Service Manual

of

PM-8000

Portable Patient Monitor

Copyright

Version: 2.0
Issued date: 2005/07/24
P/N: 8000-20-10282

Statement

Responsibility on the manufacturer party

Mindray is responsible for safety, reliability and performance of this equipment only in the condition that:

- all installation, expansion, change, modification and repair of this equipment are conducted by Mindray qualified personnel; and,
- applied electrical appliance is in compliance with relevant National Standards; and,
- the monitor is operated under strict observance of this manual.

′ NOTE ′
This equipment is not intended for family usage.

⚠ **Warning** ⚠

This monitor is not a device for treatment purpose.

It is important for the hospital or organization that employs this equipment to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.

Upon request, Mindray may provide, with compensation, necessary circuit diagrams, calibration illustration list and other information to help qualified technician to maintain and repair some parts, which Mindray may define as user serviceable.

Warranty

Workmanship & Materials

Mindray guarantees new equipment other than accessories to be free from defects in workmanship and materials for a period of one year (six months for multi-site probes and SpO2 sensor) from date of shipment under normal use and service. Mindray's obligation under this warranty is limited to repairing, at Mindray's option, any part which upon Mindray's examination proves defective.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANT ABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the substitution upon it of parts or accessories not approved by Mindray or repaired by anyone other than a Mindray authorized representative.

This warranty shall not extend to any instrument which has been subjected to misuse, negligence or accident; any instrument from which Mindray's original serial number tag or product identification markings have been altered or removed, or any product of any other manufacturer.

Safety, Reliability and Performance

Mindray is not responsible for the effects on safety, reliability and performance of the PM-8000 Portable Patient Monitor if:

- assembly operations, extensions, re-adjusts, modifications or repairs are carried out by persons other than those authorized by Mindray.
- the PM-8000 Portable Patient Monitor is not used in accordance with the instructions for use, or the electrical installation of the relevant room does not comply with NFPA 70: National Electric Code or NFPA 99: Standard for Health Care Facilities (Outside the United States, the relevant room must comply with all electrical installation regulations mandated by the local and regional bodies of government).

Return Policy

Return Procedure

In the event that it becomes necessary to return a unit to Mindray, the following procedure should be followed:

1. Obtain return authorization. Contact the Mindray Service Department and obtain a Customer Service Authorization (Mindray) number. The Mindray number must appear on the outside of the shipping container. Return shipments will not be accepted if the Mindray number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.

2. Freight policy. The customer is responsible for freight charges when equipment is shipped to Mindray for service (this includes customs charges).

Company Contact

Address: Mindray building keji 12th road south hi-tech industrial park nanshan Shenzhen, P.R.China

Phone: +86 755 26582658/26582888

Fax: +86 755 26582680

Free hot line: +86 800 830 3312

EC Representative

Name: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80 D-20537 Hamburg Germany

Phone: +49 40 2513174

Fax: +49 40 255726

Preface

This manual gives detailed description to PM-8000 Portable Patient Monitor concerning its performance, operation, and other safety information. Reading through this manual is the first step for the user to get familiar with the equipment and make the best out of it.

Following symbols indicates some important facts that you have to pay special attention to:

⚠ **Warning** ⚠ Points to be noted to avoid injury to the patient and the operator.

⚠ **Caution** ⚠ Points to be noted to avoid damage to the equipment.

′ NOTE ′ Points to be noted.

This manual is intended for persons who are trained in the use of this field and have adequate experience in operation of monitoring equipment.

Content

Chapter 1 Introduction

I. General

Environment:

Temperature

Working	0 ~ 40 °C
Transport and Storage	-20 ~ 60 °C

Humidity

Working	15% ~ 95%
Transport and Storage	10% ~ 95%

Altitude

Working	-500 to 4,600m
Transport and Storage	-500 to 13,100m

Power Supply

100~240 (V)AC, 50/60 Hz

Pmax=100VA

FUSE T 1.6A

PM-8000 Portable Patient Monitor (Figure 1-1) is adaptable to adult, pediatric and neonatal usage. It can monitor vital signals such as ECG, Respiratory Rate, SpO2, NIBP, TEMP and IBP. It integrates parameter measuring modules, display and recorder into one device, featuring in compactness, lightweight and portability. Replaceable built-in battery facilitates the transportation of patient. Large high-resolution display provides clear view of 5 waveforms and full monitoring parameters.

PM-8000 Portable Patient Monitor performs monitoring of:

ECG	Heart Rate (HR)
	2-channel ECG waveforms
	Arrhythmia and S-T segment analysis（optional）
RESP	Respiratory Rate (RR)
	Respiration Waveform
SpO2	Oxygen Saturation (SpO2), Pulse Rate (PR)
	SpO2 Plethysmogram
NIBP	Systolic Pressure (NS), Diastolic Pressure (ND), Mean Pressure (NM)

TEMP	Temperature DATA
IBP	IBP SYS, DIA, MAP IBP waveform

PM-8000 provides extensive functions as visual & audible alarm, storage and report printout for trend data, NIBP measurements, and alarm events, and drug dose calculation, etc.

II. Appearance

The POWER switch is on the right quarter of the front panel (②). The POWER indicator(④) and the BATT indicator (③) light when the device is powered on. The ALARM indicator flashes or lights when alarm occurs (①). Sockets for the sensors are on the right side. The recorder socket is on the left side. Other sockets and power plug-in are at the back.。

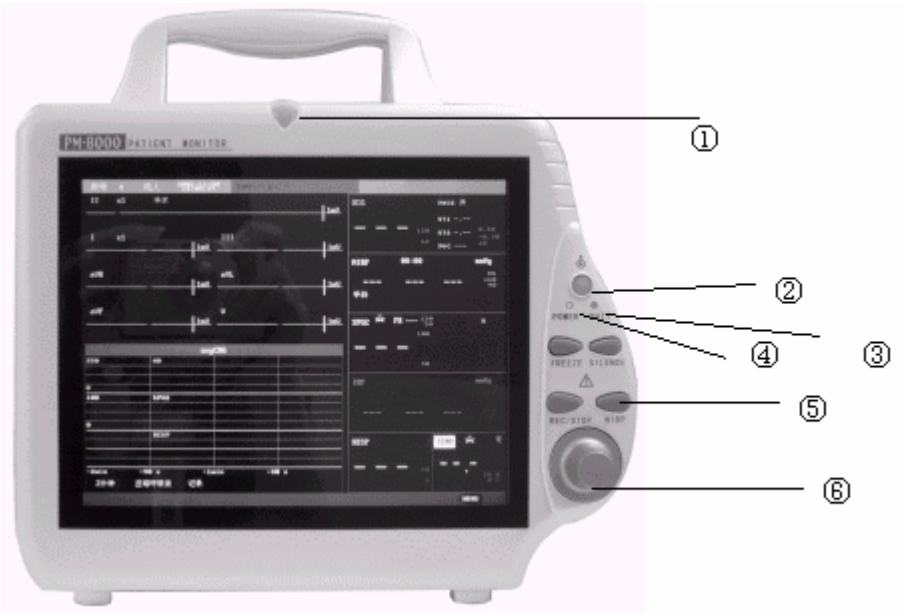


Figure 1-1 Front view of PM-8000 Portable Patient Monitor

2.1 Screen display

The display of PM-8000 may be color or monochrome liquid crystal. (The monitor of PM-8000 is available in both monochrome and color liquid crystal).Patient parameters, waveforms, alarm messages, bed numbers, date, system status and error messages can be displayed on the screen.

The screen is divided into three areas: ← message area①; ↑ waveform area②; → parameter area

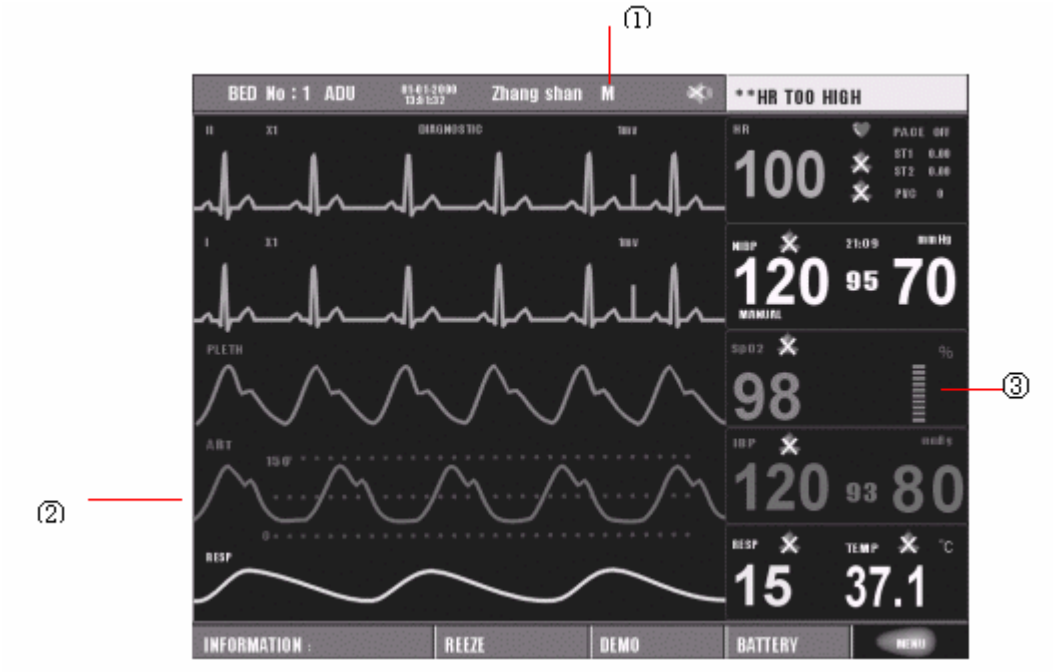


Figure 1-2 PM-8000 main screen

Message Area(①)

The Message Area is at the top of the screen and used to display operating state of the monitor and status of the patient.

The messages and their meanings are:

【BED No】	Bed number of the patient being monitored
【3/1/2001】	Current date
【10:23:45】	Current time
【M/F】	Sex of the patient being monitored
【NAME】	name of the patient being monitored. When the user is entering patient name, the name will be displayed at this position. If no patient name is entered, this position will be blank.

Other information in the Message Area comes up only with respective monitoring status. They are:

1. Signs indicating the operating status of the monitor and the sensors are displayed at the right side of time numeric. When appears, this message will cover the sex and name information of the patient.

2. "" Indicates that all sounds are disabled manually. It appears when SILENCE button is pressed for more than 1 seconds.

3. "！" is the sign indicating that the alarm volume is closed. When select the "OFF" option in the ALARM SETUP menu, this mark appears indicating that the operator has permanently closed the

audio alarm function. This audio alarm function can resume only after the operator discharges the setup of Close Alarm Volume.

′ NOTE ′

When "！" sign appears, the system can not give any audio alarm prompt. Therefore, the operator should be careful in using this function. One method of discharging this status is in the ALARM SETUP menu, select the item that the alarm volume is in Non-close. Another method is to press the SILENCE button so as to make the mark change into a . Then press SILENCE button again, the system will immediately restores the normal alarm status.

4. Alarm message is displayed always at the extreme right area on the screen.
5. When waveforms on the screen are frozen, "FREEZE" window appears at the bottom of the screen.

Waveform/Menu Area(②)

Five waveforms can be displayed at the same time. The waveforms from up to down are: 2 channels of ECG waveforms, SpO2 Plethysmogram, IBP, RESP (possibly coming from ECG module). Waveforms to be displayed are user-selectable. Refer to **Tracing Waveforms Selection in Operation Manual** for details.

The names of the waveforms are displayed to their left. The names of ECG and IBP are user-selectable. Refer to **Chapter ECG/RESP Monitoring** and **Chapter IBP Monitoring in Operation Manual** for details. Gain and filter of this ECG channel are displayed as well. A 1mv scale is marked on the right of ECG waveform. The IBP waveform scale is displayed in IBP wave area. The three dot lines from up to down respectively represent the highest scale, reference scale and lowest scale of the waveform. These values can be manually set. Refer to **Chapter IBP Monitoring in Operation Manual** for IBP setup.

The same menu always appears at a fixed area on the screen. When the menu is displayed, some waveforms become invisible. The size of the menu is also fixed, covering the lowest 3, 4 or 5 waveforms. If the system exits the menu, the screen will restore its previous look.

The waveforms are refreshed in a user-set rate. Refer to the related chapters for details of sweep speed.

Parameter Area(③)

Parameters are displayed at a fixed position (①~⑩). They are (from top to bottom):

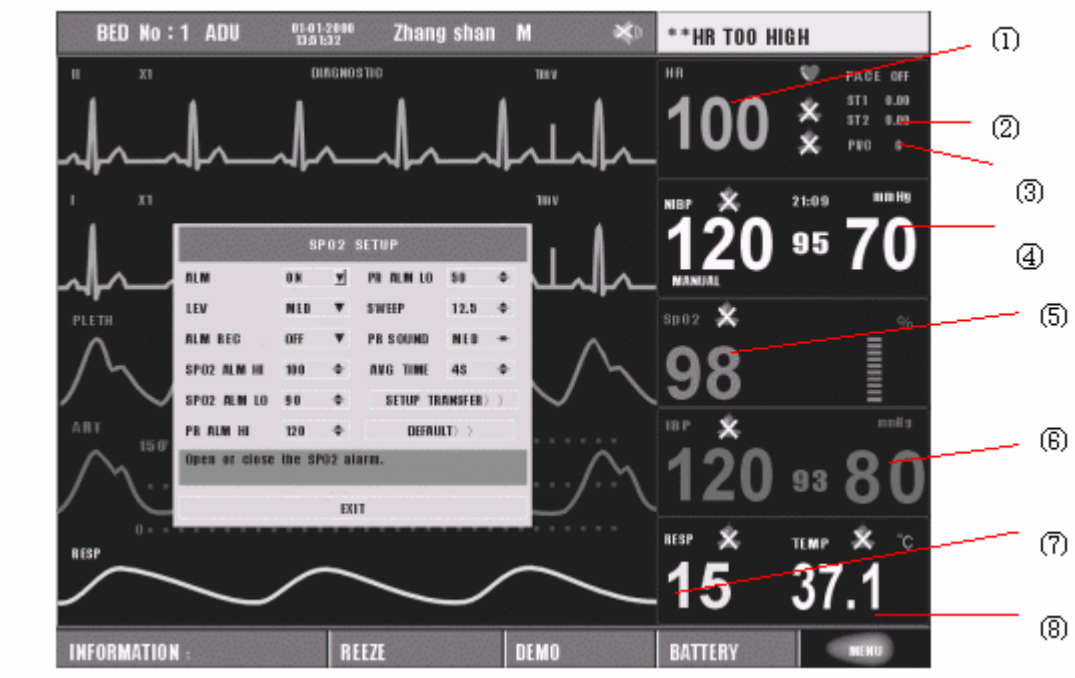


Figure 1-3 Main Screen

ECG

— Heart Rate (①, Unit: bpm)

— ST-segment analysis of Channel 1 & 2 (②, Unit: mv)

— Arrhythmia (PVCs) events (③, Unit: event/min)

NIBP

— (From left to right) Systolic, Mean, Diastolic (④, Unit: mmHg or kPa)

SpO2

— SpO2 (⑤, Unit: %)

IBP

— Blood Pressure: Systolic, Mean, and Diastolic values are displayed from left to right. (⑥, Unit: mmHg or kPa)

RESP

— Respiration Rate (⑦, Unit: breath/min)

TEMP

— Temperature (⑧, Unit:℃ or ℉)

The above monitoring results are displayed in the Parameter Area.

