Multi-parameter Patient Monitor

Deluxe-80

User Manual

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North-Vision Tech. Inc.

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This Manual is written and compiled in accordance with the IEC 60601-1（Medical electrical equipment Part1: General requirements for safety）and MDD 93/42/EEC. It complies with both international and enterprise standards and is also approved by the Food and Drug Administration, Ministry of Health and Welfare. The Manual is written for the current Deluxe-80 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.

Marks in the Manual:

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

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

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

Instructions to User

Dear Users,

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

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

- **Do NOT operate this monitor in the circumstance where flammable gas or explosion factor exists.**
- **To ensure patient safety, do NOT place the monitor in any position that might cause it to fall on patient.**
- **The user must check that the equipment functions safely and ensure that it is in proper working condition before being used.**
- **The device connected to this monitor should be in accordance with IEC 60601-1.**
- **Please shut down the monitor and remove sensors while during MRI scanning, or else induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of monitor measurements.**
- **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 suffer from anaphylaxis.**
- **All the cables and rubber tubes of the applied 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 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.**
- **If the monitor falls off accidentally, please do NOT operate it until its safety and technical indexes have been carefully tested and positive testing results obtained.**
- **Before maintenance, please switch off power.**
- **This monitor is a professional medical device, can only be operated by trained personnel with qualification.**
- **Please peruse the relative content about the clinical restrictions and contraindication.**
- **Dispose of the expired device and its accessory according to applicable local regulations.**

Table of Contents

Chapter 1 Overview

1.1 Features

- Blood Pressure, SpO_2 and Pulse Rate are displayed by big, bright digital LEDs;
- Plethysmogram and system parameters are displayed on dot matrix LCD screen;
- Accurate NIBP measurement with hardware and software over-pressure protection;
- Unique SpO2 measuring technique ensures sensitive and accurate SpO2, Pulse Rate and Perfusion Index measurement;
- SpO2 trend curve display for last 12, 24 or 96 hours;
- Up to 400 groups of NIBP measurements can be stored and reviewed by list;
- Audible & visible alarm with 3 levels of alarm events;
- Nurse call output is available;
- NIBP measurement is applicable to adult, pediatric and neonate by patient selection;
- 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: Deluxe-80

1.3 Intended Use

This device is intended for using in hospitals to monitor patient’s blood pressure, SpO2, and pulse rate.

1.4 Normal Working Environment

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

b) Relative humidity: ≤80%

c) Atmospheric pressure: 86kPa ~106kPa

1.5 Symbols on the Monitor

	Adult		Menu
	Pediatric	~	AC Power
	Neonate		DC Power
	NIBP		Type BF applied part
	Alarm Silence		Type CF applied part with defibrillator protection
	Print		Warning, refer to User Manual.
▲	Up		Equal potential terminal
■	OK		Nurse call output
▼	Down		

Chapter 2 Operating Principle

2.1 Conformation

The monitor consists of the main control unit, NIBP measuring module, SpO2 measuring module, display panel, printer, power supply block etc. and the related accessories for NIBP and SpO2 measurement.

2.2 Overall Structure

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

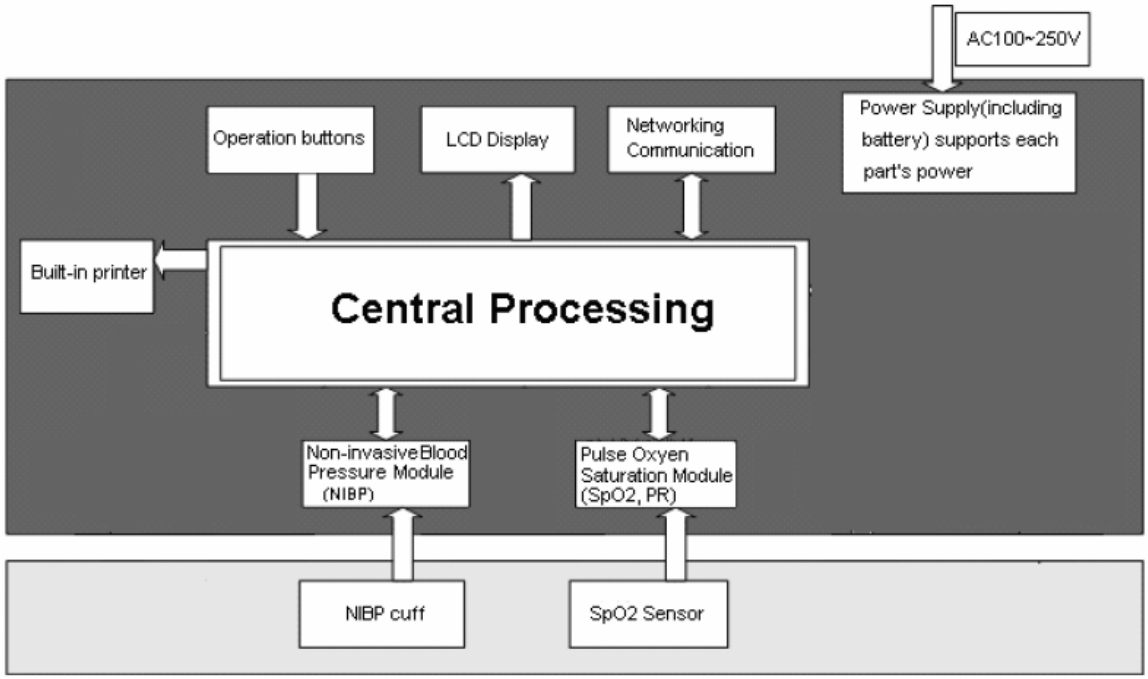

Figure 2.1

Deluxe-80 Multi-Parameter Patient Monitor is module designed product; it consists of NIBP module (optional), SpO2 module (optional), main control unit, printer module, display panel and power supply block etc.

1. The SpO2 module detects and calculates pulse rate and oxygen saturation (SpO2), 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

