Service Manual
of
PM-600
Portable Patient Monitor

Shenzhen Mindray Bio-Medical Electronic Co., LTD.

Copyright

Version: 1.0

Issued date: 2002/06/11

P/N No.: 6003-20-11803

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-9000 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-9000 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:

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.

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

Company Contact

Address: A3-4/F., New Energy Building, Nan You Road, Nanshan, 518054, Shenzhen, P. R. China

Phone: +86 755 26052668/26052277

Fax: +86 755 26492978/26649559

EC Representative

Name: **Shanghai International Holding Corp. GmbH(Europe)**

Address: Eiffestrasse 80 D-20537 Hamburg Germany

Phone: +49 40 2513174

Fax: +49 40 255726

Table of Contents

Chapter 1 Introduction

I. General

PM-600 portable patient monitor is lightweight and compact, which weights 1.8kg including battery but not cable and accessories. The AC power for the monitor is 100~250V. Also, the monitor can be connected to the recorder via RS232 interface.

Electrical Description

PM-600 can be powered both by the AC or DC power supply. The external AC power supply (100~250V, 50/60Hz) is connected to the monitor via a 3-core wire. When connected to AC power, the AC indicator on the front panel lights on indicating that the instrument is charging the built-in battery. During the charging process, the user may press POWER button to start up the monitor.

When no AC power is connected, the monitor may also work because it can be powered by the built-in battery. The battery with full capacity can support the monitor to work for 2 hours (operating conditions: temperature is 25℃, all monitoring mode, perform NIBP measurement once every 15 minutes.)

When powered by the built-in battery, the yellow BATT. indicator on the front panel lights on. At the same time, the monitor will constantly check the remaining battery capacity. When the remaining capacity can only support the monitor to work normally for 5 minutes, the yellow BATT. indicator begins flashing together with audible alarm sound. In this situation, the operator should connect the AC power to the monitor to avoid it sudden shutdown.

If the monitor stops working suddenly when powered by the external AC power, the built-in battery can automatically begin to power the monitor to ensure its continuous operation.

Display

The screen of PM-600 series monitors consists of some displays made up of LED nixie tubes. These displays are used to show the system status and measured results of those parameters in numerical form. The appearance of the screen is shown in figure 1-1.

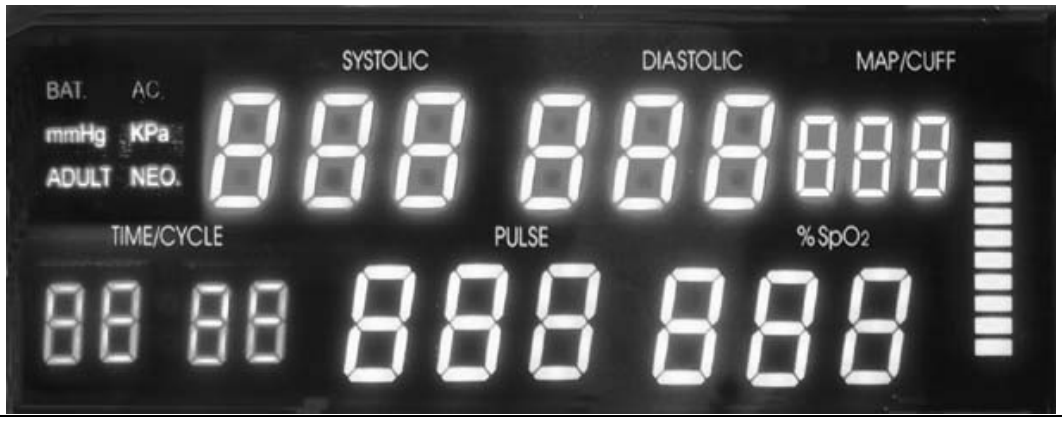


Figure 1-1 LED Display

AC	Red indicator for AC power. It is effective when highlighted. When not highlighted, the indicator can not be seen on the screen.
BATT.	Yellow indicator for built-in battery. The displaying way is the same as AC indicator.
mmHg	Red indicator for NIBP unit (mmHg). The displaying way is the same as AC indicator.
kPa	Red indicator for NIBP unit (kPa). The displaying way is the same as AC indicator. Of mmHg and kPa indicators, only one can be highlighted at one time.
ADULT	Red indicator for adult/pediatric NIBP measurement mode. The displaying way is the same as AC indicator.
NEO	Red indicator for neonatal NIBP measurement mode. The displaying way is the same as AC indicator.
SYSTOLIC	3 nixie tubes are used together to display systolic pressure in red color. When no measured data are available, "_ _ _" is displayed instead.
DIATOLIC	3 nixie tubes are used together to display diastolic pressure in red color. When no measured data are available, "_ _ _" is displayed instead.
MAP/CUFF	3 nixie tubes are used together to display MAP (mean pressure) or the inside pressure of the cuff in red color. When inflating the cuff, the inside pressure of cuff is displayed. Upon the end of the measurement, the NIBP value is displayed. When no measured data are available, "_ _ _" is displayed instead.
TIME/CYCLE	3 nixie tubes are used together to display the time of 24-hour system (TIME) or auto cycle time of NIBP measurement (TIME) or the serial number in the trend review (CYCLE).
PULSE	3 nixie tubes are used together to display the Pulse value of SpO2 measurement in green color. When NIBP and SpO2 are measured at the same time, the pulse value displayed is the result of SpO2 measurement. When only NIBP is measured, the displayed pulse value is the result of NIBP measurement. When no measured data are available, "_ _ _" is displayed instead.
%SpO2	3 nixie tubes are used together to display the SpO2 value in green color. When no measured data are available, "_ _ _" is displayed instead.
Pulse intensity	A dedicated LED display is used to display the pulse intensity of SpO2. The display indicates the degree of pulse intensity by the height of light bar. During SpO2 measurement, the higher the light bar is, the stronger the pulse palpitates.

⚠ **NOTE**⚠

When only measuring NIBP, the display of PULSE is the measured result from NIBP measurement. The system updates the pulse value until the end of NIBP measurement. The value will be also saved until the end of next NIBP measurement.

The measured results of SpO2 include pulse rate (PULSE) and %SpO2. These values are updated at least once per second.

II. Buttons

PM-600 has 8 buttons. Of different models, the functions of these buttons may be different. See following table.

