Multi-parameter Patient Monitor
Elegant-1070

User Manual

Version: 3.0

Issued by: Sara Lo Date: 7/20/2020

Reviewed by: Albert Huang Date: 7/20/2020

Document No: UM-PM7-201410-01
North-Vision Tech. Inc.
CE
2460

Elegant-1070 Patient Monitor User Manual

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 the Food and Drug Administration, Ministry of Health and Welfare. The Manual is written for the current Elegant-1070 Multi-parameter Patient Monitor.

The Manual describes, in accordance with the Elegant-1070 Patient Monitor's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

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.

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

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

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

Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the following pages 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 abnormity, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormity, 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

- **WARNING-PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest. Do not relay entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.**
- **Monitoring a single person at a time.**
- **The monitor is defibrillator proof. Verify that the accessories can function safely and normally.**
- **Disconnect the monitor and sensors before MRI scanning. Use during MRI could cause burn or adversely affect the MRI image or the monitor's accuracy.**
- **If you have any doubt to the grounding layout and its performance, you must use the built-in battery to power the monitor.**
- **All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements.**
- **Check SpO2 probe application site periodically (every 30 minutes) to determine circulation, positioning and skin sensitivity.**
- **The SpO2 measurement of this monitor may not work for all testees. If stable readings can not 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.**
- **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 an pediatric's (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even**

body putrescence.

- **The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.**
- **Do NOT take blood pressure measurement from a limb receiving ongoing transfusion or intubations or skin lesion area, otherwise, damages may be caused to the limb.**
- **Continuous use of SpO2 sensor may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.**
- **SpO2 measuring position must be examined more carefully for some special patient. Do NOT install the SpO2 sensor on the finger with edema or vulnerable tissue.**
- **To prevent the risk of the short circuit and to ensure the ECG signal quality, the equipment must be properly grounded.**
- **Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.**
- **All the connecting cables and rubber tubes of the applying parts should be kept away from the patient' s cervix to prevent any possible suffocation of the patient.**
- **All the parts of the monitor should NOT be replaced at will. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility, etc. may be caused.**
- **Do NOT stare at the infrared light of SpO2 sensor when switch it on, for the infrared may do harm to the eye.**
- **If the monitor falls off accidentally, please do NOT operate it before its safety and technical indexes have been tested minutely and positive testing results obtained.**
- **It is recommended to take the blood pressure measurement manually. The automatic or continuous mode should be used at the presence of a doctor/nurse.**
- **Please peruse the relative content about the clinical restrictions and contraindication.**
- **When disposing of the monitor and its accessories, the local law should be followed.**

CONTRAINDICATIONS

- **It is contraindicated for use on active patients or for prolonged use.**

ADVERSE REACTION

- **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 finger for over two hours.**

Table of Contents

CHAPTER 1 OVERVIEW 1
1.1 FEATURES 1
1.2 PRODUCT NAME AND MODEL 2
1.3 DESCRIPTION AND INDICATION FOR USE 2
1.4 OPERATING ENVIRONMENT 2
1.5 IMPACT ON ENVIRONMENT AND RESOURCES 2
1.6 SAFETY 2

CHAPTER 2 WORKING THEORIES OF THE MAIN UNIT 3
2.1 OVERALL STRUCTURE AND WORKING THEORIES 3
2.2 COMPOSITION 3

CHAPTER 3 INSTALLATION AND CONNECTION 4
3.1 INTRODUCTION TO PANELS 4
3.1.1 Front Panel 4
3.1.2 Left and Right Panel 6
3.1.3 Rear Panel 7
3.2 INSTALLATION 8
3.2.1 Opening the Box and heck 8
3.2.2 Power Supply 8
3.2.3 Starting the Monitor 8
3.3 CONNECTION 9
3.3.1 ECG Connection 9
3.3.2 Blood Pressure Cuff Connection 11
3.3.3 To connect the SpO2 12
3.3.4 Battery Installation 14
3.3.5 Handle Installation 14

CHAPTER 4 MONITORING SCREEN 15
4.1 DATE AND TIME SETUP 15
4.2 MAIN SCREEN 16
4.3 DISPLAY 2 SCREEN 19
4.3.1 Observing Screen 19
4.3.2 Seven ECG Waveforms on the Same Screen 20
4.3.3 Five Channels Near Real-time Waveforms and Trends on the Same Screen 21
4.4 FREEZE AND S-T ANALYSIS SCREEN 22
4.4.1 Screen Description 22
4.4.2 How to Analyze the ST Segment Waveform 22

CHAPTER 5 OPERATING INSTRUCTIONS FOR SYSTEM MENU 24

5.1 SYSTEM MENU SCREEN 24
5.1.1 How to Select the Menu Item 24
5.2 SPO2 DATA LIST SCREEN 25
5.2.1 Screen Description 25
5.2.2 Operating Instructions 25
5.3 NIBP DATA LIST SCREEN 25
5.3.1 Screen Description 25
5.3.2 Operating Instructions 25
5.4 GRAPHIC TREND SCREEN 26
5.4.1 How to View the Graphic Trend 26
5.4.2 Operation Instructions 28
5.5 RECALL SCREEN 28
5.5.1 Operation Instructions 29
5.6 SYSTEM SETUP SCREEN 30
5.6.1 How to Select the System Setup Item 30
5.6.2 Parameter Settings 30
5.7 COLOR SETTINGS 35
5.7.1 How to Change the Parameter Color 35
5.8 FILE MANAGEMENT SCREEN 35
5.8.1 How to Add a New Patient 35
5.9 OXYCRG SCREEN 36
5.9.1 Operation Instructions 36
5.11 EVENT LIST SCREEN 36
5.10.1 Screen Description 37
5.10.2 Operating Instructions 37
5.11 MC CALCULATOR 37
5.11.1 Medicine Dosage Calculator 37
5.12 TOURNIQUET FUNCTION 38
5.12.1 Operation Instructions 39

CHAPTER 6 ALARM 40
6.1 ALARM PRIORITY 40
6.2 ALARM MODES 41
6.3 ALARM SILENCE 41
6.4 ALARM SETTING 42
6.5 VERIFY ADJUSTABLE ALARM FUNCTION 42

CHAPTER 7 TECHNICAL SPECIFICATIONS 43
7.1 ECG MONITORING 43
7.2 NIBP MONITORING 43
7.3 SPO2 MONITORING 44

7.4 PULSE RATE MONITORING 44
7.5 OTHER TECHNICAL SPECIFICATIONS 44

CHAPTER 8 PACKAGING AND ACCESSORIES 45
8.1 PACKAGING 45
8.2 ACCESSORIES 45

CHAPTER 9 TROUBLESHOOTING 46
9.1 NO DISPLAY ON THE SCREEN 46
9.2 EXCESSIVE ECG SIGNAL INTERFERENCE OR TOO THICK BASELINE 46
9.3 NO BLOOD PRESSURE AND PULSE OXYGEN MEASURES 46
9.4 SYSTEM ALARM 46

CHAPTER 10 MAINTENANCE AND SERVICE 47
10.1 TECHNICAL MAINTENANCES 47
10.1.1 Daily Examination 47
10.1.2 Routine Maintenance 47
10.1.3 Battery Maintenance 47
10.2 CLEANING, STERILIZATION AND DISINFECTION 48
10.3 CLEANING, STERILIZATION AND DISINFECTION OF ACCESSORIES 49
10.4 STORAGE 49
10.5 TRANSPORTATION 49

CHAPTER 11 MONITORING PARAMETER 50
11.1 ECG MONITORING 50
11.1.1 How to Obtain High Quality ECG and Accurate Heart Rate Value 50
11.1.2 Factors affecting ECG signal 50
11.2 SPO2 MONITORING 51
11.1.1 Measuring Principle 51
11.2.2 SpO2 Measurement Restrictions (interference reason) 51
11.2.3 Low SpO2 measuring value caused by pathology reason 51
11.2.4 Clinical Limitations 51
11.2.5 Points to be noted in SpO2 and Pulse Measuring 52
11.3 NIBP MONITORING 52
11.3.1 Measuring Principle 52
11.3.2 Factors affecting NIBP measuring 54
11.3.3 Clinical Limitations 54

CHAPTER 12 APPENDIX 56
12.1 ALARM INFORMATION 56
12.2 DEFAULT ALARMING VALUES AND SETUP RANGE 57
12.3 STATUS/ERROR DURING NIBP MONITORING 59
12.4 ACCESSORIES LIST 60

12.5 INSTRUCTIONS FOR SPO2 PROBE 61

Chapter 1 Overview

1.1 Features

This monitoring system may be used to monitor patient's 6 physiological parameters: ECG non-invasive blood pressure (NIBP), pulse oxygen saturation (SpO_2), and pulse rate.

- ✧ It is lightweight, easy to carry and operate;
- ✧ 7″ high-resolution (800 × 480 pixel) color TFT to display patient's ECG waveform and SpO2 waveform;
- ✧ Abundant and friendly display interface, multifold ECG display screen:
  Main monitoring screen: displays the information of all the waveforms and parameters visually.
  Observing screen: heart rate value and SpO2 value display in big fonts, and displays one channel ECG waveform.
  Seven lead waveforms on one screen: displays the information of 7 ECG lead waveforms and different monitoring parameters on one screen.
  Five channel near real-time waveforms and two hours' trends viewing: intuitionistic knowing the physiological status of patient.
  oxyCRG screen: displays heart rate trend, SpO2 trend or waveform simultaneously on oxyCRG screen.
- ✧ Intuitionistic and easy calculation. Medical consistent calculation and analysis can accurately figure out the speed of medicine supply and dose, to observe the relation between amount and effect indirectly.
- ✧ Convenient and applied accessorial tourniquet function, according to patient's condition, and different tourniquet cuff pressure can be set.
- ✧ Up to 480 hours statistic data of ECG, ST, pO2 and NIBP trends;
- ✧ Storage and recall of a list of 800 groups of NIBP measurement data, as well as heart rate and SpO2/pulse rate when measurement of blood pressure is taken;
- ✧ 36 hours of ECG data storage and recall;
- ✧ High precision NIBP measuring module;
- ✧ Special SpO2 measuring function, which ensures the accuracy of SpO2 and PR measurement;
- ✧ Visual and audible alarm, recall of alarm events;
- ✧ Flexible high and low alarm limits setting function;
- ✧ Near Real-time monitoring of battery capacity, when the battery power is insufficient, low battery voltage alarm indication will display on LCD screen.
- ✧ Easy to color-code and change the color of the font, background and waveforms if need;
- ✧ Resistance against defibrillator and electrosurgical knife interference, detects and filters the pacemaker-generated signals, and high safety level;
- ✧ Able to be used along with cardiac pacemaker;
- ✧ "Adult/pediatric" mode which may be selected via the menu, to better suit the adult and pediatric patient;
- ✧ Networking with the central station as a part of the central network;

1.2 Product Name and Model

Name: Patient Monitor

Model: Elegant-1070

1.3 Description and Indication for use

1.3.1 Device Description

Elegant-1070 is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. It is modular designed patient Monitor, which can monitor the patient's Electrocardiograph (ECG) by measuring physical parameters with variety modules. Also, it can measure non-invasive blood pressure (NIBP) including systolic, diastolic and mean as well as detect the blood oxygen saturation (SpO2) and pulse rate (PR).

The accessories and the sensors will transfer the physical parameters into electrical signals, which can be collected and amplified by the circuit in the device. After CPU analyzing and calculating the parameters are displayed on the screen in a graphical representation and it can record and/or print if necessary. The device may generate audible and/or visual alarm when a measured rate falls outside preset limits.

1.3.2 Indication for use

North-vision Elegant-1070 of Multi-parameter Patient Monitor is intended to monitor, display and record physiological signs of adult, pediatric patients. With the functions of near real-time recording and displaying parameters ECG, heart rate, non-invasive blood pressure, blood oxygen saturation and pulse rate, it allows comprehensive analysis of patient's physiological conditions. This apparatus is applicable for use in hospitals, clinics, and practitioner's office. The operation should be carried out by qualified professionals only.

