

Patient Monitor

UP-9000

User Manual (Version 1.0)

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-9000 Patient Monitor.

The Manual describes, in accordance with the UP-9000 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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Version of This Manual: Ver 1.0

Revised date: October 22, 2012

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Marks in the Manual:

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

Instructions to User

Dear Users,

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

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 abnormity, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

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

who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.

- DO NOT take blood pressure measurement from a limb receiving ongoing transfusion or intubations or skin lesion area, otherwise, damages may be caused to the limb.
- Continuous use of 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.

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Chapter 1 Overview

1.1 Features

UP-9000 Patient Monitor is the combination of the functions of patient monitor, which can 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.

- ☆ 15" high-resolution color LCD to display patient's ECG waveform, respiration waveform, SpO₂ cubage waveform, NIBP waveform, and CO₂ waveform;
- ♦ User-friendly and intuitive display interface, multiple configuration of ECG waveform display:

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

Observing screen view: heart rate value and SpO2 value display in big fonts.

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

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

- ♦ Battery power indicator, which enables real-time battery power detection and displays the battery power.
- ☆ The cuff can be also used as a tourniquet, which is convenient and practical in use as an additional function, and different cuff pressure can be set according to patient's condition.
- ♦ Up to 20 types of arrhythmia can be analyzed automatically, waveform freezing is available and automatic S-T segment measurement.
- ☆ "8/24/120/480 hours" trend graph analysis function, under working status, up to 120 hours trend data can be stored, including HR, Temp, SpO₂, RR, IBP and NIBP etc. trends;
- ♦ Up to 100 groups of arrhythmia events' data can be stored, as well as the corresponding ECG, Temp, SpO₂, RESP and pulse value of each case;
- ☆ Up to 1000 groups of NIBP measurement can be stored, as well as the corresponding HR, Temp, RR, SpO₂ and PR while the blood pressure measurement is taken, it can be recalled by list table or graphic trend.
- ♦ Up to 14 hours store and recall ECG waveform data eternally even if the device is out of power;
- ✤ Unique file management, which enables recording, modifying, deleting and saving operation of patient's information.
- Displays heart rate trend, SpO₂ trend, respiration trend or waveform simultaneously on oxyCRG screen, to know the instantaneous condition change of neonate.
- ♦ Accurate NIBP measurement with over-pressure protection.
- ♦ Software and hardware-dual excessive air pressure protection function;
- \diamond Unique pulse oximetry technique achieves accurate SpO₂ and pulse rate measurement;
- ♦ Multiple interface monitoring, which enables simultaneous monitoring of several ECG waveforms;
- Precise alarm system, different alarm events adopt different alarm degrees; 3 degrees visual and audible alarm function;

- ♦ Flexible high and low alarm limits setting function;
- Easy to color-code and change the color of the font, background and waveforms if needed;
- \diamond Cardiac pacemaker restraining function enables to be used along with cardiac pacemaker;
- ♦ Protection against defibrillator and resistance against the interference from electrosurgical unit.
- 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;
- \diamond CO₂ and IBP measuring functions are optional.
- ♦ Built-in printer to output waveforms and text;

1.2 Product Name and Model

Product name: Patient Monitor Model: UP-9000

1.3 Scope of Application

UP-9000 Patient Monitor is designed for monitoring patient's ECG, respiration value, body temperature value, non-invasive blood pressure value, pulse oxygen saturation value, pulse rate and other physiological parameters.

This equipment is applicable for use in major, medium and small-sized hospitals, clinics, and health practitioner's office etc. medical unit. The operation should be performed by qualified professionals only.

1.4 Operating Environment

- Ambient temperature range: 5 °C °C Relative humidity: 30%~80% Atmospheric pressure: 70kPa~106kPa Power supply: 100~240VAC Power frequency: 50/60Hz
- 2. This device should be situated in a place protected against direct sunlight, so as to prevent overheat inside it.
- 3. Do not use this device in an environment with toxic or inflammable gas.
- 4. This device should be fixed on a stand, so as to prevent possible shock.
- 5. Do not use 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 equal-potential grounding terminal is grounded correctly.
- 8. Do not use mobile phone nearby, so as to avoid strong radiant field interference.

1.5 Impact on the Environment and Resources

Low

1.6 Safety

- a) This device conforms to IEC60601-1, electric safety classification: Class I, with Type BF and CF applied parts.
- b) This device can resist against the discharge of defibrillator and the interference of electro-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

2.1 Overall Structure

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

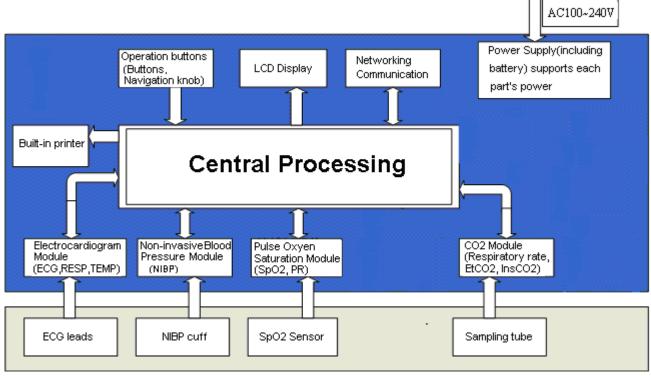


Figure. 2.1

2.2 Composition

- 1. The monitor consists of the main units and the corresponding functional components (ECG leads, non-invasive blood pressure cuff, SpO₂ probe, temperature transducer, appendix of invasive blood pressure and side-stream CO₂).
- 2. The patient monitor has 6 measurement channels: the ECG and respiration channel, the NIBP channel, the SpO₂, pulse channel, the temperature channel, IBP channel, and EtCO₂, InsCO₂ channel.
- 3. The patient monitor has two output channels: the networking communication port and the printer.
- 4. Basic parameters include: heart rate, respiration rate, EtCO₂, InsCO₂, temperature, SpO₂, NIBP and pulse.

2.3 Working Theories

UP-9000 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, SpO_2 module, IBP module, CO_2 module and the main unit.

1. The ECG module collects the heart rate, respiration waveforms through the ECG leads 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 three modes: adult, infant and neonate.
- 4. The IBP module collects the data and the waveforms of invasive blood pressure through the IBP cable.
- 5. The CO_2 module collects the data of respiration rate, $EtCO_2$, $InsCO_2$ through the sampling tube.
- 6. 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, SpO_2 module, NIBP module, IBP module, and CO_2 module.

Chapter 3 Installation and Connection

3.1 Installation

3.1.1 Opening the Box and Check

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

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

3.1.2 Connecting the AC Power Cable

Connecting procedures:

- 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.
- Connect the monitor to the grounding port with the provided ground cable.

Caution: ensure that the monitor is grounded correctly.

3.1.3 Starting the Monitor

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

- Check all the applicable functions to make sure that the monitor works normally.
- If the built-in battery is applied, please recharge it after the monitor is used to ensure sufficient power storage.
- Do not use the device to monitor the patient if the device appears obvious damage or indication of fault. Please contact the local dealer or our company.
- \bigcirc After the monitor is switched off, it's recommended to delay 1 minute to restart it.

3.2 Appearance

3.2.1 Front Panel



Figure 3.1 Front Panel

l. 🙆: Power switch

Press it for 3 seconds to turn on or turn off the monitor.

2. \sim : AC indicator

When AC indicator is on, it means this device is using mains power supply.

3. E Built-in DC power indicator

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.

Click it to shift the ECG monitoring circulatory among I, II, and III, aVR, aVL, aVF and V.

5. Alarm silence

Press this key to set or activate the system alarm silence function.

In the monitoring screen, press (Alarm) to set the alarm silent time. The time shows up on the lower 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.

The alarm silent time has four options: 2 minutes, 5 minutes, 10 minutes and 20 minutes, or the system alarm is in the alarm status.

6. 🗱 : Freeze

Press this key to freeze ECG waveforms or the waveforms of ECG, SpO_2 and RESP for S-T segment analysis according to system setting.

7. 🕗: NIBP

Press it to start or stop NIBP measure.

8. 🕒 : Print

Press it to print different waveforms of different status according to system setups.

In the main menu print lead **E**CG waveform and the second waveform, this can be selected in the system menu.

9. Display

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.

Rotate it to the left or right to select functions or parameters. Press and release it to shift the screen and to confirm the function or other operating tips.

The majority operations of this system are finished by navigation knob.

11. Alarm indicator

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

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

The cable and transducer ports are at the right panel, shown as Figure 3.3.

- (1) TEMP1, TEMP2: TEMP probe connector
- (2) NIBP: NIBP hose connector
- (3) SpO_2 : SpO_2 sensor connector

- (4) ECG/RESP: ECG cable connector
- (5) CO_2 : CO_2 sensor connector
- (6) Battery cover, remove the cover to install or change rechargeable battery. Factory default: two rechargeable batteries (12V 2.3Ah); battery specification: FB 12V 2300mAh.

 \triangle "TO AVOID BATTERY DAMAGE, ALWAYS REMOVE BATTERY(S) BEFORE SHIPPING OR STORAGE"

- ★ Type BF
- Type CF and applicable during the defibrillator is used
- A 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) $\mathbf{\nabla}$: Equipotential ground port
- (4) "FUSE 2×T3.15 A": fuse holders; fuse specification: T3.15AL/250V Φ 5×20mm.
- (5) AC100~240V: Power supply socket
- (6) S/N: Serial number
- (7) Nameplate

CE	CE mark
SN	Serial number
M	Date of manufacture
EC REP	Authorised representative in the European community
	Manufacturer (including address and date)
X	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. Recovery time after application of defibrillator pulses may be especially compromised.
- 3. Prepare the electrode sites according to the electrode manufacturer's instructions.
- 4. Skin clean
- Clean and dry-abrade skin to ensure low sensor impedance. Mild soap and Water is recommended as a skin cleanser.

Note: Alcohol is not recommended as a skin cleanser; 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:

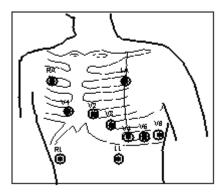


Figure 3.5 Electrode Location

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.

A It might not display ECG wave with 3 leads. Five leads should be used to have ECG wave.

Sy	mbol	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				
	C1(V1)					
C (V)	C2(V2)					
	C3 (V3)	The electrodes are placed in different places, the different lead forms will display.				
Chest	C4 (V4)					
electrode	C5 (V5)					
	C6 (V6)					

6. The ECG leads and their corresponding locations are as follows:

Safety Instructions for ECG Monitoring

- ⊕ UP-9000 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 cables are forbidden to contact any other electric parts (including ground).
- DP-9000 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 the electrodes and cable are placed proper positions according to this manual's instructions and the instructions for using electrode, the chance to occur this transient will be decreased.
- To the patient with pacemaker, because this device has been designed to resist against the interference of pacemaker, generally the pacemaker pulse is not counted in heart rate measurement and calculation unless the cycle time of pacemaker pulse is over 2ms. 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.
- The improper connection with electrosurgical unit may not only cause burns, but also damage 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 items of monitor are interconnected.

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:

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

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

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

2) When putting on the cuff, unveil and wrap it around the upper arm evenly to appropriate tightness.

- 3) Remember to empty the residual air in the cuff before the measurement is commenced.
- 4) Locate the cuff in such a way that the " ϕ " mark is at a location where the clearest pulsation of brachial artery is observed.
- 5) The cuff should be tightened to a degree where insertion of one finger is allowed.
- 6) The lower end of the cuff should be 2cm above the elbow joint.

