

PATIENT MONITOR UP-7000

User Manual

ATTENTION: *The operators must carefully read and completely understand the present manual before using the product*



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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 UP-7000 Patient Monitor.

The Manual describes, in accordance with the UP-7000 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.

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Marks in the Manual:

 **Warning:** must be followed to avoid endangering the operator and the patient.

 **Note:** some important information and tips about operations and application.











 **Attention:** must be followed to avoid causing damage to the monitor.

Instructions to User

Dear Users,

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

Read these instructions carefully before using this monitor. 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 cursoring. 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 IEC standard 60601-1-1 systems requirement.
-  Check SpO₂ probe application site periodically (every 30 minutes) to determine circulation, positioning and skin sensitivity.
-  The SpO₂ measurement of this monitor may not work for all testees. If stable readings can not be obtained at any time, discontinue to use.
-  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 SpO₂ 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.
- SpO₂ measuring position must be examined more carefully for some special patient. Do NOT install the SpO₂ 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 SpO₂ 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 CO₂ 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 CO₂ 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 CO₂ Sensor.
- After the life cycle of the Sidestream CO₂ 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.

Indice

CHAPTER 1	OVERVIEW.....	1
1.1	FEATURES	1
1.2	PRODUCT NAME AND MODEL.....	1
1.3	APPLICATIONS AND SCOPE	2
1.4	OPERATING ENVIRONMENT	2
1.5	IMPACT ON ENVIRONMENT AND RESOURCES.....	2
1.6	SAFETY 2	
CHAPTER 2	WORKING THEORIES OF THE MAIN UNIT.....	3
2.1	COMPOSITION	3
2.2	OVERALL STRUCTURE AND WORKING THEORIES.....	3
CHAPTER 3	INSTALLATION AND CONNECTION	4
3.1	INSTALLATION	4
3.1.1	Opening the box and check	4
3.1.2	Connecting the ac power cable	4
3.1.3	Starting the monitor	4
3.2	APPEARANCE.....	5
3.2.1	Front panel	5
3.2.2	Left and right panel	6
3.2.3	Rear panel	7
3.3	CONNECTION.....	8
3.3.1	ECG Connection	8
3.3.2	Blood Pressure Cuff Connection.....	10
3.3.3	SpO ₂ Probe Connection.....	12
3.3.4	TEMP Probe Connection.....	14
3.3.5	Loading Printing Paper.....	14
CHAPTER 4	MONITORING SCREEN	15
4.1	MAIN SCREEN.....	15
4.1.1	Date and Time Setup	15
4.1.2	Screen DESCRIPTION.....	16
4.2	DISPLAY 2 SCREEN	19
4.2.1	Viewing Screen.....	19
4.2.2	Seven ECG Waveforms on the Same Screen	20
4.2.3	OPERATING INSTRUCTIONS	20
4.3	FREEZE AND S-T ANALYSIS SCREEN	21
4.3.1	Screen Description.....	21
4.3.2	OPERATING INSTRUCTIONS.....	22
4.4	MODE SELECTION SCREEN.....	22
4.5	SpO ₂ DATA LIST SCREEN	23
4.5.1	Screen Description.....	23
4.6	NIBP LISTING SCREEN.....	23
4.6.1	Screen Description.....	23
4.6.2	Operating Instructions.....	24
4.7	GRAPHIC TREND SCREEN	24
4.7.1	Screen Description.....	24
4.7.2	Operating Instructions.....	28
4.8	RECALL SCREEN	28
4.9	ARR SCREEN.....	30
4.10	SYSTEM SETUP SCREEN	32
4.10.1	Screen Description.....	32
4.11	COLOR SETTINGS	37
4.12	FILE/ARCHIVE MANAGEMENT SCREEN.....	38
CHAPTER 5	CO₂ MONITORING	39
5.1	CO ₂ PARAMETER SETTINGS	39
5.2	CO ₂ SENSOR CONNECTION	40
5.2.1	Sidestream CO ₂ Sensor Connection.....	40
5.2.2	Mainstream CO ₂ Sensor Connection	42

5.3	CO ₂ MONITORING SCREEN	44
5.4	CO ₂ GRAPHIC TREND.....	45
CHAPTER 6	ALARM 46	
6.1	ALARM PRIORITY.....	46
6.2	ALARM MODES	47
6.3	ALARM SILENCE	47
6.4	ALARM SETTING	47
6.5	VERIFY ADJUSTABLE ALARM FUNCTION	48
CHAPTER 7	TECHNICAL SPECIFICATIONS.....	49
7.1	ECG MONITORING.....	49
7.2	RESP MONITORING	50
7.3	TEMP MONITORING.....	50
7.4	NIBP MONITORING	50
7.5	SpO ₂ MONITORING.....	51
7.6	PULSE MONITORING.....	51
7.7	CO ₂ MONITORING.....	51
7.8	DATA RECORDING	52
7.9	OTHER TECHNICAL SPECIFICATIONS.....	52
7.10	CLASSIFICATION.....	52
7.11	GUIDANCE AND MANUFACTURER'S DECLARATION-ELECTROMAGNETIC COMPATIBILITY	
53		
CHAPTER 8	PACKAGING AND ACCESSORIES	57
8.1	PACKAGING	57
8.2	ACCESSORIES	57
CHAPTER 9	PARAMETERS MONITORING.....	58
9.1	ECG MONITORING.....	58
	9.1.1 How to Obtain High Quality ECG and Accurate Heart Rate Value.....	58
	9.1.2 Factors affecting ECG signal.....	58
9.2	NIBP MONITORING	59
	9.2.1 Measuring Principle.....	59
	9.2.2 Factors affecting NIBP measuring	60
	9.2.3 Clinical Limitations	61
9.3	SpO ₂ MONITORING.....	62
	9.3.1 Measuring Principle.....	62
	9.3.2 SpO ₂ Measurement Restrictions (interference reason)	62
9.4	RESPIRATION MONITORING	63
	9.4.1 Measuring Principle.....	63
	9.4.2 Factors affecting respiration monitoring	63
9.5	TEMPERATURE MONITORING.....	63
9.6	CO ₂ MONITORING.....	64
	9.6.1 Measuring Principle.....	64
	9.6.2 Mainstream vs. Sidestream Sampling.....	64
CHAPTER 10	TROUBLESHOOTING	65
10.1	NO DISPLAY ON THE SCREEN.....	65
10.2	EXCESSIVE ECG SIGNAL INTERFERENCE OR TOO THICK BASELINE.....	65
10.3	NO BLOOD PRESSURE AND PULSE OXYGEN MEASURES	65
10.4	SYSTEM ALARM.....	65
CHAPTER 11	MAINTENANCE	66
11.1	SERVICE AND EXAMINATION	66
	11.1.1 Daily Examination.....	66
	11.1.2 Routine Maintenance	66
11.2	BATTERY MAINTENANCE	66
11.3	CLEANING, STERILIZATION AND DISINFECTION	67
11.4	CLEANING, STERILIZATION AND DISINFECTION OF ACCESSORIES	68
11.5	STORAGE	68
11.6	TRANSPORTATION.....	68

CHAPTER 12	APPENDIX	69
12.1	ALARM INFORMATION	69
12.2	DEFAULT ALARMING VALUES AND SETUP RANGE	70
12.3	ABBREVIATION OF ARRHYTHMIA	72
12.4	STATUS/ERROR DURING NIBP MONITORING	73
12.5	STATUS/ERROR DURING CO ₂ MONITORING	74
12.6	TYPICAL PRESSURES AND CO ₂ READINGS AT ALTITUDES	75
12.7	ACCESSORIES LIST	76
12.8	INSTRUCTIONS FOR SpO ₂ PROBE	77

Capitolo 1

PANORAMICA GENERALE

1.1 Caratteristiche

This monitoring system may be used to monitor patient's 6 physiological parameters: ECG, respiratory rate, body temperature, non-invasive blood pressure (NIBP), pulse oxygen saturation (SpO₂), and pulse rate.

- 12.1" high-resolution (800 × 600) color LCD to display patient's ECG waveform, respiratory waveform and SpO₂ waveform;
- Multiple interface monitoring, which enables simultaneous monitoring of several ECG waveforms;
- Real-time monitoring of battery capacity, when the battery power is insufficient, low battery voltage alarm indication will display on LCD screen.
- Automatic analysis of 20 arrhythmia waveforms and ARR, waveform freezing function and automatic S-T segment measurement and manual analysis;
- Up to 480 hours statistic data of HR, TEMP, SpO₂, RESP and NIBP trends with 6/24/120/480 trend graph analysis function;
- 100 groups of arrhythmia cases' data and the corresponding lead, gain and filter mode of ECG;
- storage and recall of a list of 800 groups of NIBP measurement data, as well as heart rate, body temperature, respiratory rate and SpO₂/pulse rate when the measure of blood pressure is taken;
- 24 hours of ECG data storage and recall;
- High precision NIBP measuring module;
- Special SpO₂ measuring device, which ensures the accuracy of SpO₂ and pulse rate measures;
- Visual and audible alarm, recall of alarm events;
- Flexible high and low alarm limits setting function;
- Easy to color-code and change the color of the font, background and waveforms if need to be;
- Resistance against defibrillator and electrosurgical knife interference, detects and filters the pacemaker-generated signals, and high safety level;
- Able to be used along with cardiac pacemaker;
- Built-in battery supports up to 2 hours of continuous operation;
- Blood pressure may be measured in the mode of "adult/infant/neonate", which may be selected via the menu, to better suit the adult, infant and neonatal patient;
- Built-in printer (optional) to output waveforms and text;
- Dual IBP and CO₂ are optional.
- Networking with the central station as a part of the central network;

1.2 Product Name and Model

Name: Patient Monitor

Model: UP-7000

1.3 Applications and Scope

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult and pediatric patients. With the functions of real-time recording and displaying parameters, such as ECG, heart rate, non-invasive blood pressure, functional oxygen saturation, end-tidal CO₂ concentration, respiration rate, 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°C~40°C
Relative humidity: 30%~80%
Atmospheric pressure: 70kPa~106kPa
Power supply: 100~240VAC
Power frequency: 50/60Hz
2. This apparatus should be situated in a place protected against direct sunlight, so as to prevent too high temperature inside it.
3. Do not use this apparatus in an environment with toxic or inflammable gas.
4. This apparatus should be fixed on a stand, so as to prevent possible shock.

5. Do not use this apparatus in combination with any equipment other than those expressly permitted in these instructions.
6. When using this device with electrosurgical equipment, the user (doctor or nurse) should pay attention to the safety of patient.
7. Make sure that the equipotential grounding terminal is grounded correctly.
8. 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. Conform to IEC60601-1, certified as Class I, with Type BF and CF applied parts.
- b. This device can resist against the discharge of defibrillator and the interference of eletro-surgical 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

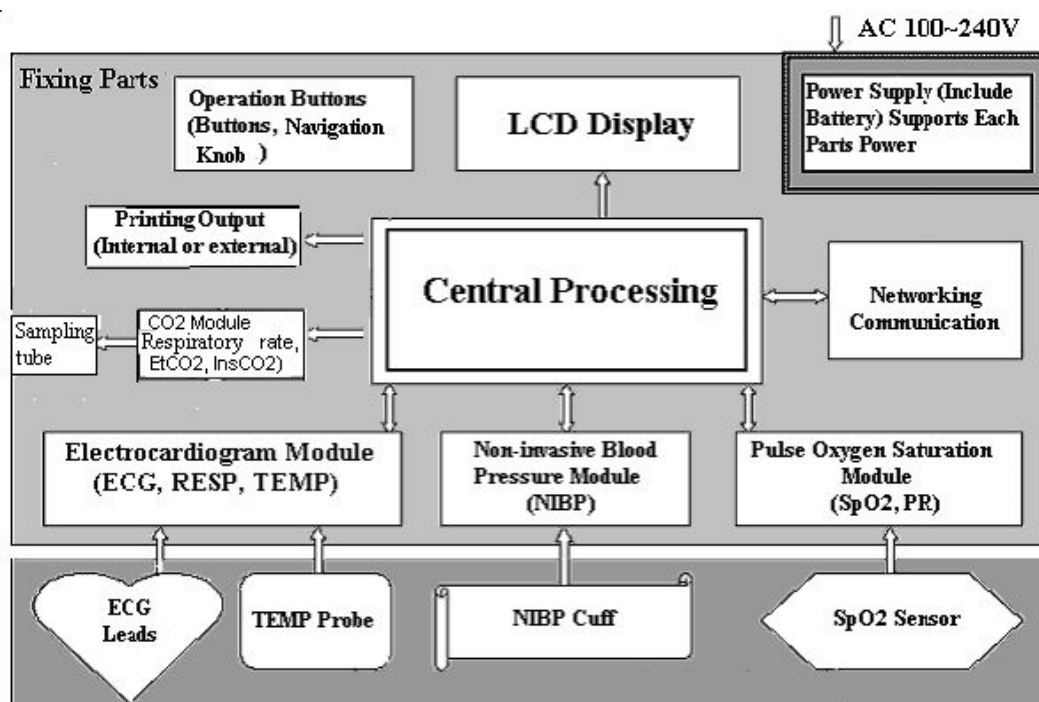
WORKING THEORIES OF THE MAIN UNIT

2.1 Composition

The monitor consists of the main unit and the corresponding functional components (ECG leads & electrodes, non-invasive blood pressure cuff, SpO₂ probe, temperature transducer, appendix of invasive blood pressure and side-stream CO₂).

2.2 Overall structure and Working Theories

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



Picture 2.1 Basic Structure

This patient monitor, which performs physiological parameter measurement through different modules, is a product of module design. It consists of six modules: ECG module, NIBP module, SpO₂ module, CO₂ module (optional) and the main unit.

1. The ECG module collects the heart rate, respiration waveforms through the ECG leads & electrodes and collects the temperature data through the temperature probes as well.

2. The SpO₂ module collects the data of pulse rate, pulse oxygen saturation (SpO₂) and SpO₂ volume waveform via the SpO₂ probe.
3. The NIBP module collects the blood pressure data, including the diastolic, systolic and mean arterial pressure through the NIBP cuff. The cuffs are designed for adult, infant and neonate respectively, and the NIBP measurement has two modes: adult, infant and neonate.
4. The CO₂ module collects the data of respiration rate, EtCO₂, InsCO₂ through the sampling tube.
5. The main unit consists of main board, multi-function board, and the keyboard. The multi-function board performs the data communication among the main board, ECG module, SpO₂ module, NIBP module, and CO₂ module.

Chapter 3

INSTALLATION AND CONNECTION

3.1 Installation

3.1.1 Opening the Box and Check

1. Open the package, take out the monitor accessories from the box carefully and place it in a safe stable and easy to watch position.
 2. Open the user 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 will offer the best solution for your satisfaction.

3.1.2 Connecting the AC Power Cable

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**
- Caution: it's better to recharge the battery after it is used up, and the charging time should be 13~15 hours long.
- 🔊 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.

3.1.3 Starting the Monitor

The system performs self-test and enters initial display after switch on the monitor, and the alarm rings 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 at least 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.

