MEDIAID

# Model M6 ASTER

## Vital Signs Monitoring System

# User's Manual


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# Contents

# Chapter 1 General Information

- For information about the monitor, please read the General Information on the Monitor chapter.
- For introduction on various information displayed on screen, please read the Screen Display chapter.
- For operational methods, please read the Button Functions and Basic Operations chapter.
- For locations of various interfaces, please read the External Interfaces chapter.
- For notices of using the monitor with power supply from a battery, please read the Built-in Chargeable Battery chapter.

**Warning**

This monitor is to monitor clinical patients, only for doctors and nurses' use.

**Warning**

For patients with pacemakers, the monitor may count pulse of the pacemakers during cardiac arrest or arrhythmia. Don't fully rely on HR alarming, instead, users should closely monitor patients with pacemakers. For inhibiting ability of relevant equipments on pacemaking pulse, refer to this manual.

**Warning**

Don't open cover of the equipment to avoid possible risks in electric shock. Any maintenance or upgrading on the monitor must be conducted by service personnel trained and authorized by **MEDIAID** Company.

**Warning**

Don't use this monitor where there are flammables such as anesthetic agent, so as to prevent from explosion.

**Warning**

Users before starting use should check whether the equipment and its accessories can work properly and safety.

**Warning**

Please make sufficient alarming setting for each patient in order to prevent from delayed therapy and make sure there is an audible effect during alarming.

**Warning**

Don't use mobile phones around the monitor. Mobile phones will generate strong emission fields and disturb the monitor.

**Warning**

During defibrillation don't touch patients, tables and the machine.

**Warning**

Equipments inter-connected with the monitor should form an equal-potential body (as protective effective earthing).

**Warning**

Users (doctors or nurses) should ensure safety of patients under monitoring, when the monitor is used together with electrosurgical equipments.

**Warning**

Package materials shall be processed in accordance with the currently executed waste control regulations and be stored where children cannot touch.

**Attention**

The software is developed in accordance with the IEC601-1-4 standard, and risks caused by program errors have been of the lowest possibility.

**Careful**

When products and accessories introduced within this manual are near the expiry dates, they must be processed in accordance with relevant product processing regulations. For further information, please contact **MEDIAID** for support.

**Careful**

In case of any questions on completeness and arrangement of external earthing of the monitor, internal batteries shall be used for operation.

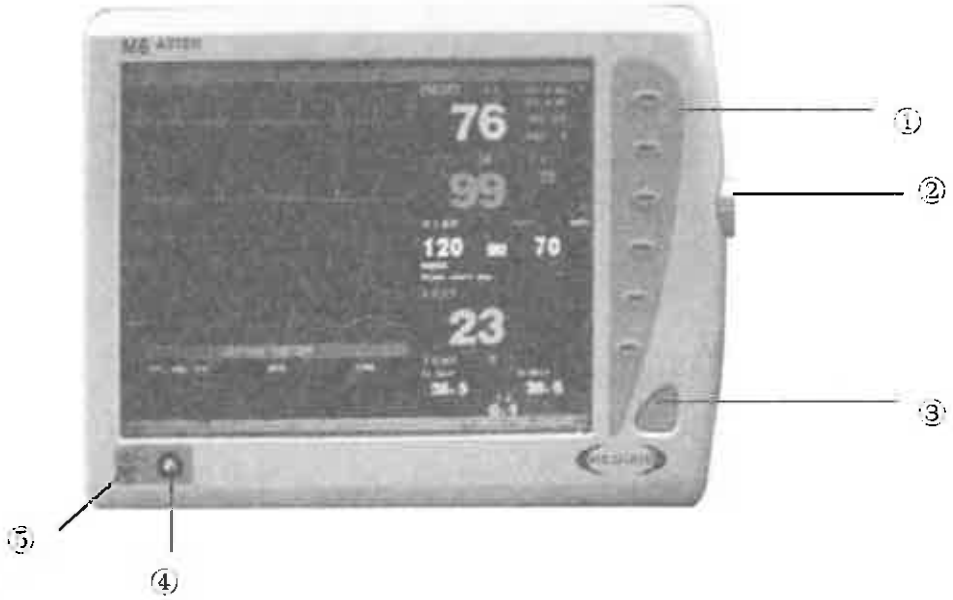
## 1.1 Monitor

The M6 ASTER monitor is of rich functions, as shown in the following picture, applicable for bedside monitoring on adults, infants and newborns. Users can select measurement parameter setting based on their various requirements.
This monitor can be connected with network and the central monitoring system, forming a network monitoring system.

This monitor can monitor main parameters including ECG/RESP, $SpO_2$, NIBP,IBP and double-channel TEMP. It integrates parameter measurement modules, display and record output to build such a solid and light monitor. Its chargeable built-in battery makes convenience for patient movement and it will clearly display 9 waveforms and all the monitoring parameter information on the high-resolution interface.

The power switch (POWER button, as shown in ③ in Pic 1.1) is located at Right below corner of the front panel of the monitor (if look along the monitor direction), and left below corner of the front panel there are two indicating lights, AC ad BAT (as shown in ⑤ in Pic 1.1). In case of the equipment is powered on with AC power, the AC indicating lights glows and concurrently the built-in battery is under charge status. The alarming light ALARM is located at left below corner of the front panel and will blink in case of alarming (as shown in ④ in Pic 1.1). Ports for sensor are at left of the equipment, while other Ports and power socket at left of the equipment. The recorder, as an optional part, is at the right side.

This monitor has a friendly operational interface, and users can complete all the operations through buttons and knobs on the front panel (as shown in ① & ② in Pic 1.1). Please refer to the Functional Buttons chapter for detailed contents.




Pic 1-1 Portable Multi-parameter Monitor

This monitor has the following monitoring functions:

| | |
|---|---|
| ECG | HR |
| | ECG waveform |
| RESP | RR |
| | Respiration waveform |
| $SpO_2$ | $SpO_2$, PR |
| | $SpO_2$ volume recording |
| NIBP | NS, ND, NM |
| TEMP | T1, T2, TD |

This monitor has rich functions, able to provide various functions such as audio-light alarming, Trend storage & output, NIBP measurement review, alarming event marking and Drug calculation.

## 1.2 Screen Display

This monitor has a color LED screen, able to concurrently display collected patient parameters, waveforms, and alarming information provided by the monitor, bed marks, clocks, monitor status and other reminder information.

The main screen is divided into 3 sub-areas, i.e., Information area 1 & 4 Waveform area 2, and Parameter area 3. (As shown in the following picture)


Pic 1-2 Main screen display of a portable multi-meter monitor

**Information area (1 & 4) :**

The information area is at top of the screen, displaying current status of the monitor and patient. Meanings for each item in this area are as follows:

**Bed number**: Bed number of the patient under monitoring

**Adult:** Type of the patient under monitoring
**Gender**: Patient gender, represented with male/female signs
**Patient name**: Patient names are displayed at right of the heads. When an operator inputs no patient name, this position will show blank.
**Connect with central monitoring:** A red cross will be displayed with the logo if no central monitoring is connected.
**External power display**: A red cross will be displayed with the socket logo if connection with external power supply is broken.
**Built-in battery volume display**: Displays volume of built-in batteries.
**"25 / 11 / 2006"**: Refers to the current date.
**"10: 23: 45"**: Refers to the current time.
**WED** Refers to Wednesday.

Other reminder information in the information area appear and disappear together with their reported status; such information include:

- Monitor reminder information: reporting status of the monitor or sensor, displayed in the technical alarming area.
- Monitor alarming information (refer to the Alarming chapter for detailed setting methods);


Is for alarm pause time. Shortly press the "MUTE" button (for less than 1 second) will have this sign, meaning all the audible alarming have been manually disabled until next short pressing on the "MUTE" button or expiry of the alarm pause time. Three options for such pause time, including 1 minute, 2 minutes and 3 minutes.


Is for alarming silence. Long press the "MUTE" button (for more than 1 second) will have this sign, meaning all the audible alarms have been manually disabled until next long pressing on the "MUTE" button or new alarming events. During the whole process if an operator shortly presses the "MUTE" button, the system will switch to alarm pause status.


Is for alarming volume off, meaning the audible alarming function has been manually disabled until operators recover the setting.

**Attention:**

When the  sign displays, the system will be unable to give audible alarms, thus operators should carefully use this function.

- Alarming information on patient physical parameters is always displayed at the right area;
- When waveforms on the screen are frozen, the reminder window for frozen (Freeze) will be displayed at bottom area.

**Introduction on the Waveform/ Menu area (②):**

The waveform area displays various waveform groups under different interfaces, varying from 7 ECG waveforms, $SpO_2$ volume recording waveforms, and RESP waveform.

All the waveforms have been listed under the "Screen Waveform Setting" menu, and users can select by themselves.

Names of waveforms are displayed at left top of every waveform. ECG lead can be selected on request. At the left top information area, there is also ECG waveform gain, ECG filtering method and scanning speed displayed. A 1mV reference ruler is displayed at right side of the ECG waveforms.

When menus pop up during screen operation, they always occupy certain area at middle of the waveform area, hiding part of waveforms. Exit from such menus will recover the previous display.
Waveforms are refreshed at the set speed. For adjustment on waveform refresh speed, refer to the Parameter Setting chapter.

**Introduction on the parameter area (③):**

The parameter area is at right to the waveform area, located roughly corresponding to waveforms. Parameters displayed in this area are:

ECG
- -- HR or PR and their upper & lower limits for alarming (unit: beat/ minute)
- -- ST segment analysis results ST1 & ST2 for Channels 1 & 2 (unit: mV)

$SpO_2$
- -- $SpO_2$(Unit: %)
- -- PR (Unit: beat/ minute) (when the "All" option is selected)
- -- Upper & lower limits for $SpO_2$ alarming

NIBP
- -- From left to right, systolic pressure and its upper & lower limits for alarming, average pressure and its upper & lower limits for alarming, and diastolic pressure and its upper & lower limits for alarming (unit: mmHg or kPa)
- -- Continued time of cuff pressure during venous puncture
- -- Status information of the NIBP module

RESP
- -- RESP rate (unit: time/ minute)
- -- Upper & lower limits for RESP alarming

TEMP
- -- Temperature T1 and T2 (respectively for Channel 1 and Channel 2), as well as their difference TD.

**Alarming light and alarming status:**

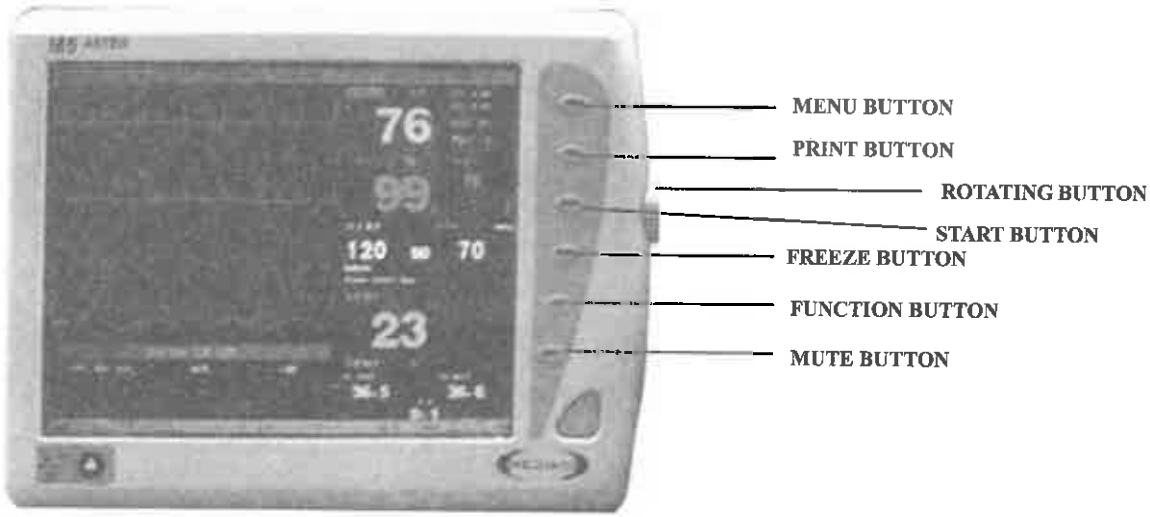
At normal status the alarming light doesn't blink.
In case of alarms, the alarming light blinks in different colors, different colors for different alarming levels; users may refer to the Alarming chapter for details.
For detailed contents on alarming information and reminder information, please check relevant contents of various parameters in relevant chapters.

**Warning**

With the monitor power on, the system will automatically detect whether the audio-light alarming system works.

## 1.3 Button Functions and Basic Operations

Operations on the monitor are realized through buttons and knobs, including:




Pic 1-3 Buttons & knobs of a portable multi-parameter monitor

- **MUTE**

  A short depression of "MUTE" button will disable audio-visual alarming as long as 3 minutes (1 minute, 2 minutes and 3 minutes are all optional) and have the symbol displayed in the information area. Press this button for more than 3 seconds will block all the audible alarms such as audible alarming, heartbeats, pulse and keyboard and have the symbol displayed in the information area; re-press this button for more than 3 seconds will recover all the audible alarms and cancel the symbol.

**Attention:**

If there is a new alarm happening under alarm disabled/ silence status, the alarm disabled/ silence status will be automatically cancelled. Refer to the Alarming chapter for details.

**Attention:**

Whether alarms can be recovered depends on existence of the factors generating the alarms; however, press the MUTE button can permanently close the audible alarms for ECG lead disconnection and $SpO_2$ sensor disconnection.

- **FUNC** (quick switch between various operation interfaces)

Press the button will sequentially switch the system operation interfaces.

- **FREEZE** (freeze waveforms)

Press this button the system will enter the Freeze status, under which users can have 16 seconds of waveform review and freeze record output of waveforms. Under the Freeze status re-press this button will defreeze the system; users may refer to the Freeze chapter for details.

- **START** (NIBP)

Press this button will start cuff pumping and blood pressure measurement. During the measurement process, press this button will stop measurement and start degassing.

- **PRINT** (record)

Press this button will start a real-time record. Recording time can be set in the "Real-time Recording Time" item under the Record Output Setting menu. Refer to the relevant chapters for details.

- **MENU**

Press this button to call up the SYSTEM MENU, in which the user may set up system information and perform review operation.

- **Rotating control button** (or known as **knob**)

Users can rotate the knob, selecting menu items and change setting. This knob can rotate clockwise or anti-clockwise or be pressed, and users, through it, can complete all the operations in the main screen, under the System menu and Parameter menu.

**Method of using the knob:**

The rectangular symbol moving along with knob rotation is called cursor; operations can be done wherever such cursor can stay.

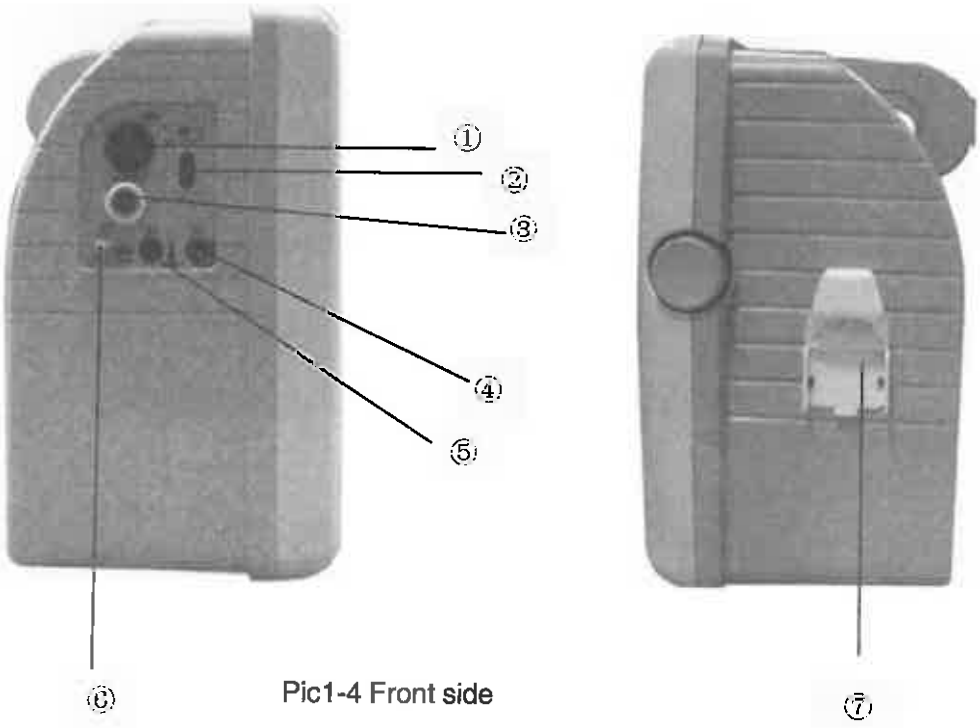
When the cursor stays within the waveform area, users can change the current setting; and when the cursor stays within the parameter area, users can open relevant parameter menus and set relevant parameter information.

The operation method is as follows:

- Move the cursor on the item to be operated;
- Press the knob;
- One of the following four system scenarios will happen:
  - On the screen pop up a menu or measurement window, or the previous menu is replaced by a new menu;
  - Cursor with background color changes to be a box without background color, which means the contents inside this box can be revised with knob rotation;
  - Pop up several options, and users can select by rotating the knob;
  - Immediately execute a certain function.

## 1.4 Monitor External Interfaces

For convenient operation, various interfaces are furnished at various locations of the monitor; however, there are no interfaces or Ports on back side of the equipment.
In the right side, there are Ports for patient cables and sensors, as shows in the following:



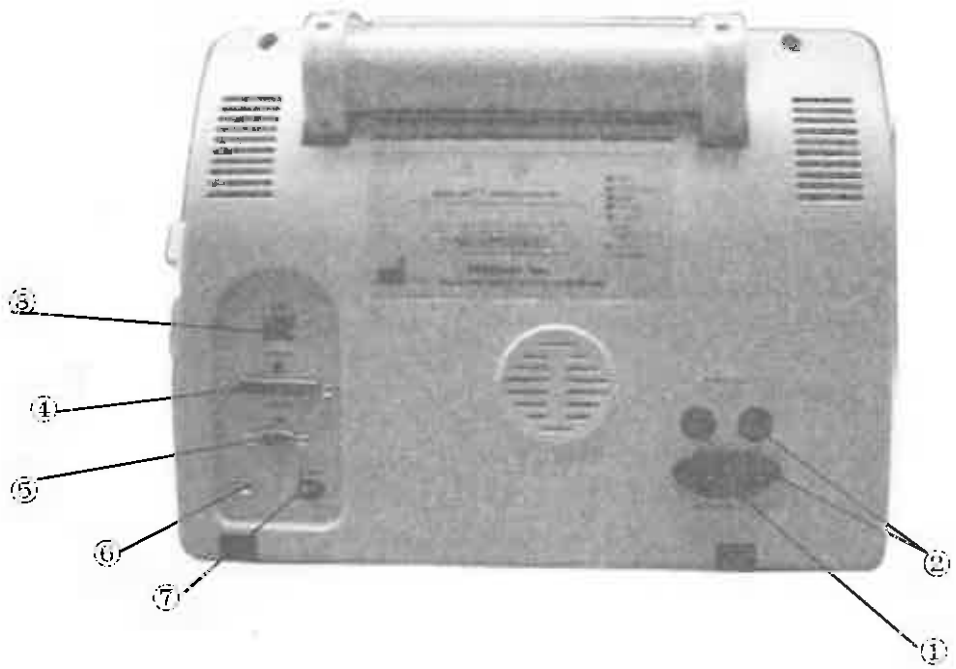

Pic1-4 Front side

① ECG Cable connector
② $SpO_2$ sensor port
③ IBP Sensor port
④ TEMP1 detector port
⑤ TEMP2 detector port
⑥ NIBP cuff connector
⑦ **$CO_2$ Module** (Optional)

This symbol means "be careful"; refer to this manual for details.

This symbol means this application part is of CF type, designed with special protection from electric shock (especially provided with F-type floating insulation apparatus for permissible leakage current) and suitable for the defibrillation process.
Other symbols will be introduced in the Patient Safety chapter.

In the left of the monitor is power socket. When a GP120 recorder is configured, the recorder will be connected at the left side (above the socket), shown as follows:




Pic 1-5 Back side

There are the following Connectors in the left side:

① Power socket AC 110V/230V
② Fuser: 2 standard FUSE T 1.5AL，250V AC
③ Network interface
④ Printer port
⑤ CRT
⑥ ⏚: equal-potential earthing terminal
⑦ DC input

When the wireless network module is in use, the module is connected with this side, then further connected with the monitor, realizing wireless connection between the monitor and the central monitoring system.

**Warning**

All the simulated or digital equipments connected with this monitor must be certified under the designated IEC standards (such as IEC 60950 Date Processing Equipment Standard and IEC 60601-1 Medical Equipment Standard). And all configurations must comply with effective versions of IEC 60601-1-1 system standards. Persons in charge of connecting additional equipments with the input/ output signal terminals should configure the medical system and be responsible for compliance of the system to IEC 60601-1-1 standard.

## 1.5 Built-in Chargeable Battery

This monitor is configured with a built-in chargeable battery, which will automatically be charged until full volume upon connection with AC supply. There is a "" symbol at right down corner of the screen, indicating charging status. In case the monitor is installed without the built-in battery, there will be "" indicating the battery status, actually meaning no battery.

**Warning**

Don't remove the battery during monitoring process.

**Attention**

1. When the battery is new and full of power, the monitor can work for at least 1 hour after connected with all the external accessories.
2. After battery out, the battery needs 6 hours to be charged to 90% volume.

In case of power supply from the battery, the monitor will alarm and automatically switch off power when the power is not enough. When power is launching the bottom level, the monitor will activate advanced alarming and make continuous audible alarm, while reminding "over low battery voltage" in the information area. In such moment users should plug in AC power supply to charge the battery, otherwise the monitor will shut down before battery out (roughly 5 minutes after alarming).

**Attention**

Used batteries should be recycled or properly treated.

- Open package and check
- Connect with AC cable
- Power on
- Connect with sensor
- Check recorder

**Attention**

For normal work of the monitor, before use please read this chapter and the Patient Safety chapter and assemble in accordance with the requirements.

## 2.1 Open Package and Check

Carefully pick up the monitor and accessories from the package box, and properly keep the package materials for future transport or storage. Please check the accessories with the package checklist.

- Check whether there is any mechanical damage;
- Check all the exposed cables and plug in some accessories for test.

Any problems should be immediately contact MEDIAID for support.

## 2.2 Connect with AC Cable

Procedures to connect with AC power cables:

- Make sure the AC supply complies with the following specification: 110/220±22 VAC, 50Hz/60Hz±1Hz (the "Power Supply Frequency" option under the User Maintenance menu should be identical to this).
- Use the power cables provided with the monitor together. Plug in the power cable into power supply interface of the monitor, while insert the other end of this cable to a 3-phase earthing power socket.

**Attention**

Connect the power cable with the sockets special for hospital use.

- If deemed necessary, connect with an equal-potential earthing cable. Refer to the equal-potential earthing part in the Patient Safety chapter.

**Attention**

In case configured with a battery, the equipment after transport or storage must have the battery taken for charging. In case of direct booting, neither such charging nor connection with AC power supply, the equipment may not work properly due to insufficient power. With AC power supply connected, the battery will be charged no matter the monitor is booted or not.

## 2.3 Power on

The system will Sound up with power on, and the alarming light will blink in different colors, one by one. After about ten seconds, the system after successful self-detection will enter the monitoring main screen, then users can start operations.

**Warning**

If any monitoring functions are found with damage or there are any error reminders, don't use this monitor to monitor patients and quickly contact MEDIAID for support.

**Attention**

In case of any fatal errors found during the self-detection process, the system will alarm.

**Attention**

Check all the available monitoring functions and make sure they work properly.

**Attention**

If a battery is configured, must charge the battery after each time of use so as to ensure sufficient power storage.

**Attention**

Reboot the equipment at least 1 minute after shut down.

## 2.4 Connect with Sensor

Connect the required sensor between the monitor and the monitoring position of a patient.

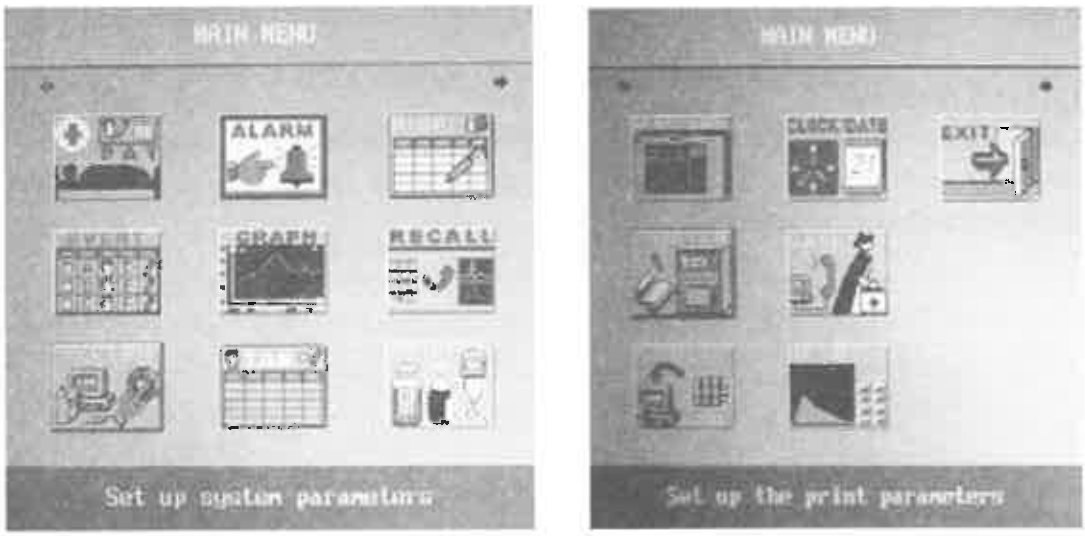
## 2.5 Check recorder

If a recorder is connected with the monitor, check whether there is paper inside the paper outlet at right side of the monitor; in case of no paper there, please refer to the relevant contents in the Record chapter.

# Chapter 3 System Menu

- Patient Information Setting
- Patient Event Setting and Record
- System Parameter Setting
- Alarm Setting
- Parameter Trend Diagram
- Parameter Trend Figure
- NIBP Historic Data
- Waveform and Physical Parameter Review
- Drug Calculation and Titration List
- Machine Information and Machine Maintenance
- Print Setting
- Load Default Parameter Setting
- System Time and Date Setting
- Nurse Call Setting
- Cardiac Output Measurement (extension option)

This monitor is of flexible configuration; users based on their requirements can configure monitoring contents, waveform scanning speed, audio volume, and output contents. Press the MENU button on the front panel will pop up the following menu for users' operations:




Pic 3-1 Main menu

## 3.1 Patient Information Setting

Select the "Patient Information Setting" item under the main menu, then press the knob to pop up the following menu:

Pic 3-2 Patient information setting

| | |
|---|---|
| Department | The department where the patient stays (Input with A-Z, 0-9 and space; up to 12 characters for names) |
| Doctor in charge | Name of the doctor in charge |
| Case number | Case number of the patient |
| Patient name | Patient name |
| Patient type | Adult, infant or newborn |
| Gender | Patient gender |
| Bed number | Patient's bed number (input with 1-255) |
| Hospitalization beginning time | Beginning date of hospitalization (format: Year: Month: Day: ) |
| Birthday | Patient's birthday (format: Year: Month: Day: ) |
| Blood type | Patient's blood type (A, AB, O, B, or X, where X means unknown) |
| Height | Patient's height (Rotate the knob to increase/ decrease 0.5), unit: cm / inch; the same unit applies to all the other menus involved with patients' height. |
| Weight | Patient's weight (Rotate the knob to increase/ decrease 0.5), unit: kg / lb; the same unit applies to all the other menus involved with patients' weight |
| Update | patient Select this item will delete all the data of the current patient |
| Exit | Exit the current menu |

## 3.2 Event mark

To make convenient to record various situations related with patients and affecting parameter monitoring into categories, such as taking or injecting Drugs and various treatments, events will be displayed on Trend diagrams or figures so as to help analyze patient parameters when any accidents happen. The monitor provides the function or event mark, operated as follows:

Under the main menu, select "Set Patient Events and Record", then press the knob to pop up the following window:


Pic 3-3 Event Mark menu

Under this menu, users by selecting one option (out of the given four options) and pressing the knob will record the corresponding event.

