CREATIVE
MEDICAL

Patient Monitor

User Manual

(Part I)

Shenzhen Creative Industry Co., Ltd

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 Patient Monitor.

The Manual describes, in accordance with the Patient Monitor's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, 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.

This manual is applicable to the product series for all our Patient Monitors. It consists of two parts, part I covers almost the all necessary content, except the operations for user interface, which is included separately in part II.

The Manual is published in English and we have the ultimate right to explain the Manual. No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent. We reserve the right to improve and amend it at any time without prior notice. Amendments will however be published in a new edition of this manual.

This manual is an integral part of the product, it should always be kept close to the equipment so that it can be obtained conveniently when needed

Version of this manual: V1.0

Date: March 13, 2014

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.**

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

3502-2000008

Instructions to User

Dear Users,

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

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

- **WARNING for PACEMAKER PATIENTS: Although the pacemaker pulse inhibition function is available in this device, the heart rate meter 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.**
- **If uncertain about the accuracy of any measurement, first check the patient's vital signs by any alternative means, and then make sure the monitor is functioning properly.**
- **The device should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition.**
- **The monitor is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.**
- **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 the standard IEC 60601-1.**
- **Check SpO_2 probe application site periodically (every 30 minutes) to determine circulation, positioning and skin sensitivity.**
- **The SpO_2 measurement of this monitor may not work for all testees. If stable readings cannot be obtained at any time, discontinue use.**
- **Do not immerse the monitor or its accessories in liquid to clean.**
- **Do not use accessories other than those provided/recommended by the**

manufacturer.

- **Each time the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.**
- **Do not silence the audible alarm if patient safety may be compromised.**
- **The alarm limit value shall be within the measuring range, or it may disable the alarm system. Please refer to the related chapter for alarm limit range.**
- **A HAZARD can exist if different alarm presets are used for the same or similar equipment in single area.**
- **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 neonates(less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.**
- **The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.**
- **DO NOT take blood pressure measurement from a limb receiving ongoing transfusion or intubations or skin lesion area, otherwise, damages may be caused to the limb.**
- **Continuous use of SpO_2 sensor may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.**
- **SpO_2 measuring position must be examined more carefully for some special patient. Do NOT install the SpO_2 sensor on the finger with edema or vulnerable tissue.**
- **To prevent the risk of the short circuit and to ensure the ECG signal quality, the equipment must be properly grounded.**
- **Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.**
- **All the connecting cables and rubber tubes of the applying parts should be kept away from the patient's cervix to prevent any possible suffocation of the patient.**
- **All the parts of the monitor should NOT be replaced at will. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused.**
- **DO NOT stare at the light of SpO_2 sensor (infrared is invisible) 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.**
- **The system might not meet its performance specifications if stored or used outside the manufacturer's specified temperature and humidity ranges.**

- **Reuse, disassembly, cleaning, disinfecting the single patient use CO_2 cannula kits and on-airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.**
- **Electrical Shock Hazard: Always disconnect the CO_2 Sensor before cleaning. Do NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.**
- **Electrical Shock Hazard:No user serviceable parts inside the CO_2 Sensor.**
- **After the life cycle of the Sidestream CO_2 Sensor and its accessories has been met, disposal should be accomplished following national and/or local requirements.**
- **Please peruse the relative content about the clinical restrictions and contraindication.**
- **The accessories which can be used repeatedly should have a thorough cleanness before it is used to another patient. Please refer to the related chapter for maintenance method.**
- **When disposing of the monitor and its accessories, the local law should be followed.**
- **Substitution of a component different from that supplied might result in measurement error.**

Table of Contents

Chapter 1 Overview

1.1 Product Name

Name: Patient Monitor

1.2 Applications and Scope

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

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

1.3 Operating Environment

1. Ambient temperature range: 5°C~40°C
   Relative humidity: 30%~80%
   Atmospheric pressure: 70kPa ~106.0kPa
   Power Voltage: (100-240)VAC
   Power frequency: 50Hz/60Hz
2. This equipment should be situated in a place protected against direct sunlight, so as to prevent overheating inside the equipment.
3. The device should be stored and used within specified temperature, humidity and atmospheric pressure range, or it may cause damage to the device or inaccurate measurement result.
4. If the device gets wet by accident, the operator should NOT power it on directly until it has been air-dry enough to avoid any damage to it.
5. Do not use this equipment in an environment with toxic or inflammable gas.
6. This equipment should be placed on a stand or flat platforms, so as to prevent possible shock.
7. Do not use this equipment in combination with any equipment other than those expressly permitted in the manual.
8. The monitor is defibrillator discharge proof and can be used with electrosurgical unit. But when the device is used together with defibrillator or electrosurgical equipment, the user (doctor or nurse) should keep the patient under close surveillance for his/her safety. Refer to the following function description for specific protective measures or notes.
9. Make sure that the equipotential grounding terminal is grounded correctly.
10. Do not use mobile phone nearby, so as to avoid strong radiant field interference.

1.4 Impact on Environment and Resources

Low

1.5 Safety

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

applied parts.

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

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

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

Chapter 2 Working Theories

2.1 Overall Structure

The overall structure of the monitor is shown as Figure 2.1

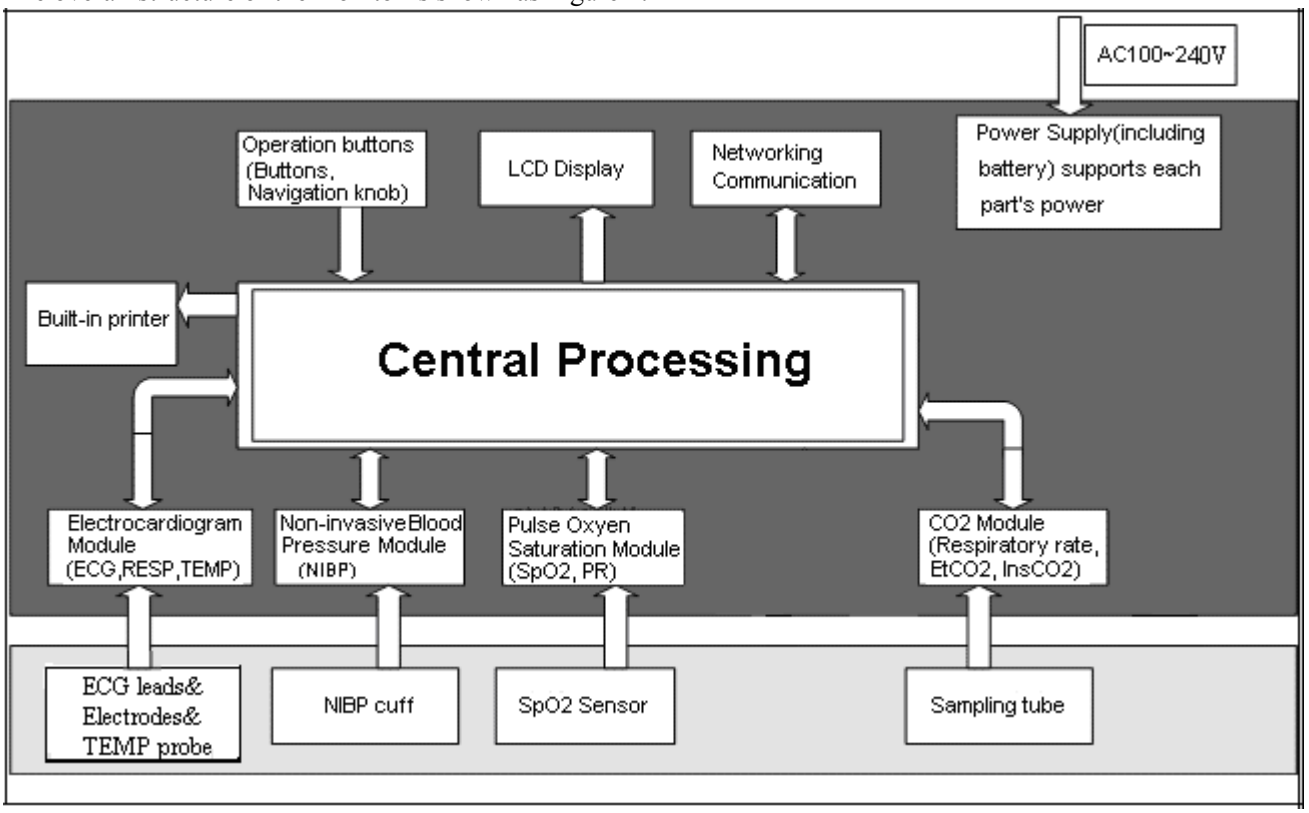


Figure 2.1

2.2 Composition

1. The monitor consists of the main units and the corresponding functional components (ECG cables/lead wires, non-invasive blood pressure cuff, SpO_2 probe, temperature transducer, accessories for invasive blood pressure and CO_2 monitoring).
2. The patient monitor has multiple measurement channels including ECG/Heart Rate, NIBP, SpO_2/Pulse Rate, Respiration Rate, Temperature, and CO_2 Concentration.
3. The patient monitor has output ports including networking communication and the built-in printer.
4. Basic configuration includes the functions of ECG/Heart Rate, NIBP (systolic, diastolic, mean aterial pressure & pulse rate), SpO_2/Pulse Rate, Respiration Rate, and Temperature.