The parameters refresh every second, except that the NIBP value refreshes each time when the measurement is over.

User can select the monitor parameters, and the screen display will change accordingly.

Alarm indicator and alarm status:

In normal mode, no indicator lights.

In alarm mode, the alarm indicator lights or flashes. The color of the indicator indicates the alarm level.

2.2 Button Functions

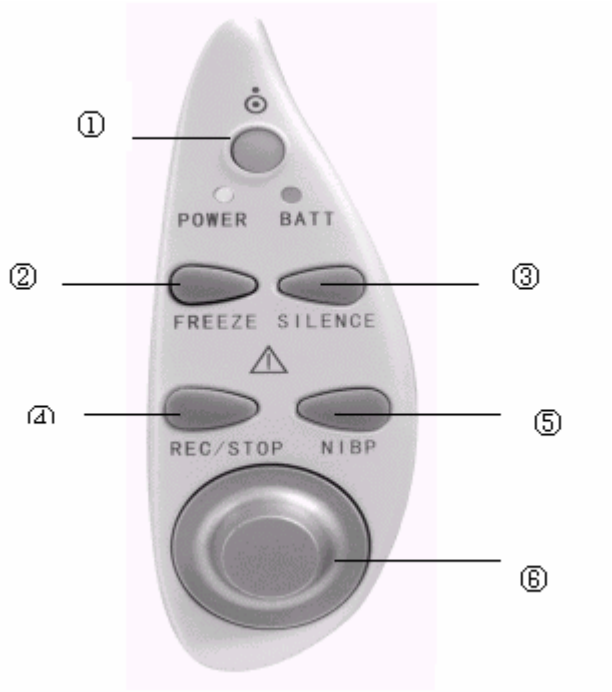


Figure 1-4 PM-8000 Buttons and Knob

All the operations of PM-8000 can be performed through using the buttons and the rotary knob at the bottom of the screen. Above the buttons are their respective names. They are (from left to right):

①POWER Press to turn on/off the monitor.

②FREEZE When in normal mode, press to enter Freeze mode to freeze all the waveforms on the screen. When in Freeze mode, press to restore the waveform refreshing.

③SILENCE Press to suspend alarm for 3 minutes (it can be selected in ALARM SETUP menu). Press this button for more than 1 seconds to disable all sound signals (heart, beat, pulse tone, key sound), and audio alarm. A symbol "🔕" displays in the Message Area. Press this key again to restore all sound signals and remove the "🔕" symbol.

NOTE:
If new alarm occurs under Alarm Suspension/Silence state, Suspension/Silence state will change. For specific rules, see Chapter Alarm.

NOTE:
Whether an alarm will be reset depends on the status of the alarm cause. But by pressing SILENCE button can permanently shut off audio sound of the ECG Lead Off and SpO2 Sensor Off alarm.

④REC/STOP Press to start a real time recording. The recording time is set in RT REC TIME of RECORD submenu (Refer to **related sections** for details). Press during recording to stop the recording. When in FREEZE mode, press to select the waveforms for report printout. Refer to **Chapter Recording** for details.

⑤START Press to inflate the cuff to start a blood pressure measurement. When measuring, press to cancel the measurement and deflate the cuff.

⑥Rotary Knob This knob can be used to select and change the settings. Operation can be performed by turning it clockwise, counterclockwise or pressing it down.

Rotary Knob

The square frame that moves when the knob is being turned is called "cursor". Operation can be executed at any place where the cursor can stay. When no menu is displayed, turning the knob clockwise can select following hot keys:

Channel 1 ECG lead

Channel 1 ECG gain

ECG filter

Channel 2 ECG lead

Channel 2 ECG gain

IBP Label

ECG menu

SpO2 menu

NIBP menu

IBP menu

RESP menu

TEMP menu

When the current cursor is placed at any of the first six items, the user can change the current settings. When at any of the last six items, related parameter menu could be called up for setting changes.

2．3 Interfaces

For the convenience of operation, different interfaces are in different parts of the monitor. Recorder is on the left side of the monitor while sockets for patient cables and sensors are on the right side. See the figure below:

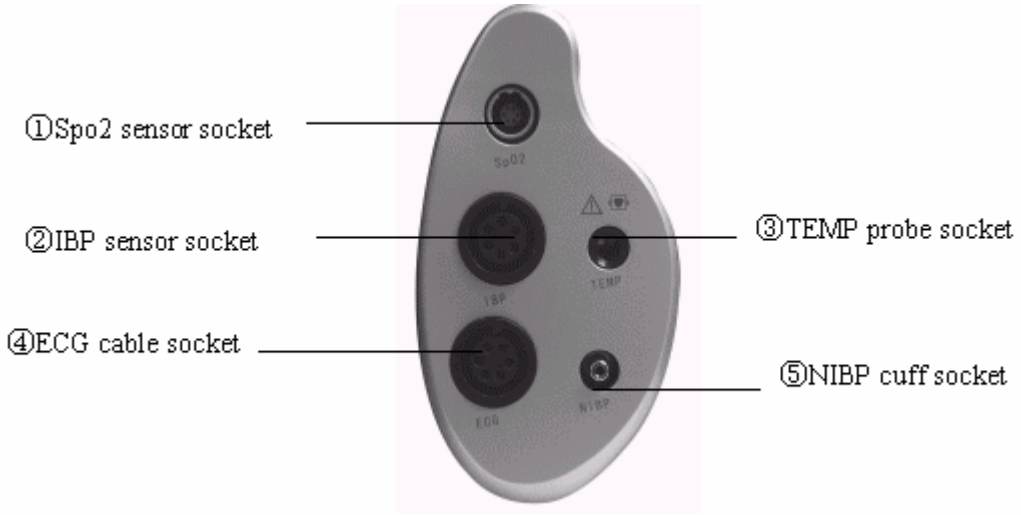


Figure 1-5 Right side view

This symbol means “BE CAREFUL". Refer to the manual.

Indicates that the instrument is IEC-60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.

Figure 1-6 Rear panel

Monitor interface for external: standard VGA color monitor.

Working mode: 640 × 480, 16 color, APA mode.

Signal: analog R G B 0.7 Vpp / 750 ohm

Hor. / Vert. TTL pos. / Neg.

Interface D-sub 15 pin

Pin 1. Red Video

Pin 2. Green Video

Pin 3. Blue Video

Pin 4. Ground

Pin 5. NC

Pin 6. Red Ground

Pin 7. Green Ground

Pin 8. Blue Ground

Pin 9. NC

Pin 10. Ground

Pin 11. NC

Pin 12. NC

Pin 13 Horizontal Sync.

Pin 14. Vertical Sync.

Pin 15. NC

Appliance: (Installation)

1) Install the VGA monitor at a place at least 1.5m away from the patient.(The VGA monitor must be installed at least 1.5m away from the patient.)This monitor is used only as an assistant monitoring device.
2) Plug the cable into proper socket before powering on the VGA monitor.
3) It is allowable to power on the VGA monitor and PM-8000 at the same time. Or power on PM-8000 after turning on VGA monitor.
4) Adjust brightness and contrast properly.

⏚ (Socket ④)

Equipotential grounding terminal for connection with the hospital's grounding system.

ANALOG OUTPUT (Socket ②)

Analog signal output terminal for connection with oscillometer and pen recorder.

The connection terminal is a BNC Jack.

Network Interfaces (Socket ①): Standard RJ45 Socket.

⚠ **Warning** ⚠

Through network interface only MINDRAY Clinical Information Center can be connected in.

⚠ **Warning** ⚠

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

2．4 Built-in rechargeable battery

PM-8000 Portable Patient Monitor is equipped with a rechargeable battery. The battery in the Monitor can automatically recharge when AC INPUT is connected until it is full. A symbol "▮" is displayed

on the bottom of the screen to indicate the status of recharging, in which the black part represents the relative electric energy of the battery. If the battery is not installed in PM-8000, battery state will be displayed as "▭" to indicate the state. Under the cable socket is the battery slot with cover.

⚠ Warning ⚠

Don't pull off battery when the monitor is working.

When operating on battery, the monitor will prompt alarm and shut off automatically when the energy is low. When the electric energy is going out, the monitor will sound continuous level 1 alarm beeping and display "BATTERY TOO LOW" in the Message Area. Connect the monitor to AC power at this moment can recharge the battery while operating. If keep operating on the battery, the monitor will shut off automatically (about 5 minutes since alarming) upon exhaustion of the battery.

Figure 1-7 Battery slot cover

III. Hardware principle

PM-8000 block diagram

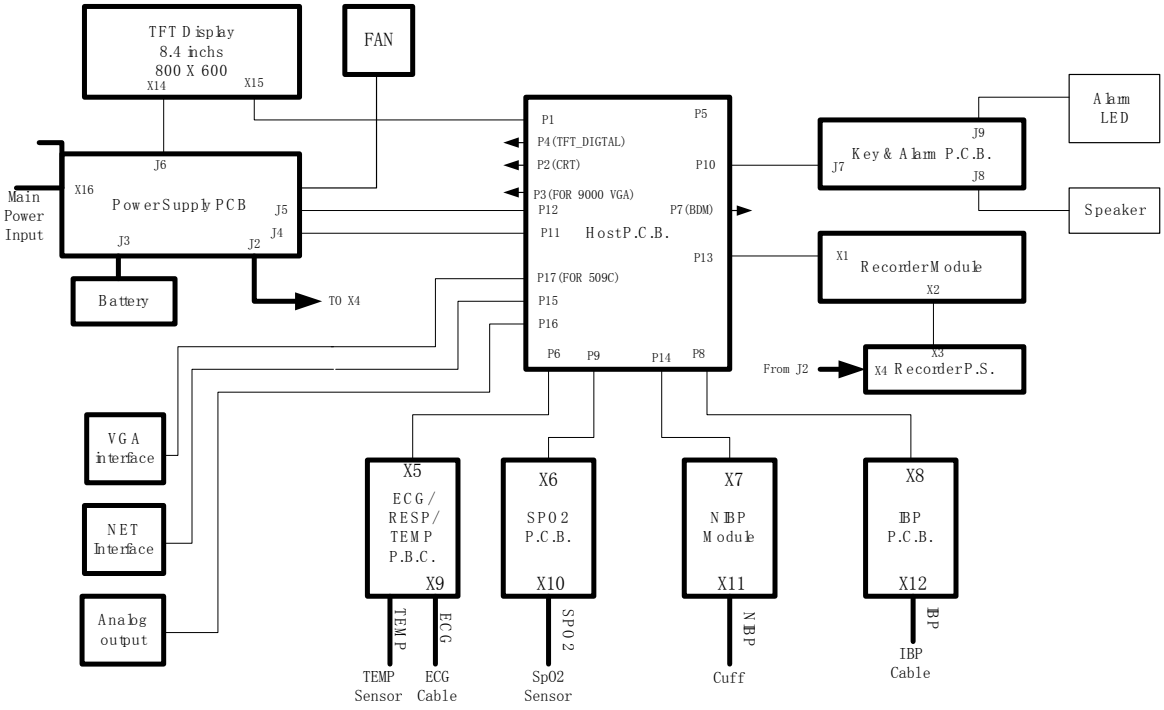


Figure 1-8 PM-8000 connection diagram

Following are brief description of basic function and operating principle of each part.

3．1 Power board

PM-8000 power board specifications:

AC input voltage:100~240VAC

AC input current: <1.6A

AC voltage frequency: 50/60HZ

Two-way output voltage: 5V/12V, normal working current is 1.5A for 5V, 2A for 12V.

Two-way output voltage has functions of short-circuit, over-current and over-voltage protection.

The power board has reset function.

The power board can manage the charging process of lead-acid battery (12V/2.3AH). The charging time is about 6 hours.

Schematic diagram of power board:

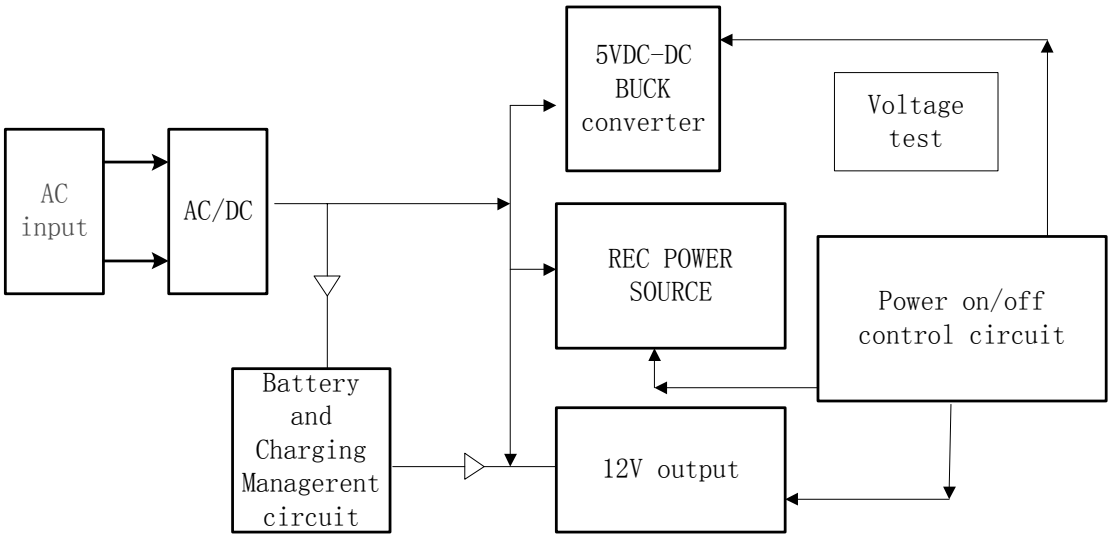


Figure 1-9 circuit diagram of PM-8000 power board

Testing key points:

Connect AC power (at this time, the Charge indicator of the battery should light on).

Test before power on the monitor.

Use multimeter to measure the DC voltage of the capacitor C12, which should be within the range of 107 ~ 354V.

Use oscillograph to measure between the PIN1 of Q1 and the negative electrode of C12, a driving

waveform with the frequency being about 110KHz should exist.

Use multimeter to measure the DC voltage of the capacitor C19, which should be 17.5V.