1.4 Operating Environment

1. Ambient temperature range: 10℃~ 40℃
   Relative humidity: ≤80%
   Atmospheric pressure: 86kPa ~106kPa
2. This equipment should be situated in a place protected against direct sunlight, so as to prevent overheating inside the equipment.
3. Do not use this equipment in an environment with toxic or inflammable gas.
4. This equipment should be placed on a stand or flat platforms, so as to prevent possible shock.
5. Do not use this equipment in combination with any equipment other than those expressly permitted in the manual.

1.5 Impact on Environment and Resources

Low

1.6 Safety

a) This device conforms to IEC60601-1, electric safety classicfication: Class I, with Type BF and CF applied parts.
b) This device can resist against the discharge of defibrillator and the interference of eletro-surgical unit.
c) This device can monitor the patients with pace-maker.
d) DO NOT use this device while the patient is under MRI scanning.

Chapter 2 Working Theories of the Main Unit

2.1 Overall Structure and Working Theories

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

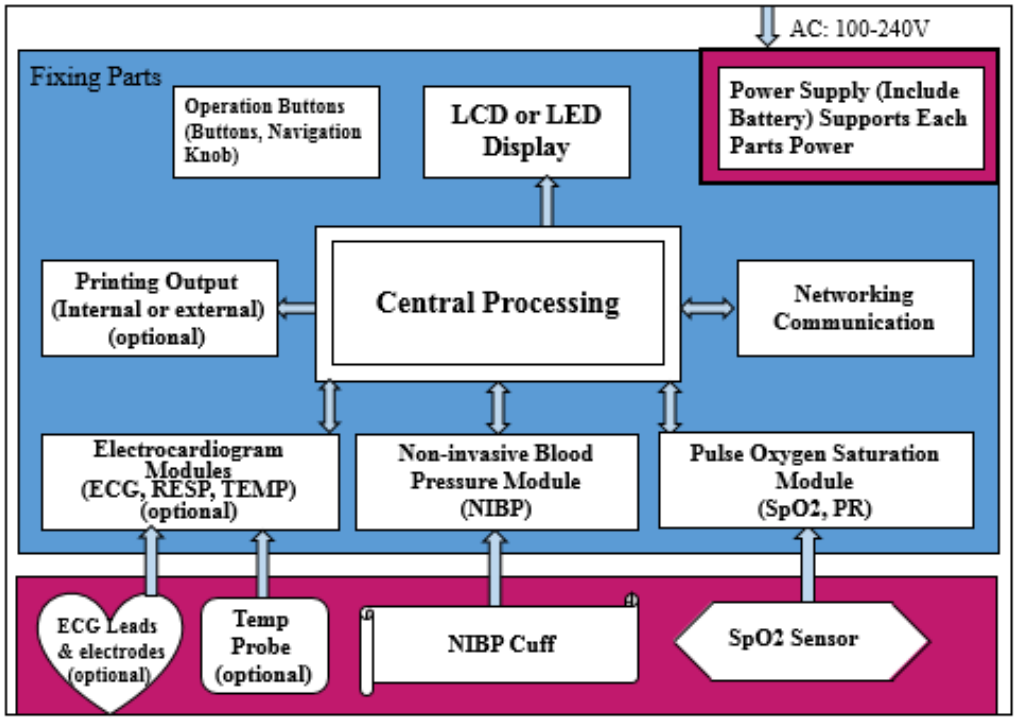


Figure 2.1

This patient monitor is a product of modular design. It performs its measurement of the physiological parameter through different modules. There are four functional modules for the monitor: ECG module, NIBP module, SpO2 module and Central Processing Unit (CPU) module.

1. ECG module collects heart rate through the ECG leads and electrodes.
2. SpO2 module collects data for pulse rate, pulse oxygen saturation (SpO2) and SpO2 volume waveform via the SpO2 probe.
3. NIBP module collects blood pressure data, including the diastolic, systolic and mean arterial pressure through the NIBP cuff. The cuffs are sized for adult and pediatric. NIBP measure has two modes: adult and pediatric.
4. CPU module consists of main board, multi-function board, and the keyboard. The multi-function board performs the data communication between the main board, ECG module, SpO2 module and NIBP module.

2.2 Composition

1. The monitor consists of the main unit and the corresponding functional components (ECG leads, non-invasive blood pressure cuff and SpO2 probe).
2. The monitor has 4 measurement channels: ECG channel, NIBP channel, SpO2 and pulse channel.
3. The monitor has a output channel: networking communication port.
4. Basic parameters include: heart rate, NIBP, SpO2 and pulse.

Chapter 3 Installation and Connection

3.1 Introduction to Panels

3.1.1 Front Panel

Figure 3.1

1. Power switch: Press it for 3 seconds to start the monitor or turn off the monitor.
2. ～AC power indicator: When it is light it means that AC power supply is being used
3. Built-in DC power indicator:

   When both AC and DC indicators are on, it means that AC power supply is applicable, and the battery is being recharged. If only DC indicator is on, it means that the battery is being used.
4. ECG lead: Click it to shift the ECG monitoring circulatory among Ⅰ, Ⅱ, Ⅲ, AVR, AVL, AVF and V.
5. Alarm silence: Press key to set or activate the system alarm. In the monitoring screen, press “Alarm” to set the alarm timer. There are four options of alarm silent time: 2 minutes, 5 minutes, 10 minutes and 20 minutes. The time shows up on the upper left corner of the screen. When the alarm timer is activated, the system begins to count down. If alarm occurs during that period, the system alarm will be actived automatically and the monitor will give alarm. If there is no alarm during that period, when the set time has passed, the system alarm will be actived as well.

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

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

6. Freeze: Press the key to freeze/unfreeze ECG waveform or the waveforms of ECG, SpO2 according to the system setting, and enter into ST segment measurement screen for analysis (on Observing Screen).

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

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

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

10. Alarm indicator:

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

3.1.2 Left and Right Panel

Figure 3.2 the left panel

Figure 3.3 the right panel

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

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

1. SpO2: SpO2 probe connector
2. NIBP: NIBP hose connector
3. ECG: ECG cable connector
4. Symbol definition

With type BF applied parts

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

Caution. Please read the manual for details.

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

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

3.1.3 Rear Panel

Figure 3.4 Rear panel

The following are at the rear panel of the monitor.

(1) S/N: Serial Number

(2) Nameplate

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

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

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

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

3.2 Installation

3.2.1 Opening the Box and Check

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

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

3.2.2 Power Supply

1. When powered by AC mains power supply:

- ◆ Make sure that the AC power supply is 100-240VAC, 50/60Hz.
- ◆ Use the AC power adapter and power code prepared by the manufacturer. Insert one end of AC power adapter to the power supply socket and the other end to the power code. Next connect the power code to AC mains.

Caution: Do not use the AC power adapter and power code not purchased from the manufacture, or serious hazard may be caused.

2. When powered by built-in battery

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

🔔 After the power supply 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.

3.2.3 Starting the Monitor

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

- ◆ Check all the applicable functions to make sure that the monitor works normally.
- ◆ If the built-in battery is applied please recharge it after using the monitor to ensure sufficient power storage.

💣 **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 30 seconds later after it is switched off.**

3.3 Connection

3.3.1 ECG Connection

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

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

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

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

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

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

The locations of the electrode are in the following Figure:

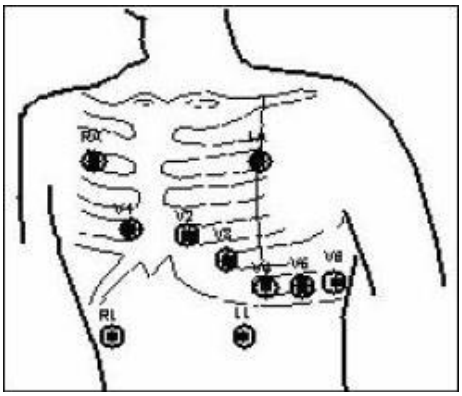


Figure 3.5 Electrode Location

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

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

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

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

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

Safety Instructions for ECG Monitoring

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

3.3.2 Blood Pressure Cuff Connection

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

Requirements of the cuff:

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

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

Cuff Model	Arm Circumference	Cuff Width
Small-sized Pediatric Cuff	6.0cm～9.5cm	3cm
Middle-sized Pediatric Cuff	12cm～19cm	8.4cm
Large-sized Pediatric Cuff	18cm～26cm	11cm
Adult Cuff	25cm～35cm	14cm
Large-sized Adult Cuff	33cm～47cm	17.5cm

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

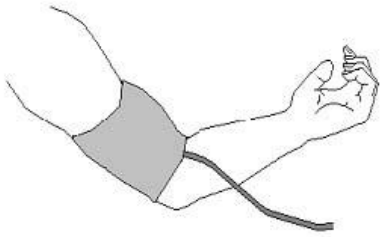


Figure 3.6 Cuff Position

Safety Instructions for NIBP Monitoring

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

circulation is not blocked. If blocked, the limb will discolor, please stop measuring or remove the cuff to other positions. Doctor should examine this timely.

- The time of the noninvasive blood pressure measurement pull too long, then the body connected with the cuff possibly have the purpura, lack the blood and the neuralgia. When guarding patient, must inspect the luster, the warmth and the sensitivity of the body far-end frequently. Once observes any exception, please immediately stop the blood pressure measurement. The subject should lie on the back so that the cuff and the heart are in a horizontal position and the most accurate measure is taken. Other postures may lead to inaccurate measurement.
- Do not speak or move before or during the measurement. Care should be taken so that the cuff will not be hit or touched by other objects.
- 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 symbol indicates that the cable and accessories are designed to have special protection against electric shocks, and is defibrillator proof.

3.3.3 To connect the SpO2

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

Operation procedure:

1. Connect the SpO2 probe to the right panel's jack labeled "SpO2". **When unplugging the probe, be sure to hold the head of the connector and pull it out.**
2. Insert one finger into the probe (index finger, middle finger or ring finger with proper nail length) according to the finger mark on the probe, shown as below.

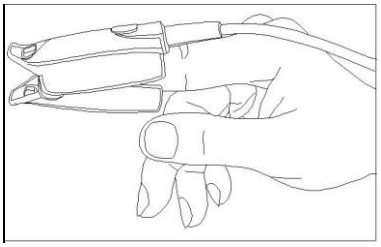


Figure 3.7 Demonstration for SpO2 probe

When selecting a sensor, consider the patient's category, adequacy of perfusion, availability of probe site and anticipated monitoring duration. Use only SpO2 probes provided by our company with this monitor. Read the following table for SpO2 probe information. Refer to Chapter 11.6 for the detailed instructions of each SpO2 probe.

SpO2 Probe	Patient Category
SpO2 Finger clip Sensor (reusable)	Pediatric
SpO2 Finger rubber Sensor(reusable)	Adult
SpO2 Finger clip Sensor(reusable)	Adult

High ambient light sources 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 SpO2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

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

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

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

Safety Introductions for SpO2 Monitoring

- Continuous use of SpO2 sensor may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.
- The measuring site is generally changed every 3hours. The measuring site should be inspected for ensuring no abnormity every 1~2 hours. If abnormity occurs, change the measuring site periodically if necessary.
- SpO2 measuring position must be examined more carefully for some special patient. Do NOT install the SpO2 sensor on the finger with edema or fragile tissue.
- Do NOT put the SpO2 sensor and pressure cuff on the same limb, otherwise the NIBP measuring will affect SpO2 measuring and cause the alarm error.
- If sterile packaging of SpO2 sensor is damaged, do not use it any more.
- Check the SpO2 sensor and cable before use. Do NOT use the damaged SpO2 sensor.
- Please do not allow the cable to be twisted or bended.
- Please do not use nail polisher or other cosmetic product on the nail.
- The fingernail should be of normal length.
- The SpO2 sensor can not be immerged into water, liquor or cleanser completely, because the sensor has no capability of waterproofness.

