(Only for YK-810)

ENSM810201809141

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Contents

Disclaimer Statement

Gives no warranty in relation to the mistakes, mis-installation and mis-operation. The company undertakes no liability to accidental failure or inevitable damage.

The company is responsible for the reliability, security and performance of the equipment only in the cases of the followings that: assembly, expansion, readjustment, performance improvement and maintenance are performed by authorized personnel or unit by our company; the electrical equipments are in compliance with the state relevant standards; operation of this equipment is followed this manual.

The company reserves the right to make change of the content of this manual without further notice.

The latest revision date: 12-2017

⚠ **Warning** ⚠**:**

If hospital or medical units using the equipment have not a satisfied maintenance scheme available, failure of the equipment may be caused in and that may endanger the human health.

- Do not just rely on the audible alarm system to monitor patients in the care of patients, such as the volume setting is too small or completely shut off may cause the patient to disaster. To remember that the most reliable vital signs monitor method is the proper use of monitoring equipment to closely monitor the patient together.
- On patients with pacemakers! Heart rate meter may be in cardiac arrest or arrhythmia pacemaker pulse through. Never rely solely on rate meter alarms should be closely monitored patients with pacemakers. Related equipment the pacing pulse suppression ability to refer to the manual.
- Monitor for clinical patient care, allowing only doctors and nurses to use the monitor.
- Do not open the monitor housing, in order to avoid the risk of electric shock. If necessary, please maintenance personnel of the Company.
- This device may interfere with the ultrasound imaging system, the performance of the interference signal on the ultrasound monitor. The distance between these two devices placed survived as far as possible.
- For the end-of-life battery, local laws should be recycled.
- It is very dangerous to the electrical contacts or the connecting means is exposed to saline or other liquid conductive adhesive. Electrical contacts and connections such as cable connectors, power, rack connector must be kept clean and dry. As they are liquid contamination must be completely dry. If you required further decontamination, please contact the company.

⚠ **Warning** ⚠

This is not a treatment device

Using this (if any) the responsibility of each hospital or medical institution can not achieve a satisfactory maintenance plan, it will cause abnormal device failure, and may endanger human health

Quality assurance:

Maintenance

Free service:

Free service is available for all the equipments within the scope of warranty service of Company.

Charge service:

(1) Charge service is available for the equipments beyond the scope of warranty service of Company;

(2) During warranty period, product servicing caused by the following reasons: mis-use; overvoltage, force majeure.

company undertakes no liability in relation to direct, indirect and final damage or delay because of the following (including but limited to) reasons: improper use; substituting component with those unauthorized by Company or maintenance performed by personnel unauthorized by Company.

Returning the machine

Procedures of returning the goods

If goods returning is needed, please follow the following steps:

1. Acquiring return permit: Contact with the After-sales Service Department of our company to offer the serial number of the product. If the serial number is not clear enough, goods returning will be refused. Please give clear indication of product model, serial number and a brief statement for reasons of returning the goods.
2. Freight: Users have to bear the freight (including customs charge) if product servicing is needed to be performed at our company.

Summary

This manual details the Monitor performance, methods of operation and other security information. This is the best starting point for new users to start using the monitor.

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The following symbols indicate some important tips, the user should be noted

⚠ **Warning** ⚠

Prompt potentially dangerous or unsafe operation, if not avoided, could result in death, severe personal injury or property damage.

⚠ **Attention** ⚠

Prompt potentially dangerous or unsafe operation, if not avoided, could result in minor personal injury, product failure, damage to or loss of property.

⚠ **Note**⚠

Emphasize the important considerations, provide instructions or explanations to better use of the product

This manual is familiar with the various measurement read and experienced personnel in the use of monitoring equipment.

Contraindication and warning occasions

- This equipment at the same time is limited to the use of one patient
- The device if there is no fixed, may fall, resulting in personal injury or equipment damage. In order to prevent personal injury or damage to the equipment, connect the device to the mounting location.
- This equipment can not be used in magnetic resonance imaging (MRI) equipment occasions, otherwise the induced current will cause patient burns.
- Keep the equipment away from the working place with flammable anesthetic gas or other gas.
- Keep the equipment away from the place with electromagnetic radiation, e.g. the place using mobile phone.
- Maintenance is to be performed only by qualified technicians.
- Do not replace the power cord of the equipment This equipment should not three-wire power cord to connect two-pin socket.

Precautions

- Calibrate and ensure normal operation of the equipment before use.
- Pay attention to the power cord, conduit and all the cables to prevent patient from strangulation and other people from trip.
- Keep the back of the equipment open for heat elimination.
- Disconnect the power supply immediately in case of liquid falling into the case of the equipment and contact the maintenance personnel.

Chapter One Vital Signs Monitor Structure

- Please read through the content of vital signs monitor summarization for an overall understanding of the vital signs monitor.
- Please refer to screen display introduction for instruction of information displayed on the screen.
- Please refer to the content involving key functions and basic operation of the equipment for command of operation method.
- Please refer to the content involving external interface for interface position.
- Please refer to the content involving internal chargeable battery for precautions for the monitor power supplied by battery.

⚠ **Warning** ⚠

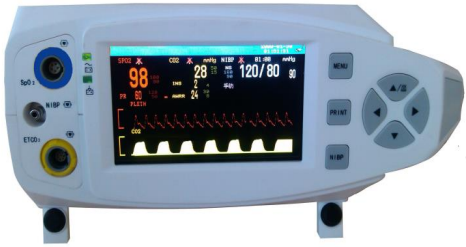
- **Portable vital signs monitor is used for clinical monitoring. Only doctors and nurses are allowed to use it.**
- **Do not open the case of the equipment to avoid electrical shock. Only the maintenance personnel trained and authorized by are allowed to perform the maintenance and upgrade of the equipment.**
- **Keep use of the equipment away from the place with flammable substances like anesthetic to avoid explosion.**
- **Users are required to check if the equipment and the components work normally before use.**
- **To avoid delay in medical treatment, please set proper alarm according to each patient and make alarm sound available with the alarm.**
- **Do not use mobile phone near the equipment. The over-strong radiated field generated by mobile phone may interfere with the function of the vital signs monitor.**
- **The equipment connected to the vital signs monitor must be formed to be an equipotential body.**
- **While using this equipment together with electrical surgical equipments, users (doctors or nurses) should ensure the monitored patient safe.**
- **Control the packing material according to the valid waste control standard, and keep the packing material beyond the touch of children.**
- **Appliance coupler is considered as disconnect device, please do not place the equipment in a difficultly operation position**
- **Do not modify this equipment without authorization of the manufacture**
- **Do not allow service or maintenance the equipment while used in patient.**
- **If any operator requests more information such as circuit diagrams, parts list and product descriptions, for repairs carried out by qualified technical personnel, please contact us.**

- **Class I equipment, to avoid the risk of electric shock, the equipment must only be connected to a supply mains with protective earth.**
- **The SIP/SOP should be connected to IEC/EN 60601-1 or IEC 60XXX certificated device. If not, there will be risk of external voltage on this part.**

⚠ Attention ⚠

- **It is a must to control the product and the components in this manual according to the relevant standard when they are to expire. Please contact its representatives for detailed information.**
- **In case of the perfection and arrangement of the external earthing of the equipment are doubtful, it is a must to operate it using the internal battery.**

1.1 The Monitor appearance picture



Picture 1-1 vital signs monitor

1.2 Equipment overview

Vital Signs Monitor referred to in this manual oximetry or instrument.
Vital Signs Monitor is power supplied by internal battery or AC. It is equipped with a handle for easy carrying.

Intend use：
Vital Signs Monitor is suitable for monitoring and measuring patients' non-invasive blood pressure (systolic blood pressure, diastolic blood pressure, mean blood pressure), respiration rate, blood oxygen saturation and Pulse rate .

Indications: the patient monitor is used for clinical monitoring for patients, and transferring physiological parameters including Pulse Oxygen Saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP) and

End-tidal carbon dioxide tension (EtCO2) of adults.
This monitor is to be used by clinical professionals or under their direction. It must only be used by persons who have received adequate training in its use. And the monitor can also be used when transferring patients, but it is not intended for helicopter transport or home use.

Contraindications:
None

The composition of the Monitor: Monitor by the host, battery, display, and oxygen probe, blood pressure cuff, power cord, ground wire and other components.
boasts the following characteristics:

- ☆ **4.3" screen with true color, wide viewing angle, high brightness LCD display.**
- ☆ **Simple and friendly operating display interface.**
- ☆ **Internal chargeable large capacity battery provides convenience for patients' moving.**
- ☆ **Playback and browse function for long term waveform and monitor data record.**
- ☆ **Optional printing output function, alarm triggers printing.**
- ☆ **Auto double alarm with audible and visible signals**

Working environment

Temperature:

Working temperature	0 － 40 (°C)
Transportation and storage temperature	-20 － 60 (°C)

Humidity:

Working humidity	<= 85 %
Transportation and storage humidity	<= 93 %

Atmospheric pressure

Operating	70.0kPa～106.0kPa;
Transportation and storage	22kPa~107.4kPa

Altitude:

Working altitude	≤2000m(≤6,562 ft)

Rating

Rated: 100-240Va.c. 50/60Hz, 70VA
Internal battery: 11.1Vd.c. 2000mAh

⚠**Attention**⚠

Do not use the monitor in the temperature and humidity outside the range specified by the manufacturer will not be able to achieve the claimed performance specifications in Appendix II.

enjoys a large range of Monitor
functions (as shown in picture 1-1). It is suitable for sickbed monitoring of adult. Users may choose different measuring parameter configuration according to different need.

This equipment may be used to monitor the parameters of blood oxygen saturation (SpO2), non-invasive blood pressure (NIBP), and Carbon dioxide(ETCO2). It integrates parameter measuring module function with output display and recording to contribute to an impact and portable patient monitor. The internal battery provides the patient with an easy moving. 2 waveforms and all monitoring parameter data are displayed on the display interface with high resolution.

Introduction buttons and interface features:

Vital Signs Monitor (referred to as instruments) power switch to "POWER" black button (as shown “ | 0 ”).

AC power indicator “ ~ ” shown in Figure 1-2 ①, battery indicator “ ” Figure 1-2 ② shown,

When the instrument is connected to the AC, the lights ① and ② are on .If the battery power has been filled, the light ② does not shine this time ① lights lit, ② light flashes when the instrument does not install battery boot.

When the instrument is not using the AC internal battery, ① and ②lights are off.

The Monitor button shown in Figure 1-2 ③ shown.

The warning lights ALARM located at the right side of the handle when an alarm occurs, this light is flashing or lit (Figure 1-2 the ④ shown).

