PM-7000

Patient Monitor

Service Manual

Copyright

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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;
- applied electrical appliance is in compliance with relevant National Standards;
- the monitor is operated under strict observance of this manual.

⚠ **Warning** ⚠

For continued safe use of this equipment, it is necessary that the listed instructions are followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

- **Do not rely only on audible alarm system to monitor patient. When monitoring**

adjusting the volume to very low or completely muting the sound may result in the disaster to the patient. The most reliable way of monitoring the patient is at the same time of using monitoring equipment correctly, manual monitoring should be carried out.

- **This multi-parameter patient monitor is intended for use only by medical professionals in health care institutions.**
- **To avoid electrical shock, you shall not open any cover by yourself. Service must be carried out by qualified personnel.**
- **Use of this device may affect ultrasonic imaging system in the presence of the interfering signal on the screen of ultrasonic imaging system. Keep the distance between the monitor and the ultrasonic imaging system as far as possible.**
- **It is dangerous to expose electrical contact or applicant coupler to normal saline, other liquid or conductive adhesive. Electrical contact and coupler such as cable connector, power supply and parameter module socket-inlet and frame must be kept clean and dry. Once being polluted by liquid, they must be thoroughly dried. If to further remove the pollution, please contact your biomedical department or Mindray.**

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.

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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.

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- assembly operations, extensions, re-adjusts, modifications or repairs are carried out by persons other than those authorized by Mindray.
- the PM-7000 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

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Safety Precautions

1. Meaning of Signal Words

In this manual, the signal words **DANGER**, **WARNING**, and **CAUTION** are used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal word	Meaning
⚠**DANGER**	**Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.**
⚠**WARNING**	**Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.**
⚠**CAUTION**	**Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.**

2. Meaning of Safety Symbols

Symbol	Description
	Type-BF applied part
⚠	"Attention" (Refer to the operation manual.)

Safety Precautions

Please observe the following precautions to ensure the safety of service engineers as well as operators when using this system.

⚠**DANGER:** **Do not use flammable gases such as anesthetics, or flammable liquids such as ethanol, near this product, because there is danger of explosion.**

⚠**WARNING:** **Do not connect this system to outlets with the same circuit breakers and fuses that control current to devices such as life-support systems. If this system malfunctions and generates an over current, or when there is an instantaneous**

current at power ON, the circuit breakers and fuses of the building's supply circuit may be tripped.

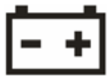
⚠**CAUTION:** **1. Malfunctions due to radio waves**

(1) Use of radio-wave-emitting devices in the proximity of this kind of medical electronic system may interfere with its operation. Do not bring or use devices which generate radio waves, such as cellular telephones, transceivers, and radio controlled toys, in the room where the system is installed.

(2) If a user brings a device which generates radio waves near the system, they must be instructed to immediately turn OFF the device. This is necessary to ensure the proper operation of the system.

2. Do not allow fluids such as water to contact the system or peripheral devices. Electric shock may result.

Symbols

	Equipotential grounding terminal		CE mark 93/42/EEC a directive of the European Economic Community
	Be Careful		Protective earth ground
	Direct current and alternating current (DC&AC)		Direct current (DC)
	Alternating current (AC)		Battery indicator
	ESD sensitivity		Power ON/OFF
	Network connector		High voltage
	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.		

Contents

Chapter 1 About the Product

1.1 Introduction

The PM-7000 Patient Monitor (hereinafter called PM-7000 for short), a portable and accessible patient monitor, is supplied by rechargeable batteries or external AC/DC power, which applies to adults, pediatric and neonates. You can select different configurations as required. Besides, the PM-7000 can be connected with the central monitoring system whereby a monitoring network will be formed. Parameters that the PM-7000 can monitor include: ECG, RESP, SpO_2, NIBP, 2-channel TEMP, 2-channel IBP, CO, CO_2 and AG. It, integrating the functions of parameter measurement, waveform monitoring, freezing and recording, is a compact and lightweight patient monitor. Its color TFT LCD is able to show patient parameters and 7 waveforms clearly. The compact control panel and knob control, and the easy-to-use menu system enable you to freeze, record, or perform other operations conveniently.

The PM-7000 measures patient's ECG, NIBP, SpO_2, TEMP, RESP, IBP, CO and CO_2 physiological signals through the ECG electrode, SpO_2 sensor, cuff, temperature sensor and pressure transducer. During the measurement, the patient monitor does not get energy or any substance from the human body, and does not release any substance to the human body. However, it releases sine wave signals to the patient when measuring the respiration rate. The patient monitor converts the measured physiological signals to the digital signals, waveforms and values, and then displays them on the screen. You can control the patient monitor through the control panel. For example, you can set different alarm limits for different patients. Thus, when the patient monitor detects any physiological parameter exceeding the preset alarm limit, it will enable the audio and visual alarm.

1.2 Application

1.2.1 General

In the treatment processes, it is necessary to monitor important physiological information of patients. Therefore, the patient monitor has been playing an outstanding role among medical devices. The development of technology does not only help medical staff get the important physiological information, but also simplifies the procedures and makes it more effective. For patients in hospital, the basic and important physiological information is required, including ECG, SpO_2, RESP, IBP, CO, CO_2, TEMP, etc. In recent years, the development of science and technology helping measure and get important physiological information of patients has made the patient monitor more comprehensive in performance and better in quality. Today, multi-parameter patient monitors are widely used.

1.2.2 Usage

Parameters that the PM-7000 include: ECG, RESP, SpO_2, NIBP, TEMP, IBP, CO AG and CO_2. PM-7000 converts these physiological signals to digital signals, processes them and displays them on the screen. You can set the alarm limit as required. When the monitored parameter exceeds the preset alarm limit, the patient monitor will start the alarm function. In addition, you can control the patient monitor through the control panel. Usually, patient monitors are seen in some clinical areas in hospital, such as ICU, CCU, intensive care units for heart disease patients, operating rooms, emergency departments and observation wards. They can also be used in clinics. The PM-7000 should be run under the control of clinical staff.

PM-7000 has the following functions:

ECG	Heart Rate (HR)
	2-channel ECG waveform
	Arrhythmia analysis and S-T analysis (optional)
RESP	Respiration Rate (RR)
	Respiration waveform
SpO_2	Pulse Oxygen Saturation(SpO_2), Pulse Rate (PR)
	SpO_2 Plethysmogram
NIBP	Systolic pressure (NS), diastolic pressure (ND), mean pressure (NM)
TEMP	T1, T2, TD
IBP	CH1: SYS, DIA
	CH2: SYS, DIA
	IBP waveform
CO	Temperature of blood (TB)
	Cardiac Output (CO)
CO_2	End-tidal carbon dioxide ($EtCO_2$)
	Inspired minimum CO_2 ($InsCO_2$)
	Airway Respiration Rate (AwRR)
AG	Inhaled and exhaled CO_2 ($FiCO_2$, $EtCO_2$) Inhaled and exhaled N_2O (FiN_2O, EtN_2O) Inhaled and exhaled O_2 (FiO_2, EtO_2) Inhaled and exhaled anesthetic agent (FiAA, EtAA, where AA refers to any of the following anesthetic agents.) HAL (Halothane) ISO (Isoflurane) ENF (Enflurane)

SEV (Sevoflurane)

DES (desflurane)

Airway Respiration Rate (rpm: Respiration Per Minute): AwRR

Minimum Alveolar Concentration (MAC)

4 AG waveforms (CO_2, N_2O, O_2, AA)

The PM-7000 provides the functions of audio/visual alarm, trend graphic storage and output, NIBP measurement, alarm event identification, large font screen, defibrillator synchronization, oxyCRG recall, drug calculation, etc.

1.3 Environment

1.3.1 Temperature

Work mode	0 ~40℃
MINDRAY CO_2 module	+5 ~ +35℃
Welch Allyn mainstream CO_2 module	+10 ~ +35℃
Microstream CO_2 module	+5 ~ +35℃
Artema AION AG module	+10 ~ +35℃
Transportation & Storage	-20 ~ 60℃

1.3.2 Humidity

Work mode	15% – 95 % (non-condensing)
Transportation & Storage	10% – 95 % (non-condensing)
Atmospheric pressure	70.0kPa – 106.0kPa

1.3.3 Electrical specification

AC power supply: 100 to 240 V AC, 50/60 Hz, Maximum input power: 140VA
DC power supply: 12 V (nominal), 10 to 16 V, Power: 80W

2.3 Ah 12V lead-acid rechargeable battery
Working time of fully-charged batteries in normal status: 75 minutes (1 battery).
From the first low-battery alarm, the batteries can supply power to the patient monitor for 5 ~ 15 minutes.
Maximum charging time: about 8h

4.4Ah 11.1V lithium battery
Working time of fully-charged batteries in normal status: 150 minutes (1 battery).
From the first low-battery alarm, the batteries can supply power to the patient monitor for 5 ~ 15 minutes.
Maximum charging time: about 8h

Chapter 2 Principles

2.1 General

The intended use of the PM-7000 is to monitor a fixed set of parameters including ECG, RESP, SpO_2, NIBP, TEMP, IBP, CO and CO_2 (IBP, CO and CO_2 are optional). It consists of the following functional parts:

Parameter measurement;
Main control part;
Man-machine interface;
Power supply;
Other auxiliary functions;
These functional units are respectively detailed below.

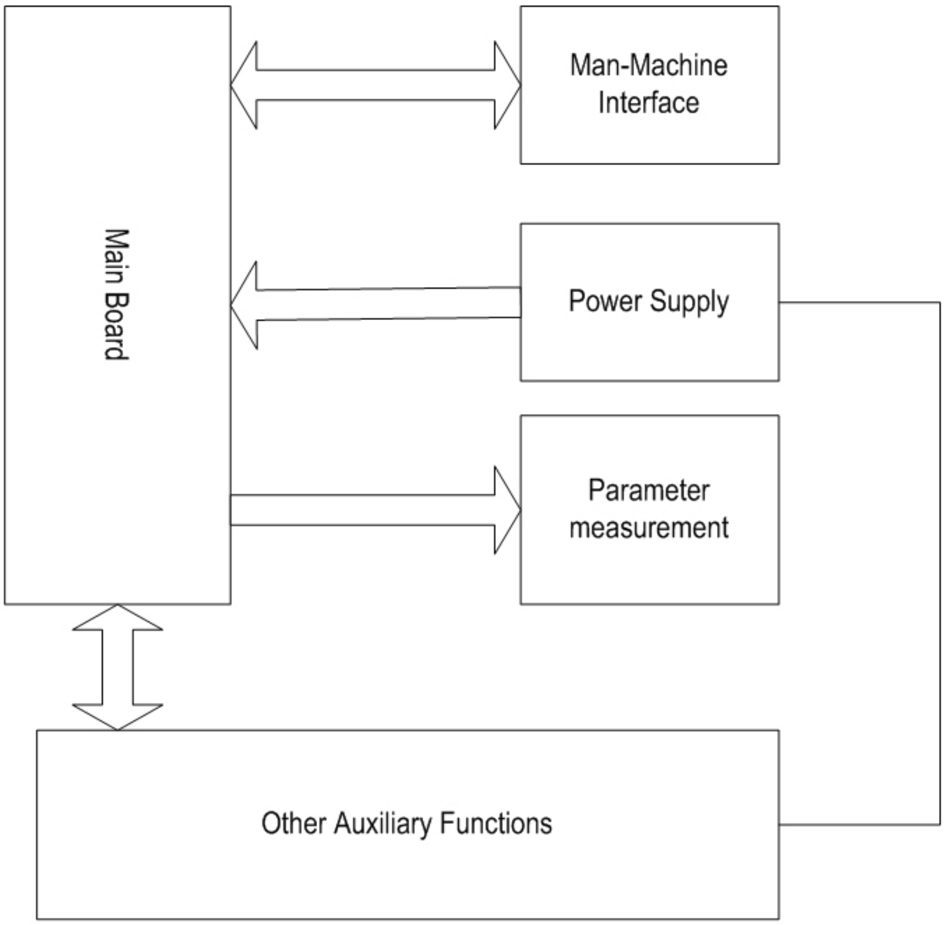


Figure 2-1 Structure of the PM-7000

2.1.1 Parameter Measurement

The parameter measurement and monitoring are the core functions of the patient monitor. The parameter measurement part of the PM-7000 consists of the measurement probe, parameter input socket assembly, NIBP assembly and the main control board.

This part converts the physiological signals to electric signals, processes the those signals and conducts the calculation by the preset program or command delivered from the main control board, and then sends the values, waveforms and alarm information (which will be displayed by using the man-machine interface) to the main control board.

2.1.2 Main Control Part

In the PM-7000, the main control part refers to the main control part of the main control board. It drives the man-machine interface, manages the parameter measurement and provides users with other special functions, such as storage, recall of waveforms and data. (See Figure 2-1)

2.1.3 Man-Machine Interface

The man-machine interface of the PM-7000 includes the TFT display, recorder, speaker, indicator, buttons and control knob.

The TFT display is the main output interface. It, with the high resolution, provides users with abundant real-time and history data and waveforms as well as various information and alarm information.

The recorder is a subsidiary of the display, which is used for the user to print data.

The speaker provides the auditory alarm function.

The indicator provides additional information about the power supply, batteries, alarms and so on.

The buttons and control knob are the input interface, which are used for the user to input the information and commands to the patient monitor.

2.1.4 Power Supply

The power supply part is an important part of the patient monitor. It includes the main power PCB, backlight board, batteries and fan.

The main power PCB converts the external AC current respectively to the 5V DC and 12V DC current, which are supplied for the whole system. For the TFT display, there is a special requirement on the power supply, so a backlight board is used. The batteries supply power for the system for a short time when there is no external AC current. The fan is used for the heat sink of the system.

2.1.5 Other Auxiliary Functions

The PM-7000 also provides the network upgrade function for the service engineers to upgrade the system software without disassembling the enclosure.

2.2 Hardware Description

The structure of the PM-7000 is shown in the following figure.

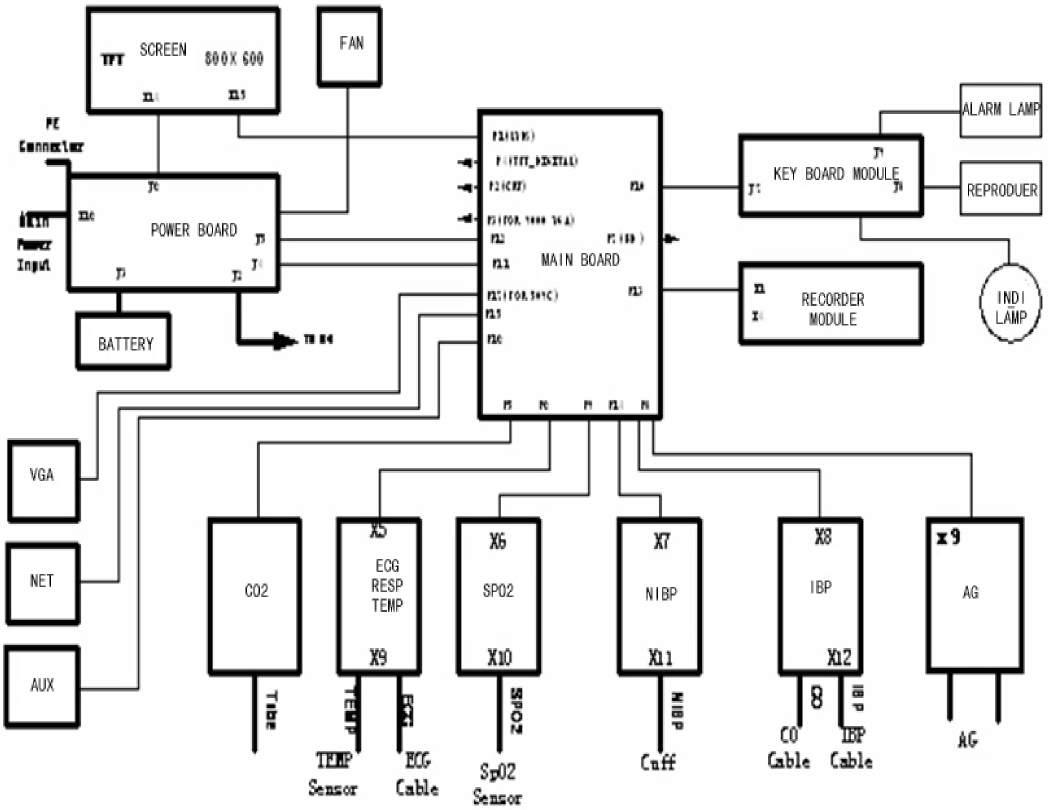


Figure 2-2 Functional structure of the PM-7000

The PM-7000 PCB connection is shown in the following figure.