3.3.4 Battery Installation

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

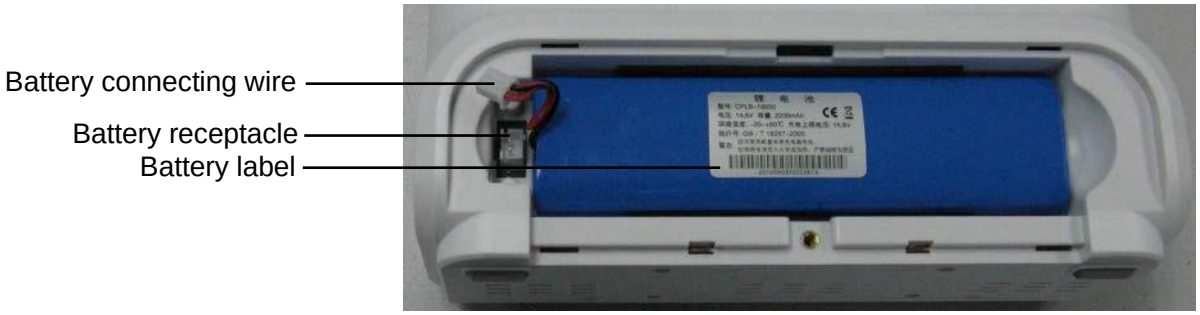


Figure 3.8 Battery Installation

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

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

3.3.5 Handle Installation

1. Take out the handle subassembly if necessary.
2. Fix the handle subassembly on the rear panel with two screws, see Figure 3.9.

Figure 3.9 Handle Installation

Chapter 4 Monitoring Screen

4.1 Date and Time Setup

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

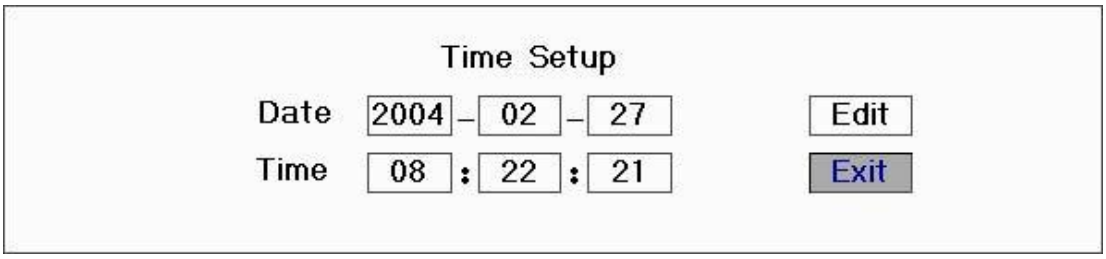


Figure 4.1 Time Setup

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

Follow the steps below to set date and time.

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

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

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

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

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

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

4.2 Main Screen

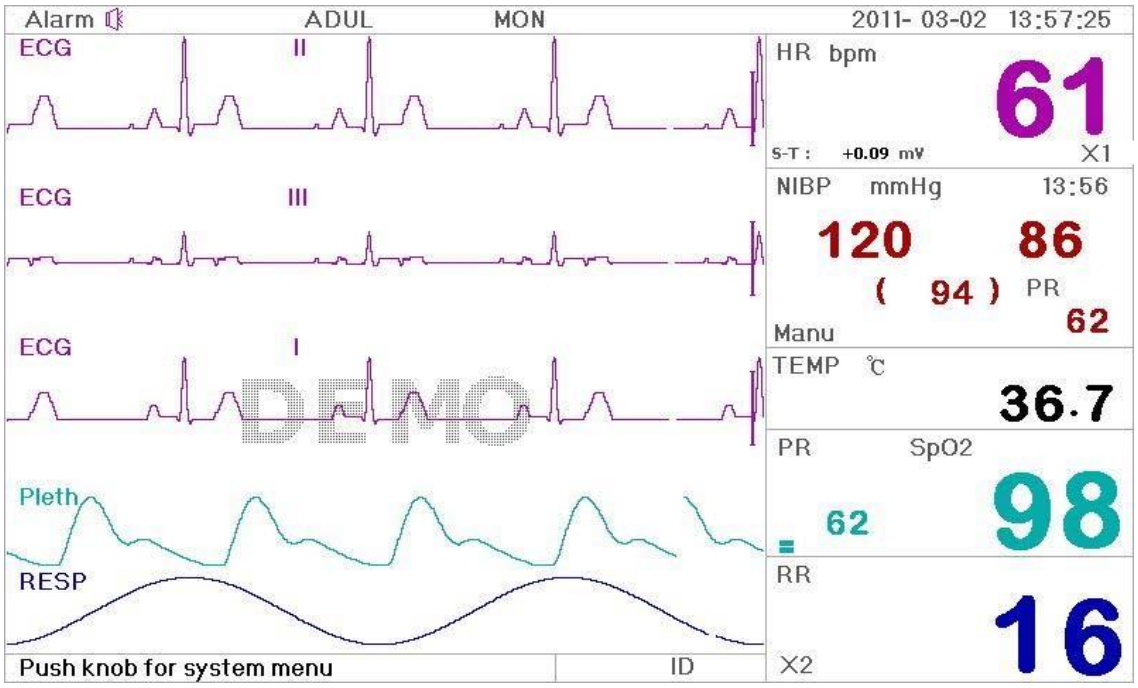


Figure 4.2 Main screen

Border area

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

Waveform area

- **1st Waveform**: The first waveform is ECG waveform for lead II. The left side of the ECG shows the sign I, which indicates the ECG scale. The scale sign changes its length according to the ECG gains. All ECG waveforms have their own scale. When the third waveform change to lead II, the first waveform will automatically change to lead I.
- **2nd Waveform**: The second waveform is for the ECG waveform of lead III. When the third waveform displays the ECG for the lead III, this waveform automatically changes to the ECG for lead I.
- **3rd waveform**: Its lead can be adjusted and will not repeat the 1st and 2nd waveforms.
- **4th waveform**: SpO2 plethysmograph.

Data area:

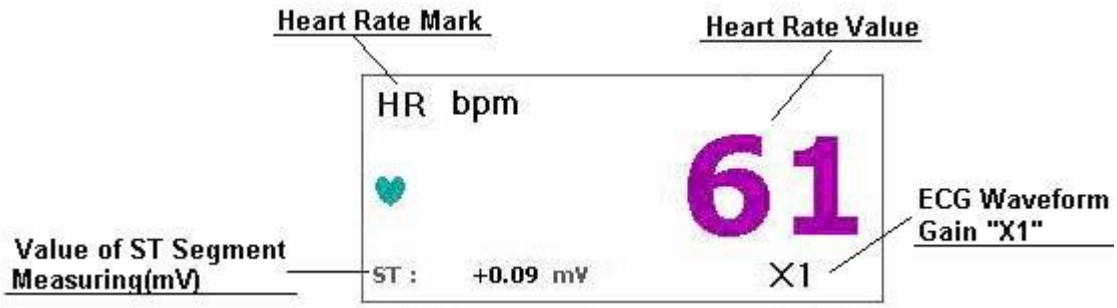


Figure 4.3 Heart rate area

- **"HR"**: The currently displayed heart rate. The 61 on the right side is the heart rate measured.
- **"bpm"**: The heart rate unit. bpm = beat per minute.
- **"♥"**: The heart beating symbol. Its flashing corresponds to the R wave of the ECG waveform. The speed is the same with the heart rate.
- **"ST+0.09mv"**: the measured mili-volts value of automatic ST measurement.
- **"X1"**: ECG waveform gain (amplification), 5 options available

  "Auto": Automatic waveform gain.

  "x1/2" half size of the basic waveform

  "x1" Basic waveform

  "x2" Twice the size of the basic waveform

  "x4" Four times the size of the basic waveform

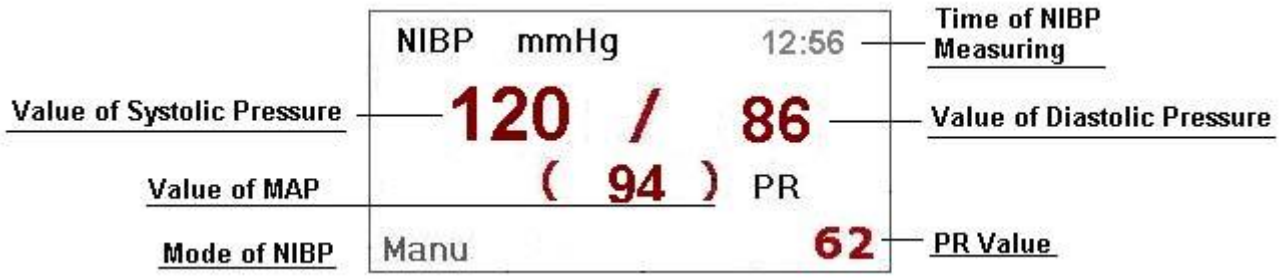


Figure 4.4 Blood pressure data area

- **"NIBP"**: The blood pressure type labels and the measured value.

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

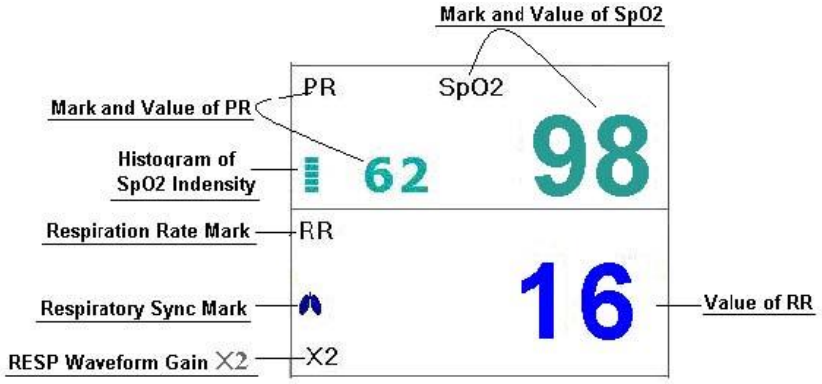


Figure 4.6 SpO_2, pulse rate, data area

- ✧ **"SpO2"**: SpO2 label. The "98" on the right side is the current SpO2 value measured.
- ✧ **"PR"**: Pulse rate label. The value "62" on the lower left shows the pulse rate value.
- ✧ **"**  **"**: SpO2 strength bar.

Operation Instructions:

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

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

Freeze: press it to freeze ECG waveform or the waveforms of ECG, SpO2 according to the system setting.

NIBP: press it to start or stop NIBP measure.

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

Navigation Knob: press it to enter System menu Screen.

4.3 Display 2 Screen

4.3.1 Observing Screen

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

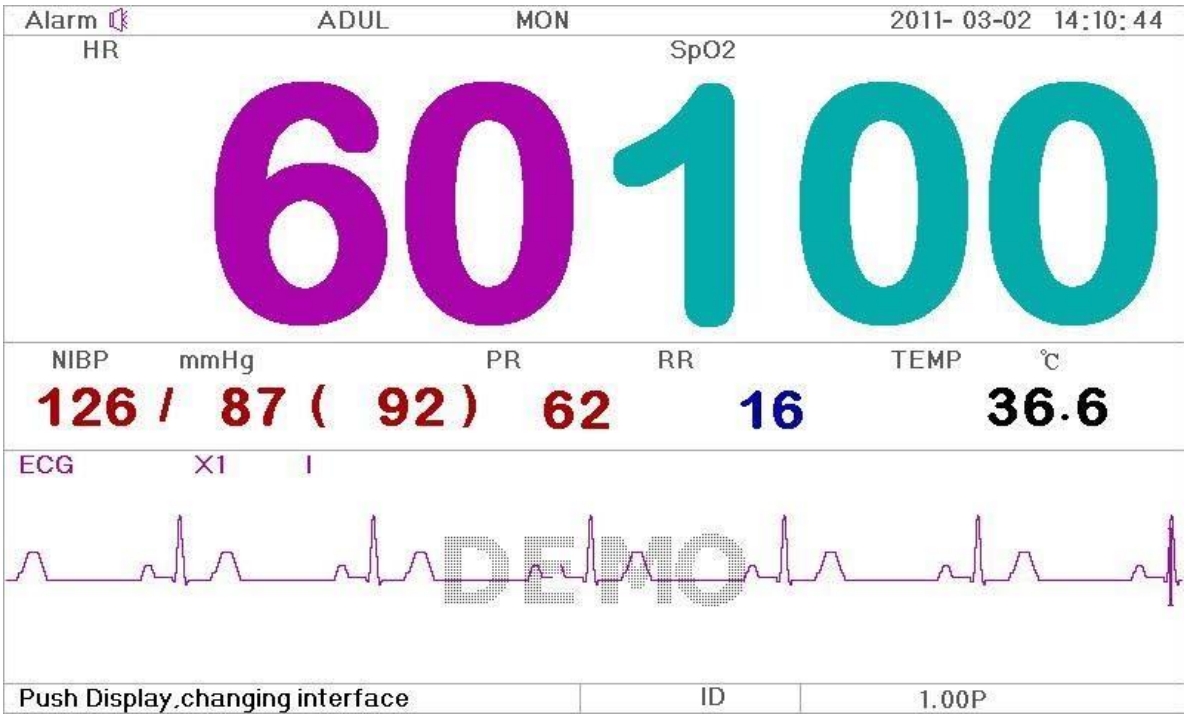


Figure 4.7 Observing Screen

Operation Instructions:

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

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

Freeze: press it to freeze the ECG waveform and perform manual ST segment analysis, refer to Section 4.4 for details.

