Patient Monitor-1

USER MANUAL

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Contents

* Carrying Warranty at Rajkot Office only on site warranty not provided free of cost.
* Due to constant upgradation design, price and features are subject to change any time without prior notice.

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Manufacture's Responsibility

Our company is responsible for safety, reliability and performance of this device only in the condition that:

- All installation operation, expansions, changes, modifications and repairs of this product are conducted by our company's authorized personnel;
- Relevant electrical equipments are complied with the applicable national standards;
- The device is operated under strict observance of this manual.

⚠ Warning ⚠

This device is not used for treatment.

It is important for the hospital or organization that employs this equipment to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.

Upon request, our company may provide, with compensation, necessary circuit diagrams, calibration illustration list and other information to help qualified technician to maintain and repair some parts, which our company may define as user serviceable.

Warranty

Workmanship & Materials

Our company guarantees new device other than accessories to be free from defects in workmanship and materials for a period of 12 months from date of shipment under normal use and service. Our company's obligation under this warranty is limited to maintain.

Exemptions

Our company's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or final damages and delay resulting from improper use, replacing parts not specified by our company , or maintaining the device by unauthorized personnel. The warranty shall not extend to: not normal use; the device without maintenance or damaged; our company's original serial number tag or identification markings changed or removed; other manufacturer's devices.

Safety, Reliability and Performance

Our company is not responsible for safety, reliability and performance in the condition that:

- Assembly operations, extensions, re-debugging are carried out;
- The device is not operated under strict observance of this manual.

Preface

This manual gives detailed description to the Patient Monitor concerning its performance, operation, and other safety information. Reading through this manual carefully is the first step for the user to get familiar with the device and make the best use of it.

The following symbols indicate some important prompts, which you should pay special attention to:

⚠ **Warning** ⚠ **Points some information you should know to avoid injury to patient and medical staff.**

⚠ **Caution** ⚠ **Points some information you should know to avoid damage to the device.**

⚠ **Note** ⚠ **Points some important information you should pay attention to.**

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Chapter1 Overview

- For an overall introduction to the patient monitor, please refer to **General Information**.
- For various messages displayed on the screen, please refer to **Screen Display**.
- For basic operating instructions and location of interface sockets, please refer to **Button Functions and External Interfaces.**
- For information on alarm silence/pause, please refer to **Alarm**.
- For notes during operation powered by battery, please refer to **Built-in Rechargeable Battery**.

⚠ Warning ⚠

- **Do not open the device enclosure to avoid possible electrical shock. All servicing and future upgrading to the device must be carried out by personnel trained and authorized by our company.**
- **Do not use the device in the presence of flammable substances as anesthetics, etc, to avoid possible explosion hazard.**
- **To ensure patient safety, verify the device and accessories can function safely and normally before use.**
- **To avoid treatment delay, please customize the alarm settings according to the individual patient situation ,and make sure the alarm sound is activated when an alarm occurs.**
- **Do not use mobile phone around the device. High level electromagnetic radiation emitted from such devices may greatly affect the device's performance.**
- **When the device is used in conjunction with electro-surgery equipment, you must give top priority to the patient safety.**
- **Observe the applicable waste control regulations to dispose the package material and keep it out of children's reach.**

⚠ Note ⚠

The software is developed complied with IEC60601-1-4 and the risk caused by errors in the program is minimized.

⚠ Caution ⚠

At the end of its service life, the product and its accessories described in this manual must be disposed of in compliance with the guidelines on the disposal of such products. Please contact our company or its representation for more related information.

1.1 General Information

Operation Environment:

Temperature	
Working:	5℃~40℃
Transport and Storage:	-40℃~+55℃
Humidity	
Working:	30%~75%
Transport and Storage:	≤95%
Atmospheric Pressure	
Working:	700hPa~1060hPa
Transport and Storage:	500hPa~1060hPa
Power Sources	
Input Power:	≤15VA
External Adapter:	Rating voltage 220V, rating power 50Hz, DC output 9V
Built-in Battery:	DC7.4V(Lithium ion polymer rechargeable battery)
Safety Classification:	Class I, Type BF defibrillator-proof applied part

Patient Monitor(hereinafter referred to as "This device") has abundant monitoring functions and is used for monitoring adult, pediatric and neonate. In addition, the user may select different parameter configurations according to different requirements. This device can monitor both NIBP and SpO_2. It integrates parameter measurement and display functions in one device to form a compact and portable patient monitor.

This device can monitor the following parameters:

SpO_2:	Functional arterial oxygen saturation(SpO_2), Pulse Rate(PR)
	SpO_2, PR graphical trend
NIBP:	Systolic Pressure(SYS), Diastolic Pressure(DIA), Mean Pressure(MAP)
	NIBP graphical trend

This device can also provide extensive functions as audio and visible alarms, NIBP and SpO_2 measurements, etc.

1.2 Screen Display

This device displays by a color LCD and LED. The LED displays NIBP and PR values, also SpO_2 value and bar indicator; while the color LCD screen displays SpO_2, PR and NIBP graphical trends, alarm status, system settings, time and other information.

What the main interface displays is shown in Figure1-1.

Figuer1-1

The information displayed:

① Alarm On/Off

② SpO_2 plethysmogram waveform.When the finger is out or oximeter probe is off, it will display the information that "Finger OUT or Probe OFF" in Figure1-1.

③ Battery strength display: The green part of the battery icon indicates the remaining capacity.

④ Taskbar: It contains system settings(SETINGS), NIBP settings(NIBP), SpO_2 settings(SpO_2) and graphical trend settings(TREND).