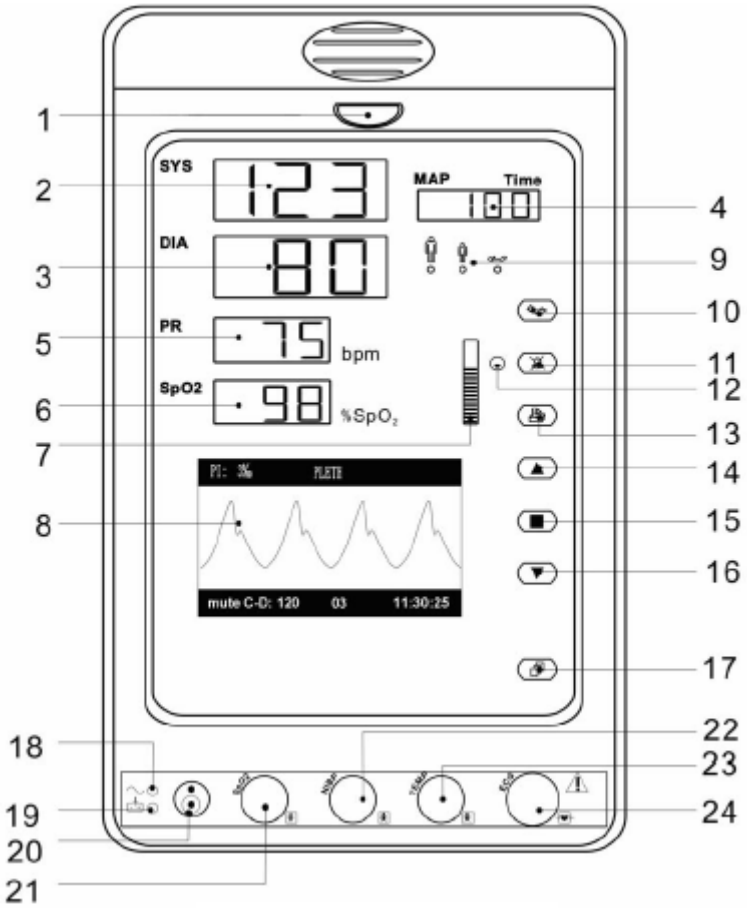

Figure 3.1 Front panel illustration

Module Configuration Instructions
According to different needs, user can customize the module configuration by choosing the necessary modules. This manual shows how to use the monitor of this model with SpO2and NIBP modules. If only NIBP module is chosen, its operations are almost the same with the operations mentioned in this manual.

Description:

1 Alarm indicator

Alarm indicator	Alarm grades	Alarm events
Red flashing	High priority alarm	Exceeding the limits, low battery voltage
Orange flashing	Medium priority alarm	Probe off
Green	Normal monitoring state	

2 SYS: display systolic pressure value

3 DIA: display diastolic pressure value.

4 MAP: 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”.

Note: two formats to display NIBP value: “×××mmHg” and “××.×kPa”. Refer to section “4.4.2 NIBP Setup” to set the unit of NIBP value; the conversion relation between “mmHg” and “kPa”: 1mmHg=0.133kPa.

5 PR: display pulse rate value measured through SpO2 probe or by NIBP measurement; Unit: “bpm (beats per minute)”.

If SpO2 and NIBP are monitoring at the same time, only the PR value measured through SpO2 probe is displayed here and the PR measuring by NIBP measurement is undergoing and recorded in NIBP list.

6 SpO2: Display SpO2 value; Unit: “%SpO2”

7 “”: Bar-graph of pulse intensity

8 LCD panel

9 Patient category indicator: “” for adult；“” for pediatric；“” for neonate; Patient category is selected under sub-menu “Patient Info” within the setup menu.

10 NIBP: start/cancel NIBP measurement

11 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 and it lasts this status for 2 minutes. When finishing counting down, the system will resume normal alarm status automatically, if alarm event occurs at this time the alarm sound will be effective again.

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

13 Print: print the current measurement data.

14 Up: shift cursor forward/upward

15 OK: to perform confirmation or modification

16 Down: shift cursor backward/downward

17 Display: shift LCD display modes

18 ～: AC Power indicator

19 : DC Power indicator

	AC Power indicator	DC Power indicator	Descriptions
Status	ON (green)	ON (green)	this device is using mains power supply
	OFF	ON (green)	the battery is being used
	OFF	ON (orange, blinking)	the battery is being used, but battery voltage is low, the beeper also gives warning.
	ON (green)	ON (orange)	this device is using mains power supply and the battery is being recharged
	ON (green)	OFF	the battery is being recharged while this device is off.

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

Note: Short time pressing power button for entering the Power Saving Mode screen, then according to your need to make the device stay in the power saving mode or exit from power saving mode (this function is optional and needs hardware support).

21 SpO2: SpO2 sensor connector

22 NIBP: NIBP hose connector

3.1.2 Side Panel

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

3.1.3 Rear Panel

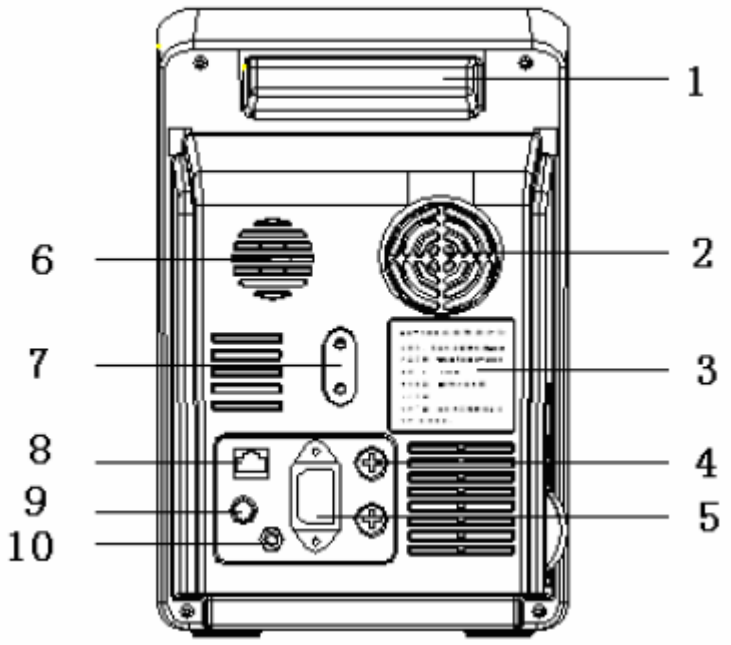

Figure 3.2 Rear Panel

Introduction to the rear panel:

1 Handle

2 Fan

3 Nameplate

4 Fuse holder: FUSE T3.15A

5 AC power supply socket

6 Loudspeaker

7 Mounting hole for hanging the monitor

8 Data interface

9 Nurse-call connector

10 : Equal potential terminal

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

   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

1. When powered by AC mains power supply:

- ◆ Make sure that the AC mains power supply is within 100-250VAC with 50Hz or 60Hz.
- ◆ Use the power cord provided by the manufacturer. Insert one end of it to the power port of the monitor and the other end to the single-phase mains power outlet with protected earth.
- ◆ Caution: if necessary, make the monitor grounded properly by the provided grounding wire.

2. When powered by built-in battery

- ◆ Install battery: refer to 3.3.4 Battery Installation.
- ◆ Caution: it’s better to recharge the battery after it is used up, the charging time should be 13~15 hours long.

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.

Do not use the device to monitor the patient if there are indications of damage or reminders of error.