2.3 Working Theories

This Patient Monitor, which performs physiological parameter measurement through different modules, is a product with modular design. It consists of several modules: ECG/RESP/TEMP module, NIBP module, SpO_2 module, CO_2 module (optional), the mother board and other auxiliary boards.

1. The ECG/RESP/TEMP module detects the ECG signal through ECG cable/lead wires via electrodes, it also measures the respiration by use of the same ECG electrodes. The temperature is measured through the temperature probe. The heart rate and respiration rate are calculated from its signal waveform respectively.

2. The SpO_2 module detects the plethysmograph data via the SpO_2 probe and calculates the pulse rate and oxygen saturation (SpO_2) accordingly.
3. The NIBP module measures the blood pressures including systolic, diastolic, mean arterial pressure and pulse rate through the pneumatic system and cuff. The cuffs are designed for adult and pediatric patients respectively, and it can work in different modes to adapt different patient categories.
4. The CO_2 module detects CO_2 concentration through the sampling line (side stream) or within the airway (main stream), and calculate the respiration rate, end tidal CO_2 concentration ($EtCO_2$), and inspired CO_2 concentration ($InsCO_2$).
5. The mother board is the main controlling unit, which also connects to the interface board and key board. The interface board inter-connects the functional modules with the mother board.

Chapter 3 Installation and Connection

3.1 Installation

3.1.1 Opening the Box and Check

1. Open the package, take out the monitor accessories from the box carefully and place it in a safe stable and easy to watch position.
2. Open the user manual to sort the accessories according to the packing list.
   - ◆ Inspect the accessories for any mechanical damages
   - ◆ Check all the exposed leads and inserted accessories
   - ◆ Check whether any risk or abnormity exists in the device and its accessories before using the monitor. If any abnormity (such as broken cable or crack of the enclosure etc.) is found, stop using this device.

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

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

3.1.2 Connecting the AC Power Cable

1. When powered by AC mains power supply:

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

Caution: ensure that the monitor is grounded correctly.

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

🔔 The monitor is applicable to connect to the public mains power network.

2. Built-in battery

The following steps should be followed to install the battery:

Step 1: open the battery cover;

Step 2: pull out the battery cable and connect it to the battery pack;

Step 3: push the battery pack into the battery compartment and lock it;

Step 4: close the battery cover.

- ◆ Caution: it’s better to recharge the battery after it is used up, and the charging time should be 13~15 hours long.
- ◆ Battery life: Provided that a battery is new and fully charged, the minimal working time of the monitor with accessories connected is declared in the table below:

Name	Battery life
Patient Monitor	120min

- NOTE: It will take 12-15 hours to charge battery from exhaust state to 90% charged.

The provided battery of the monitor must be recharged after transportation or storage. So if the monitor is switched on without being connected to the AC power supply, it may not work properly due to insufficient battery power.

3.1.3 Starting the Monitor

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

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

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

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

3.2 Connection

3.2.1 ECG Cable/Lead Wires Connection

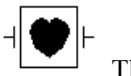
ECG measurement is to collect the ECG signal via the ECG electrodes. Electrode connects the patient and the lead wires and/or ECG cable. The lead wires and/or cable connect to the monitor. The locations of the electrodes are very important for obtaining accurate ECG signals.

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

- Clean and scrap skin to ensure low sensor impedance if necessary. Mild soap and Water is recommended as a skin cleanser.

  Note: If alcohol is used as cleanser, it is recommended to have 30-second dry time for a better connection.

- Scraping 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:

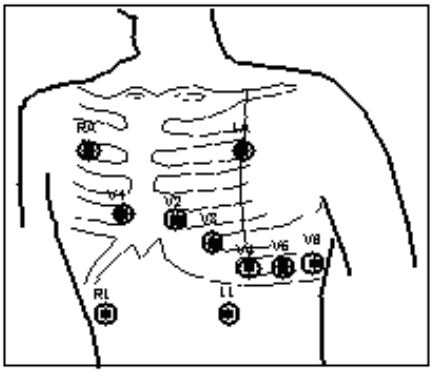


Figure 3.5 Electrode Location

Note: If any side-effect such as allergic or itchy reaction is found, remove the electrodes from the patients immediately.

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

It might not display ECG waveform when using ECG cable with 3 lead wires while the setting of "Cable" is set as "5" in the ECG parameter setup menu. The ECG cable with 5 leads wires should be used to measure ECG signal at this situation.

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

Electrode connection 1 (IEC Standard)		Electrode connection 2 (AHA Standard)		Electrode position on body surface
Color code	Label on lead wire connection	Color code	Label on lead wire connection	
Red	R	White	RA	Right Arm: The intersection between the centerline of the right clavicle and Rib 2
Yellow	L	Black	LA	Left Arm: The intersection between the centerline of the left clavicle and Rib 2
Green	F	Red	LL	Left Leg: Left part of the upper abdomen
Black	N/RF	Green	RL	Right Leg: Right part of the upper abdomen
White	C	Brown	V	Any of the following location (C1-C6 or V1-V6) on chest
White/red	C1	Brown	V1	4th Intercostal (IC) space at right border of sternum
White/yellow	C2	Brown/yellow	V2	4th IC space at left border of sternum
White/green	C3	Brown/green	V3	Midway between V2 and V4
White/brown (blue)	C4	Brown/blue	V4	5th IC space on left midclavicular line
White/black	C5	Brown/red	V5	Left anterior axillary line at the horizontal level of V4
White/purple	C6	Brown/purple	V6	Left midaxillary line at the horizontal level of V4

Safety Instructions for ECG Monitoring

- Patient Monitor can only be equipped with ECG cable and/or lead wires provided by our company; using ECG cable and/or lead wires supplied by other companies may cause improper performance or poor protection while using defibrillator.
- Using the same type of qualified and authorized electrodes which should be within its effective life on the same patient. If any side-effect such as allergic or stimulus skin is found, the measurement should be stopped at once. It is prohibited to apply the electrode to the patient with lesion and body putrescence.
- To the patient with pacemaker, due to that this device has been designed to provide function of pacemaker pulse inhibition for heart beat identification, normally the pacemaker pulse is not counted in heart rate measurement and calculation, but when the pulse width of the pacemaker pulse is larger than 2ms, the pacemaker pulse inhibition may not be fully effective. In order to reduce this possibility, observe the ECG waveforms on the screen carefully and do NOT rely entirely on the heart rate display and alarm system of this monitor when monitoring this kind of patients. Keep pacemaker patient under close surveillance.
- The improper connection with electrosurgical unit may not only cause burns, but also damage the monitor 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 them with the patient properly.
- Electric parts of electrodes, leads and cable are forbidden to contact any other conductive parts (including ground).
- 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 located in proper places according to this manual's instructions and the instructions for using electrode, the chance of this transient occurrence will be decreased.
- ECG cable and/or lead wires may be damaged while using defibrillator. If the cable and/or lead wires are used again, please do the functional check firstly.
- When the monitor is inoperable due to overload of ECG or saturation of any part of the amplifier, it will prompt "Lead off" to remind operator.
- The user should ensure that no predictable hazard will be caused by the summation of leakage currents when several item of monitor are interconnected.
- When plugging or unplugging the ECG cable, be sure to hold the head of the connector and pull it out.

3.2.2 Cuff Connection for Blood Pressure Measurement

1. Connect the tube with cuff to the connector marked with "NIBP" icon on the signal input panel.
2. Unfold the cuff and wrap it around the patient's upper arm.