NIBP: press it to start or stop NIBP measure.

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

Navigation Knob: disabled. When pressing the “Freeze” key, this key is used for ST segment analysis, refer to Section 4.4 for details.

4.3.2 Seven ECG Waveforms on the Same Screen

Press the DISP key to shift screen to 7 ECG Waveform Screen when setting Disp2 as “7 ECG” in System Setup screen. In this screen, the operator can simultaneously view the ECG waveform for 7 leads: I, II, III, AVR, AVL, AVF and V, as shown in Figure 4.8.

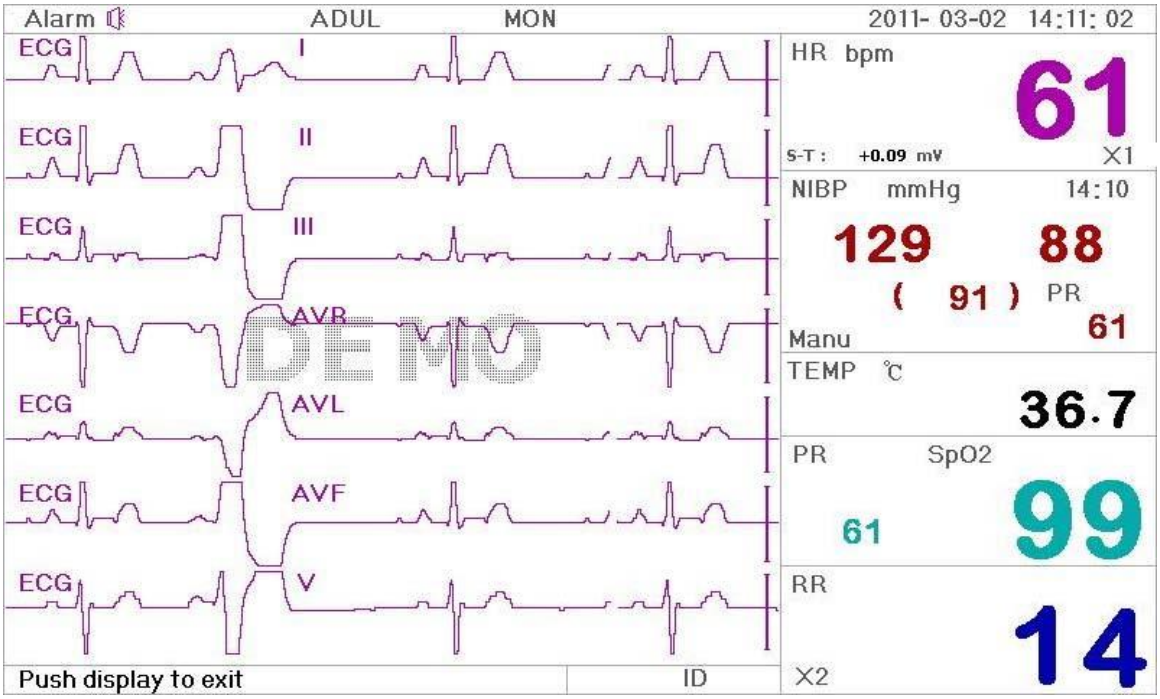


Figure 4.8 7 Leads on the Same Screen

Operation Instructions:

ECG lead: disabled.

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

Freeze: press it to freeze all 7 ECG waveforms.

NIBP: press it to start or stop NIBP measure.

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

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

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

When the Disp2 option is “Trend” on System Menu screen, press the DISP key on the Main Screen, the system will enter the trend screen, as shown in Figure 4.9. Five channel near real-time waveforms and trend graph can be viewed on this screen.

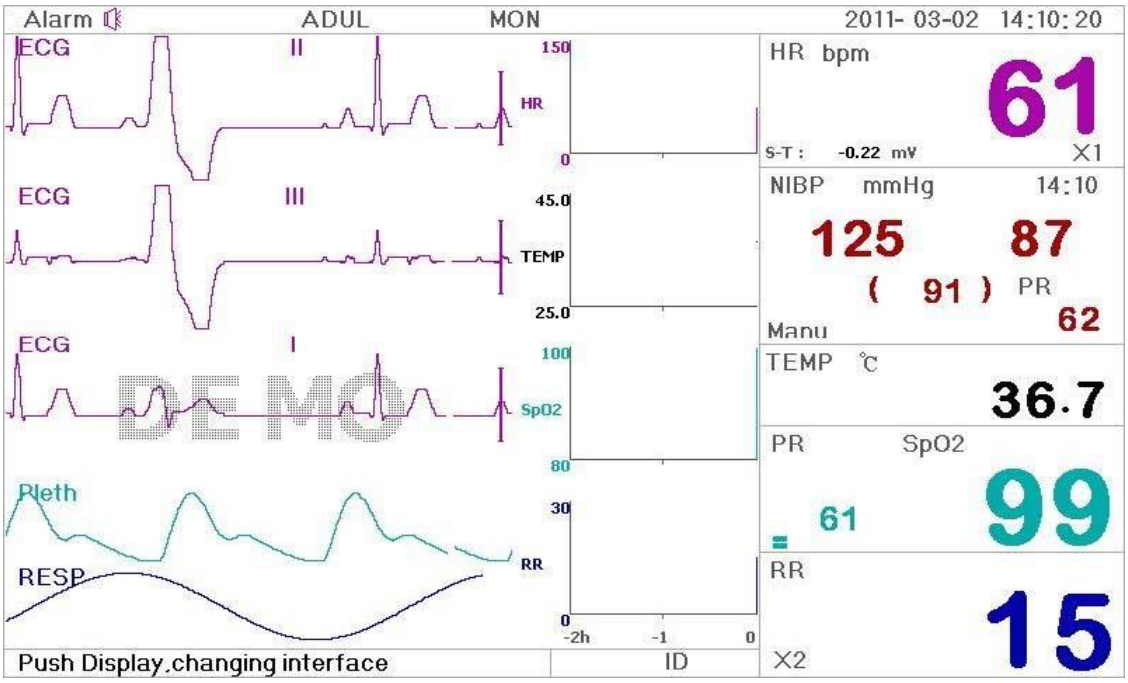


Figure 4.9 Five Channel Near Real-time Waveforms and Two Hours Trends

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

Operation Instructions:

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

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

 **Freeze:** press it to freeze ECG waveform or the waveforms of ECG, SpO2 according to the system setting.

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

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

Navigation Knob: disabled.

4.4 Freeze and S-T Analysis Screen

During the process of monitoring, the ECG waveform can be frozen to perform detailed analysis in the observing screen, as shown in Figure 4.10.

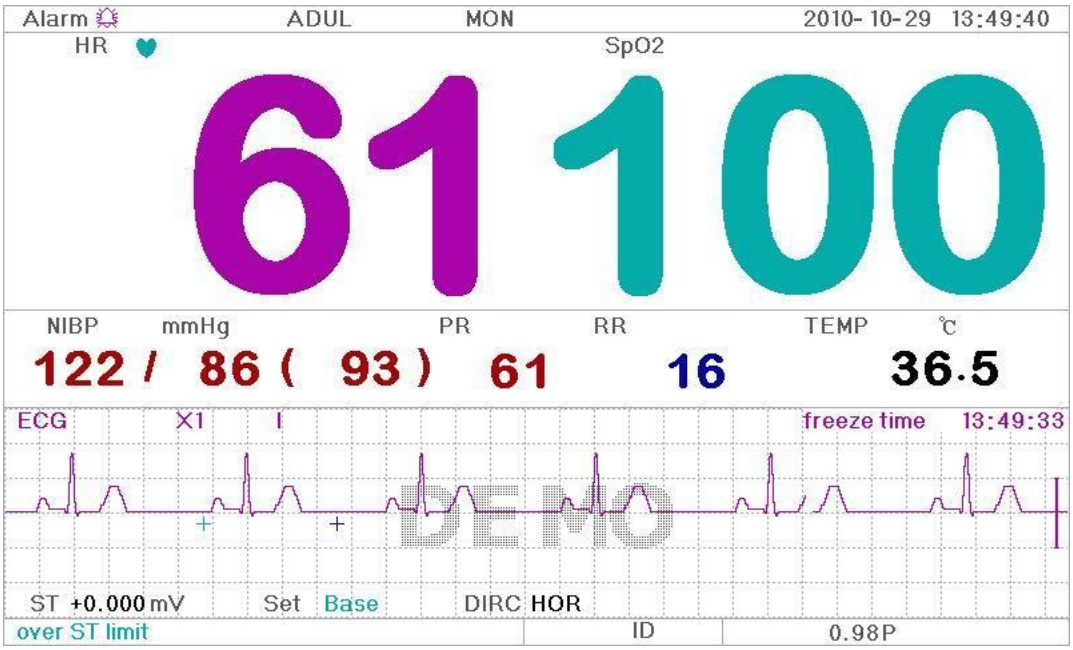


Figure 4.10 Frozen and S-T Analysis Screen

4.4.1 Screen Description

Freezing, ST segment analysis screen is similar with the observing screen, except the waveform is frozen. For example, the Figure 4.11 is a portion of the frozen waveform. The symbols on the screen were described briefly on the screen.

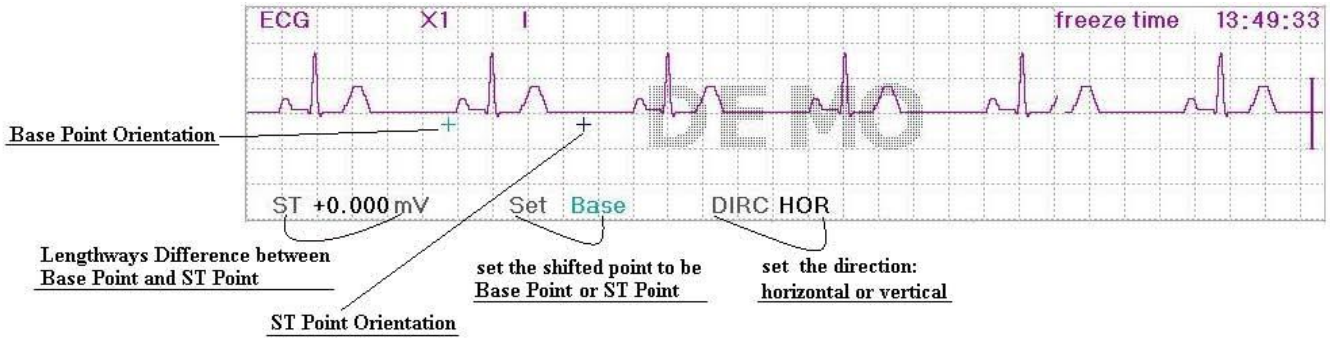


Figure 4.11 Frozen waveform

4.4.2 How to Analyze the ST Segment Waveform

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

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

Step 2: press the “Navigation Knob”. The screen shows “ST+0.xxx mV, Set Base, Dirc Ver”. Then rotate the

knob to move the base point vertically to the base line point.

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

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

Only the observing screen allows pressing the freeze key to enter the ST segment analysis screen.

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

Operation Instructions:

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

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

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

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

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

Navigation Knob: analyze the ST segment waveform.

Chapter 5 Operating Instructions for System Menu

5.1 System Menu Screen

Press the “Navigation Knob” in the Main Screen as shown in Figure 4.2, the System Menu screen will display in the lower left area on the screen, as shown in Figure 5.1.

