ module and probe

- Use probes designated by the manufacturer.

- The clip should be placed on the finger correctly, do not reverse the placement (see Figure 3.4), otherwise the measurement result will be incorrect.

⚠ **Caution:**

Do not place the blood oxygen probe on the fingers with injured skin, edema or fragile finger. Do not to place the probe on the same finger over 2 hours to prevent the finger discomfort. Use the neonatal SPO$_2$ probe to measure the neonatal blood oxygen.

- The light between the blood oxygen saturation sensor and the light-electric receiving tube must pass through the small artery bed of the patient.

- Avoid placing the blood oxygen probe to the same limb with artery catheter, blood pressure cuff or venous infusion.

- Improper fixing the probe with band will cause the venous pulse that induces the incorrect value.

- Do not place things like band to hinder the light way in the probe.

- Strong environmental lighting will affect the blood oxygen test, such as fluorescence light, double ruby light, infrared heater or direct sunshine.

- If the patient move intensely and there is interfereance by an electrosurgic, it will affect the accuracy.

- If blood oxygen monitoring is not wanted in the monitoring processes turn off this module in system setting. After turning off this module, neither shows the pulse waveform nor measures the blood oxygen value.

In following cases, their measurement should be limited:

1. Since the measurement is based on the small artery pulse, minimum artery flow is required. The weakness of the pulse or the micro-circulation disorder due to shock, cool, too low body temperature, massive hemorrhage or vasoconstrictor will decrease the pulse wave, and make the measurement more sensitive to the interference; Too much dye agent (methylene-blue, indocyamine, indigo carmine), carboxyhemoglobin (COHb), methionine (Me+Hb), sulfhemoglobin in body or in some patients with jaundice, the value may be incorrect when use this machine.

2. Drugs such as dopamine, procaine, prilocaine, lidocaine and buzucaine may induce bigger blood oxygen measurement deviation.

3. Patents with Parkinson's disease.

4. In patients with anemic hypoxia and toxic hypoxia, the pulse blood oxygen is only of reference value, for in some severe anemic patients, their blood oxygen value may also be quite normal.

- If blood oxygen monitoring is not wanted in the monitoring process, the blood oxygen module can be turned off. After it is turned off, neither the pulse waveform nor the blood oxygen value will be displayed.

⚠ **Warning:**

The SPO_2 measurement function of this monitor can't be used to replace the SPO_2 measurement of an apnea monitor.

- Do not measure SPO_2 in an environment with flammable anesthetic or mixture of flammable material and air, O_2 or N_2O.

- The measurement may be incorrect. It may be due to patients or mechanical influence. The conditions

include but not limit to: vein beat, low blood pressure, serious anemia, low temperature, shock, tight sensor.

● If, in the period of measurement it shows "pull out of SPO_2 probe" maybe the finger is not put on the right place in the SPO_2 probe, or the placement of SPO_2 probe together with the arm that measures the blood pressure. In measuring blood pressure, if the blood flow is blocked, then blood oxygen cannot be measured at this point.

● Interfering substance may lead to incorrect SPO_2 reading.

● MRI interference.

● Monitor should be used below 40 ℃.

● The cable of the probe should not be tied before using.

● The blood oxygen probe offered for our monitor must be used.

● The blood oxygen probe can be used about one year under normal usage.

● Connect one end of the cable of the probe to the monitor.

● Pleases use the neonatal probe when measuring a neonate.

● Do not to place the blood oxygen conductor probe onto the injured skin, edematous or fragile tissue.

● The conductive probe should not be placed at the same place for too long time, do not place the probe on the finger over 2 hours. The probe can be used in this patient monitor.

● The neonatal probe can be used when measuring the neonatal blood oxygen and the finger-clip and finger-cot probe used when measuring the adult's blood oxygen.

2) To Nellcor SPO_2 module and probe

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by an alternate method. Then check the instrument for proper function.

Inaccurate measurements may be caused by:

● Incorrect sensor application or use;

● Placement of a sensor on the same extremity with a blood pressure cuff, arterial catheter, or intravascular line;

● Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark material);

● Excessive patient motion;

● Venous pulsations;

● Intravascular dyes such as indocyanine green or methylene blue;

● Defibrillation;

Other physiological conditions or medical procedures that may interfere with the monitor's measurements include significant levels of dysfunctional hemoglobin, low perfusion, and dark pigment.

Loss of pulse signal can occur in the following situations:

- The sensor is too tight;

- A blood pressure cuff is inflated on the same extremity as the one with a SpO_2 sensor attached;

- There is arterial occlusion proximal to the sensor.

Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- Verify that the sensor is properly and securely applied.

- Move the sensor to a less active site.

- Use an adhesive sensor that tolerates some patient motion.

- Use a new sensor with fresh adhesive backing.

If poor perfusion affects performance, consider using the Oxisensor sensor; it obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. This sensor may obtain measurements when peripheral perfusion is relatively poor. For low peripheral perfusion, consider using the Nellcor RS-10 sensor, which is applied to the forehead or temple. These are sites that may be spared during peripheral vasoconstriction.

Measurement Limit

- Too strong environmental lighting will affect the SPO_2 test, such as fluorescence light, double ruby light, infrared heater or direct sunshine;

- Excessive patient movement;

- venous pulsations;

- Senores applied too tightly;

- Placing the SPO_2 probe to the same limb with blood pressure cuff.

3) To Masimo module and probe

- Severe anemia may cause erroneous SpO_2 readings.

- This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection

against harmful interference in a typical medical 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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 device.

> Increase the separation between the equipment.

> Consult the manufacturer for help.

- The sensor site must be inspected at least every eight (8) hours; and if the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.

- The site must be checked at least every eight (8) hours to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.

- If the sensor is wrapped to tightly or supplemental tape is used, venous congestion/pulsations may occur causing erroneous readings.

- Exercise caution when applying a sensor to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.

- With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.

- Sensors applied too tightly may cause erroneously low readings.

- Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.

- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize.

- Intravascular dyes or externally applied coloring (such as nail polish) may lead to inaccurate SpO_2 measurements.

- To protect against injury from electric shock, follow the directions below:

> Avoid placing the device on surfaces with visible liquid spills.

> Do not soak or immerse the device in liquids

> Always turn off and disconnect the power cord from the AC power supply before cleaning the device

> Use cleaning solutions sparingly.

- To ensure patient electrical isolation, connect only to other equipment with electrically isolated circuits.

- Do not use damaged sensors or patient cables. Do not use a sensor or patient cable with exposed optical or electrical components.

- Do not immerse the sensor or patient cable in water or, solvents, or cleaning solutions (The sensors and connectors are not waterproof).

- Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide. See the cleaning instructions in the directions for use for the Masimo re-useable sensors.

- Do not attempt to reprocess, recondition or recycle any Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to harm.

- To avoid cross contamination only use Masimo single use sensors on the same patient.

- Loss of pulse signal can occur when:

  ➤ The sensor is too tight.

  ➤ The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.

  ➤ There is arterial occlusion proximal to the sensor.

  ➤ The patient is in cardiac arrest or is in shock.

- Failure to apply the sensor properly may cause incorrect measurements.

- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.

- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.

- Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.

- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor)

- Venous pulsations may cause erroneous low readings (e.g. tricuspid value regurgitation).

- Circulation distal to the sensor site should be checked routinely.

Measurement Limit:
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not sterilize by irradiation, steam, autoclave or ethylene oxide.
- CLEANING: To clean the sensor, first remove it from the patient and disconnect it from the patient cable. You may then clean the sensor by wiping it with a 70% isopropyl alcohol pad. Allow the sensor to dry prior to placement on a patient.
- The site must be checked at least every four (4) hours to ensure proper adhesion, skin integrity and proper alignment.

- Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site at least every two (2) hours with poorly perfused patients.

- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.

- With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.

- Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.

- The sensor should be free of visible defects. Never use a damaged sensor or one with exposed electrical circuitry.

- Do not attempt to reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.

- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize.

- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.

- Intravascular dyes or externally applied coloring (such as nail polish) may lead to inaccurate SPO_2 measurements.

- Failure to apply the sensor properly may cause incorrect measurements.

- Do not use the sensor during MRI scanning.

- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.

- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.

- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should be not below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor)

- Venous pulsations may cause erroneous low readings (e.g. tricuspid value regurgitation).

- Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.

6.3.2 Display interface

■ **Parameter display interface**

In the main interface, SPO_2 parameters are displayed, as shown as Figure 3.2. The definition can refer to Figure 6.13.
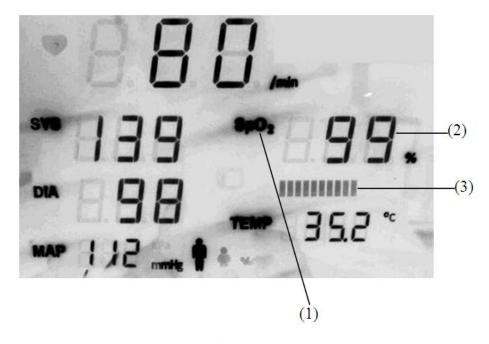

Figure 6.13

Specification:

    (1) Abbreviation of SPO_2;

    (2) Measurement values and unit of SPO_2, and the unit is "%";

    (3) Indicator light of Pulse strength of SPO_2.