⚠ **Note** ⚠

Only in this interface, can the user use the button "SILENCE" to pause alarm and turn on/off the alarm sound.

1.3 Button Functions and External Interfaces

You can use the buttons located on the front panel to operate this device, and the front panel view is shown in Figure1-2.

Figure1-2

Button functions located on right side of the front panel

- **MENU**

Menu button

- **NIBP**

Press the button to inflate the cuff and start blood pressure measurement ,while in the process, press the button again to stop measurement and deflate.

- **FREEZE**

Use the button to freeze the current SpO_2 waveform in the main interface.

- **SILENCE**

Sound On/Off button

- **MAIN**

Return to main menu.

The buttons below in turn from left to right are Up, OK, Down buttons and the yellow button is for power on/off.

- **AC**

Charging indicator light

- **RUN**

Operation indicator light

Figure1-3

The connectors located on the side panel of this device are for NIBP gas tube(①) and SpO_2

probe(②).

The connectors located on the rear panel are for the adapter, USB(Standby) and equipotential grounding cable, shown in Figure1-4.

Figure1-4

1.4 Alarm

In the main interface, long press "**SILENCE**" to turn off all sound; short press the button to exit from silence status and return to alarm pause status, then it will hang up the alarm temporarily according to the former alarm pause time; short press again to exit from alarm pause status and activate alarm sound and return to normal alarm status. When the system is silence, any new triggered alarm will break silence status and make the system return to normal.

⚠ **Note** ⚠

When "ALARM OFF" occurs, the system can not give any alarm prompt.

"🔇" represents the alarm sound is off and the system can not give audible alarm prompt, so you should be cautious to use it.

"🔊 "represents the alarm sound is on and the system is in normal alarm status.

In the main interface, short press "**SILENCE**" to turn off the alarm sound and make the system in "Alarm Pause" status. The counting down for alarm pause time will display in the main interface.

1.5 Built-in Rechargeable Battery

This device is equipped with built-in battery. Connect the device to AC power source the power adapter , the indicator light is lit yellow and the battery will be charged automatically until it is full. There is a battery capacity icon in top right corner of the screen, and the green part indicates the remaining capacity; when in low power, the battery icon is red.

Chapter2 Installation of the Monitor

- Unpack and check
- Connect the AC power cord
- Power on
- Connect oximeter probe
- Connect blood pressure cuff

⚠ **Note** ⚠

To ensure the monitor can work normally, please read this chapter and the related safety information carefully before operation and install the monitor under strict observance of the requirements.

2.1 Unpacking and Checking

Take out the monitor and its accessories from the carton carefully, and retain the packing material well for further transit or storage. Check the accessories according to the accessory list in Appendix I.

- Check whether there is any mechanical damage.
- Check the oximeter probe and blood pressure tube, and if there is no question, connect them.

If in doubt, please contact our sales department or agent immediately.

2.2 Connecting AC Power Cord

The steps for connecting AC power cord:

- Verify the AC power supply according with the specification: rating voltage 220V, rating frequency 50Hz.
- Use the power adapter equipped with the monitor.

⚠ **Note** ⚠

After device transit or storage, it is necessary to charge the battery. If the device is directly turned on without connecting to the AC power source, it may not work normally. Connect the AC power source and the power adapter to charge the battery.

2.3 Powering On

Turn on the power switch, a "Dang" sound will be heard, and the LCD will display main interface, then the user can operate. The message displayed after booting up is shown in Figure2-1.

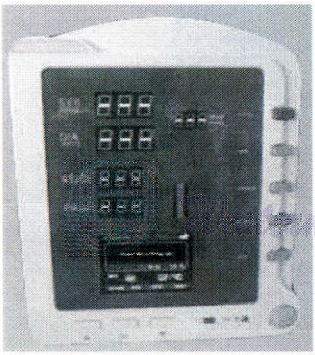


Figure2-1

⚠ **Warning** ⚠

If there is any sign of damage in function or abnormal display, do not use the monitor and contact the agent or our company's customer service center immediately.

⚠ **Note** ⚠

Inspect all monitoring functions that can be used to verify the monitor works normally.

⚠ **Note** ⚠

Each time you have used the monitor, charge the battery to ensure adequate capacity.

⚠ **Note** ⚠

You can power on again after you have powered off for one minute.

⚠ **Note** ⚠

Do not power off when measuring NIBP or SpO_2.

2.4 Connecting Oximeter Probe

Connect the oximeter probe raymer to the oximeter probe connector of the monitor, and insert patient finger into the probe.

⚠ **Note** ⚠

Refer to Figure6-1 for connecting oximeter probe.

2.5 Connecting Blood Pressure Cuff

Connect blood pressure extending tube to blood pressure cuff tubing connector of the monitor, and wrap the cuff to proper location of the patient.

⚠ **Note** ⚠

Refer to Figure7-1 for connecting NIBP cuff.

Chapter3 Safety

The device is designed in compliance with international safety standard IEC60601-1 and IEC60601-2-30 for medical electric devices.

Environment

Follow the instructions below to ensure a complete safe electrical installation. The environment where the Monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

The Monitor operates within specifications at ambient temperatures between 5℃ and 40℃. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5cm) clearance around the instrument for proper air circulation.

⚠ **Note** ⚠

The power adapter and battery with the device are in compliance with IEC60601-1 requirements.

Condensation

Make sure that during operation, the instrument is free of condensation. Condensation can form when equipment is moved from one room to another, for being exposed to moisture and differences in temperature.