Use multimeter to measure the DC voltage of the capacitor C24, which should be 13.8V (voltage after removing battery).

Use multimeter to measure the capacitor C47, which should be 5V.

Tests after powering on the monitor:

Use multimeter to measure the regulator ZD3 whose DC voltage should be 5V.

Use multimeter to measure the regulator ZD4 whose DC voltage should be 12V.

Use multimeter to measure the capacitor C54 whose DC voltage should be 17.2V.

3．2 PM-8000 main control board

Power supply

Input voltage: ＋12V±5%;

＋5V±5%;

The main control board uses the COLDFIRE series embedded microprocessor 5206e manufactured by MOTOROLA Company. It also adopts 3.3V low-voltage power supply to reduce the power consumption. Other main components on the main control board include: Flash, SRAM, FPGA, network controller, etc, all of which require 3.3V power. The capacity of the Flash has been increased to 2MB, which employs two parallel-connected 512Kx16 chips and therefore uses 32-bit character width to support CPU to operate at the highest possible speed instead of accessing to DRAM for operation. The main control board has also a 4MB memory, which is made up of two parallel-connected 1M ×16-bit chips. Because no executing program is required to be loaded, only one RTC is used. This chip uses one 225maH dry cell as the spare power supply. In addition, one 2KB E^2PROM is used to store parameters. The main control board supports a resolution of 800x600 and provides three interfaces: a LVDS interface, a 6BIT DIGITAL interface, and a VGA interface. The monitor displays both characters and waveforms in an overlapping way on the whole screen in the same color. The characters and waveforms can be browsed in a scrolling way. The support system needs 10 serial ports, and the baud rate (4800/9600/19.2k/38.4k/76.8k) can be online selected by software and interface buffer drives. The main control board adopts the network controller AX88796 (3.3V, 10MHz), which has inside 16K high-speed buffer SRAM. The MAX5102 8-bit single-way D/A converter is used to fulfil analog output. 5V and 12V stabilized voltage supplies are introduced from the power board, and therefore 3.3V and 2.5V working supplies are respectively generated. Among them, 2.5V is to be used for the internal verification of FPGA.

3．3 Structure diagram

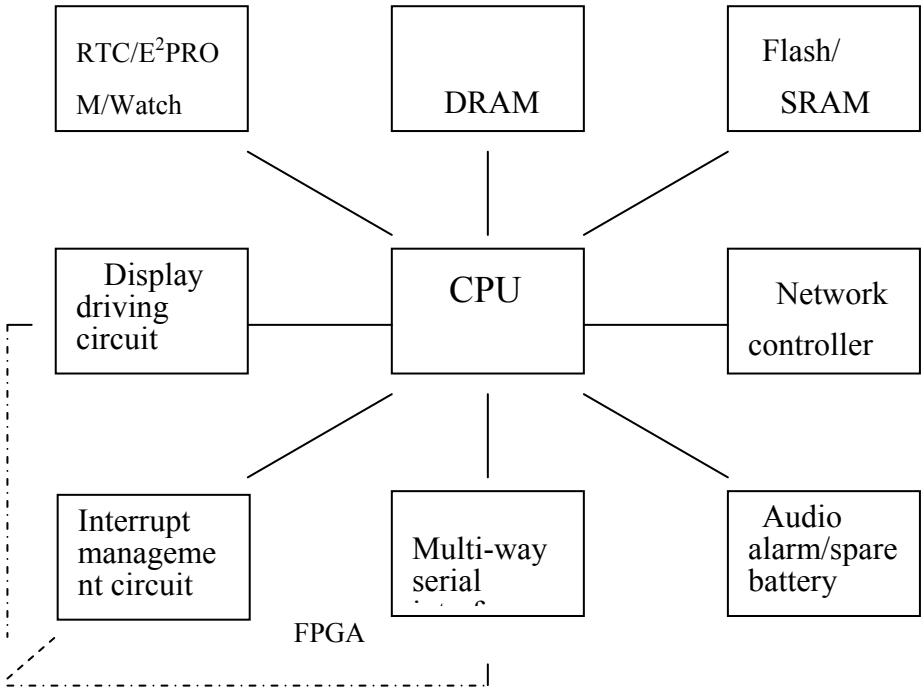


Figure 1-10 Structure diagram

3．4 Description

3.3V low-voltage power supply component is adopted. The external power is 5V, which is converted by the DC/DC converter into 3.3V and 2.5V, the latter voltage being especially used for FPGA. The main control board are connected with the external devices via following interfaces and input: the power supply connected with the interface board, the 9-way serial port, TFT interface, analog VGA interface, network interface, analog output and a spare serial port, etc. The BDM interface is reserved on the board for the aim of software testing and download.

■ CPU

It use Coldfire5206e. Clock rate is 54MHz, working voltage is 3.3V.

■ FLASH

It use tow parallel-connected 512Kx16 FLASH memories. The output terminal PP1 of CPU is used to realize write-protection of FLASH. It is effective in low-level state.。

■ DRAM

PM-8000 main control board uses two parallel-connected 1Mx16 DRAM, which construct 4M address space.

■ Display

The resolution is 800x600. Frequency is 38MHz. It works in an appropriate SVGA mode. VRAM adopts 16-bit structure and is divided into character screen and waveform screen. On the left side of the

character screen is the corresponding waveform screen. The right side to the character screen is used to display data and flashing alarms. The user can select color and dot energy. Besides the user can scroll the waveform for clear and complete observation.

■ LVDS interface

Through the way of time-sharing sampling, the LVDS interface converts multi-way CMOS/TTL signals into one-way low-voltage double-frequency difference signals, which are further to be output to the outside). LVDS interface is generally realized by special integrated circuit. The special LVDS chip used for display is DS90CF363A. This chip converts 18-way display pixel signals and 3-way display control signals with a total of 21-way messages into 3-way LVDS signals. Four ways of difference signals including these 3 ways of signals and a way of phase-locked frequency are transmitted to the display screen. On the one side of the screen, these signals are restored for driving the screen. The working frequency of DS90CF363A is 20~65MHz.

■ Reset and parameter storage

The main control board uses an integrated chip CS124C161, which has the functions of both power-on reset and parameter storage. This chip has a E^2PROM with the capacity of 2K. It can be used to on-line modify and store various nonvolatile parameters of the host. The power-on reset and WATCHDOG functions are used to realize reset function of the main control board. When J1 is open circuit, the software can also disable WATCHDOG by using the output wire PP0 of CPU in order to realize the selftest of WATCHDOG. The bus interface of this chip is I^2C.

■ Data storage

The Main control board uses one non-power-down SRAM having its internal battery to store monitoring data. Its capacity is 2M.

■ Network controller

The network controller adopts special chip AX88796. Its working clock is 25MHz. It also has internal 16K high-speed buffer SRAM. The data bus of this chip is 16-bit width.

3．5 Button schematic diagram and principle

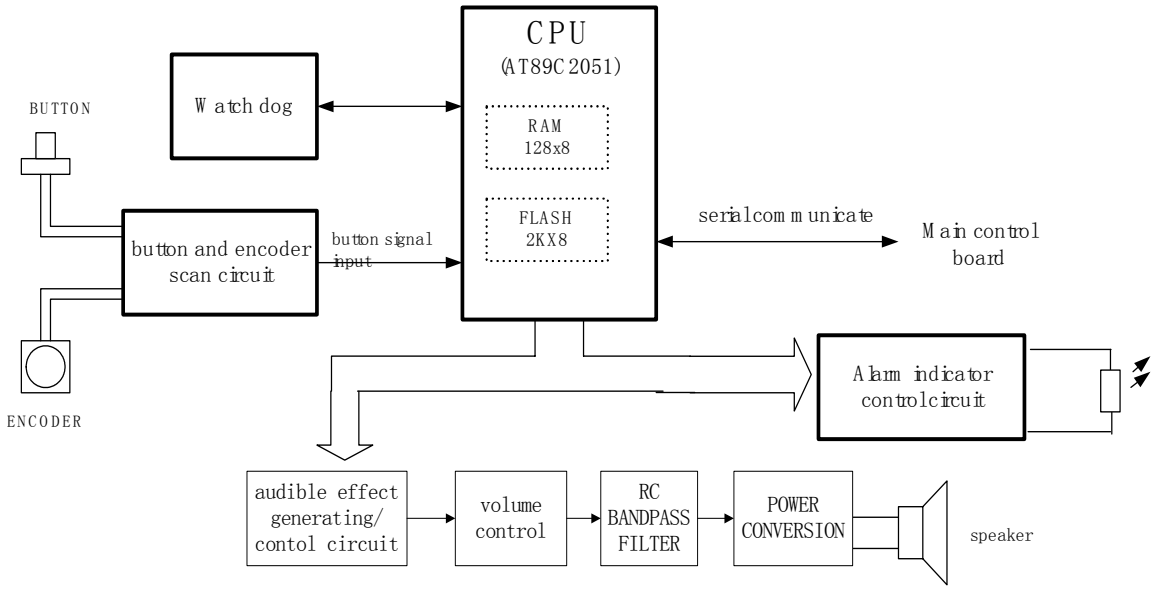


Figure 1-11 Button schematic diagram

3．5．1 Principle introduction:

The circuit has three main parts;

■ Alarm audio signal circuit: audible effect generating circuit is made up of nine components, which are U3, D1, D2, D3, Q1, C2, R15 and R9. The length of the generated aftersound is controlled by the discharge loop constructed by C2 and R15. P3.5 is used to generate alarm square waveforms (about 700Hz). When P3.3 is 1 and Q1 is on, alarm is activated, C2 is quickly charged to the full capacity and R10 outputs to the next phase. When P3.3 is 0, alarm is terminated, C2 discharges by using R15 so as to produce aftersound effect. D3 and D9 are used to overlap heart beat sound. When P3.2 is 1, the square waveform of P3.5 generates “heart beat sound” and “rotary encoder sound” through controlling the time length of the conduction of P3.2. Together with R17, R18 or R19, R10 may respectively construct potential-dividing network of different proportion, and consequently control the state of P3.4 and P3.7, decide make-and-break of Q2 and Q3 so as to realize the function of adjusting 3-level sound volume.

■ RC bandpass filter: The alarm signal is square waveform with the frequency of about 700Hz. To remove the DC component (low-frequency component) in the square waveform, a one-phase bandpass filter is added before LM386. This filter is made up of R22, C13, C11 and the input resistance Rin of LM386.

■ Audio amplifying circuit constructed by LM386: Generation of the visual alarm signal: The flashing of the indicator in red or green is realized by controling the state of singlechip P1.6 and P1.7. Scanning of buttons and encoder: Determine whether a button or the encoder is pressred through the way of scanning the state of singlechips P1.0~P1.2. Determine whether encoder is turned and its turning direction by scanning the state of P1.4 and P1.5.

3．5．2 Important measurement points

1. Test if the 5V power supply works normally (after fuse FU1);
2. Test if the crystal oscillator starts oscillating when the voltage is about between 1.5~3.5V.

3.6 Maintenance part of TR60-A recorder

3.6.1 Diagram

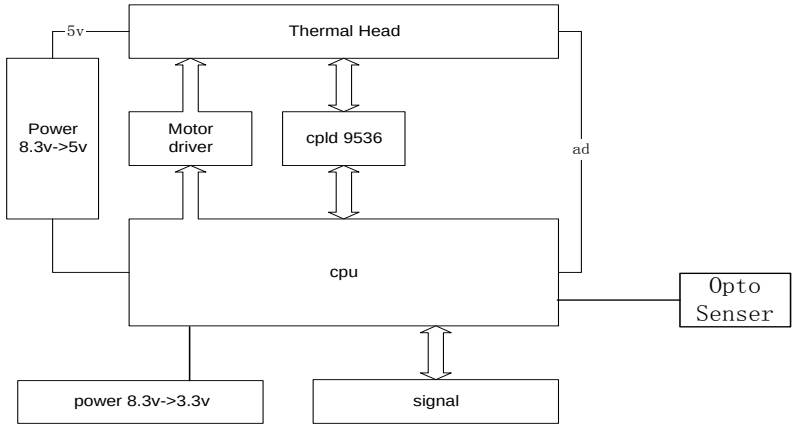


Figure 1-12 Schematic diagram of TR60-A drive board

The main function parts of the recorder are:

3.6.2 Thermal head

The thermal head is the pivot component of recorder. It is PTMBL1300A thermal head manufactured by ALPS company.

3.6.3 CPU system

The CPU system is the core of the drive board. Its task is to receive the data from the host and generate lattice messages after calculation using specified algorithm. These messages are then sent to the thermal head to be printed out. The CPU system can at the same time collect messages about both thermal head and drive board, have these messages displayed and sent to the host.

3.6.4 Power conversion

The thermal head requires two power supplies: 8.3V and 5V. CPU needs 3.3V power. 5V and 3.3V are generated on the drive board. Components using these two power supplies are SPX5205M5 and AS1117.

3.6.5 Motor drive

A small motor is used to control the paper movement at the thermal head. The processor on the drive board uses two motor drives IC LB1843V to control and drive the motor. These two ICs are able to drive the motor using constant-current. The logic drive level of the thermal head used on the CPLD9536 drive board is 5V CMOS. The processor works under 3.3V. The system uses a CPLD X9536XL, by which the output logic of the OC gate is generated, therefore converting 3.3V level into 5V.