Requirements of the cuff:

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

Note: the appropriate cuff should be selected according to the age and arm circumference of the patient.

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

2) When putting on the cuff, unfold 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 artery 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.

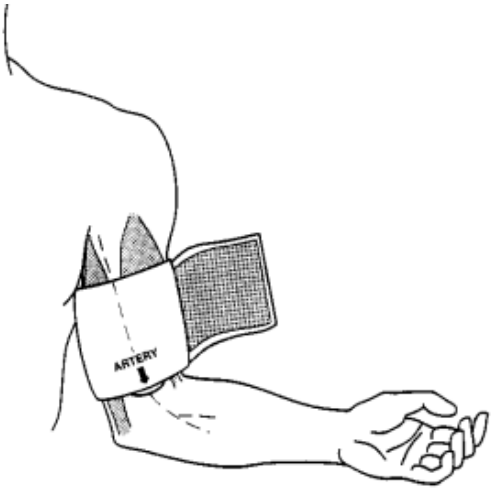


Figure 3.6 Cuff location

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

- **Pressure Accuracy Verification**

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

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

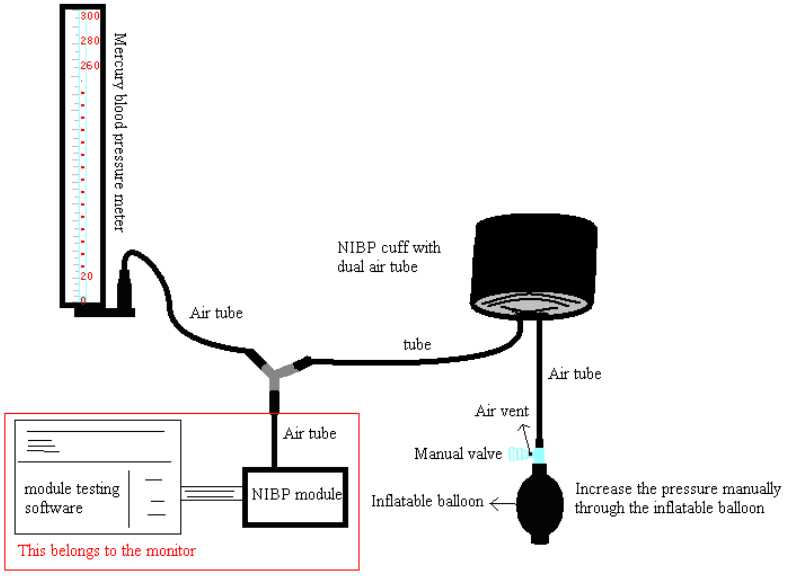


Figure 3.7 Connection of Pressure Accuracy Verification Fixture

Mode 1: Automatic inflation for the pressure accuracy verification

At this mode, the monitor can activate the inflation, so the pressure will increase automatically until it exceeds the limit value specified in table A. This pressure limit value depends on the patient type selection as shown in table A:

Adult	240mmHg
Pediatric	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: Manual inflation for the pressure accuracy verification.

At this mode, the pressure should be increased manually by a 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
Pediatric	240mmHg
Neonate	140mmHg

Table B

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

➢ **Air Leakage Check**

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

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

Safety Instructions for NIBP Measurement

- When taking the blood pressure measurement on a Pediatric or Neonate patient, do NOT operate in the Adult mode. The high inflation pressure may cause lesion or even body putrescence. Even though the monitor can identify the cuff type so it will stop inflation and indicate "wrong cuff" when taking the blood pressure measurement for a pediatric or neonate in the "adult" patient type setting. The user (doctor or nurse) should pay more attention to select the correct patient type.
- It is recommended to take the blood pressure measurement manually.
- 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.
- If the patient is moving or suffering tremble, hyperkinesia or arrhythmia, it may cause the inflation time of inflatable balloon endures longer, which may not only prolong the NIBP measurement time, but also result in the body wrapped by the cuff is troubled by purpura, hypoxemia and neuralgia because of the friction.
- Before the measurement is carried out, select an appropriate monitoring mode depending on the patient type (adult, pediatric or neonate).
- It is prohibited to wrap the cuff to a limb with skin lesion
- DO NOT take blood pressure measurement from a limb receiving ongoing transfusion or intubations. Because it may damage the limb tissue around the intubation if the transfusion becomes slower or blocked during the cuff inflation.
- The windpipe which connects the cuff and monitor should be straightway without any tangle.
- When an adult subject is monitored, the machine may fail in giving the blood pressure measure if the pediatric mode is selected.
- Prior to use of the cuff, empty the cuff until there is no residual air inside it to ensure accurate measurement.
- Do NOT twist the cuff tube or put heavy things on it.
- When unplugging the cuff, hold the head of the connector and pull it out.
- The NIBP measurement will not be affected when the monitor is connected to the patient on whom the electrosurgical device such as defibrillator or electrosurgical knife with high frequency is being used.
- The appearance of arrhythmia results in irregular heart beat which may affect the accuracy of NIBP measurement data. It is recommended to take the NIBP measurement again at this situation.
- The Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers.

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

3.2.3 SpO_2 Probe Connection

Creative reusable SpO_2 finger clip sensor is configured by default for general purpose. For further information,

please contact your local representative.

Creative reusable SpO_2 finger clip sensor can be used with a compatible patient monitor (e.g. all models of Patient Monitors and PC-900A Vital Signs Monitor made by Creative) or pulse oximeters (e.g. PC-66B Handheld Pulse Oximeter made by Creative).

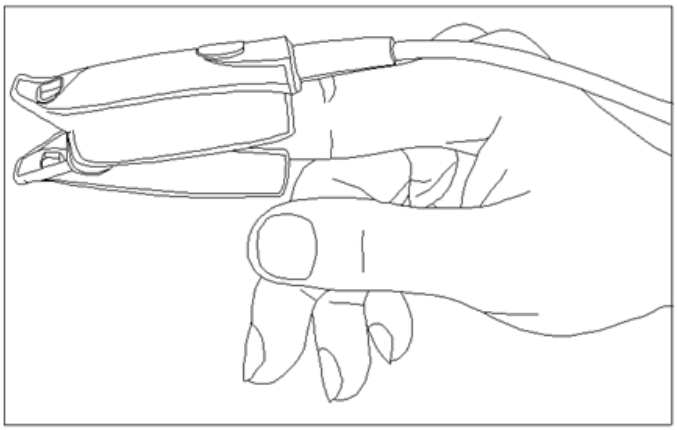
The sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for adult patients weighing greater than 40kg or pediatric patients weighing between 10~40kg.

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

Operation procedure:

1. Connect the SpO_2 probe to the connector marked with "SpO_2" icon on the signal input panel. When unplugging the probe, be sure to hold the head of the connector and pull it out.

2. Insert one finger (index finger is preferred, but middle or ring finger with proper nail length is possible as well) into the probe according to the finger mark on the probe, shown as below.



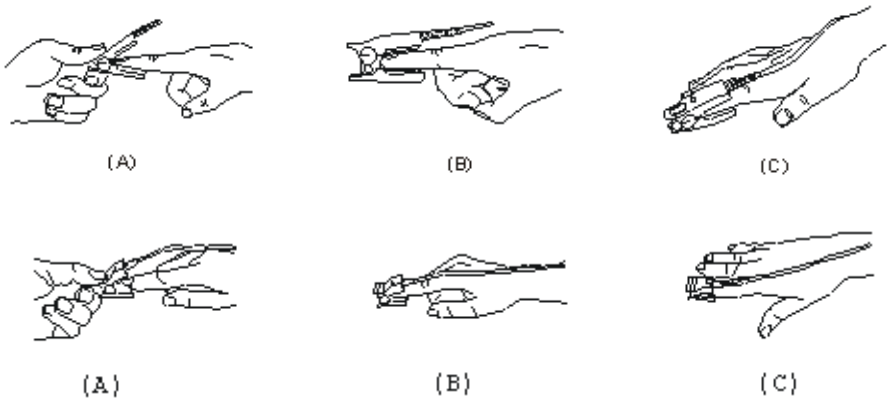


Figure 3.8A Demonstration of Adult/Pediatric SpO_2 Finger Clip Sensor

(A) With the upper and lower jaws open, place a finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window.

(B) Spread open the rear tabs of the sensor to provide even force over the length of the pads.

(C) The sensor should be oriented in such a way that the cable is positioned along the top of the hand.

