CREATIVE
MEDICAL

Patient Monitor

PC-3000

User Manual

(Version 1.3)

This Manual is written and compiled in accordance with the IEC 60601-1（Medical electrical equipment Part1: General requirements for safety）, and MDD 93/42/EEC. It complies with both international and enterprise standards and is also approved by State Technological Supervision Bureau. The Manual is written for the current PC-3000 Patient Monitor. In case of modifications and software upgrades, you will be advised in due time with a Modification Notice.

The Manual describes, in accordance with the PC-3000 Patient Monitor’s features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Version of This Manual: Ver1.3

Revised Date: October 23, 2012

Marks in the Manual:

- **Warning: must be followed to avoid endangering the operator and the patient.**
- **Note: contains some important information and tips about operations and application.**
- **Attention: must be followed to avoid causing damage to the monitor.**

3502-2560001

Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the following very carefully before using this equipment.

These instructions describe the operating procedures to be followed strictly. Failure to follow these instructions can cause monitoring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user’s negligence of the operation instructions. The manufacturer’s warranty service does not cover such faults.

- **WARNING-PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.**
- **Monitoring a single person at a time.**
- **The monitor is defibrillator proof. Verify that the accessories can function safely and normally and the monitor is grounded properly before conducting defibrillation.**
- **Disconnect the monitor and sensors before MRI scanning. Use during MRI could cause burns or adversely affect the MRI image or the monitor’s accuracy.**
- **If you have any doubt to the grounding layout and its performance, you must use the built-in battery to power the monitor.**
- **All combinations of equipment must be in compliance with standard of IEC 60601-1-1 for medical and electric system requirements.**
- **Check SpO_2 probe application site periodically (every 30 minutes) to determine circulation, positioning and skin sensitivity.**
- **The SpO_2 measurement of this monitor may not work for all testees. If stable readings cannot be obtained at any time, discontinue using.**
- **Do not immerse the monitor or its accessories in liquid to clean.**
- **Do not use accessories other than those provided/recommended by the manufacturer.**
- **Each time the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.**
- **The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**
- **When taking the measure of a pediatric or neonate’s (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.**

- **The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.**
- **DO NOT take blood pressure measurement from a limb receiving ongoing transfusion or intubations or skin lesion area, otherwise, damages may be caused to the limb.**
- **Continuous use of SpO_2 sensor may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.**
- **SpO_2 measuring position must be examined more carefully for some special patient. Do NOT install the SpO_2 sensor on the finger with edema or vulnerable tissue.**
- **To prevent the risk of the short circuit and to ensure the ECG signal quality, the equipment must be properly grounded.**
- **Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.**
- **All the connecting cables and rubber tubes of the applying parts should be kept away from the patient’ s cervix to prevent any possible suffocation of the patient.**
- **All the parts of the monitor should NOT be replaced at will. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused.**
- **DO NOT stare at the infrared light of SpO_2 sensor when switch it on, for the infrared may do harm to the eye.**
- **If the monitor falls off accidentally, please do NOT operate it before its safety and technical indexes have been tested minutely and positive testing results obtained.**
- **It is recommended to take the blood pressure measurement manually. The automatic or continuous mode should be used at the presence of a doctor/nurse.**
- **Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use CO_2 cannula kits and on-airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.**
- **Electrical Shock Hazard: Always disconnect the CO_2 Sensor before cleaning. Do NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.**
- **Electrical Shock Hazard; No user serviceable parts inside the CO_2 Sensor.**
- **After the life cycle of the Sidestream CO_2 Sensor and its accessories has been met, disposal should be accomplished following national and/or local requirements.**
- **Please peruse the relative content about the clinical restrictions and contraindication.**
- **When disposing of the monitor and its accessories, the local law should be followed.**

Table of Contents

Chapter 1 Overview

1.1 Features

This monitoring system may be used to monitor patient’s physiological parameters: ECG, respiratory rate, body temperature, non-invasive blood pressure (NIBP), pulse oxygen saturation (SpO_2), and pulse rate.

Note: If CO_2 module is added, the monitoring will not have these two functions: central networking and body temperature (temperature connector doesn't exist)

- ✧ It is lightweight, easy to carry and operate;
- ✧ 7″ high-resolution (800 × 480 pixel) color TFT to display patient’s ECG waveform, respiratory waveform and SpO_2 waveform;
- ✧ User-friendly and intuitive display interface, multiple configuration of ECG waveform display:

  Main monitoring screen view: displays the information of all the waveforms and parameters visually.

  Observing screen view: heart rate value and SpO_2 value display in big fonts, and displays one channel ECG waveform.

  Seven lead waveforms on one screen view: displays the information of 7 ECG lead waveforms and different monitoring parameters on one screen.

  Five channel real-time waveforms and two hours’ trends screen view: intuitionistic knowing the physiological status of patient.

  oxyCRG screen: displays heart rate trend, SpO_2 trend, respiration trend or waveform simultaneously on oxyCRG screen, to know the instantaneous the change of physiological parameters of respiration.
- ✧ The cuff can be also used as a tourniquet, which is convenient and practical in use as an additional function, and different cuff pressure can be set according to patient’s condition.
- ✧ Up to 20 types of arrhythmia can be analyzed automatically, waveform freezing is available and automatic S-T segment measurement and manual analysis;
- ✧ Up to 1000 hours trend data of ECG, S-T, TEMP, CO_2, SpO_2, RESP and NIBP trends;
- ✧ Up to 2000 groups of arrhythmia events’ can be stored, as well as the corresponding HR , TEMP, CO_2, SpO_2, and RR;
- ✧ Up to 12000 groups of NIBP measurement can be stored, as well as the corresponding HR, CO_2, TEMP, RR SpO_2 and PR while the blood pressure measurement is taken, it can be recalled by list table or graphic trend.
- ✧ Up to 60 hours of ECG waveform storage (non-volatile) and can be reviewed;
- ✧ Accurate NIBP measurement with over-pressure protection;
- ✧ Unique pulse oximetry technique achieves accurate SpO_2 and PR measurement;
- ✧ Visual and audible alarm, recall of alarm events;
- ✧ Flexible high and low alarm limits setting function;
- ✧ Real-time monitoring of battery capacity, when the battery power is insufficient, low battery voltage alarm indication will display on LCD screen.
- ✧ Easy to color-code and change the color of the font, background and waveforms if need;
- ✧ Protection against defibrillator discharge and resistance against the interference from electrosurgical unit;
- ✧ Pacemaker pulse detection and inhibition functions are available;
- ✧ Patient type can be selected among “Adult”, “Pediatric” and “Neonate” in setup menu;

- ✧ CO_2 measuring function is optional;
- ✧ Built-in printer to output waveforms and text.
- ✧ Networking with the central station as a part of the central network;

1.2 Product Name and Model

Name: Patient Monitor

Model: PC-3000

1.3 Applications and Scope

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult, pediatric and neonate patients. With the functions of real-time recording and displaying parameters, such as ECG, heart rate, non-invasive blood pressure, functional oxygen saturation, respiration rate, CO_2, body temperature and so on, it allows comprehensive analysis of patient’s physiological conditions.

This instrument is applicable for use in hospitals and clinical institutions. The operation should be performed by qualified professionals only.

1.4 Operating Environment

1. Ambient temperature range: 5℃~40℃
   Relative humidity: 30%~80%
   Atmospheric pressure: 70kPa~106kPa
   Power supply: 100~240VAC
   Power frequency: 50/60Hz
2. This device should be situated in a place protected against direct sunlight, so as to prevent overheat inside it.
3. The device should be stored and used within specified temperature, humidity and atmospheric pressure range, or it may cause damage to the device or inaccurate measurement result.
4. Do not use this device in an environment with toxic or inflammable gas.
5. If the device gets wet by accident, the operator should NOT power it on immediately until it has been air-dried enough to avoid any damage to it.
6. This device should be fixed on a stand, so as to prevent possible shock.
7. Do not use with any equipment other than those expressly permitted in these instructions.
8. The monitor is defibrillator discharge-proof and has certain immunity to the interference from electrosurgical unit. But when the device is used on the patient with pacemaker or used with electrosurgical equipment, the user (doctor or nurse) should keep the patient under close surveillance for his/her safety. Refer to the following function description for specific protective measures or notes.
9. Make sure that the equal-potential grounding terminal is grounded correctly.
10. Do not use mobile phone nearby, so as to avoid strong radiant field interference.

1.5 Impact on Environment and Resources

Low

1.6 Safety

a) This device conforms to IEC60601-1, electric safety classification: Class I, with Type BF and CF applied

parts.

b) This device can resist against the discharge of defibrillator and the interference of electrosurgical unit.

c) This device can monitor the patients with pace-maker.

d) DO NOT use this device while the patient is under MRI scanning.

Chapter 2 Working Theories of the Main Unit

2.1 Overall Structure and Working Theories

The overall structure of this monitor is shown as Fig.2.1.

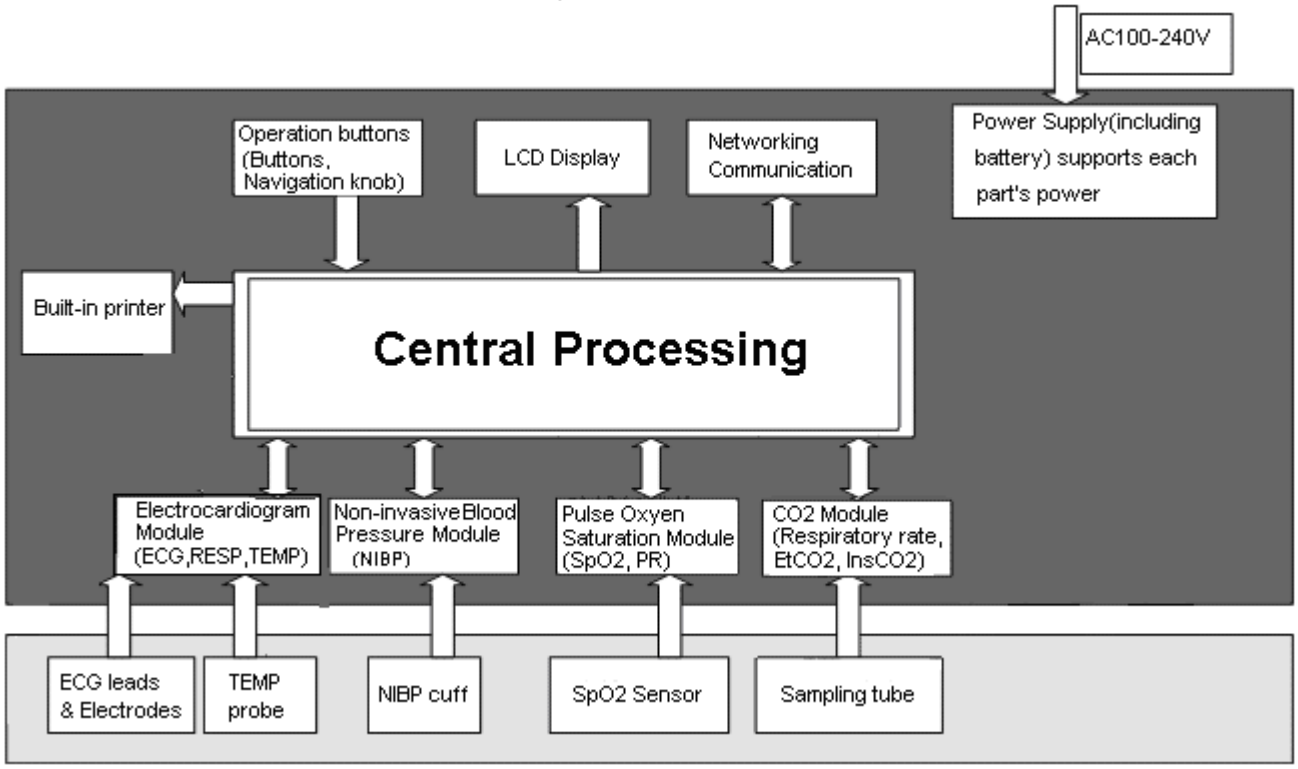


Figure 2.1

This patient monitor is a product of modular design. It performs its measurement of the physiological parameter through different modules. There are five functional modules for the monitor: ECG/RESP/TRMP module, NIBP module, SpO_2 module, CO_2 module and Central Processing Unit (CPU) module.

1. ECG/RESP/TRMP module collects heart rate, respiration waveforms through the ECG leads and electrodes. It also collects temperature data from the temperature probes.
2. SpO_2 module collects data for pulse rate, pulse oxygen saturation (SpO_2) and SpO_2 volume waveform via the SpO_2 probe.
3. NIBP module collects blood pressure data, including the diastolic, systolic and mean arterial pressure through the NIBP cuff. The cuffs are sized for adult, pediatric and neonate. NIBP measure has three modes: adult, pediatric and neonate.
4. CPU module consists of main board, multi-function board, and the keyboard. The multi-function board performs the data communication between the main board, ECG module, SpO_2 module, NIBP module and CO_2 module.
5. The CO_2 module collects the date of respiration rate, $EtCO_2$, $InsCO_2$ through the sampling tube.

2.2 Composition

1. The monitor consists of the main unit and the corresponding functional components (ECG leads, non-invasive blood pressure cuff, SpO_2 probe, and temperature transducer or CO_2 accessories.

2. The monitor has 4 measurement channels: ECG and respiration channel, NIBP channel, SpO_2 and pulse channel and TEMP channel or CO_2 channel.
3. The monitor has an output channel: networking communication port.
4. Basic parameters include: heart rate, respiration rate, NIBP, SpO_2, pulse and CO_2 ,TEMP

Chapter 3 Installation and Connection

3.1 Introduction to Panels

3.1.1 Front Panel

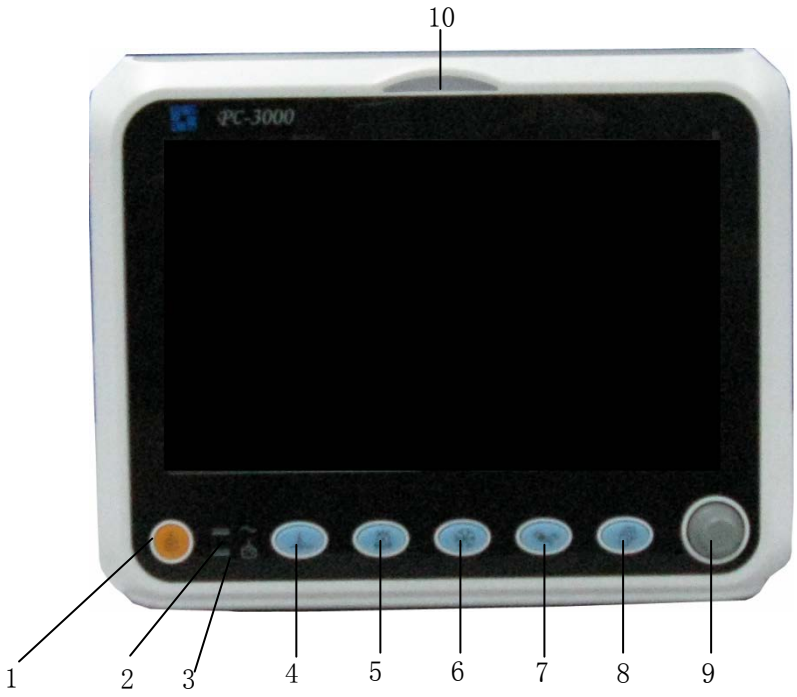


Figure 3.1 Front Panel

1. **Power switch:** Press it for 3 seconds to start the monitor or turn off the monitor.

2. **AC power indicator:** When it is light it means that AC power supply is being used

3. **Built-in DC power indicator:**

   When both AC and DC indicators are on, it means that AC power supply is applicable, and the battery is being recharged. If only DC indicator is on, it means that the battery is being used.

4. **ECG lead:** Click it to shift the ECG monitoring circulatory among Ⅰ, Ⅱ, Ⅲ, AVR, AVL, AVF and V.

- When the option of Print in the System Menu is ON, the ECG lead Key will be changed into Print Press this key to print different waveform on different screen.
- In the Initial Screen, press this key to print Lead II ECG waveform and Waveform 2 which can be selected in the System Menu.
- In the Data List Screen, press this key to print NIBP data list.
- In the Observing Screen, press this key to print Lead II ECG waveform and Waveform 2.
- In the 7 leads on the Same Screen, press this key to print Lead II ECG waveform and Waveform 2.
- In the SpO_2 Data List Screen, press this key to print SpO_2 data list.
- In the Graphic Trend Screen, press this key to print trend graph.
- In the System Parameter Setting Screen, press this key to print the system parameter setup.

- In the Recall Screen, press this key to print recalled data list or current ECG waveform and arrhythmia waveform.
- In the Arrhythmia Screen, press this key to print arrhythmia list or current ECG waveform and arrhythmia waveform.

5.  **Alarm silence:** Press key to set or activate the system alarm. In the monitoring screen, press “Alarm” to set the alarm timer. There are four options of alarm silent time: 2 minutes, 5 minutes, 10 minutes and 20 minutes. The time shows up on the upper left corner of the screen. When the alarm timer is activated, the system begins to count down. If alarm occurs during that period, the system alarm will be activated automatically and the monitor will give alarm. If there is no alarm during that period, when the set time has passed, the system alarm will be activated as well.

   When the monitor alarms, press key to suspend the alarm and set the alarm silence time.

   DO NOT silence the audible alarm or decrease its volume or patient safety could be compromised.

6.  **Freeze:** Press the key to freeze/unfreeze ECG waveform or the waveforms of ECG, SpO_2 and RESP according to the system setting, and enter into ST segment measurement screen for analysis (on Observing Screen).

7.  **NIBP:** Press it to start or stop NIBP measurement.

8.  **DISP:** Click it to shift the display modes or return to the Main Screen from other screens. Press it to shift between Main Screen and Display 2 Screen which can be set in System Menu screen.

9. **Navigation Knob:** It is the major operating key of the system, which can be used to select functions or parameters. Press and release it to shift the screen and to confirm the function or other operating tips.

10. **Alarm indicator:**

Indicator Color	**Alarm Level**	**Alarm Event**
Red flashing	High priority alarm	Exceeding the limits, pulse stop or suffocation, low battery voltage
Yellow flashing	Middle priority alarm	Leads and probe off, VE RONT and SVE RONT
Yellow light	Low priority alarm	Other arrhythmia phenomenon
Green light	Normal	

3.1.2 Left and Right Panel

Figure 3.2 the left panel

Figure 3.3 the right panel

Different ports are located in different positions of the monitor for operating convenience.

The cable and transducer ports are at the left panel, shown in Figure 3.2.

1. SpO_2: SpO_2 probe connector
2. NIBP: NIBP hose connector
3. TEMP: TEMP probe connector (CO_2: CO_2 probe connector)
4. ECG/RESP: ECG cable connector
5. Symbol definition

With type BF applied parts

With type CF applied part and applicable during the defibrillator is used.

Caution. Please read the manual for details.

The power supply socket and ports are at the left panel, shown in Figure 3.3.

1. 16.8V 1.5A ：Power supply socket(DC input)
2. ：Serial communication port which is used to network with central monitoring system.
3. ：USB port (reserved for future use);

3.1.3 Rear Panel

Figure 3.4 Rear panel

The following are at the rear panel of the monitor.

(1) S/N: Serial Number

(2) Power supply socket: 100-240VAC

(3) Nameplate

CE	CE mark
SN	Serial number
	Date of manufacture
EC REP	Authorised representative in the European community
	Manufacturer (including address and date)
	Disposal of this device according to WEEE regulations

(4) —battery lid. Remove the battery lid to install or change the rechargeable battery. Battery specifications: Li-ion 14.8V/2200mAh rechargeable battery pack.

To avoid battery damage, do remove battery(s) before shipping or storage.

Caution: Burn hazard (the built-in battery)
Do not disassemble, incinerate or expose to high temperature (60 ℃/140℉).
Refer to instruction manual.

3.2 Installation

3.2.1 Opening the Box and Check

1. Open the packaging, take out the monitor accessories from the box carefully and place it in a safe stable and easy to watch position.
2. Open the users’ manual to sort the accessories according to the packing list.
   - ◆ Inspect the accessories for any mechanical damages
   - ◆ Check all the exposed leads and inserted accessories

You can customize the module configuration by choosing necessary modules to meet your own needs. Therefore, your monitor may not have all the monitoring functions and accessories.

Please contact the local dealer or our company in case of any problems. We are to offer you the best solution for your satisfaction.

3.2.2 Power Supply

1. When powered by AC mains power supply:

- ◆ Make sure that the AC power supply is 100-240VAC, 50/60Hz.
- ◆ Use the power cable prepared by the manufacturer. Insert one end of it to the power port of the monitor and the other end to the grounded three-phase power jack.
- ◆ To eliminate potential differences, the monitor has a separate connection to the equipotential grounding system. Connect one end of the provided ground cable to equipotential grounding port on the rear of the monitor, and connect the other end to one point of the equipotential grounding system.

  Caution: ensure that the monitor is grounded correctly.

🔔 After the supply mains has been interrupted when power switch remains in the “on” position and is restored after a period of time that is longer than 30 seconds, the monitor will run by the last settings when restarting the monitor.

2. When powered by built-in battery

- ◆ The provided battery of the monitor must be recharged after transportation or storage. So if the monitor is switch on without being connected to the AC power socket, it may not work properly due to insufficient power supply.
- ◆ It will be fully charged after about 3 hours when the monitor is off and about 5 hours when the monitor is on.

3.2.3 Starting the Monitor

The system performs self-detection and enters initial display after switch on the monitor, and the yellow alarm indicator blinks to inform that the user can begin operating it.

- ◆ Check all the applicable functions to make sure that the monitor works normally.
- ◆ If the built-in battery is applied please recharge it after using the monitor to ensure sufficient power storage. It will take minimal 8 hours to charge battery from depletion to 90% charge.

💣 **Do not use the monitor to monitor the patient if there are indications of damage or reminders of error. Please contact the local dealer or our company.**

🔔 **Start the monitor again 1 minute later after it is switched off.**

3.3 Connection

3.3.1 ECG Connection

ECG measurement is to collect the ECG signal via the ECG electrodes. Electrode connects the patient and the lead. The lead connects the monitor. The locations of the electrodes are very important for obtaining accurate ECG signals.

1. Connect the cable to the right-panel connector marked with the ECG icon.
2. Select electrodes to be used. Use only one type of electrode on the same patient to avoid variations in electrical resistance. For ECG monitoring, it is strongly recommended to use silver/silver chloride electrodes. When dissimilar metals are used for different electrodes, the electrodes may be subject to large offset potentials due to polarization. Using dissimilar metals may also increase recovery time after defibrillation.
3. Prepare the electrode sites according to the electrode manufacturer’s instructions.
4. Skin clean

- Clean and dry-abrade skin to ensure low sensor impedance. Mild soap and Water is recommended as a skin cleanser.

  Note: Alcohol is not recommended as a skin cleanser; it leaves a film layer that may cause high sensor impedance. If alcohol is used, ensure 30-second dry time.

- Dry-abrading the skin gently with a dry wash cloth, gauze, or skin preparation product is helpful to remove the non-conductive skin layer.

The symbol indicates that the cable and accessories are designed to have special protection against electric shocks, and is defibrillator proof.

The locations of the electrode are in the following Figure:

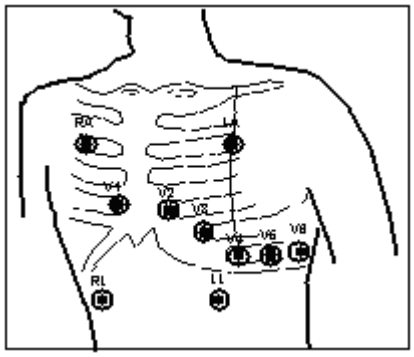


Figure 3.5 Electrode Location

Note: If skin rash or other unusual symptoms develop, remove electrodes from patient.

After starting the monitor, if the electrodes become loose or disconnected during monitoring, the system will display “*LEAD OFF*” on the screen to alarm the operator.

It might not display ECG wave with 3 leads. The 5 leads should be used to have ECG wave.

5. The ECG leads and their corresponding locations are as follows

Symbol		Position
RA		The intersection between the centerline of the right clavicle and Rib 2
LA		The intersection between the centerline of the left clavicle and Rib 2
LL		Left part of the upper abdomen
RL		Right part of the upper abdomen
C (V) Chest electrode	C1(V1)	The electrodes are placed in different places, the different lead forms will display.
	C2(V2)	
	C3 (V3)	
	C4 (V4)	
	C5 (V5)	
	C6 (V6)	

Safety Instructions for ECG Monitoring

- This Patient Monitor can only be equipped with ECG leads provided by our company; using ECG leads supplied by other companies may cause improper performance or poor protection while using defibrillator.
- Electric parts of electrodes, leads and cable are forbidden to contact any other conductive parts (including ground).
- This Patient Monitor can resist against defibrillator and electrosurgical unit. Readings may be inaccurate for a short time after or during using defibrillator or electrosurgical unit.
- Transient caused by cable circuitry blocks while monitoring may be similar to the real heartbeat waveform, as a result resistance heart rate alarm rings. If you put the electrodes and cable in proper places according to this manual’s instructions and the instructions for using electrode, the chance of this transient occurring will be decreased.
- To the patient with pacemaker, due to that this device has been designed to provide resistance to pacemaker signal interference, generally the pacemaker pulse is not counted in heart rate measurement and calculation, but when the cycle time of pacemaker pulse is over 2ms, it may be counted. In order to reduce this possibility, observe the ECG waveforms on the screen carefully and do NOT rely entirely on the heart rate display and alarm system of this monitor when monitoring this kind of patients. Keep pacemaker patient under close surveillance.
- Besides the improper connection with electrosurgical unit may cause burns, the monitor may be damaged or arouse deviations of measurement. You can take some steps to avoid this situation, such as do NOT use small ECG electrodes, choosing the position which is far away from the estimated Hertzian waves route, using larger electrosurgical return electrodes and connecting with the patient properly.
- No predictable hazard will be caused by the summation of leakage currents when several item of monitor are interconnected.
- ECG leads may be damaged while using defibrillator. If the leads are used again, please do the functional check first.
- When the monitor is inoperable due to an overload or saturation of any part of the amplifier, it will prompt “Lead off” to remind operator.

3.3.2 Blood Pressure Cuff Connection

1. Connect the cable to the right-panel connector marked with the NIBP icon.
2. Unveil and wrap the cuff around patient’s upper arm.

Requirements of the cuff:

1) Appropriate cuff should be selected according to the age of the subject. Its width should be 2/3 of the length of the upper arm. The cuff inflation part should be long enough to permit wrapping 50-80% of the limb concerned. See the table below for the dimensions:

Note: The size of the cuff selected should suit the subjects while measuring.