3.6.6 Test points are listed out in the table below：

No.	Name	Position	Function
1	VH	P1.1 or P1.2	Power input: 7.8~8.4V
2	GND	P1.4 or TP16	Power and signal grounding termals
3	VPP	U3.8	Thermal head heating and motor power: 8~8.4V
4	VDD	U9.2	Logic component power of the drive board: 3.0~3.6V
5	VCC	U4.5	Logic power of the thermal head: 4.75~5.25V
6	RESET	TP30	CPU reset signal, high level after power-on: （>2.4V）。

Chapter 2 Monitor Functions and Principles

I. Introduction

PM-8000 portable patient monitor uses parameter module as the basic unit to acquire signals. The results are transmitted to the main control board via keyset to finally process and display the data and waveforms. The commands of the main control board and status messages of modules are transmitted also through the keyset. The keyset is additionally used to realize power switching and conversion. The structure of the whole system is shown in the figure below:

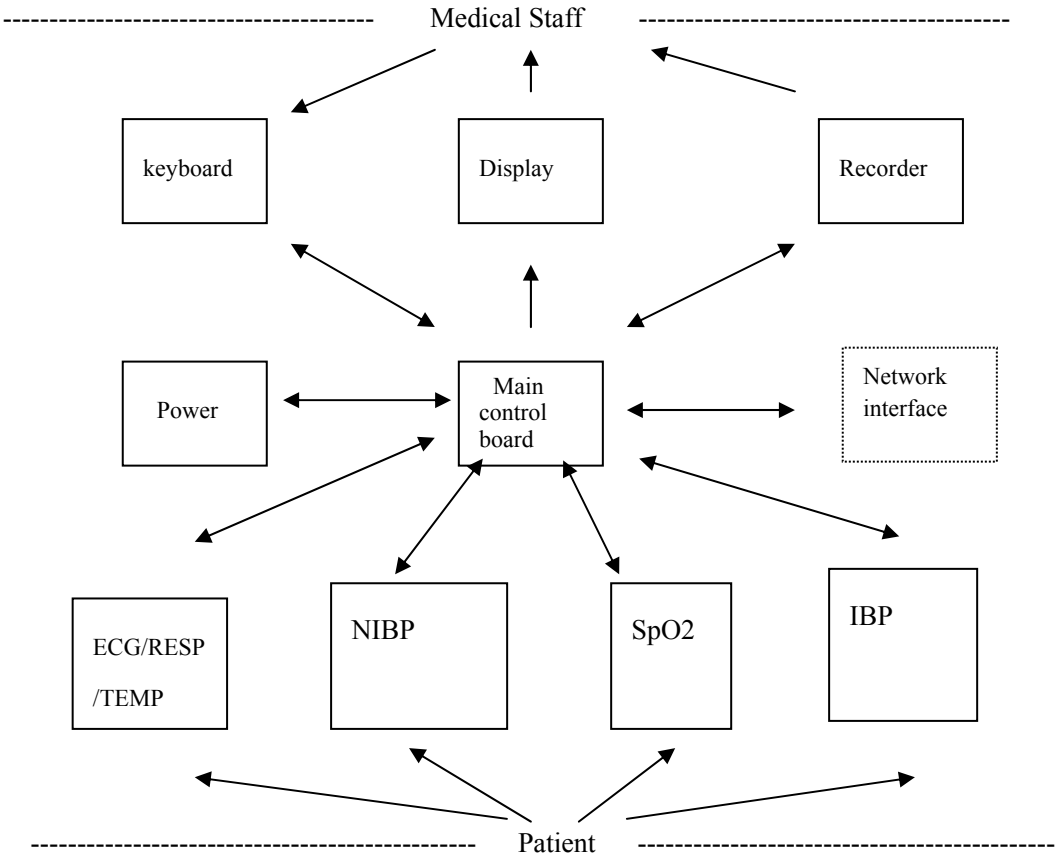


Figure 2-1 System structure diagram

As shown in the above figure, the four modules of parameters execute real-time monitoring of NIBP, SpO2, ECG/RESP/TEMP, IBP respectively through using cuff and measuring cables. The results are transmitted to the main control board for display. When required, the results can also be printed out via recorder. Coming up is the detailed information of functions.

II. ECG/RESP parameters

2.1 ECG

Main functions concerning ECG

1）lead: 3-lead, 5-lead

2）lead method; I, II, III, avR, avL, avF, V, CAL

3）Floating input

4）right-foot drive

5）lead-off detection

6）dual-channel ECG amplification, simultaneously processing ECG signals of any two leads.

The ECG circuit is responsible for processing the ECG signals of human body. The circuit consists of following parts;

1) input circuit: the ECG electrodes are connected into the circuit through the cable. This circuit is mainly used to protect ECG input stage, filter the signals so as to remove the outside interference.

2) buffer amplifying circuit: used to convert the impedance of ECG signals, so as to ensure that the ECG has a very high input impedance but only low output impedance.

3) right-foot drive circuit: the middle output point of the buffer amplifying circuit is reversely amplified and then fed to the RL of the 5-lead ECG to maintain the human body in a equipotential state. This method can reduce the interference and raise the common-mode rejection ratio of the circuit.

4) lead-off detection: based on the theory that the lead-off may cause the output of the buffer amplifying circuit to change, we can use the comparator to accurately determine if the lead has fallen off. In this way, the level can also be converted into TTl level for the singlechip to test.

5) lead connection circuit: under the control of singlechip and as per requirement, we can connect different lead electrodes into the main amplifying circuit for amplification.

6) main amplifying circuit: a measurement amplifier constructed by three standard operation amplifiers.

7) Last stage processing circuit: used mainly to couple ECG signals, program control the magnitude of the gain, filter the waveform and move the level, amplify the signal and send it to the analog-to-digital converter.

2.2 RESP

The Monitor measures temperature by measuring the changes in resistance of a thermistor located in the temperature lead. When a person is respiring, his chest goes up and down. This movement equals to

the impedance changes between electrodes RL and LL. The monitor converts the high-frequency signals passing through RL and LL into amplitude-modulated high-frequency signals, which are then demodulated and amplified into electronic signals varying with the respiration changes and then transmitted to analog-digital converter. RESP module is made up of a respiration circuit board and a coupling transformer. The circuit includes such parts as oscillation, coupling, demodulation, preliminary amplification, and high-gain amplification, etc.

2.3 NIBP

The monitor measures non-invasive blood pressure using the oscillometric method. Following are detailed measurement procedures. Inflate the cuff encircled around the upper arm until the pressure in the cuff blocking the blood flow in the artery of the upper arm. Then deflate the cuff according to the requirement of a certain algorithm. With the pressure decreasing in the cuff, the artery blood will palpitate with the pulse, which results in pulsation in the cuff. Through the pressure sensor connected with the inflating pipe of the cuff, a pulsation signal palpitating with the pulse will be generated. After being filtered by a high-pass filter (about 1Hz), this signal becomes pulsating signal and is amplified. Then the amplified signal is converted into digital signal by A/D. After using the single chip to process this digital signal, we may obtain systolic pressure, diastolic pressure and mean pressure. Be careful to choose appropriate cuffs for neonatal, pediatric and adult patients so as to avoid generating measurement errors. NIBP module also has protection circuit to prevent the cuff from being inflated to a very high pressure. The main operating modes of NIBP are;

1) adult/pediatric/neonate: select according to the patient shape, weight and age.

2) manual measurement, auto measurement, continuous measurement. Manual measurement is also called single measurement. It means the monitor only performs one measurement for each time. Auto measurement means to perform one measurement within selected cycle. Time interval can be set up as 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240 and 480 minutes. Continuous measurement means after being activated, the monitor will perform quick measurement continuously within 5 minutes. Continuous measurement is effective in monitoring changes of blood pressure.

2.4 SpO2

SpO2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO2 oxygen saturation of 97%. The SpO2 numeric on the monitor will read 97% .The SpO2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave. Arterial oxygen saturation is measured

by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side.

The sensor measurement wavelengths are nominally 660nm for the Red LED and 940nm for Infrared LED. Maximum optical power output for LED is 4 mW. The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal. The SpO_2 value and the PLETH waveform can be displayed on the main screen.

2.5 TEMP

Technical specifications:

Measurement and alarm range:	0 ~ 50 °C
Resolution:	0.1°C
Accuracy:	±0.1°C
Refreshing time:	about 1 second
Average time constant:	< 10 seconds

2.6 IBP

IBP monitors arterial pressure, central venous pressure and pulmonary arterial pressure.

Measurement method:

Stab and implant the catheter into the blood vessel of the part to be measured. The end of the catheter located outside human body connects directly with the pressure transducer. Injectate normal saline into the catheter. Because the liquid can transfer pressure, the pressure inside the blood vessel can be transferred to the outside pressure transducer. In this way we can at any time obtain the dynamic waveform of the changing pressure inside the vessel. By using specified calculating formula, we can calculate systolic, diastolic and mean pressures.

Chapter 3 Checks and Tests

I. System checks

For the conventional testing contents of PM-8000 portable patient monitor, please refer to its Operation Manual. The information in this chapter is only a brief introduction. The following sections are used to emphasize important tests and the information not clearly specified in the Operation Manual.

1. Device appearance and installation checks

1）The shell of the device is clean and has no scratches. The installation is stable. When shaking the device, these are no inside leftovers.

2）Buttons are smooth and free for operation.

3）Labels are complete and sufficient and correct in delivering information.

4）Standard configuration is complete, the sockets are installed safely.

5）Perform vibration test on the overall device before performing following operating tests.

2．Safety tests

2.1．Test equipment

1．Safety analyzer	501 PRO	1
2．Leakage current/grounding resistance measurement kit:		1
3． Connection kit of the application part:		1
4．Tinsel	20cm X 10cm	1

2.2．Test procedures

2.2.1 Leakage current to earth

2.2.1.1 Connection graph for testing is as shown in figure 3-1:

Connect one end of the 3-core power wire to AC220V network power, the other end to the leakage current testing kit (A). Insert the 3-core power wire of safety analyzer (B) into power output socket of (A). Connect the 3-core power wire of the device being tested ① into AC output of 501. Connect the sensor of the application part based on the requirements of (C). Connect the red measurement clip RED of 501 to the ground protection PE terminal. Connect the SUM terminal of (C) to the P terminal of (A). Locate all switches to “OFF” position.

(A)-----grounding resistance/leakage current measurement kit

(B)-----501 safety analyzer

(C)-----application part processing kit

①------device being tested

⑤------application part

RED---501 red measurement clip

SUM--- kit post

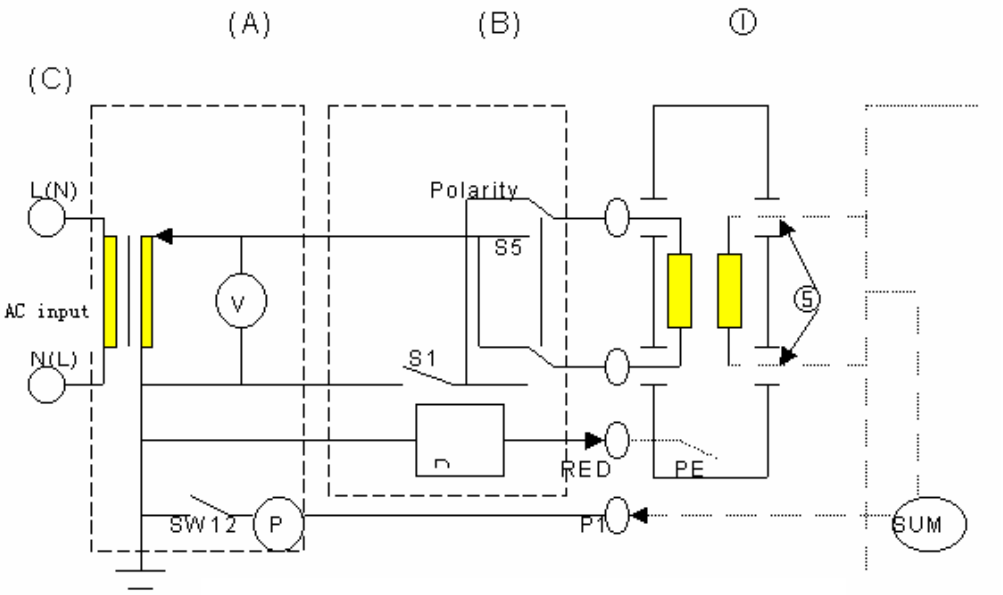


Figure 3-1 Leakage current testing connection between grounding terminal and the earth

2.2.1.2 Adjust input voltage: When the device being tested is in shutdown state, connect leakage current measurement kit (A) with the input network voltage AC220V. Adjust the booster to raise the testing voltage to 110% (that is 253V) of the nominal voltage 230V. This voltage is monitored by the voltage meter of (A). Then turn on the device to let the device be in the operating state, micro-adjust the booster to make the output voltage keep stablely at 253V. Press the [Ground] key of the 501 tester and disconnect the grounding wire.

2.2.1.3 Leakage current between network source and earth in normal state: press the [Leakage] key of the 501 tester and read the leakage current value on it. Connect SW12, in the condition that the application part is connected to the earth, respectively press and release [Polarity] key to toggle between the null line and the live wire. Then disconnect SW12 and cut off the connection between the application part and the earth. Respectively press and release the [Polarity] key. The maximum value of these four measurements should be less than 0.5mA.

2.2.1.4 Leakage current between network source and the earth in single fault condition:

Leakage current when connection between null line and live wire is being cut off: press the [Leakage] key of the 501 tester. Then press the [neutral] key of the 501 tester, disconnect N line. Respectively press and release the [Polarity] key to toggle between null line and live wire, and imitate the condition that L line is

disconnected. Read the leakage current value on the 501 tester. Connect SW12, respectively press and release the [Polarity] key. Disconnect SW12, respectively press and release the [Polarity] key. The maximum value of these four measurements should be less than 1.0mA.

2.2.2 Shell leakage current:

2.2.2.1 Connection graph for testing is shown in figure 3-2:

Connect one end of the 3-core power wire to AC220V network power, the other end to leakage current testing kit (A). Insert the 3-core power wire of safety analyzer (B) into power output socket of (A). Connect the 3-core power wire of the device being tested① into AC output of 501. Connect the sensor of the application part based on the requirements of (C). Stick the tinsel A on any position of ① (never let A touch live part, protection earth and the application part).Connect the red clip RED of the 501 tester onto the tinsel A. Connect the SUM terminal of (C) to the P terminal of (A). Locate all switches to "OFF" position.

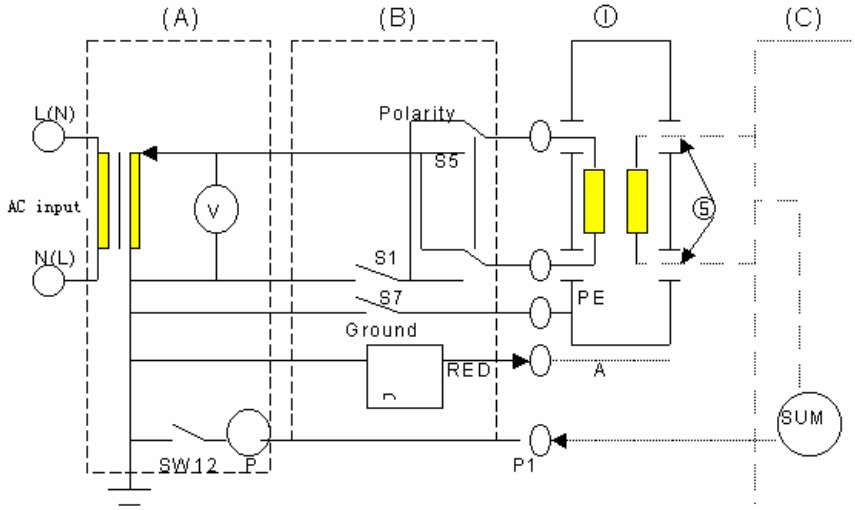


Figure 3-2 Connection graph for leakage current testing between the shell and the earth

(A)-----grounding resistance/leakage current measurement kit

(B)-----501 safety analyzer

(C)-----application part processing kit

①------device being tested

⑤------application part

A-------tinsel

RED---red measurement clip of 501

SUM---kit post

2.2.2.2 leakage current between the shell to protection earth in the normal state:

(adjust the input voltage by referring to 3.1.2) press the [Leakage] of the 501 tester and read the leakage current value on the 501. Connect SW, respectively press and release the [Polarity] key. Disconnect SW, respectively press and release the [Polarity] key. The maximum value of these four measurements should be less than 0.1mA.

2.2.2.3 Leakage current between the shell and protection earth in single fault condition:

2.2.2.3.1 Leakage current when ground wire is disconnected: press the [Leakage] key of the 501 tester. Press the [Ground] key and disconnect the ground wire. Connect SW and respectively press and release the [Polarity] key. Disconnect SW, respectively press and release the [Polarity] key. The maximum value of these four measurements should be less than 0.5mA.

2.2.2.3.2 Leakage current when null line and live wire are disconnected: press the [Leakage] key of the 501 tester. Press the [Neutral] key of the 501 tester. Disconnect N line, respectively press and release the [Polarity] key and toggle between null line and live wire. Imitate the condition that L line is disconnected and read the leakage current value on the 501 tester. Connect SW, respectively press and release the [Polarity] key. Disconnect SW and respectively press and release the [Polarity] key. The maximum value of these four measurements should be less than 0.5mA.

2.3 Patient leakage current of the application part:：

2.2.3.1 Connection graph for testing is shown in figure 3-3:

Connect one end of the 3-core power wire to AC220V network source, the other end to leakage current testing kit (A). Insert the 3-core power wire of the 501 analyzer into its output socket. Connect the 3-core power wire of the device being to be tested ① into AC output of 501. Connect the sensors including RA, LA, LL, RL, V, NIBP, SpO2, TEMP1, TEMP2 and IBP of the application part based on the requirements of (C). Connect the output SUM of (C0 to the RA post of the 501 tester. Locate all the switches on the connecting kit of the application part to [OFF] position.

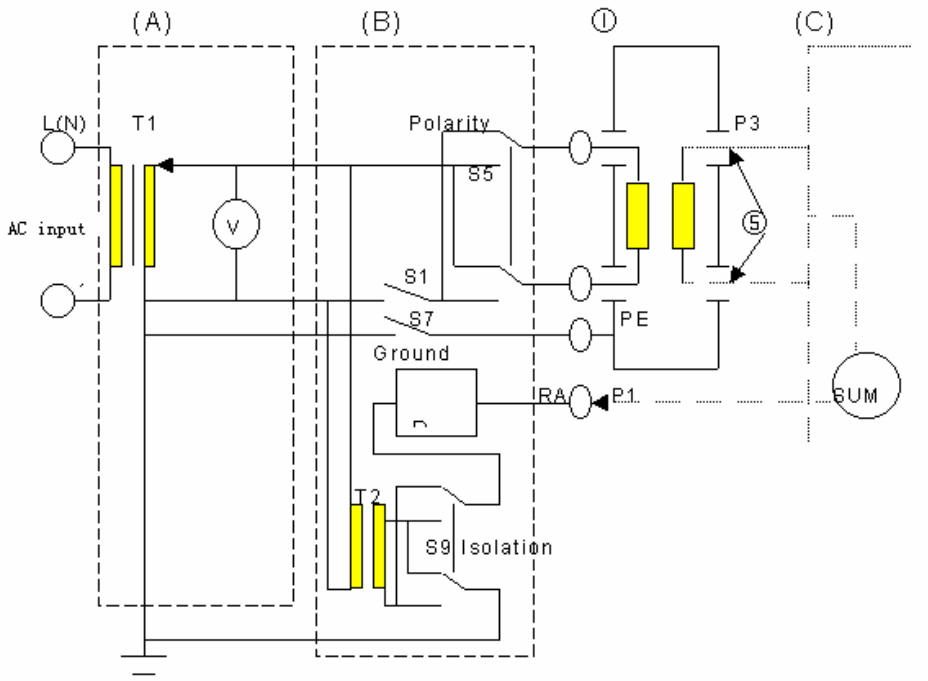


Figure 3-3 Connection graph for leakage current testing between application part (patient) and the earth

(A)-----grounding resistance/leakage current testing kit

(B)-----501 safety analyzer

(C)-----application part processing kit

①-----device being tested

⑤-----application part

P3----sensor connected with the patient

RA----RA terminal of ECG measuring post of 501

SUM--- kit post

2.2.3.2 Patient leakage current in the normal state: (adjust the input voltage by referring to 3.1.2) Press the [ECG leak] key of 501, then press the arrow on the panel of 501 to select the RA-GND item. The measured leakage current should be less than 0.01mA.

2.2.3.3 Patient leakage current in single fault condition:

2.2.3.3.1 Press the [ECG leak] key of 501, then press the arrow on the panel of 501 to select the RA-GND item. Take turns to operate the [Ground] key (for disconnecting the ground wire), the [Neutral] key (for disconnecting the null line) and the [Polarity] key (for toggling between null line and live wire). Test the AC leakage current in the above these fault conditions. The maximum current value should be less than 0.05mA.

2.2.3.3.2 Press the [DC Only] key of 501, take turns to operate the [Ground] key (for disconnecting the ground wire), the [Neutral] key (for disconnecting the null

line) and the [Polarity] key (for toggling between null line and live wire). Test the DC leakage current in the above three fault conditions, the maximum current value should be less than 0.05mA.

2.2.3.4 Patient leakage current of the application part when network voltage is added.

2.2.3.4.1 Press the [ECG leak] key of 501, then press the arrow on the panel of 501 to select the RA-GND item. Press the [Isolation] key and add network voltage. Test the leakage current of the added network voltage. The maximum current value should be less than 0.05mA.

2.2.4 Patient auxiliary current:

2.2.4.1 Connection graph for testing is shown in figure 3-4

Connect one end of the 3-core power wire to AC220V network electical source, the other end to leakage current testing kit (A). Insert the 3-core power wire of the 501 analyzer into its output socket. Connect the 3-core power wire of the device being to be tested ① into AC output of 501. Connect the sensors of the application part according to the requirements of (C). Connect the output RA-P of (C) to the RA binding post of 501. Short-circuit connect LA-P, LL-P, RL-P, V-P, NIBP-P, SpO2-P, TEMP1-P, TEMP2-P, IBP-P respectively onto the SUM binding post. Then through SUM, use lead to to connect them to the LL binding post.

(A)-----grounding resistance/leakage current measurement kit

(B)-----501 safety analyzer

(C)-----application part processing kit

①-----device being tested

⑤-----application part

P3----sensors connected to the patient

RA----RA terminal of the ECG measuring post of 501

LL----LL terminal of the ECG measuring post of 501

SUM---kit post

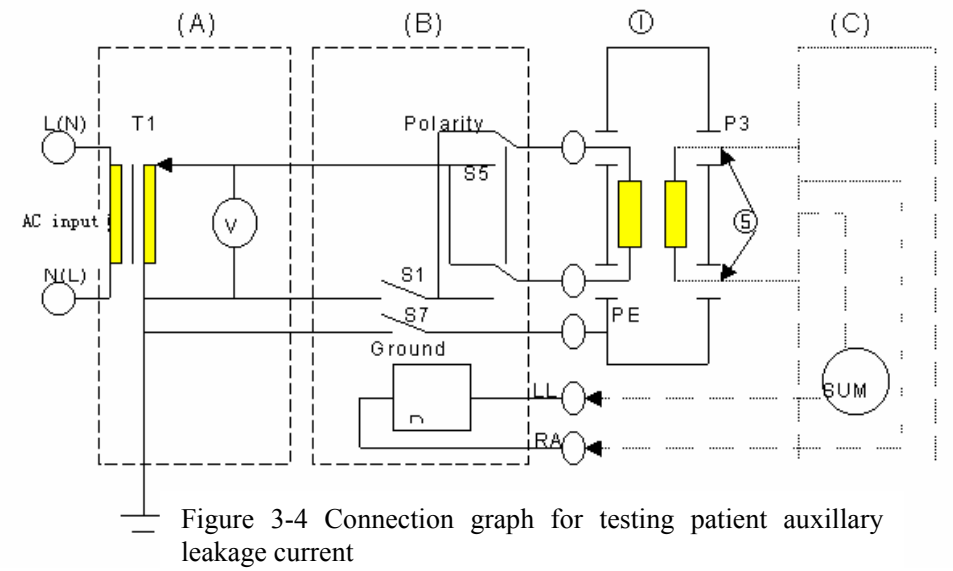


Figure 3-4 Connection graph for testing patient auxillary leakage current

2.2.4.2 Patient auxiliary current in the normal state (adjust the input voltage by referring to 3.1.2)

AC auxiliary current of the RA lead of ECG to other application parts: position the RA on the connection kit of the application part to “ON” and other switches to “OFF”. Connect RA-P to the RA binding post of 501. Connect other patient parts to LL through SUM. Press the [ECG leak] key of 501, then press the arrow on the panel of 501 to select the RA-LL item. The tested current value should be less than 0.01mA.

2.2.4.3 Patient auxiliary current in single fault condition:

2.2.4.3.1 AC auxiliary current of RA lead of ECGT to other application parts (AC value of RA). Position the RA on the connection kit of the application part to “ON” and other switches to “OFF”. Connect RA-P to the RA post of 501. Connect other parts to LL through SUM. Press the [ECG leak] key of 501, then press the arrow on the panel of 501 to select the RA-LL item. Take turns to operate the [Ground] key (for disconnecting the ground wire), the [Neutral] key (for disconnecting the null line) and the [Polarity] key (for toggling between null line and live wire). Test the current in the above three fault conditions, the maximum current value should be less than 0.05mA.

2.2.4.3.2 DC auxiliary current of the RA lead of ECG to other application parts (DC value of RA):

Press the [DC Only] key of 501, take turns to operate the [Ground] key (for disconnecting the ground wire), the [Neutral] key (for disconnecting the null line) and the [Polarity] key (for toggling between null line and live wire). Test the current in the above three fault conditions, the maximum current value should be less than 0.05mA.

2.2.5 Testing grounding resistance

2.2.5.1 Connection graph for testing ground resistance is shown in figure 3-5:

Note: In the graph, P1 and P2 are two binding post of grounding resistance testing kit. Keep the measuring wires "Black" and "Red" as short as possible. The sectional area of the wire should be larger than 10mm^2. It is acceptable to use more than 3 pieces of parallel-connected 10WAG wires. GND is the grounding terminal of either the power wire of the device being tested or the power plug. EP is the grounding terminal to the device (for the current patient monitor, EP is equipotential binding post). C are all the protecting metal covers (shells) that are connected to PE. M are all metal screws that are connected onto EP. C and M are all on the device shell.

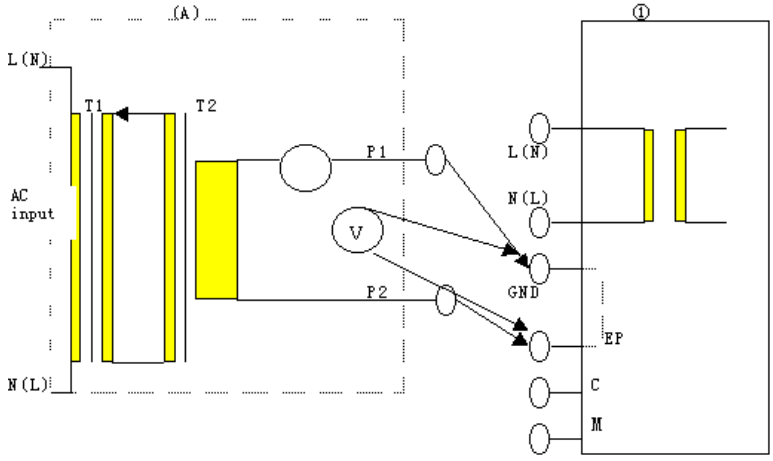


Figure 3-5 Connection graph for testing grounding resistance

2.2.5.2 Testing procedures

2.2.5.2.1 Between GND of power wire and EP: Zero the booster on (A), Connect black wire of P1 to GND of the 3-core power wire, and the red wire to the EP binding post. Connect network voltage 220V. Slowly adjust and raise the booster output and observe the reading on current meter for (A). Continue to raise the booster output until the reading of the current meter indicates 25A. Wait for 5 seconds and then read the value on the voltage meter (use AC voltage range of the multimeter), which should be less than 5V.

2.2.5.2.2 Between GND of power plug and EP: Zero the booster, Connect black wire of P1 to GND of the 3-core power wire, and the red wire to the EP binding post. Connect network voltage 220V. Slowly adjust and raise the booster output and observe the reading on the current meter. Continue to raise the booster output until the reading of the current meter indicates 25A. Wait for 5 seconds and then read the value on the voltage meter (use AC voltage range of the multimeter), which should be less than 2.5V.

2.2.5.2.3 Between GND of power plug and each C point: Zero the booster on (A), Connect black wire of P1 to GND of the 3-core power wire, and the red wire to the selected C shell (cover). Connect network voltage 220V. Slowly adjust and raise the booster output and observe the reading on the current meter. Continue to raise the booster output until the reading of the current meter indicates 25A. Wait for 5 seconds and then read the value on the voltage meter (use AC voltage range of the multimeter), which should be less than 2.5V.

2.2.5.2.4 Between GND of power plug and each M point: Zero the booster on (A), Connect black wire of P1 to GND of the 3-core power wire, and the red wire to the selected M screw. Connect network voltage 220V. Slowly adjust and raise the booster output and observe the reading on the current meter. Continue to raise the booster output until the reading of the current meter indicates 25A. Wait for 5 seconds and then read the value on the voltage meter (use AC voltage range of the multimeter), which should be less than 2.5V.

II. Testing and calibrating each parameter

Testing and calibrating follow parameters are to ensure the accuracy of PM-8000 portable patient monitor. Calibrating operation should be performed at least once a year. Calibration should be carried out each time after maintenance.

1．Testing ECG and RESP

1）Testing tool

Human physiological signals simulator

2）Testing procedures

① Use measuring cable to connect thesimulator into the ECG socket of PM-8000

② Confirm if the number of ECG waveforms displayed on the screen is consistent with that indicated in the ECG MENU and Factory MENU.

③ In default configuration, select lead II for ECG1 and lead I for ECG2 (if there is ECG2)

④ Check if ECG waveforms and RESP waveforms are normally displayed.

⑤ Set up the parameters of the simulator as following;

HR=30（gain×4）

RR=15

⑥ Check if the displayed ECG and RESP waveforms, HR and RR values are correct.

⑦ Change the simulator configuration

HR=240

RR=120

⑧ Check if the displayed ECG and RESP waveforms, HR and RR values are consistent with the parameters set up on the simulator.

⑨ Make the ECG lead fall off, in this condition, the PM-8000 should immediate give alarm.

2．Testing NIBP

1）Testing tool

NIBP simulator

2）Testing procedures

Use the NIBP simulator with calibrating function. Calibrate the blood pressure pump and determine its accuracy according to the calibrating method given in the Operation Manual. If it passes the calibration, continue to perform following tests.

① Select Adult mode for both simulator and PM-8000

② Select a group of blood pressure values within the measurement range on the NIBP simulator, such as:

NS=90

NM=70

ND=60

③ Check if the actual measured values of PM-8000 are consistent to those set up on the simulator.

