iT12 Patient Monitor

User's Manual

V1.2

Dott Medical Co., Ltd.

Digitally signed by Perminov Andrei
Date: 2022.06.17 17:30:38 EEST
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Location: Moldova

Disclaimer Statement

Our company 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 thismanual.

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

⚠**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.

Quality assurance:

Maintenance

Free service:

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

Charge service:

(1) Charge service is available for the equipment beyond the scope of warranty service of ourCompany;

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

Our 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 our Company or maintenance performed by personnel unauthorized by our Company.

Returning the goods

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 thegoods.

2. Freight: Users are to bear the freight (including customs charge) if product servicing is needed to be performed at our company.

Product Structure:

This patient monitor is a portable multi-parameter patient monitor which may use in the situation of the day of operation, operative/anesthetic recovery, emergency room for monitoring vital signs of adult, children and neonatal baby.

This patient monitor is power supplied by internal chargeable Lithium battery or AC. It is equipped with a handle for easy carrying.

Application scope:
This patient monitor is suitable for monitoring and measuring patients' vital signs of heart rate/pulse rate, non-invasive blood pressure (systolic blood pressure, diastolic blood pressure, mean blood pressure), invasive blood pressure (systolic blood pressure, diastolic blood pressure, mean blood pressure), respiration rate, electrocardiogram, blood oxygen saturation and temperature in hospital.
Use environment and cautions:

- This product is not home therapy equipment.
- Please fix secure the equipment to avoid injury to people and damage against the equipment.
- Keep the equipment away from MRI equipment to avoid patients' burn caused by inductive current.
- 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.
- Substituting the power cord of this equipment is prohibited. Do not plug three core power cord into the 2-pole socket.
- Keep it away from patient, the equipment and sickbed during defibrillation.

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 General Introduction

- Please read through the content of patient monitor summarization for an overall understanding of the patient 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 Lithium battery for precautions for the monitor power supplied by battery.

⚠**Warning**⚠

This portable multi-parameter patient monitor is used for clinical monitoring. Only doctors and nurses are allowed to use it.

⚠**Warning**⚠

Do not open the case of the equipment to avoid electrical shock. Only the maintenance personnel trained and authorized by our company, Ltd. are allowed to perform the maintenance and upgrade of the equipment.

⚠**Warring**⚠

Keep use of the equipment away from the place with flammable substances like anesthetic to avoid explosion.

⚠**Warning**⚠

Users are required to check if the equipment and the components work normally before use.

⚠**Warning**⚠

To avoid delay in medical treatment, please set proper alarm according to each patient and make alarm sound available with the alarm.

⚠**Warning**⚠

Do not use mobile phone near the equipment. The over-strong radiated field generated by mobile phone may interfere with the function of the patient monitor.

⚠**Warning**⚠

Keep away from patient, table and equipment during defibrillation.

⚠Warning⚠

The equipment connected to the patient monitor must be formed to be an equipotential body (protective and effective connection).

⚠Warning⚠

While using this equipment together with electrical surgical equipment, users (doctors or nurses) should ensure the monitored patient safe.

⚠ Warning⚠

Control the packing material according to the valid waste control standard, and keep the packing material beyond the touch of children.

⚠ 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 us and our representatives for detailed information.

⚠Attention⚠

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 General product introduction

This multi-parameter patient monitor features novel industrial design, small size and AC/DC power supply. It is equipped with a handle and built-in chargeable Lithium battery for the convenience of patients' moving. The equipment is used to monitor and measure patients' vital signs of heart rate/pulse rate, non-invasive blood pressure (systolic blood pressure, diastolic blood pressure, mean blood pressure), invasive blood pressure (systolic blood pressure, diastolic blood pressure, mean blood pressure), respiration rate, electrocardiogram, blood oxygen saturation and temperature. This patient monitor boasts the following characteristics:

- ☆ A 12.1" screen with true color, wide viewing angle, high brightness LCD display.
- ☆ Simple and friendly operating display interface.
- ☆ Internal chargeable large capacity Lithium 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
- ☆ Anti-defibrillation, anti-interference from high frequency electric knife
- ☆ A full-synchronistic lead multi-channel ECG display

Working environment

Temperature:

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

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 T 3.15A

This patient monitor enjoys a large range of multi-parameter monitor functions (as shown in picture 1-1). It is suitable for sickbed monitoring of adult, children and neonatal baby. Users may choose different measuring parameter configuration according to different need.

This equipment may be used to monitor mainly the parameters of electrocardiogram (ECG), respiration (RESP), blood oxygen saturation (Sp02), non-invasive blood pressure (NIBP), and temperature (TEMP). 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. 4 waveforms and all monitoring parameter data are displayed on the display interface with high resolution.

Power switch " ⏻/⊙" of the equipment locates at the lower left corner of front window(as shown in picture 1-1 ①. AC indicator"∼"locates at the right side of the power switch. When AC power is supplied, this indicator lights up in green. Charge indicator" ⊟ " locates right side of the AC "∼".When the equipment is power supplied by internal battery, this indicator flashes in yellow; while AC is supplied, it keeps lightening in yellow. (As shown in picture 1-1 ②

Alarm indicator ALARM locates at the top middle part of the set. When an alarm is given, this indicator flashes (As shown in picture 1-1 ④).

Picture 1-1 The Portable Multi-parameter Patient Monitor

Definition abbreviation:

Items	Definition, abbreviation
ECG	Electrocardiogram
RESP	Respiration
TEMP	Temperature
NIBP	Non-Invasive Blood Pressure
SPO2	Blood oxygen saturation
HR	Heart Rate
RR	Respiration Rate
PR	Pulse Rate
ART	Aortic Pressure
PA	Pressure of Pulmonary Artery
CVP	Central Venous Pressure
LAP	Left Atrial Pressure
RAP	Right Atrial Pressure
ICP	Intracranial Pressure
P1	Associated Pressure Channel 1
P2	Associated Pressure Channel 2
CVA	Cardio Respiratory Disturbance

1.2 Display Interface

This equipment is equipped with a color LCD capable of displaying patients' parameter, waveform parameter collected and alarm information, sickbed No., state of the patient monitor, time, and other prompts provided by

the patient monitor at the same time.

Main screen is divided into 3 areas (As shown in picture 1-2):

1. Information area ①④
2. Waveform area ②
3. Parameter area ③

Picture 1-2 Display Main Interface

1 Information Area(①/④)

Information area locates at the upper part of the screen displaying the state of the patient monitor and the patient. Meaning of the information area content is specified as below:

"BED No.": sickbed No. of the patient being monitored

"PAT TYPE" : type of patient being monitored

"2007-3-13" : current date

"10：23：45" : current time

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

- Prompt of the patient monitor displays the state of the patient monitor or probe appeared always after the area of "ADU";
- Alarm information of the patient monitor（Refer to chapter of Alarm for detailed setting method）;

 is the sign for alarm timeout. This sign will be displayed after short press the key of "SILENCE"（less than 1 second）indicating that the alarm sound is paused. The system sound will not be resumed until another short press the key of "SILENCE" or alarm time expires. "1 minute", "2 minutes" and "3 minutes" are available for option of alarm timeout.

 is the sign of mute alarm. This sign will be displayed after long press the key of "SILENCE"（more than 1 second）indicating that the alarm sound is closed. The system sound will not be resumed until another long press the key of "SILENCE" to un-mute or another alarm occurred.

Short press may switch to the state of alarm pause.

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

⚠**Attention**⚠

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 "FORZEN" will be displayed at bottom of the screen.
- Alarm information of patients' parameters is displayed always at the rightmost fixed area of the screen.

2 Waveform/Menu Area(②):

4 waveforms are displayed in the waveform area. Display sequence of the waveform is adjustable. With the largest configuration, the system may display 2 ECG waveforms, Sp02 plethysmography waveform, and respiration waveform in the waveform area.
Max. full-screen 6 ECG waveforms may be displayed in the waveform area.
Name of waveform is displayed at top left of each waveform. Cardioelectric lead may be selected according to actual need. Increase of the channel and filtering method of ECG will be displayed on each waveform. There is a 1mv scale at the left side of the ECG waveform. As long as the menu is displayed, it is displayed at the fixed position of center of the waveform area covering part of the waveform temporarily. The original interface will be resumed when exiting from the menu.
Waveform will be refreshed at the set rate. Please refer to setting of parameters for adjustment of waveform refreshing rate.

3 Parameter Area (③)

Parameter area locates at the right side of the waveform area nearly opposite to waveform. Parameters displayed in the parameter area include:

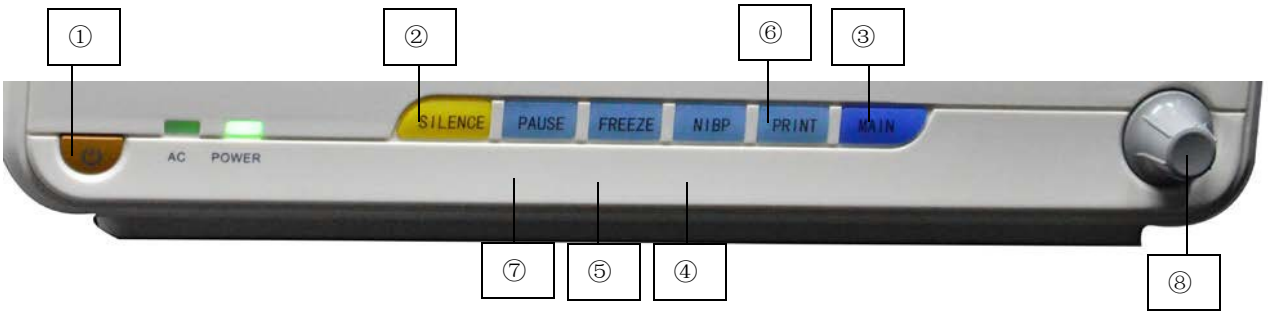
ECG -HR or PR (unit: beat/min.)
-ST segment analysis result ST1, ST2 for P1 and P2(unit: mV)
SpO2 -Blood oxygen saturation(Unit:%)
-PR(unit: beat/min.) (when "BOTH" option is chosen for source of HR)
NIBP -In sequence from left to right lie systolic blood pressure, mean blood pressure and diastolic blood pressure; (unit: mmHg or kPa)
TEMP -Temperature(unit: ℃ or ℉
RESP -Respiration rate(unit: times/min.)

1.2 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.

1.3 Key functions and Basic Operations

Operations on the patient monitor can be achieved through keys and knobs. As shown in picture 1-3:



Picture 1-3 The keys and knobs

- ⏻/⊙ (①)

  Press this key for min. 2 seconds to power On/Off the patient monitor.

- **SILENCE(②)**

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.

⚠**Attention**⚠

If new alarm occurs under alarm halt/mute, alarm halt/mute will be automatically resumed. Please refer to alarm chapter for detailed information.

⚠**Attention**⚠

Alarm resume depends on the existence of alarm factor. But pressing SILINCE key may permanently close alarm sound caused by ECG lead fail and Sp02 probe fail.

- **MAIN (③)**

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

No matter what level is the system at, as long as press this key, the system will be back to the main interface.

- **NIBP(④)**

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

- **FREEZE(⑤)**

Press this key to enter into the state of freeze (The scene keeps still for better observation). Press it again, the system will be unfreezed (Scene returns back to state of monitoring).

- **PRINT(⑥)**

Press this key to start a real time recording.

- **PAUSE (⑦)**

Press this key to silence all the alarm.

- **Rotary Control Knob （Simply the knob）(⑧)**

Users may rotate this knob to choose menu items and change setting. The knob can be rotated clockwise and counterclockwise, and can be press for operation as well. Users may achieve all operations on main screen, in system menu and parameter menu through this knob.

Screen Operation Performed through the Knob:

The rectangle sign moving along with the rotation of the knob on the screen is named cursor. Operation can be done at the place where the cursor may be positioned. When the cursor is in the waveform area, users may change the current setting. When the cursor is in the parameter area, users may open the relevant parameter menu and set relevant information of parameter.

Operation methods:

- Position cursor at the option to be operated.
- Press the knob.
- System will display one of the 4 below:
  - Menu or measuring window will be popped up on the screen. Or the menu is substituted with a new one.
  - Cursor with grounding will become into a frame without grounding, which means that the content in the frame may be changed along with the rotation of the knob.
  - A sign "√" is displayed at this place indicating this option is selected.
  - Immediately execute a certain function.

1.4 External Interfaces of the Patient Monitor

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

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

① ECG cable jack

② CUFF jack

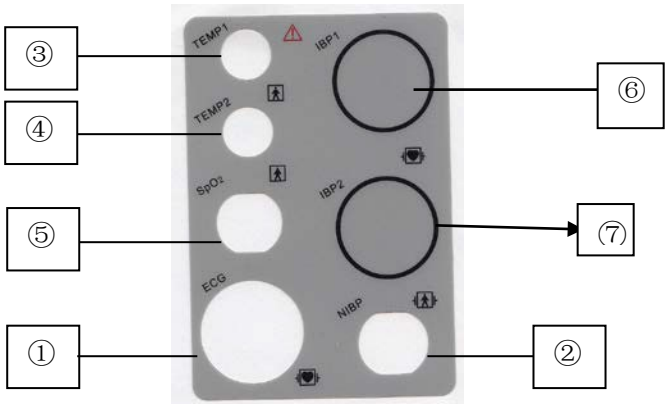
③ TEMP1 probe jack

④ TEMP2 probe jack

⑤ Spo2 probe jack

⑥ IBP cable jack

⑦ IBP cable jack

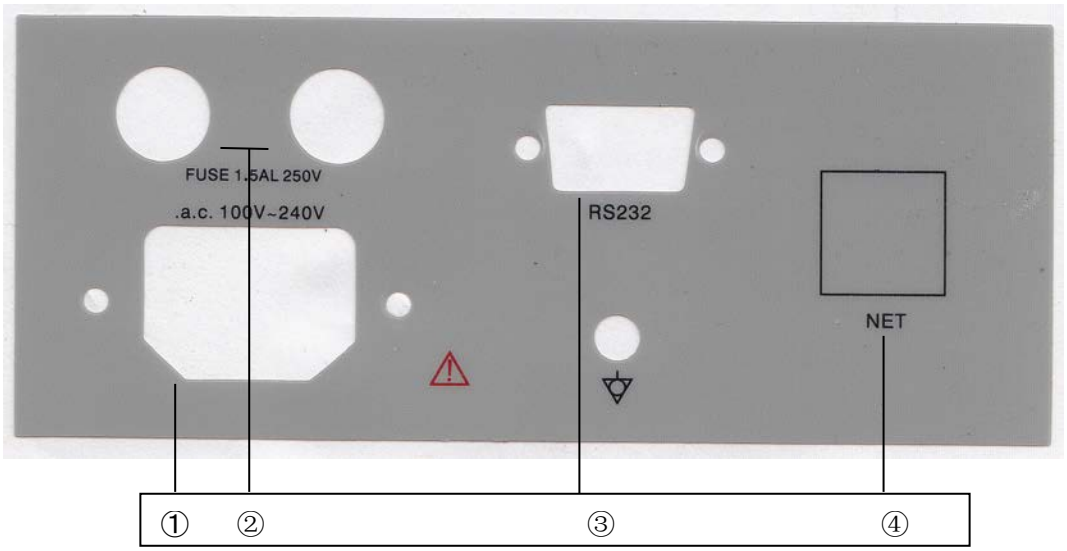


Picture 1-4 Probe Jack

This sign indicate "Attention". Refer to the attached document (this manual).

This sign means the applicable component is classified as type of CF. The design is equipped with special protection of anti-electroconvulsive shock (it is equipped with a F type ground disconnecting device particularly in the allowable currency outleakage.) Meanwhile, it is suitable for use during defibrillation.

Other signs are specified in the chapter of Patients' Safety.
Jacks on back window are shown in picture 1-5:



Picture 1-5 Back Window

① Power socket(①): power input interface

② Fuse holder(②) : for holding fuse（ φ5X20/3A）

③ COM interface(③) : for connecting with other equipment

④ Equal potential(④) : Equal potential interface

⚠ Warning ⚠

All the simulation and digital equipment connected with the patient monitor must be the product having passed appointed IEC standard certification (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 equipment 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.

1.5 Built-in Chargeable Lithium Battery

Multi-parameter patient monitor is equipped with an internal chargeable Lithium 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 "BATTERY TOO LOW" 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)

Chapter Two Patient Monitor Installation

2.1 Unpacking Inspection

Carefully take out the patient 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 patient monitor. Insert the power cord into the power interface of the patient 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 patient monitor, it is necessary to charge the battery. Therefore, the patient 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 patient monitor is opened or closed.

2.3 Power On

When powering on, the system will enter into the main monitoring screen after successful self-test about 30 seconds later. At the time, users may perform operation.

⚠ Warning ⚠

If there is function damage found or prompt of error occurred, please do not use the patient 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 patient 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 Probe

Connect the required probe with the patient monitor and the patient to be monitored.

⚠ **Attention** ⚠

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

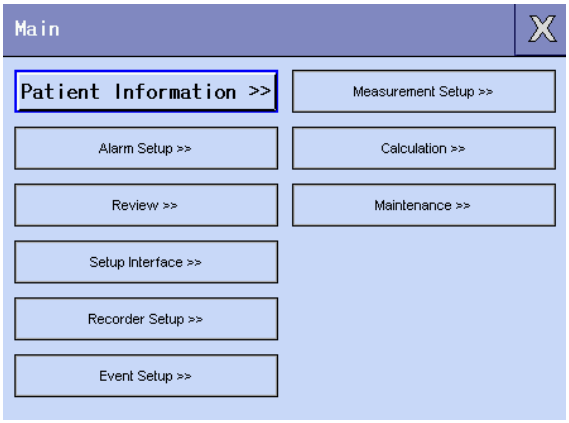
2.5 Inspection on Recorder

If the patient 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

- Patients' information management
- Default configuration
- Retrospective function
- Information of patient monitor
- Setting of patient monitor
- Maintenance of patient monitor
- Medicament calculation
- Demonstration function

The patient 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:



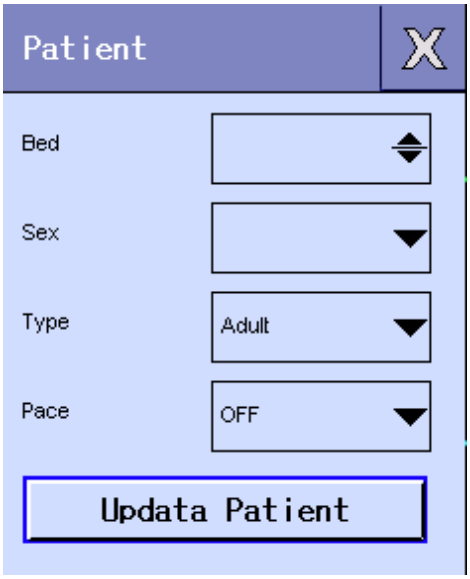
Picture 3-1 System Menu

3.1 Patients' Information Management

⚠Attention⚠

Please refer to "Update Patient" in this chapter for clearing current patients' data.

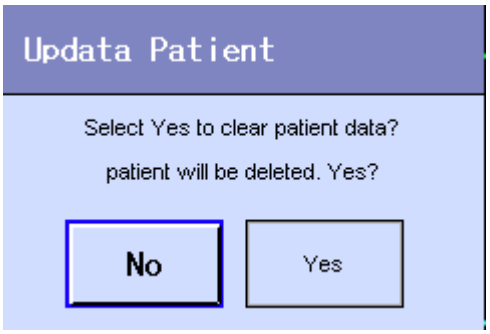
Select "Patient Information" in system menu, the menu as shown in picture 3-2 will be popped up.



Picture 3-2 Patients' Information Management

Bed	Bed No. 1-200 available.
Sex	Sex of the patient
Type	Type of patient (Adult, children, neonatal baby)
PACE	The patient is with a pacemaker or not. If YES, please select On.(If YES, there will be a row of dots displayed in the ECG waveform area.)
NEW PATIENT	Monitor a new patient, but will not delete the monitoring data of the previous patient

In this menu, users may also select the option of "NEW PATIENT" to enter into a dialog box of "CONFIRM TO UPDATE PATIENT " to determine if to clear data. As shown in picture 3-3:



Picture 3-3 Confirm update Patients' Data

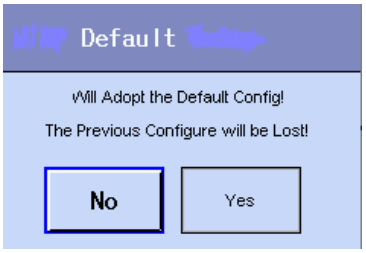
Select "YES" to delete all the information of the patient being monitored and exit menu.
Select "NO" to save the information of the patient and exit menu.

⚠Attention⚠

Selection of "YES" will delete all the information of the patient monitored.

3.2 Default Configuration

Users may set current system configuration as users' default configuration. At the time, the system will automatically save all the current parameter menu setting, ECG lead, increase and filtering as the corresponding type user default configuration content according to the type of patient, and a dialog box as shown in picture 3-4 will be popped up:



Picture 3-4 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⚠

After selecting any item in "DEFAULT" and exiting from it, a dialog box of "ADOPT FACTORY DEFAULT ADU CONFIG" will be popped up. User can confirm the selection by clicking "YES", or "NO" to cancel.

⚠Warning⚠

All the configurations in the system will be replaced by Default configuration.

3.3 Recall Function

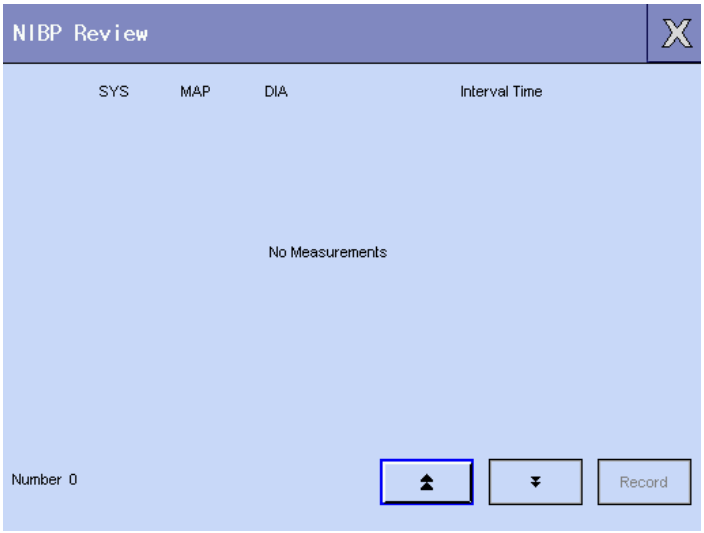
When selecting "Review" in "SYSTEM MENU ", the menu as shown in picture 3-5 will be popped up.

Picture 3-5 Retrospective Function menu

When selecting "NIBP RECALL " in "RECALL", the menu as shown in picture 3-6 will be popped up:

3.3.1 NIBP Recall

The patient monitor can display the latest 400 NIBP measurement data in NIBP retrospection.
When selecting "NIBP Review" in "Review" menu, the last 3 times of NIBP measuring result and measuring time will be displayed in the window.

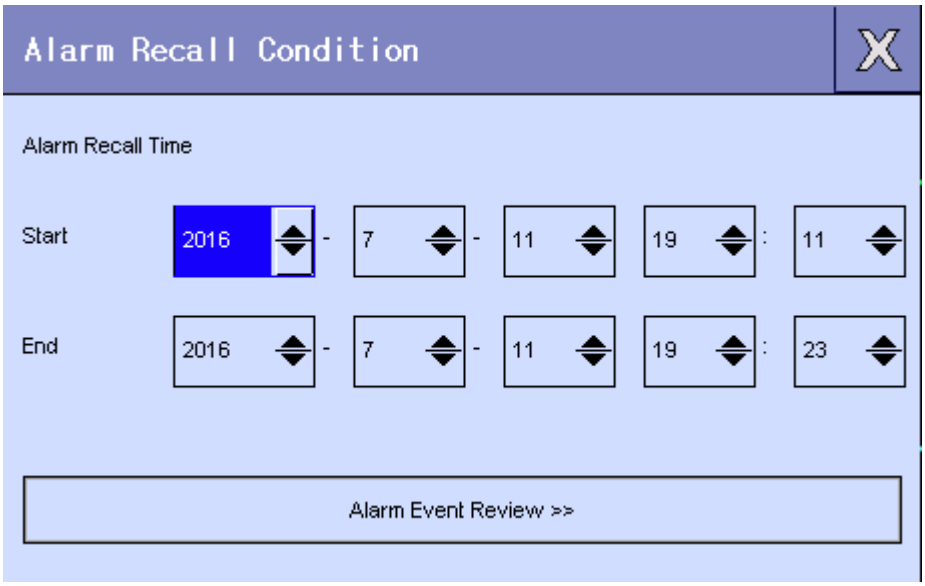


Picture 3-6 Retrospection of NIBP measurement

Data are arranged in sequence of measuring time beginning from the last time. Each screen may display 10 times of measured data. Select "UP-DOWN" 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.

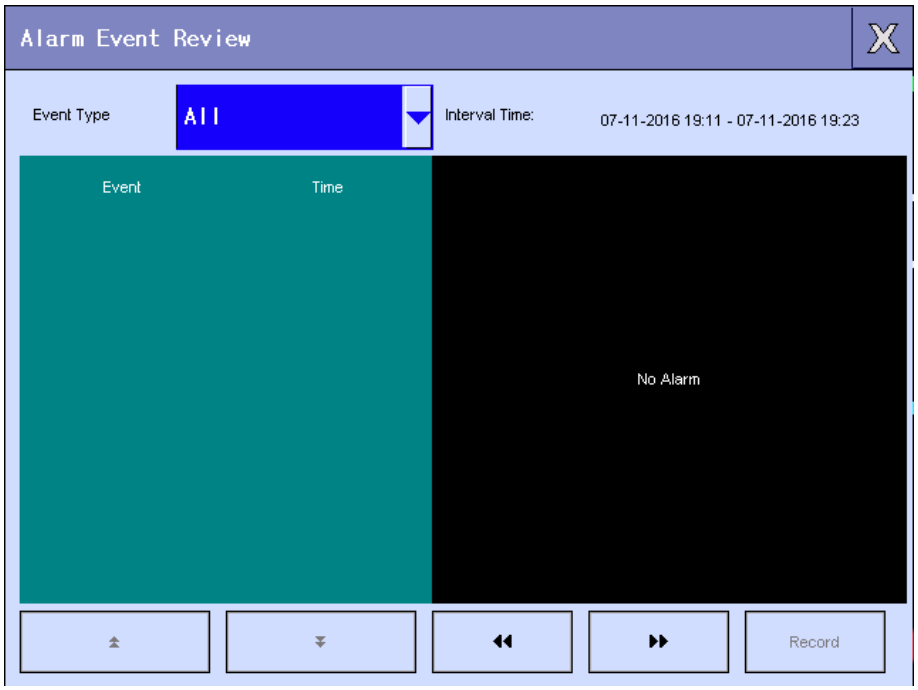
3.3.2 Alarm Event Recall

Select the "Alarm Event Review" to pop up below window, as picture 3-7 shown:



Picture 3-7 Alarm Recall Condition

Setting the start time and End time of the alarm event, then select the "Alarm Event Review" to pop up the window as shown in picture 3-8:



Picture 3-8 Alar Event Review

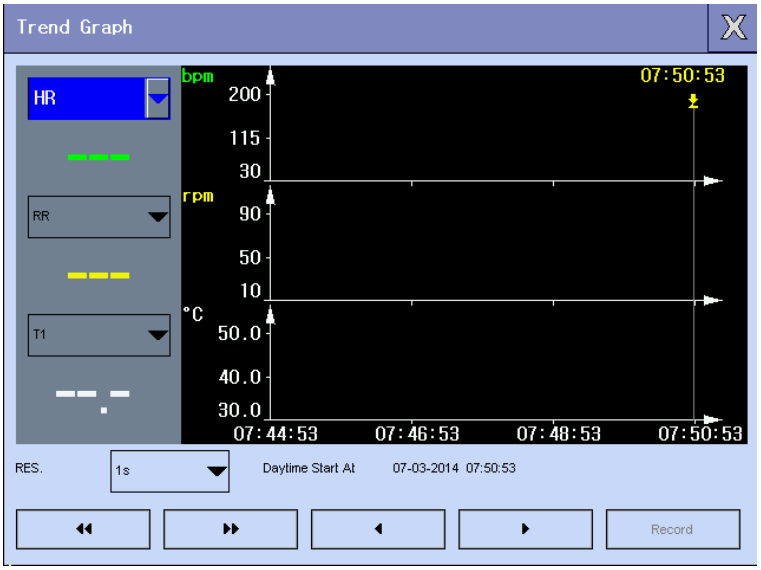
Event Type: All, ECG, SPO2, NIBP, RESP, TEMP, HR, RR.

3.3.3 Trend Graph

- The last 1 hour's trend plot can be displayed at the data resolution of 1/second or 5/second.

■ 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 "TREND GRAPH" in "RECALL", the following window will be popped up.



Picture 3-9 Trend graph 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 "PARA1" 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 "RES." 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 "L-RIGHT" 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 "L-RIGHT" key, turn the knob counterclockwise to observe the earlier trend curve;

Modify display proportion

The proportion of vertical ordinate can be changed through "SCALE" 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 "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

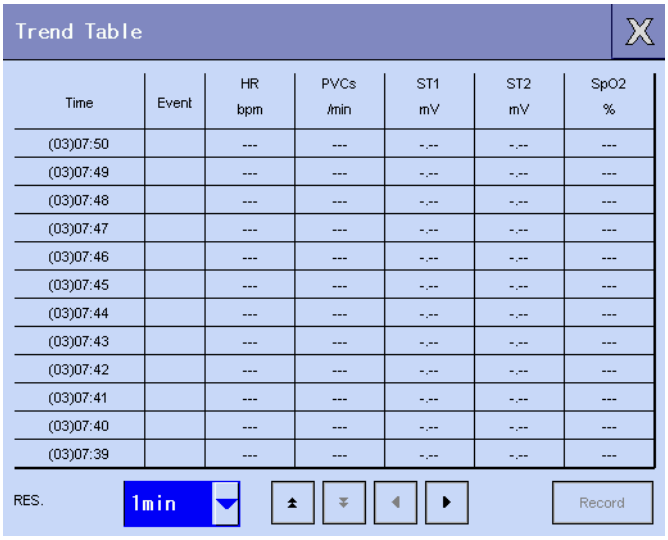
To observe NIBP trend plot for the last 1-hour:

- Press MENU key on the control window, "SYSTEM MENU" will be popped up;
- Select "RECALL" in the menu, and then select "TREND GRAPH";
- Select parameter: Turn the knob in the option of "PARA1" till "NIBP" appears in the box;
- Select "1 second" or "5 seconds" in the options of "RES.";
- Select "L-RIGHT", 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 "SCALE" for adjusting;
- For knowing the measuring value of a certain moment, select "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 "EXIT" key to exit observation of trend plot.

3.3.4 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 "TREND TABLE" in "RECALL", the following trend table will be popped up:



Picture 3-10 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 into 7 groups:

HR, PVC、

RR

STl, ST2

Tl, TD, T2

$SP0_2$, PR

NIBP S/M/D
IBP1,IBP2

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, "UP-DOWN" may be selected, turn the knob clockwise to observe the nearer trend data; if there is an instruction of ▼ under the window, "UP-DOWN" may be selected, turn the knob clockwise to observe the earlier trend data;

Observe trend data with different parameters

Select "L-RIGHT". Any one group 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.

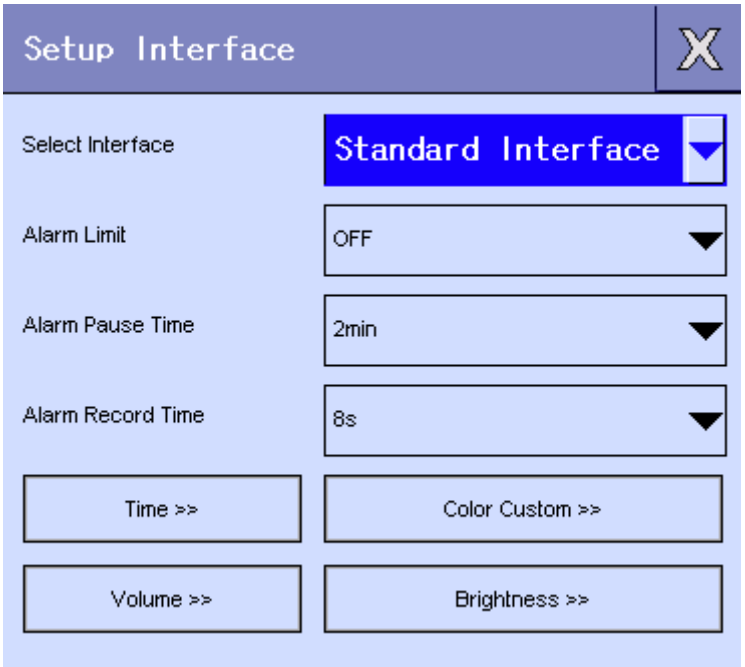
Operation example

Observe NIBP trend table:

- Press MENU key on the control window, "SYSTEM MENU" will be popped up;
- Select the option of "TREND TABLE" in the menu;
- Select parameter: Select "L-RIGHT", 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 "UP-DOWN", turn the knob, observe NIBP trend data at different time;
- Press "EXIT" key to exit observation of trend table.

3.4 Setting Patient Monitor

Select "Setup Interface" in "SYSTEM MENU", the menu as shown in the picture 3-11 will be displayed:



Picture 3-11 Patient Monitor setting

In the menu of "Setup Interface", users may set the following items:

3.4.1 Select Interface

Five differenct interfaces are available: Standard、Big Font、OxyCRG、 Dynamic Trend.

3.4.2 Alarm limit

Select "ALM LIMIT" in the menu of "MONITOR SETUP". Two states of "OFF" and "ON" are optional. When "ON" is selected, limit value of alarm will be displayed in the data display area of parameter. Whereas, when state of "OFF" is selected, limit for alarm will not be displayed.

3.4.3 Alarm Record Time

Select "ALM REC TIME" in the menu of "MONITOR SETUP", turn the knob to set recording output time while alarming. There are options of "8 seconds", "16 seconds" and "32 seconds" available.

3.4.4 Alarm Pause Time

Select "ALM PAUSE TIME" in the menu of "MONITOR SETUP", 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.

3.4.5 Alarm Sound

Select "Volume" in "Setup Interface" menu, select "Alarm Volume" and turn the knob to set alarm volume. There are four levels available for options including "0", "1", "2", and "3" . "0" means volume is shut down.

⚠Warning⚠

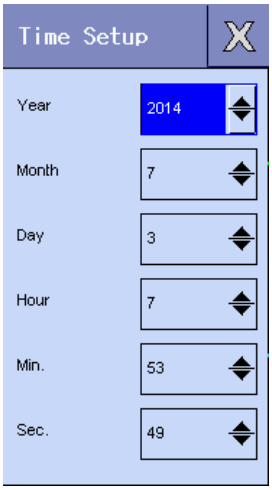
When alarm volume is shut down ("0" is selected), the patient monitor can not give audible alarm in case alarm occurrence. Operators are required to use this function carefully.
In case of selecting "OFF" for alarm volume in mute or alarm pause state, the system will automatically end mute state or alarm pause state.
In case of selecting "Mute" or "Alarm pause" when alarm volume is "OFF", the system will turn the alarm volume back to the level before being shut down, meanwhile, the system enters into mute state or alarm pause state.

⚠Attention⚠

All the states in "ALM SOUND" will still be valid for next startup. Operators are required to check this function carefully before use to avoid delayed treatment on patient caused by inaudible alarm or low audible alarm.

3.4.6 System Time Setup

After selecting the option of "Time" in the menu of "Setup Interface", the menu as shown in picture 3-12 will be popped up:

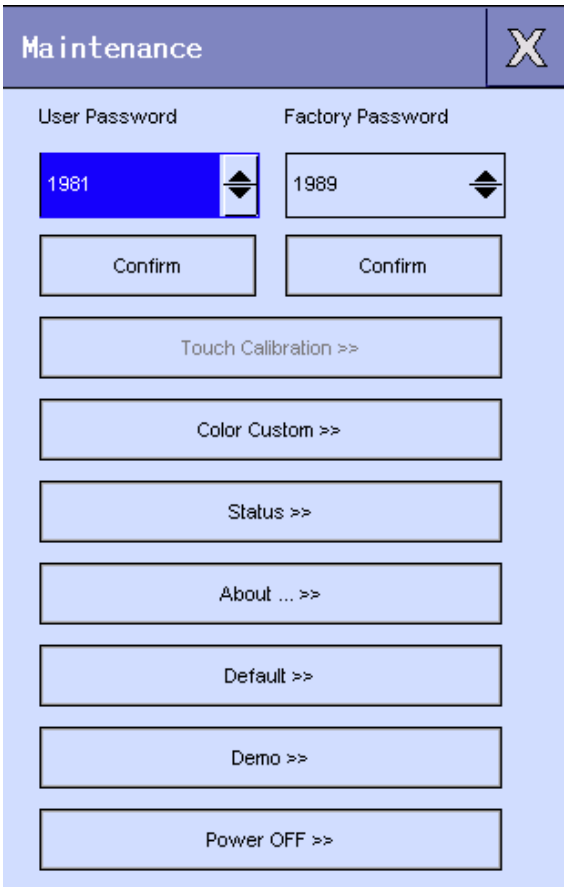


Picture 3-12 System Time Setup

3.5 Maintenance of Patient monitor

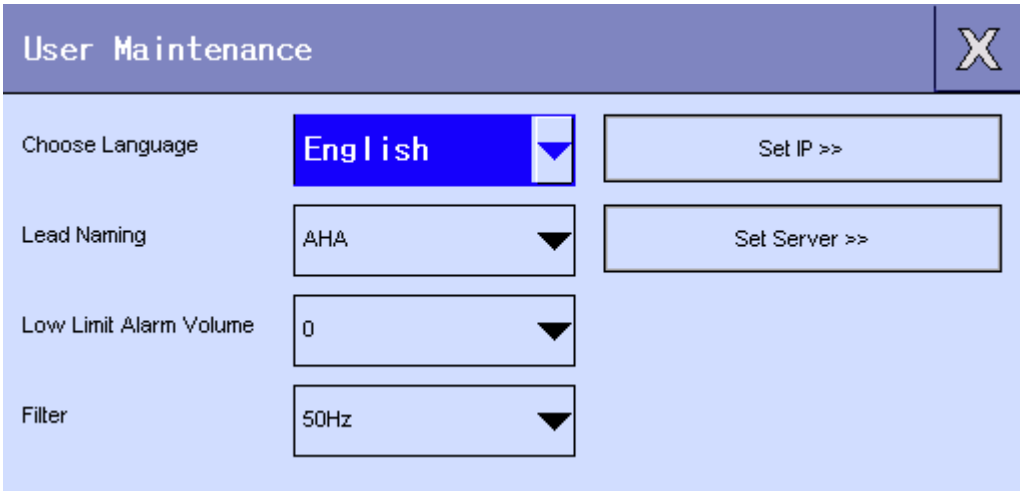
Select the option of "Maintenance" in "Setup Interface", dialog box of "ENTER MAINTAIN PASSWORD" will be popped up as shown in picture 3-13.

Users may perform maintenance in user maintenance menu by entering user password. Users can not perform factory maintenance function. This option is only accessible for the appointed maintenance personnel by our company.



Picture 3-13 Enter Maintain Password

After entering correct user's password in the "User Password" and press "Confirm" key, the menu of "USER MAINTAIN" will be popped up. The information as shown in picture 3-14 may set.



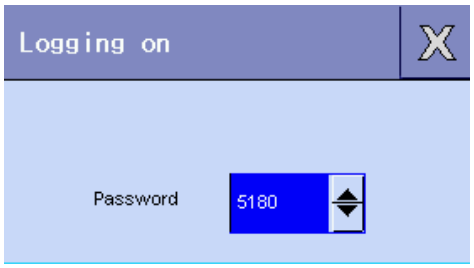
Picture 3-14 User Maintenance

Language: Users may set screen display language as "Chinese", "English", "Turkish", "Russian" and "Spanish". The option depends on the configuration of the user.

Lead naming style: Select "AHA" or "EURO". Please refer to the related content in "ECG/RESP monitor" for the detailed difference between the two styles.

3.6 Demonstration

After selecting "DEMO" in "Maintenance", the dialog box of "INPUT DEMO KEY" 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 assist users in training. In actual clinical use, the function of waveform demonstration is prohibited, because it may have the medical personnel mistake as the patient's waveform and parameter being monitored, and thus monitor on patient affected and treatment delayed. For this reason, a password is required for this key function.



Picture 3-15 Demonstration Function

Chapter Four Patients' Safety

The design of the patient monitor meets the requirements per relevant international standards of IEC60601-1, EN60601-2-27 and EN60601-2-30 constituted for medical electric equipment. This system is equipped with protection of ground disconnecting input anti-defibrillation and surgical electric knife. If adopting correct pole (refer to chapter of ECG and RESP) and mount it according to the guidance of the manufacturer, screen display may be resumed 10 seconds later after defibrillation.

This sign indicates that the component is a IEC 60601-1 type CF equipment. Its design is of special anti-shock protection (It is equipped with F type ground disconnecting isolation device particularly in allowable currency leakage.) and is suitable for use during defibrillation.

Warning

Keep away from patient, sickbed and equipment during defibrillation.

Environment:

For ensuring the safety of the electric installation, please follow the following guidance's. Use environment of the portable patient monitor should reasonably be free of vibration, dust, corrosive or explosive gas, extreme temperature and humidity, etc. When installed in a cabinet, enough room should be kept at front for convenience of operation. When the door of the cabinet is opened, there should be kept enough room 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 component or circuit damage caused in. Min. 2 inches (5 centimeter) of interspaces should be kept around the equipment for good ventilation.

Requirement for power supply

Please refer to the chapter of Product Specification.

Earthing of the portable patient monitor

To protect patient and medical personnel, the portable patient monitor must be securely earthed. The portable patient 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 not 30core 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 (e.g. 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.

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 patient 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) check can only be performed in the medical use room equipped with protective earthing system. Before use, 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 patient monitor should be power supplied by internal battery.

Condensation

During working, the equipment must be kept free of condensation. 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.

Interpretation for the signs used on patient monitor

 Be careful. Refer to the attached document (this manual).

 This sign indicates this is a CF type component designed with special anti-electric shock device (it is equipped with a F type ground disconnecting isolation device particularly in allowable leakage currency.), and it is of defibrillator resistance.

 This sign indicates this is a BF type component designed with special anti-electric shock device (it is equipped with a F type ground disconnecting isolation device particularly in allowable leakage currency.).

 This sign indicates this is a B type component.

 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

Caution: It is required to power off and disconnect power supply before cleaning this equipment and probe.

This equipment must be placed in dust-free environment.

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 patient 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.

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 formaldehde 35~37%
- Hydrogen Peroxide 3%
- ethanol
- sopropanol

Surface of the patient monitor and probe 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 ECG lead, SpO_2 probe, blood pressure cuff, temperature probe, please refer to the content in related chapters.

⚠Caution⚠

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

Chapter Six Alarm

- This chapter will introduce the general information concerning alarm and measures to be taken in case of alarm.
- Refer to the contents in related chapters involving parameter setting for the information of each parameter alarm and prompt.

6.1 General Introduction to alarm

The so-called alarm indicates the prompt sent by the patient monitor to the user when changes of vital signs of the patient being monitored are so important to arouse attention or failing in patient monitoring due to faults 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 patient 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
The measured HR of patient is at 114BPM, which exceeds HR alarm range set by user.	Physiological alarm
Ventricular fibrillation is found on patient.	Physiological alarm
ECG measurement module detects fail of ECG lead.	Technical alarm
SpO_2 measurement module is out of order.	Technical alarm

6.2.2 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. They are:

too weak of the ECG signal;

cardiac arrest; ventricular fibrillation/ventricular tachycardia；

no pulse found;

RESP cardiac interference;

RESP asphyxia;

Others belong to the former kind.

6.2.3 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.

6.24 Removable Sound and Light

"Sound and light removable" indicates some technical alarms are changed to the prompt way of prompt, if operation pause is performed, no matter in timeout state or resumed to normal alarm state, the details are as below:

1. The capability driving sound and light alarm is removed, namely, no sound and light alarm performed.
2. The capability driving character is removed, namely, the color of under color will be changed to the same color as title under color.
3. After normal alarm state resumed, when this alarm is triggered, alarm is notified in way of normal alarm.

This kind of technical alarm is caused mainly by errors of lead fail in technical alarm, other errors beyond NIBP parameter alarm limit and normal use obstacle of the recorder.

6.2.5 Removing All

Removing all: press SILENCE key for pause state, this alarm may be removed, that is no more alarm prompt given; in pause state, this alarm will not be performed; when pause is terminated, alarm will not be performed until this alarm is re-triggered. Mainly are the communication errors in technical alarm and errors of module initialization.

6.3 Alarm Prompt Method

In case of alarm, sound and light, character prompts will be given.

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 11 seconds (Interval counts from the beginning of this time to the beginning of next time.)	Alarm indicator flashes in red color and 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 and 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 Character property

Under color: red color is for high level of alarm, yellow color is for middle and low level of alarms.

Color of character string: Except prompt area of NIBP technical alarm, without reference to alarm level, is always black. Character string color displayed in NIBP technical alarm prompt area has nothing to do with level of alarm. High alarm is displayed in red color, middle and low level of alarms are displayed on yellow. When physiological alarm is caused by alarm exceedance of measuring parameter, the parameter value triggering the alarm flashes. Sing of "***"displayed in the information area at top right of the screen indicates the occurrence of alarm, its color is red. If it is a technical alarm, there is no prompt sign of "*"displayed in the information area.

6.3.3 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 for the same period of time.
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 patient 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 Alarm Timeout State

During alarm timeout, the followings may be dealt with:
Refusing sound and light prompts for all alarms.
Refusing character prompt for all physiological alarms.
The left time for alarm timeout is displayed in physiological alarm description area.
Changing alarm prompt of sound and light removable alarm to prompt.
Removing alarm prompt of complete removable alarm.

6.4.5 State Switch-over

In normal state:

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

In alarm timeout state:

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

3. If no pressing key during timeout, enters into normal state.

4. During timeout, if there are new alarms, alarm timeout state will be ended, enters into normal state.

5. During timeout, if there are new physiological alarms, the system will be still in alarm timeout 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 Method

6.5.1 General Introduction

There are two alarm methods: latch-up and latch-out.
Latch-up: when alarm conditions are inexistent, the property that the system still gives this alarm prompt is called latch-up method. Only after resetting the alarm system can inexistent alarm not be notified.

Latch-out: when alarm conditions are inexistent, the property that the system gives no alarm prompt is called latch-out method.

6.5.2 Scope of Application

All physiological alarms may work in latch-up method.
All technical alarms can work only in latch-out method.

6.5.3 Latch-up Alarm Prompt

When an alarm is latched up (meaning that this alarm happed, but the alarm was not in triggering state), prompt methods of this alarm will have the following changes:

1. measuring parameters and relevant alarm limit stop flashing.
2. After prompt lemma of alarm description, there is the system time for entering last time triggering state.

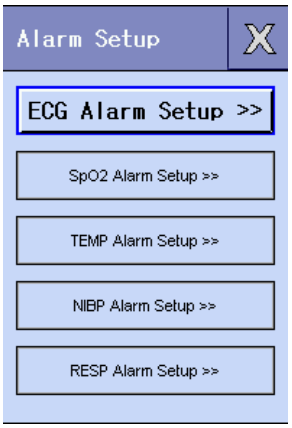
6.5.4 Removing Latch-up Method

Removing latch-up method is also names as alarm reset. Users may use alarm timeout function to reset alarm. When alarm latch-up is removed, the alarms those happened and with inexistent alarm conditions due to latch-up method yet give still alarm prompts will be removed.

When working under latch-out method, alarm timeout key on keyboard module has only timeout function but without function of reset.

6.6 Alarm Setting

Each parameter alarm can be set in "Alarm Setup" menu.
In "MONITOR SETUP" menu, alarm setting of each parameter module is displayed as shown in picture 6-1.



Picture 6-1 Alarm Setup

Public Alarm content Setting

- Alarm limit display: After selecting "ON", the set upper and lower alarm limit will be displayed in each parameter display area.
- Alarm recording time; three options are: 8 seconds, 16 seconds, 32seconds
- Alarm timeout time: four options are: 1 minute,2 minutes, 3 minutes
- Parameter alarm method: latch-up and latch-out

Alarm Setting of Measuring Parameters

Each parameter alarm setting is in the corresponding menu. For example, when entering into "ECG setup" menu, HR alarm setting can be made.

- HR alarm setting:

Step 1: Select "ON" in option of "HR ALM", at the time, only HR alarm setting parameters are displayed in the menu.
Step 2: Users may set fellow items including "HR LEV", "ALM REC", "ALM HI", "ALM LO". Users may move cursor with the knob to the options to be set, and then press the knob to set.
Other measuring parameters may be set in the same way mentioned above.

6.6.1 Sound On/Off Setting

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

6.6.2 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.

6.6.3 Power-on Lead fail

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

1. As for ECG or SPO_2 module, change alarm prompt of lead fail to prompt (that is sound and light are automatically removed), and then notify the user.
2. For other modules, there is no lead fail alarm given.

6.7 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 patient 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);

6.8 Measures Taken in Case of Alarm

⚠Attention⚠

When a certain alarm occurs, patient's status is 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 take 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 the parameter.

Chapter Seven Recorder (Optional)

7.1 General Information of Recorder

The recorder used on this patient 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 patient monitor automatically select waveform in relation to alarm parameter.

7.2 Type of Record

This patient 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 patient monitor (generally the first two waveforms are displayed).

⚠Attention⚠

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

7.3 Record Output

Date Time

HR-heart rate	PR-pulse rate	ST-ST value
SPO_2-blood oxygen saturation		
SYST-Systolic blood pressure		
MEAN-mean blood pressure		
DIAS-Diastolic blood pressure		
TEMP1-Temperature 1	TEMP2- Temperature 2	
RESP-Respiration	LEAD-Lead	

7.4 Information of Recorder's Operation and State

Requirement for recording paper

Thermosensitive recording paper which is up to the mustard is required, otherwise, fail of recording, poor quality of recording or damage of thermosensitive head will be caused in.

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.

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.

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 Electrocardiogram and Respiration (ECG/RESP)

8.1 ECG Monitoring Instruction

8.1.1 Definition of ECG Monitoring

ECG monitoring produces continuous waveform of the patient's ECG activity. It is used for accurately evaluating physiological state of the patient at that time. Ensure normal connection of ECG cable for correct measuring value. In normal working state, the portable patient monitor displays two ECG waveforms at same time.

- Use 5-lead device for monitoring. ECG may acquire two kinds of waveform from the two different leads.
- Parameters displayed by monitor include HR, ST segment measuring value and arrhythmia (optional)
- All the above parameters may be served as alarm parameters.

8.1.2 Precautions for ECG Monitoring

⚠Warning⚠

During defibrillation, keep it away from patient, table or equipment.

⚠Warning⚠

It is a must to use ECG cable provided by our company for ECG signal monitoring with the portable patient monitor.

⚠Warning⚠

When connecting pole or cable, ensure that they do not contact with other conductive parts or ground. Particularly, endure that all ECG poles including neutral pole adhere closely to patient to prevent them from contacting with conductive parts or ground.

⚠Warning⚠

ECG cable with no resistance can not be used for defibrillation on the patient monitor; it is can not be used for defibrillation on other patient monitors if the patient monitor is not equipped with a defibrillation current-limiting resistance.

⚠Warning⚠

Interference from the unearthed instruments near the patient and ESU may cause problems to waveform.

8.2 Operation Method of ECG Monitoring

8.2.1 Preparation

1) Make skin preparation of the patient before placing poles;

- Skin is a poor conductor. Therefore, patient's skin preparation is very important for a good contact between the poles and skin.
- If necessary, give a shaving for placing the poles.
- Wash clean the skin with soap and water (Aether and pure alcohol are prohibited, because they increase skin impedance).
- Dryly rub the skin to increase tissue's blood stream of the capillary vessels, and remove the skin scale and

lipid.

2) Mount pinchcock or snappers before placing the poles.

3) Place the poles onto the patient. If poles without conductive paste used, apply conductive paste before placing the poles.

4) Connect pole lead with patient cable.

5) Make sure that power is switched on.

⚠Warning⚠

Check if ECG pole shoe stimulates skin every day. If there is allergic evidence found, substitute the pole or change position for every 24 hours.

⚠Attention⚠

For protection of environment, the used pole muse be reclaimed or properly managed.

⚠Warning⚠

It is necessary to check if the leads are normal before start monitoring. After plugging out the ECG cable, "Probe fail" will be displayed on the screen and sound alarm will be triggered.

8.2.2 Installation of ECG Lead

Position of ECG Monitoring Poles

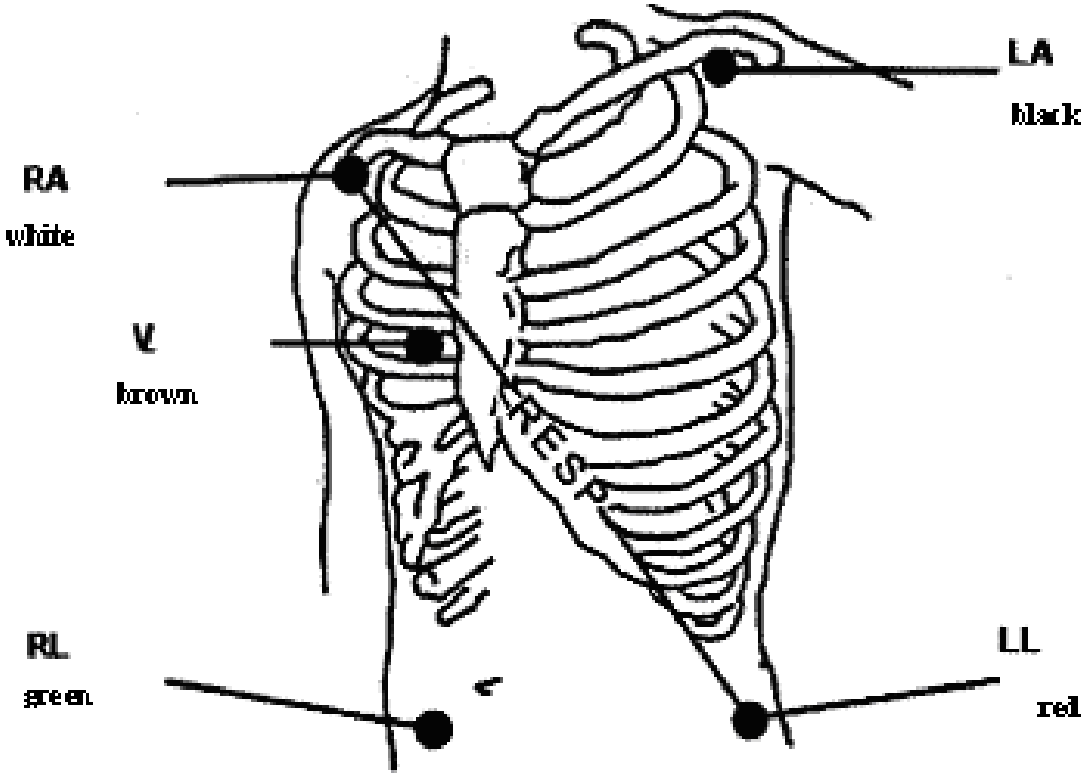
The way to place n5-lead device pole is shown in picture 8-1.

- Red (right arm) pole - place under clavicle close to right shoulder.
- Yellow (left arm) pole - place under clavicle close to left shoulder. Place onto chest as shown in the following picture.
- Black (right leg) pole — place at lower right abdomen.
- Green (left leg) pole – place at lower left abdomen.
- White (Chest) pole – place onto chest as shown in picture 10-2.

⚠Attention⚠

Lead names of USA standard and European standard are listed in the following table (R, L, N, F, C denote lead in European standard, while in USA standard, RA、LA、RL、LL、V are used instead.)

USA		Europe	
Name of lead	Color	Name of lead	Color
RA	white	R	red
LA	black	L	yellow
LL	red	F	green
RL	green	N	black
V	brown	C	white

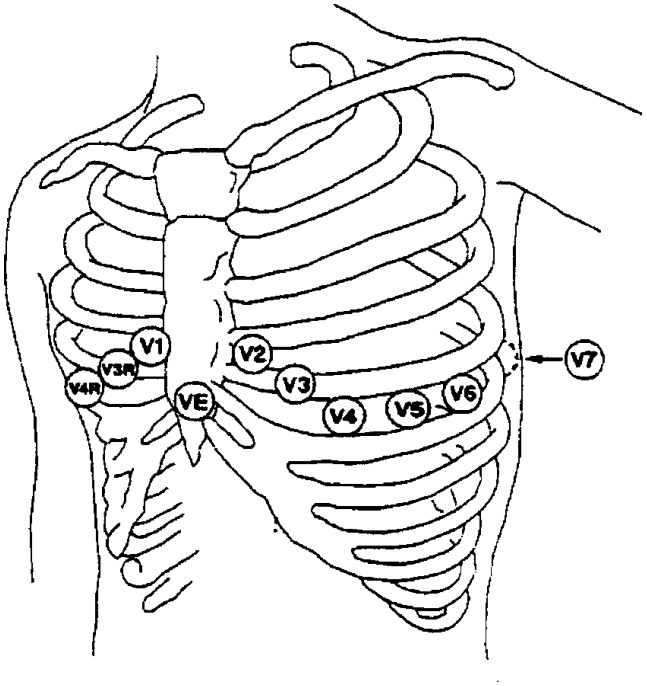


Picture 8-1 Position of 5-lead Pole

⚠Attention⚠

To ensure safety of the patient, all leads must be connected to the patient.

- As for 5-lead configuration, place chest (v) lead pole onto one of the following positions, as shown in picture 8-2:
- V1 is at the fourth right ICS.
- V2 is at the fourth left ICS.
- V3 is at middle position between V2 and V4.
- V4 is at fifth left clavicle midline.
- V5 is at left front axillary line, being on a horizontal plane as V4.
- V6 is at midaxillary line, being on a horizontal plane as V4.
- V3R-V7R is at right thoracic wall corresponding to the left.
- VE is at apophysis of processes xiphoideus. As for back "V" lead placement, it is required to place "V" pole onto one of the following positions.
- V7 is at back the fifth left posterior line.
- V7R is at back the fifth right posterior line.



Picture 8-2 Position of 5-lead Axillary Electrode

ECG Lead Connection Recommended to Surgical Patient

⚠Warning⚠

When using ES equipment, place ECG pole at the middle position between ES earth-plate and ES knife to avoid burn. Cables of ES equipment and ECG can not be intertwisted.

Placement of ECG lead depends on the type of operation. For example: for thoracotomy, poles may be placed at thorax lateral or dorsal. In operation room, because ES knife is used, sometimes fake difference may affect ECG waveform. For reducing fake difference, the pole may be placed at left and right shoulder, close to left and right side of abdomen. Axillary lead may be placed at left side of axillary center. Do not place the pole onto the upper arm, otherwise, ECG waveform may be very small.

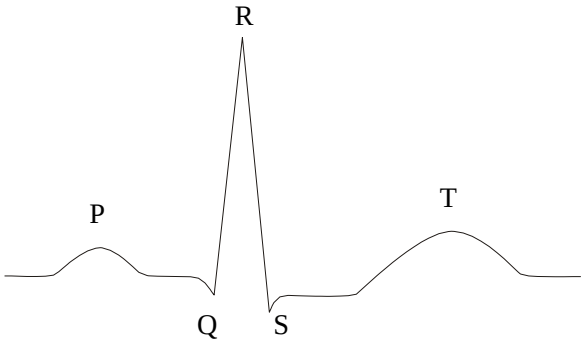
⚠Warning⚠

When using ES equipment, placing the pole onto ES equipment earth-plate is strictly prohibited. Otherwise, there will be plenty of interferences on ECG signal.

Characteristics of a good signal:

- High, narrow and free of cutting mark.
- High R wave is entirely higher or lower than the base line.
- Pace signal is not higher than R wave.
- T wave is lower than 1/3 of the R wave.
- P wave should be much smaller than T wave.

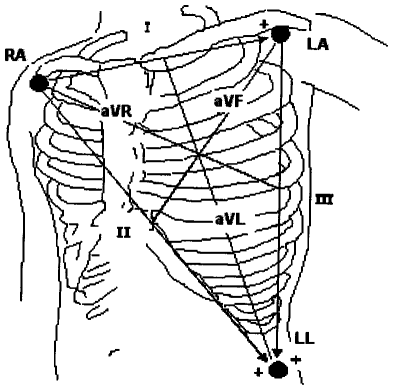
For getting 1 MV calibrated ECG wave, ECG calibration is required. At the time, the screen displays "CAL ,can't monitor."



Picture 8-3: Standard ECG wave

Using 5-lead ECG Device

Users may arrange lead on P1 and P2 according to their own need. The names of lead on the two channels are displayed at left side of the corresponding waveforms, which can be changed in ECG menu. Proper lead can be selected among **I, II, III, aVR, aVL, aVF,V.**
selects the same lead, the patient monitor automatically changes it to different lead.



Picture 8-4 ECG Lead

⚠Attention⚠

If the pole is stacked correctly, but ECG waveform is incorrect, replacing lead is required.

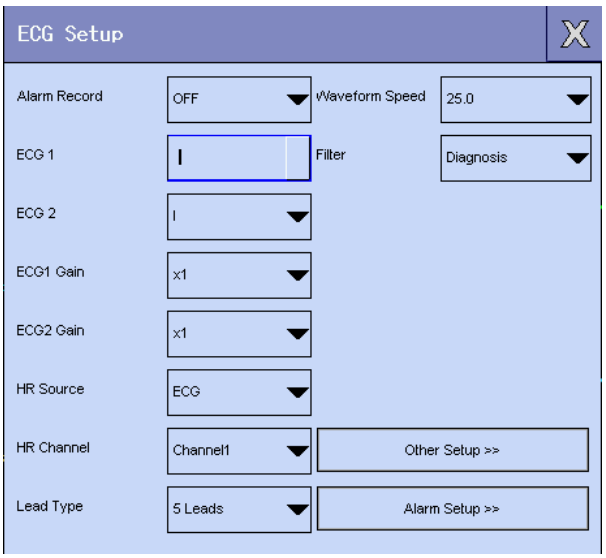
⚠Attention⚠

Interference from unearthed instruments near the patient and ESU may cause in problems to waveform.

8.3 ECG Menu

ECG Setting Menu

Turn the knob, move the cursor on the main screen to ECG hot key in parameter area, then press the knob to pop up ECG setting menu as shown in picture 8-5.



Picture 8-5 ECG Setting Menu

■ ECG SETUP

- HR alarm: if selecting "ON", alarm prompt and storing will be performed in case of HR alarm; if selecting "OFF", there will be no alarm given, and the prompt of " will be displayed by screen parameter area.
- Alarm level: "HIGH", "MED" and "LOW" are available for option. "HIGH" means the most dangerous alarm.
- Alarm recording: if selecting "ON", record output will be performed in case of HR alarm.
- Alarm upper limit: used to set HR alarm upper limit.
- Alarm lower limit: used to set HR alarm lower limit.
  Alarm will be given in case of that HR is higher than the upper limit or lower than the lower limit.

⚠Attention⚠

Set alarm upper and lower limit according to the clinical status of each patient.
Upper limit of HR alarm is very important for monitoring. The upper limit should not be set to the extreme high. Taking change into consideration, do not set HR alarm upper limit 20 beats/minute higher than HR of the patient.

■ HR FROM

ECG, SOP2 may be selected freely to test HR; if selecting "AUTO", the patient monitor will decide the source of HR according to the quality of signal; if selecting "BOTH", the patient monitor will display HR and PR at the same time . If provided by SPO_2, PULSE will be notified and PR sound available.

When SPO_2 is selected for the source of HR, HR alarm judgment will not be performed, but PR alarm judgment performed.

When selecting the option of "Select all", PR measurement value will be displayed at right of main screen SPO_2; HR and PR alarms are given at the same time. Heart beating sound is subject to HR. If HR is with data, there will be with sound prompt. If there are no HR data, there will be sound prompt for PR.

■ HR CHANNEL

"CH1"means to calculate HR with waveform data of the first ECG waveform.
"CH2" means to calculate HR with waveform data of the second ECG waveform.
"AUTO" means that HR calculation channel is selected automatically by the patient monitor.

■ LEAD TYPE: 5-lead and 3-lead are optional.

■ SWEEP

Three options of ECG scanning speed of 12.5，25.0 and 50.0mm／s are available.

■ ST ANALYSIS

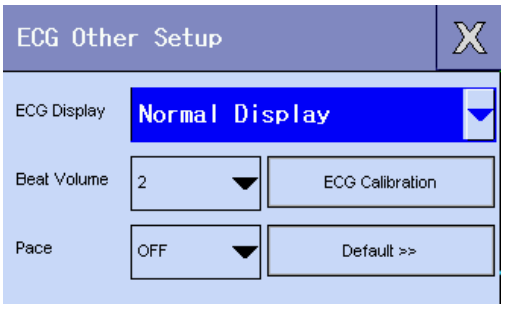
Select this option to enter into "ST ANAL" menu.

■ ARR ANALYSIS

This function is unavailable on this patient monitor.

■ OTHER SETUP

Select this option to enter into "ECG SETUP" menu as shown in picture 8-6.



Picture 8-6 ECG SETUP Menu

There are the following functions in submenu:

- ECG monitoring type: if selecting "NORMAL DISPLAY", two ECG waveforms in 5-lead will be displayed. If selecting "MUTLI-LEADS DISPLAY", six ECG waveforms will be displayed in the screen waveform area.
- Heart beating volume: volume level of 0, 1, 2, 3, 4 are optional.
- Pacing analysis: when selecting "ON", a row of small dots will be displayed in ECG waveform area.
- Industrial frequency restraint:（This function is u7navailable on this patientmonitor.）
- ECG calibration: When selecting this option, ECG waveform will be automatically calibrated.
- Default configuration: Select this option to enter into ECG default configuration dialog box. System default configuration can be selected.

⚠Attention⚠

When it is used for monitoring a patient with pace, "PACE" is required to be powered on; When it is used for monitoring a patient without pace, the "PACE" is required to be powered off; in case that the "PACE" is on, the system will not perform some ARR and ST segment analysis.

⚠Warning⚠

For patient with PACE, it is a must to start up PACE impulse analysis function. Otherwise, PACE impulse may be counted as normal QRS wave, and that will cause fail in "Over low ECG signal" alarm detection.

⚠Attention⚠

When PACE analysis is on, arrhythmia (including PVCs count) associated with ventricular premature beat will not be examined, and ST segment analysis will not be performed either.

- Power frequency restraint: Restrain grid power interference.
- ECG calibration: When this option is selected, ECG wave will be automatically calibrated.

- Default configuration: Select this option to enter into ECG default configuration dialog box. System default configuration can be selected.

■ Waveform of P1 and P2

Lead **I, II, III, aVR, aVL, aVF,V** are optional.

■ ECG increase

⚠Attention⚠

If too strong of the input signal, cutoff peak of wave crest is possible. At the time, user may change ECG waveform increase level manually according to actual waveform to avoid incomplete waveform provided.

Increase for each calculating channel can be selected. There are levels of increase: ×0.25 ×0.5, ×1, and ×2. There is 1mv scale given at left of each ECG waveform. The height of 1mv scale is proportionable with amplitude.

■ Monitoring method

⚠Warning⚠

Only in "DIA" method, the system can provide unprocessed real signals. Under filtering modes of "MON" and "SUR", there will be different level of distortion caused in to ECG waveform. At the time, the system can only provide basic information of ECG, and there will influence much of the ST segment analysis result. Under operation mode, ARR analysis result may also be influenced partially. Therefore, it is recommended that diagnosis mode is adopted for monitoring patient when interference is small.

More clean and precise waveform can be acquired through filtering.

Three filtering methods are available for option. Under diagnosis mode, unfiltered ECG waveform will be displayed; monitoring method will filtered fake difference possibly causing fake alarm; in operation room, operation method can reduce fake difference and interference from ES equipment..

8.4 ECG alarm information and prompt information

Alarm information

Alarms possibly occurred during ECG measurement are classified into two kinds: physiological alarm and technical alarm. Meanwhile, various kinds of prompt information may be given during ECG measurement. In case of the alarms and prompts, refer to related description in alarm function chapter for visual and auditory representation of the patient monitor. On the screen, physiological alarm and general alarm prompt information (General alarm) will be displayed in alarm area of the patient monitor, while technical alarm and the prompt information which can not trigger alarm will be displayed in the information area of the patient monitor. Alarms for arrhythmia and ST segment analysis will not be described in this section.

When alarm record switch in the related menu is on, the physiological alarms caused by parameters beyond alarm limit may trigger the recorder to output alarm parameters and related measured waves.

The following table shows the alarms possibly caused by the measured part.

Physiological alarm:

Prompt information	Reason	Alarm level
ECG LOST	No ECG signal detected on the patient	High
HR TOO HIGH	Measured HR value is higher than set alarm upper limit.	Optional for user
HR TOO LOW	Measured HR value is lower than set alarm lower limit	Optional for user

Technical alarm:

Prompt information	Reason	Alarm level	Solution
ECG LEAD OFF	ECG pole falls off from the patient or cable of ECG falls off from the patient monitor.	Low	Make a secure connection of pole, lead and cable.
ECG LL OR ECG F LEAD OFF			
ECG LA OR ECG L LEAD OFF			
ECG RA OR ECG R LEAD OFF			
ECG INIT ERR	Fault of ECG measuring module	High	Stop using measuring function prov ECG module, notify biomedicine en maintenance personnel of our comp servicing.
ECG INIT ERR1			
ECG INIT ERR2			
ECG INIT ERR3			
ECG INIT ERR4			
ECG INIT ERR5			
ECG INIT ERR6			
ECG INIT ERR7			
ECG INIT ERR8			
ECG COMM STOP	Fault of ECG measuring module or communication	High	Same as the above
ECG COMM ERR	Accidental communication fault	High	In case that the fault keeps still unsolved, solve it in the way mentioned above.
HR ALM LMT ERR	Fault of functional safety	High	Stop using HR alarm function, notify biomedicine engineer or maintenance personnel of our company for servicing.
ECG NOISE	ECG signal is strongly interfered	Low	It is required to keep the patient calm, and keep a reliable connection of pole and a secure ground for the AC power system.