3.3 Sensor Placement and Connection

3.3.1 Blood Pressure Cuff Connection

1. 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. See the table below for the dimensions:

Cuff Type	Arm circumference	Cuff width
Neonate Cuff	6.0cm～9.5cm	3cm
Small-sizedCuff for Pediatric	6cm～11cm	4.5cm
Middle-sized Cuff for Pediatric	10cm～19cm	8cm
Large-sized Cuff for Pediatric	18cm～26cm	10.6cm
Adult Cuff	25cm～35cm	14cm

Table 3-1

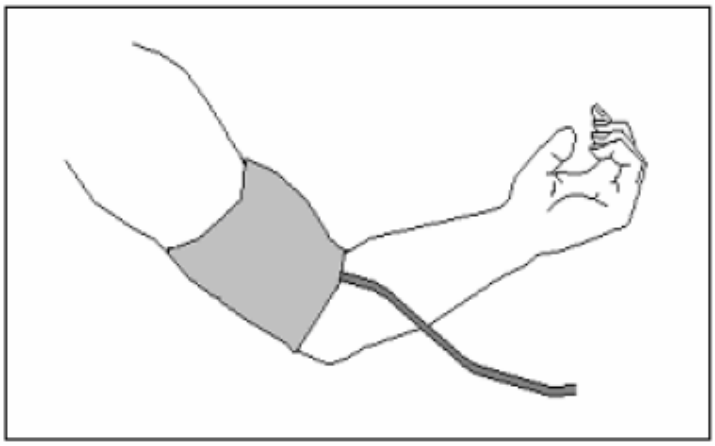

Figure 3.3 Cuff Placement

2. Connect the cable to connector marked with the NIBP icon.

Safety Instructions for NIBP Monitoring

- When taking the measurement of a pediatric or neonate's (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.
- 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.
- 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.

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 SpO2 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 SpO2 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.

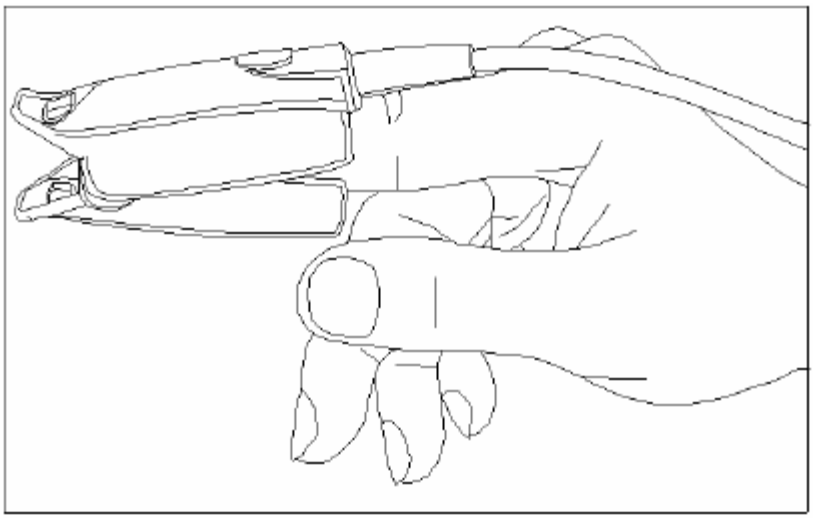

Figure 3.4 Finger clip SpO2 sensor placement

3. If the neonate SpO2 sensor is used, please follow Figure 3.5 to connect.

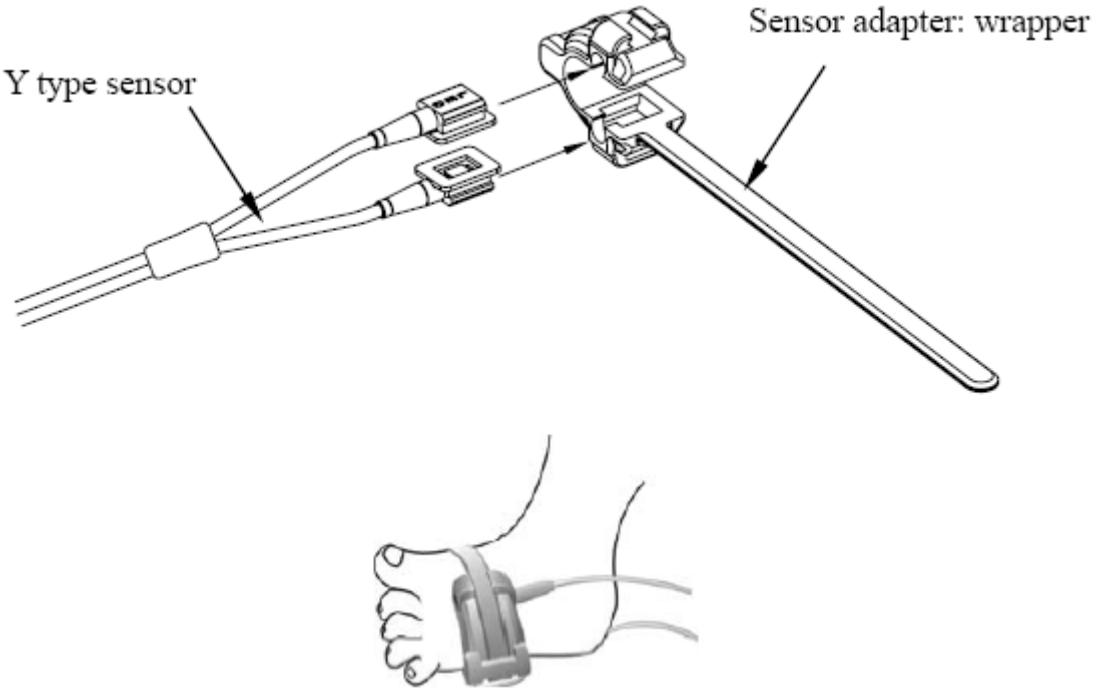

Figure 3. 5 Neonate SpO2 sensor placement

Safety Introductions for SpO2 Monitoring

- Continuous use of finger clip SpO2 sensor may result in discomfort or pain, especially for those patients with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same finger for over two hours.
- SpO2 measuring position must be examined more carefully for some special patient. Do NOT place the SpO2 sensor on the finger with edema or fragile tissue.

- 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.
- Do NOT use the damaged SpO2 sensor.
- The SpO2 sensor can not be immerged into water, liquor or cleanser completely, because the sensor has no capability of waterproofness.

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.

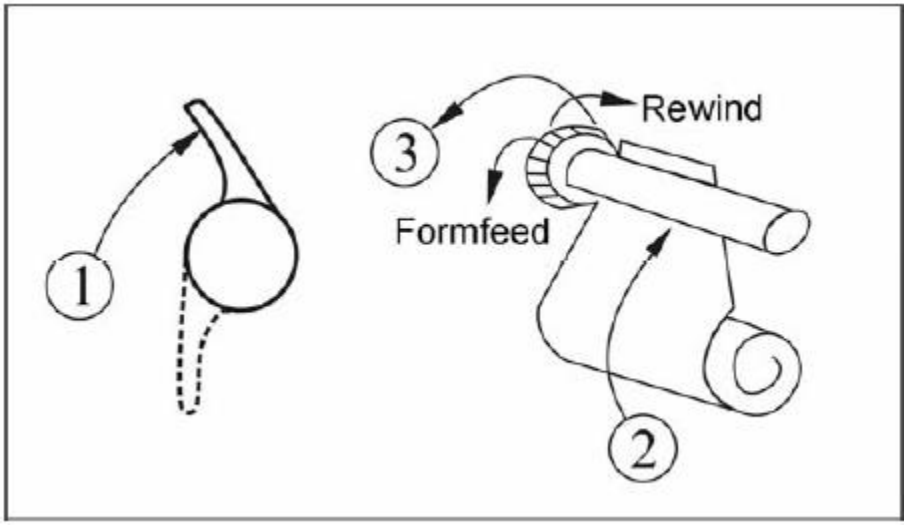

Figure 3.6 Loading and taking out printing paper

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 place the battery in the direction as shown in Fig. 3.7 to insert the battery into any one of battery compartments. Do not insert battery with their polarities reversed.
3. Move the battery baffle to secure battery.
4. Close the battery cover.

