

## GIMA 900 VET MULTIPARAMETER PATIENT MONITOR





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Manufactured date: See label on device

Service life: 5 years

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Marks in the Manual:

- Warning : must be followed to avoid endangering the operator and the patient.
- $\hfill \bigtriangleup$  Caution: must be followed to avoid causing damage to the monitor.
- PNote: some important information and tips about operations and application.

#### Instructions to User

Dear Users,

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

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

- WARNING-PACEMAKER PATIENTS. This monitor may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon this monitor ALARMS. Keep pacemaker patients under close surveillance.
- Monitoring a single person at a time.
- The monitor is defibrillator proof. Verify that the accessories can function safely and normally and the monitor is grounded properly before conducting defibrillation.
- Disconnect the monitor and sensors before MRI scanning. Use during MRI could cause burns or adversely affect the MRI image or the monitor's accuracy.
- If you have any doubt to the grounding layout and its performance, you must use the built-in battery to power the monitor.
- All combinations of equipment must be in compliance with standard of IEC 60601-1-1 for medical electric system requirements.
- Check SpO<sub>2</sub> probe application site periodically (every 30 minutes) to determine circulation, positioning and skin sensitivity.
- The SpO<sub>2</sub> probe of this monitor may not work for all patients. If stable readings can not be obtained at any time, change appropriate probe or discontinue use of SpO<sub>2</sub> monitoring.
- Do not immerse the monitor or its accessories in liquid to clean.
- Do not use accessories other than those provided/recommended by the manufacturer.
- Each time the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.
- The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- When taking the measure of an small animal blood pressure, do NOT operate in the big animal mode. The high inflation pressure may cause lesion or even body putrescence.
- The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.
- DO NOT take blood pressure measurement from a limb receiving ongoing transfusion or intubation or skin lesion area, otherwise, damages may be caused to the limb.
- Continuous use of SpO<sub>2</sub> sensor may result in discomfort or pain, especially for those with micro-circulatory problem. It

is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.

- SpO<sub>2</sub> measuring position must be examined more carefully for some special patient. Do NOT install the SpO<sub>2</sub> sensor on the finger with edema or vulnerable tissue.
- To prevent the risk of the short circuit, the equipment must be properly grounded.
- Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.
- All the connecting cables and rubber tubes of the applying parts should be kept away from the patient's cervix to prevent any possible suffocation of the patient.
- All the parts of the monitor should NOT be replaced at will. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused.
- DO NOT stare at the infrared light of SpO₂ sensor when switch it on, for the infrared may do harm to the eye.
- If the monitor falls off accidentally, please do NOT operate it before its safety and technical indexes have been tested minutely and positive testing results obtained.
- It is recommended to take the blood pressure measurement manually. The automatic or continuous mode should be used at the presence of a doctor/nurse.
- Alarm limits should not be set to exceed the measuring range, or the alarm system will not generate alarm signals because of no alarm condition. Refer to the Technical Specification for detailed measuring range.
- Please peruse the relative content about the clinical restrictions and contraindication.
- When disposing of the monitor and its accessories, the local law should be followed.
- **b** Do not replace the built-in battery when the device is at working state.

## Table of Contents

1.2 Intended Use	1
1.3 Safety	1
Chapter 2 Operating Principle	2
2.1 Conformation	2
Chapter 3 Installation and Connection	2
3.1 Appearance	2
3.1.1 Front Panel	2
3.1.2 Side Panel	
3.1.3 Rear Panel	5
3.1.4 Underside of the Monitor	6
3.2 Battery Installation	6
3.3 Installation	7
3.3.1 Unpacking and Checking	
3.3.2 Environmental Requirements	
3.4 Getting Started	
3.4.1 Connecting to Power Source	
3.4.2 Turning the Monitor On	9
3.4.3 Starting Monitoring	
3.5 Turning the Monitor Off	
3.6 Sensor Placement and Connection	
3.6.1 Blood Pressure Cuff Connection	
3.6.2 SpO <sub>2</sub> Sensor Connection	
3.7 Loading printer paper (if printer is installed)	
3.7 Loading printer paper (if printer is installed) Chapter 4 Operations	
<ul><li>3.7 Loading printer paper (if printer is installed)</li><li>Chapter 4 Operations</li><li>4.1 Initial Monitoring Screen</li></ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen .</li> <li>4.2 Default Screen .</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional).</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen .</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen .</li> <li>4.2 Default Screen .</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional).</li> <li>4.5 Alarm Event List Screen .</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option).</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen .</li> <li>4.2 Default Screen .</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional).</li> <li>4.5 Alarm Event List Screen .</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen .</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional) .</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional)</li> <li>4.7.2 NIBP Setup (Optional)</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen .</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen .</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen .</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional)</li> <li>4.7.2 NIBP Setup (Optional)</li> <li>4.7.3 Patient Info</li> </ul>	
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional)</li> <li>4.7.2 NIBP Setup (Optional)</li> <li>4.7.3 Patient Info</li> <li>4.7.4 Date/Time Setup</li> </ul>	17 19 19 19 19 21 21 21 22 22 22 22 24 24 25 25 25 28 28
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen .</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional).</li> <li>4.5 Alarm Event List Screen .</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional)</li> <li>4.7.2 NIBP Setup (Optional)</li> <li>4.7.3 Patient Info</li> <li>4.7.4 Date/Time Setup</li> <li>4.7.5 Nurse Call Setup</li> </ul>	17 19 19 19 19 21 21 21 22 22 22 22 24 25 25 28 28 29
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional)</li> <li>4.7.2 NIBP Setup (Optional)</li> <li>4.7.3 Patient Info</li> <li>4.7.4 Date/Time Setup</li> <li>4.7.5 Nurse Call Setup</li> <li>4.7.6 System Setup</li> </ul>	17 19 19 19 19 21 21 21 22 22 22 22 22 24 25 25 25 25 28 28 28 29
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional)</li> <li>4.7.2 NIBP Setup (Optional)</li> <li>4.7.3 Patient Info</li> <li>4.7.4 Date/Time Setup</li> <li>4.7.6 System Setup</li> <li>4.7.7 Reset to Factory Default Settings.</li> </ul>	17 19 19 19 19 21 21 21 22 22 22 22 22 24 25 25 25 28 28 28 29 29 30
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li></ul>	17 19 19 19 19 21 21 21 22 22 22 22 24 25 25 25 25 28 28 28 29 29 30 30
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional)</li> <li>4.7.2 NIBP Setup (Optional)</li> <li>4.7.3 Patient Info</li> <li>4.7.4 Date/Time Setup</li> <li>4.7.5 Nurse Call Setup</li> <li>4.7.6 System Setup</li> <li>4.7.7 Reset to Factory Default Settings</li> <li>4.7.8 About</li> <li>4.8 Alarm Settings</li> </ul>	17         19         19         19         19         21         21         21         21         22         22         22         22         22         24         25         25         28         29         30         30         31
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li></ul>	17 19 19 19 19 21 21 21 22 22 22 22 24 25 25 25 28 28 28 29 29 29 30 30 31 32
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li></ul>	17         19         19         19         19         21         21         21         21         22         22         22         22         24         25         25         28         29         30         30         31         32         32
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen (Optional)</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen</li> <li>4.6 Trend Graph Display (for SpO<sub>2</sub> Option)</li> <li>4.7 Setup Menu Screen</li> <li>4.7.1 SpO<sub>2</sub> Setup (Optional)</li> <li>4.7.2 NIBP Setup (Optional)</li> <li>4.7.3 Patient Info</li> <li>4.7.4 Date/Time Setup</li> <li>4.7.6 System Setup</li> <li>4.7.7 Reset to Factory Default Settings.</li> <li>4.7.8 About</li> <li>4.8 Alarm Settings.</li> <li>Chapter 5 Alarms</li> <li>5.1 Alarm Priority</li> <li>5.2 Alarm Signal Generation</li> </ul>	17         19         19         19         19         21         21         21         22         22         22         22         22         24         25         25         25         28         29         29         30         30         31         32         32         32
<ul> <li>3.7 Loading printer paper (if printer is installed)</li> <li>Chapter 4 Operations.</li> <li>4.1 Initial Monitoring Screen</li> <li>4.2 Default Screen</li> <li>4.3 NIBP List Screen (Optional)</li> <li>4.4 SpO<sub>2</sub> Data List Screen (Optional)</li> <li>4.5 Alarm Event List Screen</li></ul>	17         19         19         19         19         21         21         21         21         22         22         22         24         25         25         25         28         29         29         30         31         32         32         32         33

5.5 Verifying Alarm Function	
Chapter 6 Technical Specifications	
6.2 NIBP Monitoring	
6.3 SpO <sub>2</sub> Monitoring	
6.5 Pulse Rate monitoring	
6.6 Data Recording	
6.7 Other Technical Specifications	
6.8 Operating Environment	
6.9 Classification	
6.10 Other Technical Information	
$6.10.1$ Additional description for SpO $_2$ monitoring	
6.10.3 Additional description for NIBP measurement	
6.10.5 Additional description for alarm system	
6.10.6 Additional description for power supply, network and display	
Chapter 7 Packaging and Accessories	
7.1 Packaging	
7.2 Accessories Supplied	
Chapter 8 Monitoring Parameter	
8.1 NIBP Monitoring	43
8.1.1 Measuring Principle	
8.1.2 Factors affecting NIBP measuring	
8.1.3 Clinical Limitations and Contraindications	
8.2 SpO <sub>2</sub> Monitoring	45
8.2.1 Measuring Principle	45
8.2.2 Sources of interference for SpO <sub>2</sub> Measurement	45
8.2.3 Pathological reasons for low SpO <sub>2</sub> measurements	45
8.2.4 Clinical Limitations	45
8.2.5 Points to be noted in SpO <sub>2</sub> and Pulse Measuring	45
Chapter 9 Troubleshooting	
9.1 No Display on the Screen	
9.2 No Blood Pressure and Pulse Oxygen Readings	
9.3 Blank Print-out	
9.4 System Alarm	
Chapter 10 Maintenance	
10.1 Service and Examination	
10.1.1 Daily Examination	
10.1.2 Routine Maintenance	
10.1.3 Battery Maintenance	
10.1.4 Service	
10.2 Cleaning and Disinfection	
10.3 Cleaning and Disinfection of Accessories	
10.4 Storage	
10.5 Transportation	
Chapter 11 Appendix	
11.1 Prompt information explanations	
11.2 Factory Default Alarming Values and Setup Range	50

## **Chapter 1 Overview**

## 1.1 Features

- ♦ Blood Pressure, SpO<sub>2</sub>, and Pulse Rate on large, bright LED display;
- ♦ Color LCD to display plethysmogram;
- Accurate NIBP measurement with hardware and software over-pressure protection, hemostat function is also available by cuff;
- Unique oximetry technique ensures sensitive and accurate SpO<sub>2</sub> and pulse rate measurement, pitch tone function is also available;
- Up to 12000 groups of BP measurements can be stored in non-volatile memory and reviewed by list, the stored data can be uploaded to computer;
- Historic data records can be reviewed in waveform, list or trend graph;
- ♦ Multi-level audible & visible alarm function, nurse call output is available;
- ♦ Option of built-in printer to print out waveform, and text information.