⚠ **Warning** ⚠

There may be possible explosion hazard if used in the presence of flammable anesthetics.

Chapter4 Maintenance and Cleaning

4.1 Maintenance Check

Before using the monitor, do the following check tasks:

- Check whether there is any mechanical damage.
- Check whether the pins of oximeter probe connector are curve and broken or not, if there is no question, insert the probe and blood pressure extending tube.
- Check all the device's functions to make sure it is in good operation condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact qualified maintenance personnel immediately.

The overall check of the monitor, including function and safety check, should be performed only by qualified personnel once every 6 to 12 months, and each time after fixing up.

All the checks that need to open the monitor should be performed by qualified customer service technician. The safety and maintenance check can be conducted by personnel from our company. You can obtain the information about the customer service contract from the local office.

⚠ Warning ⚠

Failure on the part of the responsible hospital or institution employing the use of the monitor to implement a satisfactory maintenance schedule may cause undue device failure and possible human hazard.

⚠ Note ⚠

To extend battery's service life, it is recommended that you should discharge/charge it at least once a month.

4.2 General Cleaning

⚠ Warning ⚠

- **Before cleaning the monitor, cut off the power source.**
- **Keep the monitor out of dust.**

⚠ Caution ⚠

Please pay special attention to the following items to avoid damage to the device:

- **Avoid using ammonia-based or acetone-based solution such as acetone.**
- **Most cleaning solution must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.**
- **Don't use the grinding material, such as steel wool or silver polishing, etc.**
- **Don't let the cleaning agent enter into the enclosure of the device or any part of the system.**
- **Don't leave the cleaning solution on any part of the equipment.**

4.3 Cleaning Solution

The following are examples of cleaning solution, besides those mentioned in **"Notes"**:

- Diluted Ammonia Water
- Diluted Sodium Hyoichlo (Bleaching agent).

⚠ Note ⚠

The diluted sodium hyoichlo from 500ppm(1:100 diluted household bleaching agent) to 5000ppm (1:10 diluted household bleaching agents) is very effective. The concentration of the diluted sodium hyocihlo depends on how many organisms (blood, mucus) on the surface of the chassis to be cleaned.

- Diluted formaldehyde(35%~37%)
- Hydrogen peroxide(3%)
- Ethanol
- Isopropanol

⚠ Note ⚠

The exterior surfaces of the monitor may be cleaned with medical alcohol, drying off naturally or with clean and dry cloth.

⚠ Note ⚠

Our company has no responsibility for the effectiveness of controlling infectious disease using these chemical agents.

4.4 Sterilization

To avoid extended damage to the equipment, sterilization is only recommended when stipulated as necessary . Sterilization facilities should be cleaned first.

Recommended sterilization material: Ethylate, and Acetaldehyde.

Appropriate sterilization materials for probe and NIBP cuff are introduced in the corresponding chapters respectively.

⚠ Caution ⚠

- **Follow the manufacturer's instructions to dilute the solution, or adopt the lowest possible density.**
- **Do not let liquid enter the monitor.**
- **No part of this monitor can be subjected to immersion in liquid.**
- **Do not pour liquid onto the monitor during sterilization.**
- **Avoid remaining sterilization agent on the surface of the device, if it is unavoidable, use a moistened cloth to wipe it up.**

4.5 Disinfection

To avoid extended damage to the equipment, disinfection is only recommended when necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

Appropriate disinfection instructions for probe and NIBP cuff are introduced in the corresponding chapters respectively.

⚠ Caution ⚠

To avoid damage to the monitor, never use EtO gas or formaldehyde to disinfect.

Chapter5 System Menu

Press "OK" and "UP/DOWN" to choose "SETINGS" in the task bar, then press "OK" to enter system menu.

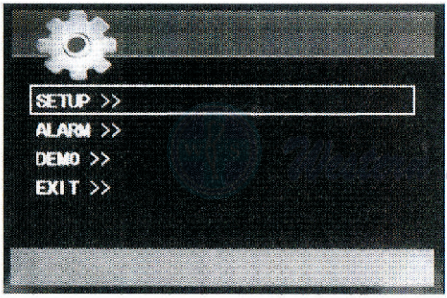


Figure5-1

5.1 SETUP Menu

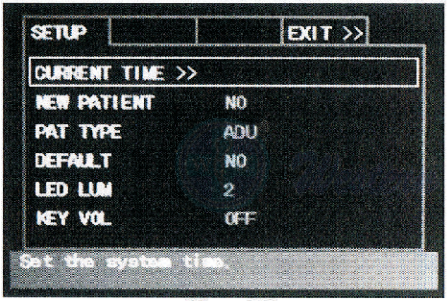


Figure5-2

The items in this menu interface in turn from top to below are shown:

- CURRENT TIME>> Current time settings
- NEW PATIENT New patient settings
- PAT TYPE Patient type settings
- DEFAULT Factory default settings
- LED LUM LED lum settings
- KEY VOL Key volume settings

Operation instruction:

- **CURRENT TIME:**

Press "OK" to select this item and enter time settings interface, use "UP/DOWN" to switch year/month/day/hour/minute/second, and again press "OK" to select, use "UP/DOWN" to select values and at last press "OK" to save the new time settings.

- **NEW PATIENT:**

Select this item and use "UP/DOWN" to set up new patient.

- **PAT TYPE:**

Select this item and use "UP/DOWN" to set up patient type, selectable for adult, pediatric, and neonatal patient.

- **DEFAULT:**

Select this item and use "UP/DOWN" to select whether to recover factory default settings.