Note: you can install optional one more battery to prolong the working time.

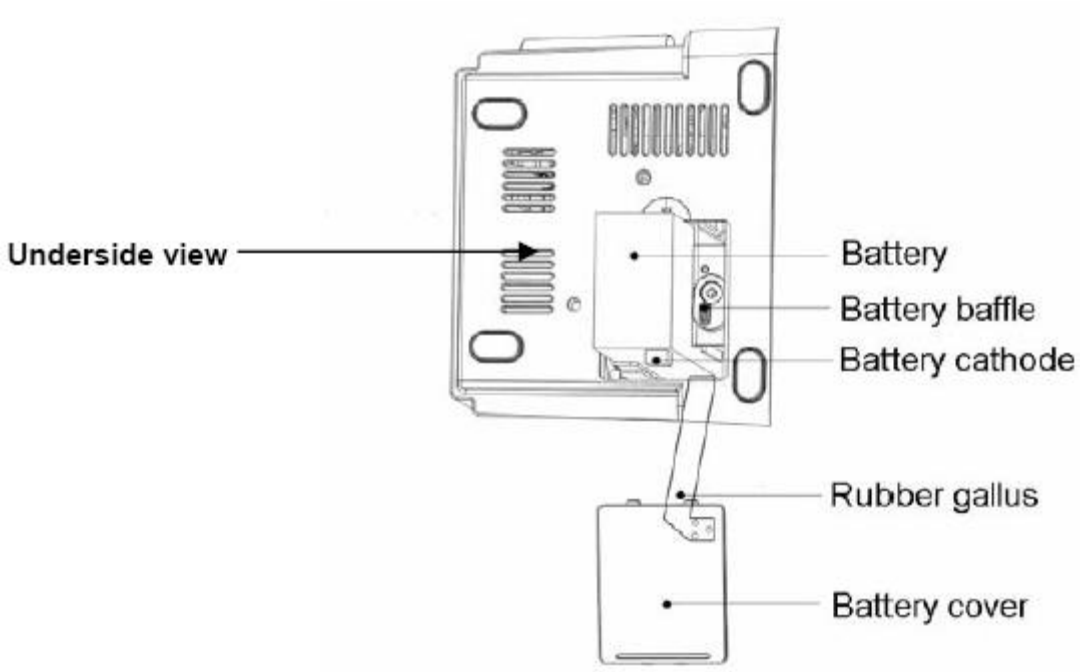

Figure 3.7 Battery Installation

Note:

- **Do not insert battery terminal with its polarities reversed, or the monitor can not be started.**
- **Please take out the battery before transport or storage.**

Chapter 4 Operations

4.1 Initial Monitoring Screen

When the module configuration is “SpO2+NIBP”, once powered up, the LCD will display the initial monitoring screen with SpO2 plethysmogram, this is the default display screen.

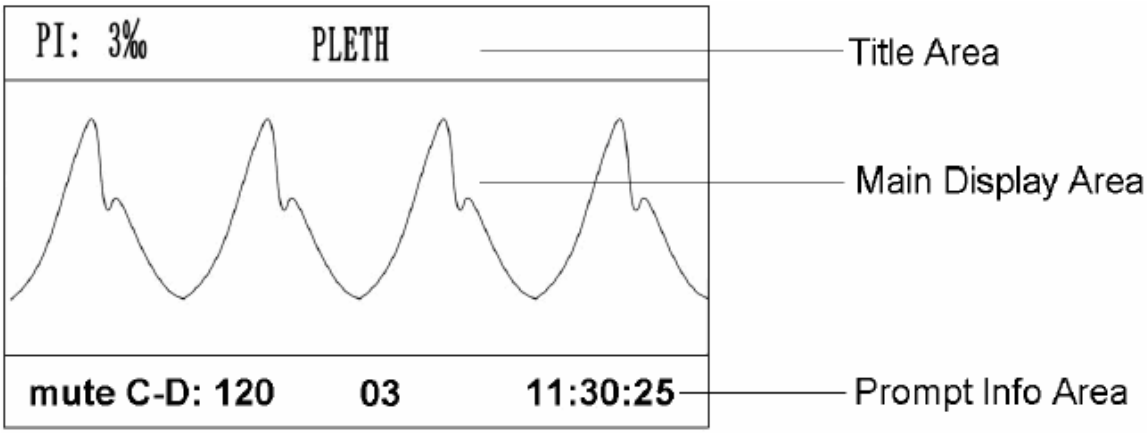

Figure 4.1 Default Display Screen

The LCD screen will display the information by different display views, short pressing “” key to shift screen display among 3 display views: SpO2 plethysmogram screen (default screen), SpO2 trend graph screen, and NIBP list screen. Long pressing “” key will enter the setup menu screen. For every display view, the display area is divided into 3 parts: title area, main display area, and prompt info area (see Figure 4.1). The prompt info area contains 3 segment of information: status or event indication at the left, patient ID number in the middle, real time clock at the right (also see Figure 4.1)

4.1.1 Screen Description

Title area:

- “PI: 3‰”: the perfusion index is 3‰; it displays only when “Setup Menu→SpO2→PI Display” is set as “ON”.
- “PLETH”: Mark of SpO2 plethysmogram，when “PLETH” displays in title area, the main display area will be SpO2 plethysmogram, and this display screen is the default screen.

Main display area:

When SpO2 sensor is placed on the patient and connected to the monitor well, a trace of sweeping waveform (plethysmogram) will be displayed in the main display area (as shown in Figure 4.1).

If the SpO2 sensor is disconnected from the monitor or off from the patient, the plethysmogram will become a base line in main display area and “Probe off” will appear at the left side of prompt info area (as shown in Figure 4.2).