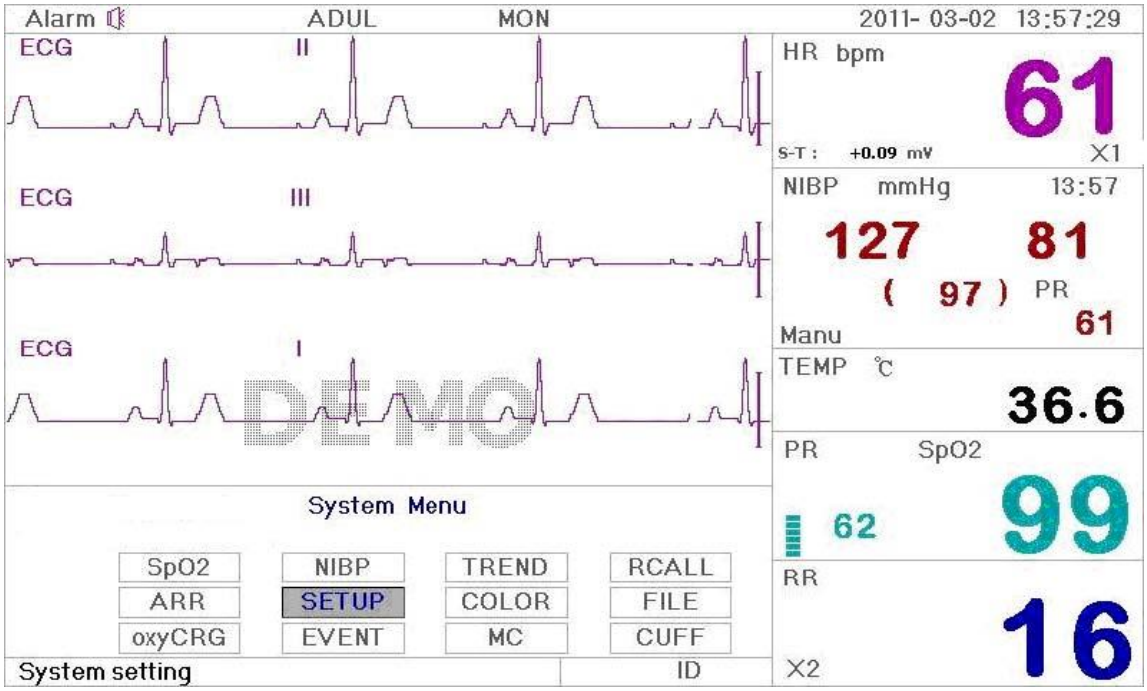


Figure 5.1 System Menu Screen

5.1.1 How to Select the Menu Item

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

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

Pressing “  ” key to return to the Main Screen.

5.2 SpO2 Data List Screen

Time	HR	RR	TEMP	SpO2	PR
10-11 15:57	61	14	36.7	99	62
10-11 15:57	60	15	36.6	98	61
10-11 15:57	61	15	36.7	98	60
10-11 15:57	60	15	36.6	100	61
10-11 15:57	60	15	36.7	99	61
10-11 15:56	60	16	36.5	100	61

Figure 5.2 SpO_2 Data Listing Screen

5.2.1 Screen Description

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

5.2.2 Operating Instructions

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

Pressing "  " key to return to the Main Screen.

5.3 NIBP Data List Screen

Time	NIBP	PR	HR	RR	TEMP
10-11 15:57	126/84(98)	62	61	14	36.7
10-11 15:57	124/88(94)	61	60	15	36.6
10-11 15:57	122/89(91)	61	60	15	36.7
10-11 15:57	123/87(90)	61	60	15	36.7
10-11 15:56	122/84(91)	60	60	16	36.6
10-11 15:56	129/85(99)	61	61	14	36.7

Figure 5.3 NIBP Data List screen

5.3.1 Screen Description

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

5.3.2 Operating Instructions

Up to 800 groups of NIBP data can be memorized. Using the Navigation Knob allows the user to scroll the list up and down to view NIBP data. When rotating the knob anti-clockwise, the list scrolls upward. When rotating knob clockwise, the list scrolls down. Please note that when the groups of data are less than 6, the Navigation Knob can not be used to scroll up or down the listing.

Pressing "  " key to return to the Main Screen.

5.4 Graphic Trend Screen

Figure 5.4 HR Trend

5.4.1 How to View the Graphic Trend

Figure 5.4 is the HR trend graph. There are 3 options on the right of the graph, as described below.

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

After choosing "Cursor", the trend graph display a triangle and a vertical line, a moving ruler mark that can be moved by rotating the knob. As shown in the figure, when you move the mark to a specific point, the data area below the graph will display the time and its corresponding heart rate, SpO_2. When rotating "Navigation Knob" key to move the mark, the moving interval is a changing value. The rule is that the initial step is 1, after moving it towards the same direction 5 times, the interval becomes 5, and with 5 more steps the interval becomes 10, then 20 and 40. No matter what the interval is, as long as you move towards the other direction, the interval becomes 1 of the other direction. Therefore, it is very easy to find the time you are looking for.

The "24" on the top shows the trend graph time. Move the cursor to the trend time, press the knob and rotate it, and the trend graph time will change to 120, 480 or 6, which changes the horizontal axis to be 120 hours, 480 hours or 6 hours. The corresponding trend graph also changes to 120- hour trend, 480- hour trend or 6 - hour trend.

The Trend graph shows parameter value of the current time. For example, in the 24 hours trend graph, when the monitoring time exceeds 24 hours, the data 24 hours ago will be move out of the graph. This ensures the screen always display the current data for review. The data moved out of the graph is not deleted but is just hidden temporarily. When the time frame changes from 24 hours to 120 hours (while the monitoring time is less than 120 hours), the complete set of data will display. Other trend graph follows the same rule.

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

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

NIBP graphic trend is a little different from the other graphic trends. Rotate the knob to move the cursor to "<< >>", then press the knob for activing this item. Next, rotate the knob towards left or right for viewing

another 400 groups' graphic trend.

Figure 5.5 S-T Graphic Trend

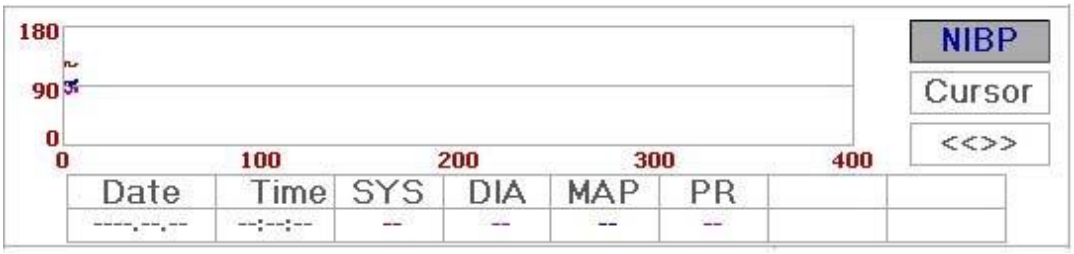


Figure 5.7 NIBP Graphic Trend

Figure 5.8 SpO_2 Trend graph

Figure 5.9 PR Graphic Trend

5.4.2 Operation Instructions

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

Pressing “ ” key to return to the Main Screen.

5.5 Recall Screen

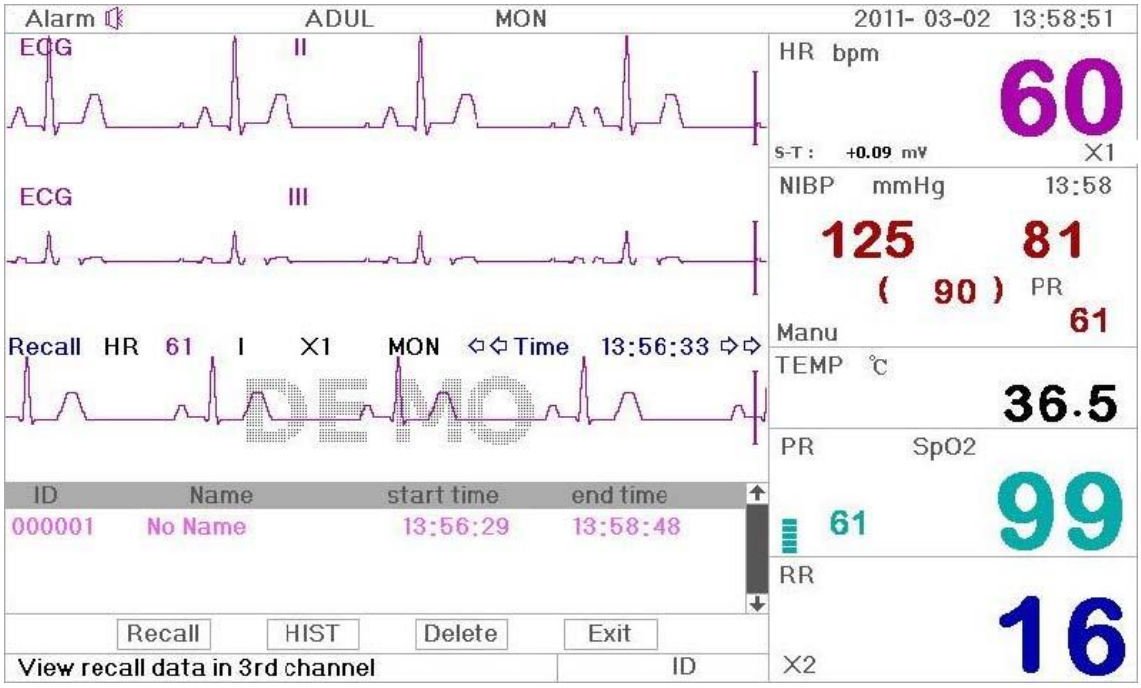


Figure 5.11 Waveform Recall Screen

In most cases, one hour will store one record. If the storing time of the record is less than one hour or change the patients within one hour, this record will be stored as a single one.

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

Shown in Figure 5.12, it is different from the Main Screen in its 3rd waveform area and the operation area. We will explain them in detail below.

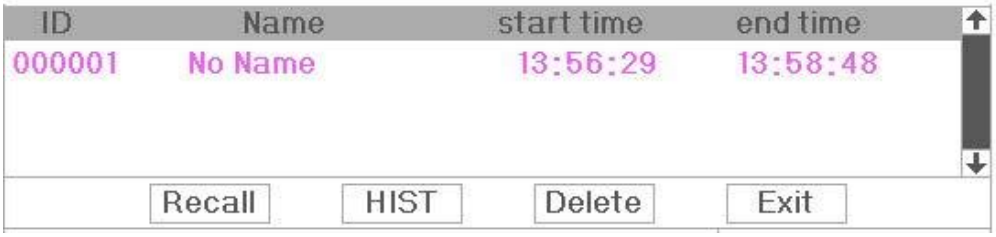


Figure 5.12 Recall Listing

5.5.1 Operation Instructions

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

Recall: Press the Recall and the first record in recall list becomes green. Rotate the knob to choose a record, and press the knob to recall it. The recalled waveform is displayed on the 3rd channel of the waveform area, as shown in Figure 5.13.

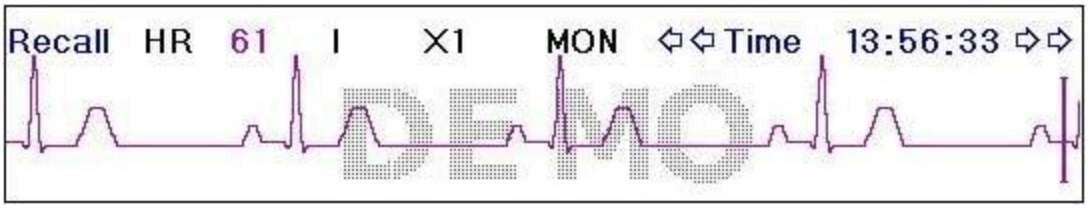


Figure 5.13 Recalled Waveform

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

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

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

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

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

5.6 System Setup Screen

Figure 5.15 System Setup

5.6.1 How to Select the System Setup Item

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

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

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

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

5.6.2 Parameter Settings

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

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

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

Pressing “ ” key to return to the Main Screen

SYSTEM PARAMETER SETTINGS

Figure 5.16 System Setup

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

  Adult: the subject is adult.

  Infant: the subject is pediatric.

  The default is “Adult”

  When changing the patient type, the system will perform the alarm settings, NIBP settings initializations. Please pay special attention to the patient type before starting the monitoring. It is

forbidden to use Adult type on the pediatric patient, or it can cause serious injury.

- ✧ **Mode**: Monitor System Menu. The “Near Real Time” shows the near real time waveform, i.e. normal monitoring state. The “Demo” shows the demo waveforms. In the demo state, all the signals and data are generated from the patient monitor for demo and testing purpose. The default is “Near Real Time”.
- ✧ **LANG**: The current language used, which can be selected by the user. There is no default for this setting. However, the setting can be saved.
- ✧ **Fill**: When the fill setting is ON, the display fills the volume for the SpO2. When it is OFF, the system displays the line graph. The default is OFF.
- ✧ **Frze**: Pressed the key to freeze the selected waveform. The options are “All” and “ECG”. When ECG is selected, the system only freezes the ECG waveform. When “All” is selected, the system freezes all the waveforms including ECG, SpO2. The factory default is “ECG”
- ✧ **Disp2**: The Display 2. Two options: Obsev (Observation) and 7 ECG (7 ECG lead) can be selected. The factory default is Observation.
- ✧ **AlmVol**: The alarm sound volume. The maximum volume is 7 and minimum is 0, i.e. no sound. When the setting is “0”, the icon “” will be displayed on screen to remind user that the alarm sound is off and Alarm Silence function is disabled. The default is 5.
- ✧ **Beep**: If the setting is ON, the press of the button will generate a keystroke sound. The factory is ON.
- ✧ **Exit**: return to the System Setup screen.

PRINTER SETUP

- ✧ **Printer**: For switch on or off the printer.
- ✧ **Timer**: If printer is ON, rotate navigation knob to set on the Timer to enable timed print, and set the value of printing intervals in the cycle category. When the time is reached, the system will automatically take the record. The interval is 1,2,3…….to 240 miniutes.
- ✧ **Wav2**: When printer is selected, you can choose SpO2, I, III, AVR, AVL, AVF or V to be printed with II-lead ECG waveform. The default is SpO2
- ✧ **Exit**: return to the System Setup screen.

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

ECG PARAMETER SETTINGS

Figure 5.17 ECG Setup

- **Lead**: Can choose from I, II, III, AVR, AVL, AVF, V (V1-V6). The default is I.
- **Gain**: The ECG gain, 5 options x1/2, x1, x2, x4 and Auto. Auto is for automatic gain control. The factory default is x1
- **HR Hi**: High limit of heart rate alarm

  Lo: Low limit of heart rate alarm

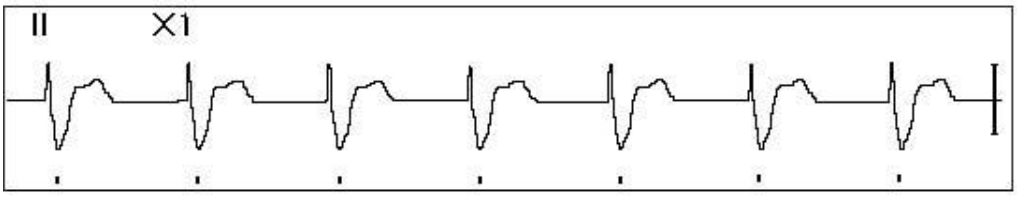
  The adjustable range and the factory default value can be found in chapter 12.2
- **Speed**: ECG display speed. 4 options: 6.25,12.5,25,50mm/s. The factory default is 25 mm/s
- **Mode**: ECG filter mode. Three options: MON, DIA, and OPE

  MON: Monitoring mode. Moderate filtering that can filter out interference and present good ECG waves.

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

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

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



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

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

NIBP PARAMETER SETTINGS

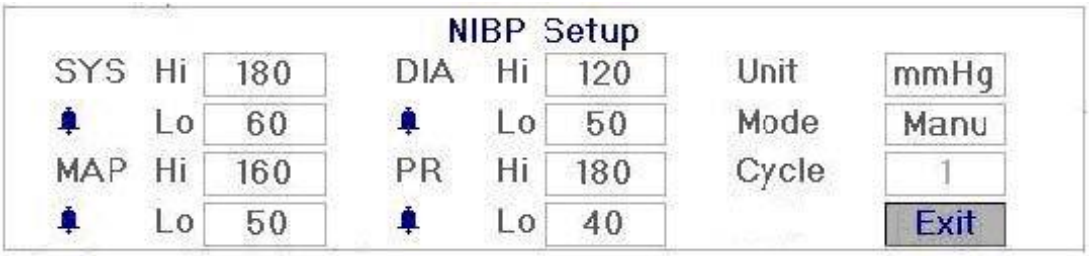


Figure 5.19 NIBP Setup

- **Unit**: The pressure unit, and mmHg and kPa can be selected. The factory default is mmHg.
- **Mode**: The factory default is manual. The operator needs to press the NIBP button to perform NIBP measurement.
- **WARNING: STAT can only be used for Adult. Using this mode to pediatric patient can cause serious injury.**
- **SYS Hi/Lo**: High and Low limits of systolic pressure alarm
- **DIA Hi/Lo**: High and Low limits of diastolic pressure alarm
- **MAP Hi/Lo**: High and Low limits of MAP alarm
- **PR Hi/Lo**: High and Low limits of PR alarm
- **Exit**: return to the System Setup screen.

SPO_2 PARAMETER SETTINGS

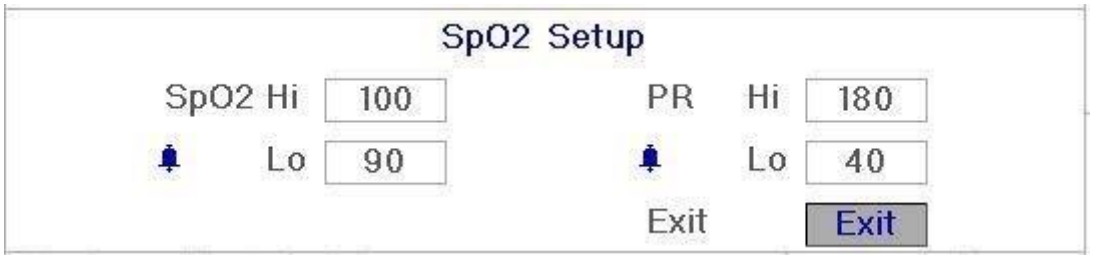


Figure 5.20 SpO_2 Setup

- **SpO2 Hi/Lo**: High and Low limits of SpO2 alarm
- **Pulse Hi/Lo**: High and Low limits of pulse rate alarm
- **Exit**: return to the System Setup screen.

RESUME DEFAULT

In the System setup screen as shown in Figure 5.15, rotate knob to choose “DEF” and then press the knob, all the value of parameters will resume default setting.

5.7 Color Settings

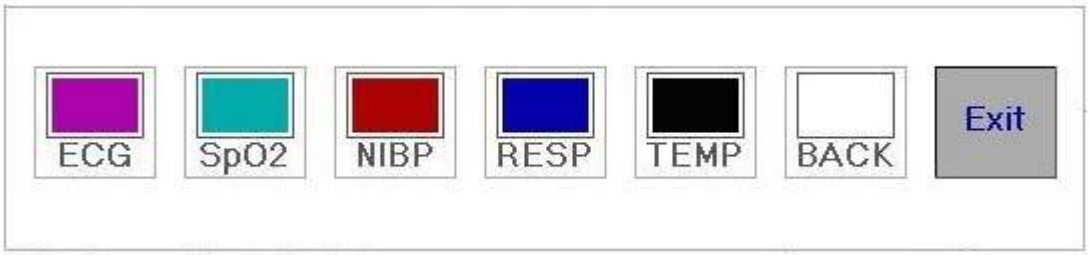


Figure 5.22 Color Setup

5.7.1 How to Change the Parameter Color

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

Step 2: rotate the knob to choose the color.

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

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

5.8 File Management Screen

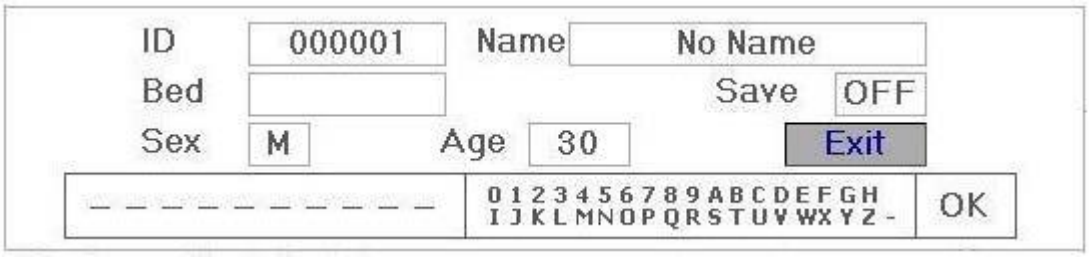


Figure 5.23 Document management screen

5.8.1 How to Add a New Patient

The document/archive management screen can be used to manage information about the patient. In the screen, the operator can enter and modify the patient ID, Name, Bed number, Sex, and Age. The operator can also choose to save the patient data in the permanent storage. The screen is shown in Figure 5.23.

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

Name: Enter the patient’s name.

Bed: Enter the bed number.

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

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

Save: The operator can choose how much of the data that needs to be saved. The unit is hour. Once the time is chosen, the system starts to save data from the current time. If OFF is selected, it means that the data will not be saved. The system will determine the time range according to the available disk space. If no disk space available, SAVE will be displayed as OFF. When the user intends to save the current ECG waveform permanently, please delete the history files. Refer to Chapter 5.1.1 for deletion methods.

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

5.9 oxyCRG Screen

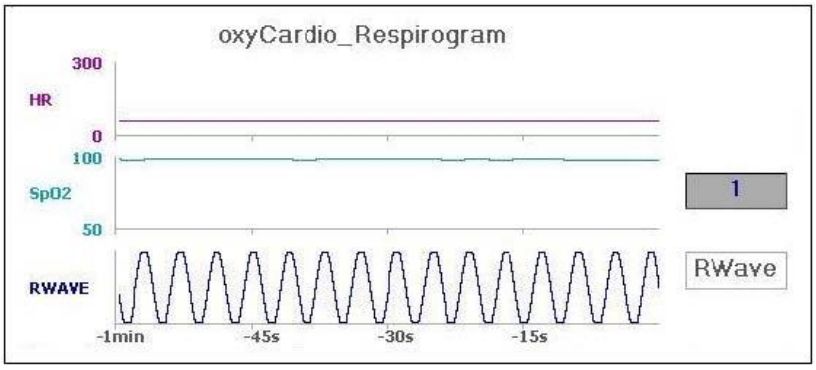


Figure 5.24 oxyCRG Screen

This screen displays the value or waveform of HR, SpO_2 in selected time.

5.9.1 Operation Instructions

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

Step 2: rotate the knob to choose the setting. The time can be set as 1 minute, 2 minutes or 4 minutes.

Step 3: press the knob to confirm your setting.

Pressing "  " key to return to the Main Screen.

5.10 Event List Screen

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

Figure 5.25 Event List

5.10.1 Screen Description

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

5.10.2 Operating Instructions

Up to 100 groups of event data can be memorized. Using the Navigation Knob allows the user to scroll the list up and down to view event data. When rotating the knob anti-clockwise, the list scrolls upward. When rotating knob clockwise, the list scrolls down. Please note that when the groups of data are less than 5, the Navigation Knob can not be used to scroll up or down the listing.

Pressing “  ” key to return to the Main Screen.

5.11 MC Calculator

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

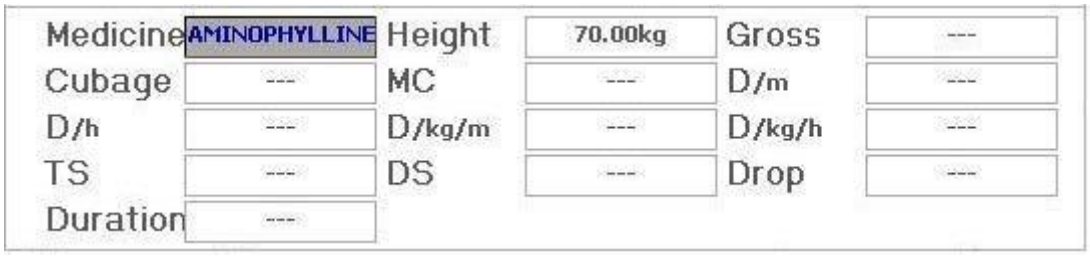


Figure 5.26 Medicine Dosage Calculator Screen

5.11.1 Medicine Dosage Calculator

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

Drug Dosage Calculation adopts the following formula:

Medicine Consistency (MC) =Medicine Gross/ Cubage

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

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

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

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

Drop Speed=TS/ (Cubage/drop)

Duration=Medicine Gross/Dose/h）

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

On medicine calculation screen, at first the operator should move the gray cursor to “Medicine” to select the calculated medicine name, and then move the cursor to “Weight” to select and confirm patient weight, at this time MC analysis screen is shown as Figure 5.38.

Figure 5.27 MC Analysis Screen

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

- On MC analysis screen, other menu options can not enter value unless entering patient's weight and medicine name again, in default status it is no effective. The values in system is a group of stochastic initial values, the operator should not consider it as calculating standard, please according to doctor's device enter a group values which are suitable for patient.
- The unit of every medicine is settled unit or unit series. The operator must select the appropriate unit according to doctor's device. In a unit series, unit carry performs automatic adjustment along with the current entering value. When exceeding the range of this unit expression, the system will display "…".
- When the operator finishes one option entering, the system will give visible indication in menu to remind operator to check the correctness of entering value.
- For every new entering value, please perform confirming. The operator should take it seriously, only the entering is correct, the calculating result is believable and reliable.

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

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

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

5.12 Tourniquet Function

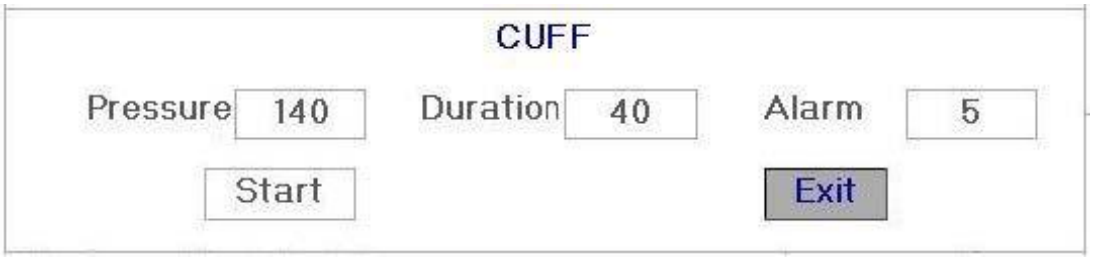


Figure 5.28 Cuff

- ✧ "**Pressure**": when you use Tourniquet function, you need to preset a cuff pressure for hemostasia. The pressure is adjustable, and its adjusting limit is different for different patient category:
  for Pediatric：preset range: 80~130 mmHg, default value: "110" mmHg;
  for adults: preset range: 80~180mmHg, default value: "140" mmHg.
- ☞ If the pressure drops down slowly under 10mmHg compared with the preset value due to little air leakage in the pneumatic system when time passes by, the monitor will re-inflate to maintain the cuff pressure close to the preset pressure value.

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

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

5.12.1 Operation Instructions

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

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

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

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

Chapter 6 Alarm

6.1 Alarm Priority

High Priority:

Over HR limit

Over RR limit

Over SpO_2 limit

Over PR limit

Over NIBP SYS limit

Over NIBP DIA limit

Over NIBP MAP limit

Over ST limit

Over NIBP PR limit

ECG VPCEST

Unable to detect HR

Unable to detect SpO_2

The battery capacity will exhaust

Medium Priority:

VE RONT

SVE RONT

Lead Off

Probe Off

6.2 Alarm modes

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

Visual Alarm Indicators

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

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

Table 6.1

Refer to Chapter 12.1 Alarm Information for detailed alarm message descriptions.

Audible Alarm Indications

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

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

Table 6.2

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

6.3 Alarm Silence

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

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

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

6.4 Alarm Setting

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

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

Refer to Chapter 12.2 for detailed Default Alarming Values of All Parameters and Setup Range.

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

6.5 Verify Adjustable Alarm Function

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

Chapter 7 Technical Specifications

7.1 ECG Monitoring

1. Input signals range in amplitude: ±0.5mV～±3mV
2. Heart rate display range: 15 bpm ~ 300 bpm
3. Heart rate display accuracy: ± 2% or ± 2bpm, whichever is greater.
4. Heart rate alarm delay time: ≤ 10s
5. Sensitivity selection: ×1/4, ×1/2, ×1, ×2, Auto, tolerance: ≤± 5%
6. Sweeping speed: 6.25mm/s ,12.5mm/s, 25mm/s, 50mm/s, tolerance: ≤±10%
7. ECG noise level: ≤ 30μV_{P-P}.
8. ECG input loop current: ≤ 0.1μA
9. Differential input impedance: ≥ 5MΩ
10. Common-mode rejection ratio (CMRR): ≥ 75dB
11. Time constant:
    Monitoring mode: ≥ 0.3s; Diagnostic mode: ≥ 3.2s
12. Frequency response:
    Monitoring mode: 1 Hz～25 Hz
    Diagnostic mode: 1 Hz～75 Hz
13. The recovery time after defibrillator charge: <10sec

7.2 NIBP Monitoring

1. Measuring method: Oscillometric Technique
2. Cuff inflation time: ≤10 seconds (typical adult cuff)
3. Air release time while the measurement is canceled: ≤2 seconds (typical adult cuff)
4. Initial cuff inflation pressure
   Adult: <150 mmHg; Pediatric: <100 mmHg;
5. Overpressure protection limit
   Adult: 300 mmHg; Pediatric: 200 mmHg;
6. NIBP measurement range:
   Systolic： 20 mmHg～290mmHg
   Diastolic： 10 mmHg～260mmHg
   MAP： 15 mmHg～275mmHg
7. NIBP accuracy:
   Systolic： ±5 mmHg
   Diastolic： ±5 mmHg
   MAP： ±5 mmHg
8. Measurement mode: Manual, Auto

9. Measurement Method: Adult, Pediatric

7.3 SpO2 Monitoring

1. Transducer: dual-wavelength LED
2. SpO2 measuring range: 0%~100%
3. SpO_2 measurement accuracy：

(1) 70%～100% ±2%

Remark：Below 70%, the value is only for reference without exact definition, the symbol for % means the "SpO_2 Percentage".

7.4 Pulse Rate Monitoring

1. Pulse rate measuring range: 15bpm~300bpm
2. Pulse rate measuring accuracy: ±2bpm or ±2%, whichever is greater.

7.5 Other Technical Specifications

1. Power supply: 100~240VAC, 50/60Hz
2. Power consumption: <100VA
3. Display mode: 7 inches TFT color LCD
4. Alarming mode: Audible & visible alarm
5. Rechargeable Li-ion battery specification: 14.8V / 2200mAh
6. Communication: NET(RJ45)
7. Classification:

Safety standard:	IEC60601-1
The type of protection against electric shock	Class I equipment.
The degree of protection against electric shock	Type BF and CF applied parts
Electro-Magnetic Compatibility:	Group I, Class A
The degree of protection against harmful ingress of water	IPX1

Chapter 8 Packaging and Accessories

8.1 Packaging

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

Gross Weight: Details see the indication on the outer package

Dimension: 355(L) ×245(W) ×245(H) mm

8.2 Accessories

(1) ECG lead	One set
(2) NIBP cuff	One piece
(3) SpO_2 probe	One piece
(4) AC power adapter	One piece
(5) Power code	One piece
(6) Li-ion battery	One piece
(7) Handle subassembly	One set
(8) Disposable electrode	Ten pieces
(9) User manual	One copy
(10) Warranty	One copy

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

Chapter 9 Troubleshooting

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

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

9.1 No Display on the Screen

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

9.2 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.

9.3 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.

9.4 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 10 Maintenance and Service

Elegant-1070 Patient Monitor should be properly maintained to ensure its maximum performance and long service life. In addition to the warranty period of one year, the company also offers long-term service for each customer. It is important that the users read and follow the operating instructions, important information and maintenance measures.

10.1 Technical Maintenances

10.1.1 Daily Examination

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

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

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

10.1.2 Routine Maintenance

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

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

10.1.3 Battery Maintenance

- Please pay attention to the polarity of battery, do NOT insert it into battery compartment with reversed polarities;
- Do NOT use the batteries manufactured by other companies, if being inserted, the device will may be damaged;
- In order to avoid damaging the battery, do NOT use other power supply device to charge the battery;

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

10.2 Cleaning, Sterilization and Disinfection

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

10.3 Cleaning, Sterilization and Disinfection of Accessories

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

- Do not use damaged accessories.
- Accessories can not be entirely immerged into water, liquor or cleanser.
- Do not use radial, steam or epoxyethane to disinfect accessories.

10.4 Storage

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

Storage environment: ambient temperature: -20~60°C
relative humidity: 10%~95%
atmosphere: 50.0 kPa~106kPa

10.5 Transportation

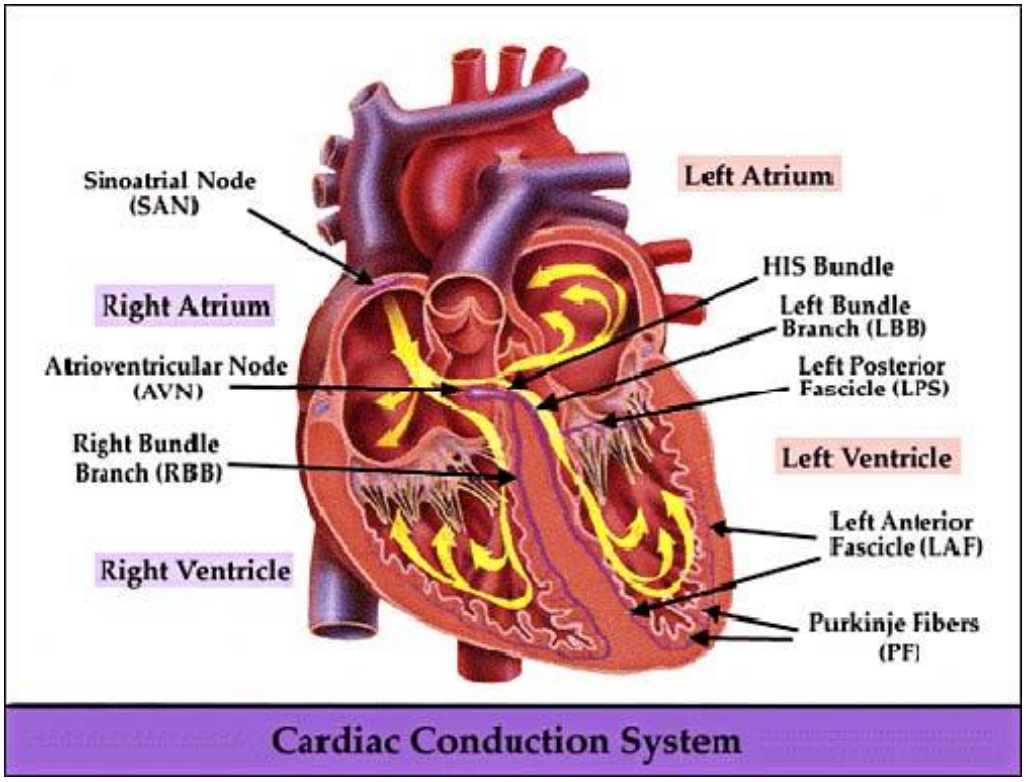
This monitor should be transported by land (vehicle or railway) or air in accordance with the contractual terms. Do not hit or drop it with force.

Chapter 11 Monitoring Parameter

11.1 ECG Monitoring

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

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



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

11.1.2 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 repeatly;
- ✧ The skin placed electrode is unclean or poor contract caused by scurf and hair;
- ✧ Electrode long-time used.