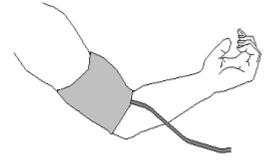


Figure 3.6 Cuff Position

Pressure Accuracy Verification

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

Before verification, please connect the monitor to a standard pressure meter as the reference equipment like a mercury pressure meter

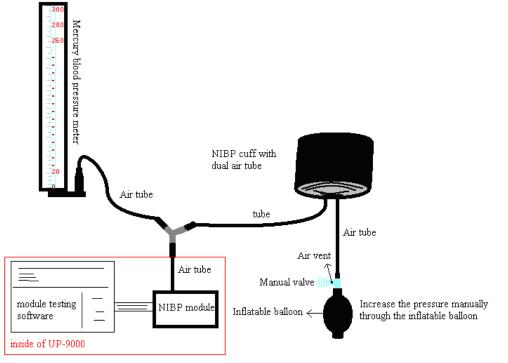


Figure 3.7 Connection of Pressure calibration fixture

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

Adult		240mmHg
Child		200mmHg
Neonate		120mmHg
	Table A	

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

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

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

Adult	300mmHg
Child	240mmHg
Neonate	140mmHg
	Table B

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

> Air Leakage Check

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

\bigcirc Please remove the cuff from patient while performing the leakage check.

Safety Instructions for NIBP Monitoring

- 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 taken 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 move the cuff to other positions. Doctor should examine this timely.
- The time of the automatic pattern noninvasive blood pressure measurement pulls too long, then the body connected with the cuff possibly have the purpura, lack the blood and the neuralgia. When guarding patient, it is a must to inspect the luster, the warmth and the sensitivity of the body far-end

frequently. Once any exception is observed, please stop the blood pressure measurement immediately.

- Do not speak or move before or during the measurement. Take care to avoid that the cuff will not be hit or touched by other objects.
- G 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 in 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.
- A 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.
- A 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 To connect the SpO₂

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

Operation procedure:

- 1. Connect the 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.

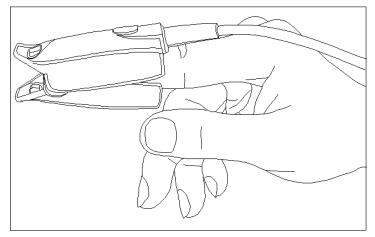


Figure 3.8 Demonstration for SpO₂ probe

When selecting a sensor, do consider the patient's category, adequacy of perfusion, availability of probe site and anticipated monitoring duration. Use only SpO_2 probes provided by our company with this monitor. Read the following table for SpO_2 probe information. Refer to Chapter 12.8 for the detailed instructions of each SpO_2 probe.

SpO2 Probe	Patient Category
SpO2 Finger clip Sensor (reusable)	Pediatric
SpO2 Finger rubber Sensor(reusable)	Adult
SpO2 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 SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

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

If patient movement presents a problem, verify that the sensor is properly and securely applied; move the sensor to a less active site; use an adhesive sensor that tolerates some patient motion; or use a new sensor with fresh adhesive backing.

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

Safety Introductions for 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.
- 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.
- \bigcirc Do NOT use the damaged SpO₂ sensor.
- \bigcirc Please do not allow the cable to be twisted or bended.
- △ Please do not use nail polisher or other cosmetic product on the nail.
- \bigcirc The fingernail should be of normal length.
- \bigcirc The SpO₂ sensor cannot be immerged into water, liquor or cleanser completely, because the sensor has no capability to resist the harmful ingress of water.

3.3.4 TEMP Transducer Connection

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

Connecting methods:

- 1. Attach the transducers to the patient firmly;
- 2. Connect them to "TEMP1" or "TEMP2" 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 Battery Installation

- 1. Make sure that monitor doesn't connect to mains power supply and stays in switch-off status.
- 2. Open the battery cover, insert the battery into any slot of battery compartment, and pay attention to the instruction of polarity direction in the compartment. Do not reverse the battery.
- 3. Move baffle plate with hand to fasten the battery.
- 4. Remove the battery cover. (According to your need, you can insert one more storage battery to prolong using time.)
- \triangle Please take out the battery from battery compartment, if it won't be used for a long time.

3.3.6 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.

Operation procedures for taking out printing paper roll:

 $1\sim2$ steps are the same with the $1\sim2$ steps mentioned above for loading printing paper.

3. Roll the loading roller anti-clockwise and pull the paper out.

 $4\sim5$ steps are the same with the $6\sim7$ steps mentioned above for loading printing paper.

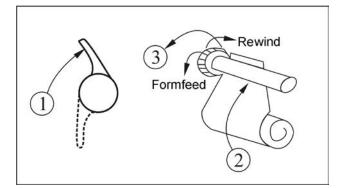


Figure 3.9 Loading and taking out printing paper

P8 printer may be used due to the different configuration. P8 printer operation instruction:

Power indicator: green light shows the power is on, while the monitor is out of power, the green light is off.

Error indicator: red light is constant which shows the printer is out of paper, or the printing paper does not install well. When the printer installs normally, the red light is off.



Figure 3.10 P8 printer

Loading printing paper:

Step 1: press and hold down the cartridge button to open the paper cartridge;

Step 2: Install the paper to the printer properly, pull the paper out of the printer for 2 cm, as shown in figure 3.11.

Step 3: Close the printer cover along the direction of arrow, as shown in figure 3.11.



Figure 3.11 printing paper

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 as Figure 4.1:

	Time Setup				
Date	2005 - 08 - 17	Edit			
Time	15 : 16 : 32	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 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. Then move the cursor to "Exit", press it to exit the date and time setting screen, meanwhile enter into the main screen shown in Figure 4.2.

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

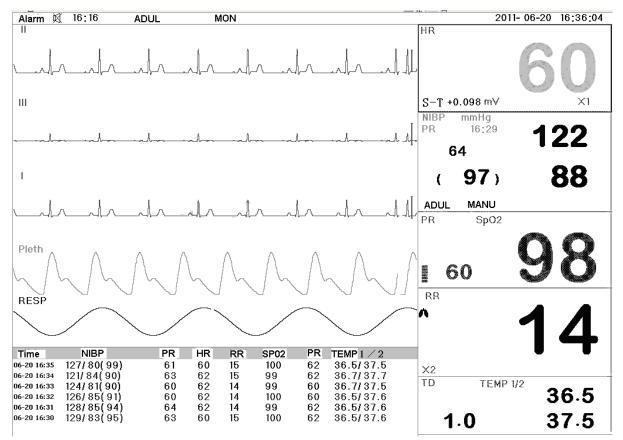


Figure 4.2 Main Screen

Navigation knob has two functions in main menu screen:

1. Long time press the navigation knob about 3 seconds to enter system menu screen.

2. Rotate navigation knob to choose corresponding parameter area circularly in data area, short time press navigation knob about 1 second to enter corresponding parameter setting screen. That is to say, adding the shortcut operation on the main screen, it is convenient to set each parameter's menu.

Border area:

- ♦ "Alarm ⁽¹⁾: ⁽¹⁾ shows the alarm is ON, and ⁽¹⁾ shows the alarm is OFF, the numbers after ⁽¹⁾ is the time when the alarm will on. The alarm will be activated automatically after the system finishes counting down.
- ♦ "ADUL": The patient type. There are three selectable patient types: "Adult", "Infant" and "Neonate".
- ☆ "MON": ECG Filter type. There are three types: "Diagnosis", "Monitor", and "Operation". The option can be set in the system menu.
- " " battery power indicator; When the indicator is yellow and displays only one "grid", it means there is a little battery power left. When the indicator turns red and blinks, as well as less than one "grid" displays, the system alarm will be on to remind the battery shortage. Please connect the device to the mains power supply in time to ensure the normal use of monitor, and the battery will be recharged. When the battery power is full, battery power indicator displays full grid. During recharging, the grids in the battery indicator are rolling circularly.
- ☆ "2011-06-20 16:36:04": Current calendar time and date. The system time and date can be set during the system start-up when the screen displays the time and data setups. The current figure shows the time and date: June 20th, 16:36:04, 2011.
- ♦ "Push Display, changing interface": System prompt or description for the current status.

✤ "ID": The patient ID. It can be entered or changed in the archive management window.

Waveform area:

- ☆ 1st trace: The first trace is ECG waveform for lead II. The left side of the ECG shows the sign I, which indicates the ECG scale. The scale sign changes its length according to the ECG gains. All ECG waveforms have their own scale. When the third measured trace change to lead II, the first trace will automatically change to lead I.
- → 3rd trace: The third trace is the measurable ECG channel. Its lead can be adjusted and will not repeat the 1st and 2nd traces.
- ♦ 4^{th} trace: SpO₂ waveform.
- \Rightarrow **5th trace:** Respiration waveform or CO₂ waveform

Data area:

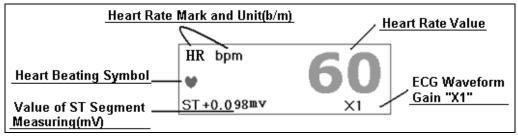


Figure 4.3 Heart Rate Area

- ♦ "HR": The currently displayed heart rate. "60" on the right side is the heart rate.
- ♦ "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+0.098mv": The measured mili-volts value during S-T measurement.
- - "Auto" Automatic scaled waveform.
 - "x1/4" Waveform scaled with 1/4 of the base gain
 - "×1/2" Waveform scaled with half of the base gain.
 - "×1" Waveform scaled with base gain.
 - "×2" Waveform scaled with twice of the base gain.
 - "×4" Waveform scaled with four times of the base gain.



Figure 4.4 TEMP Data Area

- **TEMP 1/2**: Temperature label. The values "36.7" and "37.5" are the temperature values.
- \diamond "°C": Body temperature unit. °C is Celsius, and °F is Fahrenheit.
- \diamond **TD**: the absolute value in temperature between TEMP 1 and TEMP 2.

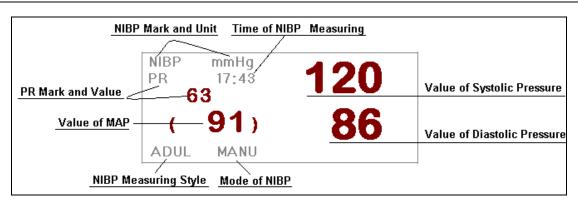


Figure 4.5 Blood Pressure Data Area

- ♦ "NIBP": The blood pressure type labels and the measured value.
- ♦ "PR": pulse rate value measured by NIBP measurement; "63": pulse rate value;
- ♦ "mmHg": NIBP unit: "mmHg" and "kPa".
- ♦ "ADUL": NIBP measurement mode. The object is adult.
- ♦ "MANU": The NIBP measurement mode: manual. "17:43": NIBP measuring time.

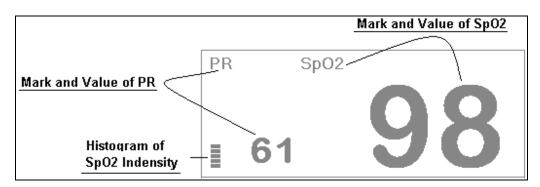


Figure 4.6 SpO₂ and Pulse Rate Area

- \diamond "SpO₂": SpO₂ label. "98" on the right side is the current SpO₂ value.
- ♦ "PR": Pulse rate label. "61" on the lower left shows the pulse rate value.
- $\diamond \qquad \text{````: SpO}_2 \text{ strength bar.}$

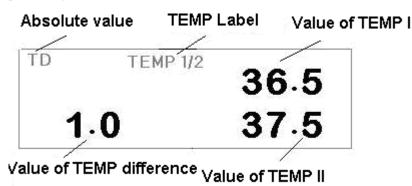


Figure 4.7 TEMP Data Area

- ♦ "TEMP 1/2: TEMP label, "1" TEMP I; "2" TEMP II
- \diamond 36.5, 37.5: the value of temperature.
- ♦ "TD": the label of temperature difference.
- \diamond "1.0": Absolute value of TEMP I and TEMP II.



