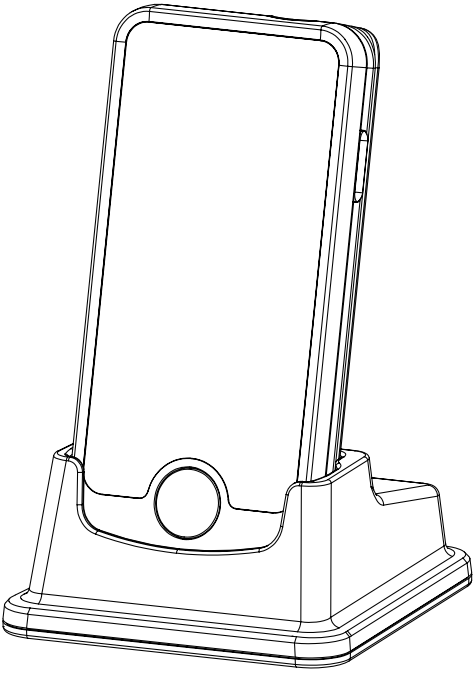
Vital Signs Monitor
User Manual



Ver. V1.3

Statement of Responsibility

TThe company does not in any form guarantee the errors in this manual, installation errors and operator errors, and does not assume any legal liability for incidental or consequential damages.

The company only considers to be responsible for the reliability, security and performance of the instrument under the following circumstances, namely assembly operation, expansion, readjustment, performance improvement and repair, all of which are performed by the personnel or institutions authorized by the company; relevant electrical devices are in line with national standards; the instrument is operated in accordance with the guidance in this manual.

The contents of this manual may be changed without notice.

Before using the product, please read the contents of this manual carefully for proper use of the product. Please keep this manual after reading it, so as to access at any time when needed.

The latest revision date: 03-2023

Foreword

This manual describes in detail the purpose, function and operational use of the product. Before using this product, please carefully read and understand the contents of this manual to ensure proper use of this product can be, and to ensure that the patient and operator safety.

The manual introduces this product according to the most complete configuration, so some contents may not apply to your purchased product. If you have any questions, please contact with the company.

Please place this manual near the product, so as to be able to convenient and timely access when needed.

Applicable objects

This instrument is suitable for home users or professional clinical staffs, and users shall read the manual carefully before using this instrument.

Illustrations

All illustrations in this manual are provided only for reference, and settings or data in the illustrations may not be entirely consistent with the actual display you see on the product.

Warranty and maintenance services

Scope of Free Services:

Any device in compliance with the range of the company's warranty service can enjoy free services.

Scope of Paid Services:

(1) The company will implement the paid services for any device beyond the range of the company' s warranty service;

(2) Even during the warranty period, the product needs to be repaired due to the following reasons: artificial damage; grid voltage exceeding the specified range of device; irresistible natural disasters.

The Company is irresponsible for the direct, indirect or final damage and delay caused by under the following circumstances (including but not limited to):

Component disassembly, stretching and re-commissioning; replacement of accessories without permission of Company or the machine repair by non-authorized personnel of our Company.

Return of goods

Return process

The goods is really necessary to be returned, follow these steps:

1. Acquired right of return. Contact our customer service department, informing of the product serial number; if the serial number is non-legible, return of goods will not be accepted. Please specify the product model, serial number, and brief reason for return.

2. Freight: The device is shipped to the company for maintenance, and meanwhile users have to bear the shipping cost (including customs fees).

After-sale Services

Any device in compliance with the range of the company's warranty service can enjoy free services.

1.Our company cannot provide the free warranty service due to the malfunction caused by personal reason, the details as follow:

1) The malfunction caused by disassemble and modify the product.

2) The product inner malfunction caused by dropping while picking up or operating.

3) The malfunction caused by improper used or lack of reasonable cared.

4) The malfunction caused by operating not following the operator' s manual.

5) The malfunction caused by natural disasters,such as flooding,fire.

6) The malfunction caused by improper repaired by repaired shop which isn' t our authorized.

2.Please show your valid warranty card and shopping vouchers when you need free service.

3.Please bring the product to repaired shop which is our authorized when you need free repaired.

4.When performing warranty service, if needed, you can provide information on product components to circuit diagrams and repairable identified by our qualified technical personnel.

5.We will collect reasonable charge when we repair some malfunctions which out warranty service.

Table of Contents

Chapter I Overview

1.1 Safety Information

⚠ Caution ⚠

Tip potentially dangers or unsafe operations, and if they are not avoided, it could result in slight personal injury, product failure, damage or property loss.

⚠ Attention ⚠

Highlight important considerations, and provide instructions or explanations to make better use of this product.

This product is not involved in the information on danger level.

1.1.1 Warning

⚠ Warning ⚠

●Users before using this Vital Signs Monitor should follow the instructions set out in this manual; or else, any incorrect operation may result in slight injury. The company will assume no warranty for improper use of this device.

The device is used in the medical field，home, and measurement results serve only as reference.

●Before use, users must check the device, cables and accessories to ensure that they can properly work safely.

●The device is not available in the presence of flammable gases or other flammable anesthetic gases, in order to avoid explosion.

●Do not open the enclosure of the monitor, to avoid the risk of electric shock. If necessary, please contact the company's maintenance personnel.

●To prevent delays in treatment, make full prompt settings for each patient, while prompt sound should also be able to be ensured when prompting.

●The physiological waveforms, physiological parameters and prompt information and others displayed by the device are for user' s reference, but can not be directly used as the basis for clinical treatment.

●Note to place the power line and all cables to avoid the hazard of strangling users or tripping other personnel.

●To avoid personal injury, in addition to qualified technicians, other persons can not repair the device.

●Do not repair or maintain during use.

●If you think the device is damaged or abnormal, please stop using the device. Contact the manufacturer. It is strictly forbidden for the user to dismantle or repair by himself.

●The Vital Signs Monitor contains sensitive elements, which should be treated with caution. The aging of the components will affect the performance of the Vital Signs Monitor . Meanwhile, it should be avoided to be used in the environment with electromagnetic interference.

●Please place the Vital Signs Monitor in a place untouchable for children and pets to prevent them from falling, biting and affecting the product performance.

●This product is suitable for professional or domestic use.

Correct usage is the key to measuring accuracy.Operators should have some knowledge of blood oxygen and carbon dioxide.Operating environment strictly according to the instruction.

●The Vital Signs Monitor is composed of high-quality precision parts, which can not be repaired by itself.

1.1.2 Caution

⚠ Caution ⚠

●To ensure users, please use the accessories designated by the company.

●When the product and accessories described in this manual are about to exceed the period of use, they must be treated in accordance with relevant product specifications. If you want to learn more information, please contact the company or its representative.

●Do not use a mobile phone near the Vital Signs Monitor, because the mobile phone will generate too strong radiation field, which thus interferes with function.

●Please properly install or carry the device to prevent the device falling or being damaged due to collision, receiving strong shock or other mechanical force.

●It contains small parts. In order to avoid swallowing, the Vital Signs Monitor placed on the children can not contact the location.

●Please do not use this product if you are allergic to ABS, silicone material.

1.1.3 Attention

⚠ Attention ⚠

●Place the device at the place where it is easy to observe, operate and maintain.

●Place this manual near the device so as to be able to easily and timely access when needed.

●Before use, verify and correct and ensure that the device is working properly.

●If a liquid is spilled into the enclosure of the device, disconnect the charge and shut down device immediately, and contact the maintenance personnel at once.

●The manual introduces the product according to the most complete configuration, and the product you purchase may not have some of the configurations or functions.

●Remove nail polish or artificial nails before oxygen probes are used. Nail polish or artificial nails may cause inaccurate oxygen saturation readings.

1.2 Symbols

	Type BF applied part		Refer to instruction manual	#	Model number
	Caution		Keep dry		Use-by date
	Manufacturer		Humidity limitation	MD	Medical device
	Date of manufacture		Temperature limit	LOT	Batch code
SN	Serial number		Consult instructions for use		
	Separate collection for electrical and electronic equipment				
IP22	Protected against solid foreign objects greater than 12.5mm in diameter and dripping water when tilted up to 15°				

Chapter II Product Overview

2.1 Introduction

2.1.1 Intended use

The Vital Signs Monitor is intended for measuring and displaying the pulse rate, functional oxygen saturation (SpO2) , carbon dioxide (CO2) and non-invasive blood pressure (NIBP)(optional). It is intended for spot checking and recording of SpO2, pulse rate , carbon dioxide and (NIBP)(optional) in clinical institutions and homes.