## Note: The monitor you purchased may not cover all the mentioned functions according to its configuration.

## 1.2 Intended Use

This Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of large and small animals, such as dog and cat. With the functions of real-time recording and displaying parameters, such as non-invasive blood pressure, functional oxygen saturation and so on, it allows comprehensive analysis of animal's physiological conditions.

This instrument is applicable for use in hospitals and clinical institutions and should be operated by qualified personnel only.

## 1.3 Safety

- a) This device is defibrillator proof and resistant to interference from electro-surgical units.
- b) This device has a cardiac pace-maker pulse inhibition function.
- c) DO NOT use this device while the patient is under MRI or CT scanning.

#### **Chapter 2 Operating Principle**

#### 2.1 Conformation

The Vital Signs Monitor is a product with modular design, consisting of NIBP module, SpO<sub>2</sub> module, main control unit, printer module (Optional), display panel, and power supply module etc. and the related accessories for NIBP and SpO<sub>2</sub> measurement.

F According to user requirement, you can order the device with different configuration to include the necessary functions. Therefore, your monitor may not have all the monitoring functions and accessories.

- 1. The SpO<sub>2</sub> module detects and calculates pulse rate and functional oxygen saturation (SpO<sub>2</sub>), and provides plethysmogram and perfusion index.
- 2. The NIBP module measures blood pressure non-invasively with way of oscillometric technology, including the diastolic, systolic and mean arterial pressure. The cuffs are designed for big animal and small animal.
- 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 3.1A Front panel illustration for monitor

## Description:



Indicator Color	Alarm Level
Red flashing	High priority alarm
Yellow flashing	Medium priority alarm
Yellow light	Low priority alarm
Green light	Normal

- 2 SYS: display of systolic pressure value.
- **3 DIA:** display of diastolic pressure value.
- 4 "MAP/Time": displays mean arterial pressure at the end of a successful measurement and end time (in Manual or STAT mode) or counting down time (in Auto mode) alternatively. Cuff pressure is displayed during BP measurement or the hemostat function is in use.
- 5 **PR:** display of pulse rate; unit: bpm.
- 6 **SpO<sub>2</sub>:** display of SpO<sub>2</sub> value; Unit: "%".
- 7 " LCD panel
- 8 "": Power button: A long press of the power button will start or shut off the monitor; A short press enters into or exits from power saving mode.
- 9  $\sim$ : AC Power indicator.

Description of AC, DC Power indicator:

	AC Power indicator	DC Power indicator	Descriptions
	ON	ON this device is on and using AC power supply	
Status	OFF ON	ON	the device is on and using built-in battery
	ON	OFF	the device is off and battery is being charged while
		OFF	the AC power is connected.

There are 2 types of display when the NIBP measurement finishes:

1) When NIBP measurement mode is set to "Manual" or "STAT", the mean arterial pressure and the measuring time will be displayed alternately, the time format is "hh:mm".

2) When NIBP measurement mode is set to "AUTO", the count down time will be displayed, the time format is "mm:ss". If the count down time is over one hour, then it displays "hh:mm".

Note: BP value can be displayed in two units, "xxx" mmHg" or "xx.x" kPa, refer to section "4.9.1 NIBP Setup" to set the display unit of BP value. The conversion between two units is: 1kPa=7.5mmHg, 1mmHg=0.133kPa.

11 SpO<sub>2</sub>: SpO<sub>2</sub> sensor connector

- 12 NIBP: NIBP hose connector
- **13 TEMP:** temperature probe connector



14 " O / O ": Patient category indicator: " O " big animal; " O " for small animal.

- 15 "INIBP Setup key: A shortcut key to change NIBP measuring mode and the cycle time for Auto mode.
- 16 "Auxiliary key: Holding this key and NIBP setup key (11) will lock or un-lock key operation. A short press of this key can also enter into or exit from "Power Saving Mode".
- 17 " Alarm silence key.
- 18 "Print. The built-in printer is optional. If installed, press this key to print the current measured data.
- .9 "〓": Bar-graph of pulse intensity.
- 20 ". ": Alarm silence indicator. When it is on, it indicates that the alarm is silenced.
- 21 "SIBP Operation key: press to start/cancel NIBP measurement.
- 22 "Up: shift cursor forward/upward
- 23 "OK: When in setting menu, press it to confirm selection or modification; On history record screen, long pressing this key, then a deleting dialog pops up.
- 24 "Down: shifts cursor backward/downward
- 25 "Display View key: short press to scroll through LCD display views or return to the upper level screen; long press to enter into root setting menu display screen.
- Note: "

Note: A long press would mean press and hold for 2 seconds.

## 3.1.2 Side Panel





The right panel of the monitor is as shown in figure 3.2.

Figure 3.3 Left side of the monitor

→

Symbol for CF type applied part with defibrillation-proof.

♦ "o": reserved port for future use.

The left panel of the monitor is as shown in figure 3.3.

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

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on, while the monitor is shut down, the green light is off. The other is for error indication, when the paper is empty or the printer is out of order, the red light is on.

## 3.1.3 Rear Panel



Figure 3.4 Rear Panel

The rear panel of the monitor is as shown in figure 3.4.

Form 3-1 Real panel Symbols and descriptions

Symbol	Description	Symbol	Description	
	Warning Refer to User Manual	FUSE 2XT1.0AL	Fuse holder	
USB connector		Å	Equipotential terminal	
		G-⊳	Nurse-call connector	

Fuse specification: T1.0AL/250V φ5\*20mm

## 3.1.4 Underside of the Monitor



Figure 3.5 Underside of the monitor

## 3.2 Battery Installation

- 1. Ensure that the monitor is not connected to AC power supply and is turned off.
- 2. Open the battery cover and move the locking bar aside.
- 3. Put the battery into the box and move the locking bar back. Please note that the battery cables should be outward.
- 4. Connect the battery cable plug to the battery power socket in right direction, as shown in figure 3.6.
- 5. Arrange the wires and close the battery cover.



Figure 3.6 Battery Installation

## Warning:

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

## **Caution:**

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

#### 3.3 Installation

- Devices connected to the equipment must meet the requirements of the applicable IEC standards. The system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance with IEC 60601-1-1. If you have any question, please contact the manufacturer or your local dealers.
- If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or else an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.
- C The equipment shall be installed by personnel authorized by manufacturer.
- The software copyright of the equipment is solely owned by the manufacturer. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by an means without due permission.

#### 3.3.1 Unpacking and Checking

- 1. Open the package, take out the monitor and accessories from the box carefully and place them on a safe sand table and surface.
- 2. Open the accompanying document to sort the accessories according to the packing list.
  - Inspect the monitor for any mechanical damages
  - Check all the exposed leads and inserted accessories
  - Check whether any risk or abnormity exists in the device and its accessories before using the monitor. If any abnormity (such as broken cable or crack of the enclosure etc.) is found, stop using this device
- When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.
- Before use, please verify whether the package are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.
- For a Save the packing case and packaging material as they can be used if the equipment must be reshipped.
- The user can customize the module configuration by choosing necessary modules to meet your own needs. Therefore, your monitor may not have all the monitoring functions and accessories.

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

#### 3.3.2 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual. Otherwise, unexpected consequences, e.g. damage to the equipment, could result.

The environment where the equipment is used shall be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances. If the equipment is installed in a cabinet, sufficient space in front and behind shall be left for convenient operation, maintenance and repair. Moreover, to maintain good ventilation, the equipment shall be at least 2 inches (5cm) away from around the cabinet.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

#### 3.4 Getting Started

#### 3.4.1 Connecting to Power Source

#### Using AC Power Source

Make sure that the AC power supply is (100-240)VAC, 50Hz/60Hz.

- Use the power cable provided by the manufacturer. Insert one end of it to the AC power input of the monitor and the other end to the three-pin outlet of the power source with protected-earth.
- To eliminate potential differences, the monitor has a separate connection to the equipotential grounding system. Connect one end of the provided ground wire to equipotential grounding terminal on the rear of the monitor, and connect the other end to one point of the equipotential grounding system.

#### Caution:

#### 1. Ensure that the monitor is grounded correctly.

## 2. If you have any doubt to the grounding layout and its performance, you must use the built-in battery to power the monitor.

- After the mains power supply has been interrupted while power switch remains in the "on" status and is restored after a period of time that is longer than 30 seconds, the monitor will run by the last settings when restarting the monitor.
- $\bigcirc$  The monitor is applicable to connect to the public mains power network.

## **Using Battery**

The following steps should be followed to install the battery:

- Step 1: open the battery cover;
- Step 2: pull out the battery cable and connect it to the battery pack;
- Step 3: push the battery pack into the battery compartment and lock it;
- Step 4: close the battery cover.

## Caution: it's better to recharge the battery after it is used up, and the charging time should be 12~15 hours long.

**Battery life**: Provided that a battery is new and fully charged, the minimal working time of the monitor with accessories connected is declared in the table below:

Name	Battery life	
Monitor	More than 120min	

#### NOTE: when the device is working, It takes at least 10 hours to charge battery from exhaust state to 90% charged.

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



	AC power indicator	Working power supply indicator	Description
	On	Off	The monitor is powered by the AC power supply and it is in off status
Status	Off	On	The monitor is powered by the build-in battery power supply
	On	On	The monitor is powered by the AC power supply and the battery is being charged

#### 3.4.2 Turning the Monitor On

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

- 1. Check all the applicable functions to make sure that the monitor works normally.
- If the built-in battery is applied, please recharge it after using the monitor to ensure sufficient power storage. It will take at least 10 hours to charge battery from depletion to 90% charge.
- 3. Press the Power on/off key on the front panel of the monitor to start the monitor.
- Do not use this device to monitor the patient if there are indications of damage or reminders of error. Please contact the local dealer or our company.
- ♦ The battery powered monitor continues to run without interruption when AC mains power is lost.
- ♦ Start the monitor again 1 minute later after it is switched off.

#### 3.4.3 Starting Monitoring

- 1. Decide which parameter measurements you want to make.
- 2. Connect the required modules, patient cables and sensors.
- 3. Check that the patient cables and sensors are correctly connected.
- 4. Check that the patient settings, such as Patient Type, NIBP measuring mode, etc, are appropriate to your patient.

Refer to the corresponding Section for details of how to perform the measurements you require.

#### 3.5 Turning the Monitor Off

To disconnect the monitor from the power, follow this procedure:

- 1. Confirm that patient monitoring is complete.
- 2. Disconnect patient cables and sensors from the patient.
- 3. Make sure to save or clear the monitoring data as required.
- 4. Press the Power on/off key on the front panel to turn off the monitor.
- Although not recommended, you can press and hold the Power on/off key for 10 seconds to forcibly shut down the monitor when it can not be shut down normally or under some special situations. This may cause loss of data of the monitor.