Figure 4.7 Respiration Data Area

- *** "RR**": Respiration Rate: The bpm after that is the unit of the respiration, i.e., beat per min.
- ♦ "14": Respiration rate value.
- ♦ A:Respiratory Sync Mark
- \diamond "EtCO2". The label and the value will become gray when CO₂ is turned off. "39.4" is EtCO2 value;
- \diamond "Ins": The label of the minimal inhalational CO₂, the label and the value will become gray when CO₂ is turned off. "2.9" is InsCO2 value;
- ✤ "X1": Respiration waveform gain (amplification):
 - " $\times 1/2$ " Waveform scaled with half of the base gain.
 - "×1" Waveform scaled with base gain.
 - "x2" Waveform scaled with twice of the base gain.
 - "x4" Waveform scaled with four times of the base gain.

4.2 Display2 Screen

4.2.1 Viewing Screen

Choose Obser of Disp2 on system setup screen, press the Display key to enter the monitoring screen, as shown in Figure 4.9.

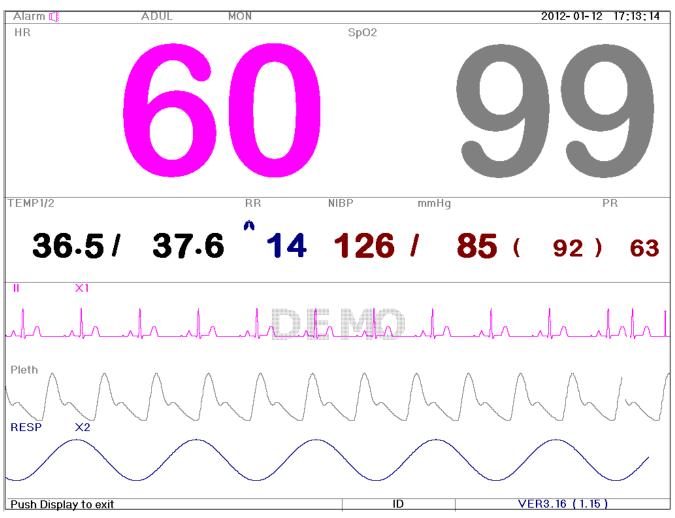


Figure 4.9 Viewing Screen

In this screen, press the Display 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.

4.2.2 Seven ECG Waveforms on the Same Screen

Choose 7 ECG of Disp2 on system setup screen, press the Display key, the system enters the 7 ECG waveform screen. In this screen, the operator can simultaneously view 9 waveforms: the ECG waveform for 7 leads: I, II, III, AVR, AVL, AVF and V, the SpO_2 Waveform and the RESP Waveform , as shown in Figure 4.10.



Figure 4.10 7 Leads on the Same Screen

In this screen, rotate the Navigation Knob to adjust the ECG gain. The ECG gain includes 6 options: "Auto", "X1/4", "X1/2", "X1", "X2", "X4". Rotate the knob to adjust the gain for all 7 ECG waveforms. Press the freeze button to freeze all 9 waveforms (including 7 ECG waveforms, SpO2 waveform and respiration waveform or CO2 waveform).

4.2.3 Eight Channels Real-time Waveforms and Trends on the Same Screen

When the Disp2 option is "Trend" on system menu screen, press the Display key on the main screen, then the system will enter the trend screen, as shown in Figure 4.11. Eight channel real-time waveforms and trend graph can be viewed on this screen.

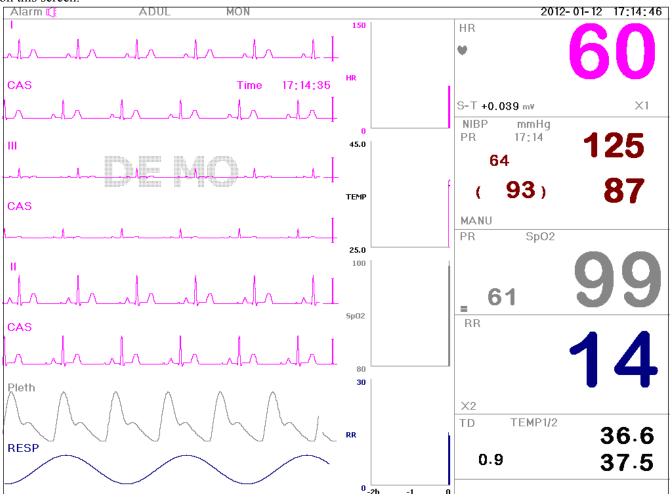


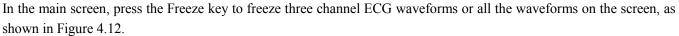
Figure 4.11 Eight Channel Real-time Waveforms and Two Hours Trends

On this screen, the first channel waveform is ECG waveform of Lead II; the second (CAS) one is the continued ECG for the first channel waveform; the third one is ECG waveform of Lead I; the fourth one is the continued ECG for the third channel waveform; the fifth one is IBP1 waveform; the sixth one is IBP2 waveform; the seventh one is SpO_2 waveform; the last channel is respiration waveform. On the right of waveform area, from the top down, respectively is heart rate, temperature, SpO2, IBP1, IBP2, EtCO₂ trend graph, the abscissa of trend graph (-2h-0) means various trend of every parameter value from now on to two hours before, waveform in trend graph shifts from right to left. On this screen press Lead key can perform switching ECG Lead status, the changing regulation of leads is the same with the leads operation on the main screen.

4.2.4 Operating Instructions

In the above monitoring screens, the operator can perform freeze, normal print and the blood pressure etc. measurement, in addition, print and blood pressure measurement can be operated at the same time. When pressing the "Display" key again on the front panel, the system returns to the main screen.

4.3 Freeze and S-T Segment Analysis Screen



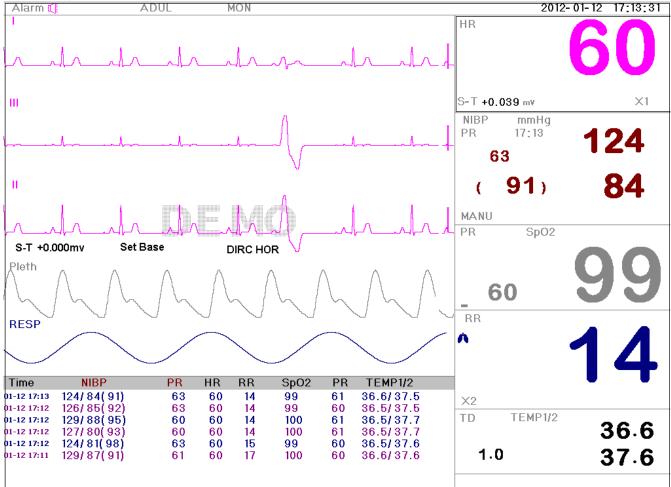


Figure 4.12 Frozen Screen

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 4.13 is a portion of the frozen waveform. The symbols on the screen were described briefly on the screen.

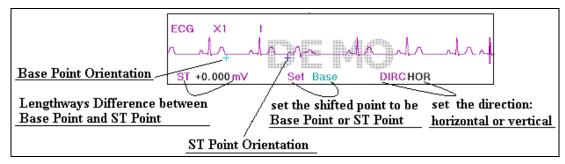


Figure 4.13 Frozen Waveform

4.3.2 Operation Instruction

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

First, rotate the Navigation Knob to move the base point (the red cross) horizontally to baseline point (the baseline is between the Q wave and the P wave). At this point, the frozen screen shows "S-T+0.xxx mV, Set Base, DIRC HOR".

Second, press the Navigation Knob. The screen shows "S-T+0.xxx mV, Set Base, DIRC VER". Then rotate the knob to move the base point vertically to the baseline point.

Third, press the Navigation Knob again. The screen shows "S-T+0.xxx mV, Set S-T, DIRC HOR". Rotate the knob to move the S-T point (the yellow cross) horizontally to the point to be measured on the S-T segment.

Last, press the Navigation Knob again. The screen shows "S-T+0.xxx mV, Set S-T, DIRC VER". Rotate the knob to move the S-T point vertically to the point to be measured on the S-T segment.

One the main screen allows pressing the Freeze key to enter the S-T segment analysis screen.

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

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 4.14.

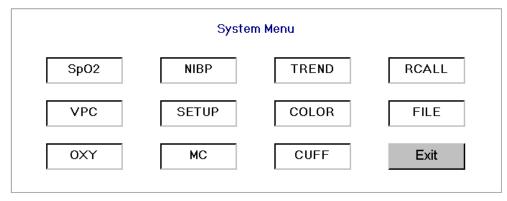


Figure 4.14 Mode Selection Screen

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 List, NIBP List, TREND, RCALL, ARR, SETUP, COLOR, FILE, OXY, MC and CUFF. Start from Chapter 4.5 these modes are described in turn. Press Display Key/ "Exit" to exit from this screen.

4.5 SpO₂ Trend List Screen

Move the gray cursor to SpO_2 List in the mode selection screen, and press Navigation Knob to enter into SpO_2 trend list screen, displays in the same position shown as Figure 4.15.

Time	HR	EtCO2	Ins	RR	TEMP1	TEMP2	SpO2	PR	Ť
08:57	60	38	03	18	36.7	37.6	99	60	
08:56	60	39	02	18	36.7	37.6	98	61	
08:56	60	39	02	18	36.6	37.5	98	60	
08:56	60	38	04	18	36.7	37.5	98	62	
08:56	60	38	04	18	36.7	37.5	99	60	
08:56	60	38	04	18	36.7	37.7	98	60	
08:56	60	38	03	18	36.5	37.6	99	61	
08:56	60	39	03	18	36.7	37.5	98	61	
08:56	60	39	03	18	36.6	37.6	99	60	
08:56	60	39	04	18	36.5	37.7	99	60	
08:56	60	39	02	18	36.5	37.6	98	60	
08:56	60	40	03	18	36.5	37.6	99	60	
08:56	58	40	03	18	36.6	37.7	99	62	Ŧ

Figure 4.15 SpO₂ List

4.5.1 Screen Description

In the SpO₂ list title bar, the front color of SpO₂, PR is the same with SpO₂ parameters' and other front color is white.

The operation on the trend 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 (i.e. use the \uparrow arrow to scroll the data). When rotating knob clockwise, the list scrolls down (i.e. use the \downarrow arrow to scroll the data). Please note that when the groups of data are less than 13, the Navigation Knob can not be used to scroll up or down the listing.

Up to 13 groups of the latest data can be printed each time when printing SpO_2 list and the printing data is the SpO_2 list on current screen. Rotate the knob to display the next screen and then press the Print key to perform printing, the next page of SpO_2 list will be printed.

All the parameters in the SpO_2 trend list are corresponding to the time when the SpO_2 measurements were taken. There is only one record every 4 seconds.

4.6 Blood Pressure Trend List Screen

4.6.1 Screen Description

Move the gray cursor to NIBP List in the mode selection screen, and press Navigation Knob to enter into NIBP trend list screen, displays in the same position shown as Figure 4.16.