Cuff Model	Arm Circumference	Cuff Width
Neonate Cuff	6.0cm~9.5cm	3cm
Small-sized Pediatric Cuff	6cm～11cm	4.5cm
Middle-sized Pediatric Cuff	10cm～19cm	8cm
Large-sized Pediatric Cuff	18cm～26cm	10.6cm
Adult Cuff	25cm～35cm	14cm

2) When putting on the cuff, unveil and wrap it around the upper arm evenly to appropriate tightness.
3) Remember to empty the residual air in the cuff before the measurement is commenced.
4) Locate the cuff in such a way that the “φ” mark is at a location where the clearest pulsation of brachial artery is observed.
5) The cuff should be tightened to a degree where insertion of one finger is allowed.
6) The lower end of the cuff should be 2cm above the elbow joint.

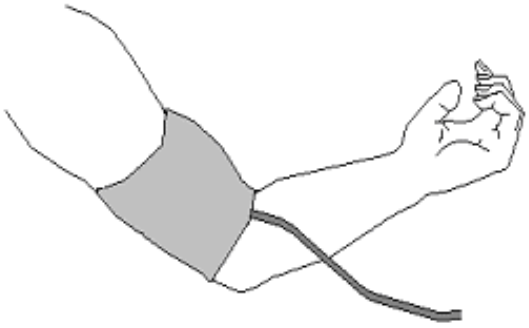


Figure 3.6 Cuff Position

Safety Instructions for NIBP Monitoring

- When taking the measure of an infant’s (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.
- It is recommended to take the blood pressure measurement manually. Automatic or continuous measurement should be used at the presence of a doctor/nurse.
- NIBP monitoring is prohibited to those who have severe hemorrhagic tendency or with sickle cell disease, or partial bleeding will appear.
- Do NOT bind NIBP cuff on limbs with transfusion tube or intubations or skin lesion area, otherwise, damages may be caused to the limbs.
- Pay attention to the color and sensitivity of the limb when measuring NIBP; make sure the blood circulation is not blocked. If blocked, the limb will discolor, please stop measuring or remove the

cuff to other positions. Doctor should examine this timely.

- The time of the automatic pattern noninvasive blood pressure measurement pull too long, then the body connected with the cuff possibly have the purpura, lack the blood and the neuralgia. When guarding patient, must inspect the luster, the warmth and the sensitivity of the body far-end frequently. Once observes any exception, please immediately stop the blood pressure measurement.
- The subject should lie on the back so that the cuff and the heart are in a horizontal position and the most accurate measure is taken. Other postures may lead to inaccurate measurement.
- Do not speak or move before or during the measurement. Care should be taken so that the cuff will not be hit or touched by other objects.
- The measurements should be taken at appropriate intervals. Continuous measurement at too short intervals may lead to pressed arm, reduced blood flow and lower blood pressure, and resulting inaccurate measure of blood pressure. It is recommended the measure be taken at intervals of more than two minutes.
- When an adult subject is monitored, the machine may fail in giving the blood pressure measure if the infant mode is selected.
- Prior to use of the cuff, empty the cuff until there is no residual air inside it to ensure accurate measurement.
- Do NOT twist the cuff tube or put heavy things on it.
- When unplugging the cuff, hold the head of the connector and pull it out.

The symbol indicates that the cable and accessories are designed to have special protection against electric shocks, and is defibrillator proof.

- **Pressure Accuracy Verification**

Pressure Accuracy Verification is a function to inspect the accuracy of pressure measurement by the NIBP module inside the device. Technician or equipment manager should do pressure accuracy verification every half year or year in order to check if the pressure measurement still conforms to the requirement of product performance. If the deviation is beyond the declared specification, it is permitted to return it to factory for repair or calibration. Before verification, please connect the monitor to a standard pressure meter as the reference equipment like a mercury pressure meter.

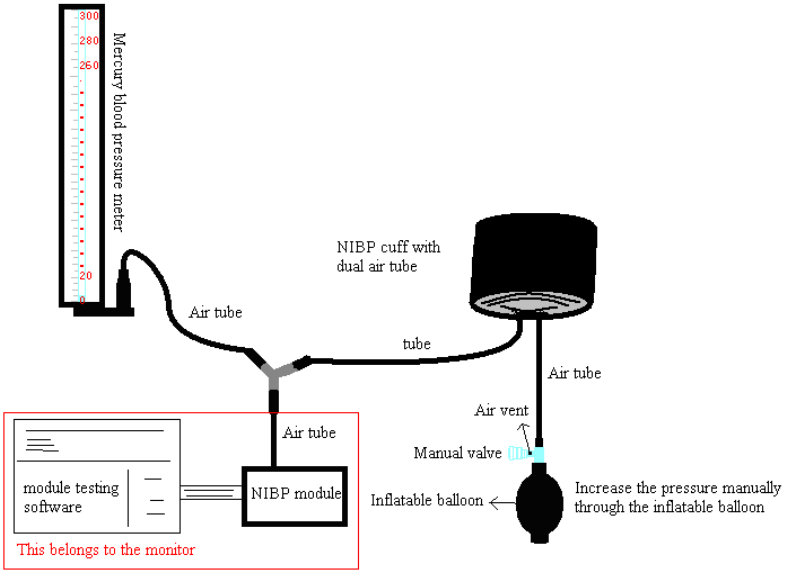


Figure 3.7 Connection of Pressure calibration fixture

Mode 1: The inflation can be activated by Monitor so the pressure will increase automatically untill it exceeds the limit value specified in table A. This pressure limit value depends on the patient type selection as shown in table A:

Adult	240mmHg
Child	200mmHg
Neonate	120mmHg

Table A

During the inflation, the Monitor will close the deflating valve, and the pressure value will be shown during the process. If there is no manual deflation operation, the pressure will persist until deflation by manual operation, so it is necessary to use a manual valve for doing adequate deflation in several steps to verify the pressure accuracy in the full scale of measurement range.

Mode 2: No automatic inflation by Monitor during the pressure accuracy verification.

Increase the pressure manually by the pumping balloon, and the verification can be done by applying different pressure value manually. If the increased pressure exceeds the given limit as shown in table B, the Monitor will deflate automatically because of over-pressure protection.

Adult	300mmHg
Child	240mmHg
Neonate	140mmHg

Table B

- **After the verification, do press the button again to return to normal working mode, then continue other operation, or the NIBP key will be invalid.**
- **Pressure accuracy verification must be operated by technician or equipment manager. Doctor or nurse is not allowed to do the verification, it is very dangerous especially when the pressure cuff is still on patients.**

➢ **Air Leakage Check**

In order to avoid significant error of blood pressure measurement or even no measurement result caused by air leakage in the pneumatic system including the cuff during measuring, it is recommended to check if there is leak in the pneumatic system as well.

- **Please remove the cuff from patient while performing the leakage check.**

3.3.3 To connect the SpO_2

SpO_2 probe is very delicate equipment. Please follow the steps and procedures in operating it. Failure to operate it correctly can cause damage to the SpO_2 probe.

Operation procedure:

1. Connect the SpO_2 probe to the right panel’s jack labeled “SpO_2”. **When unplugging the probe, be sure to hold the head of the connector and pull it out.**
2. Insert one finger into the probe (index finger, middle finger or ring finger with proper nail length) according to the finger mark on the probe, shown as below.

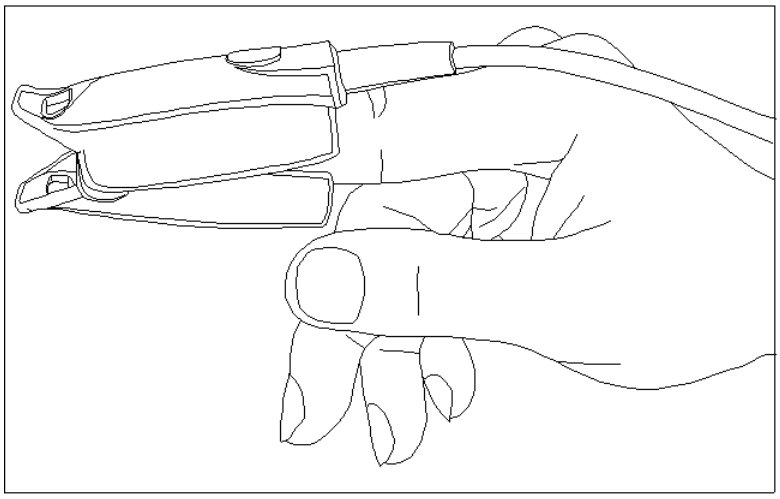


Figure 3.8 Demonstration for SpO_2 probe

When selecting a sensor, consider the patient’s category, adequacy of perfusion, availability of probe site and anticipated monitoring duration. Use only SpO_2 probes provided by our company with this monitor. Read the following table for SpO_2 probe information. Refer to Chapter 13.8 for the detailed instructions of each SpO_2 probe.

SpO_2 Probe	Patient Category
SpO_2 Finger clip Sensor (reusable)	Pediatric
SpO_2 Finger rubber Sensor(reusable)	Adult
SpO_2 Finger clip Sensor(reusable)	Adult

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

Failure to take this action in high ambient light conditions may result in inaccurate measurements.

If patient movement presents a 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; or use a new sensor with fresh adhesive backing.

For reusable sensors, follow the sensor directions for use for cleaning and reuse. For single-patient use sensors, use a new sensor for each patient. Do not sterilize any sensor by irradiation, steam, or ethylene oxide.

Safety Introductions for SpO_2 Monitoring

- Continuous use of SpO_2 sensor may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.
- The measuring site is generally changed every 3hours. The measuring site should be inspected for ensuring no abnormity every 1~2 hours. If abnormity occurs, change the measuring site periodically if necessary.
- When the ambient temperature is over 35℃, please change the measuring site every two hours if necessary.
- Burn hazard: When the ambient temperature is over 37℃, do not use the SpO_2 sensor for a long time.
- SpO_2 measuring position must be examined more carefully for some special patient. Do NOT install the SpO_2 sensor on the finger with edema or fragile tissue.

- Do NOT put the SpO_2 sensor and pressure cuff on the same limb, otherwise the NIBP measuring will affect SpO_2 measuring and cause the alarm error.
- If sterile packaging of SpO_2 sensor is damaged, do not use it any more.
- Check the SpO_2 sensor and cable before use. Do NOT use the damaged SpO_2 sensor.
- When the temperature of SpO_2 sensor is abnormal, do not use it any more.
- Please do not allow the cable to be twisted or bended.
- Please do not use nail polisher or other cosmetic product on the nail.
- The fingernail should be of normal length.
- The SpO_2 sensor can not be immerged into water, liquor or cleanser completely, because the sensor has no capability to resist the harmful ingress of water.

3.3.4 Printer connection

1. PRINTER：USB port, connect the monitor to the provided USB cable.

2. DC12V：DC power supply port. Power indicator on the front panel will be on after the adapter is connected to power supply.

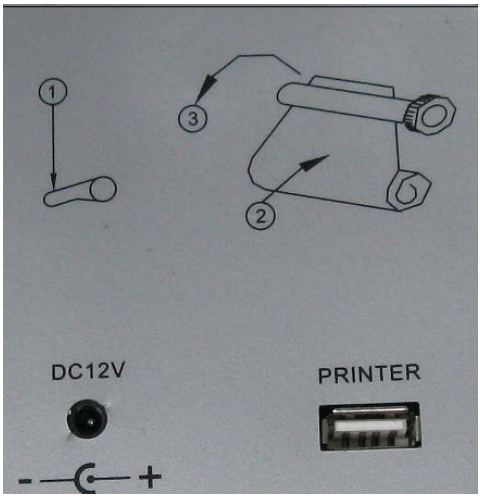


Figure3.9 rear panel of printer

3.3.5 Loading printing paper

Step 1: Open the cover of the printer
Step 2: Install the paper to the printer properly
Step 3: Pull the paper out of the printer for 2 or 3 cm
Step 4: Close the printer cover

☞ The ERROR indicator on the top right corner of the printer will be on when the printing paper runs out.

Figure 3.10 front panel

3.3.6 Battery Installation

1. Make sure that monitor doesn’t connect to mains power supply.
2. Unscrew the screw on the battery lid with a screwdriver and open the battery cover.
3. Insert the battery connecting wire into the battery receptacle (Do not insert the plug in reverse).
4. Insert it into the battery compartment.

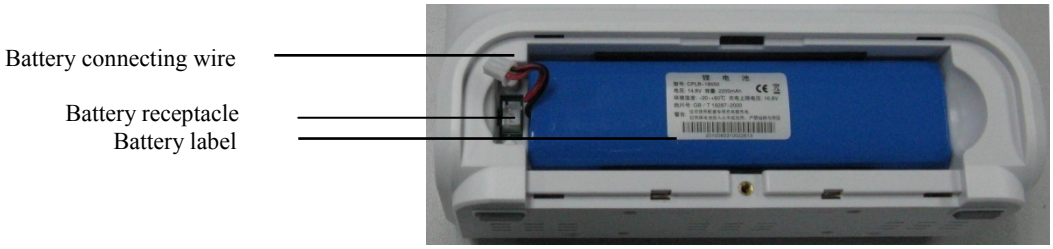


Figure 3.11 Battery Installation

5. Close the battery lid and fasten it with the screw.

🔔 Please take out the battery from battery compartment, if it won’t be used for a long time.

3.3.7 Handle Installation

1. Take out the handle subassembly if necessary.
2. Fix the handle subassembly on the rear panel with two screws, see Figure 3.12.

Figure 3.12 Handle Installation

Chapter 4 Monitoring Screen

4.1 Date and Time Setup

Instead of entering into monitoring screen, it shows the date and Time Setup screen immediately after the monitor is started, shown in Figure 4.1:

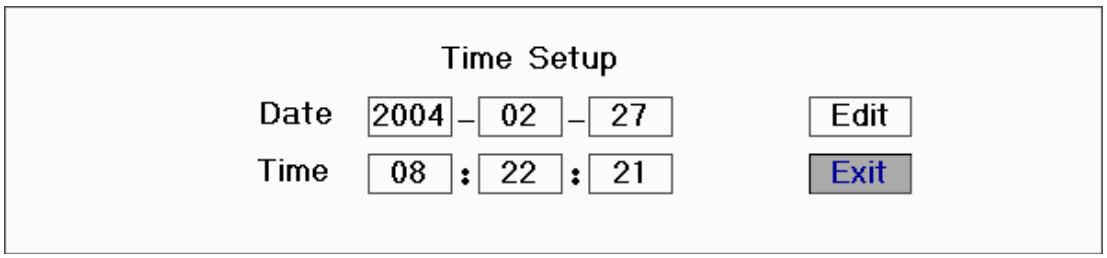


Figure 4.1 Time Setup

The system will stay on this screen for 10 seconds. If you do not rotate the navigation knob within this period, the screen will enter into the Main Screen.

Follow the steps below to set date and time.

Step 1: Rotate Navigation Knob, move the gray cursor to “Edit”.

Step 2: Press the knob, and then “Edit” turns into “Save”. The gray cursor stays on the Year of the date. Press the knob again and the gray cursor becomes highlighted. Rotate the knob left or right to increase or decrease the year value.

Step 3: When the Year is set, press the knob to move the gray cursor to the Month of the date.

Step 4: Repeat Step 2 and Step3 to adjust the Year, Month, Date, Hour and Minute.

Step 5: If you have finished adjusting the date and time, press the knob and rotate the knob to move the cursor to “Save”. Press it to save the settings and exit the date and Time Setup screen, meanwhile enter into the Main Screen shown in Figure 4.2. If you press “Exit”, the settings will not be saved.

The system is initialized and enters into Main Screen where monitoring and system operation are performed (as shown in Figure 4.2).

4.2 Main Screen

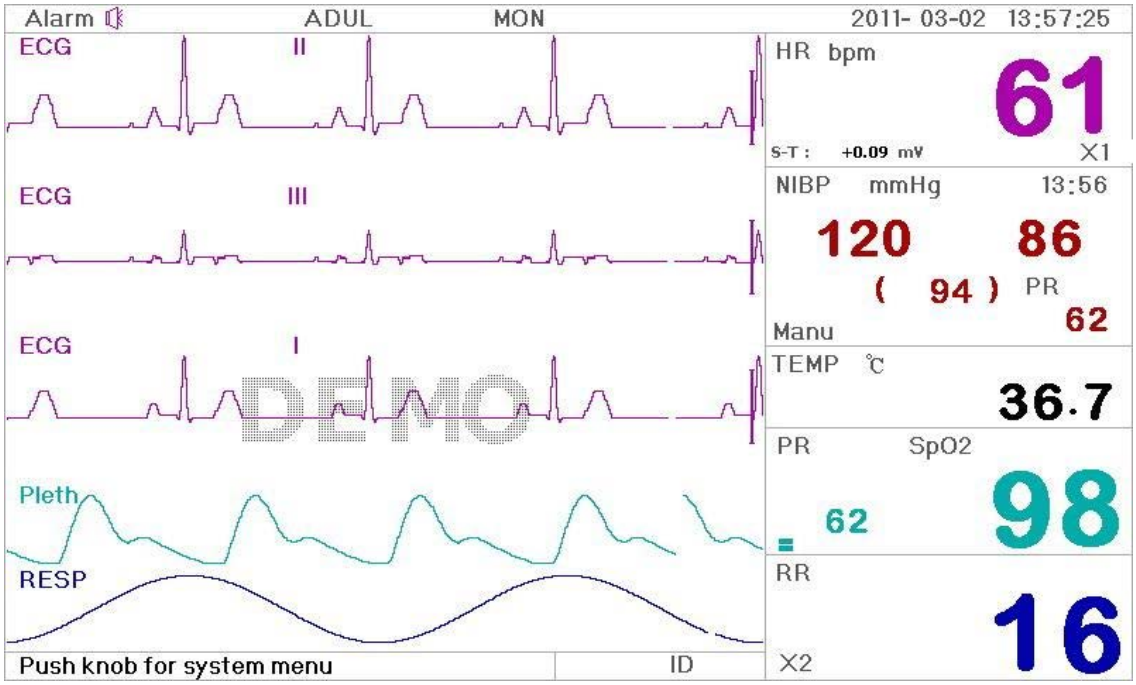


Figure 4.2 Main screen

Border area

- **“Alarm ”:** Audible alarm status, green “ ” indicates the audible alarm is enabled, yellow “ ” indicates the alarm sound is silent. The audible alarm will be activated again automatically after the end of given counting down or when a new type of alarm event occurs. Red “ ” indicates the audible alarm is disabled, that means the alarm sound is off, this is also normal situation when the alarm sound volume is set to “0” in system parameter settings.
- **“ADUL”:** The type of the monitor subject. There are two modes available: “Adult” and “Infant”.
- **“MON”:** ECG Filter type. There are three types: “Diagnosis”, “Monitor” and “Operation”. The option can be set in the System Menu.
- **:** battery power indicator; When the indicator is yellow and displays only one “grid”, it means there is a little battery power left. When the indicator turns red and blinks, as well as less than one “grid” displays, the system alarm will be on to remind the battery shortage. Please connect the device to the mains power supply in time to ensure the normal use of monitor, and the battery will be recharged. When the battery power is full, battery power indicator displays full grid. During recharging, the grids in the battery indicator are rolling circularly.
- **“2011-03-02 13:57:25”:** Current calendar time and date. The system time and date can be set during the system start-up when the screen displays the time and data setups. The current figure shows the time and date is March 2nd, 13:57:25, 2011.
- **“Push knob for System Menu”:** System prompt or description for the current status.
- **“ID”:** The patient ID. The patient ID can be entered or changed in the archive management window.

Waveform area

- 1st trace: The first trace is ECG waveform for lead II. The left side of the ECG shows the sign I, which indicates the ECG scale. The scale sign changes its length according to the ECG gains. All ECG

waveforms have their own scale. When the third trace change to lead II, the first trace will automatically change to lead I.

- ✧ 2nd trace: The second trace is for the ECG waveform of lead III. When the third trace displays the ECG for the lead III, this trace automatically changes to the ECG for lead I.
- ✧ 3rd trace: Its lead can be adjusted and will not repeat the 1st and 2nd traces.
- ✧ 4th trace: SpO_2 plethysmograph.
- ✧ 5th trace: Respiration waveform.

Data area:

Figure 4.3 Heart rate area

- ✧ **“HR”:** The currently displayed heart rate. The 61 on the right side is the heart rate measured.
- ✧ **“bpm”:** The heart rate unit. bpm = beat per minute.
- ✧ **“ ”:** The heart beating symbol. Its flashing corresponds to the R wave of the ECG waveform. The speed is the same as the heart rate.
- ✧ **“ST+0.09mv”:** the measured mili-volts value of automatic ST measurement.
- ✧ **“X1”:** ECG waveform gain (amplification), 6 options available

  “Auto” Automatic scaled waveform.

  “×1/4” Waveform scaled with 1/4 of the base gain.

  “×1/2” Waveform scaled with half of the base gain.

  “×1” Waveform scaled with base gain.

  “×2” Waveform scaled with twice of the base gain.

  “×4” Waveform scaled with four times of the base gain

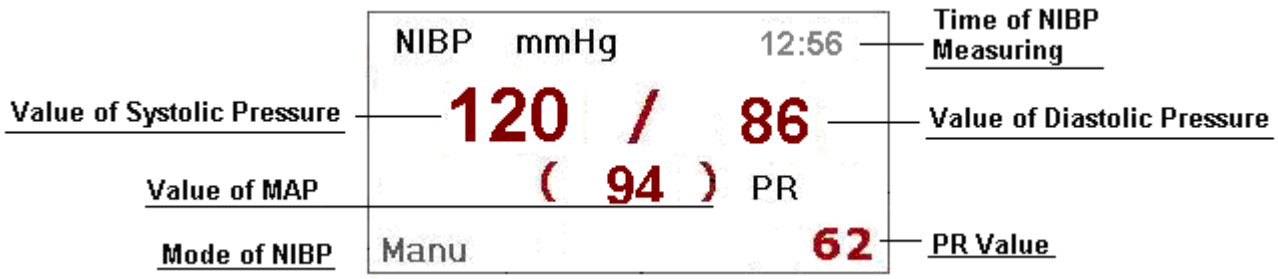


Figure 4.4 Blood pressure data area

- ✧ “**NIBP**”: The blood pressure type labels and the measured value.

- “**mmHg**”: NIBP unit
- “**12:56**”: The time of NIBP measuring
- **“Manu”:** The NIBP measurement mode.

Figure 4.5 TEMP data area

- “**TEMP**”: Temperature label. The value below “36. 7” is the temperature value.
- “**℃**”: Body temperature unit. ℃ is Celsius, and ˚F is Fahrenheit.

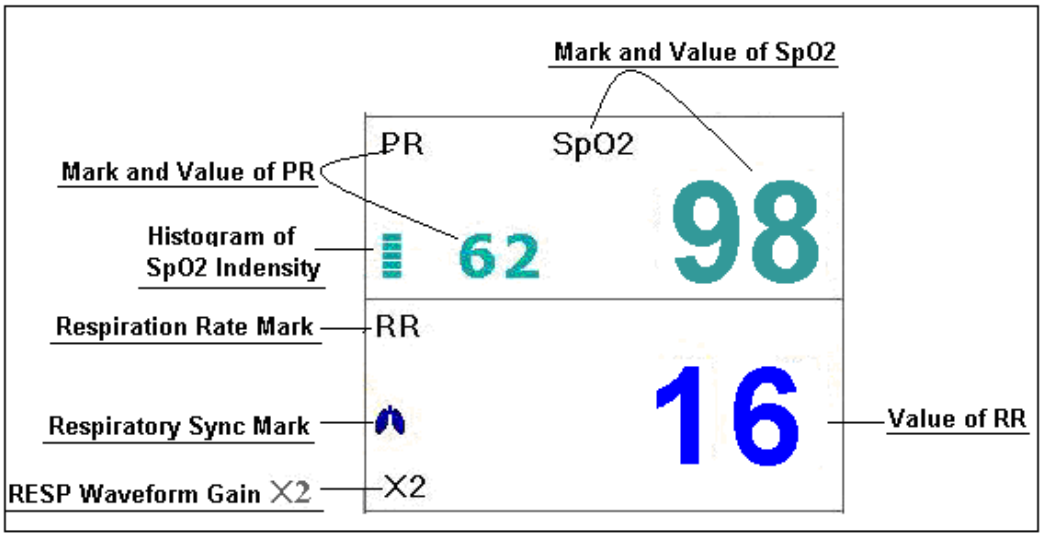


Figure 4.6 SpO_2, pulse rate, and respiration data area

- “**SpO_2**”: SpO_2 label. The “98” on the right side is the current SpO_2 value measured.
- “**PR**”: Pulse rate label. The value “62” on the lower left shows the pulse rate value.
- “ ”: SpO_2 strength bar.
- “**RR**”: Respiration Rate: The rpm is the unit of the respiration.
- “**16**”: Respiration rate.
- “**X2**”: Respiration gain (amplification)

  “×1/2” Waveform scaled with half of the base gain.

  “×1” Waveform scaled with base gain.

  “×2” Waveform scaled with twice of the base gain.

  “×4” Waveform scaled with four times of the base gain

Operation Instructions:

ECG lead: press it to shift the ECG monitoring circulatory among Ⅲ, AVR, AVL, AVF and V.

Alarm silence: press it to set or activate the system alarm.

Freeze: press it to freeze ECG waveform or the waveforms of ECG, SpO_2 and RESP according to the system setting.

NIBP: press it to start or stop NIBP measure.

DISP: press it to shift the display to Display 2 Screen.

Navigation Knob: 1. Press the navigation knob about 3 seconds, enter system menu screen.

2. Rotate the knob to move the gray cursor to the corresponding item, and press it for 1 second to enter

4.3 Display 2 Screen

4.3.1 Observing Screen

Press the DISP key to shift screen to Observing Screen when setting Disp2 as “Obsev” in System Setup screen, as shown in Figure 4.7.