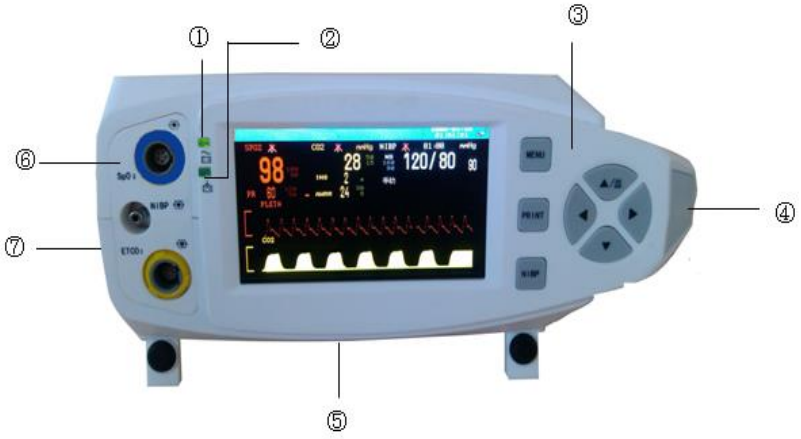
Battery jack is located on the lower side of the left side of the instrument panel (Figure 1-2 ⑤)

Sensor jack is located on the left side of the instrument panel (Figure 1-2 ⑥).

Recorder located at the bottom of the right panel (Figure 1-2 ⑦).

Jack and power outlet is located on the back panel.

The monitor has a friendly user interface, through the front panel buttons to complete all the details, see the part of the function keys.



Picture 1-2 vital signs monitor

① The ac power indicator light
② The battery indicator light
③ key-press
④ alarm light
⑤ Battery socket
⑥ Sensor hole
⑦ Recorder location

Definition abbreviation:

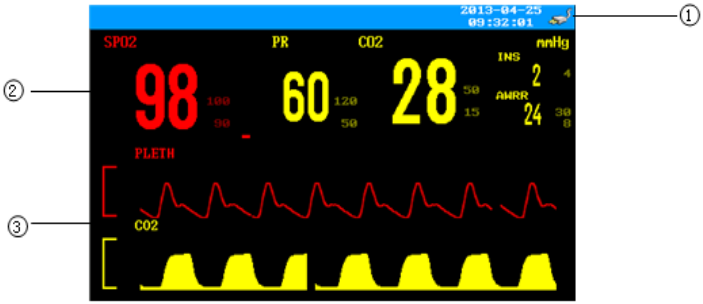
Items	Definition, abbreviation
NIBP	Non-Invasive Blood Pressure
SPO2	Blood oxygen saturation
PR	Pulse Rate

1.3 Display Interface

This equipment is equipped with a color LCD screen, can display patients' parameter, waveform parameter and collect alarm information, time, and other prompts provided by the patient monitor at the same time.

Main screen is divided into 3 areas

1. Information area ①
2. Waveform area ②
3. Parameter area ③



Picture 1-3 Display Main Interface

Information Area(①)

Information area located at the top of the screen, shows the oximetry time and quantity information.

"2013-4-25": current date

"9:32:01": current time

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

- This message, report Monitor
- or sensor status

- Alarm information of the Monitor
- （Refer to chapter of Alarm for detailed setting method.）;

 is the sign for mute. When you press this key "▲/  ",it will appear this sign. It indicates that all the sounds are closed by artificial. The system will re-appear sound until you press this key "▲/  " or there is new alarm in the system.

 is the sign for alarm volume close. It indicates sound alarm is permanently closed till the operator changes the setting to sound alarm on.

When sign  is displayed, there will be no sound alarm given. The operator is required to pay more attention while using this function.

- When waveform on the screen is frozen, the corresponding prompt window of "Freeze" will be displayed at bottom of the screen.
- Alarm information of patients' parameters is displayed always at the rightmost fixed area of the screen.

Waveform/Menu Area (②)

Under the maximum configuration, the system standard interface can be displayed in the waveform area the SPO2 plethysmography wave, CO2 waveform.

The waveform name shows on the top left of each channel. When the pop-up menu screen operate,the menu always occupy the waveform right of the fixed position so that a portion of the waveform temporarily invisible. Upon exit from the menu to restore the original screen display.

The waveform refresh at a set rate, see the setting of each parameter adjustment of the waveform refresh rate.

Parameter Area (③)

The parameter area is located in the top of the waveform area. Parameters displayed in the parameter area.

SpO2

— Blood oxygen saturation（Unit：%）

— PR（unit: beat/min.）(when "Simultaneity" option is chosen for source of HR)

NIBP

— In sequence from left to right lie systolic blood pressure, mean blood pressure and diastolic blood pressure;（unit: mmHg or kPa）

CO2

— End-tidal carbon dioxide content in CO2

— Least carbon dioxide intake of INS

—The airway breathing rate value

Alarm Indicator and Alarm State:

Alarm indicator does not light up under normal state.

In case of the occurrence of alarm, the alarm indicator flashes or keeps lightening. Color of the indicator represents the alarm level. Refer to the chapter of "Alarm" for detailed information. Please refer to relevant parameters in the related chapters for alarm information and prompts.

1.4 Key functions and Basic Operations

Operations on can be achieved through keys:

- **MENU**

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

- **PRINT**

Press this key to start a real time recording.

- **NIBP**

Press this key to inflate the cuff for blood measuring. During measuring, press this key to stop measuring and to deflate the cuff

- **SILENCE(▲/**  **)**

Press this key to halt alarm for 3 minutes ("1 minute", "2 minutes" and "3 minutes" are optional), and sign "  " will be displayed in information area. Press this key for more than 1 second for sound screen (like sound of alarm, heart beat, pulse and keyboard), and sign "  " will be displayed in information area. After pressing it again, sound will be resumed and sign "  "will disappear.

- **UDLR(Up, Down, Left,Right)(▲▼)**

The user can press this button to select the menu item and change the settings. Users can choose to complete the main screen, the system menu, all the operations in the parameter menu.

Attention

The user can press this button to select the menu item and change the settings. Users can choose to complete the main screen, the system menu, all the operations in the parameter menu.

Attention

Press (▲ /  **) key can turn off the the the SpO2 sensor shedding shedding and CO2 sensor alarm sound.**

1.5 External Interfaces of the Monitor

For operation convenience, different interfaces are designed at the different positions.

Recorder is at the top left of the vital signs monitor, while patient's cable and sensor jack are at bottom left, as shown in the picture 1-4.

① Spo2 sensor jack
② NIBP jack
③ CO2 jack

Picture 1-4 Sensor Jack

Other signs are specified in the chapter of Patients' Safety.
Back Window, as shown in the picture 1-5:

Picture 1-5 Back Window

① Switch button：open (ON), close (OFF)
② Power socket：power input interface
③ Fuse holder：for holding fuse (1.5A)
④ NET：for connecting with other equipments
⑤ USB port：for connecting with other equipments

⑥ Equipotential

⑦ Built-in speaker(To support heartbeat synchronized sound, and alarm sounds)

⚠ **Warning** ⚠

All the simulation and digital equipments connected with the patient monitor must be by specifying the IEC standards (e.g. IEC 60950 Data Processing Equipment Standard and IEC 60601-1 Medical Device Standard). Moreover, all the configurations must be followed the valid IEC 60601-1-1 system standard. The personnel who are in charge of connecting optional equipments with input/output signal port are to configure the medical system, and are responsible for system's compliance with IEC 60601-1-1 standard. In case of any questions, please contact with the supplier.

1.6 Internal Chargeable Battery

Vital Signs Monitor is equipped with an internal chargeable battery. When AC power is supplied, the battery will automatically be charged and charging will not stop until it is charged full.

When the monitor is power supplied by the battery, alarm will be given at low battery. For dead battery, top grade of alarm will be trigged giving continuous sound of toot, and "very low battery" will be displayed in information area. At the time, AC power is required for charging the battery. If the monitor is further power supplied by the battery, automatic shut-off of the monitor will be given before the battery goes dead (about 5 minute after alarming).

⚠**Attention**⚠

Battery replacement should be conducted by professional personnel

Picture 1-6 Battery

Chapter Two Vital Signs Monitor Installation

2.1 Unpacking Inspection

Carefully take out the vital signs monitor and the accessories from the packing box. Keep properly the packing material for future transportation and storage. Check the accessories according to the packing list.

- Check if any mechanical damage caused.
- Check all exposed leads, insert part of the accessories.

2.2 Electric Connection

AC power cord connecting steps:

- Make sure that AC power meets the specification of : 100-240VAC，50 / 60Hz
- Use the attached power cord with the vital signs monitor. Insert the power cord into the power interface of the vital signs monitor and connect the other end of the power cord with 3-core power socket earthed.

⚠ Attention ⚠

Connect power cord with the hospital special socket.

⚠ Attention ⚠

If battery configured, after transportation or storage of the vital signs monitor, it is necessary to charge the battery. Therefore, the vital signs monitor is not able to work normally due to low battery if a direct startup is performed without AC power supplied. As long as AC power is supplied, the battery will be charged no matter the vital signs monitor is opened or closed.

2.3 Power On and off

Boot: open the instrument after the switch button to NO, after about 20 seconds, the system self-checking success into custody the home screen, the user can operate at this time.

Power off ： 1 to confirm the end of the monitoring of the patient.

2. disconnect the monitor cable, sensor and patient

3. To ensure that the patient's monitoring data are kept or cleared.

4. Press the switch button on the back of the instrument to OFF, the machine is closed.

⚠ Attention ⚠

- If you can not properly shut down or occur in some special circumstances, you can make a forced shutdown. But the forced shutdown may cause the monitor data is lost or damaged, not recommended.
- If the power line broken, vital signs monitor will automatically switch to battery mode, the battery dissipation to maintain power equipment's normal work before 5 minutes battery will flash and sound the alarm

⚠ **Warning** ⚠

If there is function damage found or prompt of error occurred, please do not use the vital signs monitor for monitoring patient, and contact the hospital biomedical engineer or maintenance technicians of our company.

⚠ **Attention** ⚠

If vital error is found during self-test, the system will give alarm.

⚠ **Attention** ⚠

Check all the monitoring functions available to ensure normal function of the vital signs monitor.

⚠ **Attention** ⚠

If there is a battery configured, battery charging is required after each time of use to ensure sufficient battery reserve.

⚠ **Attention** ⚠

Restart the equipment for minimum 1 minute after shut-down of it.

2.4 Connection of Sensor

Connect the required sensor with the vital signs monitor and the patient to be monitored.

⚠ **Attention** ⚠

Please refer to the related chapters for correct connection and requirements of the sensor.