Functional Description of LED display and Buttons

LED display and buttons		Model		
		PM-600I	PM-600II	PM-600III
LED Display	AC	Available	Available	Available
	BAT.	Available	Available	Available
	mmHg	Available	Available	Not available
	kPa	Available	Available	Not available
	ADULT	Available	Available	Not available
	NEO.	Available	Available	Not available
	SYSTOLIC	Available	Available	Not available
	DIATOLIC	Available	Available	Not available
	MAP/CUFF	Available	Available	Not available
	TIME/CYCLE	Available	Available	Not available
	PULSE	Available	Available	Available
	%SpO2	Not available	Available	Available
	Pulse Strength	Not available	Available	Available
Operating buttons	POWER	Available	Available	Available
	STAT	Available	Available	Available but not for operation
	SETUP	Available	Available	Available
	∧	Available	Available	Available
	∨	Available	Available	Available
	MEMORY	Available	Available	Available but not for operation
	SILENCE	Available	Available	Available

	START/STOP	Available	Available	Available

The front panel has following function items（see figure 1-2）:

- LED display: used to display measured results and monitoring status.
- Buttons: used to power on the system, set up system configuration or start measurement.
- Socket for measuring sensor: sockets for SpO2 sensor and NIBP cuff.

Figure 1-2 Fornt panel

The table below gives the meanings of LED symbols on the front panel. LED display has two kinds: LED indicator and LED nixie tube.

Meanings of LED Symbols

LED symbols	Description
AC	This indicator lights on in green when the external AC power is connected implying that in this condition the monitor can work normally and charge the internal battery at the same time.
BATT.	This indicator lights on when the monitor works powered by the internal battery instead of the external AC power supply. This indicator flashes when the battery has only low capacity so as to raise the operator's attention.
mmHg	Used to indicate NIBP measurement unit. Red color.
kPa	Used to indicate NIBP measurement unit. Red color.
ADULT	Used to indicate adult patient. Red color. Pediatric and adult belong to the same patient type.
NEO.	Used to indicate neonate patient. Red color.
SYSTOLIC	Used to display the measured rsullt of systolic pressure of NIBP measurement.
DIASTOLIC	Used to display the measured result of systolic pressure of NIBP measurement.
MAP/CUFF	Used to display the measured result of mean pressure of NIBP measurement. During measurement, it is used to display the cuff pressure.
TIME/CYCLE	Used to display 24-hour system clock and countdown the time of auto NIBP measurement, i.e., display the serial No. when reviewing the measured results.

PULSE	Used to display the pulse rate of SpO2 and NIBP measurement. For PM-600I, display the pulse rate of NIBP measurement. For PM-600II, display the pulse rate of SpO2 measurement.
SpO2 (%)	Used to display the measured result of SpO2 measurement.
Pulse Strength	Indicator of the pulse strength of SpO2 measurement.

Buttons on the front panel:

Symbol	Description
POWER	On/Off button of power switch
STAT	NIBP operating mode. Measure continuously within 5 minutes.
SETUP	Used to set up the upper and lower alarm limits of NIBP and SPO2 alarms, time, adult/pediatric mode, the measurement unit and the sound volume.
∧	Used in conjunction with SETUP and RECALL to select.
∨	The same function as the above button.
MEMORY	Press this button to begin reviewing NIBP data. Used in conjunction with "∧" or "∨" button to review forward or backward.
SILENCE	Press this button quickly to enter 2-minute Alarm Suspension status. Press this button for a long time to enter the Alarm Silence status.
START/STOP	When not in NIBP measurement mode, press this button to start a NIBP measurement. When in NIBP measurement mode, press this button to stop the NIBP measurement. In auto cycle mode, press this button to start/stop the measurement. In data review mode, press this button to start/stop the printing operation of the recorder.

Rear panel:

Connectors for connecting the external power supply and RS-232 serial port are on the rear panel (figure 1-3). The label of the device is also on the rear panel. See figure below. Table below lists out the description of each connector on the rear panel.

Connector name	Type and description
External power	3-core power input socket, connected to AC power:100-250V~, 50/60Hz
RS-232 interface	9-core DB-9 pin, connected to the recorder.