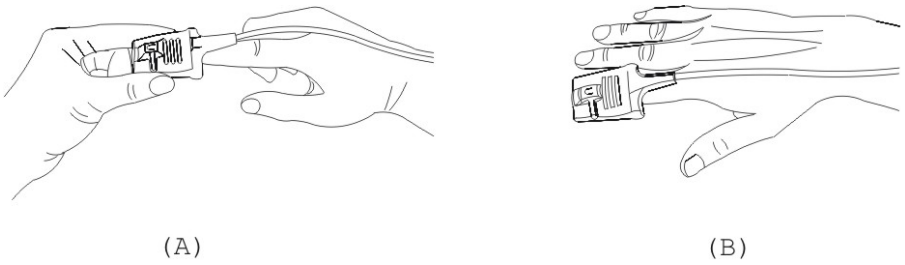


Figure 3.8B Demonstration of Adult SpO_2 Finger Rubber Sensor

(A) Hold the sensor with its opening towards the patient's finger, the sensor should be oriented in such a way that the sensor side with a finger tip sign is positioned on the top.

(B) Insert the patient's 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 if necessary.

When selecting a SpO_2 probe or 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.

SpO_2 Probe	Patient Category
Adult SpO_2 Finger Clip Sensor (reusable)	Adult
Adult SpO_2 Finger Rubber Sensor (reusable)	
Pediatric SpO_2 Finger clip Sensor (reusable)	Pediatric
SpO_2 Y-type sensor with wrapper (reusable)	Neonate

3. If the neonate SpO_2 sensor is used, please follow figure to connect.

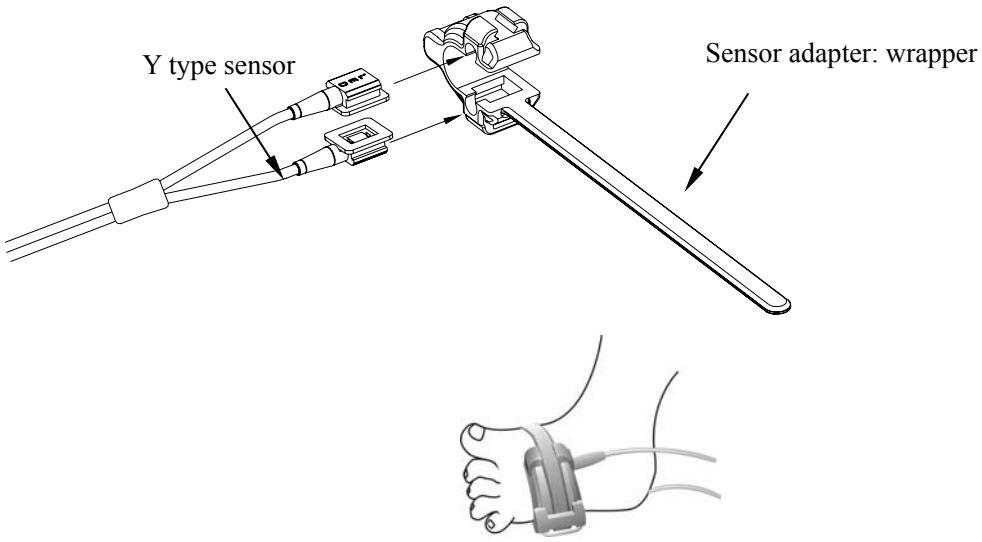


Figure 3.8C Neonate SpO_2 sensor placement

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.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO_2 sensor.

To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material if necessary. 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, cleaning and reuse. For single-patient use sensors, use a new sensor for each patient.

Caution: Do not disinfect any SpO_2 sensor by irradiation, steaming, or ethylene oxide.

Safety Introductions for SpO_2 Monitoring

- Continuous use of fingertip SpO_2 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 site for over two hours, please inspect the monitoring site every 1~2 hours for skin integrity, and change the measuring site periodically if necessary.
- SpO_2 measuring site must be examined more carefully for some special patient. Do NOT place the SpO_2 sensor on the finger with edema or fragile tissue.
- Avoid placing the SpO_2 sensor on the same extremity with an arterial catheter, blood pressure cuff, or intravascular infusion line, otherwise the blood flow could be interrupted by the cuff or the circulatory condition could make low blood perfusion so that would result in on pulse found or loss of pulse during SpO_2 monitoring and further cause false alarm.
- Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate oxygen saturation measurements.

For disposal SpO_2 sensor, If the sterile packaging is damaged, do not use it any more.

Check the SpO_2 sensor and cable before use. Do NOT use the damaged SpO_2 sensor.

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.

When the temperature of SpO_2 sensor is abnormal, do not use it any more.

Please do not allow the cable to be twisted or bended.

Please do not use nail polisher or other cosmetic product on the nail.

The fingernail should be of normal length.

The SpO_2 sensor cannot be immerged into water, liquor or cleanser completely, because the sensor has no capability to resist the harmful ingress water.

Carefully route cables to reduce the possibility of patient entanglement or strangulation.

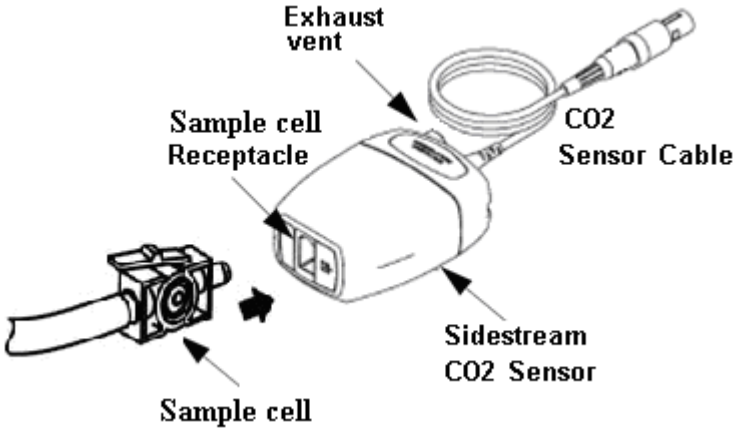
Do not use the sensor or other oximetry sensors during MRI scanning.

Our company offers a 6-month warranty against manufacturing defects for the SpO_2 sensors mentioned above in its undamaged condition.

If you have any question regarding any of SpO_2 sensor instructions, please contact your local dealer.

3.2.4 CO_2 Sensor Connection

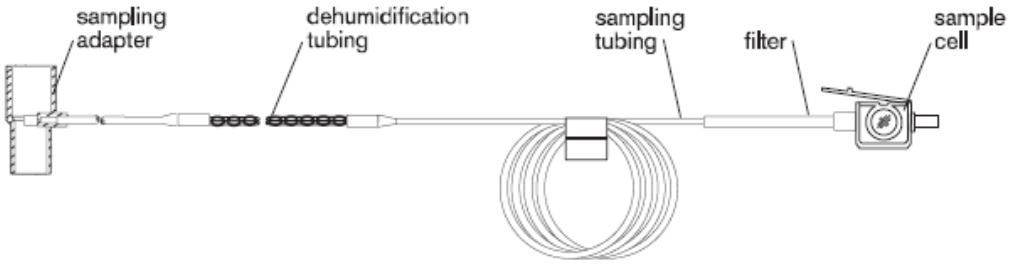
3.2.4.1 Sidestream CO2 Sensor Connection



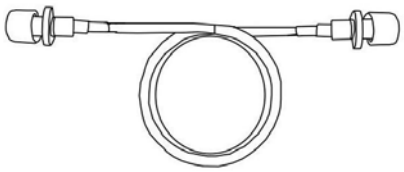
Demonstration for Sidestream CO_2 Sensor Connection

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

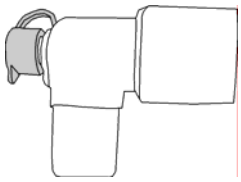
3. Default Tubing Configuration



Adapter and Sampling tube (Single patient use)