The Vital Signs Monitor is powered by a built-in rechargeable battery. It is compact and easily carried.

User Group

Age:adult，neonatalor newborn，pediatric

- Patient

-Doctor

-Other people who need to measure oxygen saturation (SpO2), pulse rate and carbon dioxide.

2.1.2 Environmental Requirements

Normal operating conditions

Ambient temperature：5℃～40℃

Relative humidity：15%～80%

Atmospheric pressure：86.0～106.0 kPa

Storage and transportation temperature

Ambient temperature：-20℃～50℃

Relative humidity：10%～95%

Atmospheric pressure：55.0～106.0 kPa

The operating environment of this device must comply with the requirements of the environment specification in this manual.

When the device is moved from one environment to another environment, due to differences in temperature or humidity, it can cause the device condensation. At this point, you must wait until the condensation condition disappears before using the device.

⚠ **Warning** ⚠

Please ensure that the device is operated under specified environmental requirements; otherwise it will not meet the technical specification claimed in this manual, and may lead to unpredictable consequences, such as damage to the device.

Direct use in the environment of electromagnetic interference shall be avoided to prevent temporary influence on its accuracy.

⚠ **Attention** ⚠

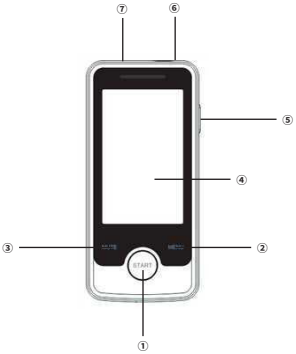
The monitor can be used for home care , and can also be used in hospitals .

2.1.3 Contraindications

No

2.2 Appearance

2.2.1Front view



Picture 2-1 Vital Signs Monitor

① Power switch “START”:Start measuring.
② MENU key:The main menu.
③ MUTE key:Same function with opinion “SILENCE” in touch menu which tunes out the system sounds.
④ Touch panel.
⑤ Power switch “ ⏻ ”:Press this key for min. 2 seconds to power On/Off the oximeter.
⑥ CO2 port.
⑦ SPO2 port.
⑧ Prompt indicator: When an prompt signal is given, this indicator flashes.

Definition abbreviation:

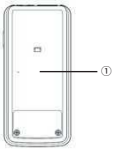
Items	Definition, abbreviation
SPO2	Blood oxygen saturation
PR	Pulse Rate
CO2	EtCO2
FiCO2	InsCO2
AWRR	Air Way Respiration Rate

2.2.2Side view

Picture 2-2 The side of the machine

① Power switch " ⏻ ".

2.2.3 Rear view



Picture 2-3 The back shell of the machine

① The shell in the back

2.3 Screen Display

2.3.1Display Interface

This equipment is equipped with a color TFT capable of displaying patients' parameter, waveform parameter collected and prompt information, state of the monitor, time, and other prompts provided by the monitor at the same time.

Main screen is divided into 3 areas (As shown in picture 2-4):

Picture 2-4 Display Main Interface

1.Information area ①

2.Parameter and Waveform area ②

3.Touch menu area ③

Information Area(①):

◆The information area is located at the top of the screen, showing the measurement items , status, battery and time.

◆Other prompts of the information area are displayed and disappeare together with displayed state. According to contents, they are sorted as:

●Prompt information of the monitor;

● ⛆ is the sign for prompt suspend. When you press this key " 🔇 ", it will appear this sign. It indicates that all the prompt are closed temporarily by artificial. The system will re-appear prompt until you press this key " 🔇 " or the prompt suspend period over. The prompt suspend time is two minute".

Parameter area and waveform area are introduced(②):

Parameter area and waveform are basically placed in correspondence. The parameters displayed are:

1.SpO2: Blood oxygen saturation (Unit:%)

2.PR : Pulse rate (unit:time/minute)

3.Pleth: SpO2 plethysmography wave (unit：mm/s)
4.CO2: ETCO2 (unit：mm/s)
5.FiCO2: InsCO2 (unit：mmHg)
6.AWRR: Air Way Respiration Rate (unit：rpm)

Prompt Indicator and Prompt State:
Prompt indicator does not light up under normal state.
In case of the occurrence of prompt, the prompt indicator flashes or keeps lightening. Color of the indicator represents the prompt level.

2.5.2 Comprehensive information area

Picture 2-5 SpO2 and PR parameter area

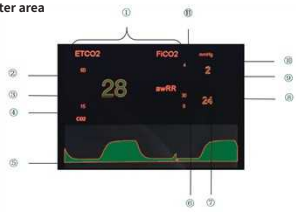
① The prompt information
② Parameter designation
③ Battery capacity
④ Real-time clock display

2.3.3 SpO2 and PR parameter area

Picture 2-6 SpO2 and PR parameter area

① Parameter designation
② SpO2 High prompt limit
③ SpO2 measurements
④ SpO2 Low prompt limit
⑤ SpO2 plethysmography wave
⑥ PR Low prompt limit
⑦ PR High prompt limit
⑧ Unit
⑨ PR measurements

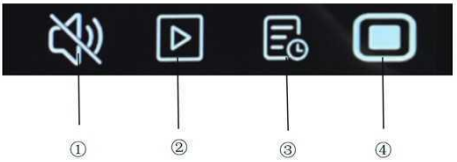
2.3.4 CO2 parameter area



Picture 2-7 CO2 parameter area

① Parameter designation
② ETCO2 High prompt limit
③ ETCO2 measurements
④ ETCO2 Low prompt limit
⑤ waveform
⑥ AWRR Low prompt limit
⑦ AWRR measurements
⑧ AWRR High prompt limit
⑨ FiCO2 measurements
⑩ Unit
⑪ FiCO2 High prompt limit

2.3.5 Touch menu area



Picture 2-8 Touch menu area

①PAUSE

When you press this key, the prompt time can be as long as 2 minute.In the information area, it will appear“ ”.

② FREEZE

Same function with the opinion “FREEZE” in touch menu.

③ RECORD

Record the numerical.

④ MENU

Press this key to pop up “system menu”. Users may set system information in system menu and execute retrospective operation.

⚠ Attention ⚠

If new prompt occurs under prompt halt/mute, prompt halt/mute will be automatically resumed.

Chapter III Preparation before use

3.1 Unpacking and inspection

Take out the Vital Signs Monitor and accessories from the box carefully, and save the packaging materials for future shipping or storage. Check the accessories according to the packing list. If any damage, please immediately contact the company’ s after-sales department or agency.

⚠ Warning ⚠

Keep packaging materials placed beyond the reach of children. Processing packaging materials must comply with local relevant laws and regulations or the waste disposal systems of hospitals.

3.2 Start

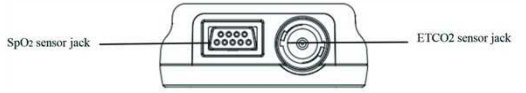
1. Before starting, check whether the monitor is mechanically damaged.

2. Make sure the battery has enough capacity.

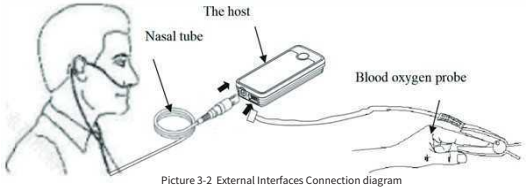
3. Connect one end of the blood oxygen probe to the SpO2 interface and clamp the other end to your finger to start measuring.

4. Connect the dehydrating column to the CO2 interface, connect one end of the nasal tube to the dehydrating column, and connect the other end to the nostril. (Optional)

5. Press and hold the "on/Off" button on the side for 2 seconds, then release your fingers to start the machine and enter the main interface.