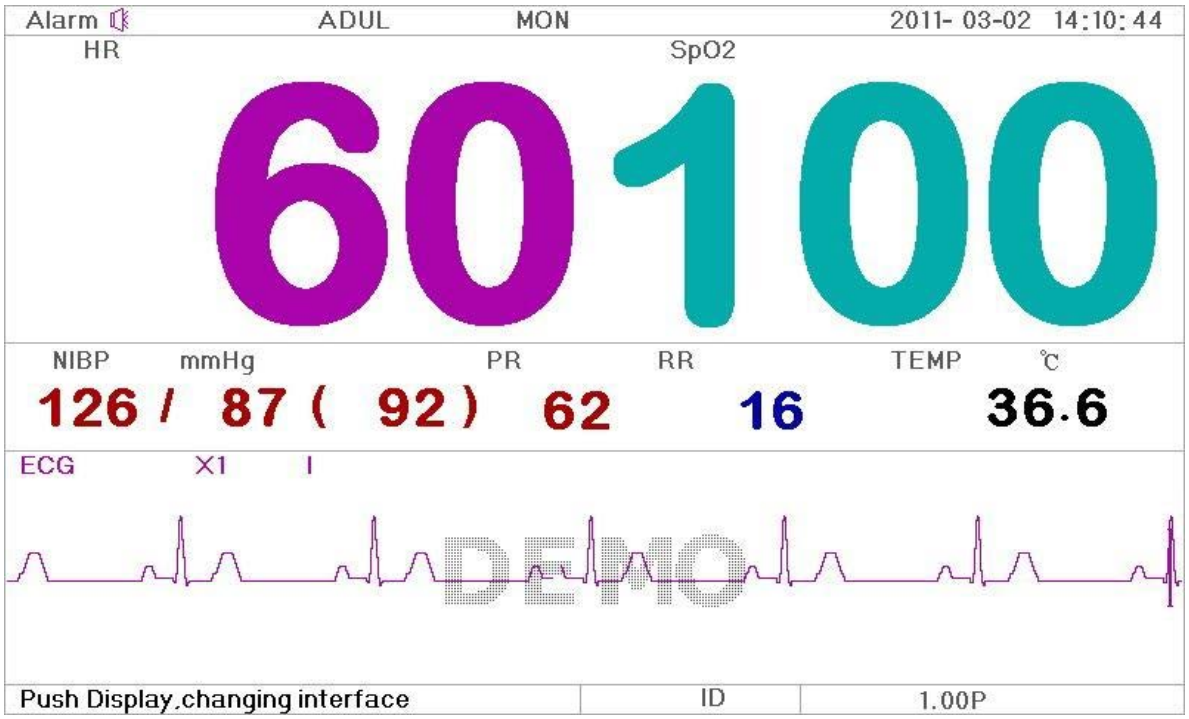


Figure 4.7 Observing Screen

Operation Instructions:

ECG lead: press it to shift the ECG monitoring circulatory among Ⅰ, Ⅱ, and and V.

Alarm silence: press it to set or activate the system alarm.

Freeze: press it to freeze the ECG waveform and perform manual S-T segment analysis. Double press this key within 2 seconds to lock or unlock the operation of all other buttons (except power switch) on the front panel.

NIBP: press it to start or stop NIBP measure.

DISP: press it to shift the display to the Main Screen.

Navigation Knob: No action. When pressing the “Freeze” key, this key is used for S-T segment analysis.

4.3.2 NIBP screen

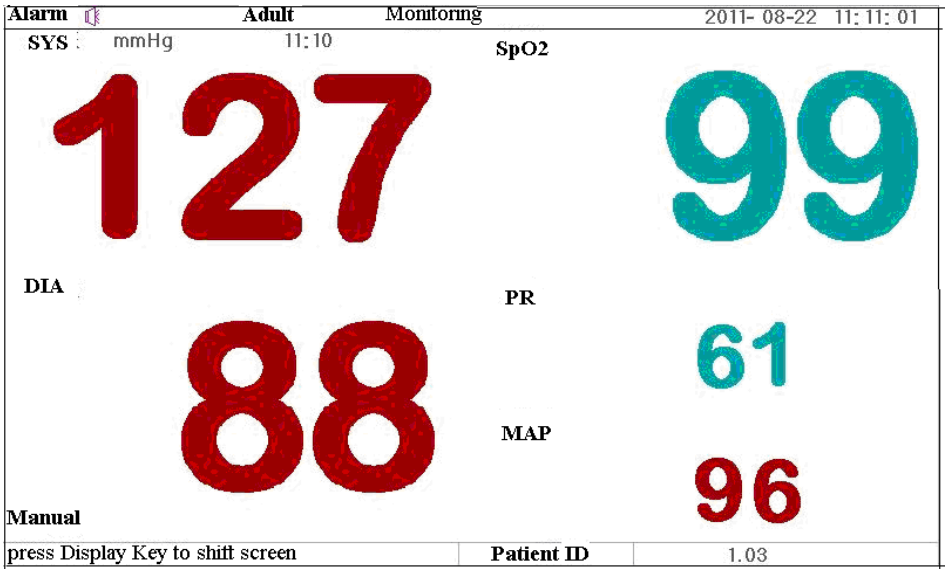


Figure 4.8 NIBP Screen

Press the DISP key to shift the Main Screen to NIBP screen , as shown in Figure, when setting Disp 2 as “NIBP” in “system menu→system setup→Disp2”. In NIBP screen, PR from SpO2 is shown prior to PR from NIBP.

Operation Instructions:

EGG lead: No action. When the printer is on, it serves as the printing key.

Alarm silence: Press it to enable/disable alarm silence.

Freeze: No action.

NIBP: Press it to start NIBP measurement, and press it again to cancel measuring NIBP.

Shift: Press it to shift the display to the Main Screen.

Navigation knob: No action.

4.3.3 Seven ECG Waveforms on the Same Screen

Press the DISP key to shift screen to 7 ECG Waveform Screen when setting Disp2 as “7 ECG” in System Setup screen. In this screen, the operator can simultaneously view the ECG waveform for 7 leads: I, II, III, AVR, AVL, AVF and V, as shown in Figure 4.9.

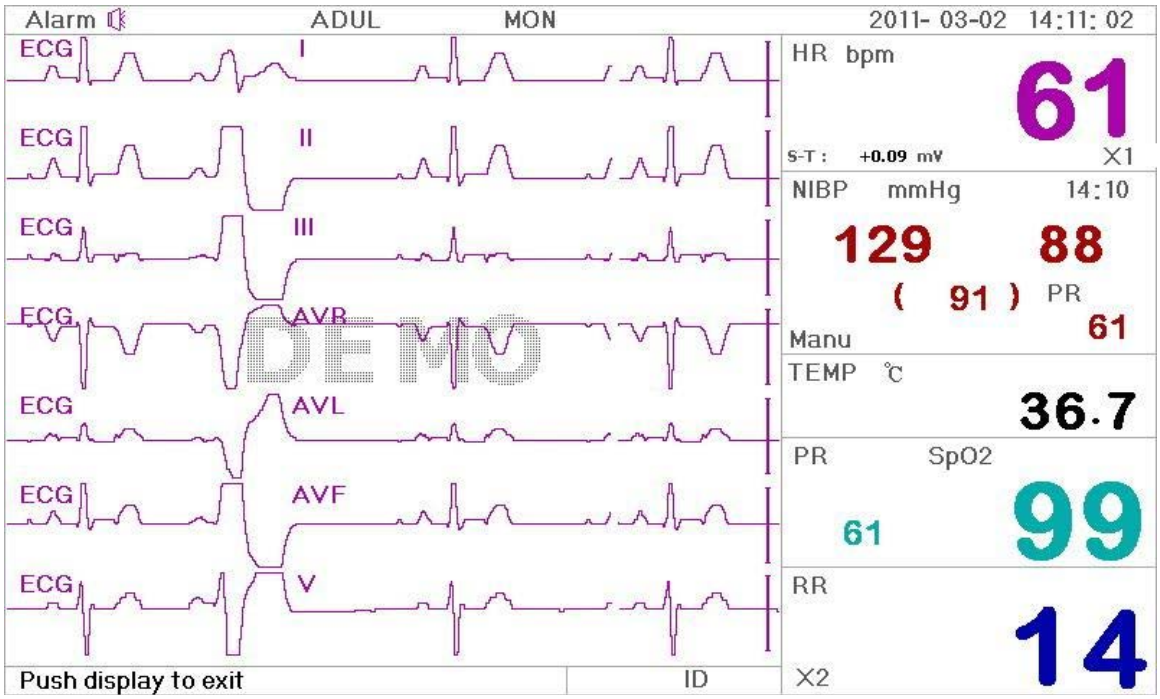


Figure 4.9 7 Leads on the Same Screen

Operation Instructions:

ECG lead: No action. When the printer is on, it serves as the printing key.

Alarm silence: press it to set or activate the system alarm.

Freeze: press it to freeze all 7 ECG waveforms. Double press this key within 2 seconds to lock or unlock the operation of all other buttons (except power switch) on the front panel.

NIBP: press it to start or stop NIBP measure.

DISP: press it to shift the display to the Main Screen.

Navigation Knob: rotate the knob to adjust the gain for all 7 ECG waveforms. The ECG gain includes 6 options: “Auto”, “X1/4” “X1/2”, “X1”, “X2”, “X4”.

4.3.4 Five Channels Real-time Waveforms and Trends on the Same Screen

When the Disp2 option is “Trend” on System Menu screen, press the DISP key on the Main Screen, the system will enter the trend screen, as shown in Figure 4.10. Five channel real-time waveforms and trend graph can be viewed on this screen.

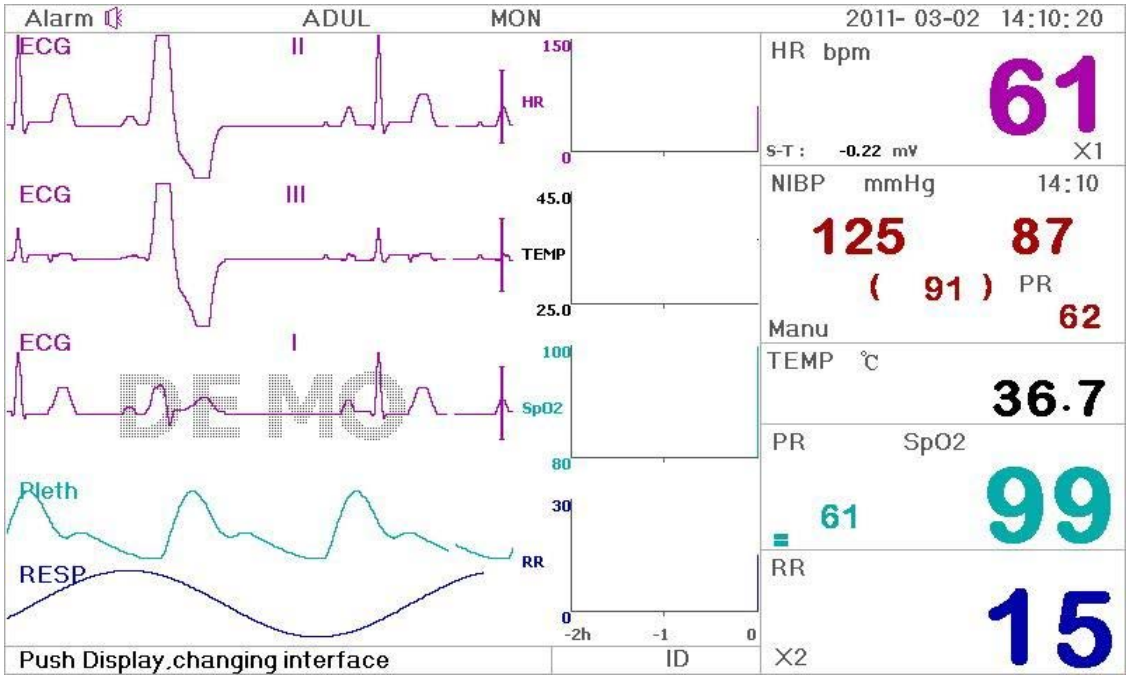


Figure 4.10 Five Channel Real-time Waveforms and Two Hours Trends

On this screen, the first channel waveform is ECG waveform of Lead II; the second (CAS) one is the continued ECG for the first channel waveform; the third one is ECG waveform of Lead I; the fourth one is SpO_2 waveform; the last channel is respiration waveform. On the right of waveform area, from the top down, respectively is heart rate, temperature, SpO_2, RR trend graph, the abscissa of trend graph (-2h-0) means various trend of every parameter value from now on to two hours before, waveform in trend graph shifts from right to left.

Operation Instructions:

ECG lead: press it to shift the ECG monitoring circulatory among Ⅰ, Ⅱ, and and V.

Alarm silence: press it to set or activate the system alarm.

Freeze: press it to freeze ECG waveform or the waveforms of ECG, SpO_2 and RESP according to the system setting. Double press this key within 2 seconds to lock or unlock the operation of all other buttons (except power switch) on the front panel.

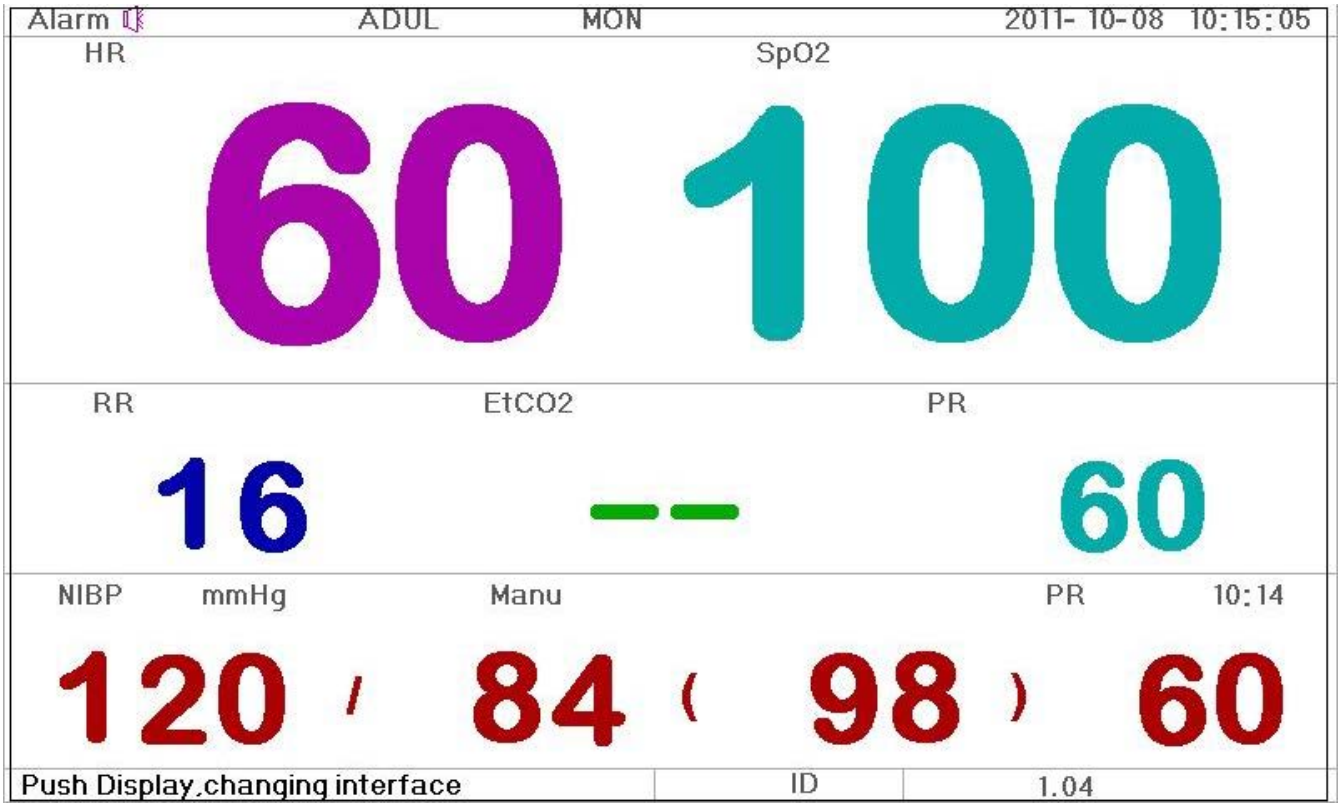
NIBP: press it to start or stop NIBP measure.

DISP: press it to shift the display to the Main Screen.

Navigation Knob: no action.

4.3.5 Parameter screen

Press the DISP key to shift screen to Parameter Screen when setting Disp2 as “Parameter” in System Setup screen, as shown in Figure 4.11



Figuer 4.11 Parameter screen

Operation Instructions:

ECG lead: when the printer is on, it serves as the printing key.

Alarm silence: press it to set or activate the system alarm.

Freeze: no action. Double press this key within 2 seconds to lock or unlock the operation of all other buttons (except power switch) on the front panel.

NIBP: press it to start or stop NIBP measurement.

DISP: press it to shift the display to the Initial Screen.

Navigation Knob: no action.

4.4 Freeze and S-T Analysis Screen

During the process of monitoring, the ECG waveform can be frozen to perform detailed analysis in the observing screen, as shown in Figure 4.12.

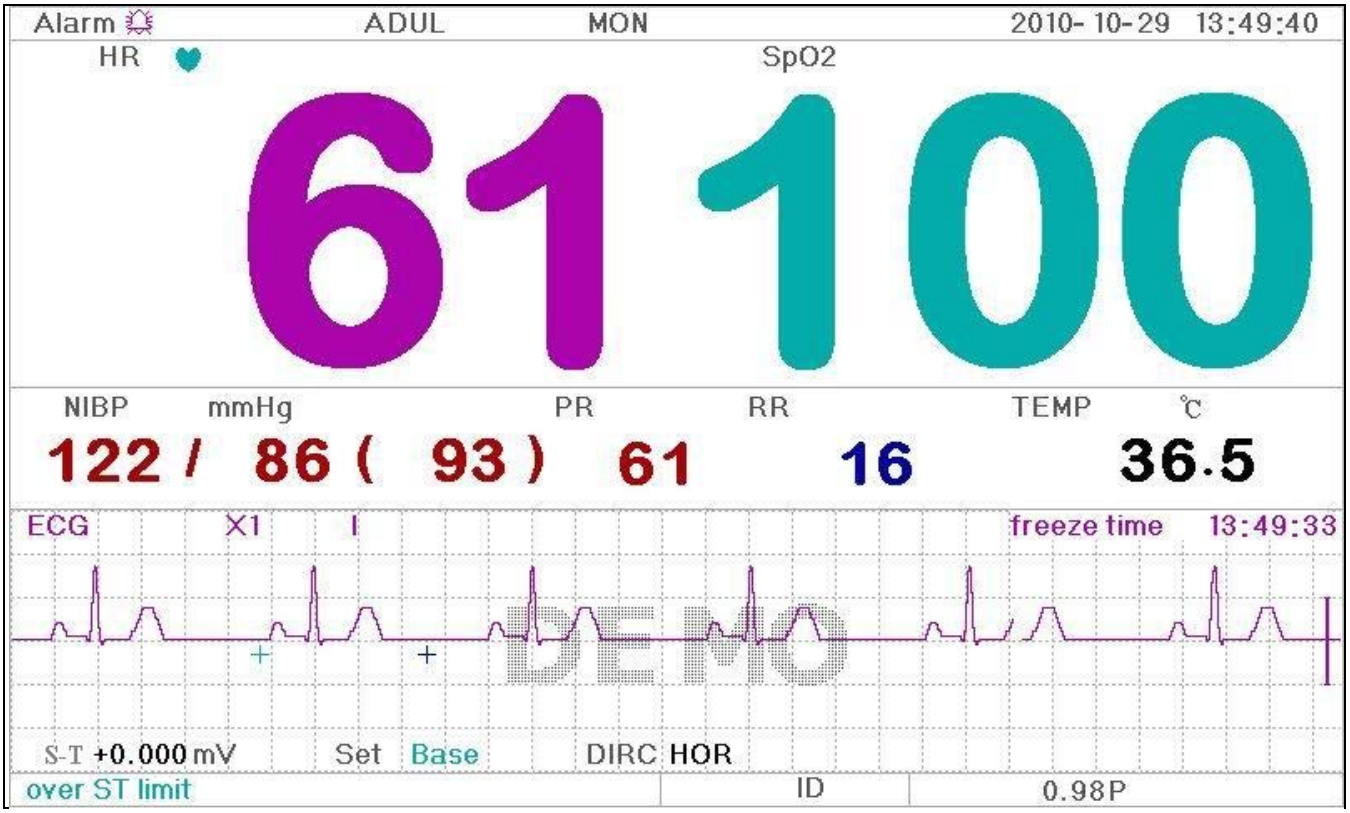


Figure 4.12 Frozen and S-T Analysis Screen

4.4.1 Screen Description

Freezing, ST segment analysis screen is similar with the observing screen, except the waveform is frozen. For example, the Figure 4.13 is a portion of the frozen waveform. The symbols on the screen were described briefly on the screen.

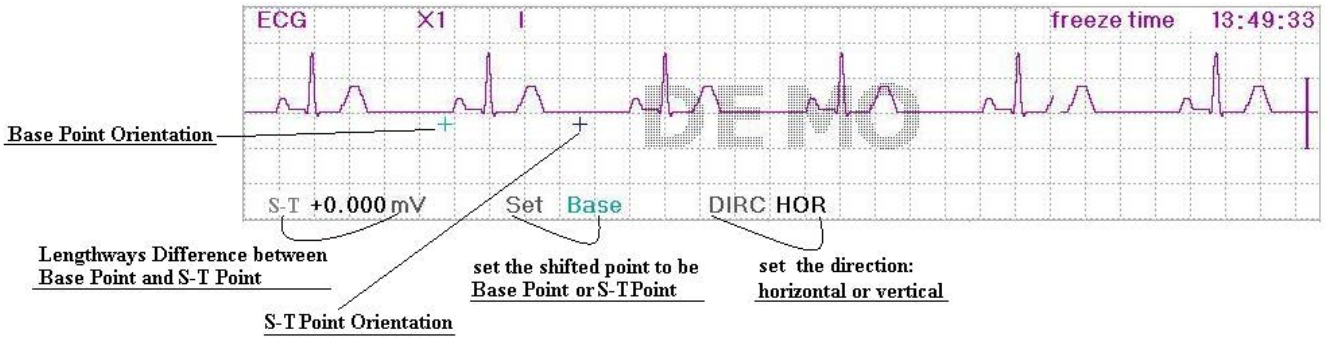


Figure 4.13 Frozen waveform

4.4.2 How to Analyze the S-T Segment on ECG Waveform

The operator can use the “Navigation Knob” to analyze the S-T segment waveform, i.e. measuring the difference between the S-T segment value and the referenced value. The value is displayed after the measure on “S-T + 0.000 mV”. The operation is carried out in 4 steps.

Step 1: rotate the “Navigation Knob” to move the base point (the red cross) horizontally to base line point (the base line is between the Q wave and the P wave). At this point, the frozen screen shows “S-T+0.xxx mV, Set Base, Dirc Hor”

Step 2: press the “Navigation Knob”. The screen shows “S-T+0.xxx mV, Set Base, Dirc Ver”. Then rotate the knob to move the base point vertically to the base line point.

Step 3: press the “Navigation Knob” again. The screen shows “S-T+0.xxx mV, Set ST, Dirc Hor”. Rotate the knob to move the S-T point (the yellow cross) horizontally to the point to be measured on the ST segment.

Step 4: press the “Navigation Knob” again. The screen shows “S-T+0.xxx mV, Set ST, Dirc Ver”. Rotate the knob to move the S-T point vertically to the point to be measured on the S-T segment.

Only the observing screen allows pressing the freeze key to enter the S-T segment analysis screen.

NOTE: The S point is the end point of S wave, and the T point is the start point of T wave.

Operation Instructions:

 **ECG lead:** press it to shift the ECG monitoring circulatory among Ⅰ, Ⅱ, and and V.

 **Alarm silence:** press it to set or activate the system alarm.

 **Freeze:** press it to unfreeze ECG waveform.

 **NIBP:** press it to start or stop NIBP measure.

 **DISP:** press it to shift the display to the Main Screen.

Navigation Knob: analyze the S-T segment waveform

Chapter 5 CO_2 Monitoring

If your monitor has CO2 monitoring function, please follow the instructions in this chapter to perform CO2 monitoring on patient. The parameter setting menu and monitoring menu differ from different models, please refer to the monitor on hand.

5.1 CO2 Parameter Settings

1. On Main Screen, press the knob to enter System Menu Screen. Then choose “SETUP→C02”to enter CO2 Parameter Settings screen.

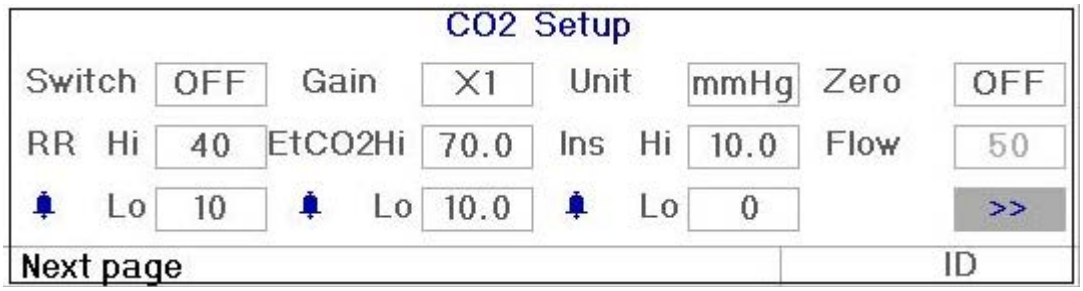
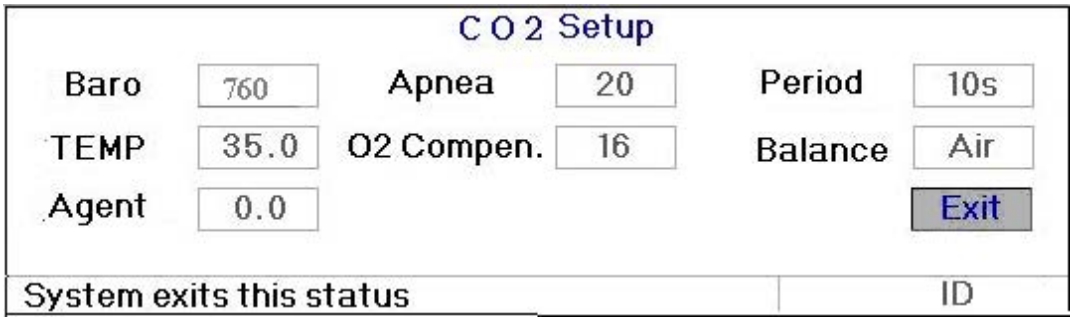


Figure 5.1 CO_2 Parameter Settings (1)



CO_2 Parameter Settings (2)

NOTE: CO_2 parameter setting screen will be displayed in two pages. Focus the gray cursor on “ >> ”, then press the navigation knob to enter the second page where the operator can set some other parameters of CO_2 (As shown in above figures).