Time	NIBP	Pulse	HR	RR	SpO2	PR	TEMP1/2	1
10:27	128/80(92)	67	60	14	99	61	36.7/37.5	
10:27	122/ 87(93)	67	60	14	99	60	36.5/37.7	
10:26	120/ 88(90)	67	60	14	99	62	36.7/37.6	
10:25	128/ 81(95)	66	60	14	98	61	36.7/37.7	
10:25	126/82(94)	67	60	14	99	61	36.5/37.7	
10:24	124/ 87(99)	65	60	16	99	62	36.6/37.6	
								Ŧ
I								

Figure 4.16 NIBP List

4.6.2 Operation Introduction

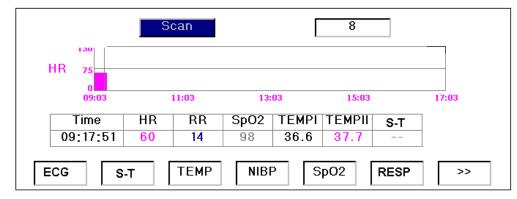
The NIBP list screen is similar with the SpO_2 trend listing screen. The difference is the title bar colors. In the NIBP list title bar, the font color of NIBP is the same with NIBP parameters' and other titles' font color is white.

All the parameters in the NIBP list are corresponding to the time when the NIBP measurements were taken. When the NIBP measurement is taken successfully each time, the NIBP list will be updated, and the latest measured data is in front of the list.

All the operations is similar to the SpO₂ trend listing screen, please refer to the previous chapter.

4.7 Trend Graph 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 4.17.

Figure 4.17 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 can view "ECG", "S-T", "Temperature", "NIBP", "SpO₂", "IBP1", "IBP2", "Respiration" and "EtCO₂" trend graphs. The corresponding screens are described in the following figures.

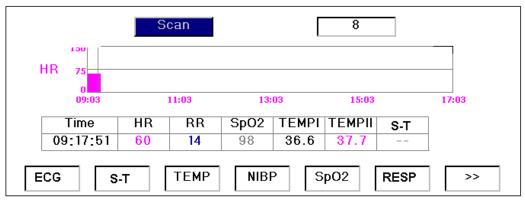




Figure 4.18 is the ECG trend graph. There are 3 options on the right of the graph, as described below.

The "8" 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 24 or 120, which changes the horizontal axis to be 24 hours or 120 hours. The corresponding trend graph also changes to 24-hour trend or 120-hour trend.

After choosing "Scan", the trend graph display a triangle and a vertical line, a moving ruler mark that can be moved by rotating the knob. As shown in the figure, when you move the mark to a specific point, the data area below the graph will display the time, and its corresponding heart rate, respiration rate, SpO_2 , temperature "Itemperature" I. 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 if ECG value exceeds 120 automatically. 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 8 hours trend graph, when the monitoring time exceeds 8 hours, the data 8 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 8 hours to 24 hours (while the monitoring time is less than 24 hours), the complete set of data will display. Other trend graphs follow the same rule.

The S-T segment, 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.

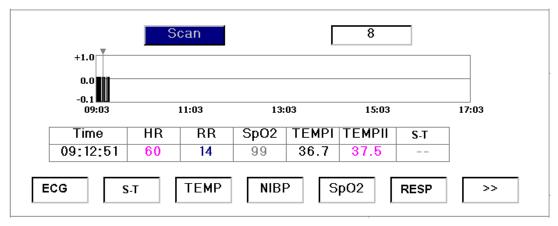


Figure 4.19 S-T Trend Graph

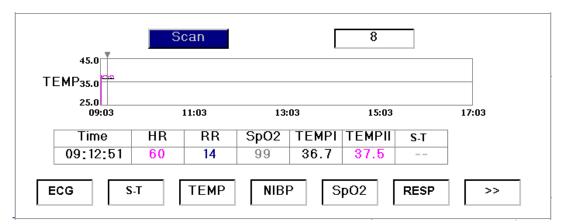


Figure 4.20 Body Temperature Trend Graph

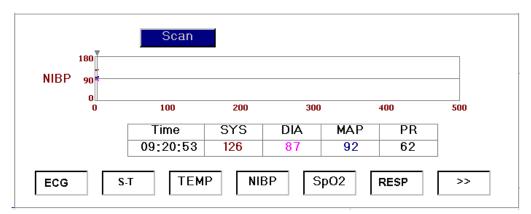


Figure 4.21 NIBP Trend Graph

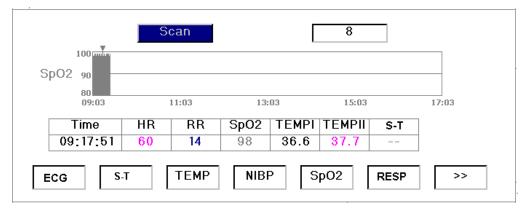


Figure 4.22 SpO₂ Trend graph

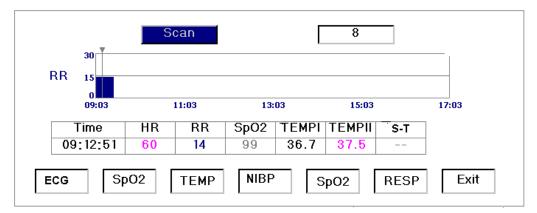
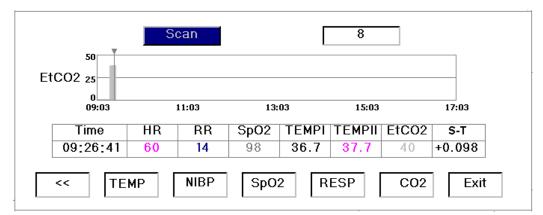


Figure 4.23 Respiration Trend Graph





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, press it to exit the trend graph.

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

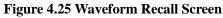
O The EtCO₂ trend graph can be viewed only when the CO₂ measurement function is activated through the setting: "System menu \rightarrow SETUP \rightarrow CO₂ \rightarrow Switch \rightarrow ON".

4.8 Recall Screen

Move the gray cursor to "RCALL" in the mode selection screen, and press Navigation Knob to enter into Recall trend screen, displays in the same position shown as Figure 4.25. The recall waveform is the selected lead waveform and displayed in third channel. Generally a piece of recall record is saved every one hour, if the time is less than one hour when the patient is changed, this record will be separately saved as a piece of recall record.

Leads and gain etc parameters of saved ECG always keep in accordance with the settings of system parameter.





In this screen ECG waveform recall can be selected, we will cover the each button function in the recall list screen. 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.

ID	Name		Start	End	+
000001	NoName		08:55:57	08:59:59	
					Ŧ
					•
	Recall	HIST	Delete	Exit	

Figure 4.26 ECG Recall List

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, as shown in Figure 4.27 Waveform Recall.

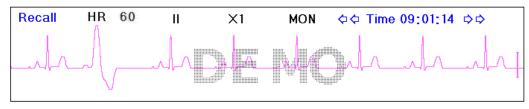


Figure 4.27 Waveform Recall

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.

Recall: press the recall button, the first record of recall list turns to green, rotate the knob to select a record, and then press the knob to perform data recall, the recalled waveform and data will be displayed in the third channel.

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

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

Exit: Press this key to return to the system setup menu.

In this screen, the system can print the recalled data list or the recalled waveform.

4.9 ARR Screen

Move the gray cursor to "ARR" and press Navigation Knob to enter ARR screen, shown in Figure 4.28. The structure is similar to recall screen. We will cover each function key below.

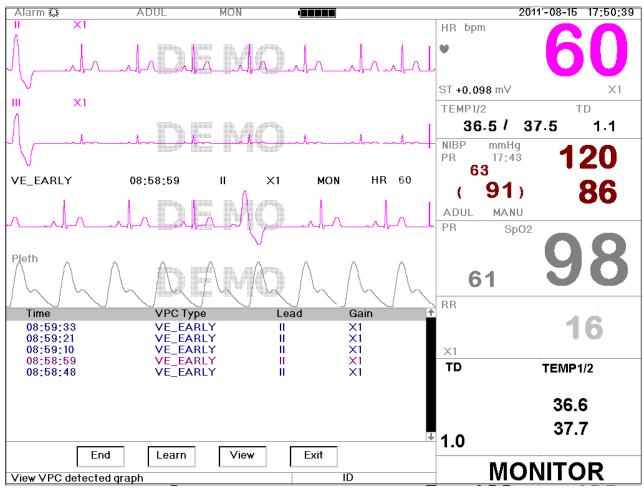


Figure 4.28 ARR Screen

End: This button is used to start and end the system arrhythmia detection. The default is End. 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 arrhythmia detection begins, the system will automatically detect the arrhythmia waveforms. If arrhythmia is detected, the arrhythmia waveform will be displayed in the 3rd ECG channel, shown in Figure 4.28

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

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

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

Exit: press this key to exit the arrhythmia detection screen and return to the system menu.

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

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

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

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 4.29.

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 DEF 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.

SYSTEM PARAMETER SETTINGS

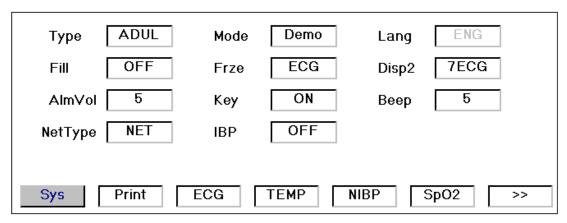


Figure 4.29 System Parameter Settings

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

Infant: the object is pediatric.

Neonate: the object is neonate.

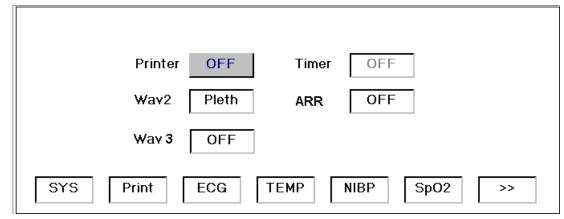
The default is "Adult"

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 infant 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: The current language used, which can be selected by the user. There is no default for this setting. However, the setting can be saved.
- ♦ Fill: When the fill setting is ON, the display fills the volume for the 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 ECG waveforms. When "All" is selected, the system freezes all the waveforms including ECG, SpO₂, and Respiration. The factory default is "ECG"
- ♦ Disp2: The display 2. Three options: Trend, Obser (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 is ON.
- ♦ Net Type: select net type: net or COM
- **Beep**: The synchronous heart beat sound. The range of setting is " $0\sim7$ ", The factory default is "5"
- \diamond **IBP:** turn on or turn off the IBP function.

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. The default is "OFF".
- ♦ 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 setting is "SpO₂".
- ♦ ARR: ARR triggering print. If the printer option is "ON", it means once ARR occurs the printer will be triggered for recording the ARR waveform information. The default is "OFF".

ECG PARAMETER SETTINGS

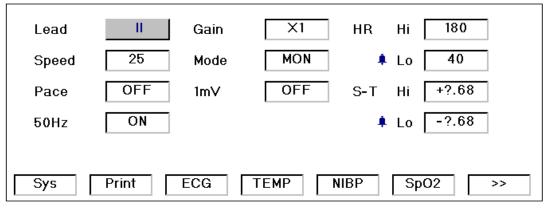


Figure 4.31 ECG Parameter Settings

✤ Lead: Can choose from I, II, III, aVR, aVL, aVF, V (V1-V6). The default is I.

- Gain: The ECG gain, 6 options x1/4, x1/2, x1, x2, x4 and Auto. Auto is for automatic gain control. The factory default is "x1".
- ♦ HR Hi: High limit of heart rate alarm

Lo: Low limit of heart rate alarm

The adjustable range and the factory default value can be found in chapter 3.9

- Speed: ECG waveform sweeping speed. 4 options: 6.25, 12.5, 25, 50 mm/s. The factory default is "25 mm/s".
- ♦ **Mode:** ECG filter mode. Three options: MON, DIA, and OPE
 - **MON**: Monitoring mode. Moderate filtering that can filter out interference and present good ECG waves.

