Multi-parameter Patient Monitor

Elegant-800

User Manual

Version: 2.0

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North-Vision Tech. Inc.

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 Food and Drug Administration, Ministry of Health and Welfare. The Manual is written for the current Elegant-800 Multi-Parameter Patient Monitor.

The Manual describes, in accordance with the Vital Signs 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 any time without prior notice. Amendments will however be published in a new edition of this manual.

Version of This Manual: Ver 1.1

Revised Date: November 4, 2015

Marks in the Manual:

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

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

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

Instructions to Users

Dear Users,

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

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

- **WARNING-PACEMAKER PATIENTS. This monitor may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon this monitor ALARMS. Keep pacemaker patients under close surveillance.**
- **Monitoring a single person at a time.**
- **The monitor is defibrillator proof. Verify that the accessories can function safely and normally and the monitor is grounded properly before conducting defibrillation.**
- **Disconnect the monitor and sensors before MRI scanning. Use during MRI could cause burns or adversely affect the MRI image or the monitor's accuracy.**
- **If you have any doubt to the grounding layout and its performance, you must use the built-in battery to power the monitor.**
- **All combinations of equipment must be in compliance with standard of IEC 60601-1-1 for medical electric system requirements.**
- **Check SpO_2 probe application site periodically (every 30 minutes) to determine circulation, positioning and skin sensitivity.**
- **The SpO_2 measurement of this monitor may not work for all testees. If stable readings 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 or neonate's (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.**

- **The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.**
- **DO NOT take blood pressure measurement from a limb receiving ongoing transfusion or intubations or skin lesion area, otherwise, damages may be caused to the limb.**
- **Continuous use of SpO_2 sensor may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.**
- **SpO_2 measuring position must be examined more carefully for some special patient. Do NOT install the SpO_2 sensor on the finger with edema or vulnerable tissue.**
- **Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.**
- **All the connecting cables and rubber tubes of the applying parts should be kept away from the patient' s cervix to prevent any possible suffocation of the patient.**
- **All the parts of the monitor should NOT be replaced at will. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused.**
- **DO NOT stare at the infrared light of SpO_2 sensor when switch it on, for the infrared may do harm to the eye.**
- **If the monitor falls off accidentally, please do NOT operate it before its safety and technical indexes have been tested minutely and positive testing results obtained.**
- **It is recommended to take the blood pressure measurement manually. The automatic or continuous mode should be used at the presence of a doctor/nurse.**
- **Please peruse the relative content about the clinical restrictions and contraindication.**
- **When disposing of the monitor and its accessories, the local law should be followed.**

Table of Contents

Chapter 1 Overview

1.1 Features

- Blood Pressure, SpO_2 and Pulse Rate are displayed by big, bright digital LEDs;
- Accurate NIBP measurement with hardware and software over-pressure protection;
- Unique SpO_2 measuring technique ensures sensitive and accurate SpO_2 and pulse rate measurement;
- SpO_2 pitch tone function is available;
- Up to 12000 groups of NIBP measurements can be stored (in nonvolatile memory) and reviewed by list;
- Up to 2000 groups of SpO_2 data can be stored (in nonvolatile memory) and reviewed by list or trend graph;
- Multi-level of audible & visible alarm function;
- Nurse call output is available
- Tourniquet function is available;
- Stored data can be uploaded to computer;
- Built-in printer is optional to print out waveforms, and text information.

1.2 Product Name and Model

Name: “North-vision” Multi-parameter patient monitor

Model: Elegant-800

1.3 Intended Use

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

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

1.4 Normal Working Environment

a) Ambient temperature range: 10°C ~40°C

b) Relative humidity: ≤80%

c) Atmospheric pressure: 86kPa ~106kPa

1.5 Safety

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

b) This device can resist against the discharge of defibrillator and the interference of electro-surgical unit.

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

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

1.6 Symbols on the Monitor

	Adult Patient		Power switch
	Pediatric Patient		NIBP setup
	Neonatal Patient		Power saving mode setup
	NIBP Start/Cancel	~	AC Power indicator
	Alarm Silence		DC Power indicator
	Print		Type BF applied part
	Up		Warning, refer to User Manual.
	OK		Equal potential terminal
	Down	MAP, Time	Mean arterial pressure. Measuring time.
	Display		Alarm lamp
	Pulse bar-graph	DIA	Diastolic Pressure
SYS	Systolic Pressure	SpO_2	Oxygen Saturation (%)
PR	Pulse Rate (bpm)		
	LCD display screen		

Chapter 2 Operating Principle

2.1 Overall Structure

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

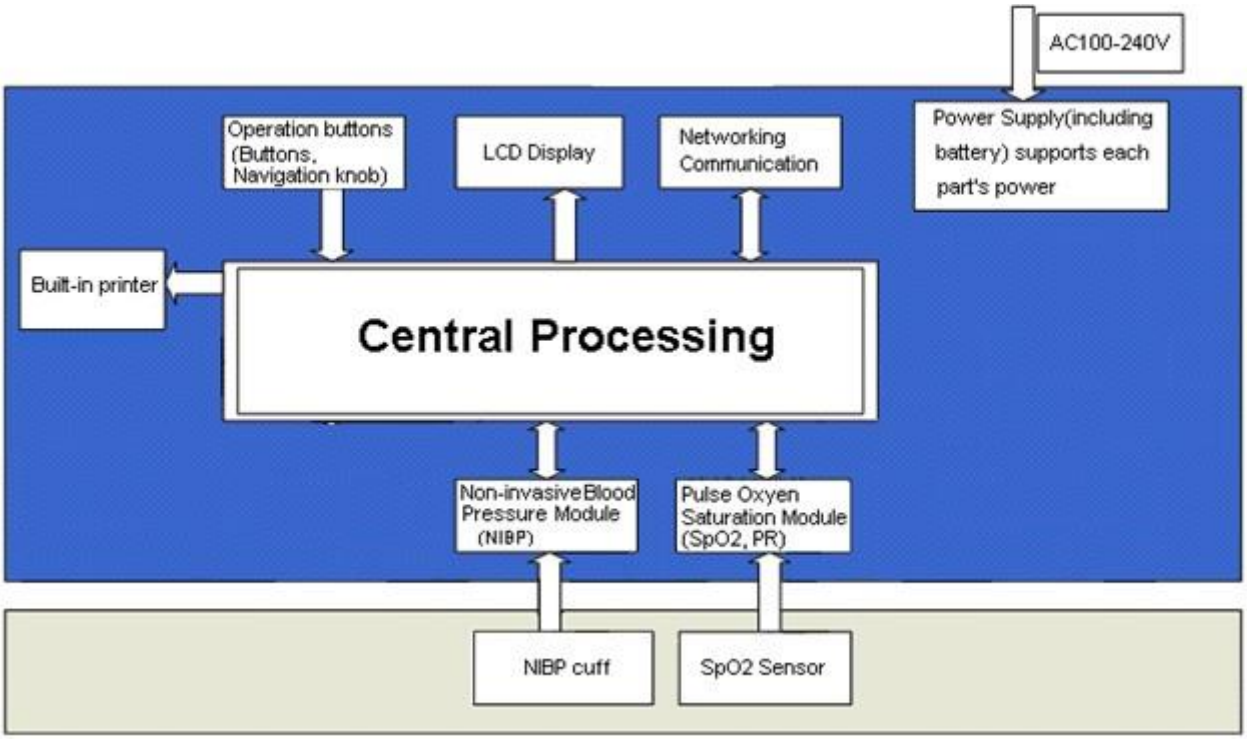


Figure 2.1

2.2 Conformation

The Vital Signs Monitor is module designed product; it consists of NIBP module (optional), SpO_2 module (optional), main control unit, printer module (optional), display panel, and power supply block etc. and the related accessories for NIBP and SpO_2 measurement.

☞ According to different needs, you can customize the module configuration by choosing necessary modules. Therefore, your monitor may not have all the monitoring functions and accessories.

1. The SpO_2 module detects and calculates pulse rate and oxygen saturation (SpO_2), and provides plethysmogram and perfusion index as well.
2. The NIBP module performs the measurement of blood pressure by non-invasive way of oscillometric technology, including the diastolic, systolic and mean arterial pressure. The cuffs are designed for adult, pediatric and neonate respectively.
3. The main control unit is in charge of LED and LCD display, keyboard input, data storage, printing and networking function.

Chapter 3 Installation and Connection

3.1 Appearance

3.1.1 Front Panel

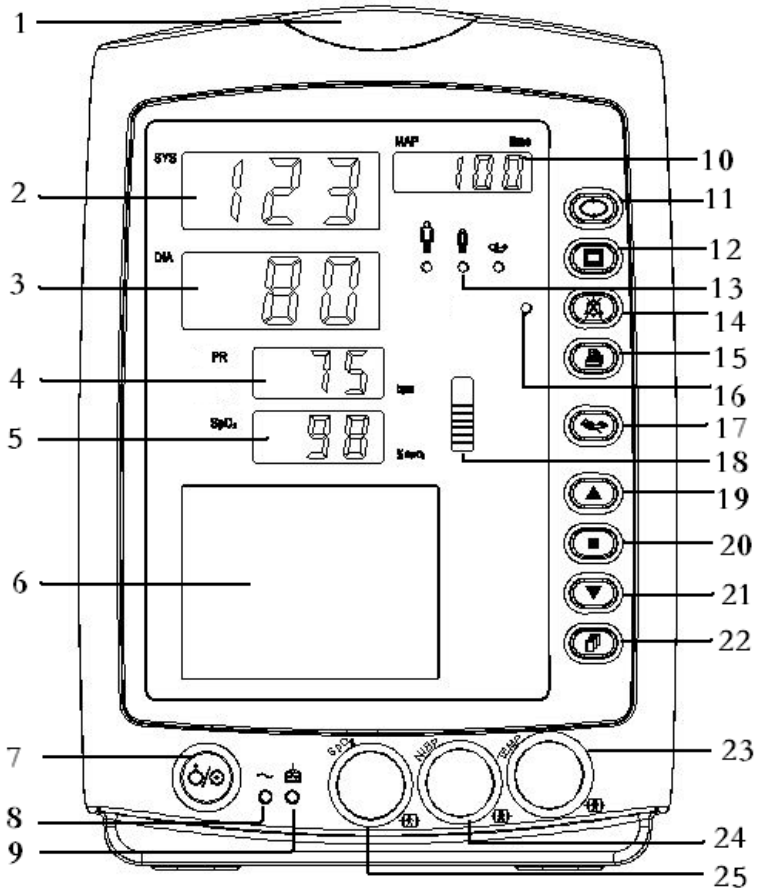


Figure 3.1 Front panel illustration

Description:

1 **Alarm indicator**

2 **SYS:** display systolic pressure value.

3 **DIA:** display diastolic pressure value.

4 **PR:** display the measured pulse rate; unit: bpm.

5 **SpO_2:** Display SpO_2 value; Unit: "%".

6 **LCD panel**

7 "**":** Power button: Press power button for 3 seconds to start the monitor or shut off the monitor.

8 ～**:** AC Power indicator.

9 **:** DC Power indicator.