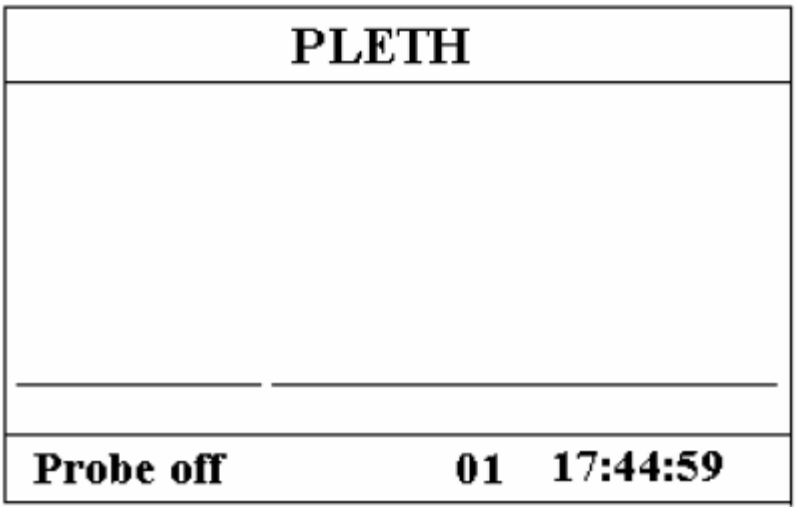

Figure 4.2 Probe Off

Prompt Info:

- Status or event indication segment:

  This segment will display the probe status, alarm silence counting-down timer, over limit warning and other error messages for technical warning. If more than one event occurs or more status appears, the indication message will be displayed alternately at this segment.

  "NIBP C-D: 120": the counting-down timer of NIBP measurement is 120 seconds. This prompt message appears only when the NIBP measuring mode is set as "AUTO X".

  "mute C-D: 120": the counting-down timer of alarm silence is 120 seconds. This prompt message appears only when the alarm silence is enabled.

- Patient ID segment:

  "01": Patient ID number.

- Real time clock segment:

  "17:44:59": the current time.

4.1.2 Operation Instructions

"  " key: press this key to shift to next display view (SpO2 trend graph).

"  " key: Press it to print a trace of SpO2 plethysmogram, press it again to stop printing.

"  " key: start/cancel NIBP measurement.

"  " key: Alarm silence switch, press it to enable/disable alarm silence.

4.2 SpO2 Trend Graph Display

Short pressing "Display" key to shift the screen view to trend graph display screen, as shown in Figure 4.3.

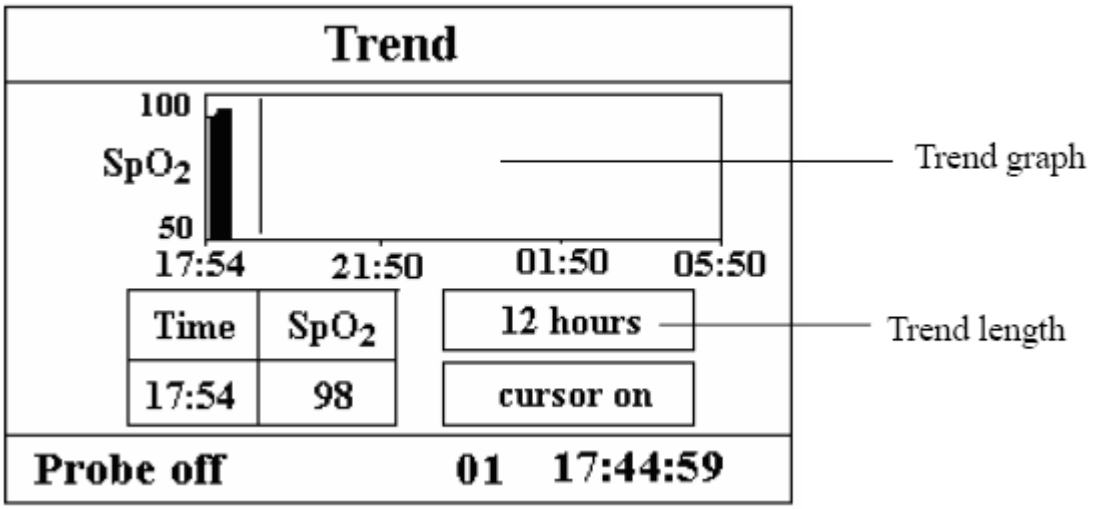

Figure 4.3 Trend Graph

- "12 hours": the trend length of trend graph; three options: "12", "24" or "96" hours; when the selection is 12 hours, the upper trend graph will display SpO2 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 SpO2 value at the given time.

Operation Instructions

1. Press "▲" key or "▼" key to highlight "trend length" or "cursor on" selection.
2. Press "■" key to confirm.
3. Press "▲" key or "▼" key again to select value of trend length (12/24/96 hours) if the selecting box stays in "trend length" option, or to move the cursor if the selecting box stays in "cursor on" option.

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 SpO2 value and the time value at the point where the cursor stays. Move cursor back and forth this way, you can view the SpO2 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 "▲" or "▼" key towards the other direction, the step becomes 1 and towards the other direction.

4. press：

"" key: press this key to shift to next display view.

"  " key: start/cancel NIBP measurement

"  " key: alarm silence switch; press it to enable/disable alarm silence.

4.3 NIBP List Screen

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

	SYS/DIA/MAP	PR
12-07 09:05	124/ 88/ 98	75
12-07 09:10	124/ 88/ 95	72
12-07 09:20	124/ 88/ 98	75
12-07 09:30	124/ 88/ 98	75
12-07 09:40	124/ 88/ 98	75
mute C-D:90	01	18:56:07

Figure 4.4 NIBP List

The first column is the date, the second column is NIBP measuring time, the third column is NIBP value, and the fourth column is pulse rate (measured by NIBP module). "SYS/DIA/MAP" indicates the value of "systolic pressure/diastolic pressure/mean arterial pressure".

4.3.1 Operation Instructions

On NIBP List screen, if NIBP measurement is more than 5 groups, press "▲" key or "▼" key to scroll up or down through all the measurement values. If NIBP measurement is not more than 5 groups, the keys "▲"or "▼" are not effective.

"  " **key:** press this key to shift to next display view.

"  " **key:** print NIBP list.

"  " **key:** start/cancel measuring NIBP.

"  " **key:** alarm silence switch; press it to enable/disable alarm silence.

4.4 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 4.5. All the functional parameters of the system can be set through Setup Menu.

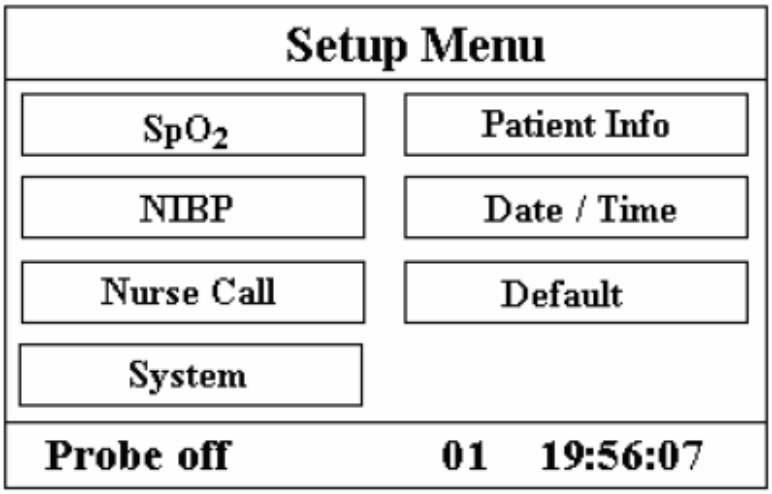

Figure 4.5 Setup Menu Screen

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. Pres“” key under the setup menu will print the SpO2 plethysmogram.
4. Press “” to exist from Setup Menu Screen.