Figure 1-3 Rear Panel

III. Hardware principle

1. General:

Device connection graph（figure 1-4）

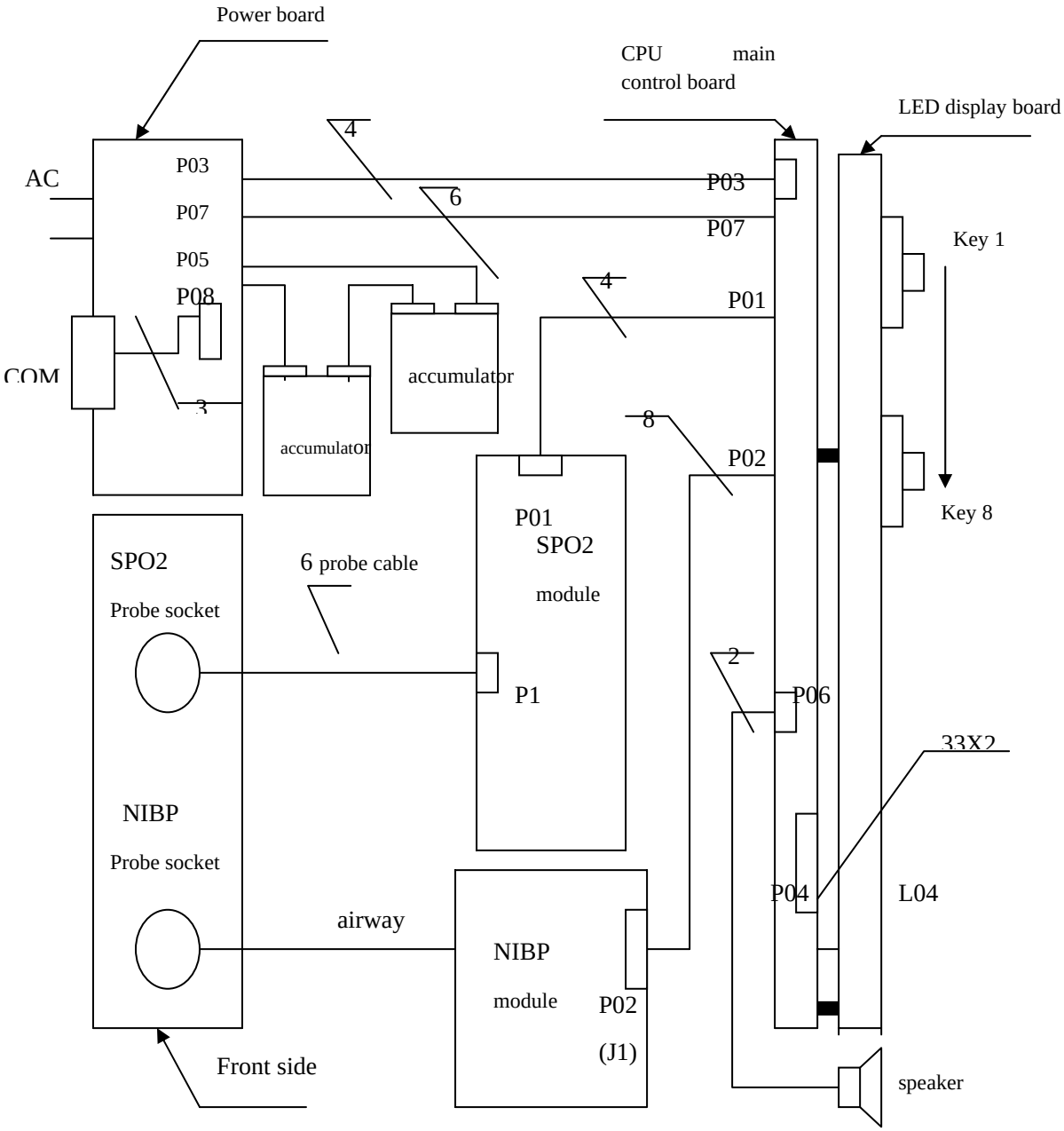


Figure 1-4 Device connection graph

2. Internal structure（figure 1-5）

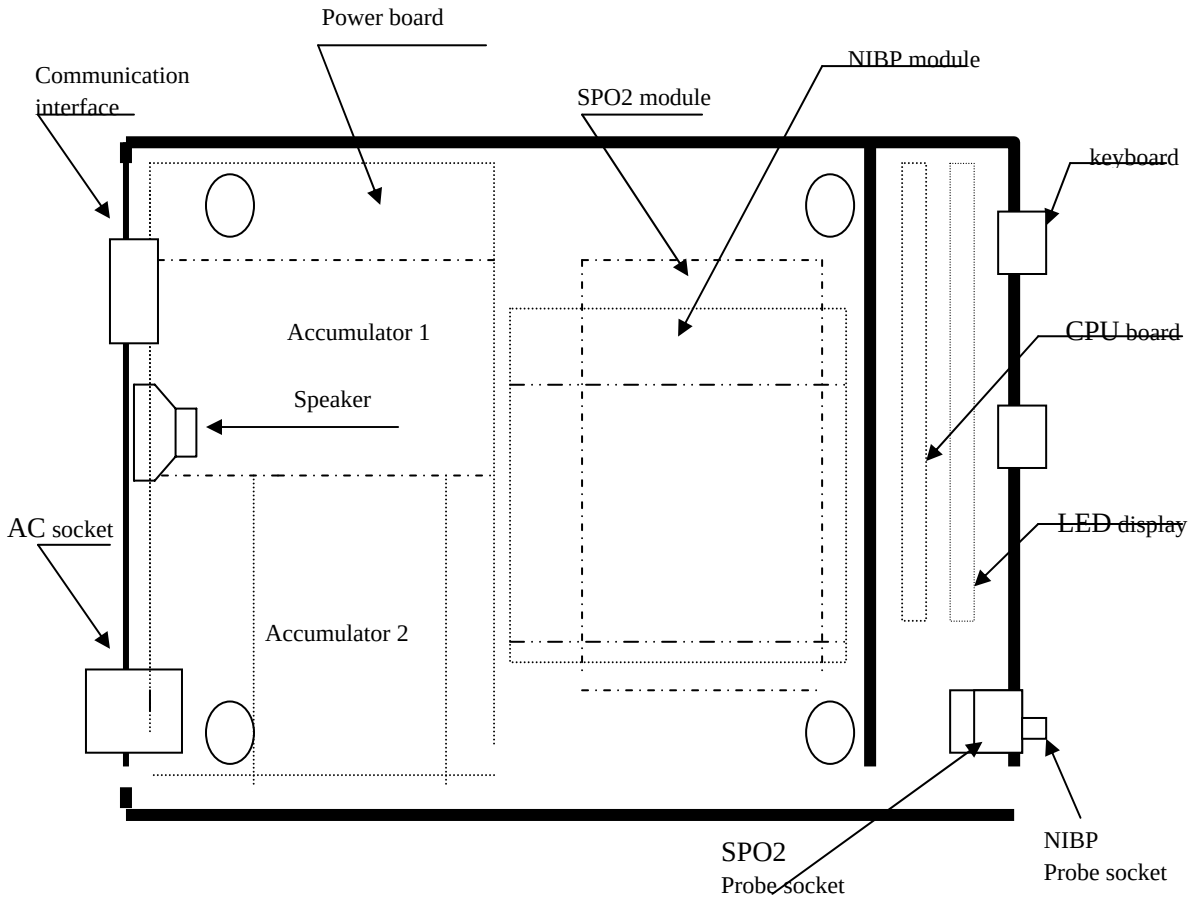


Figure 1-5 Internal structure

3. Power board:

Parameters:

Input voltage: 100~250Vac，50/60HZ

DC output: 12V/450mA，3.3V/550 mA

Lead-acid accumulator charging management

Power on/off control, over-voltage protection, over-current protection, short-circuit protection

Schematic diagram（figure 1-6）： internal electrical structure of PM-600：

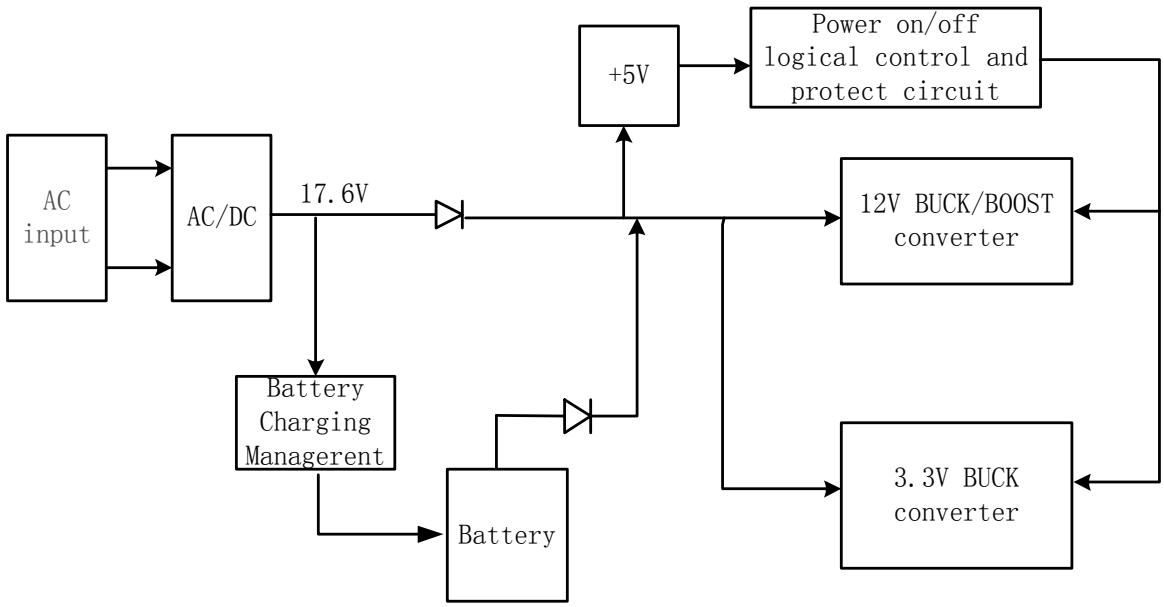


Figure 1-6 Schematic diagram

Functions of each part:

AC/DC converter:

After flowing through the EMC filter, the universal input power is rectified into DC high-voltage power, which after high-frequency power change, is output as DC 17.6. This 17.6 voltage is to be used as the supply for the input ends of battery charging circuit, 12V step-up/down converter, and 3.3V step-down converter. When AC/DC is effective, the 17.6V output is higher than the battery voltage. Therefore, compared with the battery, 17.6V has the priprority to power the monitor.

