# iM8 Series

Patient Monitor

Version 1.0



**About this Manual** 

P/N: 01.54.456009-10

Release Date: April 2013

**Statement** 

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which the

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Responsibility of the Manufacturer

The manufacturer only considers itself responsible for any effect on safety, reliability and

performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by

persons authorized by the manufacturer, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, the manufacturer may provide, with compensation, necessary circuit diagrams, and

other information to help qualified technician to maintain and repair some parts, which the

manufacturer may define as user serviceable.

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## **Terms Used in this Manual**

This guide is designed to give key concepts on safety precautions.

### **WARNING**

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

### **CAUTION**

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

### NOTE

A **NOTE** provides useful information regarding a function or a procedure

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## **Chapter 1 Intended Use and Safety Guidance**

### 1.1 Intended Use

This monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters including ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO<sub>2</sub>), non-invasive blood pressure (NIBP), invasive blood pressure (IBP) and carbon dioxide (CO<sub>2</sub>) of adults, pediatrics and neonates in hospital environments.

This monitor is suitable for use in hospital environments including wards, OR, PACU, ICU and neonate intensive care room.

## 1.2 Safety Guidance

### 1.2.1 Environment

Follow the instructions below to ensure a completely safe electrical installation. The environment where the monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

The monitor operates within specifications at ambient temperatures between 5°C and 40°C. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5cms) clearance around the instrument for proper air circulation.

## 1.2.2 Power Source Requirements

Refer to *Appendix 1*.

## 1.2.3 Grounding the Monitor

To protect the patient and hospital personnel, the cabinet of the monitor must be grounded. Accordingly, the monitor is equipped with a 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician.

Connect the grounding wire to the equipotential grounding terminal in the main system. If it is not evident from the instrument specifications whether a particular instrument combination is hazardous or not, for example due to summation of leakage currents, the user should consult the manufacturers concerned or an expert in the field, to ensure that the necessary safety of all instruments concerned will not be impaired by the proposed combination.

## 1.2.4 Equipotential Grounding

Protection class 1 instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, the monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the instrument rear panel and the other end to one point of the equipotential grounding system. The equipotential grounding system assumes the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in medically used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order. The cable connecting the patient to the instrument must be free of electrolyte.

### **WARNING**

If the protective grounding (protective earth) system is doubtful, the monitor must be supplied by internal power only.

### 1.2.5 Condensation

Make sure that during operation, the instrument is free of condensation. Condensation can form when equipment is moved from one building to another, and thus being exposed to moisture and differences in temperature.

## 1.2.6 Safety Precautions

**WARNING** and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the instrument.

### **WARNING**

- 1 The monitor is provided for the use of qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
- 2 Only qualified service engineers can install this equipment. And only service engineers authorized by the manufacturer can open the shell.
- 3 EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- 4 SHOCK HAZARD-The power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.
- 5 SHOCK HAZARD-Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

### **WARNING**

- Accessory equipments connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN60601-1-1. If in doubt, consult our technical service department or your local distributor.
- If the monitor is accidentally damped, place it in the dry circumstance, and do not operate it until it is approved for further use. If liquid is inadvertently spilled on the monitor, contact the service personnel authorized by the manufacturer.
- During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off, and only the patient information and alarm settings can be saved. After reconnecting the power supply, the user should turn on the monitor for monitoring.
- The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do not dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
- 10 The packaging is to be disposed of according to local or hospital's regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.
- 11 Only patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed, and the patient may be injured.
- 12 The user should check the monitor and accessories before use.
- 13 Be sure that all electrodes have been connected to the patient correctly before operation.
- 14 Do not touch the patient and metal part of the monitor when operating the monitor.
- 15 Do not touch the patient, bed or instrument during defibrillation.
- 16 Please set the alarm according to the individual status of patient to avoid delaying treatment. Ensure there will be alarm audio prompt when alarming.
- 17 Devices connecting with monitor should be equipotential.
- 18 When the monitor and electrosurgical device are used together, the user (physician or nurse) should guarantee the safety of patient.
- 19 This equipment is not intended for family usage.

### **CAUTION**

- 1 Federal (U.S.) laws restrict this device to sale, distribution and use by, or on the order of a physician.
- 2 Electromagnetic Interference -Ensure that the environment in which the patient monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.
- 3 Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dust area, high temperature and humid environment.
- 4 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.
- 5 Do not use autoclave or gas to sterilize the monitor, recorder or any accessories.
- 6 The device and reusable accessories could be sent back to the manufacturer for recycling or proper disposal after their useful lives.
- 7 Remove a battery whose life cycle has expired from the monitor immediately.
- 8 Avoid liquid splash and excessive temperature. The temperature must be kept between 5°C and 40°C while working. And it should be kept between -20°C and 55°C during transportation and storage.
- 9 Before use, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.

#### NOTE:

- 1 The monitor can only be used on one patient at a time.
- 2 The monitor may not be compatible with all models of USB disks. It is recommended to use USB disks that are supplied by the manufacturer.
- 3 If the monitor gets damp, put it in dry circumstance to dry it until it can work normally. If liquid pours on the monitor, please contact the service personnel of the manufacturer.
- 4 The manufacturer suggests that the lifetime of the monitor is 5 years.
- 5 This monitor is not a device for treatment purpose.
- 6 The equipment is calibrated to be display functional oxygen saturation.
- 7 The pictures and interfaces in this manual are for reference only.

## 1.2.7 Explanation of Symbols on the Monitor

<b>- ● </b>	This symbol indicates that the equipment is IEC/EN60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.	
4 <b>½</b> ŀ	This symbol indicates that the instrument is IEC/EN 60601-1 Type BF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.	
$\triangle$	Caution	
[]i	Consult Instructions For Use	
$\Rightarrow$	Equipotentiality	
<del>~~</del>	USB (Universal Serial Bus) Connection	
$\rightarrow$	VGA output, External Monitor	
Ф	Stand-by. It designates that the switch or switch position which one part of the monitor has been switched on, while the monitor is at the status of stand-by.	
SN	Serial number	
<b>C</b> € <sub>0123</sub>	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.	
EC REP	Authorised representative in the European community	

M	Date of manufacture
	Manufacturer
P/N	Part Number
	Recycle
滾	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
Rx only	Federal (U.S.) law restricts this device to sale by or on the order of a physician.

## **Chapter 2 Installation of Monitor**

Installation should be carried out by qualified service personnel, either by the hospital's biomedical department, or by the manufacturer's Support.

For mechanical and electrical installation, you need technically qualified personnel with knowledge of English. Additionally, for monitor configuration, you need clinically qualified personnel with knowledge of the use environment.

#### NOTE:

- 1 The monitor configuration settings must be specified by authorized hospital personnel.
- 2 To ensure that the monitor works properly, please read *Chapter Safety Guidance*, and follow the steps before using the monitor.

## 2.1 Opening the Package and Checking

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage. Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

- ◆ Check for any mechanical damage.
- Check all the functions, cables and accessories.

If there is any problem, contact the manufacturer or local representative immediately.

## 2.2 Connecting the Power Cable

Connection procedure of the AC power line:

- ◆ Make sure the AC power supply complies with the following specifications: 100V-240V~, 50Hz/60Hz.
- ◆ Apply the power line provided with the monitor. Plug the power line to INPUT interface of the monitor. Connect the other end of the power line to a grounded 3-phase power output.

#### NOTE:

Connect the power line to the jack special for hospital usage.

◆ Connect to the ground line if necessary. Refer to *Section1.2 Safety Guidance* for details.

#### NOTE:

When the battery configuration is provided, after the device is transported or stored, the battery must be charged. Powering on without connecting AC power supply may cause the device to malfunction. Switching on AC power supply can charge the battery no matter if the monitor is powered on.

## 2.3 Powering on the Monitor

After you power on the monitor, LOGO information will be displayed on the screen.

### **WARNING**

If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or Customer Service Center immediately.

#### NOTE:

- 1 Check all the functions of the monitor and make sure that the monitor is in good status.
- 2 If rechargeable batteries are provided, charge them after using the device every time, to ensure the electric power is enough.
- 3 The interval between double pressing of POWER switch should be longer than 1 minute.

## 2.4 Connecting Patient Sensors

Connect all the necessary patient sensors between the monitor and the patient.

#### NOTE:

For information on correct connection, refer to related chapters.

## 2.5 Checking the Recorder

If your monitor is equipped with a recorder, open the recorder's door to check if paper is properly installed in the slot. If no paper exists, refer to *Chapter8 Recording* for details.

## **Chapter 3 Introduction**

This user manual is based on the maximum configuration and therefore your monitor may not have all of the functions and options described in the manual. Also, illustrations in this manual serve as examples only and do not necessarily reflect the setup on your monitor. The content displayed on you monitor depends on the way it has been tailored for your hospital.

### 3.1 General Information

The monitor integrates the functions of parameter measurement module, display, recording and output to compose a compact, portable device. Its built-in replaceable battery provides convenience for patient movement. On the high-resolution display screen, 7 waveforms and all the monitoring parameters can be displayed clearly.

The **POWER** switch is on the left of the front panel (Figure 3-1 ①). The **POWER** indicator lights when the monitor is powered on (Figure 3-1②). The CHARGE indicator shows the charging status (Figure 3-1). The ALARM indicator flashes when the alarm is triggered (Figure 3-1④). The sockets of various sensors are on the left panel. Other sockets and the power plug-in are on the rear panel. The recorder is on the right panel.

The monitor is a user-friendly device with operations conducted by a few buttons and a trim knob on the front panel (Figure 3-156). Refer to Section 3.3 Button Functions.

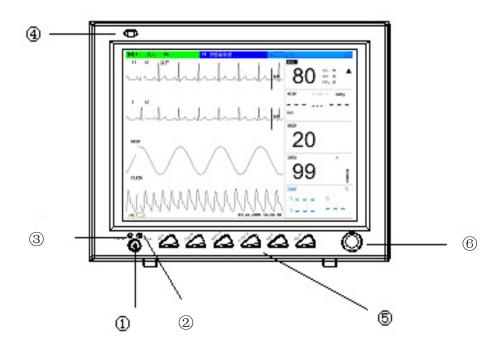


Figure 3-1 iM8 Patient Monitor

The monitor has 3 models: iM8, iM8A and iM8B.

Product models	Size (L×W×H)	Shell figure / Screen size	Functions
iM8	Host: 319mm×154mm×267.8mm	Square / 12.1-inch	ECG/RESP, SpO <sub>2</sub> , NIBP, TEMP, IBP, CO <sub>2</sub>
iM8A	Host: 319mm×154mm×267.8mm	Square / 10.4-inch	ECG/RESP, SpO <sub>2</sub> , NIBP, TEMP, IBP, CO <sub>2</sub>
iM8B	Host: 319mm×154mm×267.8mm	Square / 10.1-inch Wide-screen	ECG/RESP, SpO <sub>2</sub> , NIBP, TEMP, IBP, CO <sub>2</sub>

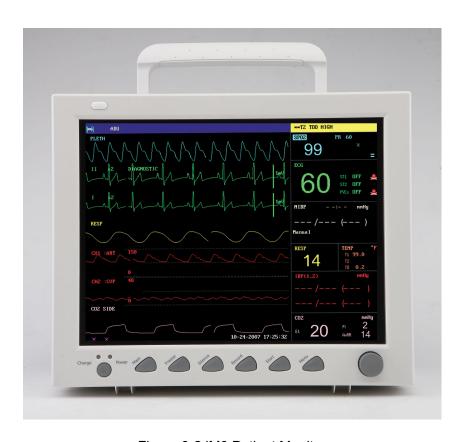


Figure 3-2 iM8 Patient Monitor



Figure 3-3 iM8A Patient Monitor



Figure 3-4 iM8B Patient Monitor

The monitor can monitor the following parameters and waveforms:

ECG: Heart Rate (HR)

Maximum 7-channel

Arrhythmia and ST-segment analysis (optional)

RESP: Respiration Rate (RR)

Respiration Waveform

SpO<sub>2</sub>: Oxygen Saturation (SpO<sub>2</sub>), Pulse Rate (PR)

SpO<sub>2</sub> Plethysmogram

NIBP: Systolic Pressure (SYS), Diastolic Pressure (DIA), Mean Pressure (MAP), PR (NIBP)

TEMP: Channel-1 Temperature (T1), Channel-2 Temperature (T2),

Temperature Difference between two channels (TD)

IBP: Channel-1 SYS, DIA, MAP

Channel-2 SYS, DIA, MAP

**Dual-IBP** waveforms

CO<sub>2</sub>: End Tidal CO<sub>2</sub> (EtCO<sub>2</sub>)

Fraction of inspired carbon dioxide (FiCO<sub>2</sub>)

Air Way Respiration Rate (AwRR)

CO<sub>2</sub> waveform

The monitor provides extensive functions such as visual and audible alarms, storage for trend data, NIBP measurements, alarm events, drug dose calculation, and so on.

## 3.2 Screen Display

The monitor is equipped with a high-resolution multicolor TFT LCD screen. The patient parameters, waveforms, alarm messages, bed number, time, monitor status and other data can be reflected from the screen.

The screen is divided into three areas:

1 Information Area ① ④;

2 Waveform Area ②;

3 Parameter Area ③.

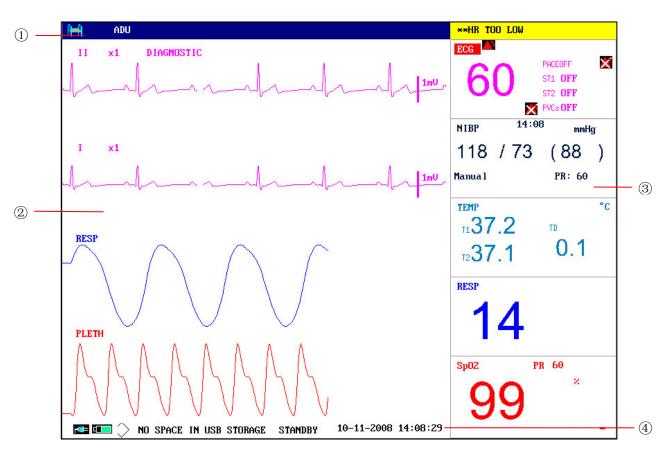


Figure 3-5 Main Display

### Information Area (① ④)

The Information Area is at the top and bottom of the screen, displaying the operating state of the monitor and the status of the patient.

The information area contains the following data:

Bed number of the monitored patient

ADU Type of patient. Three options: Adult, Pediatric, Neonatal.

Name Name of the monitored patient, when the user inputs patient name, this name will be displayed on the right side of the patient type. If the user doesn't input patient name, this position will be vacant.

10-11-2008 Current date

14: 08: 29 Current time

Indicates the status of mains power supply

Current time

Indicates the status of mains power supply

means the mains power supply is on,

means the mains power supply is off.

Indicates the battery and its capacity;

gives information about remaining battery charge, estimated

 $\times$ 

X

operating time and maintenance requirements;

means there is no battery equipped in the monitor.

Indicates the audio alarm is turned off.

Indicates the audio alarm is paused.

Displays beside a parameter to indicate the alarm is turned off.

USB storage indicator

**STANDBY** Select this item to enter Standby mode, the dialog pops up:

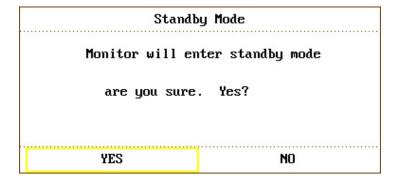


Figure 3-6 Standby Mode

Select **YES** to enter Standby mode and display the current time; if you select **NO**, the monitor will return to the main display.

Other information of the Information Area comes up only with respective monitoring status. They are:

- ◆ Signs indicating the operating status of the monitor and the sensors are displayed at the right side of patient name.
- Alarm message is displayed in the right most area.
- "FREEZE" appears when the waveforms are frozen.

### Waveform Area (2)

Seven waveforms can be displayed at the same time. The sequence of waveforms can be adjusted. With the maximum configuration, the system can display 2 ECG waveforms, an SpO<sub>2</sub> waveform, a respiration waveform (can be from ECG module), 2 IBP waveforms and a CO<sub>2</sub> waveform.

In the **TRACE SETUP** menu, all the waveforms are listed. The user can select the waveform to be displayed, and adjust the display position. Refer to *Section 4.8 Tracing Waveforms Selection* for details.

The name of the waveform is displayed on the upper left part of the waveform. The name of ECG is user-selectable. Gain and filter way of this channel are displayed as well. A 1mV scale is marked on the right of ECG waveform. The IBP waveform scale can also be selected according

to the actual requirement. Its range is described in the part: IBP Monitoring. In the IBP waveform area, the waveform scale is displayed. The three dotted lines for each IBP waveform from up to down represent respectively the upper limit scale, reference scale and lower limit scale. The values of these three scales can be set. The specific method is given in the part: IBP Monitoring.

When a certain menu is displayed, some waveforms become invisible. Main display is restored when you exit the menu.

The user may set up the rate to refresh the waveform. The method to adjust the refreshing rate of each waveform is discussed in the setup description of each parameter.

### Parameter Area (3)

Parameter area is on the right of Waveform area, and parameters are displayed corresponding to waveforms basically. They are:

#### ECG:

- Heart Rate (Unit: beats per minute, bpm)
- ST-segment analysis of Channel 1 & 2-ST1, ST2 (Unit: mV)
- PVCs (Premature Ventricular Contraction) events (Unit: event/min)

### SpO<sub>2</sub>:

- Oxygen Saturation SpO<sub>2</sub> (Unit: %)
- PR (Unit: BPM)

#### NIBP:

- Systolic pressure, Mean pressure, Diastolic pressure (Unit: mmHg or kPa)
- PR (NIBP) (Unit: BPM)

### TEMP:

— Temperatures of channel 1, channel 2 and their temperature difference: T1, T2, TD (Unit: °C or °F)

### RESP:

— Respiration Rate (Unit: breath/min)

### IBP:

— The blood pressure of channel 1 and 2. From left to right, there are Systolic pressure, Mean pressure and Diastolic pressure (Unit: mmHg or kPa)

#### $CO_2$ :

- EtCO<sub>2</sub> (Unit: %, mmHg or kPa)
- FiCO<sub>2</sub> (Unit: %, mmHg or kPa)
- AwRR (Unit: times/minute)

### **Alarm Indicator and Alarm Status**

In normal status, the alarm indicator does not light.

When an alarm occurs, the alarm indicator will light or flash. The color of light represents the alarm level. Refer to *Chapter Alarm* for details.

Refer to relative content of parameter for Alarm information and prompt.

## **Charge Indicator and Charge Status**

To indicate the status of charging: When the battery is charged, the light color turns to orange.

## 3.3 Button Functions

All the operations to the monitor can be finished by several buttons and a knob. They are:

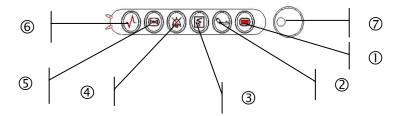


Figure 3-7 Buttons

1	Menu	Press to call up the <b>SYSTEM MENU</b> . Refer to <i>Chapter4 SYSTEM MENU</i> and <i>Chapter9 Trend and Event</i> for details.	
2	Start	Press to fill air into cuff and start blood-measuring. During the measuring process, press the button to stop measure.	
3	Record	Press to start a real-time recording. The recording time is set in <b>RT REC TIME</b> of <b>RECORD</b> submenu.	
4	Silence	When the <b>SYSTEM MENU</b> > <b>MAINTAIN</b> > <b>USER MAINTAIN</b> > <b>ALARM SETUP</b> is set to <b>ON</b> , press this button to silence the alarm. All the alarm audio will be closed. At the same time, " <b>ALARM SILENCE</b> ×× s" and will be displayed in the Information area. When you repress it or the pause time is over, the system will resume the normal monitoring status, and " <b>Alarm Pause</b> ×× s" and icon will vanish.	
		Pressing this button and holding for more than 3 seconds can turn off the audio alarm. is shown in the Information area. Pressing or holding the button again can resume the alarm.  NOTE:	
		Whether an alarm will be reset depends on the status of the alarm cause. But pressing <b>SILENCE</b> button (suspend alarm) can permanently shut off audio sound of the Lead Off or Sensor Off alarms. So the user can exit the Alarm Silence Status by Technical Alarm.	

⑤ Freeze	In normal mode, press this button to freeze all the waveforms on the screen. In <b>FREEZE</b> mode, press this button to restore the waveform refreshing.	
<b>6</b> Main	Press this button to return to the main interface.	
⑦ Trim Knob	The user can use the trim knob to select the menu item and modify the setup. It can be rotated clockwise or anticlockwise and pressed. The user can use the knob to realize the operations on the screen, in the <b>SYSTEM MENU</b> and parameter menu.	

### Method to Use the Knob to Operate on the Screen:

The rectangular mark on the screen that moves with the rotation of the knob is called "cursor". Operation can be performed at any position at which the cursor can stay.

When the cursor is in the waveform area, the user may immediately modify the current setup. When the cursor is in the parameter area, the user may open the setup menu of the corresponding parameter module so as to set up the menu items of the module.

### Operating method:

- ◆ Move the cursor to the item where the operation is required.
- Press the knob.
- One of the following four situations may appear:
  - 1. The cursor with background color may become a frame without background color, which implies that the content in the frame can change with the rotation of the knob.
  - 2. Menu or measuring window may appear on the screen, or the original menu is replaced by the new menu.
  - 3. A check mark " $\sqrt{}$ " appears at the position, indicating that the item is confirmed.
  - 4. The system immediately executes a certain function.

## 3.4 Interfaces

For the convenience of operator, interfaces of different functions are in different sites of the monitor. There is a USB port on the panel for connecting USB storage.

### **Right Side of the Monitor**

At the right side of the monitor, there are a bracket of water trap for  $CO_2$  module (1) and the recorder's paper inlet cover (2).

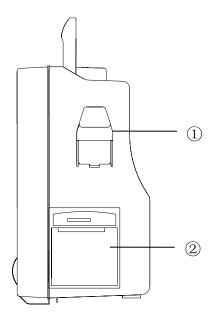


Figure 3-8 Right Panel

### **Left Side of the Monitor**

Connectors for cables and sensors are as shown in the following figure.

- 1. CO<sub>2</sub> sensor connector
- 2. IBP1 transducer connector
- 3. ECG cable connector
- 4. NIBP cuff connector
- 5. TEMP1 probe connector
- 6. TEMP2 probe connector
- 7. IBP2 transducer connector
- 8. SpO<sub>2</sub> sensor connector

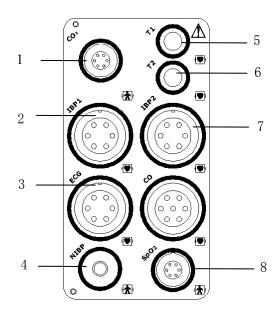


Figure 3-9 Left Panel

### **Rear Panel**



Figure 3-10 Rear Panel of iM8, iM8A and iM8B

- ① Network Interface (reserved): Standard RJ45 Socket, for connecting to MFM-CMS of the manufacturer
- ② VGA interface (optional)
- ③ USB port
- ④ Equipotential grounding terminal for connection with the hospital's grounding system.
- ⑤ Fuse box, in which fuses are put.
- **6** Power supply socket:  $100V-240V\sim$ , 50 Hz/60 Hz.

### NOTE:

The VGA function is optional.

## 3.5 Built-in Rechargeable Battery

## 3.5.1 Battery Safety Information

### **WARNING**

- 1 Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.
- 2 Do not place battery in the monitor with the (+) and (-) in the wrong way around.
- 3 Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the battery together with metal object, which can result in short circuit.
- 4 Do not unplug the battery when monitoring.
- 5 Do not heat or throw battery into a fire.
- 6 Do not use, leave battery close to fire or other places where temperature may be above  $60^{\circ}$ C.
- 7 Do not immerse, throw, or wet battery in water/seawater.
- Do not destroy the battery: do not pierce battery with a sharp object such as a needle; Do not hit with a hammer, step on or throw or drop to cause strong shock; Do not disassemble or modify the battery.
- 9 Use the battery only in the monitor.
- 10 Do not solder the leading wire and the battery terminal directly.
- 11 If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately. If liquid leaks of the battery splash onto your skin or clothes, wash well with fresh water immediately.
- 12 Keep away from fire immediately when leakage or foul odor is detected.
- 13 Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.
- 14 Do not use a battery with serious scar or deformation.

## 3.5.2 Battery Status on the Main Screen

The monitor is equipped with a built-in chargeable battery. When the AC power supply is switched on, the battery will be charged automatically until the electric energy becomes full. There is a sign " in the lower left corner of screen to show the charging status, and the green part is the electric energy of battery. When the monitor is not equipped with battery, the battery status will be shown as the sign " which means no battery.

One battery can power the monitor. Under the cable connectors is the cover of battery compartment. See Battery compartment in the following figure.

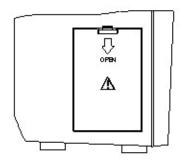


Figure 3-11 Battery Compartment

## 3.5.3 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as recommended here can help to slow down this process.

- 1. Disconnect the patient from the monitor and stop all monitoring and measurement.
- 2. Switch the monitor power on and charge the battery for more than 6 hours continuously.
- 3. Disconnect monitor from mains power and let the monitor run until there is no battery power left and the monitor shuts off.
- 4. The running time of the battery reflects the battery performance.

If the running time is obviously less than the specified time in the specification, please change the battery or contact the service personnel.

## 3.5.4 Replacing the Battery

To install or replace the battery, please follow the procedure:

- 1. Pull the battery door downwards to open it according to indication on it.
- 2. Pull the metal retainer until the battery can be removed.
- 3. Insert the new battery into the battery compartment.
- 4. Pull the metal retainer downward to fix the battery and close the battery door.

## 3.5.5 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

## 3.5.6 Maintaining the Battery

Batteries should be conditioned regularly to maintain their useful life.

Remove the batteries from the monitor if they are not used for a longer period of time. And recharge the batteries at a minimum of every 6 months when they are stored.

Discharge the battery completely once every month.

## **Chapter 4 System Menu**

The **SYSTEM MENU** is introduced in this chapter.

The monitor features in flexible configurations. You can configure various aspects of the monitor, including the parameters to be monitored, sweeping speed of the waveforms, audio signal volume, and output content.

Press the **MENU** button on the front panel to call up **SYSTEM MENU**. You can perform the following operations in this menu.

SYSTEM	1 MENU	
PATIENT SETUP >>	SYSTEM SETUP >>	
DEFAULT >>	SELECTION >>	
TREND GRAPH >>	VERSION >>	
TREND TABLE >>	DRUG CALC >>	
NIBP RECALL >>	MAINTAIN >>	
ALARM RECALL >>	DEMO >>	
DATA STORE >>		
EXIT		

Figure 4-1 System Menu

Select **SYSTEM SETUP** >> to see the following menu:

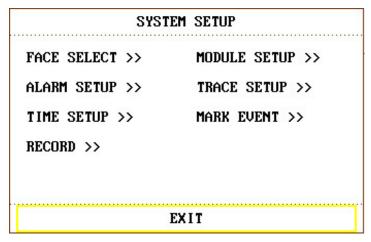


Figure 4-2 System setup

Review of trend graphs/tables, NIBP measurements and alarm recall will be described in *Chapter9 Trend and Event*.

## 4.1 Patient Setup

Pick **PATIENT SETUP** in **SYSTEM MENU** to call up the following menu.

			n.	11.51		e te t		P	ΑT	IE	NT	S	ΕT	UP						**********
DEPT.								ADMIT												
PAT	NO	ľ	2000							. 20.00	ΒI	RT	Ή							
BED	NO	ĺ									HE	IG	HT	į.						CM
DOCT	OR	ě	5945								WE	IG	HT	Č						kg
NAME	E E										BL	.00	D							
SEX	SEX								NEW PATIENT											
PAT	TY	PE	f	ìDl	J															
	A	В	С	D	E	F	G	Н	I	J	K	L	M	N	0	P	Q	R	S	TU
	U	W	X	Y	Z	0	1	2	3	4	5	6	7	8	9	,		DI	EL	OK

Figure 4-3 Patient Setup

You can set up the following patient information:

DEPT.	Department in which the patient receives treatment.
PAT NO	Patient Number
BED NO	Patient bed number (Range: 1 ~ 254)
DOCTOR	Name of the doctor.
NAME	Patient name (Valid characters: $A \sim Z$ , $0 \sim 9$ ; Maximum length: 12 characters)
SEX	Patient gender (Available options: "F" for Female, "M" for Male)
PAT TYPE	Patient type (Available options: <b>ADU, PED</b> , and <b>NEO</b> )
ADMIT	Hospitalization starting date (format: year/month/day)
BIRTH	Patient date of birth (format: year/month/day)
HEIGHT(cm/inch)	Patient height (Increase/decrease by 0.5 cm or 0.5 inch per switch)
WEIGHT(kg/lb)	Patient weight (Increase/decrease by 0.5 kg or 0.5 lb per switch)

BLOOD	Patient blood type (Pick A, B, O, AB, or N. N represents unknown blood type)
NEW PATIENT	Admission of new patient

Also in this menu, the user may select "**NEW PATIENT**" item to access "**CONFIRM TO UPDATE PATIENT**" dialog box as shown below, in which the user decides whether to monitor a new patient.

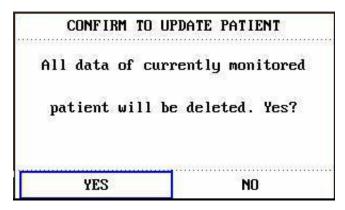


Figure 4-4 Confirm to Update Patient

Pick **YES** to delete all information of the patient being currently monitored and exit the menu. Pick **NO** to give up updating the patient and the system will keep the information of the current patient and exit the menu.

#### NOTE:

Selecting **YES** will delete all information about the currently monitored patient.

## 4.2 Default Setup

### NOTE:

Select any item in this sub-menu to cancel the current setup and use the selected default setup.

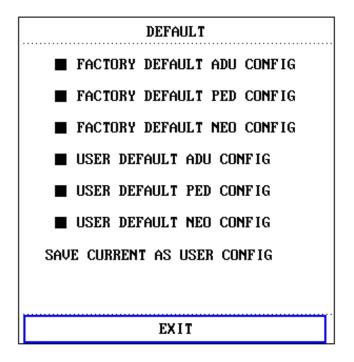


Figure 4-5 Default Menu

In this sub-menu, you can select the factory default or the user-defined default. Also in this sub-menu, you can save the current configuration as the user-defined default configuration. At this time, the system will automatically save all the setups in the parameter menu, ECG lead, gain and filter way as the user-defined default configuration according to the patient type. The dialog box as shown below will pop up.

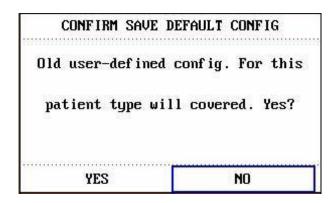


Figure 4-6 Confirm Save Default Configuration

Click on **YES** to save the current patient type configuration as the user default configuration. Click on **NO** to give up the operation.

### 4.3 Mark Event

There are four types of event that you can define.

Select MARK EVENT item in SYSTEM SETUP to call up the following menu:

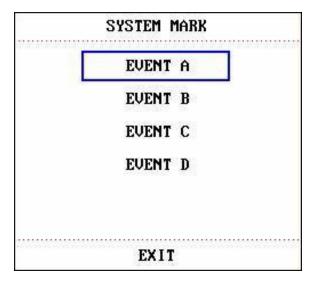


Figure 4-7 Mark Event

To mark the event: Use the trim knob to select one from event **A**, **B**, **C** and **D**. There is a "@" signal for the one selected. To cancel your selection, repress the knob at selected item. Press **EXIT** to return to the previous menu.

The point of using event function:

To differentiate the patient events that have impact on parameter monitoring, such as dose taking, injection, therapy status, etc.

The Event will be displayed on the **Trend Graph** and **Trend Table** to assist analyzing patient parameter of the time when the event happens.

### 4.4 Face Select

Select FACE SELECT item in SYSTEM SETUP menu to access FACE SELECT dialog box as shown below, in which four selections are available: STANDARD SCREEN, TREND SCREEN, oxyCRG SCREEN and LARGE FONT SCREEN. Only one selection can be chosen each time.

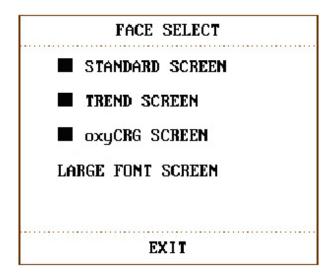


Figure 4-8 Face Select

After entering LARGE FONT FACE SCREEN, you can select three modes. See as follows:

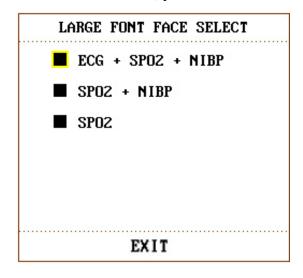


Figure 4-9 Large Font Face Select

## 4.5 Time Setup

Select **TIME SETUP** item in **SYSTEM SETUP** menu to access the sub-menu of **TIME SETUP** as shown below. System time is in the format of **MONTH-DAY-YEAR, DAY-MONTH-YEAR, YEAR-MONTH-DAY**. Pick the item and turn the knob to modify the items. Select **EXIT** item to return to the previous menu.

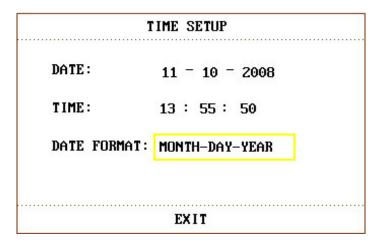


Figure 4-10 Time Setup

# 4.6 Record Setup

Select **RECORD** in **SYSTEM SETUP** menu to call up the following menu:

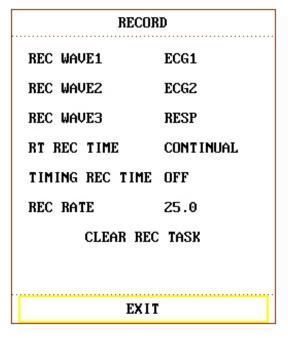


Figure 4-11 Record

In the sub-menu, the user may select the **REC WAVE1**, **REC WAVE2** or **REC WAVE3**, a maximum of 3 waveforms can be printed out.

The output waveforms can be selected for the following items:

ECG1, ECG2, ECG3	ECG1 waveform, ECG2 waveform and ECG3 waveform.  (There will be 7 ECG waveforms on the screen in Full-Lead display mode). If no ECG waveform is currently displayed on the screen, this item cannot be picked.
SpO <sub>2</sub>	$SpO_2$ Plethysmogram. (If no $SpO_2$ waveform is currently displayed on the screen, this item cannot be picked. In ECG Full-Lead display mode, this item can be picked, although no $SpO_2$ waveform is currently displayed on the screen. )
RESP	RESP waveform.  (If no RESP waveform is currently displayed on the screen, this item cannot be picked. But in ECG Full-Lead display mode, this item can be picked, although no RESP waveform is currently displayed on the screen.)
IBP1, IBP2	IBP1 waveform and IBP2 waveform.  (If no IBP waveform is currently displayed on the screen, this item cannot be picked. But in ECG Full-Lead display mode, this item can be picked, although no IBP waveform is currently displayed on the screen.)

CO <sub>2</sub>	Display CO <sub>2</sub> module waveform.  (If there is no CO <sub>2</sub> waveform on the screen, we cannot choose it. But in full screen multi-lead mode, we can choose it though we can not see it.)
OFF	No display for this channel.

- ◆ RT REC TIME: represents "real-time recording time", for which two selections are available: CONTINUAL and 8S (8 seconds). "CONTINUAL" means once pressing the "Record" button on the front panel, the recorder will continuously print out the waveform or parameter until the "Record" button is pressed again.
- ◆ TIMING REC TIME: represents "time interval between two times of timing recording".

  10 selections are available: "OFF, 10MIN, 20MIN, 30MIN, 40MIN, 50MIN, 1HOUR,

  2HOURS, 3HOURS and 4HOURS". It means that the system will trigger the recording operation according to the selected time interval. The recording time is fixed at 8 seconds.

#### NOTE:

**REC TIME** has the higher priority compared with **TIMING REC TIME**.

- ◆ REC RATE: 25.0 mm/s or 50.0 mm/s.
- ◆ CLEAR REC TASK: this item can be used to stop recorder from printing out too many tasks.

#### NOTE:

- 1 The recorder is an optional part.
- 2 If two same waveforms are selected, one of them will change to a different waveform automatically.

# 4.7 Module Setup

Select **MODULE SETUP** item in **SYSTEM SETUP** menu. You can choose the parameter you want to monitor from this menu, so that you can enhance the display efficiency, and avoid interference from other messages.

# 4.8 Tracing Waveforms Selection

Select **TRACE SETUP** item in **SYSTEM SETUP** menu to call up the following menu:

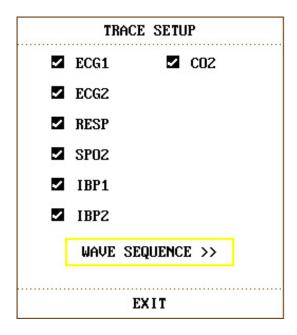


Figure 4-12 Trace Setup

You can define the traces displayed on the screen in this menu. The waveforms available for selection are those whose modules have been selected in **MODULE SETUP** menu.

# 4.9 Monitor Version

Pick **VERSION** to show the software version information of this monitor.

# 4.10 Alarm Volume

The system provides five levels of alarm volume and an alarm silence function. The system will give audio alarm prompt (except alarm sound) based on the selection.

The user may select different levels of volume as per clinical requirement. The method is listed below:

Press **ALARM SETUP** item in **SYSTEM SETUP** menu to call up **ALARM SETUP** sub-menu as shown below, in which the user may set up the alarm volume and other alarm information.

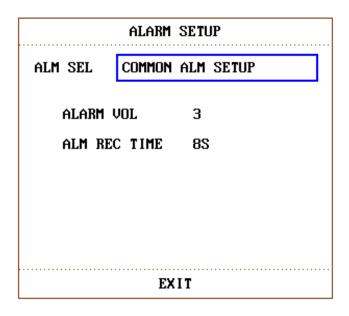


Figure 4-13 Alarm Setup

- ALARM VOL: set the alarm volume by turning the knob. The valid range is from 1 to 10.
- ALM REC TIME: set to 8s, 16s or 32s.

You can also set alarm parameters in **MAITAIN** > **USER MAINTAIN** > **ALARM SETUP**. Refer to *Chapter6 Alarm* for details.

# 4.11 Key Volume

Select **SELECTION** item in **SYSTEM SETUP** menu to call up **SELECTION** sub-menu as shown below. Select **KEY VOL** item and set the volume. The selections are **OFF**, **LOW**, **MED**, **HIGH**.

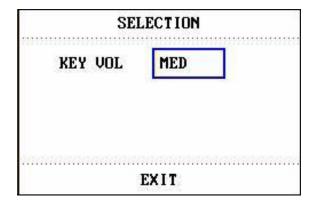


Figure 4-14 Selection

# 4.12 Drug Calculation

The monitor provides drug calculation and titration table display functions for fifteen different drugs. For details, please refer to the *Chapter10 Drug Calculation and Titration Table*.

# 4.13 Waveform Demonstration

Select **DEMO** item in **SYSTEM MENU** to call up **INPUT DEMO KEY**. After entering the password, the system enters the Demonstration Waveform status.

The purpose of waveform demonstration is only to demonstrate the machine performance and for training purposes. In clinical applications, this function is not recommended because the **DEMO** will mislead the hospital personnel to treat the waveform and parameter as actual data of the patient, which may result in delay of treatment or mistreatment.

# 4.14 Maintenance

Select **MAINTAIN** item in **SYSTEM MENU** to open the **ENTER MAINTAIN PASSWORD** dialog box as shown below, in which you can enter password and then customize maintenance settings. Factory maintenance function is only available for the service engineers of the manufacturer or representatives authorized by the manufacturer.

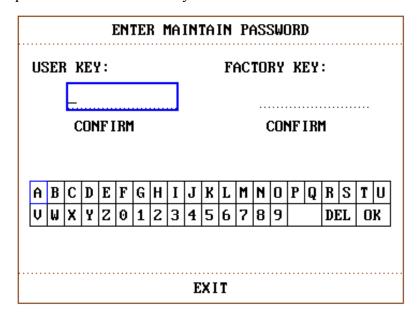


Figure 4-15 Enter Maintain Password

#### **User Maintain**

Input the password A B C into the ENTER MAINTAIN PASSWORD box and press CONFIRM, then the USER MAINTAIN menu will pop up, in which you can set up the following items.

◆ LANGUAGE: You can set the language to be displayed on the interface.

#### NOTE:

Please restart the monitor after changing the language.

◆ **LEAD NAMING**: You can select **AHA** or **IEC**. To know the difference between these two styles, refer to *Chapter12 ECG/RESP Monitoring*.

- ◆ **LOCAL NET NO**: Physical Number of monitor.
- ◆ **ALARM SETUP>>**: You can set up parameters of alarm. For more details refer to *Chapter6 Alarm*.

ALARM SETUP			
ALM PAUSE TIME	2MIN		
ALARM SILENCE	ON		
ALARM TWINKLE	BK FLASH		
ALARM LIMIT	ON		
SENSOR OFF ALARM	ON		
ALM LATCH	UNLATCH		
EXIT			

Figure 4-16 Alarm Setup

◆ OTHER SETUP >>: You can set some other functions. See as follows:

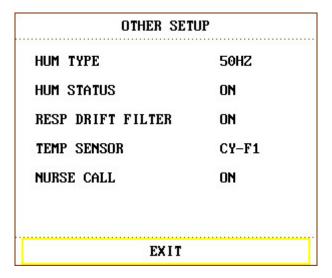


Figure 4-17 Other Setup

- ✓ **NURSE CALL**: Turn on or off the nurse call. When a new alarm of physiological parameter occurs, it gives a 3-second **NURSE CALL** alarm; if the system alarm or the audio alarm is turned off, the **NURSE CALL** is unavailable. It is connected to RJ45 socket, the same port as connected to Ethernet. **NURSE CALL** occupies the 7<sup>th</sup> and 8<sup>th</sup> pins of RJ45. When the alarm occurs, the 7<sup>th</sup> and 8<sup>th</sup> pins are in short circuit: otherwise they are disconnected.
- ◆ **SERVER IP**: The default server IP is 202.114.4.119, it can be changed by the user according to the IP address of PC installed with MFM-CMS of the manufacturer.
- ◆ **SERVER PORT**: Set server port.
- ◆ SELECT COLOR >>: Users can set the displaying colours of waveforms by this item. 16

colours can be selected. Selecting **DEFAULT** can set the colour configuration to default setup.

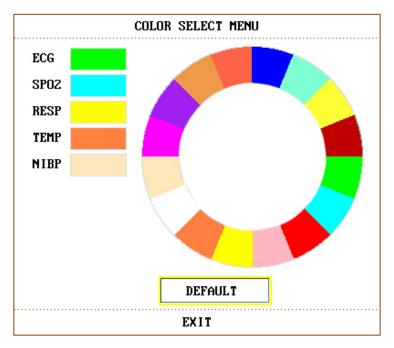


Figure 4-18 Colour select menu

# **Factory Maintain**

Factory maintenance function is only available for the service engineers of the manufacturer or representatives authorized by the manufacturer.

# 4.15 Data Storing

Users can store the measured data into USB storage by Data store function, query or delete data in the menu.

Select **DATA STORE** in **SYSTEM MENU** to call up the following dialog box:

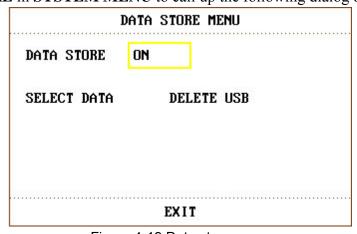


Figure 4-19 Data store menu

**DATA STORE**: set this item to **ON** or **OFF** to turn on or off the data store function.

The data file will be stored into the folder of patient-data/patient ID in the USB storage; if the

patient ID has not been set, the data will be stored into the default folder "patient" in USB storage.

Each data file is named by time, it can save 96-hour trend data with 1-min resolution, 1-hour trend data with 1-second resolution, 60 groups parameter alarm, 60 groups ARR data, 500 groups NIBP data, 720 seconds waveforms and patient information.

◆ EXIT U DISK: users should exit the U disk via the menu before dismounting it.

After selecting **EXIT U DISK**, if the data is being stored, it will indicate "**Transmitting...**, **Please Waiting**"; if the U disk is dismounted successfully, it will indicate **EXIT U DISK SUCCESS**. After the USB icon vanishes, remove the U disk.

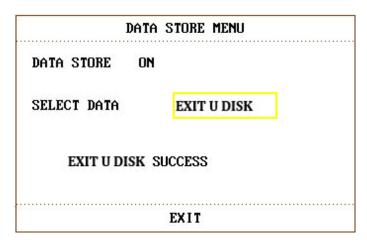


Figure 4-20 Delete USB success

**SELECT DATA**: select this item to query data. The dialog box displays as follows:

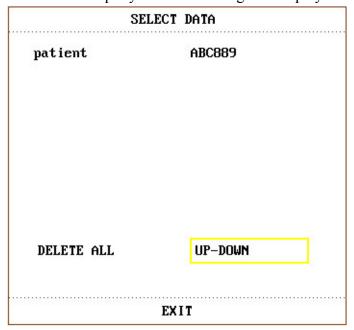


Figure 4-21 Select data

- **DELETE ALL**: users can delete all the data of selected patient ID by this item.
- UP-DOWN: users can page up or down by this item, patient ID can be displayed on few pages.

Select patient ID to enter the following dialog box for selecting the data:

SEI	LECT D	ATA (	patient)
2008.11.16.18	:24	2	2008.11.16.18:17
2008.11.16.17	:51	2	2008.11.16.17:33
2008.11.10.13	:40		
TREND TABLE	DEL	ETE ID	UP-DOWN
EXIT			

Figure 4-22 Select data

After selecting the time, the data will be imported from the USB storage to the monitor, it indicates as follows:

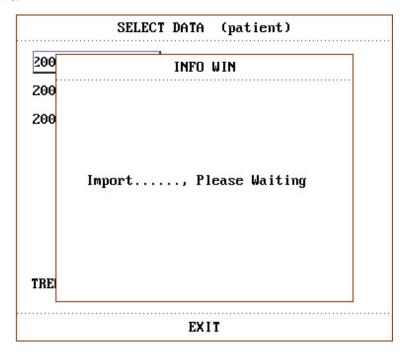


Figure 4-23 Importing data

TREND TABLE: users can select this item by trim knob after importing data, the real line box becomes broken line box, select the following contents to display: TREND TABLE, TREND GRAPH, NIBP RECALL, PATIENT INFO, FREEZE RECALL, ARR RECALL or ALARM LIST.

— **DELETE ID**: users can delete all the data for current ID by this item. The dialog box displays:

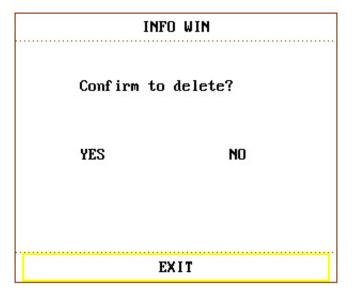


Figure 4-24 Confirm to delete

After deleting successfully, it indicates **DELETE SUCCESS!** 

### NOTE:

The data of the current monitoring patient ID can not be deleted.

If the data has not been saved successfully because of the power supply off or USB storage off, when the users queries data by **SELECT DATA**, the prompt pops up:



Figure 4-25 Invalid data!!!

If the user wants to query or delete data before selecting data, the prompt will pop up:

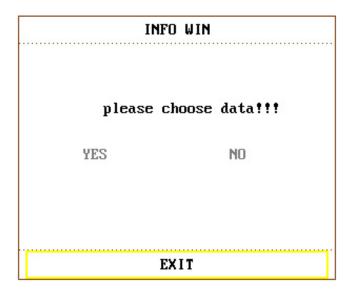


Figure 4-26 Please choose data

If the USB storage is full, it indicates **NO SPACE IN USB STORAGE** on the screen.

### NOTE:

- 1 Data store function can be set to on or off in **FACTORY MAINTAIN** by the manufacturer or the representative permitted by the manufacturer.
- 2 Remove USB disc before deleting may damage the USB storage or loss data.

# **Chapter 5 Face Select**

This monitor has four different operating screens, which are **Standard Screen**, **Trend Screen**, **oxyCRG Screen and Large Font Screen**. Users can select different operating screens for necessary information as requested.

# 5.1 Selecting Operating Screen

In the **SYSTEM MENU**, select the **FACE SELECT** option in the **SYSTEM SETUP** menu to call up the dialog box as shown in the figure below. There are four options in this dialog box, which are **STANDARD SCREEN**, **TREND SCREEN**, **oxyCRG SCREEN and LARGE FONT SCREEN**. Only one item can be selected at a time.

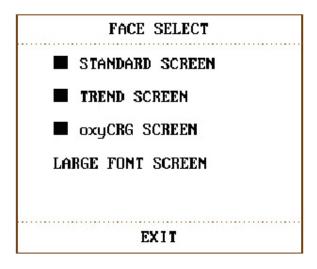


Figure 5-1 Face Select

# 5.2 Standard Screen

In the **FACE SELECT** menu, select the **STANDARD SCREEN** option to enter the Standard Screen. The Standard Screen displays to us the parameters in the Parameter area and the waveforms being monitored. This screen is the basic operating screen of the monitor.

# 5.3 Trend Screen

#### ◆ Entering **TREND SCREEN**

In the **FACE SELECT** menu, select the **TREND SCREEN** option to enter the Trend Screen.

#### Position of trend graph

Trend graph is located on the right of the corresponding waveform in the Waveform area. Its colour is the same as that of the corresponding parameter.

### Trend length

Dynamic trend length is 2 hours. On the trend graph, the scale of the right end of the X-axis is 0 hour while the left end is 2-hour.

### Select trend parameter

If multiple parameters are located at the same position on the trend graph, by selecting the corresponding hot key of a parameter on the trend graph, you can have the trend graph of this parameter displayed on the screen. For example, on ECG trend graph, you can select hot keys such as HR, ST or PVCs, then the system will display their corresponding trend graphs respectively.

#### ◆ Close trend screen

In the **FACE SELECT** menu, select options of other operating screens to close the **Trend Screen**.

# 5.4 oxyCRG Screen

## ◆ Enter **oxyCRG SCREEN**

In the **FACE SELECT** menu, select the **oxyCRG SCREEN** option to enter the oxyCRG Screen.

◆ Trend graph of oxyCRG screen

Located at the lower part of the screen, oxyCRG screen consists of three trends: HR Trend, SpO<sub>2</sub> Trend and RR Trend or Compressed Resp. Waveform.

Select oxyCRG trend length

There are two hot keys at the bottom part of the oxyCRG Screen, which are **4MIN/2MIN/1MIN** and **RR/RESP WAVE**.

By using hot keys for trend time, you may select to display trend graphs of three different lengths, i.e., 1 min, 2 min and 4 min.

Select RR trend or Compressed RESP Waveform

By using the hot keys for **RR/RESP WAVE**, you may select either RR trend graph or compressed Resp. Wave. They occupy the same position. Therefore, if you select "RR", the position displays the dynamic trend of RR. If you select **RESP WAVE**, the position displays the compressed Resp. Wave.

Close oxyCRG

In the **FACE SELECT** menu, select options of other operating screens to close the oxyCRG Screen.

# 5.5 Large Font Screen

Large Font Screen is a kind of operating screen, just like Standard Screen, Trend Screen and other operating screens. It is used by customers to meet different display requirements in monitoring.

### ◆ Enter Large Font Screen

Choose LARGE FONT SCREEN in FACE SELECT menu to enter LARGE FONT FACE SELECT. There are three modes, see as follows:

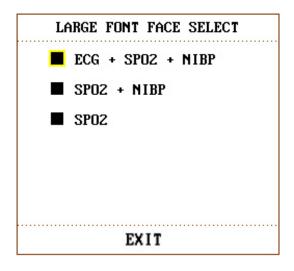


Figure 5-2 Large Font Face Select

- ◆ Three display modes
- 1. **ECG+SpO<sub>2</sub>+NIBP** display mode:

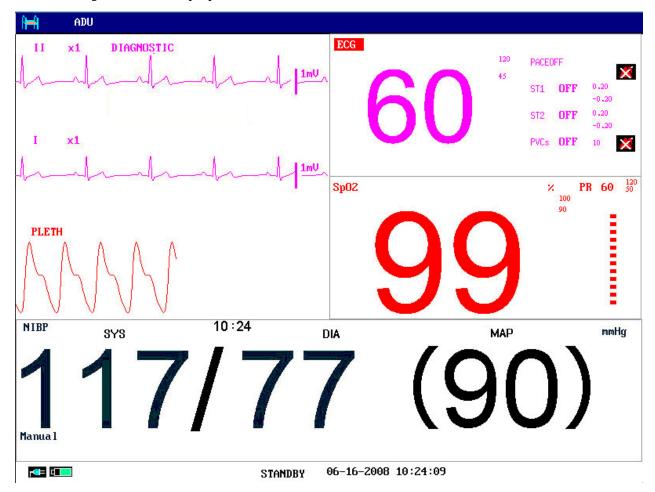


Figure 5-3 ECG+SpO<sub>2</sub>+NIBP display mode

# 2. **SpO<sub>2</sub>+NIBP** display mode:

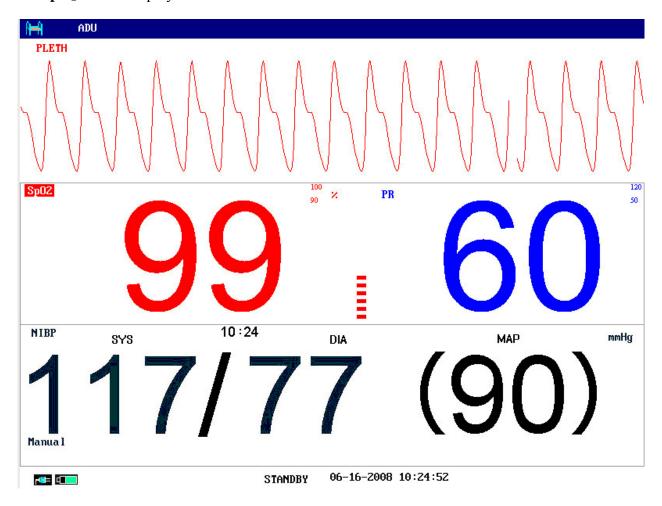


Figure 5-4 SpO<sub>2</sub>+NIBP display mode

# 3. **SpO**<sub>2</sub> display mode:

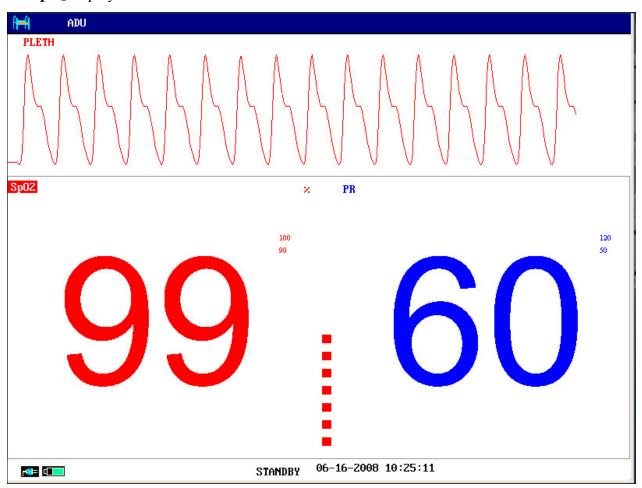


Figure 5-5 SpO<sub>2</sub> display mode

# ◆ Exit Large Font Screen

In the LARGE FONT FACE SELECT menu, choose EXIT to return to FACE SELECT screen.

# **Chapter 6 Alarm**

This chapter gives general information about the alarm and measures to be taken accordingly. Alarm setup and prompt messages are provided in respective parameter setup sections.

### **WARNING**

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.

# 6.1 Alarm Modes

### 6.1.1 Alarm Level

Each alarm, either technical or physiological, has its own level. For alarms of higher levels, when the alarm condition is active, the system will give an alarm prompt in various ways. Some alarm's level can be set by the user via software. Others can not be changed once defined by the system. Alarms in the monitor are divided into three levels, that is, high, medium and low.

A high-level alarm indicates the patient's life is in danger or the monitor in use has serious technical problems. It is the most serious alarm.

A medium-level alarm means a serious warning.

A low-level alarm is a general warning.

The monitor provides two types of alarm: physiological alarms and technical alarms. Also, the monitor provides prompts. Physiological alarms refer to those alarms triggered by patient's physiological situation which could be considered dangerous to his or her life. Technical alarms refer to system failure which can make certain monitoring process technically impossible or make monitoring result unbelievable. The monitor can give the character indication of monitoring process or other functions. And this character is called prompts.

All technical alarm levels and some of the physiological alarm levels are pre-set in the system and can not be changed by users.

# 6.1.2 Alarm Modes

When alarm condition is active, the monitor can raise the user's attention in at least three ways, which are audio prompt, visual prompt and description. Audio prompt is given by the speaker, and visual prompt is given by TFT display device and alarm indicator light. Description is displayed on the screen. Physiological alarm is displayed in the Physiological Alarm area. Most of technical alarms are displayed in the Technical Alarm area. Technical alarms related to NIBP measurement are displayed in the NIBP Technical Alarm area at the bottom of NIBP parameter area.

#### NOTE:

- 1 The Physiological Alarm area is on the upper right part of the screen. The Technical Alarm area is on the left side of the Physiological Alarm area.
- 2 If the monitor is connected to the external alarm prompt system (e.g. the alarm speaker and indicator are connected onto the rear panel of the monitor), when alarm condition is active, the external alarm prompt system responds in the same way as the monitor.
- 3 The concrete presentation of each alarm prompt is related to the alarm level.

### How to indicate that the measured parameter has exceeded its alarm limits:

When physiological alarm of the monitored parameter exceeds the alarm limit, besides using the above-mentioned three ways to give the alarm prompt, the monitor also gives alarm by making the font or the background of monitored parameter flash in the frequency of 1Hz (refer to *Chapter 6.1.3 Alarm Setup*).

The icons for parameters exceeding the alarm limits:

Alarm level	Icon
High	
Medium	
Low	

### **Screen Display**

When the measured parameter exceeds its alarm limits and triggers a physiological alarm, the corresponding parameter value will flash. "\*" signal appears on the screen indicating the occurrence of an alarm. Red "\*\*\*" indicates a high-level alarm, yellow "\*\*" indicates a medium-level alarm, and yellow "\*" indicates a low-level alarm. Technical alarms will not prompt "\*" signal.

#### **Lamp Light**

The high/medium/low-level alarms are indicated by the system in following different visual ways:

Alarm level	Visual prompt
High	Alarm indicator flashes in red with high frequency.
Medium	Alarm indicator flashes in yellow with low frequency.
Low	Alarm indicator lights on in yellow.

#### **Alarm Sound**

The high/medium/low-level alarms are indicated by the system in following different audio ways:

Alarm level	Audio prompt	
High	Mode is "DO-DO-DO-DO-DO-DO-DO-DO-DO", which is triggered once every 10 seconds.	
Medium	Mode is "DO-DO", which is triggered once every 25 seconds.	
Low	Mode is "DO-", which is triggered once every 30 seconds.	

The sound pressure range for audible alarm signals is from 45 dB to 84 dB.

### **WARNING**

Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

#### NOTE:

- 1 The monitor does not have alarm condition delay or alarm signal generation delay.
- 2 When alarms of different levels occur at the same time, the monitor prompts the one of the highest level.
- 3 If the monitor is powered off and then turned on, the alarm setup can resume to the setup which is set before the power-off.

# 6.1.3 Alarm Setup

### Setup alarm in the ALARM SETUP menu

Press the **ALARM SETUP** button in the **SYSTEM SETUP** menu to call up **ALARM SETUP** menu (default menu) as shown below. In the **ALM SEL** item, the user may set up the information about common alarm setup and the alarm setup of each parameter.

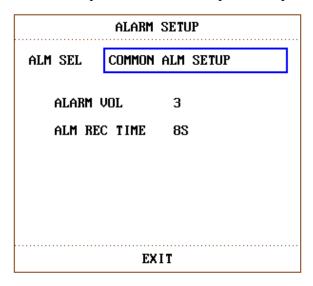


Figure 6-1 Alarm Setup

#### **♦ COMMON ALM SETUP**

Select **COMMON ALM SETUP** option in **ALM SEL** item. This operation may call up the dialog box as the default one.

- ◆ ALARM VOL: set the alarm volume by this item, the valid range is from 1 to 10.
- ◆ ALM REC TIME: this item can be set to 8S, 16S and 32S.
- **♦** Alarm setup of each parameter

In the ALARM SETUP menu, select the ALM SEL item to set up the alarm information for the following parameters. They are HR, ST, PVCs, SpO<sub>2</sub>, NIBP, IBP (1, 2), RESP, TEMP, and CO<sub>2</sub>. For example:

- Method to set up HR alarm information:
- Step 1: Select the **HR ALM SETUP** option in the **ALM SEL** item. Then the menu only displays HR setup items.
- Step 2: You can set up five items in this menu, which are **HR ALM** (on/off of the alarm switch), **ALM LEV** (alarm level), **ALM REC** (alarm recording switch), **ALM HI** (higher limit of HR alarm), **ALM LO** (lower limit of HR alarm). You can move the cursor onto the item to be setup by using the knob and press the knob to make the setup.

The method for setting the alarm information of other parameters is the same as HR.

#### **Setup alarm in the User Maintain menu**

You can also set up alarm parameters in SYSTEM MENU > MAINTAIN > USER

#### **MAINTAIN > ALARM SETUP**. See as follows:

ALARM SE	TUP
ALM SILENCE TIME	2MIN
ALARM SILENCE	ON
ALARM TWINKLE	BK FLASH
ALARM LIMIT	ON
SENSOR OFF ALARM	ON
ALM LATCH	UNLATCH
EXIT	

Figure 6-2 Alarm Setup in User Maintain

- ◆ ALM SILENCE TIME: Set up the duration of Alarm Pause status, it can be set to 1 minute, 2 minutes and 3 minutes.
- ◆ ALARM SILENCE: When it set to ON, hold the Silence button on the front panel for 3 seconds, and the alarm system will be silenced. In the alarm silence mode, the monitor gives a Low alarm for the silence state per 3 minutes. Press this button again to turn on the alarm system.
- ◆ ALARM TWINKLE: Set it to FONT FLASH or BK FLASH. When the measured parameter exceeds the alarm limit, the monitor gives an alarm by font flash or background flash.

**FONT FLASH**: When the measured parameter exceeds its alarm limits, the font of the parameter and the alarm limit flashes. For example, if the parameter exceeds high alarm limit, the parameter and the high alarm limit flash at the same time.

**BK FLASH**: When the measured parameter exceeds its alarm limits, the background of the parameter and the alarm limit flash. For High alarm, the background flashes in red; for Medium alarm, and the background flashes in yellow; for Low alarm, the background displays in yellow without flash.

- ◆ SENSOR OFF ALARM: Turn on or off the sensor off alarm. When this item is set to ON, pressing the SILENCE button on the front panel can pause the audio alarm. Press again to resume the audio alarm; when the alarm is in pause state, it will give an alarm if sensor off alarm condition is active.
- ◆ ALM LATCH: Users can set it to LATCH or UNLATCH.

If it is set to **LATCH**, when alarm occurs, the monitor will give an audio prompt and a light prompt (the **FONT FLASH** and **BK FLASH** are not active). After this alarm event is over, for example, the measured parameters resume to normal conditions, the monitor will still give the alarm prompt continuously. Press the **Silence** button or set **UNLATCH** in menu to stop this alarm prompt.

When it is set to **UNLATCH**, when alarm occurs, the monitor will give an audio prompt and a light prompt (the FONT FLASH and BK FLASH are not active). Different from the **LATCH** mode, after this alarm event is over, the monitor will stop giving the alarm prompt.

## 6.2 Alarm Cause

An alarm occurs when:

- 1. A physiological alarm is evoked;
- 2. An alarm for error of the system (technical alarm) is evoked;
- 3. A general alert occurs.

### **◆** A. Conditions that activate the parameter alarms:

The measurement value exceeds the alarm limit and the alarm is set to **ON**.

### **♦** B. Conditions that activate the system alarms (technical alarm):

Upon the system error, the monitor prompts an alarm immediately.

#### C. General alert

In some circumstances, alerts will behave as physiological alarms. But in normal sense, we do not regard them as real patient health related items.

## 6.3 Silence

Enter SYSTEM MENU > MAINTAIN > USER MAINTAIN > ALARM SETUP. If the **ALARM SILENCE** is set to **ON**, press **Silence** button to turn off the audio alarm or pause it.

# 1. Audio alarm paused icon



When the ALARM SILENCE is ON, press SILENCE button on front panel, then the audio alarm is paused. And the paused time can be set in **ALARM SETUP** menu, see figure 6-2. The audio alarm paused icon displays beside the parameter. Press **SILENCE** button again can resume the audio alarm.

# 2. Audio alarm off icon



Press and hold the **SILENCE** button for more than 3 seconds, and then the audio alarm is turned off. Then pressing **SILENCE** button again or hold it for a few seconds can turn on the audio alarm. In the audio alarm off state, the monitor gives a low alarm beep per 3 minutes to prompt that the alarm is turned off.

#### NOTE:

Whether an alarm will be reset depends on the status of the alarm cause.

# 6.4 Parameter Alarm

### **WARNING**

- 1 Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.
- 2 Setting alarm limits to extreme values may cause the alarm system to become ineffective.

The setup for parameter alarms is in their menus. In the menu of a specific parameter, you can check and set the alarm limit and alarm status. The setup is isolated from each other. The setup alarm limit will be displayed beside each parameter.

When a parameter alarm is off, a symbol displays beside the parameter. If the alarms are turned off separately, they must be turned on separately.

For the parameters whose alarms are set to **ON**, the alarm will be triggered when at least one of them exceeds the alarm limits. The following actions take place:

- 1. Alarm message displays on the screen as described in alarm mode;
- 2. The monitor beeps in its corresponding alarm class and volume;
- 3. Alarm lamp flashes;
- 4. The icons for parameters exceeding the alarm limits will display beside parameters. The icon for Medium or Low alarm is , while for High alarm is ...

# 6.5 When an Alarm Occurs

#### NOTE:

When an alarm occurs, you should always check the patient's condition first.

The alarm message appears on the top right side of the screen. You need to identify the alarm and act appropriately, according to the cause of the alarm.

- 1. Check the patient's condition.
- 2. Identify the cause of the alarm.
- 3. Identify which parameter is alarming or which alarm is happening.
- 4. When the cause of the alarm has been found out, check that the alarm is working properly.

You will find the alarm messages for the individual parameter in their appropriate parameter chapters of this manual.

# 6.6 Testing Alarms

When you switch the monitor on, a self-test is started. You must check that the alarm indicator lights and that you hear a single tone. This indicates that the visible and audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

# 6.7 Adjustable Range of Alarm Limits

ECG alarm limits are listed as follows (unit bpm):

	Patient Type	ALM HI	ALM LO
	ADU	300	15
HR	PED	350	15
	NEO	350	15

ST analysis alarm limits are listed as follows (unit mV):

	ALM HI	ALM LO
ST	2.0	-2.0

PVCs alarm upper limits are listed as follows:

	ALM HI
PVCs	10

RESP alarm limits are listed as follows (unit rpm):

Patient Type	ALM HI	ALM LO
ADU	120	6
PED	150	6
NEO	150	6

SpO<sub>2</sub> alarm limits are listed as follows (unit %):

	ALM HI	ALM LO
$SpO_2$	100	0

PR alarm limits is listed as follows (unit bpm):

	ALM HI	ALM LO
PR	300	30

NIBP alarm limits are listed as follows (unit mmHg):

<b>Patient Type</b>		ALM HI	ALM LO
ADU	SYS	270	40
	DIA	215	10
	MAP	235	20
PED	SYS	200	40
	DIA	150	10
	MAP	165	20
NEO	SYS	135	40
	DIA	100	10
	MAP	110	20

TEMP alarm limits are listed as follows:

	ALM HI	ALM LO
T1	50°C(122°F)	0°C(32°F)
T2	50°C(122°F)	0°C(32°F)
TD	50°C(90°F)	/

# IBP alarm limits are listed as follows (unit mmHg):

	ALM HI	ALM LO
Art	300	0
RAP	40	-10
LAP	40	-10
ICP	40	-10
CVP	40	-10
PA	120	-6
P1	300	-50
P2	300	-50

# CO<sub>2</sub> alarm limits are listed as follows:

	ALM HI	ALM LO
EtCO <sub>2</sub>	ADU: 150 mmHg	0 mmHg
	PED/NEO: 100 mmHg	
FiCO <sub>2</sub>	100 mmHg	/
AwRR	150 rpm	Mainstream: 0 rpm
		Sidestream: 2 rpm

# **Chapter 7 Freeze**

# 7.1 General

When monitoring a patient, you may freeze the waveforms of interest so as to view them carefully. Generally you can review a frozen waveform of a maximum of 12 minutes. The Freeze function of this monitor has the following features:

- Freeze status can be activated on any operating screen;
- ◆ Once entering the Freeze status, the system exits all other operating menus. Besides, the system freezes all waveforms in the Waveform area of the Basic Screen, and also freezes Full Lead ECG waveforms and extra waveforms on the Full Lead ECG interface (if any). Nevertheless the Parameter area refreshes normally.
- The frozen waveforms can be reviewed and recorded.

# 7.2 Entering/Exiting Freeze Status

### **♦** Enter Freeze Status

In the Non-Freeze status, press the **FREEZE** button on the control panel of the monitor to let the system exit the Menu being currently displayed (if available), then enter the Freeze status and display the popup **FROZEN** menu. In the Freeze status, all other waveforms are frozen. In other words, the system will no longer refresh all other waveforms.

#### Exit Freeze Status

In the Freeze status, executing any of the following operations will command the system to exit the Freeze status:

- ◆ Select the **EXIT** option in/from the **FROZEN** menu;
- ◆ Press the **FREEZE** button on the control panel again;
- ◆ Press the non-immediate-to-execute button (for example, once a button is pressed, a menu will pop up for you to further select an option) on the front panel and system buttons of Menu and Main;
- ◆ Execute any operation that may trigger the adjustment of the screen or the display of a new menu

After exiting the Freeze status, the system will discharge the Freeze status, clear screen waveforms and resume display real-time waveforms. In the Screen Refresh mode, the system will sweep the waveforms from left to right in the Waveform Area.

# 7.3 FROZEN Menu

Press the **FREEZE** button on the control panel, and the **FROZEN** menu will appear on the bottom part of the screen. At the same time, the system enters the Freeze status.



Figure 7-1 Frozen

- ◆ REC WAVE: it can be set to any waveform of 8s, such as IBP1, CO<sub>2</sub>, PLETH etc. It can also be set to OFF.
- ◆ **RECALL**: Used to review frozen waveforms.
- ◆ **REC**: select this item to record the setting waveform in **REC WAVE**.
- ◆ EXIT: After this button is pressed, the system closes the FROZEN menu and exits the Freeze status.

#### NOTE:

Pressing the **FREEZE** button repeatedly in a short period of time may result in discontinuous waveforms displaying on the screen.

# 7.4 Reviewing Frozen Waveform

By moving the waveform, you may review a waveform of 12 minutes before it is frozen. For a waveform of less than 12 minutes, the remaining part is displayed as a straight line. Use the rotary snob on the control panel to move the cursor to the **RECALL** option in the **FROZEN** menu. Press the knob. By turning the knob left or right, frozen waveforms on the screen will move left or right correspondingly. There is an arrow indicating upward on the right side of the last waveform. There is also a time scale beside the arrow. "-0S" is used to mark the moment when waveforms are frozen. With waveforms moving right, this time mark will in turn change into -1S, -2S, -3S... These time marks are applied to all waveforms on the screen.

# **Chapter 8 Recording (Optional)**

- General information on recording
- Instructions for configuring and recording
- Recording messages

# 8.1 General Information on Recording

A thermal dot matrices recorder with 48mm wide printout paper is used for the monitor.

#### Performance of the Recorder

- ◆ Waveform record is printed out at the rate of 25 mm/s or 50 mm/s.
- ◆ It can record up to three waveforms.
- English printout.
- ◆ User-selectable real-time recording time and waveform.
- ◆ Auto recording interval is set by the user, and the waveform is in accordance with the real time recording.

#### NOTE:

It is suggested that the user should not use the recorder when the low battery displays, or the monitor may be turned off automatically.

# 8.2 Recording Type

The monitor provides several types of stripe recording:

- Continuous real-time recording
- ◆ 8 second real-time recording
- ◆ Automatic interval recording
- Physiological alarm recording
- Frozen waveform recording
- Trend graph/table review recording
- NIBP review recording
- ◆ Alarm event review recording
- Arrhythmia review recording
- Titration table recording

#### NOTE:

- 1 When ECG waveforms are selected for printing, with gain of ×1, ×0.5 or ×0.25, a 3-channel waveform can be printed out; however, with gain of ×2, only a 2-channel waveform can be printed out to avoid overlapping of waveforms, and the third waveform will be omitted.
- 2 The 3-channel waveform can be printed only in real-time recording, while it is not

available in other recording modes, such as alarm review recording and alarm triggered recording.

### Real-time Recording

Real-time recording starts as you press the **RECORD** button on the recorder.

The waveforms for continuous real-time recording and continuous 8 second recording are automatically set by the monitor (usually the first three waveforms displayed on the screen). You can also configure it through the menu. Refer to related section for details.

In **RECORD** menu, the user can choose three waveforms to be printed out. The user can set up one or two waveforms to be off. Thus, the real time record will print out one or two waveforms. If three waveforms are off, the real time record will print out measure parameters only.

### NOTE:

The system can start executing the next alarm recording task only when the current one is finished.

### **Auto Recording**

The monitor starts the recorder for every 8 seconds according to the time interval set in the **TIMING REC TIME** of the **RECORD** menu. Refer to *Chapter8 Recording* Setup for details.

## **Alarm Recording**

#### ◆ Parameter Alarm

The monitor records waveforms 4, 8, or 16 seconds prior to and after the alarm (totally 8, 16 or 32 seconds) (which can be selected in **SYSTEM MENU**). All parameter values during the alarm will also be recorded.

When a parameter alarm occurs, two recorded waveforms can be printed out.

In order to avoid repeated printout of alarm waveforms:

- ① If more than two parameter alarms are switched on and triggered simultaneously, the recorder will print out that of the highest level. If they are of the same alarm level, the latest alarm will be printed out.
- ② If an alarm occurs during the alarm of another parameter, it will be printed out after the current recording is finished.
- ③ If many alarms occur at the same time, some of waveforms will be stored for printout in turn.

### ◆ ST Segment Alarm

The monitor records 2-channel ECG waveforms 4, 8, or 16 seconds prior to and after the alarm (totally 8, 16 or 32 seconds) (which can be selected in the **ECG SETUP** menu). All parameter values during the alarm will also be recorded.

#### ◆ Arrhythmia Alarm

The monitor records 2-channel ECG waveforms 4, 8, or 16 seconds prior to and after the alarm (totally 8, 16 or 32 seconds). All measurement results during the alarm will also be recorded.

### **Titration Table**

The monitor can print out the message in the current **TITRATION** window.

### **Notes on Recording**

◆ Recording types:

Real time Report

Periodic Report

Para Alarm Report

**Titration Table** 

Arrhythmia Report

Freeze Wave Report

Trend graph

Trend table

Para Alarm Review

**NIBP** Test Review

- ◆ Patient bed number, name, sex, height, weight, date of birth, admission date
- ◆ Parameter name and value
- ◆ Recording time
- Waveform name
- ◆ Waveform scale (for ECG waveform)
- ◆ ECG lead, scale, filter mode, (if there are ECG waveforms, they will be printed out within the first second or when changing the lead, gain and filter mode during real-time recording.)
- ◆ IBP scale (the first second of IBP waveform)
- ◆ CO<sub>2</sub> scale (the first second of CO<sub>2</sub> waveform)
- ◆ Date and time.

# 8.3 Recording Startup

You can start the recording in the following ways:

Continuous real-time recording	Press the <b>RECORD</b> button to start/stop the recording.
8 second real-time recording	Press the <b>RECORD</b> button to start recording. It will automatically stop in 8 seconds.
Auto recording	Record the three waveforms selected in <b>RECORD</b> menu according to the setup time interval in <b>RECORD</b> menu. It will automatically stop in 8 seconds.
Alarm recording	When alarm recording is set to <b>ON</b> , it automatically starts when alarm occurs.

Trend graph recording	Access the <b>TREND GRAPH</b> menu, and then press the <b>RECORD</b> button to start recording.
Trend table recording	Access the <b>TREND TABLE</b> menu, then press the <b>RECORD</b> button to start recording.
Arrhythmia review recording	Enter the ECG SETUP menu via hot key, select ARR ANALYSE > ARR RECALL, then press the RECORD button to start recording.
Alarm review recording	Access the ALARM RECALL menu, then press the RECORD button to start recording.
NIBP review recording	Access the <b>NIBP RECALL</b> menu, then press the <b>RECORD</b> button to start recording.
Titration table recording	Access the <b>DRUG CALC</b> menu from the <b>SYSTEM MENU</b> . Pick the <b>TITRATION</b> button in the menu to access the <b>TITRATION</b> window. Pick the <b>REC</b> button to print out the titration currently displayed in the window.
Frozen waveform recording	8-second frozen waveform can be recorded, 2 waveforms are selectable.

### NOTE:

You can press the **RECORD** button on the control panel to stop the current recording process.

Access the **RECORD** menu from the **SYSTEM SETUP** menu. Then pick the **CLEAR REC TASK** button to stop all recording tasks.

# 8.4 Recorder Operations and Status Messages

### **Record Paper Requirement**

Only standard thermosensitive record paper can be used: otherwise the recorder may not function, the recording quality may be poor, and the thermosensitive printhead may be damaged.

### **Proper Operation**

- ◆ When the recorder is working, the record paper goes out steadily. Do not pull the paper outward with force: otherwise the recorder may be damaged.
- Do not operate the recorder without record paper.

### **Paper Out**

When **RECORDER OUT OF PAPER** alarm is displayed, the recorder cannot start. Please

insert record paper properly.

# **Inserting Paper**

- ◆ Pull outwards the upper arc part of the recorder casing to release the casing.
- Insert a new roll of paper into the paper cassette, printing side facing upwards.
- Ensure proper position and tidy margin.
- Pull about 2cm of the paper out, and close the recorder casing.

### NOTE:

Be careful when inserting papers. Avoid damaging the thermo-sensitive print head. Unless when inserting papers or shooting troubles, do not leave the recorder catch open.

### **Removing Paper Jam**

When the recorder functions or sounds improperly, you should open the recorder casing to check for a paper jam. Removing the paper jam in the following way:

- Cut the record paper from the feeding edge.
- Open the recorder casing.
- Re-insert the paper.

#### NOTE:

If the monitor is not installed with a recorder, it will indicate **NO RECORDER** after pressing the **RECORD** button.

# **Chapter 9 Trend and Event**

The monitor provides 96-hour trend data of all parameters, storage of 500 NIBP measurement results and 60 alarm events. This chapter gives detailed instruction for review of all data.

# 9.1 Trend Graph

- ◆ The latest 1-hour trend is displayed every 1 or 5 seconds;
- ◆ The latest 96-hour trend is displayed every 1, 5 or 10 minutes;

Pick **TREND GRAPH** in the **SYSTEM MENU** to call up the following menu:

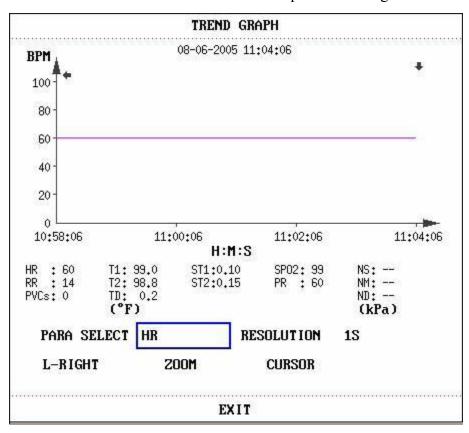


Figure 9-1 Trend Graph Menu

In the trend graph, the y-axis stands for the measured value and x-axis time. "♥" is the cursor of the trend graph, the parameter value of the position pointed by the cursor is displayed below the trend graph and the corresponding time is displayed above the trend graph. Other trends except NIBP trend are displayed as continuous curves. In NIBP trend graph, "▼" indicates systolic value, "▲" indicates diastolic value, and "\*" indicates mean value.

### To select trend graph of a specific parameter

Pick **PARA SELECT** item and select a requested parameter name by turning the knob.

### To select 1-hour or 96-hour trend graph

Pick **RESOLUTION** item, choose 1 or 5 sec for 1-hour trend graph and 1, 5 or 10 min for 96-hour trend graph.

#### To view other trend curves

When " appears on the right part of the screen, pick **L-RIGHT**, turn the knob clockwise to view later trend curves. When " uppears on the left part of the screen, pick the same item, turn the knob counterclockwise to view earlier trend curves.

## To change the display scale

Pick the **ZOOM** button to adjust the y-axis scale and thus change the trend curve in proportion. The value beyond maximum value will be represented by the maximum value.

# To obtain trend data of a specific time

The time to which the cursor points will change as the knob is turned. Parameter at this time is displayed below the x-axis. When " appears on the right part of the screen, the trend graph pages down for later trend curves as the cursor moves here. When " appears on the left part of the screen, the trend graph pages up for earlier trend curves as the cursor moves here.

#### **Mark Event**

If an event is marked **A**, **B**, **C**, or **D**, then the corresponding event type will display on the time axis of the trend graph, such as  $\square$ ,  $\square$ ,  $\square$  or  $\square$ .

### **Operation Example**

To view the NIBP trend graph of the last 1 hour:

- Pick the **Menu** button on the lower right of the screen.
- ◆ Pick **TREND GRAPH** item in the **SYSTEM MENU**.
- ◆ Select parameter: pick the **PARA** item and turn the knob until NIBP appears.
- ◆ Select **1S** or **5S** in the **RESOLUTION** item.
- ◆ Pick the **L-Right** button and turn the knob to view changes of the trend graph time and trend curve.
- ◆ Stop at requested trend time section for careful review. Pick the **ZOOM** button to adjust the display scale if necessary.
- ◆ For measurement result of a specific time, pick **CURSOR** to move the cursor to the point. Then the corresponding time and value will display above and below the waveform respectively.
- Pick **EXIT** to return to trend graph display.

# 9.2 Trend Table

◆ The latest 96-trend table data can be displayed every 1, 5, 10, 30, or 60 minutes.

Pick **TREND TABLE** in the **SYSTEM MENU** to call up the following menu:

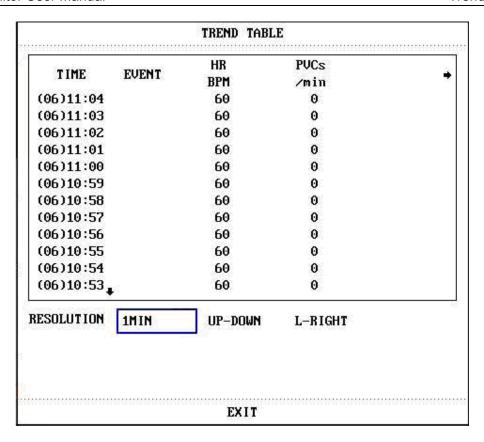


Figure 9-2 Trend Table

Time corresponding to each group of trend data is displayed in the leftmost list with date in brackets. Marked event corresponds to marking time. Trend data of each parameter is divided into 8 groups.

HR, PVC ST1, ST2 RR T1, T2, TD SpO<sub>2</sub>, PR NIBP NS/NM/ND IBP1, IBP2

CO<sub>2</sub>, FiCO<sub>2</sub>, AWRR

The **IBP1**, **IBP CO<sub>2</sub>**, **FiCO<sub>2</sub>**, **AWRR** are optional according to the product models.

#### To choose a trend table of a different resolution

Pick the **RESOLUTION** item and turn the knob to change its content so as to change the time interval of trend data.

#### To view other trend data

When "\[ \]" appears on the upper part of the screen, pick **UP-DOWN** button and turn the knob counterclockwise to view later trend data. When "\[ \]" appears on the lower part of the screen, pick the same item and turn the knob clockwise to view earlier trend data.

# To obtain trend data of different parameters

Pick **L-RIGHT** to select one from the 8 groups of parameters. " by the rightmost item indicates the next page available. " by the leftmost item indicates the previous page available.

#### **Mark Event**

If an event is marked **A**, **B**, **C**, or **D**, the corresponding event type will display on the Time axis of the trend table.

## **Operation Example**

To view a NIBP trend table:

- ◆ Pick the **Menu** button on the lower right of the screen to access **SYSTEM MENU**.
- ◆ Pick **TREND TABLE**.
- Pick **L-RIGHT** and switch to NIBP by turning the knob.
- ◆ Pick **RESOLUTION** to select requested time interval.
- ◆ Pick **UP-DOWN** and turn the knob to view NIBP trend data of different time.
- ◆ Pick **EXIT** to return to **SYSTEM MENU**.

# 9.3 NIBP Recall

The monitor can review the latest 500 NIBP measurement data.

Pick **NIBP RECALL** in the **SYSTEM MENU** to invoke the result and time of the latest 15 measurements, as shown in the figure below.

NIBP RECALL						
	NS	NM	ND	PR	TIME	
1.	111	86	74	64	2008-11-06 15	5:49:39
2.	111	89	78	58	2008-11-06 15	5:49:39
3.	110	84	72	62	2008-11-06 15	5:49:39
4.	111	87	76	66	2008-11-06 15	5:49:38
5.	116	90	77	57	2008-11-06 15	5:49:38
6.	119	92	79	59	2008-11-06 15	5:49:38
7.	113	87	75	65	2008-11-06 19	5:49:38
8.	114	88	76	66	2008-11-06 15	5:49:38
9.	112	87	75	65	2008-11-06 15	5:49:37
10.	113	89	77	57	2008-11-06 15	5:49:37
11.	119	87	71	61	2008-11-06 15	5:49:37
12.	117	90	77	67	2008-11-06 15	5:49:37
13.	118	88	73	63	2008-11-06 15	5:45:05
NUM:0	UNI	T	mmHg		UP-DOWN	REC

Figure 9-3 NIBP Recall

Data is listed chronologically from the latest to the earliest. 15 measurements can be displayed on one screen. Pick **UP-DOWN** to view up to 500 results of measurements. When you press the **RECORD** button, the recorder will print out the metrical data of current window.

## NOTE:

When the user set the **NIBP SETUP > PR (NIBP)** to **ON**, the PR parameter will display in the menu of **NIBP RECALL**; if set it to **OFF**, the PR parameter area displays — —.

# 9.4 Alarm Event Recall

The monitor can display the latest 60 alarm events.

Select ALARM RECALL in the SYSTEM MENU to access ALARM RECALL CONDITION menu as shown below.

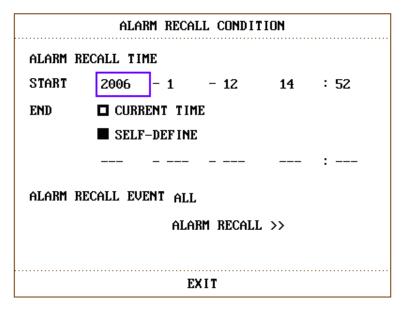


Figure 9-4 ALARM RECALL CONDITION

In this menu, the user may select the conditions for alarm review, including:

#### 1. Start and End time of review:

The user may select the start time of review in the item of **START**.

Then the user may select the end time of review. Two selections are available: current time and the user-defined time.

For user-defined end time, the user can use the knob to select.

#### 2. ALARM RECALL EVENT

In the pull-down list of **ALARM RECALL EVENT**, the user can select the parameter whose alarm events he wants to review. The selections include **ALL** (alarm events of all parameters), ECG, REST, SpO<sub>2</sub>, NIBP, PR(NIBP), IBP, TEMP, CO<sub>2</sub>, HR\_H>180 (the value of HR is above the upper alarm limit), HR\_L<60 (the value of HR is below the lower alarm limit), SpO<sub>2</sub><90%, IBP\_H>200mmHg, IBP\_L<40mmHg, RR\_H>40, RR\_L<10, TEMP H>40°C, TEMP L<34°C.

After setting up all the review conditions, press the **ALARM RECALL** button to access **ALARM RECALL** window.

#### **ALARM RECALL**

The **ALARM RECALL** window is as shown below, in which the following data are displayed:

- ① Time span (Format: month-day-year hour: minute-month-day-year hour: minute).
- ② Event type.
- ③ Serial number (Format: NO.  $\times\times$  of  $\times\times$ ).
- 4 The value at the time of alarm. NIBP result is with time.
- (5) Two 8/16/32-second waveforms.

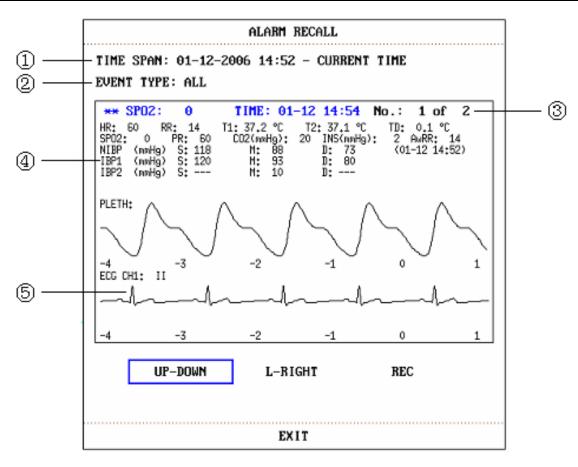


Figure 9-5 ALARM RECALL Menu

#### NOTE:

When the user set the **NIBP SETUP > PR (NIBP)** to **ON**, the **PR** parameter will display in the menu of **ALARM RECALL**; if the user set it to **OFF**, the **PR** parameter will not display.

## To view all waveforms during the alarming process

Pick **L-RIGHT** and turn the knob to view all 8/16/32-second waveforms stored.

## To view other alarm events

Events of up to 60 are listed chronologically from the latest to the earliest. Pick **UP-DOWN** button and turn the knob to view later or earlier events.

# Recording

Pick **REC** to print out all data and waveforms of this event.

# Chapter 10 Drug Calculation and Titration Table (Optional)

The patient monitor provides drug calculation and titration table display functions for fifteen drugs and outputs the content of titration table on the recorder.

# 10.1 Drug Calculation

The drug calculations that can be performed by the system are **AMINOPHYLLINE**, **DOBUTAMINE**, **DOPAMINE**, **EPINEPHRINE**, **HEPARIN**, **ISUPREL**, **LIDOCAINE**, **NIPRIDE**, **NITROGLYCERIN** and **PITOCIN**. **DRUG** A, **DRUG** B, **DRUG** C, **DRUG** D and **DRUG** E are also provided to flexibly replace any of the drugs.

By selecting **DRUG CALC** in **SYSTEM MENU**, the following **DRUG CALC** window appears:

DRUG CALC					
DRUG NAME	AM INOPHS	LLINE	INF RATE	60.00	ml/hr
WEIGHT	70.0	kg	DRIP RATE	20.00	GTT/min
AMOUNT	500.00	mg	DROP SIZE	20.00	GTT/ml
VOLUME	500.00	ml	DURATION	8.33	hr
CONCENTRAT	1.00	mg∕ml			
DOSE/min	1.00	mg	Please car	refully v	erify
DOSE/hr	60.00	mg	the input	informat	ion!
DOSE/kg/min	14.29	mcg			
DOSE/kg/hr	857.14	mcg	TITRATION	>>	
EXIT					

Figure 10-1 DRUG CALC menu

The following formulas are applied to dose calculation:

Concentrate = Amount / Volume

INF Rate = DOSE / Concentrate

Duration = Amount / Dose

Dose = Rate  $\times$  Concentrate

DRIP Rate = INF Rate  $/ 60 \times DROP$  Size

## **Operating Method:**

In the Drug Calculation window, the operator should first select the name of the drug to be calculated, and then confirm the patient weight. Afterwards, the operator should also enter other known values.

Turn the knob to select the value of the item to be calculated. Turn the knob to change the value. When it is the required value, press the knob to view the calculation result. Each item has its calculation range. If the result exceeds the range, it displays "----".

#### NOTE:

- 1 For the drug calculation, the prerequisite is that the operator must first of all enter the patient weight and drug name. The system then gives a group of random initial values, which cannot be used by the operator as the calculation reference. Instead, he should enter a new group of values at the doctor's instruction.
- 2 Each drug has its fixed unit or unit series. Operator must select the proper unit at the doctor's instruction. If the result exceeds the system-defined range, it will display "---".
- 3 After entering a value, a prompt will appear in the menu warning the operator to confirm the correctness of the entered value. The correct value is the guarantee for the reliability and safety of the calculated results.
- 4 For each entered value, the system will always give a dialog box asking for the user's confirmation. You must be careful when answering each box. The calculated result is reliable only after the entered value is confirmed to be correct.

### **Select the Drug Name:**

Turn the knob to pick the **DRUG NAME** item in **DRUG CALC** menu. The user may select the drug name in the pull-down list, including **AMINOPHYLLINE**, **DOBUTAMINE**, **DOPAMINE**, **EPINEPHRINE**, **HEPARIN**, **ISUPREL**, **LIDOCAINE**, **NIPRIDE**, **NITROGLYCERIN**, **PITOCIN**, **Drug A**, **Drug B**, **Drug C**, **Drug D** and **Drug E**. Calculation for only one type can be generated each time.

#### NOTE:

A, B, C, D or E is only code for drugs instead of their real names. The units for these five drugs are fixed. The operator may select the appropriate units according to the convention of using these drugs. The rules for expressing the units are:

- "mg" series units are fixedly used for drug A, B and C: g, mg, mcg.
- "unit" series units are fixedly used for drug D: unit, k unit, m unit.
- "mEq" is fixedly used for drug E.

# **Patient Weight:**

After accessing the **DRUG CALC** window, the operator should enter the patient weight into the first or the second item. The entered weight will be used as the independent data only for the calculation of drug concentration.

#### NOTE:

This drug calculation function acts only as a calculator. That means the patient weight in Drug Calculation menu and it in Patient Information menu is independent from each other. Therefore if the Weight in Drug Calculation changes, it will not change in Patient Information. In this way, we can say, the Drug Calculation menu is independent from other menus in the system. Any change of it will not affect other information about the patient being currently monitored.

# 10.2 Titration Table

#### **Access Titration Table:**

Select **TITRATION** item in **DRUG CALC** menu to enter titration table display. Titration table display for drug is as following:

400.00 2500.00 70.00 INF RATE	mg mcg kg	VOLUME INF RATE DRIP RATE	250.00 93.75 31.25	ml ml/hr GTT/min
70.00 INF RATE	kg	DRIP RATE		
INF RATE			31.25	GTT/min
	DOSE			
0.00		INF RATE	DOSE	INF RATE
V+00	10,00	0,38	20,00	0.75
0.04	11,00	0.41	21.00	0.79
0.08	12,00	0.45	22,00	0.83
0,11	13,00	0.49	23,00	0.86
0.15	14.00	0.53	24.00	0.90
0,19	15,00	0,56	25,00	0.94
0,23	16,00	0,60	26,00	0.98
0,26	17,00	0.64	27,00	1.01
0,30	18,00	0,68	28,00	1.05
0.34	19,00	0.71	29,00	1.09
SE	STEP	1 DOSE T	YPE DOSE	min/
UP-DOWN			REC	
		PVIT		
	0.04 0.08 0.11 0.15 0.19 0.23 0.26 0.30 0.34	0.04 11.00 0.08 12.00 0.11 13.00 0.15 14.00 0.19 15.00 0.23 16.00 0.26 17.00 0.30 18.00 0.34 19.00 SE STEP	0.04	0.04

Figure 10-2 TITRATION

- Method to operate the titration table:
- 1. In the **TITRATION** table, turn the knob to pick **BASIC** item. Press and turn the knob to select **INF RATE**, **DOSE** or **DRIP RATE**.
- 2. Then turn the knob to pick **STEP** item. Select step by pressing the knob.  $1 \sim 10$  are available for selection with the increments of 1.
- 3. Turn the knob to pick **DOSE TYPE** item. Press and turn the knob to select the unit in the pull-down list.
- 4. Use **UP-DOWN** item in the table to view the data in previous or next pages.
- 5. Turn the knob to pick **REC** item. After pressing the knob, the recorder prints out the data displayed in the current titration table.

# 6. Turn the knob to pick **EXIT** to return to **DRUG CALC** menu.

Total amount, dose, volume, INF rate, drip rate, patient weight and drug name are displayed on the top of the titration table. The meaning of each English identifier is:

**AMOUNT**: drug amount

VOLUME: liquid volume

DOSE/min: drug dose

INF RATE: flow rate

**DRIP RATE**: drop rate

WEIGHT: patient weigh

# **Chapter 11 Maintenance/Cleaning**

# 11.1 System Check

Before using the monitor, do the following:

- Check if there is any mechanical damage;
- Check if all the outer cables and accessories are in good condition;
- Check all the functions of the monitor to make sure that the monitor is in good condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or Customer Service immediately.

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

All the checks that need to open the monitor should be performed by qualified customer service technician. The safety and maintenance check can be conducted by persons from this company. You can obtain the material about the customer service contract from the local company's office.

## **WARNING**

- If the hospital or agency that is responding to using the monitor does not follow a satisfactory maintenance schedule, the monitor may become invalid, and the human health may be endangered.
- 2 Replace battery according to the instruction of our servicing engineer.

#### NOTE:

To prolong the life of rechargeable battery, it is recommended to charge it at least once every month, and it must be done after the electric energy is run out.

# 11.2 General Cleaning

## **WARNING**

Before cleaning the monitor or the sensor, make sure that the equipment is switched off and disconnected from the power line.

## **CAUTION**

Please pay special attention to the following items:

- 1 Most cleaning agents must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.
- 2 Do not use the grinding material, such as steel, wool etc.
- 3 Do not let the cleaning agent enter into the chassis of the system.
- 4 Do not leave the cleaning agents at any part of the equipment.

The monitor, cables and accessories must be kept dust-free.

Regular cleaning of the monitor shell and the screen is strongly recommended. Use only non-caustic detergents such as soap and warm water (40°C/104°F maximum) to clean the monitor shell. Do not use strong solvents such as acetone or trichloroethylene.

Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing. Do not permit any liquid to enter the monitor case and avoid pouring it on the monitor while cleaning. Do not allow water or cleaning solution to enter the measurement connectors. Wipe around, except connector sockets.

Examples of disinfectants that can be used on the instrument casing are listed below:

- ◆ Diluted ammonia < 3%;
- ◆ Ethanol 75%;
- ◆ Isopropanol 70%.

#### NOTE:

- 1 The monitor and sensor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.
- 2 This company has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

# 11.3 Disinfection

## **WARNING**

Perform regular disinfection for the monitor and reusable accessories to prevent cross infection.

## **CAUTION**

- 1 Do not mix disinfecting solutions (such as bleach and ammonia), or it may produce hazardous gases.
- 2 Do not use EtO gas or formaldehyde to disinfect the monitor.

To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first. Appropriate disinfection materials for ECG leads, SpO<sub>2</sub> sensor, blood pressure cuff, TEMP probe, IBP sensor are introduced in relative chapters respectively.

Recommended types of disinfecting agents are:

- **♦** Ethanol 75%;
- ◆ Isopropanol 70%
- ◆ Glutaraldehyde up to 3.6%

# 11.4 Replacement of Fuse

Unscrew the fuse cap anticlockwise, replace the fuse (protector tube) and screw down the fuse cap clockwise. Fuse size:  $\Phi 5 \times 20$ , Rated value: T1.6AL/250VP.

## NOTE:

Switch off the power switch of the patient monitor before examining the fuse.

# 11.5 Cleaning Battery and Battery Compartment Cover

Use only non-caustic detergents such as soap and warm water  $(40^{\circ}\text{C}/104^{\circ}\text{F} \text{ maximum})$  to clean the battery. Do not use strong solvent to clean battery, and do not dip the battery in liquid.

# **Chapter 12 ECG/RESP Monitoring**

# 12.1 What Is ECG Monitoring

Monitoring the ECG produces a continuous waveform of the patient's cardiac electric activity to enable an accurate assessment of his current physiological state. Only proper connection of the ECG cables can ensure satisfactory measurement. On the Normal Display, the monitor provides display of 2-channel ECG waveforms.

- ◆ The patient cable consists of 2 parts
  - The cable connects to the monitor
  - The lead set connects to the patient
- ◆ Use a 3-lead or 5-lead set to monitor the ECG.
- ◆ The monitor displays the Heart Rate (HR), ST segment and Arrhythmia analysis. All of the parameters above can be set as alarm parameters.
- ◆ Lead off detecting: detect all the electrodes, indicate the broken off leads.
- ◆ Anti-electrotome function: if the monitor works with high-frequency electrotome, it will not be deadlock or restarting.
- Every ECG channel has Pacing impulse rejection and Bandpass filter circuit.
- ◆ Defibrillation protection (needs 1K resistance ECG cables in series) and hardware clamp function

## NOTE:

- 1 In the default settings of the monitor, the ECG waveforms are the first two waveforms from top in the Waveform Area.
- 2 The defibrillator cables should be used in the ECG monitoring that can prevent the cables from being burned by high frequency.

# 12.2 Precautions During ECG Monitoring

## **WARNING**

- 1 Do not come into contact with the patient, table, or the monitor during defibrillation.
- 2 Use only the original ECG cable for monitoring.
- When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient but not the conductive part or ground.
- 4 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.

## **WARNING**

- For patients with pacemakers, the pacing impulse analysis function must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected.
- 6 PACEMAKER PATIENTS—Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance.
- 7 The electrodes should be made of the same metal materials.

#### NOTE:

- 1 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.
- 2 IEC/EN60601-1-2 (protection against radiation is 3v/m) specifies that the electrical field density exceeding 1v/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.
- 3 If the pacemaker signals are beyond the claimed range, the heart rate may be calculated incorrectly.

# 12.3 Monitoring Procedure

# 12.3.1 Preparation

- 1. Prepare the patient's skin prior to placing the electrodes.
  - ◆ The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.
  - ◆ Shave hair from sites, if necessary.
  - ◆ Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).
  - ◆ Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.
- 2. Attach clip or snap to electrodes prior to placement.
- 3. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.
- 4. Connect the electrode lead to the patient's cable.
- 5. Make sure the monitor is ready with power supply.

## **WARNING**

- 1 Placed the electrode carefully and ensure a good contact.
- 2 Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.
- 3 Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm is activated.

#### NOTE:

For protecting environment, the used electrodes must be recycled or disposed of properly.

# 12.3.2 Placing Electrodes for ECG Monitoring

#### NOTE:

The following table gives the corresponding lead names used in Europe and America respectively. (Lead names are represented by R, L, F, N, C, C1-C6 in Europe, whose corresponding lead names in America are RA, LA, LL, RL, V, V1-V6.)

AHA (America Standard)		IEC (Europ	oe Standard)
Lead Mode	Color	Lead Mode	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	С	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green
V4	Brown/Blue	C4	White/ Brown
V5	Brown/Orange	C5	White/ Black
V6	Brown/Purple	C6	White/ Purple

## Electrode placement for 3-lead set

Take the American standard for example, see Figure 12-1:

• Red (R) electrode - Be placed near the right shoulder, directly below the clavicle.

- ◆ Yellow (L) electrode Be placed near the left shoulder, directly below the clavicle.
- ◆ Green (F) electrode Be placed on the left hypogastrium.

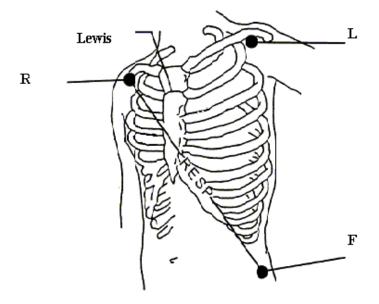


Figure 12-1 Electrode Placement for 3-lead Set

## Electrode placement for 5-lead set

Take the American standard for example, see Figure 12-2:

- Red (R) electrode Be placed near the right shoulder, directly below the clavicle.
- ◆ Yellow (L) electrode Be placed near the left shoulder, directly below the clavicle.
- ◆ Black (N) electrode Be placed on the right hypogastrium.
- Green (F) electrode Be placed on the left hypogastrium.
- ◆ White (C) electrode Be placed on the chest as illustrated in the Figure 12-3.

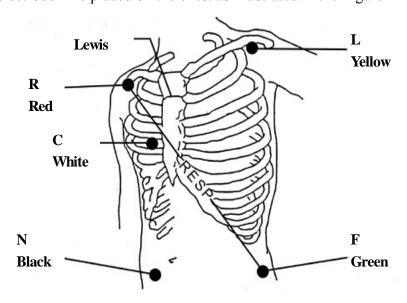


Figure 12-2 Electrode Placement for 5-lead Set

#### NOTE:

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

For 5-lead set, attach the C (V)-electrode to one of the indicated positions as below (Figure 12-3):

◆ V1 On the 4th intercostal space at the right sterna margin.

◆ V2 On the 4th intercostal space at the left sterna margin.

◆ V3 Midway between V2 and V4 electrodes.

◆ V4 On the 5th intercostal space at the left clavicular line.

◆ V5 On the left anterior axillary line, horizontal with V4 electrode.

◆ V6 On the left middle axillary line, horizontal with V4 electrode.

◆ V3R-V7R On the right side of the chest in positions corresponding to those on the left.

◆ VE Over the xiphoid position.

◆ V7 On the 5th intercostal space at the left posterior axillary line of back.

◆ V7R On the 5th intercostal space at the right posterior axillary line of back.

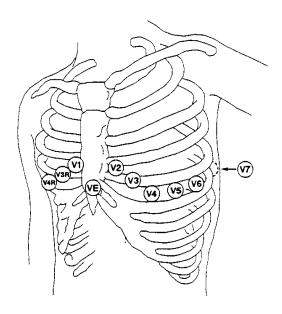


Figure 12-3 C-Electrode Placement for 5-lead Set

# **Recommended ECG Lead Placement for Surgical Patients**

#### **WARNING**

When using Electrosurgery (ES) equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the ES grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the patient monitor with other Electrosurgery equipment, it is advised to use the counteracting defibrillation ECG lead.

The placement of the ECG leads will depend on the type of surgery that is being performed. For example, in an open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts may affect the ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms. Otherwise the ECG waveform will be too small.

#### **WARNING**

- 1 When using the monitor with the defibrillator or other high-frequency equipment, please use counteracting defibrillation ECG lead to avoid cautery.
- When using Electrosurgery (ES) equipment, do not place an electrode near the grounding plate of the Electrosurgery device: otherwise there will be a great deal of interference with the ECG signal.

# **Using 5-lead ECG Set**

You can set the leads on ECG CH1 and ECG CH2 according to your needs. The lead label is displayed on the upper left part of the waveform. You can set them corresponding to any two from I, II, III, AVR, AVL, AVF and V1~V6. If you set both to the same value, one of them will be adjusted to another option automatically. (Figure 12-5)

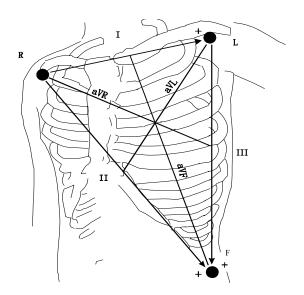


Figure12-4 ECG Lead

#### WARNING

In 5-lead mode, Pace detection ±2mV~±700mV;In 3-lead mode, for Pace detection, it is recommended to set as II, ±2mV~±700mV.

#### NOTE:

- 1 If an ECG waveform is not accurate, while the electrodes are tightly attached, try to change the lead.
- 2 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

Normal QRS complex should be:

- ◆ Tall and narrow with no notches.
- ◆ With tall R-wave completely above or below the baseline.
- ◆ With pacemaker spike no higher than R-wave height.
- ◆ With T-wave less than one-third of the R-wave height.
- ◆ With P-wave much smaller than the T-wave.

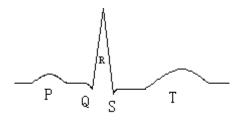


Figure 12-5 Standard ECG Waveform

# 12.4 ECG Screen Hot Keys



Figure 12-6 Hot Key for ECG

## [1]. Leads of channel 1:

I, II, III, AVR, AVL, AVF, V1 ~ V6 are available.

Leads on the ECG wave must not have the same name. Otherwise, the system will automatically change the ECG waveform name that has the same name as the waveform being currently adjusted to another name.

[2]. Waveform gain of channel 1: used to adjust the size of ECG waveforms

Signal amplification and collection of Channel 1 ECG, it can collect gain value for each channel setting as ×0.125, ×0.25, ×0.5, ×1, ×2, ×4 or AUTO mode. In AUTO mode, the monitor chooses an appropriate level automatically. A 1mV scale displays on each ECG

channel's right side. The height of 1mV bar is directly proportional to the waveform amplitude.

#### NOTE:

When the input signals are too strong, the peak of the waveform may not be able to be displayed. In this case the user may manually change the setup method of ECG waveform according to the actual waveform so as to avoid the occurrence of the unfavorable phenomena.

[3]. Filter method: used for displaying clearer and more detailed waveforms

There are three filter modes for selection: **DIAGNOSTIC**, **MONITOR** and **SURGERY**modes. **SURGERY** mode may reduce perturbance and interference from Electrosurgery equipment. The filter method is the item applicable for both channels, which is always displayed at the waveform place of the channel 1 ECG waveform.

#### NOTE:

Only in Diagnosis mode, the system can provide non-processed real signals. In Monitor or Sugery mode, ECG waveforms may be distorted to different extents. In either of the latter two modes, the system can only show the basic ECG and the results of ST analysis may also be greatly affected. In Surgery mode, results of ARR analysis may be somewhat affected. Therefore, it is suggested that in the environment where relatively small interference exists, you'd better monitor a patient in Diagnosis mode.

- [4]. Leads of channel 2: refer to [1] for detailed information.
- [5]. Waveform gain of channel 2: refer to [2] for detailed information.

#### NOTE:

Pacemaker signal detection is marked by a "|" above the ECG waveform.

## 12.5 ECG Menu

## **12.5.1 ECG SETUP**

Pick the ECG hot key on the screen, and the following menu will pop up.

55-55 TV19-575		
HR ALM	ON	HR CHANNEL CH1
ALM LEV	MED	LEAD TYPE 5 LEADS
ALM REC	OFF	ECG DISPLAY NORMAL DISPLAY
ALM HI	120	ST AMALYSIS >>
ALM LO	50	ARR AMALYSIS >>
HR FROM	ECG	OTHER SETUP >>
SWEEP	25.0	

Figure 12-7 ECG Setup

# **♦** ECG Alarm Setting

**HR ALM**: pick **ON** to enable prompt message and data record during the ECG alarm; pick **OFF** to disable the alarm function, and there will be a beside **ECG**.

## **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

**ALM LEV**: selectable from **HIGH**, **MED**, **LOW**. Level **HIGH** represents the most serious case.

**ALM REC**: pick **ON** to enable report printing upon ECG alarm.

**ALM HI**: used to set up the upper limit of ECG alarm.

**ALM LO**: used to set up the lower limit of ECG alarm.

ECG alarm is activated when the heart beat exceeds set **ALM HI** value or falls below **ALM LO** value.

#### NOTE:

Please set the alarm limits according to the clinical conditions of individual patients. The upper limit shall not be 20 beats per min higher than the patient's heart rate.

#### HR FROM

ECG, SpO<sub>2</sub>, AUTO and BOTH may detect heart rate. AUTO distinguishes the heart rate source according to the quality of signal. When the qualities of ECG signal and SpO<sub>2</sub> signal are the same, ECG takes priority over SpO<sub>2</sub>. By picking ECG, the monitor prompts HR and activates HR beep. By picking SpO<sub>2</sub>, the monitor prompts **PULSE** and activates pulse beep.

When SpO<sub>2</sub> is selected, the alarms for HR or PR are available, and the alarm prompt will display in information area, but the alarm limit and alarm flashes are different for them.

**BOTH** mode displays HR and PR simultaneously. When this item is picked, PR parameter is

displayed to the right side of SpO<sub>2</sub>. As for the sound of HR or PR in **BOTH** mode, HR is given the priority, i.e., if HR is available, the HR sound will be sent out, but if HR is not available, then the sound will be for PR.

There are 20s for stability before ECG measuring every time.

## ◆ SWEEP

Available options for **ECG SWEEP** are 6.25, 12.5, 25.0 and 50.0 mm/s.

#### ◆ HR CHANNEL

"CH1" to count the heart rate by CH 1 waveform

"CH2" to count the heart rate by CH 2 waveform

#### **◆ LEAD TYPE**

Users can select either **3 LEADS** or **5 LEADS** for this item.

◆ ECG DISPLAY: it varies according to LEAD TYPE.

When **LEAD TYPE** is set to **3 LEADS**, **ECG DISPLAY** can be set to **NORMAL DISPLAY**, it can display one ECG waveform on the main screen.

When LEAD TYPE is set to 5 LEADS, ECG DISPLAY can be set to NORMAL DISPLAY, MULTI-LEADS DISPLAY and HALF-SCN MULTI-LEADS DISPLAY. Select NORMAL DISPLAY to display two ECG waveforms on the main screen; Select MULTI-LEADS DISPLAY to display seven ECG waveforms which occupying the area of seven waveforms on the main screen; Select HALF-SCN MULTI-LEADS DISPLAY to display seven ECG waveforms on the screen, occupying the area of four waveforms.

## NOTE:

If 3 LEADS is selected in the ECG SETUP menu, only NORMAL DISPLAY can be selected for ECG DISPLAY item in the sub-menu.

#### **♦ ST ANALYSE**

Pick this item to access **ST ANALYSE**. Please refer to *Section 12.7 ST segment montoring* for details.

#### **◆** ARR ANALYSE

Pick this item to access **ARR ANALYSE**. Please refer to *Chapter 12.8 Arr. Monitoring* for details.

#### **♦ OTHER SETUP**

Pick this item to access **OTHER SETUP** as shown below:

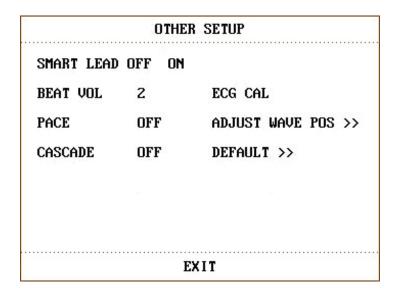


Figure 12-8 Other Setup menu

Users can access the following functions:

◆ SMART LEAD OFF: in 5 LEADS mode, if the CH1 and CH2 can not measure because of the lead off or other reasons, it can shift to other LEADS to collect a ECG waveform.

#### **♦** BEAT VOL

Six selections are available: **0**, **1**, **2**, **3**, **4**, **5**. "**5**" indicates maximum volume. "**0**" indicates no sound.

#### **◆ PACE**

**ON** detected signal will be marked by a "" above the ECG waveform **OFF** for non-paced patient.

#### NOTE:

When monitoring a patient with a pacemaker, set "PACE" to ON. If monitoring a patient without a pacemaker, set "PACE" to OFF.

If "PACE" is ON, the system will not perform some types of ARR analysis. For detailed information, please refer to the Section ARR ALARM.

◆ CASCADE: turn on or off CASCADE display. When it is set to ON, the ECG waveform is display in 2 channels. This function is available only for the NORMAL DISPLAY in ECG DISPLAY.

#### **♦ ECG CAL**

Pick this item to start ECG calibrating process. Picking this item again can finish calibrating process.

Users can turn on or off the Power frequency filter of 50Hz or 60Hz in **DIAGNOSTIC** mode. It can use standardized voltage to set the display width for 1mV signal. For example X1 is for 10mm, X2 is for 20mm.

#### **♦** ADJUST WAVE POS

Used to adjust the position of ECG waveform on the screen, pick this item to call up the **ADJUST WAVE POS** dialog box. The user may use **CH NAME** item to select the channel to be adjusted, **UP-DOWN** to adjust the position of the selected channel on the screen, **BACK TO DEFAULT** to let the waveform go back to the default position on the screen.



Figure 12-9 ADJUST WAVE POS Menu

#### **♦ DEFAULT**

Pick the **DEFAULT** item to call up the **ECG DEFAULT CONFIG** dialog box, in which you can select the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** item. After selecting any of the items and exiting the dialog box, the system will pop up a dialog box asking for your confirmation.

# **WARNING**

For patients with pacemakers, the pacing impulse analysis function must be switched **ON**. Otherwise, the pacing impulse may be counted as normal QRS complex, which results in failure of **ECG LOST** error detection.

#### NOTE:

When **PACE** Switch is **ON**, the Arrhythmia events related to **PVCs** will not be monitored. At the same time, the ST analysis will not be performed either.

If the monitor can do ST segment monitoring and Arrhythmia monitoring, please refer to *Section* 12.7 and 12.8.

# 12.6 ECG Alarm Information

Alarms occurring in the process of ECG measurement contain two types: physiological alarm and technical alarm. For the audio and visual features during the appearance of these alarms in the process of ECG measurement, please refer to the related description in *Chapter6 Alarm*. On the screen, physiological alarm messages are displayed in the Physiological Alarm area. Technical alarms messages are displayed in the Technical Alarm area. This section does not describe the content about Arr. and ST analysis.

Tables below describe respectively the possible various alarms that may occur during the measurement.

# Physiological alarms:

Message	Cause	Alarm level
HR HIGH	HR measuring value is above the upper alarm limit.	User-selectable
HR LOW	HR measuring value is below the lower alarm limit.	User-selectable

# Technical alarms:

Message	Cause	Alarm level	What to do
ECG LEAD OFF	<ol> <li>The drive lead or more than one ECG limb electrode falls off the skin;</li> <li>ECG cables fall off the monitor.</li> </ol>	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG LL LEAD OFF	ECG electrode LL falls off the skin or the ECG cable LL falls off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG LA LEAD OFF	ECG electrode LA falls off the skin or the ECG cable LA falls off the monitor.	Low	Make sure that all electrodes, leads and
ECG RA LEAD OFF	ECG electrode RA falls off the skin or the ECG cable RA falls off the monitor.	Low	patient cables are properly connected.
ECG V LEAD OFF	ECG electrode V falls off the skin or the ECG cable V falls off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG SIGNAL EXCEED	ECG measuring value is beyond measuring range.	High	Check lead connection and patient condition
ECG COMM STOP	ECG module failure or communication failure	High	Stop using measuring function of ECG module, notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm level	What to do
ECG NOISE	ECG measuring signal is greatly interrupted.	Low	Check lead connection and patient condition

# 12.7 ST Segment Monitoring

◆ ST segment monitoring function is shut off by default. You can switch it to **ON** when necessary. When using the ST analysis function, the ST analysis results will be displayed on the right of the main screen, please refer to Figure 12-15.

#### NOTE:

- 1 **ST ANALYSE** only can be used only in **ADU** mode.
- 2 When setting **ST ANALYSE** on, the monitor should in **DIAGNOSTIC** mode.
- 3 ECG/RESP monitoring should select **DIAGNOSTIC** mode.
- ◆ It is available to measure the variance of ST segment with ST analysis at the waveform tracks for selected lead. The corresponding ST measurement result displays numerically at ST1 and ST2 in the Parameter Area. The trend can be viewed in table or graphic form.
- Measurement unit of ST segment: mV.
- ◆ Measurement symbol of ST segment: "+" = elevating, "-" = depressing.
- Measurement range of ST segment:  $-2.0 \text{ mV} \sim +2.0 \text{ mV}$ .

Pick the **ST ANALYSE** item in the **ECG SETUP** menu to access the **ST ANALYSE** sub-menu as shown below.

## ST ANALYSE Menu

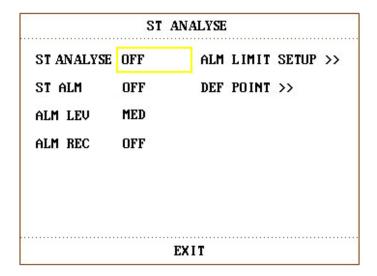


Figure 12-10 ST Analyse menu

# ST Analysis Alarm Setting

- ◆ ST ANALYSE: the switch for ST analysis. Set it to ON to activate the ST analysis or OFF to disable the ST analysis.
- ◆ ST ALM: pick ON to enable prompt message and data record during the ST analysis alarm; pick OFF to disable the alarm function, and there will be a beside ST. ST alarm is activated when the result exceeds set ST HI value or falls below ST LO value.

# **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ◆ ALM LEV: used to set up the ST alarm level. There are three selections: **HIGH, MED** and **LOW**.
- ◆ ALM REC: pick ON to enable report printing upon ST analysis alarm.
- ♦ ALM LIMIT SETUP: used to set up the upper limit and lower limit of ST alarm. The ALM HI can be set to  $0.2 \text{ mV} \sim 2.0 \text{ mV}$ , and the ALM LO can be set to  $-2.0 \text{ mV} \sim 0.2 \text{ mV}$ . the setup ALM HI should be higher than the ALM LO.
- ◆ **DEF POINT**: pick this item to access the **DEF POINT** window, in which the position of ISO and ST point can be set up.
  - □ **ISO** Base point. Default is 80 ms.
  - □ **ST** Measurement point. Default is 108 ms.

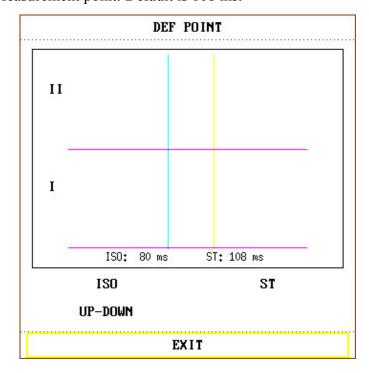


Figure 12-11 DEF POINT Window

The operator can adjust the position of both ISO and ST measurement points. Set the reference point of ST measurement point to be peak point of R-wave.

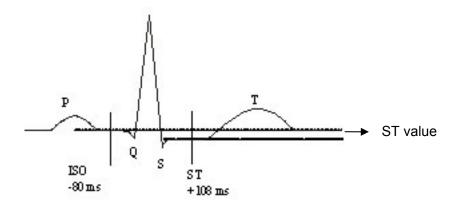


Figure 12-12 DEF POINT

The ST measurement for each beat complex is the vertical difference between the two measurement points.

#### NOTE:

- 1 The ST measurement point should be adjusted if the patient's HR or ECG morphology changes significantly.
- 2 The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.

## **Adjusting ISO, ST:**

These two points can be adjusted by turning the knob.

When adjusting ST measurement point, the system will show the ST Measurement Point Window. The system displays the QRS complex template in the window. It is adjustable for the highlight bar in the window. You may select ISO or ST, switch the knob left or right to move the cursor line. When the cursor is at the required position, you may select the base point or the measurement point.

#### NOTE:

Abnormal QRS complex is not considered in ST segment analysis.

# ST Alarm Message

## NOTE:

The alarm limits for two ST measurements are identical. No setting of alarm limits can be made only for one channel.

Tables below describe the possible physiological alarms.

Physiological alarms:

Message	Cause	Alarm Level
ST1 HIGH	ST measuring value of channel 1 is above the upper alarm limit.	User-selectable
ST1 LOW	ST measuring value of channel 1 is below the lower alarm limit.	User-selectable
ST2 HIGH	ST measuring value of channel 2 is above the upper alarm limit.	User-selectable
ST2 LOW	ST measuring value of channel 2 is below the lower alarm limit.	User-selectable

If the ST values are too high or too low, the monitor will give alarms for these parameters of ST value.

Lead Type	Parameters of ST Vaules
3-lead	ST- I , ST-II , ST-III
5-lead	ST- I , ST-II , ST-III , ST-AVR , ST-AVL , ST-AVF , ST-V

# 12.8 Arr. Monitoring

# **Arrhythmia Analysis**

The arrhythmia algorithm is used to monitor ECG of neonate and adult patients in clinical, detect the change of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarming information. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

- The arrhythmia monitoring is shut off by default. You can enable it when necessary.
- ◆ This function can call up the doctor's attention to the patient's heart rate by measuring and classifying the arrhythmia and abnormal heart beat and triggering the alarm.
- ◆ The monitor can conduct up to 16 different arrhythmia analyses.

  Pick the item **ARR ANALYSE** in **ECG SETUP** menu to access the **ARR ANALYSE** sub-menu.
- ◆ The monitor has a Pacing impulse detection circuit (select one from I, II, III, AVR, AVL, AVF and V).

Every ECG channel has a Pacing impulse rejection and a Band pass filter circuit. Pacing rate >320mV/s (RTT).

## WARNING

This device is not intended for treatment.

#### NOTE:

ECG/RESP monitoring should select **DIAGNOSTIC** mode.

#### **ARR ANALYSE Menu**

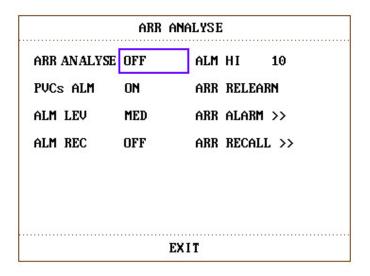


Figure 12-13 ARR ANALYSE

- ◆ ARR ANALYSE: Pick ON during monitoring. It is set to OFF by default.
- ◆ **PVCs ALM**: Pick **ON** to enable prompt message when alarm occurs; pick **OFF** to disable the alarm function, and there will be a beside **PVCs**.

# **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ◆ ALM LEV: Selectable from HIGH, MED, LOW. Level HIGH represents the most serious case.
- ◆ ALM REC: pick ON to enable report printing upon PVCs alarm.
- ◆ PVCs alarm is activated when the PVCs exceeds the set **PVCs ALM HI** value.

## **PVCs Alarm and Prompt Message:**

Tables below describe the possible physiological alarms occurring during PVCs measurement. Physiological alarms:

Message	Cause	Alarm Level
PVCs HIGH	PVCs measuring value is above the upper alarm limit.	User-selectable

- ◆ ARR RELEARN Pick this item to start a learning procedure.
- ◆ **ARR ALARM** Pick this item to access the **ARR ALARM** dialog box to set arrhythmia alarm parameters.

You can pick **ALL ALM ON** to enable the alarm function of all arrhythmia types and pick **ALL ALM OFF** to disable this function. Likewise, you can pick **ALL REC ON** to enable the recording function of all arrhythmia types and pick **ALL REC OFF** to disable this function. Changing the **ALM LEV** can reset the alarm level of all arrhythmia types to the same value.

◆ ARR RECALL Pick this item to review and edit the ARR analysis result.

The latest arrhythmia events (up to 60) are displayed.

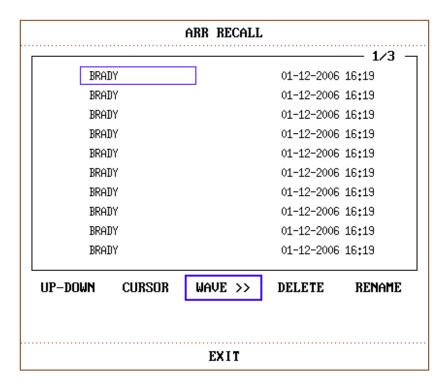


Figure 12-14 ARR RECALL

- □ **UP-DOWN** Observe the event lists on other pages.
- □ **CURSOR** Select the Arr. event, whose name is displayed in a protruding frame.
- □ **DELETE** Delete the selected Arr. event.
- □ **RENAME** Rename the selected Arr. Event displayed in a sunken frame.

Switch the knob until the name you want appears.

- □ **WAVE** Display the Arrhythmia waveform, time and parameter value.
  - O **UP-DOWN** To observe the waveforms of other Arrhythmia events.

o **L\_RIGHT** To observe the 8-second waveform of the Arrhythmia events.

o **REC** To print out the displayed Arrhythmia event.

• EXIT To return to ARR RECALL menu of Arrhythmia event.

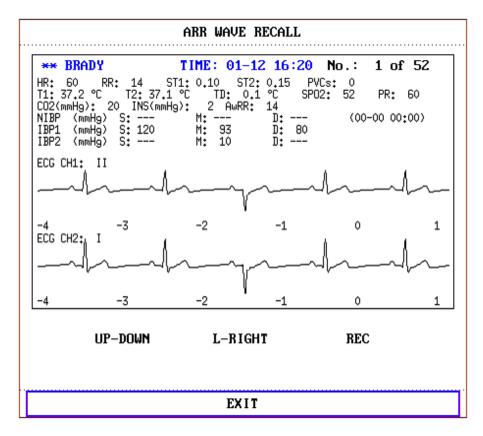


Figure 12-15 ARR WAVE RECALL

# **ARR ALARM**

The alarm is triggered when an Arrhythmia occurs. If the **ALM** is **ON**, the alarm sounds and the alarm indicator flashes.

Physiological alarms:

Prompt	Applicable Patient Type	Occurring Condition	Alarm Level
ASYSTOLE	All patients	No QRS is detected for 4 consecutive seconds	High
VFIB/VTAC	Without pacemaker	Ventricular tachycardia: The fibrillation wave lasts for consecutive 4 seconds; or the number of continuous Vent beats is larger than the upper limit of cluster Vent beats (≥5).  The RR interval is less than 600ms.	High
VT>2	Without pacemaker	3≤ the number of cluster PVCs < 5	User-selectable

Prompt	Applicable Patient Type	Occurring Condition	Alarm Level
COUPLET	Without pacemaker	2 consecutive PVCs	User-selectable
BIGEMINY	Without pacemaker	Vent Bigeminy	User-selectable
TRIGEMINY	Without pacemaker	Vent Trigeminy	User-selectable
R ON T	Without pacemaker	A type of single PVC under the condition that HR<100bpm, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Without pacemaker	Single PVC detected in normal heartbeats.	User-selectable
ТАСНҮ	All patients	Adult: 5 consecutive QRS complex, RR interval ≤ 0.5s.  Pediatric/neonatal: 5 consecutive QRS complex, RR interval ≤ 0.375s.	User-selectable
BRADY	All patients	Adult: 5 consecutive QRS complex, RR interval $\geq 1.5s$ .  Pediatric/neonatal: 5 consecutive QRS complex, RR interval $\geq 1s$ .	User-selectable
MISSED BEATS	Without pacemaker	When HR is less than 120 bpm., no heart beat is tested during the period 1.75 times of the average RR interval; or When HR is higher than 120 bpm, no beat is tested within 1 second.	User-selectable
IRR	Without pacemaker	IRREGULAR RHYTHM: The patient has irregular heart rate, check patient's condition, electrodes, cables and leads.	
PNC	With pacemaker	PACE NOT CAPTURE: After the pacemaker is paced, QRS complex can not be detected during 300ms.	
PNP	With pacemaker	PACER NOT PACED: After the QRS complex, no pace is detected during 1.75 times of RR interval.	

Prompt	Applicable Patient Type	Occurring Condition	Alarm Level
VBRADY	Inacemaker	VENTRICULAR BRADYCARDIA: The interval of 5 consecutive ventricular wave is more than 1000 ms.	
VENT	Without pacemaker	VENTRICULAR RHYTHM: The interval of 5 consecutive ventricular wave ranges from 600 ms to 1000 ms.	

### Patient type:

All patients: refers to performing Arr.analysis on patients either with pacemakers or without pacemakers.

Without pacemaker: refers to performing Arr. Analysis only on the patients without pacemakers. With pacemaker: refers to performing Arr. Analysis only on the patients with pacemakers. Prompt message:

Message	Cause	Alarm Level
ARR LEARNING	The QRS template building required for Arr. Analysis is in process.	No alarm

## NOTE:

Arrhythmia name displays in the Alarm Message Area.

# 12.9 Measuring RESP

## **WARNING**

Cardiogenic artifact in impedance respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as etCO<sub>2</sub> and SpO<sub>2</sub>.

## 12.9.1 How to Measure RESP

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

# 12.9.2 Setting Up RESP Measurement

For RESP monitoring, it is not necessary for additional electrodes, however, it is very important to attach the electrodes to the correct positions.

Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.

#### NOTE:

The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.

Checklist for RESP Monitoring

- 1. Prepare the patient's skin prior to placing the electrodes.
- Attach snap or clip to the electrodes and attach the electrodes to the patient as described below.
- 3. Switch on the monitor.

# 12.9.3 Installing Electrode for RESP Measurement

## **Placing the Electrodes for Respiratory Monitoring**

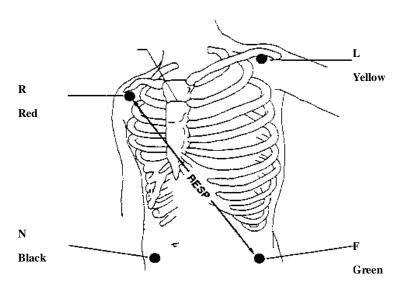


Figure 12-16 Electrodes Placement (5-lead)

#### NOTE:

Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

## 12.9.4 RESP SETUP

Pick RESP hot key on the screen to call up the following menu:

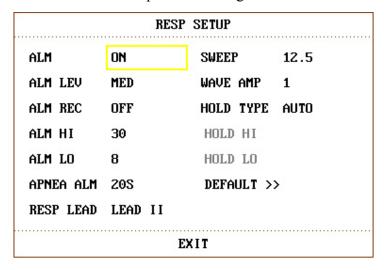


Figure 12-17 RESP Setup

## **RESP** alarm setting

◆ ALM: pick ON to enable prompt message during the RESP alarm; pick OFF to disable the alarm function, and there will be a besides "RESP".

## **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ◆ ALM LEV: selectable from HIGH, MED and LOW. Level HIGH represents the most serious case.
- ◆ ALM REC: pick ON to enable report printing upon RESP alarm.
- ◆ **ALM HI**: used to set up the upper alarm limit.
- ◆ **ALM LO**: used to set up the lower alarm limit.

RESP alarm is activated when the respiration rate exceeds set **ALM HI** value or falls below **ALM LO** value.

- ◆ APNEA ALM: to set the standard of judging an apnea case. It ranges from 10 to 40 seconds, and increases/decreases by 5.
- ◆ **RESP LEAD**: set the lead type to lead I or Lead II for respiration.

**Lead I**: Placing the leads on **R-L** (RA-LA) can measure the thoracic breathing.

**Lead II**: Placing the leads on **R-F** (RA-LL) can measure the abdominal breathing.

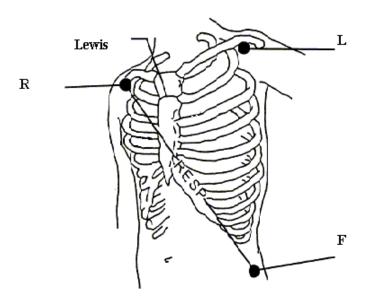


Figure 12-18 Install RESP leads

- ◆ **SWEEP**: Available options for **RESP SWEEP** are 6.25, 12.5, 25.0 and 50.0 mm/s.
- ◆ WAVE AMP: The user may set up the displaying amplitude of the RESP waveform. The selections are 0.25/0.5/1/2/3/4/5.
- ♦ HOLD TYPE: can be set to AUTO or MANUAL. When it is set to AUTO mode, the HOLD HI and HOLD LO are unavailable, and the monitor can calculate the respiration rate automatically. When it is set to MANUAL mode, you can adjust the broken lines in RESP area by the HOLD HI and HOLD LO items.
- ◆ HOLD HI/LO: when the HOLD TYPE is MANUAL, you can adjust the broken lines for higher or lower limit of the respiration rate.
- ◆ **DEFAULT**: pick this item to access the **RESP DEFAULT CONFIG** dialog box, in which the user may select whether the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.

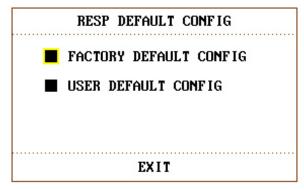


Figure 12-19 RESP default configuration

## **WARNING**

The respiration sensitivity will descend after using the defibrillation cable, and the "4" mode is recommended in the **WAVE AMP**.

# 12.9.5 RESP Alarm Message

Tables below describe the possible physiological alarms messages occurring during RESP measurement.

Physiological alarms:

Message	Cause	Alarm Level
RR HIGH	RESP measuring value is above upper alarm limit.	User-selectable
RR LOW	RESP measuring value is below lower alarm limit.	User-selectable
RESP APNEA	RESP can not be measured within the set apnea time.	HIGH

### Technical alarms:

Message	Cause	Alarm level	What to do
RESPCOMM STOP	RESP module failure or communication failure	High	Stop using measuring function of RESP module, notify biomedical engineer or the manufacturer's service staff.

# 12.10 Maintenance and Cleaning

## **WARNING**

- 1 Before cleaning the monitor or the sensor, make sure that the equipment is switched off and disconnected from the power line.
- If there is any sign that the ECG cable may be damaged or deteriorated, replace it with a new one instead of continuing its application on the patient.

## **♦** Cleaning:

Use fine-hair cloth moistened in mild soap liquid or cleaning agent containing 75% ethanol to clean the equipment.

### **♦** Disinfection

To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

# Chapter 13 SpO<sub>2</sub> Monitoring

# 13.1 What is SpO<sub>2</sub> Monitoring

The monitor uses oximetry to measure functional oxygen saturation in the blood. SpO<sub>2</sub> Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% of the hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO<sub>2</sub> oxygen saturation of 97%. The SpO<sub>2</sub> numeric on the monitor will read 97%. The SpO<sub>2</sub> numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO<sub>2</sub>/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

## How the SpO<sub>2</sub>/PLETH Parameter Works

- ◆ Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side.
- ◆ The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.
- ◆ The SpO2 value and the PLETH waveform can be displayed on the main interface.

### **WARNING**

Pulse oximetry can overestimate the SpO<sub>2</sub> value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.

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

## **WARNING**

- 1 ES (Electrosurgery) equipment wire and SpO<sub>2</sub> cable must not be tangled up.
- 2 Do not put the sensor on extremities with arterial catheter or venous syringe.

#### NOTE:

Do not perform SpO<sub>2</sub> measuring and NIBP measuring on the same arm at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO<sub>2</sub> value.

# 13.2 Precautions during SpO<sub>2</sub>/Pulse Monitoring

## **WARNING**

- 1 Verify the sensor cable fault detection before the beginning of monitoring phase. Unplug the SpO<sub>2</sub> sensor cable from the socket, and the screen will display the error message "SpO<sub>2</sub> SENSOR OFF" and the audible alarm is activated.
- 2 If the SpO<sub>2</sub> sensor can not work properly, please reconnect the sensor or change a new one.
- 3 Do not use the sterile supplied SpO<sub>2</sub> sensors if the packaging or the sensor is damaged and return them to the vendor.
- 4 Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. More frequent examinations may be required for different patients.
- Tissue damage may be caused by incorrect application or prolonged measurement duration using the sensor (more than 4 hours). Inspect the sensor periodically according to the sensor user manual.
- 6 The sensor's applicable wavelengths are 660nm of red light and 905 nm of infrared light.
- 7 The sensor accords with the ISO 10993-1: 2009 for biocompatibility.

#### NOTE:

- 1 Make sure the nail covers the light window. The wire should be on the backside of the hand.
- 2 Hand should not be too cold when measuring, and the nail polish should be cleaned before measuring, or the data accuracy may be affected.
- 3 SpO<sub>2</sub> value always displays at the same position. Pulse Rate will display when **HR FROM** is set to "**SpO<sub>2</sub>**", No ECG signal when **HR FROM** is set to AUTO.
- 4 SpO2 waveform is not proportional to the pulse volume.
- 5 A functional tester cannot be used to assess SpO<sub>2</sub> accuracy.

# 13.3 Monitoring Procedure

- 1. Switch on the monitor.
- 2. Attach the sensor to the appropriate site of the patient finger.
- 3. Plug the connector of the sensor extension cable into the SpO<sub>2</sub> socket on the SpO<sub>2</sub> module.

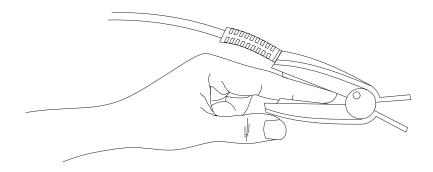


Figure 13-1 Mounting of the Sensor

## **WARNING**

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours.

#### NOTE:

Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

Interference can be caused by:

- High levels of ambient light or strobe lights or flashing lights (such as fire alarm lamps). (Hint: cover application site with opaque material.)
- High-frequency electrical noise, including electro-surgical apparatus and defibrillators
- Intravascular dye injections
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin
- Excessive patient movement and vibration
- Improper sensor application
- Low perfusion or high signal attenuation
- Venous pulsation
- Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line

# 13.4 SpO<sub>2</sub> SETUP

Pick the SpO<sub>2</sub> hot key on the main screen to open the SpO<sub>2</sub> SETUP.

## **WARNING**

Setting the SpO<sub>2</sub> upper alarm limit to 100% is equivalent to switching off the alarm on upper limit. High oxygen levels may predispose a premature infant to retrolental fibroplasia. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accordance with commonly accepted clinical practices.

## SpO<sub>2</sub> Alarm Setting

◆ ALM: pick ON to enable prompt message during the SpO₂ alarm; pick OFF to disable the alarm function, and there will be a besides "SpO₂".

## **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ◆ ALM LEV: used to set up alarm level, selectable from HIGH, MED and LOW. HIGH represents the most serious case.
- ◆ ALM REC: pick ON to enable report printing upon SpO₂ alarm.
- ◆ SpO<sub>2</sub> alarm is activated when the result exceeds SpO<sub>2</sub> ALM HI value or falls below SpO<sub>2</sub> ALM LO value. Use the knob to pick the SpO<sub>2</sub> ALM HI or SpO<sub>2</sub> ALM LOW item and turn the knob to select the desired alarm limit.
- ◆ PR alarm is activated when the pulse rate exceeds PR ALM HI value or falls below PR ALM LO value. Use the knob to pick the PR ALM HI or PR ALM LOW item and turn the knob to select the desired alarm limit.

#### **♦** SWEEP

Available options for SpO<sub>2</sub> SWEEP are 6.25, 12.5, 25.0 and 50.0mm/s.

## **♦** PR SOUND

It indicates the Pulse beep volume. Options are "0 - 5".

#### PITCH TONE

When **ON** is enabled, the system will provide prompt sound with different tone for clinic under complex monitoring environment, based on the variance of SpO<sub>2</sub> value.

#### **♦** DEFAULT

Pick this item to access the SpO<sub>2</sub> DEFAULT CONFIG dialog box, in which the user may select whether the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.

# 13.5 Alarm Description

# SpO<sub>2</sub> Alarm Message

Tables below describe the possible physiological alarms, technical alarms occurring during  $SpO_2$  measurement.

When there is no SpO<sub>2</sub> or PR input, a prompt is displayed, indicating the signal is weak.

Physiological alarm:

Message	Cause	Alarm Level
SpO <sub>2</sub> HIGH	$SpO_2$ measuring value is above upper alarm limit.	User-selectable
SpO <sub>2</sub> LOW	$SpO_2$ measuring value is below lower alarm limit.	User-selectable
PR HIGH	PR measuring value is above upper alarm limit.	User-selectable
PR LOW	PR measuring value is below lower alarm limit.	User-selectable
NO PULSE	The signal of the measurement site is too weak, so the monitor can't detect the pulse signal.	High

## Technical alarms:

Message	Cause	Alarm Level	What to do
SpO <sub>2</sub> SENSOR OFF	SpO <sub>2</sub> sensor may be disconnected from the patient or the monitor.	Low	Make sure the sensor is well connected to the patient's finger or other parts.
SpO <sub>2</sub> NO SENSOR	SpO <sub>2</sub> sensor was not connected well, or the connection is loose.	Low	Make sure the monitor and sensor is well connected, reconnect the sensor.
SpO <sub>2</sub> COMM STOP	SpO <sub>2</sub> module failure or communication failure	High	Stop using measuring function of SpO <sub>2</sub> module, notify biomedical engineer or Manufacturer's service staff.
SpO <sub>2</sub> Low Perfusion	The pulse signal is too weak or the perfusion of the measurement site is too low.	Low	Reconnect the SpO <sub>2</sub> sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm Level	What to do
SpO <sub>2</sub> Noisy Signal	There is interference with $SpO_2$ measurement signals and the waveform is abnormal.	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.

### Prompt message:

			If the Pulse is not displayed
SpO <sub>2</sub> SEARCH PULSE	SpO <sub>2</sub> sensor may be disconnected from the patient or the monitor.	Low	after 30s, check the connection between the sensor and the patient's finger, reconnect the sensor or change it to other parts.

# 13.6 Maintenance and Cleaning

## **WARNING**

- 1 Before cleaning the monitor or the sensor, make sure that the equipment is switched off and disconnected from the power line.
- 2 Do not subject the sensor to autoclaving.Do not immerse the sensor into any liquid.Do not use any sensor or cable that may be damaged or deteriorated.
- ◆ Use a cotton ball or a soft mull moistened with hospital-grade ethanol to wipe the surface of the sensor, and then dry it with a cloth. This cleaning method can also be applied to the luminotron and receiving unit.
- ◆ The cable can be cleaned with 3% hydrogen dioxide, 70% isopropanol, or other active reagent. However, connector of the sensor shall not be subjected to such solutions.

# **Chapter 14 NIBP Monitoring**

## 14.1 Overview

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

In adult and pediatric mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10-1992) in relation to mean error and standard deviation, when compared to auscultatory measurements in a representative patient population. For the auscultatory reference, the fifth Korotkoff sound was used to determine the diastolic pressure.

In neonatal mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10-1992) in relation to mean error and standard deviation, when compared to intra-arterial measurements in a representative patient population.

# 14.2 NIBP Safety Information

## **WARNING**

- You must not perform NIBP measurement on the patients with sickle-cell disease or on the patients whose skin is damaged or anticipated to be damaged.
- 2 For a thrombasthenia patient, it is important to determine whether measurement of the blood pressure shall be done automatically. The determination should be based on the clinical evaluation.
- 3 Ensure that the correct mode is selected when performing measurements on children or neonates. (For more information, please refer to the sections about menu setting.) Incorrect patient mode setting could do harm on patients. It may be dangerous for children and neonates to use an over pressure level.
- 4 The equipment is applicable in electrosurgery.
- 5 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT.
- 6 The equipment can protect against the effects of the discharge of a defibrillator.
- 7 The continuous measuring and calibration can not be operated on neonatal or pediatric patients, nor in **AUTO** measurement mode.
- 8 Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of patient.
- 9 Please do select the correct patient mode and the suitable cuff in case any damage will be caused by wrong operation or over pressure.

## **WARNING**

- 10 Repetition of measuring in the short interval automatic mode may cause discomfort in limbs.
- 11 Prior to a measurement, verify that you have selected a setting appropriate for your patient (adult, child or neonate.)
- 12 Do not apply the cuff to the limb that is intravenously infused or is catheterized. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
- 13 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled. If the air inside the cuff cannot be vented, it may cause twig dysfunction due to the lack of blood in the limbs.

#### NOTE:

- 1 Please confirm the result by referring to patients' condition if the measurement fails or if the measurements are questionable.
- 2 Once the measurement limits are exceeded or patients' condition deteriorates, you may check if the tube is twisted or is blocked.

## 14.3 Measurement Procedures

- 1. Plug in the air hose and switch on the system.
- 2. Apply the blood pressure cuff to the patient's arm or leg following the instructions below (Figure 14-1).
  - Ensure that the cuff is completely deflated.
  - Apply the appropriate size cuff to the patient. (Refer to the section NIBP Accessories for more information about the cuff size). And make sure that the symbol "Φ" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.

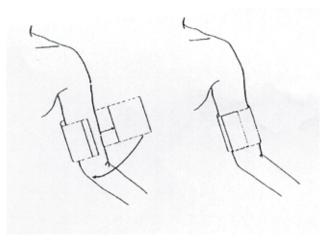


Figure 14-1 Applying Cuff

#### NOTE:

The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.

- ◆ Make sure that the cuff edge falls within the range of the mark <->. If it does not, use a larger or smaller cuff that fits better.
- 3. Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values:
- ◆ If the cuff is not level with the heart, add 0.75 mmHg (0.10 kPa) to the displayed reading for each inch of elevation above the heart, or subtract 0.75 mmHg (0.10 kPa) from the displayed reading for each inch of elevation below the heart.
- 4. Check whether the patient mode is appropriately selected. Access **PATIENT SETUP** menu from **SYSTEM MENU** and pick **PAT TYPE** item and turn the knob to select the required patient type.
- 5. Select a measurement mode in the **NIBP SETUP** menu. Refer to the following paragraphs **Operation Hints** for details.
- 6. Press the "**Start**" button on the front panel to start a measurement.

## **Operation Hints**

1. To start auto measurement:

Access **NIBP SETUP** menu and pick the **INTERVAL** item, in which the user may choose the options other than **MANUAL** to set up the time interval for auto measurement. After that, press the "**Start**" button on the front panel to start the **AUTO** measurement according to the selected time interval.

## **WARNING**

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurement.

- 2. To stop auto measurement:
  - During auto measurement, press the "Start" button on the front panel at any time to stop the auto measurement in process.
- 3. To start a manual measurement:
  - ◆ Access **NIBP SETUP** menu and pick the **INTERVAL** item. Select the **MANUAL** option. Then press the **Start** button on the front panel to start a manual measurement.
- 4. To start a continuous measurement:

Access the NIBP SETUP menu and pick the CONTINUAL item to start a continuous

measurement. The continuous measurement will last 5 minutes.

### **WARNING**

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

### 5. To stop a measurement:

During measurement press the **Start** button on the front panel at any time to stop measurement.

### NOTE:

If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the monitor.

## **WARNING**

If liquid is inadvertently splashed on the equipment or its accessories, or enters the conduit or inside the monitor, contact local Customer Service Center.

### **Measurement Limitations**

For different patients, the oscillometric measurement has different limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and the measuring time increases. The user should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive.

In the following cases, the patient's condition will make a measurement impossible:

- Measurement will be impossible under the circumstances of bad peripheral circulation, low blood pressure or low body temperature.
- Measurements will be impossible if the patient has frequent cardiac arrhythmia.
- ◆ Measurements will be impossible if the patient is connected to a heart-lung machine.

In the following cases, measurements may be incorrect:

- ◆ Measurements may be incorrect if there is movement caused by cardiac massage, external continual quivering or convulsions of the patients.
- ◆ Measurement may be incorrect if using the cuffs with an unsuitable size.
- ◆ Measurement may be incorrect if the cuff is not attached to the appropriate position that should be at the same height of the patient's heart. A deviation of 10cm in height may cause a discrepancy of 7mmHg~8mmHg in the measurements of blood pressure.
- Measurement may be incorrect while the patient is moving or speaking.

- Measurement may be incorrect if the patient wears too much clothes.
- Measurement may be incorrect if the rolled-up sleeve of the clothes presses the arm.

## **14.4 NIBP SETUP**

Pick the NIBP hot key on the main screen to open the NIBP SETUP.

- NIBP alarm setting
  - ◆ ALM: pick ON to enable prompt message during the NIBP alarm; pick OFF to disable the alarm function, and there will be a besides NIBP.

### **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ◆ ALM LEV: selectable from HIGH, MED to LOW. HIGH represents the most serious case
- ◆ ALM REC: pick ON to enable report printing upon NIBP alarm.
- ◆ SYS ALM HI, SYS ALM LO, MAP ALM HI, MAP ALM LO, DIA ALM HI, DIA ALM LO are for the user to set up the alarm limit for each type of pressure. NIBP alarm is activated when the pressure exceeds the set upper alarm limit or falls below lower alarm limit.

### UNIT

Options include mmHg and kPa.

### INTERVAL

It is used to set time interval for automatic measuring. Available selections include 1/2/3/4/5/10/15/30/60/90/120/240/480 min. Press START button to start the first auto measuring. Pick MANUAL selection in INTERVAL item to set up the measuring mode to MANUAL.

#### ■ CONTINUAL

It is used to start continuous measuring. Once this function is activated, the menu will not be shown on the screen and continual measurement will perform immediately.

#### DEFAULT

It enables you to access the menu for default configuration of NIBP. Two options are available: factory default config and user default config. A dialog box will pop up for your confirmation after either option is selected.

# 14.5 Resetting NIBP

When the pressure does not work properly and the system fails to give a message for the problem, click on **RESET** via **USER MAINTAIN** > **NIBP MAINTAIN** to activate self-test procedure, and thus restore the system from abnormal performance.

# 14.6 Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure transducers must be verified and calibrated on a yearly interval by a qualified service professional. See the Service Manual for details.

## 14.7 Leak Test

This item is used for leak test. Turn the knob to pick the **LEAK TEST** item in the **USER MAINTAIN** > **NIBP MAINTAIN** menu to start the air leakage test. When the item is selected, it will change into **STOP LEAK TEST**. If this item is selected again, the system will stop air leakage test. And the item returns to **LEAK TEST**.

## **WARNING**

This pneumatic test other than being specified in the EN 1060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

## **Procedure of Leak Test**

- Connect the cuff securely with the socket for NIBP air hole.
- Wrap the cuff around the cylinder of an appropriate size.
- Access USER MAINTAIN > NIBP MAINTAIN.
- Turn the knob to the **LEAK TEST** item and press the item. Then the prompt of **Leak testing...** will appear indicating that the system has started performing leak test.
- The system will automatically inflate the pneumatic system to about 180 mmHg.
- After 20 seconds, the system will automatically open the deflating valve, which marks the completion of a pneumatic measurement.
- If the prompt of **Pneum test over** appears, it indicates that the airway is in good situation and no air leaks exist. However if the alarm information of **NIBP AIR LEAK** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the pneumatic test. If the failure prompt still appears, please contact the manufacturer for repair.

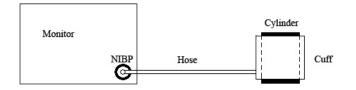


Diagram of NIBP Air Leakage Test

# 14.8 NIBP Alarm Message and Prompt Message

Tables below illustrate the possible physiological alarms, technical alarms and prompt messages occurring during NIBP measurement.

## Physiological alarms:

Message	Cause	Alarm Level
NS HIGH	NIBP SYS measuring value is above upper alarm limit.	User-selectable
NS LOW	NIBP SYS measuring value is below lower alarm limit.	User-selectable
ND HIGH	NIBP DIA measuring value is above upper alarm limit.	User-selectable
ND LOW	NIBP DIA measuring value is below lower alarm limit.	User-selectable
NM HIGN	NIBP MAP measuring value is above upper alarm limit.	User-selectable
NM LOW	NIBP MAP measuring value is below lower alarm limit.	User-selectable

Technical alarms: (display in the area below the NIBP value)

Message	Cause	Alarm Level	What to do
NIBP COMM STOP	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, notify biomedical engineer or Manufacturer's service staff.
NIBP AIR LEAK	NIBP pump, valve, cuff or tube has a leakage.	Low	Check and replace the leaking parts, if required, notify biomedical engineer or manufacturer's service staff.
NIBP OVER PRESSURE	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP INIT PRESSURE HIGH	The initial pressure is too high during measuring	Low	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP SECONDARY OVER PRESSURE	Secondary over pressure protection	High	Notify biomedical engineer or manufacturer's service staff.
NIBP TIME OUT	Measuring time has exceeded 120 seconds (adult) or 90 seconds (neonatal).	Low	Measure again or use other measuring method.
NIBP Self Test Error	When the monitor is powered on, NIBP module is detected to fail in calibration.	Low	Contact your service personnel.
NIBP CUFF TYPE ERROR	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.

Message Cause		Alarm Level	What to do
NIBP PRESSURE ERROR	Decline of air pressure is less than 2 mmHg after 6 deflations.	Low	Check whether the airway is occluded or pressure sensor works properly in pressure meter mode. If the problem still exists, contact your service personnel.
NIBP System Failure	Start up measurement, manometer and leakage test, and NIBP fail in calibration.		Contact your service personnel.
NIBP WEAK SIGNAL	Cuff is too loose or patient pulse is too weak.	Low	Use other method to measure blood pressure.
NIBP SIGNAL INTERFERENCE	Due to motion, signal noise is too large or pulse rate is not regular.	Low	Make sure that the patient under monitoring is motionless.
NIBP Range Exceeded	Maybe the patient blood pressure value is beyond the measurement range.	Low	Maybe the patient blood pressure value is beyond the measurement range.
NIBP Loose Cuff	Cuff is no properly wrapped or no cuff exists.	Low	Properly wrap the cuff.

Prompt message: (display in the prompt area below NIBP value)

Message	Cause	
Manual measuring	It is in the process of measuring.	
Continual Measuring	In continuous measuring mode.	
Auto measuring	It is in the process of automatic measuring.	
Measurement over	Measurement is over.	
Calibrating	It is in the process of calibrating.	
Calibration over	Calibration is over.	
Pneum testing	It is in the process of pneumatic testing.	
Pneum test over Pneumatic test is over.		

Resetting	NIBP module is resetting.
Please Start	NIBP module is in idle status.

# 14.9 Maintenance and Cleaning

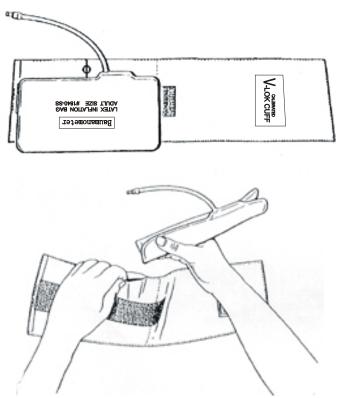
## **WARNING**

- 1 Do not squeeze the rubber tube on the cuff.
- 2 Do not allow liquid to enter the connector socket at the front of the monitor.
- 3 Do not wipe the inner part of the connector socket when cleaning the monitor.
- 4 When the reusable cuff is not connected with the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.

#### **Reusable Blood Pressure Cuff**

The cuff can be disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned.

The cuff can also be machine-washed or hand-washed, the latter method may prolong the service life of the cuff. Before washing, remove the latex rubber bag, and for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing, and then reinsert the rubber bag.



Replace Rubber Bag in Cuff

To replace the rubber bag in the cuff, first place the bag on top of the cuff so that the rubber tubes

line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the complete cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

## **Disposable Blood Pressure Cuffs**

Disposable cuffs are intended for one-patient use only. Do not use the same cuff on any other patient. Do not sterilize or use autoclave on disposable cuffs.

### NOTE:

For protecting environment, the disposable blood pressure cuffs must be recycled or disposed of properly.

# **Chapter 15 TEMP Monitoring**

# 15.1 TEMP Monitoring

Two TEMP probes can be used simultaneously to measure two TEMP data, and get the temperature difference.

## **TEMP Monitoring Setup**

- ◆ With a reusable TEMP probe you can plug the probe directly into the monitor.
- ◆ Apply the TEMP probes securely to the patient.
- Switch on the system.

### **WARNING**

- 1 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable of the channe1 from the socket, and then the screen will display the error message **TEMP1 SENSOR OFF** and the audible alarm is activated. It is the same to the other channel.
- 2 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.

## 15.2 TEMP SETUP

Pick the **TEMP** hot key on the screen to call up the **TEMP SETUP** menu shown as below:

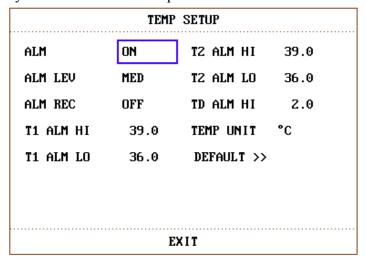


Figure 15-1 TEMP SETUP

◆ ALM: pick ON to enable prompt message during the TEMP alarm; pick OFF to disable the

alarm function, and prompt the symbol besides TEMP numeric.



## **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

- **ALM LEV**: used to set up the alarm level, selectable from **HIGH**, **MED** or **LOW**.
- **ALM REC**: used to start/stop recording TEMP alarms. Pick **ON** to enable report printing upon TEMP alarm.
- Alarm for T1, T2, TD occurs when the measured temperature exceeds the set alarm upper limit or falls below alarm lower limit.

T1 represents the TEMP of Channel 1, T2 represents the TEMP of Channel 2, TD represents the TEMP difference of T1 and T2.

- ◆ UNIT: To set temperature unit (°C or °F).
- ◆ **DEFAULT**: Pick this item to access the **TEMP DEFAULT CONFIG** dialog box, in which the user may select whether the FACTORY DEFAULT CONFIG or the USER **DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.

# 15.3 TEMP Alarm Message

Tables below describe the possible physiological alarms, technical alarms occurring during TEMP measurement.

Physiological alarms:

Message	Cause	Alarm Level
T1 HIGH	Measuring value of T1 channel is above upper alarm limit.	User-selectable
T1 LOW	Measuring value of T1 channel is below lower alarm limit.	User-selectable
T2 HIGH	Measuring value of T2 channel is above upper alarm limit.	User-selectable
T2 LOW	Measuring value of T2 channel is below lower alarm limit.	User-selectable
TD HIGH	Temperature difference of T1 and T2 is above upper temperature difference limit.	User-selectable

#### Technical alarms:

Message	Cause	Alarm Level	What to do
T1 SENSOR OFF	Temperature cable of TEMP channel may be disconnected from the monitor.	Low	Make sure that the cable is properly connected
T2 SENSOR OFF	Temperature cable of TEMP channe2 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected.
T1 EXCEED	TEMP1 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
T2 EXCEED	TEMP2 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
TEMP COMM STOP	TEMP module failure or communication failure	High	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.

# 15.4 Care and Cleaning

## **WARNING**

Before cleaning the monitor or the probe, make sure that the equipment is switched off and disconnected from the power line.

### **Reusable TEMP Probes**

- The TEMP probe should not be heated above  $100^{\circ}$ C (212°F). It should only be subject briefly to temperatures between  $80^{\circ}$ C (176°F) and  $100^{\circ}$ C (212°F).
- 2 The probe must not be sterilized in steam.
- 3 Only detergents containing no alcohol can be used for disinfection.
- 4 The rectal probes should be used, if possible, in conjunction with a protective rubber cover.
- To clean the probe, hold the tip with one hand and with the other hand rubbing the probe down in the direction of the connector using a moist lint-free cloth.

## NOTE:

- 1 Wash the probe with clean water after disinfecting and sterilizing to remove any remaining solution. The probe can only be reused after being dried thoroughly.
- 2 Do not disinfect the probe by means of water boiled.
- 3 The product has not been disinfected at the factory.
- 4 Any residue should be removed from the probe before being disinfected, and avoid contacting corrosive solvent. Dipping the cable into alcohol or alkalescent solvent for a long time may reduce the flexibility of the scarfskin of the cable. Also, the connector should not be dipped.
- After monitoring, disinfect the probe according to the instruction described in the user manual.
- 6 Cavity temperature probe is suggested to be used only inside the recta. Recommend to use the disposable cannula to prevent cross infection.
- 7 Do not force the cavity temperature probe against resistance when inserted into human body. Also it is not recommended to use it in bleeding part or cankerous part of human body.

# **Chapter 16 IBP Monitoring (Optional)**

# **16.1 Introduction**

The monitor measures direct blood pressure (SYS, DIA and MAP) of one selected blood vessel through two channels, and displays two waveforms of measured direct blood pressure (SYS, DIA and MAP).

The available pressure labels are:

Label	Definition	
ART	Arterial Blood Pressure	
PA	Pulmonary Artery Pressure	
CVP	Center Venous Pressure	
RAP	Right Atrial Pressure	
LAP	Left Atrial Pressure	
ICP	Intracranial Pressure	
P1-P2	Alternative non-specific pressure labels	

# 16.2 Precautions during IBP Monitoring

### **WARNING**

- 1 The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.
- When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
- 3 Disposable IBP transducer or domes should not be reused.

#### NOTE:

Use only the pressure transducer listed in the *Chapter 18 Accessories and Ordering Information*.

The specified transducer is designed to have the special ability to protect against the electricity shock (especially for the leak current allowed), and it is protected against the effects of a discharge of a cardiac defibrillator. It can be used in the surgical operation. When the patient is in

the defibrillation, the waveform of the pressure maybe distorted temporarily. After the defibrillation, the monitoring will go on normally, and the operation mode and the user configuration are not affected.

## **WARNING**

- 1 Verify transducer cables fault detection before the beginning of monitoring phase. Unplug the transducer of the channel 1 from the socket, and then the screen will display the error message **IBP1 SENSOR OFF** and the audible alarm is activated. The channel 2 is the same as the above channel 1.
- 2 If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.

## NOTE:

Calibrate the instrument either whenever a new transducer is used, or as frequently as dictated by your Hospital Procedures Policy.

# **16.3 Monitoring Procedure**

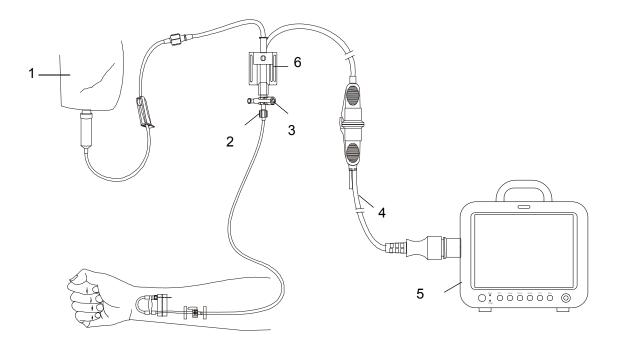
Preparatory steps for IBP measurement:

- 1. Plug the pressure cable into the corresponding socket and switch on the monitor.
- 2. Flushing through the system with normal saline solution. Ensure that the system is free of air bubbles.
- 3. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.

## **WARNING**

If there are air bubbles in the pressure line or the transducer, you should flush the system with the solution to be infused.

- 4. Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.
- 5. Check if you have selected the correct label name. See the next section for details.
- 6. Zero the transducer. See the next section for details.



1: Normal Saline with Heparin; 2: Distal end to patient; 3: 3-way stopcok; 4: Pressure transducer interface cable; 5: Monitor; 6: Pressure transducer.

Figure 16-1 IBP Monitoring

## 16.4 IBP Menu

Pick the IBP hot key on the screen to access the **IBP SELECT** menu shown as follows:

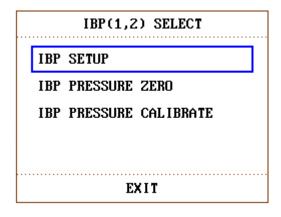


Figure 16-2 IBP SELECT Menu

Pick the **IBP SETUP** item to call up the **IBP SETUP** menu shown as follows:

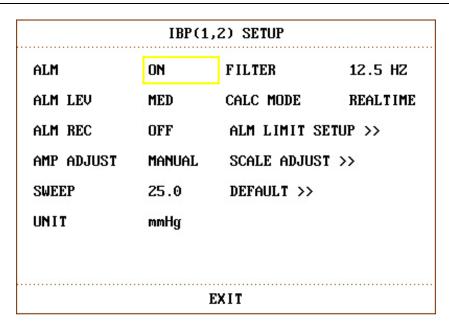


Figure 16-3 IBP SETUP Menu

The items to be set up in the menu include:

◆ ALM: select ON to enable alarm prompt during IBP alarm. Select OFF to disable audio alarm and prompt the symbol beside IBP numeric.

### **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ◆ ALM LEV: set the alarm level. Three levels are available: HIGH, MED, LOW.
- ◆ ALM REC: select ON to enable recording during the IBP alarm or to OFF to disable the alarm recording function.
- ◆ AMP ADJUST: set to adjust waveform amplitude. Two selections are available: MANUAL, AUTO. Set it to AUTO, the pressure names of IBP become P1 and P2, and the IBP scale is adjusted by system automatically. Set it to MANUAL, the pressure names of IBP can choose one of ART, PA, CVP, RAP, LAP, ICP, P1, P2 and the IBP scale is adjusted by the user via SCALE ADJUST item.
- ◆ SWEEP: set to select the scanning speed of the IBP wave. Two selections are available: 6.25mm/s, 12.5 mm/s, 25 mm/s or 50.0mm/s.
- ◆ UNIT: set to select the pressure unit (mmHg or kPa).
- ◆ FILTER: set this item to 12.5Hz or 40.0 Hz.
- ◆ ALM LIMIT SETUP: used to access the sub-menu of IBP ALM LIMIT SETUP, in which the user may set up the upper and lower alarm limits of systolic pressure, diastolic pressure and mean pressure respectively for channel 1 and channel 2.
- ◆ SCALE ADJUST: used to access the sub-menu of IBP SCALE ADJUST, in which the user

may adjust the position of the high, reference and low scales for the two waveforms displayed on the screen.

- ◆ **DEFAULT**: used to access the **IBP DEFAULT CONFIG** dialog box, in which the user may select whether the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.
- **EXIT**: used to exit the menu and return to the main interface.

## **WARNING**

Before setting the alarm limits, confirm to choose the correct label.

	IBP (	ALM LIMIT S	ETUP		
		SYS	MAP	DIA	
CH1:ART ALM	ΗI	160	110	90	
CH1:ART ALM	LO	90	70	50	
CH2:CVP ALM	HI		10		
CH2:CVP ALM	LO		0		
EXIT					

Figure 16-4 IBP ALM LIMIT SETUP

The alarm occurs when the value exceeds the set limits.

## **IBP Transducer Zero**

Press the **IBP PRESSURE ZERO** button on the **IBP SELECT** menu to call up **IBP PRESSURE ZERO** menu as shown below:

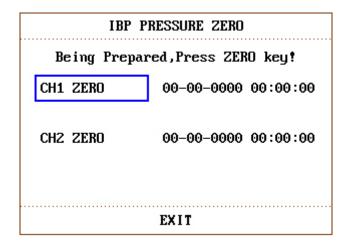


Figure 16-5 IBP PRESSURE ZERO

#### NOTE:

It is the responsibility of the user to ensure that a zero procedure has recently been done on the transducer: otherwise there will be no recent, valid zero value for the instrument to use, which may result in inaccurate measurement results.

### **Zero Calibration of Transducer**

Select CH1, and then IBP1 returns to zero. Select CH2, and then IBP2 returns to zero.

## **CAUTION**

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

## The prompt information related to zero calibration, take CH1 for example.

### ◆ "CH1 ZERO SUCCESS!"

Indicate that zero calibration is over, so you can turn off the stopcock that was open to atmospheric pressure, and turn on the patient stopcock.

#### ◆ "CH1 ZERO FAIL!"

Make sure that the transducer is not attached to the patient.

#### ◆ "CH1 SENSOR OFF, FAIL!"

Make sure that transducer is not off, and then proceed zeroing.

## ♦ "IN DEMO, FAIL!"

Make sure that the monitor is not in **DEMO** mode. Contact service technician if necessary.

## **♦** "PRESSURE OVER RANGE, FAIL!"

Make sure that the stopcock is vented to atmosphere. If the problem persists, please contact service technician.

#### **IBP** Calibration

Press the **IBP PRESSURE CALIBRATE** button on the **IBP (1, 2) SELECT** menu to call up the **IBP PRESSURE CALIBRATE** menu as shown below:

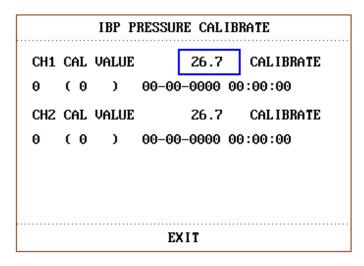


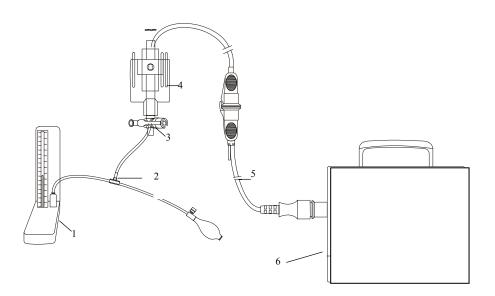
Figure 16-6 IBP Calibration Menu

### Calibrate the transducer:

Turn the knob to select the item **CH1 CAL VALUE**, press and turn the knob to select the pressure value to be calibrated for channel 1. Then turn the knob to select **CALIBRATE** in the menu to start calibrating channel 1.

Turn the knob to select the item **CH2 CAL VALUE**, press and turn the knob to select the pressure value to be calibrated for channel 2. Then turn the knob to select **CALIBRATE** in the menu to start calibrating channel 2.

◆ The pressure calibration of the portable patient monitor



1: Hydrargyrum pressure meter; 2: 3-way connector; 3: 3-way stopcock; 4: Pressure transducer; 5: Pressure transducer interface cable; 6: Monitor

Figure 16-7 IBP Calibration

### **CAUTION**

- 1 Mercury calibration should be performed by the biomedical engineering department either whenever a new transducer is used, or as frequently as dictated by your Hospital Procedures Policy.
- 2 The purpose of the calibration is to ensure that the system gives you accurate measurements.
- 3 Before starting a mercury calibration, a zero procedure must be performed.
- 4 If you need to perform this procedure yourself you will need the following equipment: Standard sphygmomanometer, 3-way stopcock and Tubing (approximately 25 cm long).

## **WARNING**

It is forbidden to perform this procedure while patient is being monitored.

The Calibration Procedure: (See Figure 16-7)

- 1. Close the stopcock that was open to atmospheric pressure for the zero calibration.
- 2. Attach the tubing to the sphygmomanometer.
- 3. Ensure that connection that would lead to patient is off.
- 4. Connect the 3-way connector to the 3-way stopcock that is not connected to the patient catheter.
- 5. Open the port of the 3-way stopcock to the sphygmomanometer.
- 6. Select the channel to be calibrated in the menu and select the pressure value to which the IBP is to be adjusted.
- 7. Inflate to make the mercury bar rise to the setup pressure value.
- 8. Adjust repeatedly until the value in the menu is equal to the pressure value shown by the mercury calibration.
- 9. Press the Start button, the device will begin calibrating.
- 10. Wait for the calibrated result. You should take corresponding measures based on the prompt information.
- 11. After calibration, disassemble the blood pressure tubing and the attached 3-way valve.

### The prompt information related to calibration, take CH1 for example.

### ♦ "CH1 CAL SUCCESS!"

Indicate that CH1 works normally, you can use CH1 to monitor the patient.

### ◆ "CH1 CAL FAIL!"

Make sure that pressure value shown by hydrargyrum pressure meter is change- less.

### ◆ "CH1 SENSOR OFF, FAIL!"

Make sure that sensor is not off, then start the calibration.

### ◆ "IN DEMO, FAIL!"

Make sure that the monitor is not in **DEMO** mode. Contact service technician if necessary.

## **♦** "PRESSURE OVER RANGE, FAIL!"

Make sure that you have selected transducer value in **IBP CAL**, then start the calibration.

#### **IBP SCALE ADJUST Submenu**

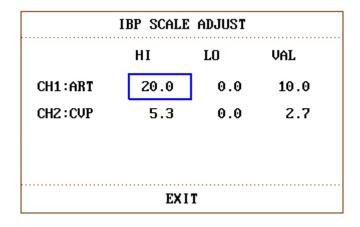


Figure 16-8 IBP SCALE ADJUST Menu

The waveform and corresponding scale appears in the IBP Waveform Area with 3 dotted lines representing High Limit Scale, Reference Scale, and Low Limit Scale from the top to the bottom. Values of the three scales can be user-set according to the instruction given below.

- ◆ IBP label: selectable from ART, PA, CVP, RAP, LAP, ICP, P1, P2;
- ◆ HI: IBP value of High Limit scale, its range is the measuring range of the current pressure.

#### NOTE:

The HI value must be higher than the LO value.

◆ LO: IBP value of Low Limit scale, its range is the measuring range of the current pressure.

#### NOTE:

The LO value must be lower than the HI value.

◆ VAL: IBP value of Reference scale (between HI and LO).

### NOTE:

When change HI scale, Low scale or Reference scale of IBP waveform and the corresponding IBP waveforms are displayed under the menu window, the waveform will come penetratingly through the menu window for observing.

## 16.5 Alarm Information

Tables below describe the possible physiological alarms, technical alarms occurring during IBP measurement.

# Physiological alarms:

Message	Cause	Alarm Level
IS1 HIGH	SYS measuring value of channel 1 is above upper alarm limit.	User-selectable
IS1 LOW	SYS measuring value of channel 1 is below lower alarm limit.	User-selectable
ID1 HIGH	DIA measuring value of channel 1 is above upper alarm limit.	User-selectable
ID1 LOW	DIA measuring value of channel 1 is below lower alarm limit.	User-selectable
IM1 HIGH	MAP measuring value of channel 1 is above upper alarm limit.	User-selectable
IM1 LOW	MAP measuring value of channel 1 is below lower alarm limit.	User-selectable
IS2 HIGH	SYS measuring value of channel 2 is above upper alarm limit.	User-selectable
IS2 LOW	SYS measuring value of channel 2 is below lower alarm limit.	User-selectable
ID2 HIGH	DIA measuring value of channel 2 is above upper alarm limit.	User-selectable
ID2 LOW	DIA measuring value of channel 2 is below lower alarm limit.	User-selectable
IM2 HIGH	MAP measuring value of channel 2 is above upper alarm limit.	User-selectable
IM2 LOW	MAP measuring value of channel 2 is below lower alarm limit.	User-selectable

### Technical alarms:

Message	Cause	Alarm Level	What to do	
IBP1 SENSOR OFF	IBP cable of channel 1 falls off from monitor.	Low	Make sure that cable is properly connected.	
IBP2 SENSOR OFF	IBP cable of channel 2 falls off from monitor.	Low		
IBP COMM STOP	IBP module communication failure	High	Stop using measuring function of IBP module, notify biomedical engineer or Manufacturer's service staff.	

# 16.6 Maintenance and Cleaning

### **WARNING**

Before cleaning the monitor or the transducer, make sure that the equipment is switched off and disconnected from the 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. Clean the transducer and cable with soap or cleaning agents 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 agents.

## NOTE:

- 1 The disposable transducers or domes must not be re-sterilized or re-used.
- 2 For protecting environment, the disposable transducers or domes must be recycled or disposed of properly.

# Chapter 17 CO<sub>2</sub> Measuring (Optional)

## 17.1 General

This chapter offers some relevant data concerning CO<sub>2</sub> monitoring.

The monitor provides the Sidestream and MainStream method for CO<sub>2</sub> monitoring. LoFlo CO<sub>2</sub> module is used for SideStream measuring. Capnostat 5 CO<sub>2</sub> module (C5) is used for MainStream measuring.

SideStream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a remote CO<sub>2</sub> sensor. You can measure SideStream CO<sub>2</sub> using the monitor's built-in CO<sub>2</sub> measurement.

MainStream measurement uses a CO<sub>2</sub> sensor attached to an airway adapter directly inserted into the patient's breathing system.

The CO<sub>2</sub> module can be applied in an operation room, monitor units etc. It can measure the CO<sub>2</sub> partial pressure or concentration of patient Air Way, obtain End tidal CO<sub>2</sub> (EtCO<sub>2</sub>), Fraction of inspired CO<sub>2</sub> (FiCO<sub>2</sub>), and Air Way Respiration Rate (AwRR), and display CO<sub>2</sub> concentration waveforms. The parameter symbols displayed on the screen are defined as follows:

 $CO_2$ : Et $CO_2$ FI: Fi $CO_2$ 

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

### **WARNING**

- 1 CO<sub>2</sub> module shall be avoided from crash and vibration.
- 2 Do not use the device in the environment with flammable anesthetic gas. For example, do not use it in the environment where flammable anesthetic is mixed with air, oxygen or nitrous oxide. The device should be operated by trained and qualified personnel who are familiar with the manual.
- 3 Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the CO<sub>2</sub> measurement.
- 4 Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- 5 Do not place the sensor cables or tubing in any manner that may cause entanglement or strangulation.
- 6 Do not store the CO<sub>2</sub> Module at temperatures less than -40° F (-40° C) or greater than 158° F (70° C).
- 7 Do not operate the CO<sub>2</sub> Module at temperatures less than 32° F (0° C) or greater than 104° F (40° C).
- In the presence of electromagnetic devices (i.e., electrocautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20V/m will not adversely affect module performance.

## **WARNING**

- 9 The patient monitor will be damaged if the water quantity in the water trap reaches the limit.
- 10 The machine will be damaged if any pipeline from the CO<sub>2</sub> module has been disconnected, or the air tube/air inlet/air outlet has been plugged by water or other materials.

### NOTE:

After the Low battery alarm is activated, please do not start the CO<sub>2</sub> measurement, or the monitor may be turned off for the low capacity of battery.

# 17.2 Monitoring Procedure

The principle of CO<sub>2</sub> measurement is primarily based on the fact that CO<sub>2</sub> molecule can absorb 4.3µm infrared ray. Absorption intensity is proportional to CO<sub>2</sub> concentration of patient sample, the CO<sub>2</sub> concentration will compute according to the detecting CO<sub>2</sub> absorption intensity of patient sample. The relation between partial pressure and percentage of CO<sub>2</sub> concentration is given below:

 $P (mmHg) = Percentage (\%) \times Pamp (Ambient Pressure)$ 

## LoFlo CO<sub>2</sub> module setup

#### NOTE:

You must perform a zero calibration as described in this procedure each time the ambient temperature changes more than 10°C (for example during transport).



Figure 17-1 LoFlo CO<sub>2</sub> module

- 1 Plug the sensor cable into the monitor's CO<sub>2</sub> input connector. Allow the sensor two minutes for warm-up.
- 2 Connect the cannula, airway adapter, or sample line as appropriate, to the sensor. It will click into place when seated correctly.



Figure 17-2 Connecting LoFlo module

- 3 To zero the sensor:
  - Expose the sensor to room air and keep it away from all sources of CO<sub>2</sub> including the ventilator, the patient's breath and your own.
  - Start up CO<sub>2</sub> SETUP, and change WORK MODE from STANDBY to MEASURE.
  - In the CO<sub>2</sub> SETUP menu, select ZERO CAL.
  - The messages indicate: "**zero started**", "**zero successful**". After the zero calibration is finished, the user can start CO<sub>2</sub> Monitoring.
- 4 For intubated patients requiring an airway adapter;



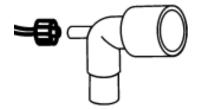


Figure 17-3 Air adapter

For non-intubated patients: Place the nasal cannula onto the patient.



Figure 17-4 Place the nasal cannula

#### NOTE:

- Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.
- 2 Always disconnect the cannula, airway adapter or sample line from the sensor when the sensor is not in use.

### C5 CO<sub>2</sub> Module Setup

#### NOTE:

You must perform a zero calibration as described in this procedure each time you use a new airway adapter.



Figure 17-5 C5 CO<sub>2</sub> module

- 1 Attach the sensor connector to the  $CO_2$  connector on the monitor.
- 2 Wait two minutes, allowing the sensor to reach its operating temperature and a stable thermal condition.
- 3 Choose the appropriate airway adapter and connect it to the sensor head. The airway adapter clicks into place when seated correctly.

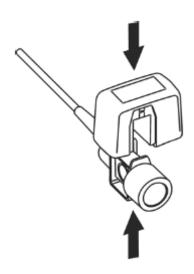


Figure 17-6 Connecting sensor

- 4 To zero the sensor:
  - Expose the sensor to room air and keep it away from all sources of CO<sub>2</sub> including the ventilator, the patient's breath and your own.
  - Start up CO<sub>2</sub> SETUP menu, and change WORK MODE from STANDBY to MEASURE
  - In the CO<sub>2</sub> SETUP menu, select ZERO CAL.
  - The messages indicate: "**zero started**", "**zero successful**". After the zero calibration is finished, the user can start CO<sub>2</sub> Monitoring.
- 5 Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y-section.

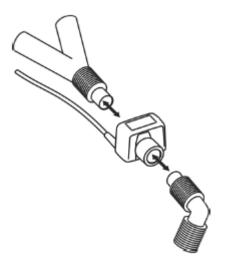


Figure 17-7 Connecting airway adapter

#### **WARNING**

- 1 Accuracy is affected by temperature and barometric pressure.
- 2 It is forbidden to insert or draw out the module when the monitor is working, for it can cause instability of the system. If you do it unconsciously, please turn off the module in menu immediately. The module enters **STANDBY** mode if you reconnect it to monitor which is powered on. If the readings are inaccurate, you should do calibration.

#### NOTE:

- 1 If the cannula is off during measurement, please perform a zero calibration after connecting it before restarting measurement.
- 2 Replace the airway adapter if excessive moisture or secretions are observed in the tubing or if the CO<sub>2</sub> waveform changes unexpectedly without a change in patient status.
- 3 To avoid infection, only use disinfected or disposable airway adapters.
- Inspect the airway adapters prior to use. Do not use if airway adapter appears damaged or broken. Periodically check the flow sensor and tubing in case of excessive moisture or secretion buildup.
- Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.

### 17.3 CO<sub>2</sub> SETUP

### **Parameter Setup and Adjustment**

Turn the knob to select and press  $CO_2$  hot key on the screen to activate  $CO_2$  SETUP.

The items to be set up in the menu include:

◆ **ALM**: Select **ON** to enable and store alarm prompt when CO<sub>2</sub> parameters have alarms. Select **OFF** to disable alarm and display beside CO<sub>2</sub>. The default is **ON**.

#### **WARNING**

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ◆ ALM LEV: Select from HIGH, MED and LOW. Level HIGH represents the most serious alarm, followed by Level MED and Level LOW with a decrease of seriousness. Change in ALM LEV can only affect the physiological alarm levels of CO₂ parameters including EtCO₂ upper limit, EtCO₂ lower limit, FiCO₂ upper limit, AwRR upper limit and AwRR lower limit. The default alarm level is MED.
- ◆ ALM REC: Select ON to generate output from the recorder ever since CO₂ parameter alarm occurs. The default value is OFF.
- ◆ CO<sub>2</sub> ALM HI: to adjust the upper alarm limit of EtCO<sub>2</sub>. If the measuring value is larger than CO<sub>2</sub> upper alarm limit, CO<sub>2</sub> HIGH appears on the screen. After the measuring value returns to the normal one, the information disappears.
- ◆ CO<sub>2</sub> ALM LO: to adjust the lower alarm limit of EtCO<sub>2</sub>. If the measuring value is smaller than CO<sub>2</sub> lower alarm limit, CO<sub>2</sub> LOW appears on the screen. After the measuring value returns to the normal one, the information disappears.
- ◆ **FiCO<sub>2</sub> ALM HI**: to adjust the upper alarm limit of FiCO<sub>2</sub>. If the measuring value is larger than FiCO<sub>2</sub> upper alarm limit, **FiCO<sub>2</sub> HIGH** appears on the screen. After the measuring value returns to the normal one, the information disappears.
- ◆ **AWRR ALM HI**: to adjust the upper alarm limit of AwRR. If the measuring value is larger than the upper alarm limit of AwRR, **AWRR HIGH** appears on the screen. After the measuring value returns to the normal one, the information disappears.
- ◆ **AWRR ALM LO**: to adjust the lower alarm limit of AwRR. If the measuring value is smaller than the lower alarm limit of AwRR, **AWRR LOW** appears on the screen. After the measuring value returns to the normal one, the information disappears.
- ♦ WORK MODE: to change the work mode of CO<sub>2</sub> with between MEASURE and STANDBY. The default is STANDBY. When it is required to monitor CO<sub>2</sub>, you should select MEASURE. In STANDBY mode, the air pump in SideStream module is disabled, which decreases the power consumption and extends the lifecycle of IR source and the whole CO<sub>2</sub> module.

#### NOTE:

When the  $CO_2$  monitoring function is not in use, please set the **WORK MODE** to **STANDBY**.

- ◆ UNIT: to change the display units of CO<sub>2</sub> and FiCO<sub>2</sub> parameters. mmHg and kPa are available for selection.
- ◆ APNEA ALM: After selecting the alarm time for APNEA alarm (having 7 levels, which are 10S, 15S, 20S, 25S, 30S, 35S and 40S), the CO₂ APNEA information will appear on the screen after the corresponding selected time. The alarm level is HIGH.
- ◆ SWEEP: to adjust the display rate of CO<sub>2</sub> waveforms with **6.25mm/s**, **12.5mm/s**, **,25.0mm/s** or **50.0mm/s** selectable.
- ◆ Exit: to exit CO<sub>2</sub> SETUP menu.

#### NOTE:

- 1 APNEA ALM cannot be canceled.
- When various alarms occur simultaneously, the alarm information of the highest level will be displayed on the screen.
- ◆ OTHER SETUP: pick this item in the menu to call up CO<sub>2</sub> SETUP.

Now we introduce you to the functions of each item in CO<sub>2</sub> SETUP submenu.

- WAVE SCALE: to adjust full scale size of CO<sub>2</sub> waveform display area with LOW or HIGH selectable. The default value is LOW.
- **BARO PRESS**: to set the barometric pressure value. For gaining accurate readings, you should set this barometric pressure correctly.
- **O**<sub>2</sub> **COMPENS**: to adjust the  $O_2$  compensation concentration as per the selection of the user. Input the proper  $O_2$  compensate value according to the  $O_2$  concentration of the inhaled gas.
- ANE AGENT: to adjust the anaesthetic compensation concentration as per the selection of the user. The concentration ranges from  $0\sim2.0\%$ . Input the proper concentration value according to the anaesthetic gas concentration of the inhaled gas.
- BALAN GAS: to balance the gas compensating operations. Select different compensating types for balancing gas. The compensation types are ROOM AIR, N<sub>2</sub>O and HELIUM.
- WATERVAPOR: determine whether to make watervapor compensate.

Water vapor compensation accounts for the effect of water vapor on the CO<sub>2</sub> IR (Infra-Red) absorption characteristics. The user may disable this compensation in certain situations. During normal operation, CO<sub>2</sub> measurements are adjusted mathematically to compensate for this effect.

The host may choose to disable this compensation when performing dry gas measurements

in which the gas does not contain water vapor.

The water vapor compensation is **ON** by default and may be enabled or disabled via a host system command.

- BTPS: The user may want to choose whether to correct values for gas that is at body temperature, ambient pressure and is saturated with water vapor (BTPS) or the ambient temperature and pressure and is dry (ATPD). BTPS compensation (Body Temperature and Pressure, Saturated) is a user-selectable compensation that accounts for the differences between the airway sample and "deep lung" CO<sub>2</sub>. Since the intent is to report "deep lung" CO<sub>2</sub>, where the sample is at 37°C and fully saturated, BTPS compensates for the variance of water vapor content due to temperature. The BTPS compensation of CO<sub>2</sub> module is on by default.
- COMPENSATE: to perform different compensate operations as per the selection of the user. The selections are GENERAL, O<sub>2</sub>, N<sub>2</sub>O and ALL. The work conditions for calculating compensation are shown in the following table. Here is the operation method. First, select the gas compensation to be used, including general compensation, O<sub>2</sub> compensate, N<sub>2</sub>O compensate and ALL compensate. Then, determine whether to make VA compensate and BTPS compensate.

<b>Work Conditions</b>	for	$CO_2$	Calculation	compensation:

Calculation Compensate Method	O <sub>2</sub> Modification	N <sub>2</sub> O Modification	Work Conditions
General	OFF	OFF	O <sub>2</sub> 20%, no N <sub>2</sub> O
$O_2$	ON	OFF	O <sub>2</sub> 80%, no N <sub>2</sub> O
ALL	OFF	ON	O <sub>2</sub> 60%, N <sub>2</sub> O 40%
N <sub>2</sub> O	ON	ON	O <sub>2</sub> 40%, N <sub>2</sub> O 60%

■ **ZERO CAL**: used to perform CO<sub>2</sub> model zero calibration.

When a dramatic change in  $CO_2$  measurement or the accuracy of reading is suspected by the clinician, please select "**ZERO CAL**" item, then the system will automatically inhale clean  $CO_2$ -free room air to the air inlet of  $CO_2$  module beside the monitor, and start zero calibration.

#### NOTE:

- 1 If Compensate item is not correctly set as per the operation conditions, the result will be far from the actual value, thus leading to severe misdiagnosis.
- 2 The default value of Water Vapor Compensate is on. Turn it off when measuring dry gas, such as when performing regular maintenance or measurement validation by using dry calibrated gas.
- 3 The default of BTPS is on. Turn it on when measuring the VA saturated "damp" gas at the body temperature and ambient pressure and turn it off when measuring the "dry" gas at the ambient temperature and pressure.

- 4 Operate by strictly observing the Compensate operation method.
- 5 The standard barometric pressure is 760mmHg, O<sub>2</sub> concentration is about 16%.
- 6 If the ANE AGENT, O<sub>2</sub> COMPENS, BALAN GAS are set incorrectly, the measure readings will deviate from the reality, leads to misdiagnosis.
- 7 The **ZERO CAL** needs about 20 seconds. During this period, you'd better not do other operations, such as respiration measuring. Or the zero calibration will fail, and you should do calibration operation again.
  - **DEFAULT** >>: pick this item to access the **CO<sub>2</sub> DEFAULT CONFIG** dialog box, in which the user may select whether the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.

### 17.4 Alarm Information and Prompt

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on condition that the alarm record switch in the related menu is **ON**.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during CO<sub>2</sub> measurement.

Physiological alarms:

Message	Cause	Alarm Level
EtCO <sub>2</sub> HIGH	EtCO <sub>2</sub> measuring value is above upper alarm limit.	User-selectable
EtCO <sub>2</sub> LOW	EtCO <sub>2</sub> measuring value is below lower alarm limit.	User-selectable
FiCO <sub>2</sub> HIGH	FiCO <sub>2</sub> measuring value is above alarm limits.	User-selectable
AWRR HIGH	AwRR measuring value is above upper alarm limit.	User-selectable
AWRR LOW	AwRR measuring value is below lower alarm limit.	User-selectable
CO <sub>2</sub> APNEA	Within the set apnea time, no RESP can be detected using CO <sub>2</sub> module.	High

#### Technical alarms:

Message	Cause	Alarm Level	What to do
CO <sub>2</sub> COMM STOP	CO <sub>2</sub> module failure or communication failure	High	Stop using CO <sub>2</sub> alarm
CO <sub>2</sub> ZERO REQUIRED	Zero calibration failure	Low	function, notify biomedical engineer or Manufacturer's service
CO2 CHECK ADAPTER	The cannula is off or disconnected	Low	staff.
CO <sub>2</sub> SENSOR TEMP HIGH	CO₂ sensor is over +40°C	High	Stop using measuring function of CO <sub>2</sub> module, notify biomedical engineer.

#### Prompt message:

Message	Cause
CO <sub>2</sub> STANDBY STATUS	Turn from measuring mode to standby mode, making the module in energy-saving status.
CO <sub>2</sub> WARM UP	The CO <sub>2</sub> module is at warm-up state

### 17.5 Maintenance and Cleaning

#### NOTE:

- 1 Before cleaning the module, it should be disconnected from the monitor.
- 2 Do not immerse the module into liquid, or the module will be damaged.

#### Cleaning LoFlo CO<sub>2</sub> Module and C5 CO<sub>2</sub> Module:

- 1. Use a cloth dampened with isopropanol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), and disinfectant spray cleaners such as mild soap
- 2. Wipe down with a clean water-dampened cloth to rinse and dry before use. Make certain that the sensor windows are clean and dry before reuse.

# **Chapter 18 Accessories and Ordering Information**

### **WARNING**

The specification of accessories recommended is listed below. Using other accessories may damage the monitor.

The following accessories are recommended when using this monitor.

SpO <sub>2</sub>	
12.01.110492	SH3 Neonate,resuable,SpO2 Warp Sensor,
12.01.109069	SH1 adult reusable SpO2 Sensor(LEMO)
12.01.109079	SH1 adult reusable SpO2 finger sensor (DB9)
01.13.210001	SpO2 extension cable, DB9 to LEMO, TPU, 2m
12.01.110515	SH4 adult soft-tip SpO2 sensor, TPU
02.01.110531	SH4 adult silicone soft-tip SpO2 sensor
12.01.110521	SH5 SpO2 Silicone Soft-tip Sensor, pediatric
01.57.040196	Adult disposable SpO2 sensor
01.57.040197	Pediatric Disposable SpO2 sensor
01.57.040198	Infant Disposable SpO2 sensor
01.57.040199	Neonatal Disposable SpO2 Sensor
02.01.210119	SH1 SpO2 Finger Sensor, adult, reusable (LEMO)
02.01.210120	SH1 SpO2 Finger Sensor, adult, reusable (DB9)
02.01.210122	SH4 SpO2 Silicone Soft-tip Sensor, adult, TPU, reusable
02.01.210123	SH4 SpO2 Silicone Soft-tip Sensor, adult, reusable
02.01.210121	SH5 SpO2 Silicone Soft-tip Sensor, pediatric, reusable
NIBP	
01.59.036118	NIBP Tube for Adult Pediatric, 3m, Grey
01.57.040210	NIBP Cuff,Adult,33cm-47cm, reusable, CM1304
01.57.040205	NIBP Cuff, Adult, 25cm-35cm, reusable, CM1303
01.57.040211	NIBP Cuff, Pediatric, 18cm-26cm, reusable, CM1302
01.57.040212	NIBP Cuff, Infant, 10cm-19cm, reusable, CM1301
11.57.40097	NIBP Cuff for Neonatal, Disposable, 5.4cm ~9.1 cm
11.57.40098	NIBP Cuff for Neonatal, Disposable, 6.9cm ~ 11.7cm

01.57.471021	NIBP Tube for neonatal cuff, 3m,disposable,Grey
01.57.471157	NIBP Cuff, neonatal #1, 3-6cm, disposable
01.57.471158	NIBP Cuff, neonatal #2, 4-8cm, disposable
01.57.471159	NIBP Cuff, neonatal #3, 6-11cm, disposable
01.57.471160	NIBP Cuff, neonatal #4, 7-13cm, disposable
01.57.471161	NIBP Cuff, neonatal #5, 8-15cm, disposable
ТЕМР	
01.15.040185	Skin Temperature Probe (2.252KΩ)
01.15.040187	Skin Temperature Probe (10KΩ)
01.15.040184	Intracavitary Temperature Probe (2.252KΩ)
01.15.040186	Intracavitary Temperature Probe (10KΩ)
ECG	
01.57.471098	ECG cable, IEC, 3-lead, snap, Defib, TPU
01.57.471099	ECG cable, IEC, 3-lead, clip, Defib, TPU
01.57.471095	ECG cable, AHA, 3-lead, snap, Defib, TPU
01.57.471087	ECG cable, AHA, 3-lead, clip, Defib, TPU
01.57.471089	ECG cable, IEC, 5-lead, snap, Defib, TPU
01.57.471088	ECG cable, IEC, 5-lead, clip, Defib, TPU
01.57.471096	ECG cable, AHA, 5-lead, snap, Defib, TPU
01.57.471097	ECG cable, AHA, 5-lead, clip, Defib, TPU
01.57.471002	ECG cable, IEC, 3-lead, clip, Defib, PVC
01.57.101027	ECG cable, AHA, 5-lead, snap, Defib, PVC
01.57.040206	ECG trunk cable, IEC, 5-lead, Defib, TPU
01.57.040207	ECG limb wires,IEC,5-lead,snap
01.57.040208	ECG limb wires,IEC,5-lead,clip
01.57.471022	ECG trunk cable,5-lead,Defib,AHA
01.57.471023	ECG limb wires,5-lead,snap,AHA
01.57.471024	ECG trunk cable,3-lead,Defib,IEC
01.57.471025	ECG limb cable,3-lead ,clip, IEC
11.57.471060	ECG Electrodes, adult, disposable, 100 pieces
11.57.471056	ECG Electrodes, adult, disposable, 30 pieces

11.57.471057	ECG Electrodes, Pediatric/neo disposable, 50 pieces	
CO <sub>2</sub>		
12.08.078137	Respironics EtCO2 Module/ (Side-stream) 1022054	
12.08.078166	LoFloTM Module Mounting Bracket (Respironics 1027730)	
11.57.078139	Disposable CO2 Nasal Cannula – Adult (Respironics 3468ADU-00)	
11.57.078140	Disposable CO2 Nasal Cannula - Pediatric (Respironics 3468PED-00)	
11.57.078141	Infant Nasal Sampling Cannula, sidestream, 3468INF-00	
11.57.078154	Disposable Sampling Line Kit with Dehumidification Tubing (Respironics 3475-00)	
11.15.040143	Respironics CAPNOSTAT 5 EtCO2 (Main-stream) Module 1015928	
11.59.078155	Disposable Adult Airway Adapter (6063-00)	
11.59.078156	Disposable Neonatal (Infant/Pediatric) Airway Adapter (6312-00)	
11.57.471019	Reuseable Adult/Pediatric Airway Adapter (7007-01)	
11.57.471020	Reuseable Neonate/Infant Airway Adapter (7053-01)	
11.57.078142	Adult Nasal CO2 with O2 delivery sampling cannula(Respironics 3469ADU-00)	
11.57.078143	Pediatric Nasal CO2 with O2 delivery sampling cannula(Respironics 3469PED-00)	
11.57.078144	Infant Nasal CO2 with O2 delivery sampling cannula(Respironics 3469INF-00)	
11.57.101019	Adult Nasal/Oral CO2 sampling cannula(Respironics 3470ADU-00)	
11.57.101020	Pediatric Nasal/Oral CO2 sampling cannula(Respironics 3470PED-00)	
11.57.101021	Adult Nasal/Oral CO2 with O2 delivery sampling cannula(Respironics 3471ADU-00)	
01.12.031598	Adult/Pediatric Airway adapter kit(Respironics 3472ADU-00)	
11.57.078151	Adult/Pediatric Airway adapter kit with dehumidification tubing(Respironics 3473ADU-00)	
11.57.078152	Pediatric/Infant Airway adapter kit with dehumidification tubing(Respironics 3473INF-00)	
11.57.078158	Pediatric Mask /Mainstream 9960PED-00	
11.57.078159	Adult standard mask /mainstream 9960STD-00	
11.57.078160	Adult large mask /mainstream 9960LGE-00	
11.57.078161	Band /Mainstream 8751-00	
11.12.078162	Card Slot /Mainstream 6934-00	
IBP		
01.57.471014	IBP cable	

11.57.40121	Disposable pressure transducer kit (BD DT-4812)
OTHERS	
01.21.064143	Rechargeable Lithium-Ion Battery /TWSLB-003
01.21.064142	Rechargeable Lithium-Ion Battery /TWSLB-002
01.57.78035	Printing Paper
21.13.036384	Power cord(USA),1.8m
11.13.01950	Power cord(3C),3m
01.13.36014	Power Cable(IEC Standard) ,1.8m
03.28.101952	Rolling Stand (MT-207)
11.13.114214	Ground Cable
11.18.078191	USB Flash Disk (2G)
01.18.052268	USB Flash Disk (8G)

# **Chapter 19 Warranty and Service**

### 19.1 Warranty

The manufacturer warrants that the manufacturer's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a)damage caused by mishandling during shipping.
- b) subsequent damage caused by improper use or maintenance.
- c)damage caused by alteration or repair by anyone not authorized by the manufacturer.
- d) damage caused by accidents.
- e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, the manufacturer will, at its discretion, repair or replace the defective part(s) free of charge. the manufacturer will not provide a substitute product for use when the defective product is being repaired.

### 19.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

# **Appendix I Specifications**

### **A1.1 Classification**

Anti-electroshock Type	Class I equipment and internal powered equipment
Anti-electroshock Degree	ECG (RESP), TEMP, IBP CF
	SpO <sub>2</sub> , NIBP, CO <sub>2</sub> BF
Ingress Protection	IPX1
Disinfection/Sterilizing method	Refer to Chapter 12 ~ Chapter 17 for details.
Working System	Continuous operation equipment
Compliant with Standards	IEC 60601-1: 1988+A1: 1991+A2: 1995; EN 60601-1: 1990+A1: 1993+A2: 1995; IEC 60601-1-2: 2001+A1: 2004; EN 60601-1-2: 2001+A1: 2006; IEC/EN 60601-2-27; IEC/EN 60601-2-30; IEC/EN 60601-2-34; IEC/EN 60601-2-49; ISO 9919; ISO 21647; EN 12470-4; EN 1060-1; EN 1060-3; EN 1060-4; ANSI/AAMI EC13; ANSI/AAMI SP10

### **A1.2 Specifications**

### A1.2.1 Size and Weight

Weight	< 5 kg (not including the battery and record)
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### A1.2.2 Environment

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Temperature		
Working	+5°C to +40°C	
Transport and Storage	-20°C to +55°C	
Humidity		

Working	25% to 80% (non-condensing)	
Transport and Storage	25% to 93% (non-condensing)	
Altitude		
Working	860hPa to 1060hPa	
Transport and Storage	700hPa to 1060hPa	
Power Supply	100V to 240V~, 50Hz/60Hz Current: 1.0-0.5A; FUSE T 1.6AL 250VP	

# A1.2.3 Display

Display Screen	10.1 inch /10.4 inch /12.1 inch, multicolour TFT LCD, 10.1-inch: Resolution 800×480; 10.4-inch /12.1-inch: Resolution 800×600.
Messages	A maximum of 11 waveforms
	iM8:
	One charge LED (Orange)
	One power LED (Green)
	One alarm LED (Yellow/Red)
	iM8A/iM8B:
	One charge LED (Orange/ Green)
	One alarm LED (Yellow/Red)
	Three indicator modes corresponding to alarm mode.

# A1.2.4 Battery

	At 25°C, with a new fully charged battery, in continual SpO <sub>2</sub> measuring mode and NIBP automatic measuring mode with the operating interval of 15 minutes; ECG/TEMP module connected; the recording interval of 10 minutes.
Rechargeable Period	2.1Ah ≤180 min 4.2Ah ≤360 min
	Monitor is on or in standby mode.

# A1.2.5 Recorder (Optional)

Record Width	48 mm
Paper Speed	25 mm/s, 50 mm/s
Channels	3
Recording Types	Continuous real-time recording
	8 second real-time recording
	Automatic interval recording
	Physiological alarm recording
	Frozen waveform recording
	Trend graph/table review recording
	NIBP review recording
	Alarm event review recording
	Arrhythmia review recording
	Titration table recording

### A1.2.6 Recall

Trend Recall	1 hrs, 1-second resolution
	96 hrs, 1-min. resolution
Recall	500 sets NIBP measurement data

# **A1.2.7 ECG**

Lead Mode	3-Lead: I, II, III 5-Lead: I, II, III, aVR, aVL, aVF, V	
Waveform	3-Lead: 1-channel waveform 5-Lead: 2-channel waveform, max. seven waveforms;	
Lead naming style	AHA, IEC	
Display Sensitivity	1.25mm/mV (×0.125), 2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2), 40mm/mV (×4), AUTO gain	
Sweep	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s	
Bandwidth (-3dB)	Diagnosis: 0.05Hz to 150Hz  Monitor: 0.5Hz to 40Hz  Surgery: 1Hz to 20Hz	
CMRR (Common Mode Rejection Ratio)	Diagnosis: >95dB (the Notch filter is off)  Monitor: >105dB (the Notch filter is on)  Surgery: >105dB (the Notch filter is on)	
Notch	50Hz/60Hz (Notch filter can be turned on or off manually)	
Differential Input Impedance	>5MΩ	
Input Signal Range	±10mV PP	
Accuracy of Input Signal Reproduction	The total error and frequency response comply with ANSI/AAMI EC13:2002, Sect. 4.2.9.8.	
Electrode Offset Potential Tolerance	±500mV	
Auxiliary Current (Leads off detection)	Active electrode: <100nA Reference electrode: <900nA	

Recovery time after Defibrillation	<5s	
Leakage current of patient	<10μΑ	
Scale signal	1mVPP, accuracy is ±5%	
System noise	<30μVPP (RTI)	
	Restore time: ≤10s	
ESU Protection	Meets the requirements of ANSI/AAMI EC13-2002: Sect. 4.1.2.1 a)	
Noise Suppression of Electrotome	Tested according to the test method in EC13: 2002 Sect.5.2.9.14, it accords with the standard.	
Pace Pulse		
	Pulse is marked if the requirements of ANSI/AAMI	
	EC13:2002, Sect. 4.1.4.1 are met:	
Pulse indicator	Amplitude: $\pm 2 \text{ mV} \sim \pm 700 \text{ mV}$	
	Width: 0.1 ms ~2.0 ms	
	Ascending time: $10 \mu s \sim 100 \mu s$	
	Pulse is rejected if the requirements of ANSI/AAMI EC13-2002: Sect. 4.1.4.1 are met:	
Pulse Rejection	Amplitude: $\pm 2 \text{ mV} \sim \pm 700 \text{ mV}$	
	Width: 0.1 ms ∼2 ms	
	Ascending time: 10 μs ~100 μs	
Minimum input slew rate	>2.5V/S	
Heart rate		
Range	ADU: 15 bpm ~ 300 bpm	
	PED/NEO: 15 bpm ~ 350 bpm	
Accuracy	±1% or 1 bpm, whichever is greater	
Resolution	1 bpm	
Sensibility	≥300 µVPP	
PVC		
Range	ADU: 0~300 PVCs/ min	
	PED/NEO: 0~350 PVCs/ min	
Resolution	1 PVCs/min	
ST value		

Range	$-2.0 \text{ mV} \sim +2.0 \text{ mV}$	
Accuracy	$\pm 0.02$ mV or 10% (-0.8 mV $\sim +0.8$ mV), whichever is greater.	
Resolution	0.01 mV	
HR averaging method		
Method 1	Normally, heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.	
Method 2	If each of three consecutive RR intervals is greater than 1200ms, then the four most recent RR intervals are averaged to compute the HR.	
Range of Sinus and SV Rhythm		
Tachy	ADU: 120 bpm ~ 300 bpm	
	PED/NEO: 160 bpm ~ 350 bpm	
Normal	ADU: 41 bpm ~ 119 bpm	
	PED/NEO: 61 bpm ~159 bpm	
Brady	ADU: 15 bpm ~ 40 bpm	
	PED/NEO: 15 bpm ~ 60 bpm	
Range of Ventricular Rhythm		
Ventricular Tachycardia	The interval of 5 consecutive ventricular wave is less than 600 ms	
Ventricular Rhythm	The interval of 5 consecutive ventricular wave ranges from 600 ms to 1000 ms	
Ventricular Bradycardia	The interval of 5 consecutive ventricular wave is more than 1000 ms	
Maximum Start-up time for Tachycardia		
Ventricular Tachycardia	Gain 1.0: 10 s	
1 mV 206bpm	Gain 0.5: 10 s	
	Gain 2.0: 10 s	
Ventricular Tachycardia	Gain 1.0: 10 s	
2 mV 195bpm	Gain 0.5: 10 s	
	Gain 2.0: 10 s	

Response time of Heart Rate	HR range: 80 bpm	~ 120 bpm		
Meter to Change in HR	Range: $7s \sim 8s$ , av	erage is 7.5s		
	HR range: 80bpm	~ 40bpm		
	Range: $7s \sim 8s$ , av	erage is 7.5s		
Tall T-wave Rejection		AMI EC13-2002 ended 1.2mV T-Wav	Sect. 4.1.2.1 C) e amplitude	
Accuracy of Heart Rate Meter	Complies with AN	SI/AAMI EC13-2002	2 Sect.4.1.2.1 e)	
and Response to Irregular Rhythm	The HR value disp	lays after a stable per	riod of 20s:	
Kilytiiii	Ventricular bigemi	ny: 80bpm±1bpm		
	Slow alternating ve	Slow alternating ventricular bigeminy: 60bpm±1bpm		
	Rapid alternating ventricular bigeminy: 120bpm±1bpm			
	Bidirectional systoles: 91bpm±1bpm			
Arrhythmia analyses	Non-Paced Patient		Paced Patient	
	ASYSTOLE	R on T	ASYSTOLE	
	VFIB/VTAC	PVC	ТАСНҮ	
	COUPLET	TACHY	BRADY	
	VT>2	BRADY	PNC	
	BIGEMINY	MISSED BEATS	PNP	
	TRIGEMINY	IRR		
	VENT	VBRADY		

# **A1.2.8 RESP**

Method	Trans-thoracic impedance: R-F(RA-LL), R-L (RA-LA)
RR measuring range	Adult: 0 to 120 rpm
	Neo/Ped: 0 to 150 rpm
	Resolution: 1 rpm
	Accuracy: ±2 rpm
Gain selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Sweep	6.25mm/s, 12.5mm/s, 25.0mm/s, 50.0mm/s

Measurement lead	Options are lead I and II. The default is lead II.
Calculation Type	Manual /Automatic
Measuring sensitivity	$0.3~\Omega$ (baseline impedance 200 to 4500 $\Omega$ )
Maximum dynamic range	Baseline impedance: $500\Omega$
	Variable impedance: $3\Omega$
	No clipping
Baseline Impedance Range	$200\Omega \sim 2500\Omega$ (no leads cables resistance)
	$2200\Omega \sim 4500\Omega$ (leads cables $1K\Omega$ resistance)
Waveform bandwidth	0.2 to 2.5 Hz (-3 dB)
Apnea Alarm Time	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.

### **A1.2.9 NIBP**

Method	Oscillometric	
Mode	Manual, Auto, Continuous	
Measuring Interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90/120/240/480 min	
Continuous	5min, interval is 5s	
Measuring Type	SYS, DIA, MAP, PR	
Alarm Type	SYS, DIA, MAP	
Measuring Rang		
Adult Mode	SYS: 40 mmHg to 270 mmHg DIA: 10 mmHg to 215 mmHg MAP: 20 mmHg to 235 mmHg	
Pediatric Mode	SYS: 40 mmHg to 200 mmHg DIA: 10 mmHg to 150 mmHg MAP: 20 mmHg to 165 mmHg	

Neonatal Mode	SYS: 40 mmHg to 135 mmHg	
	DIA: 10 mmHg to 100 mmHg	
	MAP: 20 mmHg to 110 mmHg	
Cuff Pressure Measuring Range	0 mmHg to 300 mmHg	
Pressure Resolution	1mmHg	
Maximum Mean Error	±5mmHg	
Maximum Standard Deviation	8mmHg	
Maximum Measuring Period		
Adult/ Pediatric	120s	
Neonatal	90s	
Typical Measuring Period	30s to 45s (depend on HR/motion disturbance)	
Overpressure Protection		
Adult	297±3mmHg	
Pediatric	240±3mmHg	
Neonatal	147±3mmHg	
PR		
Measuring range	40 bpm ~240bpm	
Accuracy	±3bpm or 3.5%, whichever is greater	

# A1.2.10 SpO<sub>2</sub>

Measuring Range	0 % to 100 %
Alarm Range	0 % to 100 %
Resolution	1 %
Data Update Period	1s

Accuracy		
Adult (including Pediatric)	±2% (70% to 100% SpO <sub>2</sub> )	
	Undefined (0% to 69% SpO <sub>2</sub> )	
Neonatal	±3% (70% to 100% SpO <sub>2</sub> )	
	Undefined (0% to 69% SpO <sub>2</sub> )	
Pulse Rate		
Measuring Range	25bpm to 300bpm	
Alarm Range	30bpm to 300bpm	
Resolution	1bpm	
Accuracy	±2bpm	
Sensors		
Wave Length	Red Light: 660±3 nm	
	Infrared Light: 905±5 nm	
Emitted Light Energy	<15 mW	

# **A1.2.11 TEMP**

Channel	2	
Sensor Type	YSI-10K and YSI-2.252K	
Technique	Thermal resistance	
Measuring Range	0 °C to 50 °C	
Resolution	0.1°C	
Accuracy (not including sensor)	±0.1°C	
Refresh Time	Every 1 to 2s	

# A1.2.12 IBP (Optional)

Technique	Direct invasive measurement	
Measuring range		
Art	0 to +300 mmHg	
PA	-6 to +120mmHg	
CVP/RAP/LAP/ICP	-10 to +40 mmHg	
P1/P2	-50 to +300 mmHg	
Resolution	1 mmHg	
Accuracy (not including sensor)	± 2 % or ±1 mmHg, whichever is greater	
Unit	kPa、mmHg	
Zero calibration range	±200 mmHg	
Filter	DC~12.5Hz; DC~40Hz	
Pressure sensor		
Sensitivity	5 (μV/V/mmHg)	
Impedance	$300 \text{ to } 3000 \Omega$	

# A1.2.13 CO<sub>2</sub> (Optional)

Applicable Patient Type	Adult, pediatric and neonatal patients	
Method	Infra-red Absorption Technique	
Unit	mmHg/ %/ kPa	
Measuring Range	EtCO <sub>2</sub>	0 mmHg to 150 mmHg
	FiCO <sub>2</sub>	3 to 50 mmHg
	AwRR	2 to 150 rpm (Sidestream) 0 to 150 rpm (Mainstream)
Resolution	EtCO <sub>2</sub>	1 mmHg
	FiCO <sub>2</sub>	1mmHg
	AwRR	1rpm
Measuring Accuracy		

EtCO <sub>2</sub>	±2 mmHg, 0 mmHg to 40 mmHg	
	Reading ±5%, 41 mmHg to 70 mmHg	
	Reading ±8%, 71 mmHg to 100 mmHg	
	Reading ±10%, 101 mmHg to 150 mmHg	
	Reading ±12%, RR is over 80 rpm (Sidestream)	
AwRR	± 1 rpm	
Sample Gas Flow Rate (Sidestream)	50±10 ml /min	
O <sub>2</sub> Compensation		
Range	0 to 100%	
Resolution	1%	
Default	16%	
Anesthetic Gas Compensation		
Range	0 to 20%	
Resolution	0.1%	
Default	0.0%	
Balance Gas Compensation	Options: N <sub>2</sub> O, helium, room air	
Barometric pressure compensation	User setup	
Operation Mode	Measure, standby	
Stability		
Short Term Drift	< 0.8 mmHg over 4 hours	
Long Term Drift	Accuracy specification will be maintained over 120 hours period	

Initialization time	It displays the value within 15s and meets the requirement for measurement accuracy within 2min. (Mainstream)  It displays the value within 20s and meets the requirement for measurement accuracy within 2min. (Sidestream)
Response time	60ms (Mainstream)
Calibration	Not required.
Alarm	EtCO <sub>2</sub> , FiCO <sub>2</sub> and AwRR alarm
Apnea Alarm Delay	10, 15, 20, 25, 30, 35, 40s; 20s by default

### Interfering Gas and Vapor Effect on EtCO<sub>2</sub> Measurement Values:

Gas or vapor	Gas level (%)	Quantitative effect/Comments
Nitrous oxide	60	Dry and Saturated Gas
Halothane	4	0 – 40 mmHg: ± 1 mmHg additional error
Enflurane	5	$41 - 70$ mmHg: $\pm 2.5\%$ additional error
Isoflurane	5	71 – 100 mmHg: ± 4% additional error
Sevoflurane	5	101 − 150 mmHg: ± 5% additional error
Xenon	80	*Additional worst case error when compensation
Helium	50	for P <sub>B</sub> , O <sub>2</sub> , N <sub>2</sub> O, anesthetic agents, or helium is correctly selected for the actual fractional gas
Desflurane	15	constituents present.
		Desflurane:
		The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38mmHg.
		Xenon:
		The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38mmHg.

### Barometric Pressure on EtCO<sub>2</sub> Measurement Values:

Quantitative effect
Ambient Barometric, Operational

. .

 $0-40 \ mmHg : \pm 1 \ mmHg \ additional \ error$ 

 $41 - 70 \text{ mmHg:} \pm 2.5\%$  additional error

 $71 - 100 \text{ mmHg:} \pm 4\% \text{ additional error}$ 

 $101 - 150 \text{ mmHg:} \pm 5\% \text{ additional error}$ 

\*Additional worst case error when compensation for  $P_B,\,O_2,\,N_2O$ , anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.

# **Appendix II EMC Information**

### - Guidance and Manufacture's Declaration

# A2.1 Electromagnetic Emissions - for all EQUIPMENT and SYSTEMS

### Guidance and manufacture's declaration - electromagnetic emission

The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The monitor is suitable for use in all establishments, other than domestic
Harmonic emissions IEC/EN 61000-3-2	Class A	establishments and those directly connected the public low-voltage power supply network that supplies buildings used for domes
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	purposes.

# A2.2 Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS

#### Guidance and manufacture's declaration – electromagnetic immunity

The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.

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

Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines ±1 kV for input /output signal	±2kV for power supply lines ±1 kV for input /output signal	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC/EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle  40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles  70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles  <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> )	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle  40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles  70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles  <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> )	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Patient Monitor requires continued operation during power mains interruptions, it is recommended that the Patient Monitor be powered from an uninterruptible power supply or a battery.
	for 5 sec	for 5 sec	

 $\label{eq:NOTE} \textbf{NOTE} \qquad U_T \text{ is the a.c. mains voltage prior to application of the test level.}$ 

# **A2.3 Electromagnetic Immunity - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

### Guidance and manufacture's declaration – electromagnetic immunity

The Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Patient Monitor should assure that it is used in such an environment.

T •	TECHENICOCOL :	G "	T1 4
Immunity	IEC/EN 60601 test	Compliance	Electromagnetic environment -
test	level	level	guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	$3 V_{rms}$	$3 V_{rms}$	Recommended separation distance
IEC/EN 61000-4-6	150 kHz to 80 MHz	11115	$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$
Radiated RF	3 V/m	3 V/m	$d = \left[\frac{3.5}{E_1}\right] \sqrt{P} $ 80 MHz to 800 MHz
IEC/EN 61000-4-3	80 MHz to 2.5 GHz		$d = \left[\frac{7}{E_1}\right] \sqrt{P}  800 \text{ MHz to } 2.5 \text{ GHz}$
			Where P is the maximum output
			power rating of the transmitter in
			watts (W) according to the
			transmitter manufacturer and d is the
			recommended separation distance in metres (m).
			Field strengths from fixed RF
			transmitters, as determined by an
			electromagnetic site survey, a should
			be less than the compliance level in
			each frequency range. <sup>b</sup>
			Interference may occur in the vicinity of equipment marked with
			the following symbol:
			((·•))

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

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

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Patient Monitor is used exceeds the applicable RF compliance level above, the Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Patient Monitor.
- Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

### **A2.4 Recommended Separation Distances**

# Recommended separation distances between portable and mobile RF communications equipment and the monitor

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

Rated maximum	Separation distanc	e according to frequenc	y of transmitter(m)
output power of	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
transmitter	$[3.5]_{\overline{D}}$	$d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	$\begin{bmatrix} & & & & & & & & & & & & & & & & & & &$
( <b>W</b> )	$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	$a = \left[\frac{1}{E_1}\right]^{\sqrt{P}}$	$d = \left[\frac{7}{E_1}\right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.36	0.37	0.74
1	1.16	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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

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

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

# **Appendix III Default Settings**

This appendix documents the most important default settings of your monitor as it is delivered from the factory.

#### NOTE:

If your monitor has been ordered preconfigured to your requirements, the settings at delivery will be different from those listed here.

### **A3.1 Patient Information Default Settings**

Patient Information Setting	SS .
Patient Type	Adult
Pace	Off

## A3.2 Alarm Default Settings

Alarm Settings	
Pause Time	120s
Alarm Mute	On
Sensor off Alarm	On
Alarm Latch	Off

# **A3.3 ECG Default Settings**

ECG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
Pace	Off		
Lead Type	5 Leads		
Display	Normal		
Filter	Diagnostic		
Smart Lead Off	Off		
Heart Volume	2		

ST Analysis	ADU	PED	NEO		
ST Analysis	Off				
Alarm Switch	Off	Off			
Alarm Level	Medium				
Alarm Record	Off				
Alarm High Limit (ST-X)	0.2	).2			
Alarm Low Limit (ST-X)	0.2				
X stands for I, II, II	I, aVR, aVL, aVF, V,	V1, V2, V3, V4, V5 or V6			
ARR Analysis					
ARR Analysis	Off				
PVCs Alarm Level	Medium				
PVCs Alarm Switch	Off				
PVCs Alarm Record	Off				
ARR Alarm Settings	S Alarm Switch	Alarm Level	Alarm Record		
ASYSTOLE	On	High	Off		
VFIB/VTAC	On	High	Off		
R ON T	On	Medium	Off		
VT > 2	On	Medium	Off		
COUPLET	On	Medium	Off		
PVC	On	Medium	Off		
BIGEMINY	On	Medium	Off		
TRIGEMINY	On	Medium	Off		
TACHY	On	Medium	Off		
BRADY	On	Medium	Off		
MISSEDBEATS	On	Medium	Off		
IRR	On	Medium	Off		
PNC	On	Medium	Off		
PNP	On	Medium	Off		
}		3.6.1	Off		
VBRADY	On	Medium	Oli		

### **A3.4 RESP**

RESP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	30	30	100
Alarm Low Limit	8	8	30
Apnea Time	20s		
Calculation Type	Auto		
Resp Type	II		
Sweep	12.5mm/s		
Amplitude	2		

# A3.5 SpO<sub>2</sub>

SpO <sub>2</sub> Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	100	100	95
Alarm Low Limit	90	90	88
Pitch Tone	Off		
Sweep	12.5mm/s		

# A3.6 PR

PR Settings	ADU	PED	NEO	
PR Source	$SpO_2$	$\overline{\mathrm{SpO}_2}$		
Alarm Switch	On			
Alarm Record	Off			
Alarm Level	Medium			
Alarm High Limit	120	160	200	
Alarm Low Limit	50	75	100	
Pulse Volume	3			

	Alarm Source	HR			
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### **A3.7 NIBP**

NIBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (SYS)	160	120	90
Alarm Low Limit (SYS)	90	70	40
Alarm High Limit (Map)	110	90	70
Alarm Low Limit (Map)	60	50	25
Alarm High Limit (Dia)	90	70	60
Alarm Low Limit (Dia)	50	40	20
Inflation value	160	140	100
Unit	mmHg	•	
Interval	Manual		

### **A3.8 TEMP**

TEMP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (T1)	39.0	39.0	39.0
Alarm Low Limit (T1)	36.0	36.0	36.0
Alarm High Limit (T2)	39.0	39.0	39.0
Alarm Low Limit (T2)	36.0	36.0	36.0
Alarm High Limit (TD)	2.0	2.0	2.0
Unit	$\mathbb{C}$		

# **A3.9 IBP**

IBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Unit	mmHg		
Filter	12.5Hz		
	SYS, DIA, MAP	SYS, DIA, MAP	SYS, DIA, MAP
Alarm High Limit (ART, P1, P2)	160, 90, 110	120, 70, 90	90, 60, 70
Alarm Low Limit (ART, P1, P2)	90, 50, 70	70, 40, 50	55, 20, 35
Alarm High Limit (PA)	35, 16, 20	60, 4, 26	60, 4, 26
Alarm Low Limit (PA)	10, 0, 0	24, -4, 12	24, -4, 12
	MAP	MAP	MAP
Alarm High Limit (CVP, RAP, LAP, ICP)	10	4	4
Alarm Low Limit (CVP, RAP, LAP, ICP)	0	0	0

# A3.10 CO<sub>2</sub>

CO2 Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Standby		
Unit	mmHg		
Apnea Time	20s		
O <sub>2</sub> Compensate	16%		
Anes Agent	0%		
Alarm High Limit (EtCO <sub>2</sub> )	50	50	45
Alarm Low Limit (EtCO <sub>2</sub> )	15	20	30

Alarm High Limit (FiCO <sub>2</sub> )	4	4	4
Alarm High Limit (AWRR)	30	30	100
Alarm Low Limit (AWRR)	8	8	30
Sweep	12.5mm/s		
Amplitude	Low		



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