The following will cover each functional parameter’s setting up.

4.4.1 SpO2 Setup

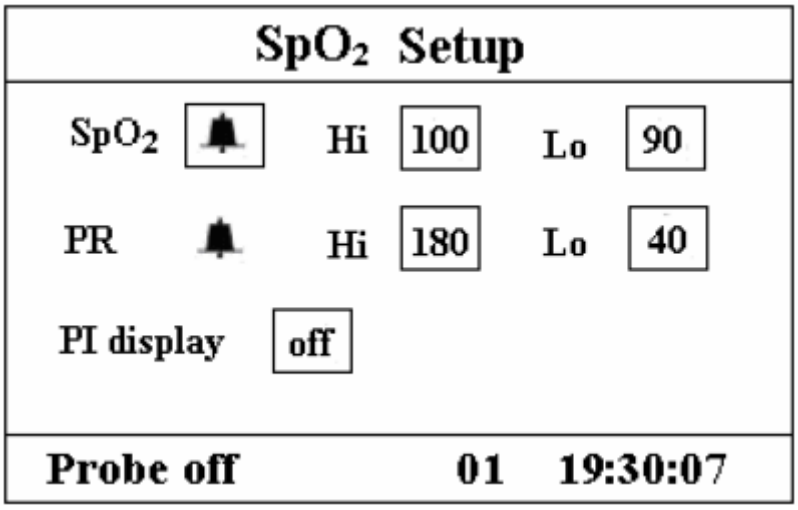

Figure 4.6 SpO_2 Setup Screen

Screen Description:

"SpO2 ": SpO_2 alarm switch; "" indicates SpO2 alarm is on; "" indicates SpO2 alarm is off.

"SpO2 Hi": high limit of SpO2 alarm; range: "1~100".

"SpO2 Lo": low limit of SpO2 alarm; range: "0~99".

"PR": pulse rate alarm switch; "" indicates PR alarm is on; "" indicates PR alarm is off.

"PR Hi": high limit of PR alarm; range: "22~250".

"PR Lo": low limit of SpO2 alarm; range: "0~248".

"PI display": "on" means PI display is enable; "off" means PI display is disable.

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.

4.4.2 NIBP Setup

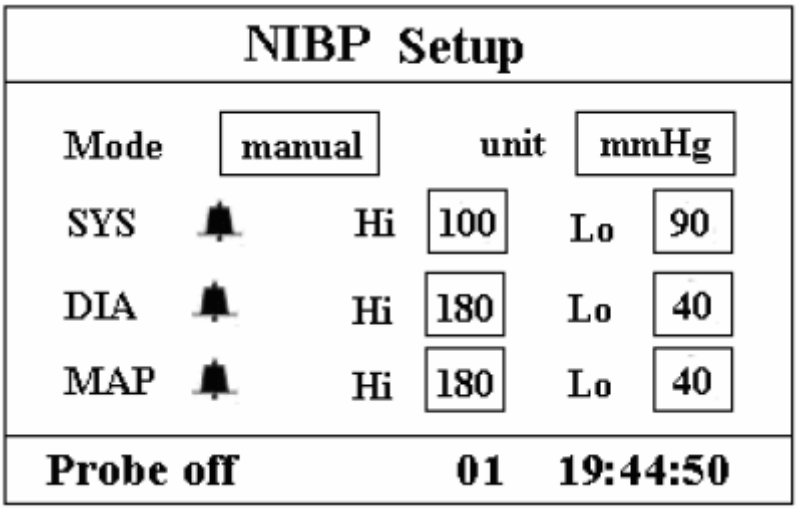

Figure 4.7 NIBP Setup Screen

- "unit": unit of the blood pressure value;
  "mmHg" or "kPa" can be selected. Conversion: 1kPa=7.5mmHg.
- "SYS": systolic pressure alarm switch; "" indicates systolic pressure alarm is on;

"" indicates systolic pressure alarm is off.

- "SYS Hi": high limit of systolic pressure alarm; range: "32~250" mmHg.
- "SYS Lo": low limit of systolic pressure alarm; range: "30~248" mmHg.
- "DIA": diastolic pressure alarm switch; "" indicates diastolic pressure alarm is on; "" indicates systolic pressure alarm is off.
- "DIA Hi": high limit of diastolic pressure alarm; range: "22~230" mmHg.
- "DIA Lo": low limit of diastolic pressure alarm; range: "20~228" mmHg.
- "MAP": mean arterial pressure alarm switch; "" indicates mean arterial pressure alarm is on; "" indicates mean arterial pressure alarm is off.
- "MAP Hi": high limit of mean arterial pressure alarm; range: "28~242" mmHg.
- "MAP Lo": low limit of mean arterial pressure alarm; range: "26~240" mmHg.

4.4.3 Nurse Call

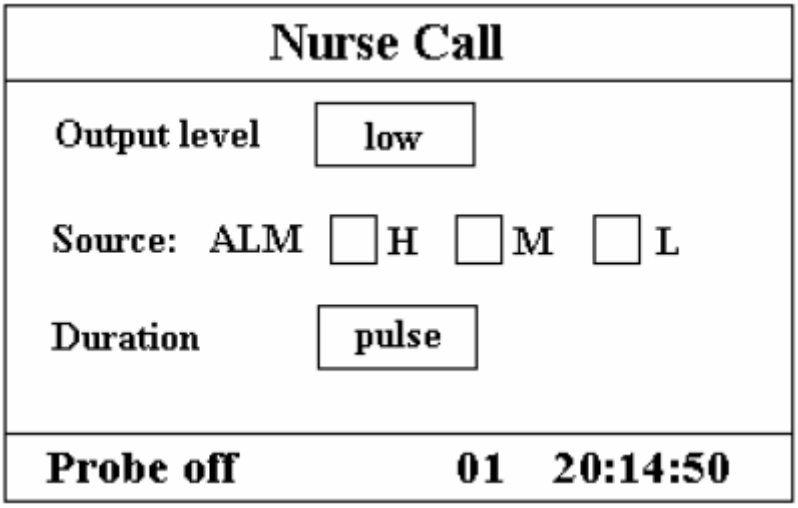

Figure 4.8 Nurse Call Setup Screen

- "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.