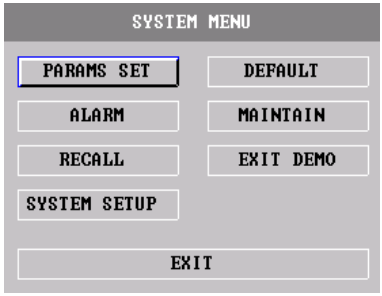
2.5 Inspection on Recorder

If the vital signs monitor is equipped with a recorder, please check if paper is available at the paper outlet on left side of the recorder.

Chapter Three System Menu

- Parameter setting
- Default configuration
- Alarm settings
- Maintenance of vital signs monitor
- Retrospective function
- Demonstration function
- System settings

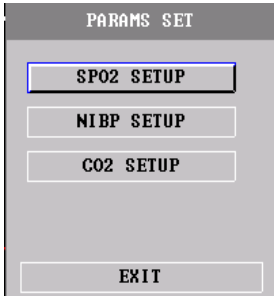
The vital signs monitor enjoys a flexible configuration. Content of monitoring and waveform scanning speed can be configured according to users' need. After pressing MENU key on the front window, menu as shown in picture 3-1 will be popped up, and the following operations can be performed:



Picture 3-1 System Menu

3.1 Parameter setting

In the system menu "parameter setting",picture 3-2:

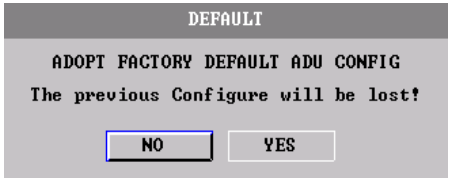


Picture 3-2 parameter setting Menu

Parameter setting parameters refer to Chapter

3.2 Default configuration

In the menu, the user can take the current system configuration for user default configuration, the system will automatically hold the current patient types according to all parameters menu settings in the user default configuration corresponding type, and the pop-up dialog box as shown in the picture 3-3:



Picture 3-3 Default configuration Menu

Select “Yes” to save all the configurations of the current patient as user default configuration.
Select “No” to delete the current operation. The system will keep the original configuration unchanged.

⚠ **Attention** ⚠

Exit select any one of the default configuration menu will pop up to confirm the default configuration dialog box, the user can choose "Yes" to confirm the selection, or "No" to abort the selection.

⚠ **Warning** ⚠

All the configuration of the system will be replaced with "the default configuration"

3.3 Alarm settings

Select the "alarm set in the system menu",picture 3-4

Picture 3-4 Alarm settings Menu

Parameters of the alarm set all parameters refer to Chapter

3.4 Maintenance of vital signs monitor

Select the option of “Maintenance of vital signs monitor” in “System menu”, dialogue box of “Enter maintenance password” will be popped up as shown in the picture 3-5

Picture 3-5 Maintenance Menu

3.5 Retrospective Function

When selecting "Retrospective function" in "System menu", the menu as shown in the picture 3-6 will be popped up.

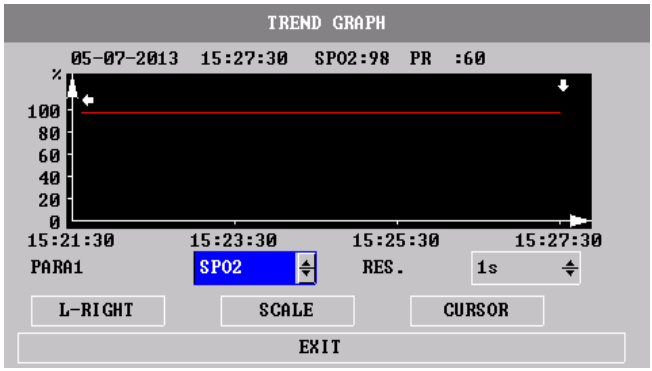
Picture 3-6 Retrospective Function Menu

When selecting "Retrospection of trend plot" in "Retrospective function", the menu as shown in picture 3-7 will be popped up:

3.5.1 Retrospection of trend plot

- The last 1 hour's trend plot can be displayed at the data resolution of 1 per second or 1 per 5 seconds.
- The last 96 hours' trend plot can be displayed at resolution of one datum for every 1 minute, 5 minutes or 10 minutes.

When selecting "Retrospection of trend plot" in " Retrospective Function menu", the following window will be popped up.



Picture 3-7 Trend Plot Menu

Vertical ordinate indicates the measuring value, while the horizontal ordinate indicates the measuring time. "🡻" is the cursor of the trend plot. The measuring value of the position indicated by "🡻" will be displayed at the lower part of the trend plot, and the corresponding time will be displayed at the upper part of the trend plot. With the exception of NIBP value, other trends will be displayed in way of continuous curves. In the NIBP trend plot, "S" represents systolic blood pressure; "D" represents diastolic blood pressure; "M" represents mean blood pressure.

Select trend plot display with different parameter:

Select the option of "Parameter selection" with cursor to modify the displayed content. When the desired parameter appears, press the knob.

The trend plot of this parameter is displayed in window.

Select 1-hour or 96-hour trend plot:

Select the option of "Resolution" with cursor. Select 1 second or 5 seconds, if 1-hour trend is desired to be observed. Select 1 minute, 5 minutes or 10 minutes, if 96-hour trend is desired to be observed.

Observe earlier or nearer trend curve:

If there is an instruction of "🡺" at the right side of the window, press "Left and right moving" key, turn the knob clockwise to observe the nearer trend curve; if there is an instruction of "🡸" at the left side of the window, press "Left and right moving" key, turn the knob counterclockwise to observe the earlier trend curve;

Modify display proportion

The proportion of vertical ordinate can be changed through "Amplitude adjustment" key, and proportion of the trend curve will then be changed accordingly. The value heater than the max. coordinate value is represented with the max. value.

Get the certain moment trend data from the current trend plot

Select "Moving cursor" and turn the knob leftward or rightward, the cursor then will move along with it, the period of time indicated by it will also change accordingly. The parameter value for this moment will be displayed under the horizontal ordinate. If there is an instruction of "🡺"at the right side of the window, when the cursor moves to this position, page down/up of the trend plot will be automatically performed to display the nearer trend curve; if there is an instruction of "🡸"at the left side of the window, when the cursor moves to this position, page down/up of the trend plot will be automatically performed to display the earlier trend curve.

Example of operation

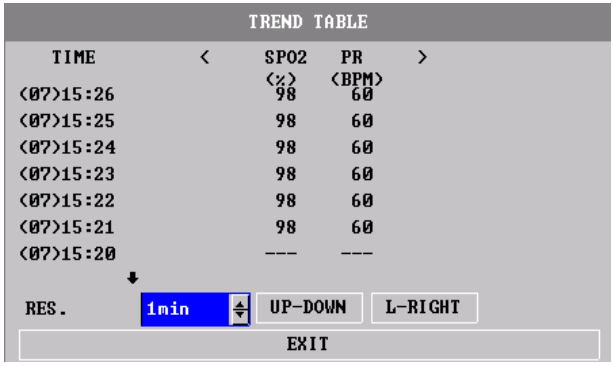
To observe NIBP trend plot for the last 1-hour:

- Press MENU key on the control window, “System menu” will be popped up;
- Select “Figure retrospection” in the menu, and then select “Retrospection of trend plot”;
- Select parameter: Turn the knob in the option of “Parameter selection” till “NIBP” appears in the box;
- Select “1 second” or “5 seconds” in the options of “Resolution”;
- Select “Left and right moving”, turn the knob, observe the time changes of trend plot and the changes of trend curve;
- Stop at the time section needed for careful observation. If there is improper proportion of the vertical ordinate, such as, partial trend value exceeds the current vertical ordinate max. value, select “Amplitude adjustment” for adjusting;
- For knowing the measuring value of a certain moment, select “Moving cursor” and move the cursor to this place. Time will be displayed at the upper part and the measuring value will be displayed at the lower part;
- Press “Exist” key to exit observation of trend plot.

3.5.2 Retrospection of trend table

- The trend table data of the last 96-hour can be displayed at the resolution of: 1 minute, 5 minutes, 10 minutes, 30 minutes, 60 minutes.

After selecting “Retrospection of trend table” in “ Retrospective Function menu”, the following trend table will be popped up:



Picture 3-8 Trend Table setting Menu

The corresponding time for each group of trend data will be displayed at the left-most line. Those in the bracket are dates. Those listed under Event are marked events corresponding to the time of mark events. Parameters in trend table can be sorted into2 groups:

SPO2 PR

NIBP S/M/D

The display of NIBP trend data is of its particularity. Except for measuring value, NIBP measuring time will also

be displayed under “Measuring point”. If there are more measuring values, only one group are to be displayed. Meanwhile, “*” will be displayed at the position of “MORE” meaning that there are two or more times of measuring result.

Select trend table at different resolutions:

Select resolution with cursor, change the options with the knob, change time interval of the trend data.

Observe earlier or nearer trend curve:

If there is an instruction of ▲ above the window, “Page down/up” may be selected, turn the knob clockwise to observe the nearer trend data; if there is an instruction of ▼ under the window, “Page down/up” may be selected, turn the knob clockwise to observe the earlier trend data;

Observe trend data with different parameters

Select “Left and right moving”. Any one of the six groups can be chosen. At the right side of the right-most parameter there marked a mark of “>” indicating that page can be turned over rightward; at the left side of the left-most parameter there marked a mark of “<” indicating that page can be turned over leftward.

Operation example

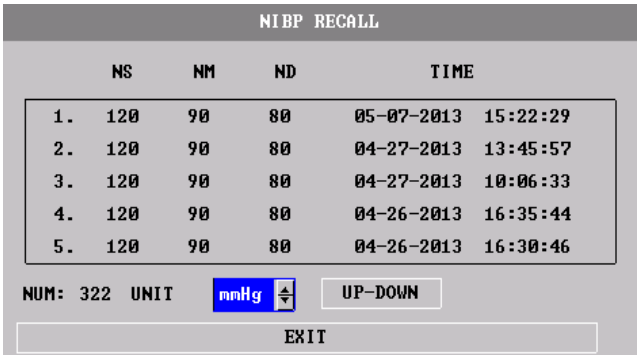
Observe NIBP trend table:

- Press MENU key on the control window, “System menu” will be popped up;
- Select the option of “Retrospection of trend table” in the menu;
- Select parameter: Select” Left and right moving”, turn the knob till NIBP data appear in the window;
- Select resolution: select the option at the left side, select the desired time interval;
- Select ” Page down/up”, turn the knob, observe NIBP trend data at different time;
- Press “Exit” key to exit observation of trend table.

3.5.3 Retrospection of NIBP:

The patient monitor can display the latest 400 NIBP measurement data in NIBP retrospection.

When selecting “Retrospection of NIBP measurement” in “Retrospective Function menu”, the last 3 times of NIBP measuring result and measuring time will be displayed in the window.