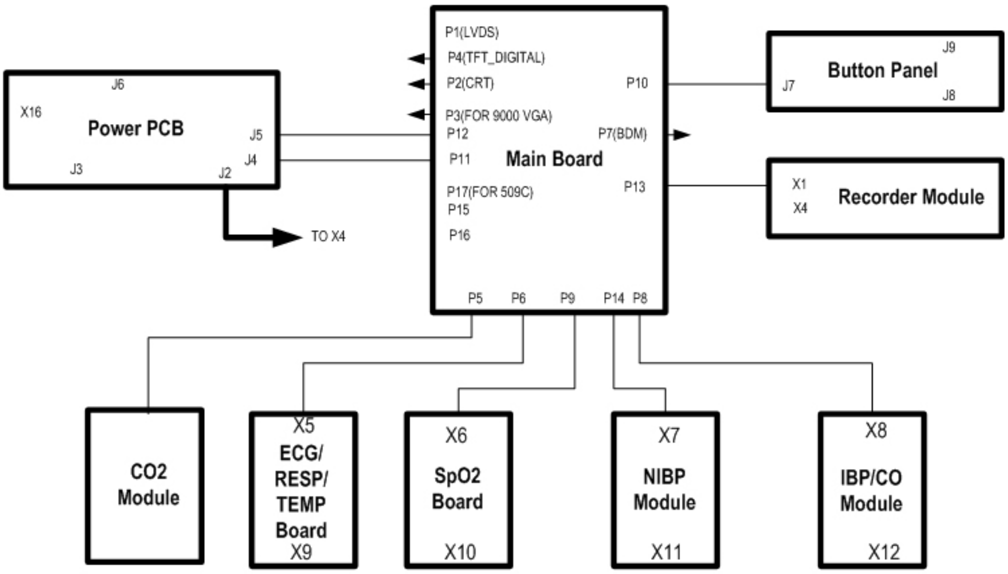


Figure 2-3 PCB connection

Basic functions and working principles of modules are described in the following sections.

2.2.1 Main Board

2.2.1.1 General

The main board is the heart of the patient monitor. It implements a series of tasks, including the system control, system scheduling, system management, data processing, file management, display processing, printing management, data storage, system diagnosis and alarm.

2.2.1.2 Principle diagram

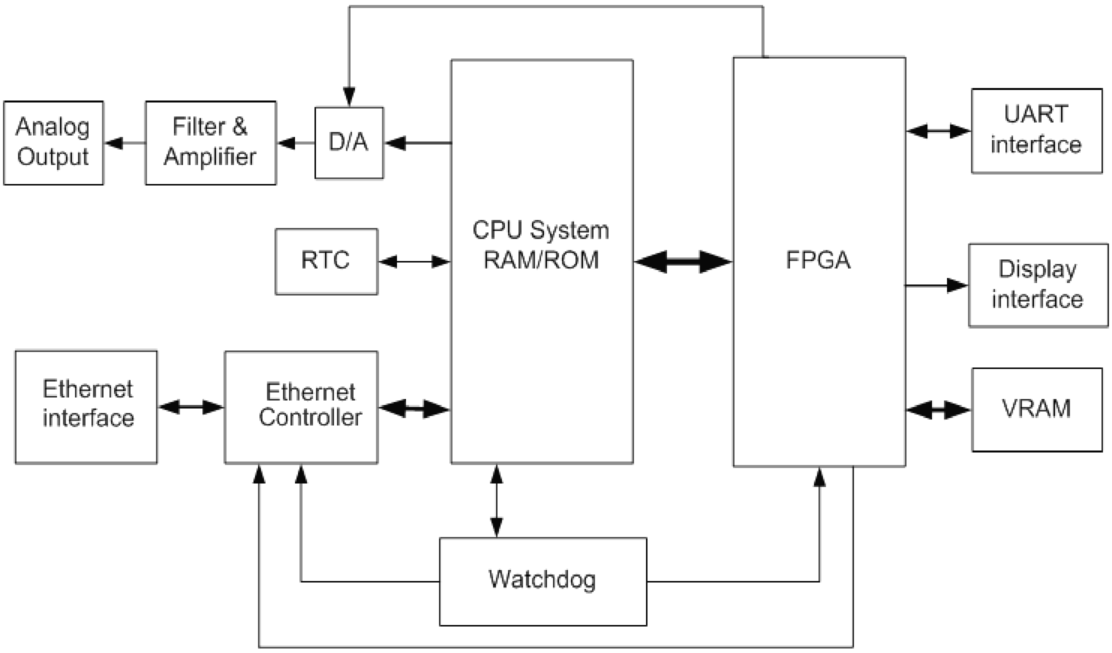


Figure 2-4 Working principle of the main board

2.2.1.3 Principle

The main board is connected with external ports, including the power input port, multi-way serial port, TFT display interface, analog VGA interface, network port and analog output port. Besides, on the main board is also a BDM interface reserved for the software debugging and software downloading.

CPU System

CPU is the core part of the main board. It, connected with other peripheral modules through the bus and I/O cable, implements the data communication, data processing, logical control and other functions.

RTC

RTC provides the calendar information (such as second, minute, hour, day, month and year). CPU can read and modify the calendar information from RTC.

Ethernet Controller

Ethernet Controller supports the IEEE802.3/IEEE802.3u LAN standard, and supports two data transmission rate: 10Mbps and 100Mbps. CPU exchanges data with the Ethernet through the Ethernet Controller.

Analog Output

The D/A converter converts the digital ECG/IBP signals sent from CPU to the analog signals, which are provided for the external after low-pass filtered by the filter and amplified by the amplifier.

FPGA and VRAM

VRAM stores the displayed data. CPU stores the displayed data to VRAM through FPGA. FPGA gets data from VRAM, processes them, and then sends them to the relevant graphic display device.

In addition, FPGA also extends multiple serial ports, which communicate with peripheral modules. FPGA transfers the received data to CPU through the bus; CPU delivers data to FPGA through the bus, and then the FPGA transfers those data to the peripheral modules.

Watchdog

When powered on, watchdog provides reset signals for CPU, FPGA and Ethernet Controller.

The patient monitor provides the watchdog timer output and voltage detection functions.

2.2.2 ECG/RESP/TEMP Module

2.2.2.1 General

This module provides the function of measuring three parameters: electrocardiograph (ECG), respiration (RESP) and temperature (TEMP).

2.2.2.2 Principle diagram

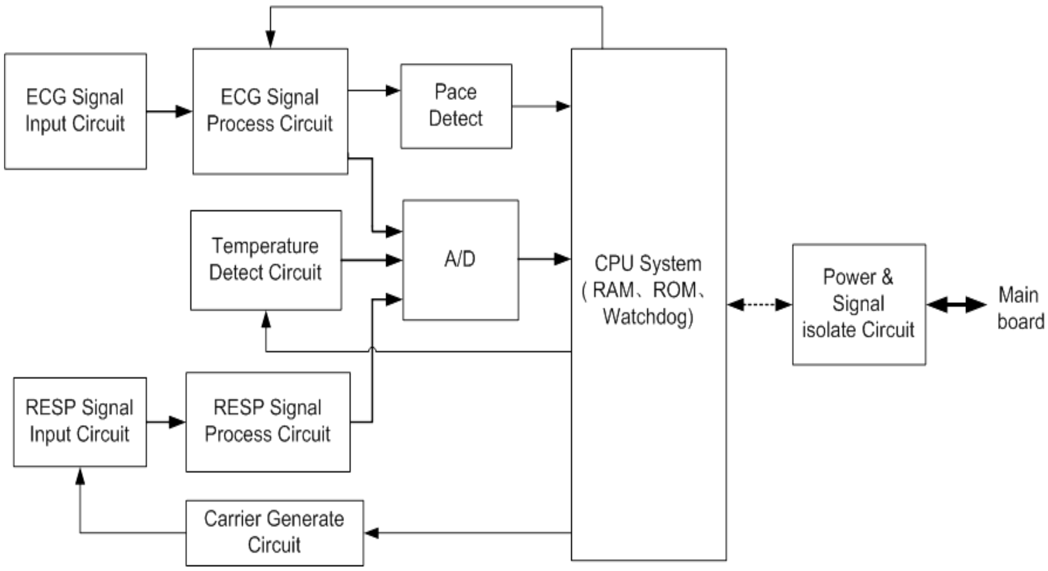


Figure 2-5 Working principle of the ECG/RESP/TEMP module

2.2.2.3 Principle

This module collects the ECG, RESP and TEMP signals through the transducer, processes the signals, and sends the data to the main board through the serial port.

ECG Signal Input Circuit

The input protection and filtering circuits receive the ECG signal from the transducer, and filter the high-frequency interference signal to protect the circuit against the damage by defibrillator high-voltage and ESD.

The right-leg drive circuit gets the 50/60Hz power common-mode signal from the lead cable, and sends the negative feedback signal to the human body to reject the common-mode interference signal on the lead cable, which helps the detection of the ECG signal.

The lead-off detecting circuit checks whether the ECG lead is off, and sends the information to CPU.

ECG Signal Process Circuit

The difference amplifying circuit conducts the primary amplification of the ECG signal and rejects the common-mode interference signal.

The low-pas filtering circuit filters the high-frequency interference signal beyond the frequency band of the ECG signal.

The PACE signal refers to the ECG pace signal. It has significant interference to the ECG signal detection. The PACE rejection circuit can rejects the PACE signal, which helps the ECG signal detection.

The main amplifying/filtering circuit conducts the secondary amplification of the ECG signal, filters the signal, and then sends the ECG signal to the A/D conversion part.

Pace Detect

This part detects the PACE signal from the ECG signal and sends it to CPU.

Temperature Detect Circuit

This circuit receives the signal from the temperature transducer, amplifies and filters it, and then sends it to the A/D conversion part.

Carrier Generate Circuit

The RESP measurement is based on the impedance method. While a man is breathing, the action of the breast leads to changes of the thoracic impedance, which modulates the amplitude of the high-frequency carrier signal. Finally, the modulated signal is sent to the measurement circuit. The purpose of this module is generating the high-frequency carrier.

RESP Signal Input Circuit

This circuit couples the RESP signal to the detecting circuit.

RESP Signal Process Circuit

The pre-amplifying circuit conducts the primary amplification of the RESP signal and filters it.

The detecting circuit detects the RESP wave that has been modulated on the actuating signal.

The level shifting circuit removes the DC component from the RESP signal.

The main amplifying/filtering circuit conducts the secondary amplification of the RESP signal, filters the signal, and then sends it to the A/D conversion part.

A/D

The A/D conversion part converts the analog signal to the digital signal, and sends the signal to CPU for further processing.

CPU System

- Implementing the logical control of all parameter parts and A/D conversion parts;
- Implementing the data processing for all parameters;
- Implementing the communication with the main board.

Power & Signal isolate Circuit

- Isolating the external circuits to ensure the safety of human body;
- Supplying power for all circuits;
- Implementing the isolation communication between the CPU System and the main board.

2.2.3 CO/IBP Module

2.2.3.1 General

This module provides the function of measuring two parameters: Cardiac Output (CO) and Invasive Blood Pressure (IBP).

2.2.3.2 Principle diagram

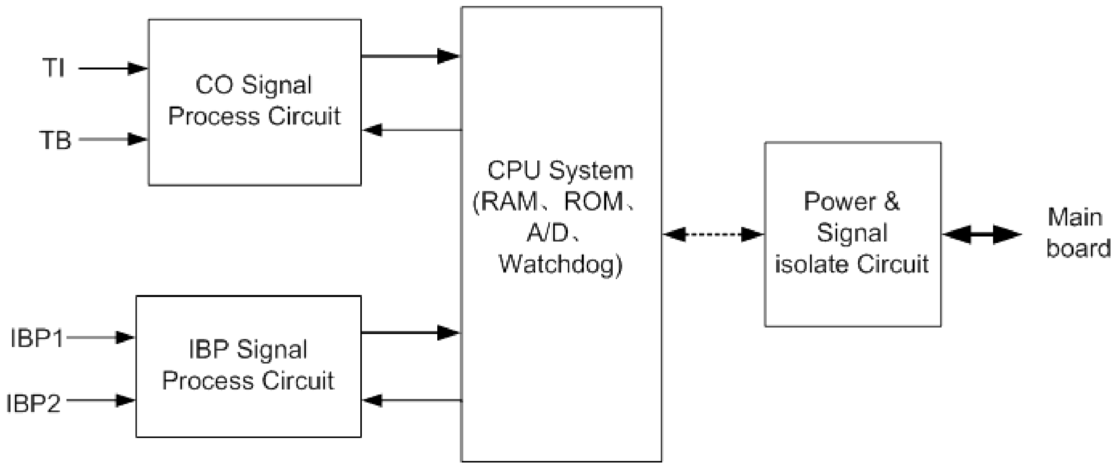


Figure 2-6 Working principle of the CO/IBP module

2.2.3.3 Principle

This module collects the CO/IBP signal through the transducers, processes it and sends it to the main board throgh the serial port.

CO Signal Process Network

The CO parameter is measured with the thermal dilution method. The transducer sends two signals (TI: Temperature of Injectate; TB: Temperature of Blood) to the CO Signal Process Network. After that, the signals are amplified and low-pass filtered, and then sent to the CPU System for processing.

IBP Signal Process Network

The IBP signal is the differential signal. After the common-mode filtering, the difference signal is amplified by the difference amplifying circuit which changes the dual-end signal to the single-end signal. After the low-pass filtering, the IBP signal is sent to the CPU System for processing.

CPU System

- Converting the analog signal obtained by the circuit to the digital signal;
- Implementing the logical control of all parameter parts;
- Implementing the data processing for the two parameters;
- Implementing the communication with the main board.

Power & Signal isolate Circuit

- Isolating the external circuits to ensure the safety of human body;
- Supplying power for all circuits;
- Implementing the isolation communication between the CPU System and the main board.

2.2.4 SpO_2 Module

2.2.4.1 General

This module provides the function of measuring the Pulse Oxygen Saturation (SPO_2).

2.2.4.2 Principle diagram

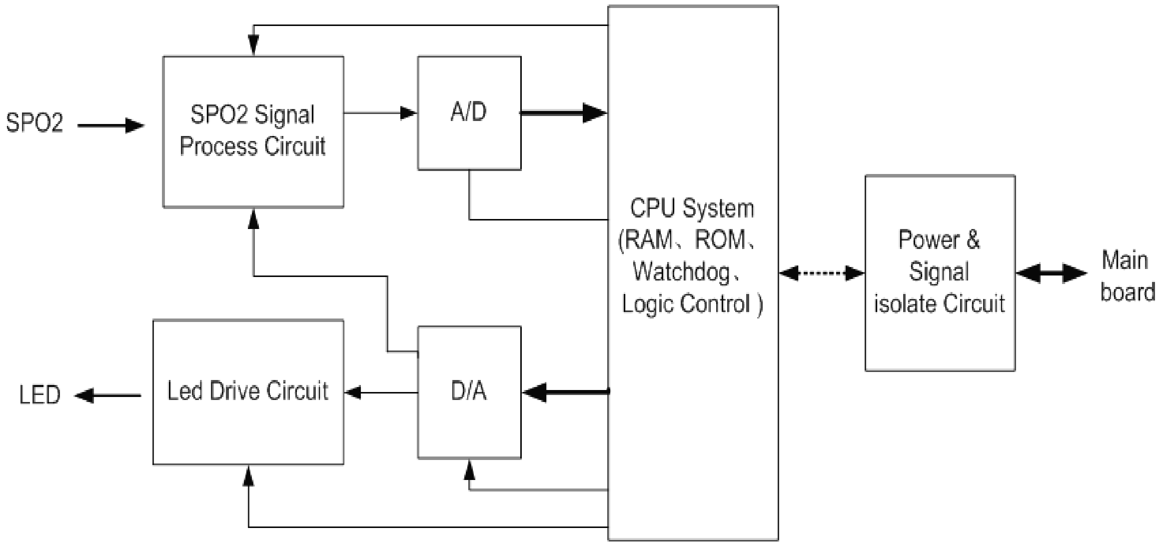


Figure2-7 Working principle of the SpO_2 module

2.2.4.3 Principle

The SpO_2 measurement principle

1. Collecting the light signal of the red light and infrared transmitting through the finger or toe which is pulsing;
2. Processing the collected signal to get the measured result.

The drive circuit of the LED and the gain of the amplifying circuit should be controlled according to the different perfusions and transmittances of the tested object.

Led Drive Circuit

This circuit supplies the LED with the drive current, which can be regulated.

SPO2 Signal Process Network

The pre-amplifying circuit converts the photoelectric signal to the voltage signal and conducts the primary amplification.

The gain adjusting and amplifying circuit conducts the secondary signal amplification and adjusts the gain.

The biasing circuit adjusts the dynamic range of the signal, and sends it to the A/D conversion part.

A/D

The A/D conversion part converts the analog signal to the digital signal, and then sends it to CPU for further processing.

D/A

The D/A conversion part converts the digital signal received from CPU to the analog signal, and provides the control signal for the Led Drive Circuit and SPO2 Signal Process Network.

CPU System

- Implementing the logical control of all the circuits;
- Implementing the data processing for the SpO_2 parameter;
- Implementing the communication with the main board.

Power & Signal isolate Circuit

- Isolating the external circuits to ensure the safety of human body;
- Supplying power for all circuits;
- Implementing the isolation communication between the CPU System and the main board.

2.2.5 NIBP Module

2.2.5.1 General

This module provides the function of measuring the Non-Invasive Blood Pressure (NIBP) parameter.