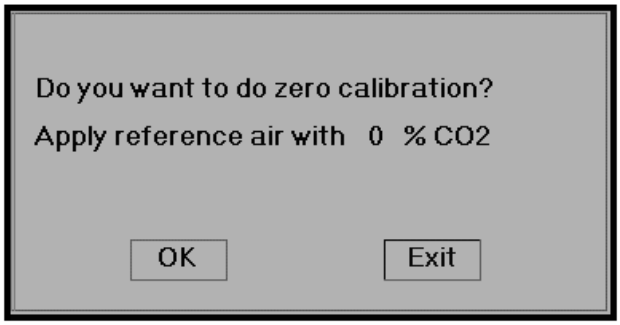
- ✧ **Switch:** choosing the mode of CO_2. It is recommended that the switch is turned on only when there is a need to monitor CO_2 parameter. This can not only reduce the power consumption and also extend the life of the CO_2 module.

In order to maintain the monitor, please set CO_2 switch at OFF state in system setup when CO_2 function is not used.

- ✧ **Gain:** the CO_2 waveform gain.
- ✧ **Unit:** Choosing the $EtCO_2$ and the minimum $InsCO_2$. It can be set up as kPa, mmHg, and %.
- ✧ **Respiration Rate High:** Setting the upper alarm limit of CO_2 respiration rate.
  Low: Setting the lower alarm limit of CO_2 respiration rate.
- ✧ **$EtCO_2$ High:** Setting the upper alarm limit of $EtCO_2$.
  Low: Setting the lower alarm limit of $EtCO_2$.
- ✧ **$InsCO_2$ High:** Setting the upper alarm limit of $InsCO_2$.
  Low: Setting the lower alarm limit of $InsCO_2$.

- ✧ **Baro (Barometric pressure):** set ambient atmospheric pressure. It can be determined by barometer or the ambient altitude. Altitude can be used to determine the typical barometric pressure if a barometer is not available, refer to Appendix Typical Pressures and CO_2 Readings at Altitudes for details.
- ✧ **Zero:** The method to calibrate CO_2: Zero calibration. Calibration must be carried out in a drafty place, and the CO_2 module must have worked continuously for 5 minutes to ensure an accurate calibration, or the calibration will not work.
- ✧ **Flow (CO_2 flow):** It is flow rate of the CO_2 sampling. Its value is 50ml/min.

The information promoted for Zero calibration is as follows:



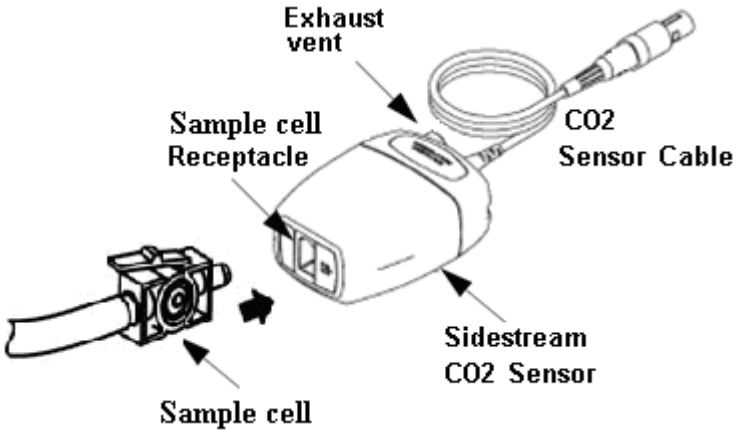
Please apply the reference air with 0% CO_2, the air in the drafty room usually can be regarded as the air with 0% CO_2. Press “OK”, and the result will be displayed on the screen several seconds later.

- ✧ **Apnea:** display time of the respiration rate value in data area when the previous respiration has been detected while the next one is not, meanwhile, the device will prompt apnea information. The setting range is 10s~60s, the default is 20s. For example, if 20 seconds is set here, it means the respiration rate value will disappear after it has been shown for 20 seconds in the data area if on respiration is detected during this period.
- ✧ **Period:** setting the calculation cycle of $EtCO_2$ value, there are three selectable options: “1b”, “10s” and “20s”. “1b”: means the $EtCO_2$ value will be calculated once every respiration cycle; “10s”: means the $EtCO_2$ value will be calculated once every 10s, and the maximum $EtCO_2$ value measured during this 10s will be displayed on data area; “20s”: means the $EtCO_2$ value will be calculated once every 20s, and the maximum $EtCO_2$ value measured during this 20s will be displayed on data area
- ✧ **TEMP:** setting the temperature value of the current measured air flow. For instance, the temperature is usually set as 37℃ while measuring the patient’s respiration by air flow. However, if the air flow to be measured is the reference gas, the temperature is set as 25℃. The setting range: 0~50; Unit: ℃; Default value: 35.0.
- ✧ **O2 Compen:** adjusting the concentration of compensating gas in patient’s respiration air flow. Generally, the compensating gas is oxygen, so it can be called oxygen compensation concentration. The unit: %; Setting range: 0%~100%; Default value: 16.
- ✧ **Balance:** setting the balance gas in patient’s respiration air flow. There are three kinds of selectable balance gas: “Air”, “N2O” and “He”, namely: air, nitrous oxide and helium. If on specific balance gas is given, the balance gas can be set as “Air”.
- ✧ **Agent:** setting whether adding the anesthetic gas to patient’s respiration air flow and the concentration of anesthetic gas. The setting range is 0.0%~20.0%, the default status is: not adding anesthetic gas, that’s to say, the concentration is 0.0%.

2. To set the color of CO_2 parameters on Color Settings screen.

5.2 CO_2 Sensor Connection

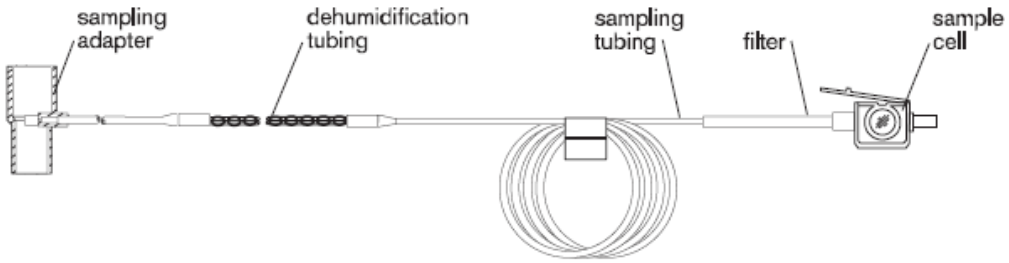
5.2.1 Sidestream CO_2 Sensor Connection



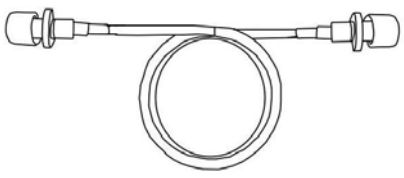
Demonstration for Sidestream CO_2 Sensor Connection

1. Take out the CO_2 Sensor and insert the CO_2 Sensor Cable into the connector labeled “CO_2” on the connector panel of the monitor;
2. The sample cell of the sampling cannula must be inserted into the sample cell receptacle of the CO_2 Sensor. A “click” will be heard when the sample cell is properly inserted. Then connect to airway tube. After finishing sensor connection, and make sure that the air input end is exposed to room air and away from all sources of CO_2, including the ventilator, the patient’s breath and your own. Next, turn on the CO_2 switch at CO_2 Setup Screen and then wait 2 minutes for the sensor warm-up.

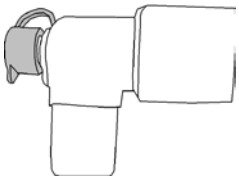
3. Default Tubing Configuration



Adapter and Sampling tube (Single patient use)



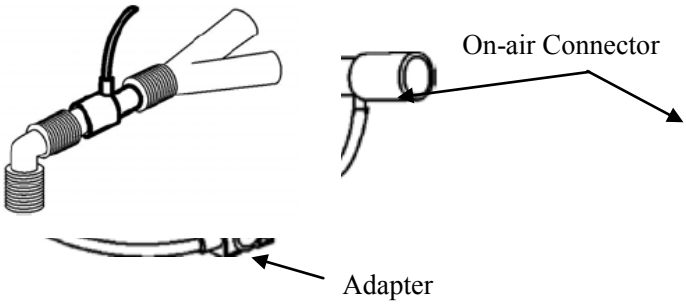
Extending airway tube for connecting to sampling tube (Single patient use)



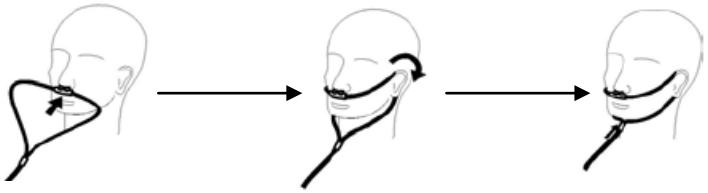
Wye Connector

4. Optional sampling cannula kits

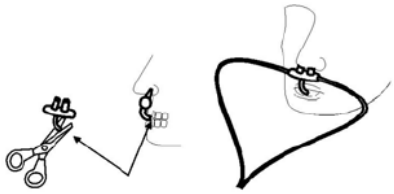
(1) T connector sampling cannula kits



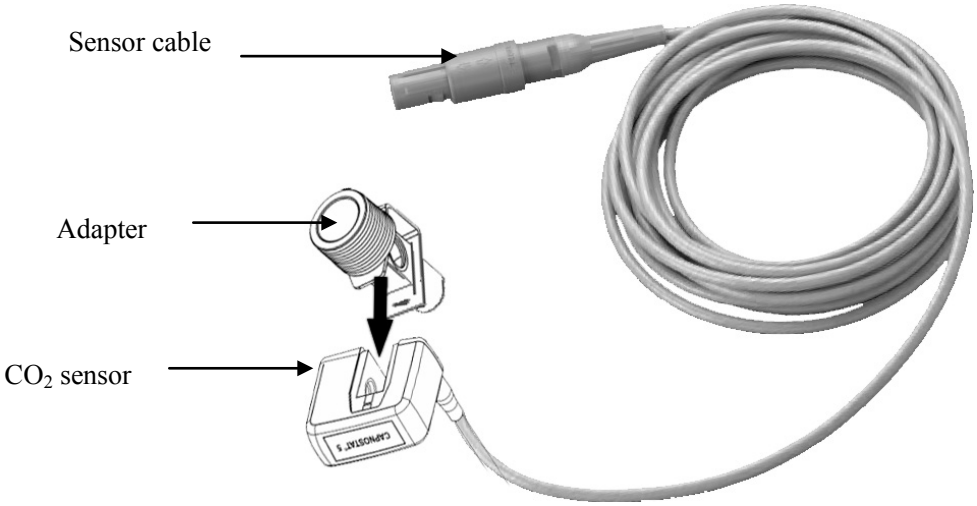
(2) Nasal Sidestream Cannula Kits



(3) Oral Sidestream Cannula Kits

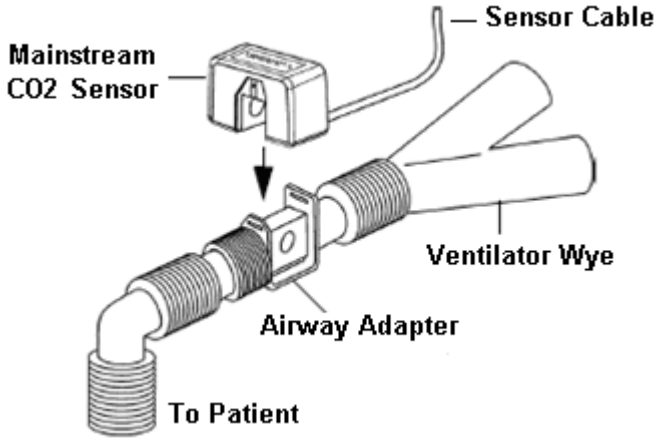


5.2.2 Mainstream CO_2 Sensor Connection



Demonstration for Mainstream CO_2 Sensor Connection

1. Take out the CO_2 Sensor and insert the CO_2 Sensor Cable into the connector labeled “CO_2” on the connector panel of the monitor;
2. Snap the CO_2 sensor onto the airway adapter as shown in Figure 6.9. A “click” will be heard when the airway adapter is properly inserted.
3. Position the airway adapter in the patient’s respiratory circuit (as close to the patient as possible) between the endotracheal tube and the ventilator circuit. Next, turn on the CO_2 switch at CO_2 Setup Screen and then wait 2 minutes for the sensor warm-up.



Safety Introductions for CO_2 Monitoring

- **CO_2 Sensor is a precision measuring part, please use it correctly and store it properly;**
- **Precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.**
- **Failure of Operation: If the CO_2 Sensor fails to respond as described in this user manual; DO NOT use it until approved for use by qualified personnel.**
- **DO NOT position the sensor cables or tubing in any manner that may cause entanglement or strangulation.**
- **Support the airway adapter to prevent stress on the ET tube.**
- **Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use CO_2 airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.**
- **Inspect the sidestream on-airway adapters and sidestream sampling kits for damage prior to use. DO NOT use the sidestream on-airway adapters and sidestream sampling kits if they appear to be damaged or broken.**
- **If the CO_2 waveform (Capnogram) appears abnormal, inspect the CO_2 airway adapters and replace if needed.**
- **Periodically check the CO_2/Flow sensor and tubing for excessive moisture or secretion buildup. Do not use them if there is excessive moisture or exterior condensation.**
- **Electric Shock Hazard: The CO_2 Sensor contains no user serviceable parts.**
- **Refer service to qualified service personnel. Do not open the sensor cabinet at will, as electric shock hazard may occur.**
- **Place the exhaust vent of the CO_2 Sensor in drafty ambient and do not let anything block the exhaust vent.**
- **Always disconnect the CO2 Sensor before cleaning. Do NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.**
- **DO NOT sterilize or immerse the CO_2 Sensor in liquids.**
- **Replace the sidestream on-airway adapters and sidestream sampling kits if excessive secretions are observed.**
- **Do not operate the CO_2 Sensor when it is wet or has exterior condensation.**
- **Monitor the CO_2 waveform (Capnogram). If you see changes or abnormal appearance, check the patient and the sampling line. Replace line if needed.**
- **DO NOT use device on patients that can not tolerate the withdrawal of 50 ml/min +/- 10 ml/min from the airway or patients that can not tolerate the added dead**

space to the airway.

- **Do not apply excessive tension to any sensor cable or pneumatic tubing.**
- **Explosion Hazard: DO NOT use in the presence of flammable anesthetics or other flammable gasses. Use of the CO_2 Sensor in such environment may present an explosion hazard.**
- **The power voltage over monitor working voltage may cause damage to CO_2 sensor. Likewise, too low power voltage may affect the CO_2 measuring accuracy or even make the CO_2 sensor not work.**
- **When changing sampling tube, it is suggested to choose the default sampling tube with dehumidifying function. The sampling tube without dehumidifying function may be easily blocked by excessive moisture. (Use life: ordinary sampling tube: 6~12 hours; the sampling tube with dehumidifying function: about 120 hours.)**
- **If the measurement appears abnormity caused by sampling tube block, please replace it.**
- **The total length of the sampling tube and extending airway tube shouldn’t be longer than 3 meters, too long may cause measurement abnormity. If using T connector sampling cannula kits, please insert the sampling tube with the tubes upward to avoid the affects of excessive moisture;**
- **Altitudes are different in different area, so set the Barometric Pressure setting value as the ambient barometric pressure.**
- **Use only our company approved accessories.**
- **While using the CO_2 sensor, a system leak which may be caused by an uncuffed endotracheal tube or a damaged CO_2 sensor, may significantly affect flow-related readings. These include flow, volume, pressure and other respiratory parameters.**
- **When stopping CO_2 monitor, please disconnected the CO_2 sensor from the patient monitor.**

Disposal of the CO_2 Sensor and its accessories should comply with national and/or local requirements.

In the presence of electromagnetic devices (i.e., electrocautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20 V/m will not adversely affect system performance.

Nitrous oxide, elevated levels of oxygen, helium and halogenated hydrocarbons can influence the CO_2 measurement.

Excessive moisture in the CO_2 may affect the accuracy of the flow measurement.

5.3 CO_2 Monitoring Screen

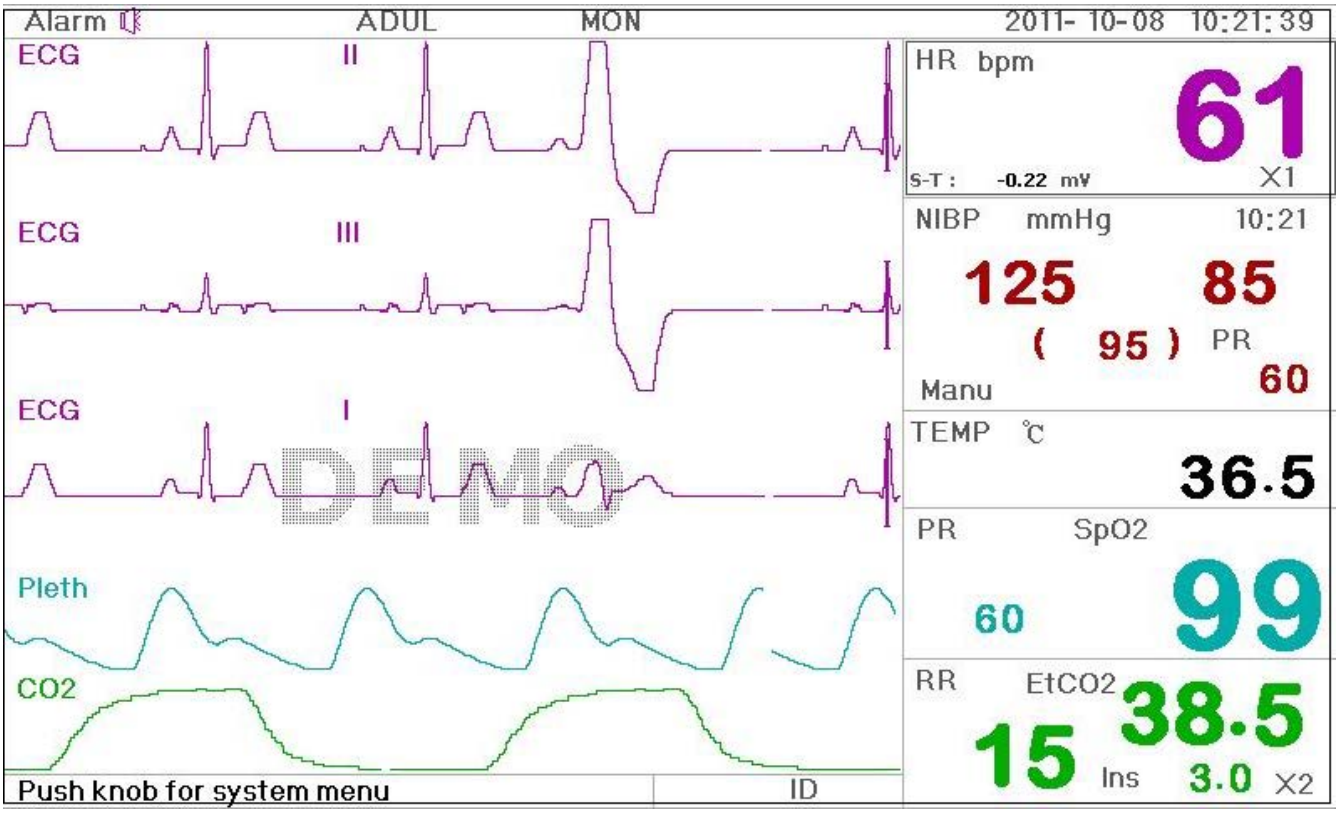


Figure 5.2 CO_2 Monitoring Screen

Waveform area

- ✧ 5th trace: CO_2 waveform. It can be respiration waveform or CO_2 waveform.

Data area

Figure 5.3 RR, $EtCO_2$, and Ins Data Area

- ✧ **“RR”:** Respiration Rate: The rpm after that is the unit of the respiration, i.e., respiration per min.
- ✧ **“$EtCO_2$ 39.0”:** The label and the value will become gray when CO_2 is turned off.
- ✧ **Ins:** The label of the minimal inhalational CO_2, the label and the value will become gray when CO_2 is turned off.
- ✧ **“16”:** Respiration rate. It will display the respiration rate of CO_2, when the switch is turned on.
- ✧ **“X1”:** Respiration gain（amplification）:

  “×1/2” Waveform scaled with half of the base gain.

  “×1” Waveform scaled with base gain.

  “×2” Waveform scaled with twice of the base gain.

  “×4” Waveform scaled with four times of the base gain

Observing Screen, 7 Leads on the Same Screen and other display screen will display CO_2 monitoring data as well besides Main Screen.

> **Note:** only when the setting item “System Menu→SETUP→CO_2→Switch”is set as “ON”, CO_2 monitoring function is available.

5.4 CO_2 Graphic Trend

On Graphic Trend screen, rotate the knob and move the cursor to “CO_2”, then press the knob to enter EtCO2 Graphic Trend. Refer to Chapter 6.4 Graphic Trend Screen for detailed instructions and operations.

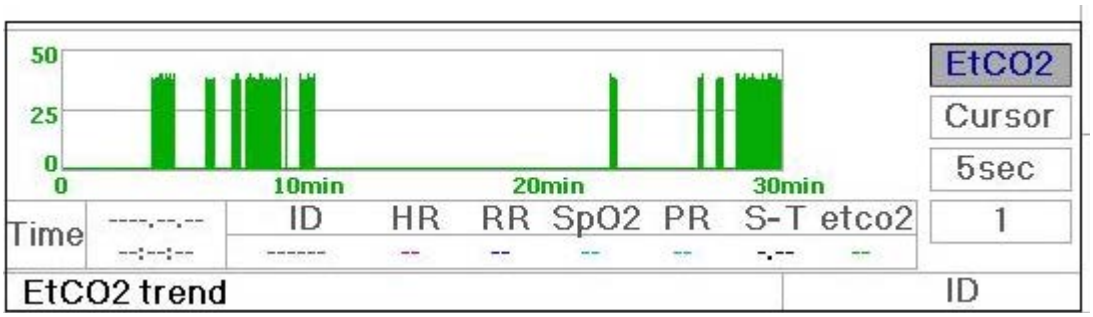


Figure 5.4 EtCO$_2$ Graphic Trend

Chapter 6 Operating Instructions for System Menu

6.1 System Menu Screen

Longtime press the “Navigation Knob” in the Main Screen as shown in Figure 4.2, the System Menu screen will display in the lower left area on the screen, as shown in Figure 6.1.

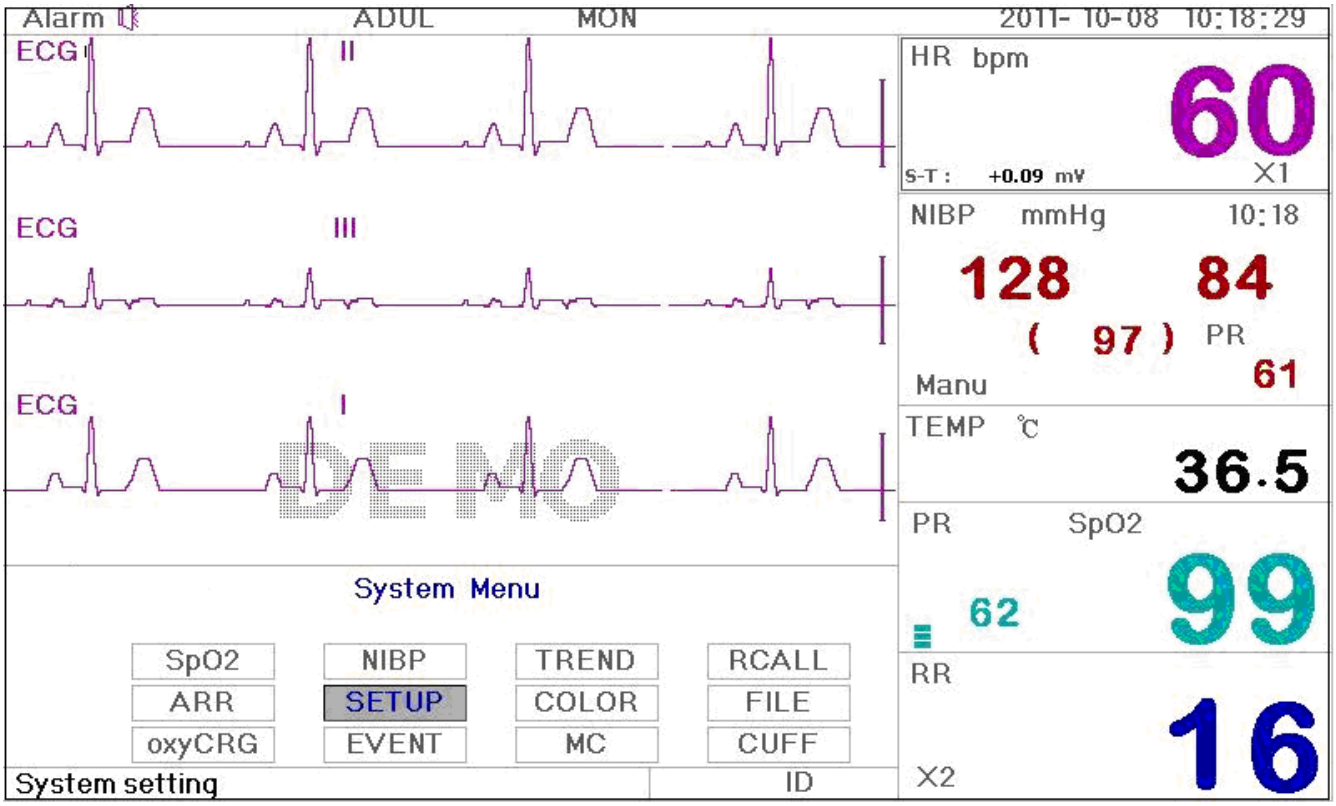


Figure 6.1 System Menu Screen

6.1.1 How to Select the Menu Item

Step 1: rotate the knob to move the gray cursor to the corresponding item.

Step 2: press the knob to enter the corresponding screen: SpO_2 Data List Screen, NIBP Data List Screen, Graphic Trend Screen, Recall Screen, Arrhythmia Screen, System Setup Screen, Color Settings, File/Archive Management Screen, oxyCRG Screen, Event List Screen, MC Calculator Screen or Cuff (Tourniquet Function) Screen. The following chapters will describe each one respectively.

Pressing “  ” key to return to the Main Screen.