④ Change the setup values on the simulator, and test again.

⑤ Check if the actual measured values are consistent with setup one.

3．Testing SpO2

1）Testing tool

SpO_2 simulator

2）Testing procedures

① Connect SpO_2 simulator with the SpO_2 probe of PM-8000

② Set up the parameters of SpO_2 simulator as following:

SpO_2=98

PR=70

③ Check if the displayed SpO_2 and PR values on PM-8000 are consistent with those on the simulator.

（Note: To observe the PR value, select PLETH as the HR source in the ECG menu.）

④ Change the setup values of SpO_2 and PR on the simulator.

⑤ Check the displayed values on PM-8000 are consistent with the setup values.

⑥ Make SpO_2 sensor fall off, in this condition, PM-8000 should immediately give alarm.

4．Testing TEMP

1）Testing tool

Human physiological signals simulator

2）Testing procedures

① Connect one end of the TEMP sensor to the simulator and the other end to the TEMP socket of

PM-8000.

② Using the simulator to set up : EMP=34℃.

③ Check if the displayed TEMP value on the screen of PM-8000 is 34℃.

④ Change the setup value of the simulator to: TEMP=40℃.

⑤ Check if the displayed TEMP value on the screen of PM-8000 is 40℃.

5 Testing IBP

1）Testing tool

Human physiological signals simulator

2）Testing procedures

Set up the BP sensitivity of the simulator to 5uv/v/mmHg, and BP to 0mmHg. Set up the name of IBP1 to ART. Access the PRESSURE ZERO option of IBP SETUP MENU of PM-8000, zero Channel 1 to perform zero calibration for IBP. After the zero calibration is successful, exit the menu to enter the main screen. Set up the BP of the simulator to 200mmHg. Access the CALIBRATION menu of PM-8000 to perform calibration operation. After the calibration is successful, exit the menu.

Set up the BP of the simulator respectively to 40mmHg, 100mmHg, and 200mmHg. In the mean time, the screen should respectively display 40±1mmHg, 100±2mmHg, and 200±4mmHg.

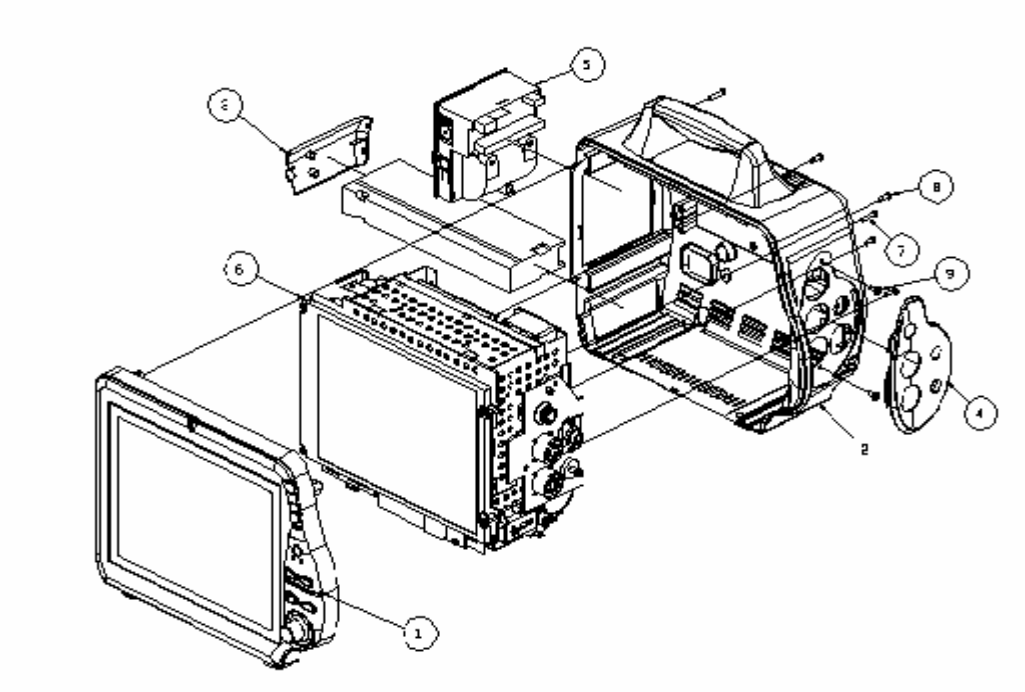
Set up the output of the simulator as the ART wave. As the result, the screen should display the corresponding waveform correctly.

Plug off the IBP sensor. The screen should display “IBP: SENSOR 1 OFF!” “IBP: SENSOR 2 OFF!”.

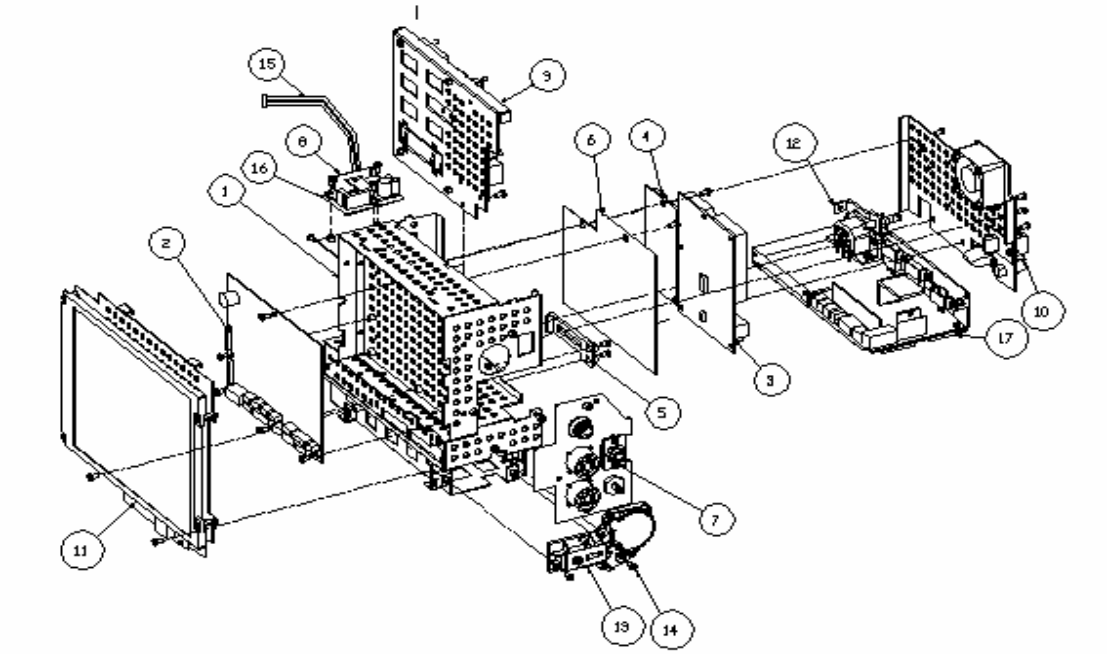
Plug OHMEDA cable into IBP1 channel, the display of “IBP: SENSOR 1 OFF!”. Should disappear from the screen.

Chapter 4 Troubleshooting

I. Disassembly graph of each part of PM-8000



1 Front panel assembly
2 Rear panel assembly
3 Battery door
4 Sockets cover
5 TR60-A recorder
6 Main bracket assembly
7 Cross panhead cuspless screw PT3x10
8 Cross panhead screw M3x6
9 Cross panhead screw with gasket M3x8



1 Main bracket
2 Main control board
3 6200 ECG/TEMP/RESP board
4 6200 SpO2 board
5 Battery hook
6 ECG insulation film
7 Parameter sockets assembly
8 6200 recorder power board
9 NIBP/IBP bracket assembly
10 back board assebmly
11 TFT screen assebmly
12 Power board
13 Speaker assembly
14 Cross panhead screw M3x6
15 Recorder power wire
16 Recorder insulation film
17 Power supply insulation film

II. Troubleshooting guidance

In transportation, storage and use of PM-8000, various factors such as unstable network voltage, changing environmental temperature, falling-down or impact, component aging may all result in PM-8000 failures and therefore affect normal application of the device. In failure conditions, professional personnel with the experience of repairing electronic medical devices should perform component-level upkeep as per the failure classification listed in the table below. Component-level upkeep means based on analyzing, replacing or trial-operating component, we can pinpoint the failure on a certain component of the device, such as power board, main control board, TFT assembly, measuring cable or parameter module, etc. Repair of only some components means component-level repair. The repair operation must be conducted by a service engineer with abundant experience and with the assistance of special equipment and in specific environment and conditions.

PM-8000 Component-level Service Table

2．1 Device failures

Failure	Possible cause	Solution
No display after power-on, power indicator does not light on, fan does not run.	①fuse damage ②power damage ③component short-circuit	①replace fuse ②replace power ③ anchor the short-circuit component
No display after power-on or black screen during operation, however, power indicator lights on and fan runs normally.	①main control board failure or display failure	① refer to the information about confirming display failure
Characters are displayed normally, however waveforms are displayed intermittently.	① Data communication error between main control board and parameter module	①Based on error prompt, replace main control board, keyset or parameter module so as to confirm the failure.
An operation or measurement function is disabled.	① main control board or corresponding component damage	① examine main control board and corresponding component
Device is occasionally stoned.	① moment intensive interference of network ② poor performance of power board ③poor performance of main control board ④ bad connection of power supply or main control board	① check power supply and grounding system ② replace power board ③ replace main control board ④ replace or repair connectors

2．2 Display failures

Failure	Possible cause	Solution
When powering on the device, power supply is in normal operation, however, there is no display or screen goes black	① backlight board damage	① connect external VGA display and confirm the failure
	② bad connecting wire of display	② repair or replace connecting wire

during normal operation.	③ damage of main control board	③ replace main control board

2．3 Operation, recording, network linking failure

Failures	Possible cause	Solution
Keys or rotary encoder is disabled.	① keyboard or rotary encoder is damaged. ② connecting wire of keyboard is damaged.	① Replace keyboard or rotary encoder. ② Replace or repair connecting wire of keyboard
Sound is raucous or there is no sound.	① keyboard failure ② Speaker or connecting wire failure	① Replace keyboard ② Replace speaker or connecting wire
Recorder cannot execute printing operation.	① Recorder has no paper or paper bar is not pressed down. ② Recorder failure ③ Driving power of the recorder has failure. ④ Connecting wire of the recorder is damaged.	① Install paper and press down the paper bar. ② replace the recorder ③ replace the power supply ④ replace or repair the connecting wire of the recorder
Record paper goes out deflection.	① Bad recorder installing or positioning.	① Adjust the installation of recorder.
Cannot be linked into network	① network linking wire is damaged. ② main control board failure	① check and repair network linking wire. ② replace main control board

2.4 Power board failure

Failure	Possible cause	Solution
Fuse is burned upon power-on	① short-circuit occurs in power supply or other part.	① Check after power-on
Fuse is burned although all loads are disconnected.	① power failure	① replace power supply
Fuse is burned after connecting a part.	① this part occurs short-circuit.	① replace this part
Indicators of power and main control board light on, however, the fan does not run	① +12V DC power is damaged.	① replace the power

and the indicator of keyset does not light.		
Indicators of power and main control board do not light on, however, the fan runs normally and the indicator of keyset lights on.	①+5V DC power is damaged.	① replace the power

2.5 Parameter failure

No ECG waveform	①poor connection of ECG electrode films ②no square waveform exists during CAL self-test ③RL electrode is suspended. ④ ECG/RESP module is damaged.	①use new electrode films to ensure good contact. ②replace ECG/RESP module ③connect RL electrode. ④replace ECG/RESP module
ECG waveform is abnormal or has interference	①Electrodes are connected incorrectly. ② There is suspending electrode film. ③ AC power has no grounding wire. ④ ECG filter way is incorrect. ⑤ ECG/RESP module is damaged.	① correctly connect electrode films. ②remove electrode films that are not used. ③use 3-wire power ④select appropriate filter way ⑤replace ECG/RESP module
No RESP waveform or RESP waveform is abnormal	①Electrodes are connected incorrectly. ② Patient is moving constantly. ③ ECG/RESP module is damaged.	①use RL-LL electrode, connect to the correct positions. ② keep patient quiet ③ replace ECG/RESP module
TEMP value is incorrect	① Measuring sensor is poorly connected.	① connect TEMP sensor stablely.
HR value is inaccurate, Arr. And ST analysis are	① ECG waveform is not good.	① Adjust the connection to make the ECG waveform become normal.

incorrect.		
NIBP cuff cannot be inflated.	①Air way is folded or has leakage.	①adjust or repair the air way.
Blood pressure cannot be measured occasionally.	① Cuff becomes loose or patient is moving.	①Keep the patient quiet, bind the cuff correctly and safely.
Error of blood pressure measurement is too great.	①Cuff size does not fit the patient. ② NIBP module has bad performance.	①Use the cuff with appropriate size. ②replace NIBP module
No SpO2 waveform	①Sensor or SpO2 module is damaged.	①replace the sensor and confirm the failure.
SpO2 waveform has strong interference.	①patient is moving. ②Environment light is very intensive.	①keep the patient quiet. ②Weaken the light intensity in the environment.
SpO2 value is inaccurate	① coloring agent has been injected into patient body.	① remove the coloring agent before perform measurement.

Chapter 5 Installation

I. Unpack inspection

Open the package and take out the packing list. Check if the names, quantity and specifications of the goods in the package are consistent with those on the packing list. Please note that:

1） If the user buys optional parts or other accessories, he should also verify if they are placed in the package.

2） If the goods in the package are not consistent with those on the packing list, please contact the supplier.

3） If the device or any part is damaged during transportation, please save all packing material and goods for future inspection and immediately contact the supplier.

II. Preparations before power-on

Before connecting the 3-core power wire into the power socket of the PM-8000, please make following checks:

1）If the network voltage complies with device requirements.

2）To protect the patient and medical personnel from injury, it is recommended to use 3-core power wire. The power receptacle should be also 3-core type so as to ensure the good grounding performance of the device. Do not connect 2-core AC power to the PM-8000.

3）When using PM-8000 and other medical devices at the same time, safely connect the equipotential post on the rear panel of PM-8000 with equipotential posts of other devices.

4）Do not put PM-8000 in any place having liquid leakage.

III. Turn on the power

1）Connect the 3-core power plug into the AC receptacle.

2）Press the power button on the panel of PM-8000, wait for about 10 seconds, the Start-up picture appears on the screen, followed by the displays of waveform scanning lines and data screen.

IV. Other precautions

1）When using PM-8000 and other medical devices at the same time, requirements regarding power distribution of medical equipment must be abided by for fear that the leakage currents of devices overlap and consequently injury the patient or the medical personnel.

2）Do not use PM-8000 in the presence of flammable anesthetics to avoid the hazard of explosion.

Chapter 6 Basic Operations

I. Basic operation guidance

On the right side of the front panel of PM-8000, there are following buttons from up to down:

1） POWER

Used to turn on/off the PM-8000.

2） FREEZE

When in normal mode, press this button to stop waveform refreshing and freeze all the waveforms on the screen. When in freeze mode, press this button to restore the waveform refreshing.

3）SILENCE

Press this button to suspend alarm for 2 minutes , in the mean time, the countdown indication bar appears on the upper right corner of the screen.

Press this button for relative long time to disable all sound signals including alarm sound, heart beat, and key sound. In the mean time, a symbol "  " appears on the upper side of the screen. In the Silence mode, press this key for a relative long time to restore all sound signals. If press this key for a very short time, no operation will be executed.

4）REC/STOP

In Non-Freeze mode, press this key to start a real time recording.

During recording process, press this key to terminate recording.

The recording length is decided by the content in the REC TIME option in the MENU/RECORD menu.

In Freeze mode, press this key to pop up the PRINT menu, in which the user can select the frozen waveform to be printed. For detailed information, refer to the chapter: Record in the Operation Manual.

5）NIBP

In Non-measure mode, press this key to inflate the cuff and start a manual NIBP measurement.

In Measure mode, if to give up the measurement, press this key to terminate the measurement and deflate the cuff.

Note: In continuous mode, pressing this key means not only giving up the measurement but also ending the operating way of continuous measurement.

II. Use PM-8000

Execute following procedures to use PM-8000 to monitor a patient.

1．Read Operation Manual carefully

2．Check if PM-8000 has any damages caused during transportation. Check if any cables, power wires, receptacles and connectors are in poor contacts or loosely connected.

3．Turn on the power switch on the rear panel of the PM-8000. After waiting for about 10 seconds, the screen displays “System is initializing, please wait…”. Wait for about another 12 seconds, monitoring picture and waveform scanning lines appear on the screen. If turning off this switch during operation process, the power indicator will light off and the PM-8000 will stop working.

4．Check all required functions and verify that the PM-8000 works normally. After that, connect the measuring cable into the patient limb to start monitoring the patient.

Chapter 7 Cleaning and Disinfection

⚠ **Warning** ⚠

Before cleaning the monitor or the sensor, make sure to turn off the power and disconnect the AC power.

I. Maintenance checks

Before using the monitor, do the following:

1. Check if there is any mechanical damage;
2. Check all the outer cables, inserted modules and accessories;
3. Check all the functions of the monitor to make sure that the monitor is in good condition.

If finding any damage on the monitor, stop using the monitor on patient.

4. The overall check of the monitor, including the safety check, should be performed only by qualified person once every 6 to 12 month and each time after fix up.

5. Check the synchronism of the defibrillator according to the maintenance plan of the hospital at least every 3 months and by a qualified customer service technician.

II. General cleaning

1. The PM-8000 Patient Monitor must be kept dust-free.
2. It is recommended to regularly cleaning the monitor shell and the screen. Use only non-caustic detergents such as soap and water.

′ Note ′

Please pay special attention to the following items to avoid damaging PM-8000:

1. **Avoid using ammonia-based or acetone-based cleaners such as acetone.**
2. **Most detergents must be diluted before use. Follow the manufacturer's directions carefully for dilution.**
3. **Don't use the grinding material, such as steel wool etc.**
4. **Don't let the detergents enter into the chassis of the system. Do not emerge any part of the device into any liquid.**
5. **Don't leave the detergents on any part of the device surface.**
6. **Except for those detergents listed in "NOTE" part, following disinfectants can be used on the**

instrument:

- **Diluted Ammonia Water**
- **Diluted Sodium Hyoichlo (Bleaching agent).**

′ Note ′

The diluted sodium hyoichlo from 500ppm(1:100 diluted bleaching agent) to 5000ppm (1:10 bleaching agents) is very effective. The concentration of the diluted sodium hyocihlo depends on how many organisms (blood, mucus) on the surface of the chassis to be cleaned.

- Diluted Mindrayhylene Oxide 35% -- 37%
- Hydrogen Peroxide 3%
- Alcohol
- Isopropanol

′ Note ′

PM-8000 monitor and sensor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.

′ Note ′

Mindray has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

III. Sterilization

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

Recommended sterilization material: Ethylate, and Acetaldehyde.

⚠ **Caution** ⚠

1. **Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.**
2. **Do not let liquid enter the monitor.**
3. **No part of this monitor can be subjected to immersion in liquid.**
4. **Do not pour liquid onto the monitor during sterilization.**
5. **Use a moistened cloth to wipe off any agent remained on the monitor.**
6. **To avoid extended damage to the equipment, disinfecting is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfecting facilities should be cleaned first.**

Appropriate disinfecting materials for ECG lead, SpO2 sensor, blood pressure cuff, TEMP probe, IBP sensor are introduced Operation Manual respectively.

⚠ **Caution** ⚠

Do not use EtO gas or formaldehyde to disinfect the monitor.

IV. Precautions and cleaning

⚠ **Warning** ⚠

Before cleaning the monitor or the sensor, make sure to turn off the power and disconnect the AC power.

If ECG cable is damaged or aged, replace with a new ECG cable.

1 Cleaning

PM-8000 monitor and sensor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.

2 Sterilization

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

3 Materials recommended for use in sterilization

Ethylate: 70%

ethanol: 70%

Acetaldehyde

4 Disinfection

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

5 Cuff maintenance and cleaning

⚠ **Warning** ⚠

1. Do not squeeze the rubber tube on the cuff.

2. Do not allow liquid to enter the connector socket at the front of the monitor to avoid damaging the monitor.

3. Do not wipe the inner part of the connector socket when cleaning the monitor. Wipe the outside its surface only.

4. When the reusable cuff is not connected with the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.

5. Reusable Blood Pressure Cuff

The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned.

The cuff can also be machine-washed or hand-washed, the latter method may extend the service life of the cuff. Before washing, remove the latex rubber bag. Allow the cuff to dry thoroughly

after washing and then reinsert the rubber bag.

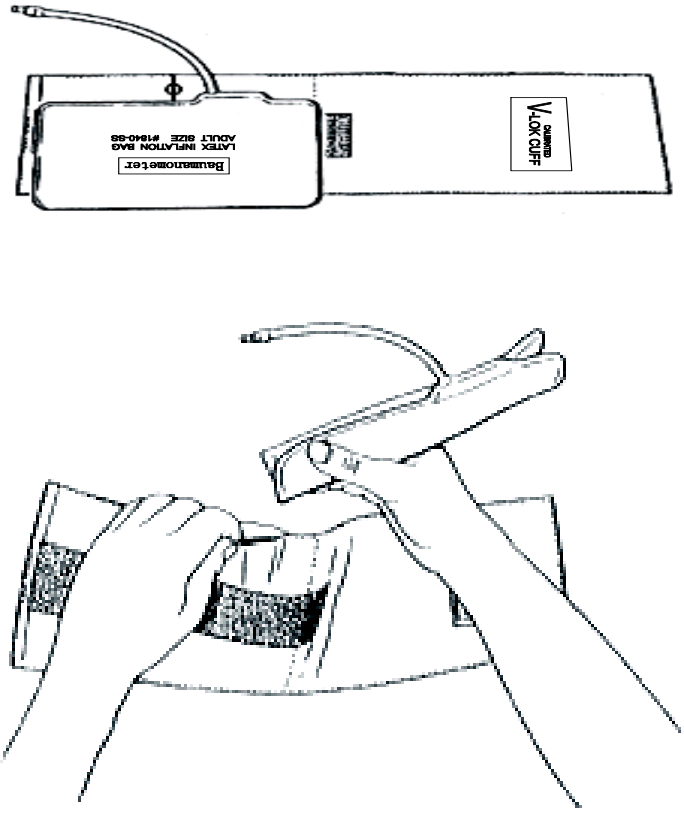


Figure 7-1 Replace the rubber bag in the cuff

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

6. **Disposable cuffs are intended for one-patient use only. Do not use the same cuff on any other patient. Do not sterilize or use autoclave on disposable cuffs. Disposable cuffs can be cleaned using soap solution to prevent infection.**

′Note′

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

V. IBP transducer cleaning and disinfection（reusable）

After the IBP monitoring operation is completed, remove the tubing and the dome from the transducer and wipe the transducer diaphragm with water. Soaking and/or wiping with soap can clean the

transducer and cable and water or cleaning agents such as those listed below:

Cetylcide

Wavicide-01

Wescodyne

Cidex

Lysol

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

′ Note ′

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

′ Note ′

For protecting environment, the disposable transducers or domes must be recycled or disposed of properly.

Chemical Liquid Sterilization

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

Gas Sterilization

For more complete asepsis, use gas sterilization.

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

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

⚠ **Warning** ⚠

The sterilize temperature must not exceed 70°C (150°F). Plastics in the pressure transducer may

deform or melt above this temperature.

VI. TEMP sensor cleaning and disinfection (reusable)

1. The TEMP probe should not be heated above 100℃ (212℉). It should only be subjected briefly to temperatures between 80℃ (176℉) and 100℃ (212℉).
2. The probe must not be sterilized in steam.
3. Only detergents containing no alcohol can be used for disaffection.
4. The rectal probes should be used, if possible, in conjunction with a protective rubber cover.
5. To clean the probe, hold the tip with one hand and with the other hand rubbing the probe down in the direction of the connector using a moist lint-free cloth.

′ Note ′

Disposable TEMP probe must not be re-sterilized or reused.

′ Note ′

For protecting environment, the disposable TEMP probe must be recycled or disposed of properly.

8 SpO2 sensor cleaning and disinfection

⚠ **Warning** ⚠

Do not subject the sensor to autoclaving.

Do not immerse the sensor into any liquid.

Do not use any sensor or cable that may be damaged or deteriorated.

1. Use a cotton ball or a soft mull moistened with hospital-grade ethanol to wipe the surface of the sensor, and then dry it with a cloth. This cleaning method can also be applied to the luminotron and receiving unit.
2. The cable can be cleaned with 3% hydrogen dioxide, 70% isopropanol, or other active reagent. However, connector of the sensor shall not be subjected to such solution.

Chapter 8 Maintenance

PM-8000 portable patient monitor is a type of precision electronic medical device having complex structure. Maintaining PM-8000 carefully will not only let the device develop its performance to the best but also ensure the long-term operating accuracy of the device and avoid various errors. To prevent cross contamination, ensure that the device has undergone cleaning and disinfection before maintenance.

1. Frequently check the device, cables, sensors and wires for damage.
2. Clean the device irregularly according to the actual requirement.
3. Perform safety test annually.
4. Perform NIBP parameter calibration test annually.
5. Calibrate TEMP parameter annually.
6. Test overall functions of the device annually.
7. Perform safety test once after each opening-chassis repair.
8. If finding problems during maintenance, contact your supplier in time.

Chapter 9 Network Link

PM-8000 can be connected to Mindray Hypervisor III (type 3000) Central Station to construct monitoring network system. A HyperVisorIII Central Station can connect up to 8 bedside monitors. At the Central Station, the user can view all waveforms and parameters of the networked bedside monitors and modify the alarm setups of the networked bedside monitors as well.

In addition, PM-8000 can be connected to Mindray HyperVisorIII (type 3100) Central Station to construct monitoring network system. A HyperVisorIII Central Station can connect up to 64 bedside monitors. At the Central Station, the user can view all waveforms and parameters of the networked bedside monitors. However, the user cannot modify the setups of the networked bedside monitors at the Central Station.

I. Network performance

1. The maximum length between the bedside monitor and the Central Station (using Hub) is 100m.
2. The maximum time length required from starting up the monitor to the successful networking is 40 seconds.
3. Network data delay ＜5 seconds.

The bedside monitor has Plug & Play function, that is, the user can dynamically plug in/out the network connector connected to PM-8000 without the need to first switch off the power.

II. Application

1. Mindray technical personnel are responsible for analyzing the layout of the network system and executing wiring and installing.
2. Perform trial-link after verifying that the network connection is correct.
3. When connected to the same Central Station, bedside monitors must have their unique serial numbers. Otherwise it may lead to linking failure.

Appendix I: System Alarm Prompt

PROMPT	CAUSE	MEASURE
“BATTERY VOLTAGE TOO LOW”	When battery voltage is too low, the monitor will automatically shut down within 5 minutes.	Use AC power supply
"XX TOO HIGH"	XX value exceeds the higher alarm limit.	Check if the alarm limits are appropriate and the current situation of the patient.
"XX TOO LOW"	XX value is below the lower alarm limit.	
XX represents the value of parameter such as HR, ST1, ST2, RR, SpO2, IBP, NIBP, etc in the system.		
"ECG WEAK SIGNAL"	The ECG signal of the patient is too small so that the system can not perform ECG analysis.	Check if the electrodes and lead wires are connected correctly and the current situation of the patient.
“NO PULSE”	The pulse signal of the patient is too small so that the system can not perform pulse analysis.	Check the connection of the sensor and the current situation of the patient.
"RESP APNEA"	The respiration signal of the patient is too small so that the system cannot perform RESP analysis.	Check the connection of the linking wire and the current situation of the patient.
"ASYSTOLE"	Patient suffers from Arr. of ASYSTOLE.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"VFIB/VTAC"	Patient suffers from Arr. of VFIB/VTAC.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.

"COUPLET"	Patient suffers from Arr. of COUPLET.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"BIGEMINY"	Patient suffers from Arr. Of BIGEMINY.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"TRIGEMINY"	Patient suffers from Arr. of TRIGEMINY.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"R ON T"	Patient suffers from Arr. of R ON T.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"PVC"	Patient suffers from Arr. of PVC.	
"TACHY"	Patient suffers from TACHY.	
" BRADY"	Patient suffers from BRADY.	
"VT>2"	Patient suffers from Arr. of VT>2.	
“MISSED BEATS”	Patient suffers from Arr. of MISSED BEATS.	
"PNP"	The pacemaker is not paced.	Check the connection of the pacemaker. Check the connection of electrodes and lead wires. Check the current situation of the patient.
"PNC"	No pacemaker signal is captured.	Check the connection of the pacemaker. Check the connection of electrodes and lead wires.

		Check the current situation of the patient.
"ECG LEAD OFF"	ECG lead is not connected correctly.	Check the connection of ECG lead wire.
"ECG V LEAD OFF";	The V lead wire of ECG is not connected correctly.	Check the connection of V lead wire.
"ECG LL LEAD OFF";	The LL lead wire of ECG is not connected correctly.	Check the connection of LL lead wire.
"ECG LA LEAD OFF";	The LA lead wire of ECG is not connected correctly.	Check the connection of LA lead wire.
"ECG RA LEAD OFF";	The RA lead wire of ECG is not connected correctly.	Check the connection of RA lead wire.
"ECG C LEAD OFF";	The C lead wire of ECG is not connected correctly.	Check the connection of C lead wire.
"ECG F LEAD OFF";	The F lead wire of ECG is not connected correctly.	Check the connection of F lead wire.
"ECG L LEAD OFF";	The L lead wire of ECG is not connected correctly.	Check the connection of L lead wire.
"ECG R LEAD OFF";	The R lead wire of ECG is not connected correctly.	Check the connection of R lead wire.
"SPO2 SENSOR OFF"	SPO2 sensor is not connected correctly.	Check the connection of SpO2 sensor.
"SEARCH PULSE"	SPO2 sensor is not connected correctly or the patient arm moves.	Check the connection of SpO2 sensor. Check the current situation of the patient.
"TEMP SENSOR OFF"	TEMP sensor is not connected correctly.	Check the connection of TEMP sensor.
"IBP LEAD OFF"	IBP sensor is not connected correctly.	Check the connection of IBP sensor.