11.2 SpO2 Monitoring

11.2.1 Measuring Principle

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

11.2.2 SpO2 Measurement Restrictions (interference reason)

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

11.2.3 Low SpO2 measuring value caused by pathology reason

- ✧ Hypoxemia disease, functional lack of HbO2
- ✧ Pigmentation or abnormal oxyhemoglobin level
- ✧ Abnormal oxyhemoglobin variation
- ✧ Methemoglobin disease
- ✧ Sulfhemoglobinemia or arterial occlusion exists near sensor
- ✧ Obvious venous pulsations
- ✧ Peripheral arterial pulsation becomes weak
- ✧ Peripheral blood supply is not enough

11.2.4 Clinical Limitations

- ✧ As the measure is taken on the basis of arteriole pulse, substantial pulsating blood stream of subject is required. For a subject with weak pulse due to shock, low ambient, major bleeding, or use of vascular contracting drug, the SpO2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
- ✧ For those with a substantial amount of staining dilution drug (methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic

hemoglobin, and some with icterus problem, the SpO2 determination by this monitor may be inaccurate.

- ✧ The drugs dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO2 measurements.
- ✧ As the SpO2 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 SpO2 value.

11.2.5 Points to be noted in SpO2 and Pulse Measuring

- ✧ The finger should be properly placed (see the attached illustration of this instruction manual), or else it may cause inaccurate measurement result.
- ✧ Make sure that capillary arterial vessel beneath the finger is penetrated through by red and infrared lights.
- ✧ The SpO2 sensor should not be used at a location or limb tied with arterial or blood pressure cuff or receiving intravenous injection.
- ✧ Do not fix the SpO2 sensor with adhesive tape, or else it may result in venous pulsation and consequential inaccurate measurement result of SpO2.
- ✧ Make sure the optical path is free from any optical obstacles like adhesive tape.
- ✧ Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, and direct sunlight etc.
- ✧ Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
- ✧ Please do not use the SpO2 sensor when having the MRI, or burn may be caused by faradism.
- ✧ Always observe the plethysmogram (waveform), which is auto-scaled within the range of 100. The SpO2 reading may be unlikely true when the waveform is not smooth or irregular. If in doubt, rely on your clinical judgment, rather than the monitor readout.
- ✧ A functional tester can not be used to assess the accuracy of the pulse oximeter monitor or a SpO2 sensor. However, a functional tester, SpO2 simulator can be used to check how accurately a particular pulse
- ✧ oximeter is reproducing the given calibration curve. Before testing the oximeter by a functional tester, please firstly ask the manufacturer which calibration curve is used, if necessary, request the manufacturer for its dedicated calibration curve and download it into the tester.

11.3 NIBP Monitoring

11.3.1 Measuring Principle

Blood pressure may be measured in an invasive way (whereby the sensor will be inserted into blood vessel directly) or a non-invasive way. The non-invasive way includes several methodologies, 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 (sudden limb movement or cuff being hit during the measurement). If the answer is negative, give up the calculation. If the answer is positive, proceed with

calculation of the blood pressure value.

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

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

Comparison between blood pressure measuring methods

To overcome the effect of human hearing variation and air release speed on measurement accuracy when the conventional Korotkoff Sound Method is used to take measure of blood pressure, people have been dedicated to study of automatic measurement of blood pressure. By now, automatic blood pressure measuring system based on the principle of oscillating method is mature. In practice, however, various problems are encountered, 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.

11.3.2 Factors affecting NIBP measuring

- ✧ Select a cuff of appropriate size according to the age of the subject.
- ✧ Its width should be 2/3 of the length of the upper arm. The cuff inflation part should be long enough to permit wrapping 50-80% of the limb concerned.
- ✧ Prior to use of the cuff, empty the cuff until there is no residual air inside it to ensure accurate measurement.
- ✧ Make the cuff mark φ in the position where artery pulsates obviously, the effect will be best.
- ✧ The lower part of cuff shall 2cm above the elbow joint.
- ✧ Do not wrap the cuff on too thick clothes(especially forcotton-padded clothes and sweater) to take measurement;
- ✧ The testee shall lie in bed or sit in chair, make the cuff and heart at the same level, the result will be most accurate, other postures may have inaccurate result;
- ✧ During measuring, do not move your arm or the cuff;
- ✧ The measuring interval shall longer than 2 minutes, in continuous measurement, too short interval may cause arm extrusion, blood quantity increases, then cause blood pressure increases.
- ✧ Keep the patient still and stop talking before and during measuring;
- ✧ The patient's mood also can affect the measuring result, when exciting, the blood pressure goes up.
- ✧ The measuring result also affected by time, lower in the morning and higher in the evening;

11.3.3 Clinical Limitations

1. Serious angiospasm, vasoconstriction, or too weak pulse.
2. When extremely low or high heart rate 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, the reading will not be reliable, for reduced peripheral blood flow will lead to reduced arterial pulsation.
6. Subject with hyperadiposis;

In addition, statistics show that 37% people report blood pressure difference of no less than 0.80kPa(6mmHg) between the left and right arms, and 13% people report difference of no less than 1.47kPa (11mmHg).

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

Chapter 12 Appendix

12.1 Alarm Information

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

12.2 Default Alarming Values and Setup Range

The default alarming value:

Parameter \ Mode		Adult	Pediatric
Heart Rate	High Limit	180bpm	200bpm
	Low Limit	40bpm	50bpm
Systolic	High Limit	180 mmHg	130 mmHg
	Low Limit	60 mmHg	50 mmHg
Diastolic	High Limit	120 mmHg	90 mmHg
	Low Limit	50 mmHg	40 mmHg
MAP	High Limit	160 mmHg	110 mmHg
	Low Limit	50 mmHg	40 mmHg
SpO_2	High Limit	100%	100%
	Low Limit	90%	85%
Pulse Rate	High Limit	180bpm	200bpm
	Low Limit	40bpm	50bpm
ST Segment	High Limit	+1.00mV	+1.00mV
	Low Limit	-1.00mV	-1.00mV

Alarm high and low limits: when the parameter value is higher than the high limit or lower than the low limit, the system will alarm.

In the monitoring screen, press the Alarm silence key to activate the alarm timer. The time shows up on the upper left corner of the screen. When the alarm timer is activated, the system will activate the alarm function when the specified time has passed.

Alarm timer has 4 options: 2 min, 5 min, 10 min, 20 min, or during alarm.

The high and low limits setting range:

Parameter \ Mode		Adult	Pediatric
Heart Rate	High Limit	1～300bpm	1～350bpm
	Low Limit	0～299bpm	0～349bpm
Systolic	High Limit	31～270 mmHg	31～200 mmHg
	Low Limit	30～269 mmHg	30～199 mmHg
Diastolic	High Limit	11～232 mmHg	11～150 mmHg
	Low Limit	10～231 mmHg	10～149 mmHg
MAP	High Limit	21～242 mmHg	21～165 mmHg
	Low Limit	20～241 mmHg	20～164 mmHg
SpO_2	High Limit	1～100%	1～100%
	Low Limit	0～99%	0～99%
Pulse Rate	High Limit	1～300bpm	1～350bpm
	Low Limit	0～299bpm	0～349bpm
ST Segment	High Limit	-2.49mV～+2.49mV	-2.49mV～+2.49mV
	Low Limit	-2.49mV～+2.49mV	-2.49mV～+2.49mV

12.3 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, 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 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
“DEMO”	—The monitor is displaying the demo waveforms, which are generated by the monitor itself.

12.4 Accessories List

		Remark
15010513	ECG cable	
5101-0101310	ECG electrode	
15044051	Adult SpO_2 Finger clip Sensor	
15044038	Adult SpO_2 Finger rubber Sensor	Optional
15044041	Pediatric SpO_2 Finger clip Sensor	Optional
15024402	Adult NIBP cuff(25~35cm)	
15021402	Small-sized Pediatric NIBP Cuff	Optional
15022402	Middle-sized Pediatric NIBP Cuff	Optional
15023402	Large-sized Pediatric NIBP	Optional
2507-1700010	Handle subassembly	
2301-1005055	AC Power Adapter	
2903-0000000	Power cord	
900093	Net wire	

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

12.5 Instructions for SpO_2 Probe

Instructions for Pediatric SpO_2 Finger Clip Sensor

Intended Use

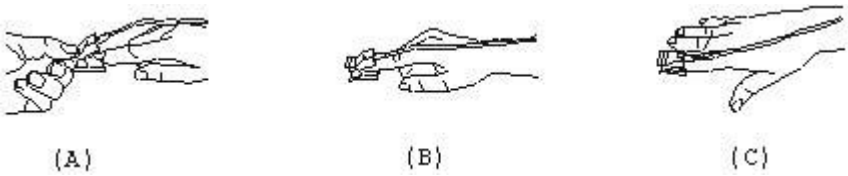
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for pediatric patients weighing between 10~40kg.

Contraindications

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

Instructions for Use

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



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

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

Warnings

1) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poor blood perfusion in the finger, extreme finger sizes or improper placement of the sensor.
2) Using the sensor in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
3) The sensor must be moved to a new site at least every 3 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
4) Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate saturation measurements.

5) Do not immerse sensor as it causes short.
6) Do not use NIBP or other constructing instruments on same appendage as sensor for blood flow interrupted by NIBP cuff or circulatory patient condition will result in no pulse found or loss of pulse.
7) Do not use the sensor or other oximeter sensors during MRI scanning.
8) Carefully route cables to reduce the possibility of patient entanglement or strangulation.
9) Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
10) Do not use the sensor if the sensor or the sensor cable appears damaged.

Instructions for Adult SpO_2 Finger Rubber Sensor

Intended Use

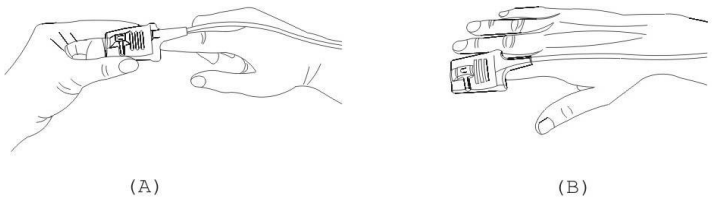
When used with a compatible patient monitor or a pulse oximeter device, this SpO_2 sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 50kg.

Contraindications

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

Instructions for Use

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



3) Plug the sensor into the oximeter and verify proper operation as described in the user manual.
4) Inspect the monitoring site every 1~2 hours for skin integrity.

Cleaning & Disinfection

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

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

Warnings

1) This sensor is for use only with compatible patient monitors or pulse oximeter devices. Use of this sensor with instruments other than compatibles may result in improper performance.

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

Instructions for Adult SpO_2 Finger Clip Sensor

Intended Use

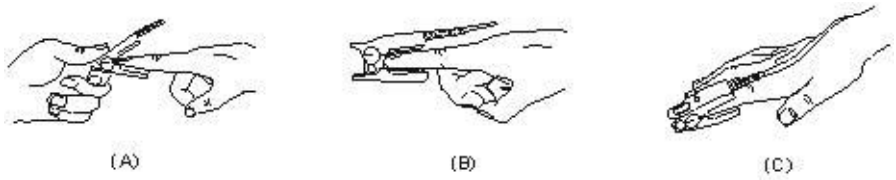
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 40kg.

Contraindications

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

Instructions for Use

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



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

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

Warnings

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

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

If you have any question regarding any of SpO_2 sensor instructions, please contact ahuang@north-vision.com, or your local dealer.

Manufacturer

North-vision Tech. Inc.

Address: 1st Fl., No.15, Gongye E. 2nd Rd., East Dist., HsinChu City 30075, Taiwan R.O.C.

International Sales

North-vision Tech. Inc.

Address: 1st Fl., No.15, Gongye E. 2nd Rd., East Dist., HsinChu City 30075, Taiwan R.O.C.

Tel +886 3-5771038

Fax +886 3-5771039

E-mail ahuang@north-vision.com

Website http://www.north-vision.com

Version 3.0

Issued date July 20, 2020

European Representative:

CMC Medical Devices & Drugs S.L.

C/Horacio Lengo N 18, CP 29006

Malaga, Spain

TEL: +34951214054 FAX:+ 34952330100