#### **3.6 Sensor Placement and Connection**

#### 3.6.1 Blood Pressure Cuff Connection

- 1. Connect the cable to the panel connector marked with the NIBP icon.
- 2. Appropriate cuff should be selected according to diameter of the patient's limb or tail. The cuff width should be appropriately 40% of the limb circumference.

Cuff Model	Limb Circumference
#1	(3~6)cm
#2	(4~8)cm
#3	(6~11)cm
#4	(7~13)cm
#5	(8~15)cm

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



Figure 3.7 Demonstration for cuff location

## Notes:

- For cats and dogs, the preferred position for all NIBP measurements is either left or right lateral recumbency for both sedated and awake conditions. This will position the limbs fairly close to heart level and makes it easier to hold an awake animal.
- ⊖ When putting on the cuff, wrap it around the limb evenly to appropriate tightness.
- A Remember to empty any residual air in the cuff before the measurement commences.
- □ Using a cuff that is the wrong size may give false and misleading results.

## Pressure Accuracy Verification

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

Before verification, please connect the monitor to a precise pressure meter such as a mercury pressure mete, which is used as the reference meter.



#### Figure 3.8 Connection of Pressure calibration fixture

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

Big animal	200mmHg
Small animal	120mmHg

Table A

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

#### Mode 2: Manual inflation for the pressure accuracy verification.

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

Big animal	240mmHg	
Small animal	140mmHg	
Table B		

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

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

#### $\bigcirc$ $\$ Please remove the cuff from patient while performing the leakage check.

#### Safety Instructions for NIBP Monitoring

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

#### 3.6.2 SpO<sub>2</sub> Sensor Connection

Please select the appropriate animal type (such as big animal, small animal) and measuring site according to the tissue thickness of the selected animal and measuring site when making measurement of the animal's SpO<sub>2</sub>. Animal type: big animal or small animal; Thinner or

lighter tissues (tissues without bone): animal ear and tongue; Thicker or darker tissues (tissues with bone): leg, claw and tail.

SpO<sub>2</sub> sensor is a kind of very delicate part. Please follow the given steps and procedures while using it. Failure to operate correctly can cause damage to the SpO<sub>2</sub> sensor.

#### $\textbf{3.6.2.1 SpO}_{2} \text{ Sensor Installation}$

The device is equipped with the universal Y-type sensors including different adapters (i.e. clips and wrapper) for different animal type and the various measuring sites, as shown in figure 3.8B and 3.9B. Please select the appropriate sensor adapter according to its shape size and the measuring site. Generally, clip adapter will be more appropriate if the measuring site is ear or tongue; and wrapper adapter will be more appropriate if the measuring site is tail or leg.

## Installation of SpO<sub>2</sub> Sensor with Clips

- 1. Fix the Y-type sensor cable to the slot as shown in figure 3.8A;
- 2. Fix the receiving part and emitting part to the clip, as shown in figure 3.8B. For thinner or lighter tissues (such as ear or tongue), if the transmitted light is too intensive for measurement (no readings), then the user can refer to figure 3.8C to wrap layers of self-adhesive tapes to the receiving part and emitting part, a single layer or 2 layers will be OK.



Figure 3.8 Demonstration for installation SpO<sub>2</sub> sensor with clips



Figure 3.9 Demonstration for installation of SpO<sub>2</sub> sensor with wrapper

Installation of SpO<sub>2</sub> sensor with wrapper

- Before wear the SpO<sub>2</sub> Sensor, please clip the emitting part and receiving part of the Y-type sensor to the round hole and button hole of the cloth wrapper respectively, as shown in figure 3.9A and 3.9B.
- Put the measuring site onto the cloth wrapper (between receiving part and emitting part), then wrap the cloth wrapper and paste the adhesive clip to the cloth wrapper to fasten the measuring site, refer to figure 3.11C and 3.11D. Note: emitting part and receiving part of the sensor should aim at each other. Otherwise, the signal quality and intensity will be affected. If the animal's limb (leg or tail) is too big, then the user can cut the buttonhole longer by scissors, so that the emitting part and receiving part of the sensor can aim at each other properly.

## 3.6.2.2 SpO<sub>2</sub> Sensor Connection

## **Operating procedure:**

1. Connect the port of SpO<sub>2</sub> sensor to one end of SpO<sub>2</sub> extension cable, and close the plastic cover, connection demonstration is as shown in figure 3.10B.



#### Figure SpO<sub>2</sub> sensor connection

2. Connect the SpO<sub>2</sub> extension cable connector to the socket marked with "SpO<sub>2</sub>" on the right signal input panel of the monitor.

3. Put the installed SpO<sub>2</sub> sensor on the appropriate measuring site. The first choice of measuring site for animal is their ears, then the second choice is their legs or tails when the animal is calm or quiet. If there is no steady result can be measured from the mentioned sites above, it's recommended that make measurement on tongue when the animal is under anaesthesia. There are different setting items in this monitor according to the equipped SpO<sub>2</sub> module with different technology. Please make sure that the setting conforms to the actual measuring site. For example, if the measuring site is set as "Ear / Tongue", then the sensor must be clipped on animal's ear or tongue, as shown in figure 3.11A and 3.11B; if the measuring site is set as "Leg / Tail", then the sensor must be wrapped on animal's leg or tail, as shown in figure 3.11A and 3.11B. If the monitor has "Response speed" setting item, then the user can make corresponding selection according to the measurement accuracy and tracking speed. For example, the "Fast" setting can track the quick change of SpO<sub>2</sub> , but it will be less accurate. While the more accuracy can be obtained but wirh slow response if "Steady" setting is seted.





Figure 3.11A clip the sensor on ear

Figure 3.11B clip the sensor on tongue





Figure 3.11C wrap the sensor on leg

Figure 3.11D wrap the sensor on tail



Figure 3.11E Clip the sensor on ear (with tapes wrapped on both sides of clip )

#### Safety Introductions for SpO<sub>2</sub> Monitoring

- The first choice of measuring site is ear, leg or tail. If the measured result is not ideal, then change the measuring site to tongue, but the animal should be under anaesthesia when make measurement.
- If the monitor has configuration item for measuring site (such as ear/tongue, leg/tail), please make sure that the setting conform to be the actual measuring site before make measurement. For example, thin tissues response to ear or tongue, and thick tissues response to leg or tail.
- When measuring on thinner or lighter tissues, it's possible that the sensor's light coming through the very thin tissues is too strong to be properly interpreted by the device, which causing no readings. In this situation, the user can wrap a single or two layers of self-adhesive cloth on the sensor to reduce the intensity of the light hitting the detector.
- If the measured tissue is too thick, then the user can shave off /wet the hair on measuring site, or move to another thinner tissue.
- If the measured tissue is too thin, then the user can move the sensor to other tissues or wrap a single or two layers of self-adhesive cloth on the sensor.
- As a general rule, measuring SpO<sub>2</sub> for animal is performed when the animal is calm or under anaesthesia, and the first choice of measuring site is their ears, then legs, and tail, the last choice is their tongues.
- To avoid make SpO<sub>2</sub> measurement under the light including surgery lamp, halogen lamp, fluorescent lamp and infrared heating lamp.
- ♦ Making effective steps to calm the animal to avoid measurement error.
- Check the device to make sure that there is no visible damage that may affect user's safety or measurement performance with regard to sensors and clips. It is recommended that the device should be inspected minimally before each use. If there is obvious damage, stop using the device.
- Special attention should be paid while the SpO<sub>2</sub> sensor is used constantly under the ambient temperature over 37°C, burning hurt may occur because of over-heating of the sensor at this situation.
- Continuous use of finger clip adapter 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 tissue for over two hours, change the measuring site periodically if necessary.
- ♦ Change the measuring site every 2 hours if the ambient temperature over 35°C.

- SpO<sub>2</sub> measuring position must be examined more carefully for some special patient. Do NOT place the SpO<sub>2</sub> sensor on the limb with edema or fragile tissue.
- Do NOT put the SpO<sub>2</sub> sensor and pressure cuff on the same limb, otherwise the NIBP measuring will affect SpO<sub>2</sub> measuring and cause the alarm error.
- E The SpO<sub>2</sub> sensor cannot be immerged into water, liquor or cleanser completely, because the sensor has no capability to resist the harmful ingress of water.
- $\triangle$  When plugging or unplugging the SpO<sub>2</sub> sensor, be sure to hold the head of the connector and pull it out.
- $\bigcirc$  Check the SpO<sub>2</sub> sensor and cable before use. Do NOT use the damaged SpO<sub>2</sub> sensor.
- $\bigcirc$  When the temperature of SpO<sub>2</sub> sensor is abnormal, do not use it any more.
- Please do not allow the cable to be twisted or bended.
- Do NOT use the damaged SpO₂ sensor.

#### 3.7 Loading printer paper (if printer is installed)

#### **Operation procedures for loading printer paper:**

- 1. To open the printer cover, press two thumbs firmly on both "OPEN" notches.
- 2. Move the tab of the left rubber roller lock 90° upwards to unlock it, refer to the following figure with mark (1).
- 3. Cut one end of the paper into a triangle, and load the paper from the underside of the rubber roller.
- 4. Turn the roller clockwise to roll the paper rolled, and put the paper roll into the compartment.
- 5. Pull the paper out of the 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 printer paper roll:

- Steps 1~2: Same as above.
- Steps 3. Roll the loading roller anti-clockwise and pull the paper out.
- Steps 4~5: As steps 6~7 above.



#### P8 printer may be used due to the different configuration

#### P8 printer operation instruction:

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

Error indicator: red light which shows the printer is out of paper or the printer paper is not properly installed. When the printer successfully installs, the red light is off.



Figure 3.12 P8 printer

## Loading printer paper:

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

Step 2: Install the paper to the printer properly, pull the paper out of the printer for 2 cm, as shown in figure 3.13.

Step 3: Close the printer cover along the direction of arrow, as shown in figure 3.13.



Figure 3.13 printer paper

## **Chapter 4 Operations**

This chapter introduces the display screen and operating instructions, including the initial screen, default screen, system menu, menu setup and data upload. Before operating the monitor, please refer to the related section for connecting the accessories.

## Note: The monitor you purchased may not cover all the mentioned functions according to its configuration.

#### 4.1 Initial Monitoring Screen

To switch on the monitor, press and hold the " power key. When you hear a "beep", the LCD will display as shown in figure 4.1, which means that the monitor has started successfully.



#### Figure 4.1 Startup screen

A short press of the power key " will switch between power saving modes and full power mode. Power saving modes mean the LED and LCD display become darker, the brightness has two levels.

A long press of the power key """ will give a black screen as the displays turn off and means that the monitor has shut down successfully.