■ **Wave display interface**

If "PLE" wave of SPO_2 is set in the WAVE WIN-1, PLE wave can be displayed in the upper windows' area of LCD display area, as shown as Figure 6.14.
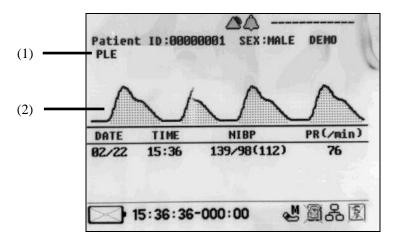

Figure 6.14

Specification:

(1) PLE: Abbreviation of the true pulse wave by SPO$_2$ measurement;

(2) PLE waveform.

6.3.3 Setup menu

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

The default first page of "**SETUP**" interface is "**SYSTEM**" interface. Select "**NEXT**" button or press " ▢ " into the "**NIBP**" page, the lower windows' area is the setup menu of SPO$_2$, as shown in figure 6.16.
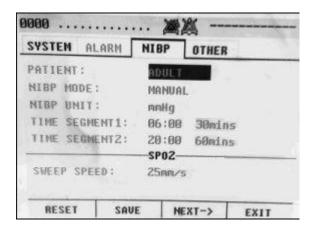
Figure 6.16

Menu	Description	Value Range
SWEEP SPEED	Set the sweep speed	12.5mm/s, 25mm/s, 50mm/s

Methods of setting the parameters as follows:

1) Rotate control knob to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press control knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the control knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the control knob to exit this functional item.(Before exit please ensure all settings have been saved.)

6.4 TEMP Monitoring (Standard)

6.4.1 Preparation

■ **TEMP Module Information**

Standard TEMP Configuration: The Biocare TEMP module (conventional body temperature means)

Standard TEMP Configuration of the instrument is the Biocare TEMP module.

The temperature (TEMP) measurement module is designed by the manufacturer that is conventional body temperature means.

The Module meets all relevant parts of the following Safety Standards:

• IEC60601-1:2005

• EN12470-4:2000+A1:2009

• AAMI E1112:2006

Optional Configuration: Infrared Thermometer probe

The optional TEMP configuration of the instrument is Infrared Thermometer probe.

The temperature (TEMP) module is designed by Radiant Innovation Inc..

The module and accessories has been certified by CE and FDA.

■ **Measuring Method**

Conventional body temperature is measured by means of a thermistor probe that is inserted in the rectum or the esophagus.

Infrared Thermometer is designed with an advanced infrared and ambient temperature compensation technology for instantaneous self-diagnosis and accurate temperature measurements.

■ **Probe Placement**

Operation for thermal temp probe

1. Connect the thermal temp probe to the TEMP socket of this patient monitor.

2. Fix the head of the probe to a proper position of the body according to the type of the probe (body surface / rectal /oral).

3. The measurement result will be shown on the screen seconds later and when it become stable within one minute, the final result is got.

Operation for thermometer

1. Connect the Infrared thermometer to the TEMP socket of this patient monitor. (see Figure 6.17)

Figure 6.17

2. Push the sides of the plastic cover lightly to take it off. Prevent pulling it strongly.(see Figure 6.18)
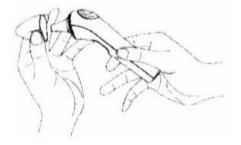
Figure 6.18

3. Please use clean, no damaged and new probe covers.

4. The method of installing the probe cover: (1) put the probe cover's non film side into the groove of the installation ring; (2) align the installation ring's center and the probe's center, push the installation ring into the bottom (see Figure 6.19)
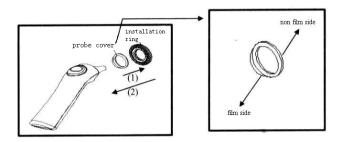
Figure 6.19

⚠ **Warning**

Keep the children away from the installation rings, probe covers and alcohol. Taking the test after the alcohol is dried. Please use our company's probe covers. The measurement result maybe incorrect with other probe covers which is not produced by our company.

5. Push "power/memory" button (see Figure 6.20)

Figure 6.20

6. All words in the display screen will stay 2 seconds. The system corrects the temperature (less than 10seconds). After hearing the tick twice, users can start the measurement (see Figure 6.21)
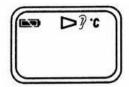
Figure 6.21

7. Fix the patient's head, put the probe into the ear and aim the eardrum, or press the probe close to the skin, then push the "measurement" button. Open the button after hearing tick in 2 seconds. (see Figure 6.22)
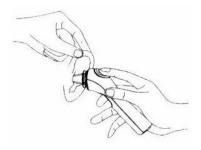
Figure 6.22

8. Take out the thermometer and read the result. The result also shows on the patient monitor's screen.(see Figure 6.23)

Figure 6.23

9. The thermometer has the function of fever alarm. When the temperature surpasses 37.5℃, the machine will alarm with one long tick and three short tick.

10. The thermometer has the function of power off automatically.

11. The conversion mode between °C and °F: push the "measurement" and "power/memory" button until The thermometer is started.(see Figure 6.24)

Figure 6.24

⚠ Caution:
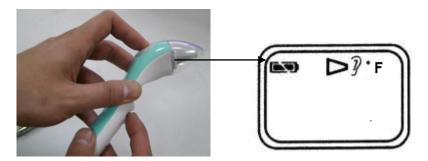
When the thermometer's mode is changed, remember to change the monitor's mode.

⚠ NOTE:

- Before the measurement, please stay in a stable environment for 5mins and avoid the exercise, bath for 30mins.
- It is recommended that you measure 3 times with the same ear. If the 3 measurements are different, select the highest temperature.
- To avoid the risk of cross contamination, please clean the probe according to "Cleaning and Storage" section after each use.
- Clinical repeatability: 0.20℃ (＜1 year old), 0.14℃ (1~5 years old), 0.14℃ (＞5 years old).

■ **Warning and caution**

To obtain the correct temperature, following points should be noticed:

⚠NOTE:

- Use only temperature probes provided by the manufacturer.
- Please use FDA approved "Thermometer Probe Covers and Sheaths".
- Ensure the connector of the temperature probe tightly plugged into the 'TEMP' socket on the panel.
- For thermal temperature probe, it is important to fix it onto the skin of a proper position and fix it.
- Temperature of the same patient but of the different body position will be different, and the value obtained will vary, please treat differently.

6.4.2 Display interface

In the main interface, TEMP parameter is displayed, as shown as Figure 6.24.

Figure 6.24

Specification:

   (1) Display unit of TEMP: ℃ or ℉ can be selected;

   (2) Measurement values of TEMP.

6.4.3 Setup menu

Select **"SETUP"** to enter into setting interface by turning Control Knob in the main monitor interface.

The default first page of "**SETUP**" interface is "**SYSTEM**" interface. Select "**NEXT**" button or press " ▣ " into the "**OTHER**" page, as shown in figure 6.25.
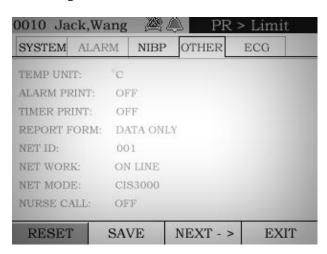
Figure 6.25

Set temperature module, print module, and network module parameters;

Menu	Description	Value Range
TEMP UNIT	Set the unit of temperature measurement	℃ / ℉
ALARM PRINT	Enable or disable the alarm print function	ON/OFF
TIMER PRINT	Enable or disable the timer print function	Off, 5mins, 15mins, 30mins, 1hour, 2hours, 5hours
REPROT FORM	Set the print content.	DATA ONLY/ DATA+TRACE
NET ID	Set the monitor ID of net for connecting the remote of internet central station	001~255
NET WORK	Enable or disable the networking function	ON LINE/ OFF LINE
NET MODE	Select net mode.	CIS3000/ CIS-120
NURSE CALL	The switch to setup nurse call function	ENABLE/ DISABLE

Methods of setting the parameters as follows:

1) Rotate the encoder to select item. The selected item will displayed with red font of yellow background.

2) If doctors want to change the content of selected item. Press rotary knob, then the selected item changes into yellow font of red background. Rotate the knob to change the content of the item. Finally, press the rotary knob. That is OK.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the rotary knob, all the parameters will return to the default.

SAVE: Select it and press the rotary knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the rotary knob, enter into to the next interface of the current interface, such as "**SYSTEM**," "**ALARM**", "**NIBP**", "**OTHER**" and **"ECG"** interface.

EXIT: Select it and press the rotary knob to exit this functional item.(Before exit please ensure all settings have been saved.)

6.5 EtCO$_2$ Monitoring (Optional)

The instrument uses two kinds of EtCO$_2$ monitoring probes supplied by Phasein, one is IRMA and the other is ISA.

The IRMA main stream multi-gas probe is intended to be connected to patient monitor for display of real time and derived monitoring data of CO$_2$ or others.

The ISA product family consists of different types of sidestream gas analyzers, intended to be connected to patient monitors for display of real time and derived monitoring data of a selection of CO$_2$, N$_2$O, O$_2$ and the anesthetic agents Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane.

IRMA and ISA are intended for monitoring of inspired gases during anesthesia, recovery and respiratory care. They may be used in the operating suite, intensive care unit, patient room and emergency medicine setting for adult, pediatric and infant patients.