- **LED LUM:**

Select this item and use "UP/DOWN" to change the brightness of the LED, selectable for .level 1,2,3.

- **KEY VOL:**

Select this item and use "UP/DOWN" to control the key volume ON/OFF.

⚠ **Note** ⚠

- **Select "NEW PATIENT" will clear the stored measurement data before.**
- **If you find the stored data is incorrect, please set up the time correctly and a new patient to measure again.**
- **After you have modifyed the parameters, press "OK" to save and take effort; press "MAIN" to cancel and exit to upper menu.**

5.2 ALARM Menu

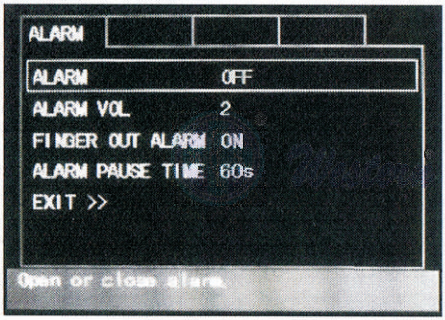


Figure5-3

The items in this menu interface in turn from top to below are shown:

- ALARM — Alarm switch
- ALARM VOL — Alarm volume
- FINGER OUT ALARM — Finger out alarm switch
- ALARM PAUSE TIME — Alarm pause time
- EXIT>> — Exit

Operation instruction:

- **ALARM:**

Select this item and use "UP/DOWN" to control the alarm ON/OFF.

- **ALM VOL:**

Select this item and use "UP/DOWN" to change the volume of the alarm, selectable for 7 options .

- **FINGER OUT ALARM:**

Select this item and use "UP/DOWN" to control the finger out alarm sound ON/OFF.

- **ALARM PAUSE TIME:**

Select this item and use "UP/DOWN" to change the alarm pause time, selectable for 30S/60S/90S/120S.

⚠ **Note** ⚠

Alarm pause setup is only effective for current alarm item, and a new alarm event will end it.

5.3 DEMO Menu

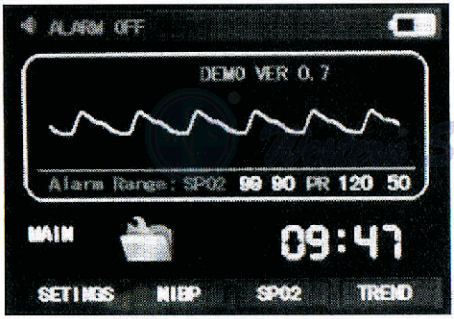


Figure5-4

Operation instruction:

■ **DEMO:**

⚠ **Note** ⚠

The software version in demo mode refers to that in the device and press any key to exit from demo interface.

⚠ **Warning** ⚠

The calibration of the NIBP measurement should be performed every two years and check its performance according to the details below.

Procedure of NIBP:

Replace the cuff of the device with a rigid metal vessel with a capacity of 500 ml±5%. Connect a calibrated reference manometer with an error less than 0.8 mmHg and a ball pump by means of a T-piece connector and hoses to the pneumatic system. Set the monitor in CALIBRATE mode. Inflate the pneumatic system to 0, 50 and 200 mmHg by ball pump separately. The difference between the indicated pressure of the reference manometer and the indicated pressure of the monitor will not exceed 3 mmHg. Otherwise, please contact our customer service.

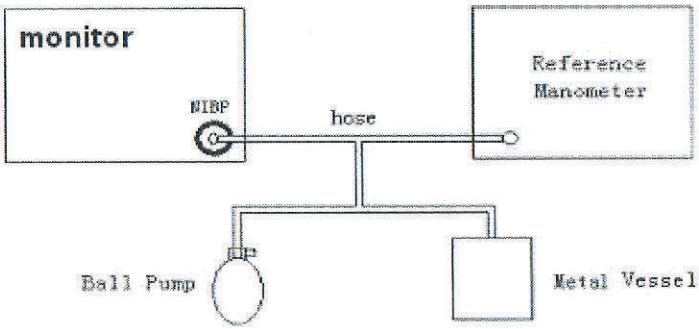


Figure5-5 Diagram of NIBP Calibration

Chapter6 SpO_2 Monitoring

6.1 What is SpO_2 Monitoring

SpO_2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the monitor will read 97% .The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

How the SpO_2 / PLETH Parameter Works

- Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the probe, is transmitted through patient tissue, to a receiver on the other side.
- The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.
- The SpO_2 value and the PLETH waveform can be displayed on the main screen.

⚠ Warning ⚠

- **Pulse oximetry can overestimate the SpO_2 value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.**
- **ES (Electrosurgery) equipment cable and SpO_2 cable must not be tangled up.**
- **Do not put the probe on extremities with arterial catheter or venous syringe.**

⚠ Note ⚠

Do not perform SpO_2 measuring and NIBP measuring on the same arm, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO_2 value.

6.2 Precautions during SpO_2 /Pulse Monitoring

⚠ Note ⚠

- **Make sure the nail covers the light window;**
- **The probe wire should be on the backside of the hand;**
- **SpO_2 value always displays on the same place;**
- **SpO_2 waveform is not proportional to the pulse volume.**

⚠ Warning ⚠

- **Check whether the probe cable is in normal condition before monitoring. After unplugging the oximeter probe cable from the socket, the system shall display "Finger OUT or Probe OFF".**
- **Do not use the oximeter probe once the package or the probe is found damaged. Instead, you shall return it to the vendor.**
- **Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the probe placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. Check per 2~3 hours the probe placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.**

6.3 Monitoring Procedure

SpO_2 plethysmogram measurement

1) Switch on the monitor.
2) Attach the probe to the appropriate site of the patient finger, as shown in Figure6-1.
3) Plug the connector of the probe extension cable into the SpO_2 socket located on the side panel of the monitor.

