DPM 4 Patient Monitor

Service Manual

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NOTE

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- 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.

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- 3. Return address: Please send the part(s) or equipment to the address offered by the Customer Service department

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Safety Precautions

1. Meaning of Signal Words

In this service manual, the signal words \triangle WARNING, \triangle CAUTION and NOTE are used to indicate safety and other important instructions The signal words and their meanings are defined as follows.

Signal word	Meaning
Awarning	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
A CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
NOTE	Indicates a potentially hazardous situation which, if not avoided, may result in property damage.

2. Meaning of Safety Symbols

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

Safety Precautions

Please observe the following precautions to ensure patient and operator safety when using this system.

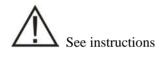
- Do not connect this system to outlets with the same circuit breakers and fuses that control current to devices such as life-support systems. If this system malfunctions and generates an overcurrent, or when there is an instantaneous current at power ON, the circuit breakers and fuses of the building's supply circuit may be tripped.
- Do not use flammable gasses such as anesthetics, or flammable liquids such as ethanol, near this product, because there is danger of explosion.

1. Malfunctions due to radio waves

- Use of radio-wave-emitting devices near the monitor 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.
- 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





Protective earth ground



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.



Equipotential grounding terminal

FOR YOUR NOTES

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FOR YOUR NOTES

1.1 Introduction

The DPM4 Patient Monitor, a portable and accessible patient monitor, which applies to adults, pediatric and neonates, is supplied by rechargeable battery or external AC power. You can select different configurations as required. Besides, the DPM4 can be connected with the central monitoring system whereby a monitoring network will be formed. Parameters that the DPM4 can monitor include: ECG, RESP, SpO₂, NIBP, 2-channel TEMP, 2-channel IBP, and CO₂. It is a compact and lightweight patient monitor. Its color TFT LCD is able to show patient parameters and 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 DPM4 Patient Monitor measures patient's ECG, NIBP, SpO₂, TEMP, RESP, IBP, and CO₂ physiological signals through the ECG electrode, SpO₂ 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, SpO2, RESP, IBP, CO2, 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

DPM4 converts 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. The DPM4 patient monitor should be run under the control of clinical staff.

DPM4 patient monitor 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 ₂	End-tidal carbon dioxide (EtCO ₂)
	Inspired minimum CO ₂ (InsCO ₂)
	Airway Respiration Rate (AwRR)

The DPM4 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.

2.1 General

The intended use of the DPM4 patient monitor is to monitor a fixed set of parameters including ECG, RESP, SpO2, NIBP, TEMP, IBP, and CO2 (IBP and CO2 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.

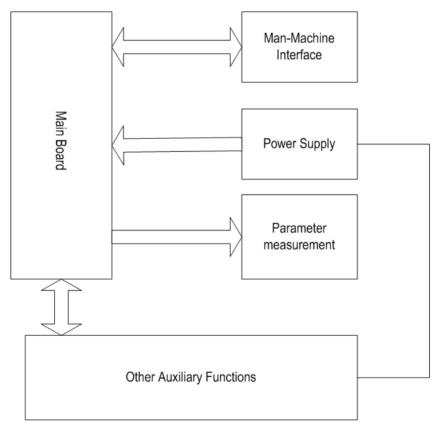


Figure 2-1 Structure of the DPM4

2.1.1 Parameter Measurement

The parameter measurement and monitoring are the core functions of the patient monitor. The parameter measurement part of the DPM4 patient monitor consists of the measurement probe, parameter input socket assembly, NIBP assembly and the main control board.

This part converts the physiological signals to electrical signals, processes 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 DPM4 patient monitor, 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 DPM4 patient monitor 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 to the 5V 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 DPM4 patient monitor 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 DPM4 patient monitor is shown in the following figure.

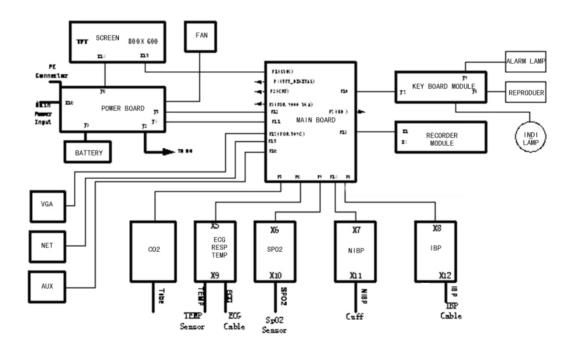


Figure 2-2 Functional structure of the DPM4

The DPM4 PCB connection is shown in the following figure.

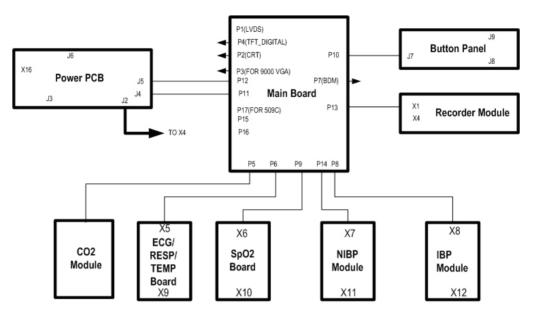


Figure 2-3 PCB connection

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

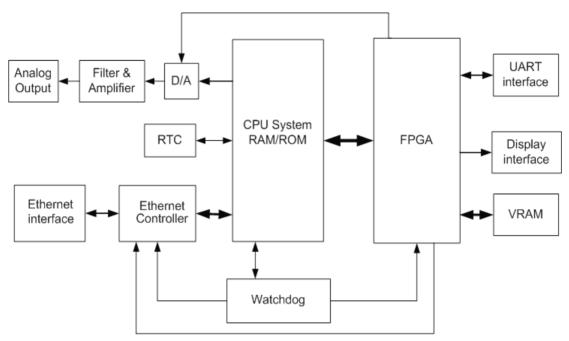


Figure 2-4 Working principle of the main board

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

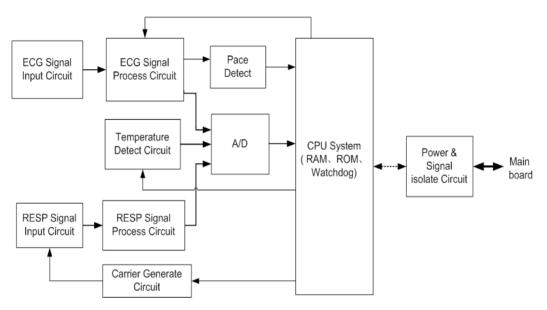


Figure 2-5 Working principle of the ECG/RESP/TEMP module

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 IBP Module

2.2.3.1 General

This module provides the function of measuring Invasive Blood Pressure (IBP).

2.2.3.2 Principle diagram

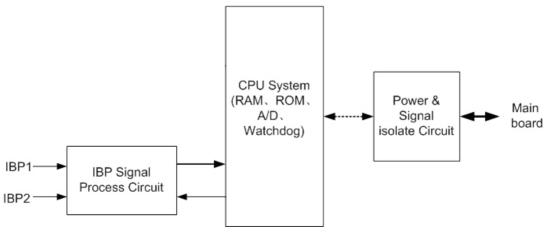


Figure 2-6 Working principle of the IBP module

2.2.3.3 Principle

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

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 CPU 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 SpO₂ Module

2.2.4.1 General

This module provides the function of measuring the Pulse Oxygen Saturation (SPO₂).