## 4.2 Default Screen



Figure 4.2 Default monitoring screen (monitor with SpO<sub>2</sub> and NIBP function only)

#### Title line:

- $\diamond$  "**T**000": the ID number of the patient currently being monitored.
- "2014/07/28 22:08": the current date and time, year/month/day hour:minute.
- ♦ "<sup>¬</sup> ··· key-lock icon, when this icon appears, it means that the key operation is disabled.

Note: the key-lock status can be set at any screen view by combining the given keys. During key-lock status, all key operations are disabled except Power button and combination keys for unlocking operation.

- "Image: net connection icon, indicates that the device is connected to the network. If the device is disconnected from the network, then the icon will disappear.
- ♦ "■■": battery voltage indicator.
- ♦ "PLETH": indicating the displayed waveform is plethysmogram.

#### Waveform area:

#### Note: PI function is optional, please refer to the monitor in your hand, we will not cover it again.

If the accessories are connected incorrectly or disconnected from the monitor, the message "Probe off" will appear on the screen.

## NIBP list area:

When blood pressure measurement is taken, the data display area displays the recent 4 groups of data, the form is as shown in figure 4.2.

- $\diamond$  "Time": the measuring time.
- ♦ "SYS/DIA/MAP": systolic/diastolic/arterial mean pressure.
- "PR": the measured pulse rate from the blood pressure measuring channel or the pulse rate value from oximetry measuring channel. The PR value from oximetry will take priority in the display.
- $\diamond$  "SpO2": oxygen saturation (SpO<sub>2</sub> for short).
- ♦ "HR": the heart rate.

## Note: 1. If the device is re-started, the data in the list data area will be cleared.

#### 2. Invalid values will be displayed as "--"

#### Prompt Info. area:

- ♦ "MAP over-limit": displays a message for current alarm event indicating that the measured MAP value exceeds the preset value.
- $\diamond$  = "Mute 112 🏯": display the status of the alarm silence, and the counting down the time that the alarm sound is silenced for.

A shows that the alarm sound is enabled; A shows that the alarm sound is silent temporarily for 120 seconds; A shows that the alarm sound is disabled.

#### **Operation instruction:**

- Short pressing the display view " key to shift screen views.
- > Long press the display view " " key to enter into Menu setup screen.
- Hold Auxiliary key " firstly, then press NIBP setup key " , by doing this it can lock / unlock key operation.

Note: This function is available in any screen view, we will not cover it again in the following.

Short press the print key " to activate printing with the format specified by "Setup Menu $\rightarrow$ System $\rightarrow$ Print" if the printer is installed.

Note: there are several screen views (depending on your configuration): default screen, NIBP list screen, SpO<sub>2</sub> data list screen, alarm event

list screen, screen for graphic trend . The following sections will describe each screen.

## 4.3 NIBP List Screen (Optional)

Note: the screen below is only for the monitor with NIBP function.

The NIBP List screen is as shown in Figure 4.3.

<mark>;</mark> 000	2014/07/28 2	2:08 <del>-</del> 0	
PID	Date/Time	SYS/DIA/MAP	PR
001	2014/12/22 09:21:20	78/99/82	8
001	2014/12/22 09:21:09	78/99/82	7
001	2014/12/22 09:20:56	78/99/82	6
001	2014/12/22 09:20:45	78/99/82	5
001	2014/12/22 09:20:30	78/99/82	4
001	2014/12/22 09:15:45	78/99/82	3
001	2014/12/22 09:15:21	78/99/82	2
001	2014/12/22 09:15:08	78/99/82	1
N	IIBP leak in gasrun		¢

## Figure 4.3 NIBP List

In this screen, the first column is the patient ID, the second column is NIBP recording time, the third column is NIBP value, and the fourth column is pulse rate (measured by NIBP module).

## **Operating instruction:**

- Short press the Up "O" or Down " " key to turn to previous or next page for view other NIBP records.
- Short press the Print " key to print the current NIBP list.
- Long press the OK " " key to bring up a dialogue for deleting data records where the user can choose to delete all NIBP data records.

## 4.4 SpO<sub>2</sub> Data List Screen (Optional)

## Note: the screen below is only for the monitor with SpO<sub>2</sub> function.

SpO<sub>2</sub> data list screen is as shown in Figure 4.4.

000	2014/07/28 22:08		
PID	Date/Time	SpO2	PR
001	2014/12/22 13:34:02	98	74
001	2014/12/22 13:33:54	97	71
001	2014/12/22 13:33:54	98	72
001	2014/04/02 17:04:31	97	71
001	2014/04/02 17:04:19	98	71
SpO2 over limit		Mute	111 🎘

## Figure 4.4 SpO<sub>2</sub> data list screen

In this screen, the first column is the patient ID, the second column is SpO<sub>2</sub> recording time, the third column is SpO<sub>2</sub> value, and the fourth column is pulse rate (measured by SpO<sub>2</sub> module).

## **Operating instruction:**

- Short press the Print " key to print the current SpO<sub>2</sub> list.
  - > Long press the OK " ( key to bring up a dialogue for deleting data records, where the user can choose to delete all SpO<sub>2</sub> data records.

## 4.5 Alarm Event List Screen

The Alarm Event List screen is as shown in Figure 4.8.

<mark>¦</mark> 000	2014/07/28 22:08	-	ю 🛄
Date/Time	Event	Value	Hi/Lo
12/22 09:21	SYS over limit	99	90/60
12/22 09:21	SYS over limit	99	90/60
12/22 09:21	SYS over limit	99	90/60
12/22 09:21	SYS over limit	99	90/60
12/22 09:21	SYS over limit	99	90/60
12/22 09:21	NIBP signal weak		
12/22 09:21	NIBP signal weak		
12/22 09:21	SYS over limit	99	90/60
Over motion			\$

## Figure 4.5Alarm event list

In this screen, the first column is the time that the alarm occurred (format is month-day hour:minute), the second column is the event description, the third column is the onset value, and the fourth column is the high/low limit value.

Short press the " or " O " key to scroll to previous/next page for view other alarm events. Note: if the event description

is too long to be shown, pressing the OK key can show the full description, but the third and fourth column will not be displayed.



Long press the " Very wey to bring up a dialogue for deleting data records, where the user can choose to delete all alarm events data.

## 4.6 Trend Graph Display (for SpO<sub>2</sub> Option)

The trend graph display screen is as shown in Figure 4.6.



Figure 4.6 Trend Graph screen

## Screen description

- "SpO<sub>2</sub>": SpO<sub>2</sub> trend graph. If the monitor has ECG function, then "SpO<sub>2</sub>" and "HR" can be optional.
- "12 hours": the trend length of SpO<sub>2</sub> trend graph; there are three options: "12", "24" or "96" hours. Press OK "
   "
   "
   the trend length from "12 Hour", "24 Hour" and "96 Hour", then the trend graph will display the SpO<sub>2</sub> trend curve for the selected period.
- Cursor on": enables the display of cursor on the trend graph, i.e. the vertical cursor line will be displayed in the trend graph, so

the user can move the cursor by pressing the up/forward " $\bigcirc$ " and down/backward " $\bigcirc$ " keys to inspect the SpO<sub>2</sub> value at the given time.

- "SpO<sub>2</sub>": indicates that the trend graph is for SpO<sub>2</sub>, and the value below it shows the SpO<sub>2</sub> value at the cursor position.
   It can be "PR" by selection.
- ♦ "Date/Time": the starting time of the trend graph.

Instructions for viewing the trend graph:

Select "cursor on" and press the OK " 🔍" key to confirm, and "cursor on" switches to "cursor off". You can then press the up

". We we to move the vertical cursor and the list box below will display  $SpO_2/HR$  value and the time value at the point where the cursor resets. Moving the cursor back and forth this way, you can view the  $SpO_2/HR$  trend (12/24/96 hours long).

Press " 🖤" key again to exit trend viewing.

- > When pressing " or " V is the to move the cursor, the increment is variable. The rule is that the initial step is 1, after
  - pressing the "O" or " O" key in the same direction 5 times, the step becomes 5, and with 5 more pressing the step

becomes 10, then 20. Pressing the other " ar " " or " " key will revert the step back to 1 in the other direction.

- > Long press the " ( key to bring up a dialogue for deleting data records, where the user can choose to delete all trend data.
- > Short press the print" " key to print this trend graph.

#### 4.7 Setup Menu Screen

The Setup Menu screen is the main menu screen and a long press of Display View " view will enter into the Setup Menu screen, as shown in Figure 4.7.

# Note: your monitor may not cover all the functional parameter settings listed in the main menu screen. Please refer to the monitor you purchased.



Figure 4.7 Root setup menu screen (refer to your monitor)

There are up to 10 functional groups for setting parameters: "SpO<sub>2</sub>, NIBP, TEMP, Patient Info, Date/Time, Nurse Call, Network, System Setup, Default and About" on the Setup Menu Screen depending on the configuration of your monitor.

## Instructions for navigation parameters:



Note: the device will save the latest setup settings automatically and the most of saved settings are non-volatile, i.e. when you shut down the device and power up it next time, every setting item shows the settings saved last time except the items like ECG cable setting and NIBP working mode.

## 4.7.1 SpO<sub>2</sub> Setup (Optional)



Figure 4.8 SpO<sub>2</sub> Setup Screen

The  $SpO_2$  setup screen is as shown in figure 4.8, please refer to the monitor in your hand.

#### **Screen Description:**

"Hi/Lo": high and low alarm limit for SpO2.

♦ "PR ALM": pulse rate alarm switch. This is set "ON" and the user cannot adjust it.

"Hi/Lo": high and low alarm limit for PR.

↔ **"PI% display": PI display switch.** "v" means PI display is enabled, "×" means PI display is disabled.

#### 4.7.2 NIBP Setup (Optional)

• 000	NIBP	
SYS ALM 🖌	Hi 140	Lo 90
DIA ALM	Hi 99	Lo 60
MAP ALM	Hi 120	Lo 80
Initial pressure 150		Unit mmHg
NIBP Mode Manua I	Lock 🖌	More 》
MAP over limi	t	4

Figure 4.9 NIBP Setup

#### **NIBP Setup Screen Description:**

SYS ALM, DIA ALM, MAP ALM are set "ON" and the user cannot adjust them.

♦ "SYS ALM": systolic pressure alarm switch.

"SYS Hi/Lo": high and low alarm limit for systolic pressure

♦ "DIA ALM": diastolic pressure alarm switch.

"DIA Hi/Lo": high and low alarm limit for diastolic pressure.

♦ "MAP ALM": mean arterial pressure alarm switch.

"MAP Hi/Lo": high and low alarm limit for mean arterial pressure.

Initial pressure: Initial cuff inflation pressure to be inflated initially, its range is different depending on patient type. Setting range for big animal is 120~280mmHg, and for small animal is 60~280mmHg.