3.2 Appearance

3.2.1 Front Panel

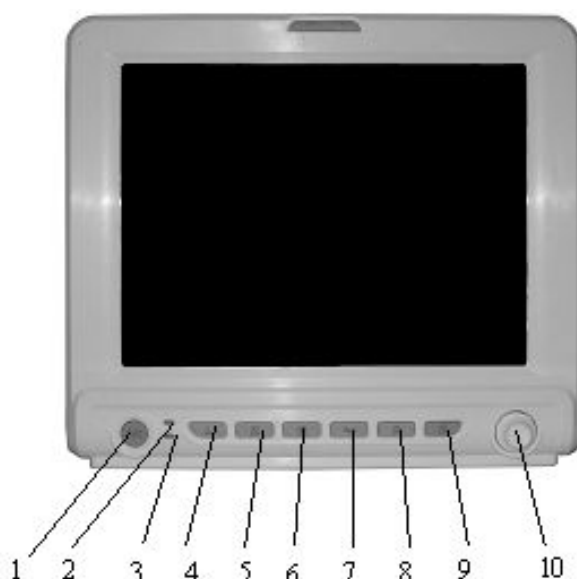








Figure 3.1 Front Panel

1. **Power switch:** Press it to switch on/ off the monitor.
2. **AC power indicator:** When AC indicator is on, it means this device is using mains power supply.
3. **DC power indicator of built-in battery:**
When DC indicator is on, it means the battery is used; when both of AC indicator and DC indicator are on, it means that this device is using mains power supply and the battery is being recharged.
4.  **ECG lead selection:** Click it to shift the ECG monitoring circulatory among , , and , AVR, AVL, AVF and V.
5.  **Alarm silence:** Press this key to set or activate the system alarm. In the monitoring screen, press “Alarm” to set the alarm timer. The time shows up on the upper left corner of the screen. When the alarm timer is activated, the system begins to count down and alarm when the set time has passed. There are four options of alarm silent time: 2 minutes, 5 minutes, 10 minutes and 20 minutes.
6.  **Freeze:** Press the key to freeze ECG waveform or the waveforms of ECG, SpO₂ and RESP for the S-T segment analysis according to the system setting.
7.  **NIBP:** Press it to start or stop NIBP measuring.
8.  **Print:** Click it to print out different waveforms under different system states.
9.  **DISP:** Click it to shift the display modes. Press it to shift the main screen, list screen, viewing screen and the seven leads on the same screen and return to the main screen from other screens.
10. **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.
11. **Alarm indicator:**

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

3.2.2 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 conveniences.

The built-in printer is at the left panel, shown in Figure 3.2.

The cable and probe ports are at the right panel, shown in Figure 3.3.

1. **TEMP1, TEMP2:** TEMP probe connector
2. **NIBP:** NIBP hose connector
3. **SpO2:** SpO₂ probe connector
4. **ECG/RESP:** ECG cable connector
5. **CO₂:** Cable connector of CO₂ sensor module
6. ↓: the cover of battery compartment, open it to replace or insert the battery. The provided standard battery is a piece of 12V and 2.3Ah rechargeable battery. (The back-up rechargeable battery is optional, and the detailed type of the battery you can see the surface of it.)

Note: Only the battery of same model with the standard battery can be used. Insert battery properly, or else the improper insertion may damage the monitor.



With type BF applied parts



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




Caution! Please read the manual for details.







3.2.3 Rear Panel



Figure 3.4 Rear panel

The following ports are at the rear panel of the monitor.

1. **Monitor:** External display port
2. **NET:** Serial communication port which is used to network with central monitoring system
3. : Equipotential grounding port
4. **Fuse 2xT3. 15A:** Fuse holders, fuse specification: T3. 15AL/250V 5 20mm.
5. **100~240VAC:** Power supply socket
6. **S/N:** Serial Number
7. **Nameplate**

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

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 manufacture'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; for 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, for skin preparation 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:

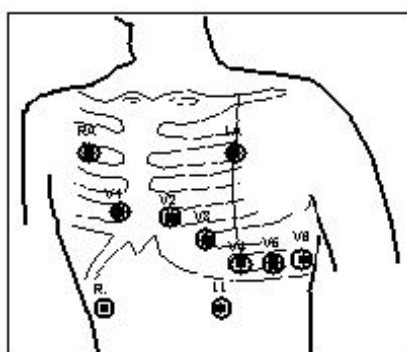


Figure 3.5 Electrode Location

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

5. 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.
6. 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

- 🔔 UP-7000 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).
- 🔔 UP-7000 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.

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

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

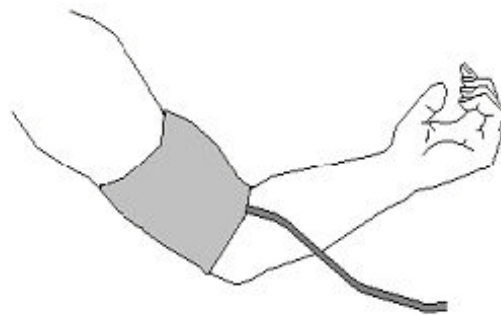


Figure 3.6 Cuff Position



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

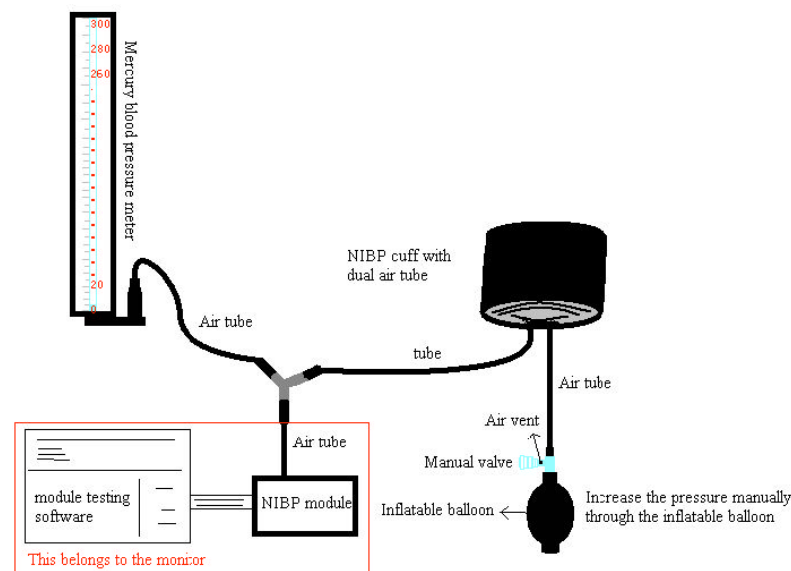


Figure 3.7 Connection of Pressure calibration fixture

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

Table A

Adult	240mmHg
Child	200mmHg
Neonate	120mmHg

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.

Table B

Adult	300mmHg
Child	240mmHg
Neonate	140mmHg

- 🔔 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.

Safety Instructions for NIBP Measurement

- ⚠️ When taking the measure of an infant 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.
- ⚠️ 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.

3.3.3 SpO₂ Probe Connection

SpO₂ probe is very delicate equipment. Please follow the steps and procedures in operating it. Failure to operate it correctly can cause damage to the SpO₂ probe.

Operation procedure:

1. Connect the SpO₂ probe to the right panel's jack labeled "SpO₂". 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.

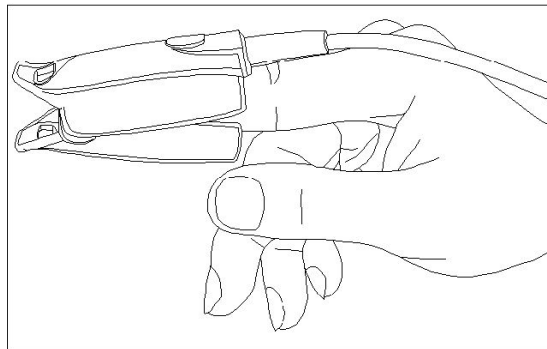


Figure 3.7 Demonstration of SpO₂ Probe

When selecting a sensor, do consider the patient's category, adequacy of perfusion, availability of probe site and anticipated monitoring duration. Use only SpO₂ probes provided by our company with this monitor. Read the following table for SpO₂ probe information. Refer to Chapter 12.8 for the detailed instructions of each SpO₂ 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 an SpO₂ 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 SpO₂ Monitoring

- 🔔 Continuous use of fingertip SpO₂ sensor may result in discomfort or pain, especially for those patients with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same finger for over two hours, change the measuring site periodically if necessary.

- 💡 SpO₂ measuring position must be examined more carefully for some special patient. Do NOT install the SpO₂ sensor on the finger with edema or fragile tissue.
- 💡 Do NOT put the SpO₂ sensor and pressure cuff on the same limb, otherwise the NIBP measuring will affect SpO₂ measuring and cause the alarm error.
- 🔔 If sterile packaging of SpO₂ sensor is damaged, do not use it any more.
- 🔔 Check the SpO₂ sensor and cable before use. Do NOT use the damaged SpO₂ sensor.
- 🔔 When the temperature of SpO₂ 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 SpO₂ sensor can not be immersed into water, liquor or cleanser completely, because the sensor has no capability of waterproofness.

3.3.4 TEMP Probe Connection

Patient Monitor has two TEMP probes to measure different body temperature.

Connecting methods:

1. Attach the probes to the patient firmly;
2. Connect them to "TEMP" on the right panel.

Note: When unplugging the probe, be sure to hold the head of the connector and pull it out.

3.3.5 Loading Printing Paper

This description is for loading paper for the built-in printer.

Operation procedures:

1. Press both "OPEN" notches with force on printer shield with two thumbs to open it.
2. Move the tab of rubber roller lock at the left 90° upwards to unlock it.
3. Cut one end of the paper into triangle, and load the paper from the underside of the rubber roller.
4. Turn the roller clockwise to get the paper rolled, and put the paper roll into the compartment.
5. Pull the paper out of paper slot on the shield.
6. Move the tab of the rubber roller lock 90° downwards to lock it.
7. Put the shield back in position and secure it.

Unloading printing paper

1. Press both "OPEN" notches vertically with force on printer shield with two fingers to open it.
2. Move the tab of roller lock at the left 90° upwards to unlock it.
3. Roll the loading roller anti-clockwise and pull the paper out.
4. Roll the loading roller clockwise to get the paper rolled, and put it into the compartment.
5. Pull the paper out of paper slot on the shield.

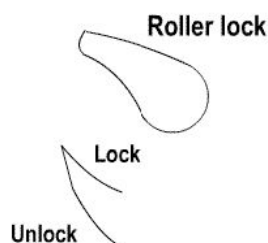


Fig.3.8

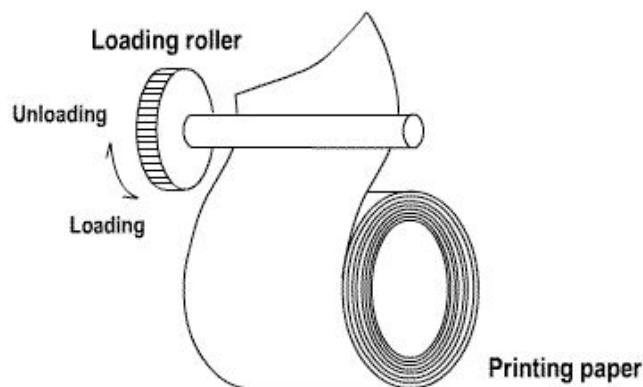


Fig.3.9

Chapter 4

MONITORING SCREEN

4.1 Main Screen

4.1.1 Date and Time Setup

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

Time Setup

Date 2004 - 02 - 27

Time 08 : 22 : 21

Edit

Exit

Figure 4.1 Date and 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 setting 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).

4.1.2 Screen Description

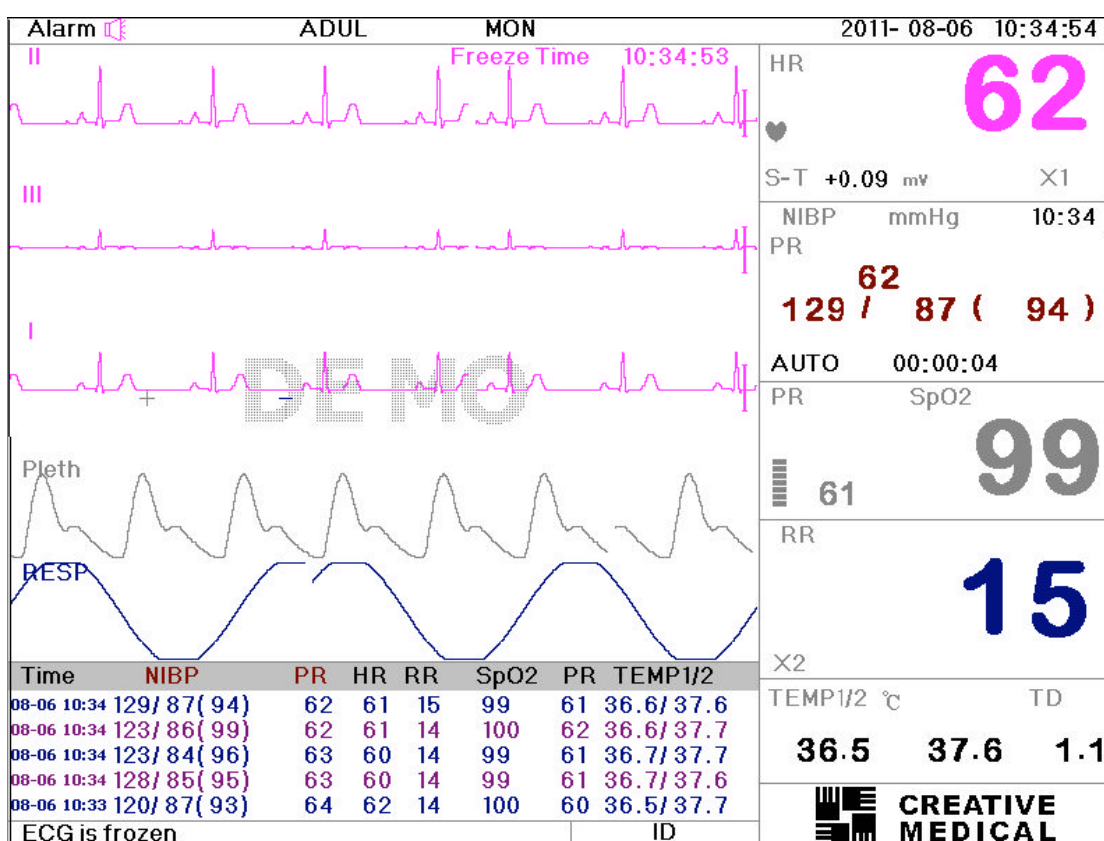





Figure 4.2
Main screen

Border area

“Alarm”:  shows the alarm is ON and  shows the alarm is in alarm silence status, the alarm will be activated automatically after the system finishes counting down. Note: the screen indicates the alarm mute is a closed state when the system volume sets to “0” and lights red, so the alarm mute setting is invalid.

“ADUL”: The type of the monitor subject. There are three modes available: “Adult”, “infant” and “Neonate”.

“MON”: ECG Filter type. There are “Diagnosis”, “Monitor”, and “Operation” three types. 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. (Note: This function is optional, and needs hardware support.)

“2011-08-06 10:34:54”: System current 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 August 6th, 10:34:54, 2011.

“Display is unfrozen”: 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 Waveform: The first waveform 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 measured waveform change to lead II, the first waveform will automatically change to lead I.

2nd Waveform: The second waveform is for the ECG waveform of lead III. When the third measured waveform displays the ECG for the lead III, this waveform automatically changes to the ECG for lead I.

3rd waveform: The third waveform is the measurable ECG channel. Its lead can be adjusted and will not repeat the 1st and 2nd waveforms.

4th waveform: SpO₂ waveform.

5th waveform: Respiration waveform.

6th: NIBP list, the last 5 NIBP list will be displayed in this area.

Data area:

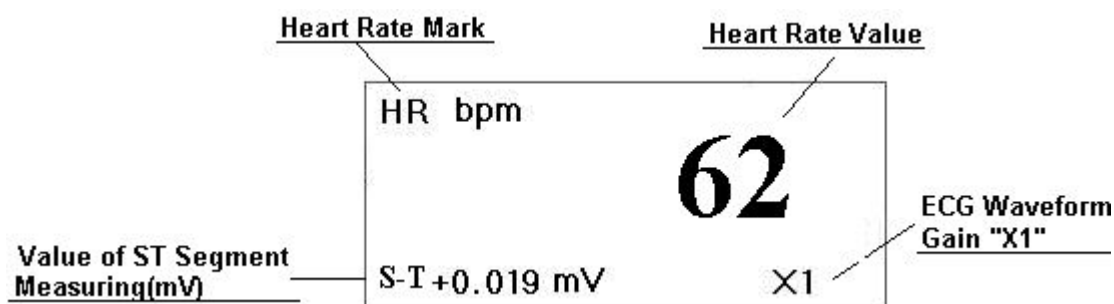



Figure 4.3 Heart rate area

“HR”: The currently displayed heart rate. The 62 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 with the heart rate.

“S-T+0.019mv”: The measured milli-volts value during S-T measurement.

“X1”: ECG waveform gain (amplification), 3 or 5 leadwire options available

“Auto”: Automatic waveform gain.