Picture 3-1 External Interfaces



Picture 3-2 External Interfaces Connection diagram

⚠ Attention ⚠

If the monitor is shut down automatically due to insufficient battery power and the lithium battery is not charged in time, the clock needs to be reset when the monitor is turned on several days later;

The clock also needs to be reset after manual shutdown and restart.

⚠ Warning ⚠

If the monitor function shows a sign of damage, or an error message, do not use this monitor to measure patients contact the manufacturer.

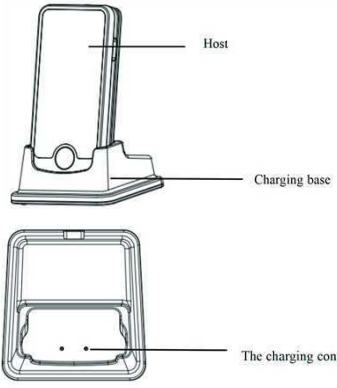
If the performance is inconsistent with the description or changes, stop using immediately and contact the manufacturer.

3.3 Shutdown

Please refer to the following steps to turn off the monitor:

1. Confirm that the work of the patient's care comes to an end.
2. Disconnect the monitor and oximeter cable.
3. Press the power switch and hold for 2 seconds to turn off the monitor

3.4 Mounting of the base



Picture 3-3 The base

Charging mode:

1、The base charges via contacts, As shown in Figure 3-3, place the host on the base and use the contacts below the host to contact the contacts above the base to power the host .

2、The host can be directly connected to the connection adapter (Type-c interface) for charging.

Chapter IV The menu Settings

The configuration of the monitor is flexible, and the oximetering content and prompt can be configured by users according to their needs.Press " " on the front panel to pop up the menu as shown in figure 4-1 :(select the menu to enter and press [menu] to enter the next sub-menu, and click [RETURN] to RETURN to the previous interface)

Figure 4-1 Main menu

In the main menu, there are options of "MONITOR SETUP", "PARAMETER SETUP", "ALARM SETUP" and "TREND ".

4.1 Monitor setup

Select "Monitor setup" from the main menu, and the menu as shown in figure 4-2 will pop up :(select the menu to enter and press [Monitor setup] to enter the next sub-menu, and click [RETURN] to RETURN to the previous interface)

Figure 4-2 Monitor Settings menu

In the monitor Settings menu, there are options of "manufacturer Settings", "version Information", "DEMO Mode" and "Restore factory Settings" respectively.

4.1.1 Factory set up

Click on the" MAINTAIN"And touch" " " "Key ENTER the correct password, ENTER the "manufacturer Settings", click "ENTER" to ENTER the option Settings; As shown in figure 4-3 :(select the item to select and press confirm, and click [RETURN] to RETURN to the previous interface)

Figure4-3 Setting menu

4.1.2 Version information

Click on the" Monitor INFO"Enter the interface, you can check the product version information, click [RETURN] to RETURN to the previous interface; As shown in Figure 4-4:

Figure 4-4 Version information menu

4.1.3 DEMO mode

Click on the" DEMO"You can enter the automatic DEMO mode. At the same time, the words "DEMO IS RUNNING" will appear in red. Click again" DEMO"Will stop the automatic demonstration mode, click [RETURN] to RETURN to the previous interface;As shown in Figure 4-5:

Figure 4-5 Menu of automatic demonstration mode

4.1.4 Factory data reset

Click on the" DEFAULT"Enter the confirmation interface for restoring factory Settings. Click [RETURN] to RETURN to the previous interface. As shown in Figure4-6:

Figure 4-6 Menu for Restoring factory Settings

Select Yes to restore the factory default Settings.
If you select No, the current operation is abandoned and the system keeps the original Settings.

4.2 Parameter Settings

Click on the" PARAMETER SETUP" Enter the parameter setting interface, click [RETURN] to RETURN to the previous interface; As shown in Figure 4-7:

Figure 4-7 Setting parameters

In the parameter setting menu, there are "CO2 SETUP", "VOLUME SETUP" and "TIME SETUP" options respectively.

4.2.1 CO2 Parameter Setting

Click on the" CO2 SETUP" Enter the CO2 parameter setting interface and click [RETURN] to RETURN to the previous interface. As shown in Figure 4-8:

Figure 4-8 Menu for setting parameters

【Working mode】: Work/standby
【CO2 unit】: "mmHg", "kPa" and "%"
【Oxygen compensation】: If oxygen exists, the measured CO2 value is lower than the actual value. This parameter can be set to compensate for oxygen. The value ranges from 0 to 100.
【Equilibrium gas】: Options include "indoor air", "nitrous oxide" and "helium".
【Anesthetic gasses】: The strength of the anesthetic. The value ranges from 0.0 to 20.0.
【zero】: Click "Zero" to zero CO2.
【BAL.GAS】:Option "air", "nitrous oxide," "oxygen".

4.2.2 Sound Settings

Click on the" VOLUME SETUP" Enter the sound setting interface, click [RETURN] to RETURN to the previous interface; As shown in Figure 4-8:

Users can modify it as required.
Anyway, select Pulse Volume from the Settings menu and press the up and down keys to change the pulse volume. The options are 00, 01, 02, 03, 04,05,06,07,08,09,10 . "0" indicates that the volume is off.
Anyway, choose prompt volume from the menu of "Settings", and press up and down keys to change the prompt volume. The options are 01, 02, 03, 04,05,06,07,08,09,10 .

⚠ **Attention** ⚠

If the user needs to turn off the pulse volume , it need to adjust to "0".

4.2.3 Set the time

Click on the" Time SETUP"Enter the time setting interface, click [SET] to confirm after setting. Click [RETURN] to RETURN to the previous interface; As shown in Figure4-9:

Figure 4-9 Time setting menu

In the time setting menu, users can set [hour] and [minute].

4.3 Prompt set

Click on the" prompt SETUP"Enter the prompt setting interface, click [RETURN] to RETURN to the previous interface;As shown in Figure4-10:

Figure 4-10 prompt setting menu

4.3.1 SPO2 prompt

Select "blood oxygen prompt" in the prompt menu, and the menu as shown in figure 4-11 pops up :(click [RETURN] to RETURN to the previous interface;)

Figure 4-11 Blood oxygen prompt

SPO2 adjustable range

●The upper limit of SPO2：100 The lower limit of SPO2：0
●The upper limit of PR：240 The lower limit of PR：30
●The SpO2 prompt: on/off
●The pulse prompt: on/off

Users can select items to be changed according to their needs, and modify the upper and lower limits of prompt;By pressing the【" " " "】Key to increase and decrease prompt limits.
The prompt switch is selected by pressing ●.

4.3.2 CO2 prompt

Select " CO2 prompt" in the prompt menu, and the menu as shown in figure 4-3-2 will pop up :(click [RETURN] to RETURN to the previous interface;)

Figure4-12 CO2 prompt

CO2 adjustable range
●The upper limit of CO2：114 The lower limit of CO2：0
●The upper limit of FiCO2：99
●The upper limit of AWRR：150 The lower limit of AWRR：0
●Static CO2 prompt switch: on/off
Adjustment method:
See adjustment method in 4.3.1.

4.4 Trend chart
Click on the"" Enter the trend chart interface to view the trend chart information. Click [RETURN] to RETURN to the previous interface. See Figure 4-13.

Figure 4-13 Trend diagram

Chapter V Data Storage

At the time for measurement of blood oxygen, the monitor stores the measurement results once every minute, including measuring time, oxygen saturation and pulse rate, and can store up to 15 hours of measurement data of individual patients continuously.
⚠ **Attention** ⚠
After the monitor is powered off or shut down, the data stored will not be deleted.

Chapter VI Prompt

Prompt refers to tips made by the monitor to medical staff through sound, light and other means when abnormal vital signs change in the patient being measured, or the patient can not be measured smoothly due to the failure of the monitor itself.