2.2.4.2 Principle diagram

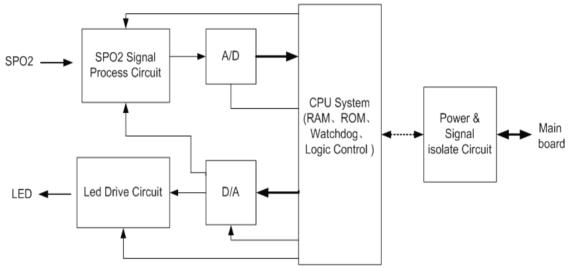


Figure 2-7 Working principle of the SpO2 module

2.2.4.3 Principle

The SpO2 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 SpO₂ parameter;
- Implementing the communication with the CPU 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 CPU 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

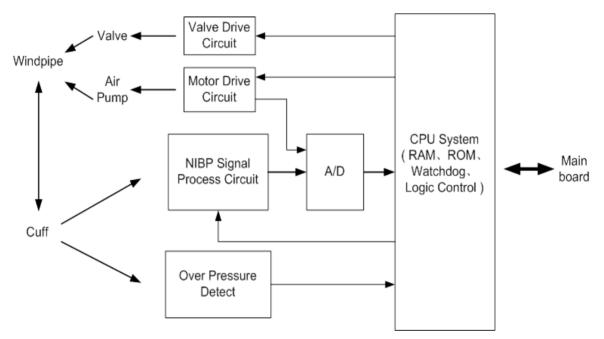


Figure 2-8 Working principle of the NIBP module

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 CPU 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

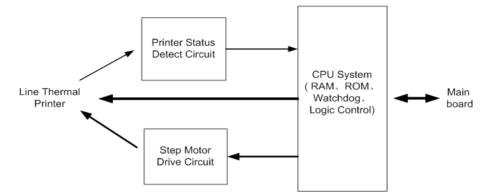


Figure 2-9 Working principle of the recorder module

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 CPU 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

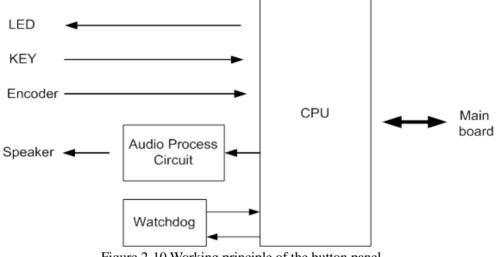


Figure 2-10 Working principle of the button panel

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 CPU 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

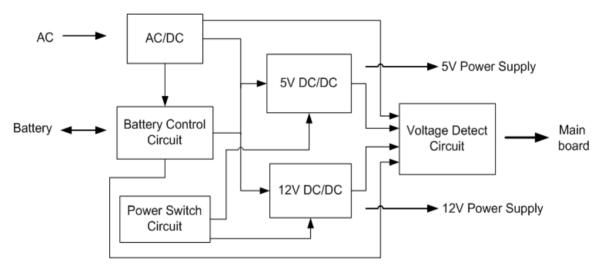


Figure 2-11 Working principle of the power PCB

2.2.8.3 Principle

This module can convert 220V AC/12V DC 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

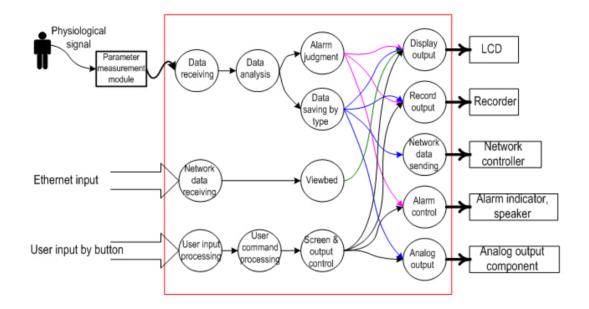


Figure 2-12 System function

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.

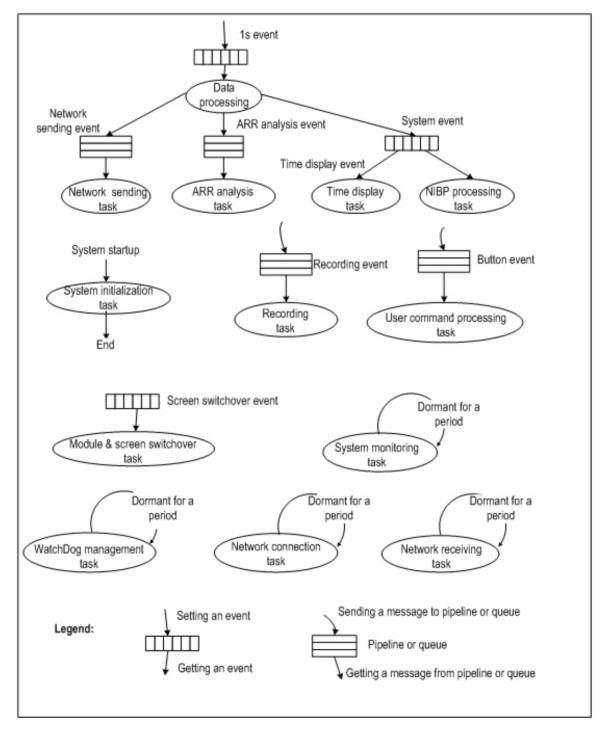
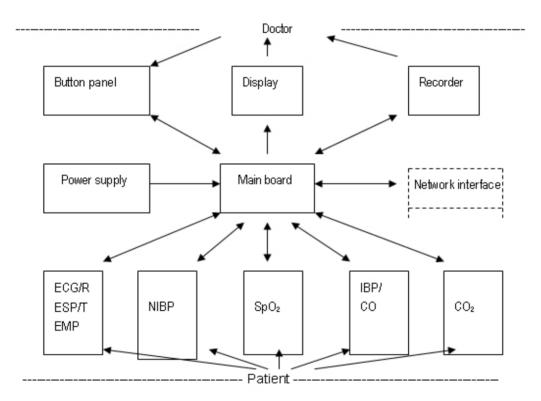


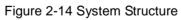
Figure 2-13 System task

2.4 System Parameter

2.4.1 General

For the DPM4 patient monitor, 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 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 DPM4 patient monitor 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, CAL

- 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 DPM4 patient monitor 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 SpO2

The SpO2 value is obtained through the pulse waves of the finger tips based on specific algorithm and clinical data. The SpO2 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 SpO2 module is involved in four parts: SpO2 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 CO2

The CO2 module works based on the infrared spectrum absorption principle. The sidestream CO2 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. In the sidestream mode, the deflation rate can be set to 100ml/min, 150ml/min or 200ml/min according to the patient situation. When the CO2 measurement is not being conducted, the sidestream deflation pump and the infrared source are expected to be shut down, thus to extend the service life and reduce the power consumption of the module.