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

- ♦ "Unit": the pressure unit. mmHg and kPa for optional.
- \* "NIBP Mode": NIBP measuring mode, "Manual", "Custom", "AUTO 1", "AUTO 2", "AUTO 3", "AUTO 4", "AUTO 5", "AUTO 10", "AUTO 15", "AUTO 20", "AUTO 30", "AUTO 40", "AUTO 50", "AUTO 60", "AUTO 90", "AUTO 120", "AUTO 240 and "AUTO 480" are optional. "AUTO 1" means NIBP measurement takes once every minute automatically; "AUTO 480" means NIBP measurement takes once every 480 minutes automatically; In AUTO mode, the count-down timer is displayed in MAP (Time) segment on upper right corner.

Note: when "Custom" mode is selected, the user can customize the related parameters: Phase, time cycle (the time interval between two measurements) and repeats. There are 5 phases: A, B, C, D and E. The user can set the time cycle (for auto blood pressure) and repeats for Phase A to Phase E.

- > Time cycle: 1min, 2min, 3min, 4min, 5min, 10min, 15min, 20min, 30min, 45min, 60min and 120min for optional.
- **Repeats**: OFF, 1, 2, ...9 and 10 for optional.

For example, firstly, the monitor enter into Phase A (making NIBP measurement once every 5 minutes, and repeat once only); Secondly, entering into Phase B (making NIBP measurement once every 10 minutes, and repeat once only); Thirdly, entering into Phase C (making NIBP measurement once every 20 minutes, and repeat 2 times); Fourthly, entering into Phase D (making NIBP measurement once every 30 minutes, and repeat 5 times); Lastly, entering into Phase E (making NIBP measurement once only). In the period of 30 minutes, if the NIBP measurement is less than 6 times and NIBP measurement mode is not changed, then the monitor will start to make NIBP measurement from Phase A to E automatically.

- "Lock": select "v" means that the cuff inflation pressure is locked at the initial setting value. After "Lock" item is selected, the cuff inflation pressure will not adapt according to the last NIBP measurement result, it will be fixed at the preset initial inflation pressure when you make the following NIBP measurement.
- \* "More >> ": page down icon. Move the cursor to the last item ("Lock"), then short press the Down " " key to enter into NIBP verification setup screen, as shown in figure 4.10.

<b>†</b> 000	NIBP				
Verificati	on Mode 1		Start		
Verificati	on Mode 1	9	Start		
Air Leak	age	-	Start		
				Back >>	
NIBP lea	ik in gasrun			Mute 70	À

#### Figure 4.10 NIBP verification setup screen

#### Screen description:

- "Verification mode 1": Pressure is generated automatically by the internal pump. Move the cursor to NIBP Verification mode 1
   "Start" button, and press the OK button to begin the pressure meter verification. (During this process, the "Start" shifts to "Stop", after the verification the "Stop" shifts to "Start").
- "Verification mode 2": Pressure is coming from an external source. Move the cursor to NIBP Verification mode 2"Start" button and press the OK key to begin the pressure meter verification. (Again, the "Start" shifts to "Stop" during this process, after the verification the "Stop" shifts to "Start").
- "Air leakage": Checks the air leakage in the pneumatic system. Move the cursor to Air Leakage "Start" button, then press the OK key. The pump inflates to certain pressure and then the valve will be closed to detect leakage for 10 seconds. The pressure will be released automatically and the screen will display the result.
- ♦ If the following messages pop up, then NIBP measurement should be stopped.
  - 1) Pressure verification...
  - 2) Air leakage preparing...
  - 3) Air leakage countdown...
  - 4) Air leakage in 10s:...

#### Safety instruction:

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

#### NIBP setup screen description:

Short press the NIBP setup " key to enter into NIBP setup screen, as shown in figure 4.11.

In NIBP setup screen, short press the "O" key to select measuring mode. Press NIBP measuring "S" key to confirm the setting

and exit from setup screen. Short press the display view "

Press up/down keys to select patient type.

- ♦ NIBP Mode: select NIBP measuring mode.
- ♦ Category: select NIBP measuring patient category, "Big Animal" and "Small Animal" for optional.

001	NIBP	
NIBP Mode	Manual	
Category	Small Animal	
		Mute Ӓ

Figure 4.11 NIBP setup screen

## 4.7.3 Patient Info



Figure 4.13 Patient Info. setup screen

#### Screen description:

- ♦ "Patient Name": to enter the patient's name.
- Sufferer ID": change or set current sufferer's ID number, 0~100 adjustable; Once the sufferer ID is changed, the history data in trend graph will be cleared, and the parameter settings will be resumed to default value.
- "Category": change or set the category of current patient; two options "Big Animal" and "Small Animal", press OK key to confirm the setting and the patient type indicator will be ON at the front panel of the device. The default is "Big Animal".

## 4.7.4 Date/Time Setup

🛉 001	Date/Time	<u> </u>
YY 2000	MM 01	DD 06
HRS02	MIN 30	SEC 21
Date format	YYYY-MM-DD	
		Mute 💢

Figure 4.14 Data/Time Setup Screen

#### Screen Description:

- "YY 2000 MM 01 DD 06": date setting.
- "HRS 02 MIN 30 SEC 21": time setting.
- Date Format: 4 options.

#### 4.7.5 Nurse Call Setup



Figure 4.15 Nurse Call Setup Screen

#### Screen Description:

- ♦ "Output level": two options "low" or "high" output levels are available.
- "Duration": two options "pulse" and "continuous" output modes are available with the Output level and Duration shown below.

Output level	Duration	Output (format)
High	Continuous	0 12
Low	Pulse	0 <sup>12</sup>
High	Continuous	120
Low	Pulse	<sup>12</sup>

"Source": three kinds of alarm sources can trigger the nurse call: high level alarm, medium level alarm and low level alarm (multi-optional). After selecting the alarm level, the device will send out the nurse call signal according to "Source" and "Output level". If you don't select any source, nurse call signal will not be generated (Note: multiple "Source" selection can be chosen.)
 Note: Nurse Call function cannot be regarded as the main alarm notification method, please do not rely on it alone. You should

combine parameter values with alarm level and patient's clinical behavior and symptom to determine patient's condition

#### 4.7.6 System Setup



Figure 4.17 System Setup Screen

#### Screen Description:

♦ "Alarm Vol.": sets alarm volume, adjustable from leve"1~10" with a factory default of 5. It is recommended that the alarm

volume shouldn't be set lower than the factory default value unless the nursing personnel attends the patient and the device at all times.

- ☆ "Key tone": turns on/off the key tone, the default is "ON".
- ↔ "Priority": this item is nonadjustable, fixed to give priority to the "HR" value display.
- "Run mode": "Real" should be set as default use. "Demo" only for demonstration purpose. Changing this item requires a password, the default password is "1234".

"Demo" shows a demonstration waveform and data, which are generated by the monitor.

"Real" shows the real signal waveform and data coming from patient, i.e. normal working state.

- ★ "Beat beep": adjusts the volume of the pulse beeping sound and is adjustable from level "0~7". "0" switches off the pulse beep sound, the factory default is set at"2". The tone of pulse beat beep changes when the measured SpO<sub>2</sub> changes i.e. the higher the SpO<sub>2</sub> value is, the higher the tone of the pulse beep (which becomes sharper); and the lower the SpO<sub>2</sub> value is, the lower the tone of the pulse beep.
- "Print Mode": sets the printing time for real-time printing mode with the options of "Continue", "10s", "20s", "30s" and "60s" for optional. "Continue" means that the device will not stop printing the real-time plethysmogram until the user change the display screen or press the print key again.

XXs: prints the real-time plethysmogram lasting for XX seconds.

#### Note: the gray background means this item is nonadjustable.

#### 4.7.7 Reset to Factory Default Settings



## Figure 4.18 Default setting

#### 4.7.8 About

This displays the software version and serial number, as shown in figure 4.19, refer to the monitor for detailed information.



Figure 4.19 About

## 4.8 Alarm Settings

Press the alarm silence "

"key to set the alarm sound status.

There are 3 options in total:

- ♦ Alarm sound is enabled, which is the default status..
- Short term alarm silence (120 seconds): a short press of the alarm silence key will display the red icon ", ", on the lower screen and the message "silence count-down time 120". At this time, the alarm silence indicator on the left side of the alarm silence key will be lit. The device will mute the alarm sound temporarily for 2 minute, ", ut keep the visual alarm flashing. When the time (120s) is up, the alarm silence will be de-activated automatically, the red icon ", will disappear as well, and the alarm silence indicator will be dark.
- Long term alarm silence: long press the alarm silence key will be display the red icon "A" on the lower screen and the alarm silence indicator on the left side of the alarm silence key will be lit. The device will mute the alarm sound on an ongoing basis but keep the visual alarm flashing untill a new type of alarm every s detected. The alarm silence status will then be terminated automatically and the alarm sound will resume, the red icon "A" will disappear as well, and the alarm silence indicator will be dark.

Note: If the current status is alarm silence, a long or short press of the alarm silence key can de-activate the alarm silence function.

## 4.9 Data Uploading

When connected to a computer via USB, the device enters into data uploading mode, as shown in figure 2.20.



Figure 4.20 Data uploading screen

In data uploading mode, the device will automatically stop SpO<sub>2</sub> measurement, NIBP measurement, pressure verification and air leakage checks etc., and all key operations will be disabled except power "

## **Chapter 5 Alarms**

## 5.1 Alarm Priority

## Low Priority:

NIBP over range

Temp over range SpO<sub>2</sub> Probe off NIBP error message

SpO<sub>2</sub> error message

#### Medium Priority:

HR over range

## High Priority:

SpO<sub>2</sub> over limit SYS over limit DIA over limit MAP over limit PR over limit Can not detect SpO<sub>2</sub> Can not detect PR

## 5.2 Alarm Signal Generation

When there is alarm condition, the monitor generates alarm signal with visual indications (which are shown by two ways: LED indicator with different color and textual message display) and audible indication.

## **Visual Alarm Indication**

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

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

Table 5.1

Refer to Chapter 11.2 Alarm Information for detailed alarm message descriptions.

#### Audible Alarm Indication

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

Alarm Category	Tone Pitch	Beep Chain
High priority alarm	~400Hz	10 beeps pause 3 sec.
Medium priority alarm	~500Hz	3 beeps pause 5 sec.

	Low priority alarm	~500Hz	Single beep
-			Table 5.2

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

#### 5.3 Alarm Reset and Silence

Press A (Alarm Silence) key to pause the audible alarm temporarily or reset the current alarm condition. During the monitoring process, press "Alarm Silence" key shortly to start the alarm silence for 2 minutes. The counting down time shows up on the upper left corner of the screen once the alarm silence is activated. Long pressing "Alarm Silence" key will reset the current alarm condition, that means the sound mute for this alarm will not resume unless another alarm condition occurs. During the alarm silence period, if there is a new alarm condition other than the current one occurs, the device will generate the audible alarm indication again automatically. After the end of alarm silence period, if the current alarm condition still exists, then the audible alarm indication will resume as well.