Battery charging management:

Circuit of this part uses the battery management chip UC3906N manufactured by UNITRODE to fulfil the management of charging lead-acid battery.

12V step-up/down converter:

This converter uses MC34167 manufactured by MOTOROLA company. It fulfuils the intented function by working together with peripheral components such as Q7, D10, D11, L4, C39 and some other components.

3.3V step-down converter:

This converter uses the Step-down Controller MAX 1653 manufactured by MAXIM company to fulfil the intended function. Functions like power on/off control, over-voltage protect circuit are realized through controlling the controlled terminals of two chips MC34167 and MAX1653.

Parameters and waveforms at some critical points: Use multimeter to measure the voltage value of the critical points.

After connecting the AC power, the DC voltage across C12 is about 1.3 ~1.4 times as much as as the incoming AC voltage. The voltage between 1PIN of PCB2 to earth is within 11~15V, which is the working voltage of U1. The voltage across C11 is 17.6V. When battery is not connected, the voltage

across C20 is 13.8V. Voltage across C46 is 5V, which is used as the working voltage of U7, U8, U9 and U14. The voltages of 8PIN of U1, 1PIN of U10 and 11PIN of U11 to earth are 5V. Following waveforms can be viewed using oscillograph. The waveform of the voltage of 4PIN of U1 is a standard sawtooth, whose oscillating frequency is about 120KHz. After connecting a rating load as the output, the waveform of the voltage of 1PIN of Q1 to earth shall be a square one, whose frequency is about 120KHz. The waveform of the voltage across D12 should be a square one, whose frequency is about 280KHz.

4. CPU main control board

The structure of the main control board is as shown in the figure below. Function of each part of the main control board are:

The main control board manages maximum 3 modules, which are NIBP, SpO2, and recorder. Communication among these modules is realized via UART. The recorder module uses RS232 standard level. The other two modules use standard CMOS 5V interface.

Voltage testing

Three voltages in the system require real-time monitoring. They are +12V, battery voltage, and AC/DC voltage. 8-bit AD/DA chip with the type of PCF8591 is used on the main control board. This chip has four AD channels, three of which are used to respectively monitor the three voltages mentioned above.

Real-time clock:

Use lead-acid battery of the system as the spare power for DS1337 clock. Therefore a potential-divider circuit is used in the system to generate a voltage of 2.4V to power DS1337. The resistance of this potential-dividercircuit is 220K. When the system is working, the current in this circuit is 60uA.

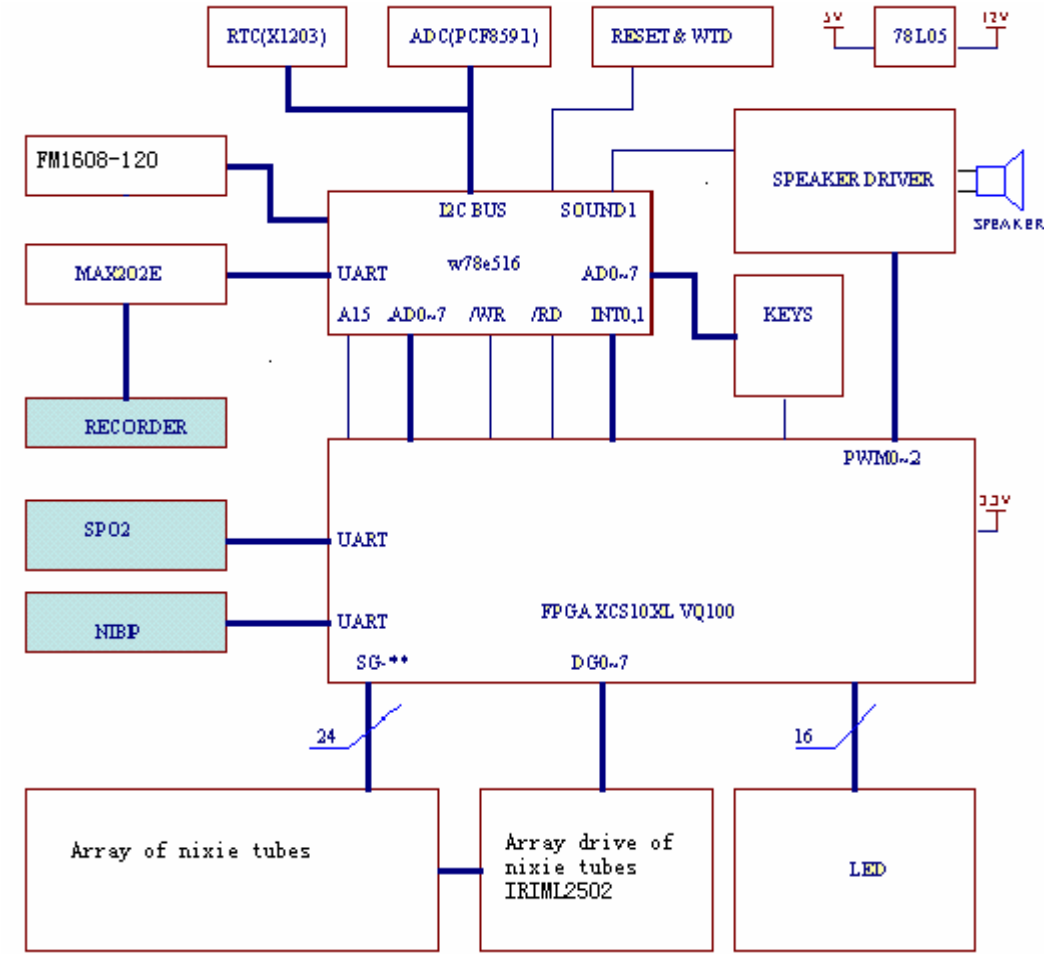


Figure 1-7 Schematic hardware diagram

LED drive and button scanning

PM-600 uses nixie tubes and LEDs for display. There are 19 nixie tubes driven by the main control board. These 19 nixie tubes are divided into 7 groups. Additionally, there are some independent LEDs and LED arrays. Based on the actual situation, nixie tubes are driven in the way of time-sharing scanning. Of the 7 groups of nixie tubes, each group contains maximum 3 nixie tubes. Accordingly,.Therefore, there are 7 groups of nixie tubes with each group containing 24 segments.. are driven by constant current by taking advange of 16 independent ports. Therefore, there are totally 48 port wires needed to drive nixie tubes and LEDs. These 48 port wires are all driven by FPGA---XCS10XL. The driving voltage of the system is 3.3V. A drive MOS tube --- IRLML2502 is added into the drive of each group. The nixie tubes used in the system are in three colors, i.e., red, green and yellow. Nixie tubes in three different colors have different brightness. To acquire even and consistent brightness, we need to adjust the scanning duty ratio in the drive of EPGA in orde to adjust the average driving current and as a result to adjust the brightness. The chip-selection signal of the port is generated by FPGA codes.