2.2.5.2 Principle diagram

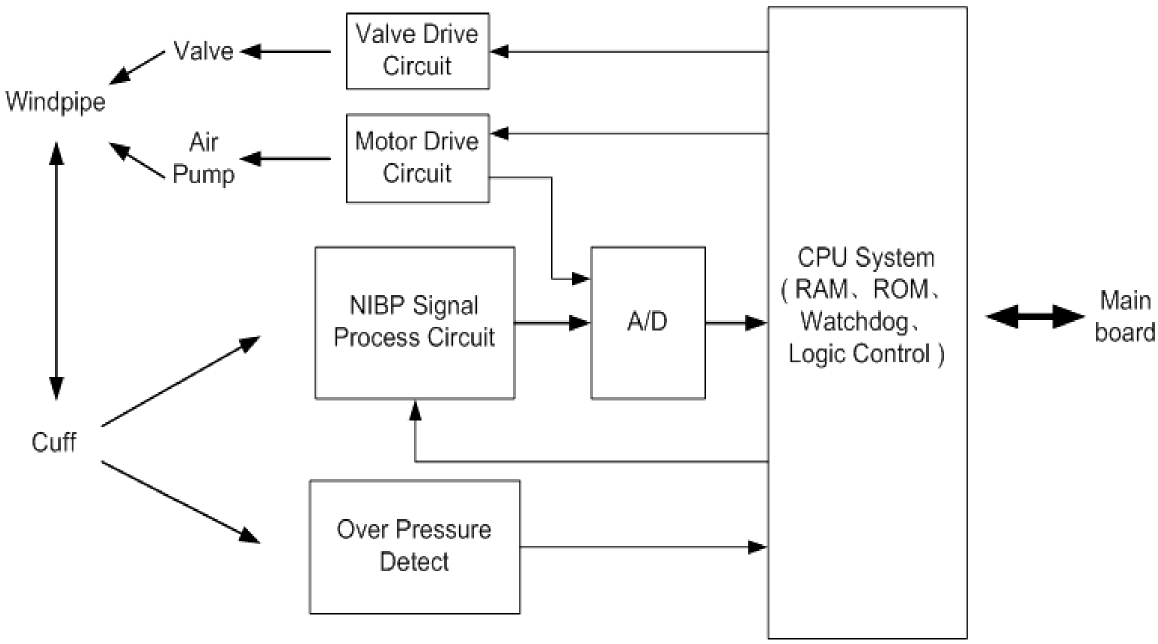


Figure 2-8 Working principle of the NIBP module

2.2.5.3 Principle

The NIBP is measured based on the pulse vibration principle. Inflate the cuff which is on the forearm till the cuff pressure blocks the arterial blood, and then deflate the cuff according to a specified algorithm. While the cuff pressure is decreasing, the arterial blood has pulses, which are sensed by the pressure transducer in the cuff. Consequently, the pressure transducer, connected with the windpipe of the cuff, generates a pulsation signal, which is then processed by the NIBP module to get the NIBP value.

Valve Drive Circuit

This circuit controls the status (ON/OFF) of valves. It, together with the Motor Drive Circuit, implements the inflation and deflation of the cuff.

Motor Drive Circuit

This circuit controls the action of the air pump. It, together with the Valve Drive Circuit, implements the inflation and deflation of the cuff. Besides, it provides the status signal of the motor for the A/D conversion part.

NIBP Signal Process Network

The NIBP signal is the differential input signal. The difference amplifying circuit amplifies the dual-end difference signal and converts it to the single-end signal; meanwhile, this circuit sends a channel of signal to the A/D conversion part, and the other to the DC isolating and amplifying circuit.

The DC isolating and amplifying circuit removes DC components from the signal, amplifies the signal, and then sends it to the A/D conversion part.

A/D

The A/D conversion part converts the analog signal to the digital signal, and sends it to the CPU System for further processing.

Over Pressure Detect

The circuit detects the NIBP pressure signal. Once the pressure value exceeds the protected pressure value, it will send a message to the CPU System, which asks the Valve Drive Circuit to open the valve to deflate the cuff.

CPU System

- Implementing the logical control of all the circuits;
- Implementing the data processing for the NIBP parameter;
- Implementing the communication with the main board.

2.2.6 Recorder Module

2.2.6.1 General

This module is used to drive the heat-sensitive printer.

2.2.6.2 Principle diagram

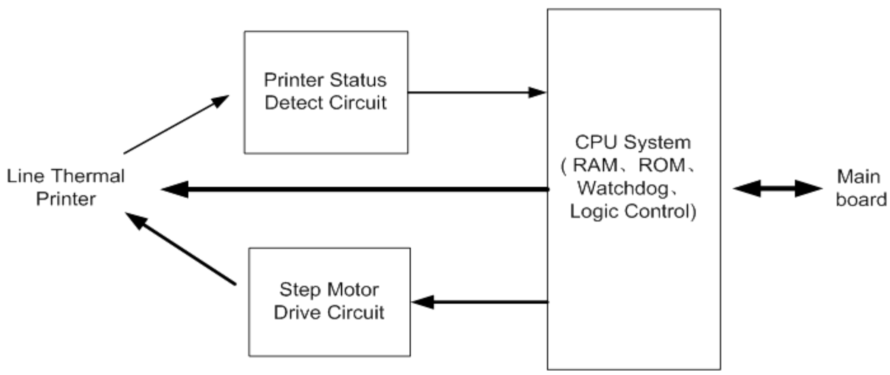


Figure 2-9 Working principle of the recorder module

2.2.6.3 Principle

This module receives the to-be-printed data from the main board, converts them to the dot matrix data, sends them to the heat-sensitive printer, and drives the printer.

Step Motor Drive Circuit

There is a step motor on the heat-sensitive printer. The step motor drives the paper. This circuit is used to drive the step motor.

Printer Status Detect Circuit

This circuit detects the status of the heat-sensitive printer, and sends the status information to the CPU system. The status information includes the position of the paper roller, status of the heat-sensitive recorder paper and the temperature of the heat-sensitive head.

CPU System

- Processing the data to be printed;
- Controlling the heat-sensitive printer and step motor;
- Collecting data about the status of the heat-sensitive printer, and controlling the printer;
- Implementing the communication with the main board.

2.2.7 Button Panel

2.2.7.1 General

This module provides a man-machine interactive interface.

2.2.7.2 Principle diagram

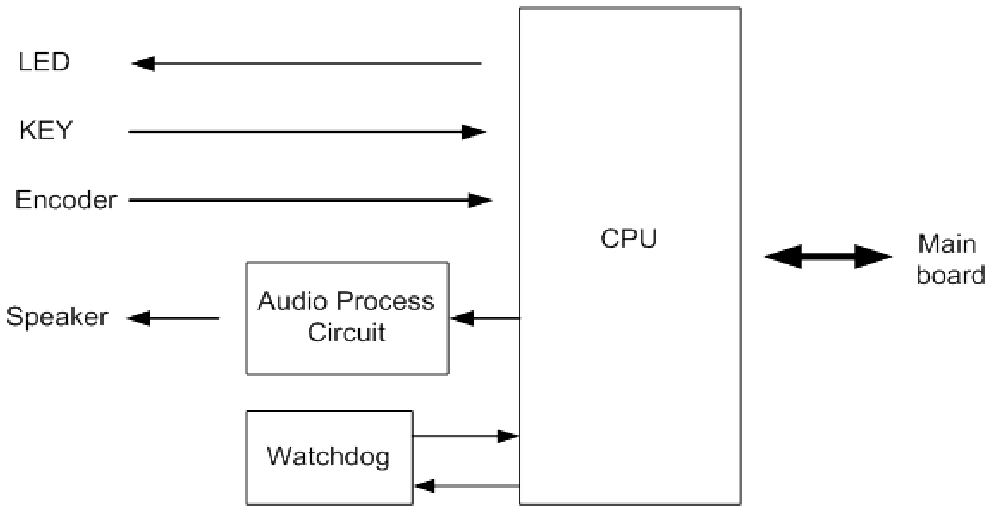


Figure 2-10 Working principle of the button panel

2.2.7.3 Principle

This module detects the input signals of the button panel and control knob, converts the detected input signals to codes and then sends to the main board. The main board sends commands to the button panel, which, according to the commands, controls the status of the LED and the audio process circuit to give auditory/visual alarms.

CPU

- Detecting the input signal of the button panel and control knob;
- Controlling the status of LED;
- Controlling the audio process circuit;
- Regularly resetting the Watchdog timer;
- Communicating with the main board.

Audio Process Circuit

This circuit generates audio signals and drives the speaker.

Watchdog

When powered on, the Watchdog provides the reset signal for CPU.

The patient monitor provides the watchdog timer output and voltage detection functions.

2.2.8 Power PCB

2.2.8.1 General

This module provides DC working current for other boards.

2.2.8.2 Principle diagram

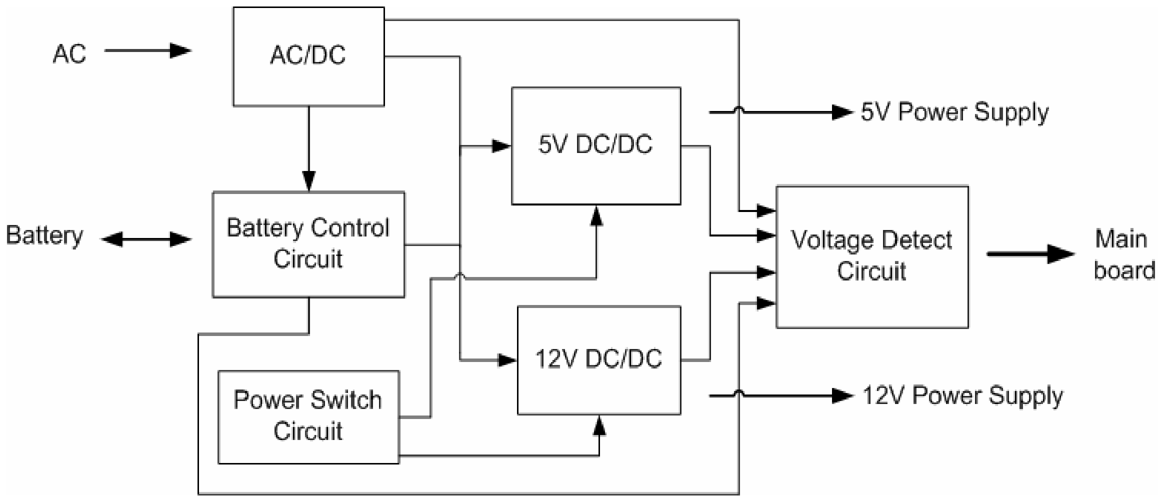


Figure 2-11 Working principle of the power PCB

2.2.8.3 Principle

This module can convert 220V AC or the battery voltage to 5V DC and 12V DC voltages, which are supplied for other boards. When the AC voltage and batteries coexist, the AC voltage is supplied for the system and used to charge the batteries.

AC/DC

This part converts the AC voltage to the low DC voltage for the subsequent circuits; besides, it supplies the power for charging the batteries.

Battery Control Circuit

When the AC voltage and batteries coexist, this circuit controls the process of charging the batteries with the DC voltage converted by the AC/DC part. When the AC voltage is unavailable, this circuit controls the batteries to supply power for the subsequent circuits.

5V DC/DC

This part converts the DC voltage to the stable 5V DC voltage and supplies it for the external boards.

12V DC/DC

This part converts the DC voltage to the stable 12V DC voltage and supplies it for the external boards.

Power Switch Circuit

This circuit controls the status of the 5V DC/DC part and the 12V DC/DC part, thus to control the switch of the patient monitor.

Voltage Detect Circuit

This circuit detects the output voltages of the circuits, converts the analog signal to the digital signal, and sends the digital signal to the main board for processing.

2.3 Software Description

2.3.1 General

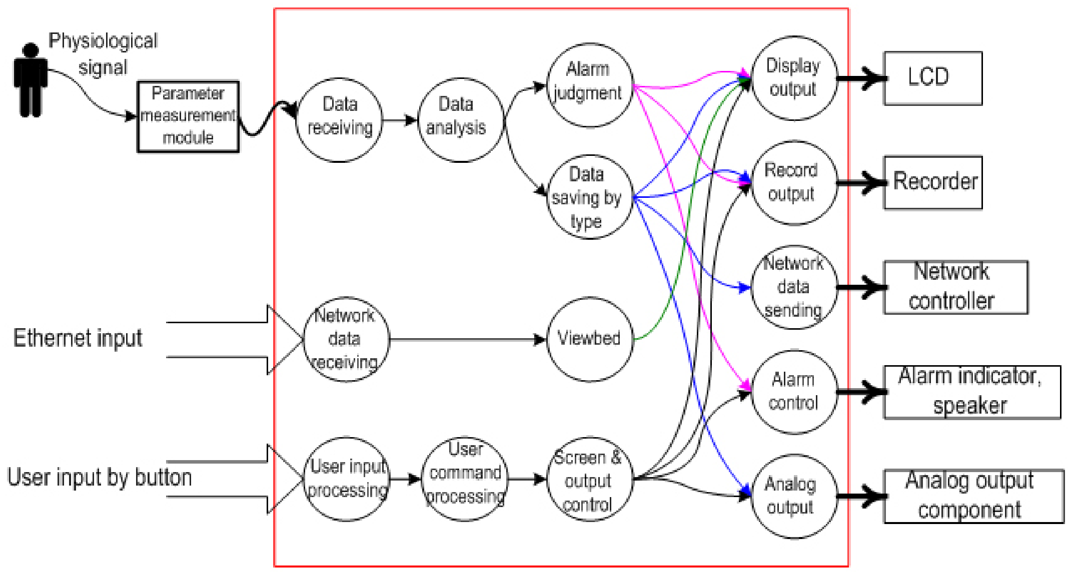


Figure 2-12 System function

As shown in Figure 2-12, in the red frame is the software system, on the left to the red frame are the inputs of the software system, and on the right to the red frame are the outputs. The parameter measurement module exchanges data with the software through the serial port, while the user interacts with the system through the button panel. Among the output devices, the recorder and alarm device receive data through the serial ports, the analog output component is an MBUS component, and the LCD and network controller are controlled directly by CPU.

2.3.2 System Task

NO	Task	Function	Period
1	System initialization	Initializing the system	In case of a startup
2	Data processing	Analyzing and saving the data	1 second
3	Display of timer information	Implementing the timed refreshing	1 second
5	Switchover of modules and screens	Switching over between waveforms and parameters on the screen	In case of a screen change event
6	Processing of user commands and screens	Processing the user inputs by buttons and displaying them on the screen.	In case of a button event
7	System monitoring	System monitoring, voltage monitoring and battery management	1 second
8	Network connection	Implementing the network connection	1 second
9	Network data sending	Sending the network data	1 second
10	Network data receiving	Receiving the network data (viewbed)	1 second
11	ECG analysis	Analyzing ECG signal, calculating ECG values (HR, ARR and ST), and saving the analysis results.	1 second
12	Record output	Outputting records	In case of a record event
13	NIBP processing	Implementing NIBP-related processing	1 second
14	WATCHDOG task	Managing the system watchdog	1 second

2.3.3 System Function

The system tasks can be classified as follows.

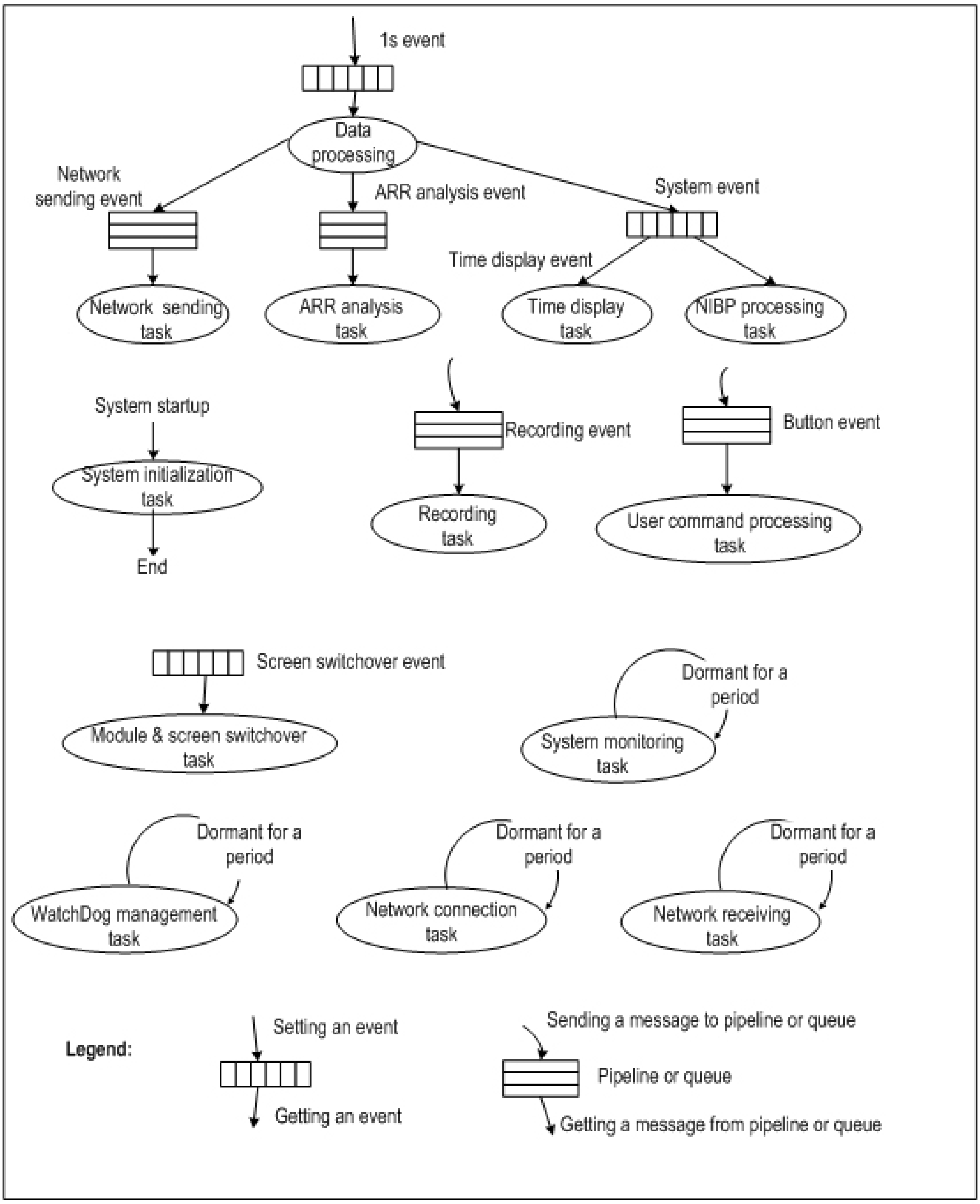
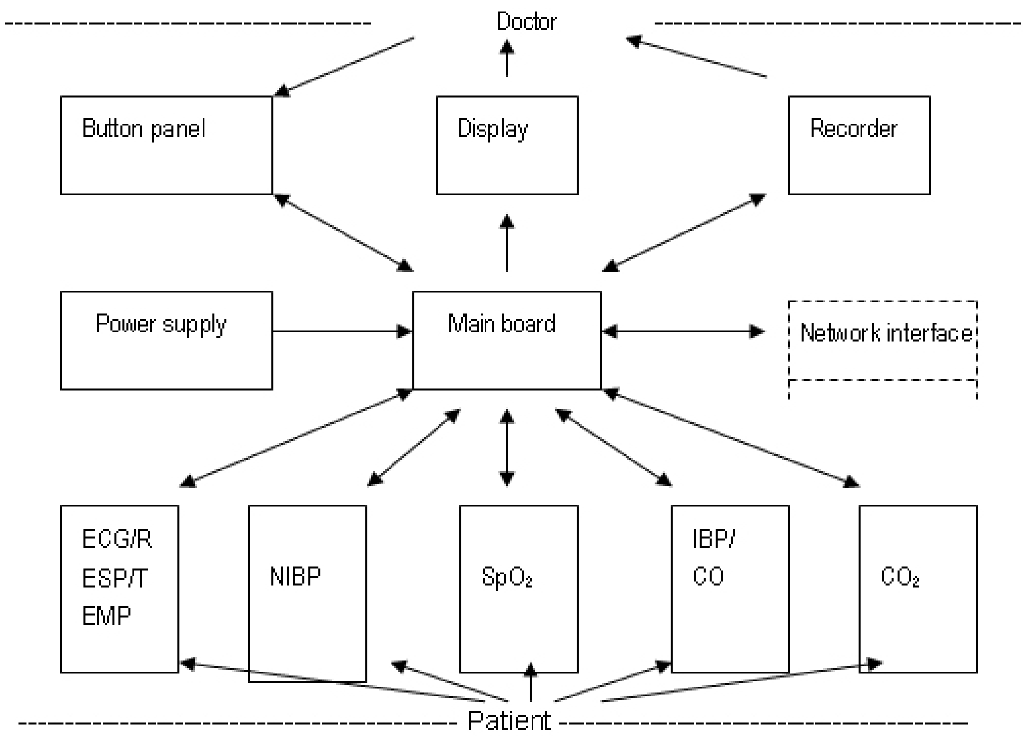