⚠ WARNING

The EtCO$_2$ probes cannot be used as the only means of monitoring a patient. It shall always be used in combination with other vital signs monitoring devices and/or professional human judgments of patient condition. The EtCO$_2$ probe is intended to be used by trained and authorized health care professionals only.

6.5.1 Preparation

IRMA

Step	Figure	Description
1		1. Plug the IRMA connector into the IRMA input of patient monitor and switch the power on.
2		2. Snap the IRMA probe on top of the IRMA airway adapter. It will click into place when properly seated.
3		3. A green LED indicates that the IRMA probe is ready for use.
4		4. Connect IRMA / airway adapter 15 mm male connector to the breathing circuit Y-piece.
5		5. Connect the IRMA / airway adapter 15 mm female connector to the patient's endotracheal tube.
		Alternatively, connect an HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing an HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.
6		6. Unless the IRMA probe is protected with an HME always position the IRMA probe with the status LED pointing upwards.

⚠ Warning

Avoid direct contact between the IRMA probe and the infant's body, or an insulation material must be placed between the probe and the body.

Pre-use Check

Always verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.

Perform the tightness check of the patient circuit with the IRMA probe snapped on the IRMA airway adapter

■ **ISA**

 ISA adapter   ISA sampling

To set up the medical backboard device for gas analysis, follow these steps:

1. Securely mount the ISA analyzer.

2. Connect the ISA analyzer interface cable to the medical backboard.

3. Connect a Nomoline Family sampling line to the ISA analyzer input connector.

4. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuitto prevent pollution of the operation room when N_2O and/or anesthetic agents are being used.

Note: Returning the ISA‟s exhaust gas to the patient circuit is not allowed in the USA.

5. Power up the medical backboard.

6. A green LED indicates that the ISA analyzer is ready for use.

7. Perform a pre-use check as described in section 1.6.

To set up the <host device> for gas analysis, follow these steps:

1. Connect a Nomoline sampling line to the inlet port of the ISA gas analyzer.

2. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit.

3. Power up the <host device>.

4. A green LED indicates that the ISA gas analyzer is ready for use.

5. Perform a pre-use check as described below.

Pre-use check

Before connecting the Nomoline sampling line to the breathing circuit, do the following:

1. Connect the sampling line to the ISA gas inlet connector (LEGI)

2. Check that the LEGI shows a steady green light (indicating that the system is OK)

3. Breathe into the sampling line and check that valid CO_2 waveforms and values are displayed on the <host device>.

4. Occlude the sampling line with a fingertip and wait for 10 seconds.

5. Check that an occlusion alarm is displayed and that the LEGI shows a flashing red light.

6. If applicable: Perform a tightness check of the patient circuit with the sampling line attached.

■ **Warning and caution**

(1) IRMA

⚠ **Warning**

- The IRMA probe is intended for use by authorized and trained medical personnel only.

- The IRMA probe must not be used with flammable anesthetic agents.

- Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.

- Used airway adapters shall be disposed of in accordance with local regulations for medical waste.

- Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.

- Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.

- Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.

- Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.

- To keep secretions and moisture from pooling on the windows or oxygen sensor port, always position the IRMA probe in a vertical position with the LED pointing upwards.

- Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.

- Do not try to open the oxygen sensor assembly. The oxygen sensor is a disposable product and contains a caustic electrolyte and lead.

- The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

- Incorrect probe zeroing will result in false gas readings.

- Replace the adapter if rainout/condensation occurs inside the airway adapter.

- Use only PHASEIN manufactured IRMA airway adapters.

- The IRMA probe is not intended to be in patient contact.

- Do not apply tension to the probe cable.
- Do not operate the IRMA probe outside the specified operating temperature environment.

(2) ISA

⚠ **Warning**

- The ISA sidestream gas analyzer is intended for use by authorized and trained medical personnel only.

Use only Nomoline sampling lines manufactured by PHASEIN.

- The ISA sidestream gas analyzer must not be used with flammable anesthetic agents.
- Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
- Do not re-use disposable sampling lines.
- Do not lift the ISA/<host device> by the sampling line as it could disconnect from the ISA/<host device>, causing the ISA/<host device> to fall on the patient.
- Used disposable sampling lines shall be disposed of in accordance with local regulations for medical waste.
- Do not use adult/pediatric type sampling line configurations with infants, as this may add dead space to the patient circuit.
- Do not use infant type sampling line configurations with adults, as this may cause excessive flow resistance.
- Do not use the ISA sidestream gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
- Check that the gas sample flow is not too high for the present patient category.
- Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the gas analyzer, ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.
- The Nomoline sampling line and its interfaces are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.
- Never sterilize or immerse the ISA sidestream gas analyzer in liquid.
- Measurements can be affected by mobile and RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.
- ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Replace the sampling line if the sampling line input connector starts flashing red, or a Nomoline occlusion message is displayed on the host.
- No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
- ISA sidestream gas analyzers are not designed for MRI environments.
- During MRI scanning, the <host device> must be placed outside the MRI suite.
- Use of high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.
- Do not use external ambient cooling of the ISA device.
- Do not apply negative pressure to the Nomoline (i.e. by a syringe) to remove condensed water.

- Too strong positive or negative pressure in the patient circuit might affect the sample flow.

- Strong scavenging suction pressure might affect the sample flow.

- Exhaust gases should be returned to the patient circuit or a scavenging system.

- Always use a bacteria filter on the evac side if sampled gas is intended to be re-breathed.

- Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.

- The ISA "plug-in and measure" analyzers should be securely mounted in order to avoid the risk of damage to the ISA.

- Do not apply tension to the ISA sidestream gas analyzer cable.

- Do not operate the ISA sidestream gas analyzer outside the specified operating temperature environment.

■ **Accuflow**

6.5.2 Display interface

When the user observes the $EtCO_2$ waveform, please put the CO_2 waveform on the main interface. Open the patient monitor and go into the main interface, push multifunction key to shift CO_2 waveform interface.

Figure 6.26 shows the sample of wave forms and parameters of CO_2.
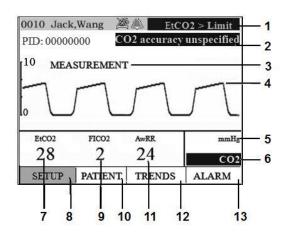
Figure 6.26 CO_2 waveform and parameters

1. Parameter alarm

2. Technique alarm

3. $EtCO_2$ working mode

4. CO_2 waveform

5. Press unit : mmHg or kPa

6. CO_2 hot-key: this key can go into "CO_2 set " menu

7. $EtCO_2$: $EtCO_2$ measured value

8. System setup

9. $FiCO_2$: the least CO_2 inhale quantity measured value

10. Patient information

11. AwRR: the air flue breath value

12. Trend

13. Alarm trend

6.5.3 Parameters Setup

Use " " to enter into "**EtCO₂ SETUP**" setting interface after insetting the EtCO₂ probe, in the main monitor interface, as shown in Figure 6.27.
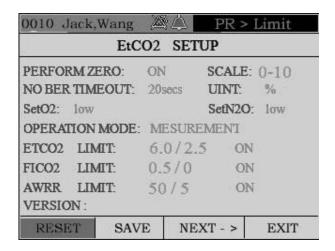
Figure 6.27

Menu	Description	Value Range
PERFORM ZERO	Choose ON the module will perform zero	ON / OFF
SCALE	Setup the range of the waveform display	0~10%(0-76mmHg), 0~15 %(0-114 mmHg)
NO BRE TIMEOUT	Non breath overtime setup	20, 40, 60 secs.
UINT	Unit choose	% or mmHg
Set O₂	O₂ supply	low (0%) and (50%)
OPERATION MODE	Set the working mode	measurement, self test, sleep
Set N₂O	N₂O supply	low (0%) and (50%)
EtCO₂ upper limit:	Set the upper limit of EtCO₂ alarm	0~12
EtCO₂ lower limit:	Set the lower limit of EtCO₂ alarm	0~12
ALARM switch	ALARM switch	On or disable
FiCO₂ upper Limit	Set the upper limit of FiCO₂ alarm	0~1
FiCO₂ lower Limit	Set the lower limit of FiCO₂ alarm	0~1
FiCO₂ alarm switch	FiCO₂ alarm switch	ON or disable
AwRR upper limi	Set the upper limit of AwRR alarm	0~100
AwRR lower limit	Set the lower limit of AwRR alarm	0~100
AwRR alarm switch	AwRR alarm switch	ON or disable

The operation of function setup:

1) Rotating the knob to select the item which will displayed with yellow background.

2) Push the knob to change the content of the item. The item will become yellow font and red background. Rotating the knob can change the content and push it again to save it.

At the bottom of the window, "**RESET**", **"SAVE", "NEXT"** and "**EXIT**" are defined as follows:

RESET: Select it and press the control knob, all the parameters will return to the default.

SAVE: Select it and press the control knob, all parameters of this page will be saved and it will return the "Monitoring" interface automatically.

NEXT: Select it and press the control knob, enter into to the next page.

EXIT: Select it and press the control knob to exit this functional item.(Before exit please ensure all settings have been saved.)

6.5.4 Zeroing Procedure

■ **IRMA**

⚠️**Warning**

Incorrect Probe Zeroing will result in false gas readings.

In order to secure high precision of the IRMA probe measurements the following zeroing recommendations should be followed.