When the monitor generates alarms, the user can press  $\bigotimes$  key to reset or pause the audible alarm indication for a given silence period when necessary.

- DO NOT silence the audible alarm or decrease its volume if patient safety could be compromised.
- For the alarm conditions of "Can not detect SpO<sub>2</sub>" and "Can not detect HR/PR", the audible alarm indication will only last for about 7 seconds.
- Alarm signal can be reset, but it can NOT be deactivated all the time.

## 5.4 Alarm Settings

- Except volume of audible alarm can be adjustable, the other properties of the alarm signal cannot be adjusted by the user, such as alarm priority setting, alarm light flashing and so on. In addition, all alarms in this monitor are "non-latched" type, that is to say, when the alarm condition does not exist, the corresponding alarm signal will automatically stop.
   The alarm volume range is shown as below:
  - $\diamond$  High: 45dB $\sim$ 80dB (The distance from the front of device to the test instrument is 1m)
  - $\diamond$  Medium: 45dB $\sim$ 75dB (The distance from the front of device to the test instrument is 1m)
  - $\diamond$  Low: 45dB $\sim$ 70dB (The distance from the front of device to the test instrument is 1m)
- 2、 When the icon 🖄 displays on the screen and its color is red, that means the alarm volume is 0 (alarm is mute), at this time the user should pay more attention to the patient.
- L It is suggested that the users should not change the alarm volume lower than the factory default setting if close and constant attention could not be paid to the patient, otherwise the negligence of alarm event might cause irreversible harm to the patient.
- During the alarm silence period, any new alarm event can activate the audible alarm again and the audible alarm function resumes normal state.
- After the alarm silence time counts down to 0, or the operator presses the Alarm Silence Key again, then the system will resume to the audible alarm signal if this alarm condition still exists.
- A The alarm limit value should NOT be set to exceed the declared measuring or display range, or the system alarm signal will not be generated.
  - 3. Alarm settings are non-volatile, that means the previous settings will still sustain if the monitor is powered off (by accidental power interrupt or by normal power down) and reboot.
  - 4. When pressing the Alarm Silence Key, the system will stay on "Alarm Silence" status and this status will last for 2 minutes.
  - $5_{s}$  It takes only 1 second from canceling alarm silence to resuming alarm sound .

Long press of Display View " " key to enter into the Setup Menu screen, and move the cursor to each parameter (such as SpO<sub>2</sub>, NIBP...) to make the high/low limit setting.

Limits setup: Move to the High or Low limits of the alarm settings, and press the "Alarm" silence key to turn ON or OFF the alarm for the setting. The alarm silence indicator will reflect this with a yellow light showing that alarms are silenced. Refer to Chapter 11.2 for detailed default alarming values of all parameters and setup range.

- Whenever the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.
- ♦ When mains power supply is lost for not more than 30s, the alarm settings prior to the power interrupt will sustain or be restored automatically.

## 5.5 Verifying Alarm Function

To verify the effectiveness of the alarm function, set the monitor working at "Demo" mode in system parameter settings menu. Adjust the alarm limits or change alarm setting, then pay a close attention to the alarm signal. If the visual and audible alarm indications appear according to your setting, it means the alarm function is effective. Do NOT set the alarm volume lower than the background noise.

#### **Chapter 6 Technical Specifications**

#### 6.2 NIBP Monitoring

- 1. Measuring method: Oscillometric Technique
- 2. Pneumatic pressure measuring range: 0 mmHg~300mmHg
- 3. Transducer Accuracy: ±3 mmHg up to full range
- 4. Cuff inflation time: <10 seconds
- 5. Average measurement time: < 90 seconds
- 6. Air release time while the measurement is canceled: ≤2 seconds
- 7. Initial cuff inflation pressure
- Big animal: 160 mmHg Small animal: 140 mmHg
- 8. Overpressure protection limit: 300 mmHg
- 9. NIBP measurement range:

Pressure (unit)		Big animal
SYS	mmHg	40~265mmHg
DIA	mmHg	20~200mmHg
MAP	mmHg	27~222mmHg
PR	mmHg	25~300mmHg

10. NIBP measurement accuracy:

Maximal mean difference: ±5 mmHg Maximal standard deviation: 8 mmHg

Measurement mode: Manual, Auto,

#### 6.3 SpO<sub>2</sub> Monitoring

1. Transducer: dual-wavelength LED

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

Maximal optical output power: less than 2mW maximum average

- 2. SpO<sub>2</sub> measuring range: 0%~100%
- 3. SpO $_2$  measuring accuracy: Arms is not greater than 3% for SpO $_2$  range from 70% to 100%

\*NOTE: Arms is the accuracy defined as root-mean-square value of deviation according to ISO 80604-2-61

4. Low perfusion performance: the declared accuracy is attained when the pulse amplitude modulation ratio is as low as 0.3%.

#### 6.5 Pulse Rate monitoring

- 1. Pulse rate measuring range: 30bpm~400bpm
- 2. Pulse rate measuring accuracy: ±2bpm or ±2% from range 30 to 250bpm, whichever is greater.

#### 6.6 Data Recording

- 1. Sensitivity selection tolerance: ±5%
- 2. Recording speed: 25mm/s
- 3. Recording speed accuracy: ±10%
- 4. Hysteresis: ≤0.5mm
- 5. Frequency response: 0.5~40Hz for normal mode, 0.05~40Hz for enhanced mode.
- 6. Time constant: ≥0.3s for normal mode, ≥3.2s for enhanced mode.

#### 6.7 Other Technical Specifications

- 1. AC power supply voltage: 100~240VAC
- 2. AC power frequency: 50/60 Hz
- 3. Battery specification: 11.1V/4400mAh (Li-ion Battery)

#### 6.8 Operating Environment

#### **Working Environment**

Ambient temperature range: 5°C ~ 40°C

Relative humidity: 30 ~ 80%

Atmospheric pressure: 70kPa ~106kPa

#### **Transport and Storage Environment**

Ambient temperature range: -20°C ~ 60°C

Relative humidity: 10 ~ 95%

Atmospheric pressure: 50.0kPa ~107.4kPa

#### 6.9 Classification

Safety standard	IEC 60601-1
The type of protection against electric shock	Class I equipment.
The degree of protection against electric shock	Type BF, CF applied parts
Electro-Magnetic Compatibility:	Group I, Class A

#### 6.10 Other Technical Information

#### 6.10.1 Additional description for SpO<sub>2</sub> monitoring

- The device is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. Any SpO<sub>2</sub> simulators should not be used to validate the accuracy of the oximeter, they can only be used as functional testers to verify its precision. The SpO<sub>2</sub> accuracy claimed in this manual is supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark skinned subjects in an independent research laboratory.
- 2. If it is necessary to verify the precision of the oximeter routinely, the user can do the verification by means of SpO<sub>2</sub> simulator, or it can be done by the local third party test house. Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO<sub>2</sub> simulator, e.g. for Index 2 series SpO2 simulator from Fluke Biomedical Corporation, please set "Make" to "DownLoadMake: KRK", then the user can use this particular R-curve to test the oximeter. If the SpO<sub>2</sub> simulator does not contain "KRK" R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO<sub>2</sub> simulator.
- 3. The average data update period:  ${\leq}10s$

#### 6.10.3 Additional description for NIBP measurement

The blood pressure measured by this device is essentially identical to that measured by auscultatory method.

#### 6.10.5 Additional description for alarm system

- 1. Alarm indication: audial and visual alarm signal
- 2. Audial alarm:
- High priority alarm: one group pulse string including 10 pulse; x, x, 2x + td, x, 1s, x, x, 2x + td, x, and x=100ms, the pulse duration is160ms, pulse frequency is 400Hz, the pulse string interval is 3s.
- Medium priority alarm: one group pulse string including 3 pulse, the pulse string interval is y, y, and y=200ms, the pulse duration is200ms, pulse frequency is 500Hz, the pulse string interval is 5s.
- ♦ Low priority alarm: the unrepeatable single pulse, frequency is 500Hz, and pulse duration is 200mx.
- 3. Visual alarm: The visual alarm includes the LED indicator located on the upper front panel of the Monitor, the numeric readings

flashing, and the alarm message displayed on the bottom of the LCD screen. Alarm indicator frequency and color see below:

Alarm LED indicator: High-priority: red light flashing with 2Hz frequency and 50% duty ratio

Low priority: Yellow light flashing with 2Hz frequency and 50% duty ratio

Medium priority: Yellow light on

No alarm: Green light on

Numeric reading alarm: the reading value flashing reversed color display

4. Alarm reset and silence: see Section 4.10.

## 6.10.6 Additional description for power supply, network and display

1. Power supply: main power supply: AC 100V~240V, 50Hz/60Hz

Internal power supply: 11.1VDC

- 2. Input power: <45VA
- 3. The minimum working time when operating with all accessories by internal power supply: 270 min.
- 4. Network connection: Ethernet network
- 5. Display panel: color TFT LCD
- 6. Working modes: Demo mode and Real-time mode

## 6.11 Guidance and manufacturer's declaration-Electromagnetic compatibility

Table 1

## Guidance and manufacturer's declaration-electromagnetic emission for all EQUIPMENT AND SYSTEM

Vital Signs Monitor is intended for use in the electromagnetic environment specified below.		
The customer or the user of the e	equipment or system s	should assure that it is used in such an environment.
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions	Group 1	Vital Signs Monitor uses RF energy only for its internal function.
CISPR 11		Therefore, its RF emissions are very low and are not likely to cause any
		interference in nearby electronic equipment.
RF emissions	Class A	Vital Signs Monitor is suitable for use in all establishments other than
CISPR 11		domestic and those directly connected to the public low-voltage
		power supply network that supplies buildings used for domestic
Harmonic emissions	Class A	purposes.
IEC61000-3-2		
Voltage fluctuations/flicker	Complies	
emissions		
IEC61000-3-3		

## Table 2

## Guidance and manufacturer's declaration-electromagnetic immunity

## for all EQUIPMENT AND SYSTEMS

Vital Signs Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the			
equipment or system should a	ssure that it is used in such an e	nvironment.	
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge(ESD)	±6 kV contact	±6 kV contact	Floors should be wood, concrete or
IEC61000-4-2	±8kV air	±8kV air	ceramic tile. if floors are covered with
			synthetic material, the relative humidity
			should be at least 30%
Electrical fast transient/burst	±2kV for power	±2kV for power	Mains power quality should be that of a
	Supply lines	Supply lines	typical commercial or hospital
IEC61000-4-4	±1 kV for	±1 kV for	environment.
	input/output lines	input/output lines	
Surge	±1kV line (s) to line(s)	±1kV differential mode	Mains power quality should be that of a
IEC 61000-4-5	±2kV line(s) to earth	±2kV common mode	typical commercial or hospital
			environment.