Figure 2-13 System task

2.4 System Parameter

2.4.1 General

For the PM-7000, signals are collected by modules, and the results are transferred to the main board through the adapter board, thus to process and display the data and waveforms. Commands from the main board, as well as the status information of modules, are transferred through the adapter board. In addition, the adapter board adapts and changes the power supply. The structure of the whole system is shown in the following figure.



As shown in Figure 2-14, the five modules and measurement cables monitor and measure NIBP, SpO_2, ECG/RESP/TEMP, IBP/CO and CO_2 in real time, and send the results to the main board for processing and displaying. If necessary, the results are sent to the recorder for printing.

The parameter monitoring functions are described respectively in the following sections.

2.4.2 ECG/RESP

■ ECG

The PM-7000 has the following ECG functions:

1) Lead type: 3-lead, 5-lead, 12-lead

2) Lead way:

3-lead (1 channel):	I, II, III
5-lead (2 channels):	I, II, III, aVR, aVL, aVF, V

12-lead (8 channels):	I, II, III, avR, avL, avF, V1-V6

3) Floating input
4) Right-foot drive
5) Lead-off detection
6) 2-channel ECG waveform amplification; processing ECG signals of any two leads

■ The ECG circuit processes the ECG signals. It consists of the following parts:

1) Input circuit: The input circuit protects the ECG input level, and filters the ECG signals and external interference. The ECG electrode is connected to the input circuit through the cable.

2) Buffer amplifying circuit: This circuit ensures extremely high input impedance and low output resistance for ECG.

3) Right-foot drive circuit: The output midpoint of the buffer amplifying circuit is fed to the RL end of the 5-lead after the inverse amplification, so as to ensure that the human body is in the equipotential state, decrease the interference, and increase the common-mode rejection ratio of the circuit.

4) Lead-off detection: The lead-off causes changes in the output level of the buffer amplifying circuit. Therefore, the lead-off can be detected with a comparator, and the state of lead-off can be converted TTL level for the Micro Controller Unit (MCU) to detect it.

5) Lead circuit: Under the control of MCU, the lead electrodes should be connected to the main amplification circuit.

6) Main amplification circuit: The measurement amplifier is composed of 3 standard operation amplifiers.

7) Subsequent processing circuit: This circuit couples the ECG signals, remotely controls the gains, filters the waves, shifts the level, amplifies the signal to the specified amplitude, and sends the signal to the A/D converter.

■ RESP

The PM-7000 measures the RESP based on the impedance principle. While a man is breathing, the action of the breast leads to impedance changes between RL and LL. Change the high-frequency signal passing the RL and LL to amplitude-modulation high-frequency signal (AM high-frequency signal), which is converted to the electric signal after being detected and amplified and then sent to the A/D converter. The RESP module consists of the RESP circuit board and coupling transformer. The circuit has several functions: vibration, coupling, wave-detection, primary amplification and high-gain amplification.

2.4.3 NIBP

The NIBP is measured based on the pulse vibration principle. Inflate the cuff which is on the forearm till the cuff pressure blocks the arterial blood, and then deflate the cuff according to a specified algorithm. While the cuff pressure is decreasing, the arterial blood has pulses, which are sensed by the pressure transducer in the cuff. Consequently, the pressure transducer, connected with the windpipe of the cuff, generates a pulsation signal. Then, the pulsation signal is filtered by a high-pass filter (about 1Hz), amplified, converted to the digital signal by the A/D converter, and finally processed by the MCU. After that, the systolic pressure, diastolic pressure and mean pressure can be obtained. For neonates, pediatric and adults, it is necessary to select the cuffs of a proper size to avoid possible measurement errors. In the NIBP measurement, there is a protection circuit used to protect patient from over-high pressure.

The NIBP measurement modes include:

1) Adult/pediatric/neonate mode: To be selected according to the build, weight and age of the patient;

2) Manual/Auto/Continuous mode: The manual measurement is also called single measurement; in this mode, only one measurement is done after being started. In the auto measurement mode, the measurement can be done once within the selected period, with the interval being 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240 or 480 minutes. In the continuous measurement mode, quick continuous measurement will be done within 5 minutes after being started; it detects the changes in blood pressure effectively.

2.4.4 SpO_2

The SpO_2 value is obtained through the pulse waves of the finger tips based on specific algorithm and clinical data. The SpO_2 probe is the measurement transducer. It has two inbuilt LEDs and an inbuilt light receiver. The two LEDs include one red-light diode and one infrared diode, which emit light in turns. When the capillaries in the finger tip are iteratively congested with blood pumped by the heart, the light emitted by the LEDs, after absorbed by the capillaries and tissue, casts on the light receiver, which can sense, in the form of electric signal, the light strength changing with the pulsated blood. The DC/AC ratio of the two photoelectric signals corresponds to the content of the oxygen in the blood. Therefore, the correct pulse oxygen saturation can be obtained with specific algorithm. Moreover, the pulse rate can be obtained according to the pulse waveform.

The circuit of the SpO_2 module is involved in four parts: SpO_2 probe, signal processing unit, LED-driven sequencing control part and the MCU.

2.4.5 TEMP

Temperature measurement principle:

1. The transducer converts the body temperature to the electric signal;
2. The amplifier amplifies the electric signal;
3. The CPU processes the data.

The circuit is a proportional amplifier consisting of operation amplifiers. When the temperature reaches the heat-sensitive probe, the heat-sensitive probe generates the voltage signal, which is sent to the A/D converter after being amplified. The probe detecting circuit is a voltage comparator consisting of operation amplifiers. When the probe is disconnected, the voltage input is lower than the comparing voltage, so the voltage comparator outputs the low level; when the probe is connected, the voltage input is higher than the comparing voltage, so the voltage comparator outputs the high level.

2.4.6 IBP

The IBP module can monitor the arterial pressure, central venous pressure and pulmonary arterial pressure.

Measurement principle: Introduce a catheter, of which the external end is connected to the pressure transducer, into the blood vessel under test, inject the physiological saline. Since the liquid can be transferred by pressure, the pressure inside the blood pressure is transferred by liquid to the pressure transducer, and the dynamic waveform of the pressure inside the blood pressure is obtained in real time. Thus, the arterial pressure, central venous pressure and pulmonary arterial pressure are obtained based on specific algorithm.

2.4.7 CO

CO measurement principle: The thermal dilution method is widely used in the clinical CO monitoring. Introduce a floating catheter into the pulmonary artery through the right atrium, and inject the physiological saline into the right atrium through the catheter whose front end is connected to the temperature transducer. When the cold liquid mixes with the blood, there will be a change of temperature. Thus, when the blood mixed with the physiological saline flows into the pulmonary artery, its temperature will be sensed by the temperature transducer. According to the injection time and temperature change, the patient monitor can analyze the CO, and calculate the Cardiac Index (CI), Stroke Volume Index (SVI), SVIs of the left atrium and right atrium, Pulmonary Vascular Resistance (PVR) and so on.

2.4.8 CO_2

The CO_2 module works based on the infrared spectrum absorption principle. According to different connection methods, the infrared light transducer is classified as the mainstream infrared light transducer and sidestream infrared light transducer. The sidestream CO_2 module is composed of the circuit board, inbuilt sidestream infrared light transducer, deflation pump and control. When used, this module requires the external water trap, drying pipe and sampling tube. The mainstream CO_2 module is composed of the circuit board and external mainstream infrared light transducer. The infrared light transducer needs to be preheated. In the sidestream mode, the deflation rate can be set to 100ml/min, 150ml/min or 200ml/min according to the patient situation. In the AG monitoring, multiple compensations can be set, such as hydrosphere, oxygen, temperature and desflurane (Des). When the CO_2 measurement is not being conducted, the sidestream deflation pump, the transducer of the mainstream module, and the infrared source are expected to be shut down, thus to extend the service life and reduce the power consumption of the module. In the mainstream mode, the infrared light transducer takes a longer time to be preheated, and there is no windpipe which is available in the sidestream mode.

2.4.9 AG

The Anesthesia Gas (AG) can be used to measure the AG and respiration gas of the anesthetized patient. The AG concentration is measured based on the principle that the AG has the property of absorbing the infrared. All gases that the AG module can measure have the property of absorbing the infrared, and every gas has their own specific absorption peculiarity.

AG measurement procedure:

1. Send the gas to be measured to a sampling chamber;
2. Use an optical infrared filter, select a specific band of infrared, and transmit it through the gas;
3. Measure the infrared that gets through the gas to obtain the gas concentration.

For a given volume, the higher the gas concentration is, the more absorbed infrared is, and the less the infrared that gets through the gas is. For the measurement of multiple gases, multiple infrared filters are required in the AG module.

The oxygen does not absorb the infrared within the above-mentioned wave band. Therefore, the oxygen is measured based on its paramagnetism. Inside the transducer of the O_2 module, there are two crystal balls full of nitrogen. They are suspended in the symmetrical magnetic field, and designed to point to the strongest outgoing part of the magnetic field. Outside the balls is the paramagnetic oxygen. Therefore, the balls are forced, by the relatively stronger paramagnetic oxygen, out of the magnetic field. The moment of the force acting on the balls is proportional to the paramagnetic strength as well as to the concentration of the paramagnetic oxygen.

Chapter 3 Product Specifications

3.1 Safety Classifications

Type of protection against electric shock	Class I with internal electric power supply. Where the integrity of the external protective earth (ground) in the installation or its conductors is in doubt, the equipment shall be operated from its internal electric power supply (batteries)
Degree of protection against electric shock	Monitor: B Sidestream CO_2/AG: BF (defibrillation proof) ECG/RESP/TEMP/SpO_2/NIBP/IBP/CO/mainstream CO_2: CF (defibrillation proof)
Degree of protection against hazards of ignition of flammable anesthetic mixtures	Not protected (ordinary)
Degree of protection against harmful ingress of water	Not protected (ordinary)
Mode of operation	Continuous
Equipment type	Portable

3.2 Environmental Specifications

Operating temperature	0 to 40℃ 5 to 35℃ (With Mindray CO_2 module) 10 to 35℃ (With Welch Allyn CO_2 module) 5 to 35℃ (With Oridion CO_2 module) 10 to 35℃ (With AION AG module)
Operating humidity	15 to 95%, noncondensing
Atmospheric pressure	70.0 kPa～106.0 kPa 86.0 kPa～106.0 kPa(With Oridion CO_2 module)
Storage temperature	–20 to 60℃
Storage humidity	10 to 95%, noncondensing

3.3 Power Source Specifications

AC mains	
Input voltage	100 to 240V
Frequency	50/60Hz
Power	140VA
DC mains	
Input voltage	10 to 16VDC（rating-12 VDC）
Power	80W
Internal battery	
Number of batteries	1
Type	Sealed lead-acid battery or lithium-ion battery
Time to shutdown	5 to 15min (after the first low-power alarm)
Sealed lead-acid battery	
Nominal voltage	12VDC
Capacity	2.3Ah
Operating time	75 minutes typical when powered by one new fully-charged battery (25℃, ECG, SpO2, NIBP measurement per 15 minutes).
Charge time	About 8 h (in the running status or standby mode)
Lithium battery	
Rated voltage	11.1VDC
Capacity	4.4Ah
Operating time	150 minutes typical when powered by one new fully-charged battery (25℃, ECG, SpO2, NIBP measurement per 15 minutes).
Charge time	About 8 h (in the running status or standby mode)

3.4 Hardware Specifications

Physical	
Size	310 × 280 × 150mm (width×height×depth)
Weight	Different due to different configurations Standard configuration: 5.5kg
Display	
Type	Color TFT LCD
Size	10.4 inches (diagonal)
Resolution	800×600 pixels
Recorder	
Type	Thermal dot array
Horizontal resolution	160 dots/cm (at 25 mm/s recording rate)
Vertical resolution	80 dots/cm
Width of the recorder paper	50 mm
Length of the recorder paper	30 m
Recording rate	25 mm/s, 50 mm/s
Recorded waveforms	2
LED indicator	
Alarm indicator	1 (yellow and red)
Running status indicator	1 (green)
AC/DC power indicator	1 (green)
Battery indicator	1 (green)
Audio indicator	
Speaker	Giving audio alarms, keypad tones, and heartbeat/pulse tone. Supporting PITCH TONE and multi-level volume. Audio alarms comply with EN475 and IEC60601-1-8.
Control	
Control knob	1 knob, which can be rotated clockwise/counterclockwise or pressed.

Button	7 buttons: POWER, MAIN, FREEZE, SILENCE, RECORD, NIBP, MENU
Connectors	
Power supply	1 AC power connector 1 DC power connector
Parameter	ECG, RESP, TEMP, SPO2, NIBP, IBP, CO, CO2, AG
Network	1 standard RJ45 network connector, 100 BASE-TX
VGA	1 standard color VGA monitor connector, 15-PIN D-sub
Auxiliary output	1 BNC connector
Equipotentiality	1 equipotential grounding connector

3.5 Wireless network

<table>
<tr><td>Standards</td><td colspan="7">IEEE 802.11b, Wi-Fi compatible</td></tr>
<tr><td>Frequenct range</td><td colspan="7">2.412 to 2.462GHz</td></tr>
<tr><td rowspan="3">Operating channel</td><td>China</td><td>America</td><td>Canada</td><td>Europe</td><td>Spain</td><td>France</td><td>Japan</td></tr>
<tr><td colspan="4">1 to 11</td><td colspan="2">10, 11</td><td>2</td></tr>
<tr><td colspan="7">For other country, please refer to your local law.</td></tr>
<tr><td>Safe distance</td><td colspan="7">10m (a circle centering AP with the diameter of 10m)</td></tr>
<tr><td>Maximum data rate</td><td colspan="7">11Mbps</td></tr>
</table>

3.6 Data Storage

Trend data	Long trend: 96 hours, resolution 1min, 5 min or 10 min. Short trend: 1 hour, resolution 1 s or 5 s.
Alarm events	70 alarm events and associated waveforms (with user selectable waveform length 8s, 16 or 32).
ARR events	80 ARR events and associated waveforms with 8s wavelength.
NIBP measurements	800 NIBP groups, including systolic pressures, mean pressures, diastolic pressures and measurement time.