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

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

The factory default is "MON".

- ♦ BtSnd: Heart beat sound. The synchronous heart beat sound during monitoring. "0~7" level adjustable.
- ImV: 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".
- ♦ 50Hz: frequency filter. It means turning on or turning off the 50Hz frequency filter.
- ✤ Pace: Pace detecting switch. The default is "OFF". When the option is on, the mark will be made in the first ECG channel of any screen if pace is detected, as shown below.

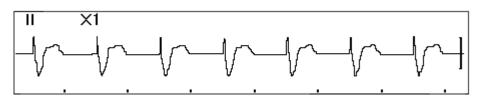


Figure 4.32 Heart Beat Detection Screen

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

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

Example 2 Limits setup: Move the gray cursor to the High or Low limits of the alarm settings, and press the "Alarm silence" key to turn ON or OFF the alarm for the setting. Yellow color shows ON status, and gray color shows the OFF status.

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

TEMPERATURE PARAMETER SETTINGS

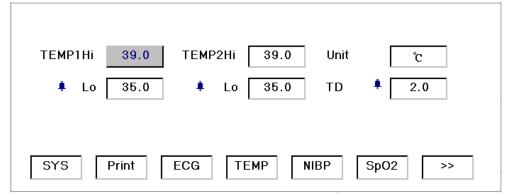


Figure 4.33 Temperature settings

- ♦ 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

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

- ✤ Unit: Temperature unit. The default is °C (Celsius) and it can be set to °F (Fahrenheit).
- ✤ TD: Temperature difference value. When the TD value is higher than the set value, the alarm will ring.

NIBP PARAMETER SETTINGS

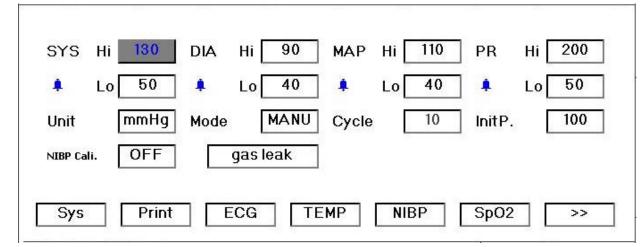


Figure 4.34 NIBP Settings

- ♦ 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 mean arterial pressure alarm
- ♦ PR Hi/Lo: High and Low limits of mean arterial pressure alarm
- ♦ Unit: The pressure unit, mmHg and kPa can be selected. The factory default is "mmHg".
- ☆ Mode: The cuff inflation mode, manual or automatic. The factory default is manual. The operator needs to press the NIBP button to perform NIBP measurement. If the Auto mode is chosen, the operator needs to set an interval cycle as well.
- ♦ Cycle: The inflation interval when the NIBP measurement is set to Auto. The options are STAT, 1 min, 2 min...240 min. Press NIBP and the system begins to count down. It takes blood pressure measurement automatically after finishing counting down If STAT is selected, press NIBP to take 5 minutes' measurement.
- ✤ Initial inflation pressure setting: Cuff pressure to be inflated initially, its options are different depending on patient type.

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

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

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

♦ 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.
- *△* WARNING: STAT can only be used for Adult. Using this mode to Infant/Neonatal patient can cause serious injury.

Limits setup: Move the gray cursor to the upper or lower limits of the alarm settings, and press the Alarm silence key to turn ON or OFF the alarm for the setting. Yellow color shows ON status, and gray color show the OFF status.

SPO₂ PARAMETER SETTINGS

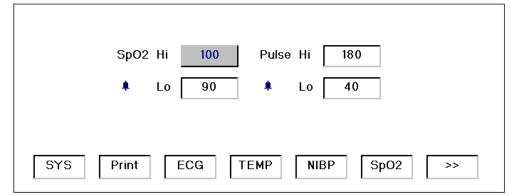


Figure 4.35 SpO₂ settings

- ♦ SpO₂ Hi/Lo: High and Low limits of SpO₂ alarm
- ♦ Pulse Hi/Lo: High and Low limits of pulse rate alarm

RESPIRATION PARAMETER SETTINGS

Gain	×2	RR Hi 40	Speed	12.5
Apnea	OFF	🖡 Lo 🛛 10	Туре	RES
<<	TEMP	IBP SpO2	RESP DE	F Exit

Figure 4.36 Respiration Settings

- \diamond Gain: Respiration amplification/gain, 4 options, x1/2, x1, x2, and x4. The default is "x2".
- ☆ Apnea: The timeout for apnea alarm (in second). The timeout setting range is 5~120 or the alarm is disabled. When the patient stop breathing for the time longer than the set period, the Respiration display channel display warning "Apnea xxx second". The default is "OFF".
- ♦ RR Hi: High limit of respiration rate alarm

Lo: Low limit of respiration rate alarm

- ♦ Speed: Respiration display speed, 2 options 6.25mm/s and 12.5 mm/s. The default is "12.5 mm/s"
- ♦ Type: Respiration impedance.

Example 2 Limits setup: Move the gray cursor to the High or Low limits of the alarm settings, and press the Alarm silence key to turn ON or OFF the alarm for the setting. Yellow color shows ON status, and gray color shows the OFF status.

4.10.2 Resume Default

System parameters default key. Move the cursor to "DEF", press the Navigation knob for 2seconds, all the value of parameters will resume default except the setting of language and printer type.

4.11 Color Settings screen

In the mode selection screen, move the gray cursor to "COLOR" and press the Navigation Knob to enter color setting screen, shown in Figure 4.37.

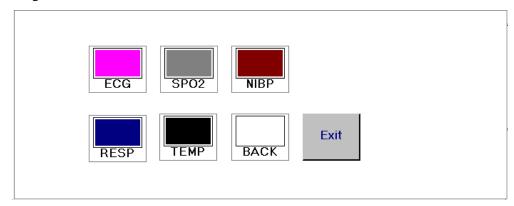


Figure 4.37 Color Settings

In this screen, rotate the knob to choose the color, press and rotate it to change the color. When the appropriate color is chosen, press the knob again to save it.

Press the Exit to exit from this color settings screen.

4.12 File/Archive Management Screen

In the mode selection screen, move the gray cursor to "FILE" and press the Navigation Knob to enter document management screen, shown in Figure 4.38.

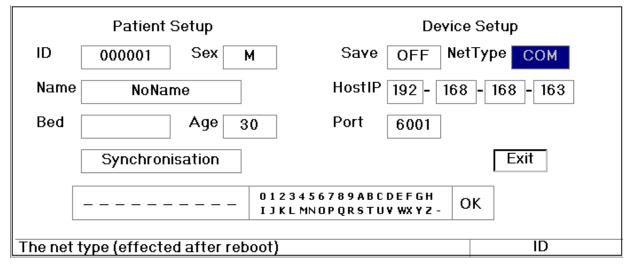


Figure 4.38 Document Management Screen

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.

♦ **ID:** or Patient ID. To enter patient ID, choose the patient ID field 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 to be deleted 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 patient's bed number.
- ♦ Sex: Choose between M or F for male and female.
- \diamond Age: Choose the age field and use the rotate knob to select an age.
- Synchro: Selecting "Synchro" can upload the current patient file to patient archive screen of center unit for management, and also can send patient archive of center unit to bedside unit for management.
- ♦ Note: The function of Synchro ONLY can be performed in communication of bedside unit and center unit with dual-screen center system.
- 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 disk space available. 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.
- Net Type: The type of network connection to the central monitoring system. There are three selectable options: "OFF", "NET" and "COM". The option "OFF" means no data transmission at all, that is to say, disconnection to the outside world; The option "NET" means the network is "Ethernet" for data transmission by TCP/IP data packet; The option "COM" means the network is "RS-232" for data transmission.

When the option of Net Type is not "NET", the field of "HostIP" and "PORT" will represent gray which tells the user these fields are inactivated and there no need to set them. If the option is "OFF", press "Exit" to end the data transmission, therefore, the data communication is terminated. Similarly, if the option is "NET" or "COM", pressing "Exit" to activate the data communication. But the change of current Net Type needs hardware initialization, so if the users want to change Net Type, they should exit from the setting screen firstly, then manually turn off the device and reboot it to make the new setting effective.

Note: The Net Type will remain the last setting when the monitor is restarted.

- ✤ Host IP: The users should set the host IP (IP number of the work station in the central monitoring system) when the option of Net Type is "NET". If it is necessary to change the IP number, as mentioned above, the user should turn off the monitor manually and reboot it to make the new setting effective.
- Port: The port number to which the monitor will connect to the work station in the central monitoring system. It can also be used to represent the patient bed number which can be set in the range from 6001 to 6064, e.g. the port number 6002 means the monitor is assigned to the bed number 2 in the CSM. It is known that the work station can connect to up to 64 bedside monitors. In order to make the new setting effective, as mentioned above, the user should power off and reboot monitor after change the port number.

Note: 1.Make sure the work station and patient monitors are in the same local domain when using "NET" type network connection, different monitor should be set to unique port number, in case causing repeated bed number and failing to connect with the work station.

2. "Help" symbol on monitor will give corresponding information prompts during the process of detecting and establishing network connection.

3. If the following situations occur: the network cable is disconnected suddenly or the software running on the work station is closed accidentially (but the bedside monitor is under normal monitoring state), the user should re-connect the network or re-run the software on the work station to enable the network re-connection automatically, at this time, please be patient to wait, as the network searching time can be up to 2 minutes.

4.13 oxyCRG Screen

In the mode selection screen, move the gray cursor to "OXY" and press the Navigation Knob to enter oxyCRG screen, shown in Figure 4.39 (1) or (2). This screen displays the value or waveform of HR, SpO₂, and Respiration waveform or Respiration Rate in selected time. The time can be set as 1 minute, 2 minutes and 4 minutes by the lower left button. Press the middle button to set the third channel waveform display: Respiration waveform (Fig.4.39) or Respiration Rate (Fig. 4.39 (2)). Press "Exit" button or Display key to exit from this screen.

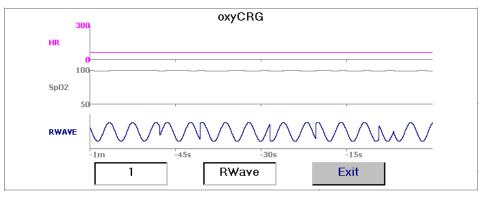


Figure 4.39 oxyCRG Screen (1)

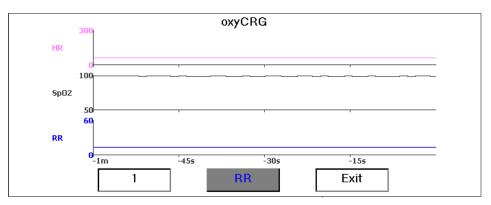


Figure 4.39 oxyCRG Screen (2)

4.14 MC Calculator

In the mode selection screen, move the gray cursor to "MC" and press the Navigation Knob to enter MC analysis screen, shown in Figure 4.40. This series monitor supplies 10 kinds of medicine calculation and titration display function

Medicine AMINOPHYLLINE	Weight	70.00kg	Gross	
Cubage	MC] D/m	
D /h	D/kg/m		D/kg/h	
TS	DS		Drop	
Duration				
MC	Titr	ation	Exit	

Figure 4.40 Medicine Dosage Calculator Screen

4.14.1 Medicine Dosage Calculator

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

Drug Dosage Calculation adopts the following formula:

Medicine Consistency (MC) = Medicine Gross/ Cubage

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

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

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

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

Drop Speed=TS/ (Cubage/drop)

Duration=Medicine Gross/Dose/h)

Formula Introduction: Names in formula are the same with the names in Figure 4.44. Dose/m=Dose per minute; Dose/h=Dose per hour; Dose/Kg/m=Dose per Kg per minute; Dose/Kg/h=Dose per Kg per hour.