10 **MAP:** When NIBP measurement mode is set to "manual" and "STAT": Display mean arterial pressure or measuring time of the latest group of NIBP measurement; they will be displayed alternately. The format of NIBP measuring time is "hh:mm". If the tourniquet is in use, the cuff pressure will be displayed here; When NIBP measurement mode is set to "AUTO": Display real-time pressure value during measurement. Countdown time will be displayed in the MAP when the measurement finishes. Countdown time has two formats (＞1 hour HH: mm; ＜1 hour mm: ss).

Note: two formats to display NIBP value: "×××mmHg" and "×××kPa". Refer to section "4.6.2 NIBP Setup" to set the unit of NIBP value; the conversion relation between "mmHg" and "kPa": 1mmHg=0.133kPa.

11 "**NIBP Setup key:** on plethysmograph displaying screen, trend graph screen and NIBP list screen, pressing this key to enter into " NIBP Mode Setup" screen.

12 "**Power Saving Mode Setup key:** on plethysmograph displaying screen, trend graph screen and SpO_2 list screen, pressing this key to enter into "Power Saving Mode" setting screen.

13 **Pulse sync indicator patient category indicator:** " " for adult; " " for pediatric; " " for neonate; Patient category is selected under sub-menu "Patient Info" within the setup menu.

14 " " **Alarm silence key**: Enable/disable alarm silence function. When the alarm silence indicator on the left of keys is on, it means the system is in alarm silence status. Short press this key and it lasts this status for 2 minutes. When finishing counting down, the system will resume normal alarm status automatically; Long press this key, the alarm sound of the current event will be disabled, but if alarm event occurs at this time, the alarm sound will be effective again.

15 " " **Print:** the internal printer is optional, press this key to print the current measuring data.

16 **Alarm silence indicator:** When it is on, it indicates that the monitor stays in alarm silence status.

17 " " **NIBP:** start/cancel NIBP measurement.

18 "**":** Bar-graph of pulse intensity.

19 " " Up: shift cursor forward/upward

20 " " OK: to confirm selection or modification

21 " "Down: shift cursor backward/downward

22 "  " Display: short time pressing to shift LCD display modes; longtime pressing to enter into Setup Menu display screen.

23 **NIBP:** NIBP hose connector

24 **SpO_2:** SpO_2 sensor connector

Description to AC, DC Power indicator：

	AC Power indicator	DC Power indicator	Descriptions
Status	ON	ON	this device is using AC power supply
	OFF	ON	the battery is being used
	ON	OFF	the battery is being recharged while the device is off

3.1.2 Side Panel

The built-in thermal printer is in the left panel. It is easy for user to print plethysmograph and data.

3.1.3 Rear Panel

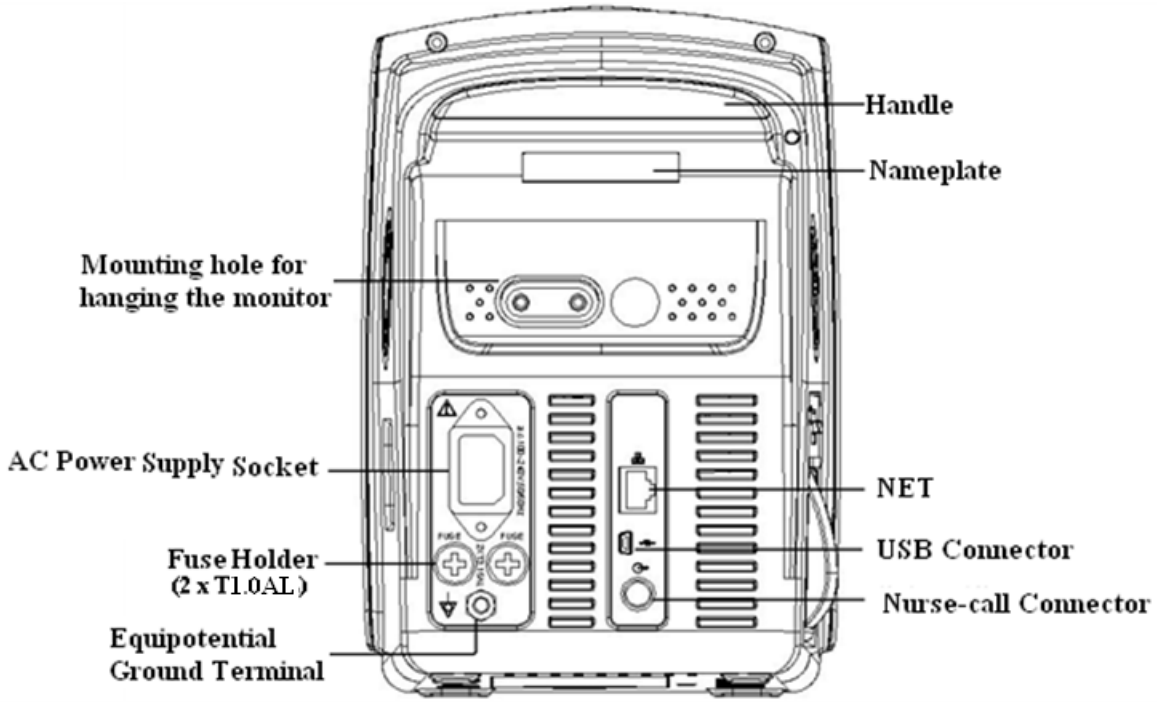


Figure 3.2 Rear Panel

Form 3-1 Real panel Symbols and its descriptions

Symbol	Description	Symbol	Description
	Type BF Applied Part with Defibrillation-proof	FUSE 2XT1.0AL	Fuse holder
	Warning-- Refer to User Manual		Equipotential ground terminal
SN	Serial number		USB connector

3.2 Installation

3.2.1 Opening the Package and Check

1. Open the package, take out the monitor accessories from the box carefully and place it in a safe stable and easy to watch position.
2. Open the accompanying document to sort the accessories according to the packing list.
   - Inspect the monitor for any mechanical damages.
   - Check all the accessories for any scratch or deformity, especially on connector, wire and probe parts

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

If in doubt, 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 Connecting the Power Supply

2. When powered by AC mains power supply:

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

Caution: ensure that the monitor is grounded correctly.

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

3. When powered by built-in battery

- Caution: it's better to recharge the battery after it is used up, the charging time should be 13~15 hours long.
- The provided battery of the monitor must be recharged after transportation or storage. So if the monitor is switch on without being connected to the AC power socket, it may not work properly due to insufficient power supply.

3.2.3 Starting the Monitor

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

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

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

It’s recommended to delay 1 minute to start it again.

3.3 Sensor Placement and Connection

3.3.1 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	6cm～11cm	4.5cm
Middle-sized Pediatric Cuff	10cm～19cm	8cm
Large-sized Pediatric Cuff	18cm～26cm	10.6cm
Adult Cuff	25cm～35cm	14cm

Table 3-2

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

2) Remember to empty the residual air in the cuff before the measurement is commenced.

3) Locate the cuff in such a way that the "φ" mark is at a location where the clearest pulsation of brachial artery is observed.

4) The cuff should be tightened to a degree where insertion of one finger is allowed.

5) The lower end of the cuff should be 2cm above the elbow joint.

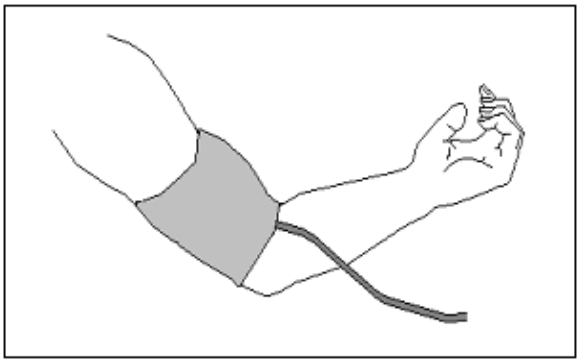


Figure 3.4 Cuff Placement

- **Pressure Accuracy Verification**

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

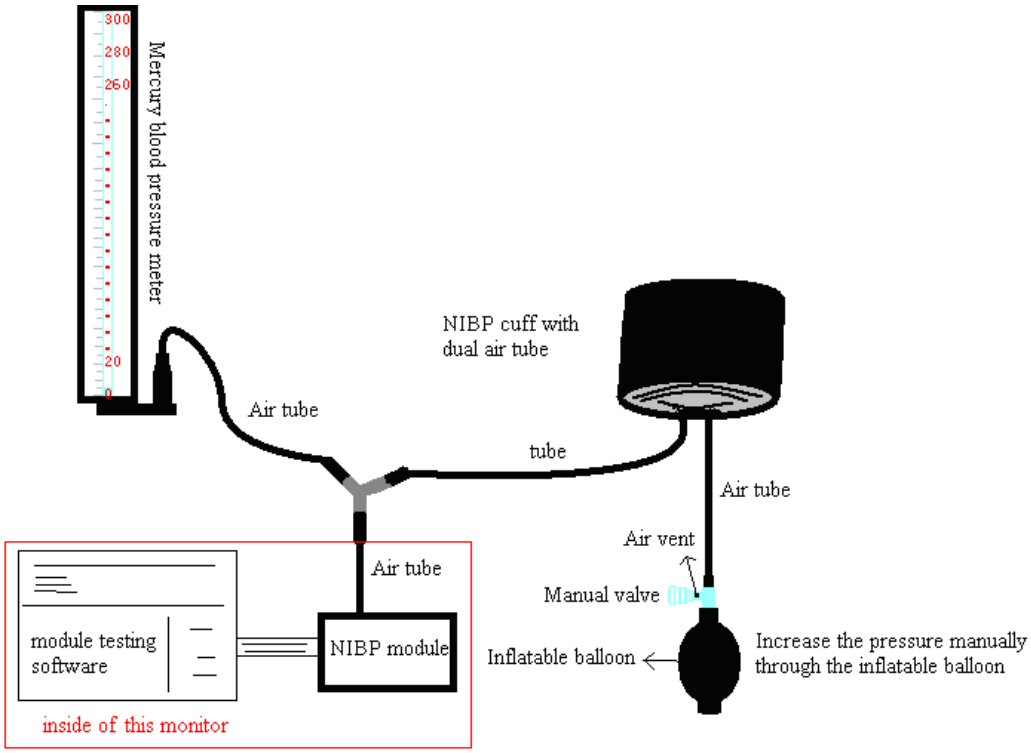


Figure 3.5 Connection of Pressure calibration fixture

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

Adult	240mmHg
Pediatric	200mmHg
Neonate	120mmHg

Table A

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

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

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

Adult	300mmHg
Pediatric	240mmHg
Neonate	140mmHg

Table B

After the verification, do press the button again to return to normal working mode, then continue other operation, or the NIBP key will be invalid.

Pressure accuracy verification must be operated by technician or equipment manager. Doctor or nurse is not allowed to do the verification, it is very dangerous especially when the pressure cuff is still on patients.

- **Air Leakage Check**

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

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

Safety Instructions for NIBP Monitoring

- "When taking the measurement of a pediatric or an pediatric or neonate's (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.
- "It is recommended to take the blood pressure measurement manually. Automatic 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.
- "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.
- "Confirm your patient category (adult, pediatric or neonate) before measurement.
- "Do NOT bind NIBP cuff on limbs with transfusion tube or intubations or skin lesion area, otherwise, damages may be caused to the limbs.
- "If the time of the automatic pattern noninvasive blood pressure measurement is too long, the body connected with the cuff will possibly occur the purpura, lack the blood and the neuralgia. In order to protect patient, it is requested to inspect the luster, the warmth and the sensitivity of the body far-end frequently. Once observes any abnormity, please immediately stop the blood pressure measurement.
- "The patient 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. Ensure that the cuff will not be hit or touched by other objects.
- "The measures should be taken at appropriate intervals. Continuous measurement at too short intervals may lead to pressed arm, reduced blood flow and lower blood pressure, and resulting inaccurate measure of blood pressure. It is recommended to take measurement at intervals of more than two minutes.
- "When an adult 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.