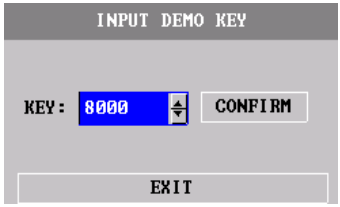
Picture 3-9 Retrospection of NIBP measurement

Data are arranged in sequence of measuring time from the near to the distant. Each screen may display 10 times

of measured data. Select “Page down/up” to the earlier or later measured data. Max. 400 times of measuring result can be displayed. When measurement exceeds 400 times, the last 400 times of data will be displayed.

3.6 Demonstration Function

After selecting “Demonstration function” in “System menu”, the dialog box of “Enter demonstration password” will be popped up. When correct password is entered, the system enters into demonstrating waveform state. Demonstration waveform is the simulation demonstration waveform set by the manufacturer for showing machine performance and assisting users in training. In actual clinical use, the function of waveform demonstration is prohibited, because it may have the medical personnel mistake it as the patient’s waveform and parameter being monitored, and thus monitor on patient could be affected and treatment delayed. For this reason, a password is equipped with this menu, as shown in the picture 3-10.



Picture 3-10 Demonstration Function

3.7 System Settings

Select "system settings" on "system menu", menu shown in the picture 3-11 will appear:

Picture 3-11 system Settings

In "System Settings" menu, the user can set the following items:

3.7.1 Work Interface Selection

Select the option of “Work interface selection” on the menu of “System Setting”, you may see that the current option is standard inter face.

3.7.2 Alarm Timeout

Select “Alarm timeout” on the menu of “System Setting”, turn the knob to set time of break. During this period of time, the system will not deal with any alarm. There are options of “1 minute”, “2 minutes” and “3 minutes” available for timeout.

3.7.3 Alarm volume

Select "alarm volume" on "System Setting" menu, press left-right key to set the alarm volume. Options are "0", "1", "2", "3" and "4" level. "0" means the volume is off.

3.7.4 Keyboard volume

Select "keyboard volume" on the "System Setting" menu , press the left-right key to set the keyboard volume. Options are "low" and "high" "mid" and "off" level. "Off" means key volume is off.

⚠ Warning ⚠

When the system alarm volume is shutdown, the patient monitor cannot give alarm sound in case of the alarm occurrence. Therefore, operator should cautiously use this function.

If select Off for alarm volume in state of mute or alarm timeout, the system will automatically terminate mute state or alarm timeout.

If operator selects Mute or Alarm Timeout when alarm volume is Off, the system will resume the alarm sound to the alarm volume before sound close, meanwhile the system enters into mute state or alarm timeout state.

⚠ Attention ⚠

The states of ”alarm volume” are effective when the machine is switched on next time. Operators should check carefully before using the function, avoid delaying treatment caused by silent alarm voice or when it is too low.

3.7.5 System Time Setting

After selecting the option of “System time setting” on “System Setting”, the menu as shown in the picture 3-12 will be popped up:

Picture 3-12 System Time Setting

⚠ **Attention** ⚠

System time Settings should be chosen to be the time when the machine switched on if users need to set, otherwise incorrect time information would be provided when reviewing the content with time message.

3.7.6 Record output setting

Select "record output setting" on "system setting" , the menu as shown in the picture 3-13 will be popped up:

Picture 3-13 Record output setting

The print content of waveform 1 and waveform 2 can be modified. The machine support to print SPO2 and CO2 waveforms.

Chapter Four Patients' Safety

The design of the portable vital signs monitor meets the requirements per relevant international standards as IEC60601-1，EN60601-2-27 and EN60601-2-30 constituted for medical electric equipments.

4.1 Environment

For ensuring the safety of the electric installation, please follow the following guidance's. Use environment of the portable vital signs monitor should reasonably be free of vibration, dust, corrosive or explosive gas, extreme temperature and humidity, etc. When installed in a cabinet, enough space should be kept in front for convenience of operation. When the door of the cabinet is opened, there should be kept enough space at back for maintenance. Good ventilation should be kept in the cabinet.

Monitoring system may satisfy technical index under the environmental temperature ranging 0℃～40℃. If environmental temperature exceeds such a range, it may affect the accuracy of the equipment or cause damage upon component or circuit. Interspaces at least 2 inches (5 centimeter) should be kept around the equipment for good ventilation.

4.2 Requirement for power supply

This equipment can be connected to public power grid.
Please refer to the chapter of Product Specification.

4.3 Earthing of the portable vital signs monitor

To protect patient and medical personnel, the portable vital signs monitor must be securely earthed. The portable vital signs monitor is equipped with a removable 3-core cable. When it is inserted into a matching 3-core socket, it is earthed through earthing cable of the power cord. If there is no 3-core socket available, please consult the hospital electric technicians.

⚠ **Warning** ⚠

Connecting the 3-core cable of the equipment with 2-core socket is prohibited.

Connect the earthing cable with equal electric potential terminal. If you are not sure that a certain equipment combination is dangerous or not from the specification of the equipment, for instance, when danger caused by accumulation of the leakage currency, you should consult the manufacturer or expert to ensure that the necessary security of the equipment will not be destroyed by the recommended combination.

4.4 Equal electric potential earthing

The first grade protection of the equipment is included in the system of house protective earthing by way of earthing of power socket. For internal check of heart or brain, the portable vital signs monitor must be connected with equal electric potential earthing system separately. One end of the equal electric potential (electric equalization lead) is connected to the equal electric potential earthing terminal on the back window of

the equipment, and the other end is connected to another terminal of the equal electric potential system. In case of protective earthing system damaged, equal electric potential system may undertake the protective function of protective earthing lead. Heart (or brain) examine can only be performed in the medical use room equipped with protective earthing system. Before every operation, it is required to check if the equipment is in good work state. Cable used for linking patient with the equipment must be free of electrolyte pollution.

⚠ Warning ⚠

If protective earthing system is unstable, the vital signs monitor should be power supplied by internal battery.

4.5 Condensation

The equipment must be kept free of condensation during working. When the equipment is moved from one room to another, condensation may be caused in. It is because the equipment has been exposed to humidity air and different temperatures.

⚠ Warning ⚠

Using in the place with inflammable anesthetic risks explosion.

4.6 Interpretation for the signs used on vital signs monitor

Symbol	Description	Symbol	Description
SN	Serial number		Manufacturing date
	Type CF defibrillation proof applied parts		Manufacturer
IP22	Waterproof grade 2 according to IEC60529		Recycled separately from other household waste under the WEEE directive
	Consult instructions for use		The symbol means dangerous voltage
I O	Power On/Off		Equal electric potential earthing end

Chapter Five Maintenance and Cleaning

5.1 Maintenance and Test

Before using this equipment, it is required to test:

- mechanical damage;
- all the exposed lead, insert and accessories;
- all equipment functions used to monitor patient, and ensure the equipment in good work state.

In case of any evidence found to indicate the damage of the equipment function, it is prohibited to use this equipment to monitor patient. Please contact the hospital biomedical engineer or maintenance technicians of our company.

Comprehensive functional test including security test must be performed once for every 6-12 months by qualified personnel and after each maintenance.

⚠ **Warning⚠: If hospital or medical units using the equipment have not a satisfied maintenance scheme available, failure of the equipment may be caused in and that may endanger health.**

5.2 General cleaning

It is recommended to clean the casing surface and screen of display. Use non-corrosive cleanser, like soap and clear water.

- Do not use strong solvent, like acetone.
- Be careful not to damage the vital signs monitor.
- Only after dilution can most of the cleansers be used. Please follow manufacturer's instruction to dilute the cleansers.
- Wear materials are strictly prohibited (for example, steel wool or silver polishing agent).
- Prevent any kind of liquid from entering into the casing. Immersion in liquid of any part of the system is strictly prohibited.
- Do not remain any cleaning liquid on surface of the equipment.

Cleaning equipment

1 turn off the power supply, and disconnect the power cord.

2 use a soft cotton ball, adsorption amount of detergent, wipe the screen.

3 use a soft cloth to clean the surface of the device after the proper amount of cleaning agent is adsorbed.

4 when necessary, use dry cloth to wipe off excess detergent.

5 place the device in a cool, ventilated environment

Equipment accessories: cuff blood pressure, SpO2 sensor, a power line with a soft cloth dipped in water or with the cleaning agent in addition to ethanol and isopropanol cleaning agent for cleaning. Recommended every 3

months to clean.

5.3 Application of Cleanser

Except the solutions listed under “Caution”, any solutions classified as the product with following properties can be used as cleanser:

- diluted ammonia
- diluted Sodium Hypochlorite (bleaching powder for washing)

Concentration range is from about 500ppm (1:100 diluted home use bleaching powder) sodium hypochlorite to 5000ppm (1:10 diluted home use bleaching powder), which is very effective. The amount of ppm depends on the amount of organic matter (blood, animal and plant mucilage) on the surface to be cleaned and disinfected.

- 35～37%diluted formaldehyde 35～37%
- Hydrogen Peroxide 3%
- ethanol
- isopropanol

Surface of the vital signs monitor and sensor may be cleaned with medical alcohol and dry it by natural wind or with clean and dry cloth.

Our company undertakes no liability for the effectiveness of the chemical products used for controlling infectious diseases. Please consult your hospital infection control principal or experts on infectious disease.

5.4 Disinfection and Sterilization

For avoiding long term damage against the equipment, product sterilization is recommended to be performed only when it is necessary in the hospital maintenance scheme. Cleaning is also recommended for the product to be sterilized.

Recommended sterilization materials: ethanol, aldehyde

⚠Caution⚠

- **Follow manufacturer’s instruction for dilution or adopt the lowest concentration possible.**
- **Keep liquid away from entering into the casing.**
- **Immersion of any part of the system is strictly prohibited.**
- **During sterilization, do not pour the liquid onto the system.**
- **Do not remain germicide on surface of the equipment. Please use a wet cloth to clean the leftover (if any).**

5.5 Disinfection

For avoiding long term damage against the equipment, product sterilization is recommended to be performed

only when it is necessary in the hospital maintenance scheme. Cleaning is also recommended for the product to be sterilized.

As for SpO2 sensor, blood pressure cuff, temperature probe, please refer to the content in related chapters.

⚠Caution⚠

Be careful not to damage the vital signs monitor. Do not disinfect the vital signs monitor with EtO or formaldehyde.

- **The host disinfection**

Disinfection operation may have a certain degree of damage of the desktop oximeter, we recommend only in your hospital maintenance procedure that is necessary before sterilization. Clean before disinfection.
Recommended disinfectant: 70% ethanol, 70% ISO alcohol, 2% glutaraldehyde solution.

⚠ careful ⚠

To prevent damage to the desktop oximeter, do not use gas (EtO) or formaldehyde to sterilize the desktop oximeter.