3.7 Signal Output Specifications

Standards	Meets the requirements of EC60601-1 for short-circuit protection and leakage current
Output impedance	50Ω
ECG analog output	
Bandwidth (-3dB; reference frequency: 10Hz)	Diagnostic mode: 0.05 to 100Hz(12-lead: 0.05 to 150Hz) Monitor mode: 0.5 to 40Hz Surgery mode: 1 to 20Hz
Signal delay	≤ 25ms
Maximum propagation delay	25ms (In DIAGNOSTIC mode, NOTCH is OFF)
Sensitivity	1V/mV±5%
PACE rejection/enhancement	No pace rejection or enhancement
IBP analog output	
Bandwidth	0 to 12.5 Hz (-3dB, reference frequency: 1Hz)
Maximum propagation Delay	55ms (the filter function is disabled)
Sensitivity	1 V/100mmHg±5%
Nurse call output	
Driver	Relay
Electrical specifications	≤60W, ≤2A, ≤36VDC, ≤25VAC
Isolation voltage	> 1500 VAC
Signal type	Normally open or normally closed, selectable
Defibrillator synchronization pulse	
Maximum time delay	35ms (R-wave peak to leading edge of the pulse)
Amplitude	3.5 V (min) at 3 mA sourcing; 0.8 V (max) at 1 mA sinking
Pulse width	100 ms ±10%
Rising and falling time	< 3ms
VGA	
Signal	RGB: 0.7 Vp-p/75Ω; Horizontal/vertical synchronization: TTL level

3.8 ECG Specifications

Lead type	3-lead (1 channel): I, II, III 5-lead (2 channels): I, II, III, aVR, aVL, aVF and V 12-lead (8 channels): I, II, III, avR, avL, avF, V1-V6
Lead naming style	AHA, EURO
Sensitivity selection	1.25mm/mV (×0.125), 2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2) and auto
Sweep speed	12.5mm/s, 25mm/s, 50mm/s
Bandwidth (– 3dB)	Diagnostic mode: 0.05 to 100Hz (12-lead: 0.05 to 150Hz) Monitor mode: 0.5 to 40Hz Surgery mode: 1 to 20Hz
Common mode rejection	Diagnostic mode: ≥90 dB Monitor mode: ≥105 dB Surgery mode: ≥105 dB (The notch filter is turned off.)
Differential input impedance	≥ 5MΩ
Input signal range	±8mV (peak-to-peak value)
DC offset voltage	±300mV (12-lead: ±500mV)
Patient leakage current	< 10uA
Recovery time after defibrillation	< 5s
Calibration signal	1mV (peak-to-peak value), precision: ±5%
HR	
Measurement range	Neonate: 15 to 350 BPM Pediatric: 15 to 350 BPM Adult: 15 to 300 BPM
Resolution	1 BPM
Precision	±1BPM or ±1%, whichever is greater.
Sensitivity	200µV (lead II)

Response time to heart rate changes	Meets the requirement of ANSI/AAMI EC13-2002: Section 4.1.2.1 f). Less than 11 sec for a step increase from 80 to 120 BPM Less than 11 sec for a step decrease from 80 to 40 BPM
Response time of tachycardia alarm	When tested in accordance with ANSI/AAMI EC13-2002 Section 4.1.2.1 g, the response time is as follows. Figure 4ah – range: 15.7 to 19.2s, average: 17.4s 4a – range: 5.7 to 8.5s, average: 7.5s 4ad – range: 3.6 to 5.1s, average: 4.2s Figure 4bh – range: 11.5 to 14.7s, average: 12.9s 4b – range: 4 to 14s, average: 7.2s 4bd – range: 6.6 to 14.5s, average: 10.5s
Pace pulse	
Pulse indicator	Pace pulses meeting the following conditions are marked by the PACE indicator. Amplitude: ±4 to ±700mV Width: 0.1ms to 2ms Rise time: 10us to 100μs
Pulse rejection	When tested in accordance with the ANSI/AAMI EC13-2002: Sections 4.1.4.1 and 4.1.4.3, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ±700mV Width: 0.1ms to 2ms Rise time: 10us to 100μs Min. input slew rate: 50V/s RTI
ST segment measurement	
Measurement range	– 2.0 to +2.0 mV
Precision	– 0.8 to +0.8mV: ±0.02mV or ±10%, whichever is greater. Beyond this range: Undefined.
Update period	10s
Arrhythmia analysis	
Type	ASYSTOLE, VFIB/VTAC, PVC, COUPLET, VT>2, BIGEMINY, TRIGEMINY, R ON T, MISSED BEATS, TACHY, BRADY, PNC and PNP

3.9 RESP Specifications

Measurement technique	Thoracic impedance
Lead	Optional: lead I and lead II; default lead II
Differential input impedance	> 2.5MΩ
Respiration impedance test range	0.3 to 3Ω
Excitation current	< 300μA
Baseline impedance range	200 to 2500Ω (using an ECG cable with 1kΩ resistance)
Bandwidth	0.2 to 2Hz (-3 dB)
Sweep speed	6.25 mm/s, 12.5 mm/s, 25 mm/s
RR	
Measurement range	Adult: 0 to 120 BrPM Pediatric/neonate: 0 to 150 BrPM
Resolution	1 BrPM
Precision	7 to 150 BrPM: ±2 BrPM or ±2%, whichever is greater. 0 to 6 BrPM: Undefined.
Apnea alarm delay	10 to 40s

3.10 SpO_2 Specifications

1.1.1. Mindray SpO_2 Module

SpO_2	
Measurement range	0 to 100%
Resolution	1%
Precision	70 to 100%: ±2 % (adult/pediatric, non-motion conditions) 70 to 100%: ±3 % (neonate, non-motion conditions) 70 to 100%: ±3 % (in motion conditions) 0% to 69%: Undefined.
Refreshing rate	1s
PR	
Measurement range	20 to 254bpm
Resolution	1bpm
Precision	±3 bpm (non-motion conditions) ±5 bpm (in motion conditions)
Refreshing rate	1s

1.1.2. Masimo SpO_2 Specifications

SpO_2	
Measurement range	1 to 100%
Resolution	1%
Precision	70 to 100%: ±2% (adult/pediatric, non-motion conditions) 70 to 100%: ±3% (neonate, non-motion conditions) 70 to 100%: ±3% (in motion conditions) 0% to 69%: Undefined.
Refreshing rate	1s
PR	

Measurement range	25 to 240bpm
Resolution	1bpm
Precision	±3bpm (non-motion conditions) ±5bpm (in motion conditions)
Refreshing rate	1s

1.1.3. Nellcor SpO_2 Specifications

SpO_2 measurement range and precision	Sensor	Range	Precision*
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST	70 to 100% 0% to 69%	±2% Undefined
	OxiCliq A, OxiCliq N, OxiCliq P, OxiCliq I	70 to 100% 0% to 69%	±2.5% Undefined
	D-YS, DS-100A, OXI-A/N and OXI-P/I	70 to 100% 0% to 69%	±3% Undefined
	MAX-R, D-YSE and D-YSPD	70 to 100% 0% to 69%	±3.5% Undefined
PR measurement range and precision	20 to 250bpm: ±3bpm 251 to 300bpm: Undefined		
Refreshing rate	1s		
*: When sensors are used on neonatal subjects as recommended, the specified precision range is increased by ±1%, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.			

3.11 IBP Specifications

<table>
<tr><td>Measurement technique</td><td colspan="4">Auto oscillation</td></tr>
<tr><td>Displayed parameters</td><td colspan="4">Systolic pressure, diastolic pressure and mean pressure</td></tr>
<tr><td>Mode of operation</td><td colspan="4">Manual, auto and continuous</td></tr>
<tr><td>Measurement interval in auto mode</td><td colspan="4">1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes</td></tr>
<tr><td>Measurement time in continuous mode</td><td colspan="4">5 minutes</td></tr>
<tr><td rowspan="4">Measurement range in normal mode</td><td>mmHg</td><td>Adult</td><td>Pediatric</td><td>Neonate</td></tr>
<tr><td>Systolic pressure</td><td>40 to 270</td><td>40 to 200</td><td>40 to 135</td></tr>
<tr><td>Diastolic pressure</td><td>10 to 210</td><td>10 to 150</td><td>10 to 100</td></tr>
<tr><td>Mean pressure</td><td>20 to 230</td><td>20 to 165</td><td>20 to 110</td></tr>
<tr><td>Measurement precision</td><td colspan="4">Maximum average error: ±5mmHg
Maximum standard deviation: 8mmHg</td></tr>
<tr><td>Resolution</td><td colspan="4">1mmHg</td></tr>
<tr><td>Over-pressure protection</td><td colspan="4">Adult: 297±3 mmHg
Pediatric: 240±3 mmHg
Neonate: 147±3 mmHg</td></tr>
</table>

3.12 TEMP Specifications

Number of channels	2
Displayed parameters	T1, T2 and TD
Measurement range	0 to 50°C (32 to 122°F)
Resolution	0.1°C
Precision	0.1°C (excluding the sensor) ±0.2°C (including the YSI 400 series sensor)
Update period	1s
Minimum time for accurate measurement	Body surface: < 100s Body cavity: < 80s (YSI 400 series sensor)

3.13 IBP Specifications

Number of channels	2	
Pressure labels	ART, PA, CVP, RAP, LAP, ICP, P1 and P2	
Measurement range	ART	0 to 300 mmHg
	PA	– 6 to 120 mmHg
	CVP/RAP/LAP/ICP	– 10 to 40 mmHg
	P1/P2	– 50 to 300 mmHg
Resolution	1 mmHg	
Precision	±2% or ±1mmHg, whichever is greater	
Update period	1s	
Pressure transducer		
Sensitivity	5 uV/V/mmHg	
Impedance range	300 to 3000Ω	

3.14 CO Specifications

Measurement technique	Thermal dilution	
Calculated parameter	CO, hemodynamics	
Measurement range	CO	0.1 to 20l/min
	TB	23 to 43°C
	TI	0 to 27°C
Resolution	CO: TB, TI:	0.1 l /min 0.1°C
Precision	CO: TB, TI:	±5% or ± 0.1 l /min 0.1°C
Alarm range	TB:	23 to 43°C

3.15 CO_2 Specifications

Measurement technique	Infrared absorption technique
Measurement mode	Sidestream, microstream or mainstream (optional)
Displayed parameter	EtCO2, FiCO2, Respiration Rate
CO2 function	Meet the requirements of EN864 and ISO9918.

1.1.4. Mindray CO_2 Specifications

CO2 measurement range	0 to 99mmHg
Precision*	0 to 40 mmHg: ±2mmHg 41 to 76 mmHg: ±5% 77 to 99 mmHg: ±10%
Deflation rate	100, 150ml/min
Precision of deflation rate	15%
Start-up time of CO2 module	< 1min. The module enters the warming up status after the startup. Ten minutes later, it enters the ready-to-measure status.
AwRR measurement range	0 to 120 BrPM
Precision	0 to 70 BrPM: ±2 BrPM > 70 BrPM: ±5 BrPM
Response time	< 240 ms (10 to 90%)
Delay time	< 2s (Length of sampling tube: 7 feet; inner diameter: 0.055 inches; sampling flow: 150ml/min)
Apnea alarm delay	AwRR: 10 to 40 s

* Conditions for measurements in typical precision: The measurement is started after the preheating mode of the module; Ambient pressure: 750mmHg to 760mmHg; room temperature: 22℃ to 28℃; The gas under test is dry, and the balance gas is N2; The deflation rate is 150ml/min, the respiration rate is no greater than 30BrPM, with a fluctuation less than ±3BrPM, and the inhale interval/exhale interval is 1:2; In other conditions, the measurement precision should meet the requirements of EN864 or ISO9918: ±4mmHg (0 to 40mmHg) or ±12% of the reading (41 to 99mmHg)

1.1.5. Oridion CO_2 Specifications

CO_2 measurement range	0 to 99mmHg	
Precision*	0 to 38 mmHg: 39 to 99 mmHg:	±2mmHg ±5% + 0.08%× (reading - 38mmHg)
Resolution	Waveform: Value:	0.1mmHg 1mmHg
Flow rate	$50^{-7.5}_{+15}$ ml/min	
Initialization time	30s (typical)	
Response time	2.9s (typical)	
Delay time	2.7s (typical)	
AwRR measurement range	0 to 150 BrPM	
AwRR measurement precision	0 to 70BrPM: 70 to 120BrPM: 121 to 150BrPM:	±1BrPM ±2BrPM ±3BrPM
Apnea alarm delay	AwRR: 10 to 40s	
* Precision applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy complies with EN 864/ISO 9918 (4 mmHg or ±12% of reading whichever is greater) for $EtCO_2$ values exceeding 18 mmHg. To achieve the specified accuracies for breath rates above 60 breaths/minute, the Microstream® FilterLine H Set for Infant/Neonatal (p/n 006324) must be used. The accuracy specification is maintained to within 4% of the values indicated in the above table in the presence of interfering gases according to EN864 Section Eleven, Part 101.		

1.1.6. Welch Allyn CO_2 Specifications

CO2 measurement range	0 to 99mmHg
Precision*	0 to 40 mmHg: ±2mmHg 41 to 76 mmHg: ±5% 77 to 99 mmHg: ±10%
Resolution	1mmHg
Refreshing rate	1s
Start-up time	< 80s (ambient temperature: 25℃; preheating power of transducer: 5W)
Response time	100ms (10% to 90 %)
Calibration	Daily calibration is unnecessary
Calibration stability	There is a difference (< 1%) from the precison criteria after a 12-month continuous service time
Alarm range	0 to 99 mmHg
AwRR measurement range	0 to 150 BrPM
AwRR alarm range	0 to 150 BrPM
Apnea alarm delay	AwRR: 10 to 40 s
* Precision specification is based upon the following standard airway conditions: sensor 42℃; airway adapter temperature 33℃; water vapor pressure 38 mmHg; standard gas mixture equals CO2 in balance air; fully hydrated at 33℃; atmospheric pressure 760 mmHg; airway flow rate 60 cc/min.	

3.16 AG Specifications

Measurement technique	Infrared absorption		
Measurement mode	Side stream		
AG functions	Meets requirements of ISO9918, ISO11196, EN12598 and ISO7767		
Warm-up time	45 seconds (warming-up status) 10 minutes (ready-to-measure status)		
Sampling flow (sidestream)	Adult/Pediatric	120, 150, 200 ml/minute (user-selectable)	
	Neonatal	70, 90, 120 ml/minute (user-selectable)	
Gas type	CO_2, N_2O, O_2 (optional), Des, Iso, Enf, Sev, Hal		
Measurement range	CO_2: N_2O: Des: Sev: Enf, Iso, Hal: O_2: AwRR:	0 to 30% 0 to 105% 0 to 30% 0 to 30% 0 to 30% 0 to 105% 2 to 100 BrPM	
Resolution	CO_2: AwRR:	1 mmHg 1 BrPM	
Precision	Gas	Range (%REL)	Precision (%ABS)
	CO2	0 to 1	±0.1
		1 to 5	±0.2
		5 to 7	±0.3
		7 to 10	±0.5
		> 10	Not specified
	N2O	0 to 20	±2
		20 to 100	±3
	Des	0 to 1	±0.15
		1to 5	±0.2

		5 to 10	±0.4
		10 to 15	±0.6
		15 to 18	±1
		>18	Not specified
	Sev	0 to 1	±0.15
		1 to 5	±0.2
		5 to 8	±0.4
		> 8	Not specified
	Enf, Iso, Hal	0 to 1	±0.15
		1 to 5	±0.2
		> 5	Not specified
	O2 (Optional)	0 to 25	±1
		25 to 80	±2
		80 to 100	±3
	AwRR	2 to 60 BrPM	±1 BrPM
		> 60 BrPM	Not specified
Alarm range	CO2: AwRR:	0 to 10 % (0 - 76 mmHg) 2 to 100 BrPM	
Apnea alarm delay	AwRR：	20 - 40 s	
Refreshing rate	1s		
Calibration	Yearly calibration requested.		
Calibration stability	After module being used for 12 consective months, the error is < 1%		

Rise time (10 % to 90 %) Sampling flow 120ml/min, using the DRYLINE™ water trap and neonatal DRYLINE™ sampling line (2.5m)	CO_2	250 ms (fall time 200 ms)
	N_2O	250 ms
	O_2	600ms
	HAL, ISO, SEV, DES	300 ms
	ENF	350 ms
Rise time (10 % to 90 %) Sampling flow 200ml/min, using the DRYLINE™ water trap and adult DRYLINE™ sampling	CO_2	250 ms (fall time 200 ms)
	N_2O	250 ms
	O_2	500ms
	HAL, ISO, SEV, DES	300 ms

line (2.5m)	ENF	350 ms
Delay time	< 4s	

Chapter 4 Disassembling/Assembling & Troubleshooting

4.1 PM-7000 Disassembling/Assembling

4.1.1 Exploded View of PM-7000

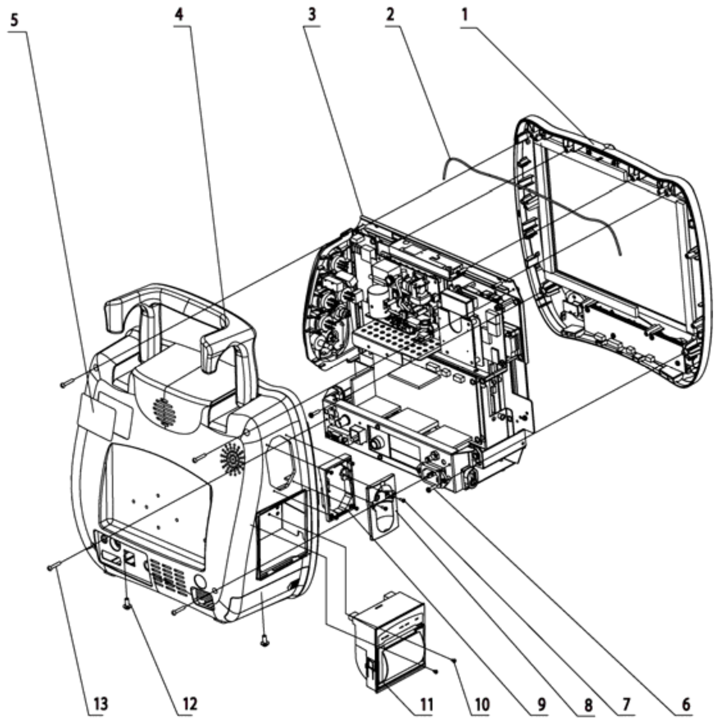


Figure 4-1 Exploded view of PM-7000

NO	Material code	Part & Specification	Quantity
1	7001-30-67413	Front bezel assembly	1
2	0000-10-10876	Hose (Φ1.5mm)	0.33
3	7001-30-67452	Main support assembly	1
4	7001-30-67450	Rear housing assembly	1
5	900E-20-05085	Label	1
6	M04-000305---	Cross head tapping screw PT3×12	6
7	M04-051003---	Cross head tapping screw PT2×6	6
8	M02A-3025913	Water trap socket assembly	1
9	M02A-20-25906	Water trap support	1
10	M04-004012---	Cross head screw	2
11	TR6C-30-16654	TR60-C recorder	1
12	M04-004014---	Cross head screw M4×10	2
13	M04-051002---	Cross head screw M3×16	4