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the host instrument to transmit a Zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air($21\%O_2$ and $0\%CO_2$)in the IRMA airway adapter is of crucial importance for a successful Zeroing. If a "ZERO_REQ" alarm should appear directly after a Zeroing procedure, the procedure has to be repeated.

IRMA CO$_2$ probes:

Zeroing needs to be performed ONLY when an offset in gas values is observed, or when an unspecified accuracy message is displayed.

Allow 10 seconds for warm up of the IRMA CO_2 probe after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

◾ **ISA**

⚠**Warning**

Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the gas analyzer, ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure

ISA CO_2 probes:

ISA sidestream gas analyzers perform zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed every 24 hours, and takes less than 3 seconds for ISA CO_2 gas analyzers and less than 10 seconds for ISA multigas analyzers.

If the ISA sidestream gas analyzer is fitted with an oxygen sensor, the automatic zeroing will also include room air calibration of the oxygen sensor.

6.5.5 Alarms

The monitor will alarm or show indications when the user operates the module improperly or the module appears abnormal situation.

(1) Module Alarm Information and illustration:

Alarm Information	Description
EtCO$_2$ surpass the limitation	The measured EtCO$_2$ value surpasses the limitation
FiCO$_2$ surpass the limitation	The measured FiCO$_2$ value surpasses the limitation
The breath rate surpasses the limitation.	The measured breath rate surpasses the limitation
No breath（CO$_2$）	The patient has no breath.

(2) Module Indication Information and Technique Alarm

Indication	Description
NO MODULE	The module isn't connected to the monitor
Software error	Restart the sensor
Hardware error	The module has malfunctions. It should be sent to the manufactory.
Sensor error	The sensor has error
Calibration lost	The module isn't performed zero

Repl adapter	Change the adapter
No adapter	The adapter is not connected well
CO_2 accuracy unspecified	
Temp outside range	The temp surpasses the range
Pressure outside range	The pressure surpasses the range
Zeroing required	Perform zero

(3) IRMA probe Alarm

Include a description of the host alarm system, including the gas reading alarm limit range and its discrimination, and the implementation of alarm and status information transmitted by the IRMA probe.

Include a description of the status LED situated on the IRMA probe:

Steady green light	System OK
Blinking green light1)	Zeroing in progress
Steady blue light2)	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check adapter

Note 1: Not valid for IRMA OR

Note 2: Valid for IRMA multi-gas probes only

(4) ISA probe Alarm

Include a description of the host alarm system, including the gas reading alarm limit range and its discrimination, as well as the implementation of the alarm and status information transmitted by the ISA sidestream gas analyzer

Also include an overview of the status indicated by the LEGI:

Steady green light	System OK
LyBlinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check sampling line

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Chapter 7 Reviewing and Printing

7.1 Reviewing

7.1.1 NIBP Table

➢ NIBP measured record form review.

Record numbers of current measured NIBP.

Display the current ID range of NIBP record.

Turning Page Button   Review Trend Chart
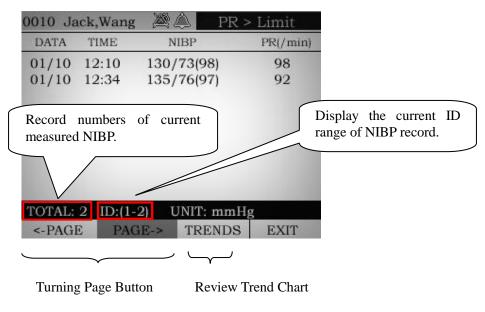
Figure 7.1

Display the current and the last blood pressure measurement recorded data of the current patient. Displayed blood pressure unit should be consistent with set blood pressure module.

7.1.2 TREND Table

➢ Trend table review

Set displayed time interval.
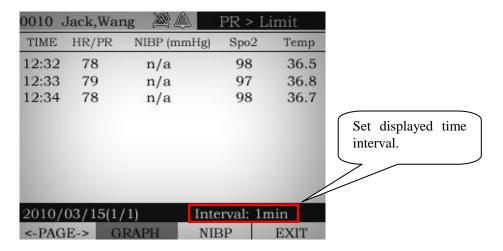
Figure 7.2

Display monitored physiological parameters in the specific table. Use Control Knob to select **"<-PAGE->"** to turn page.

Interval: Users can select 1min, 5min, 10min, 15min or 30min.

7.1.3 TREND Graph

There are two trends pages, you can click on **"MORE"** or press " " to back and forth:

(1) The first page for **"PR"** and **"SPO$_2$"** trend pages, as shown in figure 7.3
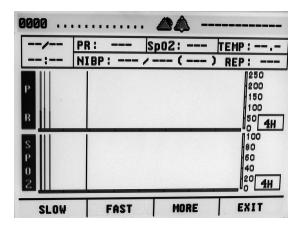
Figure 7.3

(2) The second page for **"TEMP"** and **"NIBP"** trend pages, as shown in figure 7.4.
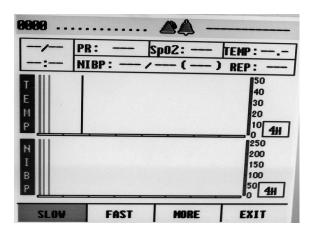
Figure 7.4

● Select "**SLOW"** or **"FAST"** and press the knob, and then rotate the knob. The knob is defined as the operation as moving of the trend cursor.

● Select **"SLOW"** and press the knob and then rotate the knob. The knob is defined as the fine movement operation of the cursor. Press it again to withdraw from the state of the cursor movement, then return to the menu operation.

● Select **"FAST"** and press the knob, and then rotate the knob. The knob is defined as the operation as fast forward or fast back of the trend cursor. Press it again to withdraw from the state of the cursor movement, then return to the menu operation.

● Select **"EXIT"** and press the knob to exit the trend page, then return to the main monitor menu.

The trend history offered review function with history monitor value of the current patient. The review mode can let the doctor direct know the patient's history trend of some physiological parameter and parameter alarm in some period of time. Under the show mode, the doctor can see the patient's monitor parameter information in some period of time and flip the trend graph automatically through rotating the Control Knob. The show mode has two parts: slow show mode and fast show mode. Under the slow show mode, when rotating one value record it will move 1 trend. Under the fast show mode, when rotating one value record it will move 5 trends. And it can adjust quantity of value and value resolution through setup the trend ruler.

7.1.4 Trend Ruler

Trend ruler is the length of history monitor value which under the status of trend history. If set 4 hours it denote that it showed 4 hours' trend history value. The value resolution is 1 minute. (1 minute 1value record) If set 12 hours it denote that it showed 8 hours' trend history value. The value resolution is 3 minutes.(3 minutes 1 value record)

1) Show the date and time custody, battery, speaker state.

2) Show all kinds of the system parameters.

3) The button of menu entrance.

4) Show SD Card, print, Net connecting, blood pressure table.
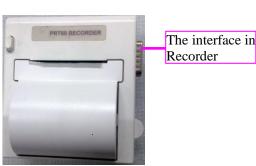
7.2 Printing

7.2.1 Installation of Recorder

The monitor can connect "PRT 60 thermal Recorder".

PRT 60 thermal Recorder insets the left of the interface of the monitor, as shown in figure7.5. And tighten the screw.

The interface in monitor

The interface in Recorder

Step1:
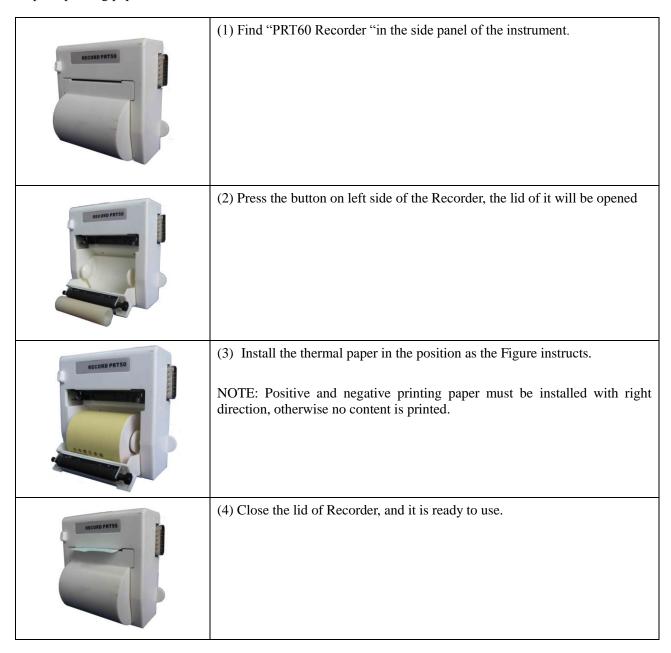
Step 2:   Step 3:

Figure 7.5

7.2.2 Installation of Printing Paper

Steps of printing paper installation for **the PRT60A** recorder is as follows:

	(1) Find "PRT60 Recorder "in the side panel of the instrument.
	(2) Press the button on left side of the Recorder, the lid of it will be opened
	(3) Install the thermal paper in the position as the Figure instructs. NOTE: Positive and negative printing paper must be installed with right direction, otherwise no content is printed.
	(4) Close the lid of Recorder, and it is ready to use.

⚠ **Caution:**

The Recorder is optional, not all the monitors produced have this function. Only when customer orders the PRT 60 thermal Recorder which is special for the monitor from manufacture, then it can be installed and used the record function.