- Accessory disinfection
  - **SPO2 sensor:** The sensor appearance can wipe with cotton with medical alcohol or soft cloth, and then dry cloth.

    The sensor's light emitting tube and the receiver can also be cleaned and disinfected by the same method.

    Cable can be used for 3% of the hydrogen peroxide or 70% of the alcohol cleaning and disinfection, the active agent is equally effective, the joints can not be immersed in the above solution.
  - A blood pressure cuff reusable:

    Cuff can be through conventional in the hot air drying oven autoclaving, gas or radioactive disinfection disinfection, or is immersed in a solution of decontamination and sterilization. But remember when using this method to remove the internal rubber bag. The cuff not dry. The cuff can machine wash can also hand washing, hand washing can prolong the life of. Before cleaning, remove latex rubber bag. Wash after cuff dry, again put the bags into the rubber.
  - CO2 sensor:Mainstream CO2 module uses a one-time gas path combination, can not be re used to disinfect.

    Next to the CO2 module sampling tube is a one-time, can not be re used to disinfect. Side stream CO2 and the mainstream CO2 do not need to carry out daily check.

⚠Attention ⚠

Sterilization operation may have a certain degree of damage to the attachment, we suggest that only in your hospital maintenance procedures, it is necessary to carry out disinfection operation. Clean before disinfection.

Chapter Six Alarm

- This chapter will introduce the general information concerning alarm and measures to be taken in case of alarm.
- Each parameter alarm and prompt information could be obtained in related chapter for parameter setting.

6.1 General Introduction to alarm

The so-called alarm indicates the prompt sent by the vital signs monitor to the user when changes of vital signs of the patient being monitored are so important to arouse attention or failing in monitoring smoothly due to breakdown of the equipment.

6.2 Alarm Property

6.2.1 Type of Alarm

There are two types of alarm: If the alarm is caused by the changes of patient's vital signs, namely the physiological parameters of the patient being monitored exceeds the specified range or the patient is with physiological abnormality unable to be measured by overrun of a single physiological parameter, the alarm is named as physiological alarm; if the alarm is caused by the equipment, namely the alarm is caused by technical obstacles in using the vital signs monitor or failure of the equipment causing inaccurate monitor on the patient, the alarm is named as technical alarm.

6-1 Examples of Physiological Alarms and Technical Alarms

Description	Type of alarm
Patient pulse frequency is beyond the scope of pulse frequency alarm set by users.	Physiological alarm
SpO2 measurement module is out of order.	Technical alarm
CO2 measuring module CO2 sensor off	Technical alarm

6.2.1.1 Classification of Physiological Alarms

There are two kinds of physiological alarms. One of them is that physiological parameters of the patient being monitored exceeds the specified range, while the other is that physiological abnormality of the patient is unable to be measured by overrun of a single physiological parameter.

The latter belongs to the alarm which can screen the former. For example: pulse is not found.

6.2.1.2 Alarm Level

Both technical alarm and physiological alarm have a level characteristic. The higher alarm level, the more watchful way of the alarm prompt given by the system. All technical alarm levels can not be changed by users. Some of the physiological alarm levels can be set by users, while some of them are not permitted to changes after being designated by the system.

6.2.1.3 System mute

Press and hold the “▲/” , you can turn off all sounds (alarm sound, key sound, heartbeat sounds, and pulse sound); Meanwhile,  will appear in the area of physiological alarm area. The warning indicator alarm and physiological alarm information will be shut down.

Again press “▲/” key to exit muted and pause the alarm in accordance with the default pause time; you will exit the “alarm pause" state at the third press, and re-activate the corresponding alarm sound back to normal alarms condition.

6.2.1.4 Alarm off

Select "Alarm settings" on "System Menu" to enter each parameter alarm settings menu, select the alarm sound, and set it to "Off" to turn off the alarm sound.  will appear in the physiological alarm area at the same time. The warning indicator alarm and physiological alarm information will be shut down.

For example: SpO2 alarm shut off .

Select the "Alarm setup" to enter "the SpO2 alarm" menu, select "alarm switch’’ and set as" OFF "to turn off the alarm sound, conversely to turn on the alarm sound.

6.3 Alarm Prompt Form

6.3.1 Sound and Light Property

6-2 Sound and light properties for different levels of alarm

Alarm Level	Alarm Sound Properties	Alarm Light Properties
High	Mode: toot-toot-toot------toot-toot, toot-toot-toot------toot-toot; the alarm sound is given once for every 10 seconds (Interval counts from the beginning of this time to the beginning of next time.)	Alarm indicator flashes in red color at high frequency.
Middle	Mode: toot-toot-toot; the alarm sound is given once for every 25 seconds (Interval counts from the beginning of this time to the beginning of next time.)	Alarm indicator flashes in yellow color at low frequency.
Low	Mode: toot-; the alarm sound is given once for every 25 seconds (Interval counts from the beginning of this time to the beginning of next time.)	Alarm indicator keeps lighting in yellow.

6.3.2 Others

If various levels of alarm occur at the same time, sound and light prompt will be given by the highest level of the current alarms.

6.4 Alarm State

6.4.1 General Introduction to Alarm State

Each alarm has two states: triggering state and removing state. Only one state is available at the same moment.
Triggering state: state of alarm existence
Removing state: state of alarm inexistence
At the beginning of work, all possible alarms are in the removing state. Afterwards, when alarm conditions are to be satisfied, alarm enters into triggering state.
The whole alarm system (all alarms) has the following states:

1. Normal state: alarm is in triggering state and able to give all prompts (including sound, light and character).

2. Alarm timeout state: alarm is in triggering state, but temporarily gives no sound, light and character prompt.

3. Alarm mute state: alarm is in triggering state giving light and character prompt, but gives no sound prompt.

4. Alarm sound closedown state: alarm volume is at 0.

Only one state is available for the whole alarm system at the same period of time.

6.4.2 Alarm Mute State

Alarm mute state means that all sounds (including sounds of alarm, key and pulse) of the vital signs monitor are closed down.

6.4.3 Alarm Sound Closedown State

Alarm sound closedown state means that all other sounds are not closed down with the exception of sound of alarm prompt.

6.4.4 State Switch-over

In normal state:

1. Short press "▲/  " key (< 2s） to enter into alarm timeout state; long press "▲/  " key（>= 2s） to enter into alarm mute state.

In alarm mute state:

1. The current alarm mute state will be ended to enter into normal state in case of occurrence of either new technical alarms or new physiological alarms.

2. Short press SILENCE key (< 2s） to enter into timeout state; long press SILENCE key（>= 2s） to enter into normal state.

In any states:

1. In user setting, setting alarm sound to Off, the system enters into alarm off state.

2. In user setting, setting alarm sound to On, the system enters into alarm on state..

6.5 Alarm Setting

Each alarm parameter can set in "Alarm" menu.
In "vital signs monitor setting" menu, alarm setting of each parameter module is displayed as shown in the picture 6-3.

Picture 6-3 Alarm Setting

Alarm Setting of Measuring Parameters

Each parameter alarm setting is in the corresponding menu. For example, when entering into “SPO2 setting” menu, PR alarm setting can be made.

- PR alarm setting:

Step 1: in the "alarm" choose "SPO2 alarm" item, SPO2 and PR alarm setting parameter display the menu.

Step 2:Users can set up in six items in the "SPO2 alarm", were "alarm switch", "alert level", "SPO2 alarm high", "SPO2 alarm low", "PR alarm high", "PR alarm low". The user can press the left key to move the cursor to set options, set press the arrow button.

- Other measuring parameters may be set in the same way mentioned above.

6.5.1 Sound On/Off Setting

Refer to the description for alarm sound on/off in maintenance of vital signs monitor of system setting.

6.5.2 Automatic Alarm Closedown

Automatic alarm closedown means the invalidation of the whole alarm function. At the time, even under the condition that alarm conditions are satisfied, the system will give no alarm prompt, alarm printing and alarm storing.

When there is a new measuring module joining in or at the beginning of work of a measurement module, within 30 seconds counting from working start of the module, all alarms in relation to this module will be automatically closed down, while other alarms will not be affected.

6.5.3 Power-on Lead fail

At power-on, if parameter module opened has not lead, the followings will be dealt with:

1. As for SPO2 or CO2 module, change alarm prompt of lead fail to prompt (means sound and light are automatically removed), and then notify the user.
2. For other modules, there is no lead fail alarm given.

6.6 Parameter alarm

In each parameter menu, alarm parameter can be set separately, and users may set alarm limit and alarm state.

When a certain parameter alarm is closed down, there will be a prompt sign of "  " displayed in parameter display area. Alarm On/Off for each parameter can be set separately.

As for set alarm parameter, when a certain parameter or couples of parameters exceed alarm limit, the vital signs monitor will automatically give alarm and deals with the followings:

1) Appearing prompt on screen, the method is as mentioned in alarm method;
2) If alarm volume is set, the alarm sound will be given according to the set alarm level and alarm volume;
3) Alarm indicator flashes (if available);

6.7 Measures Taken in Case of Alarm

⚠**Attention** ⚠

When a certain alarm occurs, patient's status is expected to be firstly checked.

Alarm information is displayed in system information area or system alarm information area. This alarm is required to be recognized and corresponding measures should be taken according to alarm reasons.

1) Check status of the patient;
2) Recognize which parameter is giving alarm or which kind of alarm is happening;
3) Recognize alarm reason;
4) Alarm is mute if needed;
5) After alarm status is released, check if alarm is removed.

Refer to chapters of parameter monitoring for alarm information and prompt of related parameters.

Chapter Seven Recorder (Optional)

- General Information of Recorder
- Method of Configuration and Recording
- Recording

7.1 General Information of Recorder

The recorder used on this vital signs monitor is a thermosensitive array recorder with a waveform printing width of 48mm.

Capability of the recorder

- Waveform output of the recorder may be at a speed of 25mm/second or 50mm/second;
- Max. two waveform are to be recorded;
- Output in English;
- Real time recording time and waveform;
- when recording alarm, the vital signs monitor automatically select waveform in relation to alarm parameter.

7.2 Type of Record

This vital signs monitor produces the following strip-beam record:

- Real time 8 seconds record

Real time Record

Waveform of 8 seconds real time record is set by the vital signs monitor (generally the first two waveforms are displayed).

⚠ **Attention** ⚠

When executing output operation, press printing key again , parameter output will be re-exported after the current output ends.

7.3 Record Output

Date Time

SPO2——blood oxygen saturation

PR——pulse rate

NIBP——Systolic / diastolic blood pressure (mean pressure)

CO2——carbon dioxide

7.4 Information of Recorder's Operation and State

7.4.1 Requirement on recording paper

Proper thermosensitive recording paper is required, otherwise would cause failing of recording, poor quality of recording or damage of thermosensitive head.