Prompt information (Including general alarm information):

Prompt information	Reason	Alarm level
HR EXCEED	Measured HR value is beyond measuring range.	High

8.5 ST Segment Monitoring

- Default setup of ST segment monitoring function is "OFF". At the time, the patient monitor can not perform ST segment analysis. Users can set it to "ON" if needed.

⚠Attention⚠

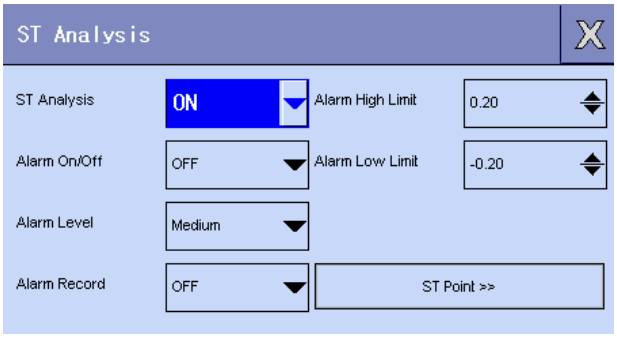
When opening ST segment analysis, the patient monitor is in a "DIA" method. User may change it to "MON" or "SUR" method according to need, but at this period of time ST segment value is seriously distorted.

- ST segment arithmetic may measure ST segment elevation or depression on the second lead. The relevant ST measuring results are displayed in ST1 and ST2 of parameter area in digits. "TREND GRAPH" and "TREND TABLE" may be opened to view the Picture and trend data displayed in form of table.
- Measurement value unit of ST segment: mv;

- Meaning of ST measurement value: positive number means elevation, while negative number means depression;
- ST segment measuring scope: -2.0mv，+2.0mv;

Select the option of "ST ANALYSIS" in the menu of "ECG SETUP" to enter into the menu as shown in picture 8-7.

ST Segment Analysis Menu



Picture 8-7 ST Segment Analysis Menu

Alarm Setting for ST Analysis Result

- ST segment analysis: This switch is used to set the state of ST segment analysis. Only the switch on can perform ST segment analysis.
- ST alarm: if selecting "ON", alarm prompt and storing will be performed in case of ST analysis result alarm; while, if selecting "OFF", there will be no alarm given and prompt of " will be displayed by ST2 in the screen parameter area.
- Alarm level: used to set ST alarm level. Three options of "HIGH", "MED" and "LOW" are available.
- Alarm recording: when "ON" is set, the system will startup the recorder and recording alarm.
- Alarm upper limit: used to set ST segment alarm upper limit. The max. limit is 2.0, while the min. limit value must be 0.2 higher than the value set.
- Alarm lower limit: used to set ST segment alarm lower limit. The min. limit value is -0.2, while the max. limit value must be 0.2 lower than upper limit set.

Adjustment range of alarm upper limit and lower limit:

	Max. upper limit	Min. lower limit	single time adjustment
ST	**2.0mv**	**-2.0mv**	**0.1 mv**

⚠Attention⚠

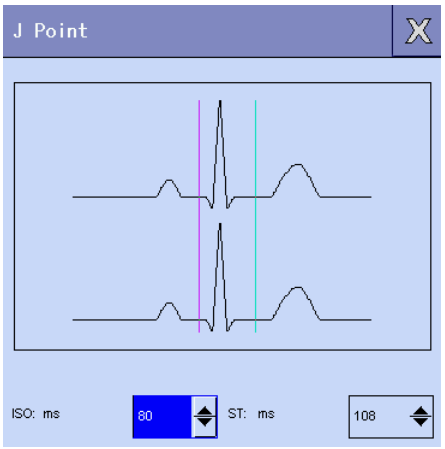
During making ST segment analysis, abnormal QRS wave group has not been taken into consideration.

Alarm Information and prompt of ST Segment Analysis

- Decide ST segment analysis point: Select this option to enter into "DEF POINT" window to set the values of ISO and ST as shown in picture 8-8.

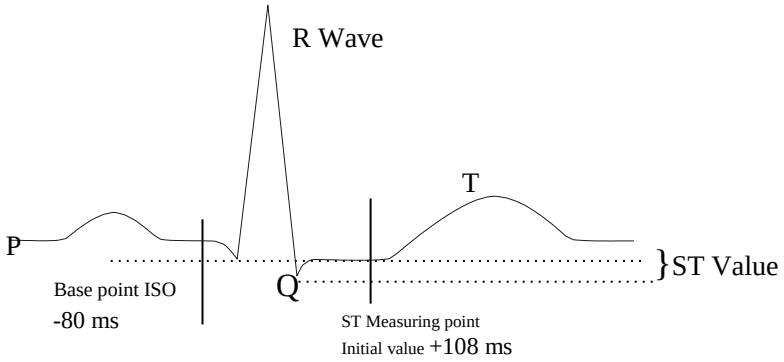
1） ISO（base point）：set baseline point. Power-on setting: 80 milliseconds 2）

ST（start point）：set measuring point. Power-on setting: 108 milliseconds



Picture 8－8 Decide ST Segment Analysis Point

ISO and ST are the two measuring points for ST segment. Both of the measuring points are adjustable. Reference point for setting ST measuring point is R wave peak point (As shown in the following Picture):



Picture 8-9: ST analysis point

Measured ST value for each PACE comprehensive wave is the vertical distance of crossing between the two measured points of the wave.

⚠Attention⚠

If HR or ECG waveform of the patient have obvious changes, ST measuring point is required to make adjustment. The method is as below:

□ Method for ISO and ST adjustment

Adjust the value through turning the knob.

When setting ST segment measuring point, open the window of "DEF POINT", at the time, QRS wave group module is displayed in the window (if the channel is not opened, notify "ST analysis switch off"), position of high brightness line in the window is adjustable, select ISO or ST firstly, then turn the knob in direction of left and right to move the brightness line in parallel to decide base point or measuring point.

⚠Attention⚠

QRS wave group has not been taken into consideration while making ST segment analysis.

Alarm Information and Prompt of ST Segment Analysis

Physiological alarm, technical alarm and prompt information possibly occurred during ST segment measurement are listed in the following table.

Physiological alarm:

Prompt information	Reason	Alarm level
ST TOO HIGH	Measured ST value is higher than the set alarm upper limit.	Optional for user
ST TOO LOW	Measured ST value is lower than the set alarm lower limit.	Optional for user

Technical alarm:

Prompt information	Reason	Alarm level	Solution
ST ALM LMT ERR	Fault of functional safety	High	Stop using ST segment alarm function, notify biomedicine engineer or maintenance personnel of our company for servicing.

Prompt information (Including general alarm information):

Prompt information	Reason	Alarm level

⚠Attention⚠

When alarm limits of two ST measurement values are the same, alarm limit for each channel is not able to be set separately.

When alarm recording switch in relevant menu is at On, those physiological alarms caused by parameter overrun of alarm limit will trigger the recorder to output alarm parameter and related measuring waveform automatically.

8.6 Respirometry

How to measure respiration?

The patient monitor measures respiration from the thorax impedance value of the two poles. The impedance changes (caused by activity of thorax) of the two poles will produce a respiration wave on the screen.

Setting Respiration Monitoring

No more poles are needed to monitor respiration, but placement of poles is very important. Because of clinical status of part of the patients, lateral expansion of their thoraxes cause in negative thorax internal pressure. Under such circumstances, it is better to place the two respiration poles onto midaxillary line and the max. movement area in case of thorax left respiration to acquire the best respiration wave.

⚠Attention⚠

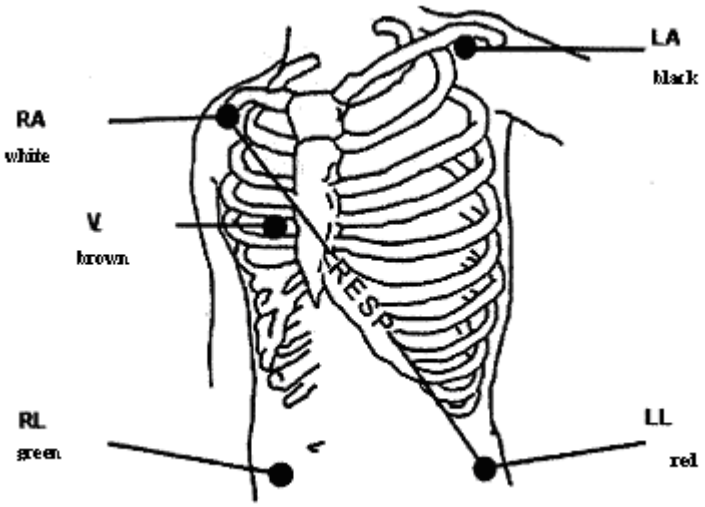
Respiration monitoring is not suitable for the very large movement range patient, because it may cause in false alarm.

RESP monitoring inspection:

1）Make patient's skin preparation before placing poles.

2）Mount pinchcock or snapper onto the pole, and place the poles onto the patient according to the method as shown in the following picture.

Placing poles for respiration measurement



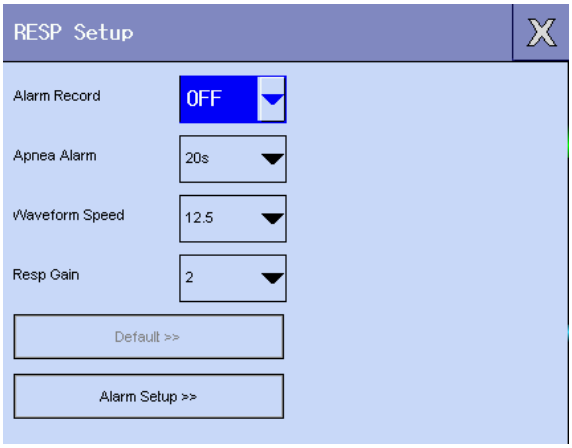
Picture 8-10 Placement of Poles (5-lead)

⚠Attention⚠

Placing white and red poles diagonally is to acquire the best respiration wave. Liver and ventricle should not be on respiration pole line. In this way, fake difference caused by heart covering or palatial blood flow is avoided. This is very important for neonatal baby.

RESP Setting Menu

Turn the knob, move the cursor to RESP hot key in the main screen parameter area, then press the knob to enter into "RESP SETUP" menu as shown in picture 8-11.



Picture 8-11 RESP Setup Menu

RESP Alarm Setting

- Alarm switch: if selecting "ON", alarm prompt and storing will be performed in case of HR alarm; if selecting "OFF", there will be no alarm given, and the prompt of  " will be displayed by RESP in screen parameter area.
- Alarm recording: if selecting "ON", recorder output will be performed in case of RESP rate alarm.
- Alarm level: "HIGH", "MED" and "LOW" are available for option. "HIGH" means the most dangerous alarm.
- Alarm higher limit: used to set alarm upper limit.
- Alarm lower limit: used to set alarm lower limit.
  RESP rate alarm is subject to the set upper limit and lower limit. In case of overrun of RESP rate, alarm is given.

Adjustment range for RESP alarm upper limit and lower limit:

	Max. upper limit	Min. lower limit	single time adjustment
RR adult	120	0	1
RR children/neonatal baby	150	0	1

- Asphyxia alarm: Set judging asphyxia time of patient, ranging 10 seconds~40 seconds, each turn of the knob will increase/reduce 5 seconds.
- Waveform speed: RESP waveform speed of 6.25mm/s，12.5mm/s，25.0mm/s are optional.
- Waveform range: user may set to zoom RESP waveform. Zoom multiple of 0.25，0.5, 1，2,4 are optional.
- Default configuration: Select this option to enter into dialog box of "RESP DEFAULT CONFIG". User may select "NO" or "YES".

8.7 RESP

Physiological alarm, technical alarm and prompt information possibly occurred during RESP measurement are listed in the following table.

Physiological alarm:

Prompt information	Reason	Alarm level
RR TOO HIGH	Measured RESP value is higher than the set alarm upper limit.	Optional for user
RR TOO LOW	Measured RESP value is lower than the set alarm lower limit.	Optional for user
RESP APNEA	No respiration can be detected within the specific time internal.	High

Technical alarm:

Prompt information	Reason	Alarm level	Solution
RR ALM LMT ERR	Fault of functional safety	High	Stop using RESP alarm function, notify biomedicine engineer or maintenance personnel of our company for servicing.

Prompt information (Including general alarm information):

Prompt information	Reason	Alarm level
RR EXCEED	Measured RR value is beyond measuring range.	High

8.8 Maintenance and Cleaning

Maintenance and Cleaning

⚠Warning⚠

It is a must to power off and disconnect AC power before cleaning the patient monitor or probe.

If there is the representation of ECG cable damage or aging, substitution with a new cable is required.

■ Cleaning

The surface of patient monitor and probe may be cleaned with medical alcohol. Dry them by natural wind or with clean and dry cloth.

■ Sterilization

To avoid long term damage against the product, it is recommended to perform sterilization in case of necessity according to regulations of the hospital. Cleaning the product before sterilization is also recommended.

Sterilization materials recommended for patient monitor:

- ◆ Ethanol:70% alcohol, 70% ethyl propel
- ◆ Aldehyde

■ Disinfection

To avoid long term damage against the product, it is recommended to perform disinfection in case of necessity according to regulations of the hospital. Cleaning the product before sterilization is also recommended.

Chapter Nine Blood Oxygen Saturation(SPO_2)

9.1 SpO_2 Monitoring Instruction

Definition of SpO_2 monitoring

SpO_2 plethysmography parameter measures arterial SpO_2, 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% SpO_2, and the reading of SpO_2 value on the patient monitor 97%. SpO_2 value displays the percentage of Oxygen-carrying hemoglobin forming HbO2. SpO_2 plethysmography parameter also provides PR signal and plethysmography wave.

SpO_2 plethysmography parameter measurement principle

- SpO_2 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 probe light source and reached the receiver at the other side.

  Wave length measured by probe 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, SpO_2 of the arterial blood can be acquired. Testing pulse may give a "plethysmography" waveform and PR signal.
- "SpO_2" value and "plethysmography" waveform can be displayed on the main screen.
- SPO_2 in this manual means physiological function blood oxygen saturation measured through non-invasive method.

⚠Warning⚠

If existing COHb, MHB or dyeing dilution chemicals, there will be windage for SpO_2 value.

SpO_2 plethysmography parameter measurement

- "SpO_2" value and plethysmography waveform can be displayed on the main screen.
- SpO_2 in this manual means physiological function blood oxygen saturation measured through non-invasive method.

⚠Warning⚠

If existing COHb, MHB or dyeing dilution chemicals, there will be windage for SpO_2 value.

SpO_2/pulse monitoring

⚠Warning⚠

Cables of ES equipment and ECG can not be intertwisted.

⚠Warning⚠

Do no place probe 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 is cause that blood obstruction during measuring blood pressure may affect the reading of SpO_2

⚠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) "HR FORM" is set to "SpO_2" or "BOTH" in ECG menu.

  2) "HR FORM" is set to "AUTO", and there is no ECG signal at that time.

⚠Attention⚠

SpO_2 waveform and pulse volume are out of proportion.

⚠Warning⚠

Before starting monitoring, check if the probe cable is normal. When plugging SpO_2 probe cable out, "PROBE OFF" will be displayed on the screen and sound alarm is triggered at the same time.,

⚠Warning⚠

If there is the evidence of damage on probe packing or probe, do not use this SpO_2 probe and return it to the factory.

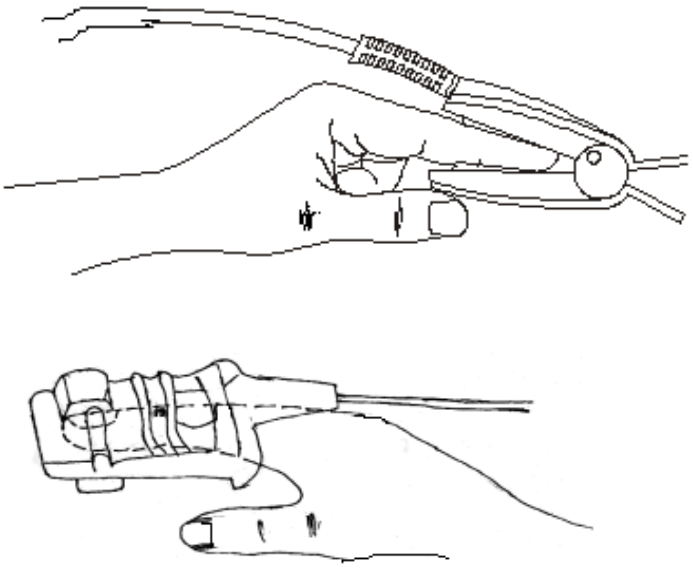
⚠Warning⚠

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 neonatal baby or 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 probe by correct light route aiming and adhering method. It is required to regularly check the adhering position of probe 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.

9.2 Operating method of SpO_2 monitoring

SpO_2 plethysmography measurement

1) Power the patient monitor on;
2) Place the probe onto the proper position of patient's finger;
3) Insert the connector on one end of probe cable into SpO_2 jack.



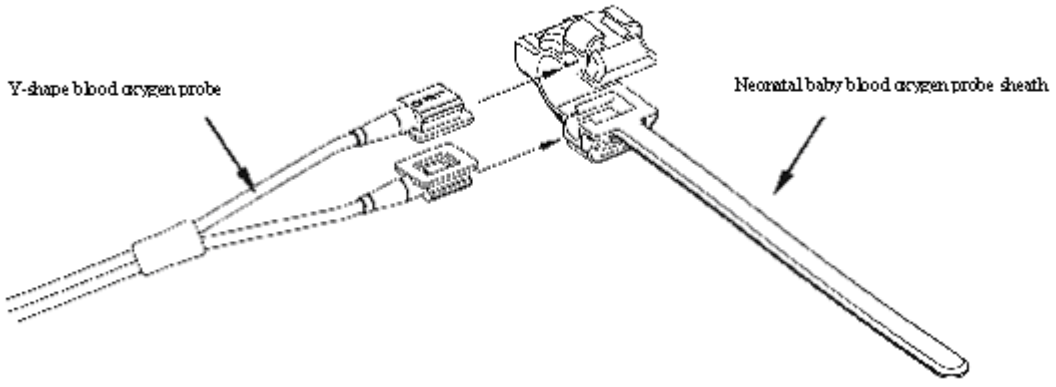
Picture 9-1 Adult Blood Oxygen Probe

■ Neonatal baby $Sp0_2$ plethysmography measurement

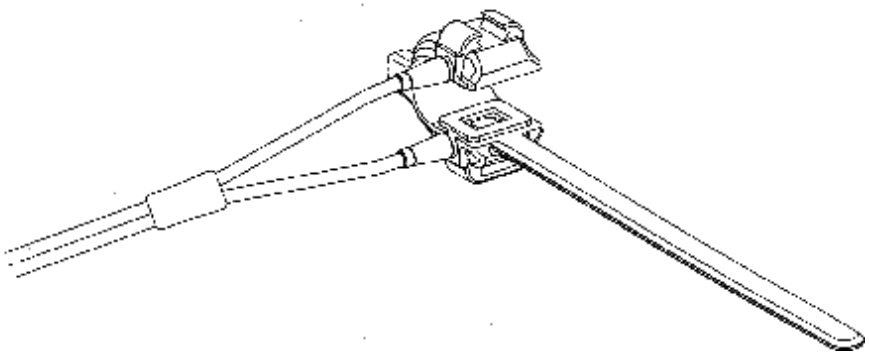
Neonatal baby $Sp0_2$ plethysmography measuring steps are basically the same as the adult. The following is the introduction on neonatal baby blood oxygen probe and placing method.

1. Neonatal baby blood oxygen probe

Neonatal baby blood oxygen probe is composed of Y-shape blood oxygen probe and neonatal baby blood oxygen probe sheath. Inlay LED end and PD end of the Y-shape blood oxygen probe into the upper and lower flutes on the neonatal baby blood oxygen sheath (as shown in picture 9-2). Neonatal baby blood oxygen probe with completion of inlay is shown as in picture 9-3.



Picture 9-2 Neonatal Baby Blood Oxygen Probe(1)

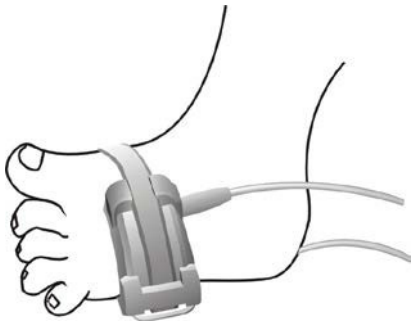


Picture 9-3 Neonatal Baby Blood Oxygen Probe(2)

2. Placement of neonatal baby blood oxygen probe

Clamp the blood oxygen probe onto the hands and feet of neonatal baby (as shown in picture 9-4).

Hold the blood oxygen probe, pull the strip and place the V-shape edge on side of the strip into the V-shape flute on the corresponding side of the sheath. Properly enlengthen the strip (about 20mm) and place the V-shape edge on another side of the strip into the V-shape flute on another side of the sheath. Then release the strip. When V-shape edge on the two sides of the strip is clasped with V-shape flute on the two sides of sheath, pull the strip into the crossbar to lock the strip, as shown in the picture. If the strip is extremely long, pull it into the second crossbar. It is a must to position the blood oxygen probe for correct position of the photo units. Meanwhile, be careful not to pull the strip extremely long. It may cause inaccurate measurement and may seriously block blood circulation.



Picture 9-4 Placement of Neonatal Baby Blood Oxygen probe

⚠Attention⚠

If measures part and probe can not be positioned accurately, it may cause in inaccurate reading of SpO_2, 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.

⚠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.

9.3 Measurement Limit of SpO_2 Monitoring

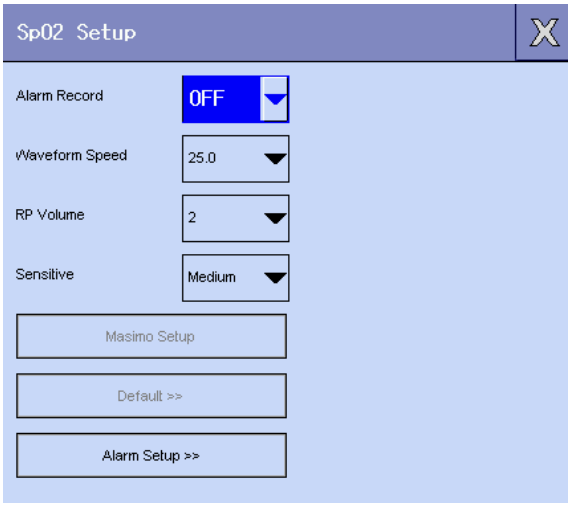
During operating, the following factors may influence the accuracy of SpO_2 measurement:

- High frequency electric interference, like interference generated by the main unit or ES equipment connecting with the system.
- During MRI, do not use oximeter, blood oxygen probe. Inductive current may cause in burn.
- Intravenous dye.
- Excessive moving the patient.
- Outside light radiation.
- Improper installation of the probe or improper contacting position with the object.
- Temperature of the probe (the most suitable temperature range: 28 ℃42 ℃)
- Place probe 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 SpO_2.
- 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 $SP0_2$ value of the measurement. E.g. COHb, MetHb, Methylene Blue, Indigo Carmine.
- SpO_2 probe。

9.4 SpO_2 Menu

SpO_2 Setting Menu

Turn the knob, move the cursor on display interface to $SP0_2$ hot key in parameter area, press the knob to enter into the menu of"SpO_2 SETUP", as shown in picture 9-5.



Picture 9-5 SpO_2 Setting Menu

⚠Warning⚠

Setting SpO_2 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 SpO_2 must be carefully set according to recognized clinical practice.

SpO_2 Alarm Setting

- Alarm switch: if selecting "ON", alarm prompt and storing will be performed in case of SpO_2 alarm; if selecting "OFF", there will be no alarm given, and the prompt of  " will be displayed by SpO_2 in screen parameter area.
- Alarm recording: if selecting "ON", record output will be performed in case of SpO_2 alarm.
- Alarm level: "HIGH", "MED" and "LOW" are available for option. "HIGH" means the most dangerous alarm.
- SpO_2 alarm higher and lower limit: used to set SpO_2 alarm upper limit. Alarm is given in case of SpO_2 overrun of alarm upper and lower limit.
- PR alarm higher 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.

SpO_2 and PR alarm range:

Parameter	Max. upper limit	Min. lower limit	Single time adjustment
SpO_2	100	0	1
PR	254	0	1

SpO_2 and PR default alarm range under default configuration:

Parameter		Max. upper limit	Min. lower limit
SpO_2	Adult	100	90
	Children	100	90
	Neonatal baby	95	85
PR	Adult	120	50
	Children	160	75
	Neonatal baby	200	100

- Waveform speed

12.5 and 25.0mm/s are optional for SpO_2 plethysmography speed.

- Pulse volume: 0、1、2、3、4 levels of pulse volume are optional.
- Calculation sensitivity: Select average time for calculating SpO_2 value. Selection of "HIGH"," Middle" and "LOW" means the average value of 4 seconds, 8 seconds and 16 seconds.
- Default configuration: Select this option to enter into SPO2 default configuration dialog box. System default configuration may be selected.

9.5 SpO2 Alarm Information

SpO_2 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.

Physiological alarm, technical alarm and prompt information possibly occurred during SpO2 measurement are listed in the following table.

Physiological alarm:

Prompt information	Reason	Alarm level
SPO2 TOO HIGH	Measured SpO2 value is higher than the set alarm upper limit.	Optional for user
SPO2 TOO LOW	Measured SpO2 value is lower than the set alarm lower limit.	Optional for user
PR TOO HIGH	Measured PR value is higher than the set alarm upper limit.	Optional for user
PR TOO LOW	Measured PR value is lower than the set alarm lower limit.	Optional for user

Technical alarm:

Prompt information	Reason	Alarm level	Remedies
SPO2 PROBE OFF	Poor connection of SpO2 with patient or the patient monitor	Low	Ensure to place the probe on patient's finger or other part, and ensure secure connection of the patient monitor with cable.
SPO2 INIT ERR	SpO2 module initialization error	High	Stop using SpO2 module measuring function, notify biomedicine engineer or service department of our company.
SPO2 INIT ERR1			
SPO2 INIT ERR2			
SPO2 INIT ERR3			
SPO2 INIT ERR4			
SPO2 INIT ERR5			
SPO2 INIT ERR6			
SPO2 INIT ERR7			
SPO2 INIT ERR8			
SPO2 COMM STOP	SpO2 module initialization or communication error	High	Stop using SpO2 module measuring function, notify biomedicine engineer or service department of our company.
SPO2 ALM LMT ERR	Fault of functional safety	High	Stop using SpO2 module measuring function, notify biomedicine engineer or service department of our company.
PR ALM LMT ERR	Fault of functional safety	High	Stop using SpO2 module measuring function, notify biomedicine engineer or service department of our company.

Prompt information (Including general alarm information):

Prompt information	Reason	Alarm level
SPO2 EXCEED	Measured SpO_2 value is beyond range.	High
PR EXCEED	Measured PR value is beyond range.	High
SEARCH PULSE	SpO_2 module is searching pulse.	No alarm
NO PULSE	SpO_2 module can not detect SpO_2 signal for long term.	High

9.6 Maintenance and Cleaning

Attention and Cleaning

⚠Warning⚠

It is a must to power off and disconnect power supply before cleaning the patient monitor or probe.

⚠Caution⚠

Do not have the probe sterilized with high pressure.

Don't dip the probe into liquid.

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

Cleaning:

- Surface of the probe 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 probe 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 Ten Temperature(TEMP)

10.1 TEMP Monitoring Instruction

Portable patient monitor may use two temperature probes at the same time. Two temperature data measured out and differences acquired.

TEMP Measurement Setting

- If the disposable temperature probe is being used, temperature cable must be inserted into the faucet and then the probe and cable are to be connected. You may insert the repeatable temperature probe directly into the faucet.
- Adhere temperature probe securely onto the patient.
- Connect through to system power supply.

⚠Warning⚠

Before starting monitoring, it is required to check if probe cable is normal. Plug out temperature probe cable of P1 out the faucet, "T1 PROBE OFF" will be displayed on the screen and sound alarm given. Other channels are similar to P1.

⚠Attention⚠

Disposable temperature probe can be used for only one time.

⚠Warning⚠

Be careful with the temperature probe and cable. If idle, twist the probe and cable into a loose ring. If the wire is pulled excessively tight, mechanical damage will be caused in.

⚠Warning⚠

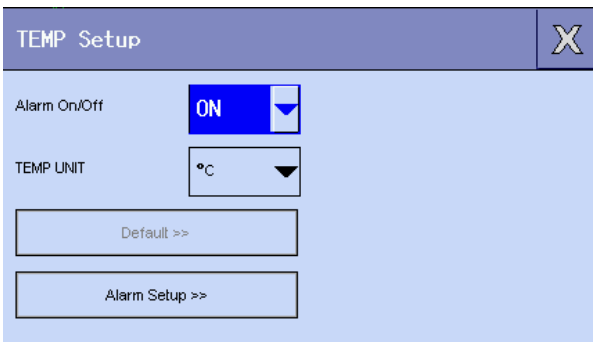
It is a must to have the temperature measuring meter calibrated once very two years (or follow hospital's regulation).

⚠Attention⚠

During monitoring, temperature measuring meter will automatically make s self-test once an hour. Self-test will last 2 seconds and that will not affect the normal operation of the temperature monitor.

10.2 TEMP Menu

User may move the cursor to TEMP hot key in parameter area on the main screen through the knob, press the knob to enter into the menu of TEMP setting, as shown in picture 10-1.



Picture 10-1 TEMP setting Menu

- Alarm switch: if selecting "ON", alarm prompt and storing will be performed in case of TEMP alarm; if selecting "OFF", there will be no alarm given, and the prompt of  " will be displayed by TEMP in screen parameter area.
- Alarm level: used to set alarm level. "HIGH", "MED" and "LOW" are available foroption.
- Alarm recording: selecting "ON"or "OFF"used to set recording TEMP alarm function. While selecting "ON", current TEMP alarm can be printed and output.
- T1, T2 and TD alarm are performed according to the set higher limit and lower limit. Alarm will be given if temperature is higher or lower than the set upper limit and lower limit. T1 indicates temperature of P1; T2 indicates the temperature of P2; TD indicates the temperature difference between the two channels.

Adjustment range of alarm higher and lower limit:

Parameter	Max. upper limit	Min. lower limit	Single time adjustment
T1, T2	50	0	0.1
TD	50	0	0.1

- Temperature unit: ℃ or℉
- Default configuration: Please refer to "DEFAULT" in "TEMP SETUP".

10.3 TEMP Alarm Information and Prompt Information

When alarm recording switch in relevant menu is at On, those physiological alarms caused by parameter overrun of alarm limit will trigger the recorder to output alarm parameter and related measuring waveform automatically.

Physiological alarm, technical alarm and prompt information possibly occurred during TEMP measurement are listed in the following table.

Physiological alarm:

Prompt information	Reason	Alarm level
T1, 2 TOO HIGH	Measured temperature value is higher than the set alarm upper limit.	Optional for user
T1, 2 TOO LOW	Measured temperature value is lower than the set alarm lower limit.	Optional for user

Technical alarm:

Prompt information	Reason	Alarm level	Solution
TEMP PROBE OFF	Connection of temperature cable with the patient monitor	Low	Make secure connection of the cable.
TEMP ALM LMT ERR	Fault of functional safety	High	Stop using TEMP alarm function, notify biomedicine engineer or maintenance personnel of our company for servicing.

Prompt information

Prompt information	Reason	Alarm level
TEMP TEXCEED	Measured temperature value is beyond range.	High

10.4 Maintenance and Cleaning

⚠Warning⚠

It is required to power off and disconnect power supply before cleaning this equipment and probe.

Repeatable temperature probe：

1) Temperature probe can not be heated over 100℃(212℉). It 80℃(176℉)~100℃(212℉) within a short period of time.
2) Do not have the probe disinfected with steam.
3) Use only the scour with alcohol for disinfection.
4) When using normal probe, try to hitch it with protective rubber.
5) For washing the probe, one hand holds the probe, the other rub the probe with a wet lint free cloth downward to the connector.

⚠Attention⚠

It is prohibited to re-disinfect or repeatedly use the disposable temperature probe.

⚠Attention⚠

For protection of environment, disposable temperature probe should be reclaimed or properly managed.

Chapter Eleven Non-invasive Blood Pressure (NIBP)

11.1 NIBP Monitoring Instruction

- NIBP is measured with oscillometry;
- May be used onto adult, children and neonatal baby;
- Measuring mode: manual, automatic and continuous. Systolic, mean and diastolic blood pressure will be display in each mode.
  - □ "MANUAL" mode measure only once.
  - □ "AUTO" mode measure repeatedly. Time interval may be set to 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes.
  - □ "CONTINUAL" 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 contact the cuff risks hematoma.

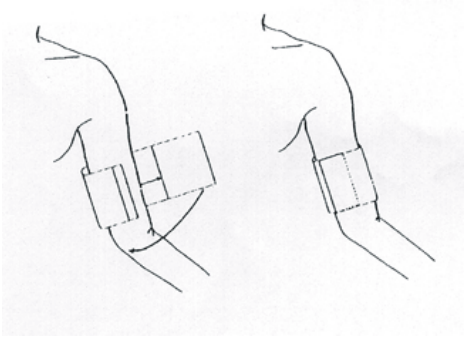
When used onto children and neonatal baby, it should be guaranteed that correct mode setting has been selected (Refer to patient's information menu setting.) Using incorrect patient's mode may endanger the patient. This is because the higher adult blood pressure level is unsuitable for children and neonatal baby.

11.2 Operating method for NIBP Monitoring

11.2.1 NIBP Measurement

Charge tube connecting cuff with the patient 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 11-1.



Picture 11－1 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.

⚠Attention⚠

Width of the cuff should be 40% of body perimeter. (50% for neonatal baby), or 2/3 of the upper arm in length. 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.

Repeatable cuff for adult/neonatal baby/infant

Type of patient	Perimeter of body	Cuff width	Length of charge tube
infant	10~19cm	8cm	1.5m or 3m
children	18~26cm	10.6cm	
adult1	25~35cm	14cm	
adult2	33~47cm	17cm	
leg	46~66cm	21cm	

Disposable cuff for neonatal baby/infant

size	Perimeter of body	Cuff width	Length of charge tube
1	3.1~5.7cm	2.5cm	1.5m or 3m
2	4.3~8.0cm	3.2cm	
3	5.8~10.9cm	4.3 cm	
4	7.1~13.1cm	5.1cm	

◆ 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 patient monitor information area at right side of sickbed number.). If changing monitoring method is needed, please enter into "PATIENT MANAGE" in "SYSTEM MENU" to change "PAT TYPE".