Press the button " ⑤ " on the panel of the instrument or set the function to print automatically. When users need to use the function of record. Before printing, ensure the paper for the Recorder is installed correctly.

Five printing modes are supported for the instrument:

Real time record: denote the record after pressing the button "RECORD" under the unfreezing or response status.

Timing record: denote printing is started automatically according to the intervals set in the menu.

Alarm record: denote that the Recorder is started automatically when there are alarm affairs.

Some functional keys or status infect the print method:

PRINT: It is an important key. Start the corresponding print function according to the current state when it is not in printing. If the print is on, press the key will stop to print. But in other states the key does not react.

FREEZE: It is an important key of the freezing state. The print startup will be affected by the freezing state.

TIME PRINT: System will set time to print automatically if the function has started.

ALARM: Alarm will start to print automatically if the function has started.

The content of print record includes two types:

Data: The instruction of alarm parameter, PR, SPO$_2$, TMEP, NIBP (SYS, DIA, MAP)

Wave: Print three channel waveforms in timing record and response record (determined by print setting).Print screen waveforms in freezing record.

Amplitude of print: setup as 3 levels (5mm/mv, 10mm/mv, 20mm/mv)

7.2.3 Printing Setup

To print information, the thermal Recorder as an option of the monitor must be installed, besides that, some print parameters must be set correctly.

The methods of setting parameters as follows:

Enter "other" of the main menu to see the functional menu, in the second page to set alarm print, regular print, print content.

Introduce the print parameters setup as follows:

- REPORT.FORM: can be set "data only" and "data + wave" are for real time. "Data only" is for time print and alarm print.

- TIME PRINT: can be set (off, 5 minutes, 15 minutes, 30 minutes, 1hour, 2hours, 5hours). Data will be printed according to the setting intervals

- ALARM PRINT: ON is to open the alarm print and off is to close the alarm print.

7.2.4 Printing Report

1) Real time record:

- Real time record denotes that the customer press the "RECORD" to start the Recorder in non-freezing status.

  In real time record, print the waveforms and the data,

  During printing, if the user presses the "RECORD" button again, record will be stopped, otherwise, it continues printing for 30 seconds then stop automatically.

2) Timing record:

- Timing record denotes the Recorder starts to print automatically according to the time interval set by the customers.

- Timing record must be set "customized timing", and a time interval in "print parameters" is set, timing record can be valid.

- Only data but not waveform is printed in timing record.

- During timing record, if the user press "RECORD" button again, the system won't pay attention to it, and continues printing until all contents is printed completely.

3) Alarm record

- Alarm record denotes the Recorder starts to print automatically when there is an alarm.

- Alarm record must be set "on" to this function's star-up.

- Only data but not waveform is printed in timing record.

- During alarm record, if the user press "RECORD" button again, the system won't pay attention to it, and continues printing until all contents is printed completely.

Chapter 8 Maintenance

In order to assure normal operation, test precision and life of the instrument, please pay attention to the maintenance of the instrument.

8.1 Clean and Sterilize

⚠ Warning

Disconnect the monitor from the power line before cleaning or disinfecting its surface.

Caustic chemical materials and high temperature are never to be used to sterilize the leads, probes, sensor or cables.

8.1.1 Exterior Surface

The equipment should be cleaned on a regular basis. (Comply with the policies of your institution's infection control unit and/or biomed department.) The exterior surfaces of the equipment may be cleaned with a dampened, lint-free cloth. Use one of the following approved solutions:

- Ammonia (diluted),

- Cidex,

- Sodium hypochlorite bleach (diluted), or

- Mild soap (diluted).

⚠ Caution

Failure to follow these rules may melt, distort, or dull the finish of the case, blur lettering on the labels, or cause equipment failures.

To avoid damage to the equipment, follow these rules:

a） Always dilute the solutions according to the manufacturer's suggestions.

b） Always wipe off all the cleaning solution with a dry cloth after cleaning.

c） Never use a cleaning substance containing wax.

d） Never pour or spray water or any cleaning solution on the equipment or permit fluids to run behind switches, into the connectors, or into any ventilation openings in the equipment.

e） Never use these cleaning agents:

  - Abrasive cleaners or solvents of any kind,

  - Acetone,

- Ketone,

- Alcohol based cleaning agents, or

- Betadine.

8.1.2 Display

To clean the display screen, use a soft, clean cloth dampened with a glass cleaner. Never spray the glass cleaner directly onto the display, and never use alcohol or hospital disinfectants like Cidex or Betadine.

8.1.3 Cleaning applied parts

■ Cables and Leadwires

⚠ **Caution**

- Do not use acetone or ketone solvents for cleaning; do not use an autoclave or steam cleaner.

- Cables and leadwires can be cleaned with a warm, damp cloth and mild soap, or isopropyl alcohol wipes.

For more intensive disinfecting (near sterile) Ethylene Oxide (ETO) is acceptable for but will reduce the useful lifetime of the cable or leadwire.

⚠ **Caution**

The decision to sterilize must be made per your institution's requirements with an awareness of the effect on the integrity of the cable or leadwire.

■ ECG cable

Clean:

> If there is any sign that the ECG cable may be damaged or deteriorated, replace it with a new one instead of continuing its application on the patient.

> Use fine-hair cloth moistened in mild soap liquid or cleaning agent containing 70% ethanol to clean the equipment.

Sterilize:

> To avoid extended damage to the equipment, sterilization is only recommended when stipulated as necessary in the Hospital Maintenance Schedule.

> Sterilization facilities should be cleaned first.

> Recommended sterilization material:

> - Ethylate: 70% alcohol, 70% isopropanol

> - Acetaldehyde

Disinfection:

> To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

- **SPO₂ probe and cable**

Probe and cable may be surface-cleaned by wiping it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (5%~5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur.

⚠ Caution

Do not expose connector pins to cleaning solution as this may damage the sensor.

To clean or disinfect the sensor:

(a) Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad.

(b) Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.

(c) Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad.

⚠ Caution

Do not sterilize by Irradiation,steam, or ethylene oxide. Such sterilization could damage the sensor.

- **Blood Pressure Cuff**
- Reusable Blood Pressure Cuff

The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned.

The cuff can also be machine-washed or hand-washed, the latter method may prolong the service life of the cuff. Before washing, remove the latex rubber bag, and for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing, then reinsert the rubber bag.

To replace the rubber bag in the cuff, first place the bag on top of the cuff so that the rubber tubes line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the complete cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

- Disposable Blood Pressure Cuffs

Disposable cuffs are intended for one-patient use only. Do not use the same cuff on any other patient. Do not sterilize or use autoclave on disposable cuffs. Disposable cuffs can be cleaned using soap solution to prevent infection.

- **Reusable TEMP Probes**

The TEMP probe should not be heated above 100℃ (212℉). It should only be subjected briefly to temperatures between 80℃ (176℉) and 100℃ (212℉).

The probe must not be sterilized in steam.

Only detergents containing no alcohol can be used for disaffection.

The rectal probes should be used, if possible, in conjunction with a protective rubber cover.

To clean the probe, hold the tip with one hand and with the other hand rubbing the probe down in the direction of the connector using a moist lint-free cloth.

⚠ Note

- Disposable TEMP probe must not be re-sterilized or reused.
- For protecting environment, the disposable TEMP probe must be recycled or disposed of properly.

■ **EtCO$_2$ Probes**

(1) IRMA Probe

The IRMA probe can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA Airway Adapter prior to cleaning the IRMA probe.

⚠ Caution

- IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
- Never sterilize or immerse the IRMA probe in liquid.

(2) ISA Probe

The "plug-in and measure" ISA sidestream gas analyzers should be cleaned on a regular basis. Use a cloth moistened with max 70% ethanol or isopropyl alcohol to clean the analyzer.

To prevent cleaning liquids and dust from entering the ISA gas analyzer through its LEGI connector, keep the Nomoline sampling line connected while cleaning the analyzer.

Caution: The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.

Caution: Never sterilize or immerse the ISA sidestream gas analyzer in liquid.

⚠ Caution

- The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line
- Never sterilize or immerse the ISA sidestream gas analyzer in liquid

8.1.4 Other

For other applied parts such as temperature sensors, catheters, pulse oximetry probes, and NIBP cuffs, you must consult the manufacturer for cleaning, sterilization, or disinfecting methods.

⚠ **Caution**

- Do not put under direct sunlight, to avoid damages by high temperatures in the monitor enclosure.
- Do not use the instrument in an environment with poisonous, flammable or caustic gas.
- Place the instrument on firm and flat desk or shelf.
- Pay attention to any voltage fluctuations. If the voltage exceeds the permitted range, we advise the use of a voltage-stabilizing device.
- If the instrument requires repair, one of our technicians or a company-designated representative must repair it. Do not tear down, maintain, debug the instrument, replace components or change electrical wires by an unauthorized technician. Otherwise, our company is not responsible for the resulting consequences.
- Do not use keyboard in order to avoid damage to internal information and procedures.

8.2 Replace Power Fuse

The instrument uses an internal fuse, please contact manufacturer for replacement.

8.3 Charge up the Internal Battery

1. When the instrument is supplied with an external AC power, the internal battery will charge. The indicatorwill remain illuminated until the battery is full.

2. Charging time is based on the electrical capacity, when the battery is exhausted at least 4~8 hours of charging is needed. In a normal situation, the battery can be used for 5~10 hours if it is fully charged.