7.4.2 Normal Operation

- During normal operation of the recorder, the recording paper is delivered smoothly. Do not pull out the paper to avoid damage against the recorder.
- Using the recorder with recording paper unavailable is prohibited.

7.4.3 Steps for replacing paper on recorder

- Open the door of recorder;
- Straightly insert the new paper into paper insert scoop with printing side towards thermosensitive head;
- When the other edge of the paper comes out, pull it out. Pay attention to place the paper properly for no dislocation of papers;
- Close the door of the recorder.

⚠ Attention ⚠

Replace the paper with care, not to touch the thermosensitive head. Do not keep the door of the recorder open unless for paper replacement or troubleshooting.

7.4.4 Removing out the jammed paper

In case of abnormal recorder operation sound heard and recording paper delivered, open the door of the recorder to check if paper jammed. For removing the jammed paper:

- Open the door of the recorder;
- Place again properly the paper so as to be without dislocation;
- Close the door of the recorder.

Chapter Eight Blood Oxygen Saturation（SpO2）

8.1 SpO2 Monitoring Instruction

Definition of SpO2 monitoring

SpO2 plethysmography parameter measures arterial SpO2, name the percentage of the HbO2. For example: in arterial blood erythrocytes, if hemoglobin counting for 97% of the total combines with oxygen, the blood is at a 97% SpO2, and the reading of SpO2 value on the vital signs monitor 97%. SpO2 value displays the percentage of Oxygen-carrying hemoglobin forming HbO2. SpO2 plethysmography parameter also provides PR signal and plethysmography wave.

SpO2 plethysmography parameter measurement principle

- SpO2 is measured with pulse dosimeter. This is a continuous non-invasive measuring method for hemoglobin oxygen saturation. What it measures is the quantity of ray penetrating through the tissues of patient (e.g. finger or ear) emitted from sensor light source and reached the receiver at the other side.

  Wave length measured by sensor is generally 660mm for red LED, 940mm for infrared LED. Max. optional output power for LED is 4mW.
- The penetrating ray quantity depends on various factors, and most of them are constant. But one of the factors, namely arterial blood stream, changes as time goes by, because it is pulsant. Through measuring absorbed ray in pulsant period, SpO2 of the arterial blood can be acquired. Testing pulse may give a “plethysmography” waveform and PR signal.
- “SpO2” value and “plethysmography” waveform can be displayed on the main screen.
- SpO2 in this manual means physiological function blood oxygen saturation measured through non-invasive method.

⚠Warning⚠

If COHb exists, MHB or dyeing dilution chemicals, there will be windage for SpO2 value.

SpO2 plethysmography parameter measurement

- “SpO2” value and plethysmography waveform can be displayed on the main screen.
- SPO2 in this manual means physiological function blood oxygen saturation measured through non-invasive method.

⚠ Warning ⚠

If COHb exists, MHB or dyeing dilution chemicals, there will be windage for SpO2 value.

SpO2/pulse monitoring

⚠ Warning ⚠

Cables of ES equipments can not be intertwisted.

⚠ Warning ⚠

Do no place sensor onto the part of body with arterial conduct or intravenous conduct.

⚠ Attention ⚠

Do not place blood oxygen probe onto as same part of body with blood pressure cuff on. This causes blood obstruction during measuring blood pressure may affect the reading of SpO2

⚠ Attention ⚠

- Ensure to shut out light with nail.
- Probe cable should be placed onto the back of the hand.

⚠ Attention ⚠

- SpO2 value is always displayed at the fixed position.
- PR is displayed only under the following circumstances:

  1) "Source of HR" is set to "SPO2" or "Select all" in ECG menu.

  2) "Source of HR" is set to "Automatic", and there is no ECG signal at that time.

⚠ Attention ⚠

SpO2 waveform and pulse volume are out of proportion.

⚠ Caution ⚠

1. Before using the equipment and the need for validation of the blood oxygen accessories

2. To ensure the use of matched blood oxygen probe

⚠ Warning ⚠

Before starting monitoring, check if the sensor cable is normal. When plugging SpO2 sensor cable out, "Sensor fail" will be displayed on the screen and sound alarm is triggered at the same time.,

⚠ Warning ⚠

If there is the evidence of damage on sensor packing or sensor, do not use this SpO2 sensor and return it to the factory.

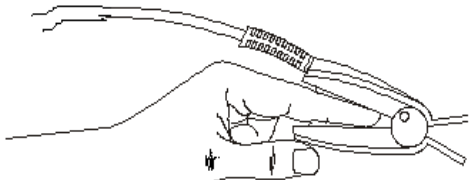
⚠ Warning ⚠

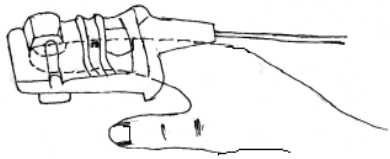
Continuous and long term monitoring may increase the risk of skin property changes, such as abnormal allergy, redden, blistering or compression necrosis. They occur more frequently on patients with perfusion obstacle and metabolic or immature skin pose chart. According to quality changes of the skin, it should be paid more attention to check the placement of sensor by correct light route aiming and adhering method. It is required to regularly check the adhering position of sensor and change the adhering position if skin quality decreased. Because of the different status of the patients, more frequent checks may be required for some of the patients.

8.2 Operating method of SpO2 monitoring

SpO2 plethysmography measurement

1) Power the vital signs monitor on;
2) Place the sensor onto the proper position of patient's finger;
3) Insert the connector on one end of sensor cable into SpO2 jack.





⚠ **Attention** ⚠

If measures part and probe can not be positioned accurately, it may cause in inaccurate reading of SpO2, even pulse wave can not be searched for monitoring blood oxygen. At the time, repositioning is required.

Excessive moving of the measured part may cause in inaccurate measurement. At the time, the patient should have been calmed or place onto a new position to reduce influences to measurement by excessive moving.

- Put your finger in the oxygen probe, wait for 5~8 seconds to display the blood oxygen and pulse rate data;
- The oximeter models of SpO2 and pulse rate function of tones, when the probe loss products or finger left probe always, display "--" message, waveform display.
- Use requirements of oxygen probe:

Weight: Adult：＞40kg；

Age: adult: 15 years of age or older

Use position: finger

⚠ **Warning** ⚠

During the course of long term and continuous monitoring, peripheral circulation status and skin

status should be checked once every 2 hours. If bad changes found, measuring position should be changed timely.

During the course of long term and continuous monitoring, it is required to regularly check the position of the probe to prevent moving of the probe from influencing the accuracy of measurement.

8.3 Measurement Limit of SpO2 Monitoring

During operating, the following factors may influence the accuracy of SpO2 measurement:

- High frequency electric interference, like interference generated by the main unit or ES equipments connecting with the system.
- During MRI, do not use Monitor
- , blood oxygen sensor. Inductive current may cause in burn.
- Intravenous dye.
- Excessive moving the patient.
- Outside light radiation.
- Improper installation of the sensor or improper contacting position with the object.
- Temperature of the sensor (the most suitable temperature range: 28℃～42℃)
- Place sensor onto part of the body with blood pressure cuff, arterial conduct or line in cavity.
- Concentration of non-functional hemoglobin like COHb and MetHb.
- Excessive low SpO2.
- Poor circulation perfusion of the measured part.
- Shock, anaemia, low temperature and vasoconstrictor may lower the arterial blood stream to the level at which measurement can not be performed.
- Measurement also depends on absorption of the oxygenated hemoglobin and reduced hemoglobin for special wave length ray. If there are other substances absorbing the same wave length existing, they cause in fake or low SPO2 value of the measurement. E.g. COHb, MetHb, Methylene Blue, Indigo Carmine.
- SpO2 sensor。

8.4 SpO2 Menu

Press "MENU" button, enter the "menu", use the arrow keys to move the cursor to the display interface of the "SPO2 hotkey parameter settings", enter "SPO2 settings" menu, as shown in the picture 8-5.

Picture 8—5 SPO2 Setting Menu

⚠ **Warning** ⚠

Setting SpO2 alarm upper limit to 100% means disconnecting alarm upper limit. High-oxygen water may cause premature ill with crystal post fiber tissue diseases. Therefore, alarm upper limit of SpO2 must be carefully set according to recognized clinical practice.

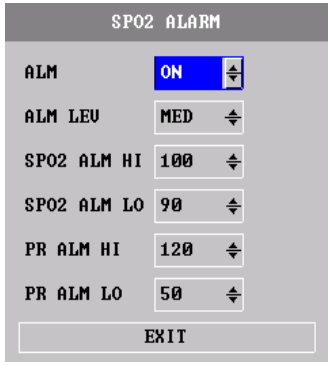
- Waveform speed

  12.5 and 25.0mm/s are optional for SpO2 plethysmography speed.
- Pulse volume: 0、1、2、3、4 levels of pulse volume are optional.
- Calculation sensitivity: Select average time for calculating SpO2 value. Selection of “High”,” Middle” and “Low” means the average value of 4 seconds, 8 seconds and 16 seconds.
- The wave style:You can choose the "lines" or "fill" mode

8.5 SPO2 Alarm

8.5.1 SpO2 Alarm Setting

Select the "MENU" button on the instrument, into the menu, using the arrow keys to select "system menu" in the "alarm", then the next key to enter "SPO2 alarm", SPO2 alarm settings, as shown in the picture 8-6.



picture 8-6 SPO2 Alarm Menu

- Alarm switch: if selecting “On”, alarm prompt and storing will be performed in case of SpO2 alarm; if selecting “Off”, there will be no alarm given, and the prompt of “” will be displayed by SpO2 in screen parameter area.
- Alarm level: “High”, “Middle” and “Low” are available for option. “High” means the most dangerous alarm.
- SpO2 alarm upper and lower limit: used to set SpO2 alarm upper limit. Alarm is given in case of SpO2 overrun of alarm upper and lower limit.
- PR alarm upper and lower limit: according to the set upper and lower limit, alarm will be given in case of PR overrun of alarm upper and lower limit.
- The physiological alarm of the blood oxygen, and set the alarm range of blood oxygen, so that it is in the range of the test, whether the alarm)
- The oximeter models of SpO2 and pulse rate function of tones, when the probe off products or the finger away from the probe, display "--" message, do not display the waveform.

SpO2 and PR alarm range:

Parameter	Max. upper limit	Min. lower limit	Single time adjustment
SpO2	100	0	1
PR	254	0	1

SpO2 and PR default alarm range under default configuration:

Parameter		Max. upper limit	Min. lower limit
SpO2	Adult	100	90
PR	Adult	120	50

8.5.2 SpO2 Alarm Information

SpO2 alarm information

When alarm recording switch in the menu is switched on, those physiological alarms caused by parameters' overrun of alarm limit will trigger the recorder to automatically output alarm parameter value and related measured waveforms.