3.3.2 SpO_2 Sensor Connection

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

Operation procedure:

1. Connect the SpO_2 sensor to the connector labeled "SpO_2". **When unplugging the probe, be sure to hold the head of the connector and pull it out.**
2. If the finger clip SpO_2 sensor is used, insert one finger into the sensor (index finger, middle finger or ring finger with short nail length) as shown in the figure below.

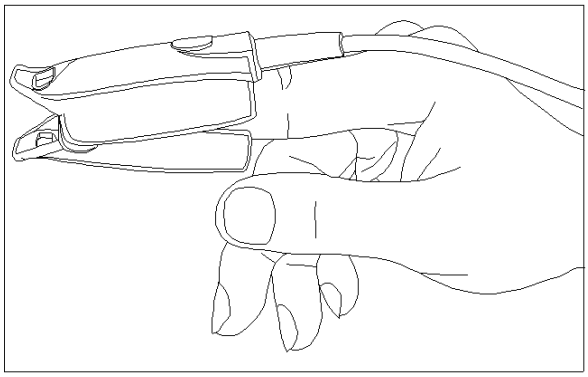


Figure 3.6 Finger clip SpO_2 sensor placement

When selecting a sensor, consider the patient's category, adequacy of perfusion, availability of probe site and anticipated monitoring duration. Use only SpO_2 probes provided by our company with this monitor. Read the following table for SpO_2 probe information. Refer to Chapter 11.5 for the detailed instructions of each SpO_2 probe.

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

3. If the neonate SpO_2 sensor is used, please follow Figure 3.7 to connect.

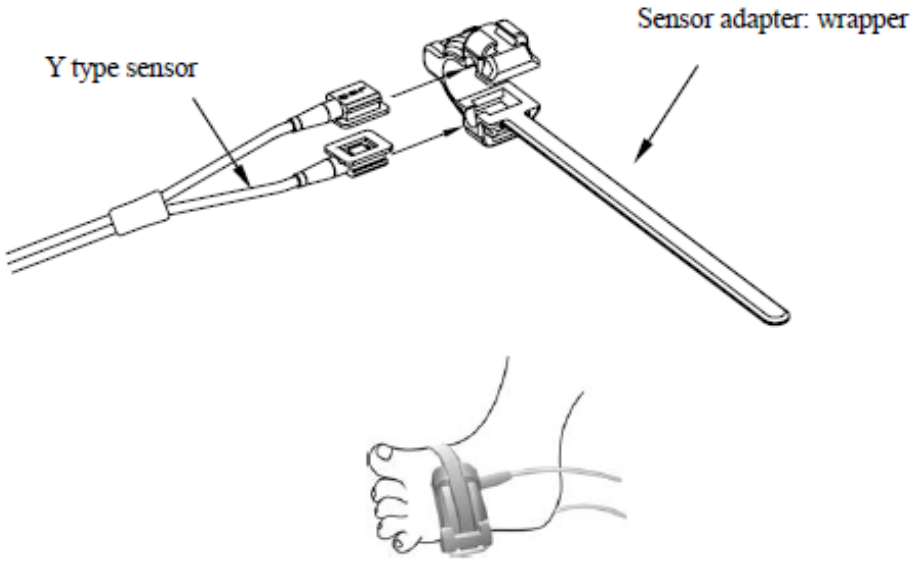


Figure 3.7 Neonate SpO_2 sensor placement

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

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

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

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

Safety Introductions for SpO_2 Monitoring

- "Continuous use of SpO_2 sensor may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.
- "SpO_2 measuring position must be examined more carefully for some special patient. Do NOT place the SpO_2 sensor on the finger with edema or fragile tissue.
- If sterile packaging of SpO_2 sensor is damaged, do not use t any more.
- Check the SpO_2 sensor and cable before use. Do NOT use the damaged SpO_2 sensor.
- When the temperature of SpO_2 sensor is abnormal, do not use it any more.
- "Please do not allow the cable to be twisted or bended.
- "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.
- "Using nail polisher or other cosmetic product on the nail may affect the accuracy of measurement.
- "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 to resist the harmful ingress of water

3.3.3 Loading printing paper

Operation procedures for loading printing paper:

1. Press both “OPEN” notches with force on printer shield with two thumbs to open it.

2. Move the tab of rubber roller lock at the left 90°upwards to unlock it, refer to the following figure with mark ①.

3. Cut one end of the paper into triangle, and load the paper from the underside of the rubber roller.

4. Turn the roller clockwise to get the paper rolled, and put the paper roll into the compartment.

5. Pull the paper out of paper slot on the shield.

6. Move the tab of the rubber roller lock 90° downwards to lock it.

7. Put the shield back in position and secure it.

Operation procedures for taking out printing paper roll:

1~2 steps are the same with the 1~2 steps mentioned above for loading printing paper.

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

4~5 steps are the same with the 6~7 steps mentioned above for loading printing paper.

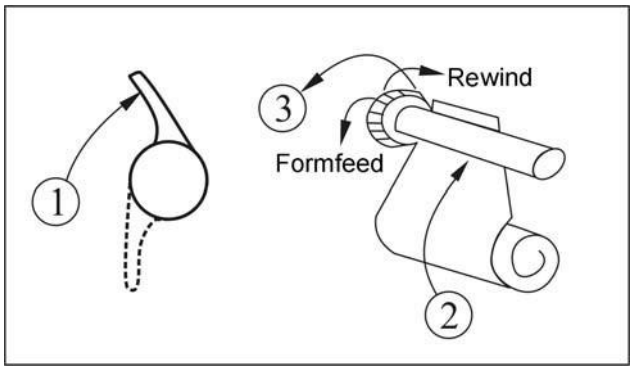


Figure 3.8 Loading and taking out printing paper

P8 printer may be used due to the different configuration.

P8 printer operation instruction:

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

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

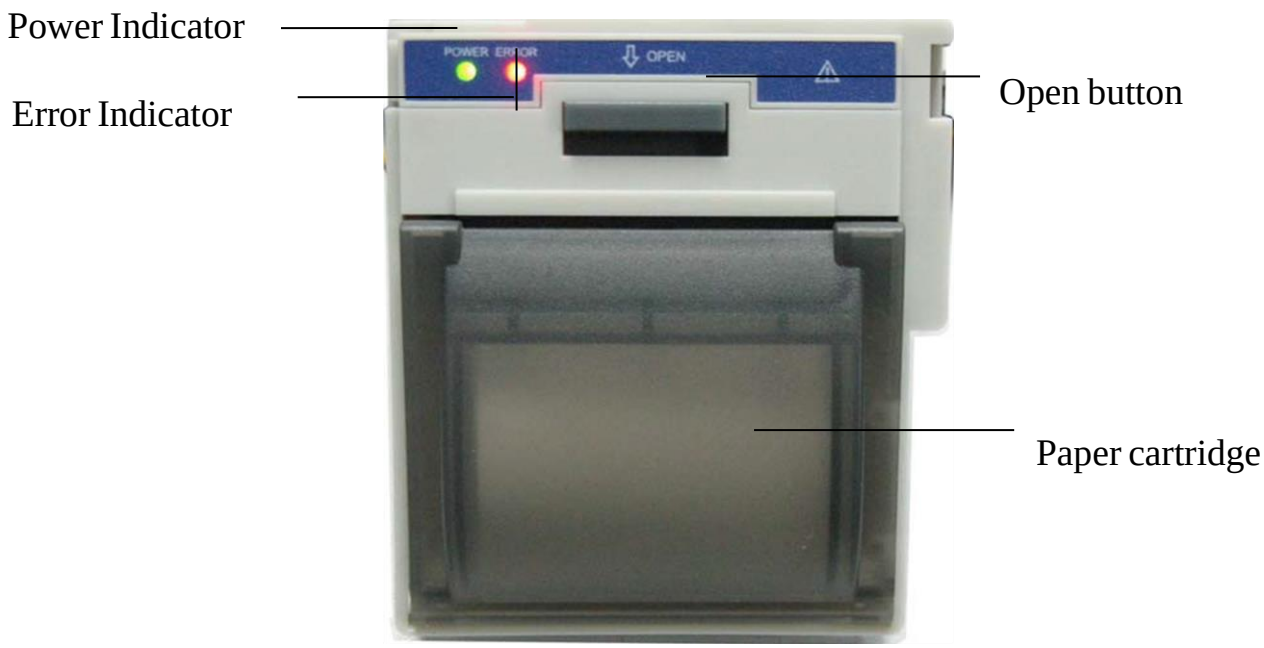


Figure 3.9 P8 printer

Loading printing paper:

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

Step 2: Install the paper to the printer properly, pull the paper out of the printer for 2 cm, as shown in figure 3.10.

Step 3: Close the printer cover along the direction of arrow, as shown in figure 3.10.

Figure 3.10 printing paper

3.3.4 Battery Installation

1. Ensure that the monitor is not connected to AC power supply and the monitor is turned off.
2. Open the battery cover and move the locked button aside.
3. Move the battery into the box. Please note that the battery connecting wire should be outward.
4. Connect the battery plug with the socket, as shown in figure 3.11.
5. Arrange the wires and close the battery cover.

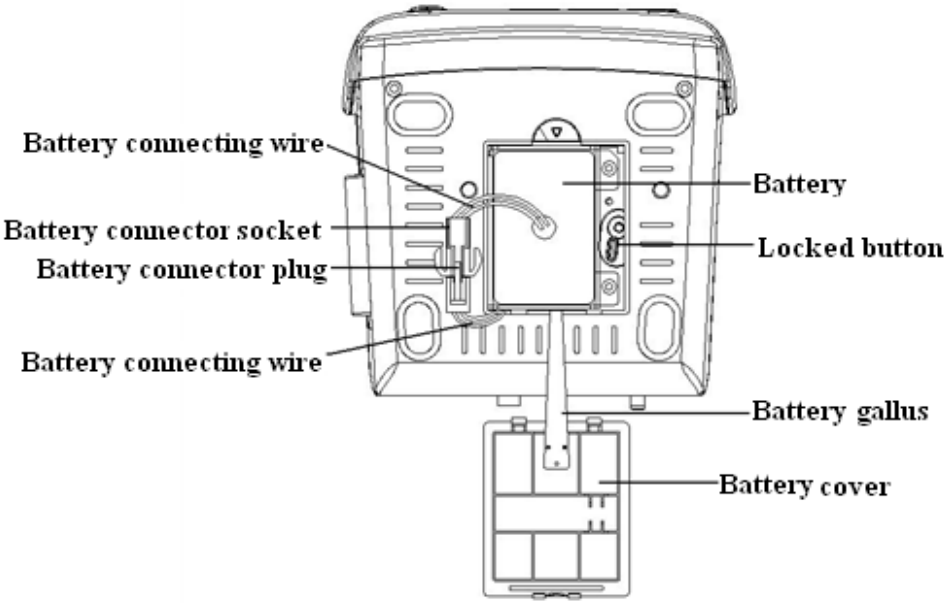


Figure 3.11 Battery Installation

Warning:

1. To avoid battery damage always remove battery(s) before shipping or storage.
2. It is recommended to use the battery specified by the manufacturer.
3. The battery service life depends on how frequent and how long it is used. For a properly maintained and stored lead-acid or lithium battery, its service life is about 2 or 3 years respectively. For more aggressive use models, service life can be less. We recommend replacing lead acid battery every 2 years and lithium battery every 3 years.