6.1 Prompt Type
Prompt is classified into two categories: If this prompt comes from the changes in the patient's vital signs, that is, the physiological parameters of the patient being measured exceed a specific range or the patient' s physiological abnormalities can not be measured by single physiological parameters beyond the range, it is referred to as physiological prompt; if the prompt is from the machine itself, that is, the prompt as a result of failure in accurate patient measuring due to the technical barriers to the use of the monitor or the failure of the machine itself, is referred to as technical prompt.
For example：

Patient or machine	Prompt category
Pulse of the patient is measured 114BPM, beyond the range of heart rate prompt set by the user.	Physiological prompt
SpO2 probe off	Technical prompt

6.2 Prompt status icon

In addition to these prompt modes above, prompt icon will appear next to SPO2 and PR and on the status bar, indicating different states of the prompt.

⚠ **Attention** ⚠

After the prompt is paused, and exceeds the prompt pause time 120s, the oximeter will automatically cancel the prompt pause. You can also press the [Up] key to manually cancel the prompt sound pause. But in the event of a new prompt situation, the system will automatically clear the pause state of prompt sound.

6.3 Prompt Pause

Press the [ ] key, and you can pause the monitor' s prompt sound:

■The prompt is suspended, and the prompt light and prompt information are no longer displayed.

■The status bar on the screen shows icon .

6.4 Set prompt sound

6.4.1 Set prompt volume

1. Select the [Menu] → [PARAMETER SETUP] → [VOLUME SETUP] → adjust the volume (PLUSE volume range: 0-10, of which 0 is minimum and 10 is maximum;prompt volume range :01-10,of which 01 is minimum and 10 is maximum).

After the monitor is shut down and restarted, the minimum prompt volume set will not change. When the prompt volume is set to 0, the prompt sound is turned off.

⚠ **Warning** ⚠

Patients can not be measured and cared only relying on the sound prompt system. The adjustment of prompt sound to a small volume may cause the patients to become dangerous. Users should pay close attention to the actual clinical condition of the patients.

6.5 Countermeasures for prompt

In case that the monitor sends out an prompt, please refer to the following steps to take appropriate measures:

1. Check the patient's condition.
2. Verify that the parameters of the ongoing prompt or the type of prompt.
3. Identify the reasons for the prompt.
4. Remove the reasons for prompt.
5. Check whether the prompt is eliminated.

The specific treatment measures for each prompt refer to Appendix D prompt information.

Chapter VII SpO2

7.1 Overview

Picture7-1 SPO2 screen

A continuous and non-invasive pulsation oximeter is adopted for SpO2 measurement. It measures the specific wavelength of light from the light source of oxygen saturation probes, and after it is absorbed by oxyhemoglobin in the patient' s tissue and reaches the luminous flux of photodetector end, thus to get oxygen saturation and pulse rate. The Blood oxygen simulator is calibrated to display functional oxygen saturation.

Measurements provide:

1. Plethysmography (Pleth) waveform: the strength of the patient' s pulse signal does not affect the amplitude of Pleth waveform.
2. Arterial oxygen saturation (SpO2): the percentage of oxyhemoglobin in the total hemoglobin.
3. Pulse rate (PR): the number of pulse detected per minute (obtained from plethysmography waveform).

7.2 Safety Information

⚠ **Warning** ⚠

●If there is carboxyhemoglobin, methemoglobin or dye dilution chemical, the SPO2 value will be biased.

●Use only the oxygen saturation probes as specified in this manual following the operating manual. Observe all warnings and precautions.

●Before starting to measure,you should first check whether the oxygen probe is normal, and

if the oxygen probe packaging or the probe has been damaged, do not use this oxygen probe.
●If a patient has a tendency to hypoxia, the monitor should be used to analyze the oxygen probe, because the induced current may cause serious burns of the patient.
●The cables of electrosurgical devices can not be entwined with oximeter cable.
●Do not place the blood oxygen probe on the limb with arterial catheter or intravenous catheter at the same time
●Do not place the oxygen probe and blood pressure cuff on the same limb.
●If the sensor packaging or sensor has been damaged, do not use this Sp02 sensor, and it should be returned to the manufacturer.
●Misapplication of a pluse oximeter probe with excessive pressure for prolonged periods can induce pressure injury.

7.3 Measuring steps
1. Clean the measurement site, such as colored nail polish.
2. Place the oxygen probe at the measurement site.
3. Connect the monitor and oximeter cable.
4. Prepare for measurement.

7.4 Set prompt limits
1. Select the [Menu] → [ALARM SETUP]
2. Set the [High Limit] of SpO2 or PR: When the measured parameter value is above the high prompt limit, a physiological prompt of too high parameters will be triggered.
3. Set the [Low Limit] of SpO2 or PR: When the measured parameter value is below the low prompt limit, a physiological prompt of too low parameters will be triggered.
In case that a parameter prompt occurs, the measured value of the parameter will flash and the appropriate prompt light will be triggered.

7.5 Measuring influence factors
If the accuracy of the measurement results is suspected, first use other methods to examine the patient's vital signs, and then check the oximeter and oxygen probe. In the measurement process, the following factors may affect the accuracy of measurements:
■Outside light radiation
■Body movement (active or passive patient movement)
■Diagnostic test
■Weak perfusion
■Electromagnetic field effects, such as nuclear magnetic resonance device
■Electrosurgical devices
■Concentration of non-functional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
■Presence of certain dyes, such as methylene blue and indigo rouge, inappropriate placement of oxygen probe or incorrect use of oxygen probe
■Shock, anemia, low temperature or application of vasoconstrictor drugs leads to reduced pulse blood flow in the water that can not be measured

Chapter Ⅷ Carbon dioxide (CO2)

8.1General
This chapter offers some relevant data concerning CO2 oximetering.
The monitor provides one kind of CO2 measuring method, which is SideStream.
This module can be applied in operation room, oximeter units etc, it can measure the CO2 partial pressure or concentration of patient Air Way, obtain EtCO2, Inspired Maximum CO2 (InsCO2), Air Way Respiration Rate (AwRR), and display CO2 concentration waveforms. The parameter symbols displayed on the screen are defined as following:
CO2:EtCO2
FiCO2: InsCO2
AWRR: Air Way Respiration (AwRR)(Resp. times/min)

Picture8-1 CO2 screen

⚠ **Note** ⚠
Don't use the device in the environment with flammable anesthetic gas.
⚠ **Warning** ⚠
CO2 module shall be avoided from crash and vibration.

8.2 Measuring Procedure
CO2 measurement principle is based on the CO2 absorption wavelength for 4.3um infrared

characteristics carried. The measuring method of the CO2 gas supplied to the measuring chamber side with the infrared irradiation, and the other side with a sensor measuring the acceptable degree of attenuation of infrared rays, the degree of attenuation is proportional to the concentration of CO2.
CO2 partial pressure and CO2 concentration conversion relationship:
CO2 partial pressure (mmHg) = CO2 concentration (%) * Pamp (ambient pressure mmHg) / 100
CO2 partial pressure (kPa) = CO2 points pressure (mmHg) / 7.5

8.3 Carbon dioxide operation method

CO2Measurement setup
1) Connect the dehydrating column to the CO2 interface, connect one end of the nasal tube to the dehydrating column, and connect the other end to the nostril. (optional)
2) Enter the "CO2 Setting" menu, set "Working Mode" to "Measurement", and the CO2 module starts to measure.

⚠ **warning** ⚠

If the package is unpacked or the internal parts are damaged, do not use this part and return it to the supplier.

side flow sampling tube is a disposable item, can not be re-disinfected use, do not allow patients to cross use.

sampling tube is made of non-toxic and harmless PVC material in contact with human nostril.

8.4Prompt Information and Prompt

"Set the prompt:" into the "CO2 ALARM SET", point to open to the[CO2 prompt] set prompt range, details please see chapter 4 (4.3.2)
Tables below describe the possible physiological prompts, technical prompts and prompt messages occurring during CO2 measurement.