8.6 Maintenance and Cleaning

Attention and Cleaning

⚠Warning⚠

It is a must to power off and disconnect power supply before cleaning the vital signs monitor or sensor.

⚠Caution⚠

Do not have the sensor sterilized with high pressure.

Don't dip the sensor into liquid.

They are prohibited to use in case of evidence of damage or degeneration of the sensor or cable.

Cleaning:

- Surface of the sensor may be wiped with cotton balls or soft cloth dipped medical alcohol, and then dry it with dry cloth. Emitting light tube and receiver of the sensor may be cleaned in the same method.
- Cable may be disinfected with 3% Hydrogen Peroxide or 70% isopropyl alcohol. Active agent is also effective. Joint can't be dipped in solution.

Chapter Nine Non-invasive Blood Pressure（NIBP）

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 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes.
  - □ “Continuous” mode measures continuously in 5 minutes.

⚠**Warning**⚠

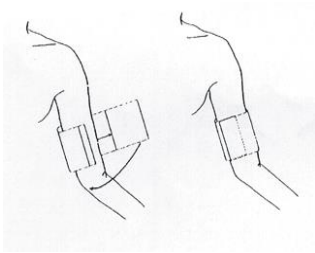
- **NIBP measurement can not be performed onto the patients who are ill with sickle-cell disease and any skin damage or foreseen damage. For the patients troubled with serious coagulation mechanism obstacle, automatic blood pressure measurement is determined by clinical evaluation. This is because the 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
leg	46～66cm	21cm	

- ◆ 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 setting" menu, select "Time 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 setting" menu, select "Continuous measuring" 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

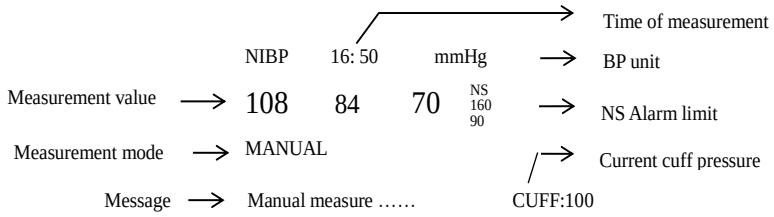
If the patient is with serious shock or excessive low TEMP, measuring is unreliable, because increase of the blood stream peripherally flowing may lower arterial pulse.

■ 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

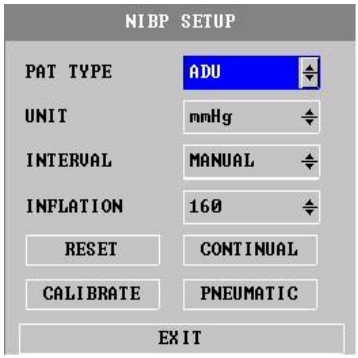
Display layout of NIBP measuring result and corresponding information on screen:



9.3 NIBP Menu

Press "MENU" button, enter the "menu", use the arrow keys to move the cursor to the display interface of the

"Parameter Settings", enter "NIBP settings" 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 1，2，3，4，5，10，15，30，60，90，120，180，240，480 minutes are available. After selecting the interval, a prompt of "Press "start" key" will be displayed in the NIBP prompt area. At the time, press START key to start charging 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.

■ Pre aeration 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	160	80/90/100/110/120/130/140/150/160/170 180/190/200/210/220/230/240

The user presses the front shell on the "MENU" button, enter the "menu" in the "default settings" menu, in recognition of the default configuration, the NIBP parameter selection area of the NIBP menu, enter "NIBP settings". 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. Move the cursor to "pre aeration" option and press, can see for manual adjustment of pre aeration selection range is as shown in the table.

■ Reset

Measure state of blood pump reset.

Press this key 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 this option, the menu will automatically disappear and 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 calibration". 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 Alarm

NIBP Alarm Setting

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

picture 9-3NIBP Setup Menu

- Alarm switch: if selecting “On”, alarm prompt and storing will be performed in case of pressure alarm; if selecting “Off”, there will be no alarm given, and the prompt of “” will be displayed by NIBP in screen parameter area.
- Alarm level: used to set alarm level. “High”, “Middle” and “Low” are available for option. “High” means the most dangerous alarm.
- Pressure alarm is performed according to the set upper limit and lower limit. Alarm will be given in case of overrun of alarm limit of the pressure. Alarm for systolic blood pressure, mean blood pressure and diastolic blood pressure may be dealt with separately.

Adjustment range of alarm upper and lower limit：

Adult

Systolic blood pressure: 40～270 mmHg

Diastolic blood pressure: 10～215 mmHg

Mean blood pressure: 20～235 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 Ten Carbon Dioxide (CO2)(optional)

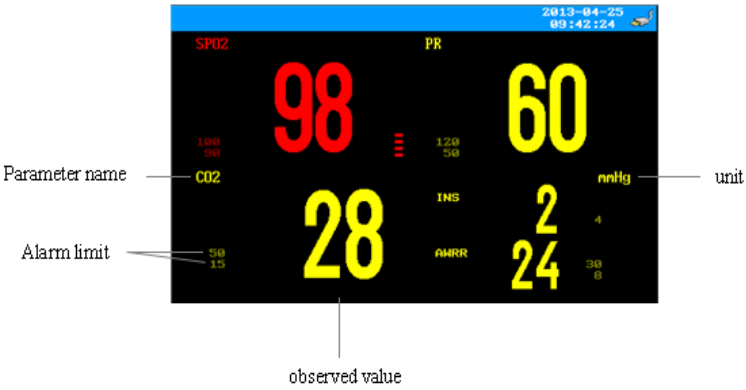
10.1 Overview

This instrument is capable of measuring disease Popularity road pressure of CO2 (carbon dioxide), the content available to end-tidal carbon dioxide (EtCO2), carbon dioxide least intake volume (Inspired Minimum CO2: InsCO2) and airway respiratory rate (Air Way Respiration Rate: AWRR), andCO2 pressure waveform. Parameters displayed on the screen label conventions are as follows:

CO2：EtCO2

INS: InsCO2。

AWRR: Air Way Respiration (AwRR)(Resp. times/MIN)



Picture 10-1The CO2 display

The following factors may affect the accuracy of measurement:

■ leakage or internal sample gas leak

■ mechanical shock

■ cyclic pressure higher than 10 kPa (100 cmH2O);

■ Other sources of interference (if any).

⚠Warning⚠

CO2 module shall be avoided from crash and vibration.

⚠Note⚠

Don't use the device in the environment with flammable anesthetic gas.

The device can only be operated by personnel having taken professional training and familiar with this manual.

10.2 Measuring principle

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

10.3 The method of operation of carbon dioxide

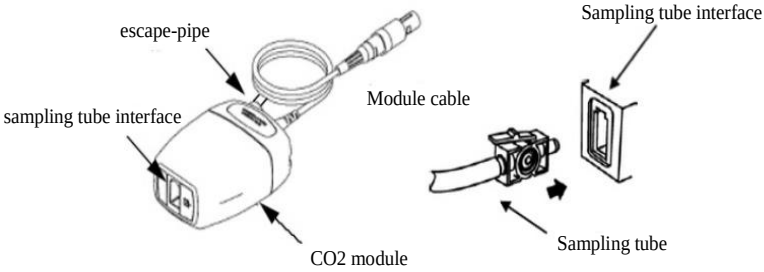
CO2 measurement setups

1.Insert the CO2 module cable into the CO2 jack which is on the side panel of the patient monitor, and then connect the sampling tube or airway adapter as picture 10-2 shows：

2. in the menu, choose “CO2 setup ”, change the “operating mode” to “measurement,”, on the screen, it will appear “Co2 module is running”.

3. after start, in the screen it will appear “Co2 module is warming up”, then the module is in precision measurement state.

4. After warming up, the module will come into the full precision measurement state.



Picture 10-2 Side-stream EtCO2 Connection Diagram

⚠Note⚠

1. Insert the sampling tube into the sampling tube interface, the sampling pump will automatically start . After the sampling tube is removed, the sampling pump will stop.

2. Press and hold the lock on the sampling tube in order to remove the sampling tube from the CO2 module.

When the instrument is turned on, the CO2 module's default mode of operation "to" standby ", the user breath" operating mode "is set to" measure "to start the CO2 module. Instrument restarts, will remain before the last shutdown "mode of operation, that if the shutdown is selected measurement, the next time you turn on the CO2 module will automatically enter the measurement mode. More information, see "mode of operation" Other Settings section 11.4 of carbon dioxide menu chapter.

⚠Warning⚠

- If the packaging has been opened or damaged parts, internal, please do not use this accessory, and returned to the supplier
- “CO2 WARM UP” or “CO2 SENSOR START UP” displayed on the screen indicates that the sensor is in

warm-up or starting-up. After the information disappears from the screen, the standard measurement can then be generated.

- Keep sampling tube apart from its socket when not in use.
- Nothing except sampling tube should be inserted to sampling tube socket of CO2 Module.
- Please insert the sampling tube before connecting the airway adapter to breathing circuit.
- Please ensure the airway adapter is removed from breathing circuit before pulling out sampling tube.
- Sampling tube is one-off consumables that can not be repeatedly used by different patients.

10.4 CO2 Menu

10.4.1Parameter Setup and Adjustment

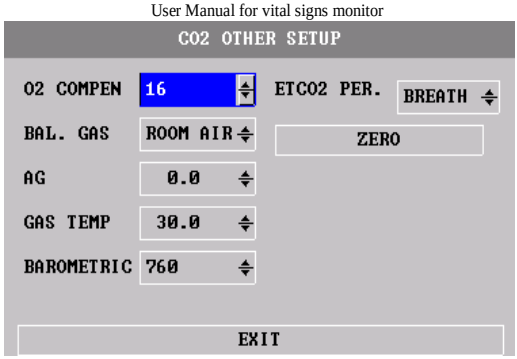
From the "System Menu" to enter the parameter menu select CO2 hotkey, and the CO2 set, as shown in Figure 10-3

Picture 10-3CO2 set

The following sequentially describes the role of each menu item in the "CO2 Settings" menu.

- WAVEFORM SPEED：used to adjust the CO2 waveform display speed, 6.25 mm / s and 12.5 mm / s "option.
- UNIT:to change the display units of CO2 and InsCO2 parameters. “mmHg” and “kPa” are available for selection.
- WAVE GAIN：to adjust full scale size of CO2 waveform display area with “LOW” or “HIGH” selectable. The default value is “LOW”.
- WORK MODE:to change the work mode of CO2 with “MEASURE” mode or “STANDBY” mode selectable.
- OTHER SETUP: Select this option into "CO2 Settings menu.