## 3.3 System Setting

Under the main menu, select the "System Parameter Setting" item will pop up the following window:


Pic 3-4 System setting

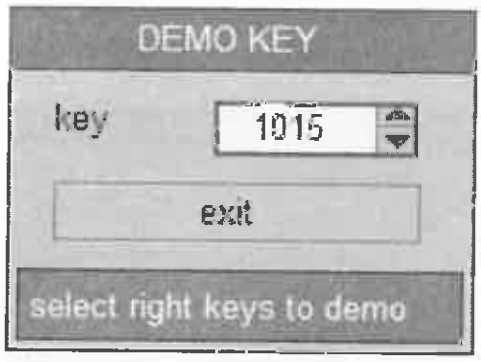
**Face Select**: select a work interface for the monitor; 11 available options: Standard face, Big-font face,Multi-leads only, Half Multi-leads, oxyCRG Face, Trend Face, NIBP list,$CO_2$ Face, IBP face, $CO_2$ & IBP and $CO_2$ & IBPII.Refer to Chapter 4 for detailed interface information.

**Key volume**: set volume of buttons, with 0-10 available, where 10 for maximum volume and 1 for minimum.
**Set Backdrop:** set screen background color, with 0-15 colors available
**Help Show**: whether to display help information for the menu

**Scan Type**: select a scanning method for waveforms (this function still need be extended)
Setting of the following items can be made under the System Setting menu:

### 3.3.1 Demo

Select the Demo option under the System Menu will pop up the Demo Password dialogue. After correct password input the system will enter to demonstrate waveform status, where the demonstrated waveforms are simulated by manufacturers to demonstrate machine performance and help train users. During actual clinical application, this Demo Waveform function should be disabled, as medical staffs may misunderstand the demonstrated to be actual patient waveforms and parameters, affecting patient monitoring and delaying treatment; that is also why there is a password for this menu.
After entering the Demo status, you can press the knob to pop up the following menu:




Pic 3-5 Demo Password

Users can input the password **(1018)** for demonstration.

## 3.4 Alarm setting

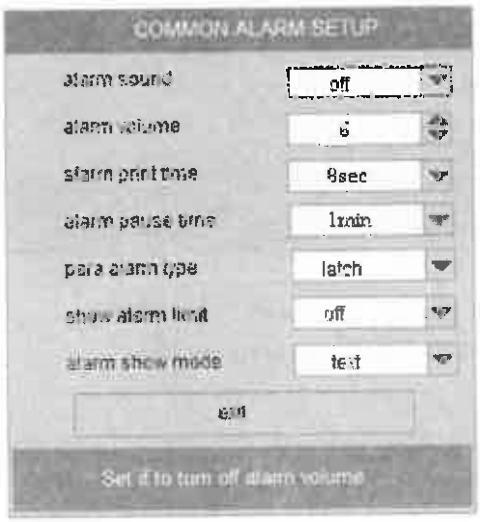
Select the "Alarm setting" option under the Main menu will pop up the following menu:


Pic 3-6 Alarm setting

Users can set alarm information and relevant information under this menu.

**General alarm setting**

Use the cursor to select the "General Alarm Setting" option and press the knob to pop up the following menu:




Pic 3-7 General alarm setting

**Alarm Sound**: set to on or off the alarm sound.

**Warning**

When system alarm sound is disabled, any new alarm will have no sound, so operators should carefully use this function.

In case the alarm sound is set to be closed under the silence or alarm pause status, the system will automatically stop the silence or alarm pause status.

In case the alarm sound is set to be OFF and operators select "silence" or "alarm pause", the system will automatically recover the alarm sound to be the volume before sound closing, and at the same time enter the silence or alarm pause status.

**Attention**

In case the alarm sound is set to be OFF, there will be displayed in the technical alarm information area.

**Attention**

The alarm pause status is only effective for the current running; upon next running, this setting will be recovered to be the previously set one.

**Alarm volume**: 0-10 available, where 10 for maximum volume and 1 for minimum
**Alarm print time**: Rotate the knob to set the time for record output during alarming, with 4seconds, 8 seconds and 16 seconds optional.
**Alarm pause time:** Rotate the knob to set the alarm pause time, during which the system will not make any alarming. "1 minute", "2 minutes" and "3 minutes", altogether 3 options.
**Para Alm Type**: Rotate the knob can select "Latch" or "Unlatch". In case "Latch" is selected, when an alarm starts the system will not stop it until manual treatment; in case "Unlatch" is selected, when an alarm starts, the system will make alarming and when the alarm ends, the system ends alarming.
**Show Alm limit**: Select whether to display alarm limits; if select to display, alarm limits will be displayed in the relevant parameter area.
**Alarm show mode**: Set to display physical alarms in text or digit.

**Alarm setting for various measurement parameters:**
After setting of general alarm information, users can continue setting parameter alarms, including ECG alarm, arrhythmia alarm, blood oxygen alarm, NIBP alarm, RESP alarm, TEMP alarm, IBP alarm 1, IBP alarm 2, carbon dioxide alarm, and CO2 alarm, where the functions for IBP alarm 1, IBP alarm 2, carbon dioxide alarm, and CO2 alarm are still to be extended. Method of setting: move the cursor to the item to be selected, and press the knob to pop up the setting menu; please refer to relevant chapters for various parameter monitoring.

## 3.5 Parameter Trend Diagram
Refer to Chapter 8 for details.

## 3.6 Parameter Trend Figure
Refer to Chapter 8 for details.

## 3.7 List of NIBP Historic Data
Refer to Chapter 8 for details.

## 3.8 Waveform and Parameter Review

The monitor can provide alarm review, FREEZE review and arrhythmia review; refer to Chapter 8 for information on the review selection menu.

## 3.9 Drug Calculation and Titration List

The function of Drug calculation and titration list can provide Drug calculation for15 types of Drug; refer to the Drug Calculation and Titration List chapter for use method.

## 3.10 Machine Information & Maintenance

Under the Main menu, select the "Machine Information & Maintenance" item will pop up the "Input Maintenance Password" dialogue as shown in the following. Users can input the user password so as to carry on user maintenance under the user maintenance menu. Whereby, the "Equipment Status" and "Configuration List" are menus for manufacturer's use and only open to designated maintenance personnel of our Company; users are not allowed to use these two functions.


Pic 3-8 Machine maintenance

This menu displays version information of the software installed on the machine.


Pic 3-9 Input password

Under the "Input Password" menu, input correct user password and press "Confirm" to pop up the "user maintenance" menu, where users can set the following information:

Pic 3-10 User maintenance

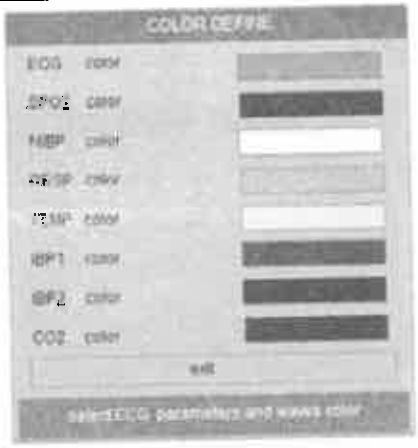
Language selection: select the language to be displayed on monitor interface; Chinese and English are optional.
AC frequency: select a frequency for the network power supply; 50HZ and 60HZ are optional.
Lead style: select a naming style for ECG leads, "AHA" and "EURO" are optional; for difference between the two styles, please refer to Chapter 12 ECG/ RESP monitoring.
Network number: set the network number of this monitor when connected with the central system; 1-16 are optional.

**Attention**

Don't directly change the network bed number when using a monitor with wireless network module. In case requiring to do this, please contact MEDIAID for Support.

LCD brightness: adjust brightness of the LCD screen (currently to be extended);
AUX output: set the AUX output type (currently to be extended);

Color definition: set colors for display of parameters and waveforms in the way of moving cursor to select and then press the knob to pop up the color definition menu.

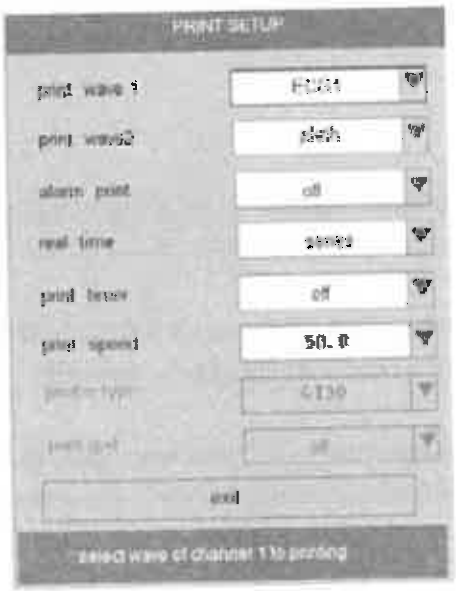


Pic 3-11 Color definition

Under this menu, users can set the colors for waveforms and parameters to be displayed in the way of moving cursor to parameter to be selected, then press the knob and rotate it, each time of rotating will change the color once, when the expected color appears just re-press the knob to confirm the selection. It's recommended to select various colors for various parameters so as to differentiate them.

## 3.11 Print Setting

Select the "set print related parameters" item under the Main Menu will pop up the following menu:



Pic 3-12 Print setting

Under this menu, users can set output of two record waveforms out of the following available options:

| | |
|---|---|
| ECG1<br>ECG2 | The first and second ECG waveforms displayed on the screen (in case of full-lead display there are 7 ECG waveforms) (if there is no ECG waveform on the screen, no relevant selection can be made) |
| $SPO_2$ | $SpO_2$ volume recording waveform (if there is no $SpO_2$ volume recording waveform on the screen, no relevant selection can be made) |
| RESP | RESP waveform (if there is no RESP waveform on the screen, no relevant selection can be made) |
| IBP1<br>IBP2<br>(Optional) | Waveforms from IBP(1,2) modules (if there is no IBP waveform on the screen, no relevant selection can be made) |
| $CO_2$<br>(Optional) | Waveforms from $CO_2$ module |

- Real-time print time: Three options, i.e., 4 seconds,8 seconds and 16 seconds.
- Print Timer: time interval between two output operations. 10 available options, i.e., off, 10 minutes, 20 minutes, 30 minutes, 40 minutes, 50 minutes, 1 hour, 2 hours, 4 hours and 8 hours. The system will activate the recorder for output operation based on the selected time interval, and the output time is fixed at 8 seconds.

**Attention**

The given priority for Real-time Print Time is higher than that for Timing Print Interval.

- Print speed: 3 available options, i.e., 12.5, 25.0 and 50.0 mm / s.
- Print grid: used to set the output format, "off" means no grid output and "on" means grid output.
- Printer type: select the type of the recorder.

**Attention**

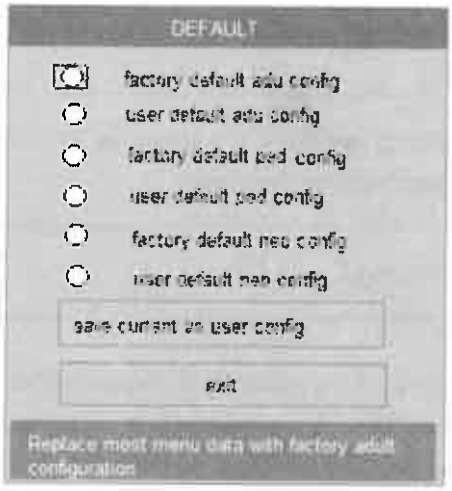
Recorder is only optional for the monitor.

**Attention**

If two same waveforms are selected, the system will automatically adjust one of them to be a different waveform.

## 3.12 Load Default Setting

Select "Load default parameter setting" under the Main Menu will pop up the following menu:



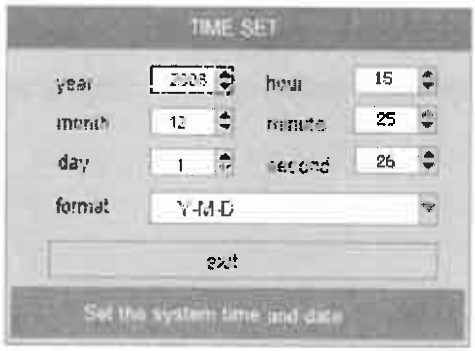

Pic 3-13 Default setting

Users can based on their requirements make corresponding default setting, in the way of moving the cursor to the default options to be loaded and pressing the knob, then the selected configuration will replace the current setting; alternatively, users may set the reserved configuration for the current patient type as the default user configuration.

After setting and exit from the default setting menu, the system will display a warning: All the relevant menu items will adopt the selected default setting, confirm? If you confirm, just press the "YES" button, otherwise press the "NO" button and continue other operations.

## 3.13 System Time Setting

Select "System time & date" under the Main Menu will pop up the following menu:




Pic 3-14 System time setting

When this monitor is used online with the central station, system time will be identical to that of the central station.

The specific adjustment method is: after successful online connection, the central station will send its current time to the monitor and the monitor will based on it update the system time; and later within every hour, the central station will send one time of current time to the monitor, keeping time of the central station and of the monitor identical to each other. However, if the system time for the two items vary only in seconds, the monitor will not adjust its system time. Please pay attention that after successful online connection if a user is just setting system time, the current system time setting menu will be immediately closed. During online period, the system time setting button under the system setting menu doesn't work and users can not enter the system time setting menu. (Not applicable if your central station doesn't support this function).

# Chapter 4 System Work Interface

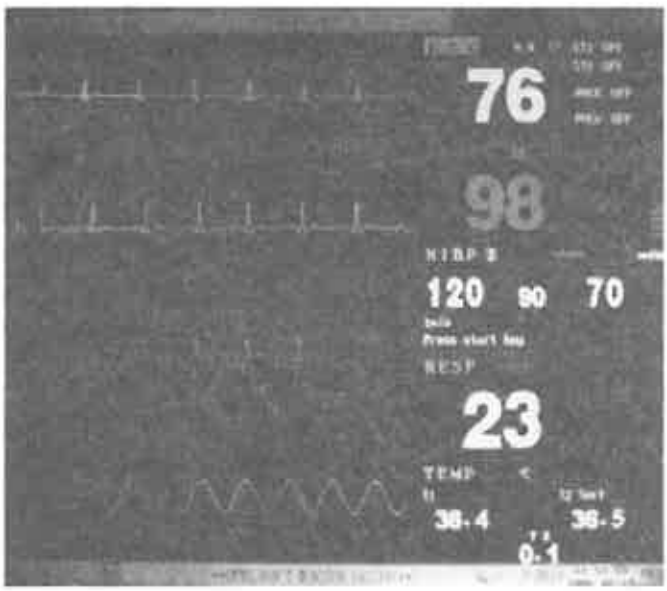
This monitor has seven work interfaces based on their various requirements, may select various work interfaces to obtain various screen information.

## 4.1 Work Interface Selection

Under the Main Menu, select one of the "FACE SLECT" options under the System Setup submenu. Out of Eleven available options: Standard face, Big-font face, multi-leads only, Half multi-leads, oxyCRG Face, Trend Face, NIBP list, $CO_2$ Face, IBP Face, $CO_2$ & IBP $CO_2$ & IBP II ,Only one option can be selected at one time.

## 4.2 Standard Interface

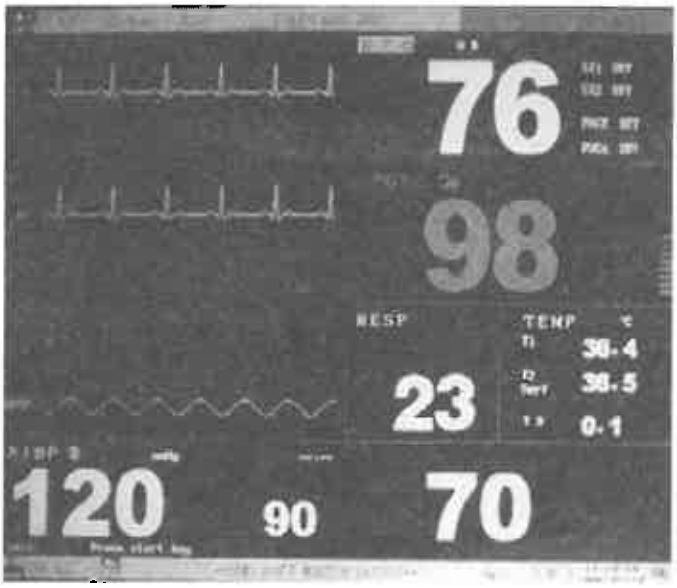
Out of the "FACE SELECT" options, select "Standard face" to enter it. It provides us the parameter waveforms under monitoring and displays the parameters in the parameter area, as shown in the following picture:




Pic 4-1 Standard face

## 4.3 Big Font Face

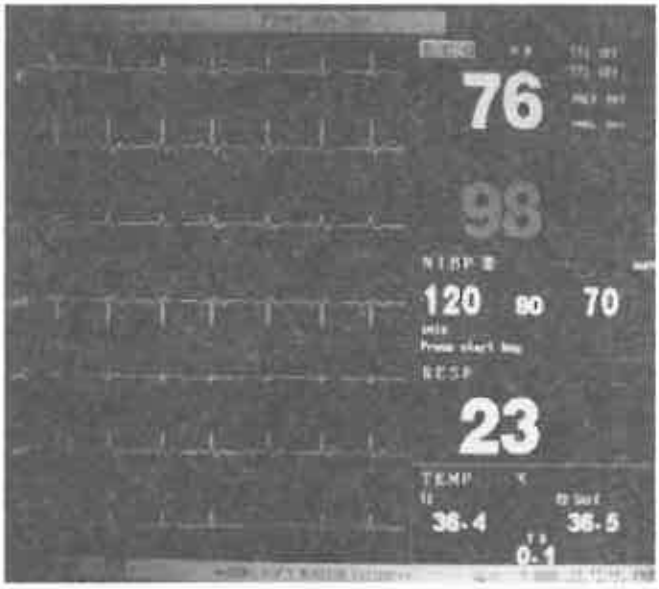
Out of the "FACE SELECT" options, select "Big font face" to enter it. It provides us the parameter waveforms under monitoring and displays the parameters in big font in the parameter area, as shown in the following picture:




Pic 4-2 Big font face

## 4.4 Multi-leads Only

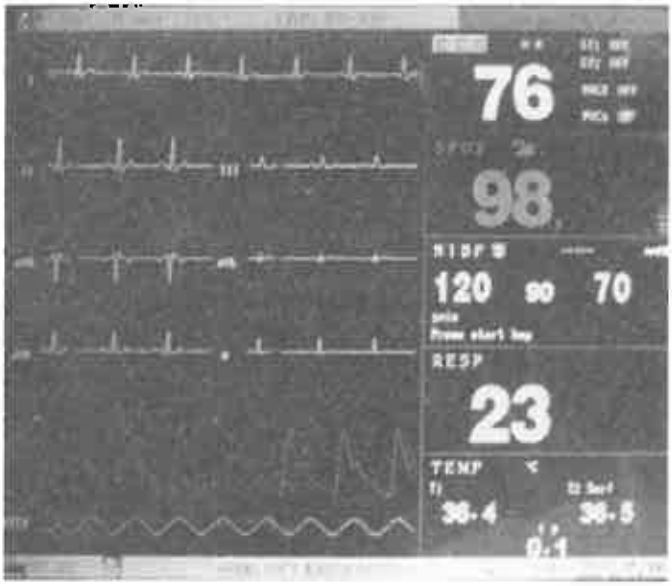
Out of the "FACE SELECT" options, select "Multi-leads only" to enter it. It provides us the 7 ECG waveforms under real-time monitoring and parameters in the parameter area.




Pic 4-3 Multi-leads only

## 4.5 Half-screen Multi-lead

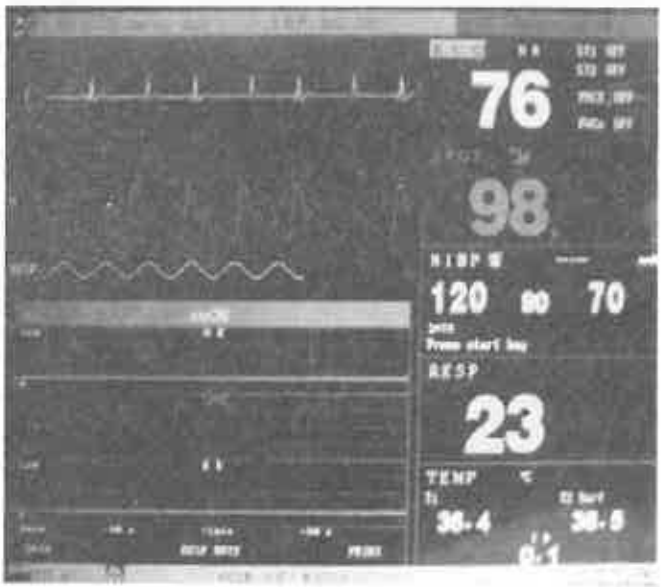
Out of the "FACE SELECT" options, select "Half-screen multi-lead" to enter it. It provides us the 9 waveforms under real-time monitoring (7 ECG waveforms, plus $SpO_2$ and RESP waveforms) and parameters in the parameter area.




Pic 4-4 Half multi-leads

## 4.6 oxyCRG

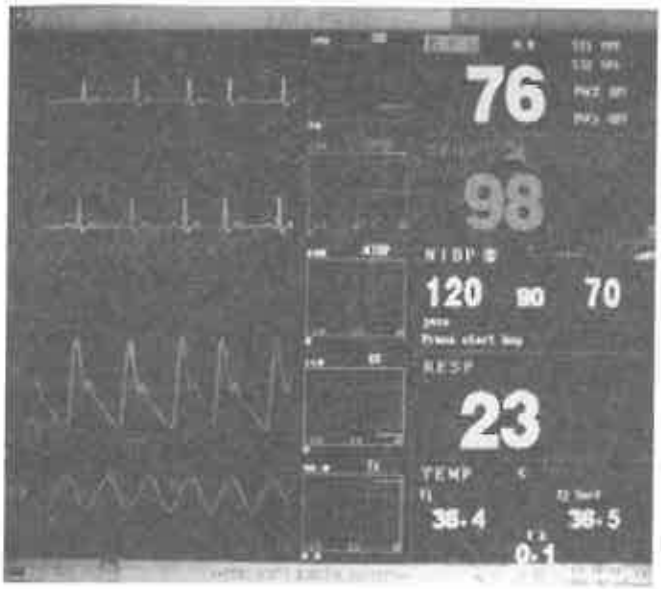
Out of the "FACE SELECT" options, select "oxyCRG" to enter it. It provides us the waveforms under real-time monitoring (Channel 1 ECG, $SpO_2$ and RESP), oxyCRG, and parameters in the parameter area.




Pic 4-5 oxyCRG face

## 4.7 Trend Face

Out of the "FACE SELECT" options, select "Trend Face" to enter it. This interface provides us the waveforms under real-time monitoring, trend diagrams, and parameters in the parameter area.




Pic 4-6 Trend face

- Location of trend diagrams

Trend diagrams are located in the right to the waveforms, with the same colors to the corresponding parameters.

- Trend length

Dynamic trend length is 2 hours; in a trend diagram, the right side of the horizontal axis is 0 hour, and the left side is 2 hours.

- Selection of trend parameters

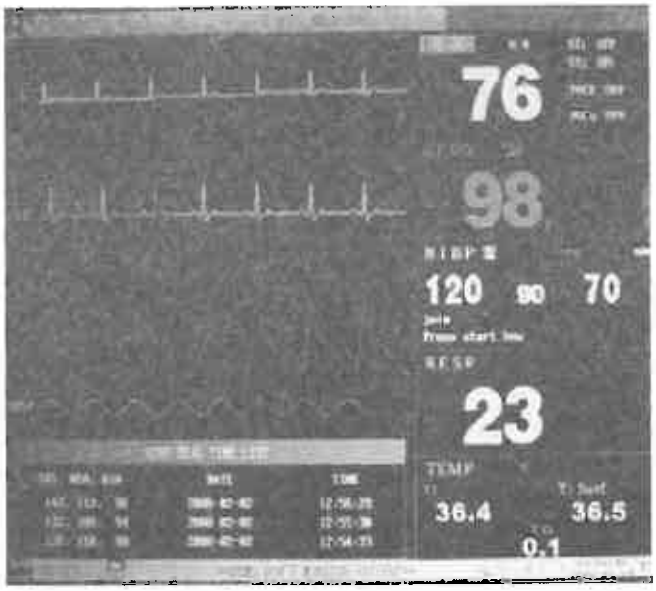
When several parameters are located at the same position in a trend diagram, users can use the trend name of the corresponding trend diagram to select a certain parameter, so as to display its own trend diagram, for example, users can select HR, $ST_1$, $ST_2$ or PVCs out of the parameter hot keys in the left side of a trend diagram, so as to display the trend diagram for HR, ST, or PVCs.

- End of trend face

Out of the "FACE SELECT" options, select any other work interface to end the trend face.

## 4.8 NIBP List

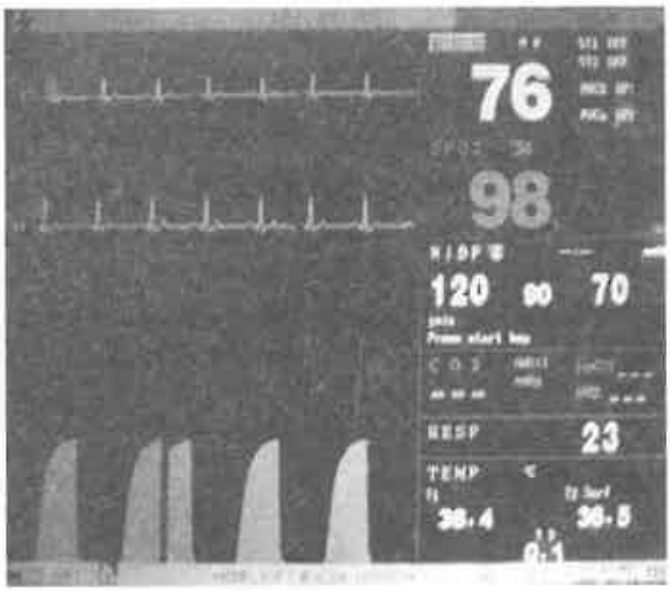
Out of the "FACE SELECT" options, select "NIBP list" to enter it. This interface provides us the waveforms under real-time monitoring, NIBP real-time list, and parameters in the parameter area.




Pic 4-7 NIBP list interface

## 4.9 $CO_2$ face ( Optional)

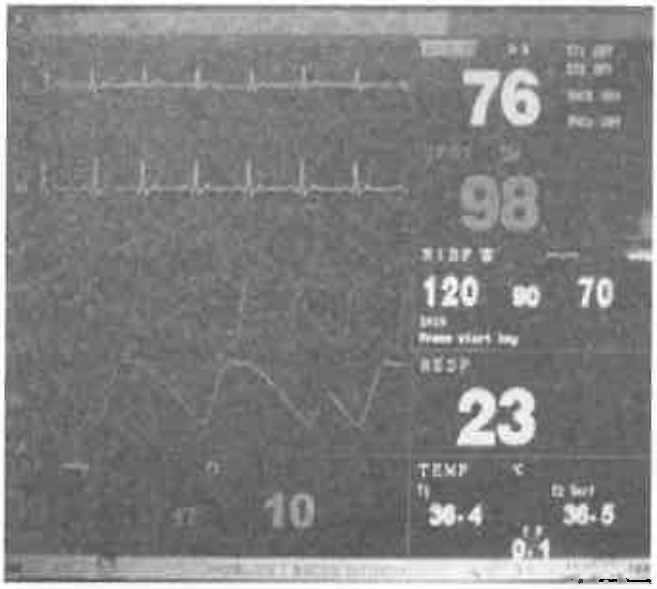
Out of the "FACE SELECT" options, select "$CO_2$ face" to enter it. This interface provides us the waveforms under real time monitoring, and parameters in the parameter area. This mode concurrently displays 4 waves (2 ECG waves ,1 pleth wave and $CO_2$ Wave ).




Pic 4-8 $CO_2$ face

## 4.10 IBP Face (Optional)

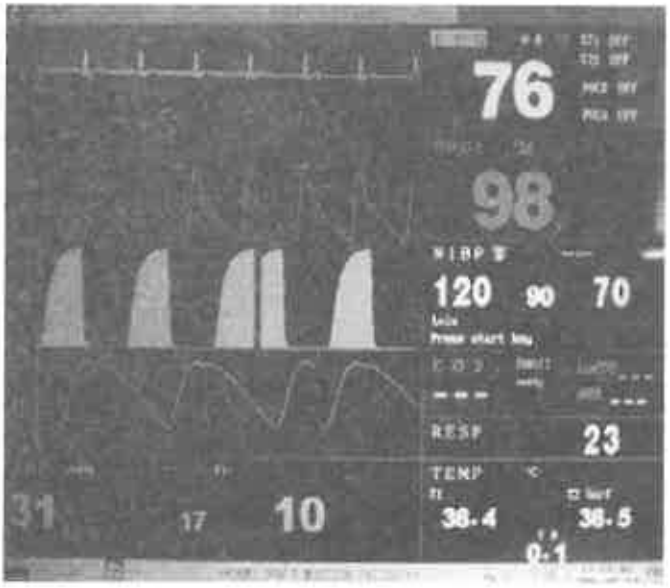
Out of the "FACE SELECT" options, select "IBP face" to enter it. This interface provides us the waveforms under real time monitoring, and parameters in the parameter area. This mode concurrently displays 4 waves (2 ECG waves ,1 pleth wave and IBP Wave ).