Technical prompts:

Message	Cause	Remedy
CO2 SENSOR FAULT	CO2 SENSOR is damaged	replace the CO2 SENSOR
CO2 INIT ERR	CO2 module is not properly connected or failed.	Stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.
CO2 COMM STOP	Measuring module failure or communication failure.	
CO2 ALM LMT ERR	Functional safety failure	Stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.
FiCO2 ALM LMT ERR	Functional safety failure	
AWRR ALM LMT ERR	Functional safety failure	
CO2 MODULE ON STABDY	From the measurement mode switch to standby mode, make the module in a state of energy saving	

8.5 Maintenance and Cleaning

■Maintenance and Storage

1. Sample line is for one-off use in SideStream module. Do not sterilize or clean for reuse on another patient.
2.Please keep the sampling tube clean, dust isolated, in case of any stoppage. It is suggested to replace sampling tube every 12 hours (Using time could extend to 120 hours when the sampling tube be used with a filter), or change the sampling tube when any leaks, damage or pollution found.
3. No routine calibration required in Sidestream CO2 module.

Chapter IX Non-invasive Blood Pressure (NIBP) (Optional)

9.1 NIBP Monitoring Instruction

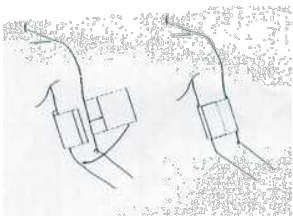
■NIBP is measured with oscillometry;
■May be used onto adult
■Measuring mode: manual, automatic and continuous. Systolic, mean and diastolic blood pressure will be display in each mode.
□"Manual" mode measure only once.
□"Automatic" mode measure repeatedly.
Time interval may be set to 1/2/3/4/5/10/15/30/60/90/120 minutes.
□"Continuous" mode measures continuously in 5 minutes.

⚠ **Warning** ⚠

■NIBP measurement can not be performed onto the patients who are ill with sickle-cell disease and any skin damage or foreseen damage. For the patients troubled with serious coagulation mechanism obstacle, automatic blood pressure measurement is determined by clinical evaluation. This is because the place where the part of body contacting the cuff risks hematoma.
■In the use of high frequency surgical equipment, should prevent the device caused by the patient's burns
■Automatic mode, if the time is too long, will affect the patient's blood circulation, cuff and body friction may cause purpura, ischemia and nerve damage. The color, warmth and sensitivity of the distal limb are frequently examined in the care of the patient. Once any observed abnormal, should be the cuff placed in another position or to immediately stop the blood pressure measurement.
■Cuff may not be used in mastectomy on one side of the upper arms, breast surgery can damage the body venous or lymphatic return, affected limb distal reflux, if in the ipsilateral quantity (pressure vessel), blood pressure, affect the patient recovery.
■When using the cuff in the wound, causing further damage to the patient
■The effect of prolonged blood pressure and the severity of the injury to the patients: the measurement is not accurate and timely.。

9.2 Operating method for NIBP Monitoring
9.2.1 NIBP Measurement

Charge tube connecting cuff with the vital signs monitor should be kept free of obstacle and entwisting.
1. Insert charge tube into cuff joint, power on the equipment.
2. In the following way, tie the cuff on upper arm or thigh of the patient, as shown in picture 9-1.



Picture 9—1 Use of cuff

◆ Make sure that the cuff is absolutely deflated.
◆ Use the suitable size cuff to ensure mark towel locating right on the proper artery. Ensure the cuff is not enlaced excessively tight the part of body, otherwise color change of even ischemia of far end of body may be caused in.
◆ Measurement patients should maintain the correct posture, legs do not cross, back and arm support and cuff center and right atrial at the same level

⚠ **Caution** ⚠
Don't talk during the measurement.

⚠ **Attention** ⚠
Width of the cuff should be 40% of body perimeter. Length of charged part of the cuff should be enough to entwist 50～80% of the body. Unsuitable size cuff may give incorrect reading. If there is problem with the cuff size, substitute with a larger one to reduce errors.

Measurement of blood pressure in the extension of the tube into the appropriate position to prevent the unconscious of the compression and limit the impact of measurement results

Repeatable cuff for adult

Type of patient	Perimeter of body	Cuff width	Length of charge tube
adult1	25～35cm	14cm	or
adult2	33～47cm	17cm	3m

◆ Cuff edge locates in the area marked with <->. If not, substitute with a larger or smaller cuff.
3. Connect cuff with charge tube. Body to be measured should be at the same level with heart. If impossible, adopt the following methods to correct the measuring result:
◆ If cuff is higher than level of heart, plus 0.75mmHg(0.10kPa) to the displayed value for very centimeter difference.
◆ If cuff is lower than level of heart, minus 0.75mmHg(0.10kPa) to the displayed value for very centimeter difference.
4. Make sure if monitoring method is correct (monitoring method is displayed in vital signs monitor information area at right side of sickbed number.). If changing monitoring method is needed, please enter into "Patient' s information setting" in "system menu" to change "Type of patient".
5. Select measuring method in NIBP menu. Refer to the "Operation prompt" below for details.
6. Press "START" key on the front panel to begin measuring pressure.

Operation Prompt

1. One automatic measuring
Enter into "NIBP setting" menu, select the option of "Time interval". User may select time interval value for automatic measurement. Then, press START key on the front panel, the system will automatically charge for measurement according to the set time interval.

⚠ **Warning** ⚠

If NIBP in automatic mode lasts excessively long, purpuric, ischemic and nervous and nerve damage may be caused in onto the place where the cuff contacts the body. During monitoring, it is required to regularly check the color, warm degree and sensitivity of body far end. If abnormality found, place the cuff onto another place or stop measuring.

2. Stop automatic measuring
Press START key at any time during automatic measuring to stop automatic measuring.

3. One manual measuring
◆ Enter into "NIBP SETUP" menu, select "INTERVAL", set the value to "MANUAL", then press "START" key on the front panel to begin a manual measuring.
◆ At an idle moment during automatic measuring, press "START" key to begin a manual measuring. If press "START" key again at that time, manual measuring will be stopped, but to execute automatic measuring.
4. One manual measuring during automatic measuring
Press "START" key on the front control panel.
5. Stop one manual measuring on midway
Press again the "START' key on the front control panel.
6. Continuous measuring
Enter into "NIBP SETUP" menu, into "OTHERS",select "CONTINUAL" to begin continuous measuring. The course lasts 5 minutes.

⚠ **Warning** ⚠

If NIBP in continuous mode lasts excessively long, purpuric, ischemic and nerve damage may be caused in onto the place where the cuff contacts the body. During monitoring, it is required to regularly check the color, warm degree and sensitivity of body far end. If abnormality found, place the cuff onto another place or stop measuring.

7. Stop continuous measuring on midway
Press "START" key at any time during continuous measuring to stop continuous measuring.

⚠ **Attention** ⚠

If doubting about the accuracy of the reading, check patient' s vital signs with possible methods before checking the function of the vital signs monitor.

Warning

If liquid splashes the equipment or accessories, particularly when the liquid is possible to enter into conduct or the vital signs monitor, please contact hospital maintenance department.

Measuring limit

According to status of the patient, measuring with oscillometry is with limitation. What this measuring seeks for is the regular pulse wave generated by arterial pressure. If this measuring becomes very difficult due to the patient, the measuring value is unreliable, and measuring time is increased. User should know that the following circumstances will interfere with measuring method making pressure measuring unreliable or pressure measuring time longer. Under such a circumstance, patient' s status causes measuring fail to be performed.
■ Moving of patient

If the patient is moving, trembling, or in convulsion, measuring is unreliable or impossible. This is because such circumstances may interfere with checking of arterial pressure pulse, and blood measuring time will be lengthened.

■ Arrhythmia

If the patient is displayed with arrhythmia and irregular heart beat caused in, measuring will be unreliable or even can not be performed, and measuring time is lengthened.

■ Heart-lung machine

If patient uses artificial heart0pung machine for connection, measuring can not be performed.

■ Changes of pressure

If in a certain period of time, arterial pressure pulse is being analyzed to acquire measuring value, blood pressure of the patient changes rapidly, and measuring is unreliable or even can not be performed.

■ Serious shock

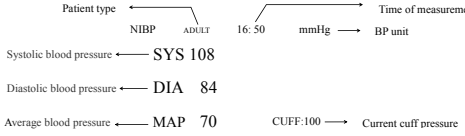
If the patient is with serious shock or excessive low TEMP, measuring is unreliable, because increase of the blood stream peripherally flowing may lower arterial pulse.