On medicine calculation screen, first the operator should move the gray cursor to "Medicine" to select the calculated medicine name, and then move the cursor to "Weight" to select and confirm patient weight, at this time MC analysis screen is shown as Figure 4.41

Medicine AMINOPHYLLINE	Weight	70.00kg	Gross	500.00mg
Cubage 500.00ml	MC	1.00mg/ml	D/m	1.00mg
D /h 60.00mg	D/kg/m	14.29mcg	D/kg/h	857.14mcg
TS 60.00ml/h	DS	20.00GTT/m	Drop	20.00GTT/ml
Duration 8.33h				
МС	Titr	ation	Exit	

Figure 4.41MC Analysis Screen

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

- On MC analysis screen, other menu options cannot enter value unless entering patient's weight and medicine name again, in default status it is no effective. The values in system is a group of stochastic initial values, the operator should not consider it as calculating standard, please follow doctor's device enter a group values which are suitable for patient.
- *△* When the operator finishes one option entering, the system will give visible indication in menu to remind operator to check the correctness of entering value.
- **Output** Under neonate mode, "DS" and "Drop" are useless.
- A For every new entering value, please perform confirming. The operator should take it seriously, only when the entering is correct, the calculating result is believable and reliable.

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

Weight: when entering into medicine calculating window, the operator should enter patient's weight; the weight is used for MC calculation only; weight: 0.5Kg to 300Kg selectable; step: 0.5Kg; default: 70 Kg for adult; 20Kg for infant; 3.0 Kg for neonate.

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

4.14.2 Titration

When entering medicine name and weight again, MC analysis screen displays as Figure 4.38, and then move the gray cursor to "Titration" button and press it with the Navigation knob, the titration screen will display on screen, as shown in Figure 4.42

Medicine	AMINOPHYLLINE	Dose	TS	Dose	TS
Weight	70.00kg	0.00 1.00	0.00 1.00	10.00 11.00	10.00 11.00
Gross	500.00mg	2.00 3.00 4.00	2.00 3.00 4.00	12.00 13.00 14.00	12.00 13.00 14.00
Cubage	500.00ml	5.00 6.00	5.00 6.00	15.00 16.00	15.00 16.00
D/h	60.00mg	7.00 8.00 9.00	7.00 8.00 9.00	17.00 18.00 19.00	17.00 18.00 19.00
TS	60.00ml/h	5.00	5.00	13.00	17.00
DS	20.00GTT/m	Dose	1	/h	<>
	MC	Titration		Exit	

Figure 4.42Titration Screen

The parameters on the left of titration screen are the MC analyzed parameter values, the right is comparison table. The four options "Dose", "1", "/h" and "<>" bellow the table will be covered in turn:

Dose: Medicine dose; "DS" and "TS" are selectable; if the option is "DS", the comparison table will be "Dose--DS" table; if the option is "TS", the comparison table will be "Dose--TS" table. The operator will choose the value of "TS" and "DS" according to this table.

- ☆ 1: means step, is has relation with "Dose" option;1~10 adjustable, if the former option selects "Dose", the dose step will can be changed in compression table; if selects "TS", the TS step will can be changed; if selects "DS", the DS step will can be changed.
- Solution in the set of the state of the s

Move gray cursor to "MC" Button and press it with the Navigation knob to return to MC analysis screen; Move the gray cursor to "Exit" and press it with the Navigation knob to return to mode selection screen.

4.15 Tourniquet Cuff

In the mode selection screen, move the gray cursor to "CUFF" and press the Navigation Knob to enter Cuff screen, shown in Figure 4.43

Pressure 140 Alarm 5	Duration 40
Start	Exit

Figure 4.43Tourniquet Cuff

4.15.1 Screen Description

Pressure: For setting the high limit of cuff pressure when inflating. When cuff pressure exceeds this value, it will stop inflating. Adjusting rage: Under Neonate mode: 70~110; Under Infant mode: 80~130; Under Adult mode: 80~180; Step: 5; Unit: mmHg. The default value for neonate is "90", for infant is "110", and for adult is "140".

Note: If in blood parameter setting option on system parameter settings screen, the blood unit option is "kPa", the unit of cuff pressure here also is "kPa".

- Duration: After inflation, the continuous time when cuff pressure is an invariableness pressure. "5, 6, 7,...120" minutes adjustable. When the set is "xx" minutes, the system will count down from "xx" minutes automatically when starting blood cuff inflation. After ending counting down, it will deflate automatically. The default value is "40" minutes.
- Alarm: the time of alarm, 1 to 60 minutes continuous adjusting range. If the set is "xx" minutes, the system will alarm until ending deflation when the time reaches ending deflation is "xx" minutes, and the alarm type is high priority alarm. The default value is "5" minutes. (For example: the duration is 40 minutes, the alarm set is 5 minutes, the alarm will ring when the duration countdown left time is 5 minutes.)
- ♦ Start: Press it with the Navigation knob, the blood cuff starts being inflated; after inflating this field displays

"End", then press "End" button to perform deflation.

✤ Exit: Press it with the Navigation knob to return to Mode Selection Screen.

Note: In CUFF status, after pressing "Start" to start CUFF function, if monitored object and inflating mode are modified, the CUFF function will be stopped.

Chapter 5 CO₂ Monitoring

If your monitor has CO_2 monitoring function, please follow the instructions in this chapter to perform CO_2 monitoring on patient.

5.1 CO₂ Parameter Settings

1. On Main Screen, press the knob to enter System Menu Screen. Then choose "SETUP \rightarrow C0₂"to enter CO₂ Parameter Settings screen.

Switch OFF	Gain X1	Unit mmHg
RR Hi 50	EtCO2Hi 70.0	Ins Hi 10.0
🕈 Lo 🚺 10	🜲 Lo 🛛 10.0	🖡 Lo 🔽
Baro 760.0	Zero OFF	Flow 50
		>>
<< SpO2	IBP1 IBP2	RESP CO2 >>
	CO ₂ Parameter Setting	gs (1)
Apnea 20	Period 10s	TEMP 35.0
O2 Compen. 16	Balance Air	Agent 0.0
Sys Print	ECG TEMP	NIBP SpO2 >>

CO₂ Parameter Settings (2)

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

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

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

- **Gain:** the CO_2 waveform gain.
- \diamond 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.
- \diamond **EtCO₂ High:** Setting the upper alarm limit of EtCO₂.

Low: Setting the lower alarm limit of EtCO₂.

 $\Rightarrow \quad InsCO_2 \text{ High: Setting the upper alarm limit of } InsCO_2.$

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.
- \diamond 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.

The information promoted for Zero calibration is as follows:

Do you want to do zero ca Apply reference air with	
ОК	Exit

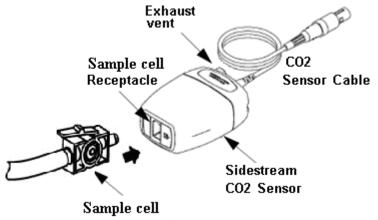
Please apply the reference air with 0% CO₂, the air in the drafty room usually can be regarded as the air with 0% CO₂. Press "OK", and the result will be displayed on the screen several seconds later.

- \Rightarrow Flow (CO₂ flow): It is flow rate of the CO₂ sampling. Its value is 50ml/min.
- ☆ Apnea: display time of the respiration rate value in data area when the previous respiration has been detected while the next one is not, meanwhile, the device will prompt apnea information. The setting range is 10s~60s, the default is 20s. For example, if 20 seconds is set here, it means the respiration rate value will disappear after it has been shown for 20 seconds in the data area if on respiration is detected during this period.
- ♦ Period: setting the calculation cycle of EtCO₂ value, there are three selectable options: "1b", "10s" and "20s". "1b": means the EtCO₂ value will be calculated once every respiration cycle; "10s": means the EtCO₂ value will be calculated once every 10s, and the maximum EtCO₂ value measured during this 10s will be displayed on data area; "20s": means the EtCO₂ value will be calculated once every 20s, and the maximum EtCO₂ value measured during this 20s will be displayed on data area
- ★ TEMP: setting the temperature value of the current measured air flow. For instance, the temperature is usually set as 37°C while measuring the patient's respiration by air flow. However, if the air flow to be measured is the reference gas, the temperature is set as 25°C. The setting range: 0~50; Unit: °C, Default value: 35.0.
- ♦ O2 Compen: adjusting the concentration of compensating gas in patient's respiration air flow. Generally, the compensating gas is oxygen, so it can be called oxygen compensation concentration. The unit: %; Setting range: 0%~100%; Default value: 16.
- Balance: setting the balance gas in patient's respiration air flow. There are three kinds of selectable balance gas: "Air", "N2O" and "He", namely: air, nitrous oxide and helium. If no specific balance gas is given, the balance gas can be set as "Air".

- ☆ Agent: setting whether adding the anesthetic gas to patient's respiration air flow and the concentration of anesthetic gas. The setting range is 0.0%~20.0%, the default status is: not adding anesthetic gas, that's to say, the concentration is 0.0%.
- 2. To set the color of CO₂ parameters on Color Settings screen.

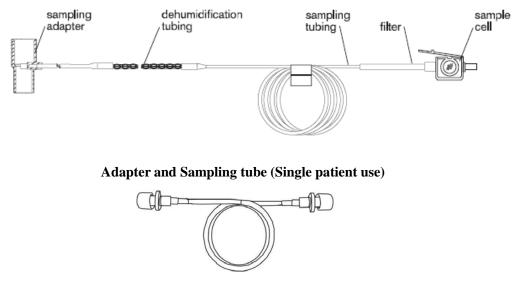
5.2 CO₂ Sensor Connection

5.2.1 Sidestream CO₂ Sensor Connection

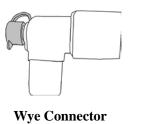


Demonstration for Sidestream CO₂ Sensor Connection

- 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 CO_2 Sensor. A "click" will be heard when the sample cell is properly inserted. Then connect to airway tube. After finishing sensor connection, and make sure that the air input end is exposed to room air and away from all sources of CO_2 , including the ventilator, the patient's breath and your own. Next, turn on the CO_2 switch at CO_2 Setup Screen and then wait 2 minutes for the sensor warm-up.
- **3. Default Tubing Configuration**

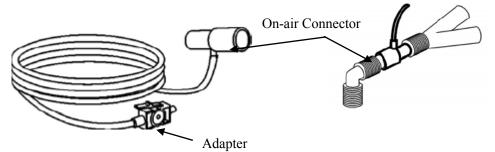


Extending airway tube for connecting to sampling tube (Single patient use)

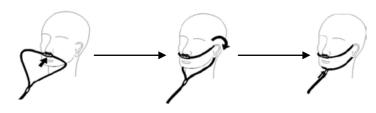


4. Optional sampling cannula kits

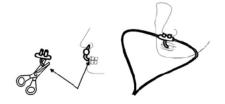
(1) T connector sampling cannula kits



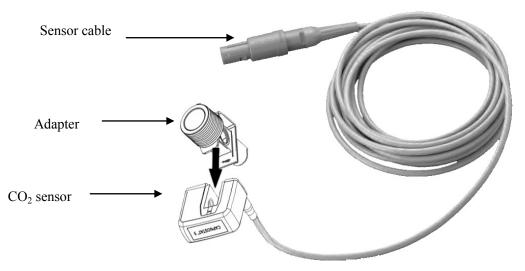
(2) Nasal Sidestream Cannula Kits



(3) Oral Sidestream Cannula Kits

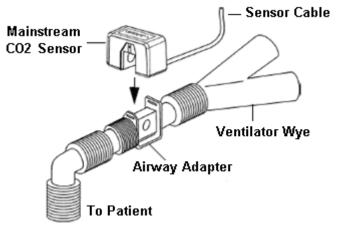


5.2.2 Mainstream CO₂ Sensor Connection



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 CO_2 switch at CO_2 Setup Screen and then wait 2 minutes for the sensor warm-up.