“x1/2” half size of the basic waveform

“x1” Basic waveform

“x2” Twice the size of the basic waveform

“x4” Four times the size of the basic waveform

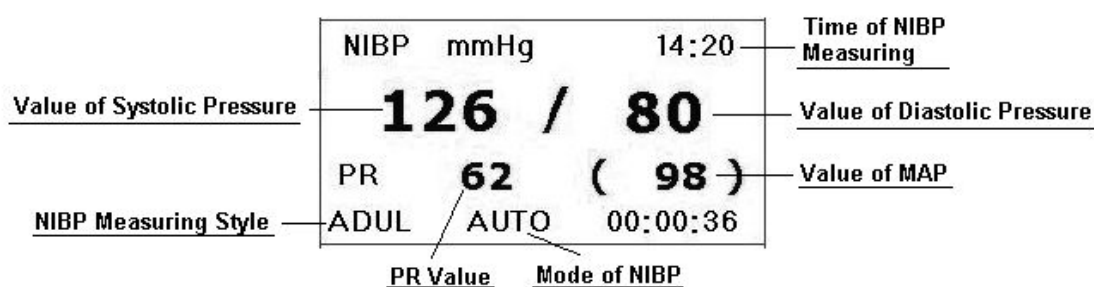


Figure 4.4 Blood pressure data area

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

“mmHg”: NIBP unit

“14:20”: The time of NIBP measuring

“ADUL”: NIBP measurement mode. The object is adult.

The 3 values from left to right are the blood pressure: Systolic, diastolic and MAP.

“AUTO”: The NIBP measurement mode. “00:00:36”: counting down time; the system will take NIBP measurement automatically when the system finishes counting down.

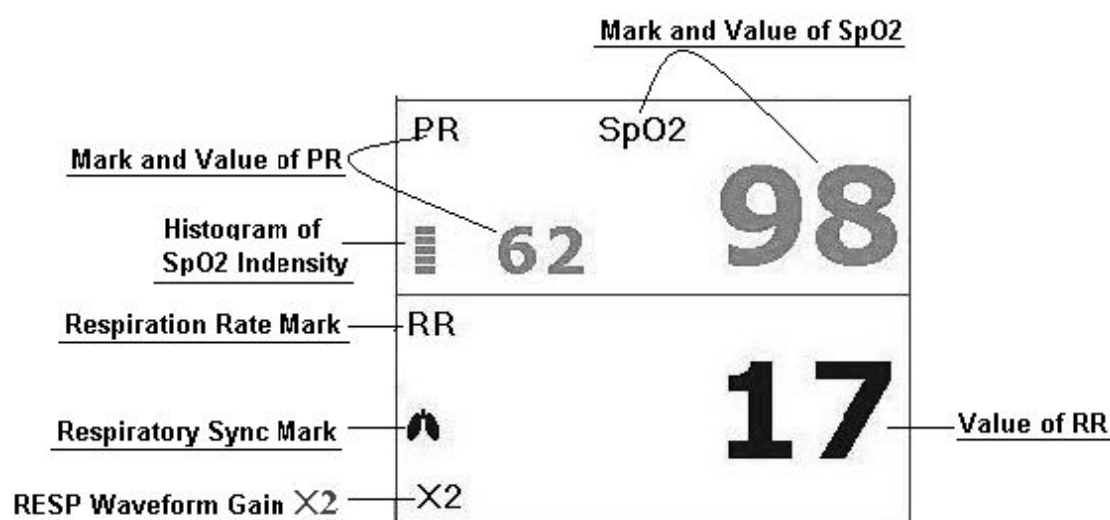


Figure 4.5 SpO2, pulse rate, and respiration data area

“SpO2”: SpO2 label. The “98” on the right side is the current SpO2 value measured.

“PR”: Pulse rate label. The value “62” on the lower left shows the pulse rate value.

“■”: SpO2 strength bar.

“RR”: Respiration Rate: The bpm after that is the unit of the respiration, i.e., beat per min.

“17”: Respiration rate.

“X2”: Respiration gain amplification :

“X1/2”: Half of the basic waveform

“X1”: Basic waveform

“X2”: Twice the size of the basic waveform.

“X4”: 4 times of the basic waveform

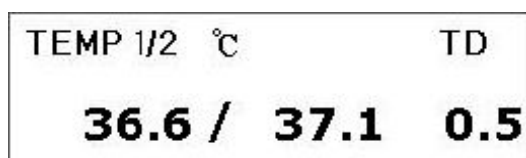


Figure 4.6 TEMP data area

“TEMP 1/2”: Temperature label. The value below “36.6, 37.1” are the temperature values.

“□”: Body temperature unit. □ is Celsius, and °F is Fahrenheit.

“TD”: the absolute value in temperature between TEMP 1 and TEMP 2.

☞ Print lead ECG waveform and waveform 2 which can be selected in the system menu.

4.2 Display 2 Screen

4.2.1 Viewing Screen

Choose Obsev of Disp2 on system setup screen, press the DISP key to enter the monitoring screen, as shown in Figure 4.7.

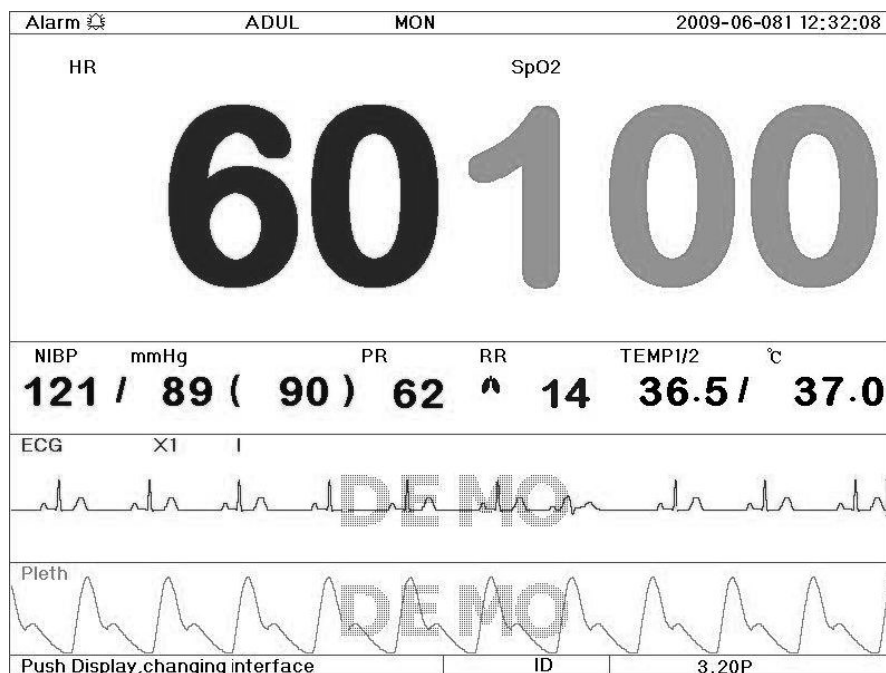


Figure 4.7 Viewing screen

In this screen, press the DISP key to switch the ECG lead, or press the Print key to print the ECG waveform and the second waveform. The second waveform can be selected in the System menu.

☞ Press print key to print lead ECG waveform and waveform 2 which can be selected in the system menu.

4.2.2 Seven ECG Waveforms on the Same Screen

Choose 7 ECG of Disp2 on system setup screen, press the DISP key, the system enters the 7 ECG waveform 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 4.8.



Figure 4.8
7 Leads on the Same Screen

In this screen, rotate the Navigation Knob to adjust the ECG gain. The ECG gain includes 3 or 5 options: "Auto", "X1/2", "X1", "X2", "X4". Rotate the knob to adjust the gain for all 7 ECG waveforms. Press the freeze button to freeze all 7 ECG waveforms.

4.2.3 Operating Instructions

In the above monitoring screens, the operator can perform normal print and the blood pressure measurement, but print and blood pressure measurement can not be operated at the same time. When pressing the "DISP" key again on the front panel, the system returns to the main screen.

Press print key to print lead II ECG waveform and waveform 2 which can be selected in the system menu.

4.3 Freeze and S-T Analysis Screen

During the process of monitoring, the whole screen or the 3 ECG waveforms can be frozen to perform detailed analysis. If necessary, the operator can send one of the frozen waveform to the printer. In the main screen, press the "Freeze" key to freeze the 3 ECG waveforms or all the waveforms on the screen, as shown in Figure 4.9.

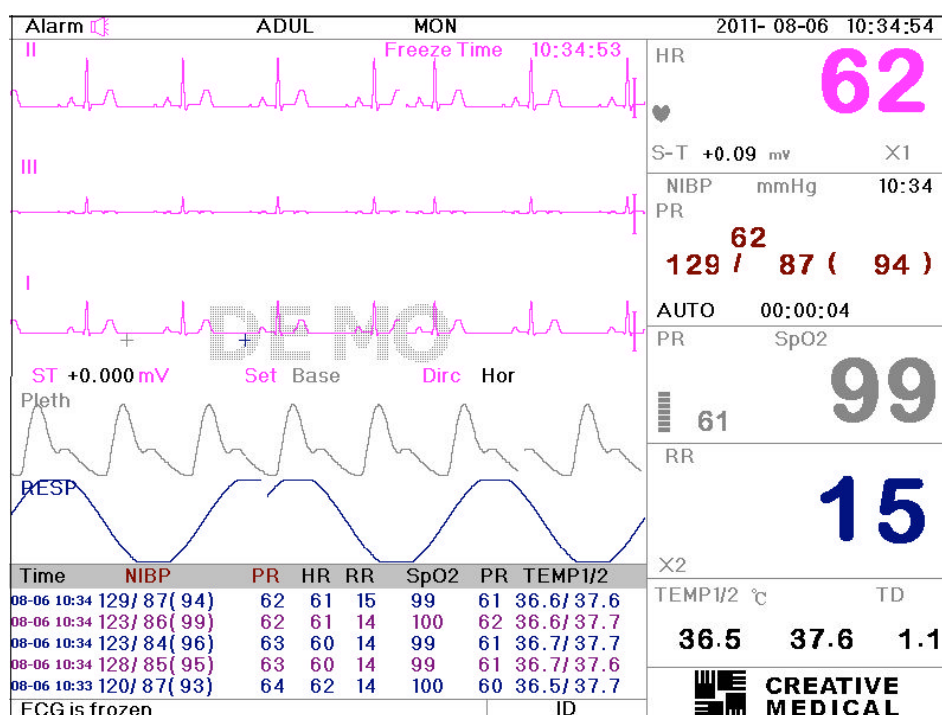


Figure 4.9 Frozen Screen

4.3.1 Screen Description

Freezing, S-T segment analysis screen is similar with the main screen, except the waveforms are frozen. For example, the Figure 4.10 is a portion of the frozen waveform from the 3rd ECG waveforms. The symbols on the screen were described briefly on the screen.

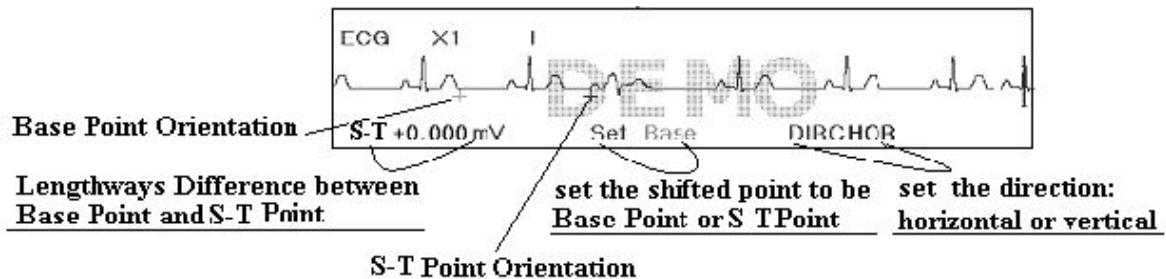


Figure 4.10 Frozen waveform

🔔 When the system setting for the freezing waveform is "ALL", the "Freeze" key will freeze all the waveforms.

4.3.2 Operating Instructions

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

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 "st+0.xxx mV, Set Base, Dirc Hor"
2. Press the "Navigation Knob". The screen shows "st+0.xxx mV, Set Base, Dirc Ver". Then rotate the knob to move the base point vertically to the base line point.
3. Press the "Navigation Knob" again. The screen shows "st+0.xxx mV, Set st, Dirc Hor". Rotate the knob to move the st point (the yellow cross) horizontally to the point to be measured on the st segment.
4. Press the "Navigation Knob" again. The screen shows "st+0.xxx mV, Set st, Dirc Ver". Rotate the knob to move the st point vertically to the point to be measured on the st segment.

Only the main screen allows pressing the freeze key to enter the st 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.

🖨️ Press print key to print lead ECG waveform and waveform 2 which can be selected in the system menu.

4.4 Mode Selection Screen

Press the "Navigation Knob" in the main screen as shown in Figure 4.2, the operating area shows the mode selection screen, as shown in Figure 4.11.

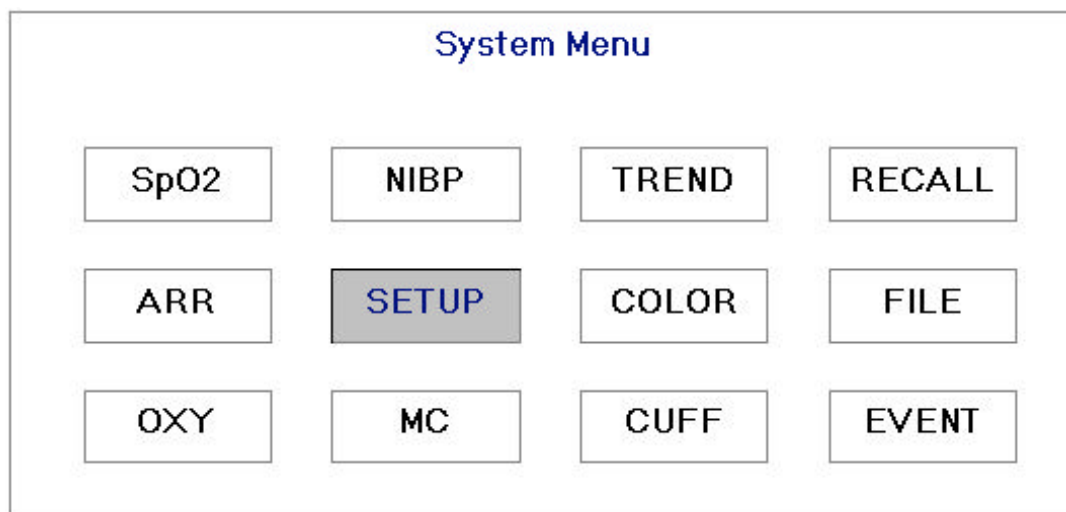


Figure 4.11 Mode selection screen

In the mode selection screen, rotate the knob to move the gray cursor to the corresponding screen. Press the knob to enter the screen of SpO₂, NIBP, RCALL, TREND, ARR, SETUP, COLOR, and FILE. The following chapter 4.5 will describe each one. Press Exit/DISP to exit from this screen.

Press print key to print lead ECG waveform and waveform 2 which can be selected in the system menu.

4.5 SpO₂ Data List Screen

Move the gray cursor to SpO₂ in the mode selection screen, and press “Navigation Knob” to enter into SpO₂ data list screen, shown in Figure 4.12

Time	HR	RR	TEMPI	TEMPH	SpO ₂	PR
11-29 15:36	60	14	36.7	37.2	99	61
11-29 15:36	60	14	36.6	37.2	98	62
11-29 15:35	60	14	36.5	37.0	99	61
11-29 15:35	60	14	36.7	37.2	98	60
11-29 15:35	60	14	36.6	37.0	99	61
11-29 15:35	60	14	36.7	37.0	98	61
11-29 15:35	60	14	36.6	37.2	99	60
11-29 15:35	60	14	36.5	37.2	98	60
11-29 15:35	60	14	36.6	37.2	98	61
11-29 15:35	60	14	36.6	37.0	98	62
11-29 15:35	60	14	36.5	37.0	98	61
11-29 15:35	60	14	36.6	37.0	98	62
11-29 15:34	60	14	36.7	37.0	98	60

Figure 4.12 SpO₂ Data Listing Screen

4.5.1 Screen Description

The SpO₂ data listing screen is similar to the NIBP listing screen. The difference is the color of title bar. All the parameters in the SpO₂ data listing are corresponding to the time when the SpO₂ measurements were taken. There is only one record every 4 seconds.