■ Ultimate heart rate

Blood pressure measuring can not be performed if HR is lower than 40bpm(beat/minute) and higher than 240bpm(beat/minute).

9.2.2 NIBP Parameter Setting and adjustment

Display layout of NIBP measuring result and corresponding information on screen:



9.3 NIBP Menu

Press "MENU" button, enter the "menu", into"PARAMETER SETUP",select "NIBP SETUP" menu as shown in the picture 9-2.

Picture 9—2 NIBP Setting Menu

■Pressure unit

mmHg or kPa are optional.

■Time interval

Automatically measure time interval (unit: minute). Options of 1, 2, 3, 4, 5, 10, 15, 30, 60 , 90, 120 minutes are available. At the time, press START key to start for the first time automatic measuring. To stop automatic measuring, it is required to select “Manual” to turn back to manual mode at measuring interval.

■Initial inflation value

Press this button to select the initial inflation value when pressuring the cuff next time, there are different inflatable values selection range under different default configurations, as shown in the following table:

Default configuration	The default inflated values(mmHg/kPa)	Inflated values manually selectable NIBP menu (mmHg/kPa)
The default factory adult configuration	180	60/70/80/100/120/140/ 160/180/200/220/240

The user presses the front shell on the "MENU" button, press “PARAMETER SETUP” ,,press the “NIBP SETUP” ,press the “NFLATION”,You can see the corresponding

"pre aeration" initial a value that corresponds to the selected initial default configuration value of inflation pressure, as shown in the table. You can see for manual adjustment of pre aeration selection range is as shown in the table.

■Reset

Measure state of blood pump reset.

Press “RESET” to have charge value of the blood pump be back to the initial setting. When blood pump is with abnormal work and the patient gives no prompt fro the problem, this key is recommended to use. This is because it will make the blood pump perform self-test and automatically recover if the abnormality is caused by accidental reasons.

■Continuous measuring

Start continuous measuring

After selecting “CONTINUAL”, start continuous measuring at once.

■Pressure calibration

It is recommended to use manometer with a min. precision of 1 mmHg (Mercurial Blood-Pressure Meter). Select “CALIBRATION” to start calibrating. Meanwhile this option changes to “STOP CAL” If pressing this key at this moment, the system will stop calibration.

⚠ **Warning** ⚠

Calibration of NIBP measuring should be made once every two years (or follow your maintenance regulation). Check its performance according to the followings.

Calibrating steps for pressure sensor:

Substitute the cuff with a metal container at a cubage of 500ml+5%. Insert a calibrated standard manometer with a max. tolerance of 0.8mmHg, an air pump with T-shape interface and a charge tube into the NIBP jacks on the module. Set the patient monitor to “Standard”, increase the pressure in the metal container to 0, 50 and 200 mmHg with air pump. At the time, the difference between the value of standard manometer and the pressure demonstrated on the patient monitor should be less than 3 mmHg. Otherwise, contact maintenance technicians of our company.

⚠ **Warning** ⚠

The leak test is different from the content in EN 1060-1 Standard. Is used to simply test leak in NIBP charge. If NIBP leak is displayed by the system, please contact the maintenance technicians of our company.

Steps for leak test:

1)Connect secure the cuff with NIBP air hole of the patient monitor.

2)Enwind the cuff onto a proper size column.

3)Enter into “NIBP setting” menu.

4)Turn the knob, move the cursor to option of “Leak test”, press the knob. At the time, on lower part of the NIBP parameter area on the screen will notify “Leak testing…”, indicating that the system starts leak test.

5)The system automatically charge to the pressure 180mmHg.

6)Roughly 20 seconds later, the system automatically opens the air valve to deflate, marks leak test completed.

7)If there is no prompt displayed in NIBP parameter area, it means no leak on the system. If “Pump leak…” is displayed, it means that there is possible leak in air route. At the time, the operator should check if the all joints are secure. If yes, make a leak test once more. If still with failure prompt, please contact the manufacturer for servicing.

■Default configuration: Select this option to enter into NIBP default configuration dialog box. System default configuration may be selected.

9.4 NIBP Prompt

NIBP prompt Setting

Select the "MENU" button on the instrument, into the "menu", select "ALARM SETUP" , then the next key to enter "NIBP ALARM", NIBP alarm settings, as shown in Figure9-3.

picture 9-3NIBP Setup Menu

♦Prompt switch: if selecting "On", prompt and storing will be performed in case of pressure exceeds the limit; if selecting "Off", there will be no prompt given, and the prompt of "  " will be displayed by NIBP in screen parameter area.
♦Pressure alarm is performed according to the set upper limit and lower limit. Prompt will be given in case of overrun of prompt limit of the pressure. Prompt for systolic blood pressure, mean blood pressure and diastolic blood pressure may be dealt with separately.
Adjustment range of upper and lower limit:

Adult
Systolic blood pressure: 0～270 mmHg
Diastolic blood pressure: 0～270 mmHg
Mean blood pressure: 0～270 mmHg

9.5 Maintenance and Cleaning

⚠ **Warning** ⚠

■Do not press the rubber tube of the cuff.
■Prevent water or wash solution from entering connector socket on front of the vital signs monitor.
■When cleaning the vital signs monitor, wipe the surface of the connector socket, but not the inside of it.
■When the repeatable cuff is not connected with the vital signs monitor or being cleaned, the lid should always be on the rubber tube to prevent liquid from entering the rubber tube and being absorbed by the module.

Repeatable cuff

The cuff can be sterilized with high pressure in regular hot air oven, or disinfected with gas or radiation, or sterilized by dipping into detergent solution. Do remember to take down the rubber bag if this method adopted. Dry-cleaning of the cuff is prohibited. The cuff can be washed with machine or hand. Hand wash will prolong its lifespan. Before washing, take out the rubber bag. After washing and when the cuff is dried absolutely, mount back the rubber bag.

⚠ **Attention** ⚠

For environment protection, the disposable blood pressure cuff must be reclaimed or managed properly.

Chapter X Battery

10.1 Overview

The monitor is mainly powered by lithium battery. Battery icon in the information bar below the screen shows the status of the battery.
When the battery capacity is too low and the [inadequate battery capacity] is displayed, the lithium battery must be timely charged; otherwise, the monitor will be automatically shut down after a period of time. In case that measuring the patient can not be interrupted, you can connect the charger with the monitor, and connect the adapter.
Whether the monitor is turned on, you can use a adapter to recharge the lithium battery, but it is not recommended to measure patients during the charging process.

⚠ **Attention** ⚠

●Before delivery of the monitor, or when the monitor is not used for a long time, take out the battery.

⚠ **Warning** ⚠

●Keep the battery out of the reach of children.
●Use only the battery specified by the manufacturer.
●The handheld pluse oximeter does not work in charging mode.

10.2 Install the battery

1. Hold the battery cover, push down, and take down the battery cover.
2. Install the battery:
1) Mount the battery into the battery box correctly
2) Place the battery cover on top of the battery, push up, and install the battery cover

⚠ **Caution** ⚠

●Do not use the batteries from other manufacturers.

10.3 Optimize the battery performance

When the lithium battery is used for the first time, at least two full optimization cycles should be ensured. A complete optimization cycle is as follows: continuous charging and then discharging until the monitor is shut off. During the use, the lithium battery should be optimized regularly in order to maintain its useful life. It is recommended to optimize the lithium battery every two months of use or storage or when the lithium battery' s operating time is significantly shortened.
When optimizing, please refer to the following steps:
1. Disconnect the monitor with the patient and stop all measuring work.

2. Install the lithium battery needed to be optimized into the battery stack of the monitor.
3. Connect the monitor to AC power supply, and keep uninterrupted charging of the lithium battery for 3 hours or more.
4. Disconnect the AC power supply, and make use of the lithium battery to supply power to the monitor until the monitor is closed.
5. Re-connect the monitor and charger base, connect the AC power supply, and keep uninterrupted charging of the lithium battery for 2 hours or more.
6. The optimization of the lithium battery is completed.