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	Sidestream, Microstream CO2: ECG/RESP/TEMP/SpO2/NIBP/IBP:	BF (defibrillation proof) 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

	0 to 40°C		
Operating temperature	$5 \text{ to } 35^{\circ}\text{C}$ (With Sidestream CO2 module)		
	$5 \text{ to } 35^{\circ}\text{C}$ (With Microstream CO2 module)		
Operating humidity	15 to 95%, noncondensing		
	-500 to 4600 m (-1640 to 15092 feet)		
Operating altitude	-305 to 3014 m (-1000 to 9889 feet) (with CO2, Masimo or		
	Nellcor SpO2 module)		
Storage temperature	-20 to 60°C		
Storage humidity	10 to 95%, noncondensing		
Storage and transportation altitude	-500 to 13100 m (-1640 to 42979 feet)		
	-305 to 6096 m (-1000 to 20000 feet) (with CO2, Masimo or		
	Nellcor SpO2 module)		

AC Power Supply Specifications		
Input voltage	100 to 240 V \sim	
Current	1.1A to 0.5A	
Frequency	50/60 Hz	
Fuse	T 3.15 A, 250 V	
Internal battery		
Number of batteries	1	
Battery type	Sealed lead-acid battery or lithium-ion battery	
Time to shutdown	>5 min (after the first low-power alarm)	
Sealed lead-acid batter	y	
Nominal voltage	12 VDC	
Capacity	2.3 Ah	
Operating time	75 minutes typical when powered by a new fully-charged battery (25°C, ECG, SpO2, NIBP measurement per 15 minutes).	
Charge time	6 hours maximum (in the running status or standby mode)	
Lithium battery		
Nominal voltage	11.1 VDC	
Capacity	4.4 Ah	
Operating time	180 minutes typical when powered by a new fully-charged battery (25°C, ECG, SpO2, NIBP measurement per 15 minutes).	
Charge time	6.5 hours maximum (in the running status or standby mode)	

3.3 Power Source Specifications

3.4 Hardware Specifications

Physical		
Size	$261 \times 240 \times 171$ mm (width×height×depth)	
Weight	< 5 kg (With no accessory and battery)	
Display		
Туре	Color TFT LCD	
Size	8.4 inches (diagonal)	
Resolution	800×600 pixels	
Recorder		
Туре	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	20 m	
Recording rate	25 mm/s, 50 mm/s	
Recorded waveforms	3	
LED indicator		
Alarm indicator	1 (yellow and red)	
AC power indicator	1 (green)	
Battery indicator	1 (green)	
Audio indicator		
Speaker	Giving audio alarms (45 to 85 dB), keypad tones, and heartbeat/pulse tone.	
Speaker	Supporting PITCH TONE and multi-level volume.	
	Audio alarms comply with EN 60601-1-8 and IEC60601-1-8.	
Connectors		
Power supply	1 AC power connector	
Parameter	ECG, RESP, TEMP, SpO2, NIBP, IBP, CO2	
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

Standards	IEEE 802.11b, Wi-Fi compatible						
Frequency range	2.412 to 2.462GHz						
	China	America	Canada	Europe	Spain	France	Japan
Operating channel	1 to 11				10, 11		2
	For other country, please refer to your local law.						
Safe distance	10m (a circle centering AP with the diameter of 10m)						
Maximum data rate	11Mbps						

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				
	Diagnostic mode:	0.05 to 100 Hz (812A module)		
Bandwidth (-3dB; reference		0.05 to 150 Hz (M08A module)		
frequency: 10Hz)	Monitor mode:	0.5 to 40 Hz		
	Surgery mode:	1 to 20 Hz		
Maximum propagation delay	25 ms (In DIAGNOSTIC mode, NOTCH is OFF)			
Sensitivity	$1 \text{ V/mV} \pm 5\%$			
PACE rejection/enhancement	No pace rejection or enhancement			

IBP analog output	
Bandwidth	0 to 12.5 Hz (-3 dB, reference frequency: 1 Hz)
Maximum propagation Delay	55 ms (the filter function is disabled)
Sensitivity	1 V/100 mmHg ±5%
Nurse call output	
Driver	Relay
Electrical specifications	≤60W, ≤2A, ≤36VDC, ≤25VAC
Conducting resistance	< 1Ω
Isolation voltage	> 1500 VAC
Signal type	Normally open or normally closed, selectable
Defibrillator synchronization p	pulse
Maximum time delay	35 ms (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	< 3 ms
VGA	
Connector type	15-PIN D-sub socket
Signal	RGB: 0.7 Vp-p/75Ω;
	Horizontal/vertical synchronization: TTL level

3.8 ECG Specifications

Mindray DS Software Package

Lead naming style	AHA, EURO	
Lead fault	The lead resistance is no greater than 51 k Ω and it is in parallel with a 0.047 μ F capacitor, it will not cause a lead fault condition. For 3/5-lead, differential offsets $\leq \pm 300$ mV, it will not cause a lead fault condition.	
Sensitivity selection	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2) and AUTO	
Sweep speed	12.5 mm/s, 25 mm/s, 50 mm/s	
Bandwidth (-3 dB)	Diagnostic mode:0.05 to 100 Hz (812A module)0.05 to 150 Hz (M08A module)	

	Monitor mode:	0.5 to 40 Hz		
	Surgery mode:	1 to 20 Hz		
	Diagnostic mode:	≥90 dB		
Common mode	Monitor mode:	≥105 dB		
rejection	Surgery mode:	≥105 dB		
	(The notch filter is turned	off.)		
50/60Hz Notch	The monitor provides soft	ware filtering against the 50/60HZ		
Filtering	industrial frequency.			
	In monitor and surgery mo	odes, the 50/60HZ filter will be turned on		
	automatically.			
	In diagnostic mode, the 50	0/60HZ filter will be turned off.		
Input offset current	$\leq 0.1 \mu A$ (except currents to	o drive leads)		
Differential input impedance	$\geq 5M\Omega$			
Input signal range	±8mV (peak-to-peak value	e)		
Accuracy of input	Methods A and D were us	ed to establish overall system error and		
signal reproduction	frequency response accord	ling to EC11.		
Auxiliary current	Active electrode: $< 0.1 \ \mu A$			
(Leads off detection)	Reference electrode: $< 1 \ \mu A$			
Patient leakage current	< 10uA			
Recovery time after defibrillation	< 5s			
Calibration signal	1 mV (peak-to-peak value), precision: ±5%			
ESU protection	Incision mode: 300W			
	Congelation mode: 100W			
	Restore time: ≤10s			
	The monitor complies wit	h the requirements of ANSI/AAMI EC13		
	Section 4.2.9.14.			
ESU noise control	The monitor uses the ECC	b leads meeting the requirements of AAMI;		
	based on the ECG baseline, the peak noise $\leq 2mV$			
	The monitor complies wit	h the test method in EC13 Section 5.2.9.14.		
HR				
	Neonate:	15 to 350 bpm		
Measurement range	Pediatric:	15 to 350 bpm		
	Adult:	15 to 300 bpm		
Resolution	1 bpm			