4.4.4 System Setup

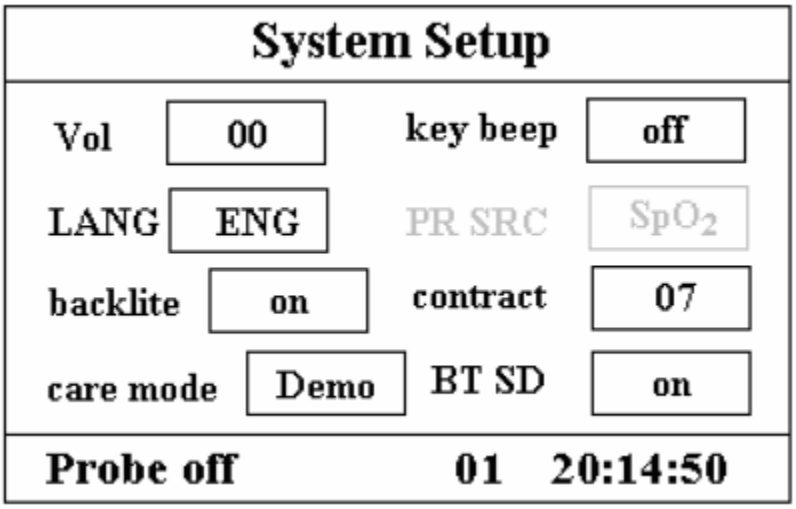

Figure 4.9 System Setup Screen

- "Vol": set beeper volume, "0~7" level adjustable, the set "0" i.e. no sound.
- "key beep": to turn on/off key beep;
- "LANG": language selection. Two options: "ENG" for English or "CHN" for Chinese.
- "PR SRC": source of pulse rate value. The default set is SpO2, it can not be adjusted.
- "backlite": turn on/off backlight;
- "contract": adjust LCD display contract, "0~7" level adjustable;
- "care mode": "Demo" shows the demo waveforms and data. In the demo state, all the signals and data are generated from the patient monitor for demonstration and testing purpose. "Real" shows the real time waveform, i.e. normal monitoring status;
- BT SD: turn on/off the pulse beeping sound.

4.4.5 Patient Info

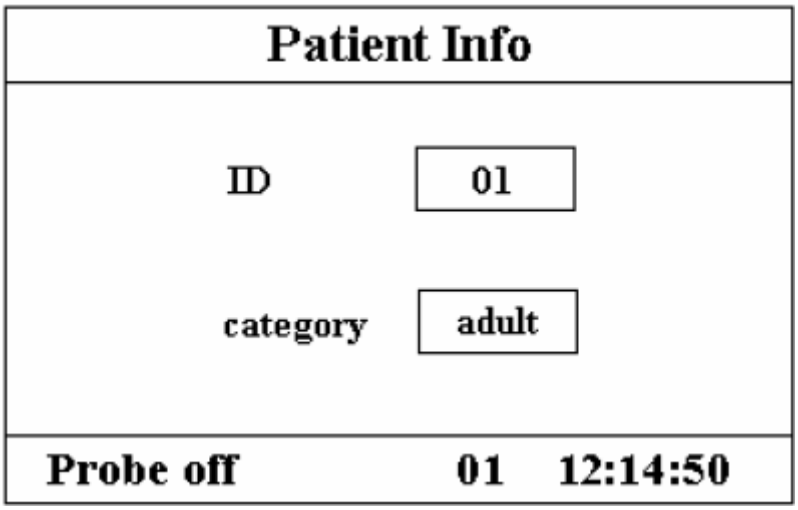

Figure 4.10 Patient Info Screen

- "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, all the history data will be cleared, that means SpO_2 trend graph and NIBP list will become empty.

4.4.6 Date/Time

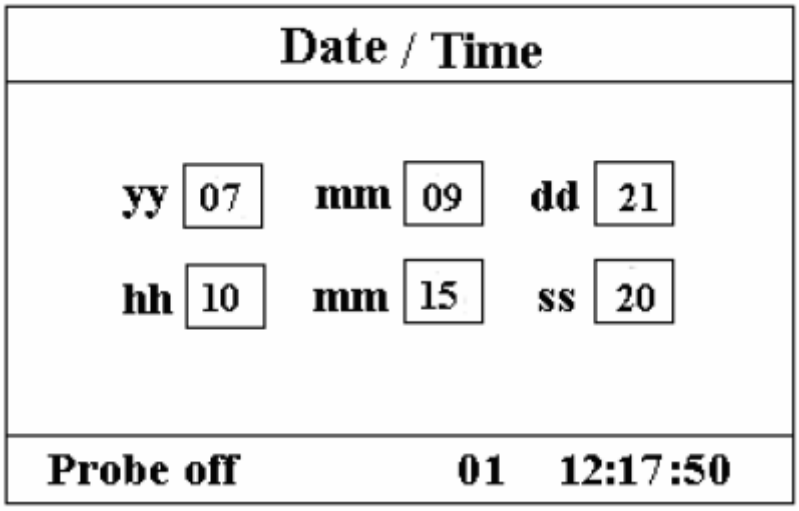

Figure 4.11 Data/Time Setup Screen

- "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.

4.4.7 Recover Default Settings

On Setup Menu screen, press "▲" button or "▼" button to shift cursor to "**Default**", and then press "■" button, all the setting parameters will be reset to factory default setting value.

4.5 Power Saving Mode

At any display view 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 4.12.

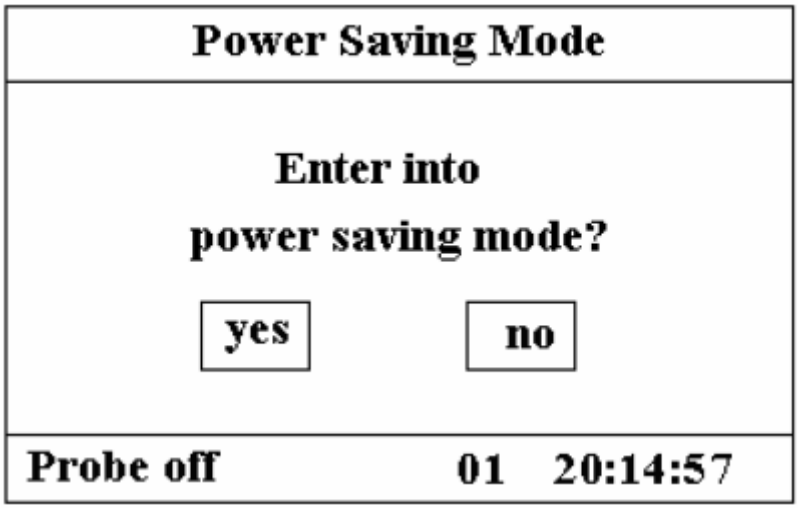

Figure 4.12 Power Saving Mode

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.