Audio alarm:

The system is designed to possess audio and visual alarm function. The visual alarm can be fulfilled by

using the software to control the brightness of LEDs and nixie tubes. Nevertheless, to realize the function of audio alarm, we have to use a special alarm circuit to drive a speaker. The signal is acquired by the frequency-sharing circuit in FPGA. FPGA can output frequency signals respectively having four different output frequencies, i.e., 2048Hz, 1024Hz, 512Hz and 256Hz.

AC power/battery monitoring and indication

After undergoing AC/DC conversion in the power board, a DC signal is introduced into the main control board. This DC signal can be used to directly drive AC LED. After this signal has been potential-divided by resistance, we can obtain a voltage of about 3V ---- ACS, which is used by MCU. When the system is powered by battery, ACS is at the low level, based on which, MCU can judge whether the power has been switched and accordingly make the power indicator light on.

Linear voltage regulating circuit:

The main control board has two power inputs, 3.3V and 12V. However, components on the main control board require 5V. Accordingly, we select a linear voltage regulator---7805, which are used to generate a 5V voltage from 12V voltage.

Display board：

LED display board consists of 7-segment LED nixie tubes of either big or small size (red, common cathod, followings are the same), LED indicators (red, green, yellow), and scan driving circuit. By pluging the socket P04 into the corresponding pin L04 on the CPU board, 5V working voltage and display data can be obtained. LED display uses the way of scanning drive.

Parameters displayed by LED:

NIBP:

Display of SYSTOLIC pressure occupies 3 7-segment nixie tubes.

Display of DIASTOLIC pressure occupies 3 7-segment nixie tubes.

Display of MEAN/CUFF pressure occupies 3 7-segment nixie tubes of small size.

SpO2: (type 503 only measures this parameter. Display of PULSE occupies 3 7-segment nixie tubes.

Display of SpO2 occupies 3 7-segment nixie tubes.

Display of indication for SpO2 pulse intensity is realized by using 10 diodes.(red) **Display 24-hour clock and measurement cycle (TIME/CYCLE)**

Occupy 4 LED nixie tubes of small size and two round (Φ3) LED lamp to indicate “second” palpitation (red).

Information displayed by LED: use square LED (2X5)

Pressure unit is mmHg or kPa (red).

Patient mode is ADULT or NEO (red).

AC power indicator is AC (green).

Battery indicator is BATTERY (yellow).

Data displayed by LED:

The LED display unit receives and displays various data coming from CPU board.

The LED nixie tubes and LED lamps of the same color have even and consistent display brightness. The frame scanning frequency of display is ≥100. The display is flicker-free. When the system has alarm, the LED nixie tubes will flash regularly on the LED numerical display position of the corresponding parameter. At the same time, speaker gives sound to realize audio and visual alarm function.

5. Battery

Use two 6V 1.0Ah closed rechargeable lead-acid accumulators, which are serial connected.

IV. Software principle

After being powered on, the system enters the idle state. By pressing different buttons, the user can command the system to execute different operations such as Single NIBP measurement, and continuous NIBP measurement.

When the system software is in the process of power-on selftest or operation, it can check related parts to see if any error takes place and accordingly generate different alarm messages, which are listed below.

When detecting Cpu or Fpga error upon power-on, the time light on the display panel will flash.

When detecting watchdog error upon power-on, the speaker will give long sound.

When detecting keyboard short-circuit error upon power-on, the speaker will give continuous and rapid sound.

When detecting low battery capacity, the battery indicator wll flash and the speaker will give alarm sound.

When detecting other errors, the system will display corresponding error code listed out in the table below.

Erro code and error solution

Error code (for user use)	Description	Solution
E01	No cuff is connected or the cuff size is not consistent with the patient type.	Check if a cuff is connected to the patient and monitor, if the cuff and the hose have leakage. Check if the patient type (adult, neonate) is correct and the cuff has appropriate size. Measure again.
E02	There is interference when measuing NIBP.	The measurement cannot be finished successfully. This error may be caused by excessive patient movement or some physiological factors. Check the patient and the cuff. Keep the patient quiet. Measure again.
E03	NIBP measurement is time out.	Cannot finish the measurement within normal time. Check the patient and the cuff. Check if the hose is clogged or damaged.

		Measure again.
E04	SpO2 sensor off	Check if the sensor is still connected to the patient. Check if the sensor is loosely connected. Check if the sensor cable is incorrectly connected or damaged.
E05	There is interference when meausring SpO2.	Check if the sensor on the patient is correctly connected. Change the measuring position. Check if the red tube inside the sensor no longer flashes (flashing means working normally). Measure again.
E06	The recorder does not work.	Check if the recorder has paper. Check if the paper is installed correctly. Check if the recorder cable is correctly and safely connected. Print again.
E77	NIBP unit failure	If there is SpO2 unit, the system can continue to execute SpO2 measurement but cannot execute NIBP measurement. NIBP unit needs repair.
E88	SpO2 unit failure	If there is NIBP unit, the system can continue to execute NIBP measurement but cannot execute SpO2 measurement. SpO2 unit needs repair.
E99	Monitor system failure	The monitor needs repair.

Chapter 2 Monitoring Principle

I. 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 decreasing of the pressure in the cuff, the artery blood will palpitate with the pulse, which results in palsation in the cuff. Through the pressure sensor connected with the inflating pipe of the cuff, a palsation 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 appropritate cuffs for neonatal, pediatric and adult patients so as to avoid the generation of measurement error. 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 in blood pressure.

II. SpO2

By tracing the pulse waveform in the fingertip, using specified algorithm and consulting the clinical data table, we can obtain the SpO2 value. The SpO_2 sensor consists of two LEDs and a photodetecter. The two LEDs are respectively red diode and infrared diode, which are lighted according to certain time sequence. When the capillary vessel of the fingertip congests repeatedly, the light of the LEDs is absorbed by blood vessels and organs and then projected onto the photodetecter. The photodetecter can detect the light intensity varying with pulse changes and display the changing light intensity in the form of changing electronic signals. The ratio between the DC and AC components of the two types of signals is the % oxygen in the blood. Then we can calculate correct SpO2 value by using specified algorithm and also calculate pulse rate according to the SpO2 waveform.