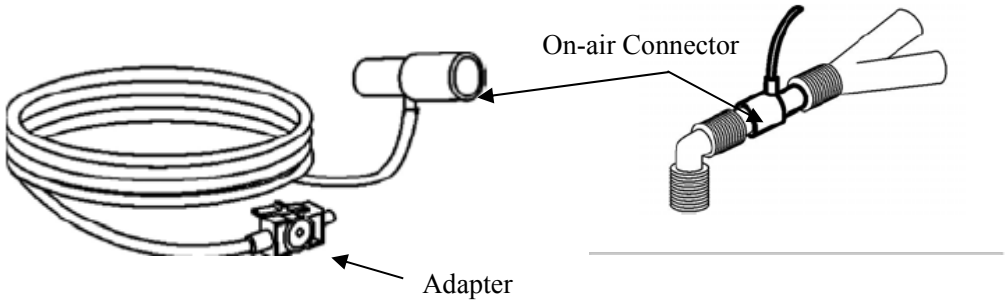
Extending airway tube for connecting to sampling tube (Single patient use)



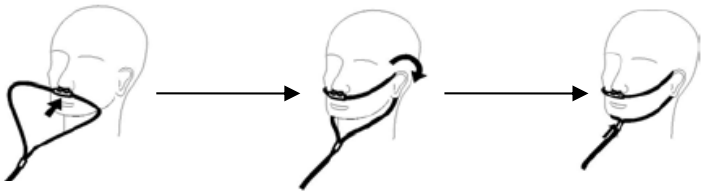
Wye Connector

4. Optional sampling cannula kits

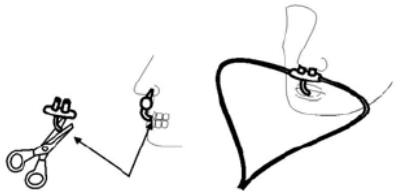
(1) T connector sampling cannula kits



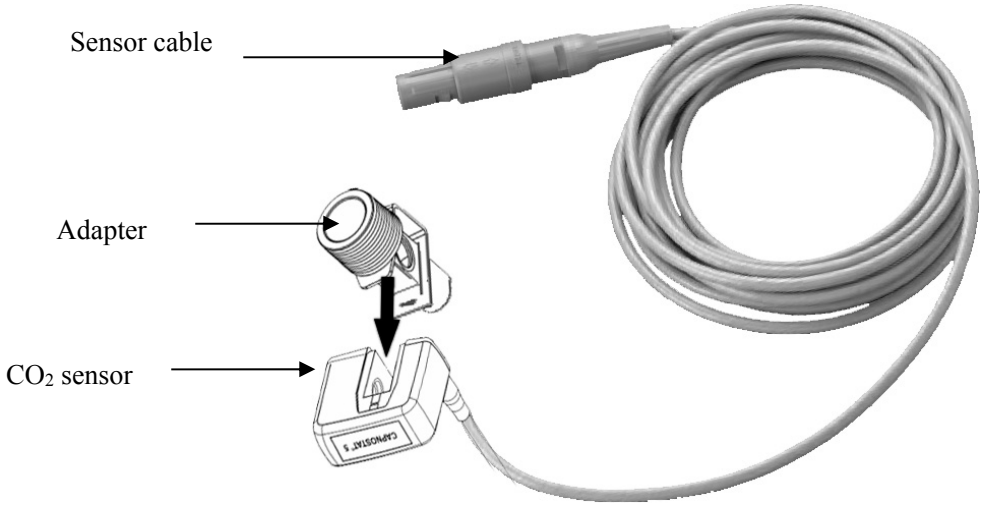
(2) Nasal Sidestream Cannula Kits



(3) Oral Sidestream Cannula Kits



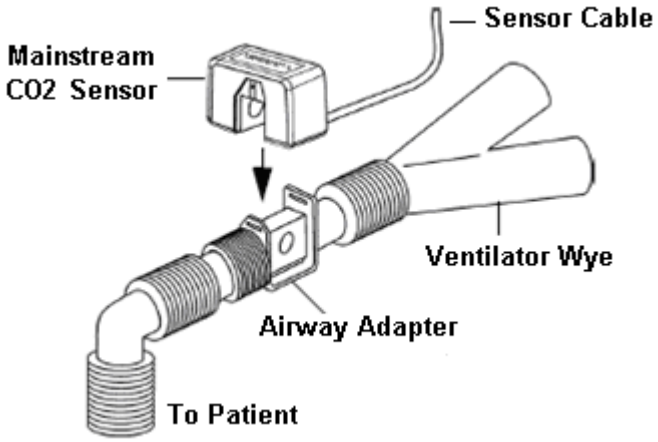
3.2.4.2 Mainstream CO2 Sensor Connection



Demonstration for Mainstream CO_2 Sensor Connection

1. Take out the CO_2 Sensor and insert the CO_2 Sensor Cable into the connector labeled "CO_2" on the connector panel of the monitor;
2. Snap the CO_2 sensor onto the airway adapter as shown in Figure 6.9. A "click" will be heard when the airway adapter is properly inserted.

3. Position the airway adapter in the patient's respiratory circuit (as close to the patient as possible) between the endotracheal tube and the ventilator circuit. Next, turn on the CO_2 switch at CO_2 Setup Screen and then wait 2 minutes for the sensor warm-up.



Safety Introductions for CO_2 Monitoring

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

- DO NOT sterilize or immerse the CO_2 Sensor in liquids.
- Replace the sidestream on-airway adapters and sidestream sampling kits if excessive secretions are observed.
- Do not operate the CO_2 Sensor when it is wet or has exterior condensation.
- Monitor the CO_2 waveform (Capnogram). If you see changes or abnormal appearance, check the patient and the sampling line. Replace line if needed.
- DO NOT use device on patients that 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 CO_2 Sensor in such environment may present an explosion hazard.

☞ The power voltage over monitor working voltage may cause damage to CO_2 sensor. Likewise, too low power voltage may affect the CO_2 measuring accuracy or even make the CO_2 sensor not work.

☞ When changing sampling tube, it is suggested to choose the default sampling tube with dehumidifying function. The sampling tube without dehumidifying function may be easily blocked by excessive moisture. (Use life: ordinary sampling tube: 6~12 hours; the sampling tube with dehumidifying function: about 120 hours.)

☞ If the measurement appears abnormity caused by sampling tube block, please replace it.

☞ The total length of the sampling tube and extending airway tube shouldn't be longer than 3 meters, too long may cause measurement abnormity. If using T connector sampling cannula kits, please insert the sampling tube with the tubes upward to avoid the affects of excessive moisture;

☞ Altitudes are different in different area, so set the Barometric Pressure setting value as the ambient barometric pressure.

☞ Use only our company approved accessories.

☞ While using the CO_2 sensor, a system leak, that may be caused by an uncuffed endotracheal tube or a damaged CO_2 sensor may significantly affect flow-related readings. These include flow, volume, pressure and other respiratory parameters.

☞ When stopping CO_2 monitor, please disconnected the CO_2 sensor from the patient monitor.

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

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

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

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

3.2.5 TEMP Probe Connection

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

Connecting methods:

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

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

3.2.6 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.

Unloading printing paper

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

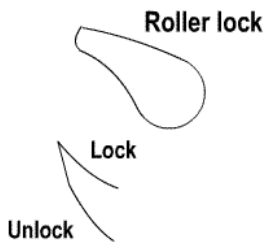


Fig.3.9

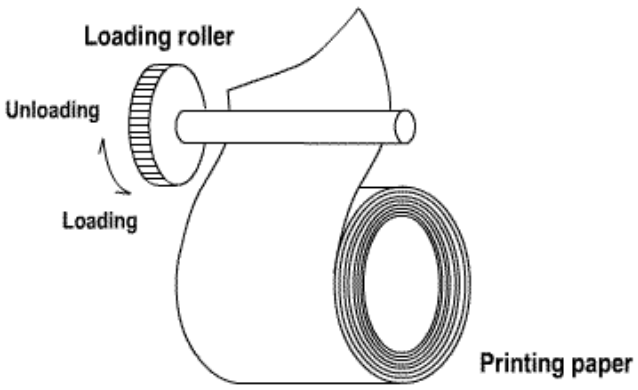


Fig.3.10

Built-in printer may be used due to the different configuration.

Printer operation instruction:

Power indicator: The 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 is not installed properly. When the printering paper is loaded correctly, the red light is off.

Figure 3.11 Built-in 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 3.12.

Step 3: Close the printer cover along the direction of arrow, as shown in figure 3.12.

Figure 3.12 printing paper

Chapter 4 Alarm

Once the patient is changed, please recheck if the monitor can work normally, alarm function works properly, and alarm setting are appropriate.