Press print key to print SpO₂ list on the SpO₂ List Screen.

4.6 NIBP Listing Screen

4.6.1 Screen Description

Move the gray cursor to NIBP on the mode selection screen, and press “Navigation Knob” to enter into NIBP data list screen, shown in Figure 4.13. The time shows the time when the measurement was taken. As shown in Figure 4.13, one blood pressure listing screen can list up to 13 groups of blood pressure data. When the measured data exceeds 13 groups, we can use the Navigation Knob to scroll up and down to show the complete list

Time	NIBP	PR	HR	RR	TEMPI	TEMPH
06-08 12:35	121/ 85(93)	62	60	14	36.5	37.0
06-08 12:35	128/ 83(98)	61	60	14	36.5	37.0
06-08 12:35	123/ 87(90)	60	60	14	36.6	37.1
06-08 12:35	121/ 89(92)	62	60	14	36.7	37.1
06-08 12:35	120/ 86(94)	61	60	14	36.5	37.0
06-08 12:34	121/ 88(94)	60	60	14	36.5	37.1
06-08 12:34	122/ 86(92)	61	60	14	36.5	37.0
06-08 12:34	128/ 83(94)	60	60	14	36.6	37.0
06-08 12:34	123/ 83(99)	62	60	14	36.6	37.0
06-08 12:34	125/ 83(99)	61	60	14	36.7	37.1
06-08 12:32	124/ 80(94)	61	60	14	36.6	37.2
06-08 12:32	129/ 82(96)	62	60	14	36.5	37.0
06-08 12:31	121/ 89(90)	62	60	14	36.5	37.2

Figure 4.13 NIBP listing screen

4.6.2 Operating Instructions

The operation on the data listing is simple. Using the Navigation Knob allows the user to scroll the list up and down. 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.

☞ Press print key to print NIBP list on the NIBP List Screen.

4.7 Graphic Trend Screen

4.7.1 Screen Description

Move the gray cursor to the “TREND” button, press the knob, and you will get the screen as shown in Figure 4.14.

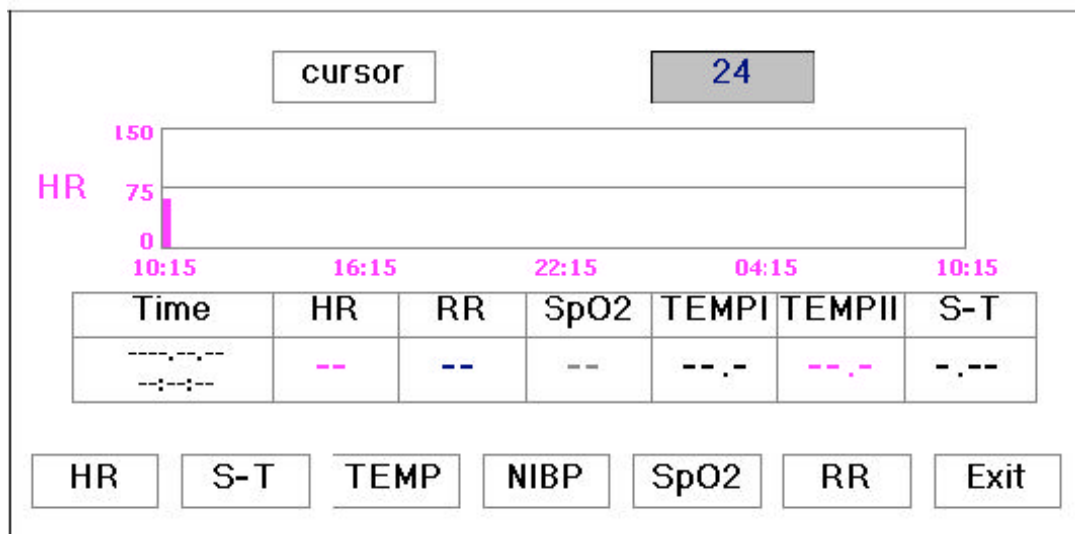


Figure 4.14 Trend Menu Screen

This is the graphic trend selection screen, i.e. Trend Menu screen.

If you want to enter one of the trend graphs, the procedures are: rotate the “Navigation Knob”, move the cursor to one of the parameter. For example, from the left to right, we are entering “ECG”, “st”, “Temperature”, “NIBP”, “Pulse rate” and “SpO₂” trend graphs. Their screens are described in the following figures.

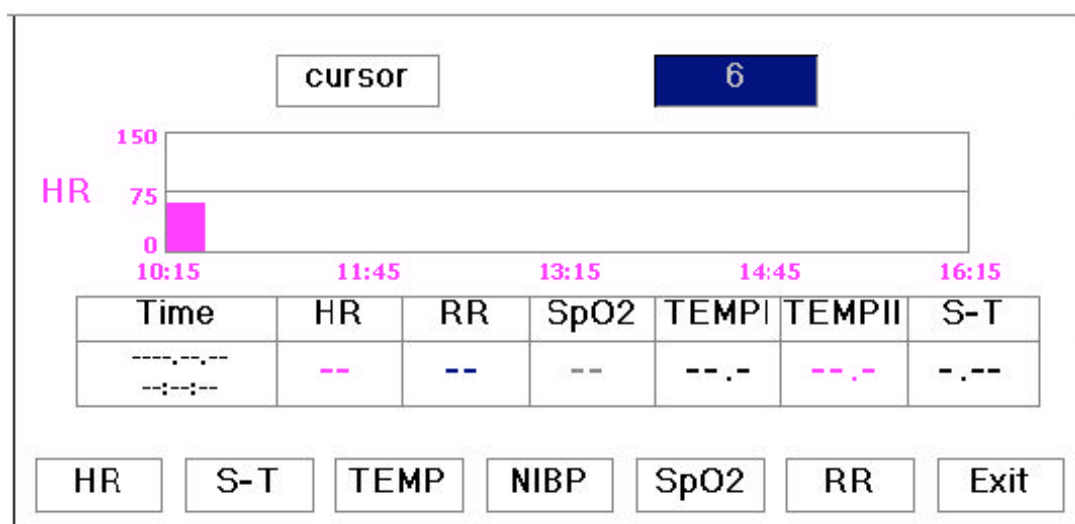


Figure 4.15 ECG Graphic Trend

Figure 4.15 is the ECG trend graph. There are 3 options on the right of the graph, as described below. The “6” on the top shows the trend graph time. Move the cursor to the trend time, press the knob and rotate it, and the trend graph time will change to 6, 24, 120 or 480, which changes the horizontal coordinates to be 24 hours, 120 hours or 480hours. The corresponding trend graph also changes to 24 - hour trend, 120 - hour trend or 480 - hour trend.

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, SpO₂, temperature, 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 1, after moving it towards the same direction 5 times, the interval becomes 5, and with 5 more steps the interval becomes 10, then 20 and 40. No matter what the interval is, as long as you move towards the other direction, the interval becomes 1 of the other direction. Therefore, it is very easy to find the time you are looking for.

The last option on the right is “Exit”. Move the cursor to the “Exit”, and press the “Navigation Knob” to return to the previous screen. The screen returned to is the Mode Selection screen.

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 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 Trend graph shows parameter value of the current time. For example, in the 12 hours trend graph, when the monitoring time exceeds 12 hours, the data 12 hours ago will be move out of the graph. This ensures the screen always display the current data for review. The data moved out of the graph is not deleted but is just hidden temporarily. When the time frame changes from 12 hours to 24 hours (while the monitoring time is less than 24 hours), the complete set of data will display. Other trend graph follows the same rule.

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.

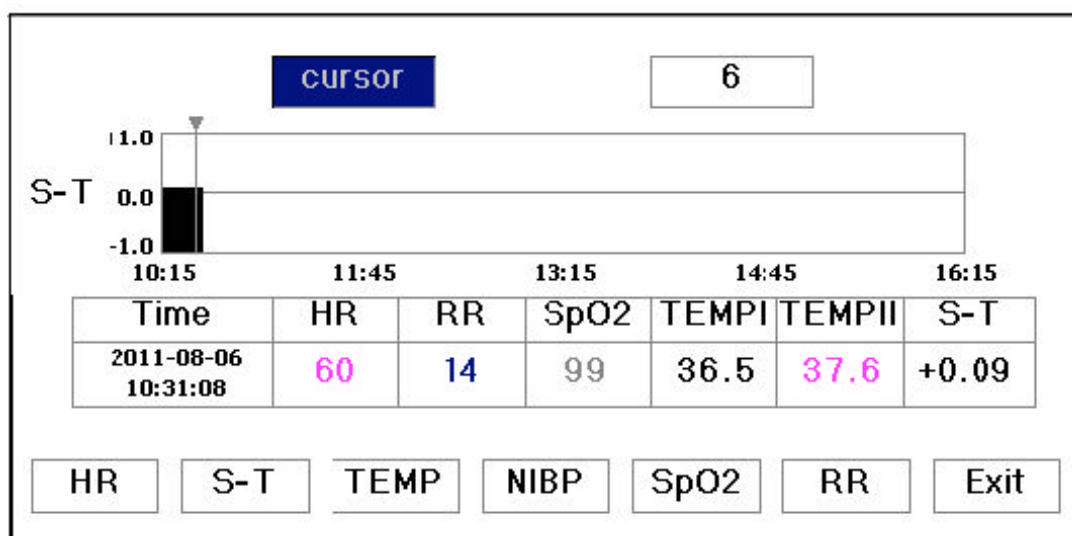


Figure 4.16 S-T Graphic Trend

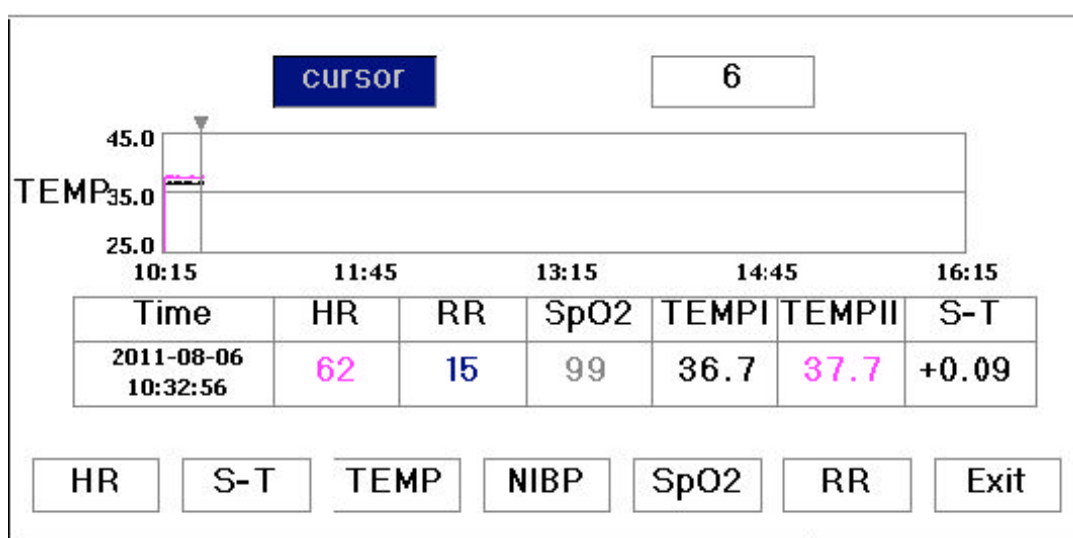


Figure 4.17 Body Temperature Graphic Trend

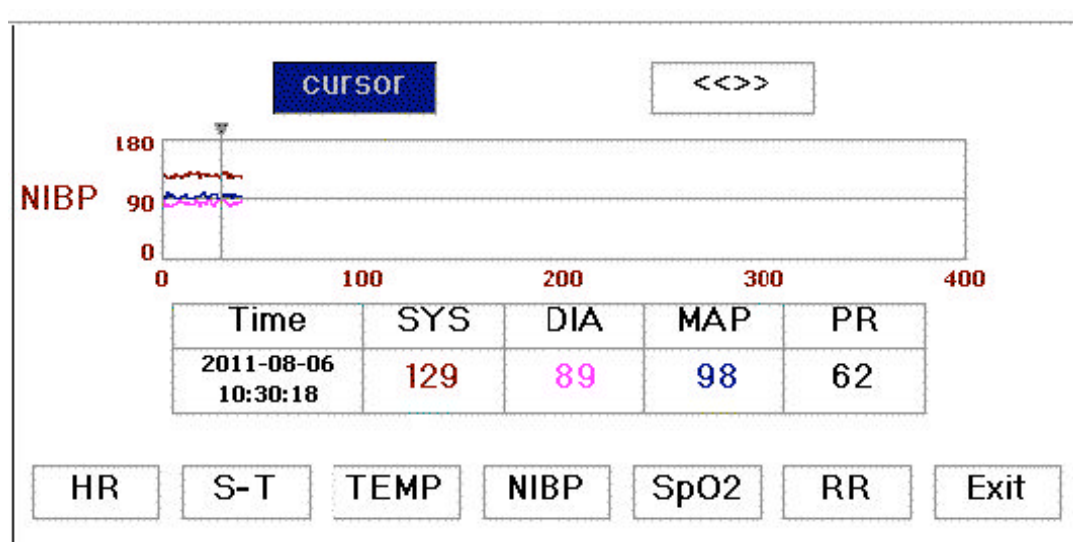
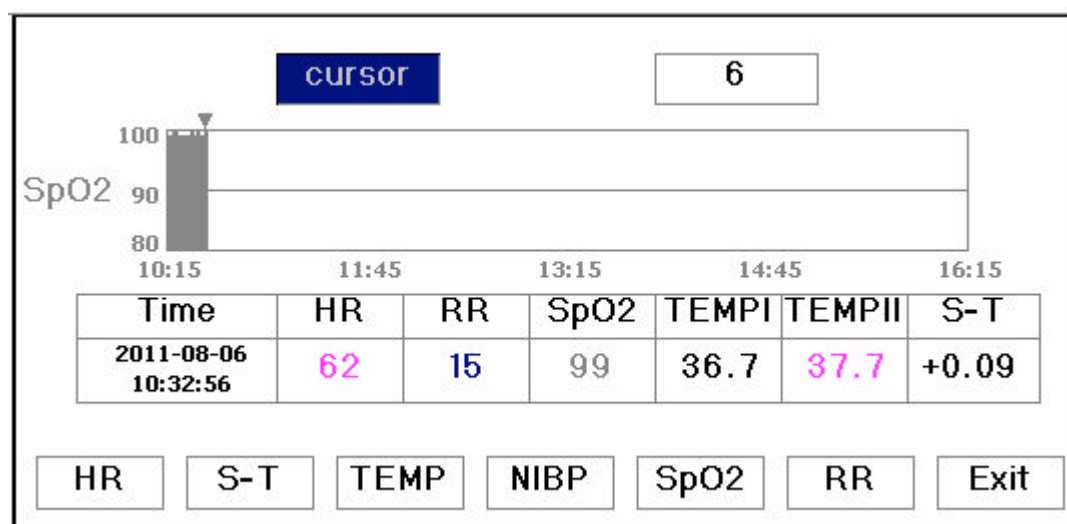