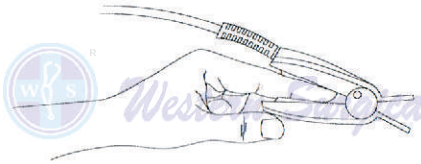


Figure6-1 Mounting of the probe

6.4 Limitations for Measurements

Measurement Limitations

In operation, the accuracy of oximeter readings can be affected by the following:

- High-frequency electrical interference, such as that from electrosurgical apparatus connected to the system.
- Do not use oximeter probe during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burn.
- Intravascular dye injections.
- Excessive patient movement.
- External light radiation.
- Improper probe installation or incorrect contact position of the patient.
- Probe temperature (optimal temperature is between 28°C and 40°C).
- Placement of the probe on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin.
- Too low SpO_2.
- Bad circular perfusion of the part being measured.
- Use the oximeter probe provided by our company, and if necessary, contact our sales department to replace new ones in time.

6.5 SpO_2 Menu

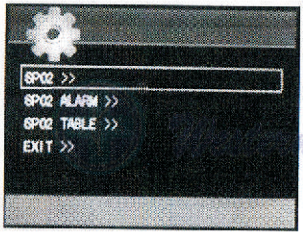


Figure6-2

6.5.1 SpO_2 Setup Interface(SpO_2)

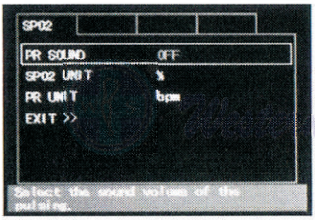


Figure6-3

The items in this menu interface in turn from top to below are shown:

- PR SOUND — PR Sound

Use this item to change the volume of the pulse sound, selectable for OFF /HIGH /MED /LOW.

- SpO_2 UNIT — SpO_2 unit
- PR UNIT — Pulse rate unit
- EXIT>> — Exit

6.5.2 SpO_2 Alarm Menu(ALARM)

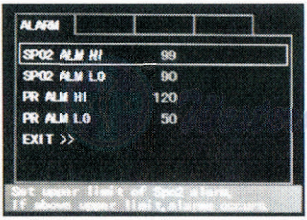


Figure6-4

The items in this menu interface in turn from top to below are shown:

- SpO_2 ALM HI — High limit for SpO_2 alarm
- SpO_2 ALM LO — Low limit for SpO_2 alarm
- PR ALM HI — High limit for PR alarm
- PR ALM LO — Low limit for PR alarm
- EXIT>> — Exit

⚠ Note ⚠

You can monitor patients on the base of the actual situation to change oxygen saturation and pulse rate alarm limits .The way to change is: in this interface, use UP/DOWN to switch the item to be changed , use OK to select it , again use UP/DOWN to change the content, at last use OK to save the change.

SpO_2 Alarm Setup

- ALARM switch: select "ON" in the main interface, the system will give alarm prompt when SpO_2 alarm occurs; select "OFF", the system will not give alarm.
- SpO_2 ALM HI and SpO_2 ALM LO: SpO_2 alarm is activated when the value exceeds set SpO_2 ALM HI value or falls below SpO_2 ALM LO value.
- PR ALM HI and PR ALM LO: PR alarm is activated when the pulse rate exceeds set PR ALM HI value or falls below PR ALM LO value.

SpO_2 and PR alarm range:

Parameter	High Limit	Low Limit	Step
SpO_2	100	0	1
PR	254	0	1

6.5.3 SpO_2 Table Menu(TABLE)

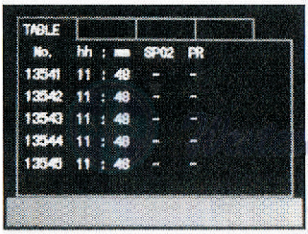


Figure6-5

The items in this menu interface in turn from left to right are: case number, measurement time, SpO_2 and PR.

⚠ Note ⚠

When too many cases are stored, user can use "OK" to enter inputing case number interface and "UP/DOWN/FREEZE/SILENCE"to input the expected case number, press "OK" to confirm the input. It is the fast access to entering the expected case review interface.

Press "MAIN" to exit from the interface to the main.

6.6 Alarm Prompt and Cause

Prompt	Cause
SpO_2 TOO HIGH/LOW	SpO_2 measuring value exceeds or falls below the alarm range you have set up.
PR TOO HIGH/LOW	PR measuring value exceeds or falls below the alarm range you have set up.

6.7 Maintenance and Cleaning

⚠ Warning ⚠

Turn off the monitor and disconnect AC supply before cleaning the monitor or the probe.

⚠ Caution ⚠

- **Do not subject the probe to autoclaving.**
- **Do not immerse the probe into any liquid.**
- **Do not use the probe or cable that may be damaged or deteriorated.**

Cleaning:

- **Use a cotton ball or a soft mull moistened with hospital-grade ethanol to wipe the surface of the probe, and then dry it with a cloth. This cleaning method can also be applied to the luminotron and receiving unit of the probe.**
- **The cable can be cleaned with 3% hydrogen dioxide, 70% isopropanol, or other active reagent. However, connector of the probe shall not be subjected to such solution.**

Chapter7 NIBP Monitoring

7.1 General

- The Non-invasive Blood Pressure (NIBP) module measures the blood pressure using the oscillometric method.
- It is applicable for adult, pediatric, and neonatal usage.
- There are two modes of measurement available: manual, automatic. Each mode displays the diastolic, systolic and mean blood pressure.
  - "In the MANUAL mode, only one measurement is conducted for each time.
  - In the AUTO mode, the measurement is cycled; you can set the interval time to 1 /2 /3 /4 /5/ 10/ 15/ 30/ 60/ 90minutes.