4.1 Alarm Description

4.1.1 Alarm Condition

The patient monitor has two alarm modes, respectively for the physiological alarm conditions and technical alarm conditions, the detailed define as follows:

- physiological alarm conditions: the device would give out alarm when the patient's physiological parameter value exceeds the preset limit, such as: Asystole, asphyxia, temperature over-limit and so on.
- technical alarm conditions: the device would give out alarm when system or sensor makes failures to cause abnormal monitoring function and inaccurate monitoring results, such as ECG lead off, probe off , low battery and so on.

4.1.2 Alarm Priority

- The patient monitor has 3 alarm levels: High priority, Medium priority and low priority. In addition, the monitor has preset alarm level about physiological alarm and technical alarm. Please refer to table 4

Alarm level	Alarm Event
High	Over TEMP1 limit, Over TD limit
	Asystole, Unable to detect HR, Over HR limit
	Over NIBP PR limit, Over NIBP SYS limit, Over NIBP DIA limit
	Unable to detect SpO_2, Over PR limit, Over SpO_2 limit,
	asphyxia ,Over RR limit
	Over $EtCO_2$ limit, Over $InsCO_2$ limit
	The battery capacity will exhaust
Medium	Lead Off, Probe off, Poor Signal, Electrode Off, High Impedance, Stifle Time Indication, Artefact.
Low	Other abnormal phenomenon

Table 4-1 Alarm priority and alarm event listing

Related to 3 levels alarm modes, medical and nursing staff should have different response to deal with potential dangerous, the detailed demands as follows:

1. High priority alarm: medical and nursing staff should response immediately.
2. Medium priority alarm: medical and nursing staff should response quickly.
3. Low priority alarm: medical and nursing staff should response as soon as possible.

NOTE: Some models may have only Medium and Low alarm priority because of the different configuration.

4.1.3 Alarm Modes

1. **When an alarm occurs, the patient monitor provides visible and audible alarm indications (which are shown by three ways: auditory alarm, light alarm and message description or numerical flash alarm). The detail is defined as follows:**
   - ✧ auditory alarm: are represented by loud speaker in monitor.
   - ✧ light alarm: are represented by flashing LEDs on the upper side of monitor.
   - ✧ message description or numerical flash alarm: are represented by waveform on the left display area or parameters display on the right area of the screen respectively.
2. **In order to inform the alarm quickly and accurately to users It is suggested that the distance between users and device should not exceed 4m. And the condition of clear alarm indication is when the distance within 1m (no block exists between the device and user)**
3. **if occurrence of multiple alarm signal at the same time, the monitor will give out alarm which has much more alarm signals alternative auditory alarm and light alarm. Meanwhile, message description or numerical flash alarm will be shown respectively in the form of words or numerical value.**
4. **The difference between pulse beep sound and alarm sound is shown below:**
   - ✧ Pulse beep sound: frequency is 300Hz, including SpO_2 sound and HR beep sound.
   - ✧ Alarm sound: please refer to Technical Specifications description.

4.1.4 Alarm Setting

1、 Except volume of audible alarm can be adjustable, the other properties of the alarm cannot be adjusted by the user, such as alarm priority setting, alarm light flashing and so on. In addition, all alarms in this patient monitor are “non-latched” type, that is to say, when the alarm event disappears, the corresponding alarm will automatically stop. The alarm volume range is shown as below:
   - ✧ High: 45dB～80dB (The distance between device front and test instrument is 1m)
   - ✧ Medium: 45dB～75dB (The distance between device front and test instrument is 1m)
   - ✧ Low: 45dB～70dB (The distance between device front and test instrument is 1m)

2、 When the icon displays on the screen and its color is red, that means the alarm volume is 0 (alarm is mute), at this time the user should pay more attention to the patient.

🔔 It is suggested that the users should not change the alarm volume lower than the factory default setting if close and constant attention could not be paid to the patient, otherwise the negligence of alarm event might cause irreversible harm to the patient.

🔔 During the alarm silence period, any new alarm event can activate the audible alarm again and the audible alarm function resumes normal state.

3、 Alarm settings are non-volatile, that means the previous settings will still sustain if the patient monitor is powered off (by accidental power interrupt or by normal power down) and reboot.

4.2 Alarm Technical Specifications

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 visual alarm indications are represented by flashing LEDs on the upper side of monitor, parameters display on the right area of the screen and the status line displayed on the bottom of the screen respectively. The LEDs flashing frequency and display colors are specified in the following table :

Alarm level	LED Colors	Blinking frequency	Duty rate
High priority	Red	2Hz	50%
Middle priority	Yellow	0.5Hz	50%
Low priority	Yellow	Continuous lighting	
No alarm	Green	Continuous lighting	

Parameters displayed on the screen will be inversed or flashing if corresponding alarm occurs.

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.

High priority: A chain of 10 beeps with pause intervals in such way: x, x, 2x+td, x, 1s, x, x, 2x+td, x, 1s, where x (pulse interval)=100ms, td (beep duration)=160ms, 1s=1 second, the beep tone is 400Hz, the pause period between every beeping chain is 5 seconds.

Middle priority: A chain of 3 beeps with 200ms pause interval and 200ms beep duration, the frequency is 500Hz, the pause period between every beeping chain is 10 seconds.

Low priority: A single beep without repeat, the frequency is 500Hz, beep duration is 200ms.

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

Chapter 5 Technical Specifications

5.1 ECG Monitoring

1. Input signals range in amplitude: ±(0.5mVp ~ 5mVp)
2. Heart rate display range: 15 bpm ~ 350 bpm
3. Heart rate display accuracy: ±1% or ±2bpm, whichever is greater.
4. **Heart rate averaging:** Averages the recent eight beats having RR intervals falling within the acceptable limits.
5. Heart rate alarm delay time: ≤10s
6. **Response time to change in heart rate:**

   Change from 80bpm to 120bpm: <8 sec

   Change from 80bpm to 40bpm: <8 sec
7. **Tall T-wave rejection:** Rejects all T-wave less than or equal to 120% of 1mV QRS.
8. **Pacemaker pulse rejection:**

   Rejects all pulses of amplitude ±2mV to ±700mV and duration 0.1 to 2 ms without overshoot;

   Rejects all pulses of amplitude ±2mV to ±400mV and duration 0.1 to 2 ms with overshoot.
9. Sensitivity selection:

   ×1/2, 5mm/mV tolerance: ±5%

   ×1, 10mm/mV tolerance: ±5%

   ×2, 20mm/mv tolerance: ±5%
10. Sweeping speed: 12.5mm/s, 25mm/s, 50mm/s tolerance: ±10%
11. ECG noise level: ≤30μV_{P-P}.
12. ECG input loop current: ≤0.1μA
13. Differential input impedance: ≥5MΩ
14. Common-mode rejection ratio (CMRR): ≥89dB
15. Time constant:

    Monitoring mode: ≥0.3s Diagnostic mode: ≥3.2s
16. Frequency response:

    Monitoring mode: 0.5 Hz～40Hz($^{+0.4\,dB}_{-3.0\,dB}$)

    Diagnostic mode: 0.05 Hz～75Hz($^{+0.4\,dB}_{-3.0\,dB}$)

Additional declarations to conform the particular standard of IEC 60601-2-27 "Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment"

Direct current for respiration, leads-off sensing, and active noise suppression	Applied current less than 0.1 microamperes.	
Response to irregular rhythm	A1 Ventricular bigeminy-80BPM A2 Slow alternating ventricular bigeminy-60BPM A3 Rapid alternating ventricular bigeminy-120BPM A4 Bidirectional systoles-90BPM	
Time to ALARM for tachycardia	Waveform B1, Amplitude 0.5 mV 1 mV 2mV	Average Time to Alarm <8 sec <8 sec <8 sec
	Waveform B2, Amplitude 1mV 2mV 4mV	Average Time to Alarm <8 sec <8 sec <8 sec

5.2 RESP Monitoring

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

5.3 TEMP Monitoring

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

5.4 NIBP Monitoring

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

   Adult: <180 mmHg; Infant: <120 mmHg; Neonate: <90 mmHg

8. Overpressure protection limit

Adult: 300 mmHg; Infant: 240mmHg; Neonate: 150 mmHg

9. NIBP measurement range:

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

10. NIBP accuracy:

Maximum mean difference: ±5 mmHg

Maximum Standard deviation: 8 mmHg

11. Measurement mode: Manual, Auto, STAT

5.5 SpO_2 Monitoring

1. Transducer: dual-wavelength LED

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

Maximal optical output power: less than 2mW maximum average

2. SpO_2 measuring range: 35%~100%

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

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

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

5.6 Pulse Rate Monitoring

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

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

5.7 CO_2 Monitoring

1. Technology: Infrared absorption method.

2. Mode of Sampling: Sidestream or Mainstream

3. CO_2 Response Time:

Sidestream: <3seconds (including transport time and rise time).