Figure 4.18 NIBP Graphic Trend

Figure 4.19 SpO₂ Trend graph

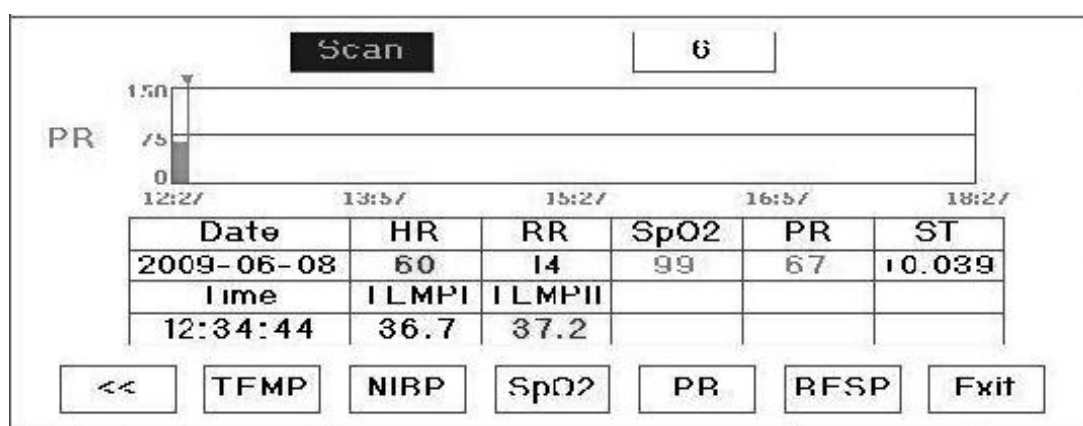


Figure 4.20 PR Graphic Trend

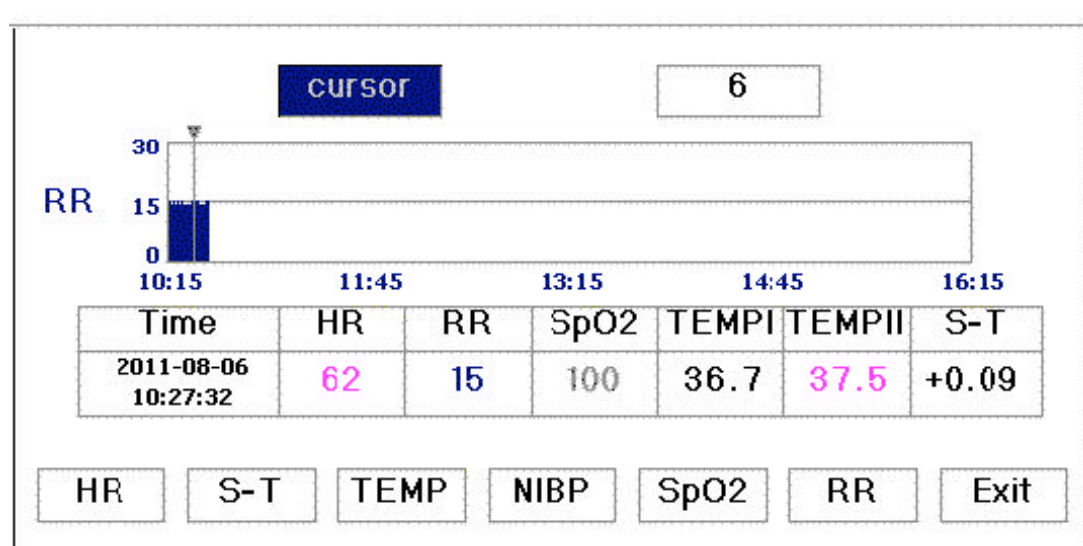


Figure 4.21 Respiration Graphic Trend

4.7.2 Operating Instructions

Rotate the knob, choose the parameter and press the knob to review the trend graph, and move the cursor to the Exit to exit the trend graph.

In the temperature trend graph, the Temperature 1 is dotted in white and Temperature 2 is dotted in green.

Press print key to print the trend graph on its corresponding Trend Graph Screen.

4.8 Recall Screen

Move the gray cursor to "RECALL" in mode selection screen and press the "Navigation Knob" to enter waveform Recall Screen, shown in Figure 4.22. In most cases, one hour will store one record. If the storing time of the record is less than one hour or change the patients within one hour, this record will be stored as a single one.

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



Figure 4.22 Waveform Recall Screen

Shown in Figure 4.23, it is different from the main screen in its 3rd waveform area and the operation area. We will explain them in detail below.



Figure 4.23 Recall listing

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 4.24.

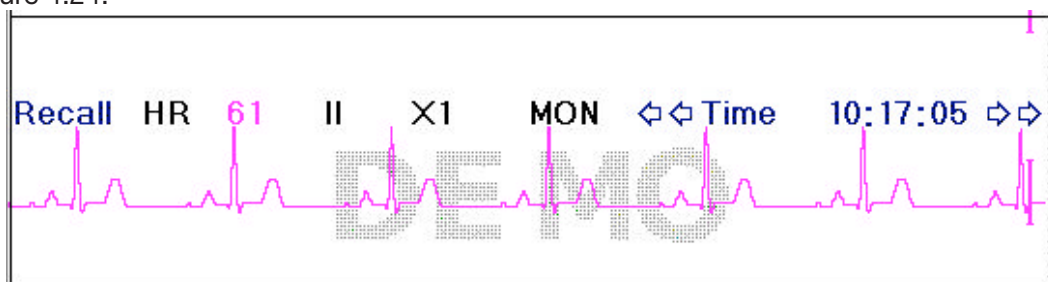


Figure 4.24
Recalled Waveform

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.

Hlst: Press the key to shift between the History key and Current key. Press Hlst 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 setup menu.

Press print key to print the recalled data list. If a piece of record is chosen, press print key to print lead ECG waveform and the recalled waveform on the Waveform Recall Screen.

4.9 ARR Screen

Move the gray cursor to “ARR” and press Navigation Knob to enter ARR screen, shown in Figure 4.25. The structure is similar to recall screen. We will cover each function key below.

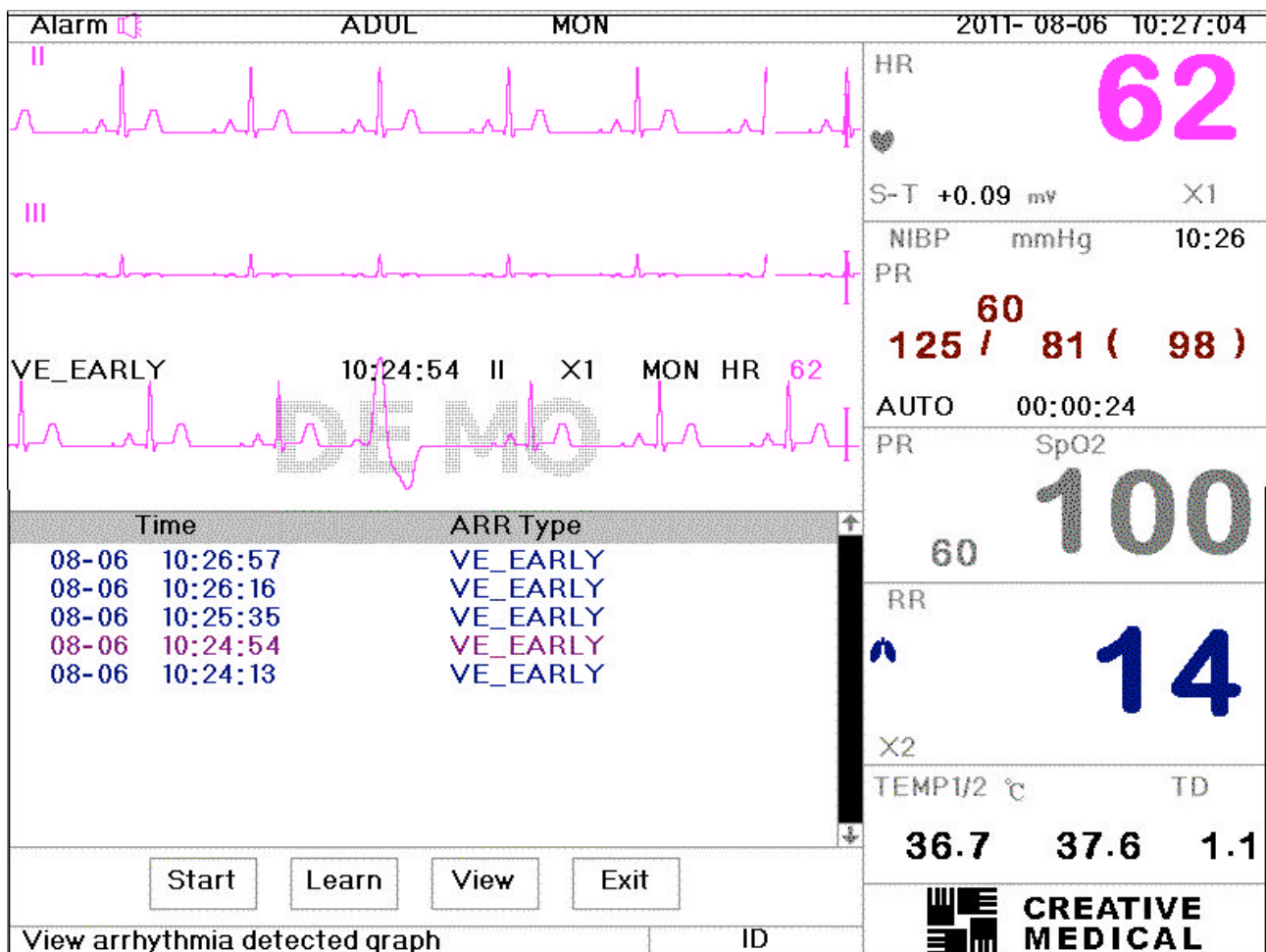


Figure 4.25 ARR screen

Start: This button is used to start and end the system ARR detection. The default is OFF. When the ARR 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 ARR detection is begins, the system will automatically detect the ARR waveforms. If ARR is detected, the ARR waveform will be displayed in the 3rd ECG channel, shown in Figure 4.25

When the system get Reset or the patient has change, the ARR needs to be re-learned.

Learn: Because the ARR detection is based on the normal ECG waveform at the same speed and same

amplitude, when the patient changes, or the ARR detection is incorrect, the ARR 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 ARR 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 ARR detection screen and return to the system menu.

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

During ARR 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 ARR detection.

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

☞ Press print key to print the arrhythmia data list. If a piece of record is chosen, press print key to print lead ECG waveform and arrhythmia waveform on the ARR Screen.

4.10 System Setup Screen

4.10.1 Screen Description

In the Mode Selection screen, move the cursor to the “SETUP”, and press it to enter system setup screen, shown in Figure 4.26.

To set up the system parameter, rotate the “Navigation Knob” to move the cursor to the corresponding button, and press it to perform corresponding settings.

At the same time, the RESET button returns the settings to the default value, but the patient document and the recalled data will not be changed. We will cover the functions of each button.

☞ Press print key to print its corresponding parameter settings on the 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.

SYSTEM PARAMETER SETTINGS

Type	ADUL	Mode	Demo	Lang	ENG
Fill	OFF	Frze	ECG	Disp2	7ECG
AlmVol	5	Key	ON	Beep	0
NetType	NET	IBP	OFF		
<div> <div>Sys</div> <div>Print</div> <div>ECG</div> <div>TEMP</div> <div>NIBP</div> <div>SpO2</div> <div>>></div> </div>					

Figure 4.26 System parameter settings

Type: The object being monitored, this can be selected among Adult, Infant and Neonate.

Adult: the object is adult.

Infant: the subject is pediatric.

Neonate: the subject is neonate.



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 and neonatal patient, or it can cause serious injury.

Mode: Monitor mode selection. 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: for setting the display language. The patient monitor is equipped with dual-language, the primary and secondary languages, which can be switched alternatively by user. The default language configuration is “ENG” (English) as the primary language, “” (Chinese) as the secondary language. The available secondary languages can be configured optionally with “” (Chinese), “ENG” (English), “PTG” (Portuguese), “CSK” (Czechish), “TRK” (Turkish) and “FRA” (French) etc.. For the special configuration without the secondary language, the display language is always “ENG” (English), and this setting item is gray so that it can not be set.

Fill: When the fill setting is ON, the display fills the volume for the SpO₂ 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, SpO₂, and Respiration. The factory default is “ECG”

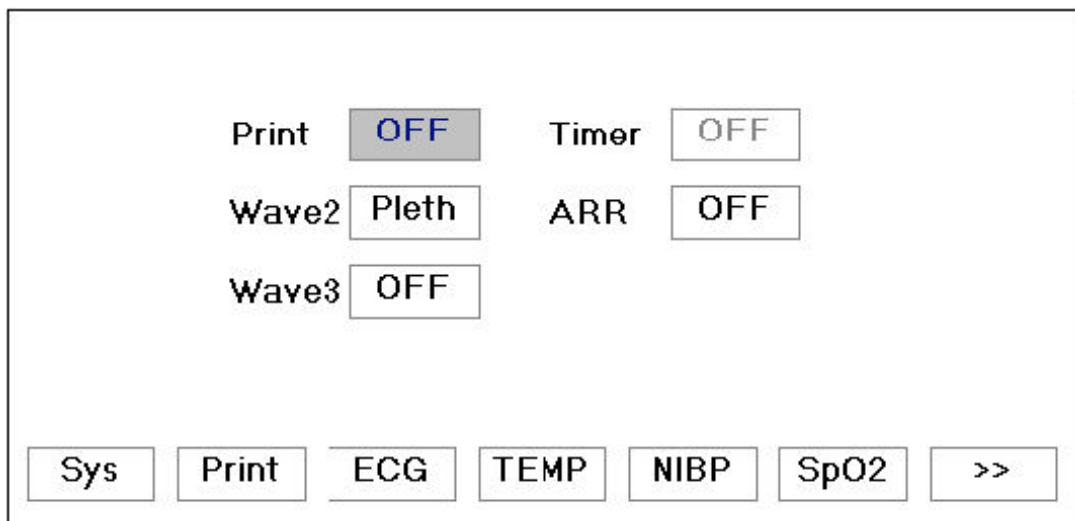
Disp2: The display 2. Two options: Obsev (Observation) and 7 ECG (7 ECG lead) can be selected. The factory default is Observation.

VOL: The sound volume. The maximum volume is 7 and minimum is 0, i.e. no sound. The default is 5.

Key: If the setting is ON, the press of the button will generate a keystroke sound. The factory default is ON.

Beep: The synchronous heart beat sound. The range of setting is “0~7”, The factory default is “5”

PRINTER SETTINGS



The image shows a printer settings menu. It contains the following settings:

- Print:** OFF (highlighted in gray)
- Timer:** OFF
- Wave2:** Pleth
- ARR:** OFF
- Wave3:** OFF

At the bottom, there is a navigation bar with the following buttons: Sys, Print, ECG, TEMP, NIBP, SpO₂, and >>.

Figure 4.27 Printer settings

Printer: the switch of printer setting, the printer can be used if you choose ON. This parameter does not have default, but the choice can be stored.

Timer: if Print 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 set is reached, the system will automatically take the record. The interval is 1, 2, 3, ...to 240 minutes.

Wave2: when built-in printer is selected, you can choose SpO₂, respiration, I, III, AVR, AVL, AVF, or V to be printed with II-lead ECG waveform. The default is SpO₂.

ARR: ARR triggering print. “ON” means the printer will trig once ARR occurs and record the ARR waveform information. The initial setting is “OFF” means close the ARR triggering record.

ECG PARAMETER SETTINGS

Lead	I	Gain	X1	HR	Hi	180
Speed	25	Mode	MON		Lo	40
Pace	OFF	1mV	OFF	S-T	Hi	+1.00
Notch	50Hz	Cable	5		Lo	-1.00

Sys	Print	ECG	TEMP	NIBP	SpO2	>>
-----	-------	-----	------	------	------	----

Figure 4.28 ECG settings

Lead: Can choose from I, II, III, AVR, AVL, AVF, V (V1-V6). The default is I.

Gain: The ECG gain, 5 options 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 5.10.

Speed: ECG display speed. 3 options: 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 that can filter out interference and present good ECG waves.

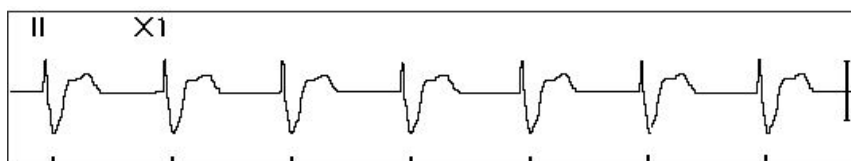
DIA: Diagnosis. No filtering, represent the true ECG without filtering.

OPE: Operation. Deep filtering, filtering 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

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. Factory default is OFF.

50Hz: 50 Hz frequency filter. The factory default is ON.