Caution:

1. Keep the battery out of the reach of children.
2. Do not disassemble battery.
3. Do not dispose of them in fire.
4. Do not cause them to short circuit.

Chapter 4 Operations

4.1 Initial Monitoring Screen

Long pressing (about 2 seconds) "⏻" power key, when you hear one "beep", the LCD will display the following figure, it means that the monitor is started successfully, as shown in figure 4.1.

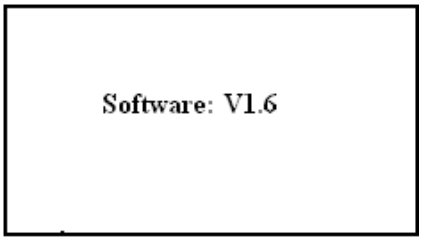


Figure 4.1 Startup screen

Long pressing power key "⏻" again, the LCD will turn to black, it means that the monitor is shutdown successfully.

4.2 Default Screen

When the monitor is powered on, the LCD will display the default display screen as well, as shown in figure 4.2.

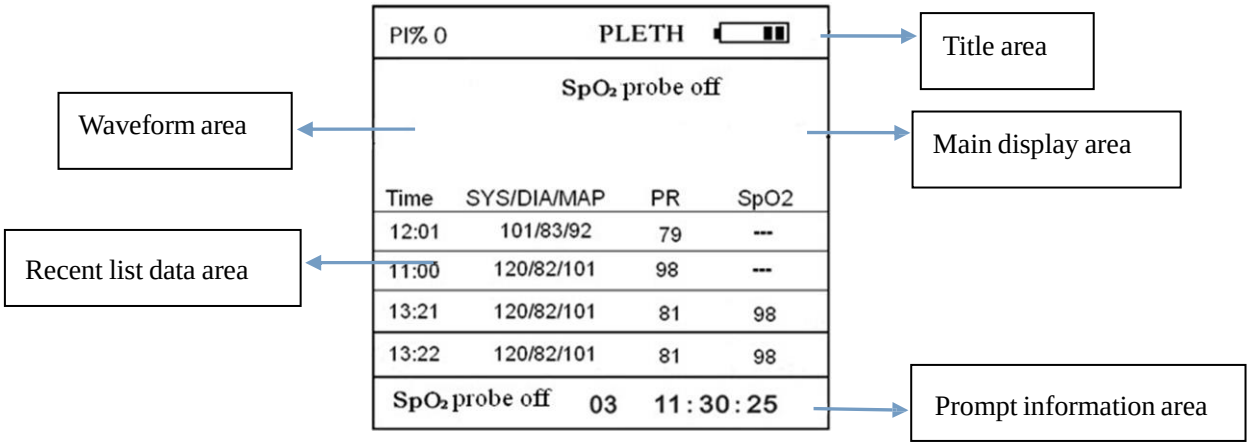


Figure 4.2 SpO_2 monitoring screen (Probe off)

4.2.1 Default Display Screen Description

Title area:

- **"PLETH":** indicates the current Plethysmograph.
- **"▭":** indicates the battery power.
- **"PI% 0":** the label of perfusion index, "0" is the current perfusion index; it displays only when "Setup Menu → SpO_2 → PI Display" is set as "ON". This function is optional, please refer to the monitor in your hand. (Note: If the monitor is configured with Nellcor SpO_2 module, then PI display is always not available.)

Main display area:

- When SpO_2 probe is clipped on the patient and connected to the monitor well, SpO_2 plethysmogram will be displayed in the main display area. If probe is disconnected or connected incorrectly, message "Probe off " pops up on the screen.

- The recent list data area: if blood pressure measurement is taken, the data display area displays the recent 4 groups of data, the form is "Time SYS/DIA/MAP PR SpO_2", as shown in figure 4.2; if no blood pressure measurement is taken, the recent data list will be empty, as shown in figure 4.3. "Time" is measuring time; "SYS/DIA/MAP" is systolic/diastolic/arterial mean pressure; "PR" is the measured pulse rate from blood pressure measuring channel or pulse rate value from oximetry measuring channel when SpO_2 measurement is available, the PR value from oximetry will be taken priority to be displayed; "SpO_2" is oxygen saturation (SpO_2 for short). Note: if the device is re-started, the data in recently data area will be cleared.

Prompt Info. Area:

- **"SpO_2 Probe off ":** this prompt message appears when the SpO_2 probe is off or the probe is disconnected with the monitor.
- Patient ID segment:

  "03": Patient ID number.

- Real time clock segment:

  "11:30:25": the current time.

4.3 SpO_2 Monitoring Screen

When the monitor is powered on, insert the SpO_2 probe cable into the connector labeled "SpO_2", in display area of the SpO_2 monitoring screen, it displays one trace of SpO_2 plethysmogram, as shown in Figure 4.3. Short pressing print"  " key to print this trace of SpO_2 plethysmogram.

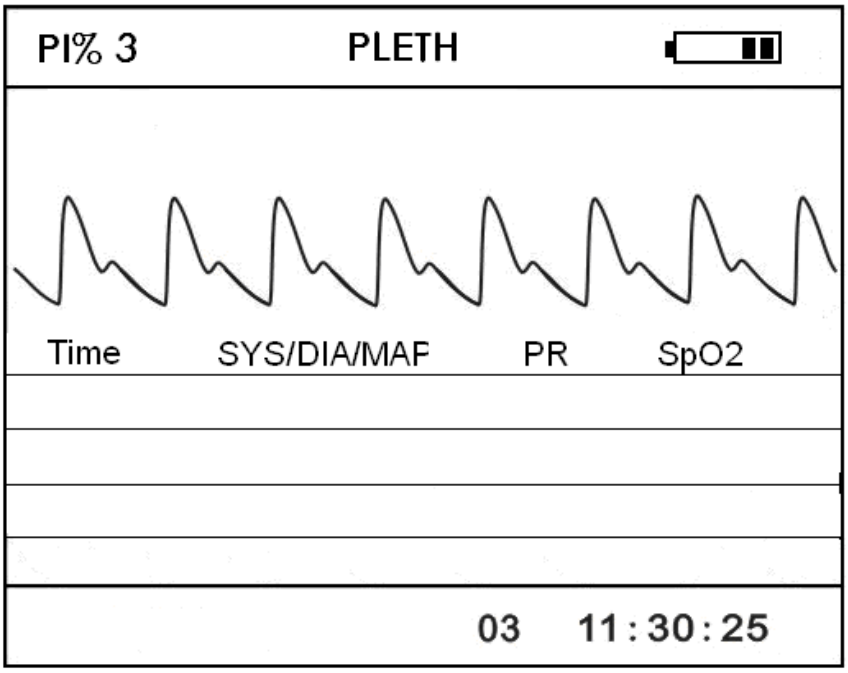


Figure 4.3 SpO_2 Monitoring Screen

The pitch tone of pulse beep (dididi...) is modulated by the SpO_2 value, that means the pitch tone changes when measured SpO_2 changes. When SpO_2 is measured, the device will activate the pitch tone function automatically. The higher the SpO_2 value is, the higher the tone frequency of pulse beep (sound becomes sharper); The lower the SpO_2 value is, the lower the tone frequency of pulse beep (sound becomes flatter);

4.4 NIBP List Screen

Short pressing “ ” Display key to shift the screen to NIBP List screen, as shown in Figure 4.4.

PID	time	SYS/DIA/MAP	PR
01	2010-04-07 09:15	100/73/95	70
01	2010-04-07 09:16	105/75/96	69
01	2010-04-07 09:17	102/73/94	68
01	2010-04-07 09:19	101/71/90	69
mute C-D:90		100	16:35:24

Figure 4.4 NIBP List

In this screen, the first column is the patient ID, the second column is NIBP recording time, the third column is NIBP value, and the fourth column is pulse rate (measured by NIBP module). Up to 12000 groups of nonvolatile data can be stored in the monitor. “SYS/DIA/MAP” indicates the value of “systolic pressure/diastolic pressure/mean arterial pressure”. Press "print key to print the current NIBP list.

On NIBP List screen, if NIBP measurement is more than 8 groups, press “ ” key or “ ” key to turn to previous/next page for view other measurement values. If NIBP measurement is not more than 8 groups, the keys “ ”or “ ” are not effective.

Long pressing " "key to enter the screen of Empty history records, the user can delete all NIBP records according to the prompt.

4.5 SpO_2/PR List Screen

Short pressing “ ” Display key to shift the screen to SpO_2 List screen, as shown in Figure 4.5.

PID	time	SpO_2	PR
01	2012-05-25 09:15	98	70
01	2012-05-25 09:16	95	69
01	2012-05-25 09:17	99	68
01	2012-05-25 09:19	100	69
		01	16:35:24

Figure 4.5 SpO_2/PR List

In this screen, the first column is the patient ID, the second column is SpO_2 recording time, the third column is SpO_2 value, and the fourth column is pulse rate. During measurement, it's no need to press any button to store the data because the device will store automatically. Up to 2000 groups data which are lately measured can be stored in the monitor when it is out of power. Press "print key to print the current SpO_2 list.

On Spo_2/PR Trend List screen, the system default display is the lately Spo_2 list. If Spo_2 measurement is more than 8 groups, press "▲" key or "▼" key to turn to previous/next page for view other measurement values. If NIBP measurement is not more than 8 groups, the keys "▲"or "▼" are not effective. The lately measured 2000 groups data can be reviewed by turning pages.

Long pressing " " key to enter the screen of clearing the recorded trend data, the user can delete all SpO_2/PR data records according to prompt.

4.6 Alarm Event List Screen

Short pressing " " Display key to shift the screen to Alarm Event List screen, as shown in Figure 4.6.

Time	Event	Value	H/L	Limit
10-20 15:53	SpO_2 Probe off			
10-20 15:50	SpO_2 Over-limit			
10-20 15:45	SpO_2 Probe off			

2 16:23:52

Figure 4.6Alarm event list

In this screen, the first column is the time the alarm occurs, the second column is the event type, which includes SpO_2 /PR/SYS/DIA/MAP over-limit, SpO_2 probe off and NIBP measurement error, the third column is the onset value, and the fourth column is the high/low limit value. Press " "print key to print the current alarm event list.

On Alarm Event List screen, if alarm events have more than 8 groups, press "▲" key or " ▼" key to turn to previous/next page for view other alarm events. If the event list contains less than 8 groups, the keys " ▲"or "▼" are not effective. The lately measured 2000 groups of alarm events can be reviewed by turning pages.

Long pressing " " key to enter the screen of clearing recorded alarm events, the user can delete all alarm events according to prompt.

4.7 SpO_2 Trend Graph Display

Short pressing " " display key to shift the screen view to trend graph display screen, as shown in Figure 4.7. Short pressing print" " key to print this trace of SpO_2 plethysmogram.