Mainstream: <60ms (rise time)

4. Warm-up Time: Not less than two minutes

5. CO_2 measurement range: 0~150mmHg

6. CO_2 Accuracy: 0~40mmHg ±2mmHg

41~70mmHg ±5% of reading

71~100mmHg ±8% of reading

101~150mmHg ±10% of reading

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

Gas temperature at 35°C for Mainstream

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

5.8 Data Recording

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

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

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

5.9 Other Technical Specifications

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

5.10 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

5.11 Guidance and manufacturer's declaration-Electromagnetic compatibility

Table 1

Guidance and manufacturer's declaration-electromagnetic emission- 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.		
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 public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

Table 2

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

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

Table 3

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

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	3 Vrms 150 kHz to 80 MHz	3V	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** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ,[a] should be less than the compliance level in each frequency range .[b] Interference may occur in the vicinity of equipment marked with the following symbol. 

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

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

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

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

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

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

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

Chapter 6 Packaging and Accessories

6.1 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
For different configuration, there are 3 types of dimension:
Dimension 1: 500(L) ×320(W) ×460(H) mm
Dimension 2: 360(L) ×320(W) ×410(H) mm
Dimension 3: 506(L) ×390(W) ×510(H) mm

6.2 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

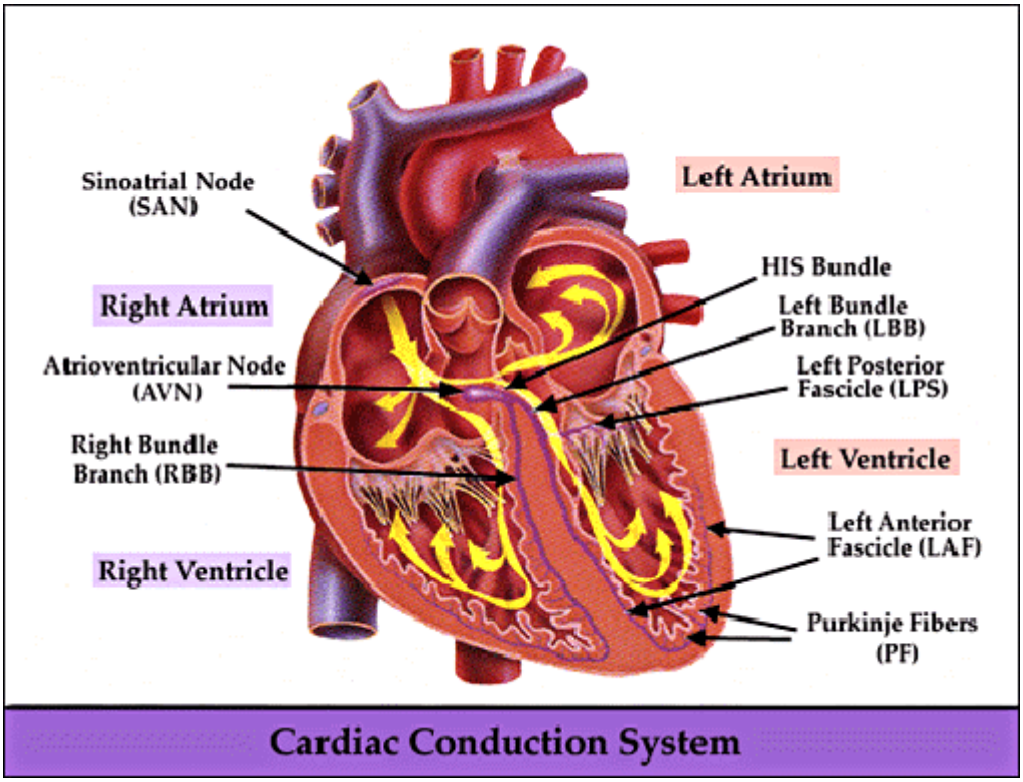
Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

Chapter 7 Working Principles

7.1 Introduction to ECG Measurement

7.1.1 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.

7.1.2 Factors affecting ECG signal

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

7.2 Introduction to Blood Pressure Measurement

7.2.1 Blood Pressure 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 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. The blood pressure at amplitude of cuff pressure forward reduced according to proper proportion is defined as systolic pressure, while the blood pressure at amplitude of cuff pressure backward reduced according to proper proportion is defined as diastolic pressure. The maximum change of pulse pressure occurs at these two points. They are equivalent to the point with pulse sound and the point without pulse sound respectively in the Korotkoff Sound Method.

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

Comparison between blood pressure measuring methods

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

The Oscillating method vs. the Korotkoff Sound Method

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

1. The measures by the Korotkoff Sound Method are liable to effect of human factors. For example, different people may have different sound judging ability, or different reactivity when listening to heart sound and reading mercury meter. The air release speed and subjectivity may also affect the judgment. By the oscillating method, the computation is accomplished by the computer, thus relieving the possibility of effect due to human factor.

2. With the Korotkoff Sound Method, the measure is taken on the basis of appearance and disappearance of heart sound. The air release speed and heart rate may have direct effect on the measurement accuracy. It also has the disadvantages of rapid air release and poor accuracy. In the contrast, with the oscillating method, the determination is calculated on the basis of cuff pressure oscillatory waveform envelope, and the air release speed and heart rate has little effect on the measurement accuracy.
3. Statistics show that, when measuring the hypertension, the measure taken by the oscillating method is likely to be lower than that taken by the Korotkoff Sound Method. When measuring the hypotension, the measure taken by the oscillating method is likely to be higher than that by the Korotkoff Sound Method. But, it doesn't mean the advantages or disadvantages between the oscillating method and the Korotkoff Sound Method. Comparison with the results taken by more accurate method, let's say comparison of the invasive pressure result with the output value by the blood pressure measuring simulator, will show which method has more accurate results. In addition, higher or lower value should be a statistical concept. It is recommended those used to adopt the Korotkoff Sound Method use different physiological calibration for values determined by the oscillating method.
4. The studies have shown that the Korotkoff Sound Method has the worst accuracy when it comes to measurement of hypotension, while the oscillating method has worse accuracy when it comes to measurement of controlled hypertension relief.

7.2.2 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 artery 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. The air tube which connects the cuff and monitor should be straightway without any tangle.
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 pediatric mode) or 80 mmHg (for the neonate mode) when it is powered on. Following that, 50mmHg (for the adult mode) or 30mmHg (for pediatric 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 Pediatric or neonate is selected.
7. When taking NIBP measurement on pediatric patients, the operator must select correct mode depending on different patient types (refer to NIBP menu setup) and do NOT operate in the adult mode. The high inflation pressure for adult is not suitable for pediatric patients.

7.2.3 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.

7.3 Introduction to Oxygen Saturation Measurement

7.3.1 SpO_2 Measuring Principle

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

7.3.2 SpO_2 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 SpO_2 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 SpO_2 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 SpO_2 reading may be unlikely true when the waveform is not smooth or irregular. If in doubt, rely on your clinical judgment, rather than the monitor readout
10. A functional tester cannot 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

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood stream of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 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 SpO_2 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 SpO_2 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.

Note: The clinical study for SpO_2 measurement accuracy was done on the subjects including Male and Female with skin color including Medium, light medium, light and dark， No subject was anemic (Hemoglobin≤10 $gm \cdot d1^{-1}$) and only healthy non-smoking individuals were tested, their age rang was from 21-49.

7.4 Introduction to Respiration Measurement

7.4.1 Respiration 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.

7.4.2 Factors affecting respiration monitoring

- ✧ Respiration monitoring doesn't support monitoring the patient who do much movement, or may lead to false alarm.

7.5 Introduction to Temperature Measurement

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

Normal value: body surface: 36.5°C ~37°C;

Notes:

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

7.6 Introduction to Capnograph Measurement

7.6.1 CO_2 Measuring Principle

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

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

7.6.2 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.

Chapter 8 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

8.1 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.If all of above is in good condition,the display screen may be malfunction.

8.2 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.

8.3 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.

8.4 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 9 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. Refer to the detailed provisions in contract for the warranty period of the main unit and the accessories of this monitor.