The SpO2 module mainly consists of following four parts: sensor, signal processing, control unit of LED driving sequence, singlechip.

1) Sensor: the two LEDs alternatively emit red light and infrared light onto the part being monitored. The photocell then converts the received lights into electro signals.

2) Signal processing: The electronic signal output from the photocell are amplified by the measurement amplifier, high-pass filter and program controller and finally converted into digital signal by A/D. The D/A converter is used to control the baseline of the signal, amplify the AC component and finally output an appropriate pulse waveform. The digital signal output from A/D are to be processed by the singlechip.

3) Control unit of LED driving sequence: The time sequence circuit and DAC together control the alternative operation of the two LEDs and the light intensity. The singlechip control the driving current based on the algorithm.

4) Singlechip: it is made up of CPU, RAM, ROM and interface circuit.

Chapter 3 Checks and Tests

I. System checks

For the conventional testing contents of PM-600 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 machine 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 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

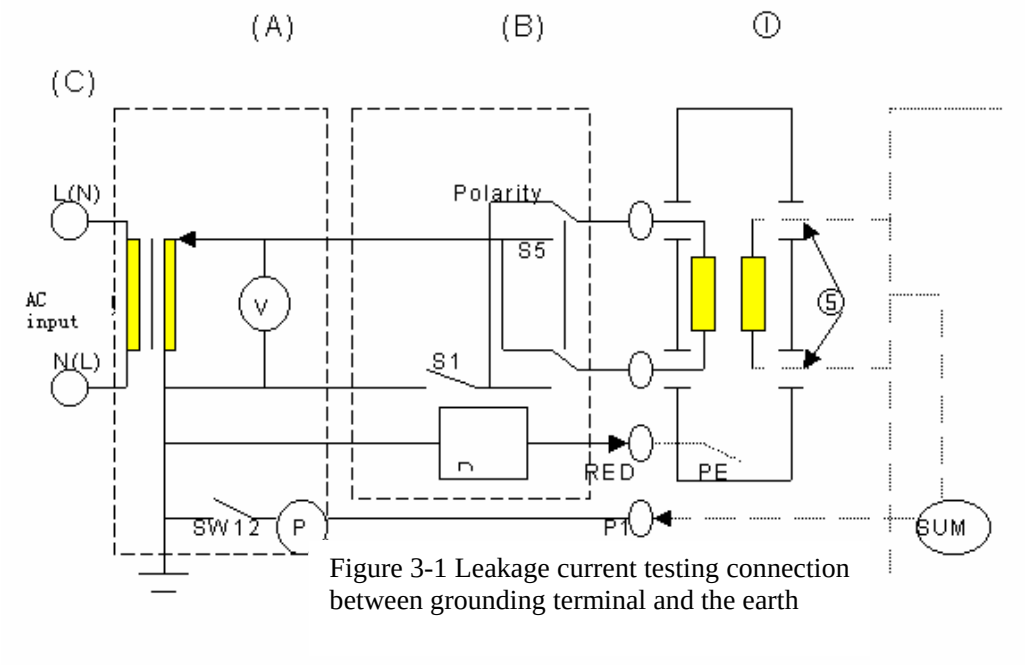


Figure 3-1 Leakage current testing connection between grounding terminal and the earth

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, press and release the [Polarity] key. Disconnect SW12, 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 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 or 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.

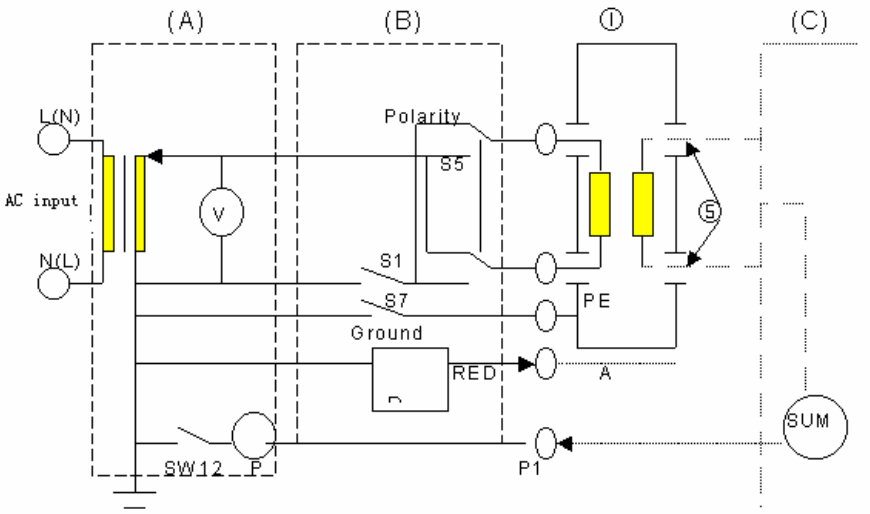


Figure 2 Connection graph to test leakage current from shell to earth

(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, press and release the [Polarity] key. Disconnect SW, 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, press and release the [Polarity] key to 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, press and release the [Polarity] key.

Disconnect SW, press and release the [Polarity] key. The maximum value of these four measurements should be less than 0.5mA.

2.2.3 Patient leakage current of the application part:：

2.2.3.1 Connection graph for testing is shown in figure 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 tested ① into AC output of 501. Connect the sensors including NIBP, SpO2 of the application part based on the requirements of (C). Connect the output SUM of (C) to the RA post of the 501 tester. Locate all the switches on the connecting kit of the application part to [OFF] position.