S-T Hi: The high limit value of S-T Segment

Lo: The low limit value of S-T Segment.

TEMPERATURE PARAMETER SETTINGS




TEMP1 Hi	39.0	TEMP2 Hi	39.0	Unit	°C
 Lo	35.0	 Lo	35.0	TD	 2.0
Sys	Print	ECG	TEMP	NIBP	SpO2 >>

Figure 4.29 Temperature settings

TEMP1 Hi: High limit of temperature 1 alarm

Lo: Low limit of temperature 1 alarm

TEMP2 Hi: High limit of temperature 2 alarm

Lo: Low limit of temperature 2 alarm

Unit: Temperature unit. The default is °C (Celsius) and it can be set to °F (Fahrenheit).

NIBP PARAMETER SETTINGS





SYS	Hi	180	DIA	Hi	120	MAP	Hi	160	PR	Hi	180
 Lo	60	 Lo	50	 Lo	50	 Lo	40				
Unit	mmHg	Mode	AUTO	Cycle	1						
NIBP Cali.	OFF	gas leak									
Sys	Print	ECG	TEMP	NIBP	SpO2	>>					

Figure 4.30 NIBP settings

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...480 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/Neonatal patient can cause serious injury.**

SYS Hi/Lo: High and Low limits of systolic pressure alarm

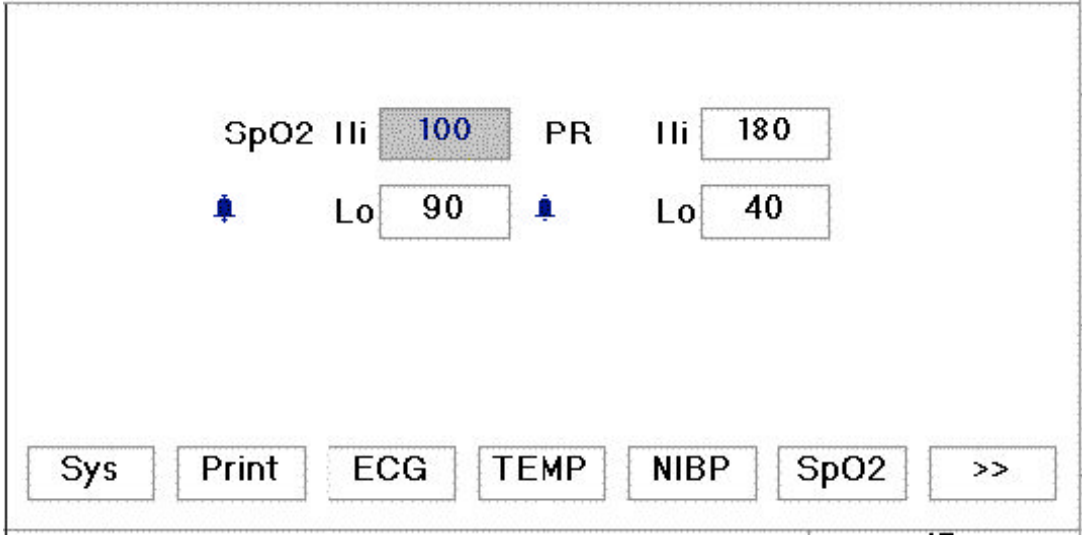
DIA Hi/Lo: High and Low limits of diastolic pressure alarm

MAP Hi/Lo: High and Low limits of MAP alarm

NIBP Cali: The NIBP Cali has three options: NIBP Cali Mode 1, NIBP Cali Mode 2 and OFF. Make sure the key is off with manual after the NIBP calibration, or the user could not do other operations. The factory default is OFF.

Gas Leak: For professional person to test gas leak on blood pressure .

SPO2 PARAMETER SETTINGS



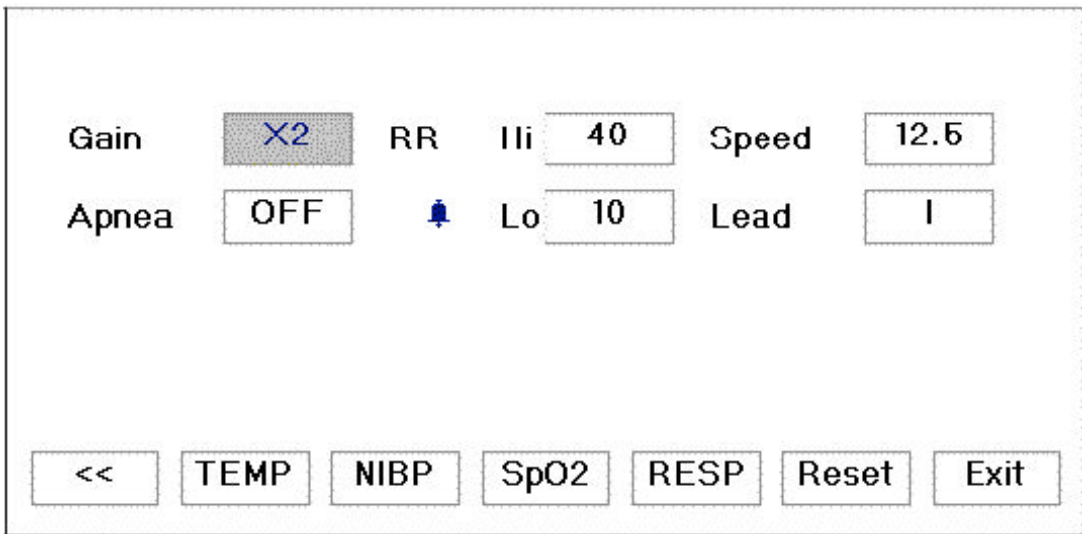
The screen displays SpO2 settings. At the top, 'SpO2 Ili' is set to 100 and 'PR Ili' is set to 180. Below these, 'Lo' values are set to 90 for SpO2 and 40 for PR, each preceded by a bell icon. At the bottom, a row of buttons includes 'Sys', 'Print', 'ECG', 'TEMP', 'NIBP', 'SpO2', and '>>'.

Figure 4.31 SpO₂ settings

SpO₂ Hi/Lo: High and Low limits of SpO₂ alarm

Pulse Hi/Lo: High and Low limits of pulse rate alarm

RESPIRATION PARAMETER SETTINGS



The screen displays respiration settings. 'Gain' is set to X2, 'RR Ili' is set to 40, and 'Speed' is set to 12.5. Below these, 'Apnea' is set to OFF, 'Lo' is set to 10 (preceded by a bell icon), and 'Lead' is set to I. At the bottom, a row of buttons includes '<<', 'TEMP', 'NIBP', 'SpO2', 'RESP', 'Reset', and 'Exit'.

Figure 4.32 Respiration settings

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

RESUME DEFAULT

On the screen as shown in Figure 4.32 rotate knob to choose “Reset” and then press the knob, all the value of parameters will resume default.

☞ See Appendix for default alarming values and setup range.

4.11 Color Settings

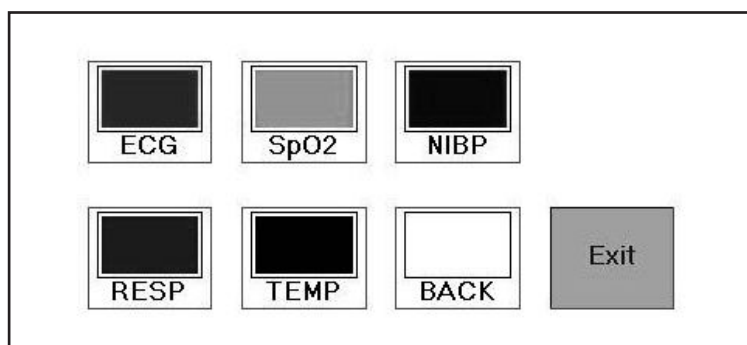



Figure 4.33 Color settings

Move the gray cursor to “Color” and press the “Navigation Knob” to enter the color setting screen, shown in Figure 4.33. In this screen, rotate the knob to choose the color, press and rotate to change the color. When the appropriate color is chosen press the knob again to save it.

Press the “Exit” to exit this color settings screen.

 Press print key to print lead II ECG waveform and waveform 2 which can be selected in the system menu on Color Setting Screen.

4.12 File/Archive Management Screen

ID	000001	Name	NoName
Bed		Sex	M
		Save	OFF
Age	30	Synchronisation	Exit

-----	0123456789ABCDEFGHIH IJKLMNOPQRSTUVWXYZ-	OK
-------	---	----

Figure 4.34 Document management screen

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 4.34.

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 4.8 for deletion methods.

Press print key to print lead II ECG waveform and waveform 2 which can be selected in the system menu on the Document Management Screen .

Chapter 5

CO₂ MONITORING

If your monitor has CO₂ monitoring function, please follow the instructions in this chapter to perform CO₂ monitoring on patient.

5.1 CO₂ Parameter Settings

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

Switch	<input checked="" type="checkbox"/> ON	Gain	<input type="text" value="X1"/>	Unit	<input type="text" value="mmHg"/>
RR	Hi <input type="text" value="40"/>	EtCO2Hi	<input type="text" value="70.0"/>	Ins	Hi <input type="text" value="10.0"/>
	Lo <input type="text" value="10"/>		Lo <input type="text" value="10.0"/>		Lo <input type="text" value="0"/>
Baro	<input type="text" value="760.0"/>	Zero	<input type="text" value="OFF"/>	Flow	<input type="text" value="50"/>
<div> <input data-bbox="427 1608 518 1653" type="button" value=" << "/> <input data-bbox="539 1608 630 1653" type="button" value=" SpO2 "/> <input data-bbox="651 1608 742 1653" type="button" value=" IBP1 "/> <input data-bbox="762 1608 853 1653" type="button" value=" IBP2 "/> <input data-bbox="874 1608 965 1653" type="button" value=" RESP "/> <input data-bbox="986 1608 1077 1653" type="button" value=" CO2 "/> <input data-bbox="1098 1608 1189 1653" type="button" value=" >> "/> </div>					

CO₂ Parameter Settings

Switch: choosing the mode of CO₂. It is recommended that the switch is turned on only when there is a need to monitor CO₂ parameter. This can not only reduce the power consumption and also extend the life of the CO₂ module.

In order to maintain the monitor, please set CO₂ switch at OFF state in system setup when CO₂ function is not used.

Gain: the CO₂ waveform gain.

Unit: Choosing the EtCO₂ and the minimum InsCO₂. It can be set up as kPa, mmHg, and %.

Respiration Rate High: Setting the upper alarm limit of CO₂ respiration rate.

Low: Setting the lower alarm limit of CO₂ respiration rate.

EtCO₂ High: Setting the upper alarm limit of EtCO₂.

Low: Setting the lower alarm limit of EtCO₂.

InsCO₂ High: Setting the upper alarm limit of InsCO₂.

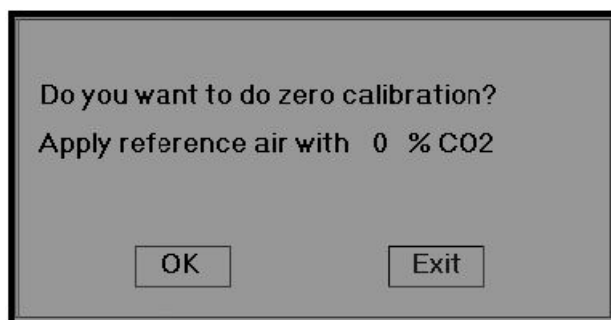
Low: Setting the lower alarm limit of InsCO₂.

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 CO₂ Readings at Altitudes for details.

Zero: The method to calibrate CO₂: Zero calibration. Calibration must be carried out in a drafty place, and the CO₂ module must have worked continuously for 5 minutes to ensure an accurate calibration, or the calibration will not work.

Flow (CO₂ flow): It is flow rate of the CO₂ sampling. Its value is 50ml/min.

The information promoted for Zero calibration is as follows:

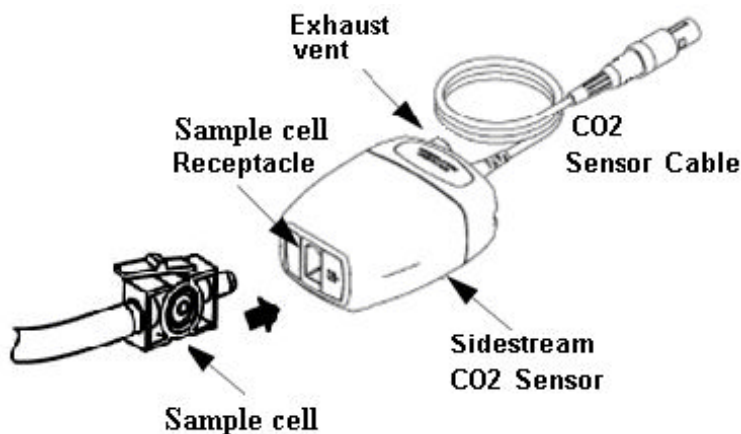


Please apply the reference air with 0% CO₂, the air in the drafty room usually can be regarded as the air with 0% CO₂. Press “OK”, and the result will be displayed on the screen several seconds later.

2. To set the color of CO₂ parameters on Color Settings screen.

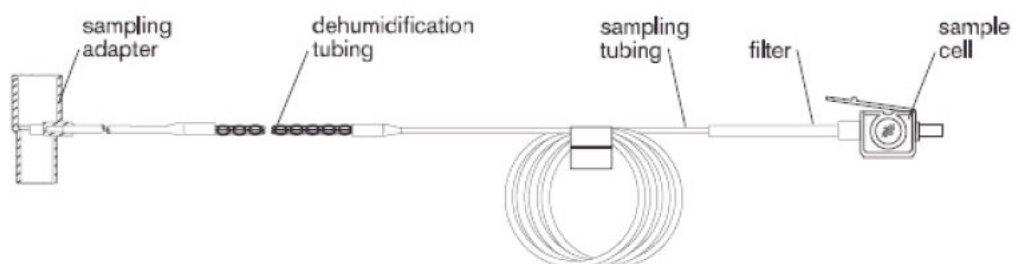
5.2 CO₂ Sensor Connection

5.2.1 Sidestream CO₂ Sensor Connection

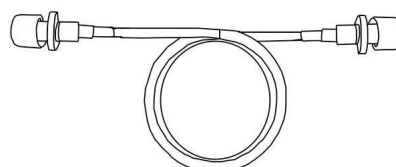


Demonstration for Sidestream CO₂ Sensor Connection

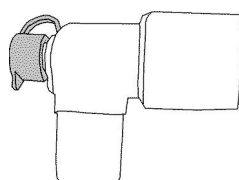
1. Take out the CO₂ Sensor and insert the CO₂ Sensor Cable into the connector labeled “CO₂” on the connector panel of the monitor;
2. The sample cell of the sampling cannula must be inserted into the sample cell receptacle of the CO₂ Sensor. A “click” will be heard when the sample cell is properly inserted. 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 CO₂, including the ventilator, the patient’s breath and your own. Next, turn on the CO₂ switch at CO₂ Setup Screen and then wait 2 minutes for the sensor warm-up.
3. Default Tubing Configuration



Adapter and Sampling tube (Single patient use)

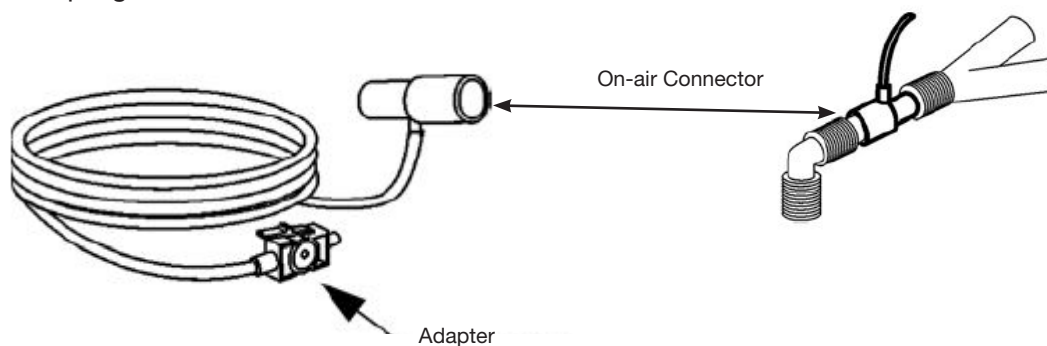


Extending airway tube for connecting to sampling tube (Single patient use)

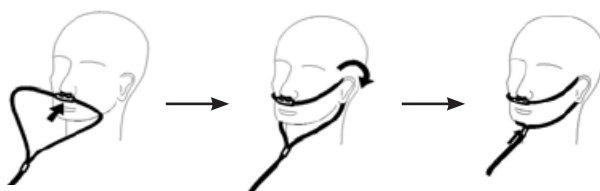


Wye Connector

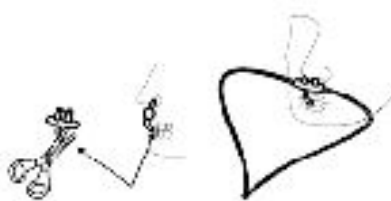
4. Optional sampling cannula kits



1) T connector sampling cannula kits

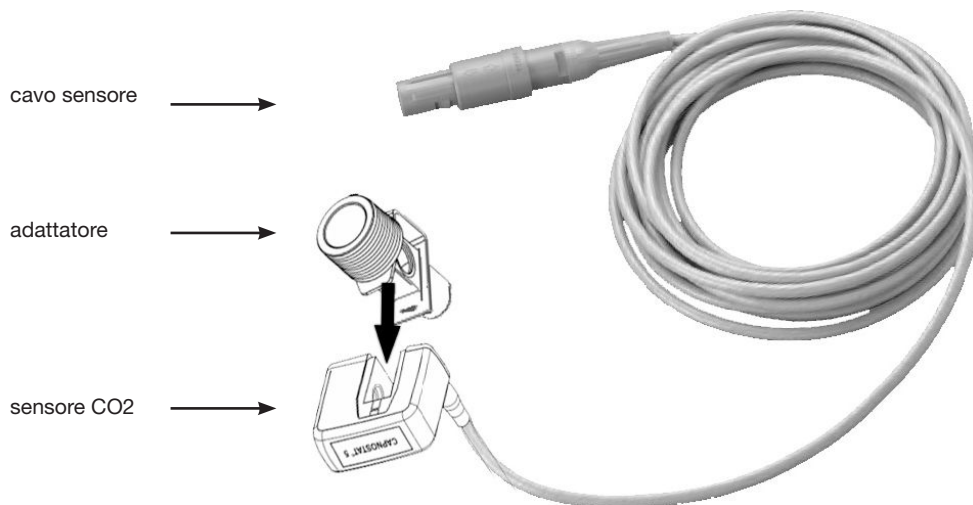


2) Nasal Sidestream Cannula Kits



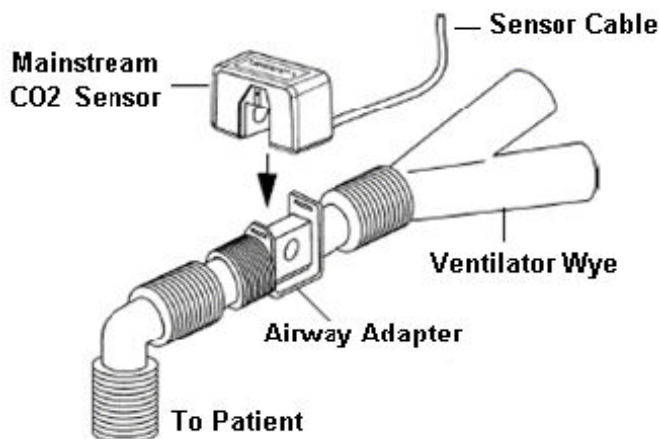
3) Oral Sidestream Cannula Kits

5.2.2 Mainstream CO₂ Sensor Connection



Demonstration for Mainstream CO₂ Sensor Connection

1. Take out the CO₂ Sensor and insert the CO₂ Sensor Cable into the connector labeled "CO₂" on the connector panel of the monitor;
2. Snap the CO₂ 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 CO₂ switch at CO₂ Setup Screen and then wait 2 minutes for the sensor warm-up.

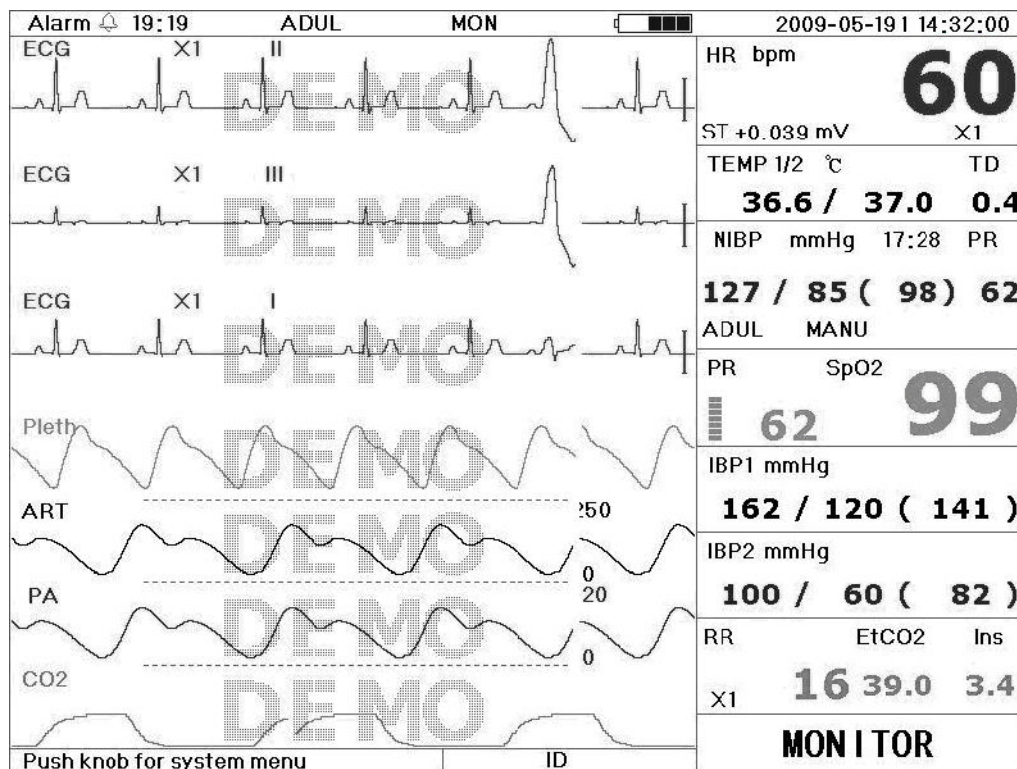


Safety Introductions for CO₂ Monitoring

- CO₂ 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 CO₂ 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 CO₂ 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 CO₂ waveform (Capnogram) appears abnormal, inspect the CO₂ airway adapters and replace if needed.
- ⚠ Periodically check the CO₂/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 CO₂ 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 CO₂ 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 CO₂ Sensor in liquids.
- ⚠ Replace the sidestream on-airway adapters and sidestream sampling kits if excessive secretions are observed.
- ⚠ Do not operate the CO₂ Sensor when it is wet or has exterior condensation.
- ⚠ Monitor the CO₂ 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 CO₂ Sensor in such environment may present an explosion hazard.
- ⚠ The power voltage over monitor working voltage may cause damage to CO₂ sensor. Likewise, too low power voltage may affect the CO₂ measuring accuracy or even make the CO₂ 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 abnormality 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 abnormality. 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 CO₂ sensor, a system leak, that may be caused by an uncuffed endotracheal tube or a damaged CO₂ sensor may significantly effect flow-related readings. These include flow, volume, pressure and other respiratory parameters.
- ⚠ When stopping CO₂ monitor, please disconnected the CO₂ sensor from the patient monitor.
- ⚠ Disposal of the CO₂ 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 CO₂ measurement.
- ⚠ Excessive moisture in the CO₂ may affect the accuracy of the flow measurement.

5.3 CO₂ Monitoring Screen



Waveform area

5th waveform: CO₂ waveform. It can be respiration waveform or CO₂ waveform.

Data area

RR	EtCO2	Ins
X1	16 39.0	3.4

RR, EtCO₂, and Ins Data Area

“RR”: Respiration Rate: The rpm after that is the unit of the respiration, i.e., respiration per min.

“EtCO₂ 39.0”: The label and the value will become gray when CO₂ is turned off.

Ins: The label of the minimal inhalational CO₂, the label and the value will become gray when CO₂ is turned off.

“16”: Respiration rate. It will display the respiration rate of CO₂, when the switch is turned on.

“X1”: Respiration gain (amplification):

“X1/2” half of the basic waveform

“X1” basic waveform

“X2” Twice the size of the basic waveform.

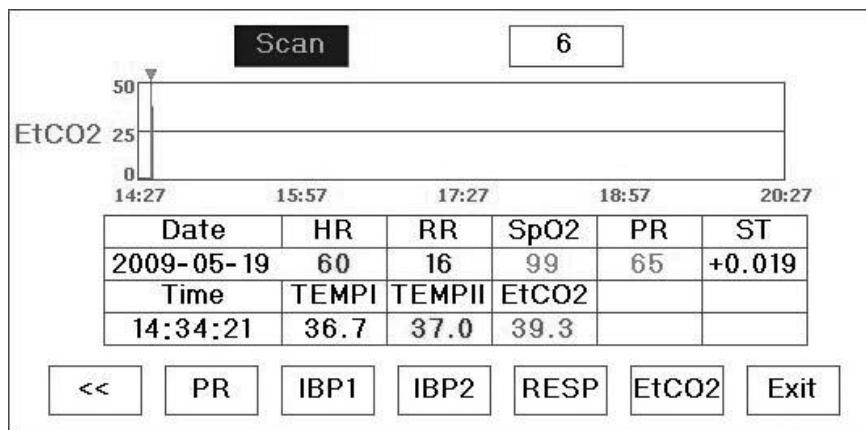
“X4” 4 times of the basic waveform

Observing Screen, 7 Leads on the Same Screen and other display screen will display CO₂ monitoring data as well besides Main Screen.

Note: only when the setting item “System Menu→SETUP→CO₂→Switch” is set as “ON”, CO₂ monitoring function is available.

5.4 CO₂ Graphic Trend

On Graphic Trend screen, rotate the knob and move the cursor to “CO₂”, then press the knob to enter EtCO₂ Graphic Trend. Refer to Chapter 4.5 Graphic Trend Screen for detailed instructions and operations.



EtCO2 Graphic Trend

Chapter 6

ALARM

6.1 Alarm Priority

High Priority:

- Over HR limit
- Over RR limit
- Over TEMP1 limit
- Over TEMP2 limit
- Over SpO₂ limit
- Over PR limit
- Over NIBP SYS limit
- Over NIBP DIA limit
- Over NIBP MAP limit
- Over EtCO₂ limit
- Over InsCO₂ limit
- Over TD limit
- Over ST limit
- Over NIBP PR limit
- ECG VPCEST
- Unable to detect HR
- Unable to detect SpO₂
- The battery capacity will exhaust

Medium Priority:

- VE RONT
- SVE RONT
- Lead Off
- Probe Off
- Sensor Over Temp
- Sensor Faulty
- Zero Required
- CO₂ Out of Range
- Check Airway Adapter
- Check Sampling Line
- The Sensor Off

Low Priority:

Other arrhythmia phenomenon (Except ECG VPCEST, VE RONT and SVE RONT, refer to 12.3 Abbreviation of arrhythmia for details).

6.2 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
Yellow flashing	Medium priority alarm	0.5 Hz
Yellow light	Low priority alarm	Constant(on)(non-flashing)



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


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

6.3 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.

6.4 Alarm Setting

In the Mode Selection 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 12.2 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.

6.5 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 7

TECHNICAL SPECIFICATIONS

7.1 ECG Monitoring

1. Input signals range in amplitude: \pm (0.5 mVp ~ 5 mVp)
2. Heart rate display range: 15 bpm ~ 350 bpm
3. Heart rate display accuracy: \pm 1% or \pm 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: \leq 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 \pm 2mV to \pm 700mV and duration 0.1 to 2 ms without overshoot;
Rejects all pulses of amplitude \pm 2mV to \pm 400mV and duration 0.1 to 2 ms with overshoot.
9. Sensitivity selection:

$\times 1/2$,	5mm/mV	tolerance: \pm 5%
$\times 1$,	10mm/mV	tolerance: \pm 5%
$\times 2$,	20mm/mV	tolerance: \pm 5%
10. Sweeping speed: 12.5mm/s, 25mm/s, 50mm/s tolerance: \pm 10%
11. ECG noise level: \leq 30 μ VP-P.
12. ECG input loop current: \leq 0.1 μ A
13. Differential input impedance: \geq 5M Ω
14. Common-mode rejection ratio (CMRR): \geq 89dB
15. Time constant: Monitoring mode: \geq 0.3s Diagnostic mode: \geq 3.2s
16. Frequency response: Monitoring mode: 0.5 Hz~40 Hz (+0.4dB, -3.0dB)
Diagnostic mode: 0.05 Hz~75 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

7.2 RESP Monitoring

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

7.3 TEMP Monitoring

1. TEMP measuring range: 25.0°C~45.0°C
2. TEMP measuring accuracy: $\pm 0.2^{\circ}\text{C}$
3. TEMP responding time: $\leq 150\text{s}$

7.4 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: <180 mmHg; Infant: <120 mmHg; Neonate: <90 mmHg
8. Overpressure protection limit
Adult: 300 mmHg; Infant: 240mmHg; Neonate: 150 mmHg
9. NIBP measurement range:

Press (unit)		Adult	Infant	Neonate
SYS	mmHg	40~255	40~200	40~135
MAP	mmHg	20~215	20~165	20~110
DIA	mmHg	10~195	10~150	10~95

10. NIBP accuracy: Maximum mean difference : ± 5 mmHg
Maximum standard deviation: 8 mmHg
11. Measurement mode: Manual, Auto, STAT

7.5 SpO₂ Monitoring

1. Probe: dual-wavelength LED
Wavelength: Red light: 660 nm, Infrared light: 905 nm.
Maximal optical output power: less than 2mW maximum average
2. SpO₂ measuring range: 35%~100%
3. SpO₂ measuring accuracy: not greater than 3% for SpO₂ range from 70% to 100%
***NOTE:** accuracy defined as root-mean-square value of deviation according to ISO 9919
4. Low perfusion performance: the declared accuracy is sustained when the pulse amplitude modulation ratio is as low as 0.4%

7.6 Pulse Monitoring

1. Pulse rate measuring range: 30bpm~240bpm
2. Pulse rate measurement accuracy: $\pm 2\text{bpm}$ or $\pm 2\%$, whichever is greater.

7.7 CO₂ Monitoring

1. Technology: Infrared absorption method.
 2. Mode of Sampling: Sidestream or Mainstream
 3. CO₂ Response Time:
Sidestream: <3seconds (including transport time and rise time).
Mainstream: <60ms (rise time)
 4. Warm-up Time: Not less than two minutes
 5. CO₂ measurement range: 0~150mmHg
 6. CO₂ Accuracy:

0~40mmHg	$\pm 2\text{mmHg}$
41~70mmHg	$\pm 5\%$ of reading
71~100mmHg	$\pm 8\%$ of reading
101~150mmHg	$\pm 10\%$ 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)

7.8 Data Recording

1. Sensitivity selection tolerance: $\pm 5\%$
2. Recording speed: 25mm/s
3. Recording speed accuracy: $\pm 10\%$
4. Hysteresis: $\leq 0.5\text{mm}$
5. Frequency response:
Monitoring mode: 0.5~40Hz Diagnostic mode: 0.05~75Hz
6. Time constant:
Monitoring mode: $\geq 0.3\text{s}$ Diagnostic mode: $\geq 3.2\text{s}$

7.9 Other Technical Specifications

1. Power supply: 100~240VAC, 50/60Hz
2. Power consumption: see the nameplate on the monitor
3. Display mode: 12.1 inches TFT color LCD
4. Alarming mode: Audible & visible alarm
5. Communication: Net port

7.10 Classification

Safety standard:	IEC 60601-1
The type of protection against electric shock	Class equipment
The degree of protection against electric shock	Type BF, CF applied parts
Electro-Magnetic Compatibility:	Group I, Class A

7.11 Guidance and manufacturer's declaration-Electromagnetic compatibility

Table 1

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

UP-7000 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	UP-7000 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	
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**

UP-7000 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 ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC61000-4-4	± 2 kV for power Supply lines ± 1 kV for input/output lines	± 2 kV for power Supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line (s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines 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


UP-7000 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of UP-7000 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 UP-7000 Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ 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. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>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 UP-7000 Patient Monitor is used exceeds the applicable RF compliance level above, UP-7000 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 UP-7000 Patient Monitor.</p> <p>b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			

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

UP-7000 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		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	80 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	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 8

PACKAGING AND ACCESSORIES

8.1 Packaging

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

Gross weight: Details see the indication on the outer package

Dimension: 500(L) × 320(W) × 460(H) mm

8.2 Accessories

1. ECG lead cable	One set
2. NIBP cuff	One set
3. SpO ₂ probe	One piece
4. Body temperature probe	One piece
5. Power supply cable	One piece
6. Equipotential grounding wire	One piece
7. Disposable electrode	Ten pieces
8. User Manual	One copy
9. Warranty	One copy
10. Quality certificate	One copy
11. Assembly report	Two copies
12. Dustproof mantle	One set
13. Printing paper (optional)	Ten rolls
14. 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.