Chapter 5 Technical Specifications

5.1 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: ±5 mmHg

Diastolic: ±5 mmHg

MAP: ±5 mmHg

H. Measurement mode: Manual, Auto

5.2 SpO_2 Monitoring

A. Sensor: dual-wavelength LED

B. SpO_2 measurement range: 0%~100%

C. SpO_2 measurement accuracy:

70% - 100% ±2%

5.3 Rulse rate Monitoring

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

B. Pulse rate measurement accuracy: ±2%

5.4 Recorder

A. Recording speed: 25mm/s

B. Recording speed accuracy: ≤5%

5.5 Other Technical Specifications

A. Power supply: 100~250VAC, 50/60Hz

B. Power consumption: <100VA

C. Alarming mode: Audible & visible alarm

D. 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

5.6 Default Alarming Values of All Parameters

Parameter \ Mode		Alarm setting range	Adult	Infant	Neonate
Systolic	High	(31~250)mmHg	180mmHg	130mmHg	110mmHg
	Low	(30~249)mmHg	60mmHg	50mmHg	50mmHg
Diastolic	High	(21~232)mmHg	120mmHg	90mmHg	90bpm
	Low	(20~231)mmHg	50mmHg	40mmHg	30bpm
MAP	High	(27~242)mmHg	160mmHg	110mmHg	100mmHg
	Low	(26~241)mmHg	50mmHg	40mmHg	30mmHg
SpO2	High	1%~100%	100%	100%	100%
	Low	0%~90%	90%	85%	85%
Pulse Rate	High	(21~250)bpm	180bpm	200bpm	220bpm
	Low	(20~249)bpm	40bpm	50bpm	50bpm
Temperature	High	(0.1~60.0)℃	39℃	39℃	39℃
	Low	(0.0~59.9)℃	35℃	35℃	35℃

Chapter 6 Packaging and Accessories

6.1 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.

6.2 Accessories

Item	Content	Quantity
1	NIBP cuff	One set
2	SpO2 probe	One set
3	Power cord	One set
4	Grounding wire	One set
5	Disposable electrode	Ten pieces
6	User manual	One copy

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

Chapter 7 Working Principle

7.1 The Principle of NIBP Measurement

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.

7.2 Points to be noted in NIBP Measurement

7.2.1 Operation instructions

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

1. Requirements of the cuff:
   1) Appropriate cuff should be selected according to the age of the subject.
   2) Remember to empty the residual air in the cuff before the measurement is commenced.
   3) Locate the cuff in such a way that the “φ” mark is at a location where the clearest pulsation of brachial artery is observed.
   4) The cuff should be tightened to a degree where insertion of one finger is allowed.
   5) The lower end of the cuff should be 2cm above the elbow joint.
2. The subject should lie on the back so that the cuff and the heart are in a horizontal position and the most accurate measure is taken. Other postures may lead to inaccurate measurement.
3. Do not speak or move before or during the measurement. Care should be taken so that the cuff will not be hit or touched by other objects.
4. With the oscillating method, when blood pressure is measured, the inflation pressure of the

cuff will be automatically adjusted according to the previous measure. Generally, the initial inflation pressure is 180mmHg (for the adult mode) or 100mmHg (for the pediatric mode) or 80 mmHg (for the neonate mode) when it is powered on. Following that, 50mmHg (for the adult mode) or 30mmHg (for pediatric mode) or 10mmHg (for the neonate mode) will be added on the basis of the last measurement of systolic pressure. In this way, when the blood pressure rises or the subject is changed, the blood pressure meter may fail in giving the result after the first-time inflation. This monitor will automatically adjust the inflation pressure until the measure is taken, after that, up to four measures will be allowed.

5. When an adult subject is monitored, the machine may fail in giving the blood pressure measure if the pediatric or neonate mode is selected.

7.2.2 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;

7.3 The Principle of SpO2/Pulse Measurement

7.3.1 Working Principle

This monitor measures the pulse oxygen saturation (SpO2) and pulse by means of the radiograph of infrared light and the red light emitted by LED through body's peripheral areas (such as fingers), whereby the photoelectric detecting circuits will analyze the absorptivity of the oxyhemoglobin and reduced hemoglobin respectively, and give the photoabsorption rates before and after pulsation. Using the measure of photoabsorption change due to pulsatory arterial blood flow caused by PLETH waveform, the SpO2 can be obtained.

7.3.2 Points to be noted in SpO_2 and Pulse Measuring

1. The finger should be properly placed (see the attached illustration of this instruction manual), or else it may cause inaccurate measurement result.
2. Make sure that capillary arterial vessel beneath the finger is penetrated through by red and infrared lights.
3. The SpO2 sensor should not be used at a location or limb tied with arterial or blood pressure cuff or receiving intravenous injection.

4. Do not fix the SpO2 sensor with adhesive tape, or else it may result in venous pulsation and consequential inaccurate measurement result of SpO2.
5. Make sure the optical path is free from any optical obstacles like adhesive tape.
6. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, and direct sunlight etc.
7. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
8. Please do not use the SpO2 sensor when having the MRI, or burn may be caused by faradism.

7.3.3 Clinical Limitations

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood stream of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO2 determination by this monitor may be inaccurate.
3. The drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO2 measurements.
4. As the SpO2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO2 value.

Chapter 8 Troubleshooting

8.1 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.

8.2 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 dealer.

8.3 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 problem first. If the attempt fails, contact the dealer in your local area or the manufacturer. Do not open the cabinet without permission.

Chapter 9 Maintenance

9.1 Service and Examination

9.1.1 Daily Examination

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

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

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

9.1.2 Routine Maintenance

After each maintenance or the yearly maintenance, the monitor can be thoroughly inspected by qualified personnel, including function and safety examinations.

- **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.

9.1.3 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.

- It is recommended to use the battery once a month to ensure its strong power supply capacity and long service life, and recharge it after running out of the power.
- In order to maintain battery supply time and prolong battery lifetime, please use the battery once a month and do not charge it until it is used up each time.

Note: 1. when battery is used to supply power, user should not charge the battery until the low battery alarm rings. (After line-haul or long-time storing, using battery may not start the monitor, please charge the battery.)

2. The battery should be charged for 10 to 15 hours.

9.2 Cleaning, Sterilization 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 wipe 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 use scrub materials.
- Do not let any liquid flow into the shell or any parts of the monitor.
- Do not let the cleanser and disinfectant stay on its surface.
- Do not perform high pressure sterilization to the monitor.
- Do not put any parts of the monitor in the liquid.
- Do not pour the disinfector on its surface while sterilization.

9.3 Cleaning, Sterilization and Disinfection of Accessories

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

- 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.

9.4 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.

9.5 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.

Prompt information explanations

Mute C-D: XXX seconds	Alarm silence 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
Selftest error	Sensor or other hardware error
Cuff error	Cuff is not wrapped correctly, or is not connected
Gas leak	Air moving part, tube or the cuff leak air
Signal weak	Very weak signal because of the cuff, or the patient has very weak pulse
Over extent	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
Leak in gas run	Leaking during the pneumatic device testing
Over press	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.
Signal overflow	Blood pressure amplifier overflow due to excessive movement
System error	Abnormal condition of CPU, such as register overflow, divided by zero
Over time	Adult measurement is more than 120 seconds, neonate measurement is more than 90 seconds.

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