10.4 Check the battery performance

The performance of lithium battery may decline over time. When checking the performance of lithium battery, please refer to the following steps:
1. Disconnect the monitor with the patient and stop all measuring work.
2. Connect the monitor to adapter, and keep uninterrupted charging of the lithium battery for 2 hours or more.
3. Disconnect the adapter, and make use of the lithium battery to supply power to the monitor until the monitor is closed.
4. The run time of the lithium battery reflects the performance of lithium battery.
If the operating time of the lithium battery is significantly lower than the time claimed in the specification, consider replacing the lithium battery or contact the maintenance personnel.

⚠ **Attention** ⚠

● The useful life of the lithium battery depends on the frequency domain time for use. If the lithium battery is properly maintained and stored, the useful life of the lithium battery is about three years. In case of improper use of the lithium battery, its useful life may be shortened. We recommend that the lithium battery is replaced every three years.
● The run time of the battery depends on the device configuration and operation.

10.5 Battery recycling

If there is a significant damage to the battery or the battery runs out of energy, it should be replaced, and properly recycled. When disposing of used batteries, appropriate regulations should be followed.

⚠ **Warning** ⚠

● Do not disassemble the battery, put it into fire or short circuit. Battery burning, explosion or leakage may cause personal injury.

Chapter XI Maintenance and Cleaning

Use only the materials and methods listed in this section for cleaning or disinfecting of the device. The company does not provide any guarantee for damage or accidents caused by other materials or methods.
The company does not bear any responsibility for the effectiveness of the chemicals or methods listed as a means of infection control. About the method for infection control, please consult the hospital' s infection prevention department or epidemiologist.
Please keep your device and its accessories free of dust. To prevent damage to the device, be sure to observe the following:
■ Please dilute the cleaning agent and disinfectant according to the manufacturer's instructions, or use the lowest possible concentrations.
■ Do not immerse the device in the liquid.
■ Do not pour liquid onto the device or accessories.
■ Do not allow liquid to enter the enclosure.
■ Do not use abrasive materials (such as steel wool or silver polish), and any strong solvents (such as acetone or acetone-containing cleaning agents).

⚠ **Warning** ⚠

● Before cleaning the device, you must turn off the power supply and disconnect the adapter.

⚠ **Caution** ⚠

● If you pour liquid onto the device or accessories due to incaution, please contact the maintenance personnel or the agency immediately.

⚠ **Attention** ⚠

● To clean or disinfect reusable accessories, please refer to the manual provided along with the accessories.

11.1 Inspection

Before the monitor is used for the first time, and after it is repaired or upgraded, or at least every two years, a comprehensive inspection on it should be conducted by qualified maintenance personnel to ensure the normal operation and work of the monitor.
Inspection items should include:
■ The environment and power supply meet the requirements.
■ The device and accessories are not mechanically damaged.
■ The adapter is not worn, with good insulation properties.
■ Use the specified accessories.
■ The prompt system functions properly.
■ Battery performance.

■The measuring function is in good working condition.
If you find any damage or unusual phenomenon, please do not use the monitor, and immediately contact the manufacturer

11.2 Cleaning

The device should be cleaned on a regular basis, and the frequency of cleaning should be increased in the areas suffering from serious environmental pollution or heavy sand. Please consult or learn about the hospital' s regulations on the device cleaning before cleaning.
1) Cleaning frequency:
When using at home, clean it before and after use
For use by medical institutions, cleaning can be carried out according to the hospital cleaning regulations. Clean approximately 5 times.
2) Cleaning methods:
The following cleaning agents are available for selection:
■Water
■Hydrogen peroxide (3%)
■Ethanol (70%)
■Isopropanol (70%)
①Cleaning of main engine:
Before cleaning, turn off the power supply first. If AC power is connected for charging, disconnect the adapter first.
1.Use a lint free cloth, dip a proper amount of detergent, squeeze it dry, and wipe the host machine;
2.When wiping the host machine, pay attention to avoid the interface at the upper end of the instrument;
3.Wipe off the detergent on the surface of the instrument with a dry lint free cloth, and place the instrument in a cool and ventilated environment to dry.
②Cleaning of accessories:
For the cleaning of reusable blood oxygen probe accessories, please refer to the relevant accessory manual. If the accessory does not come with the manual, please refer to this section.
1.Wipe accessories with a soft cloth moistened with appropriate amount of water;
2.After wiping, dry the accessories with a dry soft cloth;
3.Dry accessories in a cool environment.

11.3 Disinfection

Disinfection operation may produce some degree of damage to the monitor. It is recommended to perform disinfection only when deemed necessary in your hospital maintenance plan. The device should be cleaned before disinfection.
①main engine disinfection:
When using at home, the host and accessories do not need to be disinfected. If the host or accessories are polluted, clean them first, then wipe them with 70% ethanol or 70% isopropanol, and then dry them with a dry soft cloth.
When used in hospital, the instrument can be disinfected according to the disinfection regulations of the hospital where it is located. Before disinfection, the instrument should be cleaned first.
②Disinfection of accessories:
For the disinfection of reusable accessories of blood oxygen probe during hospital use, please refer to the instructions of relevant accessories. If the instructions are not attached, please refer to this section
Recommended disinfectants: 70% ethanol, 70% isopropanol, 2% glutaraldehyde solution
1.Clean accessories before disinfection;
2.Dip a soft cloth with a proper amount of disinfectant and wipe the accessories;
3.Wipe the residual disinfectant on the accessories with a soft cloth moistened with water;
4.Place accessories in a cool environment to dry;
It is recommended to use disposable sampling tube and disposable nasal tube in families and hospitals when measuring the end of breath carbon dioxide.
⚠ **Caution** ⚠
● Do not use gas (EtO) or formaldehyde for disinfection.
● Power must be turned off before cleaning the instrument
● If you accidentally pour liquid on the instrument or accessories, please contact the manufacturer immediately.
● Do not leave any detergent on the surface of the instrument.

11.4 Scrap

To avoid contamination or infection to others, environment or other devices, before scrapping the monitor, follow the state relevant laws or regulations for its disinfection and purification. For the oxygen probe, please follow the relevant provisions of the local hospital on waste scrap.

11.5 Sterilization

Sterilization of instruments and accessories is not allowed.

Chapter XII Accessories

⚠ **Warning** ⚠

●Use only the accessories specified in this manual, and the use of other accessories may damage the monitor.

●Disposable accessories can only be used once, because repeated use can cause performance degradation or cross-infection.

●If accessory packages or accessories are damaged, do not use the accessories.

●The blood oxygen saturation probe in the chapter complies with biocompatibility requirements and meets the standards ISO 10993-1 and ISO 10993-5 and ISO 10993-10.

A Product Specification

Safety specification (in accordance with IEC60601-1 classification)	
Protection type of electric shock	Class II (including internal power supply)
Protection class of electric shock	BF
Explosion protection class	Ordinary device, explosion protection not provided
Protection class of inlet liquid	IP22
Movement grade	Handheld
Working mode	Continuous

Environmental specification	Work	Storage
Temperature (℃)	5℃～40 ℃	-20℃～50℃
Relative humidity (non-condensing)	15%～80%	10%～95%
Atmospheric pressure (kPa)	86.0～106.0 kPa	55.0～106kPa
Recommended maximum charge and discharge ambient temperature	Charge: 35℃; discharge: 45℃	

Adapter	
Input voltage	100～240 VAC, 50/60 Hz
Output voltage	5 VDC
Output current	2.0 A
Output power	10W

Lithium battery	
Quantity	1
Rated voltage	3.7 V
Battery capacity	2000mAh
Supply time	About 5h, using the new and fully charged battery at the ambient temperature 25℃, with a typical configuration (SpO2 continuous measurement, the backlight set to minimum brightness, and the sound turned off all the time).
Charging time	About 4 hours (the charged capacity is 100%)
Shutdown delay	since the first low battery capacity prompt

Physical specification	
W × H × T	155.5*73.5*29mm
Maximum weight	About 263 g(SpO2)(Contain the battery and charging seat) About 295 g(SpO2+CO2)(Contain the battery and charging seat)

Hardware specification	
Display screen	Color TFT, 3.97-inch, dot matrix: 480× 800
Speaker	1,Prompt sound, Multi level volume function
prompt indicator light	1, yellow
Blood oxygen probe interface	1, DB9
Carbon dioxide module interface	1
Power interface	1,Connect the bottom of the charging device

Data storage	
Maximum storage	15 hours of data
Minimum resolution	1minute

Measurement specification
SpO2
Confirm the accuracy of measurements: the accuracy of SpO2 is already confirmed in human trials by comparison with the reference value of arterial blood sample measured by CO- oxygen pressure gauge. The measurement results of pulsation oxygen meter meet statistical distribution, and compared with the measurement results of CO- oxygen pressure gauge, only about two-thirds of the measurement results is expected to be within the specified precision.