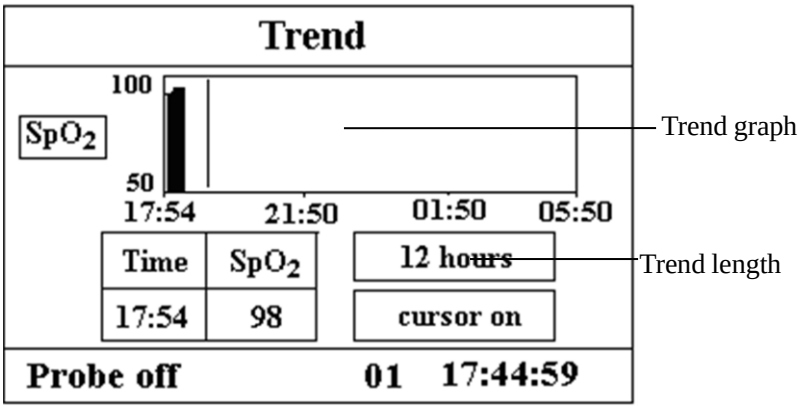


Figure 4.7 SpO_2 Trend Graph

- **"12 hours": the trend length of SpO_2 trend graph;** three options: **"**12", "24" or "96" hours; when the selection is 12 hours, the upper trend graph will display SpO_2 trend curve for last 12 hours.
- **"cursor on":** enable the display of cursor on trend graph, i.e. the vertical cursor line displayed in trend graph, so the user can move the cursor to inspect the SpO_2 value at the given time.
- **"SpO_2":** indicate that the trend graph beside it is SpO_2 trend. Let the cursor stay here and press"  " key to confirm, then press "  " key or "  " key again to select trend graph type:

  "SpO_2": SpO_2 trend graph

  "HR": HR trend graph

Instructions for viewing the trend curve:

- Select "cursor on" and press "  " key to confirm, and "cursor on" becomes "cursor off" , then you can press "  " key or "  " key to move the vertical cursor, the list box below will display SpO_2/HR value and the time value at the point where the cursor stays. Move cursor back and forth this way, you can view the SpO_2/HR trend (12/24/96 hours long). Press "  " key again to exit trend viewing.

When pressing "  " key or "  " key to move cursor, the moving step is variable. The rule is that the initial step is 1 point, after pressing "  " or  " key towards the same direction for 5 times, the step becomes 5 points, and with 5 more pressing the step becomes 10, then 20. No matter what step is, as long as you press "  " o r "  " key towards the other direction, the step becomes 1 and towards the other direction.

4.8 Setup Menu Screen

At any display view screen, long time press "  Display" key to shift the screen to Setup Menu screen, as shown in Figure 4.8. All the functional parameters of the system can be set through Setup Menu.

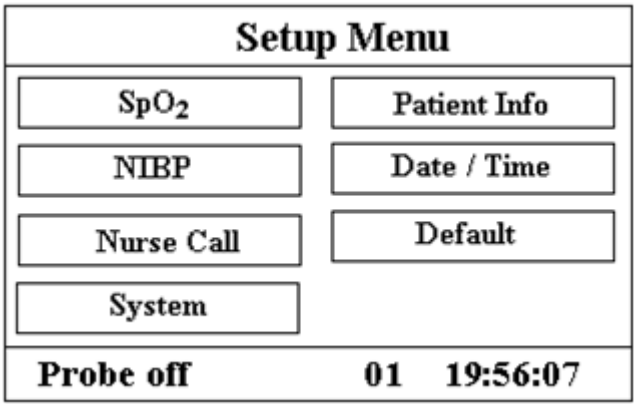


Figure 4.8 Setup Menu Screen

There are 7 functional groups for setting parameters: "SpO_2, NIBP, Nurse Call, System, Patient Info, Date/Time and Default" on the Setup Menu Screen.

1. Press"  " key or "  " key to shift cursor to corresponding functional group setting.
2. Pres "  " key to confirm and enter into corresponding functional parameter setup screen.
3. Press "  " to exit from Setup Menu Screen.

4.8.1 SpO_2 Setup

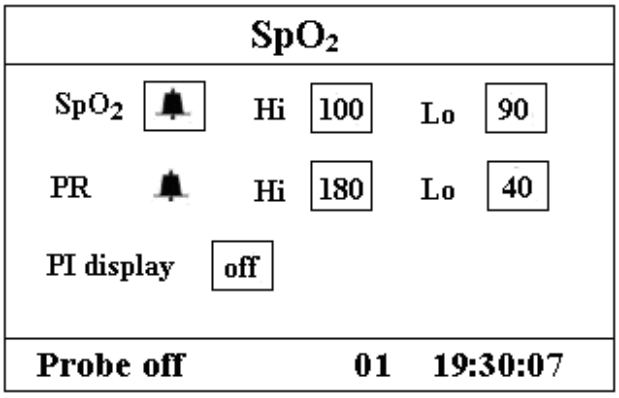


Figure 4.9 SpO_2 Setup Screen

Screen Description:

- **"SpO_2 ld":** SpO_2 alarm switch; "ld" indicates SpO_2 alarm is on; " " indicates SpO_2 alarm is off.
- **"SpO_2 Hi":** high alarm limit for SpO_2 ; range: "1~100".
- **"SpO_2 Lo":** low alarm limit for SpO_2 ; range: "0~99".
- **"PR ld":** pulse rate alarm switch; "ld" indicates PR alarm is on; " " indicates PR alarm is off.
- **"PR Hi":** high alarm limit for PR; range: "22~250".
- **"PR Lo":** low alarm limit for PR; range: "0~248".
- **"PI display":** "on" means PI display is enabled; "off" means PI display is disabled. This function is optional, please refer to the monitor in your hand. (Note: If the monitor is configured with Nellcor SpO_2 module, then PI display is always not available.)

Operation Instructions

1. Press "▲" key or "▼" key to move cursor to select parameter.
2. Press "■" key to confirm and active this parameter setting.
3. Press "▲" key or "▼" again to adjust or modify parameter value.
4. Press "■"key again to confirm and save the setting.
5. Press "⏎" key to return to upper level screen.

4.8.2 NIBP Setup

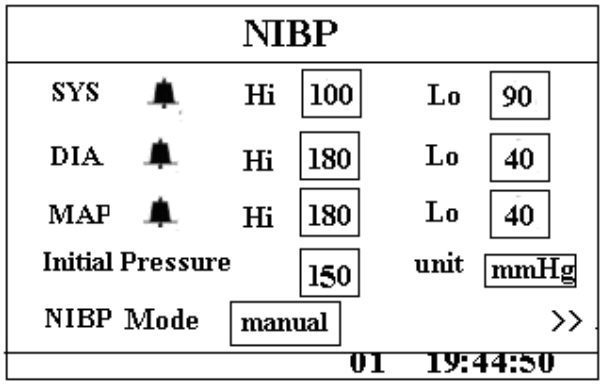


Figure 4.10 NIBP Setup

NIBP Setup Screen Description:

- **"SYS ld":** systolic pressure alarm switch; "ld" indicates systolic pressure alarm is on; " " indicates systolic pressure alarm is off.
- **"SYS Hi":** high alarm limit for systolic pressure; range: "32~250" mmHg.
- **"SYS Lo":** low alarm limit for systolic pressure; range: "30~248" mmHg.
- **"DIA ld":** diastolic pressure alarm switch; "ld" indicates diastolic pressure alarm is on; " " indicates systolic pressure alarm is off.
- **"DIA Hi":** high alarm limit for diastolic pressure; range: "22~230" mmHg.
- **"DIA Lo":** low alarm limit for diastolic pressure; range: "20~228" mmHg.
- **"MAP ld":** mean arterial pressure alarm switch; "ld" indicates mean arterial pressure alarm is on; " " indicates mean arterial pressure alarm is off.
- **"MAP Hi":** high alarm limit for mean arterial pressure; range: "28~242" mmHg.
- **"MAP Lo":** low alarm limit for mean arterial pressure; range: "26~240" mmHg.
- **"Mode":** NIBP measuring mode, "manual", "AUTO 1", "AUTO 2" …"AUTO 480" and "STAT" etc. options. When "STAT" is selected, it means the device will do a short-term automatic NIBP measurement which will last at most 5 minutes. "AUTO 1" means NIBP measurement takes once every minute automatically; "AUTO 480" means NIBP measurement takes once every 480 minutes automatically; In AUTO mode, the counting-down timer is displayed in the "Prompt Info" area.

Shortcut Key Descriptions:

In waveform display screen, trend graphic screen or NIBP list screen, short time pressing NIBP setup key" " can enter into the screen shown in Figure 4.11. Press it again to choose other measuring mode. Short time press NIBP measurement key " " to confirm and save the setting, as well as exit from the setting screen. Or you can press menu key" " to cancel this operation and return to the setting screen.

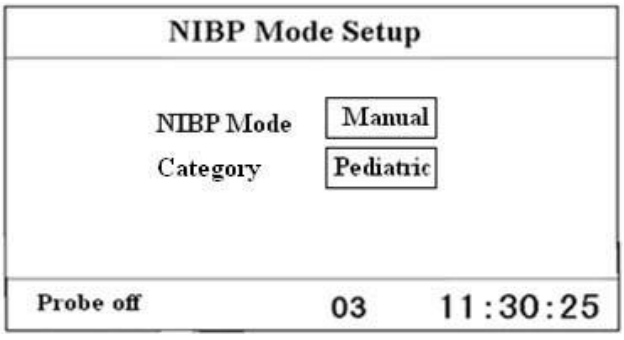


Figure 4.11 NIBP Mode Setup Shortcut Screen

- **"Initial pressure setup":** Cuff pre-inflation pressure value is default

  for neonates: pre-inflation range: 60~80mmHg, default value: "70" mmHg;

  for pediatrics: pre-inflation range: 80~140mmHg, default value: "120" mmHg;

  for adults: pre-inflation range: 80~200mmHg, default value: "150" mmHg.

Note: In order to avoid inappropriate initial pressure value which may cause harm to patients, when patient type is changed or measuring mode is altered or patient ID is changed, the inflating pressure value will rollback to the latest setting value.

- **"unit":** unit of the blood pressure value;

  "mmHg" or "kPa" can be selected. Conversion: 1kPa=7.5mmHg.

- **">>":** Page down icon. When cursor stays in the "unit" filed, press "  " key to enter Tourniquet Setup.

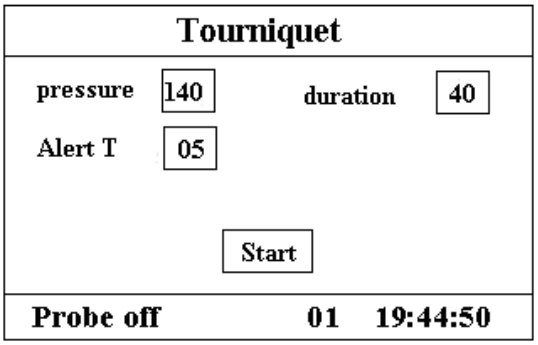


Figure 4.12 Tourniquet Setup

Tourniquet Setup Screen Description:

- **"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 neonates: preset range: 70~100mmHg, default value: "90" mmHg;

  for pediatrics: 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.

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

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

- **"Alert T":** the alert time for reminding user that the operation of tourniquet is going to be end after this time period. 1 to 60 minutes adjusting range with 1 minute step, the default value is "5" minutes. If the set value is "xx" minutes, the monitor will produce alarm sound until ending deflation when counting down time reaches to "xx" minutes. The alarm type is high priority alarm. (For example: the duration is 40 minutes, the alert time is 5 minutes, the alarm will ring for prompt when the duration counting 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.

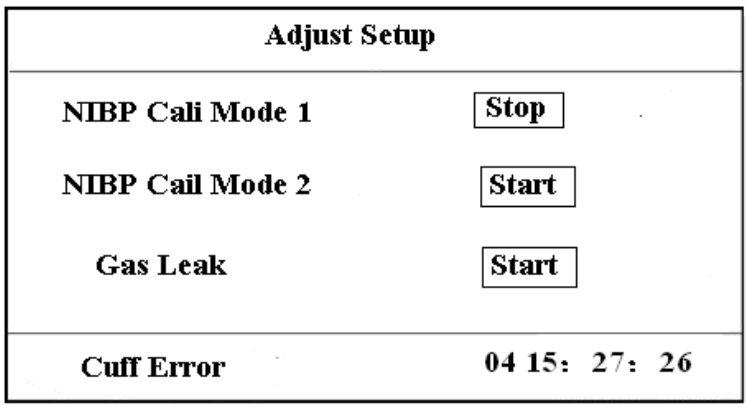


Figure 4.13A Adjust Setup

NIBP Calibration Setup Descriptions:

NIBP Cali Mode 1: Inflating the Pump. Move the cursor to NIBP Cali Mode 1"Start" button, click the OK button to begin the NIBP calibration. (Meanwhile, the "Start" shifts to "Stop", after the calibration the "Stop" shifts to "Start")

NIBP Cali Mode 2: Receiving the exterior pressure. The exterior pressure source pressurize to the module to proceed the pressure calibration. Move the cursor to NIBP calibration mode 2"Start" button, click the OK button to begin the NIBP calibration.(Meanwhile, the "Start" shifts to "Stop", after the calibration the "Stop" shifts to " Start")

Gas leak: Move the cursor to Gas leak "Start" button, click the OK button, the pump inflates to certain pressure and then the valve will be closed for leak detection for ten seconds, then the blood pressure module will deflate automatically and the screen displays measurements, as shown in figure 4.12B.

☞ The NIBP calibration and Gas leak detection can only be carried on when the NIBP measurement is set to mode "Manual".

☞ Other buttons are disabled except "  " OK button and "  " Power button during NIBP calibration and Gas leak detection.

☞ Make sure the "  " OK button is off after the test, or the user could not do other operations.

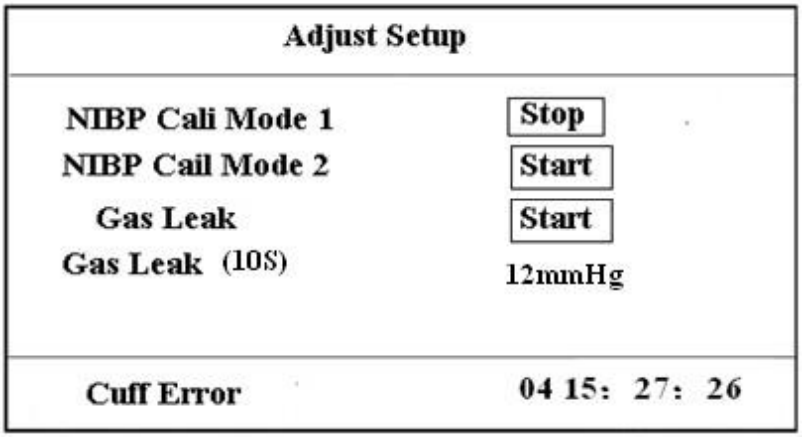


Figure 4.13B Adjust Setup screen

4.8.3 Nurse Call

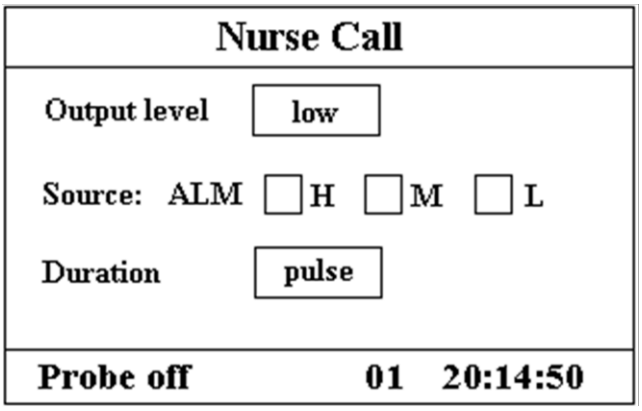


Figure 4.14 Nurse Call Setup Screen

Screen Description:

- **"Output level":** two options "low" or "high" output levels are available.

  When the calling system in hospital works in "Normal Open" mode, "low level" should be selected.

  When the calling system in hospital works in "Normal Close" mode, "high level" should be selected

- **"Source":** three kinds of alarm sources can trig the nurse call: high level alarm, medium level alarm and low level alarm (multi-optional). If you don't make choice, nurse call signal will not be sent out.
- **"Duration":** two options "pulse" or "continuous" output modes are available;
  "continuous": the continuous mode of output means the nurse call signal will keep until the selected alarm source(es) disappear, i.e. the signal will last from starting alarm to stopping alarm.
  "pulse": the output nurse call signal is pulse signal which lasts for 1 second. When several alarms occur at the same time, only one pulse signal will be sent out.

Note: Nurse Call function can not be regarded as main alarm notice method, please do not entirely relay on it. You should combine parameter values with alarm level and patient's clinical behavior and symptom to determine patient's status.

4.8.4 System Setup

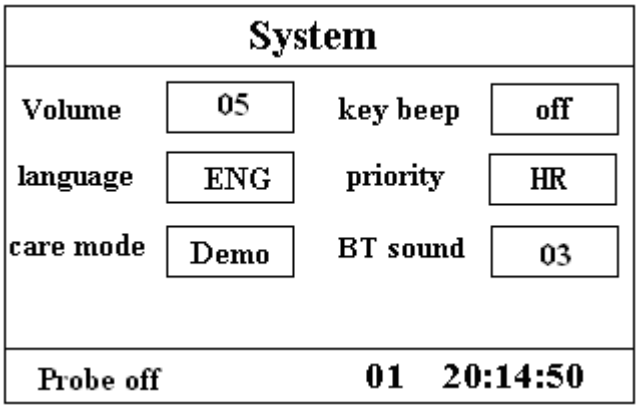


Figure 4.15 System Setup Screen

Screen Description:

- **"Volume":** set alarm volume, "1~10" level adjustable, the factory default is 05. It is recommended that the alarm volume shouldn't be adjusted lower than the factory default value unless the nursing personnel keeps close attention and surveillance on the patients and the device at all times.

- **"key beep":** to turn on/off key beep;
- **"Language":** language selection. "ENG" for English.
- **"priority":** priority of "PR" value or "HR" value display. The default set is "HR".
- **"care mode":** "Demo" shows the demo waveforms and data. In the demo state, all the signals and data are generated from the monitor for demonstration and testing purpose. When the mode "Demo" is selected, the user can test whether the visual and audible alarm system runs normally by raising or lowering the alarm limit to trigger the monitor to alarm.

  "Real" shows the real time waveform, i.e. normal monitoring status;
- **BT sound:** adjust the volume of pulse beeping sound. "0~7" level adjustable. "0" means switching off the BT sound, the factory default is "03".

  Note: the gray in background means this item is unadjustable.

4.8.5 Patient Info

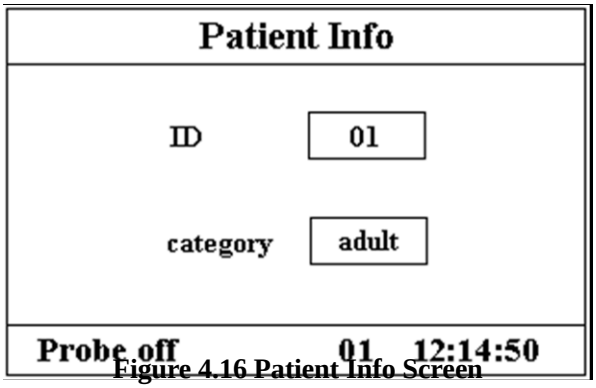


Figure 4.16 Patient Info Screen

Screen Description:

- **"ID":** change or set current patient's ID number, 0~100 adjustable;
- **"category":** change or set the category of current patient; three options "adult" ,"pediatric" and "neonate", the default is "adult".

Note: If the patient ID is changed, the history data (except NIBP list) will be cleared, that means SpO_2 trend graph and HR trend graph will become empty.

4.8.6 Date/Time

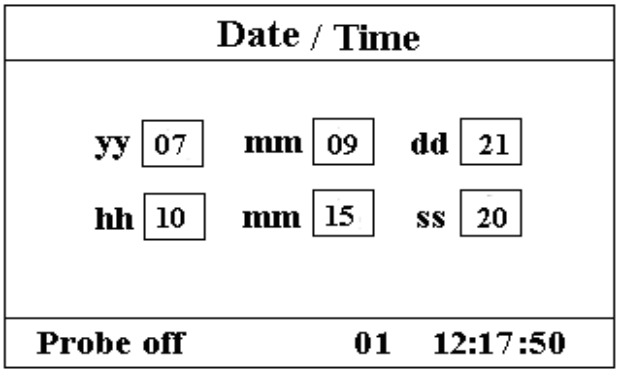


Figure 4.17 Data/Time Setup Screen

Screen Description:

- **"yy 07 mm 09 dd 21":** date setting, "07-09-21" shows the date is September 21st , 2007.
- **"hh 10 mm 15 ss 20":** time setting, "09：20：21" shows the time is10:15:20.

4.8.7 Reset to Factory Default Settings

On Setup Menu screen, press "  " Up button or "  " Down button to shift cursor to "YES", and then press "  " OK button, all the setting parameters will be reset to factory default setting value; shift cursor to "No", and then press "  " OK button, it will retain the current settings.

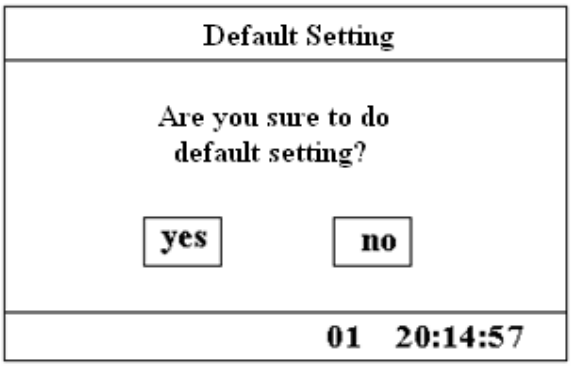


Figure 4.18 Default setting

4.9 Alarm Settings

Pressing alarm silence "  " key to mute the alarm sound.

- When the alarm silence indicator on the left side is light, it means the audible alarm is in silence status.
- Short pressing alarm silence key, the red icon "  " will be displayed on the lower screen, and message "silence count-down time 120", as shown in figure 4.19.. At this time, the alarm silence indicator on the left side of alarm silence key will be light. The device will mute the alarm sound temporarily for 2 minutes, but keep the visual alarm (lamp) flashing. When the counting down time is out, the alarm silence will be de-activated automatically, the red icon "  " will disappear as well, and the alarm silence indicator will be dark.

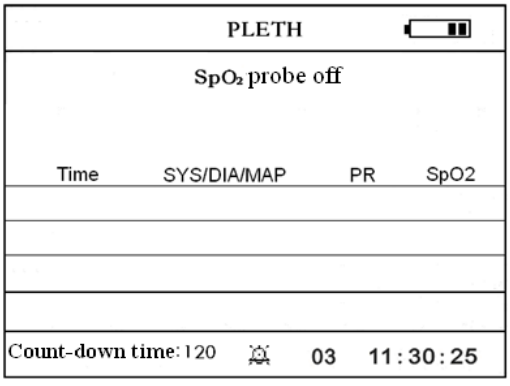


Figure 4.19 Alarm silence screen (short time press)

- Long time pressing alarm silence key, the red icon "  " will be displayed on the lower column of the screen, as shown in figure 4.20. At this time, the alarm silence indicator on the left side of alarm silence key will be light. The device will mute the alarm sound in the future, but keep the visual alarm (lamp) flashing. Till a new type of alarm event is detected, the alarm silence status will be terminated automatically and the alarm sound will resume, the red icon "  " will disappear as well, and the alarm silence indicator will be dark.

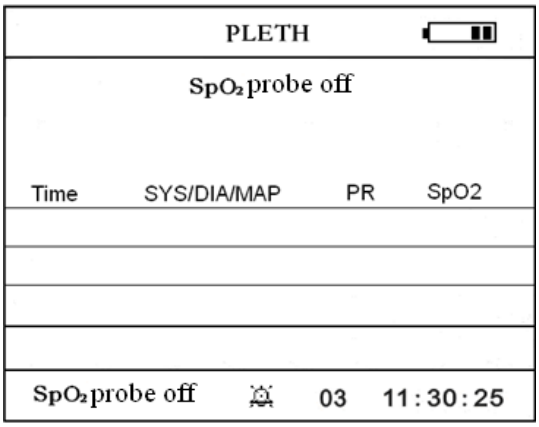


Figure 4.20 Alarm silence screen (long time press)

- If the current status is alarm silence, longtime or short time pressing the alarm silence key can de-activate the alarm silence function.

4.10 Power Saving Mode

On the initial display screen, you can make the monitor stay in power saving mode for power saving. Short time press power button to shift screen to “Power Saving Mode” display screen, as shown in Figure 4.21.

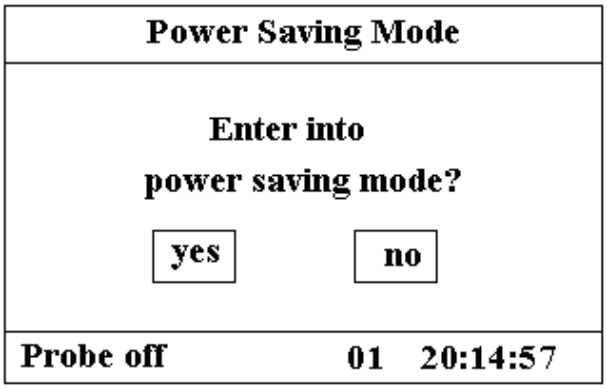


Figure 4.21 Power Saving Mode

Press “  ” button or “  ” button to shift cursor to “yes” or “no” and press “  ” button to confirm. If your selection is “yes”, all the numerical values displayed on digital LEDs display become darker and the monitor stays in power saving mode.

Short time press power button again to shift screen to “Power Saving Mode” display screen for exiting the sleeping mode.

4.11 Key-lock Mode

Press and hold OK"  " key, and then press print "  " key, the yellow icon "  " will be displayed on the left tittle bar, which means that the device enters into key-lock mode, as shown in figure 4.22. In the key-lock mode, all keys operation is unavailable. On key-lock mode status, press and hold "  ", then press print "  " key, the yellow icon "  " on tittle bar will disappear. In this way, all keys will be unlocked.

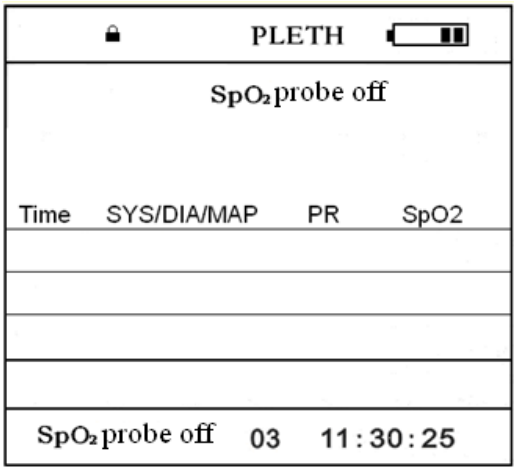


Figure 4.22 Key-lock Mode

Chapter 5 Alarm

5.1 Alarm Priority

High Priority:

TOUR C-D：XXX seconds
PR Over limit
SpO_2 over limit
SYS over limit
DIA Over limit
MAP Over limit
NIBP error 1#
NIBP error 2#
NIBP error 3#
NIBP error 4#
NIBP error 5#
Air leak
Cuff error
NIBP over range
Over motion
Over pressure
NIBP timeout

Medium Priority:

Probe Off

5.2 Alarm modes

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

Visual Alarm Indicators

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

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

Table 5.1

Refer to Chapter 11.2 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 Chain
High priority alarm	~400Hz	10 beeps pause 3 sec.
Medium priority alarm	~500Hz	3 beeps pause 5 sec.
Low priority alarm	~500Hz	Single beep

Table 5.2

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

5.3 Alarm Silence

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

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

- **DO NOT silence the audible alarm or decrease its volume if patient safety could be compromised.**
- **zero value alarm occurs must be on the condition of probe not off. If SpO_2 value is zero displayed on the screen instead of normal value, the zero value alarm will be automatically activated if the state lasts for about 7 seconds.**

5.4 Alarm Setting

In the Mode Selection screen, move the cursor to the "SETUP", and press it to enter system setup screen.

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

Refer to Chapter 11.2 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.**

5.5 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 6 Technical Specifications

6.1 NIBP Monitoring

A. Technology: Oscillometric method.

B. Cuff inflation time: ≤10seconds (typical adult cuff)

C. Air release time while the measurement is canceled: ≤2 seconds (typical adult cuff)

D. Initial cuff inflation pressure: Adult mode: <180mmHg, Pediatric mode: <120mmHg, Neonate mode: <90mmHg

E. Overpressure protection limit: Adult: 300 mmHg, Pediatric: 240 mmHg , Neonate: 140 mmHg

F. Typical measurement range:

Systolic: 20mmHg~290mmHg

Diastolic: 10mmHg~260mmHg

MAP: 15mmHg~275mmHg

G. Measurement accuracy:

Systolic: ±3% or ±8 mmHg

Diastolic: ±3% or ±8 mmHg

MAP: ±3% or ±8 mmHg

H. Measurement mode: Manual, Urgent, Auto, Self-defined

6.2 SpO_2 Monitoring

A. Sensor: dual-wavelength LED

B. SpO_2 measurement range: 0%~100%

C. SpO_2 measurement accuracy: 70% - 100% ±2%

6.3 Pulse Rate Monitoring

A. Pulse rate measurement range: 15bpm~300bpm

B. Pulse rate measurement accuracy: ±2%

6.4 Data Recording

A. Recording speed: 25mm/s

B. Recording speed accuracy: ≤5%

6.5 Other Technical Specifications

A. Power supply: 100~240VAC, 50/60Hz

B. Power consumption: <100VA

C. Fuse Specification: T3.15A/250Vφ5x20mm

D. Alarming mode: Audible & visible alarm

E. Classification:

Safety standard	IEC 60601-1
The type of protection against electric shock	Class I equipment.
The degree of protection against electric shock	Type BF applied parts
Protection against ingress of water	IPX1

6.6 Default Alarming Values of All Parameters and Setup Range

Parameter \ Mode		Alarm range	Default		
			Adult	Pediatric	Neonate
Systolic	High	(21~290) mmHg	180mmHg	130mmHg	110mmHg
	Low	(20~289) mmHg	60mmHg	50mmHg	50mmHg
Diastolic	High	(11~260) mmHg	120mmHg	90mmHg	90mmHg
	Low	(10~259) mmHg	50mmHg	40mmHg	30mmHg
MAP	High	(16~275) mmHg	160mmHg	110mmHg	100mmHg
	Low	(15~274) mmHg	50mmHg	40mmHg	30mmHg
SpO2	High	1% ~ 100%	100%	100%	100%
	Low	0% ~ 99%	90%	85%	85%
Pulse rate	High	(1~300) bpm	180bpm	200bpm	220bpm
	Low	(0~249) bpm	40bpm	50bpm	50bpm

Chapter 7 Packaging and Accessories

7.1 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.

Weight: Details see the indication on the outer package.

Dimension: 360(L)×320(W)×410(H) (mm)

7.2 Accessories

(1) NIBP cuff	One piece
(2) SpO_2 probe	One piece
(3) Power cord	One piece
(4) Grounding wire	One piece
(5) User manual	One copy
(6) Quality Certificate	One copy
(7) Warranty	Two copies
(8) Packing list	Two copies

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

Chapter 8 Monitoring Parameter

8.1 NIBP Monitoring

8.1.1 Measuring Principle

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

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

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

Comparison between blood pressure measuring methods

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

The Oscillating method vs. the Korotkoff Sound Method

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

1.The measures by the Korotkoff Sound Method are liable to effect of human factors. For example, different people may have different sound judging ability, or different reactivity when listening to heart sound and reading

mercury meter. The air release speed and subjectivity may also affect the judgment. By the oscillating method, the computation is accomplished by the computer, thus relieving the possibility of effect due to human factor.

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

8.1.2 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 for cotton-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;

8.1.3 Clinical Limitations

1. Serious angiospasm, vasoconstriction, or too weak pulse.
2. When extremely low or high heart rate or serious arrhythmia of the subject occurs. Especially auricular fibrillation will lead to unreliable or impossible measurement.
3. Do not take the measurement when the subject is connected with an artificial heart-lung machine.
4. Do not take the measurement when the subject uses diuresis or vasodilator.

5. When the subject is suffering from major hemorrhage, hypovolemic shock and other conditions with rapid blood pressure change or when the subject has too low body temperature, the reading will not be reliable, for reduced peripheral blood flow will lead to reduced arterial pulsation.
6. Subject with hyperadiposis;

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

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

8.2 SpO_2 Monitoring

8.2.1 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, such as carboxyhemoglobin or metahemoglobin.

8.2.2 SpO2 Measurement Restrictions (interference reason)

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

8.2.3 Low SpO2 measuring value caused by pathology reason

- Hypoxemia disease, functional lack of HbO_2

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

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

8.2.5 Points to be noted in SpO_2 and Pulse Measuring

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

oximeter is reproducing the given calibration curve. Before testing the oximeter by a functional tester, please firstly ask the manufacturer which calibration curve is used, if necessary, request the manufacturer for its dedicated calibration curve and download it into the tester.

Chapter 9 Troubleshooting

9.1 No Display on the Screen

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

9.2 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 probe 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 local dealer.