Pic 4-8 IBP list face

## 4.11$CO_2$ and IBP face (Optional)

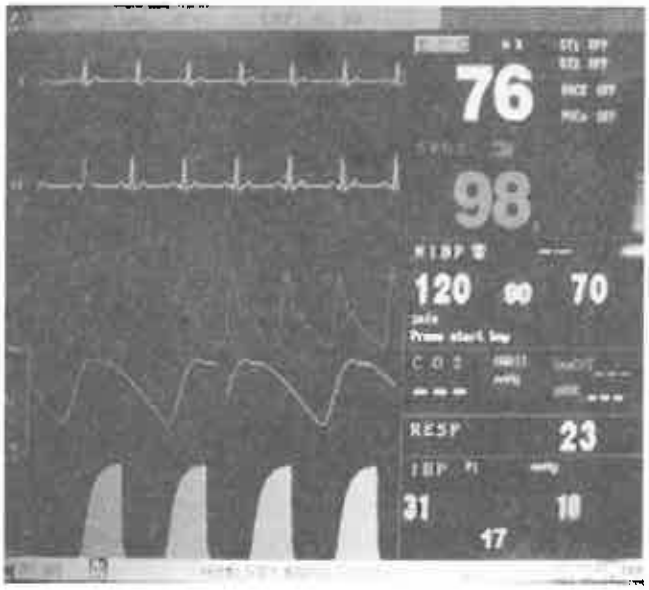
Out of the "FACE SELECT" options, select "$CO_2$ & IBP face" to enter it. This interface provides us the waveforms under real time monitoring, and parameters in the parameter area. This mode concurrently displays 4 waves (1 ECG wave, 1 pleth, 1 $CO_2$ wave and IBP Wave ).




Pic 4-10 $CO_2$ and IBP face

## 4.12 $CO_2$ and IBP il face (Optional)

Out of the "FACE SELECT" options, select "$CO_2$ & IBP II face" to enter it. This interface provides us the waveforms under real time monitoring, and parameters in the parameter area. This mode concurrently displays 5 waves (2 ECG waves, 1 pleth, 1 $CO_2$ wave and IBP Wave).




Pic 4-10 Co2 and IBP II face

# Chapter 5 Alarming

This chapter introduces general information on alarming and measures to be applied during alarming. Users can obtain alarming and reminder information on various parameters from the relevant chapters on such parameters.

**Warning**

Upon power on, the monitor system will detect whether the alarming sound and light works properly, in the way of making a "Dang!" audio and blinking the alarming light respectively in red and yellow colors. Users should observe this verification process, if this process is not as described, the system will fail to monitor patients, then users must contact MEDIAID.

## 5.1 Alarming Method

### 5.1.1 Alarming Levels

Each type of alarming, no matter technical or physical, has its own alarming level, and for high-level alarming, the system will remind in several ways. For certain alarming, users can set their levels through software, while levels of some other alarming are set by the system, not changeable for users. There are altogether 3 levels of alarming in this monitor, i.e., high, middle, and low.

High-level alarming, as the most serious alarming, means the patient has a fatal risk or the monitor has serious technical problems.

Middle-level alarming means serious warning.

Low-level alarming means general warning.

Alarmings are also categorized into 3 types, i.e., physical alarming, technical alarming and general alarming. Physical alarming means those activated by over-limit physical parameters of patients, such as HR exceeds its alarming limit; technical alarming means those activated by improperly working functions or failed monitoring results due to system failure, thus also known as system error information; and general alarming means those out of the above-mentioned types but activated by factors necessary for users' attention. This monitor has preset alarming levels for various measurement parameters, while users can also revise such levels following the methods introduced in this chapter; however, the alarming levels for system error (namely, technical alarming), and general alarming, and certain physical alarming are set by the system, not changeable for users.

### 5.1.2 Alarming Methods

This monitor has 3 ways of alarming, i.e., Sound, light and text. Audible alarm and light alarming is realized through TFT display device, speaker in the monitor, and alarming indicating light, while text description information is displayed on screen. Physical alarmings are displayed in the physical alarming reminder area on the screen, and most of

technical alarmings are displayed in the technical alarming reminder area, and the rest of technical alarmings, if related with NIBP, are displayed in the NIBP alarming reminder area at the bottom of the NIBP parameter area.

**Attention**

The physical alarming reminder area is in the right top of the whole display interface, and the technical alarming reminder area is at left to the physical alarming reminder area.

**Attention**

In case there are more than one alarming equipments inside the monitor system, during alarming all the alarming equipments will give the identical visual and audio reminder.

**Attention**

Expression methods of various reminders are up to the alarming levels.

Alarming method for measured parameters exceeding alarming limits:
In case a measured parameter exceed alarming limits, the monitor, besides of the three alarming methods as introduced above, will blink the measured parameter in 1Hz frequency; in case the upper & lower alarming limits for this parameter are also displayed at the same time, such limits will also be shined in the same frequency.

**Screen display**

In case a measured parameter exceed the specified alarming limits and activate physical alarming, such parameter value will blink, and "*" symbols will be displayed at right top of the screen for alarming purpose, "***" in red color for high-level alarming, "**" in yellow color for middle-level alarming, and "*" in yellow color for low-level alarming. In case of technical alarming, no "*" symbols will be displayed.

**Alarming light**

The system applies various lights for various levels of alarming, as shown in the following table:

| Alarming levels | Light details |
|---|---|
| High | Blink in red color, in high shining frequency |
| Middle | Blink in yellow color, in low shining frequency |
| Low | Keep in yellow color |

**Alarming Sound**

The system applies various audios for various levels of alarming, as shown in the following table:

| Alarming levels | Audio details |
|---|---|
| High | "Du-Du-Du-Du-Du, Du-Du-Du-Du-Du" mode, in interval of 8 seconds |
| Middle | "Du-Du-Du" mode, in interval of 24 seconds |
| Low | "Du-" mode, in interval of 24 seconds |

**Attention**

In case various levels of alarmings happen at the same time, the highest level will be applied for the final audible alarming.

## 5.2 Alarm Detection with Power on

With power on, the system will detect the audio and light alarming function in the way of making a "Dang!" audio and the LED indicating light on the control panel or monitor will blink in yellow and red, one by one. In case of no "Dang!" audio or shining, stop using this monitor and inform our maintenance engineers.

**Warning**

With power on, the system will detect whether the audio and light alarming functions properly. In case of failure to present the above described phenomenon, the monitor can not be used to monitor patients and users should contact MEDIAID for support.

## 5.3 Alarm Objects

The following cases will activate alarming:

1) Physical alarming;
2) Technical alarming;
3) General reminder information & alarming.

**A . Alarming condition for parameter modules**

When a measured parameter value exceeds its alarming limits and the parameter alarming function has been set as On, alarming will work, otherwise will not work.

**B. System alarming (technical alarming) condition:**

Upon any system error, the monitor will immediately make alarming and relevant treatment such as to stop display relevant parameters and waveforms and clear the final display value in order not to mislead medical treatments. In case of more than one piece of error information to be displayed, the system will display them one by one.

**C. General reminder information & alarming:**

In certain cases some alarms similar to physical alarms are still categorized in the general group, as we believe they will not affect health of patients.

## 5.4 SILENCE/ PAUSE

### SILENCE / CLOSE

On the control panel long press the "MUTE" button will close all the audible alarms, and re-press the button will exit the silence mode and return to the Alarm Pause status following the default pause time. With third time of pressing on this button, the system will close the Alarm Pause status and re-activate all the alarming audios. During the Silence mode, any newly activated alarm will relieve the mode and return the system to normal alarming status.

**Attention**

When the  sign (meaning alarming sound off) displays, the system will be unable to give audible alarms, thus operators should carefully use this function. Two optional methods of relieving this status: one is to set audio volume to be non-related under the User Maintenance menu, the other is to shortly press the MUTE button, making the sign to be  , then re-press the button, making the system recover to normal alarming status.

### PAUSE

On the control panel shortly press the "MUTE" button will close all the audible alarming, light reminders, and physical warning descriptions, bringing the system to the Alarm Pause status. Reversed timing for the alarming pause time is displayed in the physical alarming area, together with a  sign there.

Three available options for alarming pause time, specifically, 1 minute, 2 minutes and 3 minutes. User must make selection in the "alarming pause time" item under the General Alarming Setting sub-menu under the Alarming Setting menu.

Re-press the "MUTE" button will return the system to normal status; besides, any newly activated technical alarming can relieve the PAUSE status and remove the  sign.

**Attention**

Under normal status, existence of alarming depends on whether the alarming conditions are met. However, press the MUTE button will permanently close the alarming audios for lead disconnection and sensor disconnection.

## 5.5 Parameter Alarming

Under various parameter menus users can independently set alarming parameters, as well the alarming limits and alarming status. In case a certain parameter alarming is closed, beside this parameter there will be a  sign displayed in the parameter display area. Users can also independently set the alarming switches for each parameter.

For parameters set with alarming, in case one or more than one parameter value exceed the alarming limits, the monitor will automatically alarm and take the following actions:

1) Display on the screen in the way as described in alarming method part;
2) Audio up based on the specified alarming levels and volumes, if specified with alarming volume already;
3) Blink the alarming light;
4) Save all the parameter values during alarming, and 4, 8 or 16 seconds of waveforms before and after the alarming;
5) Activate the recorder for one time of alarm output, if specified with alarm output already. Please refer to the Record chapter for details.

## 5.6 Measures to be Taken during Alarming

**Attention**

Upon a certain alarm, users should firstly check patient conditions.

Alarming information is displayed in the system information area or system alarming information area; users require to identify the alarming and take corresponding measures based on the alarming reasons, specifically,

1) Check patient conditions;
2) identify which parameter is alarming or which type of alarm is happening;
3) Identify the alarming reason;
4) Manually switch to the SILENCE mode, if necessary;
5) Check whether alarms disappear after relieving of the alarming reasons.

Users can find alarming and reminder information for various parameters in the chapters on such parameters.

# Chapter 6 Freeze

- Introduction on the Freeze function
- Freeze/ Defreeze methods
- Review and record of frozen waveforms

## 6.1 Introduction

During monitoring process, medical staff can freeze those waveforms in which they are interested for careful observation. Frozen waveforms can be reviewed for 16 seconds, and if necessary, be outputted to the recorder. The Freeze function of this monitor has the following characteristics:

- Freeze status can stat at any work interface;
- At the same time of entering the Freeze status, the system will exit all the other operation menus, freeze all the waveforms on the basic interface (in case of full-lead ECG interface, freeze full-lead ECG waveforms and extra waveforms, if any) and refresh the parameter area;
- Can review and record frozen waveforms.

## 6.2 Enter/ Exit Freeze Status

**Enter the Freeze status**

Out of the Freeze status, press the FREEZE button on the control panel to exit the currently displayed menu (if any) and enter the Freeze status, while popping up the Freeze menu. At the Freeze status, all the waveforms will be frozen, no more refreshing.

**Exit the Freeze status**

At the Freeze status, any of the following operation will bring the system out of the Freeze status:

- Select the Exit option on the Freeze menu;
- Re-press the FREEZE button on the control panel;
- Make any operation that can cause screen adjustment or pop-up of new menu.

After the system exit the Freeze status, screen waveforms are replaced by real-time waveforms. If under the scanning mode, waveforms start scanning from the left side; and if under the rotating mode, waveforms start to be displayed from the right and rotate.

## 6.3 Freeze Menu

Press the FREEZE button on the control panel will pop up the Freeze menu from the screen bottom and concurrently enter the Freeze status.


Pic 6-1 Freeze menu

- **Wave 1:** Used to select the first record waveform. The dropdown menu lists all the waveforms available on the screen.
- **Wave 2**: Used to select the first record waveform. The drop menu lists all the waveforms available on the screen.
- **Froze review**: Used to review frozen waveforms. Refer to Chapter 8 for details.
- **Exit**: Close the Freeze menu and exit the Freeze status.

**Attention**

Frequently pressing the FREEZE button within a shot period will generate non-continuous waveforms on the screen.

## 6.4 Review of Frozen Waveforms

Waveforms, upon being frozen, can be reviewed for 16 seconds before its frozen time. Users need shift the waveforms to realize it, and for specific setting menu, may refer to Chapter 8. For some waveforms shorter than 16 seconds, the shortage part will be displayed in straight line.

Operation method: Users, with the knob on the control panel, move on the cursor to the "Waveform review" button under the Freeze menu, press it until the button changes its name to be "Left/ Right", and rotate the knob towards left or right, then the frozen waveforms on the screen will shift to left or right in accordance. There is a upward arrow at the right bottom of the final waveform, calibrated with time: frozen time calibrated as "0s", then along with right shifting of the waveform, changed to be -1S、-2S、-3S.....; such timing system applies to all the waveforms on the screen.

# Chapter 7 Record (optional)

- General information on the recorder
- Configuration and method for recording
- Record information

## 7.1 General Information on the Recorder

The recorder used with this monitor is a heat-sensitive array recorder, with print width of 48mm.

**Recorder compatibility:**

- Outputted waveforms run at 12.5mm/ sec, 25mm / sec or 50mm / sec.
- Maximally record two waveforms;
- Grid output function is optional (need upgrading);
- Chinese/ English output;
- Real-time record time and waveforms are selected by users through menus;
- Automatic record interval is selected by users through menus, while waveforms are identical to real-time records;
- During alarm record, the monitor automatically selects waveforms related with the alarming parameters.

## 7.2 Record Type

This monitor generates slip records of the following types:

- Real-time continuous record;
- Real-time 8-second record;
- Automatic 8-second record;
- Alarm record;
- Frozen waveform record;
- Trend diagram & list record;
- Arrhythmia event review record;
- Alarm review record;
- NIBP review record;
- Machine profile record;
- Drug calculation & titration list record

**Real-time record**

Start recording waveforms from the moment you press the REC/ STOP button.

Waveforms for real-time continuous record or real-time 8-second record are set by the system (normally only the first two waveforms are displayed) or set by users through menu. Please refer to relevant chapters for details.

Under the "Record output setting" menu, users can select to concurrently print two waveforms or close one of the two, printing the other waveform only. If the print functions for both the two waveforms are disabled, the real-time record will only output the measured parameter values.

**Attention**

During output process, the next parameter alarming output will be outputted after completion of the current output.

**Automatic record**

This monitor automatically activates the recorder for one time of real-time output, in accordance with the time interval designated at the Timing Record Interval item under the Record Output Setting menu, where the input length is 8 seconds. Please refer to the Record Output Setting part in the System Menu chapter for details.

**Alarm record**

- Parameter alarm

Alarm record length can be 4, 8, or 16 seconds before and after alarming (so altogether 8, 16, or 32 second), and the waveforms to be recorded can be selected under the System menu. All the monitoring parameters at the moment of alarming will be outputted.

Normally two waveforms will be outputted, subject with the following principles:

1) If more than one alarm records are switched on and activated, the waveforms corresponding to the parameters with the highest alarming levels will be selected; in case of same alarming levels, the latest alarms will be selected.
2) If alarms happen to other parameters during the process of recording a certain parameter alarm, response will be given after completion of this time of recording.
3) In case more than one alarms happen at the same time, the system will save some waveforms and output them in sequence.

- ST segment alarm

The monitor records two ECG waveforms (which two can be selected under the Main menu) within 4, 8, or 16 seconds before and after a ST segment alarm (so altogether 8, 16, or 32 second), and all the monitoring parameters at the moment the alarm happens.

- Arrhythmia event alarm

The monitor records the waveform within 4 seconds before and after an arrhythmia event alarm (so altogether 8 seconds), and all the monitoring parameters at the moment the alarm happens.

**Frozen waveform record**

In case waveforms are frozen, the system can output the designated waveforms on the screen and in such a way record those unusual waveforms captured by freezing.

**Trend diagram & list record**

Output the Trend diagram & list in the current Trend review window.

**Arrhythmia event review record**

Output the arrhythmia event in the current arrhythmia event review window.

**Alarm review record**

Output the parameter alarm in the current alarm review window.

**NIBP review record**

Output the NIBP review in the current NIBP review window.

**Machine profile record**

Output information in the current machine profile window.

**Titration list record**

Output information in the current Drug calculation & titration list window.

**Remark record**

- Record type:
  - Real-time record
  - Timing record
  - Parameter alarm record
  - Arrhythmia record
  - Frozen waveform record
  - Trend diagram record
  - Trend figure record
  - Parameter alarm review record
  - NIBP review record
  - Machine profile record
  - Titration list record
- Alarm parameter, alarming time, and Freeze time
- Patient bed number, name, gender, height, weight, birthday, and hospitalization beginning time
- Parameter name and value
- Record time
- Waveform name
- Waveform amplitude (only for ECG waveforms)
- ECG lead, ruler, and filtering method (in case of ECG waveforms, output from the first second or after changing the lead, gain and filtering method in the real-time record)
- Date & time
- Company name

## 7.3 Output

The following is the activation methods for various outputs:

Real-time continuous record:

Press "REC / STOP" to record and re-press to stop recording

Real-time 8-second record:

Press "REC / STOP" to record and at the 8th second automatically stop recording

Automatic record:

The monitor automatically activates in accordance with the Timing Record Interval time under the Record Output Setting menu, and automatically stop recording in 8 seconds.

Alarm record:

In case the alarm record function is on, alarms records will be automatically activated upon alarm.

Frozen waveform record:

Users, after entering the Freeze menu, select "print" in the Frozen Waveform Review window to print the currently selected frozen waveforms. In case both Waveform 1 and Waveform 2 are selected with "Off", only parameter values at the Freeze status will be outputted.

Trend diagram output:

Select the "print" button in the Trend Diagram Window to output the trend diagram for the currently displayed parameter.

Trend figure output:

Select the "print" button in the Trend Figure Window to output the trend figure for the currently displayed parameter.

Arrhythmia event review record:

Select the "print" button in the Arrhythmia Event Review Window to output the currently displayed waveforms and relevant parameters.

Alarm review record:

Select the "print" button in the Alarm Event Review sub-menu under the System menu to output the currently displayed alarm parameter waveforms and relevant parameters.

NIBP review record:

Select the "print" button in the NIBP Review sub-menu under the System menu to output the NIBP measurement value in the current window.

Machine profile record:

Select the "print" button in the Machine Status sub-menu under the System menu to output the machine status information.

Titration list record:

Select the "print" button in the Titration List window under the Drug Calculation item to output relevant contents in the current titration list.

oxyCRG record

Select the "print" button in the oxyCRG face to output the oxyCRG waveform in the current interface.

**Attention**

During process of various record output, users can stop it at any time by pressing the PRINT button on the control panel.

During process of various records, users can open the Record Output Setting sub-menu under the System Setting menu and press the "Clear Record Tasks" button, so as to stop all the records and clear all the saved alarms.

## 7.4 Operation and Status Information of Recorder

**Requirements on record paper**

Only qualified heat-sensitive record paper can be used, otherwise there may be failure or quality reduction in record, or damage to the heat-sensitive head.

**Normal service**

- While the recorder is under normal service with record paper outputted in uniform speed, users should not pull paper in order to protect the recorder.
- Don't use the recorder without paper loaded.

**Insufficient paper**

Don't boot the recorder when there is a reminder of "add paper to the recorder" in the information area. Please load qualified heat-sensitive record paper.

**Paper loading procedures**

- Open the recorder door;
- Pull up the slide switch at the left rod of the recorder;
- Load new paper exactly following the paper inlet, with the print side toward the heat-sensitive head;
- Slightly pull the paper exposed from the other side, and align the paper properly;
- Pull back the slide switch at the left rod of the recorder;
- Remove the paper from the paper outlet of the recorder;
- Close the recorder door.

**Attention**

Paper loading must be done softly so as to avoid heat on the heat sensitive head. Unless during paper loading or trouble shooting, the recorder door must be kept open.

**Solution to paper jam**

When the running audio of the recorder sounds improper or paper outputs improperly, users should open the recorder door to check whether there is paper jam. Procedures to clear paper jam:

- Cut the recorder paper at the paper outlet side;
- Pull up the slide switch at the left rod of the recorder;
- Pull out the recorder paper from the bottom;
- Re-load paper.

**Record status information (technical alarming)**

| Information reminder | Cause | Alarming level | Solution |
|---|---|---|---|
| Recorder head over-heated | Heat-sensitive head over-heated | Low | Temporarily don't use |
| Recorder head out of position | Heat-sensitive head out of the recording position | Low | Pull down the slide switch at the left rod of the recorder |
| Out of paper | Recorder out of paper | Low | Load record paper |
| Serial communication error | Communication error | Low | Restart the recorder |
| Paper jam | Continuously record for over 30m | Low | Re-load record paper |
| Recorder initialization error | Initialization error | Low | Restart recorder |
| Recorder initialization error 1 | Initialization | Low | Restart the recorder |
| Recorder initialization error 2 | Initialization | Low | Restart the recorder |
| Recorder initialization error 3 | Initialization | Low | Restart the recorder |
| Recorder initialization error 4 | Initialization | Low | Restart the recorder |
| Recorder initialization error 7 | Initialization | Low | Restart the recorder |
| Recorder initialization error 8 | Initialization | Low | Restart the recorder |
| Too many record tasks | Too many alarms happens at the same time | Low | Close alarm record |
| Recorder in initialization | Recorder in initialization | Low | Wait until completion of initialization |
| Recorder not available | Recorder out of work status | Low | Restart the recorder |
| Over high voltage | Over high voltage | Low | Stop using the record until recovery of proper |

| | | | |
|---|---|---|---|
| | | | voltage |
| Over low voltage | Over low voltage | Low | Stop using the record until recovery of proper voltage |
| Recorder communication error | Serial port communication error | Low | Restart the recorder |
| Recorder self-detection error | Error with RAM, ROM or CPU guard | Low | Re-install the recorder |
| Recorder busy | In printing | Low | Wait for completion of printing |
| Paper roller out of position | Recorder paper located wrongly | Low | Re-load paper |

If errors are still there after recorder restart, please contact MEDIAID for support.

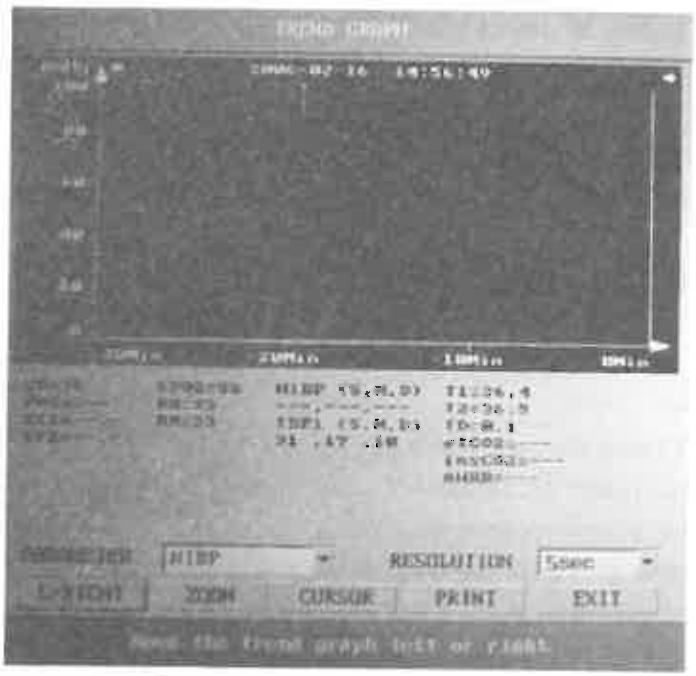
# Chapter 8 Trend & Event

This portable monitor can save 72 hours of Trend data, 1200 NIBP measurement data and 120 parameter alarm events, and output them through a recorder. Method of observation on such saved data is introduced in this chapter.

## 8.1 Trend Diagram

- Trend diagram for the previous 1 hour can be displayed in the resolution of one data per second or per 5 seconds;
- Trend diagram for the previous 72 hours can be displayed in the resolution of one data per minute, per 5 minutes, or per 10 minutes.

Users can select the Trend Diagram Review item under the System menu so as to pop up the following window:




Pic 8-1 Trend Diagram menu

Vertical axis is for measured values and horizontal axis for measurement time. The "↓" symbol is the cursor for Trend diagrams, and the measured value at the position it arrows is displayed below the Trend diagram while its corresponding time is displayed above the Trend diagram. Except NIBP values, all the other Trends are displayed in continuous curves; for NIBP Trend diagrams, "▽" refers to systolic pressure, "△" refers diastolic pressure, and "*" refers to average pressure.

**Select trend diagrams for various parameters to be displayed:**

Use the cursor to select the Parameter Selection option and revise the displayed contents. Upon display of the expected parameter, press the knob, then the Trend diagram for this parameter will be displayed in the window.

**Select 1-hour or 72-hour Trend diagrams:**

Use the cursor to select the Resolution option, then select 5 seconds or 30 seconds if you want to observe 1-hour Trend, or select 1 minute, 5 minutes or 10 minutes if you want to observe 72-hour Trend.

**Obtain the Trend data at certain time in the current Trend diagram**

Select "Cursor" and rotate the knob to control movement of the cursor; with the cursor moves, its arrowed time also changes, and the parameter value at such time will be displayed below the horizontal axis. If there is a "" indication in the right side of the window, when the cursor moves onto this indication the Trend diagram will automatically page down to display later Trend curves; and if there is a "" indication in the left side of the window, when the cursor moves onto this indication the Trend diagram will automatically page up to display earlier Trend curves.

**Output Trend curves through recorder:**

Press the "print" button to output the Trend curves of the current parameter through recorder.

**Event marks in Trend diagrams**

If users have marked A, B, C, D altogether 4 categories of events, in the Trend diagrams the corresponding event marks will be displayed at the time of event marking, such as "A", "B", "C", and "D".

**Operation sample**

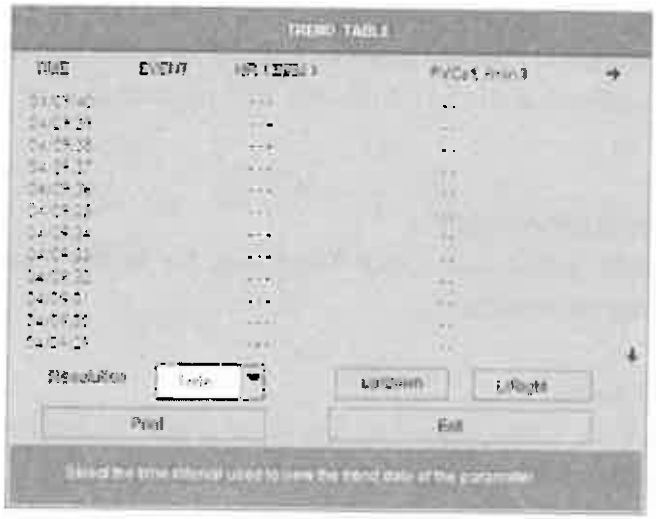
Observe the NIBP Trend diagram within the latest 1 hour:

- Press the MENU button on the control panel to pop up the Main menu;
- Select the Trend Graph option in the menu;
- Select the parameter: rotate the knob in the Parameter Selection item until "NIBP" is shown in the dropdown box;
- Select 5 seconds or 30 seconds in the Resolution item;
- Select "L/ Right" and rotate the knob, while observing changes in the Trend diagram time and Trend curves;
- Stop at the period to be carefully observed; in case the vertical axis is out of proper size, for example, some Trend values exceed the highest value of the current vertical axis, select "Adjust amplitude" to adjust;
- If users want to know the measured value at certain time, just select "move cursor" and move the cursor to where they wants, then time will be displayed above the curve and measured values below the curve;
- If users need output the Trend diagrams to the recorder, just select the "record" button so as to let the recorder output NIBP Trend of the current review window;
- Press "exit" to exit observation on Trend diagram.

## 8.2 Trend Figure

- Trend figure data over the previous 72 hours can be displayed in the following resolutions: 1 minute, 5 minutes, 10 minutes, 30 minutes and 60 minutes.

Select "Trend Table" under the Main menu to pop up the following Trend figure:



Pic 8-2 Trend figure setting menu

Time corresponding to various groups of Trend data is displayed at the left column, with dates braced. Under the Event column there are marked events, whose time is just corresponding to that of marked events. Parameters in the Trend figures can be categorized into the following 6 groups:

HR (BPM), PVCs(/min)
ST1, ST2
RESP (RPM)
$SPO_2$, PR(BPM)
NIBP NS / ND / NM
TEMP1, TEMP2, TEMPD

NIBP Trend data has its own characteristics; besides of measured values, below each "measurement point" there is time for this NIBP measurement. In case there are more than one measured values in certain duration, only one group will be displayed while there is a "*" symbol displayed beside the "More" button, and users can click it to view the other groups of measured values.

**Select Trend figures in various resolutions:**
Use the cursor to select a resolution and use the knob to change options so as to change the time interval for Trend data.

**Observe earlier or later Trend curves:**

If there is indication at the top of window, users can select "Page up/ down" and rotate the know clockwise so as to observe later Trend data; if there is indication at the bottom of window, users can select "Page up/ down" and rotate the know anticlockwise so as to observe earlier Trend data.

**Observe Trend data of various parameters**

Click "L/Right" and select one group of parameters out of 6 available groups. The ">" symbol, if displayed at the right to the right side parameters, means users can page down, and the "<" symbol, if displayed at the left to the left side parameters, means users can page up.

**Output Trend figures through recorder**

Users can press the "print" button and output Trend data for all the parameters in the current display area through a recorder.

**Event marks in Trend figures**

If users have marked A, B, C, D altogether 4 categories of events, in the Trend figures the corresponding event marks will be displayed at the time of event marking.

## 8.3 NIBP review

The monitor can display the latest 1200 NIBP measurement data in the NIBP review function. After users select the NIBP Measurement Review item under the Main menu, the windows will display the latest 10 NIBIP measurement results and measurement time, as shown in the following:

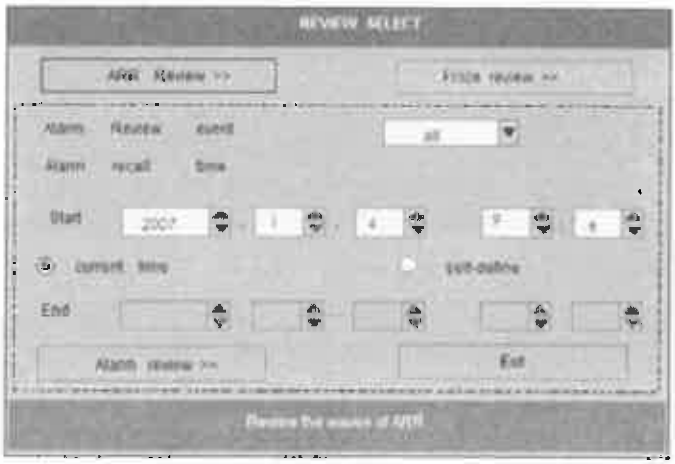

Pic 8-3 NIBP measurement review

Data is sorted in time sequence, from early to late, and each screen can display 10 times of measurement data, while users can select "Page up/ down" to view later or earlier data.

Maximally 1200 measurement results can be displayed, and when the measure times are over 1200, only the latest 1200 will be displayed. If users further select "print", the recorder will output all the measurement data in the review part.

## 8.4 Saved Waveform & Physical Parameter Data Review

- Select "RECALL" under the Main menu to enter the following menu:



Pic 8-4 Waveform & physical parameter data review menu

The monitor can provide three kinds of review, namely, arrhythmia review, Freeze review and alarm review.

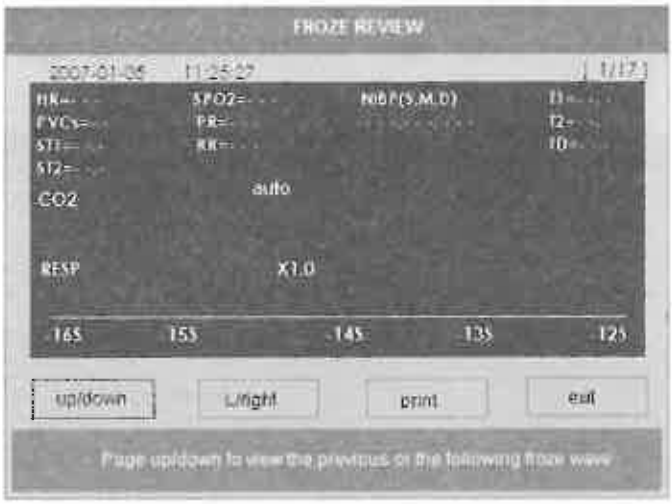
### 8.4.1 Arrhythmia review

Move the cursor to "ARR REVIEW" and press the knob to pop up the following menu:

Pic 8-5 Arrhythmia review menu

## 8.4.2 Froze review

Move the cursor to "Froze review" under the Review Selection menu, and press the knob to pop up the following menu:




Pic 8-6 Froze review menu

This monitor can save 120 times of frozen waveforms, and the "[1/17]" expression in the menu means there are altogether 17 frozen waveforms and the one being displayed is the first one. In the frozen waveform display area under the menu, 2 waveforms can be displayed and the setting method for them is to press the FREEZE button on the control panel so as to set Waveform 1 and Waveform 2. Please refer to Chapter 6 for detailed information.

## 8.4.3 Alarm review

Under the Review Selection menu, users can set the alarm review conditions, including:

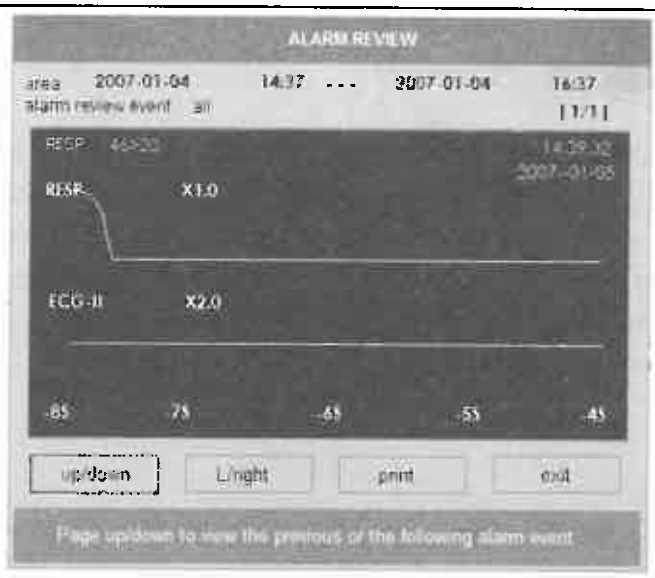
1) Alarm review event selection

In the review selection dropdown box, user can select the parameters to be viewed. Available options are "all" (alarm events for all the parameters), "ECG", "$SpO_2$", "RESP", "TEMP", "NIBP","IBP1","IBP2" and "$CO_2$".

2) Alarm Recall Time

Users can set the beginning time of the review in the "Start" option, and set the ending time in the "END" option. The ending time can be set as the current time or user customized time (SELF-DEFINE).

After setting all the review conditions, users can press the "Alarm review" button to enter the "Alarm review" menu:




Pic 8-7 Alarm event review

- Alarm review

The Alarm Review menu contains the following information:

1) Alarm review duration (Format: Year-Month-Day, Hour: Minute -- Year-Month-Day, Hour: Minute);
2) Event type;
3) Serial number (format: [ n/m ], meaning altogether m events happening, and the currently displayed is the No. n);
4) Parameter value at the moment of alarming, and the alarming time (format: Hour: Minute: Second, Year-Month-Day). NIBP is exempted;
5) Two kinds of waveforms, saved with 8 seconds / 16 seconds waveforms.

**Observe all the waveforms during an alarm process**

Select "L/ Right" and rotate the knob so as to view the saved 8 seconds/ 16 seconds waveform data.

**Observe other alarm events**

Events are sorted in time sequence, from early to late, and each screen can display 120 alarm events. Maximally 120 events can be displayed, and when the alarm events are over 120, only the latest 120 will be displayed. Users can select "Page up/ down" and rotate the knob to view later or earlier events.

**Record**

If users select "print", the recorder will output all the review data in the current window.

## 8.5 Data Storage with Power off

This monitor has the function of data storage with power off, cable to save with power off the Trend data for all the measurement parameters within 72 hours, the latest 1200 NIBP measurement data, the latest 120 alarm events and 120 arrhythmia events. After monitor power off, such data can still be safely saved and at next booting be observed through the Trend diagrams, Trend figures, NIBP measurement review, alarm event review and arrhythmia review menus.

**Attention**

If users do "Refresh patient" operations, all the measurement data and Trends will be cleared.

**Warning**

During monitoring on new patients, new measurement data will be saved together with the measurement data of previous patients. To save proper data, please refresh patients.

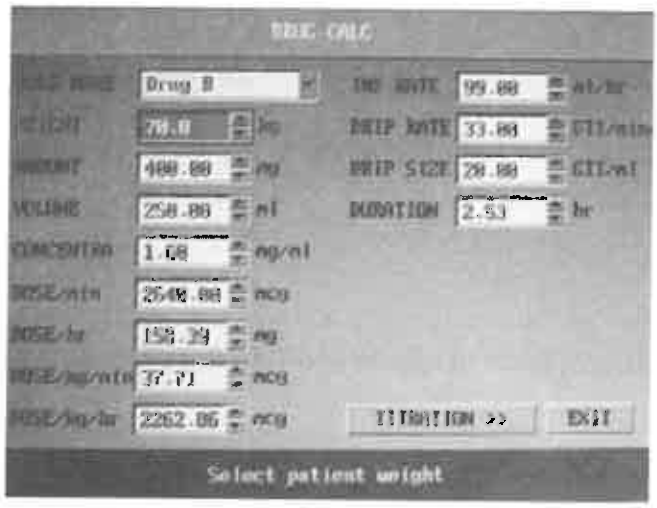
# Chapter 9 Drug Calculation & Titration List

The portable monitor provides display of Drug calculations & titration lists for 15 Drugs, and is able to output contents of the titration lists through a recorder.

## 9.1 Drug Calculation

Drugs able to be calculated under this system are: aminophylline, dobutamine, dopamine, epinephrine, heparin, isuprel, lidocaine, nipride, nitroglycerin and pitocin. Besides, there are Drug A, Drug B, Drug C, Drug D and Drug E provided to flexibly replace any Drug.

Users can select "Drug calculation" under the System menu to pop up the following window:




Pic 9-1 Drug calculation

The following formulae are used for Drug dosage calculation:

CONCENTRAT = AMOUNT / VOLUME

INFUSION RATE = DOSE/hr / CONCENTRAT

DRATION = AMOUNT / DOSE/hr

DOSE/hr = INFUSION RATE × CONCENTRA

**Operation method:**

In the Drug calculation window, operators should firstly select names of the Drugs to be calculated, then confirm patient weight, and input other known values. Subsequently, operators move the cursor to the various calculation items in the calculation formulae, press the knob and rotate it, so as to select the calculation value. After the calculation value is selected, value of the items to be calculated will be displayed at the corresponding position. Values for each calculation item have their limits, if the calculated results exceed such limits, the system will display "---.--".

**Attention**

Under this Drug calculation function, other menu items are available for input only after operators input patient weight and Drug names. The values firstly given in the system are only a random group of initial values, and operators should not take such values as calculation standard, instead, should re-input a group of values suitable for the current patient, based on the comments by doctors.

**Attention**

Each kind of Drug is subject with fixed units or unit series, and operators must select proper unit based on comments by doctors. Under the same unit series, numbering system of the units will be automatically adjusted with the current input values, and when the input value exceed out of expression of the relevant unit, the system will display "---".

**Attention**

After operators input a certain value, the system will give a clear reminder in the menu, reminding operators to check correctness of the inputted value; only inputted values are guaranteed to be correct, the calculated values will be reliable and safe.

**Attention**

In case of newborns, dropping speed and volume of an infusion drop make no sense.

**Attention**

The system gives a reminder for each inputted value, asking operators to confirm. Operators must be serious with every such reminder, as only valid and correct inputs can get reliable calculation results.

- Select Drug type: move the cursor onto "Drug name", rotate the knob and select one from aminophylline, dobutamine, dopamine, epinephrine, heparin, isuprel, lidocaine, nipride, nitroglycerin, pitocin, Drug A, Drug B, Drug C, Drug D and Drug E, altogether 15 types. For one time, only one type of Drug can be selected for calculation.

**Attention**

The above introduced A, B, C, D, and E are not actual Drug names, but only codes for Drugs. Units for these five types of Drugs are fixed, and operators can select proper units based on general practice of Drugs. The expression rule of their units are as follows:
Drugs A, B, and C are fixed under "mg" unit series, including g, mg, and mcg; Drug D is fixed under "unit" unit series, including unit, k unit, and m unit; and Drug E is fixed under "mEq" unit.

- **Weight**: When entering the Drug calculation window, operators should firstly or secondly input patient weight, which will be taken as independent information for calculation of Drug contents.

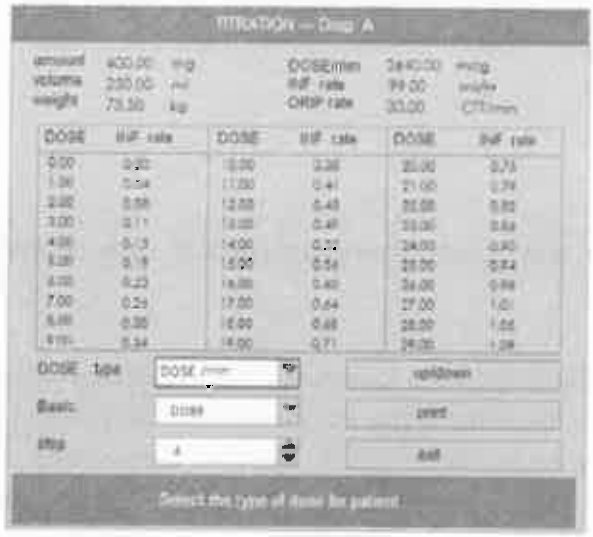
**Attention**

This function of Drug calculation is only to provide a Drug calculator, while values in the list should not be related with the patient under monitoring. Thus the patient weight under this menu is different from the patient weight in the system; when the system refresh with a new patient, values in this menu will not be affected.

## 9.2 Titration List

**Enter the titration list:**

Select "Titration list >>" under the Drug Calculation menu so as to enter the titration list interface, which is as shown in the following picture.



Pic 9-2 Titration list

- Specific operations are as follows:

1) Move the cursor to "Dose type" item and select dosage unit by pressing the knob;
2) In the titration list, move the cursor to "BASIC" and select the required item by pressing the knob. Three available options: DOSE, INF RATE, and DRIP SPEED.
3) Move the cursor to "STEP" and select the proper step length by pressing the knob. 1-10 are available options.
4) Move the cursor to "up/ down", press the knob and rotate it so as to check the previous and later page of the current table.
5) Move the cursor to "Print" and press the knob so as to input the titration list data in the currently displayed interface.
6) Move the cursor to "Exit" and press the knob so as to return to the Drug Calculation menu.

# Chapter 10 Patient safety

The portable monitor is designed to meet the international safety requirements IEC60601-1 formulated for medical electric equipments. It's furnished with floating inputted defibrillation resistance and surgery electric knife protection. If correct electrodes (referring to the ECG and RESP chapters) are installed following supervision of the manufacturer, screen display will be recovered within 5 seconds after defibrillation.

This symbol means the application part is of IEC 60601-1 type CF equipment, and designed with special electric shock resistant apparatus (especially with an F-type floating insulation apparatus for permissible leakage current), especially recommended for use during defibrillation period.

**Warning**

During defibrillation period don't touch the relevant patients, beds or equipments.

## Environment

Users should follow the following guides to ensure absolute safety of electricity installation. For an environment where the portable monitor is located, users should reasonably avoid vibration, dusts, corrosive or explosive gases, extreme temperature and moisture. In case installed inside a chamber, the front side must be given sufficient space for convenient operations, and while the chamber door is open, the rear side must be given sufficient space for easy repair. Besides, must make sure of air flow inside the chamber. The monitor, working in an ambient temperature between 0℃～40℃, can meet the technical indexes, otherwise may have equipment accuracy affected or parts or circuits damaged. Moreover, there should be at least 2 inch (5 cm) of space reserved surrounding the monitor to ensure air flow.

## Requirements in power supply

Please refer to the Product Specification chapter.

## Monitor earthing

To protect patients and medical staffs, the portable monitor must has its cover connected with the earth; for such reason the monitor is equipped with a dismountable 3-line cable, which should be plugged into a matching 3-line socket and further connected with the earth through the ground line of the power supply cable. In case of no 3-line socket, please consult with the electricity staffs of your hospital.

**Warning**

Don't connect the 3-line cable of this monitor with a 2-line socket.

Connect the ground line with the equal-potential earthing terminal of the monitor. If unaware whether a certain equipment combination is risky in terms of equipment specification, for example, whether gathered leakage current is dangerous, users should consult with relevant manufacturers or specialists, so as to make sure the necessary safety of the relevant equipment will not be damaged by the proposed combination.

## Equal-potential earthing

First class protection on the equipment has been contained in the house protective earthing system through earthing of the power socket. For heart or head internal check, this portable monitor must be individually connected with an equal-potential earthing system. One side of the equal-potential cable (potential balanced cable) should be connected with the equal-potential earthing terminal on the rear panel of the monitor, while the other side connected with one interface of the equal-potential system. In case of any damage to the protective earthing system, the equal-potential earthing system will take the safety function of protecting the earthing cable. Heart or head checks should be conducted within houses for medical use installed with protective earthing systems. Before each time of use, users should check whether the equipment is under good work status and pay attention the cable connecting patients and the equipment must be free from electrolytes pollution.

**Warning**

If the protective earthing system is instable, the monitor should be applied with internal power supply.

### Condensation

During work period the equipment must be made sure of no condensation. When the equipment is shifted from one room to another room, condensation may be formed as the equipment is exposed in moistured atmosphere and different temperature.

**Warning**

If the monitor is used where there are flammable anesthetic agents, there may be explosion.

# Chapter 11 Maintenance & Cleaning

## 11.1 Maintenance Check

Before using the monitor, users should conduct the following checks:

- Check whether there is any mechanical damage;
- Check all the exposed cables, plug-ins, and accessories;
- Check all the functions possibly to be used to monitor patients and make sure the equipment is under good work status.

If any potential to mechanical damage is found, this monitor should not be used to monitor patients and users should contact biomedical engineers of their hospitals or maintenance engineers of our Company. For each 6-12 months of after each maintenance, qualified personnel must conduct a thorough check on the equipment, including function & safety checks.

Besides, in accordance with the maintenance plan of hospitals, simultaneous defibrillation checks on the monitor must be done, and qualified maintenance personnel should come to check it at least every three months.

All the checks requiring to open the equipment must be done by qualified maintenance personnel, and general safety and maintenance checks can also be done by our staffs. The local office of our Company will also be glad to provide materials on signing maintenance contracts.

**Warning**

If a hospital or agent using this monitor fails to execute one set of satisfying maintenance plan, the monitor may not function well and even threaten to body health.

**Attention**

To extend service life of the chargeable battery, it's recommended to use the battery at least once per month, and charge it only after battery out.

**Warning**

Follow the guide of our maintenance engineers to change the battery.

## 11.2 General Cleaning of Monitor

**Warning**

Before cleaning the monitor or sensor, users must shut down the monitor and break the AC power supply.

This portable monitor must be kept free from dusts.

It's recommended to clean the external surface of the monitor cover and the screen. Only non-corrosive cleaning agents, such as soap and water, can be used to clean the monitor cover.

**Careful**

**To prevent damage to the monitor:**

1) Don't use strong solvents such as acetone.
2) Most cleaning agents must be diluted before use, and the dilution process must follow instructions of the manufacturers.
3) Never use abrasive materials such as wire wool or silver polish.
4) Keep any liquid out of the machine cover and don't immerse any part of the system into liquids.
5) Don't stay any cleaning liquid on surface of any part of the machine.

## 11.3 Cleaning Agent

Except those listed under the "Careful" part, any solvents classified as the following types can be used as cleaning agents for the monitor:

- diluted ammonia;
- diluted sodium hypochlorite (bleach powder for washing)

**Attention**

Sodium hypochlorite at the contents of 500ppm to 5000ppm (bleach powder diluted in 1:100 to 1:10) is very effective, and the amount of ppm depends on how many organics (blood, animal/ plant mucus) staying on the surface to be cleaned and infected.

- diluted oxymethylene 35~37%
- hydroperoxide 3%
- ethyl hydrate
- isopropyl alcohol

**Attention**

Surface of the monitor and sensor can be swept by medical alcohol, naturally dried or cleaned by clean and dry clothes.

**Attention**

Our Company is not responsible for effectiveness of taking such chemicals as control methods for infectious diseases. Please consult with the persons in charge of infection control of your hospital or specialists in infectious diseases.

## 11.4 Disinfection

To avoid long-term damage to the equipment, we recommend you to disinfect the products only when deemed as necessary under the maintenance plan of your hospital. We also recommend you to clean the products before disinfection.

Recommended disinfection materials for the monitor: ethanol, glyoxyl
For disinfection materials for ECG leads and blood pressure cuff, please respectively refer to relevant chapters.

**Attention**

- Follow instruction of the manufacturer to dilute or take contents as low as possible.
- Keep liquid out of the machine cover.
- Never immerse any part of the system into liquids.
- During disinfection don't pour any liquid onto the system.
- Don't keep residues of any disinfection agents on any surface of the equipment, instead, use a wet cloth to sweep them out.

## 11.5 Sterilization

To avoid long-term damage to the equipment, we recommend you to sterilize the products only when deemed as necessary under the maintenance plan of your hospital. We also recommend you to clean the products before sterilization.
For sterilization information for ECG leads, $SpO_2$ sensor, blood pressure cuff and TEMP detector, please respectively refer to relevant chapters.

**Attention**

To prevent damage to the monitor, don't use EtO gas or oxymethylene to sterilize the monitor.

# Chapter 12 ECG/ RESP Monitoring

## 12.1 Definition of ECG Monitoring

ECG monitoring generates continuous waveforms of ECG activities of patients so as to accurately assess the current psychological status of the patients. Thus proper connection of ECG cables must be ensured in order to obtain correct measurement values. This portable monitor concurrently displays less than 7 (including 7) waveforms under normal work status.

- Patient cable consist of two parts:
  wire connecting the monitor;
  leads connecting patients
- With a 5-lead facility for monitoring, ECG can obtain less than 7 (including 7) waveforms from two different leads. Users can use the knob, in the left side of the ECG waveforms on the screen, to directly select the lead to be monitored.
- Displayed monitoring parameters include HR, ST segment measurement value and arrhythmia.
- All the above parameters can be taken as alarm parameters.

## 12.2 Attentions during ECG Monitoring

**Warning**

Don't touch patients, tables or the equipment during defibrillation.

**Warning**

The ECG cable used for ECG signal monitoring by this portable monitor must be provided by our Company.

**Warning**

When connecting electrodes or patient cables, users should ensure there is no connection with other electric conductive parts or the ground, and more importantly, ensure all the ECG electrodes including neutral electrodes are attached with patient bodies instead of touching with electric conductive parts or the ground.

**Warning**

ECG cables without electric resistors can not be used for defibrillation at a monitor. Other kinds of monitors, if without current-limiting resistors, also can not be used for defibrillation purpose.

**Attention**

Disturbance from non-earthing equipments around a patient or ESU distance may affect waveforms to function improperly.

**Attention**

For one step of HR increase from 90bpm to 120bpm or reduction from 90bpm to 60bpm, the required maximum response time for the equipment to indicate the new HR is 12 seconds.

**Attention**

The time activating alarms required for two types of ventricular tachycardia (VT) waveforms after the normal HR 80bpm is 10 seconds.

## 12.3 Monitoring Procedures

### 12.3.1 Preparation

1) Take patient skin preparation before installation of electrodes:
- Skin is bad conductor, thus to ensure good touch between electrodes and skin it's very important to well prepare patient skin.
- When necessary, remove body hair surrounding the electrode positions.
- Clean thoroughly the skin with soap and water (don' t use ethyl ether or pure alcohol, as they will increase skin resistance)
- Dry sweep the skin so as to increase capillary blood flow as remove skin scraps and oil.

2) Install spring clamp or snap before installation of electrodes
3) Put the electrodes on patient body; in case the electrodes contain no conductive paste, coat the conductive paste before installation.
4) Connect electrode leads with patient cables;
5) Confirm power supply.

**Warning**

Daily check whether the ECG electrode plates stimulate skin; in case of any sensitiveness phenomenon, change the electrodes or positions every 24 hours.

**Attention**

To protect the environment, used electrode must be recycled or properly treated.

**Warning**

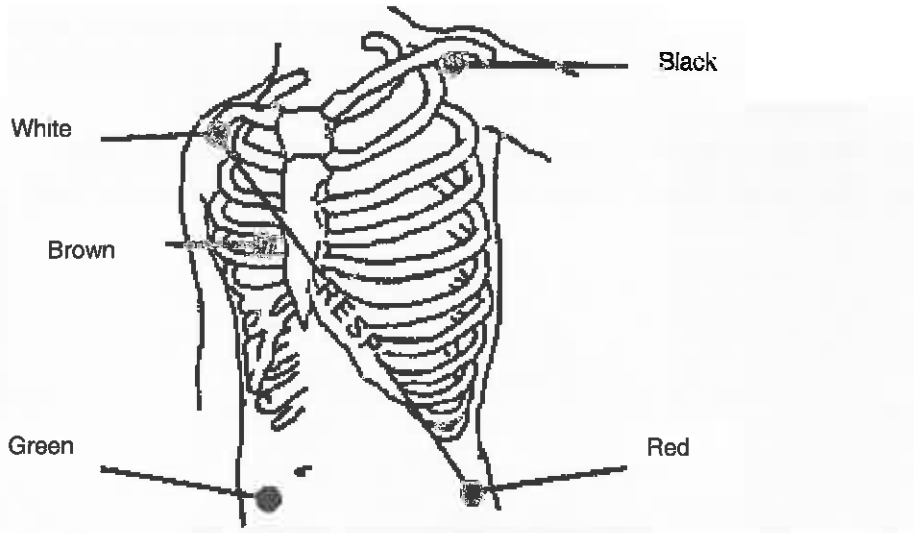
Before monitoring must check whether the leads work properly. After users plug out the ECG cables, screen will display the error information of "Sensor disconnected" and activate audio alarming.

### 12.3.2 Install ECG leads

**Positions of ECG monitoring electrodes**

Electrode positioning for 5-lead device (Pic 12-1)

- White (red arm) electrode- positioned below clavicle and near right shoulder
- Black (left arm) electrode- positioned below clavicle and near left shoulder
- Green (right leg) electrode- positioned at right lower abdomen
- Red (left leg) electrode- positioned at left lower abdomen
- Brown (breast) electrode- positioned on breast, as shown in the pictu




Pic 12-1 Positions of 5-lead electrodes

**Attention**

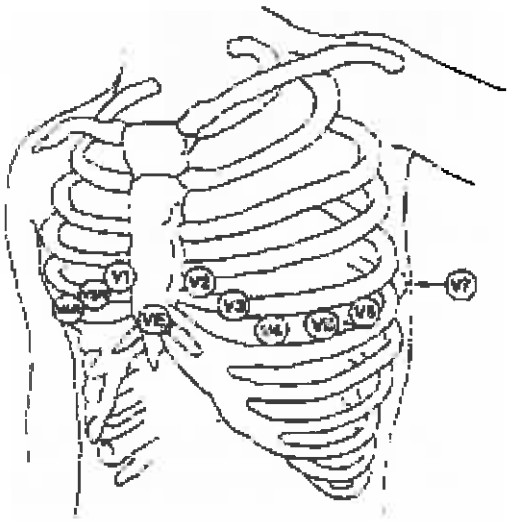
The following table lists the lead names under the European and US standards (leads are represented in R, L, N, F and C under the European standard and in RA, LA, RL, LL, and V under the US standard)

| US standard | | European standard | |
|---|---|---|---|
| Lead name | Color | Lead name | Color |
| RA | White | R | Red |
| LA | Black | L | Yellow |
| LL | Red | F | Green |
| RL | Green | N | Black |
| V | Brown | C | White |

**Attention**

For patient safety, all the leads must be connected with patient body.

- For 5-lead device, put the breast (V) electrode at one of the following positions (Pic 12-2):
- V1, around the 4th frame at right side to the breast bone
- V2, around the 4th frame at left side to the breast bone
- V3, between V2 and V4
- V4, around the 5th frame along middle line of the left clavicle
- V5, at front line of the left axilla, at the same horizontal position of V4
- V6, at middle line of the left axilla, at the same horizontal position of V4
- V3R-V7R, at right side of the breast, identical to those positions at left side
- VE, at apophysis of the xiphoid process; in case V leads are put on the back, the electrodes must be put at one of the following position:
- V7, around the 5th frame at back line of the left axilla on the back
- V7R, around the 5th frame at back line of the right axilla on the back




Pic12-2 Electrode positioning of 5-lead device

**ECG lead connection recommended for surgery patients**

**Warning**

This monitor is resistant from disturbance of high-frequency electric knife; when used with high-frequency electrosurgery (ES) equipments together, this monitor can recover to the previous operation mode within 10 seconds after eliminating high-frequency signals and electromagnetic fields, while no saved data will be lost.

**Warning**

When using ES equipments, users should put ECG electrodes at middle of the ES earthing plate and ES knives to prevent from burns. Cables of ES equipments can not be wrapped with ECG cables together.

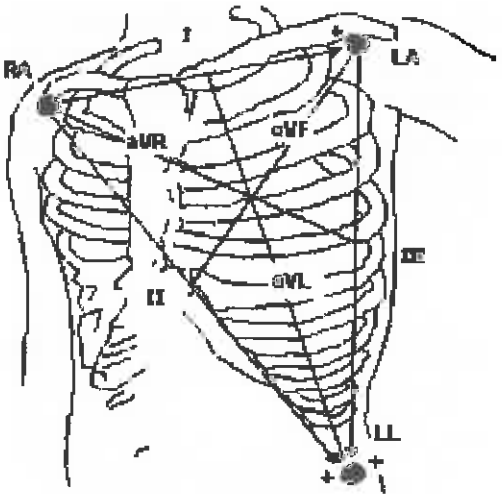
Positioning of ECG leads is up to operation types, for example, for chest operation, electrodes can be put on breast sides or back. Inside operation rooms using surgery electric knives, sometimes artificial discrepancy may affect ECG waveforms; to reduce such artificial discrepancy, users may put the electrodes at the left and right shoulders, near left and right abdomen, with breast lead at left to the middle breast. No electrodes should be put on left arm, otherwise the ECG waveforms will be very small.

**Warning**

During use of ES equipments, don't put electrodes near the earthing plate of such equipments, otherwise ECG signals will be much disturbed.

## Set ECG waveforms

Users may based on their requirements arrange leads at each channel. Lead names for each channel are displayed at right to the corresponding waveforms, ad users can directly select them for revision. Users can select proper leads from I, II, III, AVR, AVL, AVF, and V for the channels, as shown in Pic 12-3. In case a user select the same leads, the monitor will automatically adjust to different lead.




Pic 12-3 ECG leads

**Attention**

In case electrodes are pasted correctly but ECG waveforms are not accurate, users need change the leads.

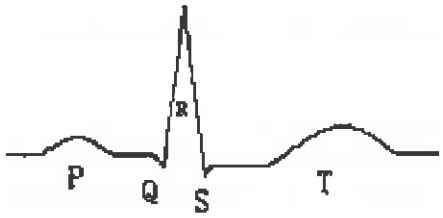
**Attention**

Disturbance from non-earthing equipments near patients or ESU distance may make troubles to waveforms.

Characteristics of a good signal:

- High and narrow, without incisura
- High R-wave, fully above or below the baseline
- Pacing signal no higher than R-wave
- T-wave lowerr than 1/3 of R-wave
- P-wave significantly lower than T-wave

To obtain 1mV of calibrated ECG waveform, users should conduct ECG calibration, in such case the screen will display "1mv ECG under calibration...." Don't monitor patients during calibration.




Pic 12-4 A standard ECG waveform

**Warning**

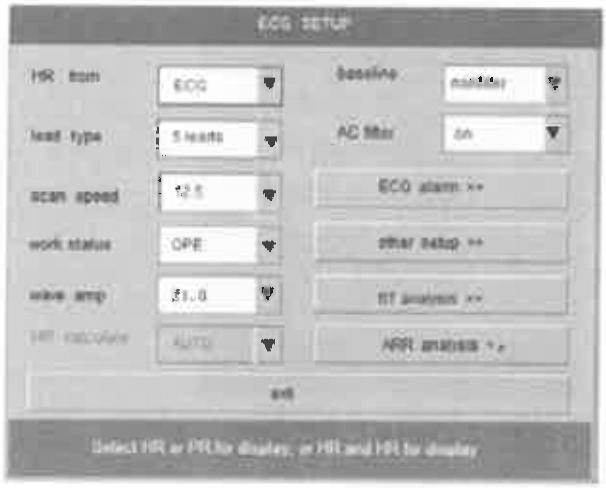
The system can provide non-treated actual signals only under the Diagnosis mode. Under the Monitoring or Operation mode, there must be discrepancy to certain extent, and what the system can provide is only basic figures of ECG, which will also much affect analysis results of ST segments. Under the Operation mode, ARR analysis results will also be partially affected. It's thus recommended, in case of little disturbance, to try to take Diagnosis mode for patient monitoring.

**Attention**

Detected pacing signals will be represented in "|" above the ECG waveforms in the waveform area.

## 12.4 ECG Menu

Users can rotate the knob and move cursor on the main screen to the ECG hot keys in the parameter area, then press the knob to pop up the ECG Setting menu:



Pic 12-5 ECG setting menu

- **HR FROM**

Users can select to check HR through ECG or PLETH; if users select "Auto", the monitor will decide HR source based on signal quality; if users select "BOTH", the monitor will concurrently display HR and PR. In case PLETH is taken as the HR FROM, the Pulse reminder will be displayed together with pulse sound.

In case PLETH is taken as HR FROM, no alarm judgment on HR but alarm judgment on PR will be conducted only in the $SpO_2$ Parameter area. .

In case "BOTH" is selected, PR measurement values will be displayed in the right to $SpO_2$ on the main screen, and HR & PR make alarms at the same time. Pulse audio will give priority to HR, as long as there is HR data, audio reminder will be there; only when there is no HR data, audio reminder will be subject with PR.

- Lead type: 5-lead or 3-lead
- Scanning speed

  Three optional ECG waveform scanning speeds: 12.5, 25.0 ad 50.0 mm/s
- Work status

  Three optional statuses for ECG monitoring: Operation, Monitoring and Diagnosis
- Waveform amplitude

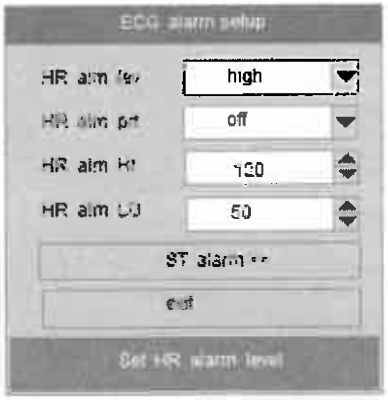
  Used to adjust amplitude of ECG waveforms. Users can select a gain (×0.25, ×0.5, ×1, ×2 or Auto) for every calculation channel, where Auto means the gain will be automatically adjusted by the monitor. There is a 1mV ruler given in the right to the ECG waveforms, whose height is proportional to the waveform amplitude.
- HR calculation

  "Auto" means the monitor will automatically choose a HR channel.
- Baseline shifting

  Filter ECG waveform baseline shifting. Users can select On or Off.
- Filtering for work frequency

  Users can select to On or Off the filtering for work frequency.
- ECG alarm setting

  Users move the cursor to the "ECG alarm" item, and press the knob to pop up the ECG alarm setting menu:




Pic 12-6 ECG alarm setting

- **HR ALM LEV**: three options, High, Middle and Low, and High is for the most serious alarm. If users select "Off", no alarm will be made while there will be a "" sign displayed beside the ECG in the parameter area.
- **HR ALM PRT** : Users can select "On" to print HR alarms when they happen
- **HR ALM HI**: used for users to set the upper limit for HR alarms
- **HR ALM LO** : used for users to set the lower limit for HR alarms

Alarms will happen once the HR values exceed the upper or lower limit.

Adjustable ranges for HR alarm upper & lower limits are as follows:

| | Highest upper limit | Lowest lower limit | Adjustment step length |
|---|---|---|---|
| HR adult | 300 | 15 | 1 |
| HR infant | 350 | 15 | 1 |
| HR newborn | 350 | 15 | 1 |

- ST segment alarm: used to set ST segment alarm。

**Attention**

Users should set the alarm upper & lower limits based on the clinical conditions of every patient. Setting of the HR alarm upper limit is very important, and users should not set it too high but consider revision factors. The set HR alarm upper limit should not be over 20 beats/ minutes than patient HR.

**Other setting**

Users can select this item to enter the ECG setting menu, as shown in the following picture:

Pic 12-7 ECG setting menu

Under this sub-menu there are the following functions:

- Cascading display: this is the ECG cascading switch; Cascading means all the ECG waveforms on the screen occupy the position of two waveforms; such function is only effective when the ECG monitoring type is "Normal Display" and the waveform scanning method is "Refresh".
- Pacing analysis: If set as "On", any detected pacing signal will generate a "|" signal above the ECG waveform; but if set as "Off", there will be pacing analysis.

**Attention**

In case the patient is under pacemaker monitoring, users should turn on the PACE switch, otherwise turn off the PACE switch. In case the PACE switch is on, the system will not carry certain types of arrhythmia analysis; for detailed contents refer to the Arrhythmia Analysis chapter.

- **Beat volume:** 11 options varying from 0 to 10. 10 for maximum volume and 0 for volume off.

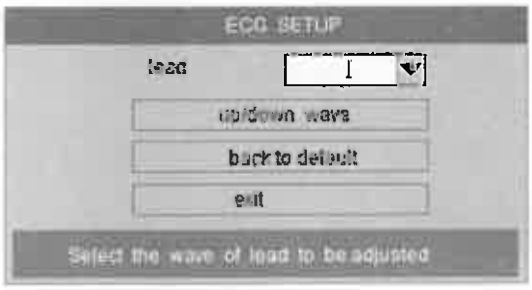
**Attention**

Volume adjustment for PITCH TONE is realized through adjustment of heartbeat volume. But once the HR Source item under the ECG Setting menu is selected with $SPO_2$, volume adjustment for PITCH TONE will turn to be controlled by the Pulse Volume item under the $SPO_2$ menu. Please refer to the $SPO_2$ chapter for detailed introduction on PITCH TONE.

- **ECG cal:** This item is used to start ECG waveform calibration. Re-select this item in the menu or change the lead name on the screen may stop waveform calibration.

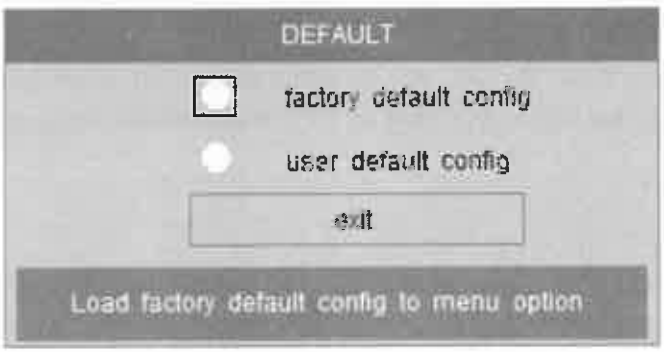
- **Adjust Wave POS:** Used to adjust positions of ECG waveforms on the screen. Users

can select this item to enter the "Adjust waveform position" dialogue, and in the "LEAD" item select the ECG waveforms to be adjusted, then press the "up/ down wave" button and rotate the knob to adjust positions of waveforms on the screen, or alternatively, press the "Back to default" button to return waveforms to the default position on the main screen.




Pic 12-8 "Adjust waveform position" menu

- **Default:** Users can select this item to enter the "DEFAULT" dialogue, then further select "Factory default Config" or "User default Config". After making a selection and exiting the dialogue, users will see a pop-up dialogue requiring their confirmation.




Pic 12-9 Default setting

**Warning**

For pacing patients, users must activate the pacing pulse analysis function, otherwise pacing pulse may be considered as normal QRS waves during counting, disabling the "ECG signal over-weak" alarm to detect.

If the monitor is furnished will ST segment analysis and arrhythmia analysis, users may refer to the ST Segment Monitoring and Arrhythmia Analysis chapters for operation methods.

- ST segment analysis

Users can select this item to enter the ST Segment Analysis menu. Please refer to the later relevant contents for details.

- Arrhythmia analysis

Users can select this item to enter the Arrhythmia Analysis menu. Please refer to the later relevant contents for details.

**Attention**

In case the pacing analysis function is activated, the monitor will not detect arrhythmia related with premature ventricular beats (including PVCs counting), neither do ST segment analysis.

## 12.5 ECG Alarming & Reminder Information

Possibly happened alarms during ECG measurement are classified into physical alarms and technical alarms, while during the same process there may be various reminders. The visual and audio appearance of the monitor upon happening of such alarms or reminders, are as described in the Alarming chapter. On the display screen, physical alarms and general reminders are displayed in the alarming area, while technical alarms and those reminders unable to activate alarms are displayed in the information area. In this chapter all the descriptions on alarming applies out of the arrhythmia and ST segment analysis parts.

When the alarming record function under relevant menu is turned on, those physical alarms activated because parameters exceed alarming limits may activate the recorder to automatically output alarming parameter values and the relevant measurement waveforms.

The following classified table lists various possible alarms during such measurement process.

Physical alarms:

| Reminders | Causes | Alarming levels |
|---|---|---|
| ECG signal over-weak | Fail to detect patient ECG signals | High |
| HR TOO HIGH | HR measurement values higher the set alarming limit | User customized |
| HR TOO LOW | HR measurement values lower the set alarming limit | User customized |

Technical alarms:

| Reminders | Causes | Alarming levels | Solution |
|---|---|---|---|
| ECG lead OFF | ECG electrodes drop off from patient body or ECG cables drop off from the monitor | Low | Make sure electrodes, leads and cables are all connected properly |
| ECG V-lead disconnected or ECG C-lead disconnected | | | |
| ECG LL-lead disconnected or ECG L-lead disconnected | | | |

| | | | |
|---|---|---|---|
| ECG RA-lead disconnected or ECG R-lead disconnected | | | |
| ECG module initialization error | Failure in ECG measurement module | High | Stop using the measurement function provided from the ECG module and contact MEDIAID for support |
| ECG module initialization error 1 | | | |
| ECG module initialization error 2 | | | |
| ECG module initialization error 3 | | | |
| ECG module initialization error 4 | | | |
| ECG module initialization error 5 | | | |
| ECG module initialization error 6 | | | |
| ECG module initialization error 7 | | | |
| ECG module initialization error 8 | | | |
| ECG module communication stopped | ECG measurement module failure or communication failure | High | Ditto |
| ECG module communication error | Casual communication error | High | Ditto if the failure continues |

| | | | |
|---|---|---|---|
| HR alarming limit error | Function / safety error | High | Stop using HR alarming and contact MEDIAID for support. |
| ECG over-disturbance | ECG measurement signals are heavily disturbed | Low | Keep patients silent, electrode connection reliable, and AC supply earthing well |

Reminders (including general alarming information):

| Reminders | Causes | Alarming levels |
|---|---|---|
| HR measurement out of scope | HR measurement values out of measurement scope | High |

## 12.6 RESP Measurement

### 12.6.1 How to measure RESP?

This monitor measures RESP values from the breast impedance values at two electrodes; impedance change between such electrodes (due to breast activities) will generate a RESP waveform on the screen.

### 12.6.2 Setting of RESP monitoring

For RESP monitoring, no additional electrodes are required, but how to install electrode is critical. For some patients with clinical condition that negative breast internal pressure will

be generated if their breast is horizontal expanded, users should put the two RESP electrodes respectively at middle line of the right axilla and left side to the breast, where there are largest activities during respiration, so as to obtain the best RESP wave.

**Attention**

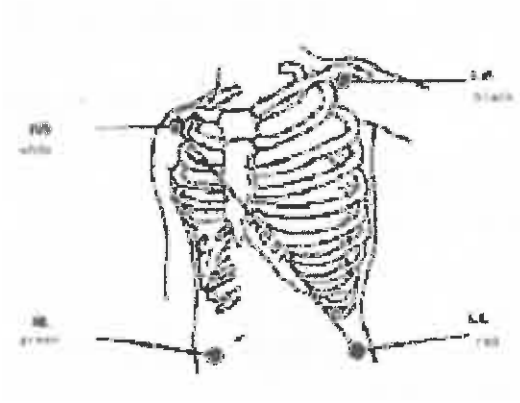
RESP monitoring is not applicable for patients with active activities, otherwise may generate wrong alarms.

RESP monitoring checks:

1) Take patient skin preparation before installation of electrodes;
2) Install spring clamp or snap for electrodes, and follow the later-introduced method to install electrodes on patient body;
3) Turn on power supply for the monitor system.

### 12.6.3 Install electrodes for RESP measurement

Install electrodes for RESP monitoring



Pic 12-10 Electrode positioning (for 5-lead case)

**Attention**

Install the white and red electrodes in a diagonal line so as to obtain the best RESP wave. Need keep the liver and heart area out of the line formed by such electrodes, so as to avoid artificial discrepancy generated from heart cover or pulsatile blood, which is very important for newborns.

### 12.6.4 RESP menu

**RESP Setting menu**

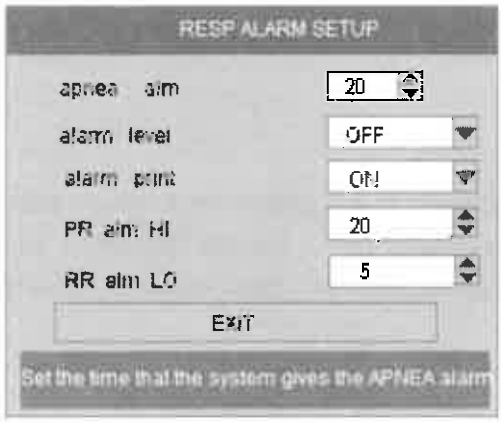
Users can rotate the knob and move the cursor to the RESP hotkeys on the parameter area of the main screen, then press the knob to enter the RESP Setting menu.

Pic 12-11 RESP Setting menu

- RESP CHECK: ON or OFF the RESP detection function
- Scanning speed: three optional speeds, 6.25mm/s, 12.5mm/s and 25.0mm/s
- Waveform amplitude: Users can set enlarged display of RESP waveforms under four optional enlargement rates: 0.5, 1.0, 2.0 and 4.0.
- Response speed: Users can set the response speed for RESP rate to be fast, normal or slow.
- Calculation mode: In case this item is selected, the monitor will automatically calculate RESP rates.
- Peak position: Function to be extended.
- Trough position: Function to be extended

**RESP Alarming Setting**

Users can move the cursor onto the "RESP alarming" item and press the knob to pop up the RESP Alarming Setting menu:




Pic 12-12 RESP Alarm Setting menu

- **APNEA ALM**: Users can set the time to judge patient choke; 10-40 seconds are optional, each rotation of knob will increase/ decrease 5 seconds.

- **Alarm level**: High, Middle or Low to be selected, and High for the most serious alarm. Users can also select "Off" to turn off the alarming function, in such case there will be a "" indication beside the RESP parameter area.
- **Alarm print**: If users select "On", upon RESP alarming, the record will output the alarm.
- **RR ALM HI**: used to be set with the alarm upper limit.
- **RR ALM LO**: used to be set with the alarm lower limit.

RESP alarming takes the set upper & lower limits as standard, and once the RESP values exceed such limits there will be alarms.
Adjustable range of RESP alarm upper & lower limits:

| | Max upper limit | Min lower limit | Adjusted amount per time |
|---|---|---|---|
| RR adult | 160 | 5 | 1 |
| RR infant/ newborn | 160 | 5 | 1 |

For adults, infants and newborns, the maximum upper limits are all 160 and the minimum lower limits are all 5.

- Default setting: Users can select this item to enter the RESP Default Setting dialogue, then further select Manufacturer Default Setting or User Default Setting. After selecting one of them and exiting the dialogue, the system will pop up a new dialogue asking the users to confirm the selection.

### 12.6.5 RESP alarm information & reminders

In case the alarm record function under relevant menus is enabled, those physical alarms caused because relevant parameters exceed relevant alarming limits will activate the recorder to automatically output alarming parameter values and relevant measurement waveforms.
The physical alarms, technical alarms and reminders possible happening during RESP measurement are listed as follows:

Physical alarms:

| Reminders | Causes | Alarming levels |
|---|---|---|
| RR TOO HIGH | RESP measurement value higher than the set upper limit | User defined |
| RR TOO LOW | RESP measurement value lower than the set lower limit | User defined |
| RESP choke | No RESP values measured within certain time interval | High |

Technical alarms:

| Reminder | Cause | Alarming level | Solution |
|---|---|---|---|
| RESP alarm limit error | Function/ safety failure | High | Stop using the RESP alarm function and contact MEDIAID for support. |

Reminders (including general alarming information):

| Reminder | Cause | Alarming level |
|---|---|---|
| RR measurement out of scope | RR measurement value out of measurement scope | High |

## 12.7 Maintenance & Cleaning

**Warning**

Before cleaning the monitor or sensor, users must turn of the equipment and break the AC power supply. In case of any appearance of ECG cable damage or aging, users should change with new cables.

■ Cleaning

Surface of the monitor and sensor can be swept by medical alcohol, naturally dried or cleaned by clean and dry clothes.

■ Disinfection

To avoid long-term damage to the equipment, we recommend you to disinfect the products only when deemed as necessary under the maintenance plan of your hospital. We also recommend you to clean the products before disinfection.

Recommended disinfection materials for the monitor:

- ethanol: 70% alcohol, 70% isopropyl
- glyoxyl

■ Sterilization

To avoid long-term damage to the equipment, we recommend you to sterilize the products only when deemed as necessary under the maintenance plan of your hospital. We also recommend you to clean the products before sterilization.

# Chapter 13 $SpO_2$ Monitoring

## General Information

$SpO_2$ measurement of this monitor is a continuous and non-invasive method of measuring $SpO_2$ through a $SpO_2$ detector. The $SpO_2$ volume recording parameter is used to measure arterial $SpO_2$, i.e., percentage of oxyhemoglobin. For example, if there are 97% of hemoglobin molecules combining with oxygen out of the arterial red blood cells, the blood will be described as $SpO_2$ 97%, and the $SpO_2$ reading on the monitor will be 97%. $SpO_2$ values thus can show the percentage of oxygen-attached hemoglobin molecules (will form oxyhemoglobin), meanwhile, $SpO_2$ volume recording parameters can also provide the PR signals and volume recording waves.

Measurement normally can be done through finger $SpO_2$ detector for adults and hand or foot detector for infants. Such detectors are directly connected with the $SpO_2$ module socket of the monitor.

1) display of arterial $SpO_2$ values in percentage in the parameter value;
2) PR;
3) Wave appearance of $SpO_2$.

## Method Statement

The basic algorithm of $SpO_2$ module is mainly based on the following three points:

- Oxyhemoglobin and deoxygenated hemoglobin have different adsorption on red and infrared lights (a spectroscopy theory);
- During pulse, arterial blood volume and energy absorbed by blood are variable (referring to pulse volume diagrams);
- Arterial- vein is convertable, and absorption discrepancy of vein blood is the main noise factor during pulse.

The basic method of $SpO_2$ module is to have red and infrared lights going into capillary and then measure periodic light absorption change so as to determine the $SpO_2$ values. Inside a $SpO_2$ detector, the diode in red and infrared light sources is the light source, and the corresponding photo-diode is a photo detector.

Traditional $SpO_2$ measurement method assumes all the pulse components inside light absorption signals are caused by filling of arterial blood and calculates ratios of arterial components (AC) absorbed by red and infrared lights of respectively 660nm and 940nm wavelength over direct component (DC):

**Red(660) = AC(660) / DC(660)** **(1)**

**Ir(910) = AC(910) / DC(910)** **(2)**

and further calculates the absorption ratio between such two light waves:

**R = Red(660) / Ir(910)** **(3)**

This calculated R value can be used to look for the corresponding $SpO_2$ value on the established R-$SpO_2$ table, which is determined based on blood-gas analysis results drawn from blood-gas analyzers against healthy adult volunteers under an activated oxygen deficient organization.

**Attention**

For red LED, normally the wavelength measurable for a sensor is 660nm±3nm, and for infrared LED, 910nm±10nm. The maximum optional output power for a LED is 4mW.

At the normal status or single failure status, the maximum energy conducted to the detector makes the touch temperature between the detector and organization is no more than 41℃.

## 13.1 Warning Information

**Warning**

Pulse wave out of RESP monitoring can not be used.

**Warning**

In case a patient tends to be short of oxygen, users should use the oximeter for lab use to analyze his/ her blood sample so as to fully understand his/ her conditions.

**Warning**

Expect those unusual situations listed here, alarms happening during alarm silence period will only be displayed in visual alarm symbols.

**Warning**

When an external equipment is connected with the serial, users should measure leakage current of the monitor; such leakage current should be less than 100mA.

**Warning**

To ensure patient is under insulation, users can only connect this monitor with other equipments with insulating circuits.

**Warning**

Avoid to connect with a wall switches or socket controlled by a light regulator.

**Warning**

Like other medical equipments, this monitor should be carefully connected with cables so as to keep patient from being wrapped or even choke.

**Warning**

Hemoglobin may wrongly increase readings, and the extent of increasing is near to the current hemoglobin quantity. Dyestuff and other materials containing dyestuff. besides of increasing readings wrongly, may also change coloring of artery.

**Warning**

Avoid using the monitor and sensor during use of MRI equipments, because the inductive current may create potential damage. The monitor may affect imaging of MRI equipments, while MRI equipments may also affect accuracy of $SpO_2$ measurement.

**Warning**

In case of existence of Hb-CO, MetHb or chemical dyestuffs, the $SpO_2$ values may higher than actual.

**Warning**

Before detection, users should check sensor cables; if you plug out a $SPO_2$ cable from its slot, the screen will display "$SpO_2$ SENSOR OFF" and make audio alarming.

**Warning**

In case of any damage appearance found with the sensor package or sensor, don't use the sensor but return it to the manufacturer.

**Warning**

Cables of electrosurgery equipments should not be wrapped with sensor cables.

**Warning**

Don't put the sensor onto a body part with an arterial duct or vein injection tube.

**Warning**

Long-time continuous monitoring may increase unexpected skin changes such as sensitiveness, redness, blister, and necrosis. It's very important to check positioning of the sensors for newborns and strictly follow skin change to properly touch skin. Users should check positioning of the sensor every 2-3 hours and shift properly if there is any change with the skin; certain patients may require more frequent checks.

**Attention**

Don't measure $SPO_2$ and NIBP on the same body at the same time, as blood blocking during NIBP measurement will affect $SPO_2$ values.

**Attention**

- Confirm nails have sheltered light windows.
- Cables should be gathered at one side of the hand back.

**Attention**

$SPO_2$ values are always displayed at a fixed position; when users select HR source as "$SPO_2$" or "Concurrent" under the ECG Setting menu, PR values will be displayed.

**Attention**

$SPO_2$ is not proportional to PR.

## 13.2 $SpO_2$ Monitoring

**Attention**

- $SpO_2$ values are always displayed at a fixed position.
- PR values are displayed on in the following cases:

1) HR FROM under the ECG menu is set as "PLETH" or "BOTH";
2) HR FROM under the ECG menu is set as "Auto" while there are no ECG signals.

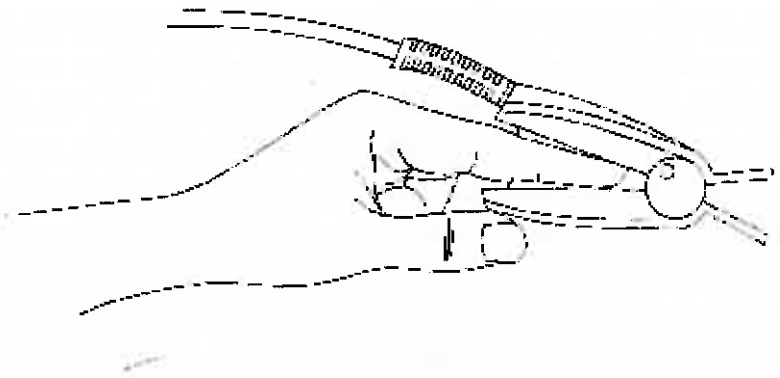
**Attention**

When a $SpO_2$ module is closed, the PITCH TONE function will be automatically closed.

### 13.2.1 monitoring procedures

$SpO_2$ volume recording measurement:

1) Turn on the monitor;
2) Paste the sensor on a proper position of the patient finger;
3) Insert the connector at the other side of the sensor cable into the $SpO_2$ sensor port of the $SpO_2$ module.



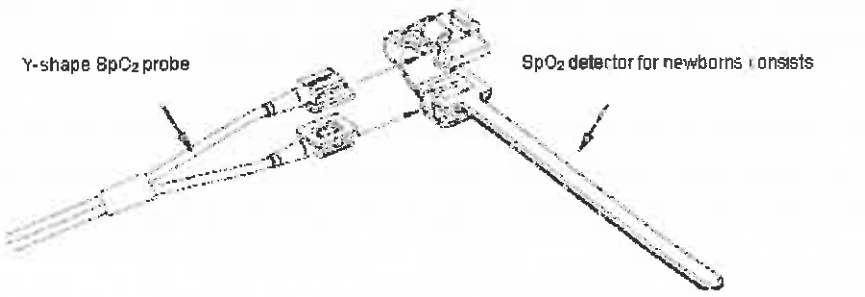
Pic 13-1 Positioning of the sensor

- $SpO_2$ volume recording measurement for newborns

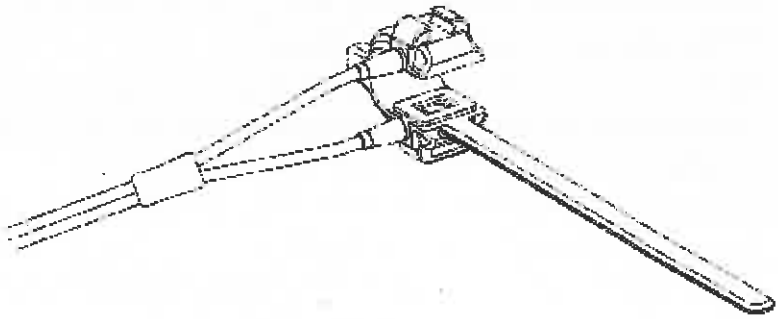
The $SpO_2$ volume recording measurement process for newborns is basically same as that for adults. The following is introduction on the $SpO_2$ detector for newborns and its positioning method.

1. $SpO_2$ detector for newborns

A $SpO_2$ detector for newborns consists of a Y-shape $SpO_2$ probe and a cover. Respectively insert the LED terminal and PD terminal of the Y-shape $SpO_2$ probe into the upper and lower slots of the cover (as shown in Pic 13-3), and the completed combination is shown in Pic 13-2.



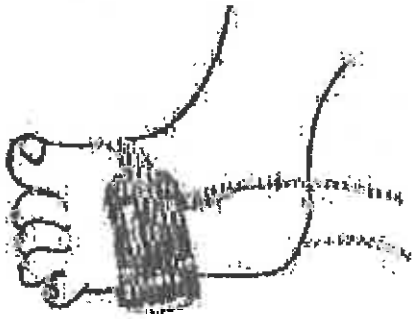

Pic 13-2 $SpO_2$ detector for newborns (1)



Pic 13-3 $SpO_2$ detector for newborns (2)

2. Positioning of a $SpO_2$ detector for newborns

Clamp the $SpO_2$ detector onto a hand/ foot of a newborn (as shown in Pic 12-4). Hold the $SpO_2$ detector, pull on the tape and put the V-edge along one side of the tape inside the V-slot along the corresponding side of the cover, properly extend the tape (for about 20mm) and put the V-edge along the other side of the tape inside the V-slot along the corresponding side of the cover, release the tape, make sure the two sides of V-edges of the tape have been matched with the cover, then insert the tape into the first latch for securing, as shown in Pic 13-6. In case the tape is too long, it may be inserted into the second latch. Users must follow such a method to secure the $SpO_2$ detector so as to make sure the opto-electronic device stat at a position to be correctly faced. Meanwhile, users must pay attention to control pulled length of the tape, otherwise measurement will be not so accurate and blood cycling may be seriously blocked.



Pic 13-4 Positioning of a $SpO_2$ detector for newborns

**Attention**

If the test position and detector fail to be positioned correctly, $SpO_2$ readings may be inaccurate, and possibly pulse wave will not be searched for $SpO_2$ monitoring. In such scenario users should re-position the test position and detector.

Over-movement of the measurement position may cause inaccurate measurement result. In such case users should calm down the relevant patient or change the measurement position so as to reduce effects of over-movement on measurement.

**Warning**

Over long time of continuous monitoring, users should check the end recycling and skin conditions at the measurement position every 2 hours. In case any bad change is found, users should timely change the measurement position.

Over long time of continuous monitoring, users should periodically check positioning of the detector, avoiding that any movement changes the detector position and further affect measurement accuracy.

### 13.2.2 Measurement restriction

**Measurement restriction**

In case the measurement results look not so accurate, users should take other methods to check life signs of the relevant patient and check the equipment.

**During operation, the following factors may affect accuracy of $SpO_2$ measurement:**

- A wrong sensor is used;
- High-frequency electric disturbance, such as disturbance generated from the system itself or electrosurgery equipments connected with the system;
- A photo-oximeter and $SpO_2$ sensor are used during MRI process, as the inductive current may cause burns;
- Dyestuff inside blood vessel, such as indocyanine green and methylene blue;
- Frequent movement by patient;
- Light radiation from outside;
- Improper installation of the sensor or improper touching position with objects;
- improper sensor temperature (ideal temperature should be 28℃-37℃);
- The sensor is put onto body with blood pressure cuff, arterial duct or vein tube;
- Contents of non-functional Hb such as COHb and MetHb;
- $SpO_2$ over low;
- Hemoglobin (such as hemoglobin and transferring) fail to function properly;
- Over exposed under light, such as surgical lamp (especially those taking xenon as the light source), CUB light, fluorescent light, infrared heating light or direct sunshine (users can use black or non-transparent materials to shelter the sensor from exposed to sunshine);
- Vein vibration in rhythm;
- Monitor used during defibrillation, possibly making readings inaccurate within a short duration;
- Bad microvascular perfusion at the test position;
- Shock, anemia, low temperature and application of vessel shrinking Drugs, which all can reduce the arterial blood flow to a non-measurable level;
- Measurement is also up to absorption of lights with special wavelengths by oxyhemoglobin and deoxygenated hemoglobin. Existence of other materials that absorbs the same wavelengths, such as carbonated hemoglobin, hemoglobin, methylene blue and indi carmine, will make artificial or low $SPO_2$ values.

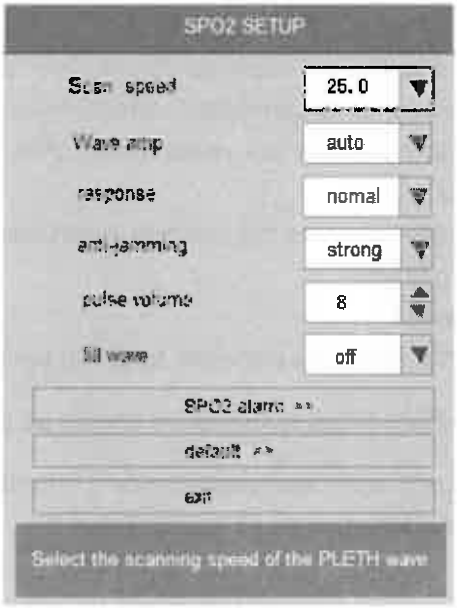
**Any of the following cases may cause loss of pulse signals:**

- Tough sensor;
- over lighting, such as under surgical lamp, CUB light or sunshine);
- SpO2 sensor and pumped blood pressure cuff are connected on the same body;
- Patient with low blood pressure, serious vessel shrinkage, anemia or low body temperature;
- Arterial vessel blocking near the sensor;
- Patient with cardiac arrest or shock.

## 13.2.3 $SpO_2$ menu

**$SpO_2$ Setting menu**

Users can rotate the knob and move the cursor onto the $SPO_2$ hotkey in the parameter area, then press the knob the enter the $SpO_2$ Setting menu.




Pic 13-5 $SPO_2$ Setting menu

- Scanning speed

Optional scanning speeds for $SpO_2$ volume recording waveform: 12.5 and 25.0mm/s

- Waveform amplitude

Users can set the gain for pulse volume waves out of the given four options: X 0.5, X1.0, X2.0, and Auto, where Auto means the system will automatically adjust the waveform amplitude.

- Response time

Three options: quick, normal, and slow, corresponding to average time of 4, 8 and 16 seconds in calculating $SpO_2$ values.

- Waveform disturbance resistance

Users can set strong or weak capability for disturbance resistance of pulse volume waves.

- Pulse volume: "0"-"10" is available, where "10" for the maximum volume and "0" for volume off.
- Fill waveform

Users can select whether the fill the pulse volume waveforms.

- Default setting: Users can select this item to enter the $SPO_2$ default setting dialogue, where users are given two options, i.e., Manufacturer Default Setting and User Default Setting. After users select one and exit this dialogue, the system will pop up a new dialogue asking users to confirm the selection.

**Warning**

Setting the $SpO_2$ alarm upper limit to be 100% means to release the upper limit. However, high $SpO_2$ level will make newly-born infants infected with retrolental fibroplasias, thus the $SpO_2$ alarm upper limit must be carefully selected based on common acknowledged clinical practice.

- $SpO_2$ alarm: Users can select this item to enter the $SpO_2$ alarm dialogue:


Pic 13-6 $SpO_2$ alarm setting

- Alarm level: used to set alarm levels and, during $SpO_2$ alarming, for alarm reminder and saving. Options include "High", "Middle", "Low", and "Off", "High" for the most serious alarm event, and if "Off" is selected, no alarm will be made and there will be a " " sign displayed beside $SpO_2$ value in the parameter area.
- Alarm Print: If "On" is selected, the recorder will output during $SpO_2$ alarming.
- $SpO_2$ alarm upper & lower limits: When the actual $SpO_2$ values exceed the upper & lower limits set here, there will be alarming.
- PR alarm upper & lower limits: When the actual PR values exceed the upper & lower limits set here, there will be alarming.

$SpO_2$ & PR adjustable limits:

| Parameter | Max upper limit | Min lower limit | Adjustable amount each time |
|---|---|---|---|
| $SpO_2$ | 100 | 0 | 1 |
| PR | 254 | 0 | 1 |

Default alarming ranges for $SpO_2$ and PR:

| Parameter | | Max upper limit | Min lower limit |
|---|---|---|---|
| $SpO_2$ | Adults | 100 | 90 |
| | Children | 100 | 90 |
| PR | Adults | 120 | 50 |
| | Children | 160 | 75 |

**PITCH TONE function**

In case of any change in $SpO_2$ values, if the Pitch Tone item under the ECG Setting menu is set out of "0", i.e., the Pitch Tone function is on, the heartbeat audio will automatically change its tone following $SpO_2$ change. This monitor provides 20 tone modulations, giving higher tone of heartbeats for higher $SpO_2$ values.

The 20 tones under the PITCH TONE function are not adjustable through menu, but their volume can be controlled. In case under the ECG Setting menu the "HR FROM" item is selected with "PLETH", volume of PITCH TONE will be controlled by "Pulse Volume" under the $SPO_2$ Setting menu. But if the "HR FROM" item is selected with other items, volume of PITCH TONE will be controlled by "Heartbeat Volume" under the ECG Setting menu.

**Attention**

While the $SpO_2$ module is closed, the PITCH TONE will be automatically closed.

## 13.3 Alarm information & reminders

**$SpO_2$ alarm information**

When the alarm record function under certain menus is on, those physical alarms caused because relevant parameters exceed the specified alarm limits will automatically output alarm parameter values and relevant measurement waveforms.

Possible physical alarms, technical alarms and reminders during $SpO_2$ module measurement are as listed here:

Physical alarms:

| Reminder information | Reasons | Alarming levels |
|---|---|---|
| $SPO_2$ TOO HIGH | $SpO_2$ measurement value higher than alarm upper limit | User defined |
| $SPO_2$ TOO LOW | $SpO_2$ measurement value lower than alarm lower limit | User defined |
| PR TOO HIGH | PR measurement value higher than alarm upper limit | User defined |
| PR TOO LOW | PR measurement value lower than alarm lower limit | User defined |

Technical alarms:

| Reminder information | Reasons | Alarming levels | Solutions |
|---|---|---|---|
| $SPO_2$ sensor OFF | $SPO_2$ sensor drop off from patient or monitor | Low | Make sure the sensor is installed onto patient finger or other body parts and the monitor and cables are connected properly |
| $SPO_2$ module initialization error | $SPO_2$ module error | | Stop using the $SPO_2$ module measurement function and contact MEDIAID for support. |
| $SPO_2$ module initialization error 1 | | | |

| | | | |
|---|---|---|---|
| $SPO_2$ module initialization error 2 | | | |
| $SPO_2$ module initialization error 3 | | | |
| $SPO_2$ module initialization error 4 | | | |
| $SPO_2$ module initialization error 5 | | | |
| $SPO_2$ module initialization error 6 | | | |
| $SPO_2$ module initialization error 7 | | | |
| $SPO_2$ module initialization error 8 | | | |
| $SPO_2$ module communication failure | $SPO_2$ module error or communicatio n error | | Stop using the $SPO_2$ module measurement function and contact MEDIAID for support. |
| $SPO_2$ alarm limit error | Function / safety failure | | Stop using the $SPO_2$ module measurement function and contact MEDIAID for support. |
| PR alarm limit error | Function / safety failure | | Stop using the $SPO_2$ module measurement function and contact MEDIAID for support. |

Reminder information (including normal alarms):

| Reminder information | Reasons | Alarming levels |
|---|---|---|
| $SPO_2$ measurement out of scope | $SPO_2$ measurement value out of scope | High |
| PR measurement out of scope | PR measurement value out of scope | High |
| Searching pulse | $SpO_2$ module is searching pulse | No alarm |
| Pulse not found | $SpO_2$ module has failed to detect $SpO_2$ signals | High |

## 13.4 Sensor & Accessories

Only sensors provided by MEDIAID Company can be used for $SPO_2$ measurement; other types of sensors may cause abnormal measurement results.

Improper use of sensor, such as sensor over-tough, may cause organization injury. Please follow the sensor use guide to check sensor positioning, making sure the touched skin is at good condition and the sensor is connected well and at right position.

**Careful**

Don't use damaged sensors or sensors without sheltering on photonic components. Don't immerse sensors into water or cleaning liquids as the sensors and connectors are not waterproof. Don't use radiation, vapor or ethylene oxide for disinfection.

**Careful**

Don't use damaged cables or immerse cables into water or cleaning liquids as the

sensors and connectors are not waterproof. Don't use fumigant or ethylene oxide for disinfection.

- Notices for using a detector

1. Select a proper position for the detector; patient forefinger is the most ideal choice, while thumb and little fingers are also recommended.
2. Patient finger top must be correctly inserted into detector bottom.
3. SpO2 detector cables should be laid along hand back of patients and parallel to arm.
4. Connect the detector cable with the monitor and check whether the operation is correct.

- Sensor selection

Selection a sensor must consider patient weight, proper saturation, positioning of this sensor and monitoring time. For more information, please refer to the following table or contact MEDIAID. Only sensors and cables provided by are allowed for use, please follow the guide to select proper sensors and comply with all the alarms or reminders during use.

High-intensity light sources, such as surgical lamps (especially those taking xenon as the light source), CUB lights, fluorescent lights, infrared heating lights or direct sunshine may affect performance of $SpO_2$ sensors. To ensure normal use of sensors, if necessary,

Table: Mediaid Sensors

| S.No. | Sensor | Part Number |
|---|---|---|
| 1 | Universal Hinged Sensor, Compushield connector, 30" cable | POX050-100S |
| 2 | Universal Hinged Sensor, Compushield connector, 96" cable | POX050-105S |

**Sensor cleaning and reuse**

Reused sensors must be cleaned in the following procedures:

- Don't connect the monitor with a detector without cleaning or disinfection
- Detectors must be cleaned and disinfected before used to new patients.
- Use soft clothes wetted with water or soft cleaning liquid to sweep detectors and patient body surface to be touched.
- It is recommended to use isopropyl alcohol as disinfection liquid to disinfect the detector, sweep the detector and disinfect patient body surface to be touched.

Recover cohesiveness of one-time sensors with adhesive:

- Keep transmitter and detector windows clean; in case the adhesiveness is sufficient to bind with skin, a one-time sensor can be reused onto the same patient.
- Before changing a patient, users should use a cotton ball wet with 70% alcohol to sweep the sensor and dry it in the air so as to partially recover the cohesiveness.

**Warning**

To prevent from cross infection, a one-time sensor can only be used for one patient.

**Attention**

In case a sensor fails to continuously display pulse, this sensor may be positioned wrongly and users need re-select the connecting position for this sensor.

**Careful**

It is prohibited to reuse any one-time sensor.

**Attention**

Be careful to connect cables so as to reduce the possibility of wrapping patients.

**Careful**

Don't immerse patient cables into any liquid. Don't use vapor jet or ethylene oxide to disinfect patient cables.

- Storage temperature: -20℃-+70℃.

**Warning**

Please make sure the power supply has been switched off or power cable plugged out before you clean the monitor and sensor.

Cleaning

- Use cotton balls or soft clothes immersed with medical alcohol to sweep the sensor, and then dry the surface with dry clothes. Such method is also applicable to clean the lighting and receiver parts.

- 3% hydrogen peroxide or 70% isopropanol as well as other applicable agents may be used to clean cables, but the connecting part of a sensor must be free from such agents.

# Chapter 14 NIBP Monitoring

## 14.1 General Information

NIBP measurement is applied with the vibration method, which is applicable for adults. Measurement modes: Manual, Automatic and Continuous. Every mode shows the systolic pressure, average pressure and diastolic pressure.

- "Manual" mode: one time of measurement only
- "Automatic" mode: continuous measurement in the time interval of 1/2/3/4/5/10/15 /30/60/90/120/180/240/480 (selected by users) minutes.
- "Continuous" mode: continuous measurement within 10 minutes

**Warning**

1) Don't apply NIBO measurement onto a patient with sickle cell disease or any skin damage or expected to have skin damage.
2) For patients with serious DIC, users should decide whether to apply NIBP measurement based on clinical assessment, as there may have blood tumor at the touching area between body and cuff.
3) In case of measurement on infants and newborns, users must ensure to select the correct mode setting (refers to Patient Information Menu setting). A wrong mode may threaten patient safety, as adult blood pressure levels are too high to be applied on infants and newborns.

## 14.2 NIBP Monitoring

### 14.2.1 NIBP Measurement

**Warning**

- Before measurement, users must make sure the selected monitoring mode is applicable for the patients (adult, infant or newborn).
- Don't install a cuff on a body part with vein duct or other tubes. During cuff pumping, slow infusion or infusion blocking may cause damage to the surrounding body area.

**Warning**

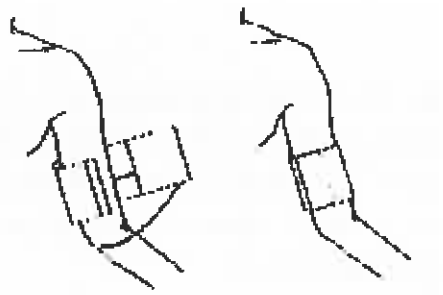
The pumping pipe connecting blood pressure cuff and the monitor must be smooth, without any entanglement.

1. Select a pressure cuff that is appropriate for the size of the patient.

**Note:** A cuff that is too narrow for the limb will result in erroneously high readings. The correct size of the pressure cuff for a given patient has, among other considerations, a direct bearing on the accuracy of the obtained NIBP measurements. Base your selection of the cuff size on the limb circumference of the patient. The design dimensions of the cuffs and their intended uses are based on recommendations of the American Heart Association.

**WARNING:** Do not squeeze the rubber tube on the cuff. Do not allow liquid to enter the connector socket of the monitor. Do not wipe the inner part of the connector socket when cleaning the monitor.

2. Attach cuff hose to NIBP connector.
3. In accordance with the following method (Pic 14-1), tie the blood pressure cuff on upper arm of upper leg of a patient.
   - Confirm the cuff is fully vented.
   - Select a cuff in proper size for the patient, and make sure the mark is just along the proper vein and cuff tie the body non-toughly, otherwise remote body part may have color change or even ischaemia.



Pic14-1 Use of a cuff

**Attention**

Cuff width should be 40% of body perimeter (50% in case of newborns) or 2/3 of upper arm length. Width of the pumping part of a cuff should be 40% of body perimeter, as long as to surround 80%-100% of the body. Cuffs in improper size will generate wrong readings. In case of size problem with a cuff, users should change it with a bigger one so as to reduce mistakes.

Ault/ newborn/ infant recyclable cuff

| Patient type | Body perimeter | Cuff width | Length of pumping pipe |
|---|---|---|---|
| Newborn | 10～19cm | 8cm | 1.5m or 3m |
| Infant | 18～26cm | 10.6cm | |
| Adult 1 | 25～35cm | 14cm | |
| Adult 2 | 33～47cm | 17cm | |
| Leg | 46～66cm | 21cm | |

Newborn/ infant one-time cuff

| Size | Body perimeter | Cuff width | Length of pumping pipe |
|---|---|---|---|
| 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 | |

4. Confirm correctness of the monitoring mode (as displayed on the information area); if requiring to change the monitoring mode, users need go to the "PATIENT SETUP" item under the Main menu and change "PAT TYPE".
5. Select the measurement mode under the NIBP menu. Refer to the following Operational Guide for details.
6. Press the START button on the front panel to start pressure measurement.

**Operational guide**

1. Conduct one time of Automatic measurement

Enter the "NIBP Setting" menu, select a proper time interval at the "Interval" item, and press the "START" button on the front panel. Then the system will start automatic pumping measurement in the specified time interval.

**Warning**

If NIBP measurement under the Automatic mode lasts too long, body touching with the cuff may have allergic purpuras, ischemia and neural injury. During monitoring on patients, users should often check color, warmness and sensitiveness of remote body parts. Once any abnormal phenomenon is found, users should put the cuff at another location or immediately stop measuring blood pressure.

2. Stop automatic measurement

At any moment during the automatic measurement process, press the START button will stop the automatic measurement.

3. Conduct one time of Manual measurement

- Enter the "NIBP Setting" menu, select the "Interval" item and set its value as "Manual", then press the START button on the front panel so as to start manual measurement.
- During spare time of an automatic measurement, press the START button will start a manual measurement; then if users press the START button again, the manual measurement will stop and the automatic measurement will continue.

4. Conduct a manual measurement during automatic measurement process

Just press the START button on the control panel.

5. Stop a manual measurement

Re-press the START button on the control panel.

6. Conduct a continuous measurement

Enter the "NIBP Setting" menu and select the "Continuous" item to start a continuous measurement, which will always last 10 minutes.

**Warning**

Continuous time for short-period mode should be controlled within 15 minutes; after completion of such short-period mode, the monitor should return to manual mode or long-period mode.

**Warning**

If NIBP measurement under the Automatic mode lasts too long, body touching with the cuff may have allergic purpuras, ischemia and neural injury. During monitoring on patients, users should often check color, warmness and sensitiveness of remote body parts. Once any abnormal phenomenon is found, users should put the cuff at another location or immediately stop measuring blood pressure.

7. Stop continuous measurement

At any moment during the continuous measurement process, press the START button will stop the continuous measurement.

**Attention**

In case of suspecting reading accuracy, users should take possible methods to check life signs of patients before checking the monitor,

**Warning**

In case any liquid is sprayed onto the equipment or its accessories, especially when the liquid may enter the tube or monitor, please contact with the maintenance department of your hospital.

**Measurement restriction**

Vibration measurement has its restriction subject with patient conditions. This measurement method looks for regular pulse waves generated from arterial pressure, so when patient conditions make this wave detection method hard to work, measured values are no more reliable and measurement time last longer. Users must understand the following cases will disturb the measurement method, making measured press unreliable or measurement time extended. In such cases, patient conditions disable measurement to be continued.

- Patient movement

In case a patient is moving, shaking or convulsing, measurement will be unreliable or even impossible, as such scenarios will disturb detection of arterial pulse and extend measurement time.

- Arrhythmia

In case a patient shows irregular heartbeats resulted from arrhythmia, measurement will be unreliable or even impossible, while measurement time will also be extended.

- Heart-lung machine

If a patient is connected with an artificial heart-lung machine, measurement can't be realized.

- Pressure change

Within certain time if the patient blood pressure immediately changes while users are analyzing arterial pulse so as to obtain measurement values, measurement will be unreliable or even impossible.

- Serious shock

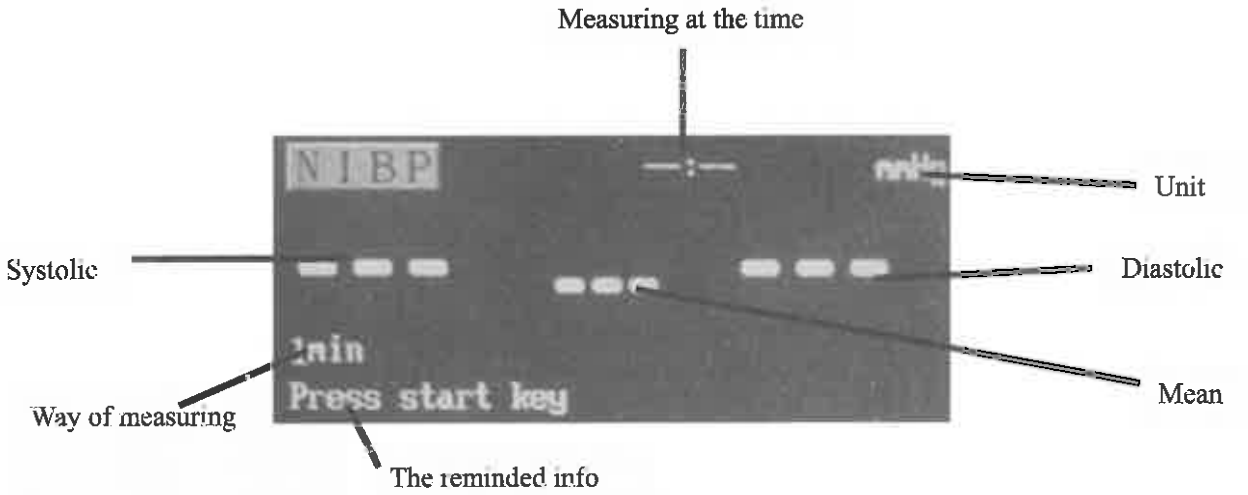
In case a patient is under serious shock or extreme low temperature, measurement will be unreliable as reduction in blood flowing peripherally will result reduction in arterial pulse.

- HR limits

In case of HR lower than 40bpm or higher than 240bpm, no blood pressure measurement can be done.

### 14.2.2 NIBP Parameter Setting & Adjustment

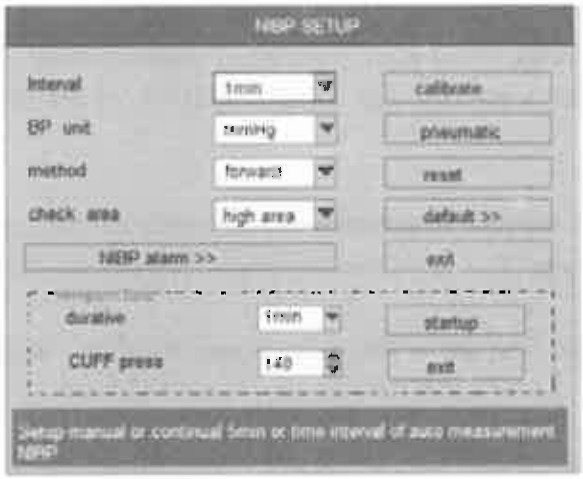
NIBP measurement results and relevant information are laid on screen as follows:




Pic14-1 NIBP Parameter

## 14.3 NIBP Setting Menu

Rotate the knob, move the cursor onto the NIBP hotkey in the parameter area, and then press the knob to enter the NIBP Setting menu.




Pic14-2 NIBP Setting menu

- Interval

Time interval (Unit: minute) for automatic measurement: 1, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240, 480 minutes, Manual, and Continuous. After users select an interval, there will be a display of "Please press the 'START/STOP' button" in the NIBP reminder area, then users just press the button to start pumping for the first time of automatic measurement. To end the automatic measurement and return to the manual mode, users need only select "Manual" during the measurement interval.

- Blood pressure unit

mmHg or kPa.

- Measurement method

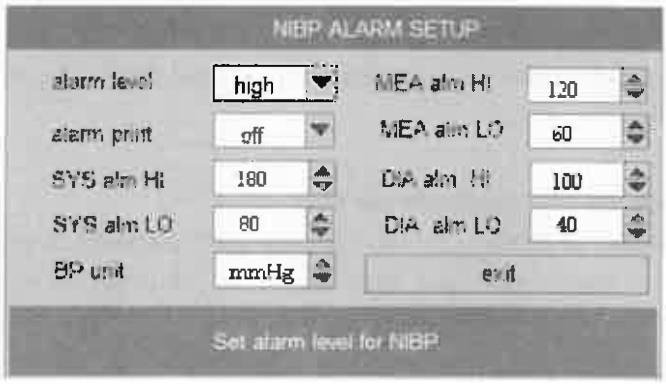
Users can select a method of NIBP measurement from "Forward", "Rewind" and "Fast Forward".