9.1 Service and Examination

9.1.1 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 cables 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 power voltage regulator 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.

9.1.2 Routine Maintenance

At each routinely maintenance or the yearly maintenance, the monitor can be thoroughly inspected by qualified personnel, including performance and safety examinations. This monitor is designed with life cycle of 5 years. It is strongly recommended to use the product which is still within its life cycle, or it may cause inaccurate measurement. 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 cable/lead wires damage or aging, please replace the cable or lead wires.**
- **If there is any indication of cable and transducer damage or they deteriorate, they are prohibited from any further use.**
- **The Monitor is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. Any patient simulators should not be used to validate the accuracy of blood pressure and oxygen saturation measurement, they can only be used as functional testers to verify its precision.**
- **The accuracy of ECG signal amplification can be verified by the built-in 1mV calibration signal, please refer to the related chapter in Part 2 of the user manual for detail operation.**
- **The accuracy of pressure measurement and air leakage in pneumatic system can be verified by means of the built-in pressure verification function and a precision pressure meter, please refer to the related chapter in Part 2 of the user manual for detail operation.**
- **The SpO_2 simulator can not be used to verify the SpO_2 measuring accuracy, which should be supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark-skinned subjects in an independent research laboratory. However it is necessary for the user to use SpO_2 simulator for routine verification of precision.**
- **Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO_2 simulator,e.g. for Index 2 series SpO_2 simulator from Fluke Biomecidal Corporation, please**

set "Make" to "DownLoadMake: KRK", then the user can use this particular R-curve to test the SpO_2 function. If the SpO_2 simulator does not contain "KRK" R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO_2 simulator.

- **The adjustable units within the monitor such as potentiometers are not allowed to adjust without permission to avoid unnecessary failures that affect normal application.**
- **It is recommended to use the battery once a month to ensure its power capability and long service life, and recharge it after run out of its power capacity.**

9.2 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.**
- **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.**
- **If battery is damaged, please replace with same type and specification battery marked by "CCC" or "CE" in time, or contact the company directly.**

9.3 Cleaning and Disinfection of the Device

- **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, please clean the monitor firstly.
- **Do not let the liquid cleanser flow into the connector jack of the monitor to avoid damage.**
- **Clean the exterior of the connector only.**
- **Dilute the cleanser.**

- **Do not use scrub materials.**
- **Do not let any liquid flow into the shell or any parts of the monitor.**
- **Do not let the cleanser and disinfectant stay on its surface.**
- **Do not perform high pressure sterilization to the monitor.**
- **Do not put any parts of the monitor or its accessories in the liquid.**
- **Do not pour the disinfectant on its surface while disinfectant.**
- **If the monitor is accidentally wetted it should be thoroughly dried before use. The rear cover can be removed by qualified service technician to verify absence of water.**
- **Never use this machine in an environment with inflammable gas.**
- **Avoid being hit by lightning. The power cable should be plugged into an outlet with grounding wire. Do not use an outlet with poor condition. If possible, use power supply system with regulator.**
- **It must be used in a clean environment protected against shock. Keep it away from corrosive substances, explosive substances, high temperature and dampness.**
- **If it is installed in a cabinet, make sure the installation allows for good ventilation, and easy maintenance, observation and operation.**

9.4 Cleaning and Disinfection of Accessories

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

- **Do not use damaged accessories.**
- **Accessories can not be entirely immerged into water, liquor or cleanser.**
- **Do not use radiation, steam or EO 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.**

9.5 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

9.6 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 10 Appendix

10.1 Alarm Information

Alarm Information	Descriptions
Over HR limit	The related parameter value exceeds the preset high/low alarm limits.
Over RR limit	
Over TEMP limit	
Over SpO_2 limit	
Over PR limit	
Over NIBP SYS limit	
Over NIBP DIA 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

10.2 Default Alarming Values and Setup Range

The default alarming value:

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

The high and low limits setting range:

Parameter / Mode			Adult	Pediatric	Neonate
Heart Rate		High limit	1~300bpm	1~350bpm	1~350bpm
		Low limit	0~299bpm	0~349bpm	0~349bpm
Respiration		High limit	1~120rpm	1~150rpm	1~150rpm
		Low limit	0~119rpm	0~149rpm	0~149rpm
Temperature		High limit	0.1~50°C	0.1~50°C	0.1~50°C
		Low limit	0~49. 9°C	0~49. 9°C	0~49. 9°C
Systolic		High limit	31~270 mmHg	31~200 mmHg	31~135 mmHg
		Low limit	30~269 mmHg	30~199 mmHg	30~134 mmHg
Diastolic		High limit	11~232 mmHg	11~150 mmHg	11~100 mmHg
		Low limit	10~231 mmHg	10~149 mmHg	10~99 mmHg
Mean		High limit	21~242 mmHg	21~165 mmHg	21~110 mmHg
		Low limit	20~241 mmHg	20~164 mmHg	20~109 mmHg
SpO_2		High limit	1~100%	1~100%	1~100%
		Low limit	0~99%	0~99%	0~99%
Pulse Rate		High limit	1~300bpm	1~350bpm	1~350bpm
		Low limit	0~299bpm	0~349bpm	0~349bpm
ST Segment		High Limit	-2.49Mv~+2.49mV	-2.49mV~+2.49mV	-2.49mV~+2.49mV
		Low Limit	-2.49mV~+2.49mV	-2.49mV~+2.49mV	-2.49mV~+2.49mV
Temperature Difference			0.0~5.0℃	0.0~5.0℃	0.0~5.0℃
Arterial Pressure	Systolic	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
	Diastolic	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
	Mean	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
Pulmonary Artery Pressure	Systolic	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
	Diastolic	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
	Mean	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
Central Venous Pressure	Systolic	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
	Diastolic	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
	Mean	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
CO_2	Respiration Rate	High limit	（1~120）rpm	(1~150)rpm	(1~150)rpm
		Low limit	（0~119）rpm	(0~149)rpm	(0~149)rpm
	$EtCO_2$	High limit	（1~100）mmHg	(1~100) mmHg	(1~100) mmHg
		Low limit	（0~99）mmHg	(0~99) mmHg	(0~99) mmHg
	$InsCO_2$	High limit	（1~30）mmHg	(1~30) mmHg	(1~30) mmHg
		Low limit	（0~29）mmHg	(0~29) mmHg	(0~29) mmHg

10.3 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 (Pediatric 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 Pediatric or neonatal patient. Otherwise, there may be serious danger to the Pediatric monitored.

“Pediatric” —The blood pressure module is now worked in Pediatric 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.

10.4 Status/Error during CO_2 Monitoring

Suggested Message/Response	Description
"Sensor Over Temp" Make sure sensor is not exposed to extreme heat (heat lamp, etc.). If error persists, return sensor to factory for servicing.	The sensor temperature is greater than 40 °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 CO_2 sensor is not ready for a Capnostat Zero. If the "Zero Required" and this massage both prompt message both promptone or more of the following conditions may exist: • Breaths detected • Temperature is not stable • Source Current unstable • In sleep mode.
Zero in already progress	Normal zero calibration is in already progress.
Zero Fault and Breaths Detected	Zero attempted and breaths have been detected in the last 20 seconds.
Zero Ok	Zero calibration is successful

10.5 Typical Pressures and CO_2 Readings at Altitudes

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

10.6 Accessories List

Part No.	Part Name	Remark
15010513	ECG cable	
5101-0101310	ECG electrode	
15044051	Adult SpO_2 Finger clip Sensor	
15044041	Pediatric SpO_2 Finger clip Sensor	Optional
15024402	Adult NIBP cuff(25~35cm)	
15021402	Small-sized Pediatric NIBP Cuff	Optional
15022402	Middle-sized Pediatric NIBP Cuff	Optional
15023402	Large-sized Pediatric NIBP	Optional
15084120	Skin TEMP probe	
15100420	CO_2 Mainstream sensor	Optional for mainstream
15100411	Adult airway adapter	Optional for mainstream
15100421	Pediatric airway adapter	Optional for mainstream
15100410	CO_2 Sidestream sensor	Optional for sidestream
15100130	Sampling line kit	Optional for sidestream
15100214	Extending airway tube	Optional for sidestream
15100210	Wye connector	Optional for sidestream
2903-0000000	Power cord	
900093	Net wire	

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

Note: Part No. is subject to change without prior notice, please refer to the label of parts or package list.

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