6.2 SpO_2 Data List Screen

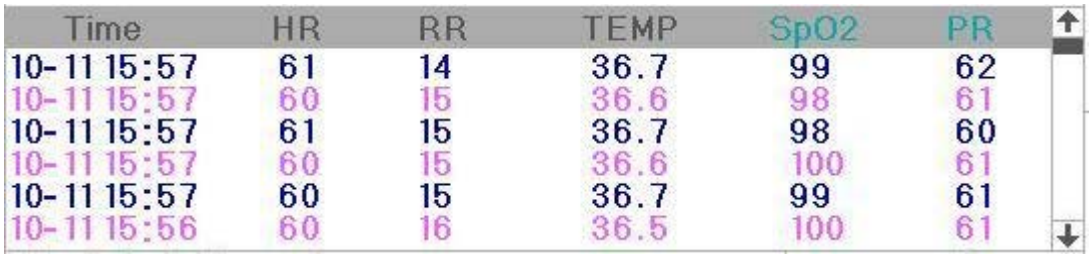


Figure 6.2 SpO_2 Data Listing Screen

6.2.1 Screen Description

When monitoring, the newest data will be displayed on the top of list including “Time, HR, RR, TEMP, SpO_2, PR”. The time shows the time when the SpO_2 measurement was taken. Up to 6 groups of SpO_2 data can be displayed on one screen. There is only one record every 4 seconds.

6.2.2 Operating Instructions

Up to 400 groups of SpO_2 data can be memorized. Using the Navigation Knob allows the user to scroll the list up and down to view SpO_2 data. When rotating the knob anti-clockwise, the list scrolls upward. When rotating knob clockwise, the list scrolls down. Please note that when the groups of data are less than 6, the Navigation Knob can not be used to scroll up or down the listing.

Pressing “ ” key to return to the Main Screen.

6.3 NIBP Data List Screen

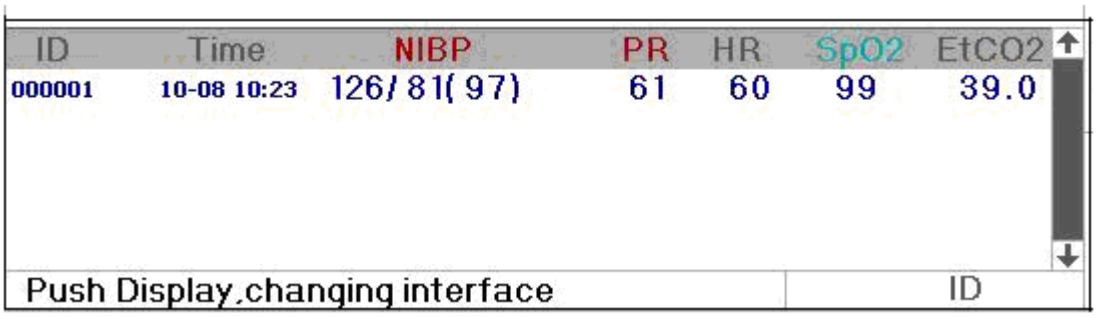


Figure 6.3 NIBP Data List screen

6.3.1 Screen Description

When monitoring, the newest data will be displayed on the top of list including “ Time, NIBP, PR, HR, RR,TEMP”. The time shows the time when the NIBP measurement was taken. Up to 6 groups of NIBP data can be displayed on one screen. There is only one record every 4 seconds.

6.3.2 Operating Instructions

Up to 12000 groups of NIBP data can be memorized. Using the Navigation Knob allows the user to scroll the list up and down to view NIBP data. When rotating the knob anti-clockwise, the list scrolls upward. When rotating knob clockwise, the list scrolls down. Please note that when the groups of data are less than 6, the Navigation Knob can not be used to scroll up or down the listing.

Pressing “ ” key to return to the Main Screen.

6.4 Graphic Trend Screen

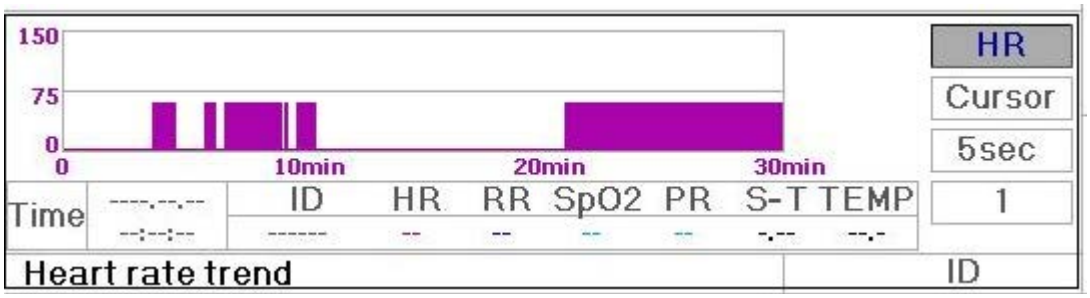


Figure 6.4 HR Trend

6.4.1 How to View the Graphic Trend

Figure 6.4 is the HR trend graph. There are 3 options on the right of the graph, as described below.

“HR” indicates the current trend graph is HR trend graph. If you want to enter other trend graphs, the procedures are: move cursor to “HR” and rotate the “Navigation Knob” to choose the trend graph from “HR”, “S-T”, “Temperature”, “NIBP”, “PR”, “RR” and “SpO_2” trend graphs, next press the knob to confirm. Their screens are described in the following figures.

After choosing “Cursor”, the trend graph display a triangle and a vertical line, a moving ruler mark that can be moved by rotating the knob. As shown in the figure, when you move the mark to a specific point, the data area below the graph will display the time and its corresponding heart rate, respiration rate, SpO_2, temperature. When rotating “Navigation Knob” key to move the mark, the moving interval is a changing value. The rule is that the initial step is 5sec, after moving it towards the same direction 1 time, the interval becomes 30 sec, and with more steps the interval becomes 1min, 10min and 30min. Therefore, it is very easy to find the time you are looking for.

The “5 sec” on the top shows the interval time. Move the cursor to the trend time, press the knob and rotate it, and the trend graph time will change to 30 sec, 1 min, 10 min, 30 min, which changes the horizontal axis to be 30 min, 3 hour, 6 hours, 60 hours, 180 hours. For example, the monitoring can record 360 times data continuously when setting to “5 sec” within 30 minutes. Changing the interval time of 30 seconds, it can record 360 times data within 3 hours. Other changes are similar to that situation.

The Trend graph shows parameter value of the current time. For example, in the “5 sec” trend graph, the monitoring can record the current data with the interval of 5 seconds. Once the monitor is out of power, the data can be stored automatically and you can scan the history record when turning on the monitor next time. This ensures the screen always display the current data continuously. Other trend graph follows the same rule.

Please note that the maximum value on the vertical axis of the ECG is 150, not the value of ECG upper limit 300. The graph is scaled down for better view of the waveforms. When the ECG value exceeds 150, the vertical axis’s maximum value will automatically change to 300. That is to say, the vertical axis value 0-75-150 will change to 0-150-300 automatically if the ECG value exceeds 150. When system gets reset or the patient ID is changed, the vertical axis will return to its original value of 0, 75, and 150. Other changes of vertical axis value in other trend graph are similar to that of ECG.

The respiration rate, body temperature and other trend graph are similar to that of ECG’s and we will not cover them in detail again. Please note that for those trend graphs, the horizontal axis is the number of times the blood pressure measured instead of time.

NIBP graphic trend is a little different from the other graphic trends. Rotate the knob to move the cursor to “ << >> ”, then press the knob for activating this item. Next, rotate the knob towards left or right for viewing another 400 groups’ graphic trend.

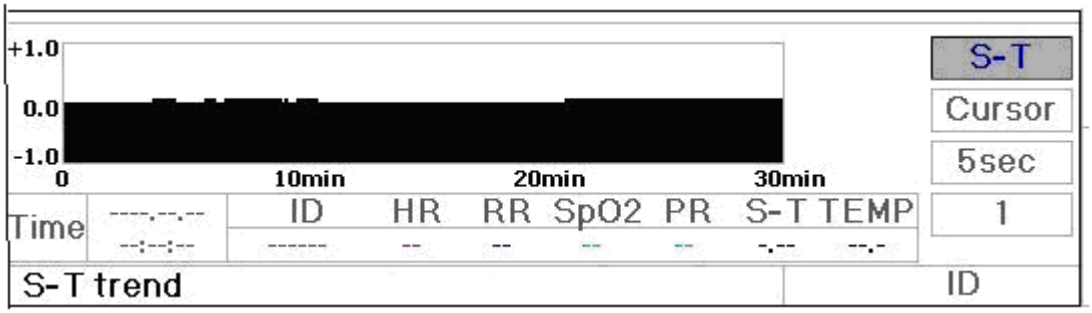


Figure 6.5 S-T Graphic Trend

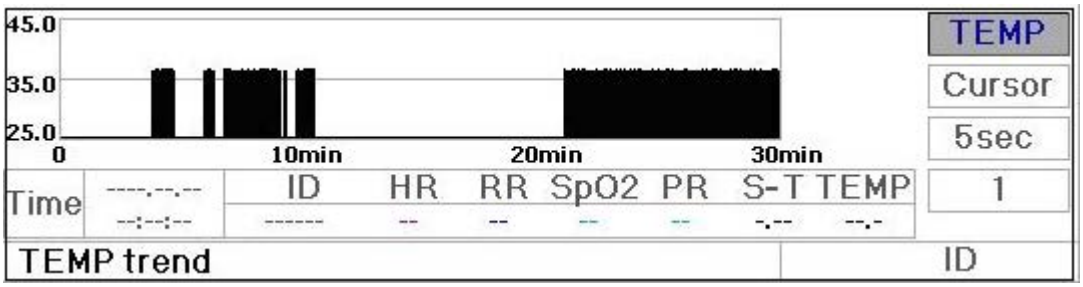


Figure 6.6 Body Temperature Graphic Trend

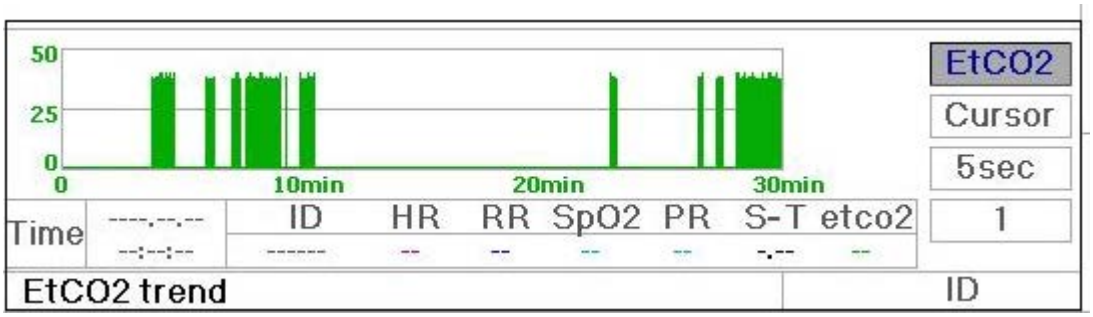


Figure 6.7 $ETCO_2$ Graphic Trend

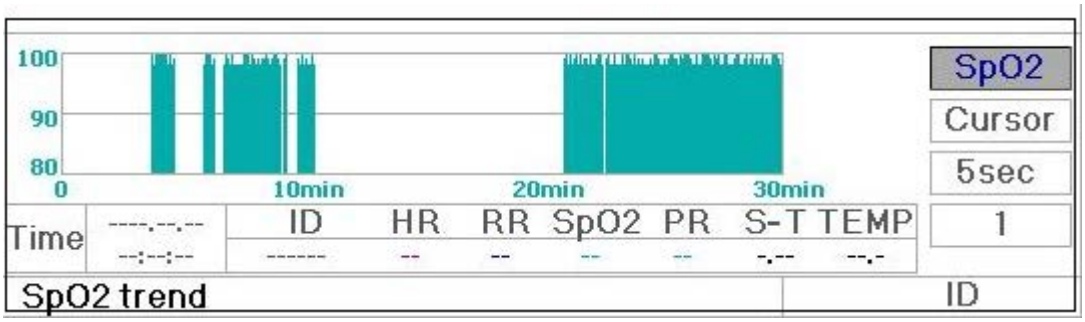


Figure 6.8 SpO_2 Trend graph

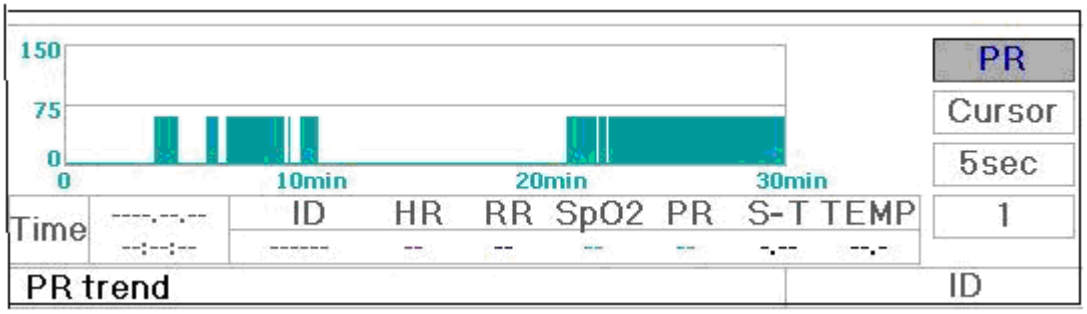


Figure 6.9 PR Graphic Trend

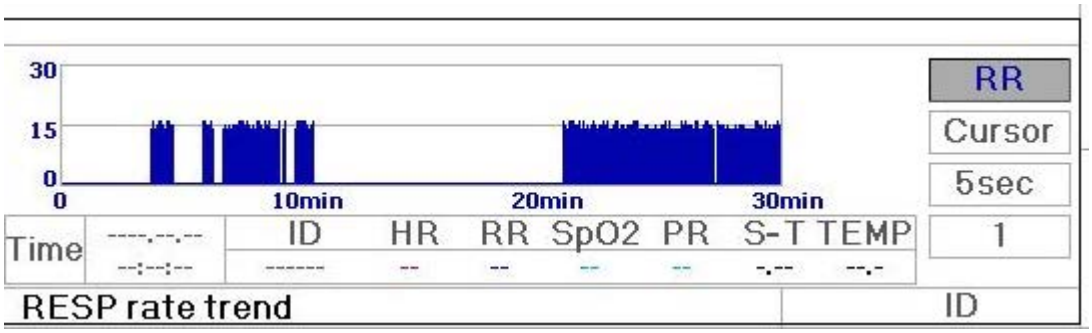


Figure 6.10 Respiration Graphic Trend

6.4.2 Operation Instructions

Rotate the Navigation Knob to choose the parameter and press the knob to review the trend graph.

Pressing “  ” key to return to the Main Screen.

6.5 Recall Screen

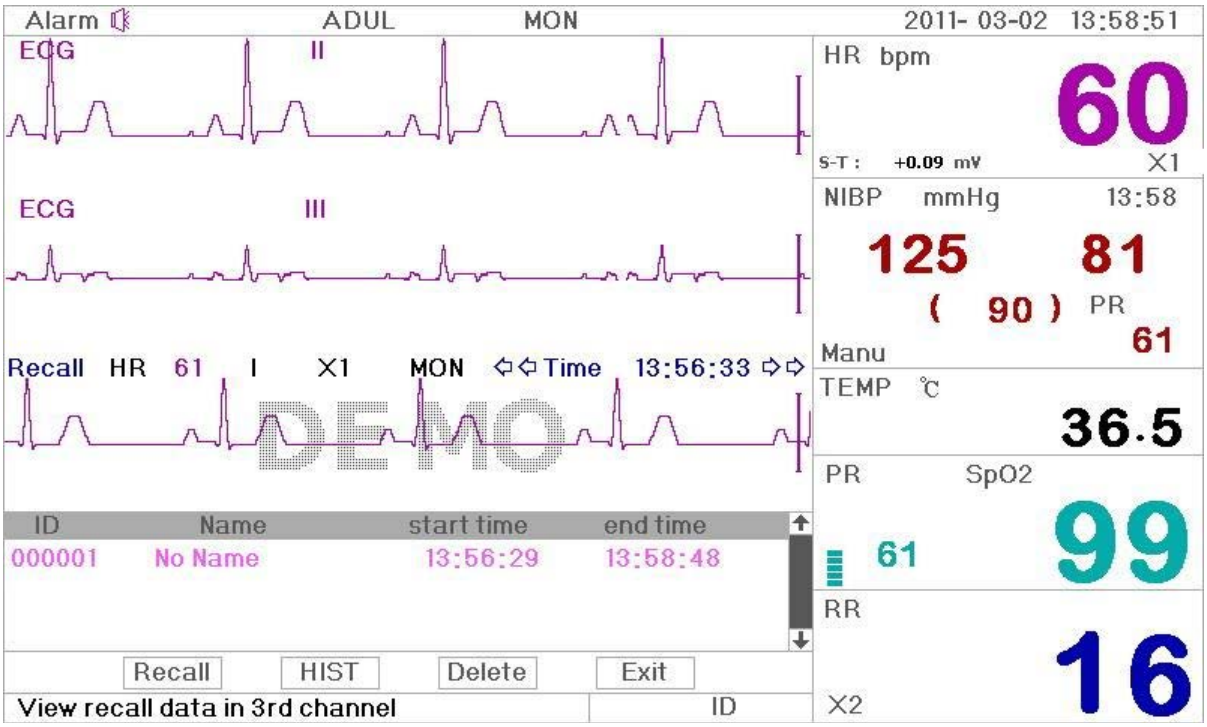


Figure 6.11 Waveform Recall Screen

It shows the monitoring can recall the history data continuously. If you change the patients’ ID or the monitor is out of power, the measuring data will not being a new single record, but connect to the last record you have measured. It is a continuous record.

The ECG lead, gain and other parameters will not change during recall.

Shown in Figure 6.12, it is different from the Main Screen in its 3rd waveform area and the operation area. We will explain them in detail below.

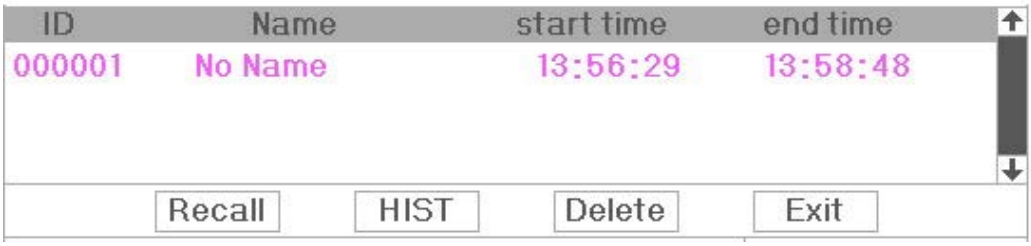


Figure 6.12 Recall Listing

6.5.1 Operation Instructions

Rotate the “Navigation Knob” and choose “Recall”, “HIST”, “Delete” or “Exit”. We explain the functions of each button below.

Recall: Press the Recall and the first record in recall list becomes green. Rotate the knob to choose a record, and press the knob to recall it. The recalled waveform is displayed on the 3rd channel of the waveform area, as shown in Figure 6.13.

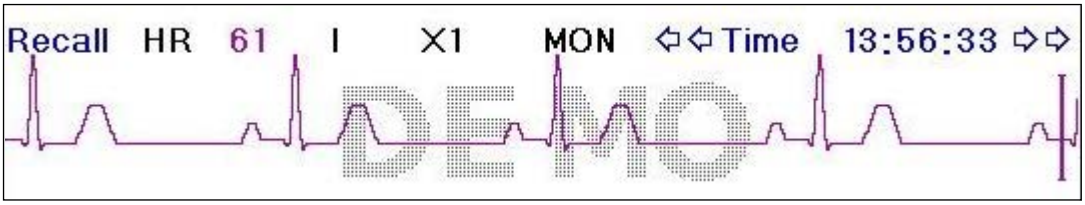


Figure 6.13

Rotate the “Navigation Knob” to move forward or backward to review the waveform. Press the “Navigation Knob” to exit the waveform recall and return to the initial waveform recall screen.

During waveform recall, the system not only displays the current recalled waveform, but also displays the lead status, gain and filter type of the waveform and time.

HIST: Press the key to shift between the History key and Current key. Press HIST and the recall list on the left displays the history data list. Press the Current, the recall list on the left side displays the current one. When entering the recall screen, the system defaults the current one.

Delete: Press this key, and the selected record in the recall list becomes green. Rotate the “Navigation Knob” to choose the reviewed record that is to be detected, press it, release it 2 seconds later, and then the record is deleted. The current record cannot be deleted, or system will exit Delete screen.

Exit: Press this key to return to the System Menu screen.

6.6 Arrhythmia Screen

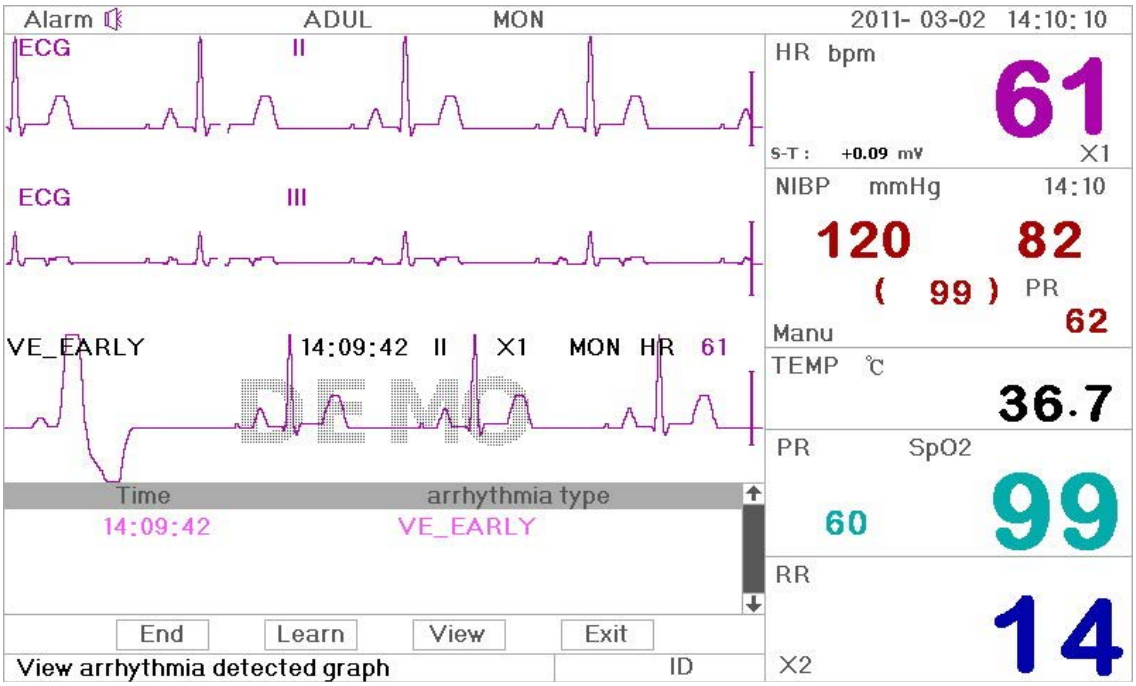


Figure 6.14 Arrhythmia Screen

6.6.1 Operation Instructions

The structure is similar to recall screen. We will cover each function key below.

Start: This button is used to start and end the system Arrhythmia detection. The default is OFF. When the Arrhythmia is not ON, the “Learn” key is disabled. Press this key and the system enters learning mode. The Start changes to End. Press it again to end the learning. When “Learn” key change to yellow from gray, it indicates the learning has finished. After the Arrhythmia detection is begins, the system will automatically detect the Arrhythmia waveforms. If Arrhythmia is detected, the Arrhythmia waveform will be displayed in the 3rd ECG channel, shown in Figure 6.14.

When the system get reset or the patient has changed, the Arrhythmia needs to be re-learned.

Learn: Because the Arrhythmia detection is based on the normal ECG waveform at the same speed and same amplitude, when the patient changes, or the Arrhythmia detection is incorrect, the Arrhythmia needs re-learn. To better use the learn function, it is recommended to use a good ECG waveform to learn during the monitoring.

View: Press this key, and the selected record in the Arrhythmia list, which is to be reviewed, becomes the green. Rotate the “Navigation Knob” to choose the record and display the corresponding waveform in the 3rd ECG channel. Press the knob again to exit.

Exit: press this key to exit the Arrhythmia detection screen and return to the System Menu screen.

During monitoring, if Arrhythmia is detected, the system will alarm. The Arrhythmia alarm is system default and does not need setup.

During Arrhythmia detection, incorrect detection might occur if the non-ECG waveforms (e.g.; square wave and triangle wave) appear.

Before start 1mV testing, please turn off the Arrhythmia detection.

During Arrhythmia detection, the Arrhythmia module is very important. The system requires a group of stable ECG waveforms. If the system detects the Arrhythmia incorrectly, please re-learn Arrhythmia by pressing “Learn” button and capture correct template.

6.7 System Setup Screen

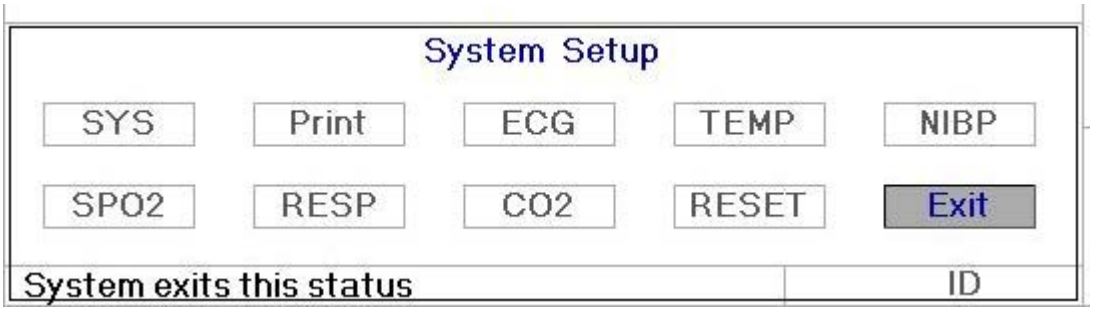


Figure 6.15 System Setup

6.7.1 How to Select the System Setup Item

Step 1: rotate the knob to move the gray cursor to the corresponding item.

Step 2: press the knob to enter the corresponding setting screen: System Setup, Printer Setup, ECG Setup, TEMP setup, CO_2 Setup, NIBP Setup, SpO_2 Setup, RESP Setup or resuming Default setting. The following contents will be described each one respectively.

Pressing “ ” key to return to the Main Screen or “Exit” button to return to the System Menu screen.

Note: If you disabled Hi and Lo limit alarm function of parameter monitoring, all the alarms related to its parameter monitoring will be disabled as well.

6.7.2 Parameter Settings

Step 1: rotate the knob to move the gray cursor to the setting item and press the knob to confirm your selection.

Step 2: rotate the knob to change the setting or modify the setting value.

Step 3: press the knob again to change and repress it to save the setting.

Pressing “ ” key to return to the Main Screen

SYSTEM PARAMETER SETTINGS

Figure 6.16 System Setup

- **Type**: The object being monitored, this can be selected between Adult and Infant.