- Check Area

Different search ranges are used to measure different ranges of blood pressure values. "ALL AREA" is applicable for high pressure measurement, "LOW AREA" for low pressure measurement, and "HIGH AREA" for general research.

- NIBP alarm

Move the cursor onto "NIBP Alarm" and press the knob to pop up the NIBP Alarm Setting menu:




Pic14-3 NIBP Alarm Setting

- Alarming levels: Used to set alarming levels or in case of no NIBP alarms used for alarming reminders and saving. Optional levels are "High", "Middle" and "Low" , where "High" is the highest alarm. There is also an "OFF" item representing to close the NIBP alarming function, in such case there will be a sign beside the NIBP in the parameter area.
- Alarm print: Users can select "On" to output through recorder when pressure alarms happen
- Pressure alarms are based on the specified upper & lower limits; there will alarms once pressure is higher than the upper limits or lower than the lower limits. Systolic pressure, average pressure and diastolic pressure can have their respective alarming treatment.

Adjustable range for alarm upper & lower limits:

Adult

Systolic pressure 40～270 mmHg

Diastolic pressure 10～215 mmHg

Average pressure 20～235 mmHg

Infant

Systolic pressure 40～200 mmHg

Diastolic pressure 10～150 mmHg

Average pressure 20～165 mmHg

Newborn

Systolic pressure 40～135 mmHg

Diastolic pressure 10～100 mmHg

Average pressure 20～110 mmHg

- Calibration

The manufacturer recommends to use pressure meter or mercurial sphygmomanometer with calibrated precision higher than 1mmHg for calibration.

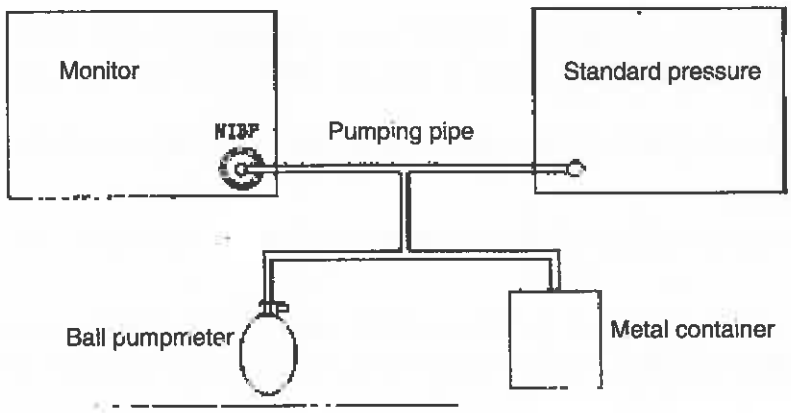
Users can select the Calibration item to start calibration, while this item turns to be "Stop calibration"; if at such moment press the button, the system will stop calibration.

**Warning**

Calibration for NIBP measurement should be done every two years (or conducted following the maintenance plan of your hospital). Please follow the following details to check its performance.

**Calibration procedures of a pressure sensor:**

Use a metal container of 500ml±5% to replace cuff. Connect a calibrated standard pressure meter with inaccuracy less than 0.8mmHg, T-interface ball pump and the pumping tube into the NIBP Connectors on the module. Set the monitor to be under "Standard" mode, then take the ball pumps to pump the metal container to be 0, 50 ad 200mmHg; in such cases values of standard pressure meter and press values indicated on the monitor will differ within 3mmHg, otherwise please contact with our Maintenance engineers.




Pic14-4 NIBP calibration connection

- Gas Leakage Detection

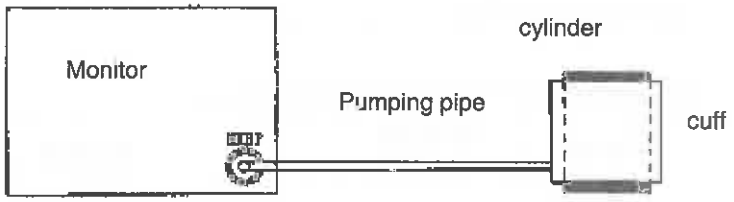
This button is used to detect gas leakage from the NIBP measurement pump. Users, after connecting with a NIBP cuff, can use this button to start NIBP pumping process so as to observe whether the NIBP gas route is sealed well. If such a gas leakage test gives a good result, the system will make no reminder, otherwise there will be the corresponding error reminder in the NIBP information area.

**Warning**

This gas leakage test, different from as described in the EN 1060-1 Standard, is only for users to simply detect gas leakage during NIBP pumping process. In case the system shows there is NIBP gas leakage, please contact with our maintenance engineers.

**Gas leakage detection process:**

1) Properly connect the cuff with the NIBP Port of the monitor.
2) Wrap the cuff onto a column body in proper size.
3) Enter the "NIBP Setting" menu.
4) Rotate the knob, move the cursor onto the "Gas Leakage Detection" item, then press the knob. There will be a reminder of "Gas leakage detection in progress" at bottom of the NIBP parameter area of the screen, showing the system has started executing gas leakage detection.
5) The system automatically pumps to the pressure of 180mmHg.
6) In about 20 seconds, the system will automatically open the air bleeder, indicating completion of gas leakage measurement.
7) No reminder information displayed on the NIBP parameter area doesn't mean no gas leakage within the system. Display of "Pump leaking..." means there is possible gas leakage with the gas route, in such case operators should check whether there is any loose connection, and after making sure of no more loose connection re-do the gas leakage detection; if the error reminder is still displayed, please contact with the manufacturer for repair.




Pic14-5 Connection of NIBP gas leakage detection

- Reset

Used to reset measurement status for the blood pressure pump; users, if pressing this button, will recover the pumping value of the pump to be its initial setting.

When the blood pressure pump works unwell while the monitor doesn't remind of any problem, users are recommended to use this button, as it will bring the blood pressure pump for self-detection and automatic recovery during any accidental pumping failure.

- Default setting: Users can select this item to enter the "NIBP Default Setting" dialogue, and then further select "Manufacturer default setting" or "User default setting". After making a selection and exiting the dialogue, users will see a pop-up dialogue requiring their confirmation.

Besides, the above-introduced NIBP test system of the monitor can be used in vein catheterization operations, while the cuff pressure and continuous time of such cuff pressure for vein catheterization operations can be set in the NIBP Test menu.

- Continuous time: how long will the cuff pressure lasts during vein catheterization: 1min, 2min, 3min, 4min, and 5min are optional.
- Cuff pressure: pressure value for cuff during vein catheterization, within 40mmHg-240mmHg.
- START: In case the NIBP measurement system is required during a vein catheterization operation, users just press this button to activate the function.

## 14.4 NIBP Alarming & Reminder Information

Provided that the alarming record function under relevant menu is turned on, those physical alarms activated because parameters exceed alarming limits may activate the recorder to automatically output alarming parameter values and the relevant measurement waveforms.

The following table lists various possible alarms during NIBP measurement process.

Physical alarms:

| Reminders | Causes | Alarming levels |
|---|---|---|
| NS TOO HIGH | Measured NIBP systolic pressure higher than specified alarming upper limit | User defined |
| NS TOO LOW | Measured NIBP systolic pressure lower than specified alarming lower limit | User defined |
| ND TOO HIGH | Measured diastolic pressure higher than specified alarming upper limit | User defined |
| ND TOO LOW | Measured diastolic pressure lower than specified alarming lower limit | User defined |
| NM TOO HIGH | Measured average pressure higher than specified alarming upper limit | User defined |
| NM TOO LOW | Measured average pressure lower than specified alarming lower limit | User defined |

Technical alarms 1 (displayed in the monitor information area):

| Reminders | Causes | Alarming levels | Solution |
|---|---|---|---|
| NS alarming limit error | Function/ safety failure | High | Stop using the NIBP module alarming function and contact MEDIAID for support. |
| NM alarming limit error | Function/ safety failure | High | Stop using the NIBP module alarming function and contact MEDIAID for support. |
| ND alarming limit error | Function/ safety failure | High | Stop using the NIBP module alarming function and contact MEDIAID for support. |

Technical alarms 2 (displayed in the reminder area below NIBP values):

| Reminders | Causes | Alarming levels | Solution |
|---|---|---|---|
| NIBP self-detection error | sensor or other hardware failure | High | Stop using the NIBP measurement function and contact MEDIAID for support. |
| NIBP communication error | Communication failure with NIBP measurement module | High | If the failure continues, stop using the NIBP measurement function and contact MEDIAID for support. |
| Cuff loose or out of connection | Cuff isn't properly wrapped or no cuff | Low | Wrap the cuff properly |
| Gas leakage with cuff pumping pipe | Damage with cuff, pipe or connector | Low | Check and change the part with leakage, and if necessary also contact MEDIAID for support. |
| Air pressure error | Fail to obtain stable pressure value, e.g., because of pipe wrapping | Low | Check whether there is pipe wrapping; if the problem continuous, contact MEDIAID for support. |
| Signal too weak | Cuff too loose or patient pulse too weak | Low | Apply other methods to measure blood pressure |
| Pressure out of scope | Measurement scope exceeding specified upper limit | High | Reset the NIBP measurement module; and if the problem continuous, stop using the NIBP measurement module and contact MEDIAID for support. |
| Arm movement | Big signal noise or irregular PR due to arm movement | Low | Make sure the patient is silent, without movement |
| Overpressure protection | Pressure exceeding specified upper limit | High | Re-measure. If the problem continuous, stop using the NIBP measurement module and contact MEDIAID for support. |
| Signal saturation | Significant movement | Low | Stop the patient from movement |
| Pump leakage | Leakage during the leakage test | Low | Check and change the part(s) with leakage, and if necessary, contact MEDIAID for support. |
| NIBP system failure | Blood pressure pump system running failure | High | Stop using the NIBP measurement function and contact MEDIAID for support. |
| Wrong cuff type | Current cuff type not suitable for patient | Low | Select proper cuff |
| Measurement time out | Measurement time over 120 seconds (for adults) or 90 seconds (for newborns) | High | Re-measure or apply other measurement methods |
| NIBP reset error | Module reset improperly | High | Re-use the reset function |
| Measurement error | During measurement the system can not execute measurement analysis or calculation | High | Check the cuff and re-measure while making sure the patient is silent during monitoring |

Reminders (displayed in the reminder area below NIBP values):

| Reminders | Causes | Alarming levels |
|---|---|---|
| Manual measurement... | Manual measurement in process | No alarm |
| Continuous measurement... | Continuous measurement in process | |
| Automatic measurement... | Automatic measurement in process | |
| Please press START | After you select the measurement time interval | |
| Measurement stopped | During measurement users press the START button to stop measurement | |
| Calibration... | Calibration in process | |
| Calibration stopped | Calibration completed | |
| Gas leakage detection... | Gas leakage detection in process | |
| Gas leakage detection stopped | Gas leakage detection is stopped | |
| Module reset... | Reset after NIBP module is loaded | |
| Manual reset... | NIBP reset (activated by users) in process | |
| Fail to reset | Fail to reset | |

## 14.5 Maintenance & Cleaning

**Warning**

- Don't compress the rubber pipe on a cuff.
- Keep water or cleaning liquids out of the connector socket in the front of the monitor, otherwise the equipment may be damaged.
- During monitor cleaning, users need only sweep the outer surface of the connector socket instead of its inner surface.
- In case a recyclable cuff is disconnected with the monitor or being cleaned, users should locate the cover cap above the rubber pipe so as to prevent any liquids from entering the rubber pipe and being absorbed into the module.

**Recyclable blood pressure cuff**

Normally cuff may be disinfected within a hot air cabinet under the high pressure, gas or radiation disinfection methods or sterilized by immersion into decontamination solutions. But users must take away the rubber bag when applying such methods. Cuff can not be dry washed but machine washed or hand washed only, and hand wash can extend service life of cuff. Before cleaning, users should take away the rubber bag and put back after cleaning and cuff drying.

Pic14-6 Change the tape inside cuff

To put the rubber bag back into the cuff, users should put the rubber bag near the cuff opening side, making the rubber pipe aligned with the long opening of the cuff, then vertically roll the rubber bag and insert it into the long opening, hold on the rubber pipe and cuff, and then shake the whole cuff until the rubber gag is positioned exactly. Insert the rubber pipe into the cuff, letting it go through the Port liner and extend out.

**One-time blood pressure cuff**

Cuffs for one-time use can only be used for one patient. Don't use the same cuff with different patients. Don't take one-time cuffs for disinfection or high-pressure vapor sterilization. However, users can use soap to clean one-time cuffs for infection control purpose.

**Attention**

To protect the environment, one-time blood cuffs after use must be recycled or properly treated.

# Chapter 15 TEMP Monitoring

## 15.1 TEMP Monitoring

This portable monitor can use two TEMP detectors at the same time, measuring two TEMP data so as to give the temperature difference.

**TEMP measurement setting**

- For one-time TEMP detectors, users must insert the TEMP cables into slots and then connect the detectors and such cables; for reusable TEMP detectors, users can directly insert them into slots
- Closely paste TEMP detectors with patient body.
- Turn on the system power supply.

**Warning**

Before monitoring users should check status of detector cables by plugging out the TEMP detector cable at Channel 1 from the corresponding Port, then the screen will display the error information "T1 sensor disconnected" and make audio alarming. Similar method may be applied to other channels.

**Warning**

TEMP detectors compatible with this monitor can only be used to measure temperature at body surface and rectum. For accurate readings, the required minimum measurement time is 5 minutes for body surface measurement or 1 minute for rectum measurement.

**Attention**

An one-time TEM detector can only be used once.

**Warning**

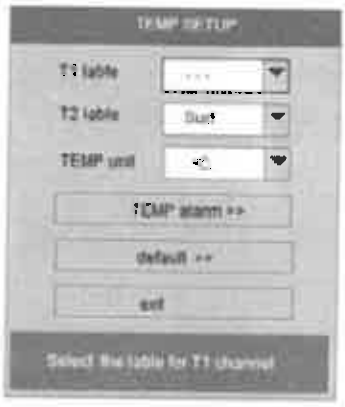
Be careful to use or store TEMP detector and cables; free detectors and cables should be wrapped into loose rolls. Tough wires inside the detector and cables, if any, may cause mechanical injury.

**Attention**

During monitoring process a TEMP detector will self-detect once per hour; such self-detection last for 2 seconds and will not affect normal work of the TESP monitor.

## 15.2 TEMP Setting Menu

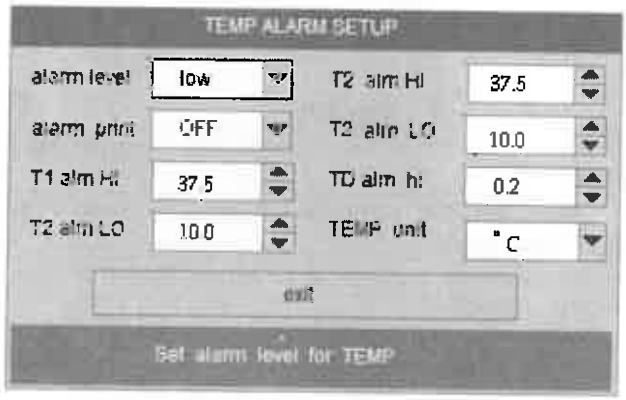
Users can use the knob to move the cursor onto the TEMP hotkey in the parameter area and press the knob to enter the TEMP Setting menu.



Pic15-1 TEMP Setting menu

- T1 Lable: for users to select the measurement position for the detector at T1 Channel, with "Body surface", "Anus" and "Rectum", etc. . available
- T2 Lable: for users to select the measurement position for the detector at T2 Channel, with "Body surface", "Anus" and "Rectum",etc.. available.
- TEMP unit: for users to select °C (or) °F.
- TEMP alarming:

Users can conduct TEMP alarming setting in the "TEMP Setting" menu: move the cursor onto the "TEMP Setting" item and press the knob to pop up the following menu:




Pic15-2 TEMP alarming setting

- Alarming levels: High, Middle or Low to be selected by users to set alarming levels, and High for the most serious alarm. Users can also select "Off" to turn off the alarming function, in such case there will be a "" indication beside the TEMP parameter area.
- Alarm print: Used to start or close the function of recording TEMP alarming. If users select "On", upon TEMP alarming, the record will output the alarm.

T1, T2 and TD alarms are based on the specified upper and lower limits; upon temperature higher than the upper limits or lower than the lower limits, there will be alarms.

T1 is for temperature at Channel 1, T2 for temperature at Channel, and TD for temperature difference between such two channels.

Adjustable range of TEMP alarm upper & lower limits:

| Parameters | Max upper limit | Min lower limit | Adjusted amount per time |
|---|---|---|---|
| T1, T2 | 50 | 0 | 0.1 |
| TD | 50 | 0 | 0.1 |

- Default setting: Users can select this item to enter the "TEMP Default Setting" dialogue, then further select "Manufacturer default setting" or "User default setting". After making a selection and exiting the dialogue, users will see a pop-up dialogue requiring their confirmation.

## 15.3 Alarming & Reminder Information

In case the alarm record function under relevant menus is enabled, those physical alarms caused because relevant parameters exceed relevant alarming limits will activate the recorder to automatically output alarming parameter values and relevant measurement waveforms. The physical alarms, technical alarms and reminders possible happening during TEMP measurement are listed as follows:

Physical alarms:

| Reminders | Causes | Alarming levels |
|---|---|---|
| TEMP1 TOO HIGH | TEMP measurement value at Channel 1 higher than the set upper limit | User defined |
| TEMP2 TOO LOW | TEMP measurement value at Channel 1 lower than the set lower limit | User defined |
| TEMP2 TOO HIGH | TEMP measurement value at Channel 2 higher than the set upper limit | User defined |
| T2 TOO LOW | TEMP measurement value at Channel 2 lower than the set lower limit | User defined |
| TD TOO HIGH | TEMP difference between the two channels bigger than the set limit for temperature difference | User defined |

Technical alarms:

| Reminders | Causes | Alarming levels | Solutions |
|---|---|---|---|
| TEMP1 NO SENSOR | TEMP cable at Channel 1 disconnected from the monitor | Low | Make sure the cable is reliably connected |
| TEMP2 NO SENSOR | TEMP cable at Channel 2 disconnected from the monitor | Low | Make sure the cable is reliably connected |
| TEMP1 alarming limit error | Function/ safety failure | High | Stop using the TEMP alarm function and contact MEDIAID for support. |

Reminders:

| Reminders | Causes | Alarming levels |
|---|---|---|
| TEMP1 measurement out of scope | TEMP measurement value at Channel 1 out of measurement scope | High |
| TEMP2 measurement out of scope | TEMP measurement value at Channel 2 out of measurement scope | High |

## 15.4 Maintenance & Cleaning

**Warning**

Users must turn off the equipment and shut down the AC power supply before cleaning the monitor or the connected sensor.

This monitor is compatible with YSI400 series TEMP detectors, whose cleaning procedures are as follows:

Reusable TEMP detectors:

1) Heating onto a TEMP detector can not be over 100°C (212°F), as such detector can only undertake 80°C (176°F) --100°C (212°F) within short period.
2) Detectors can not be vapor disinfected.
3) Only cleaning agents with alcohol can be used for disinfection.
4) During use of straight detectors, users should cover them with protective adhesive.
5) When cleaning detectors, users should use one hand to hold on one end and the other hand to downward hold wet lint-free cloth to wash detectors towards the connector direction.

**Attention**

If you are using a one-time TEMP detector, this detector is allowed to be re-disinfected or reused.

**Attention**

To protect the environment, one-time TEMP detectors should be recycled or properly treated.

# Chapter 16 $CO_2$ Monitoring (Optional )

## 16.1 General Principle

Principle of $CO_2$ measurement is primarily based on the fact that $CO_2$ molecule can absorb infrared ray. The measurement method is to send $CO_2$ to measurement chamber in the module through airway system; then irradiate one side of chamber with 4.26um infrared ray and measure with sensor the attenuation degree of the infrared ray received at the other side.

The attenuation degree of infrared ray and concentration of $CO_2$ have certain corresponding relation. The measured $CO_2$ concentration can be displayed by being converting into partial pressure under same temperature and pressure.

The relation between partial pressure of $CO_2$ and percentage of $CO_2$ concentration is given below:

$CO_2$ partial pressure (mmHg) =Percentage of $CO_2$ (%)* Pamp (ambient pressure mmHg)/100

$CO_2$ partial pressure (kPa) = $CO_2$ partial pressure (mmHg)/7.5

$CO_2$ module is in standby state when being electrified for the first time, waiting for commands sent by users, i.e., $CO_2$ module starts up only after selecting measurement mode.

Each start-up in the future will enter the state saved last time automatically, i.e., if the measurement mode is applied last time, the system will enter the measurement mode automatically when turning on the monitor for the next time, and the system need not resend the commands.

**Warning**

$CO_2$ module should be protected from crash and vibration.

$CO_2$ module $CO_2$ is only applicable to pediatric and adult, not applicable to neonate.

Excessively high concentration (>0.5%) in the environment may lead to inaccurate measurement.

**Note**

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

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

### 16.1.1 Monitoring Procedure

$CO_2$ module offers some relevant data concerning Sidestream $CO_2$ monitoring.

$CO_2$ module measures the $CO_2$ partial pressure or concentration of patient Air Way, obtain $EtCO_2$, Inspired Minimum CO (Ins $CO_2$) Air Way Respiration Rate (AWRR), and display $CO_2$ concentration waveforms.

The parameter symbols displayed on the screen are defined as following:

**$CO_2$:** **$EtCO_2$**

**Ins $CO_2$**: Inspiratory $CO_2$

**AWRR**: Air Way Respiratory rate (AwRR) (Resp: times/MIN).

## 16.2 $CO_2$ measurement setup:

1. Verify the type of the configured $CO_2$ module (Mainstream or Sidestream);
2. For Sidestream $CO_2$ module, plug the $CO_2$ gadgets into the $CO_2$ Module. $CO_2$ gadgets consists of a collecting tube, a moisture bottle, and a 3-way connector. The collecting tube is disposable. Open the sealed bag and connect one end to the moisture bottle which is installed on the monitor, and put the other end at the patient's exhaling part or connect it to the "snake head" of the 3-way connector which is connected to a device like respiration machine; and all is ready

> **Note:** The moisture bottle functions as a strainer to filter the moisture in the collecting tube and send the carbon dioxide to the gas sensor inside the monitor for processing.

3. Power on the system, after setting the display to the $CO_2$ measurement mode Rotate and press the knob onto the CO2 hotkey parameter area. Choose "MEASURE" option in OPT MODE.
5. After $CO_2$ module is activated, the $CO_2$ waveform identifier displayed in the waveform area and corresponding value displayed in the $CO_2$ parameter area.

Pic16-1 Sidestream connection

**Note**

$CO_2$ module may offer the measured result under condition of ATPD (Ambient

Temperature and Pressure, Dry Gas) and BTPS (Body temperature and pressure, Saturated). The default measurement condition is ATPD. ATPD equals to the measurement condition under ambient temperature and pressure and dry gas while BTPS equals to the condition when temperature is $37^{O}C$, relative humidity is 95% and partial pressure of moisture is 47mmHg (pH20). The respective calculating methods of $CO_2$ partial pressure under above conditions are:

ATPD: $pCO_2$ (mmHg) = $CO_2$ (vol %) * Pamp/100

BTPS: $pCO_2$ (mmHg) = $CO_2$ (vol%) * (Pamp-47)/100

In the above formulas:

$pCO_2$ is partial pressure

vol% is the percentage of gas concentration and

Pamp is ambient pressure, the unit of which is mmHg.

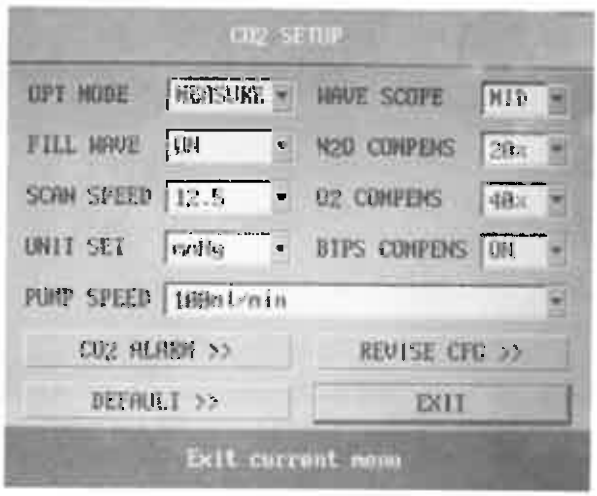
**Warning**

1. Do not use the accessory if the packaging or the internal accessory is damaged and return them to the vendor.
2. The Sidestream sampling tube is one-off consumable that cannot be repeatedly sterilized and used by different patients.
3. Water trap is used to collect water drops condensed in sampling airway and prevent water drops from entering the module. When collected water in the water trap comes to certain amount, pour away the water to avoid block of the airway.

4.In long-term use, dust or other impurity may lower air permeability of filter material in water trap and may block the airway. In this situation, water trap must be changed.

## 16.3 $CO_2$ SETUP

Users can use the knob to move the cursor onto the $CO_2$ SETUP hotkey in the parameter area and press the knob to enter the $CO_2$ Setting menu.




Pic16-2 : CO2 setup setting

- **OPT MODE:**: for users to select the $CO_2$ module to operate mode. "MEASURE" mode will start measuring operation.
- **FILL WAVE:** If users select "ON" in FILLWAVE option, then filled $CO_2$ wave form will display.
- **SCAN SPEED:** for users to select the different scanning speed of the $CO_2$ wave, such as 6.25, 12.5 and 25.0.
- **UNIT SET:** for user to select the unit of the $CO_2$
- **WAVE SCOPE:** for user to select the different $CO_2$ wave scope, such as low, medium and High.
- **$N_2O$ COMPENS:** for user to check the $CO_2$ density using different $N_2O$ compensate, such as 20%, 40% and 60%.
- **$O_2$ COMPENS:** for user to check the $CO_2$ density using different $O_2$ compensate, such as 40%, 60% and 80%.
- **BTPS COMPENS:** for user to check the $CO_2$ density using BTPS (Body temperature and pressure saturated) compensate.
- **PUMP SPEED:** for user to measure $CO_2$ using different Pump speed such as 50ml/min, 75ml/min, 100ml/min,150 ml/min,200 ml/min

## 16.4 $CO_2$ ALARM SETUP


Pic16.3 : CO2 ALARAM SETUP

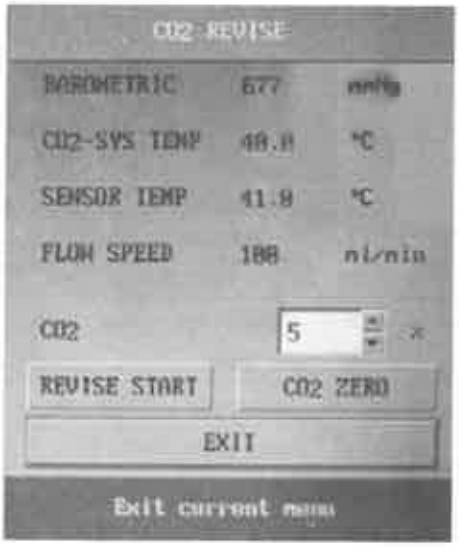
**ALARM LEVEL**: High, Middle or Low to be selected by users to set alarming levels, and High for the most serious alarm. Users can also select "Off" to turn off the alarming function, in such case there will be a " " indication beside the $CO_2$ parameter area.

**ALARM PRINT:** Used to start or close the function of recording $CO_2$ alarming. If users select "On", upon $CO_2$ alarming, the record will output the alarm.

**ETCO2**, **INS** and **AWRR** alarms are based on the specified upper and lower limits; upon $CO_2$ higher than the upper limits or lower than the lower limits, there will be alarms.

**APNEA ALM**: For users to select the alarm time for APNEA alarm (having 7 levels,which are 10S, 15S,20S,25S,30S,35S,40S).

## 16.5 $CO_2$ REVISE :




Pic 16.4: CO2 REVISE

**REVISE START:**

For use to start the revise process in CO2 module. Revise Process will start the calibration in CO2 Module .

**$CO_2$ ZERO** :

For user to set the $CO_2$ Module to Zero process

**Default:** Users can select this item to enter the "DEFAULT" dialogue, then further select "Factory default Config" or "User default Config". After making a selection and exiting the dialogue, users will see a pop-up dialogue requiring their confirmation.