⚠ Warning ⚠

- **You must not perform NIBP measurements on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.**
- **For a thrombasthemia patient, it is important to determine whether auto measurement of the blood pressure shall be done . The determination should be based on the clinical evaluation due to hematoma danger.**
- **Ensure that the correct pattern and blood pressure cuff are selected when performing measurements on children. It may be dangerous for the children to use an over pressure level.**

7.2 NIBP Monitoring

7.2.1 NIBP Measurement

⚠ Warning ⚠

- **Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric or neonate).**
- **Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.**

⚠ Warning ⚠

Make sure that the airway tube connecting the blood pressure cuff and the monitor is neither blocked nor tangled.

Operation steps

1. Plug in the extension conduit and switch on the system.
2. Apply the blood pressure cuff to the patient's arm following the instructions below (Figure7-1).
   - Ensure that the cuff is completely deflated.
   - Apply the appropriate size cuff to the patient, and make sure that the symbol "Φ" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.

Figure7-1 Applying the cuff

⚠ Note ⚠

The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, then use a larger cuff.

Size of reusable cuff for neonate/children/adult

Patient Type	Limb perimeter	Cuff width	Hose
Infant	10 ~19 cm	8 cm	1.5 m or 3 m
Child	18 ~ 26 cm	10.6 cm	
Adult	25 ~ 35 cm	14 cm	
Large Adult	33 ~ 47 cm	17 cm	
Thigh	46 ~ 66 cm	21 cm	

Size of disposable cuff for neonate/children/adult

Size No.	Limb perimeter	Cuff width	Hose
1	3.1 ~ 5.7 cm	2.5 cm	1.5 m or 3 m
2	4.3 ~ 8.0 cm	3.2 cm	
3	5.8 ~ 10.9 cm	4.4 cm	
4	7.1 ~ 13.1 cm	5.1 cm	

◆ Make sure that the cuff edge falls within the range of mark <->. If it does not, use a larger or smaller cuff that fits better.

3. Connect the cuff to the extension trachea. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible, you should apply the following corrections to the measured values:
   ◆ If the cuff is placed higher than the heart level, add 0.75 mmHg for each inch of difference.
   ◆ If it is placed lower than the heart level, deduct 0.75 mmHg for each inch of difference.
4. Select the measurement mode in NIBP setup menu, refer to the following operation instructions for details.
5. Press "NIBP" on the front panel to start a measurement. Repress "NIBP" to stop measuring.

7.3 NIBP Menu

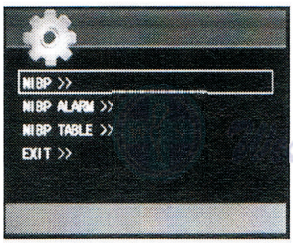


Figure7-2

7.3.1 NIBP Menu

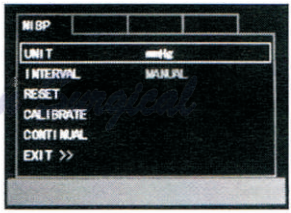


Figure7-3

The items in this menu interface in turn from top to below are shown:

- UNIT — NIBP Unit
- INTERVAL — Interval
- RESET — Reset
- CALIBRATE — NIBP Calibration
- CONTINUAL — Continual measurement for 5 minutes
- EXIT>> — Exit

⚠ Note ⚠

Please press "UP/DOWN" to switch among items, use "OK" to choose the item to be changed, again use "OK" to confirm. Here to the "INTERVAL" item, you can select the interval for auto or manual measurement.

- **RESET**

NIBP module reset

Pick this item to restore initial settings of NIBP module.

When the pressure does not work properly and the system fails to give message for the problem, pick this item to activate self-test procedure, thus restore the system from abnormal performance.

- **INTERVAL**

Interval time for automatic measuring. Available selections: 1/2/3/4/5/10/15-255 minutes

- **CONTINUAL**

Continual measurement for 5 minutes without interval.

Operation Instructions:

1. To start a auto measuring

Access "NIBP SETUP" menu and pick the "INTERVAL" item, in which the user may choose the selections other than MANUAL to set up the time interval for auto measurement.

⚠ Warning ⚠

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

2. To stop auto measuring:

During auto measuring press "NIBP" button on the front panel at any time to stop auto measurement.

3. To start a manual measurement:
   - Access "NIBP SETUP" menu and pick the "INTERVAL" item. Select the "MANUAL" selection. Then press the "NIBP" button on the front panel to start a manual measurement.
   - During the idle period of auto measuring process, press the "NIBP" button on the

front panel at any time to start a manual measurement. Then press the "NIBP" button again to stop manual measurement and the system continues executes auto-measuring program according to selected time interval.

4. To start a manual measurement during the AUTO mode:

Press "NIBP" button on the front panel.

5. To stop a manual measurement:

Press "NIBP" button on the front panel again.

⚠ Note ⚠

After you have set up the interval, manual measurement will affect the interval of auto measurement, and the auto measurement interval begins from the time the last measurement finishes, after the interval time to begin auto measurement. If in the interval, the device is powered off, it will re-start from the time it is powered on.