10.4.2 OTHER SETUP



Picture 10-4 CO2 Other setup menu

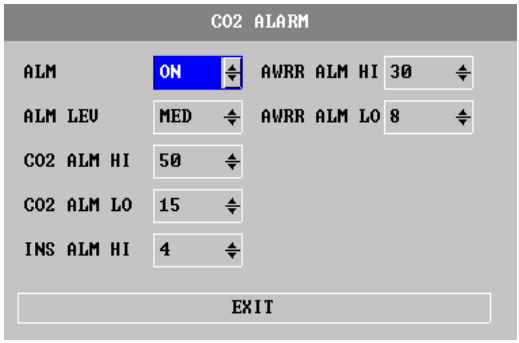
Introduced in turn "CO2 Settings menu menu item below：

- O2 COMPEN：Oxygen could result in measuring the value of CO2 is lower than the actual value, the use of this option can be used for compensating the existence of oxygen.
- BALANCE GAS: ROOM AIR, N2O, HELIUM.
- Anaesthesia Agent: The intensity of the Anaesthesia Agent
- GAS TEMP: Current Temperature of the gas
- Barometric: Current Atmospheric Pressure
- ETCO2 Period: The period to calculate the ETCO2, Per breath, 10s, 20s
- Calibration: Select "Calibration" to confirm the calibration of the CO2 module.

10.5 CO2 alarm

10.5.1 CO2 Alarm Setting

Select instrument "MENU" button to enter the system menu, use the arrow keys to select the "Alarm setup" in the "System Menu", then through the arrow keys to enter the CO2 alarm, the CO2 alarm settings, as shown



Picture 10-5 CO2 alarm set

The following introduces "the menu item CO2 alarm" menu function.

- Alarm switch: ON: In the event of a CO2 alarm, alarm and storage;

  Off: In the event of a CO2 alarm, alarm and storage; select "Off", "CO2" hotkey

  on the right side appears "  "icon.

- Alarm level three options "high", "medium", "low." Alarm level changes affect only the parameters of

carbon dioxide.

(including the the EtCO2 ceiling, EtCO2 lower limit, InsCO2 ceiling, AwRR upper limit and minimum AwRR).

- CO2 ALM HI: to adjust the upper alarm limit of EtCO2.
- CO2 ALM LO: to adjust the lower alarm limit of EtCO2.
- INS ALM HI: to adjust the upper alarm limit of InsCO2.
- AWRR ALM HI: to adjust the upper alarm limit of AwRR.
- AWRR ALM LO: to adjust the lower alarm limit of AwRR.

10.5.2 Alarm Information and Prompt

Alarm setting range

Parameter	MAX ALM HI	MIN ALM LO	Step
CO2	100	0	1
INS	100	/	1
AwRR	150	0	1

The default alarm limit

Parameter	The type of patient	ALM HI	ALM LO
CO2	Adult	50	15
INS	Adult	4	/
AwRR	Adult	30	8

⚠Note⚠

When multiple alarms occur simultaneously, the screen will display the highest level of alarm information.

Do not use CO2 monitoring function, it is best not to take the sampling tube, and the measurement mode is selected as the "standby" mode.

Physiological alarms:

Message	Cause	Alarm Level
CO2 TOO HIGH	EtCO2 measuring value is above upper alarm limit.	User-selectable
CO2 TOO LOW	EtCO2 measuring value is below lower alarm limit.	User-selectable
INS TOO HIGH	InsCO2 measuring value is above alarm limits.	User-selectable
AWRR TOO HIGH	AwRR measuring value is above upper alarm limit.	User-selectable
AWRR TOO LOW	AwRR measuring value is below lower alarm limit.	User-selectable

Technical alarms:

Message	Cause	Alarm Level	Remedy
CO2 SENSOR OFF	Mainstream sensor is not properly connected or has fallen off.	LOW	Make sure that Mainstream sensor is properly connected.
CO2 SIGNAL LOW	Measuring module technical failure	LOW	If necessary, re-start the monitor. If failure persists, stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.
CO2 SIGNAL TOO LOW		LOW	
CO2 BAROMETRIC TOO LARGE		MED	
CO2 PNEUMATIC LEAK		MED	
CO2 SIGNAL NOISY		LOW	
CO2 SIGNAL SATURATE		LOW	
CO2 CALCULATION ERR		HIGH	
CO2 SENSOR FAULT		HIGH	
CO2 SENSOR TEMP HIGH		HIGH	
CO2 SENSOR TEMP LOW		HIGH	
CO2 WATCHDOG TIMEOUT		HIGH	
CO2 INT COMM ERR		HIGH	
CO2 SYSTEM ROM ERR		HIGH	
CO2 PUMP FAULT		HIGH	
CO2 REVERSE FLOW		HIGH	
CO2 FORWARD FLOW		HIGH	
CO2 MALFUNCTION		HIGH	
CO2 BAROMETRIC HIGH		HIGH	
CO2 BAROMETRIC LOW		HIGH	
CO2 COMM ERR	CO2 module communication failure	HIGH	Stop using measuring function of CO2 module, notify biomedical engineer or

			Our service staff.
CO2 INIT ERR	CO2 module is not properly connected or failed.	HIGH	Stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.
CO2 COMM STOP	Measuring module failure or communication failure.	HIGH	
CO2 ALM LMT ERR	Functional safety failure	HIGH	Stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.
INS ALM LMT ERR	Functional safety failure	HIGH	
AWRR ALM LMT ERR	Functional safety failure	HIGH	
CO2 STANDBY STATUS	Turn from measuring mode to standby mode, making the module in energy-saving status.	No alarm	
CO2 WARM UP	Shows that the sensor is in warming-up stage.	No alarm	
CO2 SENSOR START UP	Shows that the sensor has just entering start-up stage.	No alarm	

10.6 Maintenance and Cleaning

1. Sample line is for one-off use in Sidestream module. Do not sterilize or clean for reuse on another patient.
2. Airway adapter is for one-off use in Mainstream module. Do not sterilize or clean for reuse on another patient.
3. 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.
4. No routine calibration required in both Mainstream and Sidestream CO2 module.

Appendix I: Product Specification

I.1 Classification of the Monitor

1) Standard electric shock resistance class: I class electric shock resistance equipment
2) EMC class: A class
3) Standard degree of resistance to shock: CF type
4) Degree of preventing from liquid in: IP22
5) sterilization/Disinfection method : detailed information refer to chapter 5
6) Working mode: continuous working
7) Duration of use: 5 years

I.2 Specification of the Monitor

I.2.1 Size and weight of the monitor

Size: 255*152*100mm

Weight: Approx. 1.30 (kg)

I.2.2Working environment

Temperature:

Working temperature	0 － 40（ ℃）
Transportation and storage temperature	-20 － 60（℃）

Humidity:

Working humidity	<= 85 %
Transportation and storage humidity	<= 93 %

Altitude:

Working altitude	-500 － 4,600m(-1,600 － 15,000feet)
Transportation and storage altitude	-500－13,100m(-1,600 － 43,000feet)

Voltage

100－240 (V)AC, 50/60 (Hz)
Pmax=70VA
FUSE 2AL 250V

I.2.3 Display information

4.3inch, TFT screen,
One alarm indicator(yellow/red)
One working indicator(green)
One battery charge state indicator(green)
Three modes in accordance with the alarm state

I.2.4 Battery

2Ah 11.1V lithium battery
More than 60minutes working capability

When the low power indicator gives an alarm for the first time, the patient monitor can still work for 5 minutes.

Maximum rechargeable time of battery should not over 6 hours.

I.3 NIBP Specification

I.3.1 Measuring Method

Pulse wave oscillometry

I.3.2 Work Mode

Manual/Automatic/STAT

I.3.3 Measuring Interval of Automatic Measuring Mode

1,2,3,4,5,10,15,30,60,90,120,180,240,480 minute(s)

I.3.4 Measuring Time of STAT Mode

5 minutes

I.3.5 PR range

40 – 240 bpm

I.3.6 Measuring Range and Precision

Range		
Adult	Systolic blood pressure	40～270mmHg
	Diastolic blood pressure	10～215mmHg
	Mean blood pressure	20～235mmHg
Static pressure range	0～300mmHg	
Static pressure precision	±3mmHg	
Pressure precision:	Max. average error: ±5mmHg；Max. standard deviation: 8mmHg	

I.3.7 Overvoltage protection

Adult mode	300 mmHg

I.4 SpO2 Specification

I.4.1 SpO2

Range	0～100%
Resolution	1%
Precision	70～100%：±2 DIGIT
	0%～69%：no definition given

I.4.2 PR

Range	20～300bpm
Resolution	1bpm
Precision	±3bpm

I.5 CO2 Specification

I.5.1 Side stream:

Warm-up time

When the ambient temperature is 25 ℃, the carbon dioxide curve (capnogram) can be displayed within 20 seconds, and all the specifications can be fulfilled within 2 minutes.

Measurement range

0-150mmHg,0-19.7%,0-20kPa (at 760mmHg), atmospheric pressure provided by the host.

Resolution

0.1mmHg ：0-69mmHg　　0.25mmHg：70-150mmHg

Precision

0-40mmHg：±2mmHg

41-70mmHg：±5%（reading）

71-100mmHg：±8%（reading）

101-150mmHg：±10%（reading）

Respiratory rate range

0- 150 BPM

Respiratory rate accuracy:

±1BPM.

I.5.2 Main stream:

Warm-up time

When the ambient temperature is 25 ℃, the carbon dioxide curve (capnogram) can be displayed within 15 seconds, and all the specifications can be fulfilled within 2 minutes.

Measurement range

0-150mmHg,0-19.7%,0-20kPa (at 760mmHg), atmospheric pressure provided by the host.

Resolution

0.1mmHg ：0-69mmHg　　0.25mmHg：70-150mmHg

Precision

0-40mmHg：±2mmHg

41-70mmHg：±5%（reading）

71-100mmHg：±8%（reading）

101-150mmHg：±10%（reading）

Respiratory rate range

0- 150 BPM

Respiratory rate accuracy:

±1BPM.

Appendix Ⅱ: Manufacturer’s Declaration of the EUT

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	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The Vital Signs Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class A	The Vital Signs Monitor is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded.
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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	< 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vital Signs Monitor requires continued operation during power mains interruptions, it is recommended that the Vital Signs Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Vital Signs Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF 3 V/m IEC 61000-4-3	80 MHz to 2.5 GHz	3 V/m	where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Vital Signs Monitor is used exceeds the applicable RF compliance level above, the Vital Signs Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Vital Signs Monitor.

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Vital Signs Monitor

The 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 Vital Signs Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Vital Signs Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
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 metres (m) can be estimated 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.