Measuring range	0～100%	
Resolution	1%	
Precision	70～100%: 0%～69%:	± 4% (in the non-moving state) not defined

PR	
Measuring range	30～240 bpm
Resolution	1 bpm
Precision	±3 bpm (in the non-moving state)
Update cycle	1 s

Prompt limit specification		
prompt limit	Range (%)	Step length (%)
SpO2 high limit	(low limit +1) ～100	1
SpO2 low limit	0～ (high limit -1)	
prompt limit	Range (bpm)	Step length (bpm)
PR high limit	(low limit +1) ～240	1
PR low limit	30～ (high limit -1)	

CO2		
Measuring range	0 ~ 114mmHg	
Resolution	1mmHg	
Precision	0～40mmHg：±2mmHg) 41～76mmHg：±5% numerical reading 77～114mmHg：±8% numerical reading Breathing rate gets 80 BPM：±12% numerical reading	
prompt limit	Range (mmHg)	Step length (mmHg)
CO2 high limit	114 mmHg	1
CO2 low limit	0 mmHg	

AWRR	
Measuring range	0 ~150BrPM
Precision	0 ~70BrPM: ±2BrPM >70BrPM:± 5BrPM

prompt limit specification	
AWRR high limit	150BrPM
AWRR low limit	0BrPM

Using life	5 years
Applied parts specified	Oxygen probe ,DB9, Carbon dioxide module,side streamx
Pollution degree	Pollution degree2:Micro-environment with non-conductive pollution,expect occasional conductivity caused by condensation

NIBP	
Measuring Method	Pulse wave oscillometry
Work Mode	Manual/Automatic
Measuring Interval of Automatic Measuring Mode(minutes)	1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120
Measuring Range and Precision	Range: Adult Systolic blood pressure 0～270mmHg Diastolic blood pressure 0～270mmHg Mean blood pressure 0～270mmHg Static pressure range 0～280mmHg Static pressure precision 3mmHg Pressure precision: Max. average error: 5mmHg;Max. standard deviation: 8mmHg
Overvoltage protection	Adult mode 280mmHg

B Default factory settings

This chapter lists some of the most important default factory settings of the Vital Signs Monitor. If users can not change the factory settings, but when needed, the default factory settings of the Vital Signs Monitor can be restored.
Attention, the column A in the chapter indicates whether the item is affected by factory configuration or user configuration.

B.1 Prompt

Prompt setting	Default factory settings
Prompt volume *	3
Pause time for prompt tone	120 s
Prompt switch	open
Probe off	low
SPO2 prompt	open
PR prompt	open
CO2 prompt	open

B.2 System

System	Default factory settings
Interface selection	Conventional interface
System time	08:00
Date format	Day - month - year
Time format	24-hour
Language selection	English
Pulse volume	3

B.3 SpO2

SpO2 Settings	
SpO2 high prompt limit	99
SpO2 low prompt limit	90
PR Settings	
PR high prompt limit	125
PR low prompt limit	50

B.4 CO2

CO2 Settings	
CO2 high prompt limit	50
CO2 low prompt limit	15
AWRR high prompt limit	30
AWRR low prompt limit	8
FICO2	4

B.5 NIBP

NIBP Settings	
SYS high prompt limit	160
SYS low prompt limit	90
MAP high prompt limit	110
MAP low prompt limit	60
DIA high prompt limit	90
DIA low prompt limit	50

C Prompt Information

This chapter lists some of the most important physiological and technical prompt information, but some prompt information is not necessarily listed.
Attention, in this chapter: the column L indicates the default prompt level: H is High, M is medium, and L is low;
For each prompt information, appropriate countermeasures are given out. If the problem persists after operations following the countermeasures, contact the maintenance personnel.

C.1 Physiological prompt information

prompt information	Reasons and countermeasures
SpO2 too high SpO2 too low PR too high PR too low	Check the physiological condition of the patient, and confirm whether the patient type and prompt limit settings are applied to the patient.
No pulse found	If the patient's pulse signal is too weak, the system can not analyze. Check the patient's condition, oxygen probe and measurement site.

prompt information	Reasons and countermeasures
CO2 too high CO2 too low	Check the physiological condition of the patient, and confirm whether the patient type and prompt limit settings are applied to the patient.

C.2 Technical prompt information

prompt information	Reasons and countermeasures
The probe off	If the oxygen probe is off from the patient or host, if it fails, or an oxygen probe not specified in this manual is used, check whether the oxygen probe type and installation position are correct, and whether the oxygen probe is damaged. Reconnect the oxygen probe or use a new oxygen probe.
Inadequate battery capacity	When the low battery voltage is below the prompt voltage, If the battery in use is a lithium battery, connect the charger base and adapter to recharge the lithium battery, and then use the battery to supply power as needed.

D Manufacturer' s Declaration of the EUT

Statement:
1.The Vital Signs Monitor or user should use the product in the electromagnetic environment specified in the following table, otherwise it may cause abnormal operation of the product.

2.The internal structure of the Vital Signs Monitor adds magnetic rings, magnetic beads, and conductive cloth to spray conductive paint to avoid electromagnetic interference, so as to prevent adverse events to patients and operators due to electromagnetic interference.

3.Vital Signs Monitor is a table-top equipment, it suitable for medical unit and home use.

4.Warning: Use of this Vital Signs Monitor adjacent to or stacked with other equipment should be avoided because it could result in improper observed to verify that they are operating normally.

5.Warning：Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in impropre operation.

6.Warning：Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Arm type blood pressure oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this Vital Signs Monitor could result.

Guidance and manufacturer´s declaration –
electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer´s declaration – electromagnetic emission	
2	The 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 environment.	
3	Emissions test	Compliance
4	RF emissions CISPR 11	Group 1
5	RF emissions CISPR 11	Class B
6	Harmonic emissions IEC 61000-3-2	N/A
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A

Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacturer' s declaration – electromagnetic immunity		
The Vital Signs Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Vital Signs Monitor should assure that it is used in such an environment.		
Immunity test	EN 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15kV air
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lnes	N/A
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m
NOTE UT is the a. c. mains voltage prior to application of the test level.		

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

Guidance and manufacturer´s declaration – electromagnetic immunity		
The Vital Signs Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Vital Signs Monitor should assure that it is used in such an environment.		
Immunity test	EN 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A

Table 9 - Test specifications for enclosure port immunity to RF wireless communications equipmentfor EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity TEST LEVEL (V/m)
385	380 -390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FMc) ± 5 kHz deviation	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0.3	9
810 870 930	800 - 960	GSM 800/900. TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1 720 1 845 1 970	1 700-1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2 450	2 400-9 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5 240 5 500 5 785	5 100-5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0.3	9

NOTE:
If necessary to achieve the immunity test level, the distance between the transmitting antenna and the me
equipment or me system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Appendix Parts List

Product model	Item:SpO2
Name	Quantity
Host	1
Adapter	1
Oxygen probe	1
User manual	1

Product model	Item:SpO2+CO2
Name	Quantity
Host	1
Adapter	1
Oxygen probe	1
User manual	1
Dehydration column	1
Nasal tube	1
Extension tube	1
L joint	1

Product model	Item:SpO2+NIBP
Name	Quantity
Host	1
Adapter	1
Oxygen probe	1
User manual	1
Blood pressure cuff	1
Blood pressure extension tube	1
USB wire	1

Product model	Item:NIBP
Name	Quantity
Host	1
Adapter	1
User manual	1
Blood pressure cuff	1
Blood pressure extension tube	1
USB wire	1