4.1.2 PM-7000 Support Assembly

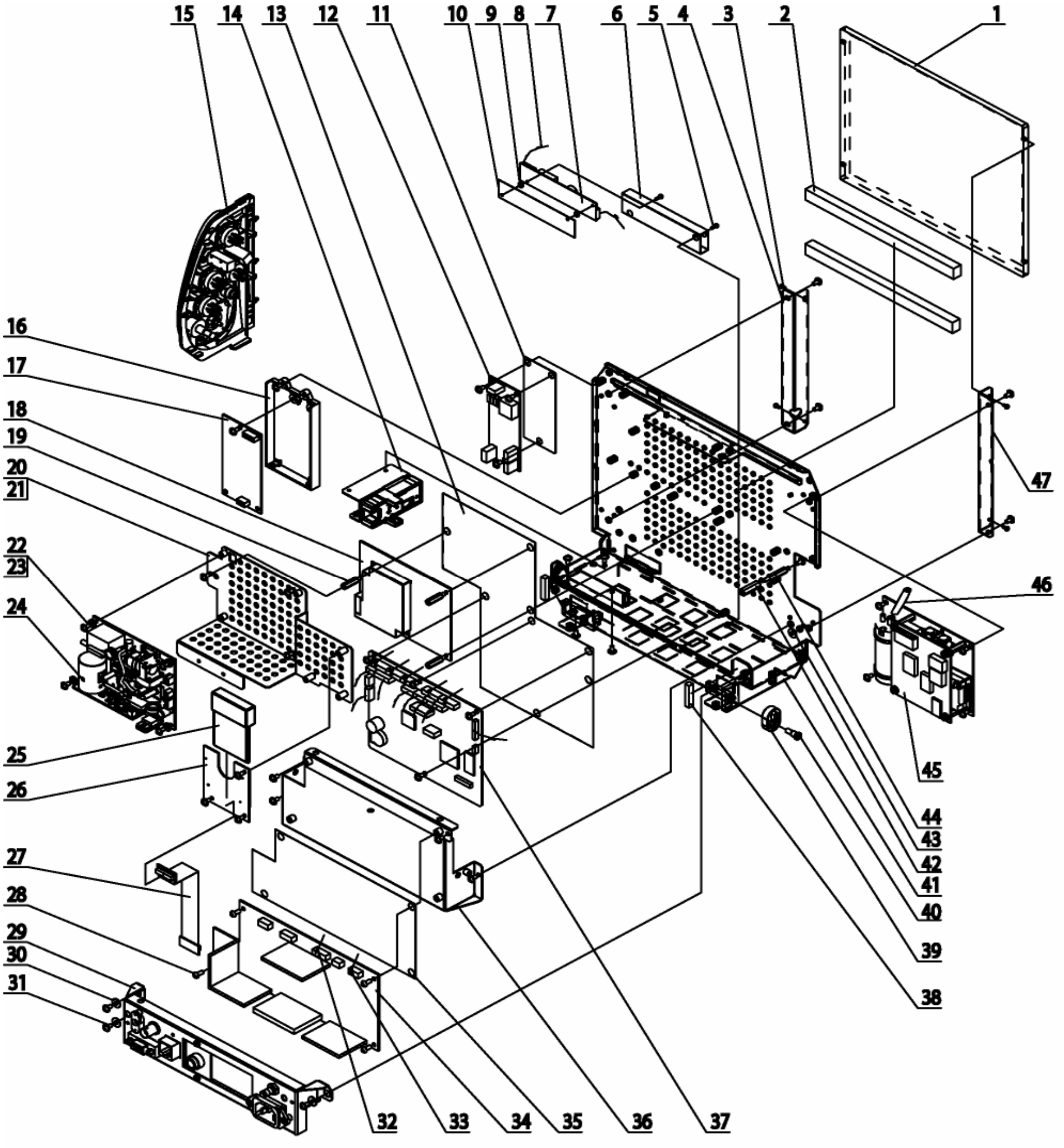


Figure 4-2 PM-7000 support assembly

NO	Material Code	Part & Specification	Quantity
1	0000-10-11021	LCD, TFT, 10.4 inch	1
2	7000-20-24508	LCD pad, AU	2
3	M04-051137---	Stainless steel cross head screw M2×4	4
4	7000-20-24540	LCD support, LG	1
5	M04-002405---	Cross head screw M2×6	2
6	7000-20-24417	Backlight board insulation plate	1
7	0010-10-12096	Inverter	1
8	8000-21-10239	Connecting wire for TFT backlight board	1
9	M90-000002-01	Insulation flat washer	2

10	9300-20-13901	Backlight insulation plate	1
11	8000-20-10214	IBP insulation plate	1
12	M03A-30-26050	CO/IBP board	1
13	7000-20-24418	Insulation plate for main board	1
14	7000-30-24425	Battery rack assembly	1
15	7000-30-24424	Socket assembly	1
16	DA8K-20-14426	SPO2 mount	1
17	9006-30-33900	9006 SPO2 board	1
18	812A-30-08569	812A ECG board assembly	1
19	M04-060009---	Bolt M3×14	3
20	7001-20-67403	CO_2 module mounting board	1
21	7000-20-24509	Insulation plate for ECG board	1
22	M04-051121---	Cross head screw M2.5×8	4
23	M90-000002---	Insulation flat washer	4
24	M02A-30-25930	CO_2 module	1
25	0000-10-11002	Wireless network card	1
26	9201-30-35920	CF card interface board	1
27	7001-30-67468	Flexible cable for CF card	1
28	M04-002505---	Cross head screw M3×6	4
29	7001-30-67454	Power socket assembly	1
30	M04-021024---	Washer	3
31	M04-003012---	Cross head screw M3×6	39
32	9200-21-10442	Backlight board connecting wire	1
33	8000-21-10141	Power cord for DC/DC converter	1
34	7001-30-67438	Lead acid battery power board	1
35	7000-20-24387	Power board insulation sheet	1
36	7001-20-67470	Power board mount	1
37	9210-30-30150	Main board	1
38	9901-10-23920	Conducting pad	0.1m
39	7000-20-24365	Battery latch	1
40	7000-20-24420	Screw for fixing battery latch	1
41	7000-20-24366	Main support	1
42	M04-030031---	Hex bolt M3×20	1
43	M04-000603---	Lock washer	1
44	M04-000306---	Bolt M3×16	1
45	630D-30-09111	630D PCB assembly	1
46	A21-000009---	Hose	0.4m
47	7000-20-24539	Screen support 1 for LG screen	1
48	7000-20-24446	Keypad connecting wire	1
49	7000-20-24447	Net twine	1
50	9200-21-10446	Communication wire to ECG/TEMP/RESP board	1
51	7000-20-24442	Communication wire to SPO_2 board	1

52	M02A-20-25909	Communication wire to CO_2 module	1
53	7000-20-24444	Communication wire to IBP module	1
54	7000-20-24439	Communication wire to power board	1
55	7000-20-24438	Power cord	1
56	7000-20-24500	Signal wire to recorder	1
57	7000-20-24443	Communication wire to NIBP board	1
58	9200-21-10454	TFT connecting wire	1

4.1.3 Front Bezel Assembly

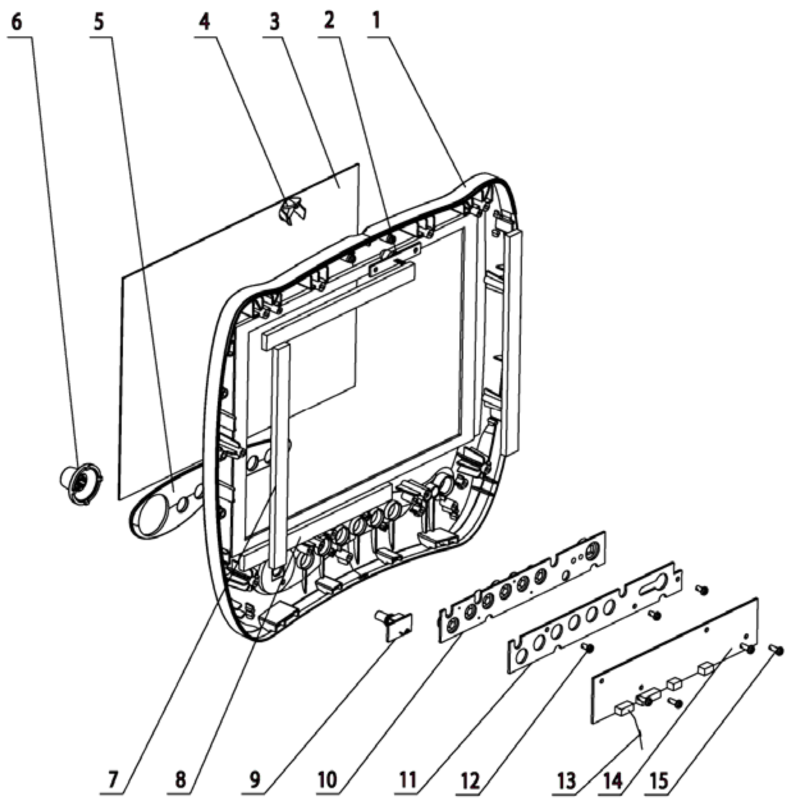


Figure 4-3 Front bezel assembly

SN	P/N	Description	Qty
1	7000-20-24354-51	Front bezel	1
2	9200-30-10701	Alarm light board	1
3	7000-20-24373	Anti-glare screen	1
4	7000-20-24358	Alarm light shade	1
5	7000-20-24357-52	Transparent plate for protecting buttons	1
6	7000-20-24369	Knob	1
7	900E-20-04895	Dust pad 2	2
8	900E-20-04894	Dust pad 1	2
9	6200-30-09774	Screen encoder mount	1

10	7000-20-24356-51	Silicon button	1
11	7000-20-24368	Button fixture	1
12	M04-003905---	Cross head tapping screw PT3×6	2
13	DA8K-20-14416	Connecting wires for encoder	1
14	7001-30-67441	Button board	1
15	M04-003105---	Cross head tapping screw PT3×8	6

4.1.4 Rear Housing Assembly

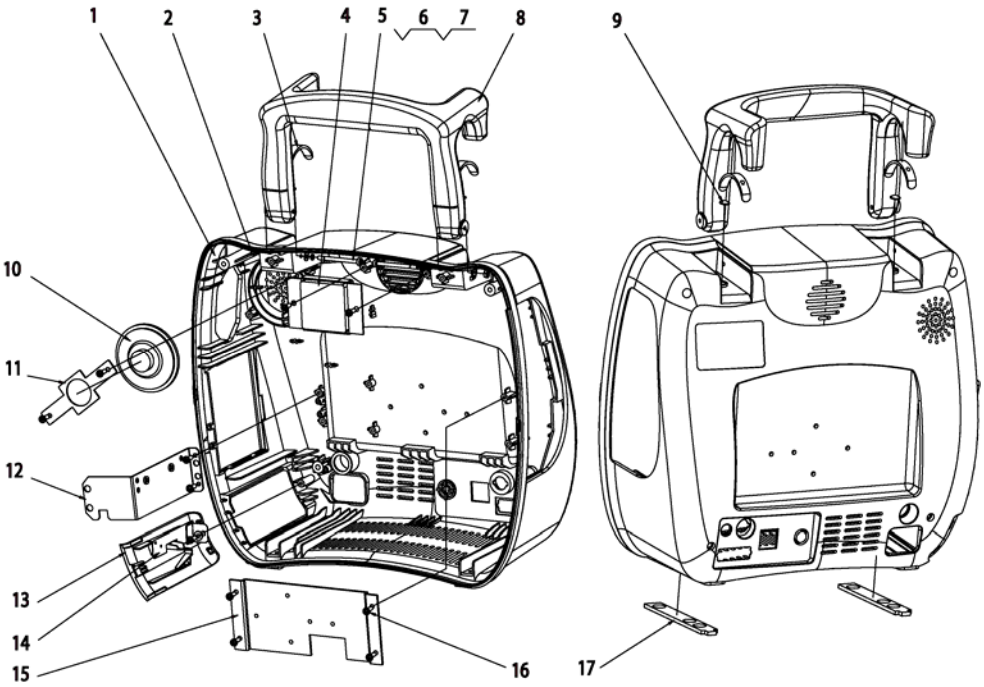


Figure 4-4 Rear housing assembly

SN	P/N	Description	Qty
1	7000-21-24435	Rear housing	1
2	M04-000301---	Stainless steel nut	2
3	7000-20-24435	Non-skid strip	2
4	9200-30-10522	Fan assembly	1
5	7000-20-24370	Handle shaft	2
6	M04-000802---	Flat washer	3
7	M04-000104---	Spring washer	2
8	7000-20-24359	Handle	1
9	DA8K-10-14410	Buffer	2
10	9200-21-10633	Speaker and connecting wires	1
11	9200-20-10620	Speaker fixture	1
12	7000-20-24388	Recorder support	1
13	7000-20-24361	Battery door	1
14	7000-20-24376	Battery door link	1

15	9200-20-10622	Mounting plate	1
16	M04-003105---	Cross head tapping screw PT3×8	11
17	7000-20-24377	Cushion	2

4.1.5 Microstream CO_2 Assembly

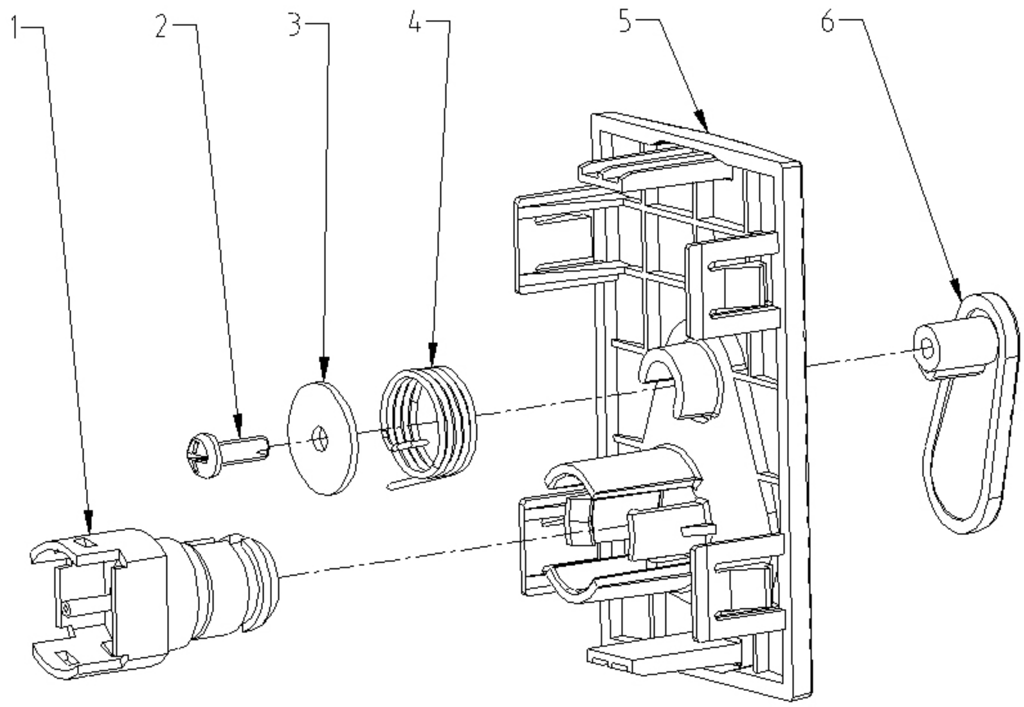


Figure 4-5 Microstream CO_2 assembly

NO	Material Code	Part & Specification
1	9201-30-35959	Microstream CO_2 connector
2	M04-003105---	Cross-head self-tapping screw 3*8
3	9201-20-36010	Baffle of torsional spring
4	9201-20-35961	Retaining torsional spring of microstream CO_2 connector
5	9201-20-35915	Mounting plate of CO_2 connector
6	9201-20-35914	Baffle of CO_2 connector