3. Internal battery models are divided into two types, one is the standard, and the capacity is 2200mAh. The other is optional, the capacity is 4400mAh.

8.4 Install and Replace the Battery

⚠ **Warning**

- The battery our instrument uses has high capacity and charged up circularly. Use only batteries that our company recommends, or it may damage the instrument.
- Please do not short, fire, extrude and disconnect the battery, or this may lead to fire or explosion. Pull the power plug when the battery is installed or replaced.

This instrument uses Li- battery. It provides the maximum 8.4 V (average of 7.2 V) of the DC voltage. Li-battery designs by internal configuration, as shown in Figure 8.1.

Figure 8.1

The battery position is at the bottom, and two screws fix it. It is connected with the internal modules by connectors (Refer to Figure 8.2).

Installing and replacing the battery, please pull the power line first.

Because of the characteristic of the battery, it needs to be charged up at least once every six months. Otherwise, the battery performance will be affected or invalid. The battery is charged up via plug power for about 4~8 hours.

Scrap batteries are disposed of in accordance with local environmental requirements or may be recycled by returning to the manufacturer.

⚠ **Note**

If the AC power is not supplied, whether the battery is full or not, the charge indicator will not be lighted, but it doesn't mean the battery is full.

Figure 8.2

8.5 Periodic Check

1) The designed lifecycle of the instrument is 5 years.

2) Check the instrument once a year.

3) Check the accessories every six months.

4) If the instrument with battery has not been used for a long time, then it needs to be charged up at least every six months. The battery performance will be affected or invalid if it is not charged regularly. The battery is charged via the AC plug into the power socket for about 4~8 hours at least

8.6 Service

1) If the instrument has some malfunctions, please contact with the dealer or our service department at once, we will remedy the problem as soon as possible.

2) If the instrument has some malfunctions to repair, one of our technicians must make repairs or a company designated repair person. Tearing down, maintaining, debugging the instrument, replacing components or changing electrical wires by anyone without our agreement or commission voids any warranty and our company is not responsible for the resulting consequences.

3) The components for replacement must be produced by our company or adaptable to use with our approval.

4) Necessary accessories for maintenance are supplied to an authorized service and supply representative.

5) If the customer wants to use the accessories as SPO_2 probes, blood pressure sleeves which are not approved by our company, the user must contact our service department to confirm if they are compatible.

6) The manufacturer will provide, for a fee, the circuit diagrams, component part lists, etc.

8.7 Transportation and Storage

The transportation must be complied with the requirements of the ordering contract.

1) Environmental temperature: -40 ℃ ~55 ℃ (-40 ℉ ~131 ℉)

2) Environmental relative humidity: ≤95% (non-condensing)

3) Air pressure : 16.5kPa~106kPa

4) The room is well ventilated and without caustic gas.

⚠ **Note**

Please properly store the package. If the monitor needs to be returned, please use the package to protect the monitor.

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Chapter 9 Trouble Shooting

If the instrument has malfunctions in use, the problems can be addressed as shown in the table below. If the malfunction is not debugged, please contact our dealer or service department.

⚠ **Warning**

If there are signs of problems, such as fire or smoke, do not open the instrument to find the malfunctions. The best way is to contact with local dealer or service department of the manufacturer at once.

⚠ **Caution**

- Only a trained technician can open the monitor, replace or adjust the components
- Do not open the instrument to or attempt to repair the, as it may lead damage to the instrument.
- If there are no available trained technicians, please contact with service department of the manufacturer.

9.1 Simple and Apparent Malfunction Checking

When you check the malfunctions of the monitor, two problems must be checked first.

1) Whether the battery is full(if the monitor is on the rechargeable battery)

2) If AC supplies it, check if the monitor is plugged in and if the power line is connected to the monitor.

If there is no problem with power supply, observe the three power indicator lights on the front panel to judge where the malfunction exits.

1) "~ " blue indicator for AC

   If AC power is supplied, press the "start/stop" button for about 2~3 seconds when the instrument is off, the instruments will start, and the blue indicator is on (the blue DC indicator is off). If the light is not on, the problem may be as follows: the power line is not plugged in well, the fuse is broken, the power module is broken or the indicator is bad.

2) " ▬▬▬ " : blue DC indicator light(suitable for the instrument power supplied by the battery)

   The instrument is not plugged in but if there is sufficient battery light, press the "start/stop" button for about 2~3 seconds when the instrument is off, the instruments will start, and the blue indicator is on(the blue DC indicator is off), and it shows that the instrument can operate with battery supply. If the indicator is not on, there may be some problems as follows: the "start/stop" button has a loose contact, some malfunctions in the charging control board, DC indicator is bad, the capacity of the battery is not enough or the battery is damaged.

3) "➔▥" : blue indicator light(suitable for the instrument with battery installed supplied by the AC power)

When AC is supplied, the instrument will charge up automatically. If the blue light is on, it shows that the battery is charging. If the capacity of the battery is full, the blue light will be off. Generally, the battery needs 4~8 hours to be charged up with full capacity. If the time for charging up is above 24 hours and the blue light is on yet, there may be the problems as follows: the charging control board has malfunction or the battery is damaged.

9.2 Malfunction Instructions Displayed on the Screen

Failure indication	Possible reason	resolution
initialization	1. malfunction of blood pressure module 2. the communicational signal line or NIBP signal line connected the NIBP module and connect board is loose contact 3. malfunction with SPO$_2$ module 4. the communicational signal line or SPO$_2$ signal line connected the SPO$_2$ module and connect board has loose contact 5. malfunction with ECG module 6. the communicational signal line or ECG signal line connected the ECG module and connect board is loose contact	1.replace NIBP module 2.re-plug or replace communicational signal lines or NIBP signal lines 3.replace SPO$_2$ module 4. re-plug or replace communicational signal lines or SPO$_2$ signal lines 5.replace ECG module 6.re-plug or replace communicational signal lines or ECG signal lines
×mark on the Recorder	1. Recorder electric line off or bad connection 2. Recorder cable line off or bad connection Recorder failure 3. No Recorder	1. reconnect or replace the Recorder electric line 2. reconnect or replace the Recorder cable line 3. replace the Recorder
Lead off	1. Broken SPO$_2$ Probe 2. SPO$_2$ line slot failure 3. the SPO$_2$ module failure RA electrode invalidation .LA electrode invalidation LL electrode invalidation C electrode invalidation RL electrode invalidation	1. replace the SPO$_2$ Probe 2. replace SPO$_2$ line slot replace the SPO$_2$ module 4.replace high quality electrode

9.3 Error Code Displayed on the Screen

The error code is only used in blood pressure measurement in this monitor.

Malfunction instruction	Possible cause	Means to dispose
The blood pressure value cannot be read(For error reminding, see "Appendix: blood pressure error code contrast table") or the value is incorrect	1. Cuff tied incorrectly	Tie the cuff again according to 2.3
	2.The patient's arm with cuff is moving	Keep the patient quiet when taking the blood pressure
	3.Cuff is tied outside the clothes	Tie the cuff after taking off the clothe
	4. Air leakage for the cuff	Change the new cuff
	5.The connection between the cuff tube and the plug is not tight	Connect again and ensure its tightness
	6.Rubber tube of the cuff twisting	Release the tube to keep the airway smooth
	7. This Patient is not suitable for NIBP measurement.	Take the value repeatedly

Blood pressure measurement error code table

Error Code	Description
00	No error
06	Wrong cuff (Cuff not connected or not tied)
07	Air leakage
08	Air pressure wrong(unstable pressure)
09	Signal weak
10	Upper measurement
11	Too much motion
12	Over pressure tested
13	Signal saturated
19	Over time testing

9.4 Other Phenomena of Malfunctions

If the malfunctions must be disposed by replacing some components, please contact with local dealer or service department of the manufacturer.

Malfunction phenomena	Possible causes	Means to dispose
The screen is black when power on	1. the LCD is damaged 2. the lines of the LCD is loose contact or damaged	1. replace the LCD 2. re-plug or replace the lines
The color of the screen seems red	1. the backlight of the LCD is damaged	1. replace the LCD
Can't save system time	1. CMOS battery is invalid 2. malfunction of clock CMOS chip	1. replace CMOS battery 2. replace clock CMOS chip
The buttons and the knob are of no effect	1. the keyboard signal lines is loose contact or damaged 2. malfunction of keyboard PCB	1. re-plug the signal line 2. replace the keyboard
The buttons are good, the knob is of no effect	1. the lines between the knob and the keyboard are loose contact or damaged 2. the knob is damaged	1. re-plug the leads of knob 2. replace the knob
The knob is good, the buttons are of no effect	1. the buttons don't flip after pressed 2. the buttons are damaged	1. check if the button-caps are locked 2. replace the keyboard
Not connect to the center station	1. "offline" is set in the menu 2. the net wires are loose contact or damaged 3. the connect board is damaged	1. set "online" in the menu 2. rep-plug or replace the net wires 3. replace the connect board
The temperature value is abnormal	1. the temperature probe is damaged 2. the temperature probe is not contact well with the socket 3. the socket doesn't contact the temperature signal lines of ECG module well or it is damaged 4. malfunction of the ECG module	1. replace the temperature probe 2. re-plug the temperature probe 3. re-plug or replace the temperature signal lines 4. replace the ECG module
SPO_2 value can't be read or incorrect	1. the probe is placed reversely 2. the finger with the probe is moving 3. dirt on the finger with the probe 4. if the luminous diode does not flash, then it shows that the SPO_2 probe is	1. clip the probe correctly onto the finger 2. keep the patient quiet 3. clean the finger 4. re-plug or replace the probe or SPO_2 signal lines.