"ECG NOISE"	Rather large interference signals appear in the ECG signals.	Check the connection of ECG lead wire. Check the current situation of the patient. Check if the patient moves a lot.
XX represents all the parameter modules in the system such as ECG, NIBP, SpO2, IBP module, etc.		
"XX ALM LMT ERR"	The alarm limit of XX parameter is modified by chance.	Contact the manufacturer for repair.
"XX RANGE EXCEEDED"	The measured value of XX parameter has exceeded the measuring range of the system.	Contact the manufacturer for repair.
XX represents the parameter name in the system such as HR, ST1, ST2, RR, SpO2, IBP, NIBP, etc.		
"REAL CLOCK NEEDSET"	When the system displays 2000-1-1, the system gives this prompt reminding the user that the current system time is not right.	Re-set up the system time. It is better to set up the time just after the start-up and prior to monitoring the patient. After modifying the time, the user had better re-start up the monitor to avoid storing error time.
"REAL CLOCK NOT EXIST"	The system has no cell battery or the battery has run out of the capacity.	Install or replace the rechargeable battery.
"SYSTEM WD FAILURE"	The system has serious error.	Re-start up the system. If the failure still exists, contact the manufacturer.
"SYSTEM SOFTWARE ERR"		
"SYSTEM CMOS FULL"		
"SYSTEM CMOS ERR"		
"SYSTEM EPGA FAILURE"		
"SYSTEM FAILURE2"		
"SYSTEM FAILURE3"		
"SYSTEM FAILURE4"		
"SYSTEM FAILURE5"		
"SYSTEM FAILURE6"		
"SYSTEM FAILURE7"		

"SYSTEM FAILURE8"		
"SYSTEM FAILURE9"		
"SYSTEM FAILURE10"		
"SYSTEM FAILURE11"		
"SYSTEM FAILURE12"		
"KEYBOARD NOT AVAILABLE";	The keys on the keyboard cannot be used.	Check the keys to see whether it is pressed manually or by other object. If the key is not pressed abnormally, contact the manufacturer for repair.
"KEYBOARD COMM ERR";	The keyboard has failure, which cannot be used.	Contact the manufacturer for repair.
"KEBOARD ERROR";		
“KEYBOARD FAILURE”		
"KEYBOARD ERR1";		
"KEYBOARD ERR2";		
"NET INIT ERR(G.)"	The network part in the system has failure. The system cannot be linked to the net.	Contact the manufacturer for repair.
"NET INIT ERR(Ram)"		
"NET INIT ERR(Reg)"		
"NET INIT ERR(Mii)"		
"NET INIT ERR(Loop)"		
"NET ERR(Run1)"		
"NET ERR(Run2)"		
"NET ERR(Run3)"		
"5V TOO HIGH"	The power part of the system has failure.	If the prompt appears repeatedly, contact the manufacturer for repair.
"5V TOO LOW"		
"POWER ERR3"		
"POWER ERR4"		
"12V TOO HIGH"		
"12V TOO LOW"		
"POWER ERR7"		
"POWER ERR8"		
"3.3V TOO HIGH"		

"3.3V TOO LOW"		
"CELL BAT TOO HIGH"	Cell battery has problem.	Replace the battery. If the failure still exists, contact the manufacturer.
"CELL BAT TOO LOW"	The cell battery has low capacity or the cell battery is not installed or the connection is loose.	
"RECORDER SELFTEST ERR"	During the selftest, the system fails connecting with the recorder module.	Execute 'Clear Record Task' function in the recorder setup menu to re-connect the host and the recorder. If the failure still exists, contact the manufacturer for repair.
"RECORDER VLT HIGH"	The recorder module has voltage failure.	Contact the manufacturer for repair.
"RECORDER VLT LOW"		
"RECORDER HEAD HOT"	The continuous recording time may be too long.	After the recorder becomes cool, use the recorder for output again. If the failure still exists, contact the manufacturer for repair.
"REC HEAD IN WRONG POSITION"	The handle for pressing the paper is not pressed down.	Press down the recorder handle for pressing the paper.
"RECORDER OUT OF PAPER"	No paper is in the recorder.	Place the paper into the recorder.
"RECORDER PAPER JAM"	The paper in the recorder is jammed.	Place the recorder correctly and try again.
"RECORDER COMM ERR"	The communication of the recorder is abnormal.	In the recorder setup menu, execute the function of clearing record task. The function can make the host and the recorder connect again. If the failure still exists, contact the manufacturer for repair.
"RECORDER S. COMM ERR"		
"RECORDER PAPER W.P."	The paper roll of the recorder is not placed in the	Place the paper roll in the correct position.

	correction position.	
"REC NOT AVAILABLE"	Cannot communicate with the recorder.	In the recorder setup menu, execute the function of clearing record task. The function can make the host and the recorder connect again. If the failure still exists, contact the manufacturer for repair.
"NIBP INIT ERR"	NIBP initialization error	Execute the reset program in the NIBP menu. If the failure still exists, contact the manufacturer for repair.
"NIBP SELFTEST ERR"		
"NIBP ILLEGALLY RESET"	During NIBP measurement, illegal reset occurs.	Check the airway of NIBP to see if there are clogs. Then measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP COMM ERR"	The NIBP communication part has problem.	Execute the reset program in the NIBP menu. If the failure still exists, contact the manufacturer for repair.
"LOOSE CUFF"	The NIBP cuff is not connected correctly.	Re-connect the NIBP cuff.
"AIR LEAK"	The NIBP cuff is not connected correctly or there are leaks in the airway.	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"NIBP ILLEGALLY RESET"	During NIBP measurement, illegal reset occurs.	Check the airway of NIBP to see if there are clogs. Then measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP COMM ERR"	The NIBP communication part has problem.	Execute the reset program in the NIBP menu. If the failure

		still exists, contact the manufacturer for repair.
"LOOSE CUFF"	The NIBP cuff is not connected correctly.	Re-connect the NIBP cuff.
"AIR LEAK"	The NIBP cuff is not connected correctly or there are leaks in the airway.	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"OVER PRESSURE"	Perhaps folds exist in the airway.	Check for the smoothness in the airway and patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"SIGNAL SATURATED"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"TIME OUT"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"CUFF TYPE ERR"	Perhaps the used cuff does not fit the setup patient type.	Check if the patient type is set up correctly. Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"PNEUMATIC LEAK"	NIBP airway has leaks.	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"MEASURE FAIL"	Problem happens when	Check the connection of each

	measuring the curve. The system cannot perform measurement, analysis or calculation.	part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP SYSTEM FAILURE"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.

Appendix II: Product Specifications

1. Classification

Anti-electroshock type	Class I equipment and internal powered equipment
EMC type	Class A
Anti-electroshock degree	
	ECG(RESP), SpO2, NIBP, TEMP, IBP CF
Harmful liquid proof degree	Ordinary equipment (sealed equipment without liquid proof)
Working system	Continuous running equipment

2. Specifications

Size and Weight

Size	260mm x 137mm x 244mm
Weight	4.5 kg

Environment

Temperature

Working	0 ~ 40 °C
Transport and Storage	-20 ~ 60 °C

Humidity

Working	15% - 95 %
Transport and Storage	10% - 95 %（no coagulate）

Altitude

Working	-500 to 4,600m
Transport and Storage	-500 to 13,100m

Power Supply

100~240 VAC, 50/60 Hz

Pmax=100VA

FUSE T 1.6A

Display

Device

8 inch. Color TFT, 800 x 600 Resolution

3 LED indictors

Messages

5 Waveforms Maximum

1 Alarm LED (Yellow/Red)

1 Working LED (Green)

1 Battery recharge/Standby LED (Yellow)

3 Sound Mode corresponding Alarm Mode

Signal Interface

External Display	Standard VGA(See detail information in Chapter 1.4)
AUX Output	BNC
ECG Output	
Sensitivity	1 V/mv ± 5%(reference 10Hz)BNC
Impedance	50 (ohm)
Signal Delay	ECG：25ms
IBP Output	
Sensitivity	1 V/100mmhg± 5% (reference 1Hz)
Impedance	50 (ohm)
Signal Delay	IBP：55ms

Nurse Call

Drive mode:	Relay Driven
Max. voltage:	36 VDC , 25 VAC
Max. load current:	2A
Through resistance:	<1 ohm
Isolating voltage:	>1500 VAC
Relay drive:	ON/OFF

Battery

Rechargeable 2.3 Ah 12V Lead-Acid battery

Operating time under the normal use and full charge greater than 100minutes

Operating time after the first alarm of low battery will be about 5 minutes

Maximum charging time of single battery is 4 hours.

Recorder (Option)

Record Width	48 mm
Paper Speed	25/50 mm/S
Trace	2
Recording types:	

Continuous real-time recording
8 second real-time recording
Auto 8 second recording
Parameter alarm recording
Waveform freeze recording
Trend graph/table recording
ARR events review recording
Alarm event review recording
NIBP review recording
Drug Calculation and titration table recording
Monitor information recording
OxyCRG recording

Recall and data storage

Trend Recall

Short	1 hrs, 1 Second Resolution
Long	72 hrs, 1 Min. Resolution

Alarm Event Recall

60 alarm events of all parameters and 8/16/32seconds of corresponding waveform.

NIBP Measurement Recall

400 NIBP measurement data.

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,
Waveform	2 channel
Lead mode	3 Leads (R, L, F or RA, LA, LL)
Lead selection	I, II, III,
Waveform	1 channel
Gain	×2.5mm/mV, ×5.0mm/mV, ×10mm/mV, ×20mm/mV, auto

HR and Alarm

Range	
Adult	15 ~ 300 bpm
Neo/Ped	15 ~ 350 bpm
Accuracy	± 1% or ± 1bpm,which great
Resolution	1 bpm
Sensitivity	≥ 200 uV $_{P-P}$

Differential Input Impedance	> 5 MOhm	
CMRR		
	Monitor	≥ 105 dB
	Operation	≥ 105 dB
	Diagnosis	≥ 90 dB
Electrode offset potential	±300mV	
Patient Leakage Current	< 10 uA	
Recovery After Defi.	< 3 s	
ECG Signal Range	±8 m V (Vp-p)	
Bandwidth		
Surgery	1 ~ 20(Hz)	
Monitor	0.5 ~ 40 Hz	
Diagnostic	0.05 ~ 10 Hz	
Calibration Signal	1 mV $_{p-p}$, Accuracy ： ±5%	
ST Segment Monitoring Range		
Measure and Alarm	-2.0 ~ +2.0 mV	
Accuracy	-0.8mV～+0.8mV：±0.02mV or ±10%, use the greater	
ARR Detecting		
Type	PVCs, ASYSTOLE, VFIB/VTAC, COUPLET, BIGEMINY, TRIGEMINY, R ON T, PVC, TACHY, BRADY, MISSED BEATS, PNP, PNC	
Alarm	Available	
Review	Available	

RESPARATION

Method	Impedance between R-F(RA-LL)
Differential Input Impedance	>2.5 MOhm
Measuring Impedance Range:	0.3~5.0 Ω
Base line Impedance Range:	200Ω ~2.5 KΩ
Bandwidth	0.2 ~ 2.0Hz(-3dB)
Resp. Rate	
Measuring and Alarm Range	
Adult	0 ~ 120 BrPM
Neo/Ped	0 ~ 150 BrPM
Resolution	1 rpm

Accuracy 7～150 BrPM：±2 BrPM 或±2%,which ever is greater
0～6 BrPM：unspecified

Apean Alarm 10 ~ 40 s

NIBP

Method Oscillometric

Mode Manual, Auto, STAT

Measuring Interval in AUTO Mode

1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240,480 Min

Measuring Period in STAT Mode 5 Min

Alarm

Type SYS, DIA, MEAN

Measuring and alarm range

Adult Mode

SYS 40 ~ 270 mmHg

DIA 10 ~ 210 mmHg

MEAN 20 ~ 230mmHg

Pediatric Mode

SYS 40 ~ 200 mmHg

DIA 10 ~ 150 mmHg

MEAN 20 ~ 165 mmHg

Neonatal Mode

SYS 40 ~ 135 mmHg

DIA 10 ~ 100 mmHg

MEAN 20 ~ 110 mmHg

Resolution

Pressure 1mmHg

Accuracy

Pressure

Maximum Mean error ±5mmHg

Maximum Standard deviation ±8mmHg

Overpressure Protection

Adult Mode 297±3 mmHg

Pediatric Mode 240±3 mmHg

Neonatal Mode 147±3 mmHg

SpO2

Measuring Range 0 ~ 100 %

Alarm Range 0 ~ 100 %

Resolution 1 %

Accuracy

70% ~ 100% ±2 %

0% ~ 69% unspecified

Actualization interval about 1s

Alarm Delay 10 s

Pulse Rate

Measuring and Alarm Range

20~254bpm

Resolution 1bpm

Accuracy ±3bpm

MASIMO SpO2 Specification:

Range

Saturation(%SpO2) 1%~100%

Pulse Rate(bmp) 25~240

Accuracy

Saturation(%SpO2) － During No Motion Conditions

Adults/pediatric 70%～100％±2%

0%～69% unspecified

Neonates 70%～100%±3%

0%～69% unspecified

Saturation(%SpO2) － During Motion Conditions

Adults/ pediatric/ Neonates 70%～100％±3%

0%～69% unspecified

Pulse(bpm) － During No Motion Condition

25 to 240 ± 3BPM

Pulse(bpm) － During Motion Condition

25 to 240 ± 5BPM

Resolution

Saturation(%SpO2)	1%
Pulse Rate(bpm)	1

TEMPERATURE

Channel	2
Measuring and Alarm Range	0 ~ 50 °C
Resolution	0.1°C
Accuracy	±0.1°C
Actualization interval	about 1s
Average Time Constant	< 10 s

IBP

Channel	1
Label	ART, PA, CVP, RAP, LAP, ICP, P1, P2
Measuring and alarm range	
ART	0 ~ 300 mmHg
PA	-6 ~ 120 mmHg
CVP/RAP/LAP/ICP	-10 ~ 40 mmHg
P1/P2	-50 ~ 300 mmHg
Press Sensor	
Sensitivity	5 uV/V/mmHg
Impedance	300-3000 Ω
Resolution	1 mmHg
Accuracy	±2% or ±1mmHg, which great
Actualization interval	about 1s

.