4.2 Troubleshooting

4.2.1 Black Screen, Startup Failure

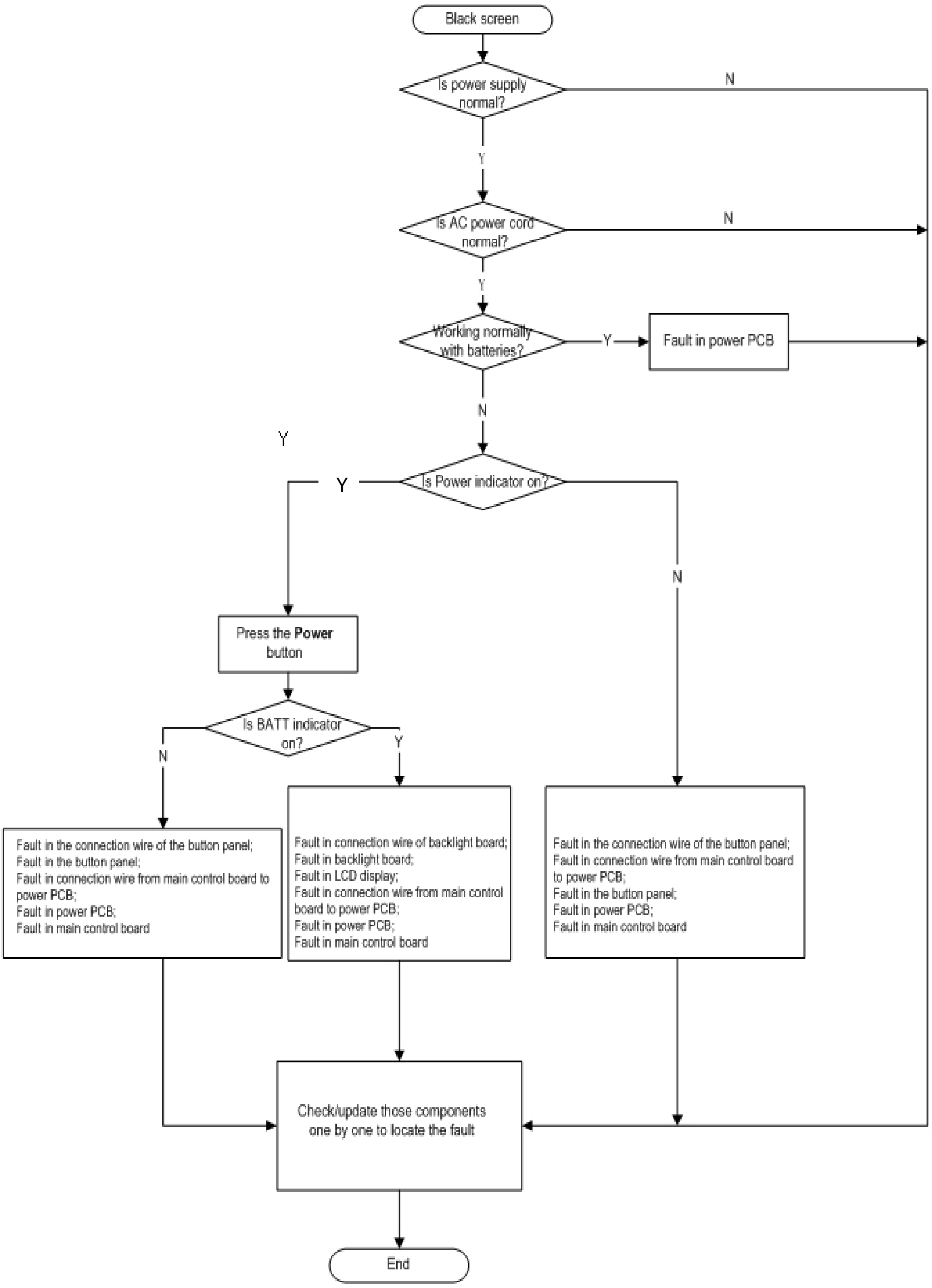


Figure 4-6 Location flow of faults causing black screen

4.2.2 White Screen & Other Abnormal Screen

In case of faults causing white screen or other abnormal screens,

- Check whether the LCD connection wires are in good contact;
- Replace the LCD connection wires, or replace the LCD if necessary;
- Replace the main control board if the fault still exists.

4.2.3 Encoder Faults

1. If all other functions (indicator, alarm, buttons) of the button panel are normal, proceed to step 2; otherwise, replace the button panel;
2. Check whether short-circuit or abnormal open-circuit occurs in the encoder pad;
3. Replace the encoder.

4.2.4 No Audio Alarm

1. Check whether the audio alarm function is disabled in the software settings;
2. Replace the speaker;
3. Replace the button panel.

4.2.5 Printing Failure

1. Check whether there is any alarm about the recorder. If any, eliminate it;
2. Check whether the recorder indictor is on;
3. If not, check the connection wire for inputting signals to the recorder;
4. Check whether the recorder module is enabled in the maintenance menu;
5. Check the power cord of the recorder (including the recorder power PCB);
6. Replace the recorder module.

4.2.6 Abnormal Paper Drive

1. Check whether there are blocks on the paper roller of the recorder;
2. Check whether there are blocks in the gear cluster of thermal assembly of the recorder;
3. Check whether the voltage input of the recorder is larger than 17.6V.

Chapter 5 Test and Material List

5.1 Test Procedure

5.1.1 Connection and Checking

Connect the simulators, power supply and test fixture properly to the PM-7000, and power it on. Then, the patient monitor displays the start-up screen on the TFT screen and enters the system screen.

5.1.2 Functions of Buttons

Press every button on the button panel to check their functions as specified in *PM-7000 Patient Monitor Operation Manual*. Rotate the control knob to check its functions.

5.1.3 ECG/RESP

The TFT screen displays the standard ECG waveform, and the error between the heart rate and the set value of the simulator is no more than ±1, namely 60±1; the RESP waveform is smooth, and the respiration rate is 20±1.

1. Select all leads in order, including **Cal**, select all the four gains and **AUTO**, ensure the waveforms are displayed properly, and check whether the 50Hz/60Hz interference can be filtered.
2. Check, in all the above-mentioned cases, the consistency between the heartbeats, the flashes of the red heart-like indicator, and the R-wave.
3. The gain has no impact on the message "ECG signal over weak" in the HR calculation.
4. Verify the range and precision: Suppose that the amplitude of the GCG signal of the simulator is 1mV, the heart rates are respectively 30, 60, 120, 200, 240 and 300. Check leads I, II and III. The results should meet 29-31, 59-61, 119-121, 198-202, 238-242, and 297-303.
5. PACE pulse test: Set the simulator to PACE. You should be able to view the pace. Change PACE amplitude to ±8 – 700mv, and pulse width to 0.1ms – 2ms. The PACE should be legible, and LEAD OFF is displayed properly.
6. RESP measurement: Set the baseline impedance to 1K, the respiration impedance to 0.5Ω and 3Ω, and the respiration rate to 30 and 120. The respiration rate should be 29 – 31, 118 –122.
7. PVC test: Set the simulator to the PVC mode, and set the occurrence times. The relevant PVCS should be obtained.
8. Set the simulator as follows: RR: 40, baseline impedance: 2KΩ, RESP waveform: 3:1. Open the apnea alarm, set the respiration resistance to 0Ω, and set various alarm time. Alarms should be given.

5.1.4 Temperature

1. YSI probe

   Select YSI probe from the manufacturer menu, select YSI temperature probe as the test fixture, set the analog resistance to 1.471K, 1.355K and 1.249K. Then the TEMP parameter should be 35±0.1℃, 37±0.1℃ and 39±0.1℃.

2. CY-F1 probe

   Select CY-F1 probe from the manufacturer menu, select CY-F1 temperature probe as the test fixture, set the analog resistance to 6.534K, 6.018K and 5.548K. Then the TEMP parameter should be 35±0.1℃, 37±0.1℃ and 39±0.1℃.

5.1.5 NIBP

Connect the NIBP simulator, adult cuff and accessories, and then connect the module CUFF and clockwise screw it tightly.

1. After the simulator self-test, press <ENT> to enter the ADULT analog blood pressure mode. Set the blood pressure to the 255/195/215 mmHg level, SHIFT to +15, and the HR to 80BPM. Set PM-7000 to the adult mode. Press <START>. Then the results will be obtained in about 30s. The measured results should be respectively 270±8mmHg, 210±8mmHg and 230±8mmHg.
2. Press <ESC> and <↓> on the simulator to enter the NEONATE mode. Set the blood pressure to the 120/80/90 mmHg level, HR to 120bmp, and PM-7000 to the pediatric mode. Press <START>. Then the results will be obtained in about 30s. The measured results should be respectively 120±8mmHg, 80±8mmHg and 90±8mmHg.
3. Press <ESC> and <↓> on the simulator to enter the NEONATE mode. Set the blood pressure to the 60/30/40 mmHg level, SHIFT to -20, HR to 120bmp, and PM-7000 to the neonate mode. Change the simulator accessory to the neonatal cuff. Press <START>. Then the results will be obtained in about 30s. The measured results should be respectively 40±8mmHg, 10±8mmHg and 20±8mmHg.

5.1.6 SpO_2

Select PLETH as the HR source of PM-7000, and put the finger into the SpO_2 sensor. The screen should display the PR and SpO_2 values normally. The normal SpO_2 value is above 97%.

5.1.7 IBP

1. Test fixture

   Physiological signal simulator

2. Test procedure

   ① IBP1 test:

   Set the BP sensitivity of the ECG simulator to 5uv/v/mmHg, BP to 0mmHG, and the IBP channel 1 to ART. Enter the IBP PRESSURE ZERO menu of the PM-7000, zero Channel 1, and then return to the main screen. Set the BP of the simulator to 200mmHg. Enter the IBP PRESSURE CALIBRATE menu of the PM-7000, conduct calibration, and then exit the IBP PRESSURE CALIBRATE menu.

Set the BP value of the simulator respectively to 40mmHg, 100mmHg and 200mmHg. Then the screen of the PM-7000 should display 40±1mmHg, 100±2mmHg and 200±4mmHg.

Set the simulator output to ART wave. Then the screen of the PM-7000 should display relevant waveform properly.

Unplug the IBP probe. Then the screen should prompt “IBP: Transducer 1 OFF!” and “IBP: Transducer 2 OFF!”

Plug the OHMEDA cable to the IBP1 channel. Then the prompting message “IBP: Transducer 1 OFF!” disappears.

② IBP2 test:

Plug the IBP cable to the IBP2 channel, and repeat the procedure in Section ①.

5.1.8 CO

1. Test fixture

   Physiological signal simulator

2. Test procedure

   Injectate and blood temperature test: Assemble the TB and TI test fixture, output three TB temperature values: 36℃, 37℃ and 38℃. Then TB should be respectively 36.0±0.1℃, 37.0±0.1℃ and 38.0±0.1℃. Set the injectate switch to ON, output two TI temperature values: 0℃ and 2℃. Then the screen should display 0±0.1℃ and 2.0±0.1℃.

   CO measurement: Set the CO.CONST and T_I to the default values: 0.542 and 0℃, set the injectate switch to OFF, and then press START. Then the simulator will output 0℃, 2.5L/M and 0℃, 5L/M within 2s. The CO values should be 2.5±0.25L/M and 5±0.5L/M.

5.1.9 CO_2

1. Test fixture

   CO_2 steel bottle (containing 10% CO_2)

2. Test procedure

   ① Mainstream CO_2 measurement: Set the calculation compensation of PM-7000 to COMMON.

   Plug the mainstream transducer to the CO_2 socket, connect the windpipe connector with the CO_2 steel bottle, and open/close the valve of the CO_2 steel bottle based on the interval of 3s. The CO_2 value should be the calibration gas pressure value: 76±5%mmHg. When the valve is opened permanently, the patient monitor prompts “APNEA ALARM”.

   Unplug the transducer. The patient monitor prompts “CO_2 transducer OFF” on the main screen. Plug the transducer again. The patient monitor prompts “CO_2 transducer pre-heated”.

   ② Sidestream CO_2 measurement: Set the calculation compensation of PM-7000 to COMMON.

   Plug the water trap to the water trap socket, connect the sampling tube with the CO_2 steel bottle, and open//close the valve of the CO_2 steel bottle based on the interval of 3s. The CO_2 value should be the calibration gas pressure value: 76±5%mmHg. When the valve is opened permanently, the patient monitor prompts "APNEA ALARM".

Unplug the water trap. The patient monitor prompts "CO_2 water trap OFF". Plug the water trap again. The prompting message disappears.

③ When the measured value exceeds the high limit of CO_2, the patient monitor prompts "CO_2 too high" on the main screen. When the measured value is lower than the low limit, the patient monitor prompts "CO_2 too low".

5.1.10 Recorder

1. Print the ECG waveform. The recorder should print it normally and clearly. Set the recorder to the fault of lack of paper and abnormal clip. There should be relevant prompting messages on the main screen. When the fault is cleared, the patient monitor should become normal.
2. Print the alarm messages of all parameters. Set the alarm print switch to ON for all parameters, and set different alarm limits. Then the recorder should print the alarm message in case of an alarm.

5.1.12 Power Supply

When the patient monitor is supplied with the external AC power, the CHARGE indicator becomes ON. When it is disconnected from the external AC power, the CHARGE indicator becomes OFF. After the patient monitor is started without assembling the batteries, "x" is displayed in the battery indication frame on the main screen. After the batteries are assembled, the battery electricity is displayed in the battery indication frame on the main screen. The patient monitor can work normally with or without batteries. It, however, should give an alarm when the batteries are exhausted.

5.1.13 Clock

Verify the correctness of the clock in the system test, and then set the clock to the current time.

5.1.14 System Test

Load all parameters, and conduct operations respectively on the loaded parameters. During the synchronization, no exceptions (for example, mutual interference) occur. Set all parameter setups in menus to the default values which are those at the time of software loading, and conduct operations on the menus, for example, managing the patient information, recalling data, and so on. All the operations should be done normally, and the corresponding functions should be correct and meet the product requirements.

5.2 NIBP Calibration

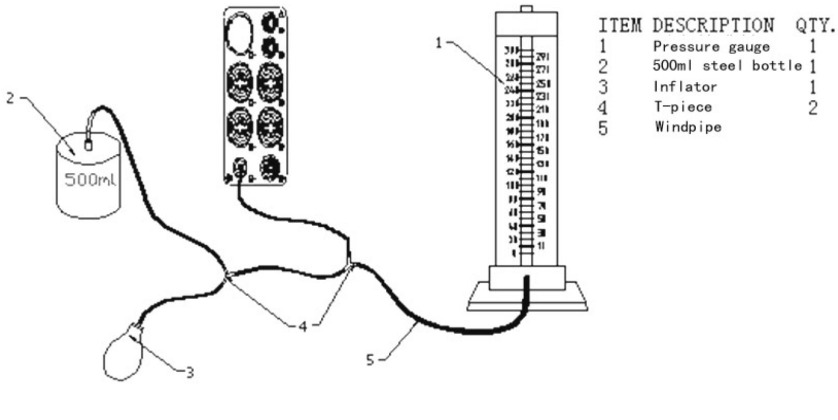


Figure 5-1 NIBP Calibration

Calibration method:

Based on the precision of 50mmHg (6.7kPa), increase the pressure step by step. The maximum error at any pressure point within the NIBP measurement range of the patient monitor should be no more than ±3mmHg (±0.4kPa). Decrease the pressure step by step. The maximum error at any pressure point within the NIBP measurement range of the patient monitor should be no more than ±3mmHg (±0.4kPa).

5.3 IBP CALIBRATE

5.3.1 IBP Transducer Zero

- Press the ZERO button on the IBP module to call up IBP PRESSURE ZERO menu as shown below:

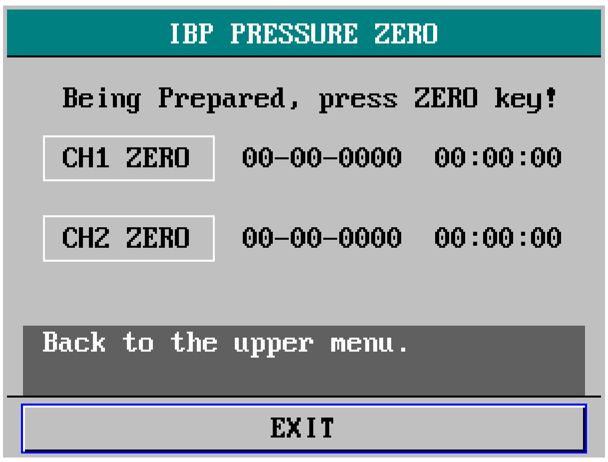


Figure 5-2 IBP PRESSURE ZERO

Zero Calibration of Transducer

Select CH1, the system will zero IBP1. Select CH2, the system will zero IBP2.