⚠ Note ⚠

If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by other methods before checking the functioning of the monitor.

⚠ Warning ⚠

If liquid is inadvertently splashed on the equipment or its accessories, or especially enter the inside the monitor, contact with qualified maintenance personnel.

Measurement Limitations

To different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In these cases, the patient's condition will make a measurement impossible.

- **Patient Movement**

Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

- **Cardiac Arrhythmia's**

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus will be prolonged.

- **Heart-lung Machine**

Measurements will not be possible if the patient is connected to a heart-lung machine.

- **Pressure Changes**

Measurements will be unreliable and may not be possible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

- **Severe Shock**

If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

- **Heart Rate Extremes**

Measurements can not be made at a heart rate of less than 40 bpm and higher than 240 bpm.

- **Too Fat Patient**

The thick fat layer will lower the accuracy of the measurement,because the fat will prevent arterial shock from returning the cuff.

7.3.2 ALARM Menu

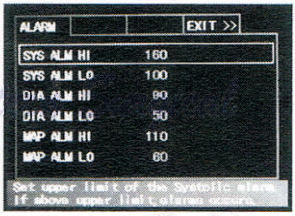


Figure7-4

The items in this menu interface in turn from top to below are shown:

- SYS ALM HI — SYS alarm high limit
- SYS ALM LO — SYS alarm low limit
- DIA ALM HI — DIA alarm high limit
- DIA ALM LO — DIA alarm low limit
- MAP ALM HI — MAP alarm high limit
- MAP ALM LO — MAP alarm low limit

Operation Instructions:

Please press "UP/DOWN" to switch among items, use "OK" to choose the item to be changed, press "UP/DOWN" to change, again use "OK" to confirm.

Range of the alarm value for different patients:

SYS 40mmHg~270mmHg;
MAP 20mmHg~235mmHg;
DIA 10mmHg~215mmHg.

7.3.3 TABLE Menu

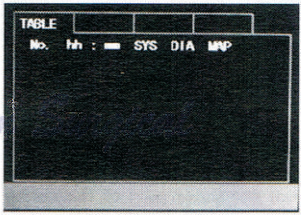


Figure7-5

Here in this interface, you can view the stored patient's NIBP information, the items in turn from left to right are: Data number, measurement time, SYS, DIA, MAP.

⚠ Note ⚠

When too much NIBP information are stored, please review according to the method that for SpO_2 above.

Press "MAIN" to exit from the current interface to the main.

7.4 NIBP Alarm Message and Explanations

Message	Cause
SYS TOO HIGH/LOW	SYS is above or below the limits of SYS alarm you have set up.
DIA TOO HIGH/LOW	DIA is above or below the limits of DIA alarm you have set up.

MAP TOO HIGH/LOW	MAP is above or below the limits of MAP alarm you have set up.

7.5 NIBP Message on LED and Explanations

Message	Explanation	Cause
E02	Self-test failure	SpO_2 Probe or A/D sampling error.
E06	Loose cuff	Cuff is not connected correctly.
E07	Air leakage	Air leakage in the valve or airway.
E08	Atmospheric pressure error	Valve can not be opened.
E09	Signal is too weak	Object measuring the pulse of the cuff is too weak or too loose.
E10	It is beyond the range	Object measuring blood pressure exceeds the measurement range.
E11	Excessive movement	When measuring, signal the presence of excessive movement or pseudo-differential interference.
E12	Overpressure	Cuff pressure is above the scope, ADU 290 mmHg, NEO 145 mmHg.
E13	Saturated signal	Movement or other factors lead to too big signal amplitude.
E14	Air leakage	There is air leakage in the system.
E15	System failure	There is something wrong with NIBP module, A/D sampling or software of system after turning on the device.
E19	It spends too much time	Measuring is above certain specified time When pressure of adult cuff is 200mmHg, it may spend 120s. If not, it may spend 90s, while it is 90S for NEO.

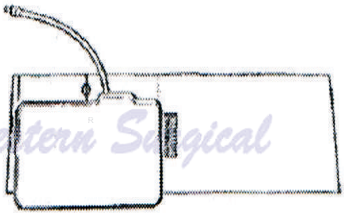
7.6 Maintenance and Cleaning

⚠ Warning ⚠

- **Do not squeeze the rubber tube on the cuff.**
- **Do not allow liquid to enter the connector socket at the side of the monitor.**
- **Wipe the external surface not inner part of the connector socket when cleaning the monitor.**
- **When the reusable cuff is not connected with the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.**

Reusable Blood Pressure Cuff

The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned.The cuff can also be machine-washed or hand-washed, the latter method may prolong the service life of the cuff. Before washing, remove the latex rubber bag, and for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing, then reinsert the rubber bag.



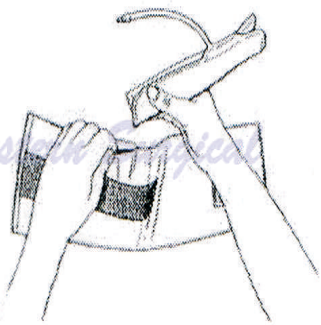


Figure7-6 Replace Rubber Bag in Cuff

To replace the rubber bag in the cuff, first place the bag on top of the cuff so that the rubber tubes line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the complete cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

Disposable Blood Pressure Cuffs

Disposable cuffs are intended for one-patient use only. Do not use the same cuff on any other patient. Do not sterilize or use autoclave on disposable cuffs. Disposable cuffs can be cleaned using soap solution to prevent infection.