9.3 Blank Printing Paper

1. Check whether the printing paper is installed with its face reversed. Please reinstall it and let the sensitive page face upward.
2. If the problems still exist, please contact the local dealer.

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. Probe off. Please check the connection of the probes.

Note: In case of trouble of this machine in the 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 cabinet without permission.

Chapter 10 Maintenance

10.1 Service and Examination

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;
- Make sure that the monitor is grounded properly.
- Pay close attention to the fluctuation of the local power supply voltage. A manostat is recommended when necessary.
- In case any indication of damage about the function of the monitor is detected and proven, it is not allowed to apply it to the patient for any monitoring.

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.**
- **If there is any indication of cable and transducer damage or they deteriorate, they are prohibited from any further use.**

The adjustable units in the monitor such as potentiometer are not allowed to adjust without permission to avoid unnecessary failures that affect normal application.

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, to avoid explosion risk do NOT throw the battery into fire.**

- **Do not hit or strike it with force;**
- **Do not use this battery on other devices;**
- **Do not use this battery below -10℃ or above 40℃;**
- **Dispose of the battery, the local law should be followed.**

In order to maintain battery supply time and prolong battery lifetime, please charge the battery every one or two months if don't use battery for a long time. And do charge battery at least 12-15 hours every time. Before connect to AC, do start monitor with battery's power supply, until battery power is used up and monitor turn off automatically, then connect monitor to AC and have it charged for 12-15 hours continuously. The speed of charge will be the same no matter whether the monitor is working or not. The reason why discharge the battery before charge is to avoid the decrease of capacity caused by battery's memory effect. If the monitor won't be used for a long time, do have it charged fully before conservation.

When starting the monitor by battery power only which is short of supply, monitor will turn off automatically. In order to avoid the damage to battery caused by excessive discharge, please pay attention to following. After monitor turns off automatically, there is still small drain current inside battery, so it is suggested that user should press the power button again to cut off the power supply. If battery keeps in a state of small drain current, battery will be damaged and can't be repaired because of excessive discharged.s recommended to use the battery once a month to ensure its strong power supply capacity and long service life, and recharge it after running out of the power.

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

10.1.4 Service

If the monitor has functional malfunction or is not working, please contact the local dealer or our company, and we are to offer the best solution as soon as possible for your satisfaction. Only qualified service engineer specified by the manufacture can perform the service. Users are not permitted to repair it by themselves.

10.2 Cleaning and Disinfection

- Kept the monitor from dust.
- It is recommended to clean the outer shell and screen of the monitor to keep it clean. Only non-corrosive cleanser such as clear water is permitted.
- Use the cloth with alcohol to wipe the surface of the monitor and transducers, and dry it with dry and clean cloth or simply air-dry.
- The monitor can be sterilized and disinfected, please clean it first.

- **Switch off the monitor and disconnect the power cable before cleaning.**
- **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 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 disinfecting.**

10.3 Cleaning and Disinfection of Accessories

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

- **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.**
- **Do wipe off the remained alcohol or ispropanol on the accessories after disinfection, for good maintenance can extend the life of 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: 50kPa~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 Appendix

11.1 Prompt information explanations

Mute C-D: XXX seconds	Alarm silence count down: XXX seconds
NIBP C-D: XXX seconds	NIBP auto measuring cycle count down: XXX seconds
TOUR C-D: XXX seconds	Tourniquet alert count down: XXX seconds
Probe off	SpO_2 probe fells off
PR over limit	PR value exceeds the high/low alarm limit
SpO_2 over limit	SpO_2 value exceeds the high/low alarm limit
SYS over limit	Systolic pressure value exceeds the high/low alarm limit
DIA over limit	Diastolic pressure value exceeds the high/low alarm limit
MAP over limit	MAP value exceeds the high/low alarm limit
NIBP error 1#	Sensor or other hardware error
NIBP error 2#	Very weak signal because of the cuff, or the patient has very weak pulse
NIBP error 3#	Blood pressure amplifier overflow due to excessive movement
NIBP error 4#	Leaking during the pneumatic device testing
Cuff error	Cuff is not wrapped correctly, or is not connected
NIBP error 5#	Abnormal condition of CPU, such as register overflow, divided by zero
Air leak	Air moving part, tube or the cuff leak air
NIBP over range	The measurement range exceeds 255mmHg (for neonates: 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
Over pressure	Cuff press exceeds the safety limit value of software. Limit value for adult: 290mmHg; Limit value for pediatric: 145mmHg; Or caused by cuff extrusion or flapping cuff with force.
NIBP timeout	Adult measurement is more than 120 seconds, neonate measurement is more than 90 seconds.

11.2 Default Alarming Values and Setup Range

The default alarming value:

Parameter \ Mode		Adult	Pediatric	Neonate
HR	High limit	180bpm	200bpm	220bpm
	Low limit	40bpm	50bpm	50bpm
SYS	High limit	180mmHg	130mmHg	110mmHg
	Low limit	60mmHg	50mmHg	50mmHg
DIA	High limit	120mmHg	90mmHg	90mmHg
	Low limit	50mmHg	40mmHg	30mmHg
MAP	High limit	160mmHg	110mmHg	100mmHg
	Low limit	50mmHg	40mmHg	30mmHg
SpO_2	High limit	100%	100%	100%
	Low limit	90%	85%	85%
Pulse rate	High limit	180bpm	200bpm	220bpm
	Low limit	40bpm	50bpm	50bpm

The high and low limits setting range:

Parameter \ Mode		Adult	Pediatric	Neonate
HR	High limit	(1~350) bpm	(1~350) bpm	(1~350) bpm
	Low limit	(0~349) bpm	(0~349) bpm	(0~349) bpm
SYS	High limit	(30~280) mmHg	(30~200) mmHg	(30~135) mmHg
	Low limit	(29~179) mmHg	(29~199) mmHg	(29~134) mmHg
DIA	High limit	(11~232) mmHg	(11~150) mmHg	(11~100) mmHg
	Low limit	(10~231) mmHg	(10~149) mmHg	(10~99)mmHg
MAP	High limit	(21~242) mmHg	(21~165) mmHg	(21~110) mmHg
	Low limit	(20~241) mmHg	(20~164) mmHg	(20~109)mmHg
SpO_2	High limit	1~100%	1~100%	1~100%
	Low limit	0~99%	0~99%	0~99%
Pulse rate	High limit	(1~300) bpm	(1~350) bpm	(1~350) bpm
	Low limit	(0~299) bpm	(0~349) bpm	(0~349) bpm

11.3 Abbreviation of arrhythmia

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

11.4 Accessories List

Part No.	Part Name	Remark
15044051	Adult SpO_2 Finger clip sensor	
15044061	Adult SpO_2 Finger rubber sensor	Optional
15044041	Pediatric SpO_2 Finger clip sensor	Optional
15044063	Neonate SpO_2 Y-type 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 cuff	Optional
15020400	Neonate NIBP cuff(5.4*9.1cm)	Optional
5101-5236310	Thermal printer paper	Optional
2903-0000000	Power cord	
2911-0003032	Grounding wire	
900093	Net wire	Optional

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

Note: Part no. is subject to change without prior notice, please refer to the label of parts or Packing List.

11.5 Instructions for SpO_2 Probe

Instructions for Neonate SpO_2 Y-type Sensor

Intended Use

When used with a compatible patient monitor or a pulse oximeter device, this sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for neonates (1-3 kg).

Contraindications

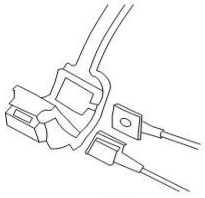
This sensor is contraindicated for use on active patients or for prolonged use.

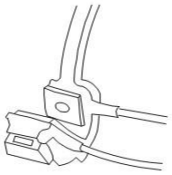
Instructions for Use

1) Insert the two sensor tips into the slots on the rubber wrap **(A)**; place the sensor on the neonate's foot **(B)**, wrap the rubber belt around the foot and tighten accordingly **(C)**.

2) Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.

3) Inspect the monitoring site every 4 hours for skin integrity.


(A)


(B)


(C)

Cleaning & Disinfection

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

Warnings

1) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive
2) 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 must be checked for skin integrity at least every 4 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site.
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.
5) Do not use the sensor during MRI scanning. 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.

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

Instructions for Pediatric SpO_2 Finger Clip Sensor

Intended Use

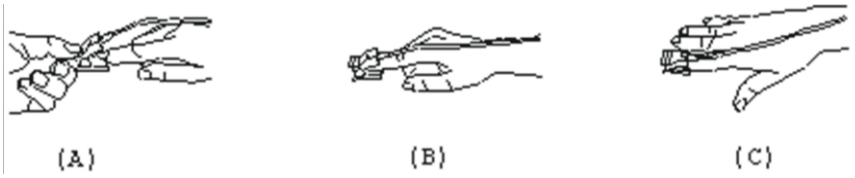
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO2) and pulse rate monitoring for pediatric patients weighing between 10~40kg.

Contraindications

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

Instructions for Use

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



6) Inspect the monitoring site every 4 hours for skin integrity.
7) Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

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

Warnings

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

Instructions for Adult SpO_2 Finger Rubber Sensor

Intended Use

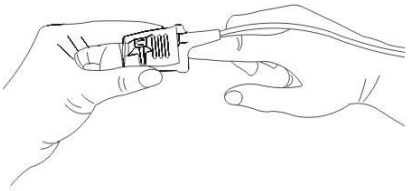
When used with a compatible patient monitor or a pulse oximeter device, this SpO_2 sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 50kg.

Contraindications

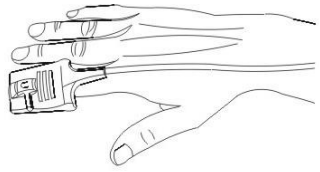
This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

1) Hold the sensor with its opening towards the patient's index finger (A). The sensor should be oriented in such a way that the sensor side with a finger tip sign is positioned on the top.
2) Insert the patient's index finger into the sensor until the fingernail tip rests against the stop at the end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor. Direct the cable along the top of the patient's hand. Apply adhesive tape to secure the cable (B). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
3) Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.
4) Inspect the monitoring site every 4 hours for skin integrity.



(A)



(B)

Cleaning & Disinfection

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

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

Warnings

1) This sensor is for use only with compatible patient monitors or pulse oximeter devices. Use of this sensor with instruments other than compatibles may result in improper performance.
2) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poorly perfused finger, extreme finger sizes or improper placement of the sensor.
3) The sensor site must be checked for skin integrity at least every 4 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

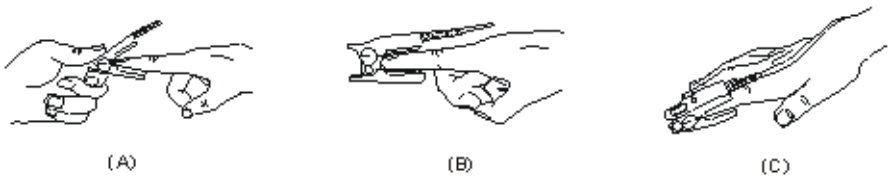
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 40kg.

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 oximeter operator's manual.
6) Inspect the monitoring site every 4 hours for skin integrity.
7) Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

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

Warnings

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

We offer a 6-month warranty against manufacturing defects for the SpO_2 sensors mentioned above in its undamaged condition.

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

Manufacturer

North-vision Tech. Inc.

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Information is subject to change and/or updating without notice.

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