Voltage dips, short	<5 % U <sub>T</sub>	<5 % U⊤	Mains power quality should be that of a
interruptions and voltage	(>95 % dip in U <sub>T</sub> )	(>95 % dip in U <sub>T</sub> )	typical commercial or hospital
variations on power supply	for 0,5 cycle	for 0,5 cycle	environment. If the user of the
input lines	40 % U <sub>T</sub>	40 % <i>U</i> <sub>T</sub>	equipment or system requires
IEC61000-4-11	(60 % dip in $U_T$ ) for 5 cycles	(60 % dip in $U_T$ ) for 5 cycles	continued operation during power
			mains interruptions, it is recommended
	70 % $U_{\rm T}$ 70 % $U_{\rm T}$ (30 % dip in $U_{\rm T}$ )	70 % U <sub>T</sub> (30 % din in U <sub>T</sub> )	that the equipment or system be
	for 25 cycles	for 25 cycles	powered from an uninterruptible power
	<5 % <i>U</i> ⊤	<5 % <i>U</i> ⊤	supply or a battery.
	(>95 % dip in U <sub>T</sub> )	(>95 % dip in U <sub>T</sub> )	
	for 5 s	for 5 s	
Power			Power frequency magnetic fields should
frequency(50Hz/60Hz)	24/100	24/100	be at levels characteristic of a typical
magnetic field	SA/III	3A/111	location in a typical commercial or
IEC61000-4-8			hospital environment.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

## Table 3

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

Vital Signs Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Vital				
Signs Monitor should assure that it is used in such an electromagnetic environment.				
		Compliance	Electromagnetic environment quidance	
ININIOINITT LESC		level	Liettomagnetic environment - guidance	
			Portable and mobile RF communications equipment	
			should be used no closer to any part of Vital Signs	
			Monitor, including cables, than the recommended	
			separation distance calculated from the equation	
			applicable to the frequency of the transmitter.	
			Recommended separation distance	
Conducted RF	3 Vrms	3V	$d = 1.2 \sqrt{P}$	
IEC 61000-4-6	150 kHz to 80 MHz		$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz	
			$d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz	
			Where <i>P</i> is the maximum output power rating of the	
Radiated RF	3 V/m	3 V/m	transmitter in watts (W) according to the transmitter	
IEC 61000-4-3	80 MHz to 2.5 GHz		manufacturer and <i>d</i> is the recommended separation	
			distance in metres (m). <sup>b</sup>	
			Field strengths from fixed RF transmitters, as determined	
			by an electromagnetic site survey , <sup>a</sup> should be less than	
			the compliance level in each frequency range . <sup>b</sup>	
			Interference may occur in the vicinity of equipment	
			marked with the following symbol.	
			$\begin{pmatrix} (\bullet) \end{pmatrix}$	
NOTE 1: At 80 MHz a	nd 800 MHz, the higher frequ	ency range applie	25.	
NOTE 2: These guide	lines may not apply in all situ	ations. Electroma	agnetic propagation is affected by absorption and reflection	
from structures, object	s and people.			
a: Field strengths from	fixed transmitters, such as ba	ase stations for ra	adio (cellular / cordless) telephones and land mobile radios,	
amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the				
electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the				
measured field strengt	h in the location in which Vit	tal Signs Monitor	is used exceeds the applicable RF compliance level above,	

Vital Signs Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Vital Signs Monitor.

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

#### Table 4

## Recommended separation distances between portable and mobile RF communications equipment and The equipment or systemfor EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Vital Signs Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment or system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment or system as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

## **Chapter 7 Packaging and Accessories**

## 7.1 Packaging

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

Weight: Details see the indication on the outer package.

Dimension: 360(L)×320(W)×410(H) (mm)

## 7.2 Accessories Supplied

NIBP cuff	One piece
SpO <sub>2</sub> probe	One piece
Power cord	One piece
Grounding wire	One piece
User manual	One copy
Quality Certificate	One copy
Warranty	Two copies
Packing list	Two copies

Note: The accessories are subject to change depending on the configuration of the monitor that you have ordered. Refer to the package for the detailed items and quantity.

#### **Chapter 8 Monitoring Parameter**

#### 8.1 NIBP Monitoring

#### 8.1.1 Measuring Principle

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

As change of the blood pressure is recorded by electric sensor, which sensitivity is much higher than that of human ears, the oscillating method uses different definitions for measurement of diastolic pressure, mean arterial pressure and systolic pressure from the Korotkoff Sound Method. When the oscillating method is used, the circuit in the measuring apparatus will separate the amplitude of the cuff pressure from its change with pulsation. With the oscillating method, the blood pressure at the maximum amplitude of cuff pressure is defined as the mean arterial pressure. The blood pressure at amplitude of cuff pressure forward reduced according to proper proportion is defined as systolic pressure, while the blood pressure at amplitude of cuff pressure backward reduced according to proper proportion is defined as diastolic pressure. The maximum change of pulse pressure occurs at these two points. They are equivalent to the point with pulse sound respectively in the Korotkoff Sound Method.

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

#### Comparison between blood pressure measuring methods

To overcome the effect of human hearing variation and air release speed on measurement accuracy when the conventional Korotkoff Sound Method is used to take measure of blood pressure, people have been dedicated to study of automatic measurement of blood pressure. By now, automatic blood pressure measuring system based on the principle of oscillating method is mature. In practice, however, various problems are encountered, such as why the measures taken by the oscillating method is lower or higher than those taken by Korotkoff Sound Method? Why the measures are inclined to decline? Why, in some cases, no result is obtained in spite of the inflation actions? Why the measure values have big discreteness and even abnormal data in some cases? Why the SpO<sub>2</sub> waveforms may disappear suddenly? ...and so on. The following explanations are devised to give the answers.

#### The Oscillating method vs. the Korotkoff Sound Method

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

- 1. The measures by the Korotkoff Sound Method are liable to effect of human factors. For example, different people may have different sound judging ability, or different reactivity when listening to heart sound and reading mercury meter. The air release speed and subjectivity may also affect the judgment. By the oscillating method, the computation is accomplished by the computer, thus relieving the possibility of effect due to human factor.
- 2. With the Korotkoff Sound Method, the measure is taken on the basis of appearance and disappearance of heart sound. The air release speed and heart rate may have direct effect on the measurement accuracy. It also has the disadvantages of rapid air release and poor accuracy. In the contrast, with the oscillating method, the determination is calculated on the basis of cuff pressure oscillatory waveform envelope, and the air release speed and heart rate has little effect on the measurement accuracy.

- 3. Statistics show that, when measuring the hypertension, the measure taken by the oscillating method is likely to be lower than that taken by the Korotkoff Sound Method. When measuring the hypotension, the measure taken by the oscillating method is likely to be higher than that by the Korotkoff Sound Method. But, it doesn't mean the advantages or disadvantages between the oscillating method and the Korotkoff Sound Method. Comparison with the results taken by more accurate method, let's say comparison of the invasive pressure result with the output value by the blood pressure measuring simulator, will show which method has more accurate results. In addition, higher or lower value should be a statistical concept. It is recommended those used to adopt the Korotkoff Sound Method use different physiological calibration for values determined by the oscillating method.
- 4. The studies have shown that the Korotkoff Sound Method has the worst accuracy when it comes to measurement of hypotension, while the oscillating method has worse accuracy when it comes to measurement of controlled hypertension relief.

## 8.1.2 Factors affecting NIBP measuring

- $\diamond$  Select a cuff of appropriate size according to the size of the subject.
- ♦ Prior to use of the cuff, empty the cuff of any residual air inside it to ensure accurate measurement.
- $\diamond$  Locate the cuff in such a way that the mark " $\phi$ " is in the position where artery pulsates clearly for best effect.
- ♦ The lower part of the cuff should be 2cm above the elbow joint.
- ♦ Do not wrap the cuff over thick clothing;
- The patient should lie in bed or sit in a chair, in order for the cuff and heart to be at the same level and the most accurate measurement to be taken. Other postures may lead to inaccurate results;
- During measuring, do not move the arm or the cuff;
- The measuring interval shall longer than 2 minutes, in continuous measurement, too short interval may cause arm extrusion, blood quantity increases, then cause blood pressure increases.
- Keep the patient still and calm before and during measuring as the patient's state also affect the measuring result, e.g. when excited or anxious, their blood pressure will go up.
- Results will also be affected by the time of day, tending to be lower in the morning and higher in the evening;

#### 8.1.3 Clinical Limitations and Contraindications

- 1. Serious angiospasm, vasoconstriction, or too weak pulse.
- 2. Extremely low or high heart rate or serious arrhythmia (especially auricular fibrillation) will lead to unreliable measurements or an inability to take a reading.
- 3. Patients connected to an artificial heart-lung machine.
- 4. Patient taking diuretics or vasodilators.
- 5. With patient suffering from major hemorrhage, hypovolemic shock and other conditions with rapid blood pressure change or when the body temperature is too low, the readings will not be reliable, as reduced peripheral blood flow will lead to reduced arterial pulsation.
- 6. patient with hyperadiposis;

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

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

#### 8.2 SpO<sub>2</sub> Monitoring

#### 8.2.1 Measuring Principle

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO<sub>2</sub>) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO<sub>2</sub> can be determined. SpO<sub>2</sub> measured by this monitor is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractional oxygen saturation -- a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

#### 8.2.2 Sources of interference for SpO<sub>2</sub> Measurement

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

#### 8.2.3 Pathological reasons for low SpO<sub>2</sub> measurements

- ♦ Hypoxemia, functional lack of HbO<sub>2</sub>
- ♦ Pigmentation or abnormal oxyhemoglobin level
- ♦ Abnormal oxyhemoglobin variation
- ♦ Methemoglobin disease
- ♦ Sulfhemoglobinemia or arterial occlusion exists near sensor
- ♦ Obvious venous pulsations
- ♦ Peripheral arterial pulsation becoming weak
- ♦ Insufficient peripheral blood supply

#### 8.2.4 Clinical Limitations

- As the measurement is taken on the basis of arteriole pulse, a substantial pulsating blood stream is required. For a patient with weak pulse, perhaps due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drugs, the SpO₂ waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
- For those with a substantial amount of staining dilution agent (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO<sub>2</sub> readings may be inaccurate.
- Drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor resulting in serious SpO<sub>2</sub> measurement errors.
- ☆ As the SpO<sub>2</sub> value serves as a reference value for judgment of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO<sub>2</sub> value.

#### 8.2.5 Points to be noted in SpO<sub>2</sub> and Pulse Measuring

- The finger should be properly placed (see the illustration to follow in this instruction manual), or else it may cause inaccurate measurement results.
- $\diamond$  Make sure that the sensor is lined up so the red and infrared LEDs pass through the capillary arterial vessels .