  Adult: the subject is adult.

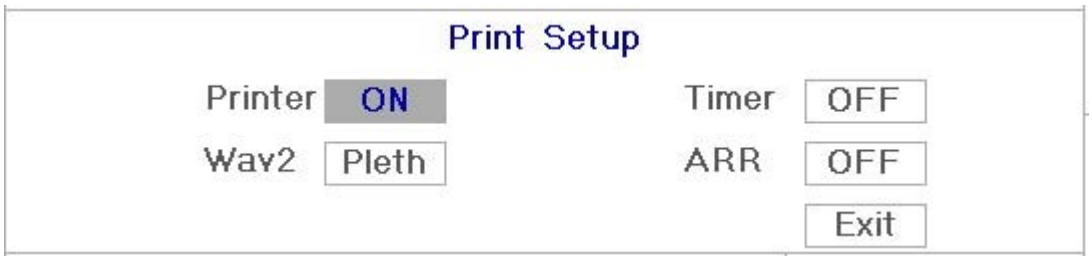
  Infant: the subject is pediatric.

  The default is “Adult”

  When changing the patient type, the system will perform the alarm settings, NIBP settings initializations. Please pay special attention to the patient type before starting the monitoring. It is forbidden to use Adult type on the pediatric patient, or it can cause serious injury.

- **Mode**: Monitor System Menu. The “Real Time” shows the real time waveform, i.e. normal monitoring state. The “Demo” shows the demo waveforms. In the demo state, all the signals and data are generated from the patient monitor for demo and testing purpose. The default is “Real Time”.
- **LANG**: The current language used, which can be selected by the user. There is no default for this setting. However, the setting can be saved.
- **Fill**: When the fill setting is ON, the display fills the volume for the SpO_2 and Respiration. When it is OFF, the system displays the line graph. The default is OFF.
- **Frze**: Pressed the key to freeze the selected waveform. The options are “All” and “ECG”. When ECG is selected, the system only freezes the ECG waveform. When “All” is selected, the system freezes all the waveforms including ECG, SpO_2, and Respiration. The factory default is “ECG”
- **Disp2**: The Display 2. Two options: Obsev (Observation) and 7 ECG (7 ECG lead) can be selected. The factory default is Observation.
- **AlmVol**: The alarm sound volume. The maximum volume is 7 and minimum is 0, i.e. no sound. When the setting is “0”, the icon “” will be displayed on screen to remind user that the alarm sound is off and Alarm Silence function is disabled. The default is 5.
- **Beep**: If the setting is ON, the press of the button will generate a keystroke sound. The factory is ON.
- **Exit:** return to the System Setup screen.

PRINTER SETUP



- **Printer:** For switch on or off the printer.
- **Timer:** If printer is ON, rotate navigation knob to set on the Timer to enable timed print, and set the value of printing intervals in the cycle category. When the time is reached, the system will automatically take the record. The interval is 1,2,3…….to 240 minutes.
- **Wav2:** When printer is selected, you can choose SpO_2, respiration, I, III, AVR, AVL, AVF or V to be printed with II-lead ECG waveform. The default is SpO_2
- **ARR:** Arrhythmia trigging print. “ON” means the printer will trig once arrhythmia occurs and record the arrhythmia waveform information. The initial setting is “OFF” means closing the arrhythmia trigging record.
- **Exit:** return to the System Setup screen.

☞ Printer is optional function. If the purchased machine has printer, please refer to above Printer Setup.

ECG PARAMETER SETTINGS

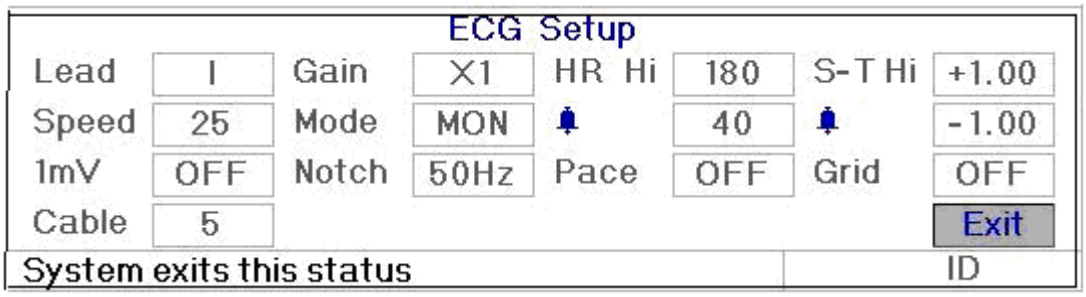


Figure 6.17 ECG Setup

- **Lead**: Can choose from I, II, III, AVR, AVL, AVF, V (V1-V6). The default is I.
- **Gain**: The ECG gain, 6 options x1/4, x1/2, x1, x2, x4 and Auto. Auto is for automatic gain control. The factory default is x1
- **HR Hi**: High limit of heart rate alarm

  Lo: Low limit of heart rate alarm

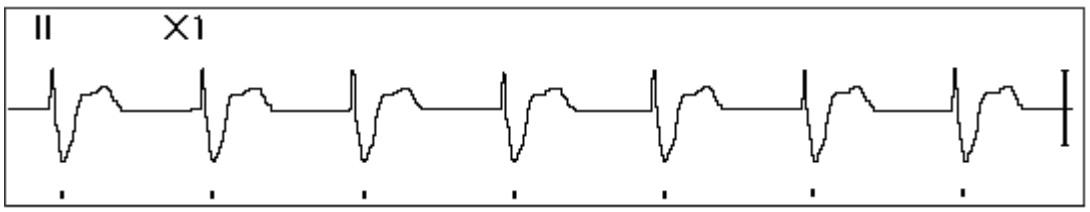
  The adjustable range and the factory default value can be found in chapter 12.2
- **Speed**: ECG waveform sweeping speed. 4 options: 6.25, 12.5, 25, 50 mm/s. The factory default is 25 mm/s
- **Mode**: ECG filter mode. Three options: MON, DIA, and OPE

  MON: Monitoring mode. Moderate filtering, it can filter out interference and present good ECG waveforms.

  DIA: Diagnosis mode. No filtering, represent the true ECG without filtering.

  OPE: Operation mode**.** Deep filtering, it can filter out strong interference.

  The factory default is MON.
- **1mV**: Generating the 1mV signal. This signal is used to test the function of the machine. It is not used during normal operation. Factory default is OFF
- **Notch:** frequency filter. Different hardware configuration may make its options various. One is “ON”/ “OFF” (The factory default is ON.), and it means turn on or turn off the 50Hz frequency filter. The other option is “OFF”/ “50 Hz”/ “60 Hz”, please choose “50 Hz” or “60 Hz” frequency filter according to your power supply frequency. The factory default is “50 Hz”.
- **Pace:** Cardiac pacemaker detection. When Pace is “ON”, a mark will be displayed on the ECG waveform if the patient fitted with a cardiac pacemaker. The factory default is OFF.



- **Grid**: The grid on the background for Observing Screen and Frozen & S-T Analysis Screen. Factory default is OFF.
- **Exit:** return to the System Setup screen.

☞ **Limits setup: Move the gray cursor to the High or Low limits of the alarm settings, and press the “Alarm silence” key to turn ON or OFF the alarm for the setting. Yellow color shows ON status, and gray color shows the OFF status.**

TEMPERATURE PARAMETER SETTINGS

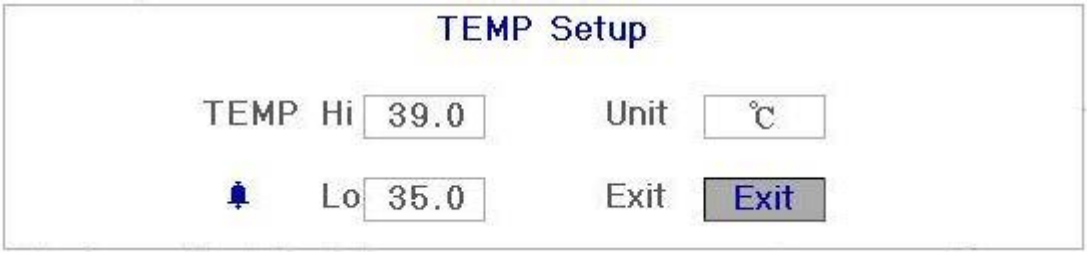


Figure 6.18 Temperature Setup

- **TEMP Hi**: High limit of temperature alarm

  Lo: Low limit of temperature alarm

NIBP PARAMETER SETTINGS

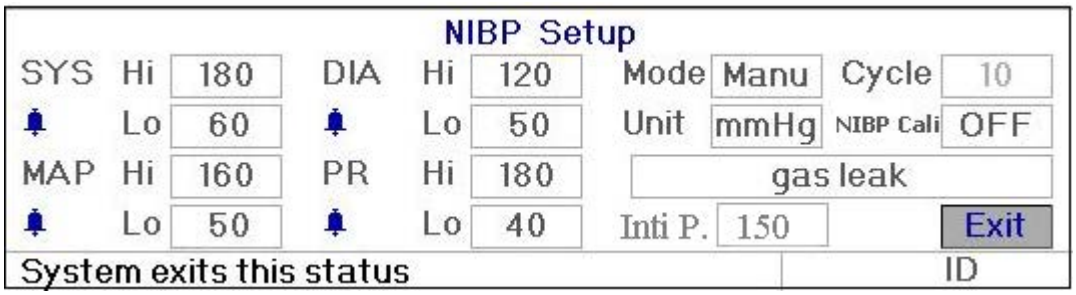


Figure 6.20 NIBP Setup

- **Unit**: The pressure unit, and mmHg and kPa can be selected. The factory default is mmHg.
- **Mode**: The cuff inflation mode, manual or automatic. The factory default is manual. The operator needs to press the NIBP button to perform NIBP measurement. If the Auto mode is chosen, the operator needs to set an interval cycle as well.
- **Cycle:** The inflation interval when the NIBP measurement is set to Auto. The options are STAT, 1 min, 2 min…240 min. Press NIBP and the system begins to count down. It takes blood pressure measurement automatically after finishing counting down If STAT is selected, press NIBP to take 5 minutes’ measurement.

WARNING: STAT can only be used for Adult. Using this mode to Infant patient can cause serious injury.

- **NIBP Cali:** It is used to check the accuracy of pressure measuring system within NIBP module, which should be conducted by technicians in test house or service department. There are three options: “Mode 1”, “Mode 2” and “OFF” available. After the verification, it is necessary to make sure it is in “OFF” status again, or other operations can’t be carried out and NIBP key will be inactivated. Factory default status is “OFF”.
- **Gas Leak:** it is used by technicians to perform a leakage inspection for NIBP pneumatic system.
- **SYS Hi/Lo**: High and Low limits of systolic pressure alarm
- **DIA Hi/Lo**: High and Low limits of diastolic pressure alarm
- **MAP Hi/Lo**: High and Low limits of MAP alarm
- **PR Hi/Lo**: High and Low limits of PR alarm
- **Initial inflation pressure setting:** Cuff pressure to be inflated initially, its options are different depending on patient type.

  for neonate: initial inflation pressure can be: 60, 70, 80mmHg, default setting: 70 mmHg;

for infant: initial inflation pressure can be: 80, 100, 120, 140 mmHg, default setting: 100 mmHg;

for adult: initial inflation pressure can be: 80, 100, 120, 140, 160, 180, 200mmHg, default setting: 150 mmHg.

- **Exit:** return to the System Setup screen.

SPO_2 PARAMETER SETTINGS

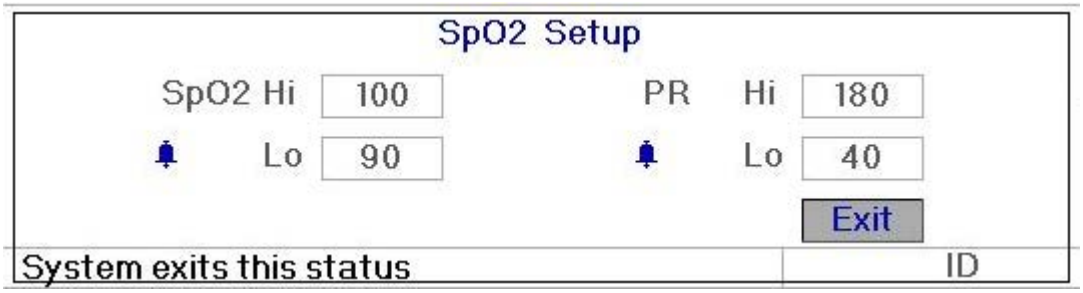


Figure 6.21 SpO_2 Setup

- **SpO_2 Hi/Lo**: High and Low limits of SpO_2 alarm
- **Pulse Hi/Lo**: High and Low limits of pulse rate alarm
- **Exit:** return to the System Setup screen.

RESPIRATION PARAMETER SETTINGS

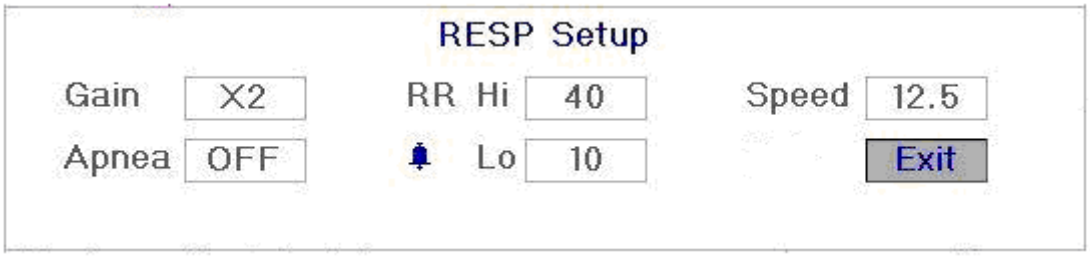


Figure 6.22 Respiration Setup

- **Gain**: Respiration amplification/gain, 4 options, x1/2, x1, x2, and x4. The default is x2
- **Speed**: Respiration display speed, 2 options 6.25mm/s and 12.5 mm/s. The default is 12.5 mm/s
- **Apnea**: The apnea alarm time (in second). When the patient stop breathing for the time longer than the set period, the Respiration display channel display warning “Apnea xxx second”.
- **Type**: Respiration impedance
- **RR Hi**: High limit of respiratory rate alarm
- **Lo**: Low limit of respiratory rate alarm
- **Exit:** return to the System Setup screen.

RESUME DEFAULT

In the System setup screen as shown in Figure 6.15, rotate knob to choose “DEF” and then press the knob, all the value of parameters will resume default setting.

6.8 Color Settings

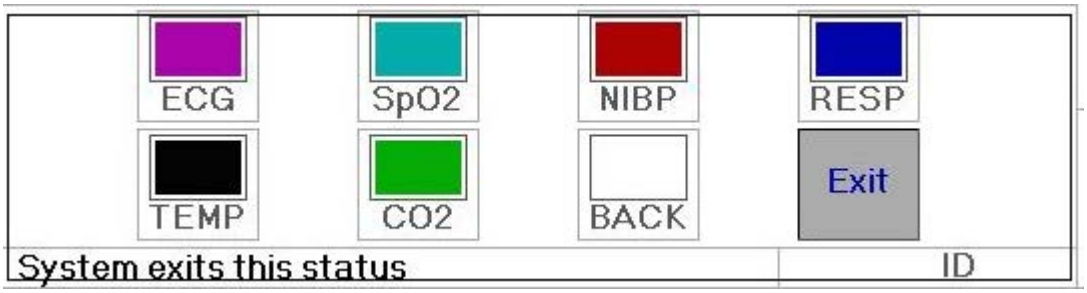


Figure 6.23 Color Setup

6.8.1 How to Change the Parameter Color

Step 1: rotate the knob to move the gray cursor to the setting item and press the knob to confirm your selection.

Step 2: rotate the knob to choose the color.

Step 3: press the knob again to confirm the chosen color.

Pressing “ ” key to return to the Main Screen or “Exit” button to return to the System Menu screen.

6.9 File Management Screen

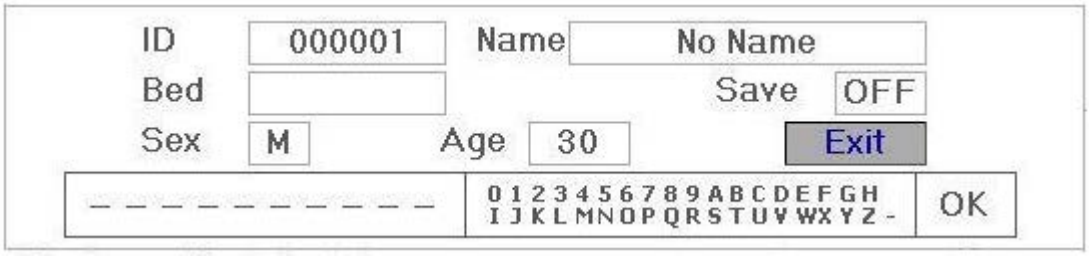


Figure 6.24 Document management screen

6.9.1 How to Add a New Patient

The document/archive management screen can be used to manage information about the patient. In the screen, the operator can enter and modify the patient ID, Name, Bed number, Sex, and Age. The operator can also choose to save the patient data in the permanent storage. The screen is shown in Figure 6.24.

ID: Or Patient ID. To enter patient ID, choose the patient ID field by using the “Navigation Knob”. Press it to enter the text entry box. Rotate the knob to choose the letter and press the knob to enter the letter. To delete the letter, move the cursor to the letter and rotate the knob to enter spaces (after the H). Use the spaces to replace the letters. After finishing entering the patient ID, choose “Exit” button and press the knob to exit the text entry. The patient ID is the unique identifier for the patient. When the patient ID changes, the system considers the patient has changed.

Name: Enter the patient’s name.

Bed: Enter the bed number.

Sex: Choose between M or F for male and female.

Age: Choose the age field and use the “Navigation Knob” to select an age.

Save: The operator can choose how much of the data that needs to be saved. The unit is hour. Once the time is chosen, the system starts to save data from the current time. If OFF is selected, it means that the data will not be

saved. The system will determine the time range according to the available disk space. If no disk space available, SAVE will be displayed as OFF. When the user intends to save the current ECG waveform permanently, please delete the history files. Refer to Chapter 6.1.1 for deletion methods.

Exit: Press this key to return to the System Menu screen.

6.10 oxyCRG Screen

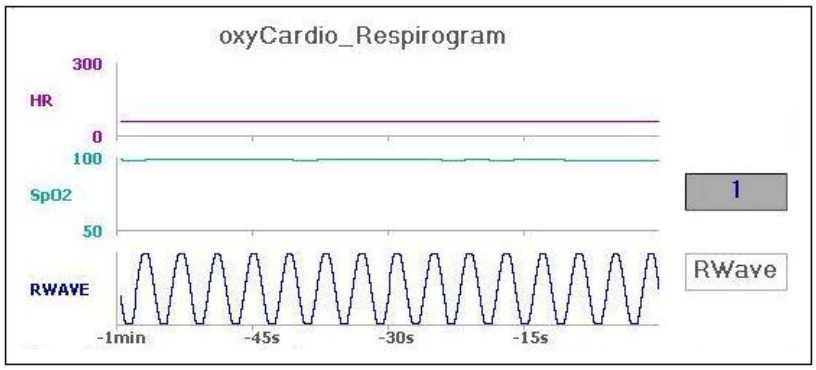


Figure 6.25 oxyCRG Screen

This screen displays the value or waveform of HR, SpO_2, and RESP waveform or Respiration Rate in selected time.

6.10.1 Operation Instructions

Step 1: rotate the knob to move the gray cursor to the button “ 1 ” or “ RWave ” and press the knob to confirm your selection.

Step 2: rotate the knob to choose the setting. The time can be set as 1 minute, 2 minutes or 4 minutes. The third channel waveform display can be set as RWAVE (Respiration waveform) or RR (Respiration Rate).

Step 3: press the knob to confirm your setting.

Pressing “  ” key to return to the Main Screen.

6.11 Event List Screen

Time	Event Type	Value	Hi/Low Limit
16:03:05	Over HR limit	60	180 / 61
16:03:03	Over SpO2 limit	100	98 / 90
16:02:57	Over TEMP1 limit	36.6	39.0 / 36.7
16:02:57	Over HR limit	60	180 / 61
16:02:54	Over SpO2 limit	99	98 / 90

Figure 6.26 Event List

6.11.1 Screen Description

The Event List displays the time, event type, the value detected and high and low alarm limits. The time shows the time when the event occurred. Up to 5 groups of event data can be displayed on one screen.

6.11.2 Operating Instructions

Up to 2000 groups of event data can be memorized. Using the Navigation Knob allows the user to scroll the list up and

down to view event data. When rotating the knob anti-clockwise, the list scrolls upward. When rotating knob clockwise, the list scrolls down. Please note that when the groups of data are less than 5, the Navigation Knob can not be used to scroll up or down the listing.

Pressing “ ” key to return to the Main Screen.

6.12 MC Calculator

This monitor supplies 10 kinds of medicine calculation and titration display function.

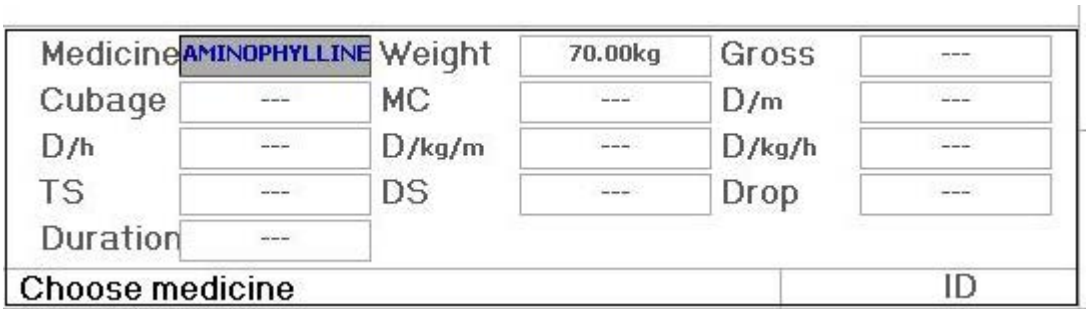


Figure 6.27 Medicine Dosage Calculator Screen

6.12.1 Medicine Dosage Calculator

Medicine types which can be perform drug dosage calculation: AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN, and PITOCIN.

Drug Dosage Calculation adopts the following formula:

Medicine Consistency (MC) =Medicine Gross/ Cubage

(Dose/minute)= (Dose/hour) /60

(Dose/Kg/m)= (Dose/m) /Weight

(Dose/Kg/h)= (Dose/h) /Weight

Transfusion Speed (TS) = (Dose/h) /MC

Drop Speed=TS/ (Cubage/drop)

Duration=Medicine Gross/Dose/h）

Formula Introduction： Dose/m=Dose per minute; Dose/h=Dose per hour; Dose/Kg/m=Dose per Kg per minute; Dose/Kg/h=Dose per Kg per hour.

On medicine calculation screen, at first the operator should move the gray cursor to “Medicine” to select the calculated medicine name, and then move the cursor to “Weight” to select and confirm patient weight, at this time MC analysis screen is shown as Figure 6.28

Figure 6.28 MC Analysis Screen

Rotate the Navigation knob to move the cursor to the option which needs to be calculated, press the knob and rotate it to obtain calculating value. When the calculating value is selected, the calculated value will be displayed in corresponding position. Each calculating option has limit range, if the result exceeds range, it will display “…”.

- **On MC analysis screen, other menu options can not enter value unless entering patient’s weight and**

medicine name again, in default status it is no effective. The values in system is a group of stochastic initial values, the operator should not consider it as calculating standard, please according to doctor’s device enter a group values which are suitable for patient.

- **The unit of every medicine is settled unit or unit series. The operator must select the appropriate unit according to doctor’s device. In a unit series, unit carry performs automatic adjustment along with the current entering value. When exceeding the range of this unit expression, the system will display “…”.**
- **When the operator finishes one option entering, the system will give visible indication in menu to remind operator to check the correctness of entering value.**
- **For every new entering value, please perform confirming. The operator should take it seriously, only the entering is correct, the calculating result is believable and reliable.**

Select Medicine Type: Move the cursor to “Medicine”, rotate Navigation knob to perform selection. Ten options: AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN, and PITOCIN. The default medicine is AMINOPHYLLINE.

Weight: when entering into medicine calculating window, the operator should enter patient’s weight; the weight is used for MC calculation only; weight: 0.5Kg to 300Kg selectable; step: 0.5Kg; default: 70 Kg for adult; 20Kg for infant.

- **Medicine calculation function just supplies a medicine calculator function. The values in table can have no relation with the monitored patient, so the weight in this menu and the weight in system are two different values. When update a patient in system operation, the value in this menu will not be affected.**

6.13 Tourniquet Function

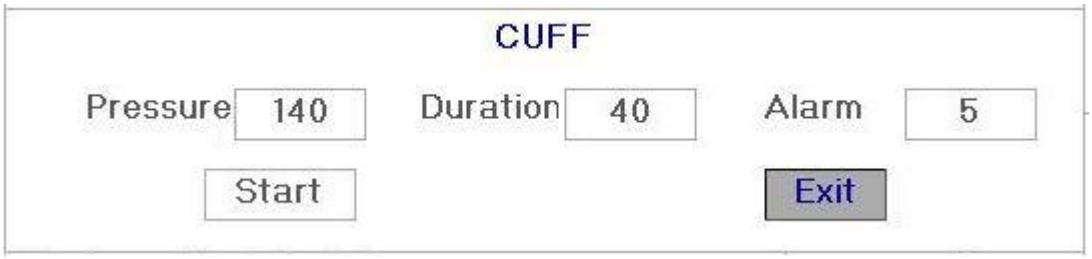


Figure 6.29 Cuff

✧ **“Pressure”:** when you use Tourniquet function, you need to preset a cuff pressure for hemostasia. The pressure is adjustable, and its adjusting limit is different depending on patient type:

for neonate: preset range: 70~100 mmHg, default value: “90” mmHg;

for infant: preset range: 80~130 mmHg, default value: “110” mmHg;

for adult: preset range: 80~180mmHg, default value: “140” mmHg.

☞ If the pressure drops down slowly under 10mmHg compared with the preset value due to little air leakage in the pneumatic system when time passes by, the monitor will re-inflate to maintain the cuff pressure close to the preset pressure value.

Note: the unit of cuff pressure is the same as the NIBP unit in NIBP Setup.

✧ **“Duration”:** After presetting the cuff pressure, you need to set the time period for maintaining the preset pressure after inflation. “5, 6, 7,…120” minutes adjustable. The default value is “40” minutes.

If the set value is “xx” minutes, the monitor will count down from “xx” minutes automatically when starting cuff inflation. When time is up, it will deflate automatically.