Pic 16.5 Default setting

## 16.6 Alarm Information and prompts

### Alarm Messages

Physiological alarm, caused by the parameter value exceeds the limits, will activate the recorder to automatically outputting the parameter and related measuring waveforms once the alarm occur while ALARM REC in related menu switch ON.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during $CO_2$ measurement

**Physiological alarms:**

| Message | Cause | Alarm-Level |
|---|---|---|
| $CO_2$ TOO HIGH | $EtCO_2$ measuring Value is above upper alarm limit | User-selectable |
| $CO_2$ TOO LOW | $EtCO_2$ measuring Value is below lower alarm limit | User-selectable |
| INS TOO HIGH | $InsCO_2$ measuring Value is above upper alarm limit | User-selectable |
| AWRR TOO HIGH | AWRR measuring value is above upper limit | User-selectable |
| AWRR TOO LOW | AWRR measuring Value is below lower alarm limit | User-selectable |
| $CO_2$ APNEA | In specific time interval, no RESP can be detected using $CO_2$ module. | User-selectable |

**Technical Alarms:**

| Message | Cause | Alarm Level | Remedy |
|---|---|---|---|
| $CO_2$ SENSOR OFF | Mainstream sensor is not properly connected or has fallen off. | LOW | Make sure that mainstream sensor is properly connected. |
| $CO_2$ NO WATER TRAP | Side stream Water trap is not properly connected or has fallen off. | LOW | |
| $CO_2$ WATERTRAP OCCLUDE | Side stream Water trap is occluded. | LOW | |
| $CO_2$ SIGNAL LOW | Measuring module technical failure | LOW | |
| $CO_2$ SIGNAL TOO LOW | | LOW | |
| $CO_2$ BAROMETRIC TOO LARGE | | MED | |
| $CO_2$ PNEUMATIC LEAK | | MED | |
| $CO_2$ SIGNAL NOISY | | LOW | |
| $CO_2$ SIGNAL SATURATE | | LOW | |
| $CO_2$ CALCULATION ERR | | HIGH | |
| $CO_2$ SENSOR FAULT | | HIGH | |

| | | | |
|---|---|---|---|
| $CO_2$ SENSOR TEMP HIGH | | HIGH | |
| $CO_2$ SENSOR TEMP LOW | | HIGH | |
| $CO_2$ WATCHDOG TIMEOUT | | HIGH | |
| $CO_2$ INT COMM ERR | | HIGH | |
| $CO_2$ SYSTEM ROM ERR | | HIGH | |
| $CO_2$ MALFUNCTION | | HIGH | |
| $CO_2$ COMM ERR | $CO_2$ module communication failure. | HIGH | Stop using measuring function of $CO_2$ module, notify MEDIAID for support. |
| $CO_2$ INIT ERR | $CO_2$ module is not properly connected or failed. | HIGH | Stop using measuring function of $CO_2$ module, notify MEDIAID for support. |
| $CO_2$ COMM STOP | Measuring module failure or communication failure. | HIGH | |
| $CO_2$ ALM LMT ERR | Functional Safety failure | HIGH | Stop using measuring function of $CO_2$ module, notify MEDIAID for support. |
| INS ALM LMT ERR | Functional Safety failure | HIGH | |
| AWRR ALM LMT ERR | Functional Safety failure | HIGH | |

Prompt Message:

| Message | Cause | Alarm Level |
|---|---|---|
| $CO_2$ STANDBY STATUS | Turn from measuring mode to standby mode, making the module in energy-saving status. | No alarm |
| $CO_2$ WARM UP | Shows that the sensor is in warming-up stage. | No alarm |
| $CO_2$ SENSOR START UP | Shows that the sensor has just entering start-up stage. | No alarm |

# Chapter 17 IBP Monitoring (Optional)

The Monitor measures direct blood pressure (SYS, DIA and MAP) of one selected blood vessel through IBP channel, and displays two BP waveforms measures direct blood pressure (SYS, DIA and MAP).

The available pressure labels are:

| Label | Definition |
|---|---|
| ART | Arterial Blood Pressure |
| PA | Pulmonary Arterial Pressure |
| CVP | Center Venous Pressure |
| RAP | Right Atrial Pressure |
| LAP | Left Atrial Pressure Intracranial Pressure (ICT/B |
| ICP | Transducer information ) |
| P1 | Expand Pressure |

## 17.1 Precautions during IBP Monitoring

**Warning**

Parts and accessories used must meet the safety requirements of the medical electrical equipment standards.

**Warning**

Do not contact the metal part connected to the electrical appliance when connecting or using the accessory.

**Warning**

When the monitor is used with HF surgical equipment, do not let the transducer and cable contact the HF surgical equipment to prevent the patient from burning caused by leakage current.

**Warning**

Disposable IBP transducer or domes should not be reused.

**Note**

Use only the pressure transducer specified in this operation manual.
The specified transducer (except for ICT/B transducer) has the function of protecting against the electric shock (especially the leakage current) and the influence of cardiac defibrillator. It can be used in surgical operation. When the patient is in the defibrillation, the pressure waveform may become temporarily distorted. However the monitor will work normally after defibrillation with the operation mode and user configuration being not affected.

**Warning**

Inspect the transducer cable is in normal condition before monitoring. Unplug the transducer of the channel 1, the monitor should display the error message "IBP: SENSOR 1 OFF" and trigger audible alarm. The other channel should act the same.

**Note**

Periodically calibrate the transducer either new or used according to the Hospital Regulation.

**Warning**

If any kind of liquid, other than the solution to be infused in the pressure line or transducer, is splashed on the equipment or its accessories, especially enters the transducer or the monitor, contact the Service Center of the Hospital immediately.

## 17.2 Monitoring Procedure

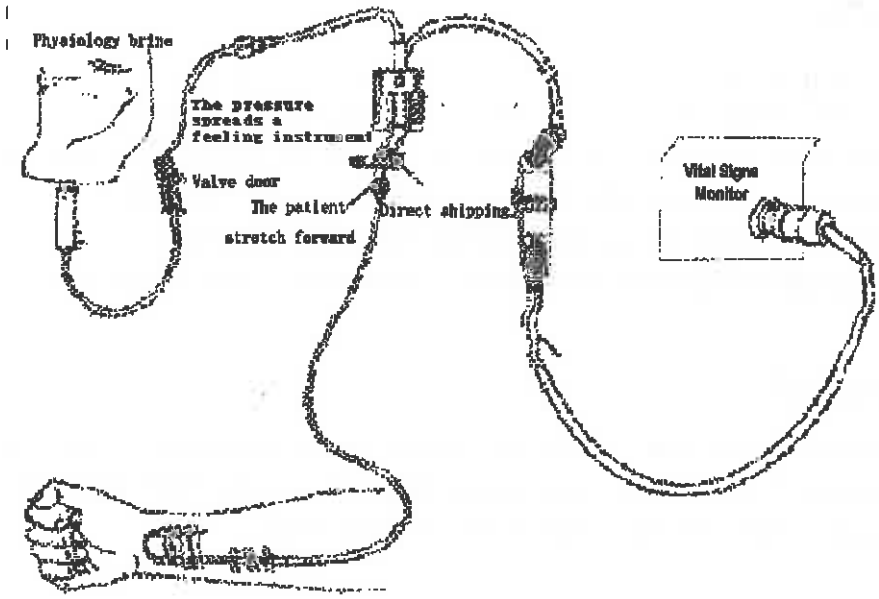
Preparation before IBP measurement:

1. Plug the pressure cable into corresponding socket and check that the monitor is switched on.
2. Any entrapped air should be removed from the pressure system (pressure line and transducer) by filling with normal saline.
3. Connect the arterial catheter to the pressure line, ensure any entrapped air removed.

**Warning**

If any entrapped air in pressure system, re-fill system with normal saline.

4. Position the transducer at the same level of the patient's heart, approximately mid-auxiliary line.
5. Ensure the correct label name has been selected.
6. Zero the transducer.




pic.17.1: IBP Connection

## 17.3 IBP Setup

Users can use the knob to move the cursor onto the IBP SETUP hotkey in the parameter area and press the knob to enter the IBP Setup menu.


pic.17.2: IBP SETUP

- **SCAN SPEED:** for users to select the different scanning speed of the IBP wave, such as 12.5 and 25.0.
- **FILL WAVE:** If users select "ON" in FILLWAVE option, then filled IBP wave form will display.

- **UNIT SET:** for user to select the unit of the IBP
- **IBP1/IBP2 WAVE AMP :** for user to setup the display amplitude of the IBP waves

## 17.4 IBP1 ALARM SETUP


pic.17.3: IBP Alarm setup

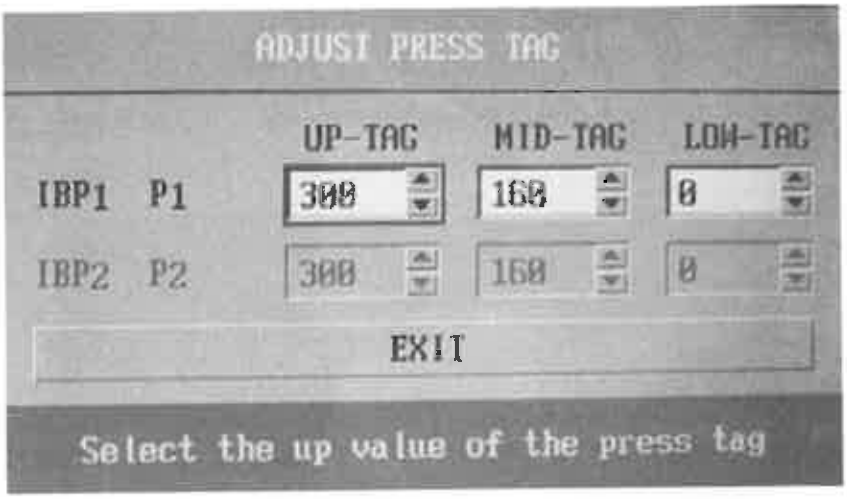
**ALARM LEVEL** : High, Middle or Low to be selected by users to set alarming levels, and High for the most serious alarm. Users can also select "Off" to turn off the alarming function, in such case there will be a " " indication beside the IBP parameter area.

**ALARM PRINT:** Used to start or close the function of recording IBP alarming. If users select "On", upon IBP alarming, the record will output the alarm.

**SYS**, **MEA** and **DIA** alarms are based on the specified upper and lower limits; upon IBP higher than the upper limits or lower than the lower limits, there will be alarms.

## 17.5 PRESS TAG

The Waveform and corresponding scale appears in the IBP waveform Area with 3 dotted lines representing UP-TAG,MID-TAG and LOW-TAG from top to the bottom. Values of three scales can be set according to the instruction given below.




pic.17.4: Adjust Press Tag

- **IBP label :** Selectable from ART1,PA1,CVP1,RAP1,LAP1,ICP1 and P1.
- **UP-TAG:** IBP value of higher scale,the **range of which is the measurable range of current pressure.**

**Note**

The UP-TAG value must be higher than the LOW-TAG value.

- **LOW-TAG:** IBP value of lower scale,the range of which is the measurable range of current pressure.

**Note**

The LOW-TAG Value must be lower than the UP-TAG value.

- **MID- TAG:** IBP value of reference scale (Between UP-TAG and LOW-TAG)

**Note**

When change up-tag scale, low-tag scale or mid-tag scale of IBP wave form and the corresponding IBP wave form are displayed under the menu window, the wave form will come penetratingly through the menu window for observing.

## 17.6 PRESS ZERO

Press the "PRESS ZERO" button in IBP SETUP menu to call up IBP Pressure Zero menu as shown below:


pic.17.5: Press zero

**Note**

User should ensure that the transducer has been zeroed before measurement ; otherwise the device does not have valid zero value,which may result in inaccurate measuring data.

**Zero Calibration of Transducer**

Select "CH1 TO ZERO", the system will Zero IBP1

**Caution**

- Turn off the patient stopcock before you start the zero procedure
- The transducer must be vented to atmospheric pressure before the Zero procedure.
- The transducer should be placed at the same height level with the heart, approximately mid-axially line.
- Zero procedure should be performed before starting the monitoring and at least once a day after each disconnect-and-connect of the cable.

## 17.7 PRESS REVISE

Press the "press revise" button on the IBP setup menu to call up the IBP Press Revise menu as shown below:


Pic. 17.6: Press Revise

**Calibrate the transducer:**

Turn the knob to select the item CH1 REVISE VALUE, press and turn the knob to select the pressure value to be calibrated for channel 1. Then turn the knob to select REVISE to start calibrating channel 1.

- The purpose of the calibration is to ensure that the system gives you accurate measurements.
- Before starting a mercury calibration, a zero procedure must be performed.

**Default:** Users can select this item to enter the "DEFAULT" dialogue, then further select "Factory default Config" or "User default Config". After making a selection and exiting the dialogue, users will see a pop-up dialogue requiring their confirmation.


Pic 17-7 Default setting

## 17.8 Alarm Information and prompts

**Alarm Messages**

Physiological alarm, caused by the parameter value exceeds the limits, will activate the recorder to automatically outputting the parameter and related measuring waveforms once the alarm occur while ALARM REC in related menu switch ON.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during IBP measurement

**Physiological alarms:**

| Message | Cause | Alarm-Level |
|---|---|---|
| I1-SYS TOO HIGH | SYS Measuring value of channel1 is above upper limit. | User-selectable |
| I1-SYS TOO LOW | SYS Measuring value of channel1 is below Lower limit. | User-selectable |
| I1-DIA TOO HIGH | DIA Measuring value of channel1 is above upper limit. | User-selectable |
| I1-DIA TOO HIGH | DIA Measuring value of channel1 is Below Lower limit. | User-selectable |
| I1-MEA TOO HIGH | MEA Measuring value of channel1 is above upper limit. | User-selectable |
| I1-MEA TOO HIGH | MEA Measuring value of channel1 is Below lower limit. | User-selectable |

**Technical Alarms:**

| Message | Cause | Alarm Level | Remedy |
|---|---|---|---|
| IBP1 SENSOR OFF | IBP cable of channel1 falls off from monitor. | LOW | Make sure that cable is properly connected. |
| IBP1 INIT ERR | IBP Module failure | HIGH | Stop using measuring function of IBP module, notify to MEDIAID for support |
| IBP1 INIT ERR1 | | | |
| IBP1 INIT ERR2 | | | |
| IBP1 INIT ERR3 | | | |
| IBP1 INIT ERR4 | | | |
| IBP1 INIT ERR5 | | | |
| IBP1 INIT ERR6 | | | |
| IBP1 INIT ERR7 | | | |
| IBP1 INIT ERR8 | | | |
| IBP1 COMM STOP | IBP1 module failure or communication failure | HIGH | Stop using ALARM function of IBP module, notify to MEDIAID for support |
| IBP1 COMM ERR | IBP1 communication Error | HIGH | Stop using ALARM function of IBP module, notify to MEDIAID for support |

| | | | |
|---|---|---|---|
| IBP1 ALM LMT ERR | Functional safety failure | HIGH | Stop using ALARM function of IBP module, notify to MEDIAID for support |

**Prompt Message:**

| Message | Cause | Alarm Level |
|---|---|---|
| IBP1 SYS EXCEED | Systolic measuring value of channel 1 is beyond measurement range. | HIGH |
| IBP1 DIA EXCEED | Diastolic measuring value of channel 1 is beyond measurement range. | HIGH |
| IBP1 MEAN EXCEED | Mean measuring value of channel 1 is beyond measurement range. | HIGH |
| IBP1 NEED ZERO | Zero calibrating must be done before measuring in IBP channel 1. | HIGH |

## 17.9 Maintenance and Cleaning
## Care and cleaning

**Warning**

Before cleaning the monitor or the transducer, turn off the power and disconnect from power line.

**Cleaning of IBP Transducer (Reusable)**

After the IBP monitoring operation is completed, remove the tubing and the dome .from the transducer and wipe the transducer diaphragm with water. To clean the transducer and the cable, soak or wipe them by using soap or the detergents listed below:

Cetylcide
Wavicide-01
Wescodyne
Cidex
Lysol
Vesphene

Do not immerse the connector in any liquid. After cleaning, dry the transducer thoroughly before storing. Slight discoloration or temporary increase of surface stickiness of the cable should not be considered abnormal If adhesive tape residue must be removed from the transducer cable, double seal tape remover is effective and will cause a minimum of damage to the cable if used sparingly. Acetone, Alcohol, Ammonia and Chloroform, or other strong solvents are not recommended because over time the vinyl cabling will be damaged by these

**Note**

The disposable transducers or domes must not be re-sterilized or re-used.

**Note**

For protecting environment, the disposable transducers or domes must be reclaimed or disposed properly Chemical solution Sterilization

Remove obvious contamination by using the cleaning procedure described previously. Select a sterilant that has been found effective to your hospital or institution for chemical solution sterilization of operating room equipment. Buffered glutaraldehyde (e.g. Cidex or Hospisept) has been found to be effective. Do not use quaternary cationic detergents such as zephiran chloride. If the whole unit is to be sterilized, immerse the transducer but not the electrical connector into the sterilant for the recommended sterilizing period. Ensure that the dome has been removed. Then rinse all transducer parts except the electrical connector with sterilized water or saline. The transducer must be thoroughly dried before storing.

**Gas Sterilization**

For more complete asepsis, use gas sterilization.

Remove obvious contamination by using the cleaning procedure described previously. To inhibit the formation of ethylene glycol when ethylene oxide gas is used as the disinfectant, the transducer should be completely dry.

Follow the operating instructions provided by the manufacturer of the gas disinfectant.

**Warning**

The sterilize temperature must not exceed 70°C (158°F). Plastics in the pressure transducer may deform or melt above this temperature.

# CHAPTER 18 MEDIAID INC. WARRANTY

**Warranty Information**
**Owner's Registration**
**Product Information**

## 18.1 WARRANTY INFORMATION

Please note: THIS PRODUCT IS MANUFACTURED AND SOLD BY MEDIAID INC. (HEREAFTER REFERRED TO AS MEDIAID) UNDER THE WARRANTIES SET FORTH BELOW.

### Application of Warranty

This warranty covers only the Mediaid Model M6 ASTER it is not extended to the other products or components that the customer uses in conjunction with the Mediaid product. This warranty shall not apply if the manufacturer determines that the product has been damaged due to abuse, misuse, misapplication, accident, negligence, tampering or as a result of service or modification by any other person other that an authorized Mediaid service technician. Opening of the sealed enclosure or altering the serial number will void warranty. Use of equipment contrary to or inconsistent with the User manual will also void the Warranty.

### What is covered by this Warranty?

Mediaid warrants that the Mediaid product enclosed with this warranty will conform to the manufacturer's specifications, and shall be free from defects in workmanship and materials for a period of one (1) year from the date of original purchase. Items excluded from this one year term are the batteries, sensor extension cables, sensors and other accessories.

### What Mediaid will do to correct the problems?

Should your Mediaid product prove to be defective, contact Mediaid Inc. or the Mediaid local authorized distributor/service center for repairs. Please have your model and serial number available when calling. Mediaid will then issue a "Return Authorization Number (RAN)". Return your instrument securely packaged in its original shipping carton (or equivalent packaging), include your Return Authorization Number. Mediaid Inc. will repair any faulty workmanship and either repair or replace (at its option) any defective part with new or refurbished parts. For non-warranty repairs, the customer will be charged the current repair rate at the time of receipt by Mediaid and all transportation charges shall be customer's responsibility. Mediaid shall not be liable for any damages including, but not

limited to, incidental damages, consequential damages or special damages. This Warranty does not cover any damage to the equipment during shipping, which shall be the sole responsibility of the transportation company.

Always read the User's Manual carefully: The information included in the User's Manual will assist the user in preventing equipment misuse and ensuring patient safety. Operation of the equipment in a manner contrary or inconsistent with the User's Manual will void the Warranty.

## 18.2 OWNER'S REGISTRATION

To assist Mediaid Inc. in serving you, please complete the warranty Registration Card that is included and return it to **MEDIAID INC., 17517 Fabrica Way Suite H Cerritos, CA 90703 USA. (Tel) 714-367-2848 (Fax) 714-367-2852 Website: www.mediaidinc.com**

NOTE: THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, WHICH EXTEND BEYOND THE WARRANTIES SET FORTH ABOVE. MEDIAID INC., MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCT OR PARTS THEREOF. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY HAVE OTHER LEGAL RIGHTS WHICH VARY FROM STATE TO STATE. MEDIAID INC., WILL NOT BE LIABLE TO THE USER FOR INCIDENTAL OR CONSEQUENTIAL DAMAGE OR LOSS ARISING OUT OF THE USER'S INABILITY TO USE THIS PRODUCT.

## 18.3 PRODUCT INFORMATION

To better assist customers, Mediaid Inc., recommends all users write down all pertinent product and warranty information.

Product #_____

Serial #_____

Software Version # _____

WarrantyExpirationDate _____

# Appendix : Product specification

**Monitor dimensions & weight**

| | |
|---|---|
| Dimensions: | 325mm*145mm*290mm |
| Weight: | 3.30kg |

**Work environment**

| | |
|---|---|
| Temperature range: | |
| Work condition: | - 45°C; |
| Storage condition: | -20 - 55°C. |
| Humidity range: | |
| Work at 45°C: | 85%; |
| Storage at 40°C: | 93%. |

| | |
|---|---|
| Electrical specification: | AC110/220V, 50/60Hz, Max input power 70VA<br>DC 12-20V, Max input current 4A |

**Scope:**

Newborns, infants, adults

**Monitor functional specification**

| | |
|---|---|
| Display: | Color 12.1" TFT screen, resolution640*480 |
| Language options: | English |
| Indicators: | |
| | 7-waveform display |
| | Alarm indicating light |
| | External DC supply indicating light |
| | QRS audio & audio alarming |
| Interfaces: | Measurement parameter cable interface |
| | Power supply socket |
| | Tolerance <20%), output impedance 50ohm, signal delay <30ms |
| Battery: | Chargeable, maximally for 1 hour use |
| Trend time: | 1-72 hours |
| Recorder: | |
| Recording waveforms: | 2 |
| Record width: | 48mm |
| Paper width: | 57.5mm |
| Paper feeding speed: | 25mm/S |

**ECG specification**

Lead

Input:

| | |
|---|---|
| 5-lead cable: | RA; LA; RL; LL; C |
| Lead method: | I; II; III; avR; avL; avF; V; CAL (calibration) |
| No. of channels: | 7 channels |
| Gain: | X0.5; X1; X2; X4; Automatic |

HR

| | |
|---|---|
| Adult measurement & alarming range: | 15-300bpm |
| Newborn/ infant measurement & alarming range: | 15-350bpm) |
| Precision: | ±1% |
| Resolution: | 1bpm |

| | |
|---|---|
| Sensitivity: | >200uV (peak-to-peak value) |
| Differential input impedance: | over 5M ohm |
| CMR: Non-filtering mode | >60dB |
| Filtering mode | >80dB |
| Electrode polarized voltage range: | ±300mV |
| Leakage current: | less than 10uA |
| Protection: | Electric isolation: 4000VAC/50Hz voltage<br>Defibrillation/ electric knife resistant, Grid/ EMG resistant |
| Baseline recovery time: | After defibrillation <5 seconds (under Filtering mode) |
| Scaling signal: | 1mV (peak-to-peak value) Accuracy: ±3% |

Frequency response (bandwidth):

| | |
|---|---|
| Filtering mode: | 0.5-25Hz |
| Non-filtering mode: | 0.05-75Hz |
| Alarm: | Audio-alarm dual alarms, with review function |
| Pacing: | Pacemaker works only after capturing pacing |

**RESP specification**

| | |
|---|---|
| Method: | RA-LL impedance method |
| RESP measurement & alarming range: | |
| Adult: | 7-100rpm |
| Infant/ newborn: | 7-100rpm |
| Resolution: | 1rpm |
| Precision: | ±2rpm |
| Differential input impedance: | Over 2.5M ohm, RA-LL lead |
| Choke alarm: | 10-40 seconds |

**NIBP specification**

| | |
|---|---|
| Measurement method: | Automatic vibration |
| Work mode: | Manual / Automatic/ Continuous; |

Unit: mmHg/ Kpa optional;

Measurement range:

| | | |
|---|---|---|
| Adult: | Systolic pressure | 25-255mmHg |
| | Diastolic pressure | 10-220mmHg |
| | Average pressure | 20-235mmHg |
| | Overpressure protection: dual protection | |
| | (1) 300mmHg | |
| | (2) 300±10%mmHg | |
| Infant: | Systolic pressure | 20-180mmHg |
| | Diastolic pressure | 10-150mmHg |
| | Average pressure | 10-160mmHg |
| | Overpressure protection: | 180mmHg |
| Newborn: | Systolic pressure | 20-120mmHg |
| | Diastolic pressure | 5-100mmHg |
| | Average pressure | 10-110mmHg |
| | Overpressure protection: | dual protection |
| | (1) 120 mmHg | |
| | (2) 120±10%mmHg | |

Resolution: 1mmHg

Precision: Tolerance < ±5mmHg, less than 8 mmHg

PR range: 40-240bpm

Alarm: Systolic/diastolic/average pressure: 0-300mmHg

**$SpO_2$ specification**

Measurement & alarm range: 0-100%

Resolution: 1%

Precision: ±2% (70-100%); ±3%(60-70%)
(no statement (below 60%))

PR and alarm range: 0-254bpm

Resolution: 1bpm

Precision: ±1%

**TEMP specification**

Measurement & alarm range: 0-45°C

Resolution: 0.1°C

Precision: ±0.1°C (circuit precision)
±0.2°C (including TEMP sensor)

No. of channels: 2 channels, giving display of T1, T2 and ΔT

**IBP specification (Optional)**

| | |
|---|---|
| Channel | 2 |
| Label | ART, PA, CVP, RAP, LAP, ICP, P1,P2. |
| Measuring and alarm range | |
| ART | 0 ~ 300 mmHg |
| PA | -6 ~120 mmHg |
| CVP/RA/LAP/ICP | -10 ~40 mmHg |
| P1/P2 | -10 ~300 mmHg |
| Press Sensor | |
| Sensitivity | 5 uV/V/ mmHg |
| Impedance | 300-3000 Ω |
| Resolution | 1 mmHg |
| Accuracy | ±2% or 1 mmHg which great |
| Actualization interval | about 1 sec. |

**$CO_2$ specification (Optional)**

| | |
|---|---|
| Method | Infra-red Absorption Technique |
| Measuring mode | Side stream or Mainstream (Option) |
| Side-stream mode sampling gas flow rate | 100,150,200 ml/Min (Option) |
| Measuring range | |
| $CO_2$ | 0 ~ 99 mmHg |
| $INSCO_2$ | 0 ~ 99 mmHg |
| AWRR | 0 ~ 150 rpm |
| Resolution | |
| $CO_2$ | 1 mmHg |
| $INSCO_2$ | 1 mmHg |
| AWRR | 1 rpm |
| Accuracy | |
| $CO_2$ | ±2 mmHg, 0 ~ 40 mmHg |
| | ±5% of reading, 41 ~ 76 mmHg |
| | ±10% of reading, 71 ~ 99 mmHg |
| AWRR | ±2 rpm |
| Actualization interval | about 1 sec. |

Start-up Time:

<30 sec typical in side stream mode

<80 seconds in main stream mode from 25ºC ambient,5W supplied to sensor heater

(Mainstream sensor temperature controlled to 42ºC )

Mainstream Response Time:

100 msec (10% to 90%)

Sidestream Rise Time:

240 msec (10% to 90%)

Sidestream Delay Time:

1.12 Seconds maximum with 7' length, 0.055 "ID.
Sampling line at 175 ml/min.

Alarm range

| | |
|---|---|
| $CO_2$ | 0 ~ 99 mmHg |
| $INSCO_2$ | 0 ~ 99 mmHg |
| AWRR | 0 ~ 150 rpm |

Suffocation Alarm Delay

| | |
|---|---|
| AWRR | 10 ~ 40 Sec. |

# WARRANTY REGISTRATION FORM

**Please return to Mediaid Inc. / local distributor for validation**

MEDIAID INC.

**17517 Fabrica Way Suite H Cerritos, CA 90703 USA**

**(Tel) 714-367-2848 (Fax) 714-367-2852**

**Email: info@mediaidinc.com Website: www.mediaidinc.com**

Model _____ Serial Number _____

Date of Purchase _____ _____

Institution/Physician _____ _____

Address _____ _____

_____ _____

_____ _____

Contact Department _____ _____

Telephone _____ _____

Distributor _____ Phone _____

Comments _____ _____

1007-60001-002