- The SpO<sub>2</sub> sensor should not be used at a location or limb with an arterial or blood pressure cuff attached or receiving intravenous injection.
- ✤ Do not fix the SpO<sub>2</sub> sensor with adhesive tape, which may result in venous pulsation and consequential inaccurate measurement result of SpO<sub>2</sub>.
- $\diamond$  Make sure the optical path is free from any obstacles such as adhesive tape.
- ♦ Excessive ambient light (such as fluorescent lights, infrared heaters and direct sunlight) may affect the measuring result.
- Strenuous activity of the patient or extreme electrosurgical interference may also affect the accuracy.
- $\diamond$  Please do not use the SpO<sub>2</sub> sensor when having the MRI, or burn may be caused by faradism.
- Always observe the plethysmogram (waveform), which is auto-scaled within the range of 100. If the waveform is not smooth or is irregular, this may indicate that the SpO<sub>2</sub> readings are not accurate. If in doubt, rely on your clinical judgment, rather than the monitor readout.
- A functional tester cannot be used to assess the accuracy of the pulse oximeter monitor or a SpO<sub>2</sub> sensor. However, a functional tester, such as SpO<sub>2</sub> simulator can be used to check how accurately a particular pulse oximeter is reproducing the given calibration curve. Before testing the oximeter, please determine that the appropriate calibration curve is being used. If necessary, request this from the manufacturer and download it into the test device.

#### **Chapter 9 Troubleshooting**

#### 9.1 No Display on the Screen

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

#### 9.2 No Blood Pressure and Pulse Oxygen Readings

- Check that the blood pressure cuff is properly wrapped around the arm according to the operating instructions, that the cuff does not have a leak, that connections are secure on the cuff and tubing and that the inlet is closely connected with the NIBP jack on the side panel. Check that the LED of SpO<sub>2</sub> probe flashes and that the pulse oxygen probe is properly connected to the SpO<sub>2</sub> jack on the side panel.
- 2. If the problems still exist, please contact the local dealer.

## 9.3 Blank Print-out

- 1. Check whether the printing paper is installed the right way around (i.e. with the sensitive side upwards). Please reinstall it if necessary.
- 2. If the problems still exist, please contact the local dealer.

#### 9.4 System Alarm

- 1. When the parameter value is higher or lower than the alarm limits, the alarm will sound. Please examine the condition of the patient and check whether the alarm limit values are set appropriately.
- 2. Probe off. Please check the connection of the probes.

Note: If a problem arises with this machine in service, follow the instructions below to attempt to eliminate the problem first. If the attempt fails, contact the dealer in your local area or the manufacturer. Do not open the monitor casing without permission.

#### **Chapter 10 Maintenance**

#### 10.1 Service and Examination

#### 10.1.1 Daily Examination

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

- Check the monitor for any mechanical damage;
- Inspect the exposed parts and the connectors, 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 the event that any damage to the monitor is found or any irregular function is detected and proven, do not use it.

#### 10.1.2 Routine Maintenance

An annual maintenance inspection by qualified personnel, including functional and safety examination is recommended.. The designed life of this monitor is 5 years. In order to ensure a long service life, please pay attention to the required maintenance.

- Failure to carry out a satisfactory maintenance program for the monitor, may result in functional failures and harm the patient's safety and health.
- If there is any indication of cable or transducer damage or deterioration, they must not be used.
- A The adjustable units in the monitor such as potentiometer should bot be altered without permission to avoid unnecessary failures that may affect normal use. Maintenance repairs must only be carried out by suitably trained technicians.

#### 10.1.3 Battery Maintenance

- Please pay attention to the polarity of battery, and do NOT insert it into battery compartment with polarities reversed ;
- **Do NOT** use batteries manufactured by other companies, which may cause damage to the device;
- In order to avoid damaging the battery, do NOT use another power supply to charge the battery;
- At the end of their lifetime, dispose of batteries in line with local guidelines.
- Do not hit or strike with force;
- Do not use this battery on other devices;
- Do not use this battery below -10°C or above 40°C;
- Dispose of the battery, the local law should be followed.
- In order to maintain battery supply time and prolong battery lifetime, please charge the battery every one or two months if the monitor is not in regular use. Charge battery at least 12-15 hours every time. Before charging, run down the internal battery until the monitor turns off automatically to minimize memory effects. Charging time will be the same no matter whether the monitor is working or not. Charge fully before putting the monitor into storage.
- Using a monitor powered solely by an internal battery power which has short charge power will cause the monitor turn off automatically when the battery is depleted.
- Do NOT use batteries manufactured by other companies, which may cause damage to the device;(If battery is damaged,

#### please replace with same type and specification battery marked by "CCC" or "CE" in time, or contact the company directly. )

#### 10.1.4 Service

If the monitor malfunctions and you are not able to resolve an issue using the troubleshooting guide, please contact the supplier. Only qualified service engineers, specified by the manufacturer can perform maintenance and users are not permitted to repair the monitor or conduct maintenance by themselves.

## **10.2** Cleaning and Disinfection

- Keep the monitor free from dust.
- It is recommended to regularly clean the outer shell and screen of the monitor to keep it clean. Only a non-corrosive cleanser such as clear water is permitted.
- Wipe the surface of the monitor with a cloth slightly dampened with warm water and a mild, non-corrosive detergent or an alcohol impregnated wipe. Dry with a clean cloth or simply air-dry.
- The monitor can be sterilized and disinfected, please clean it first.
- Switch off the monitor and disconnect the power cable before cleaning.
- Do not let the liquid cleanser flow into the connector jack of the monitor to avoid damage.
- Clean the exterior of the connector only.
- **b** Dilute the cleaning product in line with the manufacturer's instructions.
- $egin{array}{c} & egin{array}{c} & egin{arra$
- **b** Do not leave any cleanser or disinfectant on the surface of the monitor.
- **Do not perform high pressure sterilization on the monitor.**
- **b** Do not submerge any parts of the monitor or its accessories in the liquid.
- If the monitor accidentally becomes wet, it should be thoroughly dried before use. The rear cover can be removed by a qualified service technician to verify absence of water.
- **b** Do not pour the disinfectant onto the monitor surface while disinfecting.

#### **10.3 Cleaning and Disinfection of Accessories**

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

- ●<sup>™</sup> Do not use damaged accessories.
- Second contraction of the entirely immerged into water, alcohol or cleanser.
- To not use radial, steam or epoxyethane to disinfect accessories.
  - Wipe off any remaining alcohol or ispropanol on the accessories after disinfection, for good maintenance can extend the life of accessories.

#### 10.4 Storage

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

Storage environment: Ambient temperature: -20~60°C

Relative humidity: 10%~95%

Atmosphere: 50kPa~107.4kPa

## 10.5 Transportation

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

## Chapter 11 Appendix

## **11.1 Prompt information explanations**

Mute C-D: XXX seconds	Alarm silence count down: XXX seconds
NIBP C-D: XXX seconds	NIBP auto measuring cycle count down: XXX seconds
TOUR C-D: XXX seconds	Hemostat alert count down: XXX seconds
Probe off	$SpO_2$ probe is off form the patient or disconnected from the device
PR over limit	PR value exceeds the high/low alarm limit
SpO <sub>2</sub> over limit	$SpO_2$ value exceeds the high/low alarm limit
SYS over limit	Systolic pressure value exceeds the high/low alarm limit
DIA over limit	Diastolic pressure value exceeds the high/low alarm limit
MAP over limit	MAP value exceeds the high/low alarm limit
NIBP error 1#	Sensor or other hardware error
NIBP error 2#	Very weak signal because of the cuff, or the patient has very weak pulse
NIBP error 3#	Blood pressure amplifier overflow due to excessive movement
NIBP error 4#	Leaking during the pneumatic device testing
Cuff error	Cuff is not wrapped correctly, or is not connected
NIBP error 5#	Hardware fault of NIBP module
Air leak	Pneumatic part, tube or the cuff leak air
NIBP over range	The measurement range exceeds limits setting value
Over motion	Excessive movement or noise during inflation and measurement. Another measurement will be taken.
Over pressure	Cuff pressure exceeds the safety limit value of software. Or caused by cuff extrusion or flapping cuff with force.
NIBP timeout	Big animal measurement is more than 120 seconds, small animal measurement is more than 90 seconds.

## 11.2 Factory Default Alarming Values and Setup Range

The factory default alarming value:

Mode				
Parameter		Big animal	Small animal	
cvc	High limit	160mmHg	120mmHg	
515	Low limit	90mmHg	70mmHg	
DIA	High limit	110mmHg	90mmHg	
DIA	Low limit	60mmHg	50mmHg	
MAP	High limit	90mmHg	70mmHg	
	Low limit	50mmHg	40mmHg	
60	High limit	100%	100%	
SpO <sub>2</sub>	Low limit	85%	85%	
	High limit	120bpm	160bpm	
Puise rate	Low limit	50bpm	75bpm	

## The high and low limits setting range:

Parameter	Mode	Big animal	Small animal	Setting Step
CVC	High limit	(Low+1)~265 mmHg	(Low+1)~200 mmHg	1mmHg
515	Low limit	40~(High-1) mmHg	40~(High-1) mmHg	1mmHg
DIA	High limit	(Low+1)~222 mmHg	(Low+1)~165 mmHg	1mmHg
DIA	Low limit	27~(High-1) mmHg	27~(High-1) mmHg	1mmHg
МАР	High limit	(Low+1)~210 mmHg	(Low+1)~150 mmHg	1mmHg
	Low limit	20~(High-1) mmHg	20~(High-1) mmHg	1mmHg
6-0	High limit	1~100%	1~100%	1%
SpO <sub>2</sub>	Low limit	0~99%	0~99%	1%
Pulse rate	High limit	(1~350) bpm	(1~350) bpm	1bpm
	Low limit	(0~349) bpm	(0~349) bpm	1bpm

Note: it's limited for the high/low alarm setting value, which ensure that the high-limit setting value will not less than (or equal to) that of the low-limit setting value. See the above table for detailed setting step.

## 11.3 Accessories List

Part Name	Remark
SpO <sub>2</sub> sensor	Optional
NIBP cuff (3~6)cm	Optional
NIBP cuff (4~8)cm	Optional
NIBP cuff (6~11)cm	Optional
NIBP cuff (7~13)cm	Optional
NIBP cuff (8~15)cm	Optional
Thermal printer paper	Optional
Power cord	Optional
Grounding wire	Optional
Net wire	Optional

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

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

	Manufacturer
~~	Date of manufacture
LOT	Lot number
	Follow instructions for use
Ť	Keep in a cool, dry place
	Imported by
REF	Product code
EC REP	Authorized representative in the European community
X.	WEEE disposal
CE	Product complies with European Directive
Â	Caution: read instructions (warnings) carefully
×	Keep away from sunlight
IPX2	Covering Protection rate
	Humidity limit
	Atmospheric pressure limit
X	Temperature limit

## **GIMA WARRANTY TERMS**

The Gima 12-month standard B2B warranty applies



Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment