promedic

by COMEN


Model: **C60**

SPECIALIZED NEONATAL MONITOR

# EN Instruction Manual

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## Statements

Our company makes no warranty of any kind with regard to this material, including, but not limited to the implied warranties of merchantability and fitness for a particular purpose. Our company assumes no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material.



## Responsibility of the Manufacturer

Our company only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by personnel authorized by our company, and the electrical installation of the relevant room complies with safety standards, and the instrument is used in accordance with the instructions for use.

⚠**Note**: This device is not intended for home use.

⚠**WARNING**⚠:This device is not intended for treatment.

⚠**WARNING**⚠

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

⚠**Note**

A NOTE label provides useful information about a function or procedure.

# Contents

# Revision history

The table below shows major changes and additions in each revision of this manual.

| No. | Edition | Date | Description |
|---|---|---|---|
| 1 | A | 2012/10 | See edition A of this document |
| 2 | B | 2014/10 | Changed the EC representative and its address as “Lotus Medical Equipment Limited; Add: 26B Cameron Court, Cork Street, Dublin 8,Ireland; Tel: +00353-1-6571034; Email: peter@lotusme.org” |

# Chapter 1 General Information

For information about the monitor, please read the General Information on the Monitor chapter.

For introduction on various information displayed on screen, please read the Screen Display chapter.

For operational methods, please read the Button Functions and Basic Operations chapter.

For locations of various interfaces, please read the External Interfaces chapter.

For notices of using the monitor with power supply from a battery, please read the Built-in Chargeable Battery chapter.

**Warning**

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

**Warning**

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

**Warning**

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

**Warning**

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

**Warning**

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

**Warning**

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

**Warning**

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

**Warning**

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

**Warning**

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

## 1.1 General Information

The portable multi-parameter monitor is of rich functions, applicable for bedside monitoring on adults, infants and newborns.

This monitor can monitor main parameters including ECG, RESP, $SpO_2$, NIBP and TEMP. It integrates parameter measurement modules, display and record output to build such a solid and light monitor. Its replaceable built-in battery makes convenience for patient movement and it will clearly display 7 waveforms and all the monitoring parameter information on the high-resolution interface.

**'Attention**

**IBP and $CO_2$ are optional.**

From left to right they are in turn:

(1) ALARM INDICATOR; (2) Charging INDICATOR; (3) Working INDICATOR; (4) ON/OFF button; (5) SILENCE button; (6) FREEZE button; (7) PRINT button; (8) START button (for blood pressure); (9) MAIN button (for key frame return); (10)Knob; (11) MENU; (12) Parameter area; (13) Waveform area; (14) Information area. The Knob has three working methods as turning left, turning right and pressing to confirm parameters are mainly applied to the operation of menu.

The outlet of the recorder is located on the left side of monitor and AC power line sockets are on the rear panel of the monitor.

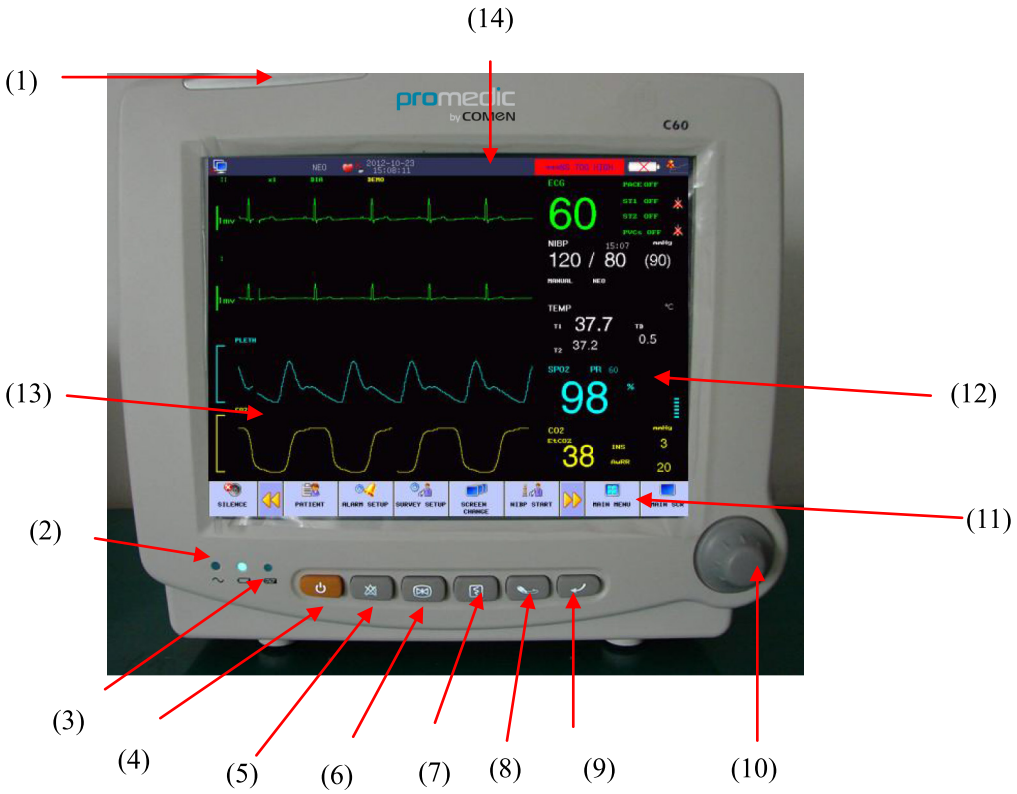



Figure 1-1Multi-parameter Monitor

This monitor has rich functions, able to provide various functions such as visual/audio alarming, TREND storage & output, NIBP measurement save and review, medicine calculation, ST analysis, pulse analysis, heart rate turbulence analysis, etc.

This monitor has a friendly operation interface, able to provide all functions with the keys and buttons on the front panel, refer to Function Keys part for details.

## 1.2 Button Functions and Basic Operations

The monitor can be operated through use of the buttons and knobs. Here are the functions of the buttons as follows:

| | |
|---|---|
| | (SILENCE button): Press this button and the alarm will be silencefor 3 minutes (this item can be set in the “Alarm Setting” menu). Press this button over 1 second and the alarm sound can be shielded. In the information area appears sign. Repress this button again to pause alarm, resume heart beat sound and cancel some technical alarm (ECG off, $SPO_2$ off), and the sign disappears. |
| | (FREEZE button): Press this button and all waveforms on the screen can be frozen in the normal mode. Press this button once again and the frozen waveforms can be freed. |
| | (PRINT button): Press this button to start a real-time recording. The recording length is determined according to the “real-time recording time” in the “Recorder” submenu of “Setting” menu. Press this button once again in the |

| | |
|---|---|
| | recording process and the recording will stop at once. Each interval of pressing this button should be greater than 2 seconds and the frequency should not be excessively high. |
|  | （To start/stop NIBP measurement）, press to inflate the cuff to start a blood pressure measurement. When measuring, press to stop the measurement and deflate the cuff. |
|  | (MENU button): Press this button to have the main menu pop up when the interface is in the state of non-window setting. |
|  | (ON/OFF button): Press this button to control the startup and shutdown of the monitor. |
|  | a.c. INDICATOR |
|  | Work INDICATOR |
| JOG-DIAL | JOG-DIAL to select and change the settings. Operation can be performed by turning it clockwise, counterclockwise or pressing it down. JOG-DIAL is mainly used in menu and window operation |

## 1.3 Screen display

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

The main screen is divided into 4 sub-areas, i.e., Information Area ①, Waveform Area ②, Parameter Area ③ and Menu Area④ (As shown in Figure 0-2)

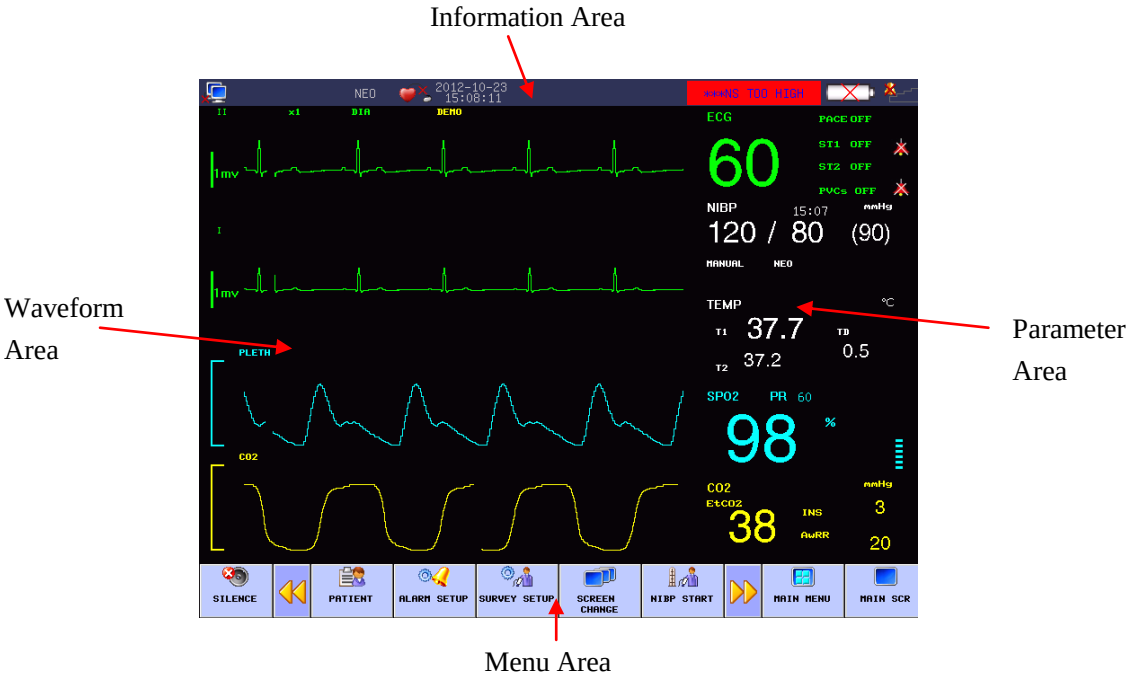


Figure1-2Main screen display

## Information Area (①):

Prompt message in the information area appears and disappears together with the reported state. In accordance with the content, it is divided into:

- Network setup: Cursor stops in sign, press to enter system setup.
- Network Bed No.: refer to IP address for monitor, The IP is 200.200.200.X,（X is Network Bed No.:, from 1 to 100）

### 'attention'

**Connection state of CMS (central monitoring system) : when displaying , no connection; when displaying ,connection.**

**Network Bed No. should not conflict with other monitors, or there will be unnecessary problems for the monitor.**

If any problem happens because of confliction, unplug network wire, restart the monitor, reset the Network Bed No. and connect the network wire again.

1. Patient Information: press to enter the Patient Information menu when cursor is in bed No., name or patient group area.
   - PAT NO: can input four character.
   - Bed No.: Refer to the bed number of the patient being monitored, this area will be blank if there is no input.
   - Name: Patient name, this area will be blank if there is no input.
   - Sex: Male and Female.
   - Patient Type: neonatal, pediatric, adult
   - Pacer: pacer state, pacer detected displaying , otherwise displaying
   - Height(cm): patient's height
   - Weight(kg): patient's weight
   - Blood： A,B,O,AB,unkown
   - DEPT.(department): According to the department's name pop-up keypad input, support English, spelling, handwriting input function.
   - Doctor : According to the department's name pop-up keypad input, support English, spelling, handwriting input function.
   - Update patient : current patient information, it will be deleted if the update patient.
2. Time setup: set up local time

time: display system time

3. Technical alarm: display technical alarm, such as ECG lead off.

4. Physical alarm: display physical alarm, such as T2 too low.

5. Battery: display capacity of batter.

 Full capacity
 Not full capacity
 Low capacity
 Very low capacity, need to charge soon.

6. Volume setup: setup alarm volume, heart beat volume, key volume.

- Alarm volume: there are five Alarm Vol levels, 1, 2, 3, 4 and OFF, where "OFF" level means the alarm sound is closed.

 Alarm volume on, alarm level 4
 Alarm volume off

- Beat volume: here are five Alarm Vol levels, 1, 2, 3, 4 and OFF.
- Key volume: here are five Alarm Vol levels, 1, 2, 3, 4 and OFF
- Touch sound: on, off. When open touch sound, click on the screen, will issue a point in the sound of the screen, when close touch sound, no voice prompts

**'Attention'**

Visual alarm and alarm status

Alarm light winks or shines when there is an alarm. The colour of light means the alarm level. Refer to alarm function chapter for details.

## Waveform Area (②)

**There are four waveforms in the waveform area, which are respectively from up to down: two-channel ECG waveform, SpO2 volume graphic waveform and respiratory waveform (possibly from ECG module).**

The name of selected waveform is displayed on the upper left part. For details, please refer to chapter of ECG Monitoring. Each ECG waveform still shows the gain of this channel and the filtering method of ECG waveform. A 1-mv rod is on the leftof ECG waveform.

When you choose/toucheach waveform, submenu of waveform will be pop up, which always occupies most of space of waveform area, so that some waveforms are invisible. The original image will come back after the menu exit.

Waveforms are refreshed at the set speed. For adjustment on waveform refresh speed, refer to the chapter of each Parameter Setting.

## Parameter Area(③):

Parameters can display at the fixed position (as shown in ①~⑫ of the following picture), which are separately:

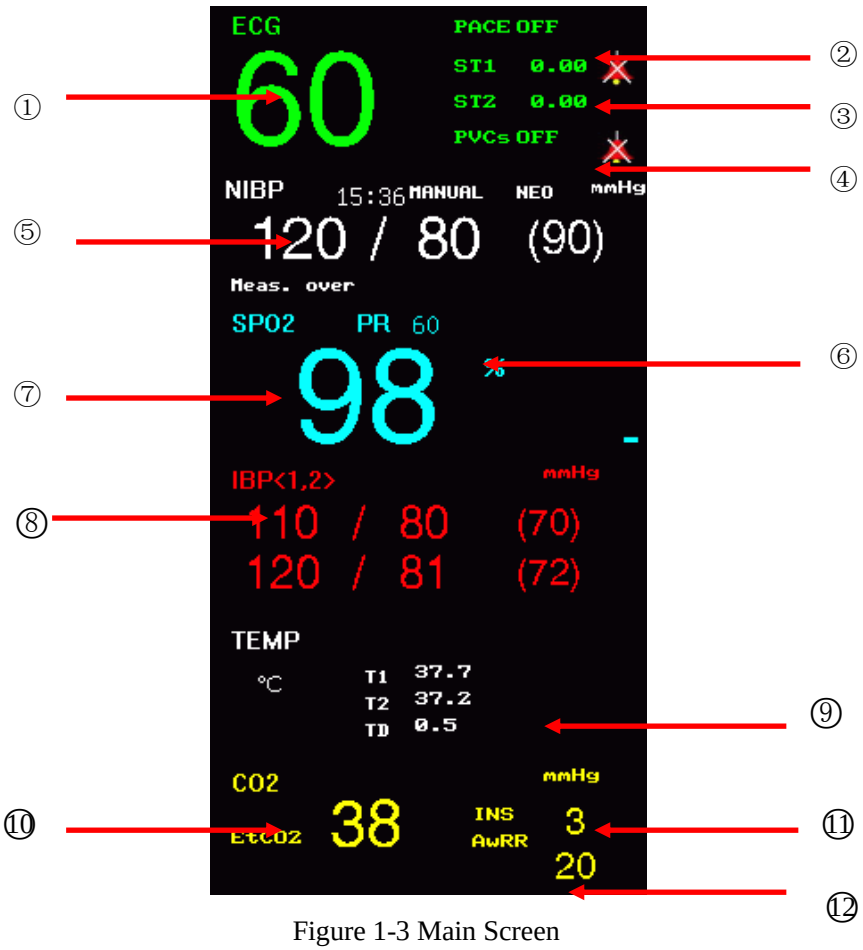



Figure 1-3 Main Screen

ECG

—Heart Rate or Pulse Rate（①,unit：bpm）

—pacer detection (②PACE)

—ST-segment of channel 1 and channel 2 (③, unit: mv)

— PVCs times (④ Unit: times/minute)

NIBP

— None-Invisive Blood Pressure

(From left to right) Systolic, Diastolic, Mean (⑤, Unit: mmHg or kPa)

SpO2

—SpO2（⑥,unit：%）

—Pulse Rate（⑦unit：bpm）

IBP (optional)

— Invisive Blood Pressure

(From left to right) Systolic, Diastolic, Mean (⑧, Unit: mmHg or kPa)

TEMP

—TEMP

—Temperature（⑨,unit: ℃ or℉）

CO2 (optional)

—end-tidal CO2 (⑩, Unit: mmHg or kPa)

—inspiratory CO2 (⑪, Unit: mmHg or kPa)

—Air Way Respiration Rate (AWRR)（⑫,unit：bpm）

RESP
—Respiration Rate（,unit：bpm）

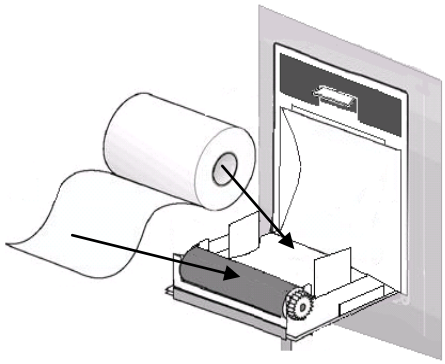
The above monitored results will show in the parameter area.
The parameters are refreshed once per second, but NIBP value, once per measurement.
Users can select the monitoring parameters and the main screen will display the relative content.

## Menu Area(4)

1. PATIENT: patient information configuration. Refer to chapter of Patient Informatio for details.
2. ALARM SETUP: set up alarm type
   - ALARM RECORD TIME: in case of physiological alarm, the system can record the information before and after the alarm time. The system can give three kinds of time, i.e., 8 seconds, 16 seconds. The seconds in the options are the sum of seconds before and after the alarm time. For example, 8 seconds mean the information within 4 seconds before the alarm time and within 4 seconds after such a time.
   - ALM PAUSE TIME (Alarm pause time):“1 minute”, “2 minutes” or “3 minutes”
   - ALAM LIMIT (Display alarm limits):”ON” and”OFF”
   - ALM LATER:disabled ,5s,10s,15s ,20s.
3. SURVEY SETUP: ECG, RESP, $SpO_2$, NIBP and TEMP setup, refer to each chapter for details
4. SCREEN CHANGE: STANDARD, LIST FACE, TREND SCREEN, oxyCRG SCREEN, BIG FONT.For details,please refer to chapters for each parameter.
5. NIBPSTARTt: press this button to start/stop NIBP measurement.
6. FREEZEN: the screen freezes when press this button, turn the knob to review all the waveform stored for the last 4 minutes.
7. TREND GRAPH ,TREND TABLE, NIBP RECALL: refer to chapter 3 for details.
8. PRINT: press this button to record waveforms and patient information.

## 1.4 External Socket

**Left Panel**
Recorder is optional
Open the recorder door.
Take away the no-paper rod
Fix the new paper correctly, tip of paper out from the head of printer.
3mmpaper must out of recorder door, close the door.



Press PRINT to check if the paper fixed well or not.
If no printing, prease re-fix the paper.

Figure1-4 recorder

**Right Panel**

On the right side of the monitor are sockets for each transducer

①TEMP1
②TEMP2
③SPO2
④ECG
⑤NIBP
⑥O2（optional）
⑦CO2/AG(optional)
⑧WAKE(optional)

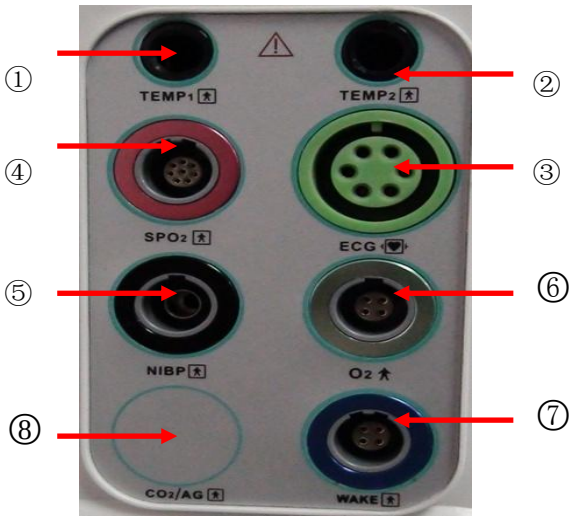



Figure 1-5Right Side

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

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

Other symbols will be introduced in the **Patient Safety** chapter.

symbol means: BF type

means the equipotential grounding terminal.

A.C. indicator

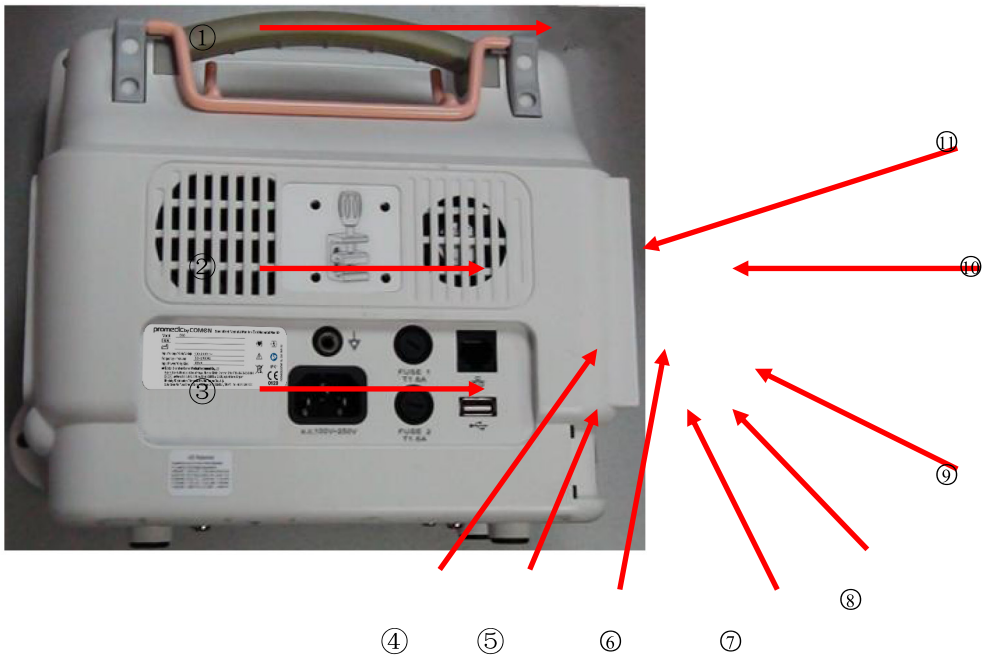
work indicator

ower-up

down

**Rear Panel**

There are the following soclets in the rear panel:




1. Handle 2. Speaker 3.Label 4.Earth line socket 5. AC power socket 6. Fuse holder 1
7. Fuse holder 2 8.SD card socket 9. Networksocket10.Fan 11.Place for clamp or hook

**⚠Warning⚠**

This network port can only be connected with CARL NOVEL's central monitoring system.

**⚠Warning⚠**

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

**⚠Attention⚠**

**Patient cable interface, network interface and other interfaces connected to different equipments, the leakage current should not exceed the limit.**

## 1.5 Built-in charge battery

The multi-parameter monitor has a built-in charge battery. When connected with AC power, the battery will charge automatically until it is full. On the right side of the screen, there is a "▬", it means charging state. Its yellow part means the quantity of the battery. If this monitor has no built-in battery, the battery state will display "▭", it means no battery or defective battery.

# Chapter 2 Monitor Assembly

**′Attention′**

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

## 2.1 Open Package and Check

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

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

Any problems should be immediately raised to the Sales Department of our Company or our agents.

## 2.2 Connect with AC Cable

Procedures to connect with AC power cables:

Make sure the AC supply complies with the following specification: 100-250VAC，50/60Hz
Use the power cables provided with the monitor together. Plug in the power cable into power supply interface of the monitor, while insert the other end of this cable to a 3-phase earthing power socket.

**′Attention′**

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

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

**′Attention′**

**In case configured with a battery, the equipment after transport or storage must have the battery taken for charging. Thus in case of direct booting without connection with AC power supply, the equipment may not work properly due to insufficient power. With AC power supply connected, the battery will be charged no matter the monitor is booted or not.**

## 2.3 Power on

The logo displays when the power is on, and appears the processing screen. After the 3~5 seconds checking process, the system enters the monitoring main screen and the users can start operations.

**′Attention′**

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

′Attention′

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

′Attention′

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

′Attention′

**If any monitoring functions are found with damage or there are any error reminders, don't use this monitor to monitor patients and quickly contact with the biomedical engineers of your hospital or maintenance engineers of our Company**

′Attention′

**Reboot the equipment at least 1 minute after shut down.**

## 2.4 Connect with Sensor

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

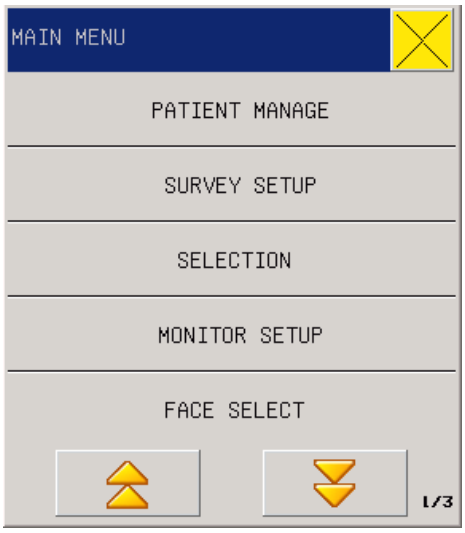
> **′Attention′**
> **For correct connection methods and relevant requirements of various sensors, please refer to Chapters 10-15.**

## 2.5 Check Recorder

If there is recorder in monitor, check the paper. If there is no paper, see reference related in chapter 1.

# Chapter 3 Syetem Menu

The monitor system setting is more flexible. Monitoring, waveform speed, volume and output, all can be setup by user. Press the "↵" button or use turn-knob to choose main menu, popping up MAIN MENU.




MAIN MENU including: PATIENT MANAGE, SURVEY SETUP, SELECTION, MONITOR SETUP, FACE SELECT, TREND GRAPH, TREND TABLE, NIBP RECALL, ASPHYXIA STIMULATE REVIEW, ALM RECALL ,WAVE RECALL ,INFO, DRUG CALC, MAINTAIN,DEMO.

## 3.1 PATIENT MANAGE

**Attention′**

**For deleting the patient's current data, please refer to the "NEW PATIENT" in this chapter.**

Select the "PATIENT MANAGE" item under the system menu, and then pop up the following menu:

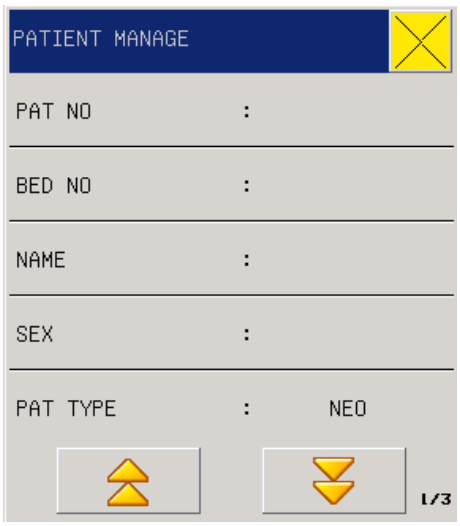



Figure 3-1 Patient Manage

Users can set the following content:

1. PAT NO can input four character
2. Bed NO.0-999 for option, for example, 666
3. Nameinput patient name to the popping up menu

| Lock | Shift | Del | Clr | Enter |
|---|---|---|---|---|
| Caps Lock（permanent） | Caps shift（one-off） | delete | clear | enter |

4. SEXPatient gender( female, male)
5. PAT TYPEPATIENT TYPE(Neonate)
6. PACEPackmaker ON/OFF
7. Height(cm)0~300, for example, 180
8. Weight(kg)0~200, for example, 100
9. Blood： A,B,O,AB,unkown
10. DEPT.(department): According to the department's name pop-up keypad input, support English, spelling, handwriting input function.
11. Doctor : According to the department's name pop-up keypad input, support English, spelling, handwriting input function.
12. Update patient : current patient information, it will be deleted if the update patient.

**Attention′**

**PACE: The default setting is OFF after you restart the monitor.**

In this menu, user can select the “UPDATE PATIENT” and select “CONFIRM TO UPDATE PATIENT” to update patient information.

**⚠Warning⚠**

**Patient type changed, the alarm parameters such as heart beat and NBP may vary, usually make sure the limits are suitable for the patient.**

**Pacer detection must be on for pacing patients. If falsely setting OFF, the monitor would miktake pacing pulse as QRS, and not alarm for heatbeat stop**

## 3.2 SURVEY SETUP

In the main menu, select SURVEY SETUP , Measurement settings include: ECG SETUP, SPO2 SETUP, NIBP SETUP, TEMP SETUP, RESP SETUP , CO2 SETUP (RESP SETUP and CO2 SETUP both can appear only one of them), IBP <1,2>SETUP the parameters set in this menu parameters chapters details in the description of this ignored the pop-up menu ,as shown below:

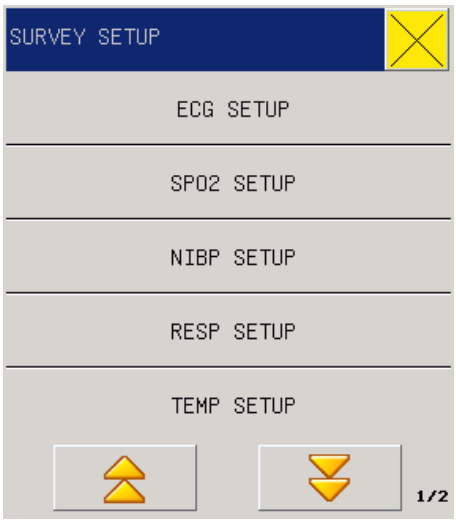



Figure3-2Survey Setup

## 3.3 SELECTION

Select the “SELECTION SETUP” in the “MENU MENU” and sub-menu following with Figure below, including

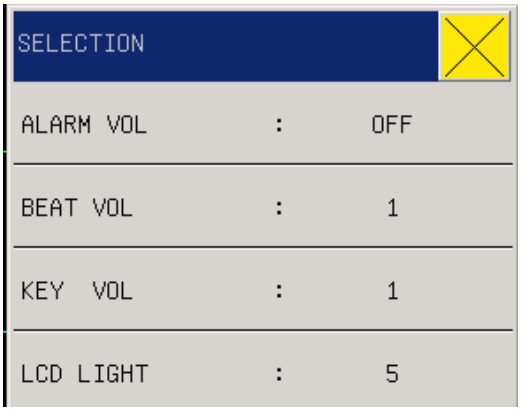



Figure3-3Selection Setup

### 3.3.1 ALARM Volume

In the system there are five levels of Alarm Vol: OFF, 1~4.

"OFF" level means the alarm sound is closed.

**⚠WARINING⚠**

**Where the alarm volume of the system is set at OFF, the monitor will not give alarm sound in case of alarm, so you should use this function carefully.**

### 3.3.2 HEART BEAT VOLUME

In the “SYSTEM MENU” select the “SELECTION”. Pitch on the “BEAT VOL ” with the cursor and turn the knob to select the volume from such five options as “OFF”, “1”,“2”、“3” and “4”.

### 3.3.3 KEY VOL (Keyboard Vol )

Pitch on the “KEY VOL ” with the cursor and select the volume from such five options as “OFF”, “1”,“2”、“3” and “4”.

### 3.3.4 LCD Brightness (LCD LIGHT)

In the system there are five Brightness level, i.e. “1~5”, where “5” means the maximum brightness.

## 3.4 MONITOR SETUP (Monitor Setting)

Select MONITOR SETUP in MAIN MENU, sub-menu following with figure below, including

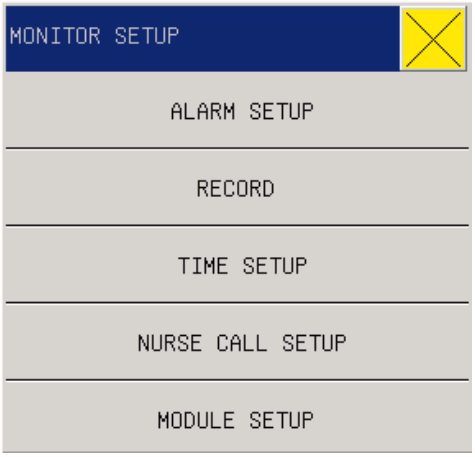



Figure3-4 Monitor Setup

### 3.4.1 ALARM SETUP (Alarm Setting)

Alarm Setup has the following options:

ALM REC TIME (Alarm Record Time):

In case of physiological alarm, the system can record the information before and after the alarm time. The system can give three kinds of time, i.e., 4 seconds, 8 seconds, 16 seconds. The seconds in the options are the sum of seconds before and after the alarm time. For example, 8 seconds mean the information within 4 seconds before the alarm time and within 4 seconds after such a time.

ALM PAUSE TIME (Alarm pause time)：“1 minute”, “2 minutes” or “3 minutes”

ALM LIMIT (Display alarm limits)：”ON” and”OFF”

ALM LATER:disabled ,5s,10s,15s ,20s

### 3.4.2 RECORD (Record output setting)

Options for record output:

- REC WAVE1/ REC WAVE2: can not change
- REC RATE: 25.0/50.0 mm/s, record speed
- REC GRID: ON/OFF
- RT REC TIME: 3S/5S/8S/CONTINUAL (real-time record time)

CONTINUAL means after pressing PRINT BUTTON  , monitor will keep printing parameters and waveform, until press  to stop

**″Attention′**
**The recorder is a component for option.**
**′Attention′**
**Where two similar waveforms are selected, the system will automatically adjust the other one into a different one.**

### 3.4.3 TIME SETUP (System Time Setting)

"TIME SETUP" with options below:
Setup year, month, day, hours, minutes and seconds.
Pitch on the content required for correction.

### 3.4.4 NURSE CALL SETUP

Options in nurse call setting:
Alarm on/off:on/off
Alarm level: high, middle, low

### 3.4.5 MODULE SETUP

Options in module setup:

- ECG and $SpO_2$ are not optional.
- TEMP: ON/OFF. When it is ON, machinecan monitor TEMP, when it is OFF, machine can not monitor TEMP, and no parameter area of TEMP in main interface.
- RESP: ON/OFF. When it is ON, machinecan monitorRESP, when it is OFF, machine can not monitor REST, and no parameter area of RESP in main interface.
- NIBP: ON/OFF. When it is ON, machinecan monitor NIBP, when it is OFF, machine can not monitor NIBP, and no parameter area of NIBP in main interface.
- CO2(optional): ON/OFF. When it is ON, machinecan monitor CO2, when it is OFF, machine can not monitor CO2, and no parameter area of CO2 in main interface
- IBP(optional): ON/OFF. When it is ON, machinecan monitor IBP, when it is OFF, machine can not monitor IBP, and no parameter area of IBP in main interface

## 3.5 WORK INTERFACE SELECTION

In the System Menu, select the “FACE SELECT” to enter the dialog box in the following Figure. Here there are such six options as “STANDARD”, “LIST FACE” “TREND SCREEN”, “oxyCRG SCREEN” , “BIG FONT” .


Figure3-5Work Interface

## 3.6 TREND SCREEN

Trend gragh for the previous 1 hour can be diplayed in the resolution of one data per one second or one data per five seconds.

Trend gragh for the previous 120 hour can be diplayed in the resolution of one data per minute, per five minutes or per ten minutes.

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

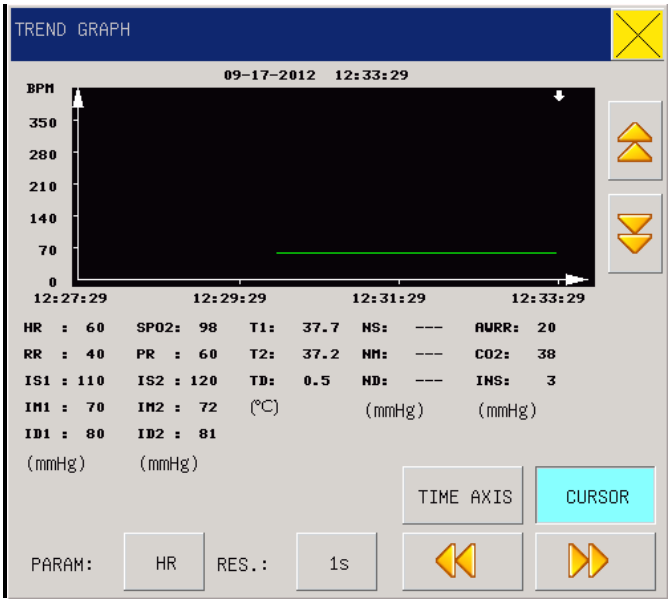



Figure3-6Trend Graph

Parameter selection: HR、RR、$SPO_2$、PR、TEMP、NIBP、IBP1、IBP2、$CO_2$、INS、AwRR.Y-axis means measurement value, X-axis means measurement time. "↓" is cursor for trend graph, The measurement values it points to display at the bottome of the graph, corresponding time at the upper end of the graph: 2012-07-1712：33：29.

Vertical axis is for measured values and horizontal axis for measurement time. The "↓" symbol is the cursor for TREND diagrams, and the measured value at the position it arrows is displayed below the TREND diagram while its corresponding time is displayed above the TREND diagram.

## 3.7 TREND TABLE

TREND Figure data over the previous 120 hours can be displayed in the following resolutions: 1 minute, 5 minutes, 10 minutes, 30 minutes and 60 minutes.

Select "TREND Figure review" under the system menu to pop up the following TREND Figure:

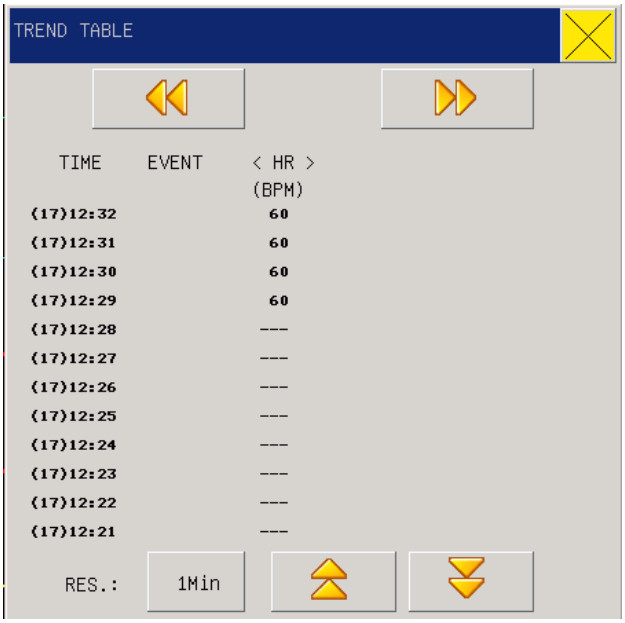



Figure3-7Trend Table

Time corresponding to various groups of TREND data is displayed at the left column, with dates braced. What are listed is the cases that have once been marked, which corresponds to the time of the marked cases. Parameters in the TREND Figures can be categorized into the following 9 groups:

HR,

ST1, ST2

RR,

T1，T2，TD

$SPO_2$, PR

NIBP （S/D/M）DATE

IBP1（S/D/M）

IBP2（S/D/M）

$CO_2$ INS AwRR

NIBP TREND data has its own characteristics; besides of measured values, below each “measurement point” there is time for this NIBP measurement.

## 3.8 NIBP RECALL

The monitor can display the latest 2000 NIBP measurement data in the NIBP review function. After users select the NIBP Data Review item under the System menu, the windows will display the latest 10 NIBP measurement results and measurement time, as shown in the following:

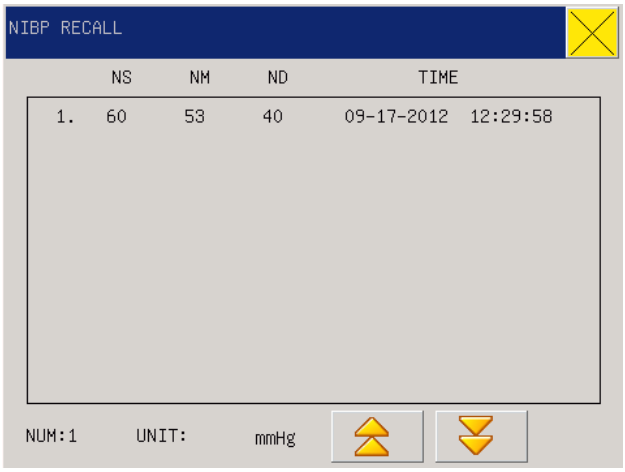



Figure3-8NIBPRecall

Data is sorted in time sequence, from early to late, and each screen can display 10 times of measurement data, while users can select “Page up/ down” to view later or earlier data. Maximally 2000 measurement results can be displayed, and when the measure times are over 2000, only the latest 2000 will be displayed.

## 3.9 ASPHYXIA STIMULATE REVIEW

In the “MAIN MENU” select the “ASPHYXIA STIMULATE REVIEW” to look through the version information of the software and hardware.

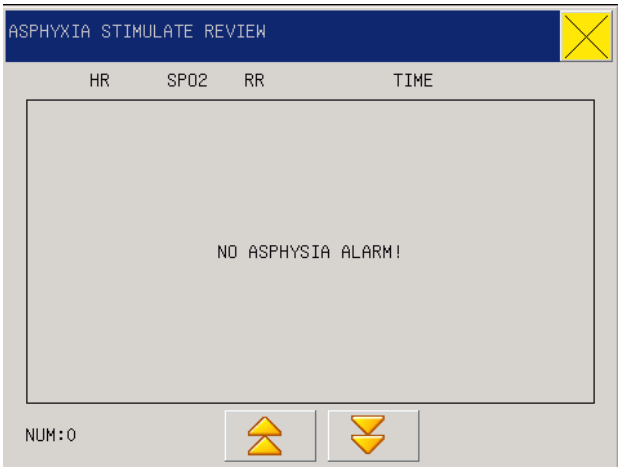



Figure3-9 Asphyxia Stimulate Review

## 3.10 ALM RECALL(Alarm recall)

When parameter alarm occured ,the monitor would be memory the alarm parameter data. Enter the “MAIN MENU” selected “ALM RECALL” could be recheck the patient status in “RECALL EVENT”：


Fig 3-10 Alarm Recall condition

Setup up the “recall event” from start time/date to end time/date

Would be re-check the alarm status in “RECALL EVENT” menu , the events include “ALL , ECG ,SPO2 , NIBP , IBP , CO2 , RESP , TEMP” status.

Optional “ALM-RECALL_Condition” window , would be recall the alarm parameter and waveform ， following with figure below:

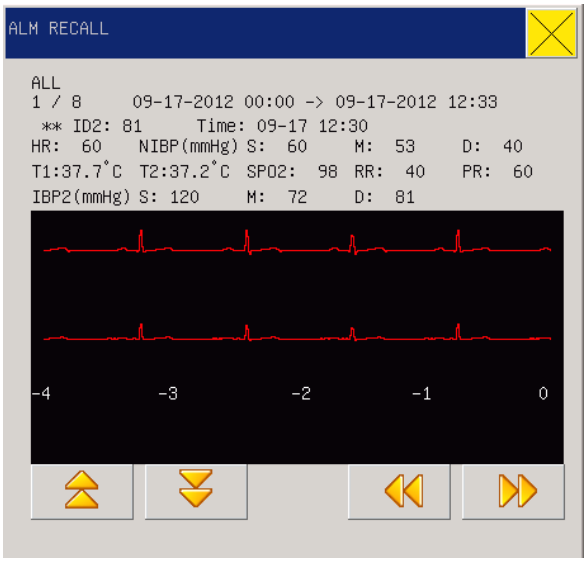



Fig 3-11 Recall event

## 3.11 WAVE RECALL

In “MAIN MENU” selected the “WALL RECALL”could be recall the parts information or all information within memory data , following with figure below.

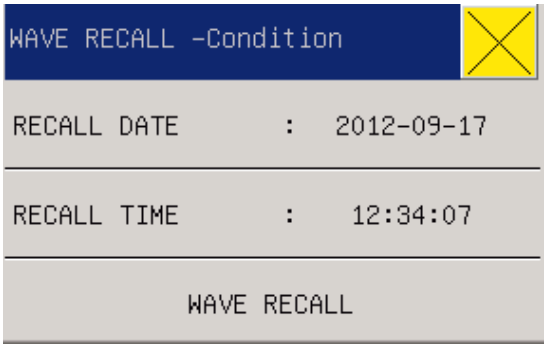



Fig 3-12 Wave Recall-Condition

Setup the review types of the recall events and times , enter in “WAVE RECALL-Condition” selected “WAVE RECALL ” would be display the window , following with figure below:

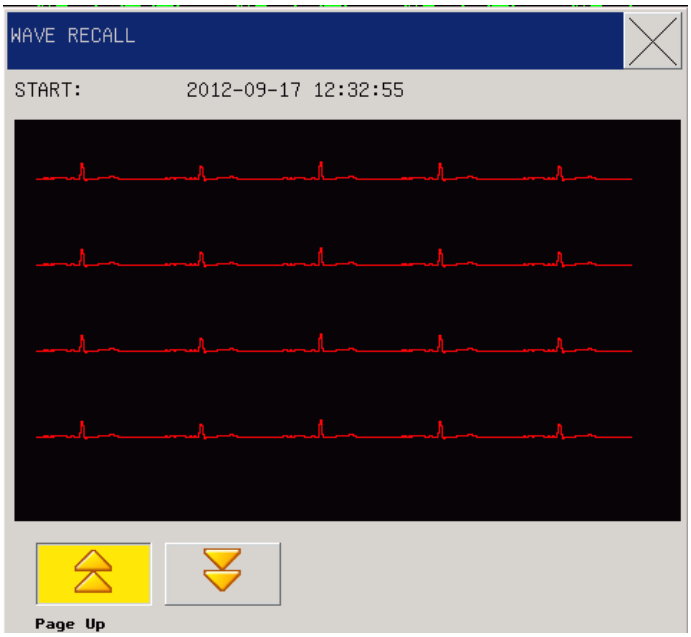



Fig 3-13 Wave Recall

## 3.12 INFO (Monitoring Information)

In the “MAIN MENU” select the “INFO” to look through the version information of the software and hardware.


Figure3-14 Monitoring Information

## 3.13 DRUG CAL

The portable-type multi-parameter monitor can provide the computation for 15 kinds of medicines as well as the Titration List Display Function, and output the content of Titration list on the recorder.

## 3.14 MAINTAIN

In the “MAIN MENU” select the “MAINTAIN”, submenu pop out:
Password: 5188

1. Wave type: SpO2 waveform and RESP waveform has two type to select: LINE and FILL
2. VGA size:8.4′ TFT
3. Wave Mode: Color or not
4. Wave type:SPO2 wave ,RESP wave have two type , line and fill
5. Secreen Adjust: switch on touch screen as monitor indicated
6. Factory default :yes or no. Select “Yes” and you can save all configuration of the current patient type as the user’s default setting. Select “No” and you can abandon the current operation so that the system can continuously keep unchanged the original setting.

Password: 2016

1. Language Selection
2. Filter Hz: OFF/ON

## 3.15 DEMO (Password: 5188)

In the “System Menu” select the “Demo” to have the “Input Demo Password” dialog box pop up. Input the correct password and the system will enter the waveform demonstration state.
Demo Waveform means the simulated one set by the manufacturer for showing the monitor performance and helping users with training.
In the practical clinical l use it is prohibited to use such a function because it will make the medical personnel misthink they are the monitored patient’s waveforms and parameters so as to affect patient monitoring and delay treatment. So this menu is set with the password.

## 3.16 SCR LOCK(screen lock)

Screen Lock: In order to avoid non-operators misuse Monitor, the instrument has a touch screen lock function. Click on the "SCR LOCK" button to lock the touch screen in the main interface. For To unlock the screen , continuous point lived “ SCR UNLOCK” option for three seconds, you can unlock the screen is locked.

# Chapter 4 System Work Interface

## 4.1 Work Interface Selection

In the Main Menu, select the “FACE SELECT” to enter the dialog box in the following Figure. Here there are such six interfaces to choose:
STANDARD, LIST FACE, TREND SCREEN, oxyCRG SCREEN, BIG FONT.

### 4.1.1 STANDARD

In the “FACE SELECT” menu, select the “STANDARD” to enter the standard work interface. The Standard interface provides us the parameter waveforms under monitoring and displays the parameters in the parameter area, as shown in the following picture:

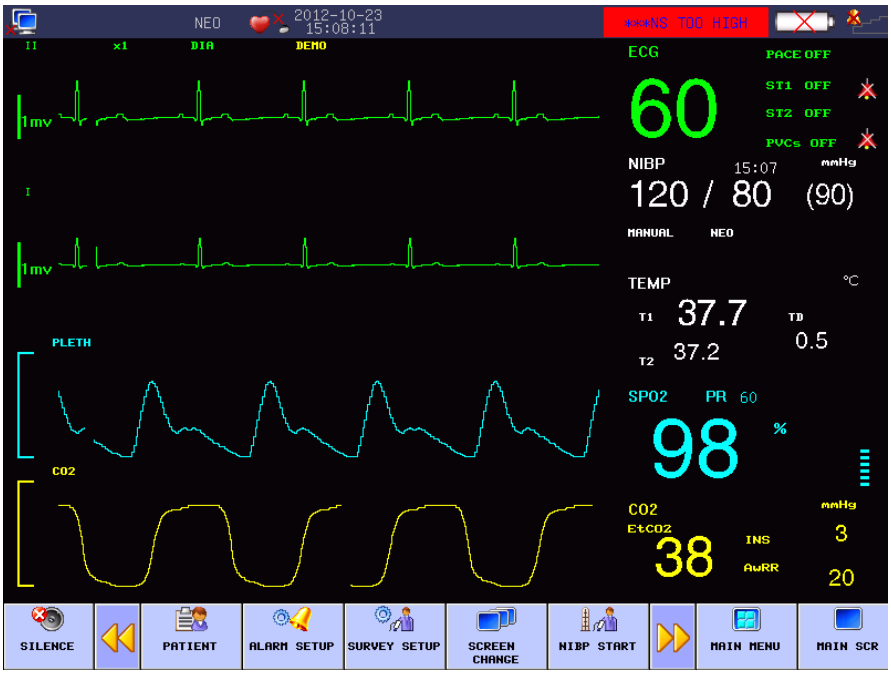



Figure4-1 Standard Interface

### 4.1.2 LIST FACE

In the “FACE SELECT” menu, select the “LIST FACE” to enter the LIST FACE work interface.

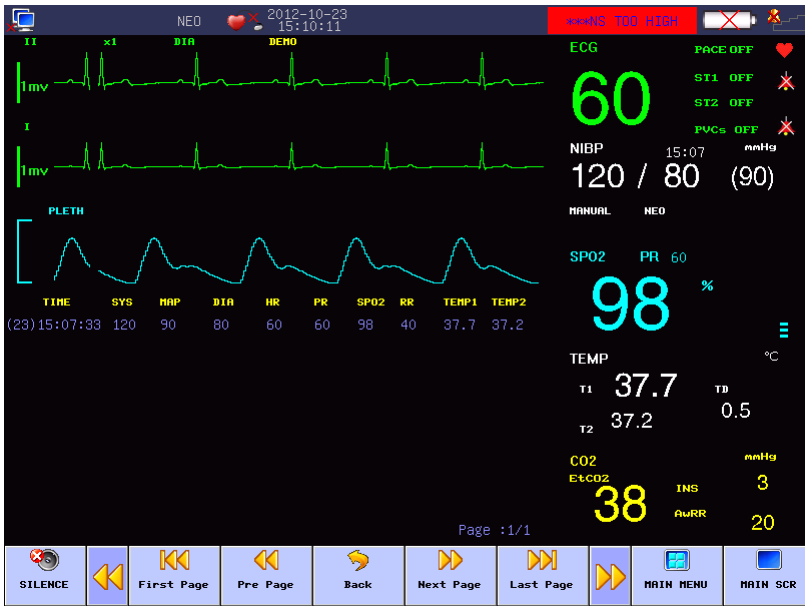



Figure4-2List interface

## 4.1.3 TREND SCREEN

Enter the “FACE SELECT” and select the “TREND SCREEN” in the Work Interface Selection menu to enter such an interface.

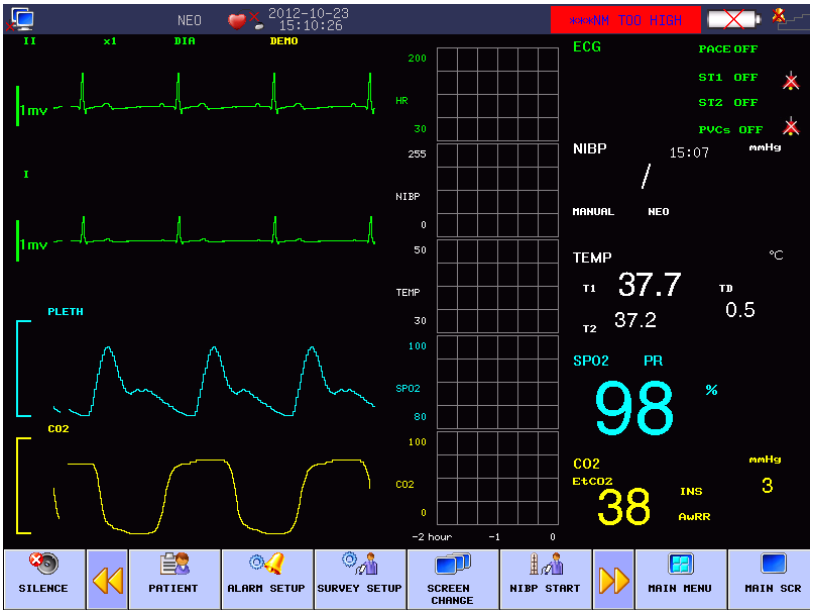



Figure4-3TrendSreen Interface

■ Location of trend diagrams

TREND diagrams is located at right side of waveforms, with the same colors to the corresponding

parameters.

- TREND length

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

- End of trend concurrence interface

Out of the “Interface Selection” options, select any other work interface to end the trend concurrence interface.

### 4.1.4 OxyCRGSCREEN

In the Work Interface Selection menu, select the “oxyCRG Screen” to enter the oxyCRG work interface.

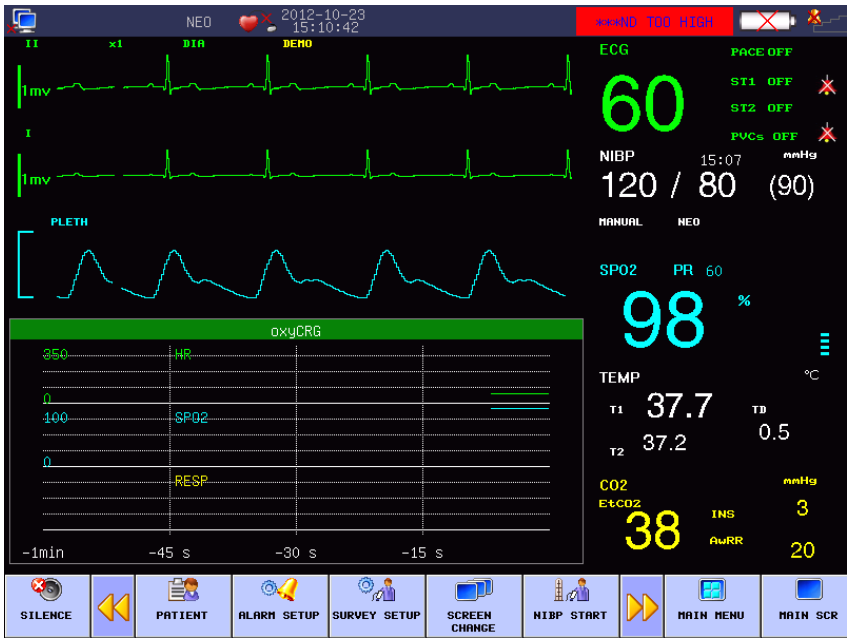



Figure4-4OxyCRG Screen

- TREND Diagram in oxyCRG Interface

  OxyCRG Dynamic Interface is consist of compressed respiratory wave and RR.

- OxyCRG Trend Length Selection

  Two hot key at the below part of dynamic interface: TIME and TYPE

  TREND Diagram for “1 minute” and “2 minute” can be selected through the trend time buttons.

- Compressed Respiratory Wave and RR

  “The function of “Respiratory Rate/Compressed Respiratory Wave” means the operator can select the “PR Trend” or “Compressed Respiratory Wave” as needed, under which the displayed content occupies the same position. Select the “PR Trend” and this position will show the TREND Diagram of the respiratory rate; select the “Compressed Respiratory Wave” and this

position will show the respiratory wave after compression.

In the Work Interface Selection menu, select other work interface to end the OxyCRG work interface.

### 4.1.5 BIGFONT INTERFACE

In the Work Interface Selection menu, select the “BIGFONT” to enter the big font interface.

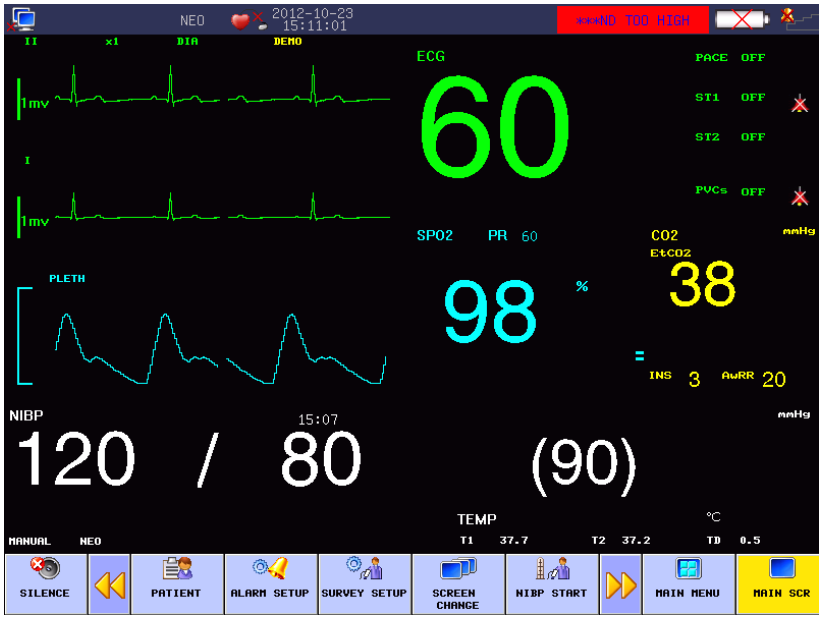



Figure4-5Bif Font Interface

# Chapter 5 Recording

In the Main Menu, select the “MONITOR SETUP”, then to RECORD menu

## 5.1 General Information on the Recorder

The recorder used with this monitor is a heat-sensitive array recorder, with print width of 50mm.

**Recorder capability**

Outputted waveforms run at25mm /sec. or 50mm / sec

Maximally record two waveforms

Grid output function is optional

English output

Real-time record time and waveforms are selected by users through menus

Automatic record interval is selected by users through menus, while waveforms are identical to real-time records

## 5.2 Record Type

This monitor generates slip records of the following types:

Real-time continuous record;

Real-time 3, 5, 8-second record;

Automatic alarm record;

Frozen waveform record;

Start recording waveforms from the moment you press the button.

Real-time continuous record for 8-second defaulted by machine system (normally only for two waveforms) or set by users through menu. Please refer to relevant chapters for details.

**′Attention′**

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

**Frozen waveform record**

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

**Remark record**

Real-time record

Alarm parameter, alarming time, and FREEZE time

Bed number

Parameter name and value
Record time

Waveform name
Waveform amplitude (only for ECG waveforms)
ECG lead, ruler, and gain

## 5.3 Operation and Status Information of Recorder

**Requirements on record paper**

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

**Normal service**

Do not pull out paper when the recorder is working.
Do not use recorder without record paper.

**Insufficient paper**

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

**Paper loading procedures**

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

′Attention′

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

**Solution to paper jam**

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

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

# Chapter 6 Trend

It can store 120 hours trend data, 2000NIBP and 60 alarm events and support recording. Observation methods are provided in this chapter.

## 6.1 TREND GRAPH (TREND Diagram)

TREND diagram for the latest 1 hour can be displayed one data per second or one data per five seconds;

TREND diagram for latest120 hours can be displayed one data per minute, per 5 minutes, or per 10 minutes.

Select “TREND GRAPH” in the “MAIN MENU” to pop up the following TREND figure:

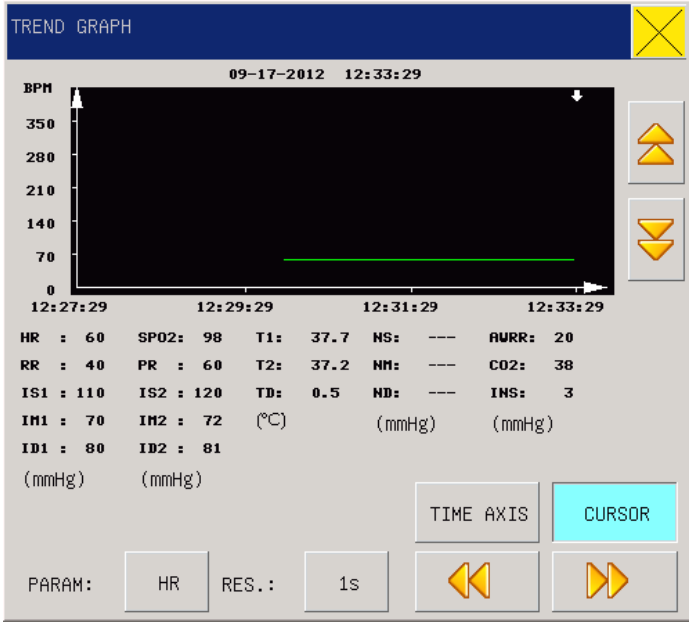



Figure6-1Trend Graph

Vertical axis is for measured values and horizontal axis for measurement time. The “🡻” symbol is the cursor for TREND diagrams, and the measured value at the position it arrows is displayed below the TREND diagram while its corresponding time is displayed above the TREND diagram.

### 6.1.1 Select trend diagrams for various parameters to be displayed:

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

### 6.1.2 Select 1-hour or 120-hour TREND diagrams:

Use the cursor to select the Resolution option, then select 1 seconds or 5 seconds if you want to observe 1-hour TREND, or select 1 minute, 5 minutes or 10 minutes if you want to observe 120-hour TREND.

### 6.1.3 Observe TREND diagrams of later or earlier duration:

Press the "  or  " button or rotate the knob clockwise or anticlockwise so as to observe later or earlier TREND curves.

### 6.1.4 Change the display zoom

Use the "  or  " button to change displayed size of the vertical axis, while displayed size of the TREND curves will follow to change. Values higher than the biggest axis value will be represented by the biggest axis value.

### 6.1.5 Obtain the TREND data at certain time in the current TREND diagram

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

### 6.1.6 Operation sample

Observe the NIBP TREND diagram within the latest 1 hour:

Press the TREND button on the control panel to pop up the Main menu;

Select the TREND Diagram Review option in the menu;

1. Select the parameter: rotate the knob in the Parameter Selection item until "NIBP" is shown in the dropdown box;
2. Select 1 or 5 seconds in the Resolution item;
3. Press the "  or  " button or rotate the knob, while observing changes in the TREND diagram time and TREND curves;
4. Stop at the period to be carefully observed; in case the vertical axis is out of proper size, for example, some TREND values exceed the highest value of the current vertical axis, select

"Adjust amplitude" to adjust;

5. If users want to know the measured value at certain time, just select "move cursor" and move the cursor to where they wants, then time will be displayed above the curve and measured values below the curve;
6. If users need output the TREND diagrams to the recorder, just select the "record" button so as to let the recorder output NIBP TREND of the current review window;
7. Press "☒" to exit observation on TREND diagram.

## 6.2 TREND TABLE (TREND Figure)

TREND Figure data over the previous 120 hours can be displayed in the following resolutions: 1 minute, 5 minutes, 10 minutes, 30 minutes and 60 minutes.

Select "TREND TABLE" under the "Main Menu" to pop up the following TREND figure:

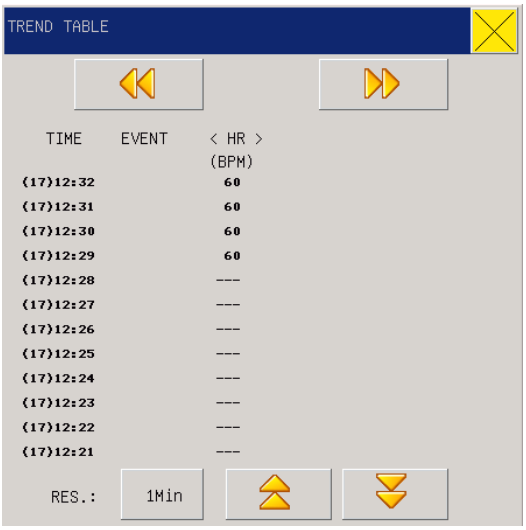



Figure 6-2Trend Table

Time corresponding to various groups of TREND data is displayed at the left column, with dates braced. What are listed is the cases that have once been marked, which corresponds to the time of the marked cases. Parameters in the TREND Figures can be categorized into the following 9 groups:

HR,

ST1, ST2

RR,

T1，T2，TD

$SPO_2$, PR

NIBP （S/M/D）DATE

IBP1（S/M/D）

IBP2（S/M/D）

$CO_2$, INS, AwRR

NIBP TREND data has its own characteristics; besides of measured values, below each "measurement point" there is time for this NIBP measurement.

### 6.2.1 Select TREND Figures in various resolutions

Use the cursor to select a resolution and use the knob to change options so as to change the time interval for TREND data.

### 6.2.2 Observe earlier or later TREND curves

Press "  or  " button or rotate the knob clockwise or anticlockwise so as to observe later or earlier TREND curves.

### 6.2.3 Observe TREND data of various parameters

Press "  or  " button and select one group of parameters out of 6 available groups.

### 6.2.4 Operation sample

To observe a NIBP TREND Figure:

Press the TREND button on the control panel to pop up the Main menu;

Select the TREND Figure Review option in the menu;

1. Press "  or  " button or rotate the knob to select the NIBP （S/M/D）DATE;
2. Select the resolution: click the left item and select the expected data interval;
3. Press "  or  " button or rotate the knob, while observing NIBP TREND data over various time;
4. Press "  " to exit observation on TREND table.

## 6.3 NIBP RECALL

The monitor can record the latest 2000 NIBP datas. After select the NIBP RECALL in MAIN MENU, the window will display 10 groups of NIBP records as follows:

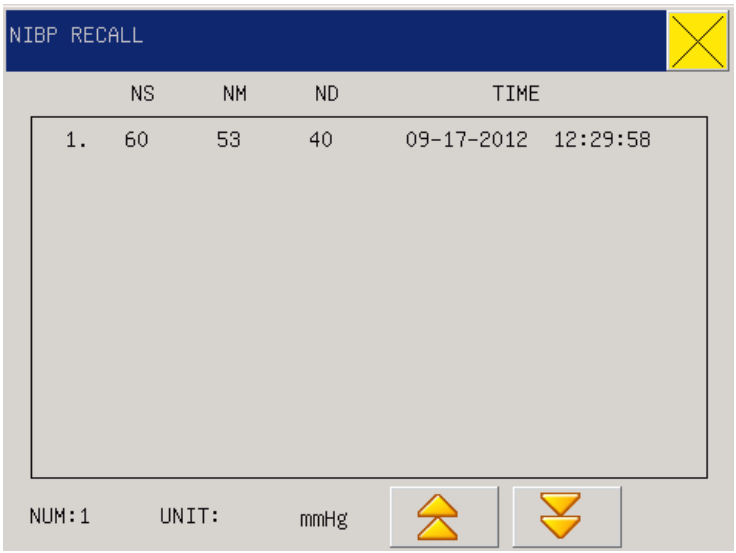



Figure 6-3 NIBPRECALL

Data is sorted in time sequence, from early to late, and each screen can display 10 times of measurement data, while users can Press "  or  " button to view later or earlier data. Maximally 2000 measurement results can be displayed, and when the measure times are over 2000, only the latest 2000 will be displayed.

# Chapter 7 Drug Calculation & Titration List

The portable-type multi-parameter monitor can provide the computation for 15 kinds of medicines as well as the Titration List Display Function, and output the content of Titration list on the recorder.

## 7.1 DRUG CALC

Medicines able to be calculated under this system are: aminophylline, dobutamine, dopamine, epinephrine, heparin, isuprel, lidocaine, nipride, nitroglycerin and pitocin. Besides, there are Drag A, Drag B, Drag C, Drag D and Drag E provided to flexibly replace any medicine.
Users can select “Drug Calculation” under the MAIN MENU to pop up the following window:

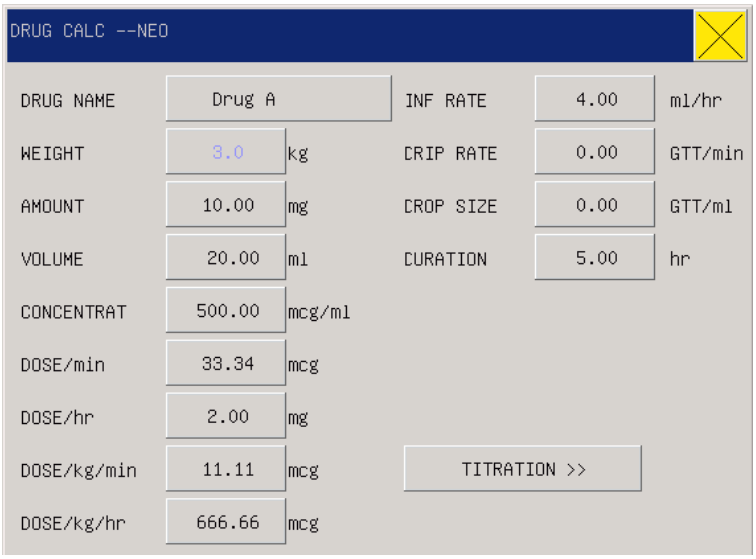



Figure7-1DrugCalculation

The following formulae are used for medicine dosage calculation:
Medicine contents = Total medicine volume / Liquid volume
Infusion speed = Medicine dosage / Medicine contents
Continued time = Total medicine volume / Medicine dosage
Medicine dosage = Infusion speed × Medicine contents

### 7.1.1 Operation method:

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

limits, if the calculated results exceed such limits, the system will display "---.--".

**′Attention′**

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

**′Attention′**

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

**′Attention′**

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

**′Attention′**

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

**′Attention′**

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

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

**′Attention′**

**The above introduced A, B, C, D, and E are not actual medicine names but only codes for medicines. Units for these five types of medicines are fixed, and operators can select proper units based on general practice of medicines. The expression rules of their units are as follows:**

Medicines A, B, and C are fixed under the "mg" unit series, including g, mg, and mcg; Medicine D is fixed under the "unit" unit series, including unit, k unit, and m unit; and Medicine E is fixed under the "mEq" unit.

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

**′Attention′**

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

## 7.2 TITRATION

### 7.2.1 Enter the Titration list:

In the “Drug Calculation” menu, pitch on the “Titration” to enter the Titration list interface.

The Titration list interface for medicines is shown in the following Figure:

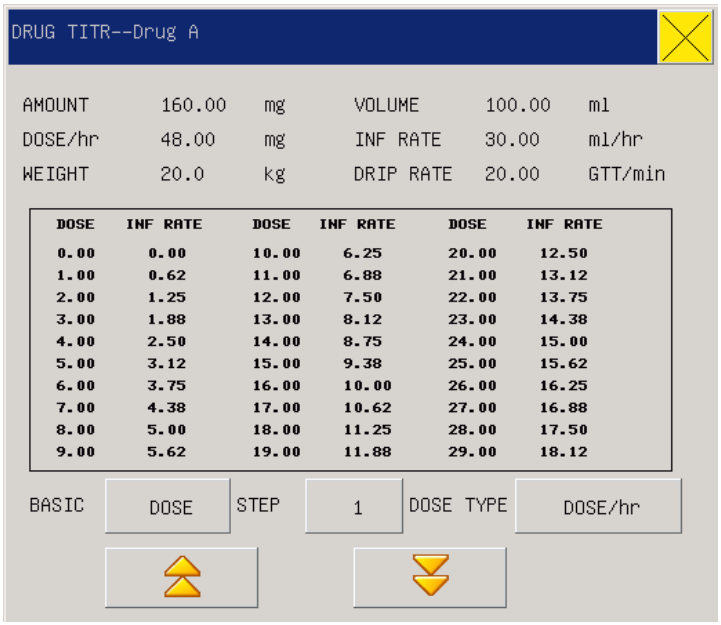



Figure7-2 Titration List

The specific operations are as follows:

In the Titration list, move the cursor to the “Reference Item” with the knob first, and then press the knob to select the required item. “Dosage” and “Injection Speed” are two options.

Move the cursor to the “Step Length” and press the knob to select the step length in the range of 1~10.

Move the cursor to the “Dosage Type” and press the knob to select the dosage unit.

Move the cursor to the “ or ” button and press and turn the knob to check the previous and next pages of the list.

Move the cursor to the”Record” and press the knob to output the Titration list data on the current display interface.

Move the cursor to the “ ” and press the knob to return to the “Medicine Calculation” menu.

# Chapter 8 Patient Safety

The portable monitor is designed to meet the international safety requirements IEC60601-1, EN60601-2-27 and EN60601-2-30 formulated for medical electric equipments. It's furnished with floating inputted defibrillation resistance and surgery electric knife protection. If correct electrodes (referring to the ECG and RESP chapters) are installed following supervision of the manufacturer, screen display will be recovered within 10 seconds after defibrillation.

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

**Warning**

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

## Environment

Users should follow the following guides to ensure absolute safety of electricity installation. For an environment where the portable monitor is located, users should reasonably avoid vibration, dusts, corrosive or explosive gases, extreme temperature and moisture. In case installed inside a chamber, the front side must be given sufficient space for convenient operations, and while the chamber door is open, the rear side must be given sufficient space for easy repair. Besides, must make sure of air flow inside the chamber.

The monitor, when working in an ambient temperature between 0℃～40℃, can meet the technical indexes, otherwise may have equipment accuracy affected or parts or circuits damaged. Moreover, there should be at least 2 inch (5 cm) of space reserved surrounding the monitor to ensure air flow.

## Power Source

Please refer to the **Product Specification** chapter.

## Monitor earthing

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

**Warning**

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

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

## Equal-potential earthing

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

**Warning**

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

## Condensation

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

**Warning**

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

Explanations on Symbols Used in the Monitor

See reference in external interface in chapter 1.

# Chapter 9 ECG Monitoring

## 9.1 Definition of ECG Monitoring

ECG monitoring describes continuous waveforms of cardiac activities of patients so as to accurately assess the current psychological status of the patients. Thus proper connection of ECG cables must be ensured in order to obtain correct measurement values. This portable monitor concurrently can display 2 waveforms under normal work status.

A patient cable consists of two parts:

Wire connecting the monitor;

Leads connecting patients

With a 3-lead facility for monitoring, ECG can obtain two waveforms from two different leads. Users can use the knob, in the left side of the ECG waveforms on the screen, to directly select the lead to be monitored.

Displayed monitoring parameters include HR, ST segment measurement value and arrhythmia.

All the above parameters can be taken as alarm parameters.

**′Attention′**

**In the ex-factory setting of the monitor the ECG waveform displays at the position of the first two waveforms in the waveform area.**

## 9.2 Attentions during ECG Monitoring

**Warning**

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

**Warning**

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

**Warning**

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

′Attention′

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

**Where this monitor is operated according to the conditions specified in the EN60601-1-2 (anti-radiation ability: 3V/M) and the electric-field strength above 1V/M may give rise to the**

**measurement mistakes under various frequencies, it is suggested that the electroradiant equipment should not be used in the place next to the ECG/Respirometer.**

## 9.3 Monitoring Procedures

### 9.3.1 Preparation

Take patient skin preparation before installation of electrodes:
Skin is bad conductor, thus to ensure good touch between electrodes and skin it's very important to well prepare patient skin.
When necessary, remove body hair surrounding the electrode positions.
Clean thoroughly the skin with soap and water (don't use ethyl ether or pure alcohol, as they will increase skin resistance)
Drily sweep the skin so as to increase capillary blood flow as remove skin scraps and oil.
Install spring clamp or snap before installation of electrodes
Put the electrodes on patient body; in case the electrodes contain no conductive paste, coat the conductive paste before installation.
Confirm power supply.

**Warning**

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

′Attention′

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

**Warning**

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

### 9.3.2 Install ECG leads

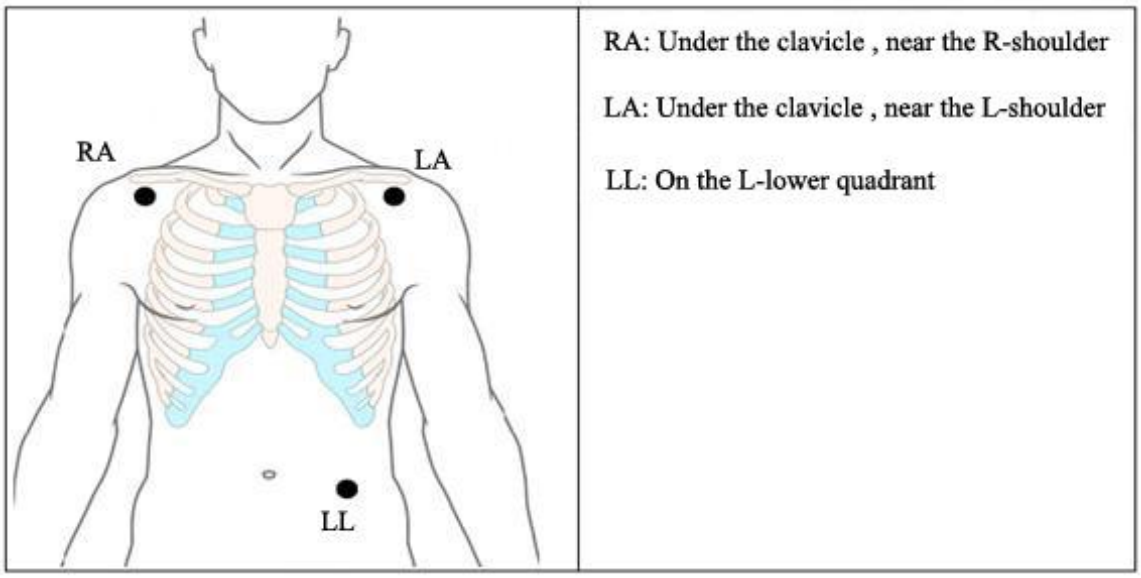
′′Attention′

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

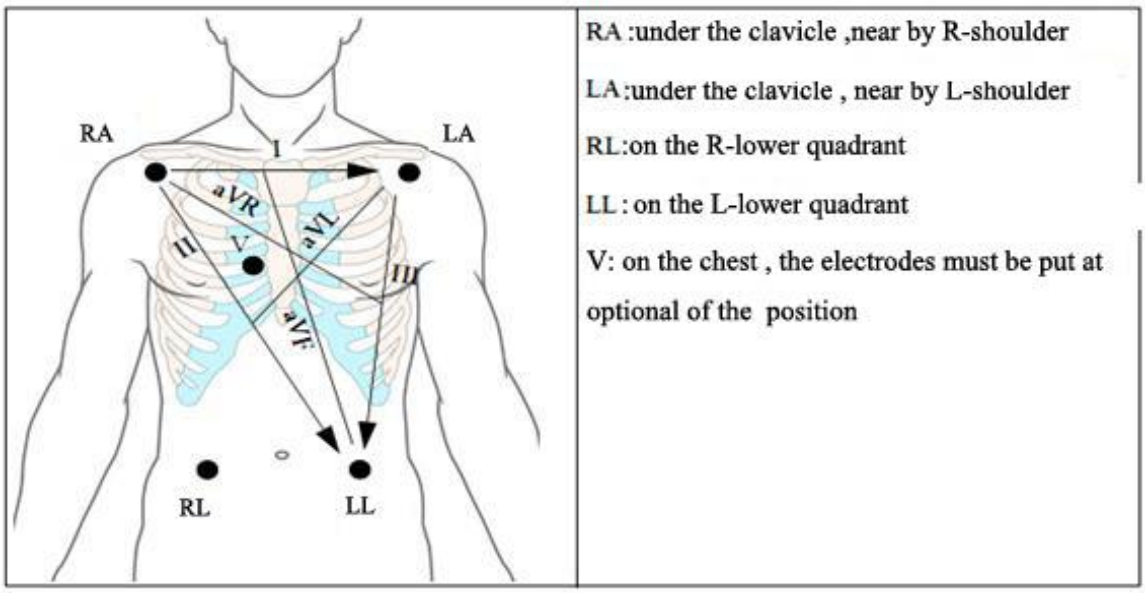
| US standard | | European standard | |
|---|---|---|---|
| Lead name | Color | Lead name | Color |
| RA | White | R | Red |
| LA | Black | L | Yellow |

| | | | |
|---|---|---|---|
| LL | Red | F | Green |
| RL | Green | N | Black |
| V | Brown | C | White |

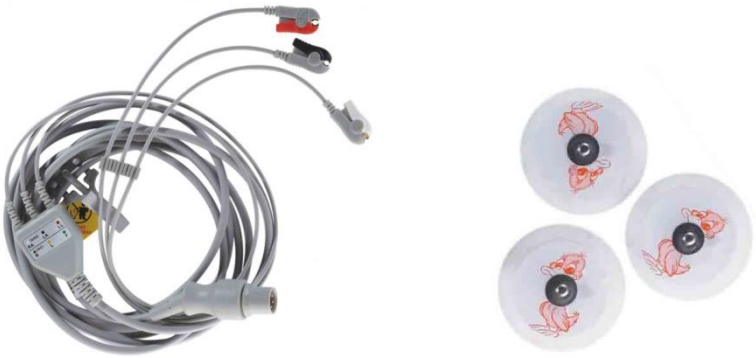
**Three-lead ECG electrodes position (Figure 9-1):**




**Five-lead ECG electrodes position(Figure 9-2):**




Speical 3-leads ECG for neonate monitoring



′ Attention′

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

For 5-lead device, put the breast (V) electrode at one of the following positions:

V1, around the 4th frame at right side to the breast bone

V2, around the 4th frame at left side to the breast bone

V3, between V2 and V4

V4, around the 5th frame along middle line of the left clavicle

V5, at front line of the left axilla, at the same horizontal position of V4

V6, at middle line of the left axilla, at the same horizontal position of V4

V3R-V7R, at right side of the breast, identical to those positions at left side

VE, at apophysis of the xiphoid process; in case V leads are put on the back, the electrodes must be put at one of the following position:

V7, around the 5th frame at back line of the left axilla on the back

V7R, around the 5th frame at back line of the right axilla on the back

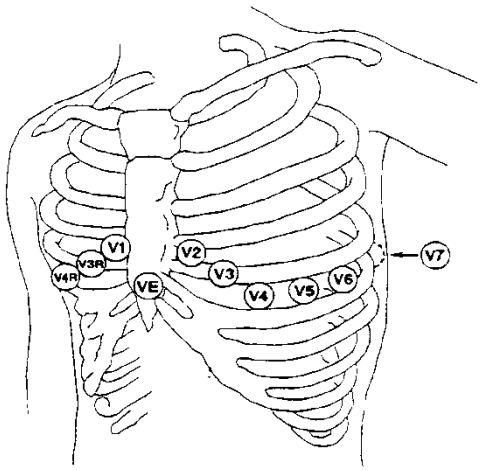



Figure9-35-lead Chest Electrode Position

### 9.3.3 ECG lead connection recommended for surgery patients

**Warning**

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

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

**Warning**

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

## 9.4 ECG Hot Key

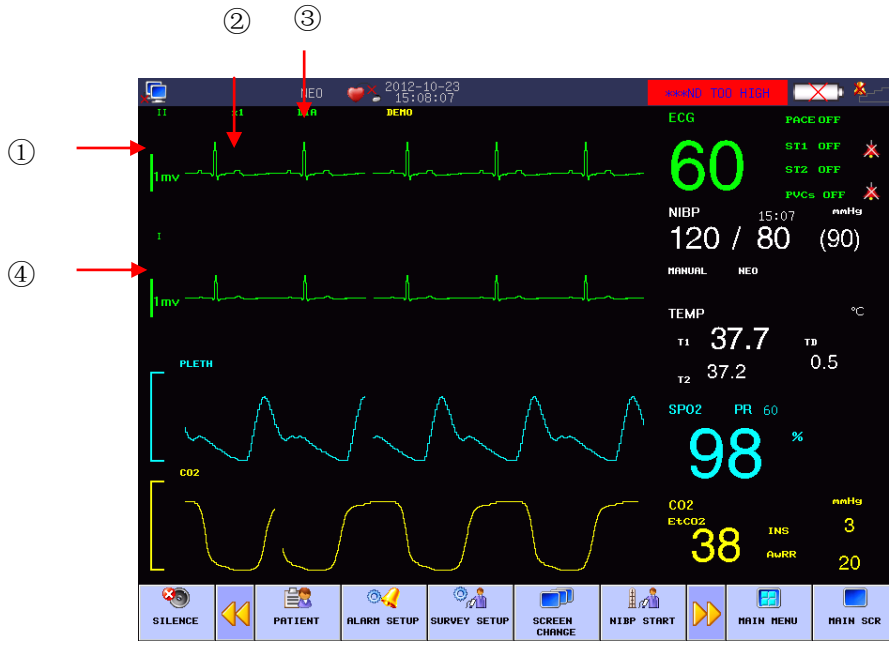



Figure9-4 ECGHotKey

Name of the First ECG Lead①:

ECG using 5-lead, the selectable leads include I, II, III, aVR, aVL, aVF and V;
ECG using 3-lead, the selectable leads include I, II and III. (For neonate)

The leads on the ECG waveform should not have the same name, otherwise the system will automatically change the similar name into another.

The 1st-ECG Waveform Gain ②: used to adjust the amplitude of ECG waveform.

The gain of each calculation channel can be selected, which has such columns as ×0.25, ×0.5, ×1 and ×2 as well as auto mode. Auto mode means that the monitor can automatically adjust the gain. On the right side of each ECG waveform there is a 1-mv rod of which height and amplitude are proportional.
′

Attention′
The input signal being too strong, the wave crest may be truncated. At this time users can manually change the gain column of ECG waveform by reference to the actual waveform for fear of incompleteness of waveform.

Filtering Mode ③: The cleaner or precise waveform can be obtained through filtering.

There are three filtering modes for option. The unfiltered ECG waveform is shown in the diagnostic mode; the monitoring mode will possibly lead to the artifact filtering; the operation mode used in the surgery can reduce the artifact and interference from the electrosurgery unit. The filtering mode can be used in two channels and displayed on the upper part of the first ECG waveform.

⚠**Warning**⚠

**Only in the diagnostic mode can the system provide the real signal that has not been treated. In the filtering modes such as "Monitoring" and "Operation", the ECG waveform will abnormally occur to the different extents. At this time the system can only provide the basic ECG status, and will produce greater influence on the analysis result of ST Segment. The analysis result of ARR may partially be affected in the operating mode, so it is suggested that efforts are made to monitor patients in the diagnostic mode when the interference is small.**

④The Name of 2nd-ECG Waveform Gain: for details, please refer to ①。

′Attention′
The detected pacing signal displays on the upper part of the ECG waveform in the waveform area, which is expressed as " ▮ ".

## 9.5 ECG Menu

### 9.5.1 ECG setting menu

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

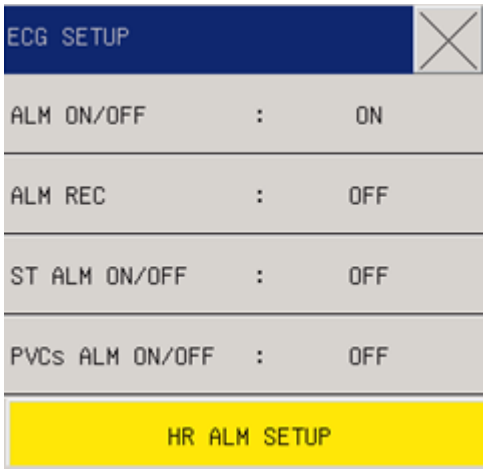



Figure9-5ECGSetup

- Alarm: Select “ON” to give alarm prompt and storage when the heart rate alarm happens. will be prompted beside ECG.
- Alarm level: three options: High, MED and Low, and high is for the most serious alarm.
- Alarm record: Users can select “On” to print HR alarms when they happen
- ST ALM ON/OFF: Select "ON”in the event of ST1 or ST1 overrun alarm prompt and storage, select the "OFFs not an alarm, and ST1 next have" ” pompt.
- PVCs ALM ON/OFF: Select "ON”in the event of PVCs or PVCs overrun alarm prompt and storage, select the "OFFs not an alarm, and PVCs next have" ” pompt.
- HR ALM SETUP: setup heart rate hight limit ,middle limit ,low limit of the upper and lower limits .

Alarms will happen once the HR values exceed the upper or lower limit.
Adjustable ranges for HR alarm upper & lower limits are as follows:

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

′Attention′

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

## 9.5.2 ECG setting in waveform area

Turn the knob to waveform area,press the knob to enter ECG waveform setting

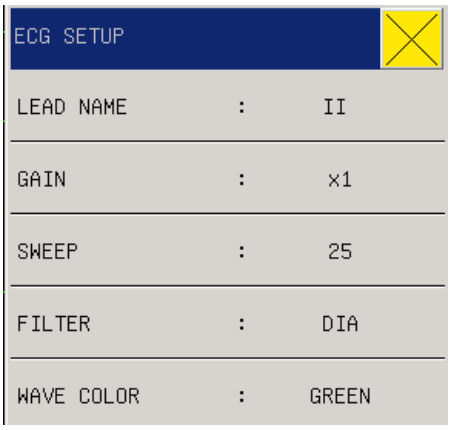



Figure9-6 ECGSetup

- Lead Name：

  ECG using 5-lead, the selectable leads include I, II, III, aVR, aVL, aVF and V;

  ECG using 3-lead, the selectable leads include I, II and III.

- Gain: used to adjust the amplitude of ECG waveform. The gain of each calculation channel can be selected, which has such columns as ×0.25, ×0.5, ×1 and ×2 as well as auto mode. Auto mode means that the monitor can automatically adjust the gain. On the right side of each ECG waveform there is a 1-mv rod of which height and amplitude are proportional.

- Sweep:ECG Waveform scanning wave has four levels for option, such as 6.25, 12.5, 25.0 and 50.0mm/s.

- Filtering Mode: The cleaner or precise waveform can be obtained through filtering. There are three filtering modes for option. The unfiltered ECG waveform is shown in the diagnostic mode; the monitoring mode will possibly lead to the artifact filtering; the operation mode used in the surgery can reduce the artifact and interference from the electrosurgery unit. The filtering mode can be used in two channels and displayed on the upper part of the first ECG waveform.

- Wave Color: green, cyan, red, yellow, white, blue, violet.

### 9.5.3 ECG setting in measurements

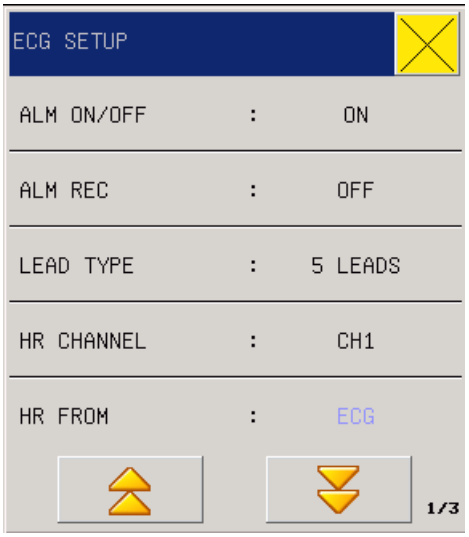



Figure9-7ECGSetting menu

- ALM ON/OFF:on or off When the heart rate alarm happens. Select "OFF"  will be prompted beside ECG.
- Alarm record: Users can select "On" to print HR alarms when they happen
- Lead type: 5-lead or 3-lead
- HR channel
- "Channel 1" means the HR is calculated according to the first ECG waveform data.
- "Channel 2" means the HR is calculated according to the second ECG waveform data.
- "Auto" means the monitor will automatically select the channel of calculating HR.
- HR From
- Users can select to check HR through ECG or PLETH (blood-oxygen volume recording waveform); if users select "Automatic", the monitor will decide HR source based on signal quality; if users select "All", the monitor will concurrently display HR and PR. In case PLETH is taken as the HR source, the PULSE reminder will be displayed together with pulse voice.

  In case PLETH is taken as HR source, no alarm judgment on HR but alarm judgment on PR will be conducted. In case "All" is selected, PR measurement values will be displayed in the right to $SpO_2$ on the main screen, and HR & PR make alarms at the same time. Pulse voice will give priority to HR, as long as there is HR data, voice reminder will be there; only when there is no HR data, voice reminder will be subject with PR.
- FILTER,SWEEP ,WAVE COLOR : See this chapter "ECG Settings"parameter area corresponding
- NOTCH: When set to ON, it is a method of inhibiting the method and apparatus of the power frequency common mode interference, for bioelectric signals measurement system including a

common mode interference signal extraction circuit and a drive circuit connected to the circuit; particular, the apparatus furtherincludes a phase compensation processing means for receiving from the subject organisms of biological signals and the driver circuit to provide the amplified signal, the output is sent to a feedback signal by measuring biometric.

- HR ALM SETUP: setup heart rate hight limit ,middle limit ,low limit of the upper and lower limits .
- ST AMALYSIS : ST Segment Analysis Select this item and enter the “ST Segment Analysis” menu.
- ARR ANALYSIS:ARR Analysis Select this item and enter the “Arrhythmia Analysis” menu.
- ECG CAL : When the ECG calibration, you can not monitor the patient. Tip: in the middle of the screen of the instrument calibration can not monitor the patient.Stop the calibration is required to return to the “ECG Setup” select to “stop ECG calibration”menus.
- DEFAULT : Select "default configuration" dialog box, the user can choose "No" or “Yes" to be “the default configuration”or“original configuration will be set”

## About ST Monitoring

The monitor performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics and snippets on the monitor.
All available leads can be monitored continuously. The ECG waveform does not need to be displayed on the Screen for ST segment analysis.

⚠**Warning**⚠

**This monitor provides ST level change information; the clinical significance of the ST level changeinformation should be determined by a physician.**

## ST Segment Analysis Menu

ST Analysis: this switch is mainly used to set the state of ST Segment Analysis. Only when the switch is ON, ST Segment Analysis can proceed.
Alarm on/off: Where “ON” is selected, the alarm prompt and saving will proceed when ST analysis result is alarmed; where “OFF” is selected, alarming will not happen, but  will be prompted beside ST in the screen parameter area. ST Alarm will be triggered only when its measured value exceeds ST Alarm Upper Limit or ST Alarm Lower Limit.
Alarm Level: used to set the ST Alarm Level according to three options such as “High”, “Middle” and “Low”.
Alarm Record: when it is set at “ON”, the system will start the recorder for alarm record.
ST alarm setup: setup ST alarm hight limit ,middle limit ,low limit of the upper and lower limits

- The adjustable range for upper limit and lower limit of alarm as follows:

| | Max. Upper Limit | Min. Lower Limit | Single Adjustable Quantity |
|---|---|---|---|
| ST | 2.0mv | -2.0mv | 0.1mv |

- DEF POINT (Determine the ST Segment AP (Analysis Point)): Select this option to enter the

"Determine the ST Segment AP" window and set the values at ISO and ST.

ISO (BP: base point): set the baseline point. Power on time is ste at 78 ms.
ST (SP: starting point): set the measuring point. Power on time is set at 109ms.

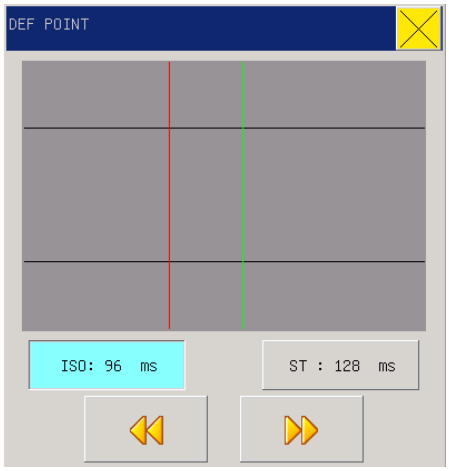



Figure10-8 Determine the ST Segment AP

ISO and ST are two measuring points of ST Segment, which are adjustable.

R wave crest point is the reference point in setting of ST measuring point (as shown in the following figure):

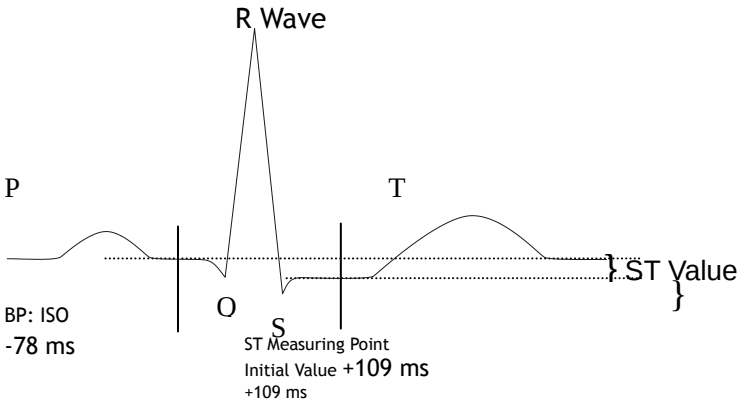



Figure10-9 ST Analysis Point

ST measured value of each HB composite waveform is the vertical distance between this waveform and the crossing of two measuring points.

**Caution**

**Where obvious changes happen to the patient's HR or ECG Waveform, it is necessary to adjust the ST measuring point in the following methods.**

Method of Adjusting ISO and ST

Adjust the values by turning the knob.

Setting the measuring point of ST Segment, please open the "Determine Analysis Point" window and the window will show QRS wave-group module (if the channel is not opened, "ST Analysis Switch OFF" will be prompted). The location for high-brightness line in the window can be adjusted. Select the ISO or ST first, and then turn the knob both leftward and rightward to move such a line in parallel

so as to determine the reference point or measuring point.

**Caution**

**The abnormal QRS wave group will not be taken into consideration when ST segment is analyzed.**

Alarms & Reminders used in ST Segment Analysis.

**Caution**

**The alarm limits for two measured values of ST SEGMENT are coincident. The alarm limit of each channel can't be set alone.**

The alarm record switch in the related menu being opened, the physical alarm caused by the parameter alarm super-limit will make the recorder automatically output the alarm parameter values and related measured waveforms.

For the physical alarm, technical alarm and noticed information possible to happen in the ST Segment Measurement, please see the following table.

Physical alarms:

| Prompt Messages | Causes | Alarm Levels |
|---|---|---|
| ST1 too high | The measured value for ST Segment of Channel 1 is higher than the set alarm upper limit. | Selectable by users |
| ST1 too low | The measured value for ST Segment of Channel 1 is lower than the set alarm lower limit. | Selectable by users |
| ST2 too high | The measured value for ST Segment of Channel 2 is higher than the set alarm upper limit. | Selectable by users |
| ST2 too low | The measured value for ST Segment of Channel 2 is lower than the set alarm lower limit. | Selectable by users |

Technical alarms

| Prompt Message | Causes | Alarm Level | Solutions |
|---|---|---|---|
| ST Alarm Limit is wrong. | Function safety failure | High | Stop use of ST SEGMENT alarm and advise the biomedicine engineer or our company's servicemen. |

Prompt Message (including general alarm message):

| Prompt Messages | Causes | Alarm Level |
|---|---|---|
| ST1 measurement out of scope | The measured value for ST Segment of Channel 1 exceeds the measured range. | High |
| ST2 measurement out of scope | The measured value for ST Segment of Channel 2 exceeds the measured range. | High |

# Arrhythmia Analysis

Press SURVEY in main interface, one submenu pop up; choose ECG SETUP, Arrhythmia analysis information inside.

Arrhythmia analysis is used in clinically monitoring the ECG of patients, detecting the HR change and PVB, saving the arrhythmia events and producing alarm messages. Besides, it can be used to monitor the patients with or without the pacemaker. The qualified personnel can evaluate the patient's status (such as HR, PVCS (PVB), frequency, rhythm and abnormal HB) according to arrhythmia analysis

and make a diagnosis and give treatment. In addition to detect the ECG change, arrhythmia analysis can monitor patients and give a suitable alarm.

The default of arrhythmia monitoring function is off. Users can start this function as needed.

Arrhythmia monitoring can arouse the doctor's attention to the patient's cardiac rhythm and give an alarm through test and classification of arrhythmia and HB abnormality.

This monitor can support 13 kinds of arrhythmia analysis.

In arrhythmia analysis, the system will save the latest 60 alarm events (the single-channel ECG waveform four seconds before and after alarm). The operator can edit the arrhythmia events through this menu.

## Arrhythmia Analysis

In the "ECG SETUP" menu, select the "Arrhythmia Analysis" to enter the following submenu
ARR ANAL(Arrhythmia Analysis): During monitoring it can be set at "ON" and during default, "OFF"

- Alarm on/off: Select the "ON" and the alarm prompt and saving will proceed; select the "OFF" and PVCs alarm won't start, but prompting  do beside PVCs in the screen parameter area.
- Alarm Level: There are such three options as "high", "middle" and "low". "High" means the most serious PVCs alarm.
- Alarm Record: Select the "ON" and the recorder will output during PVCs alarm.
- Alarm Upper Limit: PVCs alarm is based upon the set alarm upper limit. The alarm will happen when PVCs exceeds the upper limit.
- ARR ALARM(ARR alarm setup):
- ARR TYPE :ASYSRTOLE、VFIB/VTAC、R ON T、VT>2、COUPLET、PVC、BIGEMINY、TRIGEMINY、TACHY、BRADY、PNC、PNP、MISSED BEATS、ARRHYTHMIA、LEARNING、NOIS SIGNAL 、SIGNAL WEAK.
- ALM ON/OFF :ON ,OFF
- ALM LEV :HIGH ,MED, LOW
    - ALM REC :ON/OFF
    - ARR ALM QUICK SETUP :The alarm fully open, the alarm fully closed, the record fully open, to record fully closed, the alarm level. The user can select the alarm fully open various arrhythmia alarm is set to "On", select "Alarm full off various arrhythmia alarm set to" Off ". Similarly, the record fully open "alarm record switch can be all set to" On ", the The record fully closed alarm record switch can be all set to" Off ".
- ARR RECALL(Arrhythmia Recall): Select this option and you can view and edit the patient's arrhythmia information.

The latest saved arrhythmia events are listed in the window (one page can show 10 events and at most 6 pages can display).

Press or to observe the list of arrhythmia events in other pages.

Cursor Movement: to move the cursor to select the arrhythmia events in the list.


Figure9-8Arrhythmia EventsReview


Figure9-9 Arrhythmia Waveform Review

**'Attention'**

**In the event that the number of arrhythmia event is more than 200, the monitor will retain the latest instead of the earliest. As for the monitor with the power-fail saving function, it can save 200 arrhythmia events with power-fail.**

PVCs Alarm Message and Prompt Message**:**

When the alarm record switch in the related menu is turned on, the physical alarm arising out of that the parameters exceeds the alarm limit will make the recorder automatically output the alarm parameter values and related waveforms.

The physical alarm and technical alarm that may happen in PVCs parameter measurement are listed in

the following table.

Physical alarms:

| Prompt Message | Causes | Alarm Level |
|---|---|---|
| PVCs too high | PVCs measured value is above the set alarm upper limit. | Selectable by users |

Technical alarms

| prompt message | Causes | Alarm Level | Solutions |
|---|---|---|---|
| PVCs alarm limit is wrong. | Function safety failure | High | Stop use of PVCs alarm and advise the biomedicine engineer or our company's servicemen. |

# Chapter 10RESP Measurement

## 10.1 Measure RESP

### 10.1.1 How to measure RESP

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

### 10.1.2 Setting of RESP monitoring

For RESP monitoring, no additional electrodes are required, but how to install electrode is critical. For some patients, especially with clinical condition that negative breast internal pressure will be generated if their breast is horizontal expanded. In that case, users should put the two RESP electrodes respectively at middle line of the right axilla and left side to the breast, where there are largest activities during respiration, so as to obtain the best RESP wave.

> **″Attention′**
> **RESP monitoring is not applicable for patients with active activities otherwise may generate wrong alarms.**

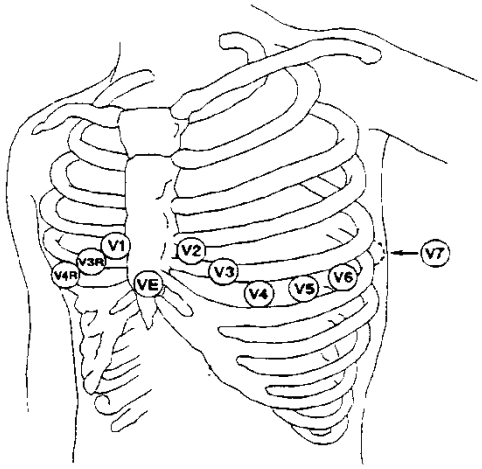
RESP monitoring checks:

Take patient skin preparation before installation of electrodes;

Install spring clamp or snap for electrodes, and follow the later-introduced method to install electrodes on patient body;

Turn on power supply for the monitor system.

Install electrodes for RESP monitoring




**′Attention′**

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

## 10.2 RESP Setting menu (RESTP SETUP)

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

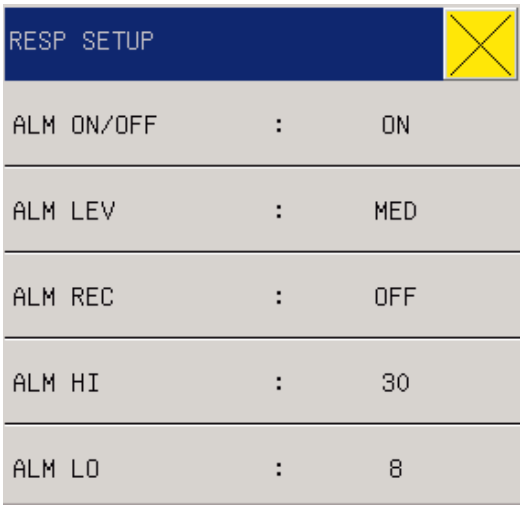



Figure10-1 RESPSetup

1. Alarm ON/OFF: select the “ON” and the alarm prompt and saving will proceed during RR alarm; select the “OFF” and “ ” will be prompted beside RESP in the screen parameter area.

2. Alarm lever: “High”, “Middle” and “Low”.
3. Alarm record: If users select “On”, upon RESP alarming, the recorder will output the alarm.
4. Alarm levels: High, MED or Low to be selected, and High for the most serious alarm.
5. Alarm HI: used to be set with the upper limit for RR alarm.
6. Alarm LO: used to be set with the alarm lower limit.

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

Adjustable range of RESP alarm upper & lower limits:

| | Max upper limit | Min lower limit | Adjusted amount per time |
|---|---|---|---|
| RR infant/ newborn | 150 | 6 | 1 |

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

## 10.3 RESP setting in waveform area

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

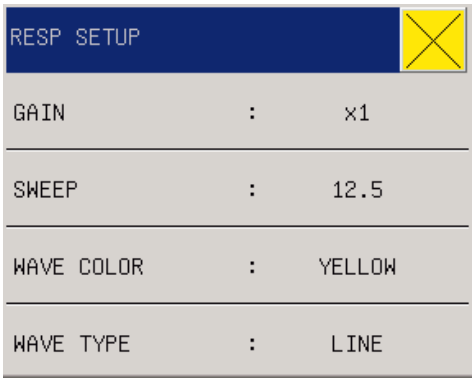



Figure10-2RESP Setup

- GAIN(Waveform amplitude): Users can set enlarged display of RESP waveforms under five optional enlargement rates: ×0.25, ×0.5, ×1, × 2 and ×4.
- SWEEP(Waveform speed): Three optional speeds, 6.25mm/s, 12.5mm/s and 25.0mm/s
- WAVE COLOR: green, cyan, red, yellow, white, blue, violet.
- WAVE TYPE : LINE or FILL

## 10.4 RESP setting in measurements

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

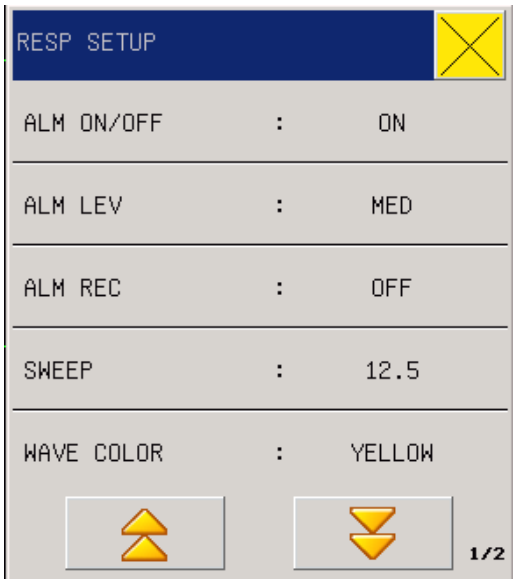



Figure 10-3 RESP Alarm Setup

1. ALM ON/OFF: see reference in RESP Setting menu
2. ALM LEV: see reference in RESP Setting menu
3. ALM REC:see reference in RESP Setting menu
4. SWEEP: Waveform speed, Three optional speeds, 6.25mm/s, 12.5mm/s and 25.0mm/s
5. WAVE COLOR: see reference in RESP Setting menu
6. RR Gain: Users can set enlarged display of RESP waveforms under four optional enlargement rates: 0.25, 0.5, 1.0, 2.0 and 4.0.
7. APNEA ALM :Set the time dignosing a patient suffocation .NO , 1s ,2s ,5s ,10s ,15s ,20s, 25s ,30s ,35s ,40s.
7. ALM HI: used to be set with the upper limit for RR alarm.
8. ALM LO: used to be set with the alarm lower limit.
9. DEFAULT:Select this option to enter "default configuration" dialog box, select the "Yes", that is, using the default default configuration, the original configuration will be overwritten, select "No" to abandon the current operation, the system remains the original configuration unchanged

## 10.5 Maintenance & Cleaning

## Note and Cleaning

**Warning**

**Before cleaning the monitor or sensor, users must turn of the equipment and break the**

**AC power supply. In case of any appearance of ECG cable damage or aging, users should change with new cables.**

**Cleaning**

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

**Disinfection**

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

Recommended disinfection materials for the monitor:
Ethanol: 70% alcohol, 70% isopropyl
Glyoxyl

**Sterilization**

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

# Chapter 11SpO2 Monitoring

## 11.1 Definition of SpO2 Monitoring

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

### 11.1.1 Principle for Measurement of $SpO_2$ Volume Recording Parameter

BOS (blood oxygen saturation) is measured and determined in the method of pulse oximetry, which is a method of measuring and determining the oxyhemoglobin saturation continuously and without any hurt, mainly used to measure and determine how many rays from the light source of the sensor penetrate the patient's tissue (such as fingers or ears) and reach another receiver.

As for the wave length measurable by the sensor, generally the red LED is 660nm and the infrared LED, 940nm. The maximum selectable output power of LED is 4mW.

The number of penetrated rays rests with many factors where most are constant, but one of these factors means the arterial flow changes through time because it is pulsant. The arterialized blood's BOS can be obtained through measurement of absorbed rays during pulsation. A "volume recording" waveform and PR signal can be given through detection of pulsation.

"SpO2" value and "Volume Recording" waveform can display on the main screen.

**Warning**

**Where there is carboxyhemoglobin, ferrihemoglobin ordye dilution chemicals, SpO2 value will have a deviation.**

### 11.1.2 BOS/Pulse Monitoring

**Warning**

**The cable for the equipment of electrosurgery can't be twisted together with the sensor cable.**

**Warning**

**Please don't place the senor on the limb with arterial duct or vein injection syringe.**

**'Attention'**

**Please don't place $SpO_2$ detector and cover on the same limb for measurement of blood pressure, because in the course of measuring blood pressure the vascular obstruction will affect the BOS reading.**

## 11.2 Precautions in $SpO_2$/Pulse Monitoring

**'Attention'**

**Guarantee the nail can shut out the light.**

**The detector cable should be fixed on the back of hand.**

**'Attention'**

**SpO2 value always displays at the fixed place.**

**Only in the following cases PR will appear:**

- In ECG menu, set "HR Source" as SPO2 or all.
- In ECG menu, set "HR Source" as "AUTO" and there is no ECG signal at this time.

**'Attention'**

**$SpO_2$ waveform and pulse are out of proportion.**

**Warning**

**Prior to monitoring, the first inspection should be given to whether the sensor cable is normal. SpO2 sensor cable being pulled out of the jack, the screen will display the "Sensor Off" mistaken information, and trigger the sound alarm.**

**Warning**

**Where the sensor packing or the sensor has the sign of damage, please don't use this $SpO_2$ sensor, but return it to the manufacturer.**

**Warning**

**Continuous and overlong monitoring may increase the undesirable dangers that skin features change, such as extraordinary sensitivity, reddening, blistering or pressure necrosis, which are especially easy to happen to the newborns or the patients with perfusion disorder or immature skin. In such a case special attention should be given to aiming the correct beam path at detection of sensor position according to the change of skin quality. Regular inspection should also be given to the laid-on position of sensor and the change of such a position when the skin quality goes worse. It is possible to require for the more frequent inspection due to different patient status.**

## 11.3 Monitoring Procedures

**(1)$SpO_2$ volume recording measurement**:

Turn on the monitor;

Paste the sensor on a proper position of the patient finger;

Insert the connector at the other side of the sensor cable into the $SpO_2$ hole of the$SpO_2$ module.

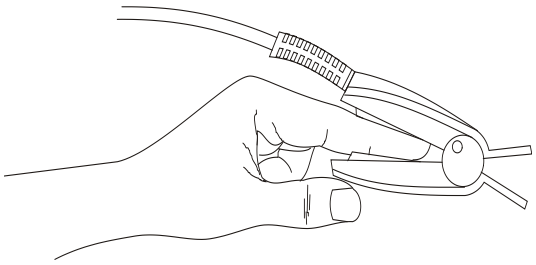


Figure 11-1 placement of senseor

**(2)Neonate $SPO_2$ measurements**

The measurement method for neonate is almost the same with adult, the sensor is introduced below.

1. neonate $SPO_2$ sensor

Neonate $SPO_2$ sensor includes Y type $SPO_2$sensor and $SPO_2$sensor jacket, put the LED end of Y type $SPO_2$sensor into the $SPO_2$sensor jacket, refer to the Figure below

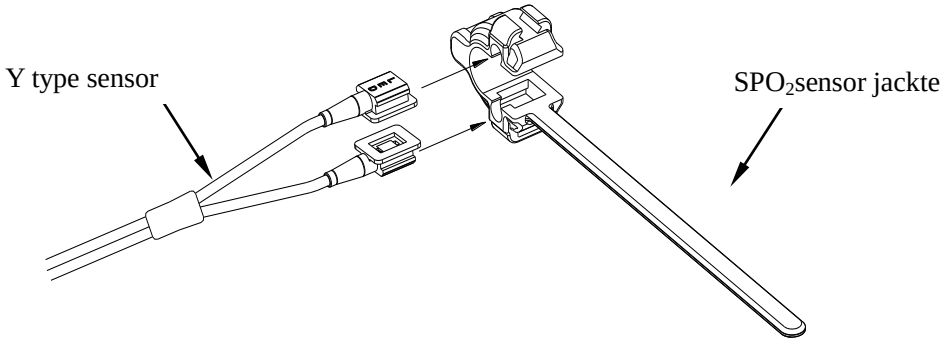



Figure 11-2 neonate $SPO_2$ sensor（1）

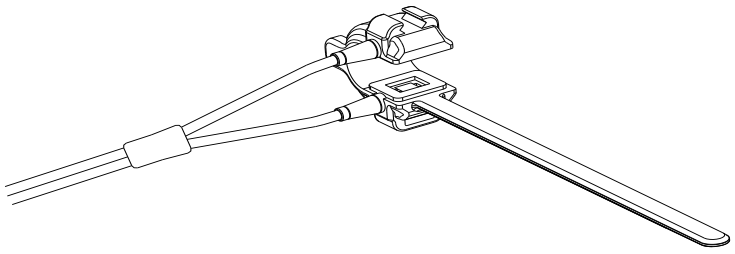


Figure 11-3 neonate $SPO_2$ sensor（2）

2. The placement for the neonatal $SPO_2$ sensor

Put the neonatal $SPO_2$ sensor on hand or foot of neonate patients (Figure11-4). Fix the $SPO_2$ sensor in the right position.

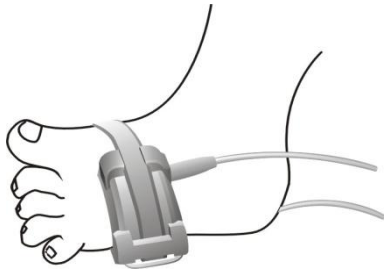
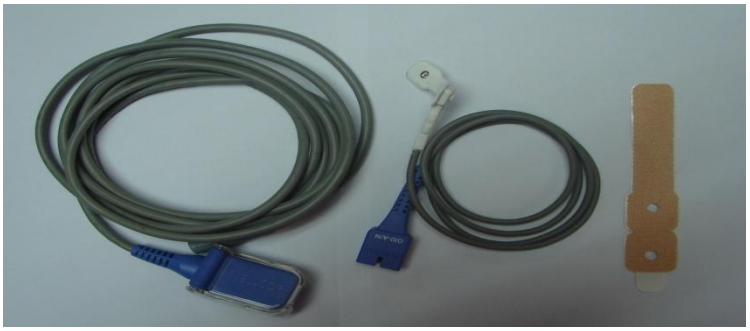


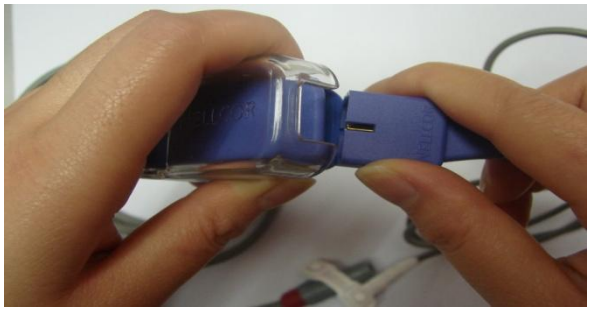
Figure 11-4 The placement for the neonatal $SPO_2$ sensor

**(3)Nellcor SpO2**

NELLCOR SpO2 transducer is consist of Nellcor SpO2 connection cable, Nellcor infant SpO2 sensor, and wraps, as picture shown:

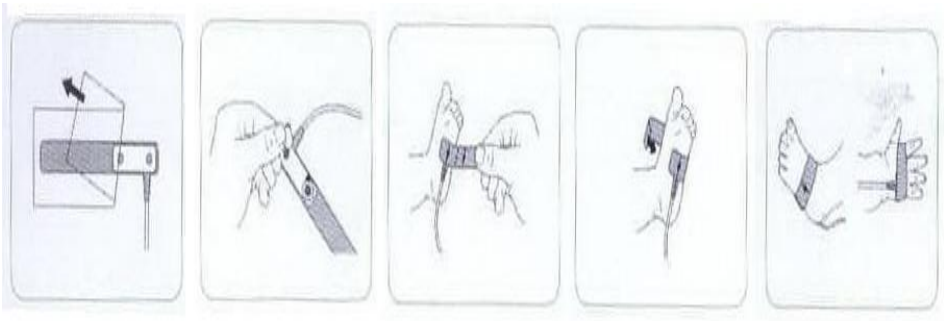


Consist of Nellocr SpO2



Connection between extension cable and sensor

Fix Nellcor SpO2 sensor



## 11.4 Measurement restriction

**Measurement restriction**

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

- High-frequency electric disturbance, such as disturbance generated from the system itself or electrosurgery equipments connected with the system;
- A photo-oximeter and $SPO_2$ sensor are used during MRI process, as the inductive current may cause burns;
- Intravenous Dye;
- Frequent movement by patient;
- Light radiation from outside;
- Improper installation of the sensor or improper touching position with objects;
- Improper sensor temperature (ideal temperature should be 28℃-42℃);
- The sensor is put onto body with blood pressure cuff, arterial duct or vein tube;
- Contents of non-functional Hb such as COHb and MetHb;
- $SPO_2$ over low;
- Bad microvascular perfusion at the test position;
- Shock, anemia, low temperature and application of vessel shrinking medicines, which all can reduce the arterial blood flow to a non-measurable level;
- Measurement is also up to absorption of lights with special wavelengths by oxyhemoglobin and deoxygenated hemoglobin. Existence of other materials that absorbs the same wavelengths, such as carbonated hemoglobin, hemoglobin, methylene blue and indi carmine, will make artificial or low $SPO_2$ values.
- $SPO_2$ sensor introduced in the accessory is recommended.

## 11.5 $SpO_2$ Setting menu

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

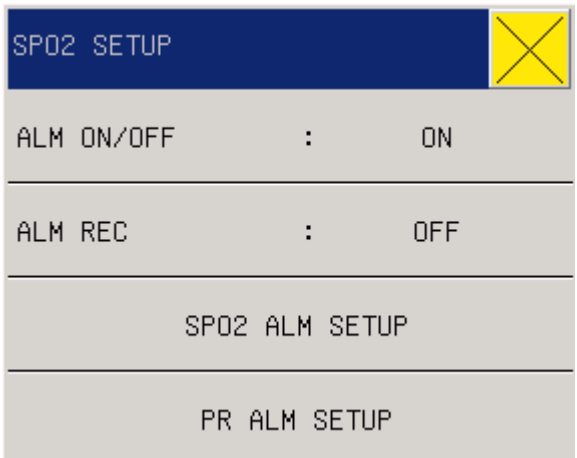



Figure11-5$SPO_2$Setup

**Warning**

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

- Alarm ON/OFF: Where "ON" is selected, the alarm prompt and saving will proceed when SpO2 (BOS) is alarmed; where "OFF" is selected, alarming will not happen, but  will be prompted beside SpO2 in the screen parameter area.
- Alarm level: used to set alarm levels and, during SpO2 alarming, for alarm reminder and saving. Options include "High", "Middle", and "Low"; "High" for the most serious alarm.(This feature is only effective NELLCOR blood-oxygen)
- Alarm record: If "On" is selected, the recorder will output during SpO2 alarming.
- SPO2 ALM SETUP:setup SPO2 hight limit ,middle limit ,low limit of the upper and lower limits .( If the monitor SPO2 is NELLCOR, setup alarm limit, have not hight limit ,middle limit ,low limit )
- PR ALM SETUP: setup pulse rate hight limit ,middle limit ,low limit of the upper and lower limits . ( If the monitor SPO2 is NELLCOR, setup alarm limit, have not hight limit ,middle limit ,low limit )

Masimo SPO2 can can automatically identify the hardware inside the machine , the following featuea is only effective Masimo blood-oxygen , is unchangeable items.

- DSP VERSION:2.0.1.7
- HARD VERSION:0.1.0.1
- PRODUCT ID:0.0.0.1
- MCU VERSION:0.0.0.0
- SENSOR TYPE: no sensor

$SpO_2$& PR adjustable limits:

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

## 11.6 SPO2 setting in waveform area

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

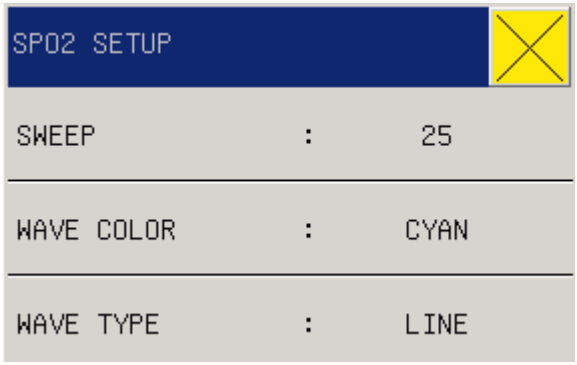



Figure11-6 $SPO_2$Setting

- SWEEP: Waveform Speed, the scanning speed of $SpO_2$ volume recording waveform is provided with 12.5 and 25.0mm/s for option.
- Waveform Colour: green, cyan, red, yellow, white, blue, violet.
- Wave type: line or filled.(Masimo SPO2 have not the feature)

## 11.7 SpO2 Setting in measurement menu


Figure 11-7 SPO2 setup

- ALM ON/OFF: see the content of this chapter parameter area the SPO2 set the “ALM ON/OFF”
- ALM LEV: see the content of this chapter parameter area the SPO2 set " ALM LEV ".(This feature is only effective NELLCOR oxygen)
- ALM REC: see this chapter parameter area the SPO2 set “ALM REC”.
- SWEEP: see this chapter waveform area the SPO2 set "SWEEP”.
- WAVE COLOR:.see this chapter waveform area the SPO2 set "WAVE COLOR”

- Apnea alarm：1,2,5,10,20,25,30,35,40 not alarm. This setting, monitor patients detected asphyxia, how long instrument alarm signal.
- Satsecond ： 10, 25, 50, 100 seconds, disable, for example, intelligent alarm range is set to 50, then when NELLCOR oximeter alarm limit 97, and the lower limit is 90, and the measured oxygen value is 99, then from exceeding the alarm limit commences consecutive exceeds the alarm limit of 25 seconds as soon as they sound and light alarm at the same time the oxygen values next to the circle and draw back to square one. The intelligent alarm to reduce false alarms, allow doctors to more accurate and timely master oxygen changes. (This feature is only effective NELLCOR blood-oxygen)
- SAMARTTONE:On, Off. When this menu is started, "signaling" and "pulse audio" are simultaneously turned on, they can be smartly managed. However, turning off the menu can't manage these two. (This feature is only available on the Masimo blood-oxygen)
- SIGNAL IQ:Turning on and off.When it is turned on, below the $SPO_2$ waveform, there is a logo for signal collection, which is mainly reflecting the quality of the signal during the acquisition process. The signal disappears as it is turned off. (This feature is only available on the Masimo blood-oxygen)
- BEEP:on, off. Turning on the pulse sound, you can get a prompt of PULSE (pulse) sound. No PULSE (pulse) sound prompt as it is turning off. (This feature is only available on the Masimo blood-oxygen)
- FAST SAT: On, Off. When you start the rapid blood-oxygen measurements, you can choose "on ", also "off" not using this feature. (This feature is only available on the Masimo blood-oxygen)
- AVE TIME(S):2-4, 4-6, 8s, 10s, 12s, 14s, 16s. The average time, $SPO_2$ value displayed on the monitor, is the result of averaged data collected during a period of time. The shorter the average time, then the faster is the monitors response to the patient's $SPO_2$ value changes, but lower measurement accuracy. Conversely, the longer it is, the more slowly the monitors response to the patient's $SPO_2$ value changes, but the higher the measurement accuracy will be. In the care of critically ill patients, to set a smaller average time is beneficial to the immediate analysis of the disease. (This feature is only available on the Masimo blood-oxygen)
- SENSITIVE:normal, sensitive, APOD. According to the level, "APOD" has the highest sensitivity. For typical patient monitoring, use the "normal" sensitivity. As for those patients who have moist skin, active exercise, or for other reasons, the probe may be dropped off a patient's body, then use the "sensitive " sensitivity. If the patient has very low perfusion levels and wants to improve the sensitivity performance, please use the "APOD "sensitivity. (This feature is only available on the Masimo blood-oxygen)
- SPO2 ALM SETUP: see the content of this chapter parameter area the SPO2 set alarm settings.
- PR ALM SETUP: see the content of this chapter parameter area the SPO2 set alarm settings.
- DEFAULT: Select this option to enter the the SPO2 default configuration dialog box, the user can choose "yes" or "no" to "will be the default configuration" or "original configuration will be set.

## 11.8 Alarms & Reminders

### $SpO_2$ alarm information

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

## 11.9 Maintenance & Cleaning

⚠**Warning**⚠

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

⚠**Careful**⚠

**Please don't sterilize the senor with pressure.**
**Please don't soak the sensor in the liquid.**
**Use of the senor or cable is prohibited if they are damaged or degenerated.**

**Cleaning:**

Having cleansed the surface of the sensor with the cotton ball or cotton cloth soaked with medical alcohol, dry it with the dry cloth. The luminotron and receiver of the sensor can be cleaned in the same method. The cable can be cleaned and sterilized with 3% of hydrogen peroxide or 70% of isopropyl alcohol. Active reagent can also be used for this purpose. However, the joint can't be soaked in the above solution.

# Chapter 12NIBP Monitoring

## 12.1 General Information

NIBP measurement can be performed in the oscillation method;
It can be used in adults, children and newborns;
Measurement mode: manual, automatic and continuous measurement. Each mode can show NS, NM and ND.

- □ "Manual" mode: measurement can only be done once.
- □ "Auto" mode: measurement can be repeated. The interval time can be set as 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes.
- □ "Continuous" mode: measurement can continuously be done within 5 minutes.

**⚠Warning⚠**

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

## 12.2 NIBP Monitoring

### 12.2.1 NlBP Measurement

**⚠Warning⚠**

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

**⚠Warning⚠**

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

1. Insert the pumping pipe into the interface of a blood pressure cuff and turn on the power supply.
2. In accordance with the following method (Pic 14-1), tie the blood pressure cuff on upper arm of upper leg of a patient.
   - Confirm the cuff is fully vented.

Select a cuff in proper size for the patient, and make sure the mark is just along the proper vein and cuff tie the body non-toughly, otherwise remote body part may have color change or even ischaemia.

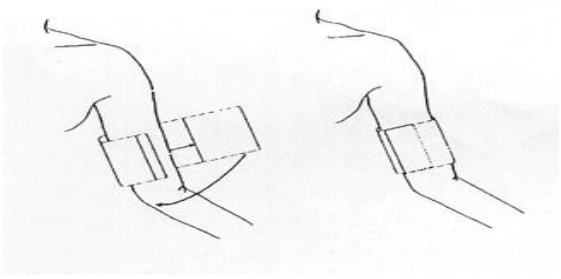
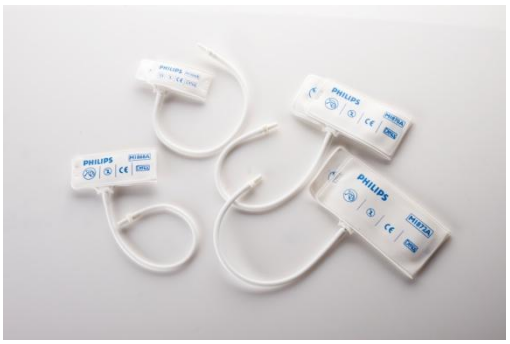


Figure12-1Use of a Cuff

## Neonate NIBP cuff

Different four size of Philips NIBP cuff for neonate monitoring




**'Attention'**

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

NeonateReusable NIBP cuff

| Patient Type | Body Perimeter | Cuff width | NIBP extension air tube |
|---|---|---|---|
| Neonate | 10 ~19 cm | 8 cm | 1.5 m or 2m |
| Leg | 46 ~ 66 cm | 21 cm | |

neonateone-time cuff：

| size | Circular of arm | Cuff width | Tube length |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 1 | 3.1 ~ 5.7 cm | 2.5 cm | 1.5 m or 3 m |
| 2 | 4.3 ~ 8.0 cm | 3.2 cm | |
| 3 | 5.8 ~ 10.9 cm | 4.3 cm | |
| 4 | 7.1 ~ 13.1 cm | 5.1 cm | |

3. Check the cuff edges are between the "<->" marks; otherwise users should change with a more proper cuff.

4. Connect the cuff with a pumping pipe. Make sure the body part used for pressure measurement is at the same horizontal level with patient heart, and if failing to realize this, users should apply the following correction method to correct the measurement results:

- In case horizontal level of cuff is higher than that of heart, add 0.75mmHg (0.10kPa) onto the displayed value for each cm difference.
- In case horizontal level of cuff is lower than that of heart, deduct 0.75mmHg (0.10kPa) onto the displayed value for each cm difference.

5. Confirm correctness of the monitoring mode (as displayed on the information area); if requiring to change the monitoring mode, users need go to the "Patient Information Setting" item under the Main menu and change "Patient Type".

6. Select the measurement mode under the NIBP menu. Refer to the following Operational Guide for details.

7. Press the START button on the front panel to start pressure measurement.

**Operational guide**

■ Conduct one time of Automatic measurement

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

**⚠Warning⚠**

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

■ Stop automatic measurement

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

■ Conduct one time of manual measurement

Enter the "NIBP Setting" menu, select the "Time Interval" item and set its value as "Manual", then

press the START/STOP button on the front panel so as to start manual measurement.
During spare time of an automatic measurement, press the START/STOP button will start a manual measurement; then if users press the START/STOP button again, the manual measurement will stop and the automatic measurement will continue.

- Conduct a manual measurement during automatic measurement process

Just press the START/STOP button on the control panel.

- Stop a manual measurement

Re-press the START/STOP button on the control panel.

- Conduct a continuous measurement

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

⚠**Warning**⚠

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

- Stop continuous measurement

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

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

⚠**Warning**⚠

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

**Measurement restriction**

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

measurement to be continued.

- Patient movement

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

- Arrhythmia

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

- Heart-lung machine

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

- Pressure change

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

- Serious shock

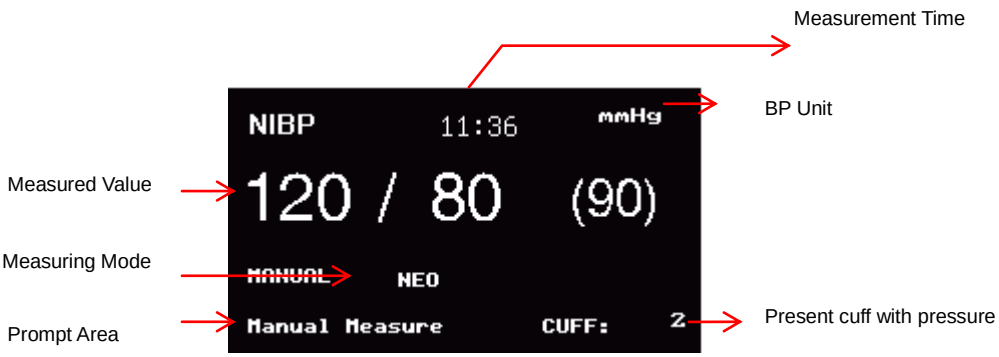
  In case a patient is under serious shock or extreme low temperature, measurement will be unreliable as reduction in blood flowing peripherally will result reduction in arterial pulse.

- HR limits

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

## 12.2.2 NIBP Parameter Setting & Adjustment

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




## 12.3 NIBP setting in parameter area

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

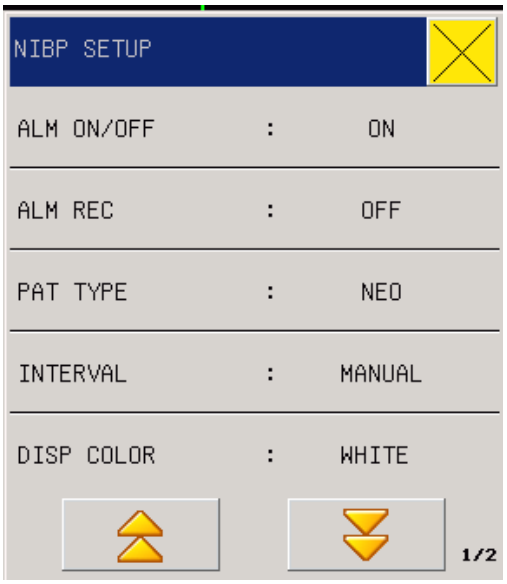



Figure12-2NIBP Setup

- Alarm switch: Where “ON” is selected, the alarm prompt and saving will proceed when the pressure is alarmed; where “OFF” is selected, alarming will not happen, but  will be prompted beside NIBP in the screen parameter area.
- Alarm record: Users can select “On” to output through recorder when blood pressure alarms happen
- Patient type： neonate
- INTERVAL: MANUAL and auto(1min, 2min , 3min, 4min, 5min ,10min ,15min ,30 min ,60min ,90min ,120min ,180 min ,240 min ,480min)
- Display Colour: green, cyan, red, yellow, white, blue, violet.
- NIBP SYS / NIBP MEA / NIBP DIA ALM STEUP: set the valve of NS ,NM ,ND high limit ,middle limit ,low limit

  Neonate:

  NS: upper limit: 42-135 mmHg lower limit: 40-133 mmHg

  ND: upper limit:12-95mmHg lower limit:10-93 mmHg

  NM: upper limit:22-110 mmHg lower limit:22-108 mmHg

## 12.4 NIBP setting in measurements

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

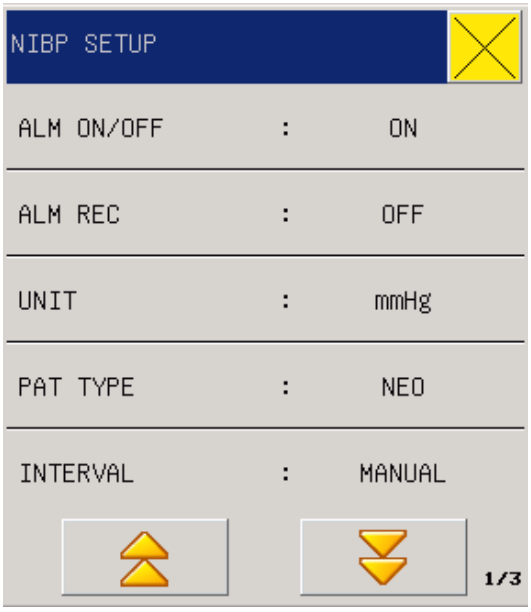



Figure12-3NIBP Setup

- Alarm ON/OFF: Where “ON” is selected, the alarm prompt and saving will proceed when the pressure is alarmed; where “OFF” is selected, alarming will not happen, but  will be prompted beside NIBP in the screen parameter area.
- Alarm record: Users can select “On” to output through recorder when blood pressure alarms happen
- Unit: mmHg/kPa
- Patient type： neonate
- Interval: Time interval (Unit: minute) for automatic measurement: 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240, 480 minutes, Manual, and Continuous. After users select an interval, there will be a display of “Please press the ‘START/STOP’ button” in the NIBP reminder area, then users just press the button to start pumping for the first time of automatic measurement. To end the automatic measurement and return to the manual mode, users need only select “Manual” during the measurement interval.
- DISP Colour: green, cyan, red, yellow, white, blue, violet.
- NIBP SYS / NIBP MEA / NIBP DIA ALM STEUP: set the valve of NS ,NM ,ND high limit ,middle limit ,low limit.
- RESET : reset of measuring status of blood pressure pump. Press the reset button, the inflated value of blood pressure pump will recover the initial settings. When blood pressure pump is not working properly but the monitor does not question why, this is the recommended key. Because it allows self checking of blood pressure pumps, allowing automatic recovery of pump exception due to some accident.
- CONTINAL : After select continuous measurement, the menu will disappear automatically and continuous measurement starts immediately; If you want to stop it, press the key of blood pressure measurement on the shell.

- CALIBRATE : (pressure calibration); For calibration of NIBP pressure, it should be carried out at least every two years or when do you think the value is not accurate.
- PENUMATIC(Leak detection):For detecting the closed conditions of NIBP gas path.
- DEFAULT: Select this item to enter "NIBP default settings" dialog box, the user can choose "no" or "Yes" to exit or select "the default configuration is to be used, the original configuration will be overwritten."

## Calibration

The manufacturer recommends to use pressure meter or mercurial sphygmomanometer with calibrated precision higher than 1mmHg for calibration. Users can select the Calibration item to start calibration, while this item turns to be "Stop calibration"; if at such moment press the button, the system will stop calibration.

⚠**Warning**⚠

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

### 1) Calibration procedures of a pressure sensor:

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

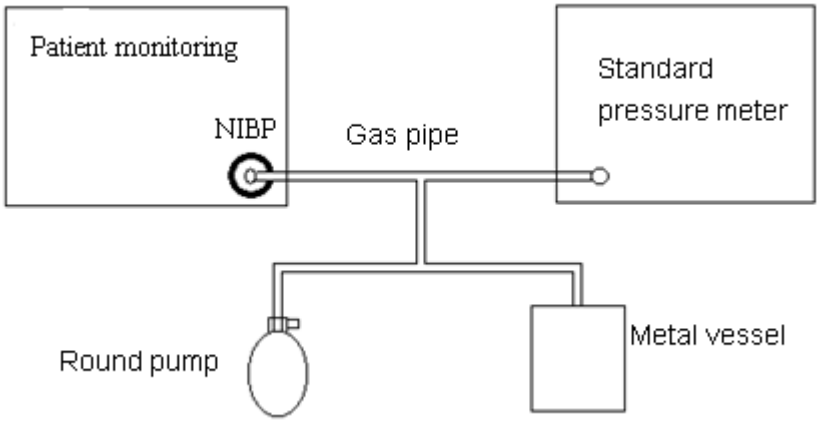



Figure 12-4 Connection for NIBP calibration

Gas leakage detection

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

reminder, otherwise there will be the corresponding error reminder in the NIBP information area.

Default Setting

Users can select this item to enter the "NIBP Default Setting" dialogue box, then further select "Manufacturer Default" or "User Default". After making a selection, the system will eject a dialog box for confirmation of selection by users.

⚠**Warning**⚠

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

## 2) Gas leakage detection process:

Properly connect the cuff with the NIBP hole of the monitor.

Wrap the cuff onto a column body in proper size.

Enter the "NIBP Setting" menu

Rotate the knob, move the cursor onto the "Gas Leakage Detection" item, then press the knob. There will be a reminder of "Gas leakage detection in progress" at bottom of the NIBP parameter area of the screen, meaning the system has started executing gas leakage detection

The system automatically pumps to the pressure of 180mmHg.

In about 20 seconds, the system will automatically open the air bleeder, indicating completion of gas leakage measurement.

No reminder information displaying on the NIBP parameter area doesn't mean no gas leakage within the system. Display of "Pump leaking…" means there is possible gas leakage with the gas route, in such case operators should check whether there is any loose connection, and after making sure of no more loose connection re-do the gas leakage detection; if the error reminder is still displayed, please contact with the manufacturer for repair

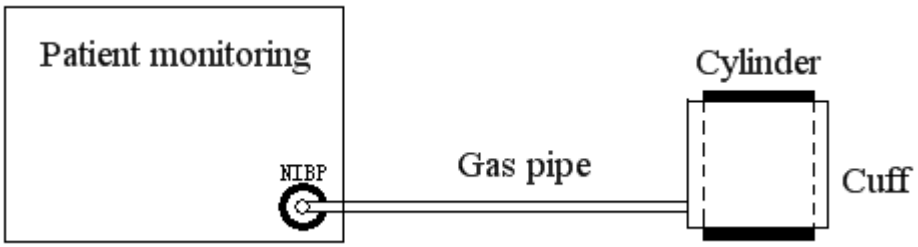



Figure 12-5 Connection for NIBP Gas Leakage Detection

# 12.5 NIBP alarm information

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

alarming parameter values and the relevant measurement waveforms. The following table lists various possible alarms during NIBP measurement process.

Physical alarms:

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

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

| Reminders | Causes | Alarming levels | Solution |
|---|---|---|---|
| NS alarming limit error | Function/ safety failure | High | Stop using the NIBP module alarming function and inform biochemical engineers or our maintenance team |
| NM alarming limit error | Function/ safety failure | High | Stop using the NIBP module alarming function and inform biochemical engineers or our maintenance team |
| ND alarming limit error | Function/ safety failure | High | Stop using the NIBP module alarming function and inform biochemical engineers or our maintenance team |

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

| Reminders | Causes | Alarming levels | Solution |
|---|---|---|---|
| NIBP self-detection error | Sensor or other hardware failure | High | Stop using the NIBP measurement function and inform biochemical engineers or our maintenance team |
| NIBP communication error | Communication failure with NIBP measurement module | High | If the failure continues, stop using the NIBP measurement function and inform biochemical engineers or our maintenance team |
| Cuff loose or out of connection | Cuff isn't properly wrapped or no cuff | Low | Wrap the cuff properly |
| Gas leakage with cuff pumping pipe | Damage with cuff, pipe or connector | Low | Check and change the part with leakage, and if necessary also inform biochemical engineers or our maintenance team |
| Air pressure error | Fail to obtain stable pressure value, e.g., because of pipe wrapping | Low | Check whether there is pipe wrapping; if the problem continuous, inform biochemical engineers or our maintenance team |
| Signal too weak | Cuff too loose | Low | Apply other methods to measure blood |

| | | | |
|---|---|---|---|
| | or patient pulse too weak | | pressure |
| Pressure out of scope | Measurement scope exceeding specified upper limit | High | Reset the NIBP measurement module; and if the problem continuous, stop using the NIBP measurement module and inform biochemical engineers or our maintenance team |
| Arm movement | Big signal noise or irregular PR due to arm movement | Low | Make sure the patient is silent, without movement |
| Overpressure protection | Pressure exceeding specified upper limit | High | Re-measure. If the problem continuous, stop using the NIBP measurement module and inform biochemical engineers or our maintenance team |
| Signal saturation | Significant movement | Low | Stop the patient from movement |
| Pump leakage | Leakage during the leakage test | Low | Check and change the part(s) with leakage, and if necessary, inform biochemical engineers or our maintenance team |
| NIBP system failure | Blood pressure pump system running failure | High | Stop using the NIBP measurement function and inform biochemical engineers or our maintenance team |
| Wrong cuff type | Current cuff type not suitable for patient | Low | Select proper cuff |
| Measurement time out | Measurement time over 120 seconds (for adults) or 90 seconds (for newborns) | High | Re-measure or apply other measurement methods |
| NIBP reset error | Module reset improperly | High | Re-use the reset function |
| Measurement error | During measurement the system can not execute measurement analysis or calculation | High | Check the cuff and re-measure while making sure the patient is silent during monitoring |

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

| Reminders | Causes | Alarming levels |
|---|---|---|
| Manual measurement… | Manual measurement in process | |
| Continuous measurement… | Continuous measurement in process | |
| Automatic measurement… | Automatic measurement in process | |
| Please press START | After you select the measurement time interval | No alarm |
| Measurement stopped | During measurement users press the START button to stop measurement | |
| Calibration… | Calibration in process | |
| Calibration stopped | Calibration completed | |
| Gas leakage detection… | Gas leakage detection in process | |
| Gas leakage detection stopped | Gas leakage detection is stopped | |

| | |
|---|---|
| Module reset… | Reset after NIBP module is loaded |
| Manual reset… | NIBP reset (activated by users) in process |
| Fail to reset | Fail to reset |

## 12.6 Maintenance & Cleaning

⚠**Warning**⚠

**Don’t compress the rubber pipe on a cuff.**

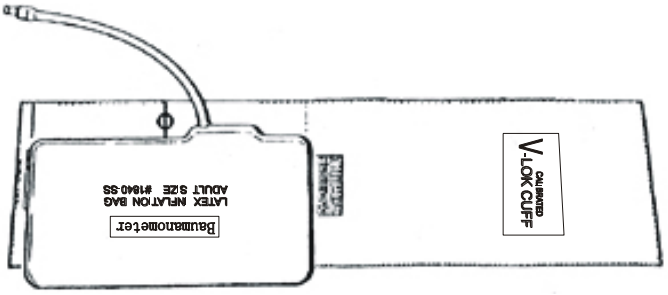
**Keep water or cleaning liquids out of the connector socket in the front of the monitor, otherwise the equipment may be damaged.**

**During monitor cleaning, users need only sweep the outer surface of theconnector socket instead of its inner surface.**

**In case a recyclable cuff is disconnected with the monitor or being cleaned, users should locate the cover cap above the rubber pipe so as to prevent any liquids from entering the rubber pipe and being absorbed into the module.**

### 12.6.1.1 Recyclable blood pressure cuff

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



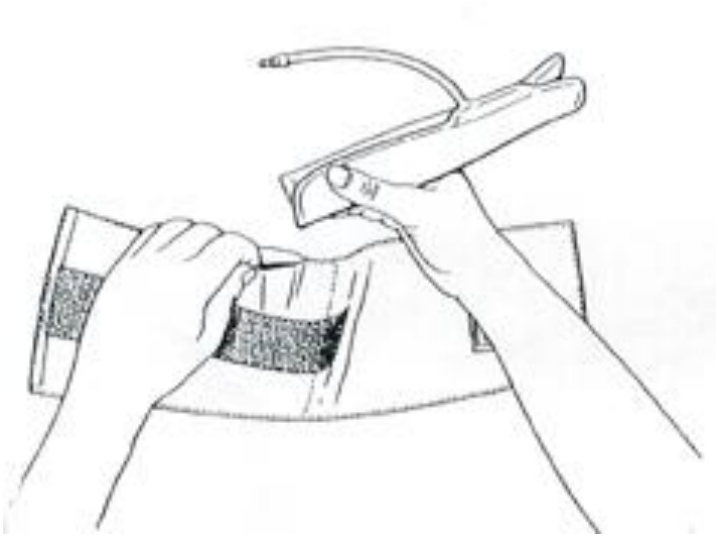


**Figure 13-8 Change the tape inside cuff**

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

#### 12.6.1.2 One-time blood pressure cuff

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

**Caution**

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

# Chapter 13TEMP Monitoring

## 13.1 TEMP Monitoring

The monitor has two TEMP measuring channels. The temperature data can be measured with the TEMP detector.Teperature is not a standard configuration for the neonatal monitor.

### TEMP measurement setting

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

⚠**Warning**⚠

**Before monitoring users should check status of detector cables by plugging out the TEMP detector cable from the hole, then the screen will display the error information "T sensor disconnected" and make voice alarming.**

**′Attention′**

**A one-time TEM detector can only be used once.**

⚠**Warning**⚠

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

⚠**Warning**⚠

**Calibration of a TEMP detector must be done for every two years or comply with your hospital's specified schedule. When requiring calibration, please contact the manufacturer.**

**′Attention′**

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

## 13.2 TEMP setting in parameter area

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

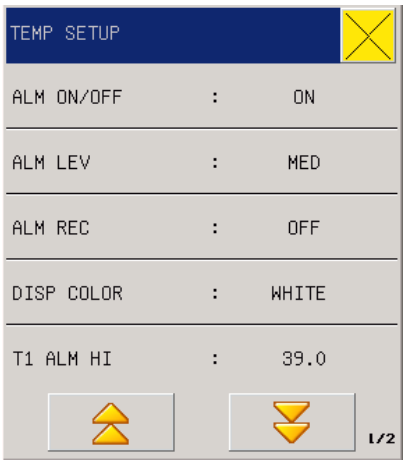



Figure13-1TEMP setting

- Alarm ON/OFF: Select “ON” and the alarm prompt and saving will proceed when TEMP is alarmed; select “OFF” and no alarm will happen, but will be prompted beside TEMP in the screen parameter area.
- Alarm levels: High, Middle or Low to be selected by users to set alarming levels.
- Alarm Record: it is mainly used in starting/closing the output function of TEMP alarm record. If “On” is selected, the present TEMP alarm will be outputted through the recorder.
- Disp Color: green, cyan, red, yellow, white, blue, violet.
- T1\T2 ALM HI/LO: Temperature alarm is set high limit and low limit alarm when the temperature exceeds the high limit or below the lower limit.
- TD ALM HI: Temperature alarm is set high limit when the temperature exceeds the high limit

## 13.3 TEMP setting in measurements

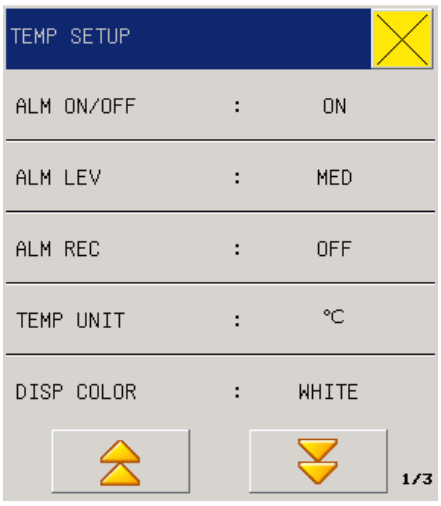



Figure13-2 TEMP setting

- Alarm ON/OFF: Select “ON” and the alarm prompt and saving will proceed when TEMP is alarmed; select “OFF” and no alarm will happen, but will be prompted beside TEMP in the

screen parameter area.

- Alarm levels: High, Middle or Low to be selected by users to set alarming levels.
- Alarm Record: it is mainly used in starting/closing the output function of TEMP alarm record. If "On" is selected, the present TEMP alarm will be outputted through the recorder.
- TEMP unit: ℃ or ℉
- Disp Color: green, cyan, red, yellow, white, blue, violet.
- T1\T2\TD ALM HI/LO: Temperature alarm is set high limit and low limit alarm when the temperature exceeds the high limit or below the lower limit.
- TD ALM HI: Temperature alarm is set high limit when the temperature exceeds the high limit.
- Default: Please refer to the "ECG Default Setting" in the "ECG/TEMP Monitoring".

## 13.4 Alarm information and prompt information

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

## 13.5 Maintenance & Cleaning

⚠**Warning**⚠

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

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

Reusable TEMP detectors:

Heating onto a TEMP detector can not be over 100°C (212°F), as such detector can only undertake 80°C (176°F) --100°C (212°F) within short period.

Detectors can not be vapor disinfected.
Only cleaning agents with alcohol can be used for disinfection.
During use of straight detectors, users should cover them with protective adhesive.

When cleaning detectors, users should use one hand to hold on one end and the other hand to downward hold wet lint-free cloth to wash detectors towards the connector direction.

**′Attention′**

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

**′Attention′**

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

# Chapter 14CO2 Monitoring

## 14.1 General information

Monitor adopts Sidestream and Mainstream CO2 measurement modes. The module measures CO2 pressure (PCO2) to get end-tidal CO2 (EtCO2), inspiratory CO2 (InsCO2) and air way respiration rate (AWRR) and displays pressure waveform of CO2.

**⚠Warning⚠**

**Avoid hit or vibration of carbon dioxide as far as possible.**

**Caution**

**Don’t use the instrument in an environment with inflammables or anesthetic gas.**

**The instrument can only be operated by professionals having received career training and possessed a good knowledge of the Manual.**

Select the “Module Setup” option in the “monitor setup” menu and set the CO2 on-off to be on. The following figure (the present figure is in demonstrating mode) will come out:

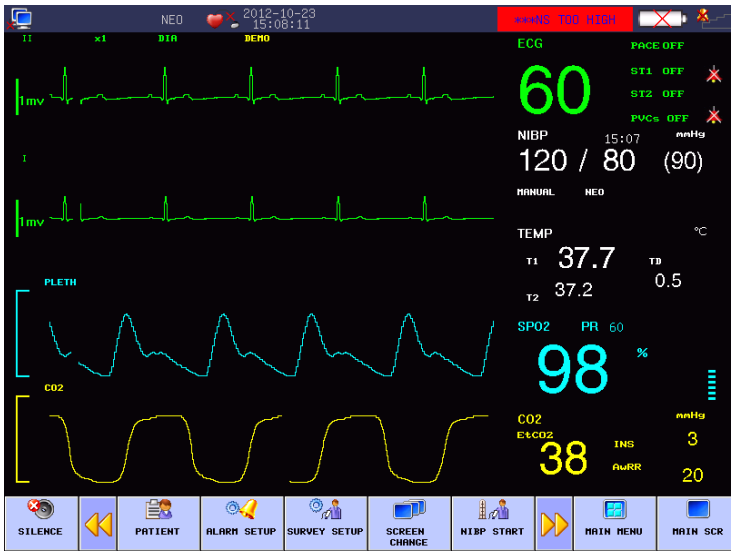



Figure14-1 Main interface of CO2 module

## 14.2 Measuring principle and working procedure

The $CO_2$ measuring principle is mainly based on the characteristic that $CO_2$ can absorb the infrared rays having a wavelength of 4. 3um. The measuring method works as follows:Gaseous $CO_2$ is introduced to a measuring chamber of which one side is irradiated by infrared rays, and sensors are

employed to measure the attenuation degrees of received infrared rays at the other side of the measuring chamber, and the attenuation degree is directly proportional to the $CO_2$ concentrations.

The comparison expression for the conversion between $CO_2$ partial pressure and $CO_2$ concentration is:

$CO_2$ Partial Pressure (mmHg)= $CO_2$ Concentration (%) ¡ÁPamp (Ambient Pressure)

For example:5% $CO_2$ = 38mmHg at 760mmHg

5% $CO_2$ = 35mmHg at 700mmHg

$CO_2$ Module:adopting Autorun instruction measurement mode, and the waveform is sampled once in every 31 milliseconds.

## 14.3 Operating Instruction for $CO_2$ Connection

(1) The schematic of connection of the mainstream module produced by the RESPIRONICS company is shown in the figure below:

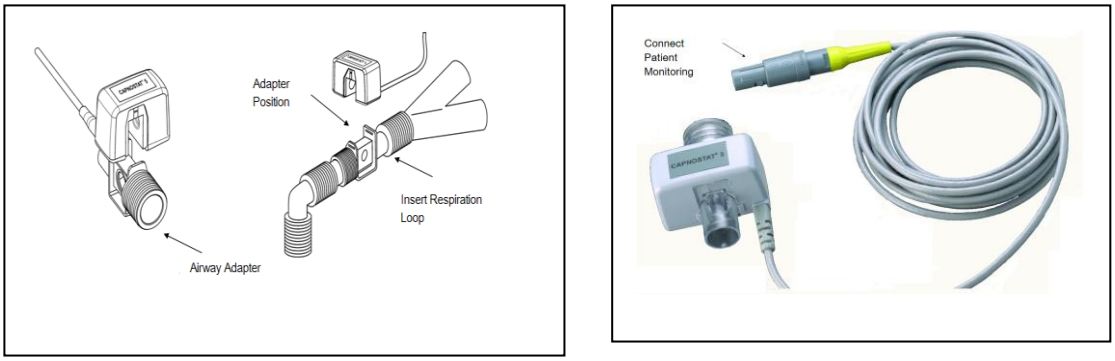
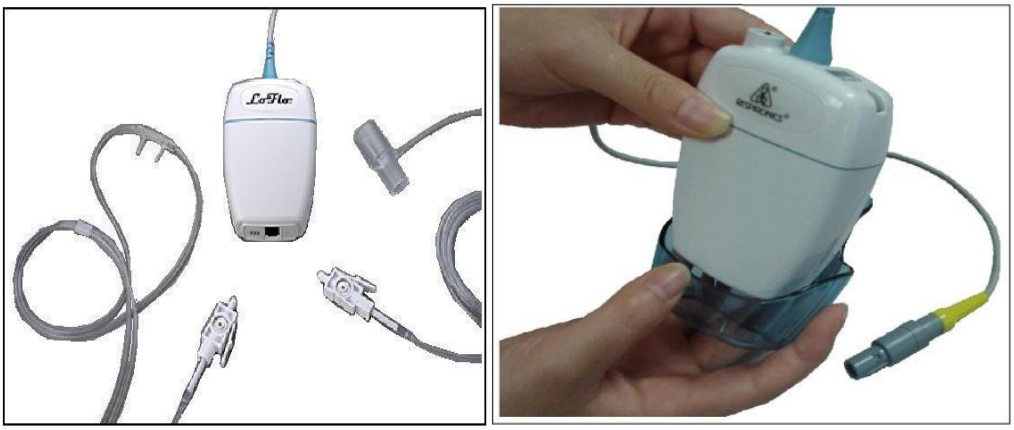



Figure 14-2 Mainstream Mode $CO_2$ Connection

The schematic of connection of the sidestream module produced by the RESPIRONICS company is shown in the figure below:



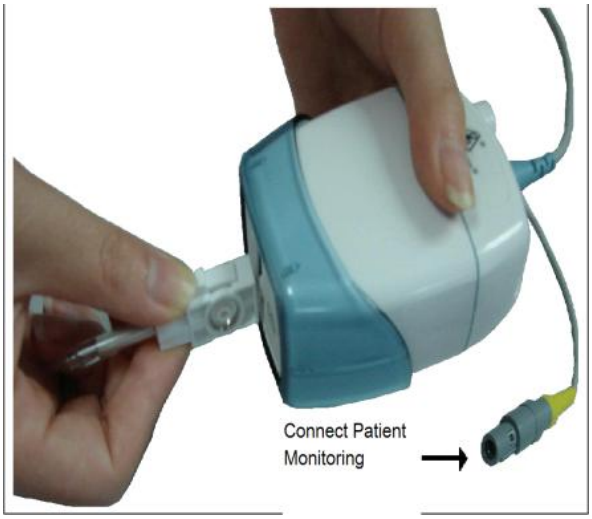



Figure 14-3 Sidestream Mode $CO_2$ Connection Schematic

The schematic of connection of the ISA™sidestream analyzer produced by the PHASEIN company is shown in the figure below:

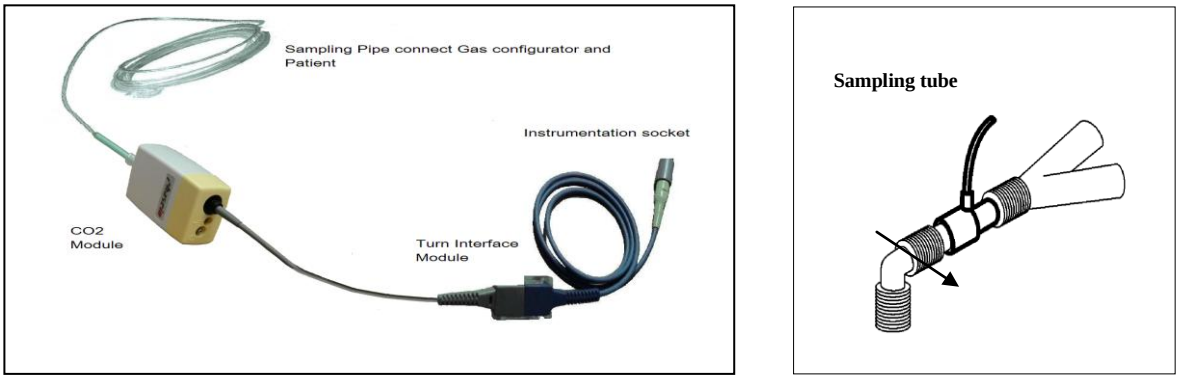



Figure 14-4ISA™ Sidestream Analyzer (ISA $CO_2$) $CO_2$ Connection Schematic

The schematic of connection of the IRMA™ mainstream analyzer produced by the PHASEIN company is shown in the figure below:

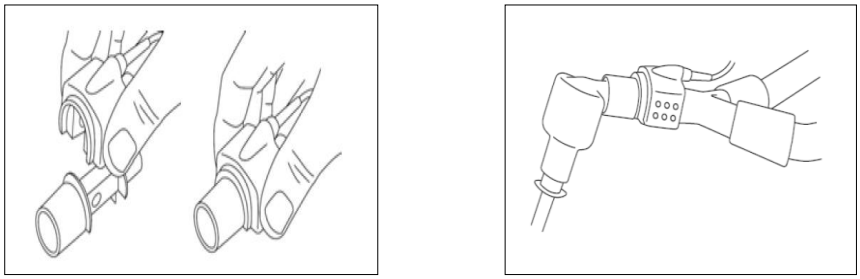


Figure 14-5 IRMA™ Mainstream Analyzer (IRMA $CO_2$) $CO_2$ Connection Schematic

The monitoring equipment produced by this company supports $CO_2$ measurement by using a sidestream or mainstream module produced by the IRONICES company, or an ISA™ sidestream analyzer (ISA $CO_2$ ($CO_2$) CAT. NO. 800101) produced by the PHASEIN company.

**⚠Attention⚠**

**When an ISA™ sidestream analyzer (ISA $CO_2$ ($CO_2$) CAT. NO. 800101) produced by the PHASEIN company is used for monitoring $CO_2$, please refer to the contents of the section titled "17.6 Measuring Procedure and Before-Using Checking" for the measuring procedure, and change the procedure for setting the AG module menu to $CO_2$ menu setting.**

⚠**Warning**⚠

**Before use, please check airway joints. Do not use when visible damage or breaks are found on the airway adapter.**

⚠**Warning**⚠

**When $CO_2$ is not used, it must be turned off, otherwise the $CO_2$ module will be in a working condition all the time**

## 14.4 $CO_2$ Measurement Procedures

Based on different $CO_2$ modules used, determine if it is necessary to set such menu items as "Oxygen Compensation", "Balancing Gas", "Altitude" and "Atmospheric Pressure" etc for the instrument. When an ISA™ sidestream analyzer (ISA $CO_2$ ($CO_2$) CAT. NO. 800101) produced by the PHASEIN company is used, if there are no such settings as altitude and atmospheric pressure etc, it means that such functions have been carried by the module itself, need not to be set manually. Please refer to the instruction manual coming with the module.

If you need the $CO_2$ alarm message function, you can set this function in "$CO_2$ Settings".

## 14.5 Measuring Procedure of RESPIRONICS Branded Mainstream and Sidestream Modules

The RESPIRONICS branded sidestream analyzer operating procedure is roughly the same as the mainstream analyzer operating procedure; please refer to the sidestream analyzer operating procedure for the mainstream analyzer operating procedure.

(1) Start the host monitoring equipment (if a minihost is used, please start the minihost monitoring equipment at the same time).

(2) Or insert the $CO_2$ plug-in module into the host monitoring equipment; the indicator of the $CO_2$ plug-in module will illuminate, which means that the module has been successfully connected to the host monitoring equipment; otherwise, please reinsert the $CO_2$ plug-in module.

(3) Make connections according to the $CO_2$ module type or Figure 15-4 or Figure 15-5, and connect

the $CO_2$ module interface cable to the $CO_2$ interface of the $CO_2$ plug-in module or the minihost.

(4) Enter into the conventional screen of the host monitoring equipment, select [Exchange Waveform] to call out the "$CO_2$" waveform and parameters which you want to monitor, such as [$CO_2$] (this step can be skipped if the screen has already displayed the "$CO_2$" waveform and parameters).

(5) When the $CO_2$ module is connected to the monitor, its module working mode is in the "Measurement" state; however, in order to make sure that it is in the correct working state, please do enter into the [$CO_2$ Settings] menu to set its "Working Mode" to the [Measurement] mode.

(6) Set [$CO_2$ Switch] to [On].

(7) In the [$CO_2$ Settings] menu, set [Oxygen Compensation] to 21 (usually, although it is 21 in this menu, in order to make sure that its datum is in an activated state, the customer still needs to reselect it);

(8) In the [$CO_2$ Settings] menu, select an appropriate [Balancing Gas]:Indoor air, laughing gas or helium (usually if there is no unused laughing gas or helium indoors, you can just select indoor air);

(9) In the [$CO_2$ Settings] menu, select a correct [Altitude]:0～5029. 2m, instrument default:0m; mainly refer to the following table for its standard:

Air Pressure Conversion Table – End-of-Respiration $CO_2$ Data Read By Basing the Standard on Altitude

| **Sea-Level Elevation** | | **Atmospheric Pressure** | **5%$CO_2$** |
|---|---|---|---|
| **Inch** | **m** | **mmHg** | **$ETCO_2$ mmHg** |
| Sea Level (0) | Sea Level (0) | 760 | 38 |
| 500 | 152. 4 | 745 | 37 |
| 750 | 228. 6 | 738 | 37 |
| 1, 000 | 304. 8 | 731 | 37 |
| 1, 500 | 457. 2 | 717 | 36 |
| 2, 000 | 609. 6 | 704 | 35 |
| 2, 500 | 762 | 690 | 35 |
| 3, 000 | 914. 9 | 677 | 34 |
| 3, 500 | 1066. 8 | 665 | 33 |
| 4, 000 | 1219. 2 | 652 | 33 |
| 4, 500 | 1371. 6 | 640 | 32 |
| 5, 000 | 1524 | 628 | 31 |
| 5, 500 | 1676. 4 | 616 | 31 |

| | | | |
|---|---|---|---|
| 6, 000 | 1828. 8 | 604 | 30 |
| 6, 500 | 1981. 2 | 593 | 30 |
| 7, 000 | 2133. 6 | 581 | 29 |
| 7, 500 | 2286 | 570 | 29 |
| 8, 000 | 2438. 4 | 560 | 28 |
| 8, 500 | 2590. 8 | 549 | 27 |
| 9, 000 | 2743. 2 | 539 | 27 |
| 10, 000 | 3048 | 518 | 26 |
| 10, 500 | 3200. 4 | 509 | 25 |
| 11, 000 | 3352. 8 | 499 | 25 |
| 11, 500 | 3505. 2 | 490 | 24 |
| 12, 000 | 3657. 6 | 480 | 24 |
| 12, 500 | 3810 | 471 | 24 |
| 13, 000 | 3962. 4 | 462 | 23 |
| 13, 500 | 4114. 8 | 454 | 23 |
| 14, 000 | 4267. 2 | 445 | 22 |
| 14, 500 | 4419. 6 | 437 | 22 |
| 15, 000 | 4572 | 428 | 21 |
| 15, 500 | 4724. 4 | 420 | 21 |
| 16, 000 | 4876. 8 | 412 | 21 |
| 16, 500 | 5029. 2 | 405 | 20 |
| 16, 800 | 5120. 6 | 400 | 20 |

Table 14-1

Note:It is assumed that the atmospheric pressure is 760mmHg and the ambient temperature is 0℃ at the sea level. Calculation of Atmospheric Pressure:the sea-level based ambient temperature is assumed as 0℃. Refer to the above Table.

⚠**Warning**⚠

**By setting sea-level elevation, the monitor is not automatically changed with air pressure compensations. Correct sea-level elevation must be set before the first use of $CO_2$ Measurement Program. Improper setting of sea-level elevation will result in incorrect $CO_2$ readings. A 5% $CO_2$ deviation is generally generated corresponding to difference of each 1000m height.**

(10) In the [$CO_2$ Settings] menu, select a correct [Atmospheric Pressure]:405～760mmHg, the instrument default is 760 mmHg; when $CO_2$ value is on the high side or on the low side, select an appropriate atmospheric pressure based on the local condition by referring to the table above

(since the atmospheric pressure and the altitude are corresponding, the atmospheric pressure can be adjusted only by setting the altitude. )

(11) In the [$CO_2$ Settings] menu, select [Zeroing]; after zeroing, the following prompt is displayed at the lower right corner of the screen:Zeroing…Please Wait for 30s; you can start measuring $CO_2$ only after the prompt disappears.

## 14.6 Measuring Procedure of PHASEIN Branded Sidestream and Mainstream Analyzers

The PHASEIN branded sidestream analyzer operating procedure is roughly the same as the mainstream analyzer operating procedure; please refer to the sidestream analyzer operating procedure for the mainstream analyzer operating procedure.

### 14.6.1 Measurement Steps

If you want to set the host monitoring equipment in order to start gas analysis, please execute the following procedure:

a) Start the host monitoring equipment (if a minihost is used, please start the minihost monitoring equipment at the same time).

b) Or insert the $CO_2$ plug-in module into the host monitoring equipment; the indicator of the $CO_2$ plug-in module will illuminate, which means that the module has been successfully connected to the host monitoring equipment; otherwise, please reinsert the $CO_2$ plug-in module.

c) Connect the Nomoline sampling tube to the input interface of the ISA analyzer ($CO_2$ module)

d) Connect the interface cable of the ISA analyzer to the $CO_2$ interface of the $CO_2$ plug-in module or the minihost.

e) Enter into the conventional screen of the host monitoring equipment, select [Exchange Waveform] to call out the "$CO_2$" waveform and parameters which you want to monitor, such as [$CO_2$] (this step can be skipped if the screen has already displayed the "$CO_2$" waveform and parameters).

f) When the $CO_2$ module is connected to the monitor, its module working mode is in the "Measurement" state; however, in order to make sure that it is in the correct working state, please do enter into the [$CO_2$ Settings] menu to set its "Working Mode" to the [Measurement] mode.

g) Set [$CO_2$ Switch] to [On].

h) Set appropriate [Oxygen Compensation], [Laughing Gas Compensation].

i) To connect the outlet of the sample gas to the discharge system, or to make the gas to flow back to the patient's circuit.

j) If it is green LED indication, ISA Analyzer is available.

k) To carry out inspection before use according to the statement in the "check before use".

l) If the inspection is normal, start to monitor the Anaesthetic Gas.

## 14.6.2 Check before use

Before connecting the Nomoline sampling pipe to the breathing circuit, carry out the following steps:

a) Connect the sampling tube to the gas entrance interface (LEGI) of the ISA $CO_2$ module.

b) Check whether the green light of LEGI is steadily on or not（The indication system is normal. ）.

c) Exhale to the sampling tube, check if a valid $CO_2$ waveform and value are displayed on the host monitoring equipment.

d) Use the finger tip to block up the sampling pipe, and hold on for 10 seconds.

e) Examine whether there is obstruction warning and if the LEGI shows a red flashing light.

f) Under proper circumstances：Carry out enclosure check on the patient's circuit that is linked with the sampling pipe.

⚠**Warning**

- **Hang the external $CO_2$ analyzer onto the $CO_2$ bracket on the rear casing of the instrument; prevent the dropping damage of the $CO_2$ module.**
- **Unless HME is used to protect the IRMA probe, the state indicating LED should face upward all the time during IRMA probe placement.**
- **Do not pull the cable of ISA Gas Analyzer.**
- **Do not operate the ISA Gas Analyzer in the environment beyond the designated working temperature.**
- **Make sure all connections are firm and reliable. Any leakage will result in the inclusion of ambient air in the patients respiratory gas, which leads to a wrong reading.**

## 14.7 CO2 Settings in Parameter Area

Rotate the rotary shuttle button to move the cursor on the display interface to the CO2 hotkey in the parameter area, and then press the rotary shuttle button to enter the menu “CO2 Settings”.


Figure 14-6 CO2 Settings

- ALM ON/OFF(Alarm Switch): select “On" to enable CO2 alarms, or select “Off" to disable CO2 alarms with the icon “ ” appearing beside “CO2” in the parameter area on the screen.
- ALM REC(Alarm Record): select “On” to enable the recorder output when there is any CO2 alarm.
- SWEEP(Alarm Speed): 12.5mm/s~25.0mm/s.
- WAVE COLOR(Waveform Color): Green, Cyan, Red, Yellow, White, Blue, or Purple
- Unit: mmHg/kpa.
- CO2 ON(CO2 Switch): On or Off; select "On" to monitor the CO2.
- O2 COMPEN(Oxygen Compensation): 0~100.(RESPIRONICS);HI,MED ,LOW （PHASEIN）
- N2O COMPEN:ON/OFF( This feature isonly available on PHASEIN )
- BALAN GAS(Balance Gas): Indoor Air, Laughing Gas, or Helium. （PHASEIN has not the feature）
- ALTITUDE: 120~4920 mmHg (adjustable based on the geographical location).（PHASEIN has not the feature）
- BARO PRE(Atmospheric Pressure): 400~850 mmHg (adjustable based on the geographical location: either Altitude or Atmospheric Pressure, not both). （PHASEIN has not the feature）
- INS ALM HI(Upper Limit of INS Alarm): adjust the upper limit of INS alarm; if the

measured INS value exceeds the upper limit, there will be an alarm and prompting.

- APNEA ALM(apnea alarm):No ,1s ,2s ,5s ,10s ,15s ,20s ,25s ,30s ,35s ,40s.
- CO2 ALM SETUP:Used for to adjust CO2 the upper and lower limits of the range of the high limit, middle limit and lower limit alarm . When the alarm limit CO2 measurement value is greater than or less than the alarm limit, the instrument alarm and prompt.
- AWRR ALM SETUP: Used for to adjust AWRR the upper and lower limits of the range of the high limit, middle limit and lower limit alarm . When the alarm limit CO2 measurement value is greater than or less than the alarm limit, the instrument alarm and prompt
- ZERO CAL: zero before monitoring the CO2, in order to obtain a more accurate measured value.
- DEFAULT : override the original settings.

## 14.8 CO2 Settings in Waveform Area

Rotate the shuttle button to move the cursor on the display interface to the CO2 hotkey in the waveform area, and then press the shuttle button to enter the menu “CO2 Settings” as below:

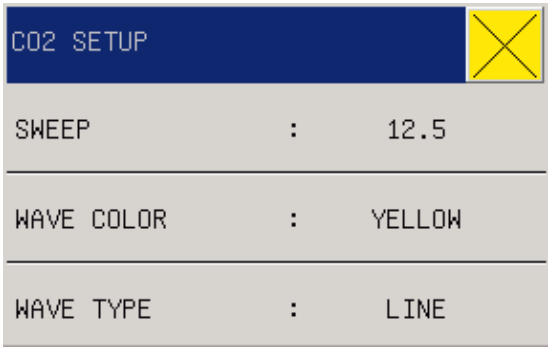



Figure 14-7 CO2 Settings

- SWEEP: 12.5mm/s~25.0mm/s.
- WAVE COLOR: Green, Cyan, Red, Yellow, White, Blue, or Purple.
- WAVE TYPE: Line or Fill.

## 14.9 $CO_2$ Settings in Measurement Setup

Select “CO2 SETUP” in the menu “SURVEY SETUP " or rotate the shuttle button to move the cursor to CO2 hotkey in the parameter area on the main screen, and then press the shuttle button to enter the menu “CO2 SETUP” as below:


Figure 14-8 CO2 Settings

Note: Refer to the section "CO2 Settings in Parameter Area" for the specific options of the menu "CO2 Settings" in "Measurement Setup".

⚠**Warning**⚠

**This monitor does not provide auto atmospheric pressure compensation. Please set a correct altitude before the first use of the CO2 for measuring. Any wrong altitude could result in an inaccurate CO2 reading: a reading error of 5% for each altitude deviation of 1000m.**

## 14.10 Discharging Waste Gases

When nitrous oxide and/or an anesthetic gas is used, you should prevent these gases from polluting the operating room. Usually the gas discharging outlet should be connected to (via the gas discharging pipe connected to the sample gas outlet of the host equipment):

A discharging system (used for discharging collected gases) or the patient circuit (used for the back flowing of collected gases).

⚠**Warning**⚠

**Anesthetics:When an anesthetic which is being used or a patient who recently used an anesthetic is measured, the gas discharging hole on the module must be connected to a waste gas processing system or the patient circuit (on the anesthesia machine or the respirator), so as to prevent medical personnel from inhaling the anesthetic.**

## 14.11 Maintenance and Cleaning of RESPIRONICS Branded Mainstream and Sdestream Modules

### 14.11.1 Common Cleaning

Clean with cloth, optionally dipped with 70% isopropanol, aqueous solution containing 10% sodium hypochlorite (bleacher), sterilizing spray cleaner (such as Steris Coverage Spray HB), ammonia water or mild soap water. Before cleaning, wash the cloth with rinse water and then wring out and air-dry the washed cloth. Make sure that sensor windows are clean and are air-dried before being used repeatedly.

### 14.11.2 Airway Adapter for Cleaning Reusable Mainstream Sensor

Rinse it with warm soapy water first and soak it in liquid sterilizing fluid, such as 70% isopropanol, aqueous solution containing 10% sodium hypochlorite (bleacher), 2. 4% glutaraldehyde solvent, e. g. Cidex Plus or Steris System 1 or ammonia water. Wash it with clean water completely.

### 14.11.3 Method for Sterilizing Reusable Adapter

Autoclave Sterilizer-operable only to adult-used adapters.

Ethylene oxide (ETO)- Sterilizing for 1. 5h.

Soaking in Cidex Plus for 10h.

Soaking in Perasafe for 10h.

U. S. Steris System 1pasteurizer.

Before adapters are reused, please make sure that the windows are dried without any residuals and that adapters stand intact during operation or cleaning/sterilization.

### 14.11.4 Sterilization Times for Reusable Airway Adapter

The reusable airway adapters can be reused 100 times if the above sterilization method is used.

### 14.11.5 Zeroing

Please zero before monitoring $CO_2$; zeroing is to eliminate the effect of baseline drifting on the results

during measurement, thus ensuring the correctness of measured results.

Usually, the module will zero itself automatically when necessary. The user can zero the module manually when the user considers it necessary:Select [$CO_2$] in the parameter area, in the [$CO_2$ Settings] menu popping up, select [Zeroing] to zero the $CO_2$ module. During zeroing, make sure that the patient circuit is exposed to the ambient air (21% oxygen and 0% $CO_2$) for approximately 30 seconds; when the 30s zeroing prompt on the screen ends, it means zeroing is completed.

## 14.12 PHASEIN Branded Mainstream and Sidestream Analyzer Related Information

### 14.12.1Zeroing

An infrared gas analyzer needs to determine the zero reference level for $CO_2$ measurement. This zeroing standard is called as “zeroing” here.

**Automatic Zeroing**

(1) The ISA sidestream gas analyzer execute zeroing automatically by switching the gas sample from the respiration circuit to the ambient air. To execute automatic zeroing once every 24 hours, the ISA sidestream gas analyzer takes less than 3 seconds. If the ISA sidestream gas analyzer is equipped with an oxygen sensor, automatic zeroing also includes the indoor air calibration of the oxygen sensor.

(2) IRMA CO2 probes:

Zeroing needs to be performed ONLY when an offset in gas values is observed, or when an unspecified accuracy message is displayed.
Allow 10 seconds for warm up of the IRMA CO2 probe after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

**Manual Zeroing**

Select [$CO_2$] in the parameter area, in the [$CO_2$ Settings] menu popping up, select [Zeroing] to zero the $CO_2$ module. During zeroing, make sure that the patient circuit is exposed to the ambient air (21% oxygen and 0% $CO_2$) for approximately 30 seconds; when this menu is in a non default (settable) condition, zeroing can be executed.

⚠**Warning**

**Since successful zeroing requires that the gas analyzer exists in the ambient air (21% oxygen and 0% $CO_2$), you should make sure that the ISA is placed at a well ventilated position. Before and after executing the zeroing procedure, avoid breathing in the vicinity of the ISA sidestream gas analyzer.**

## 14.13 $CO_2$ Module Lighting Information

Overview of States Indicated by LEGI:

| Indicating Signal | State |
|---|---|
| Not blinking green light | The system is normal |
| Blinking green light | Zeroing |
| Not blinking red light | Sensor Error |
| Blinking red light | Checking the sampling tube/airway adapter |

## 14.14 Safety Alarm Information

## 14.14.1ISA Sidestream Gas Analyzer Safety Warning Information

⚠**Warning**⚠

- **The ISA sidestream gas analyzer is designed to be used by authorized or trained medical personnel.**
- **Only Nomoline sampling tubes produced by PHASEIN can be used.**
- **The ISA sidestream gas analyzer shall not be used in an inflammable anesthetic gas.**
- **You should earnestly neaten the sampling tube in order to reduce the risk of it wrapping or reining the patient.**
- **Do not repeatedly use a disposable sampling tube.**
- **Do not lift the ISA/host equipment by grasping the sampling tube; otherwise it may break away from the ISA/host equipment, which may result in that the ISA/host equipment falls onto the patient.**
- **Used disposable sampling tubes should be disposed according to local medical waste stipulations.**
- **Do not use a sampling tube configured for an adult or a child on an infant; otherwise the**

**invalid cavity in the patient circuit will increase.**

- **Do notuse a sampling tube configured for an infant on an adult; otherwise it will result in a too big flowing resistance.**
- **Do not use the ISA sidestream gas analyzer together with a quantitative spraying agent or spray; otherwise it may result in the clogging of the germ filter.**
- **Check if the flowing speed of the gas sample is too high for the given patient type.**
- **Since successful zeroing requires that the gas analyzer exists in the ambient air (21% oxygen and 0% $CO_2$), you should make sure that the ISA is placed at a well ventilated position. Before and after executing the zeroing procedure, avoid breathing in the vicinity of the ISA sidestream gas analyzer.**
- **The Nomoline sampling tube and its interface are not germ free devices. In order to prevent the sampling tube from causing damages, please never carry out high pressure sterilization on any part of the sampling tube.**
- **Never disinfect the ISA sidestream gas analyzer or soak it into a liquid.**
- **Mobile and radio frequency communication equipment will affect measurement. Make sure that the ISA gas analyzer is used in the electromagnetic environment designated in this operating instruction manual.**
- **The ISA gas analyzer can only be used as a piece of auxiliary equipment for patent evaluation. It must be used together with other vital sign and symptom evaluation equipment.**
- **If the input interface of the sampling tube starts showing red blinking, or a Nomoline clogging message is displayed on the host, the sampling tube should be replaced.**
- **It is not allowed to alter this equipment without the manufacturer's authorization. If this equipment is altered, appropriate checking and testing must be conducted in order to make sure that it can be safely operated over a long period of time.**
- **The ISA gas analyzer is not designed for being used in a MRI environment.**
- **During MRI scanning, the host equipment must be placed outside the MRI room.**
- **Using high frequency electrosurgical equipment in the vicinity of the ISA/host equipment may produce interference, which will result into incorrect measurements.**
- **Do not use the external natural heat dissipation function of the ISA equipment.**
- **Do not apply a negative pressure (such as using a syringe) onto the Nomoline to remove condensed water.**
- **If the positive or negative pressure in the patient circuit is too high, it may affect the sample's flowing speed.**
- **If the discharging or sucking pressure is too high, it may affect the sample's flowing speed.**
- **The discharged gas should be discharged into the patient circuit, or into a discharging system.**
- **If the collected gas sample needs to supply air for respiration, a germ filter should be used at the discharging side all the time.**

- **When placing the ISA gas analyzer, try not to place it at a position where the analyzer might fall onto the patient's body.**

## 14.14.2IRMA Mainstream Gas Analyzer Safety Warning Information

⚠**Warning**⚠

- **Do not use an IRMA airway adapter configured for an adult or a child on an infant, since the adapter will add 6ml of invalid cavity to the patient circuit.**
- **If the airway adapter has water drops/condensation, it should be replaced.**
- **Use an IRMA airway adapter made by PHASEIN.**
- **Do not use an IRMA infant airway adapter on an adult; otherwise it will result in a too big flowing resistance.**
- **When an energized part is contacted, sufficient protection should be provided to the host equipment.**
- **Only an adapter cable approved by PHASEIN AB can be used.**
- **A warning must be implemented in the host equipment, displayed during demonstrative data displaying.**
- **The host equipment should be equipped with an appropriate alarm system to remind the user of circumstances which may cause death or serious damages to the patient's health.**
- **Every corresponding alarm message in IRMA state abstract fields must be implemented in the host equipment.**
- **The IRMA probe is not designed to be contactable to the patient.**
- **Incorrect probe zeroing will result in false gas readings.**
- **The IRMA probe is designed for being used by authorized or trained medical personnel.**
- **The IRMA probe is not designed shall not be used in an inflammable anesthetic gas.**
- **A disposable IRMA airway adapter shall not be used repeatedly. Repeatedly using a disposable adapter will cause cross infection.**
- **Used disposable airway adapters should be disposed according to local medical waste stipulations.**
- **Only oxygen sensors made by PHASEIN can be used. Oxygen exhausted oxygen sensors should be disposed according to local battery disposal stipulations.**
- **Never try to open the oxygen sensor device. The oxygen sensor in the IRMA probe is a disposable product, containing corrosive electrolytes and lead.**
- **The IRMA probe is designed only as an auxiliary means for patient evaluation. It must be used together with other vital sign and symptom evaluation equipment.**
- **Never place the IRMA airway adapter somewhere between the trachea catheter and the elbow; otherwise it may result in the adapter window being clogged by the**

**patient's secretions and operating errors.**

- **In order to prevent secretions and moisture from aggregating at the window and the oxygen sensor port, always place the IRMA probe at a vertical position and let the LED face upwards.**
- **Never use the IRMA airway adapter together with a quantitative spraying agent or spray; otherwise it may affect the light traveling of the airway adapter window.**
- **If an IRMA OR (without the automatic anesthetic gas identification function) user select a wrong anesthetic gas, it will result in false anesthetic gas readings.**
- **If the IRMA OR (without the automatic anesthetic gas identification function) is applied to a mixed gas containing several anesthetic gases, it will result in false anesthetic gas readings.**
- **Mobile and radio frequency communication equipment will affect measurement. You should make sure that the IRMA probe is used in the electromagnetic environment designated in this operating instruction manual.**
- **Never disinfect the IRMA probe or soak it into a liquid.**
- **The IRMA oxygen cell and the IRMA airway adapter are not germ free devices. Never carry out high pressure sterilization on the equipment; otherwise it will result in equipment damage.**
- **Even if an IRMA probe has not been used, do not install an oxygen exhausted oxygen cell on the probe.**
- **Do not stretch the sensor cable.**
- **Do not run this equipment beyond the temperature environment designated by this operating instruction manual.**
- **(USA): According to the federal law, this product can only be sold by doctors or based on prescriptions.**

## 14.15 Airway Obstruction

When the anesthetic gas airway is obstructed, on the screen there will be such a prompt message as "The anesthetic gas airway is obstructed"; under such a circumstance, replace the Nomoline sampling tube.

⚠**Warning**⚠

- **Do not use the ISA gas analyzer together with a quantitative spraying agent or pulverization treatment; otherwise it may result in the clogging of the germ filter.**

## 14.16 Discharging Waste Gases

When nitrous oxide and/or an anesthetic gas is used, you should prevent these gases from polluting the operating room. Usually the gas discharging outlet should be connected to (via the gas discharging pipe connected to the sample gas outlet of the host equipment):

A discharging system (used for discharging collected gases) or the patient circuit (used for the back flowing of collected gases).

⚠**Warning**⚠

- **Anesthetics: When an anesthetic which is being used or a patient who recently used an anesthetic is measured, the gas discharging hole on the module must be connected to a waste gas processing system or the patient circuit (on the anesthesia machine or the respirator), so as to prevent medical personnel from inhaling the anesthetic.**

## 14.17 Consumables

The Nomoline sampling tube cannot be used repeatedly.

Replace the Nomoline sampling tube every two weeks or when "The sampling tube is clogged" is displayed (based on whichever comes first).

#### 14.17.1.1 Replacement of Nomoline and Nomoline Airway Adapter Set

The Nomoline and Nomoline Airway Adapter Set are single-patient use products.
They should be replaced according to good clinical practice or when an occlusion message appears. Occlusion occurs when the sample flow is too low. This is indicated by a flashing red LEGI together with a message on the medical backboard device.

#### 14.17.1.2 Replacement of Nomoline Adapter

The Nomoline Adapter is a multiple-patient use product.
The Nomoline Adapter should be replaced according to good clinical practice or when an occlusion message appears. Occlusion occurs when the sample flow is too low. This is indicated by a flashing red LEGI together with a message on the medical backboard device.
Replacement of T-adapter and Nomo Extension
The T-adapter and Nomo Extension are single-patient use products.
They should be replaced according to good clinical practice or when an occlusion message appears. Occlusion occurs when the sample flow is too low. This is indicated by a flashing red LEGI together with a message on the medical backboard device.

## 14.18 Safety Symbol Information

| Symbol | Title | Explanation |
|---|---|---|
|  | Instructions for use | Consult instructions for use |
|  | Catalog number | |
|  | Serial number | |
|  | Batch code | |
|  | Year of manufacture | |
|  | Use by date [YYYY-MM-DD] | The device should not be taken into operation after the date accompanying the symbol. |
|  | Temperature limitation | |
|  | Pressure limitation | |
|  | Humidity limitation | |
|  | Do not re-use | Nomoline and Nomoline Airway Adapter Set are intended for single patient use |
|  | Biohazardous waste | Nomoline Family sampling lines shall be disposed as biohazardous waste |
|  | For EU only:<br>Waste Electrical and Electronic Equipment (WEEE) | For EU only:<br>Electrical and electric equipment shall be collected and recycled in accordance with (Directive 2002/96/EC) |
|  | ETL Listing Mark | Conforms to ANSI/AAMI 60601-1:2005 Cert. to CAN/CSA-C22.2 No.60601.1:2008. |
|  | Conformité Européenne | Complies with 93/42/EEC Medical Device Directive when connected to medical devices approved by PHASEIN AB. |
|  | IP classification indicating level of water protection | “Splash-proof” |
|  | Rx only | (US Only) Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. |
|  | $CO_2$ | ISA equipped to measure $CO_2$ only |

| Symbol | Title | Explanation |
|---|---|---|
|  | Multigas (AX+ or OR+) | ISA equipped to measure multiple gases |
|  | Sigma Multigas Technology | The product is fitted with PHASEIN Sigma Multigas Technology |
|  | Gas Inlet | |
|  | Gas Outlet | |
|  | Defibrillation-proof type BF applied part | The applied part of ISA is the Nomoline Family sampling line |

## 14.19 Patents and Trademarks

(1) Patent Statement

PHASEIN AB owns the following patents for relevant products described in this operating instruction manual: SE519766; SE519779; SE523461; SE524086. Other patents are being applied.

(2) Trademark

PHASEIN IRMA™, PHASEIN ISA™, PHASEIN XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, PHASEIN GasMaster™ and ISA MaintenanceMaster™ are trademarks of PHASEIN AB.

Tygothane® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

## 14.20 Maintenance

The user should verify gas readings regularly; If finding any problem, please contact an engineer of the manufacturer for maintenance.

## 14.21 Cleaning the Analyzer

The “Plug in and measure” ISA/IRMA gas analyzer should be cleaned regularly. Use ethanol or isopropyl alcohol with a maximum concentration of 70% and a wet rag to clean the analyzer..

In order to prevent the cleaning liquid and dust from entering into the ISA gas analyzer from the LEGI interface, the Nomoline sampling tube should be connected all the time during analyzer cleaning.

Before cleaning the IRMA probe, take off the disposable IRMA airway adapter.

⚠**Warning**⚠

- **The Nomoline sampling tube is not a germ free device. In order to prevent the sampling tube from causing damages, please never carry out high pressure sterilization on any part of the sampling tube.**
- **Never sterilize the ISA sidestream gas analyzer and the IRMA probe or soak them into a liquid.**
- **The IRMA airway adapter are not germ free devices. Never carry out high pressure sterilization on the equipment; otherwise it will result in equipment damage.**

.

# Chapter 15Neonates Awakening Function

## 15.1 Neonates Awakening Function

It awakens neonates with bradypnea caused by deep sleep or other reasons. The enabling of the awakening function of the monitor depends on breathing frequency. The awakening device will wake up neonates with vibration mode when the breathing frequency of neonates is lower than 7 bpm and lasting time exceeds the limit set for asphyxia alarm; and it will stop working when breathing frequency is above 7 bpm.

## 15.2 Connect Awakening Device

Place the awakening device at the sole centre of one foot of the neonate, and wind the bands around the foot. DO NOT bond the band too loose as it may slip off which may disable its awakening function; nor bond it too tight to avoid obstructed blood circulation and cause change in foot color, as shown in the following figure:

Figure 15-1 Connect Awakening Device

**⚠Warning⚠**

**Do not disinfect the awakening device or submerge it into liquid.**

**Do not pull the cables of awakening device.**

**Do not use the awakening device in a circumstance out of working temperature limit.**

**Do not apply the awakening device on an injured foot.**

## 15.3 Application Precautions and Procedures

Insert the cable plug into WAKE socket on left side of the monitor.
Wind the band of awakening device at the sole centre of neonate's foot, referring to *14.2 Awakening Device Connection* in this Chapter
Install ECG leads, referring to *9.3.2 Installing* ECG Leads in C60 multi-parameter monitor manual.
Set asphyxias alarming time. Enter "MEASURING SETTINGS" and select "RESP SETTINGS". Set "ASPHYXIA ALARMING" as 10 to 40 seconds. It is advised not to set an excessively long time
Awakening device begin vibrating to wake up the neonates when the breathing frequency is lower than 7 bpm, and lasting longer than the set asphyxia alarming time limit. The device stops after neonates' breathing frequency is over 7 bpm.

⚠**Warning**⚠

**Following conditions must be met for normal working of awakening device under system settings:**
**ALARMING SWITCH of RESP must be set as ON;**
**ASPHYXIA ALARM cannot be set as NON-ALARM.**

## 15.4 Cleaning

Clean the awakening device under regular intervals with cloth dipped with ethanol or isopropanol with maximum concentration at 70%.

⚠**Warning**⚠

**Never disinfect the oxygen sensor or submerge it into liquid**

# Chapter 16OxygenConcentration Monitoring

## 16.1 About Oxygen Concentration

Oxygen is diffused into battery through the osmotic membrane of the oxygen sensor. There is a sensing electrode (cathode) made of precious metals (gold or platinum etc.), and a working electrode (anode) made of basic metals (lead or zinc etc.).. Both of the two electrodes are submerged into electrolyte. Oxygen sensor is current generator, which needs no external power supply. Voltage which is in direct ratio with oxygen concentration will be generated when a resistor is connected between the anode and the cathode.

Chemical reaction occurs during measuring process, thus the batteries need to be replaced regularly when the battery powers runs low (even before the equipment is used).

Oxygen concentration monitoring is mainly intended to prevent oxygen poisoning. Oxygen therapy is a common treatment since some organs of premature and low weighted infants are immature. But high oxygen concentration may cause side effects such as retinopathy of prematurity (ROP), lung hurt, denitrified absorption atelectasis or other syndromes.

Currently in developed countries, as central oxygen supplying and compressed air are adopted, proper oxygen therapy for neonates is realized through oxygen mixture of different concentrations using an air mixer. Most of the developing countries are still directly applying pure oxygen therapy. Oxygen concentration probe of the device will monitor the oxygen concentration and protect neonates from oxygen poisoning for intaking oxygen of over high concentration.

Infants with premature lungs will survive well when put into 100% oxygen masks, while they often suffer problems when they breathe 21% oxygen (concentration in the nature air) after leaving 100% pure oxygen environment. For example, increased blood supplying and increased brain blood flow may cause bleeding inside brain and on retinas, and lead to cerebral injury and blindness; and oxygen poisoning is tend to happen for neonates, especially premature infants, after breathing 100% pure oxygen in a long time.

## 16.2 Connecting Oxygen Sensors

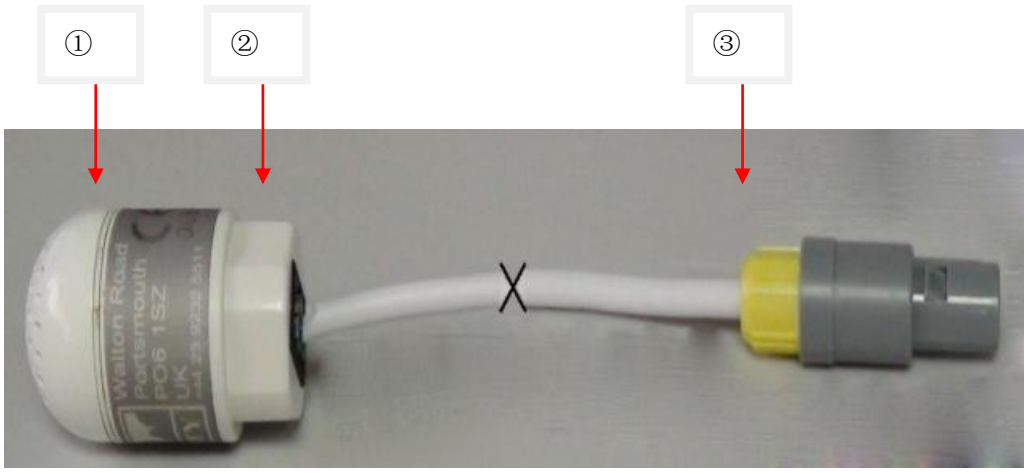



Figure 16-1 Connecting Oxygen Sensor

1. Screw tight the top cover of the oxygen sensor probe clockwise.
2. Insert the connector into the oxygen sensor, with a click sound indicating that it is inserted firmly.
3. Insert the cable plug of oxygen sensor into the $O_2$ socket on left side of the monitor.

## 16.3 21% Calibration

1. Start the monitor;
2. Enter "MAIN MENU "of the monitor, and select "MODULE SWITCH SETTINGS" in"MONITOR SETTINGS", select $O_2$ as ON.
3. Insert the cable plug of oxygen sensor into the $O_2$ socket on left side of the monitor, referring to ***15.2 Connecting Oxygen Sensor*** of in this Chapter.
4. Place the oxygen sensor in the air.
5. Enter "$O_2$ SETTINGS" menu, and select "21% CALIBRATION". Choose "YES" in the pop-updialogue box.
6. "CALIBRATION SUCEED"appears in the prompt area of the instrument, if calibration succeeds after 3 minutes; and recalibration is needed when"CALIBRATION FAILED" prompt appears for a failed calibration.

**'Attention'**

**Make $O_2$ calibration when oxygen concentration measuring error is oversized or when replacing oxygen sensor.**

**′Attention′**

**$O_2$ calibration must be made when there is no patient under monitoring.**

**′Attention′**

**Observe for relative technical fault alarm if calibration fails, and recalibrate after eliminating the fault.**

**′Attention′**

**Replace the oxygen sensor and recalibrate it after repeated failure calibration, or contact the equipment maintenance staff or our company if problems still exist.**

**′Attention′**

**Do not burn the oxygen sensor during disposal. Please follow relative regulations on biological hazard.**

## 16.4 100% Calibration

1. Ensure“21% CALIBRATION”is made with success;
2. Place oxygen sensor into pure oxygen;
3. Select “100 % CALIBRATION” in $O_2$ SETTINGS menu, and choose “YES” in the pop-up dialogue box;
4. “CALIBRATION SUCEED” appears in the prompt area of the instrument, if calibration succeeds after 3 minutes; and recalibration is needed when “CALIBRATION FAILED” prompt appears for a failed calibration.

**′Attention′**

**Observe for relative technical fault alarm if 100％ $O_2$ calibration fails, and recalibrate it after eliminating the fault.**

**′Attention′**

**Replace the oxygen sensor and repeat 21% $O_2$ calibration after repeated failure calibration, and then make 100% $O_2$ calibration. Contact the equipment maintenance staff or our company if problems still exist.**

## 16.5 Alarm Settings

1. Enter “$O_2$ SETTINGS” menu .
2. Set“ ALARMING SWITCH” to ON.
3. Select “$O_2$ ALARM SETTINGS”, and enter upper and lower limit short-cut keys of the High,

Middle, and Low alarms, and set proper upper/lower limit.

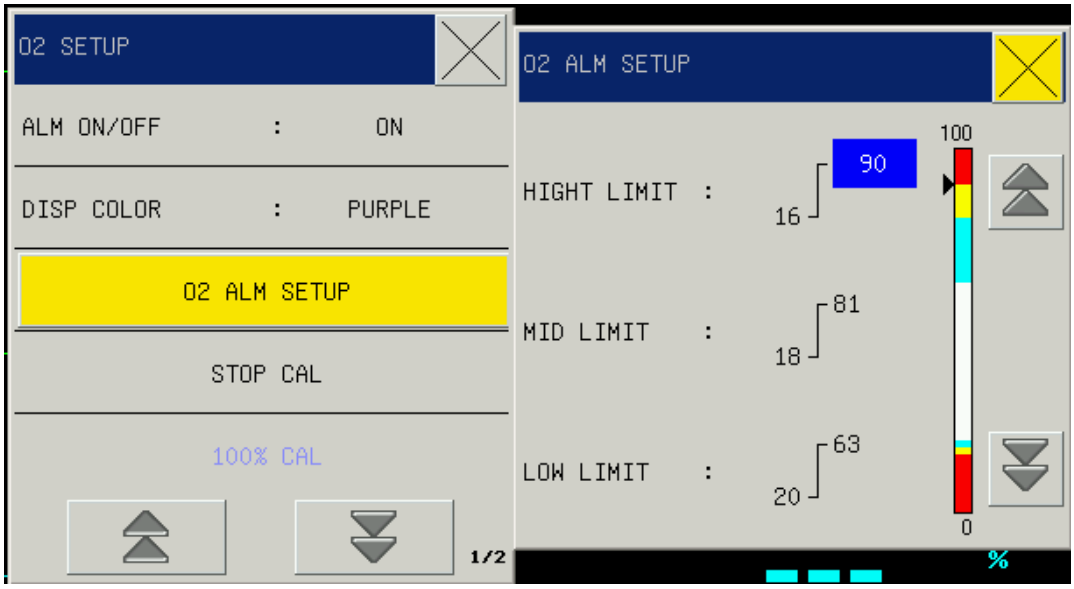



Figure 16-2 Set $O_2$ Alarm

| | High | Medium | Low | Steplength |
|---|---|---|---|---|
| O2 Upper limit | (10～100)% | （8～High upper limit-2）% | （6～Medium upper limit-2）% | 1% |
| O2 Lower limit | (0～medium lower limit-2）% | （2～Low lower down limit-2）% | （4～94）% | 1% |

## 16.6 Oxygen Concentration Measure Procedures

1. Make pre-monitoring preparation referring to *Connecting Oxygen Sensor, 21% Calibration, and 100 % Calibration* above in this Chapter.
2. Set properly alarm switch, upper/lower alarm limit etc.
3. Put the oxygen sensor into the oxygen environment to be tested.
4. Read $O_2$ concentration value indicated in the parameter area.

⚠**Warning**⚠

**Place the oxygen sensor securely and firmly to avoid injury or damage from dropping.**
**Do not stretch the oxygen sensor cable**
**Do not operate the oxygen sensor out of designated working temperature environment.**

## 16.7 Cleaning

Clean the oxygen sensor regularly with cloth dipped with ethanol or isopropanol with maximum concentration at 70%.

Keep the crystal plug connected when the cleaning oxygen sensor to prevent the cleaning liquid or dust from entering the device via the port, and avoid liquid around the plug.

**⚠Warning⚠**

**Do not disinfect or submerge the oxygen sensor.**

# Chapter 17IBP Monitoring

## 17.1 General information

This chapter mainly introduces invasive blood pressure (IBP) monitoring methods and contents relevant to maintenance and cleaning of accessories.

STAR8000H portable-type multi-parameter monitor can be directly used for measuring vascular pressures (diastolic pressure, systolic pressure and mean blood pressure). The following waveforms can be displayed:

| Waveform Name | Definition |
|---|---|
| ART | arterial pressure |
| PA | pulmonary arterial pressure |
| CVP | central venous pressure |
| RAP | right atrial pressure |
| LAP | left atrial pressure |
| ICP | intracranial pressure |

Remark: IBP monitoring part is an optional component.

## 17.2 Considerations of IBP monitoring

⚠**Warning**⚠

**The chosen accessory, if applied, should confirm to safety requirements of medical equipment.**

⚠**Warning**⚠

**In connection and application, accessories should be avoided from contacting metal parts connected with electric apparatus.**

⚠**Warning**⚠

**Users, when connecting the monitor with a high-frequency surgical instrument, should avoid the sensor and cable of the monitor from contacting the high-frequency surgical instrument so as to prevent patients from being burnt in case of electricity leakage.**

**⚠Warning⚠**

**The disposable pressure sensor should not be reused.**

**◈Caution◈**

**Only the pressure sensor specified in the Manual can be used.**

The specified sensor has shock-proof function (with resistance to leakage current) and can prevent influence of cardiac defivrillators. It can be used in surgeries. When the patient is in the defibrillation period, the pressure wave may exhibit temporary disorders; but after defibrillation, the monitor will work normally and the operation mode and user configuration of it won't be affected.

**⚠Warning⚠**

**Before monitoring, the sensor should be examined for normality assurance. If the sensor is pulled out of the jack, an error-warning message, "IBP sensor detached", will appear on the screen and alarm sounds will be sent out.**

**◈Caution◈**

**Sensors, new or used, should be regularly calibrated according to hospital practice.**

**⚠Warning⚠**

**If liquid (not solution applied to the pressure pipe and the sensor) is splashed on the instrument or accessories, especially when the liquid may enter the sensor or the monitor, place contact with the maintenance department of your hospital.**

## 17.3 Monitoring procedure

**Measurement preparation:**

Insert cables into corresponding sockets and check to ensure the monitor has been plugged in.

Have the pressure pipe and the sensor prepared. Fill the system full with physiological saline solution to make sure no bubble exists therein.

Connect the patient catheter to the pressure pipe and make sure that there is no air in the catheter and the pressure pipe or the sensor.

**⚠Warning⚠**

**If bubbles are found in the pressure pipe or the sensor, flush the system with the perfusion liquid.**

Position the sensor on the same level as the heart, approximately on the midaxiallary line

Confirm correct ruler names have been chosen. See the following section for details.

Do zero-adjustment of the sensor. See the following section for details.

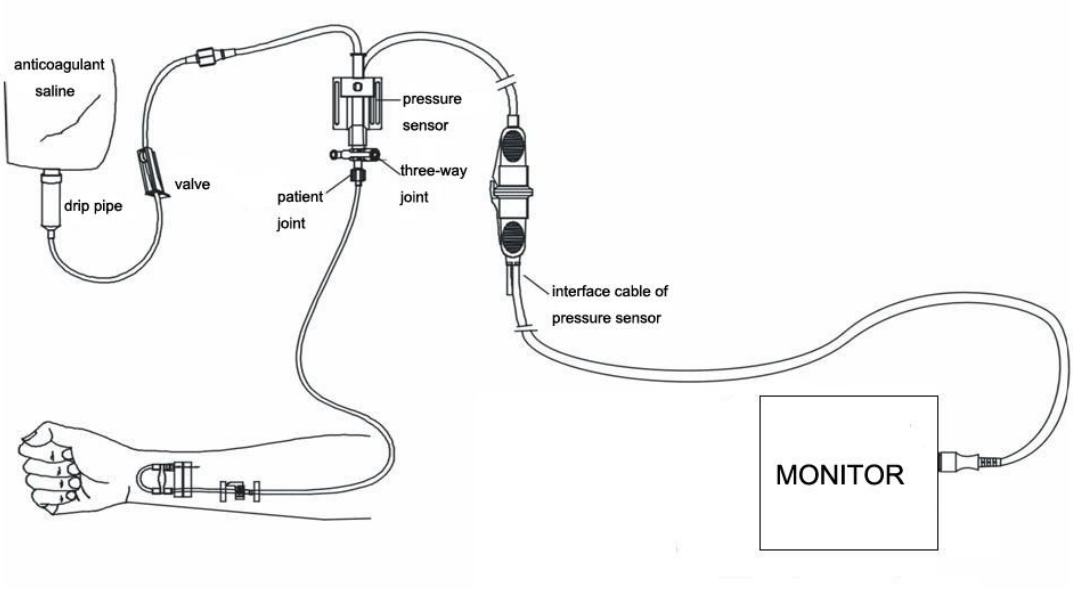



Figure 17-1 IBP Monitoring

## 17.4 IBP Menu

Select the “Module Setup” option in the “monitor setup” menu and set the CO2 on-off to be on. The following figure (the present figure is in demonstrating mode) will come out:

Rotate the knob and move the cursor to the IBP hotkey in the parameter area of the screen.

Press the knob to enter the “IBP selection” menu.

### 17.4.1 IBP<1,2>setup in the parameter area

Rotate the knob and move the cursor to the IBP hotkey in the parameter area of the screen.

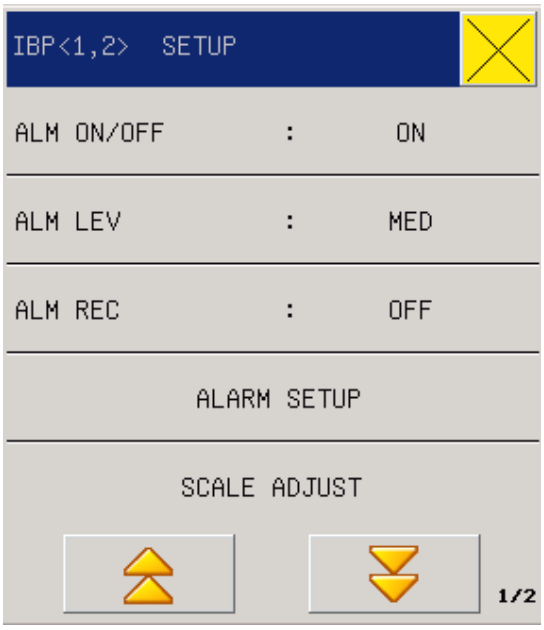



Fig 17-2 IBP Parameter Setting Menu

Settings can be done on the following items:

- ALM ON/OFF(Alarm switch): Where “ON” is selected, the alarm prompt and saving will proceed when the IBP (invasive blood pressure) is alarmed; where “OFF” is selected, alarming will not happen, but will be prompted beside IBP in the screen parameter area.
- ALM LEV(Alarmlevels): Optional levels are “High”, “Middle” and “Low”.
- ALM REC(Alarm record): select “On” to enable the recorder output when there is any IBP alarm.
- ALARM SETUP: When the alarm measurement value is greater than or less than the alarm limit, the instrument alarm and prompt.

CH1: ART, PA, CVP, RAP, LAP ,LAP ,ICP ,P1,P2 limit Hi setup:

SYS: UpperSYS alarm limit: used for setting the upper alarm limit

MEA: Upper MEA alarm limit:used for setting the upper alarm limit

DIA: Upper DIA alarm limit: used for setting the upper alarm limit

CH1: ART, PA, CVP, RAP, LAP ,LAP ,ICP ,P1,P2 limit Lo setup:

SYS: LowerSYS alarm limit: used for setting the lower alarm limit

MEA: Lower MEA alarm limit:used for setting the lower alarm limit

DIA: Lower DIA alarm limit: used for setting the lower alarm limit

CH2: ART, PA, CVP, RAP, LAP ,LAP ,ICP ,P1,P2 limit Hi setup:

SYS: UpperSYS alarm limit: used for setting the upper alarm limit

MEA: Upper MEA alarm limit:used for setting the upper alarm limit

DIA: Upper DIA alarm limit: used for setting the upper alarm limit

CH2: ART, PA, CVP, RAP, LAP ,LAP ,ICP ,P1,P2 limit Lo setup:

SYS: LowerSYS alarm limit: used for setting the lower alarm limit

MEA: Lower MEA alarm limit:used for setting the lower alarm limit

DIA: Lower DIA alarm limit: used for setting the lower alarm limit

**Caution**

**Users should guarantee that zero calibration has been done on the sensor before the measurement; otherwise the instrument has no effective zero value, which may lead to inaccuracy of measured data.**

Once the measured data exceed the alarm limits, the alarm will be triggered.

IBP alarm limits:

| Pressure Scale Name | Max Upper Limit (mmHg) | Min Lower Limit (mmHg) | Adjustable Single-Step Length （mmHg） |
|---|---|---|---|
| ART | 300 | 0 | 1 |
| PA | 120 | -6 | 1 |
| CVP | 40 | -10 | 1 |
| RAP | 40 | -10 | 1 |
| LAP | 40 | -10 | 1 |
| ICP | 40 | -10 | 1 |

- SCALE AGJUST : The IBP waveform area provides scales for waveforms. Two dash line of each IBP waveform, from the upper to the lower, respectively represents the upper-limit scale and the lower-limit scale of the waveform. Values of the two scales may be set. The detailed setting method is introduced in the current menu.
  - ◆ CH1:ATR ,PA ,CVP ,RAP ,LAP ,ICP ,P1 ,P2 Setup:
  - Upper scale: The pressure value represented by the upper scale limit. The choice range is the measurement range of the current pressure.
  - Lower scale: The pressure value represented by the lower scale limit. The choice range is the measurement range of the current pressure.
  - Mean scale: he pressure value represented by the middle scale limit. The choice range is the measurement range of the current pressure.
  - ◆ CH2:ATR ,PA ,CVP ,RAP ,LAP ,ICP ,P1 ,P2 Setup:
  - Upper scale: The pressure value represented by the upper scale limit. The choice range is the measurement range of the current pressure.
  - Lower scale: The pressure value represented by the lower scale limit. The choice range is the measurement range of the current pressure.
  - Mean scale: he pressure value represented by the middle scale limit. The choice range is the measurement range of the current pressure.

**Caution**

**The upper scale limit value should not be lower than the lower limit value.**

**Caution**

**The lower scale limit value should not be higher than the upper limit value.**

**Caution**

**The lower pressure limit, the upper pressure limit, the reference scale and the waveform are displayed simultaneously on the screen so that users can observe waveform changes after the scales are adjusted.**

- CH1/CH2 ZERO: the IBP1 and IBP2 module into the socket, the need for invasive pressure zeroing.

## 17.4.2 IBP<1,2>setup in the waveform area

Rotate the knob and move the cursor to the IBP hotkey in the waveform area of the screen.

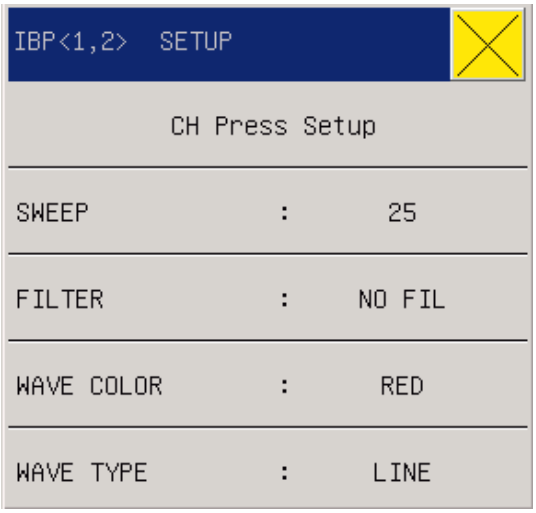



Figure 17-3 IBP Parameter Setting Menu

Settings can be done on the following items:

- CH Press Setup:eight options including ART, PA, CVP, RAP, LAP,ICP ,P1 and P2 are provided.
- SWEEP:12.5mm/s,25mm/s
- FILTER: smooth, normal ,no filter
- WAVE COLOR:green ,cyan , red ,yellow ,white ,blue , purple
- WAVE TYPE:line,fill

## 17.4.3 IBP<1,2>setup in the measurement setup

Select the “Module Setup” option in the “monitor setup” menu and set the CO2 on-off to be on. The following figure (the present figure is in demonstrating mode) will come out:

Press the knob to enter the “IBP selection” menu.

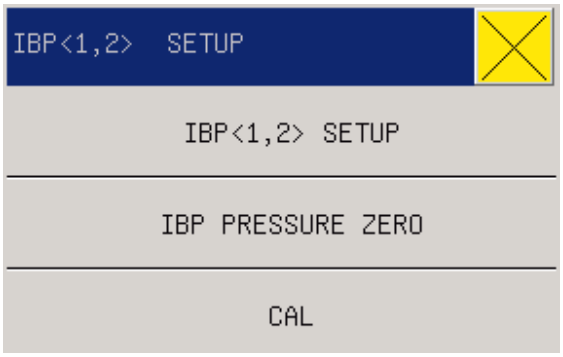



Figure 17-4 IBP Parameter Setting Menu

Settings can be done on the following items:

- IBP<1,2>SETUP:
  - ALM ON/OFF: see this chapter parameter area IBP <1,2>setup the ALM ON/OFF.
  - ALM LEV: see this chapter parameter area IBP <1,2>setup the ALM LEV
  - ALM REC: see this chapter parameter area IBP <1,2>setup the ALM REC
  - SWEEP: see this chapter waveform area IBP <1,2>setup the SWEEP
  - WAVE COLOR: see this chapter waveform area IBP <1,2>setup the WAVE COLOR.
  - UNIT : mmHg,kPa,cmH2O
  - FILTER: see this chapter waveform area IBP <1,2>setup the FILTER.
  - CH Press Setup: see this chapter waceform area IBP <1,2>setup the CH Press Setup
  - ALARM SETUP: see this chapter parameter area IBP <1,2>setup the ALARM SETUP
  - SCALE AGJUST see this chapter parameter area IBP <1,2>setup the SCALE AGJUST
  - DEFAULT: checked into the IBP <1,2> Default Settings dialog box, select "No" to abandon the current operation, the system remains the original configuration unchanged, select "Yes", and will be using the default settings,the original configuration will be overwritten.
- IBP PRESSURE ZERO
  - CH1 ZERO: the IBP1 and IBP2 module into the socket, the need for invasive pressure zeroing.
  - CH2 ZERO: the IBP1 and IBP2 module into the socket, the need for invasive pressure

zeroing.

- CAL(calibration)
  - CH1 CAL VALUE:Adjustable from 80 to 300 values.
  - CH2 CAL VALUE: Adjustable from 80 to 300 values.
  - CH1 ADJUST
  - CH2 ADJUST

**⚠Warning⚠**

**When setting alarm limits, users should confirm the item to be set.**

**Caution**

**Users should guarantee that zero calibration has been done on the sensor before the measurement; otherwise the instrument has no effective zero value, which may lead to inaccuracy of measured data.**

Once the measured data exceed the alarm limits, the alarm will be triggered.

IBP alarm limits:

| Pressure Scale Name | Max Upper Limit (mmHg) | Min Lower Limit (mmHg) | Adjustable Single-Step Length （mmHg） |
|---|---|---|---|
| ART | 300 | 0 | 1 |
| PA | 120 | -6 | 1 |
| CVP | 40 | -10 | 1 |
| RAP | 40 | -10 | 1 |
| LAP | 40 | -10 | 1 |
| ICP | 40 | -10 | 1 |

### 17.4.3.1 Zero calibration of sensor:

Press the “IBP zero calibration” key with the rotary knob and the system will begin zero calibration.

Zero calibration consideration:

Before zero calibration, close the three-way stop cock at the patient side.

Before zero calibration, the sensor should communicate with the atmosphere.

The sensor must be positioned at the same level with the heart, approximately on the midaxillary line.

Zero calibration should be done before monitoring start and at lease once per day (zero calibration must be done each time after the cable is plugged or pulled.)

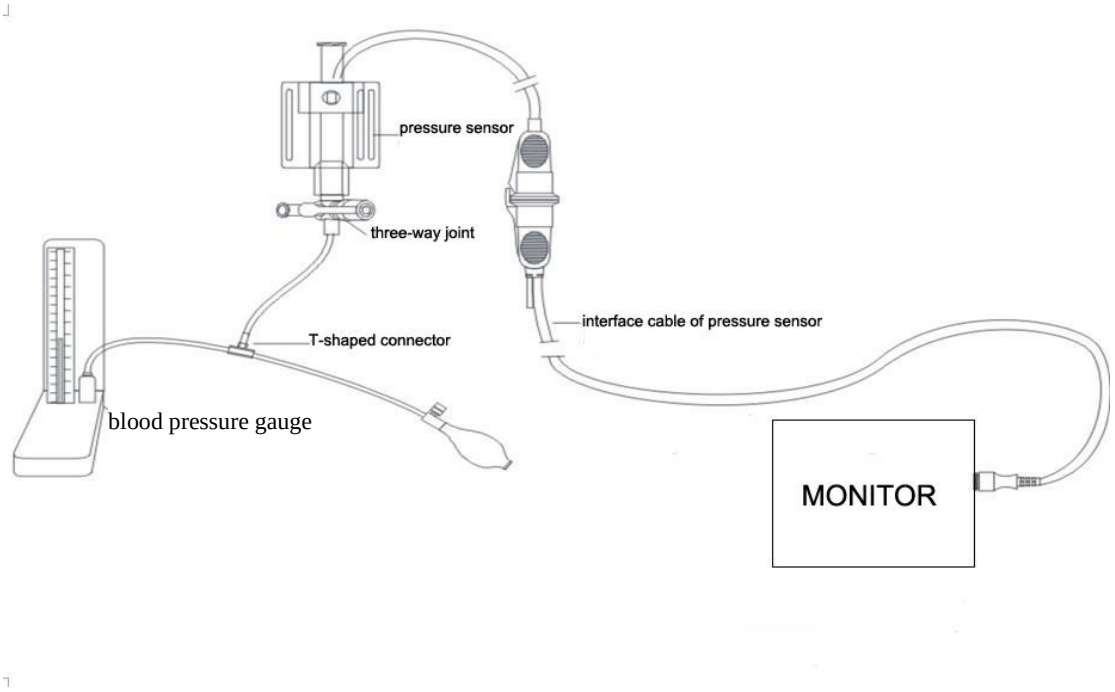



Figure17-5 Connection layout of IBP pressure calibration

Calibration of the mercury manometer should be done when a new sensor is being started to use or at the specified cycle in the hospital practice.

The purpose of calibration is to ensure the system to provide accurate measured results.

Before calibration of the mercury manometer, pressure zero calibration should be done.

If the procedure is to be carried out by yourself, you should have the following devices.

- standard blood pressure gauge
- three-way stop cock
- pipeline with a length of about 25cm

## 17.4.3.2 Mercury manometer calibration procedures:

⚠**Warning**⚠

**The following operation should never be done when a patient is being monitored.**

Close the three-way stop cock which is opened to the atmosphere for zero calibration.
Connect the pipeline with the blood pressure gauge.
Confirm that connection to the patient has been off.
Connect a three-way stop cock with the three-way joint that hasn't been connected to the patient catheter (when the patient is being monitored). Connect a syringe to one end of the three-way stop cock and connect the blood pressure gauge and the pipeline with the other end.
Open the end open to the blood pressure gauge.
Select the channel to be calibrated in the pressure calibration menu and adjust the pressure values of the channel to be calibrated.
Charge gas to raise the scale of the mercury column to the set pressure value in the menu.

Repeatedly adjust until values in the menu equal to pressure values in the blood pressure gauge.
Press once the calibration button in the calibration menu to command the instrument to begin calibration.
Wait until the calibration ends. Make corresponding countermeasures to be taken according to prompt information.
Detach the pipeline of the blood pressure gauge and the added three-way stop cock after completion of the calibration.
The IBP waveform area provides scales for waveforms. Two dash line of each IBP waveform, from the upper to the lower, respectively represents the upper-limit scale and the lower-limit scale of the waveform. Values of the two scales may be set. The detailed setting method is introduced in the current menu.
IBP pressure scale name: ART, RA, CVP, RAP, LAP and ICP are available for selection in the hotkey area of the IBP menu;
Upper scale: The pressure value represented by the upper scale limit. The choice range is the measurement range of the current pressure.

**Caution**

**The upper scale limit value should not be lower than the lower limit value.**
Lower scale: The pressure value represented by the lower scale limit. The choice range is the measurement range of the current pressure.

**Caution**

**The lower scale limit value should not be higher than the upper limit value.**

**Caution**

**The lower pressure limit, the upper pressure limit, the reference scale and the waveform are displayed simultaneously on the screen so that users can observe waveform changes after the scales are adjusted.**

## 17.5 Alarm information and prompt information

### 17.5.1.1 Alarm information

When alarm record switches in related menus are turned on, physiological alarms given when parameters exceeds alarm limits will trigger the recorder to automatically output alarmed parameters and related measured waveforms.

Possible physiological alarms, technical alarms and prompt messages in IBP module measurement are listed in the following tables:

Physiological alarms：

| PROMPT MESSAGE | CAUSE | ALARM LEVEL |
|---|---|---|

| | | |
|---|---|---|
| IS too high | Measured SP value is higher than the set upper alarm limit. | User Optional |
| IS too low | Measured SP value is lower than the set lower alarm limit. | User Optional |
| ID too high | Measured DP value is higher than the set upper alarm limit. | User Optional |
| ID too low | Measured DP value is lower than the set lower alarm limit. | User Optional |
| IM too high | Measured MP value is higher than the set upper alarm limit. | User Optional |
| IM too low | Measured MP value is lower than the set lower alarm limit. | User Optional |

Technical alarms:

| PROMPT MESSAGE | CAUSE | ALARM LEVEL | SOLUTION |
|---|---|---|---|
| IBP lead detached | IBP cable is detached from the monitor | Low | Make sure the cable is connected reliably. |
| IBP module initialization wrong | IBP measurement module has faults | High | Suspend the IBP measurement function and inform biomedical engineers or maintenance workers. |

## 17.6 Maintenance and Cleaning

⚠**Warning**⚠

**Please turn off the monitor and disconnect the AC power supply before cleaning the monitor or sensor.**

When the operations of pressure monitor is finished, please remove the airway and cap from the sensor and clean the film of the sensor with water. You can use the soapy solution or any of the following detergents to clean the sensor and cable.

Cetylcide

Wavicide-01

Wescodyne

Glutaraldehyde

Lysol

Vesphene

Do not immerse the connector in any liquid. After cleaning, do not put it away until the sensor is completely dry. It is normal that the cable fades slightly or has a stronger adhesiveness on the surface. If it is necessary to remove the residue of adhesive tape from the sensor, please use the double-sided adhesive scavenger. Be careful to use the cable, in order to minimize the damage. Please do not use such strong solvents as acetone, alcohol, ammonia water or chloroform, as they could damage the

vinyl cable as time goes on.

**Caution**

**No one-off sensor or cap is allowed to be re-disinfected or reused.**

**Caution**

**For the purpose of environmental protection, please recycle or dispose of the one-off sensor or cap in a proper way.**

## Disinfection

## Disinfection by Chemical Liquid

Follow the above steps to remove the visible dirt. Select an effective chemical disinfectant applicable to the equipments in the operation room, like buffered glutaraldehyde (glutaraldehyde or preservative). Do not use any quadrivalent cationic detergent, like benzalkonium chloride. To disinfect the whole instrument, please remove the cap, immerse the sensor (except the electrical connector) in the disinfectant for the recommended time, and then use the sterile water or physiological saline to rinse out all components (except the electrical connector) of the sensor. Do not put the sensor away until it is completely dry.

## Disinfection by Gas

For a complete sterility, a gas disinfectant is necessary:

- Follow the above steps to remove the visible dirt. In order to restrict the ethylene glycol, please make sure the sensor is completely dry when you use the ethylene oxide gas disinfectant.
- Please follow the operating instructions provided by the manufacturer of the gas disinfectant.

**Warning**

**The disinfectant temperature should not be higher than 70℃(150℉), or the plastics inside the pressure sensor could deform or melt.**

# Appendix I Accessories

Here we recommend the following accessories for the Monitor.

**⚠ Warning**

- **Use the accessories of designated types only, or the Monitor may be damaged.**
- **To prevent reduced performance and cross infections, please do no reuse any disposable accessory.**

| Accessories | Type | Description |
|---|---|---|
| ECG lead cable | 98ME01AD473 | 3-lead American-standard integral clip-on defibrillation-resistant cable |
| | 98ME01AD474 | 5-lead American-standard integral clip-on defibrillation-resistant cable |
| | 98ME01EB477 | 3-lead European-standard integral clip-on defibrillation-resistant cable |
| | 98ME01EB478 | 5-lead European-standard integral clip-on defibrillation-resistant cable |
| | 98ME01AC458 | 3-lead American-standard integral clip-on defibrillation-resistant cable |
| | 98ME01AC457 | 5-lead American-standard integral clip-on defibrillation-resistant cable |
| | 98ME01EC681 | 3-lead European-standard split clip-off defibrillation-resistant cable |
| | 98ME01EC680 | 5-lead European-standard split clip-off defibrillation-resistant cable |
| | A3105-EC1 | 3-lead American-standard integral clip-on defibrillation-resistant cable |
| | A5105-EC1 | 5-lead American-standard integral clip-on defibrillation-resistant cable |
| | A3105-EC0 | 3-lead European-standard integral clip-on defibrillation-resistant cable |
| | A5105-EC0 | 5-lead European-standard integral clip-on defibrillation-resistant cable |
| | 98ME01EB046 | 3-lead main lead cable for neonates (AHA/IEC) |
| | 98ME01AC658 | 3-lead European-standard split clip-on branch lead cable for children/neonates |
| ECG Electrode | SKINTACT | Neonatal electrode |
| | / | Neonatal electrode |
| Nellcor $SpO_2$ Sensor | D-YS | Strap-on $SpO_2$ sensor for finger or toe |
| Masimo $SpO_2$ sensor | M-LNCS YI | Masimo reusable Y-shaped $SpO_2$ sensor for neonates for finger or toe |

| | | |
|---|---|---|
| | / | Y-type sheath |
| $SpO_2$ sensor extension cord | / | Simulated main $SpO_2$ cable |
| | DOC-10 | Nellcor $SpO_2$ extension cord |
| | M-LNC-10 | Masimo sensor extension cord (main cable) |
| Blood Pressure Cuff | U1882S | Blood pressure cuff |
| | U1883S | Blood pressure cuff |
| | U1681S | Blood pressure cuff |
| | U1682S | Blood pressure cuff |
| | U1683S | Blood pressure cuff |
| | U1684S | Blood pressure cuff |
| | U1685S | Blood pressure cuff |
| | 98-0400-99 | Blood pressure cuff |
| | 98-0400-96 | Blood pressure cuff |
| | 98-0400-97 | Blood pressure cuff |
| | 98-0400-98 | Blood pressure cuff |
| | 98-0400-90 | Blood pressure cuff |
| | M5111 | Blood pressure cuff |
| NIBP pipe | / | Neonatal NIBP pipe |
| | / | White NIBP pipe |
| Temp Sensor | TPS03-01 | Temp sensor for neonate surface |
| | TPE03-01 | Temp sensor for neonate cavity |
| | TPS03-04 | Temp sensor for neonate surface |
| | TPE03-05 | Temp sensor for neonate cavity |
| CO2 Accessories | 1015928 | Respironics CAPNOSTAT mainstream $CO_2$ sensor |
| | C500 | NMED mainstream CO2 module |
| | CAT.NO.200101 | PHASEIN (Masimo) IRMA sidestream $CO_2$ mainstream analyzer |
| | 1022054 | Respironics LOFLO sidestream $CO_2$ sensor |
| | C300 | NMED external sidestream CO2 module |
| | CAT.NO.800101 | PHASEIN (Masimo) ISA sidestream $CO_2$ sensor |
| | \ | CO2 connector cable extender |
| | 6312-00 | Neonatal airway adapter |
| | 8751-00 | Cable fixing slot |
| | 3473ADU-00 | Sidestream airway adapter |
| | 1027730 | Sidestream module fixing clip |
| | CAT.NO.106220 | Mainstream airway adapter |
| | 98ME07GC968 | CO2 connector cable extender |
| | CAT.NO.108210 | Sample line |

| | | |
|---|---|---|
| IBP Accessories | PT-01 | IBP sensor with Abbott interface |
| | SAO-BAXTER-01 | IBP sensor with Edwards interface |
| | SCW-R-01 | IBP sensor with BBRAUN interface |
| | SCW-D-01 | IBP sensor with BD interface |
| | SCW-U-01 | IBP sensor with Utah interface<br>BD IBP cable |
| | PT-1 1500 | IBP sensor with Abbott interface |
| | PT-1 1400 | IBP sensor with Edwards interface |
| | PT-1 1200 | IBP sensor with BBRAUN interface |
| | PT-1 1300 | IBP sensor with BD interface |
| | PT-1 1100 | IBP sensor with Utah interface |
| | MC06-141110-01 | IBP Cable with Abbott interface |
| | MC06-141112-02 | IBP Cable with Edwards interface |
| | MC06-141115-02 | IBP Cable with BBRAUN interface |
| | MC06-141113-02 | IBP Cable with BD interface |
| | MC06-141111-01 | IBP Cable with Utah interface |
| Neonatal Asphyxia Awakening Accessories | 040-000443 | Awakening Asphyxiator |
| | 040-000199 | Awakening Asphyxiator Band |
| Oxygen Concentration Accessories | MOX-3 | Oxygen battery |
| | / | Oxygen Concentration sensor cable |

# Appendix IIProduct Specifications

## Classification

Anti- electric-shock type: Class I equipment with the external power supply, anti-defibrillation equipment with internal power supply, continuously operating equipment;
Anti-electroshock degree: equipment belonging to application part of BF, CF Type(among which,ECG testingpart belongs to CF-based application, remaining all othertesting parts belong to BFtype application parts);
Harmful Ingress of Water proof degree: Ordinary equipment (sealed equipment without liquid proof)
Duty: continuous work
EMC type A level

## Product specification

**Size and weight**
Size: 245.5mm×220mm×110mm
Weight:about 3kg
**Power environment**
Rated Voltage：a.c.100V~250V
Rated Frequency：50Hz/60Hz
Built-in Battery：12VRechargeable Lithium Battery
Power Supply：Built-in Rechargeable Battery，or external power supply
Rated Power：40VA~60VA
Resolution： 800×600
**Transportation and Storage**
Transport: Must avoid severe shock ,vibration, rain and snow during transport
Storage : Packed monitors must be stored in well ventilated rooms with -10℃～+40℃ temperature, relative humidity no more than 80%, and without corrosive gases

**Normal Operation**
a) Temperature：5℃～40℃；
b) Relative Humidity：≤80%；
c) Atmospheric pressure：86kPa～106kPa；
**LCD specification:**
Dispiay 8.4’’ color TFT
Display information6 channels waveform display
**Record ( optional )**
Record Width 48 (mm)
Paper Speed 25/50 (mm/S)
Trace 2
Recording types: 3s,5s,8s,continuous
**ECG**
Lead Mode 5 Leads ( R,L,F,N,C or RA,LA,LL,RL,V)
Lead selection I, II, III, avR, avL, avF, V, and MCL for calibration

Lead mode 3 Leads (R, L, F or RA,LA,LL)
Lead selection I, II, III
Gain 2.5mm/mv , 5 mm/mv , 10 mm/mv , 20 mm/mv , auto
HR Range neonate15 ~ 350 (bpm)
Accuracy ± 1% or ±1bpm（both maximum）
Input Impedance > 5 (MΩ)
CMRR > 105 (dB)
Cardiac Electrophysiology Noise level≤30μVP-P.
Cardiac Electrophysiology Input loop current≤0.1μA
Time constantMonitoring, surgical mode: ≥0.3s;
Diagnosis mode: ≥3.2s.
Heart rate alarm occurring time ＜12s
cardiac electrophysiology channel bandwidthMonitoring mode: 0.5～40Hz;
Diagnostic mode: 0.05～130Hz;
Surgical mode: 1～20Hz.

**RESP**

Method Impedance between RA-LL
Measuring Range
neonate 7 ~ 150 (bpm)
Alarm range
neonate upper limit 9~ 150 (bpm)
lower limit 6~148(bpm)
Resolution 1 (bpm)
Accuracy ±2 (bpm) or ±2% （both maximum）
Apean Alarm 10 ~ 40 (S),no alarm

**NIBP**

Method AutomaticOscillometric
Mode Manual, Auto, Continuous
Measuring Interval in AUTO Mode
1 ~ 480 (Min)
Pulse Rate Range 20-300 (bpm)
Type SYS, DIA, MEAN
Measuring Range
Neonatal Mode
SYS 40~150 (mmHg)
DIA 10~100 (mmHg)
MEAN 20~110 (mmHg)
Accuracy ±5mmHg
Overpressure Protection
Pediatric Mode 240 (mmHg)
Neonatal Mode 150 (mmHg)
Alarm limit
Neonatal Mode
SYS Upper limit42 ~ 135 (mmHg)
Lower limit40 ~ 133 (mmHg)

DIA Upper limit 10 ~ 110 (mmHg)
Lower limit15 ~ 235 (mmHg)
MEAN Upper limit 15 ~ 125 (mmHg)
Lower limit15 ~ 235 (mmHg)
NIBP Measurement review 2000

**SPO2**

Measuring Range 0 ~ 100 %
Resolution 1 %
Accuracy 70% ~ 90% (±2%)
90% ~ 100%(±1%)
Alarm range upper limit 1% ~ 100%
` lower limit 0% ~ 99%
Accuracy±1%
Pulse Rate
Measuring and Alarm Range 20~300bpm
Resolution ±1bpm
Accuracy 1bpm

**TEMP**

Measuring and Alarm Range 0 ~ 50 °C
Resolution 0.1°C
Accuracy ±0.1°C
Alarm range upper limit 0.1 ~ 50 °C
lower limit 0 ~ 49.9°C

**CO2**

CO2 Measurement Range: 0 -150 mm Hg, 0 to 79%, 0 to 20kPa (at 760mmHg)
Accuracy: ±2 mm Hg (0 – 40 mm Hg)
±5% of reading (41 – 70 mm Hg)
±8% of reading (71 –100 mm Hg)
±10% of reading (101 –150 mm Hg)
Setting range and error of alarm 0 mmHg～150mmHg or 0 kPa～20kPa (at 760mmHg)
Error ±0.1kPa or±1mmHg

**IBP 1/2**

Channel 1/2 pressure ： ART、PA、CVP、LAP、ICP、RAP、P1、P2
Measurement unit ： mmHg、KPa
ART 0~300 mmHg
PA -6~120 mmHg
CVP -10~40 mmHg
RAP -10~40 mmHg
LAP -10~40 mmHg
ICP -10~40 mmHg
P1- P2 -10~300 mmHg
Resistance range: 300~3000Ω

# Oxygen Sensor Specifications

| | |
|---|---|
| Output | Output 9-13 mV on 210hPa $O_2$ |
| Range | 0～1500hPa $O_2$ |
| 100% $O_2$ signal bias | 100±1% |
| 100% $O_2$ measuring bias | 0-100±3%ss |
| Resolution | 1hPa $O_2$ |
| Expected service life | $1.5\times10^6$ % measured at 20℃<br>$0.8\times10^6$ % measured at 40℃ |
| Response Time (21% air to 100% oxygen) | < 15s |
| **app:ds:linearity** | 0-100% $O_2$ |
| Working temperature | -20℃～+50℃ |
| Temperature compensation | 0-40℃ with ±2% fluctuation |
| Pressure range | 50～200KPa |
| Relative humidity | 0 ～ 99% |
| 100% oxygen concentration output shift | Typical value over 1 year <5% |
| Material | White ABS |
| Package | Sealed package |
| Expiration | Validity period after unpacking is no more than 13 months (under manufacturer-specified conditions, otherwise validity period differs) |

# AppendixIIIInstruction to System Alarm Prompts

## Physical Alarms:

| Prompting Information | Causes | Alarm Grade | Corrections |
|---|---|---|---|
| $O_2$ concentration too high | $O_2$ concentration is higher than set alarming upper limit | Optional | Check whether alarming limits fit for patient's current conditions |
| $O_2$ concentration too low | $O_2$ concentration is lower than set alarming lower limit | Optional | |

## Technical Alarms:

| Prompting Information | Cause | Alarm Grade | Corrections |
|---|---|---|---|
| $O_2$ module disconnected | Cable of oxygen sensor disconnected with monitor | Low | Reinsert $O_2$ module and ensure a reliable cable connection |
| 21% $O_2$ concentration calibrating | 21% $O_2$ concentration calibration is going on | Low | Wait for calibration result |
| 100% $O_2$ concentration calibrating | 100% $O_2$ concentration calibration is going on | Low | Wait for calibration result |

## Prompts:

| Prompts | Causes | Alarm Grade | Corrections |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 21% $O_2$ concentration calibration succeeded | Calibration succeed | Low | None |
| ss100% $O_2$ concentration calibration succeeded | Calibration succeed | Low | None |

# Appendix IVGuidance and Manufacturer's Declaration

## Guidance and manufacturer's declaration

| **Guidance and manufacturer's declaration – electromagnetic emissions** The C60 is intended for use in the electromagnetic environment specified below. The customer or the user of the C60 should assure that it is used in such an environment. | | |
|---|---|---|
| **Emissions test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions CISPR 11 | Group 1 | The C60 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 emissions CISPR 11 | Class A | |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicke r emissions IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** The C60 is intended for use in the electromagnetic environment specified below. The customer or the user of the C60 should assure that it is used in such an environment. | | | |
|---|---|---|---|
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±4kV Contact ±8kV Air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines ±1 kV for input/output lines | ±2 kV for Power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |

| | | | |
|---|---|---|---|
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | ±1kV differential mode ±2kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec | <5% UT for 0.5 cycle 40% UT for 5 cycles 70% UT for 25 cycles <5% UT for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the C60 requires continued operation during power mains interruptions, it is recommended that the C60 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

## Guidance And Manufacturer'S Declaration – Electromagnetic Immunity – for equipment and systems that are not life-supporting

| **Guidance and manufacturer's declaration – electromagnetic immunity** The C60 is intended for use in the electromagnetic environment specified below. The customer or the user of the C60 should assure that it is used in such an environment. | | | |
|---|---|---|---|
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |

| | | | |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6<br><br><br><br>Radiated RF<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br><br><br><br>3 V/m<br>80 MHz to 2,5 GHz | 3V<br><br><br><br>3V/m | Portable and mobile RF communications equipment should be used no closer to any part of the C60, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 $p$ d = 1.2 $p$ 80 MHz to 800 MHz d = 2.3 $p$ 800 MHz to 2,5 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: |

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

| Recommended separation distances between Portable and mobile RF communications equipment and the C60 | | | |
|---|---|---|---|
| The C60 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the C60 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the C60 as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
| | 150 kHz to 80 MHz d = 1.2 $p$ | 80 MHz to 800 MHz d = 1.2 $p$ | 800 MHz to 2.5 GHz d = 2.3 $p$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

promedic
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Read the instructions carefully before using this device.

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