- ✧ **“Alarm”:** the alert time is for reminding user that the preset operation of tourniquet is going to end. It can be chosen from 1 to 60 minutes, and the default value is “5” minutes. If the set value is “xx” minutes and when counting down time reaches “xx” minutes, the monitor will give off alarm sound until deflation ends. The alarm type is high priority alarm. (For example: if the duration is 40 minutes and the alert time is 5 minutes, the alarm will ring to prompt when the duration counts down to 5 minutes. The Prompt Info area starts to prompt: TOUR C-D 300 seconds.)
- ✧ **“Start”:** shift cursor to “Start” and press “■” key, “Start” becomes “Stop” and meanwhile the blood cuff starts being inflated; Pressing “Stop” button can stop using this function. After deflation, it will change to “Start” again.

6.13.1 Operation Instructions

Step 1: rotate the knob to move the gray cursor to the setting item and press the knob to confirm your selection.

Step 2: rotate the knob to change the setting or modify the setting value.

Step 3: press the knob again to change and repress it to save the setting.

Pressing “  ” key to return to the Main Screen or “Exit” button to return to the System Menu screen.

Chapter 7 Alarm

7.1 Alarm Priority

High Priority:

Over HR limit
Over TEMP limit
Over RR limit
Over SpO_2 limit
Over PR limit
Over NIBP SYS limit
Over NIBP DIA limit
Over NIBP MAP limit
Over $EtCO_2$ limit
Over $InsCO_2$ limit
Over ST limit
Over NIBP PR limit
ECG VPCEST
Unable to detect HR
Unable to detect SpO_2
The battery capacity will exhaust

Medium Priority:

VE RONT
SVE RONT
Lead Off
Probe Off
CO_2 Out of Range

Low Priority:

Other arrhythmia phenomenon（Except ECG VPCEST, VE RONT and SVE RONT, refer to 13.3 Abbreviation of arrhythmia for details.）

7.2 Alarm modes

When an alarm occurs, the monitor responds with visual alarm indications (which are shown by two ways: alarm indicator and alarm message description) and audible alarm indications.

Visual Alarm Indicators

The flashing rates for the three categories of alarms are shown in the table below.

Indicator Color	Alarm Category	Flashing Rate
Red flashing	High priority alarm	2 Hz
Orange flashing	Medium priority alarm	0.5 Hz
Orange light	Low priority alarm	Constant(on)(non-flashing)

Table 6.1

Refer to Chapter 13.1 Alarm Information for detailed alarm message descriptions.

Audible Alarm Indications

The audible alarm has different tone pitch and on-off beep patterns for each priority category. These are summarized in the Table below.

Alarm Category	Tone Pitch	Beep Rate
High priority alarm	~500Hz	2 beeps per 7 sec.
Medium priority alarm	~700Hz	4 beeps per 9 sec.
Low priority alarm	~600Hz	20 beeps per 13 sec.
Normal	~300Hz	continuous

Table 6.2

Note: Visual alarm indicators can not be suspended or removed. Audible alarms may be decreased in volume or silenced as described in Chapter 5.

7.3 Alarm Silence

Press key to set or activate the system alarm. In the monitoring screen, press “Alarm” to set the alarm timer. There are four options of alarm silent time: 2 minutes, 5 minutes, 10 minutes and 20 minutes. The time shows up on the upper left corner of the screen. When the alarm timer is activated, the system begins to count down. If alarm occurs during that period, the system alarm will be activated automatically and the monitor will give alarm. If there is no alarm during that period, when the set time has passed the system alarm will be activated as well.

When the monitor alarms, press key to suspend the alarm and set the alarm silence time.

- **DO NOT silence the audible alarm or decrease its volume if patient safety could be compromised.**

7.4 Alarm Setting

In the System menu screen, move the cursor to the “SETUP”, and press it to enter System Setup screen.

Limits setup: Move the gray cursor to the High or Low limits of the alarm settings, and press the “Alarm” key to turn ON or OFF the alarm for the setting. Yellow color shows ON status, and gray color shows the OFF status.

Refer to Chapter 13.2 for detailed Default Alarming Values of All Parameters and Setup Range.

Whenever the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.

7.5 Verify Adjustable Alarm Function

To verify adjustable alarm function, select “Demo” for the item of Mode in system parameter settings menu and adjust alarm limits or change alarm setting, then pay a close attention to the alarm. If the alarm is sent out according to your setting, it means the alarm function is effective.

Chapter 8 Technical Specifications

8.1 ECG Monitoring

1. Input signals range in amplitude: ± (0.5 mVp ~ 5 mVp)
2. Heart rate display range: 15 bpm ~ 350 bpm
3. Heart rate display accuracy: ± 1% or ± 2 bpm, whichever is greater.
4. Heart rate averaging: Averages the recent eight beats having RR intervals falling within the acceptable limits.
5. Heart rate alarm delay time: ≤ 10s
6. Response time to change in heart rate:
   Change from 80 bpm to 120 bpm: < 8 sec
   Change from 80 bpm to 40 bpm: < 8 sec
7. Tall T-wave rejection: Rejects all T-wave less than or equal to 120% of 1mV QRS.
8. Pacemaker pulse rejection:
   Rejects all pulses of amplitude ± 2mV to ± 700mV and duration 0.1 to 2 ms without overshoot;
   Rejects all pulses of amplitude ± 2mV to ± 400mV and duration 0.1 to 2 ms with overshoot.
9. Sensitivity selection:
   AUTO, Automatic scaled waveform
   ×1/4, 2.5mm/mV tolerance: ± 5%
   ×1/2, 5mm/mV tolerance: ± 5%
   ×1, 10mm/mV tolerance: ± 5%
   ×2, 20mm/mV tolerance: ± 5%
   ×4, 40mm/mV tolerance: ± 5%
10. Sweeping speed: 6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s tolerance: ±10%
11. ECG noise level: ≤ 30μV_{P-P}.
12. ECG input loop current: ≤ 0.1μA
13. Differential input impedance: ≥ 5MΩ
14. Common-mode rejection ratio (CMRR):
    Diagnostic mode: ≥ 90dB
    Operation, monitoring mode: ≥ 105dB
15. Time constant:
    Monitoring mode: ≥ 0.3s Diagnostic mode: ≥ 3.2s

16. Frequency response:

Monitoring mode: 0.67 Hz～40 Hz(+0．4dB,－3．0dB)

Diagnostic mode: 0.05 Hz～150 Hz(+0．4dB,－3．0dB)

Additional declarations to conform the particular standard of IEC 60601-2-27 “Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment”		
Direct current for respiration, leads-off sensing, and active noise suppression	Applied current less than 0.1 microamperes.	
Response to irregular rhythm	A1 Ventricular bigeminy-80BPM A2 Slow alternating ventricular bigeminy-60BPM A3 Rapid alternating ventricular bigeminy-120BPM A4 Bidirectional systoles-90BPM	
Time to ALARM for tachycardia	Waveform B1, Amplitude 0.5 mV 1 mV 2mV	Average Time to Alarm <8 sec <8 sec <8 sec
	Waveform B2, Amplitude 1mV 2mV 4mV	Average Time to Alarm <8 sec <8 sec <8 sec

8.2 RESP Monitoring

1. RESP rate measuring range: 0rpm~120rpm
2. RESP rate accuracy: ±5% or ±2 rpm, whichever is greater
3. RESP rate alarm limit setting range: 0rpm~120rpm.
4. Alarm tolerance: ±5% or ±2 rpm, whichever is greater

8.3 TEMP Monitoring

1. TEMP measuring range: 25.0℃~45.0℃
2. TEMP measuring accuracy: ±0.2℃
3. TEMP responding time: ≤150s

8.4 NIBP Monitoring

1. Measuring method: Oscillometric Technique
2. Pneumatic pressure measuring range: 0 mmHg~300mmHg
3. Accuracy of pressure measurement: ±3 mmHg
4. Cuff inflation time: <10 seconds (typical adult cuff)
5. Measurement time on the average: < 90 seconds
6. Air release time while the measurement is canceled: <2 seconds (typical adult cuff)
7. Initial cuff inflation pressure

Adult: 175 mmHg Pediatric: 135 mmHg Neonate: 65 mmHg

8. Overpressure protection limit

Adult: ≤ 300 mmHg Pediatric: ≤ 240mmHg Neonate: ≤ 150 mm

9. NIBP measurement range:

press（unit）		Adult	Infant	Neonate
SYS	mmHg	40~275	40~200	40~135
MAP	mmHg	20~230	20~165	20~110
DIA	mmHg	10~210	10~150	10~95

10. NIBP accuracy:

Maximal mean deviation: ±5 mmHg

Maximal standard deviation: 8 mmHg

11. Measurement mode: Manual, Auto, STAT

8.5 SpO_2 Monitoring

1. Transducer: dual-wavelength LED

Wavelength: Red light: 660 nm, Infrared light: 905 nm.

Maximal optical output power: less than 2mW maximum average

2. SpO_2 measuring range: 35%~100%

3. Low perfusion capability: 0.4%~5%

4. SpO_2 measuring accuracy: not greater than 3% for SpO_2 range from 70% to 100%

*NOTE: accuracy defined as root-mean-square value of deviation according to ISO 9919

5. Low perfusion performance: the declared accuracy is attained when the pulse amplitude modulation ratio is as low as 0.4%

8.6 Pulse Rate Monitoring

1. Pulse rate measuring range: 30bpm~240bpm

2. Pulse rate measuring accuracy: ±2bpm or ±2%, whichever is greater.

8.7 CO_2 Monitoring

1. Technology: Infrared absorption method.
2. Mode of Sampling: Sidestream or Mainstream
3. CO_2 Response Time:
   Sidestream: <3seconds (including transport time and rise time).
   Mainstream: <60ms (rise time)
4. Warm-up Time: Not less than two minutes
5. CO_2 measurement range: 0~150mmHg
6. CO_2 Accuracy: 0~40mmHg ±2mmHg
   41~70mmHg ±5% of reading
   71~100mmHg ±8% of reading
   101~150mmHg ±10% of reading

*NOTE: Gas temperature at 25°C for Sidestream;
Gas temperature at 35°C for Mainstream

7. Flow rate: 50ml/min ±10 ml/min (Sidestream)

8.8 Data Recording

1. Sensitivity selection tolerance: ±5%
2. Recording speed: 25mm/s
3. Recording speed accuracy: ±10%
4. Hysteresis: ≤0.5mm
5. Frequency response:

   Monitoring mode: 0.5~40Hz Diagnostic mode: 0.05~75Hz
6. Time constant:

   Monitoring mode: ≥0.3s Diagnostic mode: ≥3.2s

8.9 Other Technical Specifications

1. Power supply: 100~240VAC, 50/60Hz
2. Power consumption: see the nameplate on the monitor
3. Rechargeable Li-ion battery specification: 14.8V 2200mAh
4. Display mode: 7 inches TFT color LCD Resolution: 800×480pixel
5. Alarming mode: Audible & visible alarm
6. Communication: Serial/Net port

8.10 Classification

Safety standard:	IEC 60601-1
The type of protection against electric shock	Class I equipment.
The degree of protection against electric shock	Type BF and CF applied parts
Electro-Magnetic Compatibility:	Group I, Class A
The degree of protection against harmful ingress of water	Ordinary equipment without protection against ingress of water.
The safety degree of flammable gas	Not suitable to use in the environment where flammable gas exits.

8.11 Guidance and manufacturer’s declaration-Electromagnetic compatibility

Table 1

Guidance and manufacturer’s declaration-electromagnetic emission- for all EQUIPMENT AND SYSTEMS

PC-3000 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	PC-3000 Patient Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	PC-3000 Patient Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

Table 2

Guidance and manufacturer’s declaration-electromagnetic immunity for all EQUIPMENT AND SYSTEMS

PC-3000 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge(ESD) **IEC61000-4-2**	±6 kV contact ±8kV air	±6 kV contact ±8kV 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 **IEC61000-4-4**	±2kV for power Supply lines ±1 kV for input/output lines	±2kV 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**	±1kV line (s) to line(s) ±2kV line(s) to earth	±1kV differential mode ±2kV 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 **IEC61000-4-11**	<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 equipment or system requires continued operation during power mains interruptions, it is recommended that the equipment or system be powered from an uninterruptible power supply or a battery.
Power frequency(50Hz/60Hz) magnetic field **IEC61000-4-8**	3A/m	3A/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.			

Table 3

Guidance and manufacturer’s declaration – electromagnetic immunity-for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

PC-3000 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of PC-3000 Patient Monitor should assure that it is used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of PC-3000 Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ,[a] should be less than the compliance level in each frequency range .[b] Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which PC-3000 Patient Monitor is used exceeds the applicable RF compliance level above, PC-3000 Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating PC-3000 Patient Monitor.

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

Table 4

Recommended separation distances between portable and mobile RF communications equipment and The equipment or system- for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

PC-3000 Patient Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment or system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment or system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	80MHz to 2,5GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

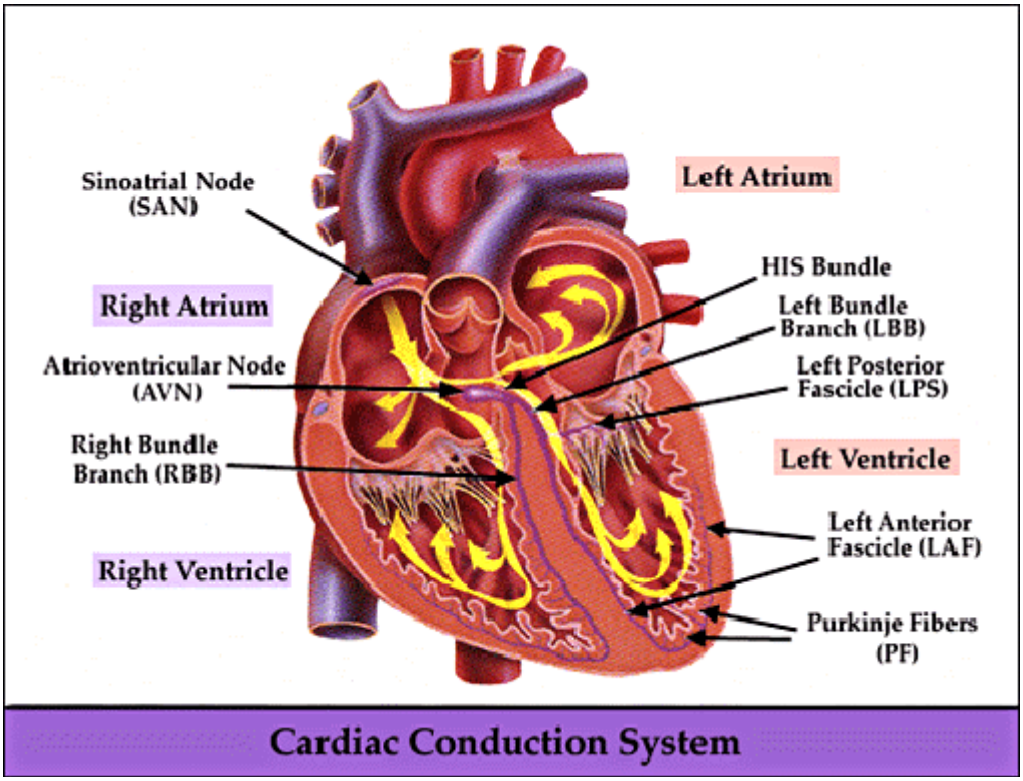
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Chapter 9 Monitoring Parameter

9.1 ECG Monitoring

9.1.1 How to Obtain High Quality ECG and Accurate Heart Rate Value

The electrocardiogram (ECG or EKG) is primarily a tool for evaluating the electrical events within the heart. The action potentials of cardiac-muscle cells can be viewed as batteries that cause charge to move throughout the body fluids. These currents represent the sum of the action potentials occurring simultaneously in many individual cells and can be detected by recording electrodes at the surface of the skin. The figure below shows the system of the heart.



A common ECG plate electrode used together with this monitor has short shelf life. Generally, the shelf life is only one month after the package is opened. When outdated plate electrode is used, due to skin’s contact impedance and big electrode potential, the chance of interference will be increased, and the ECG baseline will have an unstable inclination. Therefore, always use valid plate electrodes.

9.1.2 Factors affecting ECG signal

- ✧ Interference from Electrosurgical Unit;
- ✧ Doesn’t filter the interference waveform;
- ✧ Poor grounding;
- ✧ Electrodes are not placed properly;
- ✧ Use expired electrode or use disposable electrode repeatedly;
- ✧ The skin placed electrode is unclean or poor contract caused by scurf and hair;
- ✧ Electrode long-time used.

9.2 Respiration Monitoring

9.2.1 Measuring Principle

The air will be filled into alveolus or be expelled during respiration, and the chest’s volume changes with this process. Because the conductivity of air is lower than body tissues, the chest’s impedance will be changed by the inflation. With this specialization, the respiration can be monitored through putting safe current into body and measuring the change of voltage between the electrodes. The product will transmit the high-frequency current whose frequency is much higher than ECG frequency (but with the safe current limit) to the ECG electrodes (placed at the both sides of chest), which can be detect ECG signal and chest’s impedance at the same time, and the respiratory rate will be measured through impedance method by the software. So the additional electrodes for respiratory measurement are unnecessary.

9.2.2 Factors affecting respiration monitoring

- ✧ Place the white (RA) and red (LL) electrodes on the cross, if the line between two electrodes in liver area or heart area, the artifical error may occur.
- ✧ Respiration monitoring doesn’t support monitoring the patient who do much movement, or may lead to wrong alarm.

9.3 SpO_2 Monitoring

9.3.1 Measuring Principle

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this monitor is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

9.3.2 SpO_2 Measurement Restrictions (interference reason)

- ✧ Intravascular dyes such as indocyanine green or methylene blue
- ✧ Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- ✧ Vascular dyes or external used color-up product such as nail enamel or color skin care
- ✧ Excessive patient movement
- ✧ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ✧ Exposure to the chamber with high pressure oxygen
- ✧ There is an arterial occlusion proximal to the sensor
- ✧ Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

9.3.3 Low SpO_2 measuring value caused by pathology reason

- ✧ Hypoxemia disease, functional lack of HbO_2
- ✧ Pigmentation or abnormal oxyhemoglobin level
- ✧ Abnormal oxyhemoglobin variation
- ✧ Methemoglobin disease
- ✧ Sulfhemoglobinemia or arterial occlusion exists near sensor
- ✧ Obvious venous pulsations
- ✧ Peripheral arterial pulsation becomes weak
- ✧ Peripheral blood supply is not enough

9.3.4 Clinical Limitations

- ✧ As the measure is taken on the basis of arteriole pulse, substantial pulsating blood stream of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
- ✧ For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.
- ✧ The drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measurements.
- ✧ As the SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO_2 value.

9.3.5 Points to be noted in SpO_2 and Pulse Measuring

- ✧ The finger should be properly placed (see the attached illustration of this instruction manual), or else it may cause inaccurate measurement result.
- ✧ Make sure that capillary arterial vessel beneath the finger is penetrated through by red and infrared lights.
- ✧ The SpO_2 sensor should not be used at a location or limb tied with arterial or blood pressure cuff or receiving intravenous injection.
- ✧ Do not fix the SpO_2 sensor with adhesive tape, or else it may result in venous pulsation and consequential inaccurate measurement result of SpO_2.
- ✧ Make sure the optical path is free from any optical obstacles like adhesive tape.
- ✧ Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, and direct sunlight etc.
- ✧ Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
- ✧ Please do not use the SpO_2 sensor when having the MRI, or burn may be caused by faradism.
- ✧ Always observe the plethysmogram (waveform), which is auto-scaled within the range of 100. The SpO_2 reading may be unlikely true when the waveform is not smooth or irregular. If in doubt, rely on your clinical judgment, rather than the monitor readout.
- ✧ A functional tester can not be used to assess the accuracy of the pulse oximeter monitor or a SpO_2 sensor. However, a functional tester, such as SpO_2 simulator can be used to check how accurately a particular pulse oximeter is reproducing the given calibration curve. Before testing the oximeter by a functional tester, please firstly ask the manufacturer which calibration curve is used, if necessary, request the manufacturer for its dedicated calibration curve and download it into the tester.

9.4 Temperature Monitoring

The sensor is thermo-resistor type (25℃ 5kΩ) and is supplied with constant micro current. Calculating the temperature of measured part through measuring the voltage. There is a period responding time, so the accurate temperature value display after a while. The temperature monitoring can be divided into two measuring method: measure through body surface temperature and through the temperature inside the body cavity (placed in mouth or anus).

Normal value: body surface: 36.5℃~37℃; inside body cavity: 36.5℃~37.7℃

Notes:

- Attach the TEMP transducer to the patient; generally if the TEMP transducer and skin doesn’t contact closely, the measured value becomes lower, so for those who have requirement for temperature, add a proper martial to transducer and fix it with adhesive tape to make them contact firmly.
- Especially for pediatric patient, they like sports, pay more attention to the transducer fixing.

9.5 CO_2 Monitoring

9.5.1 Measuring Principle

The principle is based on the fact that CO_2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR light beam is passed through a gas sample containing CO_2, the electronic signal from a photodetector (which measures the remaining light energy), can be obtained. This signal is then compared to the energy of the IR source, and calibrated to accurately reflect CO_2 concentration in the sample. To calibrated, the photodetector’s response to a known concentration of CO_2 is stored in the monitor’s memory.

The monitor determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases.EtCO_2 is display as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 waveform (capnogram) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube placement. Respiration rate is calculated by measuring the time interval between detected breaths.

9.5.2 Mainstream vs. Sidestream Sampling

Mainstream CO_2 sensors are placed at the airway of an intubated patient, allowing the inspired and expired gas to pass directly across the IR light path. The major advantages of mainstream sensors are fast response time and elimination of water traps.

Sidestream CO_2 sensors are located away from the airway, requiring a gas sample to be continuously aspirated from the breathing circuit and transported to the sensor by means of a pump. This type of system is needed for non-intubated patients.

When using mainstream CO_2 sensors, check the window for the patient secretions pooled on periodically. Because that condition may affect the accuracy of the measurement or even make the sensor not work.

When using sidestream CO_2 sensors, there is a water trap or a part of the sampling tube with dehumidifying function. Please periodically check the flow sensor and tubing for excessive moisture or secretion buildup.

9.6 NIBP Monitoring

9.6.1 Measuring Principle

Blood pressure may be measured in an invasive way (whereby the sensor will be inserted into blood vessel directly) or a non-invasive way. The non-invasive way includes several methodologies, such as the Korotkoff Sound Method and oscillating method. The Korotkoff Sound Method is used as a conventional way, whereby stethoscope is used to measure the blood pressure. By the oscillating method, an inflation pump will fill the air, and release it slowly. A computer will record change of the cuff pressure when the air is released. With this record, the blood pressure value will be determined. First of all, make sure the signal quality judgment by computer meets the requirements of accurate calculation (such as sudden limb movement or cuff being hit during the measurement). If the answer is negative, give up the calculation. If the answer is positive, proceed with calculation of the blood pressure value.

As change of the blood pressure is recorded by electric sensor, which sensitivity is much higher than that of human ears, the oscillating method uses different definitions for measurement of diastolic pressure, mean arterial pressure and systolic pressure from the Korotkoff Sound Method. When the oscillating method is used, the circuit in the measuring apparatus will separate the amplitude of the cuff pressure from its change with pulsation. With the oscillating method, the blood pressure at the maximum amplitude of cuff pressure is defined as the mean arterial pressure. The blood pressure at amplitude of cuff pressure forward reduced according to proper proportion is defined as systolic pressure, while the blood pressure at amplitude of cuff pressure backward reduced according to proper proportion is defined as diastolic pressure. The maximum change of pulse pressure occurs at these two points. They are equivalent to the point with pulse sound and the point without pulse sound respectively in the Korotkoff Sound Method.

When the risk of invasive monitoring method outweighs its advantage of accuracy, non-invasive monitoring method shall be used.

Comparison between blood pressure measuring methods

To overcome the effect of human hearing variation and air release speed on measurement accuracy when the conventional Korotkoff Sound Method is used to take measure of blood pressure, people have been dedicated to study of automatic measurement of blood pressure. By now, automatic blood pressure measuring system based on the principle of oscillating method is mature. In practice, however, various problems are encountered, such as why the measures taken by the oscillating method is lower or higher than those taken by Korotkoff Sound Method? Why the measures are inclined to decline? Why, in some cases, no result is obtained in spite of the inflation actions? Why the measure values have big discreteness and even abnormal data in some cases? Why the SpO_2 waveforms may disappear suddenly? ...and so on. The following explanations are devised to give the answers.

The Oscillating method vs. the Korotkoff Sound Method

Blood pressure measurement by the oscillating method and Korotkoff Sound Method has good correlation with the invasive measurement. Notwithstanding, any of the non-invasive blood pressure measurements has its one-sidedness when it is compared to the invasive measurement. The oscillating method has its advantages over the Korotkoff Sound Method in less error, higher reliability and stability. Their differences may be reflected in the following aspects.

1. The measures by the Korotkoff Sound Method are liable to effect of human factors. For example, different people may have different sound judging ability, or different reactivity when listening to heart sound and reading mercury meter. The air release speed and subjectivity may also affect the judgment. By the oscillating method, the computation is accomplished by the computer, thus relieving the possibility of effect due to human factor.
2. With the Korotkoff Sound Method, the measure is taken on the basis of appearance and disappearance of heart sound. The air release speed and heart rate may have direct effect on the measurement accuracy. It also has the disadvantages of rapid air release and poor accuracy. In the contrast, with the oscillating method, the

determination is calculated on the basis of cuff pressure oscillatory waveform envelope, and the air release speed and heart rate has little effect on the measurement accuracy.

3. Statistics show that, when measuring the hypertension, the measure taken by the oscillating method is likely to be lower than that taken by the Korotkoff Sound Method. When measuring the hypotension, the measure taken by the oscillating method is likely to be higher than that by the Korotkoff Sound Method. But, it doesn’t mean the advantages or disadvantages between the oscillating method and the Korotkoff Sound Method. Comparison with the results taken by more accurate method, let’s say comparison of the invasive pressure result with the output value by the blood pressure measuring simulator, will show which method has more accurate results. In addition, higher or lower value should be a statistical concept. It is recommended those used to adopt the Korotkoff Sound Method use different physiological calibration for values determined by the oscillating method.
4. The studies have shown that the Korotkoff Sound Method has the worst accuracy when it comes to measurement of hypotension, while the oscillating method has worse accuracy when it comes to measurement of controlled hypertension relief.

9.6.2 Factors affecting NIBP measuring

- ✧ Select a cuff of appropriate size according to the age of the subject.
- ✧ Its width should be 2/3 of the length of the upper arm. The cuff inflation part should be long enough to permit wrapping 50-80% of the limb concerned.