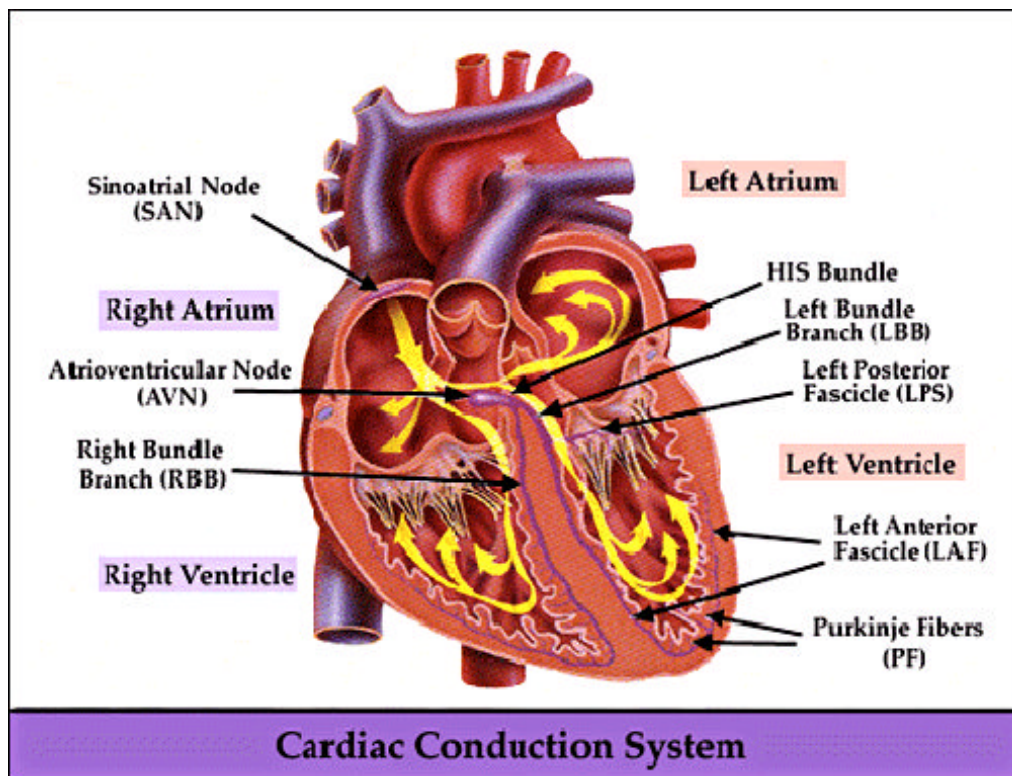
Chapter 9

PARAMETERS MONITORING

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.



First of all, the hospital should be equipped with a 100~250V power supply system with a typical grounding wire. If big interference in ECG continues, connect one end of the grounding wire provided with this equipment to the grounding wire on the back panel of this monitor, and the other end to the special grounding wire, water pipe or radiator.

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 uncleaned or poor contact caused by scurf and hair;
- Electrode long-time used.

9.2 NIBP Monitoring

9.2.1 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 SpO₂ 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.

9.2.2 Factors affecting NIBP measuring

Like common non-invasive blood pressure measurement, improper operation may cause inaccurate or blank result or misunderstanding of the measuring information when the oscillating method is used to take the measure of blood pressure. This point needs particular attention of the operators.

1. Requirements of the cuff:
 1. Appropriate cuff should be selected according to the age of the subject. For more information, see Chapter 3.
 2. Remember to empty the residual air in the cuff before the measurement is commenced.
 3. Locate the cuff in such a way that the "φ" mark is at a location where the clearest pulsation of brachial artery is observed.
 4. The cuff should be tightened to a degree where insertion of one finger is allowed.
 5. The lower end of the cuff should be 2cm above the elbow joint.
2. 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.
3. 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.
4. The measures 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.
5. With the oscillating method, when blood pressure is measured, the inflation pressure of the cuff will be automatically adjusted according to the previous measure. Generally, the initial inflation pressure is 180mmHg (for the adult mode) or 100mmHg (for the infant mode) or 80 mmHg (for the neonate mode) when it is powered on. Following that, 50mmHg (for the adult mode) or 30mmHg (for infant mode) or 10mmHg (for the neonate mode) will be added on the basis of the last measurement of systolic pressure. In this way, when the blood pressure rises or the subject is changed, the blood pressure meter may fail in giving the result after the first-time inflation. This monitor will automatically adjust the inflation pressure until the measure is taken, after that, up to four measures will be allowed.
6. When an adult subject is monitored, the machine may fail in giving the blood pressure measure if the infant or neonate mode is selected.

9.2.3 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.

Operation Introduction:

1. Take a measurement in manual mode:
 - Enter into the screen of NIBP setting, select “Mode” option and set it as “MANU”, and then press the NIBP key on the front panel to start measure. If press the NIBP key again, the measurement will be stopped.
 - During the automatic measurement interval when no NIBP measurement is taken, press the NIBP key, a measurement in manual mode will be taken. If at this time press the NIBP key again, the manual mode will be stopped and continue the automatic mode.
2. Take a measurement in automatic mode:
Enter into the screen of NIBP setting, select “Cycle” option and select time interval according needs, then press the NIBP key on the front panel to start the automatic measurement at a certain interval.
3. Stop automatic measurement
In the procedure of automatic measurement, press the NIBP key at any time, the measurement will be stopped.
4. STAT measurement
Enter into the screen of NIBP settings, select Cycle option and set as STAT, the STAT measurement will be taken. This procedure will last for 5 minutes.
5. Stop STAT measurement on the halfway
In the procedure of STAT measurement, press the NIBP key at any time, the measurement will be stopped.

9.3 SpO₂ 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 (HbO₂) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO₂ can be determined. SpO₂ 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 SpO₂ Measurement Restrictions (interference reason)

1. The fingers should be properly placed (see the attached illustration of this instruction manual), or else it may cause inaccurate measurement result.
2. Make sure that capillary arterial vessel beneath the finger is penetrated through by red and infrared lights.
3. The SpO₂ sensor should not be used at a location or limb tied with arterial or blood pressure cuff or receiving intravenous injection.
4. Do not fix the SpO₂ sensor with adhesive tape, or else it may result in venous pulsation and consequential inaccurate measurement result of SpO₂.
5. Make sure the optical path is free from any optical obstacles like adhesive tape.
6. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, and direct sunlight etc.
7. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
8. Please do not use the SpO₂ sensor when having the MRI, or burn may be caused by faradism.
9. Always observe the plethysmogram (waveform), which is auto-scaled within the range of 100. The SpO₂ 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
10. A functional tester can not be used to assess the accuracy of the pulse oximeter monitor or a SpO₂ sensor. However, a functional tester, such as SpO₂ 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.

Clinical Limit

1. 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 SpO₂ waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. 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 SpO₂ determination by this monitor may be inaccurate.
3. The drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO₂ measurements.
4. As the SpO₂ value serves as a reference value for judgement of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO₂ value.

9.4 Respiration Monitoring

9.4.1 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.

9.4.2 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 artificial error may occur.
- Respiration monitoring doesn't support monitoring the patient who do much movement, or may lead to wrong alarm.

9.5 Temperature Monitoring

The sensor is thermo-resistor type (25°C 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°C~37°C; inside body cavity: 36.5°C~37.7°C

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.

9.6 CO₂ Monitoring

9.6.1 Measuring Principle

The principle is based on the fact that CO₂ molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO₂ concentration. When an IR light beam is passed through a gas sample containing CO₂, 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 CO₂ concentration in the sample. To calibrated, the photodetector's response to a known concentration of CO₂ is stored in the monitor's memory.

The monitor determines CO₂ concentration in the breathing gases by measuring the amount of light absorbed by these gases. EtCO₂ is display as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO₂ 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.

9.6.2 Mainstream vs. Sidestream Sampling

Mainstream CO₂ 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 CO₂ 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 CO₂ 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 CO₂ 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.

Chapter 10

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 cabinet without permission

10.1 No Display on the Screen

Shut down the machine and unplug the power cable. Use a universal meter to check if the outlet has proper voltage, if the power cable is in good condition, and if the power cable 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.

10.2 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.
3. Make sure the mains outlet has standard grounding wire.
4. Check if the grounding wire of the apparatus properly grounded.

10.3 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 SpO₂ jack on the side panel.
2. If the problems still exist, please contact the manufacturer.

10.4 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 11

MAINTENANCE

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

11.1 Service and Examination

11.1.1 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;
- Make sure that the monitor is grounded properly.
- 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.

11.1.2 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.

11.2 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 -10 ° or above 40 ° ;
- ⚠ Dispose of the battery, the local law should be followed.
- 🔔 In order to maintain battery supply time and prolong battery lifetime, please charge the battery every one or two months if don't use battery for a long time. And do charge battery at least 12-15 hours every time. Before connect to AC, do start monitor with battery's power supply, until battery power is used up and monitor turn off automatically, then connect monitor to AC and have it charged for 12-15 hours continuously. The speed of charge will be the same no matter whether the monitor is working or not. The reason why discharge the battery before charge is to avoid the decrease of capacity caused by battery's memory effect. If the monitor won't be used for a long time, do have it charged fully before conservation.
- 🔔 When starting the monitor by battery power only which is short of supply, monitor will turn off automatically. In order to avoid the damage to battery caused by excessive discharge, please pay attention to following. After monitor turns off automatically, there is still small drain current inside battery, so it is suggested that user should press the power button again to cut off the power supply. If battery keeps in a state of small drain current, battery will be damaged and can't be repaired because of excessive discharged.

- 🔔 If battery is damaged, please replace with same type and specification battery marked by “CCC” or “CE” in time, or contact the company directly.

11.3 Cleaning, Sterilization and Disinfection

- 🔌 Switch off the monitor and disconnect the power cable 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.
- This 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.
- 🔔 Do not pour the disinfectant on its surface while sterilization.
- 🔔 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.
- 🔔 Never use this machine in an environment with inflammable gas.
- 🔔 Avoid being hit by lightning. The power cable should be plugged into an outlet with grounding wire. Do not use an outlet with poor condition. If possible, use power supply system with regulator.
- 🔔 It must be used in a clean environment protected against shock. Keep it away from corrosive substances, explosive substances, high temperature and dampness.
- 🔔 If it is installed in a cabinet, make sure the installation allows for good ventilation, and easy maintenance, observation and operation.

11.4 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% Isopropanol before use.

- 🔌 Do not use damaged accessories.
- 🔌 Accessories can not be entirely immersed into water, liquor or cleanser.
- 🔌 Do not use radial, steam or epoxyethane to disinfect accessories.
- 🔌 Do wipe off the remained alcohol or isopropanol on the accessories after disinfection, for good maintenance can extend the life of accessories.

11.5 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%~95%
 atmosphere: 53kPa~106kPa

11.6 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 12

APPENDIX

12.1 Alarm Information

Alarm Information	Descriptions
Over HR limit	The related parameter value exceeds the preset high/low alarm limit
Over RR limit	
Over TEMP 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

12.2 Default Alarming Values and Setup Range

The default alarming value:

Mode - Parameter			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:

Mode - Parameter			Adult	Infant	Neonate
Heart Rate		High limit	1~300bpm	1~350bpm	1~350bpm
		Low limit	0~299bpm	0~349bpm	0~349bpm
Respiration		High limit	1~120rpm	1~150rpm	1~150rpm
		Low limit	0~119rpm	0~149rpm	0~149rpm
Temperature		High limit	0.1~50°C	0.1~50°C	0.1~50°C
		Low limit	0~49. 9°C	0~49. 9°C	0~49. 9°C
Systolic		High limit	31~270 mmHg	31~200 mmHg	31~135 mmHg
		Low limit	30~269 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°C	0.0~5.0°C	0.0~5.0°C
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

12.3 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

12.4 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 or neonatal 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.

12.5 Status/Error during CO₂ 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 °C
"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
"CO₂ 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 message both prompt message both prompt one or more of the following conditions may exist: <ul style="list-style-type: none"> • 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

12.6 Typical Pressures and CO₂ Readings at Altitudes

Altitude	Barometric Pressure(mmHg)	EtCO ₂ Reading	
		(%)	(mmHg)
0 m	760	5	38.0
70 m	754	5	37.7
100 m	751	5	37.5
200 m	743	5	37.1
1500 m	641	5	32.0
3000 m	537	5	26.8
5000 m	420	5	21.0

12.7 Accessories List

Part No.	Part Name	Remark
15010513	ECG cable	
5101-0101310	ECG electrode	
15044051	Adult SpO ₂ Finger clip Sensor	
15044061	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 (6cm~11cm)	Optional
15022402	Middle-sized Pediatric NIBP Cuff (10cm~19cm)	Optional
15023402	Large-sized Pediatric NIBP Cuff(18cm~26cm)	Optional
15084120	Skin TEMP probe	
15100420	CO ₂ Mainstream sensor	Optional for mainstream
15100411	Adult airway adapter	Optional for mainstream
15100421	Pediatric airway adapter	Optional for mainstream
15100410	CO ₂ Sidestream sensor	Optional for sidestream
15100130	Sampling line kit	Optional for sidestream
15100214	Extending airway tube	Optional for sidestream
15100210	Wye connector	Optional for sidestream
2903-0000000	Power cord	
900093	Net wire	

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

12.8 Instructions for SpO₂ Probe

Instructions for Pediatric SpO₂ Finger Clip Sensor

Intended Use

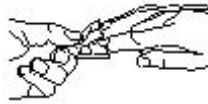
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO₂) and pulse rate monitoring for pediatric patients weighing between 10~40kg.

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.



(A)



(B)



(C)

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 constraining 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 SpO₂ Finger Rubber Sensor

Intended Use

When used with a compatible patient monitor or a pulse oximeter device, this SpO₂ sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO₂) and pulse rate monitoring for patients weighing greater than 50kg.

Contraindications

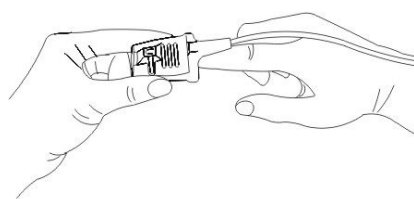
This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

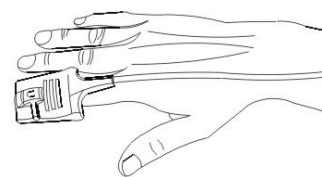
1. Hold the sensor with its opening towards the patient's index finger (A). The sensor should be oriented in such a way that the sensor side with a finger tip sign is positioned on the top.
2. Insert the patient's index finger into the sensor until the fingernail tip rests against the stop at the end 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.
- 4) Inspect the monitoring site every 1~2 hours for skin integrity.



(A)



(B)

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 constraining 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 SpO₂ 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 (SpO₂) 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.



(A)



(B)



(C)

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.



Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA.

During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included. All components subject to wear are not included in the warranty. The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.

The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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