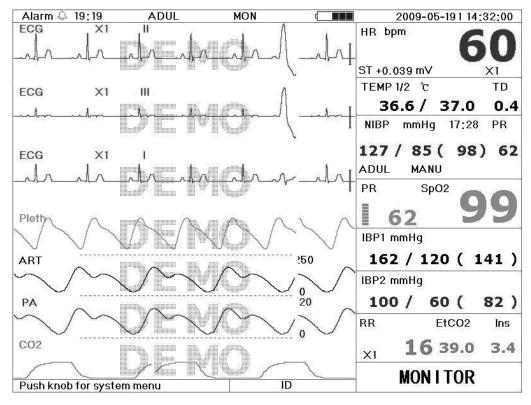
Safety Introductions for CO₂ Monitoring

- 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.
- \bullet 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 cannot tolerate the withdrawal of 50 ml/min +/- 10 ml/min from the airway or patients that cannot 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 abnormity caused by sampling tube block, please replace it.
- The total length of the sampling tube and extending airway tube shouldn't be longer than 3 meters, too long may cause measurement abnormity. If using T connector sampling cannula kits, please insert the sampling tube with the tubes upward to avoid the affects of excessive moisture;
- Altitudes are different in different area, so set the Barometric Pressure setting value as the ambient barometric pressure.
- Ise 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 affect 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.
- In 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.

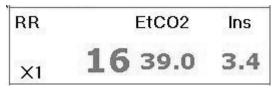
5.3 CO₂ Monitoring Screen



Waveform area

 \diamond 5th trace: CO₂ waveform. It can be respiration waveform or CO₂ waveform.

Data area



RR, EtCO₂, and Ins Data Area

- **"RR":** Respiration Rate: The rpm after that is the unit of the respiration, i.e., respiration per min.
- \diamond "EtCO₂ 39.0": The label and the value will become gray when CO₂ is turned off.
- ♦ Ins: The label of the minimal inhalational CO_2 , the label and the value will become gray when CO_2 is turned off.
- \diamond "16": Respiration rate. It will display the respiration rate of CO₂, when the switch is turned on.

- " $\times 1/2$ " Waveform scaled with half of the base gain.
- "x1" Waveform scaled with base gain.
- "x2" Waveform scaled with twice of the base gain.
- "×4" Waveform scaled with four times of the base gain.

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

Note: CO_2 monitoring function can be effective only when the setting item "System Menu \rightarrow SETUP \rightarrow CO₂ \rightarrow Switch"is set as "ON".

5.4 CO₂ Graphic Trend

On Graphic Trend screen, rotate the knob and move the cursor to " CO_2 ", then press the knob to enter $EtCO_2$ Graphic Trend. Refer to Chapter 4.5 Graphic Trend Screen for detailed instructions and operations.

	50	can		6	-	
02						
	14:27	15:57	17:27	1	8:57	20:27
	Date	HR	RR	SpO2	PR	ST
	2009-05-19	60	16	99	65	+0.019
	Time	TEMPI	TEMPII	EtCO2		
		36.7	37.0	39.3		

EtCO₂ Graphic Trend

Chapter 6 Alarm

6.1 Alarm Priority

High Priority:

Over IR Imit 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 S-T limit Over NIBP PR limit ECG ARREST 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 ARREST, 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 Caregory	Flashing Rate
Red flashing	High priority alarm	2 Hz
Yellow flashing	Medium priority aarm	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 \bigotimes 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 \bigotimes 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 \sim 5 mVp)
- 2. Heart rate display range: 15 bpm ~ 350 bpm
- 3. Heart rate display accuracy: $\pm 1\%$ or ± 2 bpm, whichever is greater.
- 4. Heart rate averaging: Averages the recent eight beats having RR intervals falling within the acceptable limits.
- 5. Heart rate alarm delay time: $\leq 10s$
- 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:

AUTO, Automatic scaled waveform

- $\times 1/4$, 2.5mm/mV tolerance: $\pm 5\%$
- $\times 1/2$, 5mm/mV tolerance: \pm 5%
- $\times 1$, 10mm/mV tolerance: $\pm 5\%$
- $\times 2$, 20mm/mV tolerance: $\pm 5\%$
- $\times 4$, 40mm/mV tolerance: $\pm 5\%$
- 10. Sweeping speed: 6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s tolerance: ±10%
- 11. ECG noise level: $\leq 30 \mu V_{P-P}$.
- 12. ECG input loop current: $\leq 0.1 \mu A$
- 13. Differential input impedance: $\geq 5M\Omega$
- 14. Common-mode rejection ratio (CMRR):

Diagnostic mode: \geq 90dB

Operation, monitoring mode: $\geq 105 dB$

15. Time constant:

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

16. Frequency response:

Monitoring mode: 0.67 Hz \sim 40 Hz($^{+0}$. 4 d B, -3. 0 d B)

Diagnostic mode: $0.05 \text{ Hz} \sim 150 \text{ Hz} (+ 0 \cdot 4 \text{ d B}, -3 \cdot 0 \text{ d B})$

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"

essentant pertormance, or electrocal angl apme monitoring equipment					
Direct current for	Applied current less than 0.1 microamperes.				
respiration, leads-off					
sensing, and active noise					
suppression					
Response to irregular	A1 Ventricular bigeminy-80BPM				
rhythm	A2 Slow alternating ventricular bigeminy-60BPM				
	A3 Rapid alternating ventricular bigeminy-120BPM				
	A4 Bidirectional systoles-9	0BPM			
Time to ALARM for	Waveform B1, Amplitude Average Time to Alarm				
tachycardia	0.5 mV	<8 sec			
	1 mV	<8 sec			
	2mV <8 sec				
	Waveform B2, Amplitude Average Time to Alarm				
	1mV	<8 sec			
	2mV	<8 sec			
	4mV	<8 sec			

7.2 RESP Monitoring

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

7.3 TEMP Monitoring

- 1. TEMP measuring range: 25.0 °C
- 2. TEMP measuring accuracy: ±0.2°C
- 3. TEMP responding time: $\leq 150s$

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

8. Overpressure protection limit

```
Adult: \leq 300 mmHg Infant: \leq 240mmHg Neonate: \leq 150 mm
```

9. NIBP measurement range:

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

10. NIBP accuracy:

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 Rate Monitoring

- 1. Pulse rate measuring range: 30bpm~240bpm
- 2. Pulse rate measurement accuracy: ± 2 bpm or ± 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

CO ₂ Accuracy:	0~40mmHg	±2mmHg
	41~70mmHg	$\pm 5\%$ of reading
	71~100mmHg	±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

6.

1. Sensitivity selection tolerance: $\pm 5\%$

- 2. Recording speed: 25mm/s
- 3. Recording speed accuracy: $\pm 10\%$
- 4. Hysteresis: ≤0.5mm
- 5. Frequency response:
 - Monitoring mode: 0.5~40Hz Diagnostic mode: 0.05~75Hz
- 6. Time constant:
 - Monitoring mode: ≥ 0.3 s Diagnostic mode: ≥ 3.2 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: Ethernet port

7.10 Classification

Safety standard:	IEC 60601-1
The type of protection against electric shock	Class I equipment
The degree of protection against electric shock	Type BF, 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 emissionfor all EQUIPMENT AND SYSTEMS

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	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	Patient Monitor is suitable for use in all establishments other than domestic and those directly connected to the	
Harmonic emissions IEC61000-3-2	Class A	 public low-voltage power supply network that supp buildings used for domestic purposes. 	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies		

Table 2

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

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. **Electromagnetic environment** IEC60601 test level Compliance level **Immunity test** -guidance ± 6 kV contact Electrostatic ± 6 kV contact Floors should be wood, concrete ±8kV air ±8kV air or ceramic tile. if floors are discharge(ESD) IEC61000-4-2 covered with synthetic material, the relative humidity should be at least 30% Electrical fast ±2kV for power ±2kV for power Mains power quality should be transient/burst Supply lines Supply lines that of a typical commercial or $\pm 1 \text{ kV for}$ ± 1 kV for hospital environment. IEC61000-4-4 input/output lines input/output lines ± 1 kV line (s) to line(s) ±1kV differential Mains power quality should be Surge IEC 61000-4-5 $\pm 2kV$ line(s) to earth mode that of a typical commercial or $\pm 2kV$ common hospital environment. mode <5 % U_T <5 % U_T Voltage dips, short Mains power quality should be (>95 % dip in U_T) (>95 % dip in U_T) interruptions and voltage that of a typical commercial or for 0,5 cycle for 0,5 cycle variations on power hospital environment. If the user 40 % U_T 40 % U_T supply input lines of the equipment or system (60 % dip in U_T) (60 % dip in U_T) IEC61000-4-11 requires continued operation for 5 cycles for 5 cycles during power mains interruptions, 70 % U_T 70 % U_T it is recommended that the (30 % dip in U_T) (30 % dip in U_T) for 25 cycles for 25 cycles equipment or system be powered from an uninterruptible power <5 % U_T <5 % U_T (>95 % dip in UT) (>95 % dip in U_T) supply or a battery. for 5 s for 5 s Power Power frequency magnetic fields frequency(50Hz/60Hz) should be at levels characteristic of magnetic field a typical location in a typical 3A/m 3A/m IEC61000-4-8 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

Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the			
user of 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol.

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

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

a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which Patient Monitor is used exceeds the applicable RF compliance level above, 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 Patient Monitor.

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

Table 4

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

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.

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

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

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

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

Chapter 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: $500(L) \times 320(W) \times 460(H)$ 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

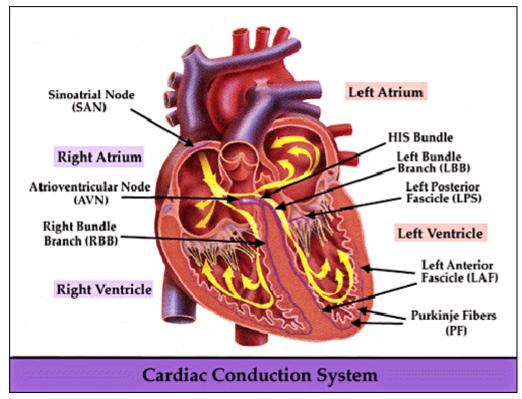
Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

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;
- \diamond Electrodes are not placed properly;
- ♦ Use expired electrode or use disposable electrode repeatedly;
- ♦ The skin placed electrode is uncleaned or poor contract caused by scurf and hair;
- \diamond 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.
- 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.
- 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 SpO_2 sensor with adhesive tape, or else it may result in venous pulsation and consequential inaccurate measurement result of SpO_2 .
- 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 SpO_2 sensor. However, a functional tester, such as SpO_2 simulator can be used to check how accurately a particular pulse oximeter is reproducing the given calibration curve. Before testing the oximeter by a functional tester, please firstly ask the manufacturer which calibration curve is used, if necessary, request the manufacturer for its dedicated calibration curve and download it into the tester.