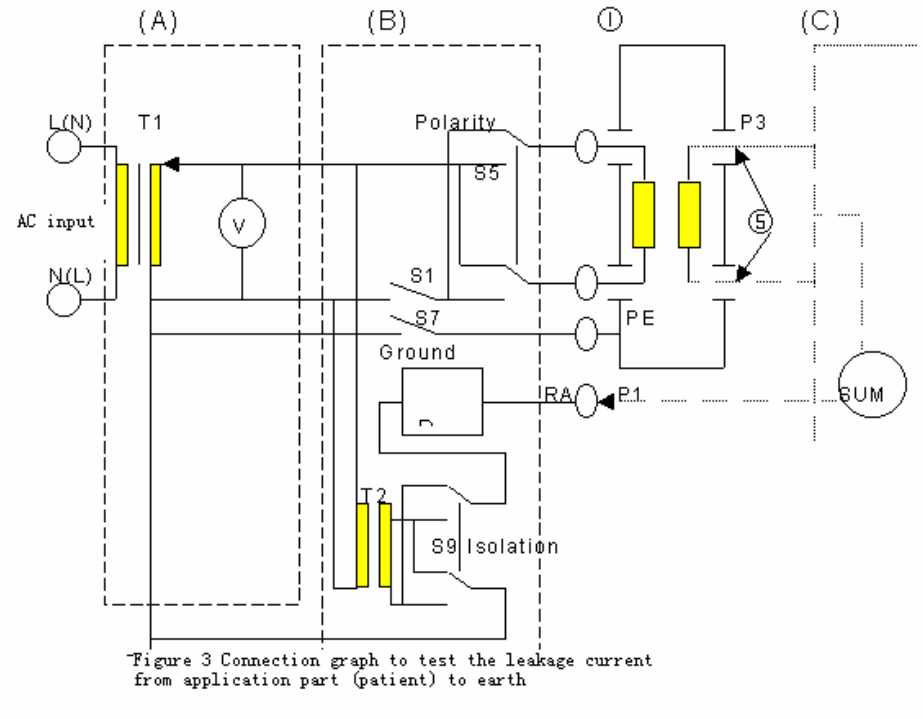


Figure 3 Connection graph to test the leakage current from application part (patient) to earth

(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

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 4

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 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 NIBP-P, SpO2-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

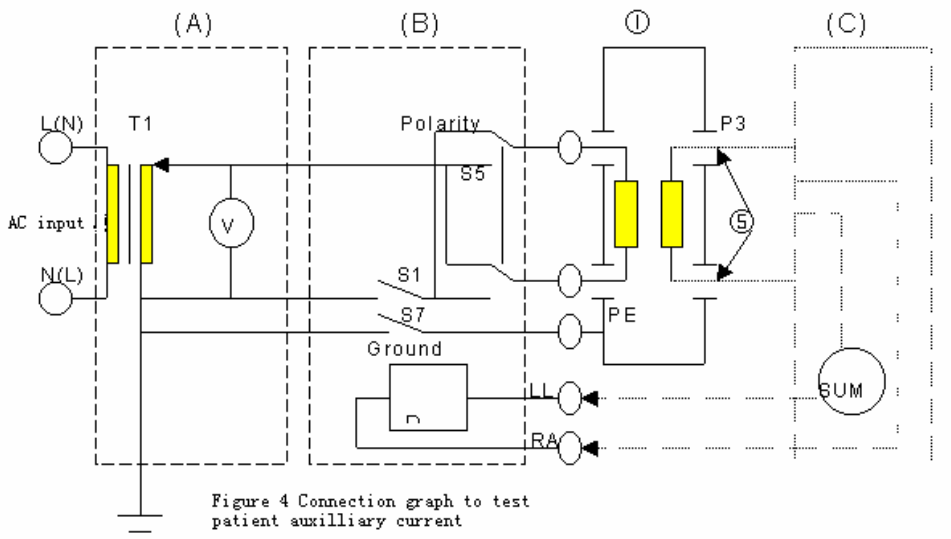


Figure 4 Connection graph to test patient auxilliary current

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 lead 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 5:

Note: In the graph, P1 and P2 are two binding posts 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.

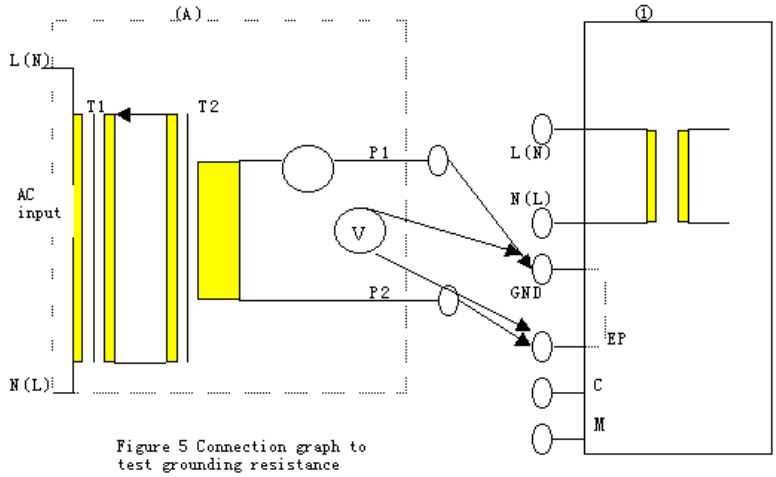


Figure 5 Connection graph to test grounding resistance

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 shall 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 P1to 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. Test and calibrat each parameter

Testing and calibrating follow parameters are to ensure the accuracy of PM-600 portable patient monitor. Calibrating operation should be performed at least once a year. Calibration should be carried out each time after maintenance.

1. 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-600

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-600 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-600

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-600 are consistent with those on the simulator.

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

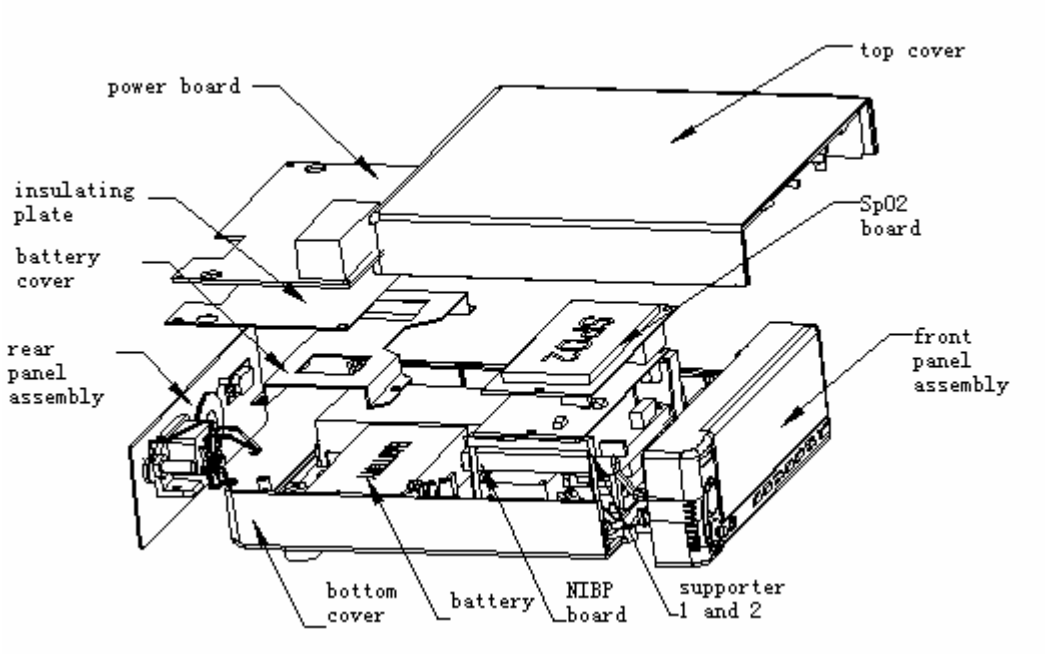
④ Change the setup values of SpO_2 and PR on the simulator.