⚠ **Note** ⚠

For protecting environment, the disposable blood pressure cuffs must be recycled or disposed of properly.

Chapter8 Trend Graph

8.1 General

Review NIBP and SpO_2 data in form of trend graph.

8.2 TREND Interface

Figure8-1

8.2.1 SpO_2 TREND(SpO_2 Trend Graph)

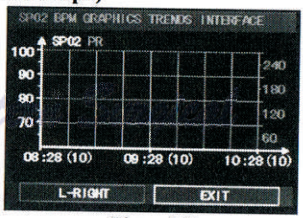


Figure8-2

The items in this menu interface in turn from left to right are shown:

- L-RIGHT — Move left or right
- EXIT>> — Exit

Operation Instructions:

- **L-RIGHT:**

Select this item and use "UP/DOWN" to review SpO_2 and PR data in form of trend graph stored in device.

8.2.2 NIBP TREND (NIBP Trend Graph)

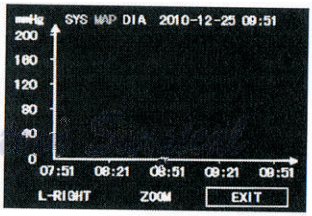


Figure8-3

The items in this menu interface in turn from left to right are shown:

- L-RIGHT — Move left or right
- ZOOM — Adjust Range
- EXIT>> — Exit

Operation Instructions:

■ **L-RIGHT**

Select this item and use "UP/DOWN" to review NIBP data in form of trend graph for 24 hours until current time.

■ **ZOOM**

Select this item and use "UP/DOWN" to adjust the Y-axis range of NIBP.

Appendix I Product Specification and Accessories

Type of the monitor	Class I, Type BF defibrillation-proof applied part equipment
Operation mode	Continuous operation
Review	
NIBP measurement review	Not less than 2000 NIBP data review
SpO_2 measurement review	Not more than 78000 SpO_2 data review
Display	**Display mode**
SpO_2	3 figures LED display
NIBP	3 figures LED display
Pulse Rate	3 figures LED display
SpO_2, Pulse Rate trend graphy SpO_2 plethysmogram waveform	Waveform LCD display

SpO_2 Specification	
Measurement range	0%～100%;(Below 70% is not defined.)
Alarm range	0%～100%
Accuracy	±2%
Pulse Rate	
Measurement range	30bpm～250bpm
Alarm range	0bpm～250bpm
Accuracy	±2bpm or ±2% selecting larger
NIBP Specification	
Measurement mode	Oscillometric
Operation mode	Manual, auto
Measurement interval in auto mode	1,2,3,4,5,10,15,30,60,90minutes
Alarm type	Audio and Visible
Accuracy	
Resolution	1mmHg
Accuracy for cuff pressure	±3mmHg
Accuracy for measurement	
Maximum mean error	±5mmHg
Maximum standard deviation	8mmHg

Overpressure protection	
Adult mode	297mmHg±3mmHg
New born mode	147mmHg±3mmHg
Battery	
7.4V Lithium ion polymer rechargeable battery Fully charged and in normal operation, the battery can supply power source for about 5 hours continuously.	
Dimension and Weight	
Dimension	240mm×190mm×162mm(without casing)
Net weight	1.6Kg
Product Accessories	
Power cable (1) Power adapter (1) Oximeter probe (1) Adult blood pressure cuff (1) Blood pressure extending tube (1)	

*** Carrying Warranty at Rajkot Office only on site warranty not provided free of cost.**

*** Due to constant upgradation design, price and features are subject to change any time without prior notice.**

7.3 WARRANTY CERTIFICATE

western surgical product is warranted to be free from electrical and mechanical defects in material and workmanship, under normal use. The western surgical product must not have been moved from the site of original installation. A new or remanufactured part to replace the defective part will be provided without charge for the part itself, through an authorized western surgical service dealer. The replacement part assumes the unused portion of the warranty.

WESTERN SURGICAL WILL NOT BE RESPONSIBLE FOR:

1. Damage or repairs required as a consequence of faulty installation or application by others.
2. Damage or repairs needed as a consequence of any misapplication, negligent handling, improper servicing, unauthorized alteration, or improper operations.
3. Failure to start due to voltage conditions, blown fuses, open circuit breakers or other damages due to the inadequacy or interruption of electrical service.
4. Damage as a result of floods, winds, fires, lightning, accidents, corrosive atmosphere, or other conditions beyond the control of western surgical
5. Parts not supplied or designated by western surgical.

Date of Installation	**Installed By**
Model No.	**Serial No.**
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

Marketed By: Western Surgical
Sign. With Stamps

No Claim Warranty :

1) Any Defect Througut Power Supply

2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

* Carrying Warranty at Rajkot Office only on site warranty not provided free of cost.
* Due to constant upgradation design, price and features are subject to change any time without prior notice.

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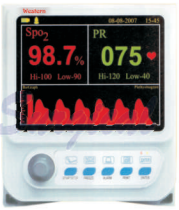
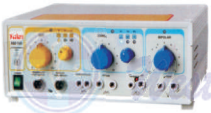
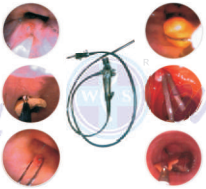
OUR OTHER PRODUCTS RANGE



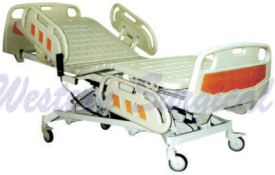












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