	loose contact or damaged 5. the patients belongs to the ones who are not allowed the measure the SPO$_2$	5. do measurement after the patient is normal.
Blood pressure can't be measured	1. The hardware and software did overpressure protection automatically. 2. The software in the protected state of pressure measurement, then it lead the manual measurement key can't response.	1.restart the machine 2.restart the machine
There is interference in the electro cardio wave, or the base line floats	1. place the electrode incorrectly or unstably, or the electrode plate is invalid 2. incorrect grounding of the instrument 3. server body motion such as turning the body frequently, server cough	1. choose high quality electrode to place it again 2. if no grounding lines is available in the power supplied circuit, connect the special grounding lines of the instrument to the pipes for tap water or heating. 3. keep the patient quiet

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Appendix A Product Specifications

A.1 Safety Information

Class	Specification
Type of protection against electric shock	Class I, with internal power supply
Degree of protection against electric shock	Anti-defibrillation: CF type
Degree of protection against ingress of water as detailed in the current edition of IEC 529	Ordinary equipment (sealed equipment without liquid proof)
Degree of protection against hazards of ignition of flammable anesthetic mixtures with air, oxygen or nitrous oxide	Not suitable for use in the presence of a flammable anesthetic mixtures with air, oxygen or nitrous oxide
Mode of operation	Continuous

A.2 Environment Requirements

Parameters	Specification
Runtime Environment Requirements	
Temperature	5 ~ 40 ℃ (41 ℉ ~ 104 ℉)
Relative humidity	≤95% (non-condensing)
Air pressure	70kPa ~ 106kPa
Other	Drafty and without corrosive gas
Transportation and Storage Environment Requirement	
Temperature	-40 ℃ ~ 55 ℃ (-40 ℉ ~131 ℉)
Relative humidity	≤95% (non-condensing)
Air pressure	16.5kPa ~ 106kPa
Other	Drafty and without corrosive gas

A.3 Power Supply Requirements

AC power supply	
Input Voltage	100V~240V (±10%)
Frequency	50/60Hz (±3Hz)
Power	≤40VA
Internal battery input	
Type	Rechargeable Lithium battery
Output Voltage	6.4V~8.4V
Capability	2200mAh
Charge time	Less than 6 hours when the monitor is on
DC power input	
Input Voltage	9V~15V

A.4 ECG (Optional)

ECG	
Lead	3 leads(RA,LA,LL) / 5 leads(RA,RL,LA,LL,V)
Lead system option	monitoring lead / standard lead
Gain	5mm/mv, 10mm/mv
Sweep speed	12.5mm/s, 25mm/s, 50mm/s
Wave gain	5%
Range of heart rate	Adult: 20~300bpm Neonate/Pediatric: 20~350bpm
Resolution	1 bpm
Precision	20~200bpm: 5% or ±5bpm whichever is greater 201~350bpm: 10%
Alarm setting	the limit of alarm (setup range: 20～350 bpm), and leads-off alarm display.
Aalarm method	Alarm with sound and lights, and record the data during alarm for the review.
Input resistance	≧5 MΩ
CMRR	≧89 dB
S-T detecting range	-2.00~2.00mv
Heart disorder analysis	No
Anti-polarized voltage	±500 mV
Baseline renewing time	<5 s after the defibrillation
ECG filter mode	mode 1(diagnostic), mode 2(monitoring), mode 3(operation)
Frequency characteristic	0.67Hz~40Hz
Safeguard	4000V high voltage isolation, anti-defibrillation,

A.5 NIBP

NIBP (Biocare) (Standard)	
Method	Oscillometric
Application	Neonatal, pediatric and adult patients
Measurement Modes	
Manual	Adaptive or preset cuff inflation
Automatic	Host controlled (1-90 minutes as selected by host)
STAT	Restarts a new measurement after 5 or 10 second pause (host selectable); terminates after 5 minutes
Test Mode	Provides continuous output of system pressure
Data unit	mmHg / kPa optional
Data storage/review	4000 blood pressure value at most
Alarm setup	The range is the same as parameter measurement range of SYS, DIA, MAP
Alarm method	Sound light alarm，and record the alarm status for review
Measuring range	
Adult Mode	
SYS	40~60 (mmHg)
DIA	20~200 (mmHg)
MAP	26~220 (mmHg)
Pediatric Mode	
SYS	40~160(mmHg)
DIA	20~120(mmHg)
MAP	26~133(mmHg)
Neonate Mode	
SYS	40~130(mmHg)
DIA	20~100(mmHg)
MAP	26~110 (mmHg)
Resolution	1 mmHg
Transducer Accuracy	±3 mmHg, over full range
Max Average Error	±0.67kPa (±5 mmHg)
Max Standard Error	±1.067kPa (±8 mmHg)
Overpressure limit	Adult/Pediatric /Neonate Mode: 290/220/150 (mmHg)
Pulse Rate	30-220 BPM
Pulse Rate Accuracy	±2% or ±3 BPM, whichever is greater

NIBP (SunTech) (Optional)	
Method of Measurement	Oscillometric. Diastolic values correspond to Phase 5 Korotkoff sounds.
Patients	Neonatal, pediatric and adult patients
Measurement Modes:	
Manual	Adaptive or preset cuff inflation

Automatic	Host controlled (1-90 minutes as selected by host)
STAT	Restarts a new measurement after 5 or 10 second pause (host selectable); terminates after 5 minutes
Test Mode	Cuff pressure will be hold after inflation for test
Data unit	mmHg / kPa optional
Data storage/review	4000 groups of NIBP results at most
Alarm setup	The range is the same as parameter measurement range of SYS, DIA, MAP
Alarm method	Alarm with sound and lights, and record the alarm status for review
Measuring range	
Adult Mode	
SYS	40~260 (mmHg)
DIA	20~200 (mmHg)
MAP	26~220 (mmHg)
Pediatric Mode	
SYS	40~160(mmHg)
DIA	20~120(mmHg)
MAP	26~133(mmHg)
Neonate Mode	
SYS	40~130(mmHg)
DIA	20~100 (mmHg)
MAP	26~110 (mmHg)
Resolution	1 mmHg
Pulse Rate Range	30 to 220 BPM (Beats Per Minute)
Pulse Rate Accuracy:	$\pm 2\%$ or ± 3 BPM, whichever is greater
Cuff Deflate Rate:	Deflation step size varies with heart rate, cuff pressure and cuff volume
Initial Inflation Pressure:	Adult: 160 mmHg (default),variable from 120 to 280 mmHg Pediatric: 120 mmHg (default), variable from 80 to 170 mmHg Neonate: 90 mmHg (default), variable from 60 to 140 mmHg
Clinical Accuracy	Meets accuracy requirements of ANSI/AAMI SP10: 1992 and 2002.
Transducer Accuracy	± 3 mmHg between 0 mmHg and 300 mmHg for operating conditions between 0 ℃ and 50 ℃.
Recommended Frequency of Pressure Transducer Calibration	The Pressure Transducer calibration should be verified on a yearly interval.
Operating Conditions	0 ℃ to 50 ℃, 15% to 95% non-condensing humidity
Storage Conditions	-20 ℃ to 65 ℃, 15% to 95% non-condensing humidity
Altitude	Measurement accuracy is not affected by altitude
Startup Initialization Period:	7 seconds
Patient Safety	Internal operating software ensures that: • Maximum cuff inflation time is limited to 75 seconds • Duration of blood pressure reading is limited to 　　130 seconds (Adult mode) 　　120 seconds (Adult Motion Tolerant mode)

	90 seconds (Pediatric mode)
	75 seconds (Neonate mode)
	Additional redundant safety circuitry oversees normal operation and will override to abort a reading if: • cuff pressure exceeds 300 mmHg (Adult &Pediatric modes) or 150mmHg (Neonate mode) at any time • the cuff has been inflated for 180 seconds (Adult & Pediatric modes) or 90 seconds (Neonate mode) The Module meets all relevant parts of the following Safety Standards: • IEC60601-1:1997 • IEC/EN60601-2-30:1999/2000 • AAMI SP10:1992/2002 • EN1060-1:1996 • EN1060-3:1997

A.6 SPO_2

SPO_2 (**Biocare**)(Standard)	
SPO_2	
Measuring method	Dual wave length infrared wave
Measuring Range	0~100%
Alarm setup range	70~100%
Resolution	1%
Precision	±2% (70~100% adult/ Pediatric)
	±3% (70~100% neonate)
	Unspecified (0~69%)
Pulse rate	
Measuring Range	25~240bpm
Alarm setup range	25~240bpm
Precision	±3bpm (Geostationary) or ±5 bpm (Campaign)
Sweep speed	12.5mm/s, 25mm/s
Alarm setup	SPO_2 overruns, pulse rate overruns
Alarm method	Alarm with sound and lights, and record the alarm status for review

SPO_2 (**NELLCOR**) (Optional)	
SPO_2	
Measuring method	Dual wave length infrared wave
Measuring Range	0~100%
Alarm setup range	70~100%
Resolution	1%
Precision	±2% (70~100% adult/ Pediatric)