Precision	± 1 bpm or $\pm 1\%$, whichever is greater.
Trigger threshold level	200 µV (lead II)
Trigger indication	There will be an audible beep on every beat captured.
Heart Rate Averaging	The average Heart Rate is computed in line with the ANSI/AAMI EC13 Section 4.1.2.1 d) as follows:
	When the last 3 R-to-R intervals > 1200 ms, compute the average
	of the last 4 R-to-R intervals; otherwise, compute the average of
	the last 12 R-to-R intervals minus the longest and shortest intervals.
	The displayed Heart Rate is updated once per second.
Heart Rate Meter Accuracy and Response to Irregular Rhythm	When tested in accordance with the ANSI/AAMI EC13 Section 4.1.2.1 e), the indicated heart rate after a 20 second stabilization period is:
	Figure 3a (Ventricular Bigeminy) -80±1 bpm
	Figure 3b (Slow Alternating Ventricular Bigeminy) -60±1 bpm
	Figure 3c (Rapid Alternating Ventricular Bigeminy) -120±1bpm
	Figure 3d (Bi-directional Systoles) -90±2 bpm
Desmanas time to beaut note	Meets the requirement of ANSI/AAMI EC13 Section 4.1.2.1 f).
Response time to heart rate changes	Less than 11 sec for a step increase from 80 to 120 BPM
changes	Less than 11 sec for a step decrease from 80 to 40 BPM
	When tested in accordance with ANSI/AAMI EC13 Section 4.1.2.1 g, the response time is as follows:
	Figure 4ah – range: 15.7 to 19.2s, average: 17.4s
Response time of	4a – range: 5.7 to 8.5s, average: 7.5s
tachycardia alarm	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
Tall T-Wave Rejection	When tested in accordance with the ANSI/AAMI EC13 Section 4.1.2.1 c), the heart rate meter will reject all T-waves with amplitudes less than 1.2 mV, 100 ms QRS, a T wave duration of 180ms and a Q-T interval of 350 ms.

Pace pulse			
	Pace pulses meeting the following conditions are marked by the PACE indicator.		
Pulse indicator	Amplitude:	±4 to ±700 mV (3/5-lead)	
	Width:	0.1 to 2 ms	
	Rise time:	10 to 100 µs	
	nce with the ANSI/AAMI EC13 Sections		
	4.1.4.1 and 4.1.4.3, the heart rate meter rejects all pulses meeting		
	the following conditions.		
Pulse rejection	Amplitude:	± 2 to ± 700 mV	
	Width:	0.1 to 2 ms	
	Rise time:	10 to 100 µs	
	Min. input slew rate:	20 V/s RTI	
ST segment measurement			
Measurement range	-2.0 to +2.0 mV		
Precision	-0.8 to +0.8 mV: ± 0.02 mV or $\pm 10\%$, whichever is greater		
FIECISIOII	Beyond this range: Undefined		
Update period	10 s		

Mortara Software Package

Lead naming style	AHA, EURO		
Lead fault	The lead resistance is no greater than 51 k Ω and it is in parallel with a 0.047 μ F capacitor, it will not cause a lead fault condition. For 3/5-lead, differential offsets $\leq \pm 300$ mV, it will not cause a lead fault condition. For 12-lead, differential offsets $\leq \pm 500$ mV, it will not cause a lead fault condition.		
Sensitivity selection	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2) and AUTO		
Sweep speed	12.5 mm/s, 25 mm/s, 50 mm/s		
Bandwidth (-3 dB)	Diagnostic mode: Monitor mode: Surgery mode:	0.05 to 150 Hz (M08A module) 0.5 to 40 Hz 1 to 20 Hz	

	Diagnostic mode: ≥90 dB		
Common mode rejection	Monitor mode: $\geq 105 \text{ dB}$		
	Surgery mode: $\geq 105 \text{ dB}$		
	(The notch filter is turned off.)		
50/60Hz Notch Filtering	The monitor provides software filtering against the 50/60HZ		
	industrial frequency.		
	In monitor and surgery modes, the 50/60HZ filter will be turned on automatically.		
	In diagnostic mode, the 50/60HZ filter will be turned off.		
Input offset current	$\leq 0.1 \mu A$ (except currents to drive leads)		
Differential input impedance	$\geq 5M\Omega$		
Input signal range	±8mV (peak-to-peak value)		
Accuracy of input signal reproduction	Methods A and D were used to establish overall system error and frequency response according to EC11.		
Auxiliary current (Leads off	Active electrode: $< 0.1 \mu\text{A}$		
detection)	Reference electrode: $< 1 \ \mu A$		
Patient leakage current	< 10uA		
Recovery time after defibrillation	< 5s		
Calibration signal	1 mV (peak-to-peak value), precision: ±5%		
ESU protection	Incision mode: 300W		
	Congelation mode: 100W		
	Restore time: ≤10s		
	The monitor complies with the requirements of ANSI/AAMI EC13 Section 4.2.9.14.		
ESU noise control	The monitor uses the ECG leads meeting the requirements of AAMI; based on the ECG baseline, the peak noise $\leq 2 \text{ mV}$		
	The monitor complies with the test method in EC13 Section $5.2.9.14$.		
HR	1		
	Neonate: 15 to 350 bpm		
Measurement range	Pediatric: 15 to 350 bpm		
č	Adult: 15 to 300 bpm		
Resolution	1 bpm		
Precision	± 1 bpm or $\pm 1\%$, whichever is greater.		
Trigger threshold level	$200 \mu\text{V}$ (lead II)		

Heart Rate Averaging Heart Rate Averaging The EC1 The RR- usin used The Heart Rate Meter Accuracy and Response to Irregular Rhythm Period Figur Figur Figur Figur Figur	e displayed Heart Rate is updated once per second. en tested in accordance with the ANSI/AAMI EC13 Section 2.1 e), the indicated heart rate after a 20 second stabilization iod is: ure 3a (Ventricular Bigeminy) -80±1 bpm ure 3b (Slow Alternating Ventricular Bigeminy) -60±1 bpm ure 3c (Rapid Alternating Ventricular Bigeminy) -120±1 bpm ure 3d (Bi-directional Systoles) -90±2 bpm ets the requirement of ANSI/AAMI EC13 Section 4.1.2.1 f).		
EC1 The RR- usin used The Heart Rate Meter Accuracy and Response to Irregular Rhythm EFigu Figu Figu Figu	 13 Section 4.1.2.1 d) as follows: average heart rate is calculated on the basis of the mean interval of the last 16 beats, unless the heart rate calculated interval of the last 16 beats, unless the heart rate calculated interval of the last 16 beats, unless the heart rate calculated interval of the last 16 beats, unless the heart rate calculated interval of the last 16 beats, unless the heart rate calculated interval of the last 16 beats, unless the heart rate calculated interval of the last 16 beats, unless the heart rate calculated interval of the last 16 beats, unless the heart rate calculated interval of the last 16 beats, unless the heart rate calculated interval of the last 4 beats is less than or equal to 48, then this rate is interval of the last 4 beats is less than or equal to 48, then this rate is interval of the last 4 beats is less than or equal to 48, then this rate is interval of the last 4 beats is less than or equal to 48, then this rate is interval of the last 4 beats is less than or equal to 48, then this rate is interval of the last 4 beats is less than or equal to 48, then this rate is interval of the last 4 beats is less than or equal to 48, then this rate is interval of the last 4 beats is less than or equal to 48, then this rate is interval of the last 4 beats is less the requirement of ANSI/AAMI EC13 Section 4.1.2.1 f). 		
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Figu	ure 3d (Bi-directional Systoles) -90±2 bpm ets the requirement of ANSI/AAMI EC13 Section 4.1.2.1 f).		
	ets the requirement of ANSI/AAMI EC13 Section 4.1.2.1 f).		
Mee			
Despense time to heart rote	a than 11 and for a star increase from 90 to 100 DDM		
Response time to heart rate changes	Less than 11 sec for a step increase from 80 to 120 BPM		
Less	Less than 11 sec for a step decrease from 80 to 40 BPM		
Whe	When tested in accordance with ANSI/AAMI EC13 Section		
4.1.2	4.1.2.1 g, the response time is as follows.		
Figu	ure 4ah – range: 4.30 to 5.34s, average: 4.75s		
Response time of tachycardia 4a –	- range: 3.94 to 5.92s, average: 4.69s		
alarm 4ad	- range: 4.28 to 5.18s, average: 4.78s		
Figu	ure 4bh – range: 3.57 to 8.22s, average: 4.83s		
4b	- range: 3.09 to 4.11s, average: 3.64s		
4bd	- range: 3.20 to 4.52s, average: 4.09s		
Tall T-Wave Rejection Whe	en tested in accordance with the ANSI/AAMI EC13 Section		
4.1.2	2.1 c), the heart rate meter will reject all T-waves with		
-	amplitudes less than 1.2 mV, 100 ms QRS, a T wave duration of		
1801	ms and a Q-T interval of 350 ms.		
Pace pulse			
	e pulses meeting the following conditions are marked by the CE indicator.		
Amp	plitude: ± 4 to ± 700 mV (3/5-lead)		
Pulse indicator	± 2 to ± 700 mV (12-lead)		
Wid	th: 0.1 to 2 ms		
Rise	e time: 10 to 100 μs		

	When tested in accordance with the ANSI/AAMI EC13 Sections 4.1.4.1 and 4.1.4.3, the heart rate meter rejects all pulses meeting the following conditions.		
Pulse rejection	Amplitude:	± 2 to ± 700 mV	
	Width:	0.1 to 2 ms	
	Rise time:	10 to 100 µs	
	Min. input slew rate:	20 V/s RTI	
ST segment measurement			
Measurement range	-2.0 to +2.0 mV		
Drasision	-0.8 to +0.8 mV: ± 0.02 mV or $\pm 10\%$, whichever is greater		
Precision	Beyond this range: Und	lefined	
Update period	Updated every 16 valid beats		

3.9 RESP Specifications

Measurement technique	Thoracic impedance		
Lead	Optional: lead I and lead II; default lead II		
Respiration excitation waveform	< 300 µA, sinusoid, 62.8 kHz (±10%)		
Respiration impedance test range	0.3 to 3 Ω		
Baseline impedance range	200 to 2500 Ω (using a	an ECG cable with $1k\Omega$ resistance)	
Differential input impedance	> 2.5 MΩ		
Linear Signal Range	3 Ω p-p minimum		
Bandwidth	0.2 to 2 Hz (-3 dB)		
Sweep speed	6.25 mm/s, 12.5 mm/s, 25 mm/s		
RR			
Maaaaaa	Adult:	0 to 120 BrPM	
Measurement range	Pediatric/neonate:	0 to 150 BrPM	
Resolution	1 BrPM		
Precision	7 to 150 BrPM:	± 2 BrPM or $\pm 2\%$, whichever is greater.	
	0 to 6 BrPM:	Undefined.	
Apnea alarm delay	10 to 40 s		

3.10 SpO₂ Specifications

Mindray DS SpO₂ Module

All SpO₂ sensors specified in the section *Mindray DS SpO₂ Accessories* meets the following specifications when used with Mindray DS SpO₂ module.

SpO ₂			
Measurement range	0 to 100%		
Resolution	1%		
	70 to 100%:	± 2 % (adult/pediatric, non-motion conditions)	
Precision	70 to 100%:	$\pm 3\%$ (neonate, non-motion conditions)*	
	0% to 69%:	Undefined.	
Refreshing rate	1 s		
	7 s (When the ser	7 s (When the sensitivity is set to High)	
Averaging time	9 s (When the sensitivity is set to Medium)		
	11 s (When the sensitivity is set to Low)		
PR			
Measurement range	20 to 254 bpm		
Resolution	1 bpm		
Precision	±3 bpm (non-motion conditions)		
Refreshing rate	1 s		

* A study was performed to validate the accuracy of this monitor with 520N SpO₂ sensor. Totally 122 neonates (65 male & 57 female) aged from 1 day to 30 days with a gestation age of 22 weeks to full term were involved in this study. The statistical analysis of the 200 pairs of data over the range of 72% to 100% SaO₂ of this study shows that the accuracy (Arms) is 2.47 digits, which is within the stated accuracy specification. Another study performed on adult subjects also shows the effectiveness.

This monitor with 520N SpO₂ sensor was validated on adult subjects (1.62% Arms) and that actual performance in the neonatal population was observed.

Masimo SpO₂ Module

All SpO₂ sensors specified in the section *Masimo SpO2 Accessories* meets the following specifications when used with Masimo SpO₂ module.

SpO2			
Measurement range	1 to 100%		
Resolution	1%		
	70 to 100%:	±2% (adult/pediatric, non-motion conditions)	
Precision	70 to 100%:	±3% (neonate, non-motion conditions)	
Precision	70 to 100%:	±3% (in motion conditions)	
	0% to 69%:	Undefined.	
Refreshing rate	1 s		
Averaging time	2-4 s, 4-6 s, 8 s, 10 s, 12 s, 14 s, 16 s		
I	Pulse amplitude: >0.02%		
Low perfusion conditions	Light penetration: >5%		
Low perfusion accuracy	±2%		
PR			
Measurement range	25 to 240 bpm		
Resolution	1 bpm		
Duraisian	±3 bpm (non-motion conditions)		
Precision	±5 bpm (in motion conditions)		
Refreshing rate	1 s		

Nellcor SpO₂ Module

All SpO₂ sensors specified in the section *Nellcor SpO2 Accessories* meets the following specifications when used with Nellcor SpO₂ module.

	Sensor	Range	Precision*
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST	70 to 100% 0% to 69%	±2% Undefined
SpO2 measurement range and precision	OxiCliq A, OxiCliq N, OxiCliq P, OxiCliq I	70 to 100%	±2.5% Undefined
	D-YS, DS-100A, OXI-A/N and OXI-P/I	70 to 100% 0% to 69%	±3% Undefined

	MAY B D VSE and D VSDD	70 to 100%	±3.5%
	MAX-R, D-YSE and D-YSPD 0% to 69%		Undefined
PR measurement range and 20 to 250 bpm: ±3 bpm			
precision 251 to 300 bpm: Undefined			
Refreshing rate	Refreshing rate 1 s		
Averaging time 8 s, 16 s			
*: When sensors are used on neonatal subjects as recommended, the specified precision range is			
increased by $\pm 1\%$, to account for the theoretical effect on oximeter measurements of fetal			
hemoglobin in neonatal blood.			

3.11 NIBP Specifications

Measurement technique	Auto oscillation			
Displayed parameters	Systolic pressure, diastolic pressure, mean pressure and PR			
Mode of operation	Manual, auto and continuous			
Measurement interval in auto mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes			
Measurement time in continuous mode	5 minutes			
	mmHg	Adult	Pediatric	Neonate
Measurement range in	Systolic pressure	40 to 270	40 to 200	40 to 135
normal mode	Diastolic pressure	10 to 210	10 to 150	10 to 100
	Mean pressure	20 to 230	20 to 165	20 to 110
Measurement precision	Maximum average error: ±5mmHg Maximum standard deviation: 8mmHg			
Resolution	1mmHg			
Static pressure measurement range	0 to 300mmHg			
Static accuracy	± 3 mmHg			
Over management and a stick	Adult: 2	97±3 mmHg		
Over-pressure protection by software	Pediatric: 2	40±3 mmHg		
	Neonate: 1	leonate: 147±3 mmHg		
Over-pressure protection	Adult: 3	30 mmHg		
by hardware	Pediatric: 330 mmHg			
y	Neonate: 1	65 mmHg		

	Adult:	178±5 mmHg
Default start pressure	Pediatric:	133±10 mmHg
	Neonate:	67±5 mmHg
PR from NIBP		
Measurement range	40 to 240 bpm	
Precision	± 3 bpm or $\pm 3\%$, whichever is greater	
Resolution	1 bpm	

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 readings	Systolic, diastolic, mean p	ressures and PR
Pressure labels	ART, PA, CVP, RAP, LAP	P, ICP, P1 and P2
Linear input range	will be -50 to + 300 mmHg, after zeroing.	
	ART	0 to 300 mmHg
Maggurantant	РА	-6 to 120 mmHg
Measurement range	CVP/RAP/LAP/ICP	-10 to 40 mmHg
	P1/P2	-50 to 300 mmHg
Resolution	1 mmHg	
Precision	$\pm 2\%$ or ± 1 mmHg, whichever is greater	

Excitation	will be 5 Volts DC, $\pm 2\%$ Minimum load resistance will be 300 Ω per transducer.
Update period	18
Zero offset range	± 200 mmHg
Zero accuracy	± 1 mmHg
Noise	<0.5 mmHg RTI, DC to 12.5 Hz, 300 Ω source impedance.
Drift	$<0.15 \text{ mmHg/}^{\circ}\text{C}$; will not exceed $\pm 1 \text{ mmHg in 24 hours.}$
Frequency Response	DC-12.5Hz ±1 Hz, -3db
PR from IBP	
Measurement range	25 to 350 bpm
Precision	25 to 350 bpm: ± 1 or $\pm 1\%$, whichever is greater.
Resolution	1 bpm

Pressure transducer	
Excitement voltage	5 VDC, ±2%
Sensitivity	5 uV/V/mmHg
Impedance range	300 to 3000Ω
Volume displacement (ABBOTT)	<0.04 mm3 /100 mmHg

3.14 CO₂ Specifications

Measurement technique	Infrared absorption technique
Displayed parameter	EtCO2, FiCO2, Respiration Rate
CO2 function	Meet the requirements of EN ISO 21647/ISO 21647 and ISO9918.

Mindray DS CO₂ Specifications

CO ₂ measurement range	0 to 99mmHg		
	0 to 40 mmHg:	±2 mmHg	
Precision*	41 to 76 mmHg:	$\pm 5\%$	
	77 to 99 mmHg:	±10%	
Resolution	1 mmHg		

Drift	meet the requirement of accurancy in 6 hours	
Sample flow rate	70, 100 ml/min	
Precision of deflation rate	$\pm 15\%$ or 15 ml/min, whichever is great	
Start-up time of CO ₂ module	< 1min, the module enters the warming up status after the startup. One minute 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	When measured with a neonatal watertrap and a 2.5 m-long neonatal sampling line: <3.5 s @ 100 ml/min <4 s @ 70 ml/min When measured with an adult watertrap and a 2.5 m-long adult sampling line: <5.5 s @ 100 ml/min <7 s @ 70 ml/min	
Delay time	When measured with a neonatal watertrap and a 2.5m-long neonatal sampling line: <3 s @ 100 ml/min <3.5 s @ 70 ml/min When measured with an adult watertrap and a 2.5m-long adult sampling line: <5 s @ 100 ml/min <6.5 s @ 70 ml/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: 750 mmHg to 760 mmHg; room temperature: 22° C to 28° C;

The gas under test is dry, and the balance gas is N2;

The deflation rate is 100 ml/min, the respiration rate is no greater than 50 BrPM, with a

fluctuation less than ± 3 BrPM, and the inhale interval/exhale interval is 1:2;

When the working temperature is from 15 to 25 degree, or from 50 to 55 degree, or when the breath rate is greater than 50Brpm, the measurement precision should meet the requirements of ISO21647: \pm 4mmHg (0 to 40mmHg) or \pm 12% of the reading (41 to 99 mmHg)

Oridion CO₂ Specifications

CO2 measurement range	0 to 99mmHg		
Precision*	0 to 38 mmHg:	±2 mmHg	
Precision	39 to 99 mmHg:	$\pm 5\%$ + 0.08% \times (reading - 38 mmHg)	
Drift	meet the requirement	of accurancy in 6 hours	
Resolution	Waveform:	0.1 mmHg	
Resolution	Value:	1 mmHg	
Sample flow rate	50 ^{-7.5} ₊₁₅ ml/min		
Initialization time	30 s (typical)		
Response time	2.9 s (typical)		
Delay time	2.7 s (typical)		
AwRR measurement range	0 to 150 BrPM		
ADD	0 to 70 BrPM:	±1 BrPM	
AwRR measurement precision	70 to 120 BrPM:	±2 BrPM	
precision	121 to 150 BrPM:	±3 BrPM	
Apnea alarm delay	AwRR: 10 to 40 s		
* Precision applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy complies with EN ISO 21647/ISO 21647/ISO 9918 (4 mmHg or $\pm 12\%$ of reading whichever is greater) for EtCO2 values exceeding 18 mmHg. To achieve the specified accuracies for breath			

complies with EN ISO 21647/ISO 21647/ISO 9918 (4 mmHg or $\pm 12\%$ of reading whichever is greater) for EtCO2 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 EN ISO 21647/ISO 21647/ISO 21647 Section Eleven, Part 101.

4 Disassembling/Assembling & Troubleshooting

4.1 DPM4 Disassembling/Assembling

4.1.1 Exploded View of DPM4

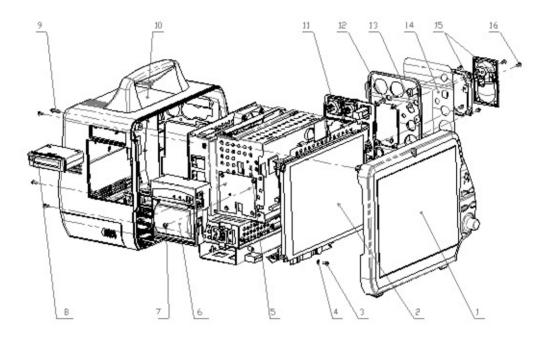


Figure 4-1 Exploded view of DPM4

NO	Material code	Part & Specification	Quantity
1	115-001437-00	Front bezel assembly	1
2	115-031392-00	Screen assembly	1
3	M04-002505	Cross-head screw M3*6	8
4	M04-000104	Elastic gasket GB93 3	2
5	8002-30-36185	Main Unit	1
6	115-031469-00	TR6F Recorder	1
7	M04-004012	Gasketed cross-head screw M3*6	2

8	8002-30-36209	CF Card assembly	1
9	M04-000305	Self-tapping screw PT3X12	2
10	8002-30-36342	Back housing assembly	1
11	8002-30-36378	Back housing assembly (supporting wireless network adapter)	1
12	8002-30-36204	Parameter connector assembly(with CO2)	1
13	M04-004015	Gasketed cross-head screw M3*8	4
14	8002-21-36169	Parameter connector panel(with CO2)	1
15	8002-20-36222	Parameter connector label(with CO2)	1
16	9211-30-87429	Water trap assembly	1
17	M04-051003	Cross-pad self-tapping screw PT2X6	6

4.1.2 DPM4 Front Bezel Assembly

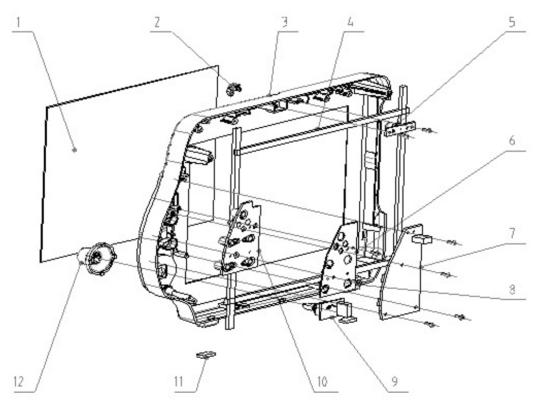
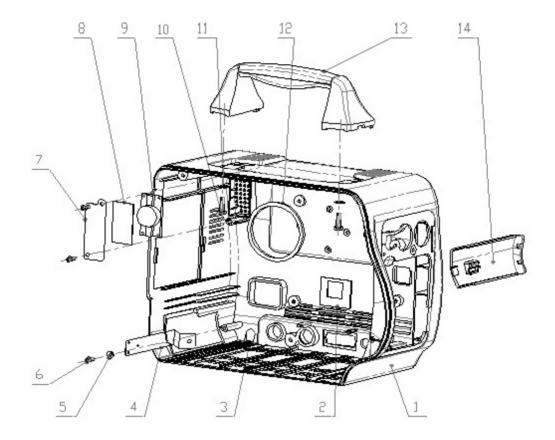


Figure 4-2 DPM4 display front bezel assembly

NO	Material code	Part & Specification	Quantity
1	8000-20-10290	Anti-glare mask	1
2	8002-20-36238	Alarm indicator mask	1
3	043-000087-00	Front bezel	1
4	8002-20-36265	Dust washer	4
5	8001-30-25667	Alarm indicator board	1
6	8000-20-10193	Key plate	1
7	8002-30-36165	Keyboard	1
8	M04-051003	Self-tapping screw PT2X6	8
9	0010-30-43089	Encoder board	1
10	8000-20-10194	Rubber button	1
11	8000-20-10220	feet	2
12	9201-20-35972	Knob	1



4.1.3 DPM4 Back Housing Assembly (Lithium Battery)

Figure 4-3 DPM4 back housing assembly

NO	Material code	Part & Specification	Quantity
1	8002-20-36167	Back housing	1
2	8000-20-10339	Sealed cushion for back housing	1
3	8000-20-10220	Feet	2
4	8002-20-36219	Battery Door bond	1
5	M04-000802	Pad GB97.1 3	1
6	M04-003105	Self-tapping screw PT3X8	3
7	8002-20-36217	Speaker press plate	1
8	8002-20-36218	Cushion for Speaker press plate	1
9	8002-21-36202	Speaker	1
10	M04-051085	Self-tapping screw PT4X14	2
11	M04-004702	Gasket GB97.1 4	2

12	8002-20-36224	Fan cushion	1
13	8002-20-36237	Handle	1
14	8002-20-36174	Battery door	1

4.1.4 Screen Assembly

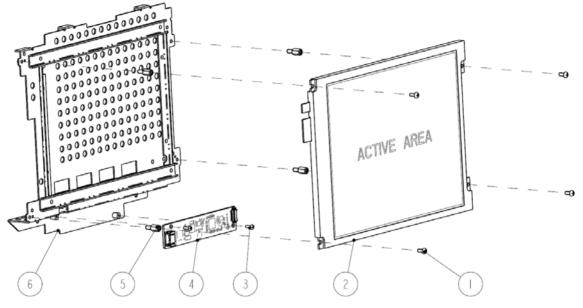


Figure 4-4 Screen assembly

NO	Material code	Part & Specification	Quantity
1	M04-051045	Cross-head screw M2.5X6	4
2	021-000166-00	LCD TFT 8.4" 800*600 3.3V LED-bl	1
3	M04-002405	Cross-head screw M2X6	2
4	051-001281-00	8.4 inch LED BACKLIGHT PCBA	1
5	8000-20-10217	Stud screw for screen	4
6	8002-20-36175	Screen supporter	1

4.1.5 Battery Connector Assembly

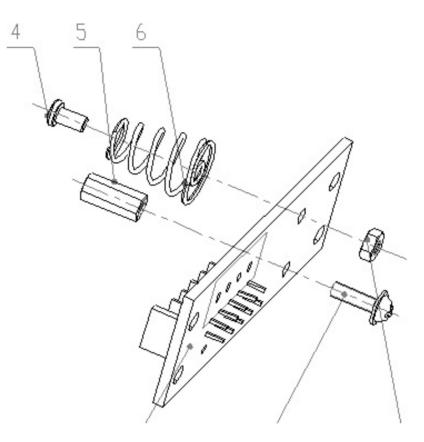


Figure 4-5 Battery Connector assembly

NO	Material code	Part & Specification	Quantity
1	M04-000301	Nut GB6170 M3	1
2	M04-004013	Gasketed cross-head screw M3X10	1
3	8002-30-36226	Lithium battery board	1
4	M04-002505	Cross-head screw GB818-85 M3X6	1
5	M04-030030	Stud M3X12	1
6	9201-20-36038	Spring	1

4.1.6 Parameter Connector Assembly

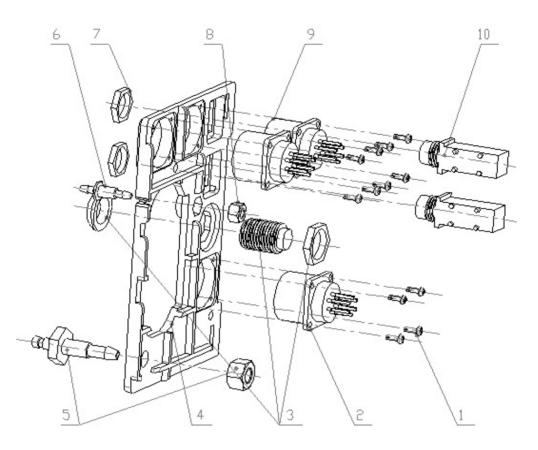


Figure 4-6 Parameter connector assembly

NO	Material code	Part & Specification	Quantity
1	M04-051003	Self-tapping screw PT2X6	12
2	0010-10-12279	ECG connector	1
3	0010-21-12306	6PIN SPO2 Cable	1
4	8002-21-36171	Panel for parameter connector(with CO2)	1
5	0010-20-12194	NIBP Connector	1
6	6200-20-11614	Exhaust	1
7	9000-20-07459	Nut for Temp connector	2
8	M04-000501	Nut GB6170 M5	1
9	6000-10-02010	IBP PROBE SOCKET	2
10	M33-109002	Temp connector	2