Clinical Limit

- 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 SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO_2 value.

9.4 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

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).

30.737°C inside body cavity: 36.5°C

Normal value: body surface: 36.5 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 CO_2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR light beam is passed through a gas sample containing CO_2 , the electronic signal from a photodetector (which measures the remaining light energy), can be obtained. This signal is then compared to the energy of the IR source, and calibrated to accurately reflect CO_2 concentration in the sample. To calibrated, the photodetector's response to a known concentration of CO_2 is stored in the monitor's memory.

The monitor determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases. EtCO₂ is display as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 waveform (capnogram) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube placement. Respiration rate is calculated by measuring the time interval between detected breaths.

9.6.2 Mainstream vs. Sidestream Sampling

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

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

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

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

°C 5kΩ)

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 SpO_2 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.

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°C or above 40°C;
- Dispose of the battery, the local law should be followed.
- A 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.

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.
- \triangle Do not let any liquid flow into the shell or any parts of the monitor.
- \bigcirc Do not let the cleanser and disinfectant stay on its surface.
- \bigcirc Do not perform high pressure sterilization to the monitor.
- \bigcirc Do not put any parts of the monitor or its accessories in the liquid.
- \bigcirc Do not pour the disinfector on its surface while sterilization.
- \bigcirc 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.
- **A** 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% Ispropanol before use.

- Do not use damaged accessories.
- Accessories cannot be entirely immerged into water, liquor or cleanser.
- Do not use radial, steam or epoxyethane to disinfect accessories.
- Do wipe off the remained alcohol or ispropanol on the accessories after disinfection, for good 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% atmospheric pressure: 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	
Over RR limit	
Over TEMP limit	
Over SpO ₂ limit	
Over PR limit	
Over NIBP SYS limit	The related parameter value exceeds the preset high/low
Over NIBP DIA limit	alarm limit.
Over NIBP MAP limit	
Over S-T 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		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
T		High limit	39 °C	39 °C	39 °C
Temp	erature	Low limit	35 °C	35 °C	35 °C
	Systolic	High limit	180 mmHg	130 mmHg	110 mmHg
		Low limit	60 mmHg	50 mmHg	50 mmHg
NIDD	Diastalia	High limit	120 mmHg	90 mmHg	90 mmHg
NIBP	Diastolic	Low limit	50 mmHg	40 mmHg	30 mmHg
	MAD	High limit	160 mmHg	110 mmHg	100 mmHg
	MAP	Low limit	50 mmHg	40 mmHg	30 mmHg
C.	02	High limit	100%	100%	100%
Sp	002	Low limit	90%	85%	85%
D 1.	. D. ()	High limit	180 bpm	200 bpm	220 bpm
Puise	e Rate	Low limit	40 bpm	50 bpm	50 bpm
0.7.0		High Limit	+1.00mV	+1.00mV	+1.00mV
8-1 80	egment	Low Limit	-1.00mV	-1.00mV	-1.00mV
Temperature Difference		Range	2 °C	2 °C	2 °C
	GVG	High limit	200mmHg	160mmHg	140mmHg
	SYS	Low limit	10mmHg	10mmHg	10mmHg
Dragging	DIA	High limit	200mmHg	160mmHg	140mmHg
Pressure	DIA	Low limit	10mmHg	10mmHg	10mmHg
	MAD	High limit	200mmHg	160mmHg	140mmHg
	MAP	Low limit	10mmHg	10mmHg	10mmHg
	CVC	High limit	120mmHg	100mmHg	90mmHg
	SYS	Low limit	10mmHg	10mmHg	10mmHg
Pulmonary	DIA	High limit	120mmHg	100mmHg	90mmHg
Artery Pressure		Low limit	10mmHg	10mmHg	10mmHg
11055010	MAP	High limit	120mmHg	100mmHg	90mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	SYS	High limit	30mmHg	30mmHg	30mmHg
		Low limit	0mmHg	0mmHg	0mmHg
Central	DIA	High limit	30mmHg	30mmHg	30mmHg
Venous Pressure	DIA	Low limit	0mmHg	0mmHg	0mmHg
11005010	MAD	High limit	30mmHg	30mmHg	30mmHg
	MAP	Low limit	0mmHg	0mmHg	0mmHg
	Respiration	High limit	40 rpm	50 rpm	60 rpm
	Rate	Low limit	10 rpm	10 rpm	10 rpm
CO2	EtCO2	High limit	70 mmHg	70 mmHg	70 mmHg
002	EtCO2	Low limit	10 mmHg	10 mmHg	10 mmHg
	InsCO2	High limit	10 mmHg	10 mmHg	10 mmHg
		Low limit	0 mmHg	0 mmHg	0 mmHg

The high and low limits setting range:

Parameter Mode		Adult	Infant	Neonate	
Heart Rate		High limit	1~350bpm	1~350bpm	1~350bpm
		Low limit	0~349bpm	0~349bpm	0~349bpm
Respiration		High limit	1~120rpm	1~150rpm	1~150rpm
		Low limit	0~119rpm	0~149rpm	0~149rpm
Tom	oratura	High limit	0.1~60°C	0.1~60°C	0.1~60°C
Temperature		Low limit	0~59. 9°C	0~59. 9°C	0~59. 9°C
Systolic		High limit	31~280 mmHg	31~200 mmHg	31~135 mmHg
		Low limit	30~279 mmHg	30~199 mmHg	30~134 mmHg
Die	istolic	High limit	11~232 mmHg	11~150 mmHg	11~100 mmHg
Di	istone	Low limit	10~231 mmHg	10~149 mmHg	10~99 mmHg
N	lean	High limit	21~242 mmHg	21~165 mmHg	21~110 mmHg
14	ican	Low limit	20~241 mmHg	20~164 mmHg	20~109 mmHg
S	pO2	High limit	1~100%	1~100%	1~100%
5	p02	Low limit	0~99%	0~99%	0~99%
Puls	e Rate	High limit	1~300bpm	1~350bpm	1~350bpm
1 uit	e ruite	Low limit	0~299bpm	0~349bpm	0~349bpm
S-T S	legment	High Limit	-2.49Mv~+2.49mV	-2.49mV~+2.49mV	-2.49mV~+2.49mV
515	,eginent	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
	Systolic	High limit	(1~250) mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	(0~249) mmHg	(0~249)mmHg	(0~249)mmHg
Arterial	Diastolic	High limit	(1~250) mmHg	(1~250)mmHg	(1~250)mmHg
Pressure		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
	Systolic -	High limit	(1~120) mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	(0~119) mmHg	(0~119)mmHg	(0~119)mmHg
Pulmonar	Diastolic -	High limit	(1~120) mmHg	(1~120)mmHg	(1~120)mmHg
Artery		Low limit	(0~119) mmHg	(0~119)mmHg	(0~119)mmHg
Pressure	Mean -	High limit	(1~120) mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	(0~119) mmHg	(0~119)mmHg	(0~119)mmHg
	Systolic	High limit	(-9~40) mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	(-10~39) mmHg	(-10~39)mmHg	(-10~39)mmHg
Central	Diastolic -	High limit	(-9~40) mmHg	(-9~40)mmHg	(-9~40)mmHg
Venous Pressure		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
	Respiration Rate	High limit	(1~120) rpm	(1~150)rpm	(1~150)rpm
		Low limit	(0~119) rpm	(0~149)rpm	(0~149)rpm
	EtCO2	High limit	(1~100) mmHg	(1~100) mmHg	(1~100) mmHg
CO ₂		Low limit	(0~99) mmHg	(0~99) mmHg	(0~99) mmHg
	InsCO2 -	High limit		, , ,	
		ę	$(1\sim30)$ mmHg	$(1 \sim 30) \text{ mmHg}$	$(1 \sim 30) \text{ mmHg}$
		Low limit	(0~29) mmHg	(0~29) mmHg	(0~29) mmHg

12.3 Abbreviation of Arrhythmia

- 1. ECG TACHY
- 2. ECG BRADY
- 3. ECG ARREST
- 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
" CO_2 Out of Range" If error persists, perform a zero.	The value being calculated is greater than the upper CO_2 limit (150 mmHg, 20.0 kPa, or 19.7 %). The maximum value output is the upper CO_2 limit.
"Check Airway Adapter" To clear, clean airway adapter if mucus or moisture is seen. If the adapter is clean, perform a Capnostat zero.	Usually caused when the airway adapter is removed from the sensor or when there is an optical blockage on the windows of the airway adapter. May also be caused by failure to perform sensor zero to when adapter type is changed.
The Sensor not Ready	 This is prompted if the CO₂ sensor is not ready for a Capnostat Zero. If the "Zero Required" and this massage both prompt message both promptone or more of the following conditions may exist: Breaths detected Temperature is not stable Source Current unstable In sleep mode.
Zero in already progress	Normal zero calibration is in already progress.
Zero Fault and Breaths Detected	Zero attempted and breaths have been detected in the last 20 seconds.
Zero Ok	Zero calibration is successful

12.6 Typical Pressures and CO₂ Readings at Altitudes

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

12.7 Accessories List

(1) ECG cable	One set			
(2) NIBP cuff	One piece			
(3) SpO_2 probe	One piece			
(4) Body surface temperature transducer	One piece			
(5) Rectal temperature probe (optional)	One piece			
(6) Power cable	One piece			
(7) Grounding wire	One piece			
(8) Disposable electrode	Ten pieces			
(9) IBP transducers (Dual) (optional)	One set			
(10) Sidestream/Mainstream CO ₂ accessories One set				
(11) Printing paper (optional) Ten rolls				
(12) User manual One copy				
(13) Warranty One copy				
(14) Packing list One piece				
Note: The accessories are subject to change. Detailed items and quantity see the Packing List.				

12.8 Instructions for SpO₂ Probe

Instructions for Pediatric SpO₂ Finger Clip Sensor

Intended Use

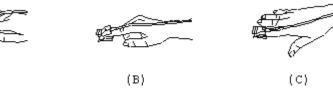
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for pediatric patients weighing between $10\sim40$ kg.

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.



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

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

<u>Warnings</u>

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

Instructions for Adult SpO₂ Finger Rubber Sensor

Intended Use

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

Contraindications

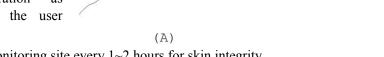
This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

- 1) Hold the sensor with its opening towards the patient's index finger (A). The sensor should be oriented in such a way that the sensor side with a finger tip sign is positioned on the top.
- 2) Insert the patient's index finger into the sensor until the fingernail tip rests against the stop at the end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor. Direct the cable along the top of the patient's hand. Apply adhesive tape to secure the cable (B). If an index finger cannot be positioned correctly, or is not

available, other fingers can be used.

 Plug the sensor into the oximeter and verify proper operation as described in the user manual.



4) Inspect the monitoring site every $1 \sim 2$ hours for skin integrity.

Cleaning & Disinfection

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

(B)

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

<u>Warnings</u>

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

Instructions for Adult SpO₂ Finger Clip Sensor

Intended Use

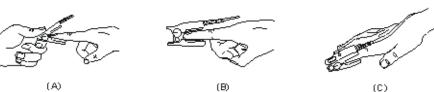
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 40kg.

Contraindications

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

Instructions for Use

- 1) With the upper and lower jaws open, place an index finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window (A). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
- 2) Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.
- 3) Spread open the rear tabs of the sensor to provide even force over the length of the pads (B).
- 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 $1 \sim 2$ hours for skin integrity.
- 7) Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

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

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

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

If you have any question regarding any of SpO₂ sensor instructions, please contact market @ creative-sz.com your local dealer.