⑤ Check the displayed values on PM-600 are consistent with the setup values.

⑥ Make SpO_2 sensor fall off, in this condition, PM-600 should immediately give alarm.

Chapter 4 Troubleshooting

I. Disassembly graph of each part of PM-600



II. Troubleshooting guidance

In transportation, storage and use of PM-600, various factors such as unstable network voltage, changing environmental temperature, falling-down or impact, component aging may all result in PM-600 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-600 Component-level Service Table

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
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．Parameter failures

Failure	Possible cause	Solution
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-600, 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-600.

3） When using PM-600 and other medical devices at the same time, safely connect the equipotential post on the rear panel of PM-600 with equipotential posts of other devices.

4） Do not put PM-600 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-600, the data screen will appear.

IV. Other precautions

1）When using PM-600 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 harm the patient or the medical personnel.

2）Do not use PM-600 in the presence of flammable anesthetics to avoid the hazard of explosion.

Chapter 6 Cleaning

The user should use specified method to clean the PM-600 portable multi-parameter monitor. To prevent the monitor from being contaminated or damaged, please use recommended materials. To guarantee patient safety, do not use cables, sensor or accessories that have already been deteriorated or damaged.

I. Cleaning

1) Use soft cloth to clean the monitor.

2) Use soap, amino, or ethanol based material to clean the host.

3) Use soap, amino or ethanol based material to clean the reusable cuff.

4) Use soap, amino or ethanol based material to clean the reusable SpO2 sensor.

⚠ **NOTE** ⚠

1) Ammonia solution: diluted ammonia solution ＜3%;

Ethanol: ethonal 70%, isopropanol 70%

2) Don't use the grinding material, such as steel wool etc.

3) Do not let cleaner enter the device or immerse the part being cleaned.

II. Sterilization: based on cleaning, sterilize the PM-600 when necessary

1) Use ethanol or ethanal based cleaner;

2) Use ethanol or ethanal based cleaner to clean the reusable cuff;

3) Use ethanol or ethanal based cleaner to clean the reusable SpO2 sensor.

⚠ **NOTE** ⚠

1) Ethanol: ethanol 70%

Ethanal: methanal（35～37%）

Bleacher: diluted sodium hypochlorite solution (bleacher used for washing) with a concentration of 500ppm～5000ppm.

2) Do not let the sterilization liquid enter the device or immerse the device or any part into the liquid.

3) Do not leave any sterilization liquid on the surface of the device.

III. Disinfection

Disinfect the PM-600 when necessary. Because disinfection process is complex, please execute the

procedures according to the hospital regulation. Pay special attention to safety. EtO gas is usually used for disinfection.

Chapter 7 Maintenance

PM-600 portable patient monitor is a type of precision electronic medical device having complex structure. Maintaining PM-600 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. Test overall functions of the device annually.
6. Perform safety test once after each opening-chassis repair.
7. If finding problems during maintenance, contact your supplier in time.

Appendix: Specifications

Following is the specifications of PM-600II monitor, which has complete configuration of both NIBP and SpO2. For PM-600III (measure SpO2 only) and PM-600I (measure NIBP only), without special declariation, their specifications are included in the specifications of PM-600II.

1.General specifications:

Size: 60mm×180mm×220mm

Weight: 1.8 kg

Display Specification:

Display: LED

Display Information:

Power Supply Indicator: AC & BATT

NIBP Measurement Unit: mmHg & kPa

NIBP Patient Kind:: ADULT & NEO (neonate)

NIBP Measurement Display: SYSTOLIC; DIASTOLIC, MAP

Pulse: PULSE

SpO2: %SpO2

Clock: 24-hour

Cuff Pressure: CUFF

Pulse Intensity: LED Indicator

2.Safety Specifications

Standard compliable: IEC60601-1

Anti-electroshock type Class I equipment and internal powered equipment

EMC type Class A

Anti-electroshock degree SpO2 and NIBP are CF degree

Against water ingress degree Ordinary equipment (sealed equipment without liquid proof)

Operation mode Continuous running equipment

3.Power Supply

AC input：

100-250VAC, 50/60Hz, 40VA

FUSE: T 0.5A

Battery:

Two rechargeable 1.3 A/Hr 6V Lead-Acid battery

Operating time: (Condition: 25℃, NIBP working period is 10 min.)

PM-600I Monitor: working time is 4 hours with full battery capacity.

PM-600II Monitor: working time is 2 hours with full battery capacity.

PM-600III Monitor: working time is 3 hours with full battery capacity.

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

4.Environment

Temperature

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

Humidity

Working	30% - 85 %
Transport and Storage	30% - 93 %（no condensation）

EMC According with the requirement of EN60601-1-2.

5.Monitoring Parameter

5.1 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

Pulse Rate Range	40 - 240 (bpm)
Cuff Pressure Range:	0 - 300 (mmHg)

NIBP Measurement:

Measuring and Alarm Range

Adult Mode

SYS	40 ~ 270 (mmHg)
DIA	10 ~ 215 (mmHg)
MAP	20 ~ 235 (mmHg)

Neonatal Mode

SYS	40 ~ 135 (mmHg)
DIA	10 ~ 100 (mmHg)
MAP	20 ~ 110 (mmHg)

Resolution

Pressure	1mmHg

Blood Pressure Accuracy: average error and standard deviation according to the requirement in ANSI/AAMI SP-10-1992

Maximum Mean error:	±5mmHg
Maximum Standard deviation:	±8mmHg

The SYSTOLIC and DIASTOLIC values measured using this device shall be equal to those measured by trained medical personnel using cuff and stethoscope. The MEAN value measured using this device is equal to that measured using endartery blood pressure measurement device.

Pulse Accuracy:	±2bpm or ±2%, which great

Overpressure Protection

Adult Mode	297±3 (mmHg)
Neonatal Mode	147±3 (mmHg)

5.2 SpO2

Measuring Range	0 - 100 %
Alarm Range	0 - 100 %
Resolution	1 %
Accuracy	
	70% - 100%, ±2 %
	0% - 69%, unspecified
Pulse Rate	
Measuring and Alarm Range	0~2540bpm
Resolution	1bpm
Accuracy	±2bpm

5.3 Trend

Storage method of trend data: combined storage in two ways specified below:

NIBP: store NIBP data each time after one measurement. Maximumly store NIBP data of 600 times.

SpO2: sotre once every 30 seconds (the average value of the measured results within these

30 seconds). Max. storing time is 10 hours.

6. Signal Interface

To connect Recorder: RS-232 serial Interface

7. Recorder (optional)

Type: thermal

Record Width 48 mm

Recording types:

Real-time recording

Trend data printing

Power Supply:

100-250VAC, 50/60Hz