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 SETUP" menu, select the option of "INTERVAL". User may select time interval value for automatic measurement. Then, press START key on the front panel, the system will automatically charge for measurement according to the set time interval.

⚠Warning⚠

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

2．Stop automatic measuring

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

3．One manual measuring

◆ Enter into "NIBP SETUP" menu, select "INTERVAL", set the value to "MANUAL", then press START key on the front panel to begin a manual measuring.

◆ At an idle moment during automatic measuring, press START key to begin a manual measuring. If press START key again at that time, manual measuring will be stopped, but to execute automatic measuring.

4． One manual measuring during automatic measuring

Press START key on the front control panel.

5． Stop one manual measuring on midway

Press again the START key on the front control panel.

6． Continuous measuring

Enter into "NIBP SETUP" menu, select "CONTINUAL" to begin continuous measuring. The course lasts 5 minutes.

⚠Warning⚠

If NIBP in continuous mode lasts excessively long, purpuric, ischemic and neverous 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 patient monitor.

⚠Warning⚠

If liquid splashes the equipment or accessories, particularly when the liquid is possible to enter into conduct or the patient 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 unably 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 enlengthened.

■ 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 enlengthened.

■ 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

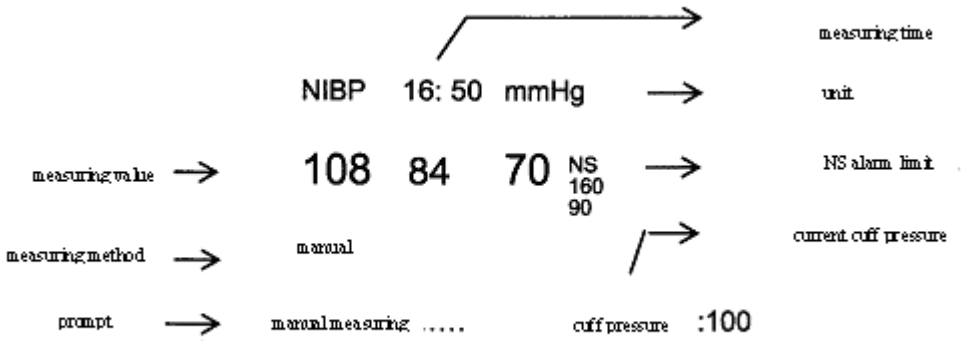
If the patient is with serious shock or excessive low TEMP, measuring is unreliable, because increase of the blood stream peripherally flowing may lower arterial pulse.

■ Ultimate heart rate

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

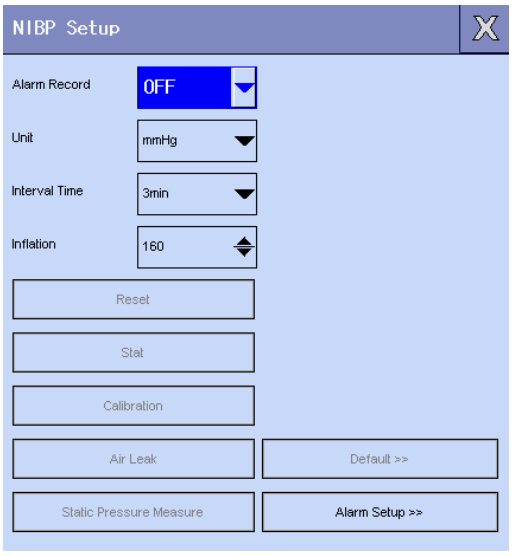
11.2.2 NIBP Parameter Setting and adjustment

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



11.3 NIBP Menu

Turn the knob, move the cursor to NIBP hot key in parameter area of the screen, press the knob to enter into the menu of "NIBP SETUP", as shown in the picture 11-2.



Picture 11-2 NIBP Setting Menu

■ NIBP Alarm Setting

- ◆ 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", "MED" and "LOW" are available for option. "HIGH" means the most dangerous alarm.
- ◆ Alarm recording: While selecting "ON", recorder output is performed in case of pressure alarm.

- Pressure alarm is performed according to the set upper limit and lower limit. Alarm will be given incase 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

Children

Systolic blood pressure: 40~200 mmHg

Diastolic blood pressure: 10~150 mmHg

Mean blood pressure: 20~165 mmHg

Neonatal baby

Systolic blood pressure: 40~135 mmHg

Diastolic blood pressure: 10~100 mmHg

Mean blood pressure: 20~110 mmHg

■ Reset

Measuring 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 for 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.

■ Continual

Start continuous measuring

After selecting this option, the menu will automatically disappear and start continuous measuring at once.

■ 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.

■ Inflating

Press this key to select initial pressure value for next time air inflating to cuff. Under different default configurations, there are different air pre-inflating value ranges for selection as shown in the following table:

Default configuration	Default air pre-inflating value (mmHg/kPa)	Manually selectable air pre-inflating value in NIBP menu (mmHg/kPa)
Default manufacturer adult configuration	160	80/90/100/110/120/130/140/150/160/170 180/190/200/210/220/230/240
Default manufacturer infant configuration	120	80/90/100/110/120/130/140/150/160/170 180/190/200
Default manufacturer newborn infant configuration	70	60/70/80/90/100/110/120

After pressing MENU key on front panel of the casing, users can enter into "DEFAULT" menu in "SYSTEM MENU" . After confirming this default configuration, return back to main interface to select NIBP menu

hotkey in NIBP parameter area, enter into "NIBP SETUP". Users can see the initial value corresponding to "INFLATION" which is the initial value for air inflating corresponding to the selected default configuration, as shown in the above table. After moving cursor to "INFLATION" option and press it, users can see the manually regulating air pre-inflating selection range as shown in the above table.

⚠Attention⚠

"INFLATION" aims to assist users in selecting cuff inflating pressure for next time. The air pre-inflating value performed during later measurement is the last time systolic pressure based on the same patient. The system memorizes this value for shortening measuring time for the same patient and improving the accuracy of the measurement.

⚠Attention⚠

When users only set "PAT TYPE" in "PATUENT MANAGE" and have no any selection in "DEFAULT ", the system will perform initial setup for the related module parameter according to "PAT TYPE". In addition, Change of default type setup in "DEFAULT" will also change "PAT TYPE" in "PATUENT MANAGE".

■ Unit

mmHg or kPa are optional pressure unit.

■ Pressure calibration

⚠Warning⚠

It is required to have a NIBP measuring calibration for very two years (or follow your maintenance regulation).

■ Default

Select this option to enter into NIBP default configuration dialog box. In the dialog box, there are two options available: "YES" and "NO". Select any one to exit dialog box.

■ Calibrate

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

⚠Warning⚠

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

Calibrating steps for pressure probe:

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 "CALIBRATE", 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.

■ Leak test

It is used to test leak of NIBP measuring pump. When connecting through with the cuff, use this key to start NIBP charge to check if the enclosed air route is normal. If passed the leak test, the system gives no prompt; if

failed, there will be error prompt displayed in NIBP information area.

⚠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 SETUP" menu.
4) Turn the knob, move the cursor to option of "PNEUMATIC", press the knob. At the time, on lower part of the NIBP parameter area on the screen will notify "Penum 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 "PNEUMATIC 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.

11.4 NIBP alarm information and prompt information

Parameters beyond alarm limit in physiological alarm can possibly trigger recorder to automatically output the parameters and related measured waves occurred at the time when alarm given. The precondition is that alarm record switch in relevant menu should be on. Physiological alarm, technical alarm and prompt information occurred during NIBP measurement are listed in the following table:
Physiological alarm:

Prompt information	Reason	Alarm level
NS TOO HIGH	Measured NIBP systolic pressure value is higher than the set alarm upper limit.	Optional for user
NS TOO LOW	Measured NIBP systolic pressure value is lower than the set alarm lower limit.	Optional for user
ND TOO HIGH	Measured NIBP diastolic pressure value is higher than the set alarm upper limit.	Optional for user
ND TOO LOW	Measured NIBP diastolic pressure value is lower than the set alarm lower limit.	Optional for user
NM TOO HIGH	Measured NIBP average pressure value is higher than the set alarm upper limit.	Optional for user
Version 1.0 NM TOO LOW	Page 94 of 105 Measured NIBP average pressure value is lower than the set alarm lower limit.	Optional for user

Technical alarm 1 (Displayed in information area of the patient monitor):

Prompt information	Reason	Alarm level	Solution
NS ALM LMT ERR	Fault of functional safety	High	Stop using NIBP module alarm function, notify biomedicine engineer or maintenance personnel of our company for servicing.
NM ALM LMT ERR	Fault of functional safety	High	Stop using NIBP module alarm function, notify biomedicine engineer or maintenance personnel of our company for servicing.
ND ALM LMT ERR	Fault of functional safety	High	Stop using NIBP module alarm function, notify biomedicine engineer or maintenance personnel of our company for servicing.

Technical alarm 2 (Displayed in the prompt area below the NIBP pressure value):

Prompt information	Reason	Alarm level	Solution
NIBP SELFTEST ERR	Error of probe on NIBP measuring module or other hardware	High	Stop using NIBP measuring function, notify biomedicine engineer or maintenance personnel of our company for servicing.
NIBP COMM ERR	Fail in communication with NIBP measuring module	High	If fault keeps still unsolved, stop using NIBP measuring function, notify biomedicine engineer or maintenance personnel of our company for servicing.
LOOSE CUFF	Poor contact of cuff or without cuff	Low	Tie securely the cuff.
AIR LEAK	Damaged cuff, rubber tube or connector	Low	Check and replace the leaking component. If necessary, notify biomedicine engineer or maintenance personnel of our company for servicing.
AIR PRESSURE ERROR	No stable pressure value can be got, e.g. entwisted rubber tube.	Low	Check if rubber tube is entwisted. If the fault keeps still unsolved, notify biomedicine engineer or maintenance personnel of our company for servicing.
WEAK SIGNAL	Loose cuff or weak pulse of the patient	Low	Measure blood pressure with other methods.
RANGE EXCEEDED	Measured range is beyond the set upper limit	High	Rest NIBP measuring module. If the fault keeps still unsolved, stop using NIBP measuring function, notify biomedicine engineer or maintenance personnel of our company for servicing.
EXCESSIVE MOTION	Noisy signal or irregular pulse rate caused by arm movement	Low	Keep the patient calm and free of action.
OVER PRESSURE	Pressure is beyond the set upper limit.	High	Measure it again. If the fault keeps still unsolved, stop using NIBP measuring function, notify biomedicine engineer or maintenance personnel of our company for servicing.
SIGNAL SATUATED	Large movement	Low	Keep the patient free of action.
PNEUMATIC LEAK	Leakage found during leakage testing	Low	Check and replace the leaking component. If necessary, notify biomedicine engineer or maintenance personnel of our company for servicing.
NIBP SYSTEM FAILURE	Fault of blood pressure pump system	High	Stop using NIBP measuring function, notify biomedicine engineer or maintenance personnel of our company for servicing.
CUFF TYPE ERR	Type of cuff does not accord with patient type.	Low	Select the correct type of cuff.
NIBP TIME OUT	Measuring time is beyond 120 seconds (Adult/Children) or 90 seconds (Newborn infant)	High	Measure again or use other measuring methods.
NIBP ILLEGALLY RESET	Abnormal module reset	High	Use reset function once more.
NIBP MEASURE ERR	The system can not perform measuring analysis or calculation during measuring.	High	Check the cuff. After confirming that the patient has no movement given, make a measurement once more.

Prompt information (Displayed in the prompt area below the NIBP pressure value):

Prompt information	Reason	Alarm level
Manual measure	In course of manually measuring	No alarm
Cont measuring	In course of continuously measuring	
Auto measuring	In course of automatically measuring	
Please start	After selecting measuring time interval in menu	
Meas. over	Press startup key to stop measuring during measuring	
Calibrating	In course of calibrating	
Cal over	Calibration course has been finished.	
Pneum testing	In course of leakage detecting	
Pneu test over	Leakage detection is terminated.	
Resetting	Reset process after NIBP module loaded	No alarm
Resetting	In course of NIBP reset (Triggered by user)	
Reset failed	Reset action failure	

11.5 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 patient monitor.**
- **When cleaning the patient monitor, wipe the surface of the connector socket, but not the inside of it.**
- **When the repeatable cuff is not connected with the patient 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 protection of environment, the disposable blood pressure cuff must be reclaimed or managed properly.

Chapter Twelve Monitoring Invasive Blood Pressure (Optional)

Invasive blood pressure (IBP), or direct blood pressure measurement, provides accurate blood pressure values of the cardio-artery area. IBP monitoring can track transient variations of arterial blood pressure; however a catheter must be inserted through the skin into the blood vessel where skin damage can occur. IBP measurements are typically used only on seriously ill patients or patients in surgery.

The IBP measurement can generate:

- IBP waveforms
- Systolic pressure value (SYS)
- Diastolic pressure value (DIA)
- Mean arterial pressure value (MAP)

12.1 Using the IBP

This monitor can measure two invasive blood pressures at one time, IBP1, IBP2.

12.2 Selecting a Pressure Transducer

There are different types of disposable and reusable IBP transducers. Use IBP transducers compliant with the ANSI/AAMIBP23-1986 standard and an accuracy of 5 uV/V/mmHg.

For more information on IBP transducers, see IBP Accessories on page 76.

12.3 Before Measuring Invasive Blood Pressure

Before starting an IBP measurement, set the correct pressure measurement and corresponding pressure label.

12.3.1 Connecting and Flushing the IBP Tubing

To connect and flush the tubing:

1. Plug the pressure cable into the IBP1/IBP2 connector.
2. Use saline to flush the tubing system to exhaust all air from the tubing. Ensure that the transducer and stopcocks are free of air bubbles.
3. Connect the pressure line to the patient catheter.
4. If you are using an infusion pressure cuff with the pressure line, attach the pressure cuff to the fluid to be infused. Inflate it according to your standard hospital procedure, and then start the infusion.
5. Position the transducer so that it is level with the heart, approximately at the level of the midaxillary line.

Warning **If measuring intracranial pressure with a sitting patient, level the transducer with the top of the patient's ear. Incorrect leveling may give incorrect values.**

12.3.2 Selecting a Pressure for Monitoring

According to the position of the tubing, select the pressure label to identify the pressure type. The label is a unique identifier for each type of pressure. It displays on the top left side of the IBP waveform area.

To select a pressure:

1. Enter **IBP Setup** at numeric pane.
2. Choose Channel 1 or Channel 2 at **IBP Setup** Menu.
3. Choose the needful pressure label; refer to table 10-1.
4. Exit the menu.

Table IBP Pressure Labels

Label	Description	Label	Description
ART	Arterial blood pressure	**PA**	Pulmonary artery pressure
CVP	Central venous pressure	**RAP**	Right atrial pressure
LAP	Right atrial pressure	**ICP**	Intracranial pressure

12.4 Zeroing the Pressure Transducer

To avoid inaccurate pressure readings, the monitor requires a valid zero. Zero the transducer in accordance with your hospital policy. You must perform a zero:

- When you use a new transducer or tubing.
- Every time you reconnect the transducer cable to the monitor.
- If you think the monitor's pressure readings are incorrect.

To zero the transducer:

1. Turn off the stopcock to the patient.
2. Vent the transducer to atmospheric pressure, to compensate for the static and atmospheric pressure exerted on the transducer.
3. Position the transducer so that it is level with the heart, approximately at the level of the midaxillary line.
4. Enter **IBP Setup** at numeric panes.
5. Choose **Channel 1 Zeroing** or **Channel 2 Zeroing**.
6. Close the stopcock to atmospheric pressure and open the stopcock to the patient, IBP calibration is complete.

12.5 Measuring Invasive Blood Pressure

To measure IBP:

1. Correctly prepare for the pressure measurement. See Before Measuring Invasive Blood Pressure on page 57.
2. Zero the transducer. See Zeroing the Pressure Transducer on page 57.
3. Turn on IBP alarms and set the correct IBP alarm limits. See Changing the IBP Alarm Settings on page 60
4. Start measuring.

Note — If air bubbles appear in the tubing system, flush the system with the infusion solution again. Air bubbles may lead to a wrong pressure reading.

12.6 The Invasive Blood Pressure Display

The following figure shows an example of the IBP1 waveform; however, the waveforms for IBP1 and IBP2 are the same. On the IBP channel, there are two grid lines that display as dotted lines along the top and bottom of the waveform. A scale displays on the left side.

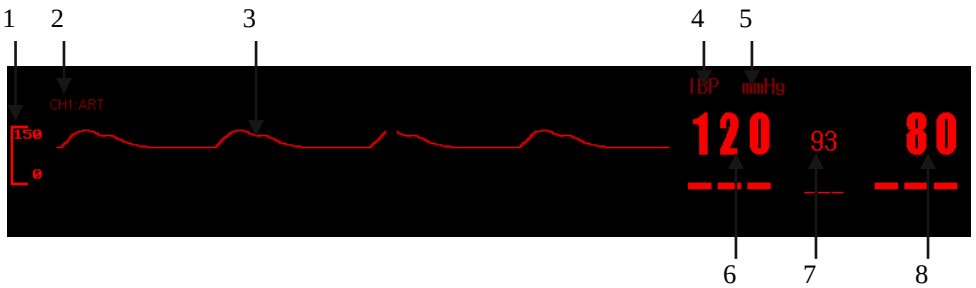


Figure 10-1 IBP Waveform and Numeric Pane

1 = calibration bar
2 = CH1 pressure type

3 = IBP1 waveform
4 = IBP Numeric Pane label
5 = IBP unit
6 = Systolic pressure (CH1 in this example)
7 = Mean arterial pressure (CH1 in this example)
8 = Diastolic pressure (CH1 in this example)

12.7 Changing the Invasive Blood Pressure Waveform Display

You can configure the monitor IBP display by changing the IBP settings.

12.7.1 Changing the Invasive Blood Pressure Waveform Size

You can configure the IBP waveform size by selecting an IBP gain to increase/decrease the waveform height. The difference between the two numbers on the left side of the baselines is equal to the selected IBP waveform gain. You may configure the IBP gain by Manual or Auto.

If Auto is selected, the monitor will choose one of the gain options as the IBP waveform gain according to the measured pressure.

To change the IBP gain:

1. Enter **IBP Setup** Menu at numeric panes.
2. Choose **Channel Gain** or **Channel2 Gain.** The IBP gain options are: 40mmHg, 60mmHg, 80mmHg, 120mmHg, 180mmHg, 240mmHg, 330mmHg, 450mmHg and AUTO.
3. Exit the menu.

12.7.2 Changing the Invasive Blood Pressure Waveform Speed

The waveform speed you configure determines the speed of the waveform scanning on the screen. For more information on changing the speed of waveform, see Changing the Waveform Speed on page 20

The options for the waveform speed are: **25.0 mm/s**, **12.5 mm/s** and **6.25 mm/s**.

12.7.3 Changing the Invasive Pressure Waveform Color

For more information on changing IBP color, see Changing the Waveform Color on page 20.

12.8 Changing the Invasive Blood Pressure Unit

You can configure the IBP unit to mmHg or kPa. The unit displays in the IBP numeric pane.

To change the IBP unit:

1. Enter **IBP Setup** menu at numeric area.
2. Choose **Unit**.
3. IBP unit have **mmHg** and **kPa**.
4. Exit the menu.

Note — When you change the IBP unit, the change displays wherever pressure parameters are.

12.9 Changing the IBP Alarm Settings

IBP alarms include alarms for SYS, DIA and MAP. IBP default alarm limits are different according to the IBP pressure type. When CVP or ICP is selected as the pressure type, only MAP alarms are available for alarm settings.

To turn on the SYS, DIA and MAP audible alarm, see Turning On/Off Audible Alarms on page 26
For more information on IBP alarm limit settings see Setting Individual Alarm Limits on page 27

Warning **Set correct alarm limits for the selected pressure type. Alarm limits change if you change pressure types.**

12.10 Safety Information

Warning **Only use IBP cables, transducers and domes recommended by the manufacturer or that are in conformity with medical device safety requirements.**

Connect the IBP cable to the IBP connector and ensure that the IBP components do not come into contact with other conductive parts or with ground.

Check the IBP cable for damage. If any damage is found, change the cable or replace the transducer connector.

Only use disposable transducers and domes once. Discard them properly as medical waste. Perform regular or continuous flushing during IBP measurements to prevent clotting or blocking.

Chapter Thirteen EtCO2 (Optional)

12.1 Instructions for monitoring EtCO2 concentration

EtCO2 is the main monitoring index for patient with anesthesia or respiratory dysfunction. Through monitoring EtCO2, airway state can be detected; reduce the times of arterial blood gases. According to sampling method, it can be classified into:

MainStream: Gas probe is directly placed in respiratory loop of the patient for achieving switchover of CO_2 concentration free of ejecting air. Electrical signal is treated in the patient monitor.

SideStream: Gas probe is placed in the monitor to supply and drain the respiratory air sample in the patient monitor for further treatment.

Through measuring CO_2 pressure of the patient at supply and drain system to get concentration of $EtCO_2$, Inspired Minimum CO_2 ($InsCO_2$) and Air Way Respiration Rate (AWRR), and to display CO_2 pressure waveform.

Prescription for parameter marks displayed on the screen:

CO_2: Concentration of $EtCO_2$;

INS: concentration of Inspired Minimum CO_2;

AWRR: Air Way Respiration Rate (Respiratory times per minute);

Normal $EtCO_2$ value of normal adult: 35-45mmHg (4.6-6KPa);

12.2 Measurement principle and work process for monitoring $EtCO_2$ concentration

The principle of CO_2 measurement is mainly based on the feature of CO_2 that can absorb infrared at wavelength of 4.3um. The measurement is to send CO_2 to the measuring room. When performing irradiation with infrared on one side and detecting the decline of the received infrared with a probe on the other side, the decline is in direct ratio to concentration of CO_2.

Conversion of CO_2 partial pressure:

CO_2 Partial pressure (mmHg) = CO_2 Concentration (%) * Pamp (Environmental pressure)

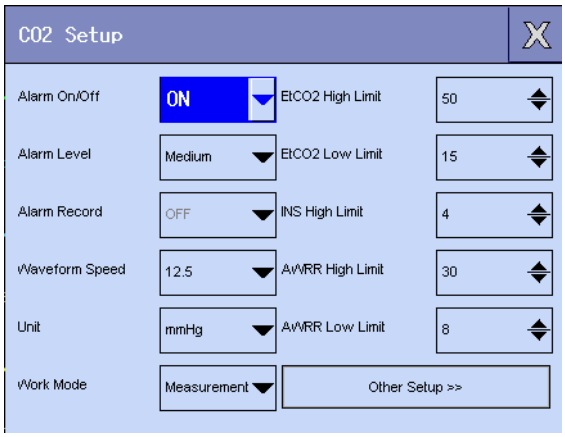
No matter users select MainStream or SicdeStream, Autorun measurement will be adopted at waveform sampling speed of once for every 31 millisecond. The work sequence is as below:

MainStream work sequence: after powering the system on, CO_2 module will automatically preheat the probe. 45S to 90S later, it starts up the motor of probe. 5S to 10S later, it turns on infrared light source, and 10S later, enters into normal measuring state.

SideStream work sequence: Except for no need of preheating and starting vacuum pump of the system, others are similar with those for MainStream.

12.3 $EtCO_2$ concentration menu

Turn the knob, move the cursor on the main screen to hotkey of CO2 in parameter area, and then press the knob to enter into CO2 setup menu, as shown in Picture 12-1:



12-1 CO2 Setup menu

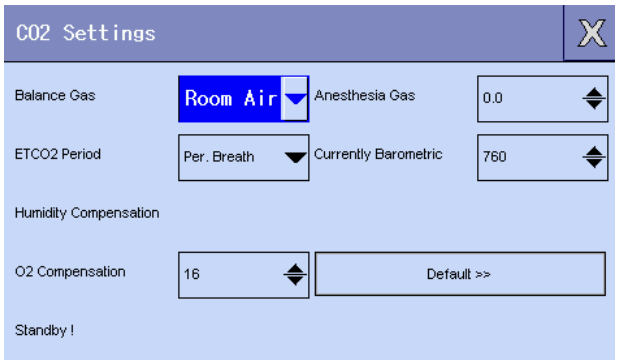
- CO2 alarm setup
  - ALM: If "On" is selected, alarm prompt and storage will be performed in case of CO2 alarm. If "Off" is selected, there will be no alarm given and the prompt of  will be displayed by CO2 menu in the screen parameter area.
  - ALM LEV: It is used for setting up alarm level with three options including "HIGH", "MED" and "LOW". "High" indicates the most serious alarm event.
  - ALM REC: If "On" is selected, recorder output will be performed in case of CO2 alarm.
  - CO2 ALM HI/ CO2 ALM LO: According to the setup of upper limit and lower limit, alarm will be given in case that CO2 is over or lower than the limits.
  - Respective alarm for INS and AWRR is available.

Range of alarm upper and lower limit:

CO2: 0-99
INS： 0-99
AWRR：0-99

- CO2 waveform speed: 6.25mm/s and 12.5mm/s
- Options for pressure unit: mmHg, kPa, %
- CO2 other setups

Turn the knob, move the cursor on the main screen to CO2 other setups of CO2 setup, and then press the knob to enter into CO2 other setups menu, as shown in Picture 12-2:



12-2 CO2 Another setup

Waveform gain: High or low;

Work mode: measurement or standby. When measurement is needed, please select measurement level;

O2 compensation: 0-100

Balancing air: Three modes for option;

Anesthesia gas setup: 0.0-20.0

Gas temperature setup: 0-50;

Atmospheric pressure setup: 400-850

Calculation period: 10 seconds, 20 seconds, one breath;

Zero: Calibration;

CO2 default config: use configuration.

Appendix Ⅰ： Accessory specification

⚠Warning⚠

Specified accessory types by manufacturer are listed as below. Using other types of accessory may possibly cause damages against the patient monitor.

I.1 ECG accessories

Name	Specification	Type
Integral 5LD (USA standard)	Plug: AMP type 6PIN Patient cable: 5-cores shield Patient lead: Single-core double-shield Pole connector: 4.0 buckle	A5037-EC1
Adult ECG pole clip	Liquid rubber, Ag/AgCL probe Press button, foam liner, φ55MM	2416
Children ECG pole clip	Liquid rubber, Ag/AgCL probe Press button, foam liner, φ30MM	2502

I.2 SpO_2 accessories

Name	Specification	Type
Finger clip blood oxygen probe	Adopting imported and special Nellcor probe and non-toxic TPU medical cable; two frequently used specification probes: adult/children	A1802-SA126PV
Soft finger cots blood oxygen probe	Adopting imported and special Nellcor probe and non-toxic TPU medical cable; four frequently used specification probes: adult/children/infant/newborn infant	L6078/L6142
Multi-function blood oxygen probe	Infant binding type	L6143

I.3 TEMP (Temperature) accessories

Name	**Specification**	**Type**
YSI-401esophageal/rectal probe	Plug: 6.3 mono Lead: 3.0 26AWG/1C shield 2.5m Probe: 4mm Resistance: 2252 Ohm B value at 25 ℃: 3935 Precision: ±0.1 ℃ at 30~45℃	A-TP-01
YSI-409B skin temperature probe	Plug: 6.3 mono Lead: 3.0 26AWG/1C shield 2.5m Probe: 12mm stainless steel tab Resistance: 2252 Ohm B value at 25 ℃: 3935 Precision: ±0.1 ℃ at 30~45℃	A-TP-03

I.4 NIBP accessories

■Repeatable cuff

Patient type	Body parts perimeter	Cuff width	Connecting air pipe length
Infant	10 ~19 cm	8 cm	1.5m~3m
Children	18 ~26 cm	10.6 cm	
Adult 1	25 ~35 cm	14 cm	
Adult 2	33 ~47 cm	17 cm	
Leg	46 ~ 66 cm	21 cm	

■Disposal cuff

Size	Body parts perimeter	Cuff width	Connecting air pipe length
1	3.1 ~5.7 cm	2.5 cm	1.5m~3m
2	4.3 ~ 8.0 cm	3.2 cm	
3	5.8 ~ 10.9 cm	4.3 cm	
4	7.1 ~13.1 cm	5.1 cm	

I.5 CO2 accessories (Optional)

Item	Specification
EtCO2 probe	Composed of two parts: module and sampling tube
	The sampling tube is a kind of disposal product.

Appendix II: Product Specification

II.1 Patient monitor type

Standard electric shock proof	Class I electric shock proof equipment
EMC	Class A
Standard electric shock proof level	ECG(RESP): GF type; SpO_2;NIBP: B type; TEMP: BF type
Liquid-proof level:	Generally sealed equipment without liquid-proof function
Disinfection/sterilization method	Refer to Chapter Five for detailed information
Working method	Continuous

II.2 Patient monitor specification

II.2.1 Patient monitor dimensions and weight

Dimensions	320mm×190mm×290mm
Weight	8 (Kg)

II.2.2 Working environment

Temperature range

Working	0 ~ 40 °C
Transportation and store	-20 ~ 60 °C

Humidity range

Working	≤85 %
Transportation and store	≤93% (No dew condensation)

Altitude range

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

Electric specification

AC 100-240 V, 50/60 Hz, max. 70VA of input power
Fuse is T 3.15A display specification.

II.2.3 Displayed information

Max. 6 waves
One alarm indicator (Yellow/Red)
One working indicator (Green)
One battery charging state indicator (Yellow)
Three audible alarm modes corresponding to alarm states

II.2.4 Battery (Optional)

2.2 Ah 14.8V Li-ion rechargeable battery
Normal state full battery working time: >100 minutes
Counting from the first alarm for low battery, it can still work for 5 minutes.
Max. charge time for battery: 8 hours

II.2.5 Recorder

Record width	48mm
Paper speed	25 mm/S
Description wave	2 waves
Record type	8 seconds real time record

II.2.6 Retrospection

Trend retrospection

Short trend	1 hour, resolution: 1 second or 5 seconds
Long trend	72 hours, resolution: 1 minute, 5 minute or 10 minutes
NIBP measurement retrospection	Retrospection on 400 NIBP measured data

II.3 ECG Specification

II.3.1 Lead configuration

Standard 3-lead or 5-lead

3-lead	RA、LA、LL，Lead method: I, II, III
5-lead	RA、LA、LL、RL、V，Lead method：I, II, III, aVR, aVL, Avf, V

II.3.2 Increase

×0.25, ×0.5, ×1, ×2, AUTO

II.3.3 HR

Range

Adult	15 ~ 300bpm (beat/minute)
Neonatal baby/children	15 ~ 350 bpm(beat/minute)
Precision	±1% or ±1bpm, the larger prevails
Resolution	1 bpm(beat/minute)

II.3.4 Sensitivity

> 200 μV (Peak-to-peak value)

II.3.5 Input Impedance

> 5 (megohm)

II.3.6 Bandwidth

Diagnostic mode	0.05~130Hz
Monitoring Mode	0.5~40Hz
Operation mode	1~20Hz

II.3.7 Common Mode rejection Ratio

Diagnostic mode	> 90 dB
Monitoring Mode	> 100 dB
Operation mode	> 100 dB

II.3.8 Pole Polarization Voltage Range

±300mV

II.3.9 Pacing Pulse Test

Test pacing pulse in accordance with the following conditions:

Amplitude:	±2 mV ~ ±700mV
Width:	0.1ms ~ 2ms
Risetime:	10μs~100μs

II.3.10 Pacing Pulse Inhibition

When pacing analysis switch is on, pacing pulse in accordance with the following conditions are restrained, but affection against HR calculation.

Amplitude:	±2 mV ~ ±700mV
Width:	0.1ms ~ 2ms
Risetime:	10μs ~ 100μs

II.3.11 Baseline Recovering Time

After defibrillation< 3 seconds

II.3.12 Signal Range

±8 mV （Peak-to-peak value）

II.3.13 Calibrating Signal

1mV(Peak-to-peak value)，precision ±5%

II.3.14 ST Segment Measuring Volume

Measuring range: -2.0mV ~ +2.0mV

Measuring precision: Ranging -0.8 mV~+0.8mV, measuring error is ±0.02mV or ±10% . The larger prevails.No definition for other ranges.

II.4 RESP Specification

II.4.1 Measuring Method

RA-LL impedance

II.4.2 RESP Impedance Measuring Range

0.3~3Ω

II.4.3 Base Impedance Range

200~4000Ω

II.4.4 Bandwidth

0.1~2.5Hz

II.4.5 RESP Rate

Range

Adult	0~120 BrPM
Children and neonatal baby	0~150 BrPM
Resolution	1 BrPM
Precision	±2 BrPM

II.4.6 Asphyxia Alarm

10~40 seconds

II.5 SpO_2 specification

II.5.1 Blood Oxygen Saturation

Measuring range 0~100%

Resolution 1%

Precision 70~100%: ±2 DIGIT

0%~69%: No definition

II.5.2 Pulse rate

Measuring range 20~300bpm

Resolution 1bpm

Precision ±3bpm

II.6 TEMP specification

II.6.1 Applicable Temperature Probe

YSI series, CYF series

II.6.2 Channels quantity

2 channels

II.6.3 Measurement

Range 0~50°C

Resolution 0.1°C

Precision ±0.1°C (Excluding probe error)

II.7 NIBP Specification

II.7.1 Measuring Method

Pulse wave oscillometry

II.7.2 Work Mode

Manual/Auto/Continual

II.7.3 Measuring Interval of AUTO Measuring Mode

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

II.7.4 Measuring Time of CONTINUAL Mode

5 minutes

II.7.5 PR range

40 – 240 bpm

II.7.6 Measuring Range and Precision

Range

Adult	Systolic blood pressure	40~270mmHg
	Diastolic blood pressure	10~215mmHg
	Mean blood pressure	20~235mmHg
Children	Systolic blood pressure	40~200mmHg
	Diastolic blood pressure	10~150mmHg
	Mean blood pressure	20~165mmHg
Neonatal baby	Systolic blood pressure	40~135mmHg
	Diastolic blood pressure	10~100mmHg
	Mean blood pressure	20~110mmHg

Static pressure range 0~300mmHg

Static pressure precision ±3mmHg

Pressure precision: Max. average error: ±5mmHg; Max. standard deviation: 8mmHg

II.7.7 Overvoltage Protection

Adult mode	300 mmHg±10mmHg
Children mode	240 mmHg±10mmHg
Neonatal baby mode	150 mmHg±10mmHg

II.8 CO2 Specification(Optional)

II.8.1 Measuring Method

SideStream

II.8.2 Measuring Range

CO2: 0-99

INS: 0-99

AWRR: 0-99

II.9 IBP Specification(Optional)

The following table describes the IBP specifications.

III Table B-7 IBP Specifications

Parameter	Specification
IBP range	ART 0 - 300 mmHg PA -6 - 120 mmHg

	CVP -10 - 40 mmHg RAP -10 - 40 mmHg LAP -10 - 40 mmHg ICP -10 - 40 mmHg
IBP accuracy	1 mmHg or 2%, whichever is greater
Unit	mmHg or kPa
Sampling rate	62.5 times per second
Waveform speed	6.25 mm/s, 12.5 mm/s, 25.0 mm/s
Transducer sensitivity (Intellivue: Input sensitivity)	5 uV/V/mmHg
Resolution	1 mmHg (0.13 kPa)
Transducer type	Disposable
Updating time	Approximately 1 second
Alarm delay	<10s