	±3% (70~100% neonate)
	Unspecified (0~69%)
Pulse rate	
Measuring Range	25~240bpm
Alarm setup range	25~240bpm
Precision	±3bpm (Geostationary) or ±5 bpm (Campaign)
Sweep speed	12.5mm/s, 25mm/s
Alarm setup	SPO$_2$ overruns, pulse rate overruns
Alarm method	Alarm with sound and lights, and record the alarm status for review

SPO$_2$ (MASIMO) (Optional)	
SPO$_2$	
Display Range	0.0%-100.0%
Calibration Range	60%-80%, 70%-100%
Calibration Standard	Invasive Co-oximeter
No Motion Accuracy(RMS)	≤2.0%, ≤3.0%
Motion Accuracy(RMS)	≤3.0%
Resolution	≤0.1%
Time to Display	≤8, ≤10, ≤20 seconds
Asystole Detection Time	≤8 seconds
Delay	≤10 seconds
Response Time	≤20 seconds
Display Update Frequency	≥1 HZ
Averaging Time	2-4,4-6,82,10,12,14,16secs
Trend	Every 2secs for 72hrs

A.7 RESP (Optional)

RESP	
Measuring method	The thorax impedance method (used with ECG leads)
Measuring range	15 ~ 120rpm
Resolution	1 rpm
Precision	The bigger one between ±2 rpm or ±2 %
Alarm setup	Respiration rate overruns, asphyxiation
Alarm method	Alarm with sound and lights, and record the alarm status for review

A.8 TEMP

TEMP (Thermal Probe) (Standard)	
Channel	1
Measuring mode	Thermal
Measuring and Alarm Range	0 ~ 50 ℃ (32~122 ℉)
Resolution	0.1 ℃
Measurement accuracy	±0.1 ℃ (25 ~ 45 ℃)
	±0.2 ℃ (others)
Average measurement time	< 60 s
Data unit	℃/ ℉
TEMP(Infrared Probe) (Optional)	
Measurement range	34 ℃~42.2 ℃ (93.2 ℉ ~108 ℉)
Resolution	0.1 ℃
Measurement accuracy	35.5 ℃~42 ℃: ±0.2 ℃
	Other: ±0.3 ℃
Measurement time	≤1s
Power supply of module	Power supply: DC3V button lithium battery Power consumption: ≤20mW Auto power off time: 60s±10s
Module size	140mm×38mm×30mm
Module weight	about 70g

A.9 EtCO$_2$ (Optional)

IRMA (Phasein mainstream)	
General	
Description	Extremely compact infrared mainstream multi-gas probe. Available in various parameter configurations.
Dimensions (WxDxH)	IRMA CO$_2$: 38 x37 x 34 mm (1.49x1.45x1.34 inch)
Cable length	2.50 m±0.02 m
Weight	<25 g (cable excluded)
Power supply	IRMA CO$_2$: 4.5-5.5 VDC, max 1.0 W (power on surge@5 V less than 350 mA during 200 ms)
Surface temperature (at ambient temp 23 ℃)	IRMA CO$_2$: Max 41 ℃/106 ℉

Interface	Modified RS-232 serial interface operating at 9600 bps

Airway adapters	Disposable adult/pediatric:
	    Adds less than 6 ml dead space
	    Pressure drop less than 0.3 cm H2O@30 LPM
	Disposable infant:
	    Adds less than 1 ml dead space
	    Pressure drop less than 1.3 cm H2O@10 LPM

Data output	
Breath detection	Adaptive threshold, minimum 1 vol. % change in CO_2 concentration
Respiration rate	0~150 bpm. The respiration rate is displayed after three breaths and the average value is updated every breath
Fi and ET	Fi and ET are displayed after one breath and have a continually updated breath average. IRMA CO_2: CO_2
Waveforms	YES
Diagnostic parameters	Atmospheric pressure, software and hardware revision, serial number.
Flags	Breath detected, apnea, check adapter, unspecified accuracy and sensor error.
Gas analyzer	
Probe	2~9 channel NDIR type gas analyzer measuring at 4–10μm. Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing Airway adapter. No span calibration required for the IR bench. Room air calibration of oxygen sensor performed automatically when changing airway adapter(<5 seconds)
Warm-up time	Full accuracy within 10 seconds for IRMA CO_2
Rise time (@10 l/min)	$CO_2 \leq 90$ ms
Total system response time	<1 second

ISA (Phasein Sidestream)	
General	
Description	Ultra-compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Dimensions (W×D×H)	ISA CO_2/AX+: 33 x 78 x 49 mm (1.3" x 3.1" x 1.9")
Weight	ISA CO_2/AX+: 130 g including cable
Ambient CO_2	$\leq$ 800 ppm
Power supply	4.5 to 5.5 VDC, ISA CO_2: < 1.4 W (normal op.), < 1.8 W (peak @ 5 VDC)
Interface	USB or RS-232 serial interface. Software upgrade possible using the RS-232 serial interface.

Water handling	Sampling line with proprietary water removal tubing.
Sampling lines	2 ± 0.1 m and 3 ± 0.1 m versions
Sampling flow rate	50 ± 10 ml/min
Data output	
Breath detection	Adaptive threshold, minimum 1 vol % change in CO_2 concentration.
Respiration rate	0 to 150 ± 1 breaths/min
Fi and ET	CO_2
Waveforms	Up to five simultaneous gas concentration waveforms.
Diagnostic parameters	Atmospheric pressure, Cuvette pressure, Serial number, Software revision, Hardware revision
Flags	Breath detected, No breaths detected, Replace O_2 sensor, Check sampling line, Unspecified accuracy, Sensor error
Gas analyzer	
Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 μm.
Compensations	ISA CO_2: Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO_2.
Calibration	No span calibration is required for the IR bench. An automatic zero reference calibration is performed at startup and then every 24 hours
Warm-up time	ISA CO_2: < 10 seconds (Concentrations reported and full accuracy)
Typical rise time at 50 ml/min sample flow	$CO_2 \leq 200$ ms
Total system response time	< 3 seconds (with 2 m sampling line)

Accuracy and Interference Specification		
Accuracy		
Gas	**Range**	**Accuracy**
CO_2	standard conditions: CO_2: 0~15	$\pm$(0.2 vol%+2% of reading)
	standard conditions: CO_2:15~25	Unspecified
	all conditions	$\pm$(0.3 vol%+4% of reading)
Note: The accuracy specification is valid for the operating temperature and humidity conditions specified, except for interference specified in the table "Interfering gas and vapour effects" below.		
Interfering Gas and Vapour Effects		
Gas or Vapour	**Gas level**	**IRMA CO_2**
N_2O [4]	60 vol%	- [1&2]
HAL [4]	4 vol%	- [1]
ENF,ISO,SEV [4]	5 vol%	+8% of reading [3]
DES [4]	15 vol%	+12% of reading [3]

Xe (Xenon) [4]	80 vol%	-10% of reading [3]
He(Helium) [4]	50 vol%	-6% of reading [3]
Metered dose inhaler propellants [4]	Not for use with metered dose inhaler propellants	
C_2H_5OH(Ethanol) [4]	0.3 vol%	- [1]
C_3H_7OH(Isopropanol) [4]	0.5 vol%	- [1]
CH_3COCH_3(Acetone) [4]	1 vol%	- [1]
CH_4(Methane) [4]	3 vol%	- [1]
CO(Carbon monoxide) [5]	1 vol%	- [1]
NO(Nitrogen monoxide) [5]	0.02vo%	- [1]
O_2 [5]	100vol%	- [1&2]

Note 1:	Negligible interference, effect included in the specification "Accuracy, all conditions" above.
Note 2:	For probes not measuring N_2O and/or O_2 the concentrations shall be set from host. according to the instructions in section 4.2(Set N_2O/Set O_2),see also Appendix B. (IRMA CO_2 measures neither N_2O,nor O_2.IRMA AX+ does not measure O_2.)
Note 3:	Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%.This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the measured CO_2 concentration will typically be (1-0.06)*5.0 vol%=4.7 vol% CO_2.
Note 4:	According to the EN ISO 21647:2004 standard.
Note 5:	In addition to the EN ISO 21647:2004 standard.

⚠ Caution:

After being in a condensing atmosphere, the unit shall be stored for more than 24 hours in an environment equivalent to the operating humidity. The humidity range 50~100% is valid within the temperature range-40~40 ℃ only.

Appendix B EMC Statement

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

The equipment meets the requirements of EN 60601-1-2:2007.

⚠ Note

Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The equipment complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.

- It is not normally affected by nearby equipment and devices.

- It is not safe to operate the monitor in the presence of high-frequency surgical equipment.

- However, it is good practice to avoid using the monitor in extremely close proximity to other equipment.

B.1 Electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below.

The customer or user of the equipment should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The equipment 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 equipment is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC61000-3-3	Compliance	

B.2 Electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below.

The customer or the user of the monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±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 common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $$d = 1.2 \times \sqrt{P}$$ $$d = 1.2 \times \sqrt{P} \quad \text{80MHz to 800MHz}$$ $$d = 2.3 \times \sqrt{P} \quad \text{800MHz to 2.5GHz}$$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a]. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.
[b]. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

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

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

Note 1: At 80 MHz and 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.

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