  Prior to use of the cuff, empty the cuff until there is no residual air inside it to ensure accurate measurement.

  Make the cuff mark φ in the position where artery pulsates obviously, the effect will be best.

  The lower part of cuff shall 2cm above the elbow joint.
- ✧ Do not wrap the cuff on too thick clothes(especially forcotton-padded clothes and sweater) to take measurement;
- ✧ The testee shall lie in bed or sit in chair, make the cuff and heart at the same level, the result will be most accurate, other postures may have inaccurate result;
- ✧ During measuring, do not move your arm or the cuff;
- ✧ The measuring interval shall longer than 2 minutes, in continuous measurement, too short interval may cause arm extrusion, blood quantity increases, then cause blood pressure increases.
- ✧ Keep the patient still and stop talking before and during measuring;
- ✧ The patient’s mood also can affect the measuring result, when exciting, the blood pressure goes up.
- ✧ The measuring result also affected by time, lower in the morning and higher in the evening;

9.6.3 Clinical Limitations

1. Serious angiospasm, vasoconstriction, or too weak pulse.
2. When extremely low or high heart rate or serious arrhythmia of the subject occurs. Especially auricular fibrillation will lead to unreliable or impossible measurement.
3. Do not take the measurement when the subject is connected with an artificial heart-lung machine.
4. Do not take the measurement when the subject uses diuresis or vasodilator.
5. When the subject is suffering from major hemorrhage, hypovolemic shock and other conditions with rapid blood pressure change or when the subject has too low body temperature, the reading will not be reliable, for reduced peripheral blood flow will lead to reduced arterial pulsation.
6. Subject with hyperadiposis; In addition, statistics show that 37% people report blood pressure difference of no

less than 0.80kPa(6mmHg) between the left and right arms, and 13% people report difference of no less than 1.47kPa (11mmHg).

Note: Some practitioners may report big discreteness or abnormal value of the blood pressure measures when the oscillating method is used. As a matter of fact, the so-called “big discreteness” must be a term in the sense of statistical significance of mass data. Abnormal data may be observed in some individual cases. It is normal in the scientific experiments. It may be caused by an apparent reason, or by an unknown factor in some cases. Such individual doubtful experimental data may be identified and eliminated using the special statistical technique. It is not a part of this manual. The practitioner may eliminate the apparently unreasonable data according to the experience.

Chapter 10 Packaging and Accessories

10.1 Packaging

The product is packed in high quality corrugated cartons with foam inside to protect the equipment against damage in the shipping and handling process.

Gross Weight: Details see the indication on the outer package

Dimension: 355(L) ×245(W) ×245(H) mm

10.2 Accessories

(1) ECG lead One set

(2) NIBP cuff One piece

(3) SpO_2 probe One piece

(4) Body surface temperature transducer One piece

(6) AC power adapter One piece

(7) Power code One piece

(8) Li-ion battery One piece

(9) Handle subassembly One set

(10) Disposable electrode Ten pieces

(11) User manual One copy

(12) Warranty One copy

(13) CO_2 accessories(optional)

For Mainstream		**For Sidestream**	
Mainstream sensor (CAPNOSTAT 5)	One set	Sidestream Sensor (LoFlo C5)	One set
Airway adapter	One piece	Sampling Line Kit	One set

Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

Chapter 11 Troubleshooting

Note: In case of trouble of this machine in service, follow the instructions below to eliminate the problem first. If the attempt fails, contact the dealer in your local area or the manufacturer.

- **DO NOT open the monitor without permission**

11.1 No Display on the Screen

Shut down the machine and unplug the power code. Use a universal meter to check if the outlet has proper voltage, if the power code is in good condition, and if the power code is properly connected with this apparatus or outlet. Remove the fuse from the back cover of this machine, and make sure it is in good condition.

11.2 Excessive ECG Signal Interference or Too Thick Baseline

1. Check if the plate electrodes are properly located, and if valid plate electrodes are used.
2. Check whether the lead wires are properly inserted. If no ECG curve displayed, check if the ECG lead wires are broken.

11.3 No Blood Pressure and Pulse Oxygen Measures

1. Check if the blood pressure cuff is properly wrapped around the arm according to the operating instructions, if the cuff leaks, and if the inlet is closely connected with the NIBP jack on the side panel. Check if the indicator of the pulse oxygen sensor flashes and if the pulse oxygen probe is properly connected to the SpO_2 jack on the side panel.
2. If the problems still exist, please contact the manufacturer.

11.4 System Alarm

1. When the parameter value is higher or lower than the alarm limits, the alarm will ring. Please check whether the alarm limit value is proper or the condition of the patient.
2. Leads off. Please check the connection of the leads.
3. Probe off Please check the connection of the probes.

Chapter 12 Maintenance and Service

PC-3000 Patient Monitor should be properly maintained to ensure its maximum performance and long service life. In addition to the warranty period of one year, the company also offers long-term service for each customer. It is important that the users read and follow the operating instructions, important information and maintenance measures.

12.1 Technical Maintenances

12.1.1 Daily Examination

Before using the monitor, the checks below should be carried out:

- Check the monitor for any mechanical damage;
- Inspect the exposed parts and the inserted parts of all the leads, and the accessories;
- Examine all the functions of the monitor that are likely to be used for patient monitoring, and ensure that it is in good working condition;
- Pay close attention to the fluctuation of the local power supply voltage. A manostat is recommended when necessary.

In case any indication of damage about the function of the monitor is detected and proven, it is not allowed to apply it to the patient for any monitoring. Please contact the local dealer or our company, and we are to offer the best solution as soon as possible for your satisfaction.

12.1.2 Routine Maintenance

After each maintenance or the yearly maintenance, the monitor can be thoroughly inspected by qualified personnel, including function and safety examinations. The designed life of this monitor is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- **If the hospital fails to carry out a satisfactory maintenance program about the monitor, it may get disabled and harm the patient’s safety and health.**
- **In case of ECG leads damage or aging, please replace the lead.**
- **If there is any indication of cable and transducer damage or they deteriorate, they are prohibited from any further use.**
- **The adjustable units in the monitor such as potentiometer are not allowed to adjust without permission to avoid unnecessary failures that affect normal application.**
- **It is recommended to use the battery once a month to ensure its strong power supply capacity and long service life, and recharge it after run out of the power volume.**

12.1.3 Battery Maintenance

- **Please pay attention to the polarity of battery, do NOT insert it into battery compartment with reversed polarities;**
- **Do NOT use the batteries manufactured by other companies, if being inserted, the device will may be damaged;**
- **In order to avoid damaging the battery, do NOT use other power supply device to charge the battery;**
- **After battery ageing phenomenon occurring, do NOT throw the battery into fire to avoid explosion risk.**
- **Do not hit or strike it with force;**

- **Do not use this battery on other devices;**
- **Do not use this battery below -20℃ or above 60℃;**
- **In order to maintain battery supply time and prolong battery lifetime, please charge the battery periodically. Generally, charge the battery every 3~6 months and 2~5hours each time. When the battery power is full, battery power indicator displays full grid. Before storage, please discharge the battery until it remains 80% power. Do not use the AC power adapter and power code not purchased from the manufacture.**
- **Whether the monitor is on or off, the built-in battery will be charged as long as the monitor is connected to an AC outlet. When the battery is full, it will stop charging for protecting from damage. If the monitor is connected to an AC outlet and turned on, it will use AC power, but when AC power is cut off, the DC power will be used. Priority of using AC power and power shift between AC and DC are automatically and uninterrupted.**
- **If the battery is damaged, please change it. The model and specifications of the new battery should be the same as the original battery. The user must ensure that the battery meets all applicable safety codes. The user can also contact the local dealer for service.**

12.2 Cleaning, Sterilization and Disinfection

- **Switch off the monitor and disconnect the power code before cleaning.**
- **Kept the monitor from dust.**
- **It is recommended to clean the outer shell and screen of the monitor to keep it clean. Only non-corrosive cleanser such as clear water is permitted.**
- **Wipe the surface of the monitor and transducers with an alcohol impregnated wipe, and dry it with dry and clean wipe or simply air-dry.**
- **The monitor can be disinfected and sterilized. Please clear the monitor first.**
- **Do not let the liquid cleanser flow into the connector jack of the monitor to avoid damage.**
- **Clean the exterior of the connector only.**
- **Dilute the cleanser.**
- **Do not use scrub materials.**
- **Do not let any liquid flow into the shell or any parts of the monitor.**
- **Do not let the cleanser and disinfectant stay on its surface.**
- **Do not perform high pressure sterilization to the monitor.**
- **Do not put any parts of the monitor or its accessories in the liquid.**
- **If the monitor is accidentally wetted it should be thoroughly dried before use. The rear cover can be removed by qualified service technician to verify absence of water.**
- **Do not pour the disinfector on its surface while sterilization.**

12.3 Cleaning, Sterilization and Disinfection of Accessories

It is recommended to clean the accessories (including sensor, leads and plugs) with a piece of gauze which has been soaked in 75% Alcohol or 70% Ispropanol before using.

- **Do not use damaged accessories.**
- **Accessories cannot be entirely immerged into water, liquor or cleanser.**
- **Do not use radial, steam or epoxyethane to disinfect accessories.**
- **Do wipe off the remained alcohol or ispropanol on the accessories after disinfection, for good maintanance can extend the life of accessories.**

12.4 Storage

If the equipment will not be used for long period of time, wipe it clean and keep it in the packaging, which shall be kept in a dry and good ventilation place free from dust and corrosive gases.

Storage environment: ambient temperature: -20~60°C
relative humidity: 10%~90%
atmospheric pressure: 53 kPa~106kPa

12.5 Transportation

This monitor should be transported by land (vehicle or railway) or air in accordance with the contractual terms. Do not hit or drop it with force.

Chapter 13 Appendix

13.1 Alarm Information

Alarm Information	Descriptions
Over HR limit	The related parameter value exceeds the preset high/low alarm limit.
Over TEMP limit	
Over RR limit	
Over SpO_2 limit	
Over PR limit	
Over NIBP SYS limit	
Over NIBP DIA limit	
Over NIBP MAP limit	
Over ST limit	
Over NIBP PR limit	
Unable to detect HR	ECG cable and leads are connected to monitor and patient well, but HR is unable to be detected. It may caused by inconformity HR signal.
Unable to detect SpO_2	SpO_2 probe is connected to monitor and patient well, but SpO_2 is unable to be detected. It may be caused by inconformity SpO_2 signal.
The battery capacity will exhaust	Low battery voltage
Lead Off	The ECG electrodes or cable fell off
Probe Off	SpO_2 probe fell off

13.2 Default Alarming Values and Setup Range

The default alarming value:

Parameter \ Mode			Adult	Infant	Neonate
Heart Rate		High limit	180 bpm	200 bpm	220 bpm
		Low limit	40 bpm	50 bpm	50 bpm
Respiration		High limit	40 rpm	50 rpm	60 rpm
		Low limit	10 rpm	10 rpm	10 rpm
Temperature		High limit	39℃	39℃	39℃
		Low limit	35℃	35℃	35 ℃
NIBP	Systolic	High limit	180 mmHg	130 mmHg	110 mmHg
		Low limit	60 mmHg	50 mmHg	50 mmHg
	Diastolic	High limit	120 mmHg	90 mmHg	90 mmHg
		Low limit	50 mmHg	40 mmHg	30 mmHg
	MAP	High limit	160 mmHg	110 mmHg	100 mmHg
		Low limit	50 mmHg	40 mmHg	30 mmHg
SpO_2		High limit	100%	100%	100%
		Low limit	90%	85%	85%
Pulse Rate		High limit	180 bpm	200 bpm	220 bpm
		Low limit	40 bpm	50 bpm	50 bpm
ST Segment		High Limit	+1.00mV	+1.00mV	+1.00mV
		Low Limit	-1.00mV	-1.00mV	-1.00mV
Temperature Difference		Range	2 ℃	2 ℃	2 ℃
Arterial Pressure	SYS	High limit	200mmHg	160mmHg	140mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	DIA	High limit	200mmHg	160mmHg	140mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	MAP	High limit	200mmHg	160mmHg	140mmHg
		Low limit	10mmHg	10mmHg	10mmHg
Pulmonary Artery Pressure	SYS	High limit	120mmHg	100mmHg	90mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	DIA	High limit	120mmHg	100mmHg	90mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	MAP	High limit	120mmHg	100mmHg	90mmHg
		Low limit	10mmHg	10mmHg	10mmHg
Central Venous Pressure	SYS	High limit	30mmHg	30mmHg	30mmHg
		Low limit	0mmHg	0mmHg	0mmHg
	DIA	High limit	30mmHg	30mmHg	30mmHg
		Low limit	0mmHg	0mmHg	0mmHg
	MAP	High limit	30mmHg	30mmHg	30mmHg
		Low limit	0mmHg	0mmHg	0mmHg
CO_2	Respiration Rate	High limit	40 rpm	50 rpm	60 rpm
		Low limit	10 rpm	10 rpm	10 rpm
	$EtCO_2$	High limit	70 mmHg	70 mmHg	70 mmHg
		Low limit	10 mmHg	10 mmHg	10 mmHg
	$InsCO_2$	High limit	10 mmHg	10 mmHg	10 mmHg
		Low limit	0 mmHg	0 mmHg	0 mmHg

The high and low limits setting range:

Parameter \ Mode			Adult	Infant	Neonate
Heart Rate		High limit	1~350bpm	1~350bpm	1~350bpm
		Low limit	0~349bpm	0~349bpm	0~349bpm
Respiration		High limit	1~120rpm	1~150rpm	1~150rpm
		Low limit	0~119rpm	0~149rpm	0~149rpm
Temperature		High limit	0.1~60℃	0.1~60℃	0.1~60℃
		Low limit	0~59. 9℃	0~59. 9℃	0~59. 9℃
Systolic		High limit	31~280 mmHg	31~200 mmHg	31~135 mmHg
		Low limit	30~279 mmHg	30~199 mmHg	30~134 mmHg
Diastolic		High limit	11~232 mmHg	11~150 mmHg	11~100 mmHg
		Low limit	10~231 mmHg	10~149 mmHg	10~99 mmHg
Mean		High limit	21~242 mmHg	21~165 mmHg	21~110 mmHg
		Low limit	20~241 mmHg	20~164 mmHg	20~109 mmHg
SpO_2		High limit	1~100%	1~100%	1~100%
		Low limit	0~99%	0~99%	0~99%
Pulse Rate		High limit	1~300bpm	1~350bpm	1~350bpm
		Low limit	0~299bpm	0~349bpm	0~349bpm
ST Segment		High Limit	-2.49Mv~+2.49mV	-2.49mV~+2.49mV	-2.49mV~+2.49mV
		Low Limit	-2.49mV~+2.49mV	-2.49mV~+2.49mV	-2.49mV~+2.49mV
Temperature Difference			0.0~5.0 ℃	0.0~5.0 ℃	0.0~5.0 ℃
Arterial Pressure	Systolic	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
	Diastolic	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
	Mean	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
Pulmonary Artery Pressure	Systolic	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
	Diastolic	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
	Mean	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
Central Venous Pressure	Systolic	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
	Diastolic	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
	Mean	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
CO_2	Respiration Rate	High limit	（1~120）rpm	(1~150)rpm	(1~150)rpm
		Low limit	（0~119）rpm	(0~149)rpm	(0~149)rpm
	$EtCO_2$	High limit	（1~100）mmHg	(1~100) mmHg	(1~100) mmHg
		Low limit	（0~99）mmHg	(0~99) mmHg	(0~99) mmHg
	$InsCO_2$	High limit	（1~30）mmHg	(1~30) mmHg	(1~30) mmHg
		Low limit	（0~29）mmHg	(0~29) mmHg	(0~29) mmHg

13.3 Abbreviation of Arrhythmia

1. ECG TACHY
2. ECG BRADY
3. ECG VPCEST
4. MISS BEAT
5. VE EARLY
6. SVE EARLY
7. VE COUPLET
8. SVE COUPLET
9. VE RUN
10. SVE RUN
11. VE SHORT RUN
12. SVE SHORT RUN
13. VE BIGEMINY
14. SVE BIGEMINY
15. VE TRIGEMINY
16. SVE TRIGEMINY
17. VE INSERT
18. SVE INSERT
19. VE RONT
20. SVE RONT

13.4 Status/Error during NIBP Monitoring

“Cuff error” —cuff is not wrapped correctly, or is not connected

“Air leak” —Air moving part, tube or the cuff leak air.

“Pressure error” —Unstable cuff pressure or tangled cuff tubing

“Signal weak” —Very weak signal because of the cuff, or the patient has very weak pulse

“Over extent” —The measurement range exceeds 255 mmHg (Infant patient over 135 mmHg)

“Over motion” —The repeated measurement due to moving, excessive noise during the stepping inflation and measuring pressure and pulse, e.g. during patient shaking motion

“Signal overflow” —Blood pressure amplifier overflow due to excessive movement

“Leak in gas run” —Leaking during the pneumatic device testing

“System error” —Abnormal condition of CPU, such as register overflow, divided by zero

“Adult” —The blood pressure measuring now is in adult mode. In this case, it is not allowed to monitoring infant patient. Otherwise, there may be serious danger to the infant monitored.

“Infant” —The blood pressure module is now worked in infant measuring mode.

“PROBE OFF” —SpO_2 probe fell off

“LEADS OFF” —The ECG electrodes or cable fell off

“LEARNING” —Learning arrhythmia for 15 seconds

“DEMO” —The monitor is displaying the demo waveforms, which are generated by the monitor itself.

13.5 Status/Error during CO_2 Monitoring

Suggested Message/Response	Description
“Sensor Over Temp” Make sure sensor is not exposed to extreme heat (heat lamp, etc.). If error persists, return sensor to factory for servicing.	The sensor temperature is greater than 40 ℃.
“Sensor Faulty” Check that the sensor is properly plugged in. Reinsert or reset the sensor if necessary. If error persists, return sensor to factory for servicing	One of the following conditions exist: Source Current Failure, EEPROM Checksum Faulty, Hardware Error
No Parameter Message The host must set the Barometric Pressure and compensations to clear this error; no user intervention should be required.	Barometric Pressure and/or gas compensations have not been set since power on. For CO_2 to be calculated with the stated accuracy, these values should be set whenever the sensor is plugged in.
“Module in Sleep Mode”	This bit is set when sensor has been placed in sleep mode.
“Zero In Progress “	A Module Zero is currently in progress.
“Sensor Warm Up” This error condition is normal at startup. This error should clear when the warm up is complete.	One of the following conditions exist: Sensor under temperature Temperature not stable Source Current unstable
“Check Sampling Line” Check that the sampling line is not occluded or kinked.	This error occurs whenever the pneumatic pressure is outside the expected range.
“Zero Required” To clear, check airway adapter and clean if necessary. If this does not correct the error, perform an adapter zero. If you must adapter zero more than once, a possible hardware error may exist.	One of the following conditions exist: Zero Required; Zero Required: Zero Error
“CO_2 Out of Range” If error persists, perform a zero.	The value being calculated is greater than the upper CO_2 limit (150 mmHg, 20.0 kPa, or 19.7 %). The maximum value output is the upper CO_2 limit.
“Check Airway Adapter” To clear, clean airway adapter if mucus or moisture is seen. If the adapter is clean, perform a Capnostat zero.	Usually caused when the airway adapter is removed from the sensor or when there is an optical blockage on the windows of the airway adapter. May also be caused by failure to perform sensor zero to when adapter type is changed.
The Sensor not Ready	This is prompted if the CO_2 sensor is not ready for a Capnostat Zero. If the “Zero Required” and this massage both prompt message both promptone or more of the following conditions may exist: • Breaths detected • Temperature is not stable • Source Current unstable • In sleep mode.
Zero in already progress	Normal zero calibration is in already progress.
Zero Fault and Breaths Detected	Zero attempted and breaths have been detected in the last 20 seconds.
Zero Ok	Zero calibration is successful

13.6 Typical Pressures and CO_2 Readings at Altitudes

Altitude	Barometric Pressure(mmHg)	$EtCO_2$ Reading	
		（%）	（mmHg）
0m	760	5	38.0
70m	754	5	37.7
100m	751	5	37.5
200m	743	5	37.1
1500m	641	5	32.0
3000m	537	5	26.8
5000m	420	5	21.0

13.7 Accessories List

Part No.	Part Name	Remark
15010513	ECG cable	
5101-0101310	ECG electrode	
15044051	Adult SpO_2 Finger clip Sensor	
15044038	Adult SpO_2 Finger rubber Sensor	Optional
15044041	Pediatric SpO_2 Finger clip Sensor	Optional
15024402	Adult NIBP cuff(25~35cm)	
15021402	Small-sized Pediatric NIBP Cuff	Optional
15022402	Middle-sized Pediatric NIBP Cuff	Optional
15023402	Large-sized Pediatric NIBP	Optional
2507-1700010	Handle subassembly	
2301-1005055	AC Power Adapter	
2903-0000000	Power cord	
900093	Net wire	
15100420	CO_2 Mainstream sensor	Optional for
15100410	CO_2 Sidestream sensor	Optional for

For more information regarding the accessories, please contact your local sales representative or the manufacturer.

13.8 Instructions for SpO_2 Probe

Instructions for Pediatric SpO_2 Finger Clip Sensor

Intended Use

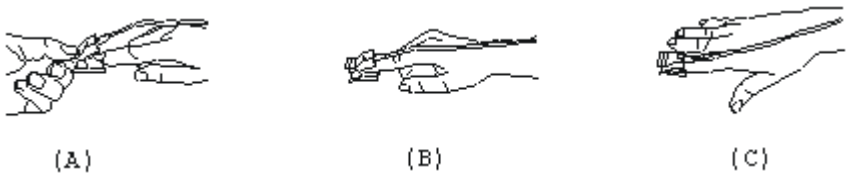
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for pediatric patients weighing between 10~40kg.

Contraindications

This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

1) With the upper and lower jaws open, place an index finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window (A). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
2) Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.
3) Spread open the rear tabs of the sensor to provide even force over the length of the pads (B).
4) The sensor should be oriented in such a way that the cable is positioned along the top of the hand (C).
5) Plug the sensor into the oximeter and verify proper operation as described in the user manual.



6) Inspect the monitoring site every 1~2 hours for skin integrity.
7) Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Warnings

1) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poor blood perfusion in the finger, extreme finger sizes or improper placement of the sensor.
2) Using the sensor in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
3) The sensor must be moved to a new site at least every 3 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
4) Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate saturation measurements.
5) Do not immerse sensor as it causes short.
6) Do not use NIBP or other constructing instruments on same appendage as sensor for blood flow interrupted by NIBP cuff or circulatory patient condition will result in no pulse found or loss of pulse.
7) Do not use the sensor or other oximetry sensors during MRI scanning.
8) Carefully route cables to reduce the possibility of patient entanglement or strangulation.
9) Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
10) Do not use the sensor if the sensor or the sensor cable appears damaged.

Instructions for Adult SpO_2 Finger Rubber Sensor

Intended Use

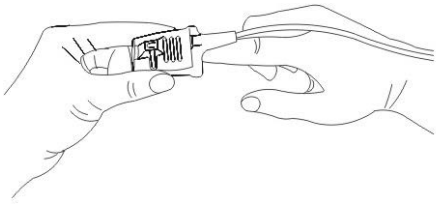
When used with a compatible patient monitor or a pulse oximeter device, this SpO_2 sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 50kg.

Contraindications

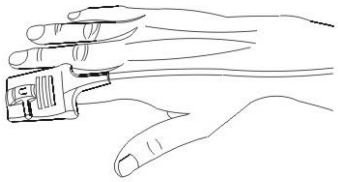
This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

1) Hold the sensor with its opening towards the patient’s index finger (A). The sensor should be oriented in such a way that the sensor side with a finger tip sign is positioned on the top.
2) Insert the patient’s index finger into the sensor until the fingernail tip rests against the stop at the end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor. Direct the cable along the top of the patient’s hand. Apply adhesive tape to secure the cable (B). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
3) Plug the sensor into the oximeter and verify proper operation as described in the user manual.



(A)



(B)

4) Inspect the monitoring site every 1~2 hours for skin integrity.

Cleaning & Disinfection

Unplug the sensor before cleaning or disinfecting. Surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Warnings

1) This sensor is for use only with compatible patient monitors or pulse oximeter devices. Use of this sensor with instruments other than compatibles may result in improper performance.
2) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poorly perfused finger, extreme finger sizes or improper placement of the sensor.
3) The sensor site must be checked for skin integrity at least every 1~2 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor to another finger.
4) Do not use NIBP or other constructing instruments on same appendage as sensor for blood flow interrupted by NIBP cuff or circulatory patient condition will result in no pulse found or loss of pulse. Do not use the sensor during MRI scanning.
5) Carefully route cables to reduce the possibility of patient entanglement or strangulation.
6) Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
7) Do not use the sensor if the sensor or the sensor cable appears damaged.

Instructions for Adult SpO_2 Finger Clip Sensor

Intended Use

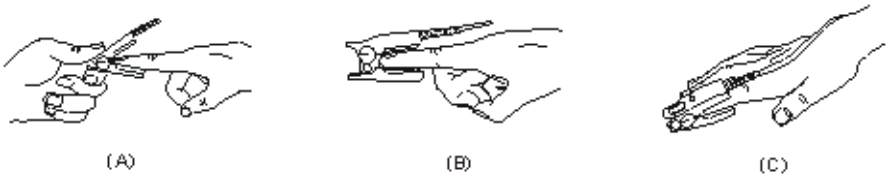
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 40kg.

Contraindications

This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

1) With the upper and lower jaws open, place an index finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window (A). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
2) Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.
3) Spread open the rear tabs of the sensor to provide even force over the length of the pads (B).
4) The sensor should be oriented in such a way that the cable is positioned along the top of the hand (C).



5) Plug the sensor into the oximeter and verify proper operation as described in the user manual.
6) Inspect the monitoring site every 1~2 hours for skin integrity.
7) Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Warnings

1) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poorly perfused finger, extreme finger sizes or improper placement of the sensor.
2) Using the sensor in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
3) The sensor must be moved to a new site at least every 3 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
4) Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate saturation measurements.
5) Do not immerse sensor as it causes short.
6) Do not use NIBP or other constructing instruments on same appendage as sensor for blood flow interrupted by NIBP cuff or circulatory patient condition will result in no pulse found or loss of pulse.
7) Do not use the sensor or other oximetry sensors during MRI scanning.
8) Carefully route cables to reduce the possibility of patient entanglement or strangulation.
9) Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
10) Do not use the sensor if the sensor or the sensor cable appears damaged.

Creative offers a 6-momth warranty against manufacturing defects for the SpO_2 sensors mentioned above in its undamaged condition.

If you have any question regarding any of SpO_2 sensor instructions, please contact info @ creative-sz.com, or your local dealer.