Cautions:(Use the PM-6000 IBP module as a example)

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

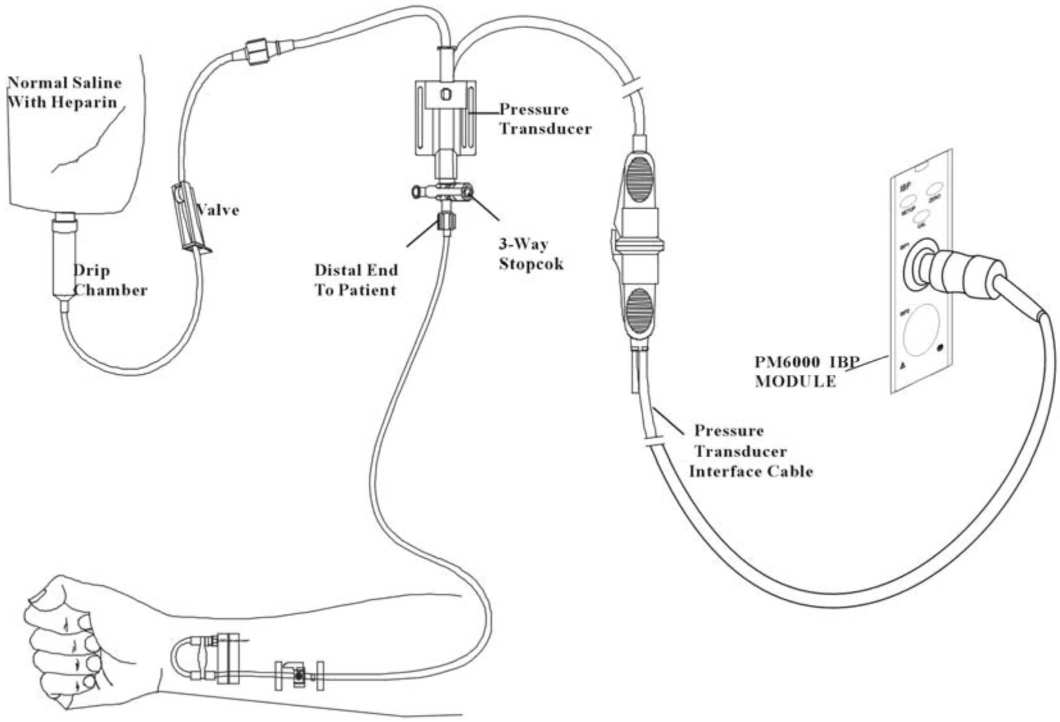


Figure 5-3 IBP Zero

5.3.2 IBP Calibration

- Press CAL button on the IBP module to call up the IBP PRESSURE CALIBRATE menu as shown below:

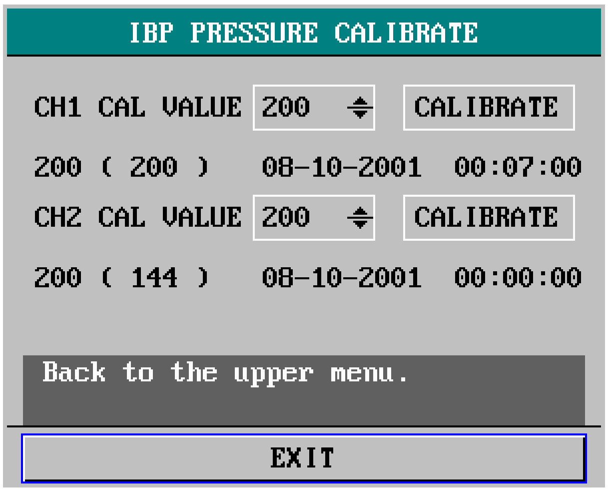


Figure 5-4 IBP Calibration Menu

Calibrate the transducer:

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

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

■ The pressure calibration of PM-7000:

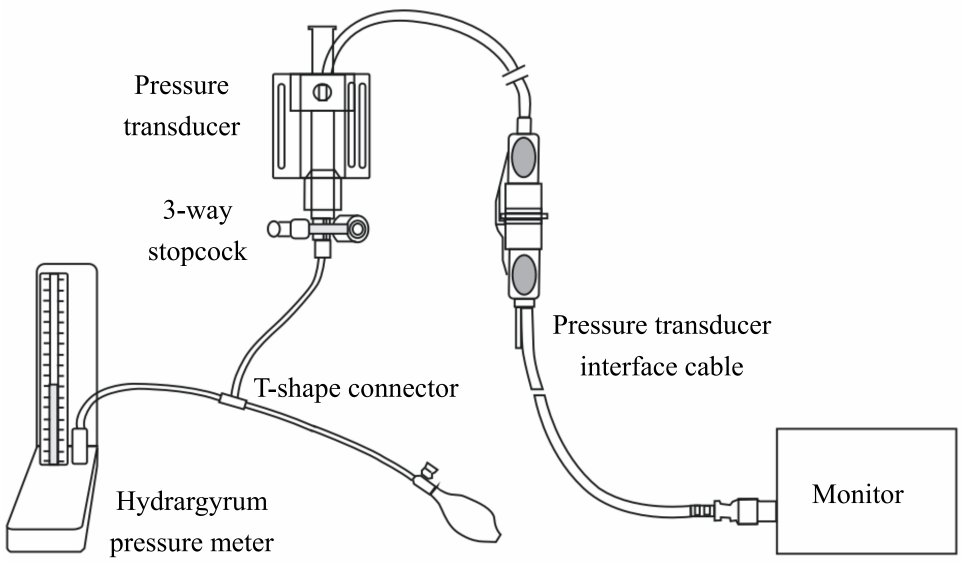


Figure 5-5 IBP Calibration

You will need the following pieces of equipment:

- Standard sphygmomanometer
- 3-way stopcock
- Tubing approximately 25 cm long

The Calibration Procedure:

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

Calibration completion message: “SUCCESSFUL CALIBRATE”

5.4 CO2 CHECK

Check procedure for sidestream module only

Via the PM-7000’s system and maintain menus you are prompted for a password for entering the factory key. After entering the password you get access to the pump rate settings and to check the accuracy of the CO2 measurement. Using the below test set up to verify the accuracy of the CO2 module.

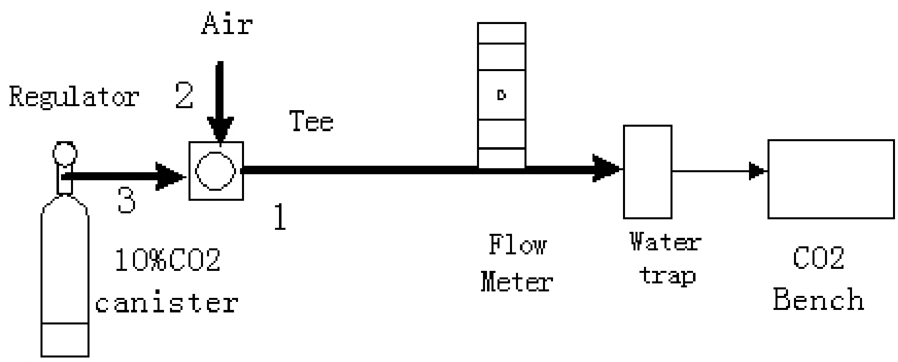


Figure 5-6 Sidestream test set up

⚠ **Note** ⚠ Neither the mainstream nor the sidestream module can be calibrated. Only the overall performance and accuracy is checked. If the Co2 module fails the tests it should be replaced.

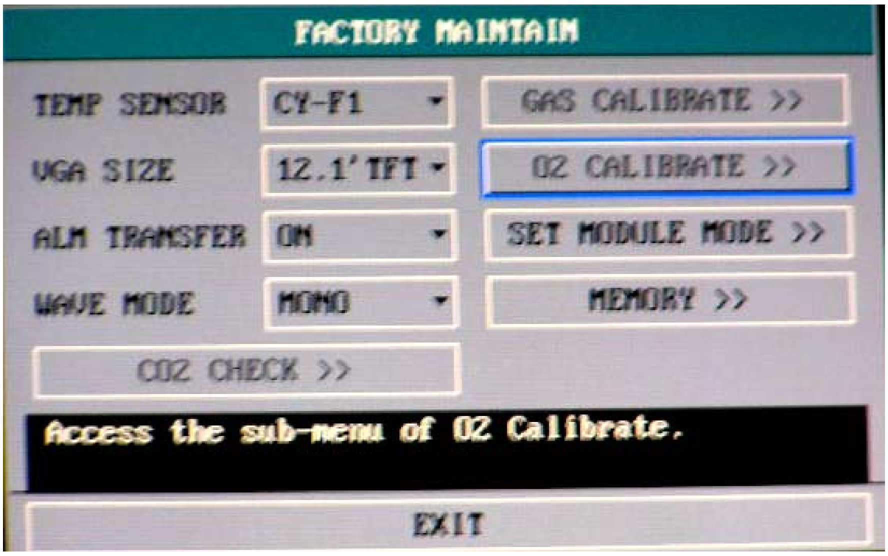


Figure 5-7 Factory Maintain Menu

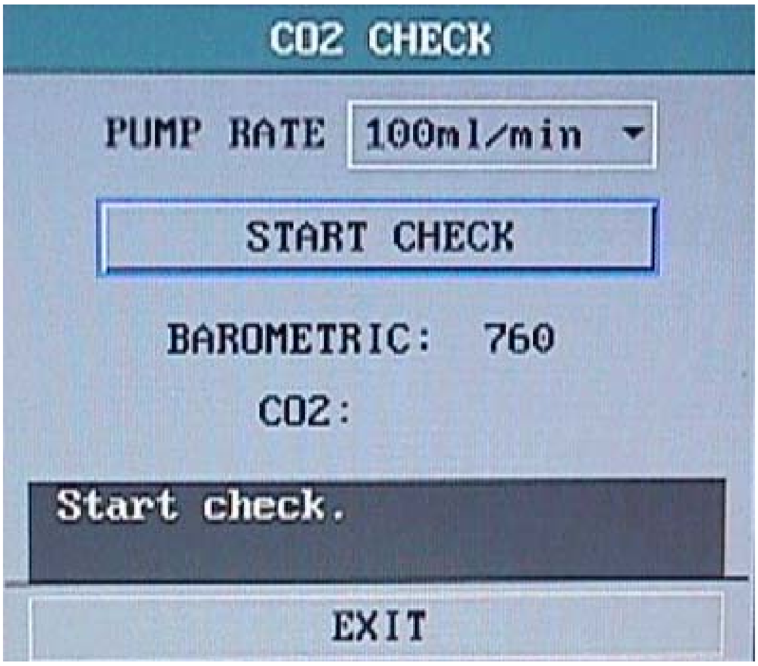


Figure 5-8 CO2 check menu

5.5 AG CALIBRATE

5.5.1 AG Check

1、Using T-piece to connect the watertrap and Agent steel bottle well. One of the T-piece ports must be vented to atmospheric pressure.

2、Select ‘MEASURE’ from work mode item in “AG SETUP” menu, then set pump rate ‘low’ and wait for 10 minutes after the warm up information disappears.

3、Enter ‘CALIBRATE’ menu, then open AG bottle and press the ‘VERIFY ACCURACY’ item.

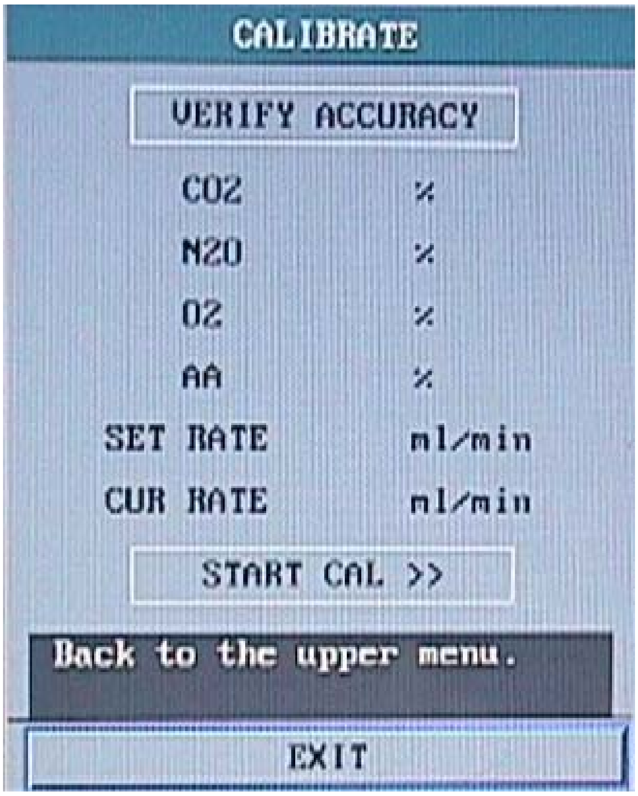


Figure 5-9 AG Check Menu

4、Observe the display value after 1 minute. The agent concentration accurate should be less than ±5%.

5、Choose other pump rate ‘middle’ or ‘high’，and repeat the previous procedures.

(pump rate definition: three pump rate under adult mode: 100/150/200ml/min; neonate: 70/90/110 ml/min）

6、If the accurate over range, please press ‘START CAL’.

5.5.2 AG CALIBRATE

（Agent>1.5%, CO2>1.5%, N2O>40%, O2>40% ）

1、Press 'START CAL', then input password 'MINDRAY' entering 'CALIBRATE' menu.

Note: Make sure the AG in 'Measure' mode not 'Standby' mode before you do calibrate.

Figure 5-10

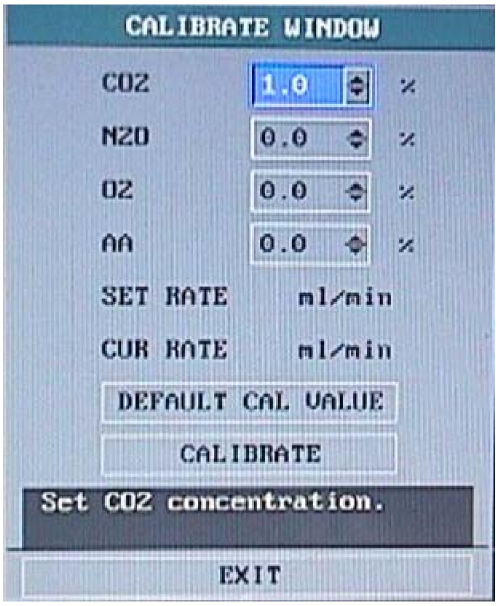


Figure 5-11

2、Input each gas concentration value according to the label on the AG bottle label.

Note: If your monitor do not have O2 module, input '0.0' in O2 item.

3、Open AG cover, wait for the display value stabilization.

4、If the display value does not accord with the input value, please press 'CALIBRATE' item and exit.

AG concentration must fit the following requirements:

Agent>1.5%, CO2>1.5%, N2O>40%, O2>40%

5.6 Bill of Materials for PM-7000 Main Unit

SN	P/N	Description	Quantity
1	M04-004012---	Cross-head screw M3*6	39
2	TR6C-30-16650	Recorder drive board	1
5	7000-20-24422	Main support (with lithium battery)	1
6	M04-002505---	Cross-head screw M3*6	10
7	7001-30-67428	CF wireless network card module assembly	1
8	9210-30-30150	Main board	1
9	7001-30-67438	Power board for lead acid battery	1
10	M05-302R3R---	Lead acid battery	1
11	0010-10-12329	Lithium battery	1
12	DA8K-20-14520	Insulation sheet for ECG board	1
13	812A-30-08557	812A ECG board	1
14	M04-060009---	Bolt M3*14	1
15	DA8K-20-14426	SPO2 board mount	1
16	9006-30-33900	SPO2 board	1
17	630D-30-09121	630D pump	1
18	7000-30-24511	Nellcor SP02 module	1
19	0010-10-12274	MASIMO SPO2 module	1
20	7000-20-24387	Insulation sheet for power board	1
21	7001-30-67439	Power board for lithium battery	1
22	7001-30-67464	AG module (with $O_{2)}$	1
23	7001-30-67461	AG module (without $O_{2)}$	1
24	7001-30-67458	Mainstream CO2 module	1
25	9000-20-07289	Mainstream CO2 module mounting board	1
26	7001-30-67441	Button board	1
27	9200-30-10701	Alarm light board	1
28	6200-30-09774	Display encoder mounting board	1
29	7001-20-67403	CO2 module mounting board	1
30	M05-010R03---	Button cell battery	1
31	7001-30-67456	Display assembly	1
32	M08A-30-34703	Digiboard for 12 lead ECG module	1
33	M08A-30-34701	Analog board for 12 lead ECG module	1
34	7001-30-67436	Oridion CO2 module	1
35	7000-30-24574	Mindray CO2 module	1

Chapter 6 Maintenance and Cleaning

6.1 Maintenance

6.1.1Checking Before Using

- Check the patient monitor for mechanical damages;
- Check all exposed conductors, connectors and accessories;
- Check all functions that are possibly enabled for the monitored patient, and ensure the device is in good working status.

In case of any damage, stop using this patient monitor, and contact biomedical engineers of the hospital or Mindray maintenance engineers.

6.1.2 Regular Checking

An all-around check, including the safety check, should be done by qualified personnel every 6-12 months or after maintenance each time.

All checks in which the patient monitor should be disassembled should be done by qualified maintenance personnel. The safety and maintenance checks can be done by Mindray engineers. The local office of Mindray at your region will be pleased to provide you with the information about the maintenance contract.

6.2 Cleaning

Do switch off the patient monitor and disconnect the AC power supply before cleaning it or the probes.

The PM-7000r should be dust free. To clean the surface of its enclosure and screen, use the cleaning agent that is not corrosive, for example, soap and water.

1. Do not use strong solvent, such as acetone;
2. Most cleaning agents must be diluted before being used, so conduct dilution under the instruction of manufacturers;
3. Do not use any erosive material (such as steel wool or polishing agent);
4. Prevent the ingress of any liquid to the enclosure and any part of the device;
5. Ensure no residue of cleaning liquid on the surface of the device.

6.3 Cleaning Reagent

1. Diluted aqua ammonia
2. Diluted sodium hypochlorite (bleaching powder for washing)
3. Hydrogen peroxide 3%
4. Ethanol
5. Isopropyl alcohol

6.4 Sterilization

To avoid the long-time damage to the patient monitor, we recommend you

- ✓ To conduct only sterilization which is considered necessary in your maintenance plan;
- ✓ To clean the patient monitor before the sterilization;
- ✓ To sterilize the patient monitor with specified sterilization agent: Ethylate, and Acetaldehyde.

⚠**Caution**⚠

- **Conduct dilution or use the liquid of the possibly-lowest concentration under the instructions by the manufacturer.**
- **Prevent the ingress of liquid to the enclosure.**
- **Prevent any part of the system from being dipped.**
- **In sterilization, do not spill the liquid to the patient monitor.**
- **Ensure no residue of sterilization agent on the surface of the patient monitor. Clean it if any.**

6.5 Disinfection

To avoid the long-time damage to the patient monitor, we recommend you

- ✓ To conduct only disinfection which is considered necessary in your maintenance plan;
- ✓ To clean the patient monitor before the disinfection;

Gas (EtO) or formaldehyde are forbidden for the disinfection of the patient monitor.

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