4.1.7 CF Card Assembly

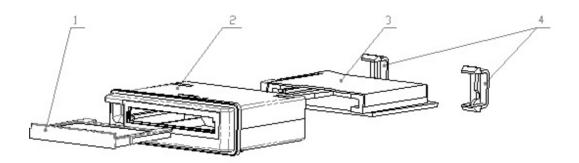


Figure 4-7 CF card assembly

NO	Material code	Part & Specification	Quantity
1	8002-20-36196	CF model card	1
2	8002-20-36172	CFcard housing	1
3	8002-30-36192	CFconnector board	1
4	8002-20-36173	CFcard housing hook	2

4.2 Troubleshooting

4.2.1 Black Screen, Startup Failure

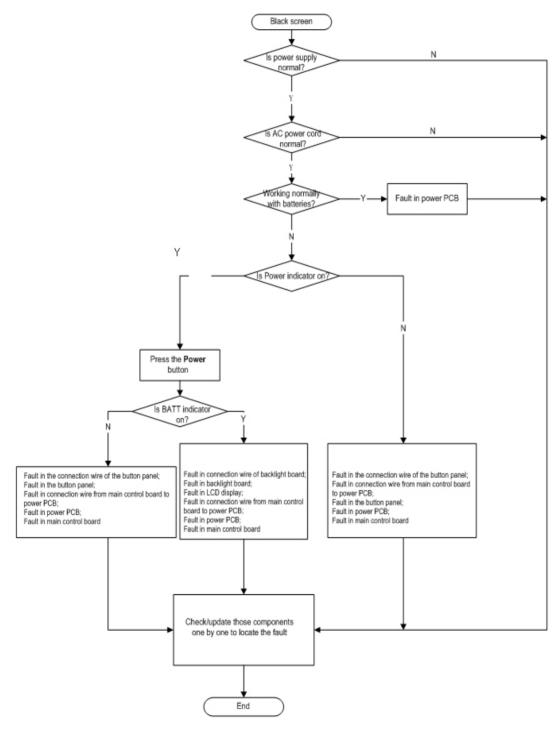


Figure 4-7 Location flow of faults causing black screen

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

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

4.2.4 No Audio Alarm

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

4.2.5 Printing Failure

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

4.2.6 Abnormal Paper Drive

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

5.1 Test Procedure

5.1.1 Connection and Checking

Connect the simulators, power supply and test fixture properly to the DPM4 patient monitor, 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 *DPM4 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, 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 $\pm 8 700$ mv, and pulse width to 0.1 ms 2 ms. 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: $2K\Omega$, 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 $35\pm0.1^{\circ}$ C, $37\pm0.1^{\circ}$ C and $39\pm0.1^{\circ}$ C.

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 $35\pm0.1^{\circ}$ C, $37\pm0.1^{\circ}$ C and $39\pm0.1^{\circ}$ C.

5.1.5 NIBP

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

- 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 DPM4 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.
- 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 DPM4 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 DPM4 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 SpO2

Select PLETH as the HR source of DPM4, 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 DPM4, 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 DPM4, 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 DPM4 should display 40±1mmHg, 100±2mmHg and 200±4mmHg.

Set the simulator output to ART wave. Then the screen of the DPM4 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 CO2

1. Test fixture

CO2 steel bottle (containing 10% CO2)

2. Test procedure

①Sidestream CO2 measurement: Set the calculation compensation of DPM4 to COMMON.

Plug the water trap to the water trap socket, connect the sampling tube with the CO2 steel bottle, and open//close the valve of the CO2 steel bottle based on the interval of 3s. The CO2 value should be the calibration gas pressure value: 76±5% nmHg. When the valve is opened permanently, the patient monitor prompts "APNEA ALARM".

Unplug the water trap. The patient monitor prompts "CO2 water trap OFF". Plug the water trap again. The prompting message disappears.

⁽²⁾When the measured value exceeds the high limit of CO2, the patient monitor prompts "CO2 too high" on the main screen. When the measured value is lower than the low limit, the patient monitor prompts "CO2 too low".

5.1.9 Watertrap

- Connect the airway and block the inlet of the sampling line with your finger. Check if the message CO2 SAMPLE LINE ABNORMAL is displayed and the current pump rate in the CO2 USER MAINTAIN menu drops below 5 ml/min. If yes, it indicates the airway is normal. Otherwise, proceed with step 2.
- 2. Remove the sampling line and block the inlet of the watertrap with your finger. Check if the message CO2 SAMPLE LINE ABNORMAL is displayed and the current pump rate in the CO2 USER MAINTAIN menu drops below 5 ml/min. If yes, it indicates there may be a problem with the connection between the sampling line and watertrap or a leakage in the sampling line. Otherwise, proceed with step 3.
- 3. Remove the watertrap and block the two inlets in the receptacle for the watertrap. Check if the message CO2 SAMPLE LINE ABNORMAL is displayed and the current pump rate in the CO2 USER MAINTAIN menu drops below 5 ml/min. If yes, it indicates there may be a problem with the connection between the watertrap and its receptacle or a leakage in the watertrap. Otherwise, there may be a problem with the internal airway in the monitor. The internal airway has two parts, one part in the receptacle and the other part in the module. Block the small tubes between the watertrap receptacle and module with your fingers and check if the message CO2 SAMPLE LINE ABNORMAL is displayed and the current pump

rate in the CO2 USER MAINTAIN menu drops below 5 ml/min. If yes, it indicates there is a problem with the airway in the receptacle. Replace the receptacle. Otherwise, replace the module.

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.

5.1.11 Power Supply

When the patient monitor is supplied with the external AC power, the Battery indicator becomes ON. When it is disconnected from the external AC power, the Battery 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.

5.1.12 Clock

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

5.1.13 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

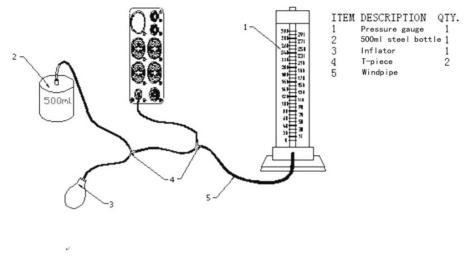


Figure 5-1 NIBP Calibration

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 \pm 3mmHg (\pm 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 \pm 3mmHg (\pm 0.4kPa).

5.3 IBP Calibration

5.3.1 IBP Transducer Zero

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

IBP PRESSURE ZERO		
Being Prepared, press ZERO key!		
CH1 ZERO	00-00-0000 00:00:00	
CH2 ZERO	00-00-0000 00:00:00	
Back to the upper menu.		
EXIT		

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.

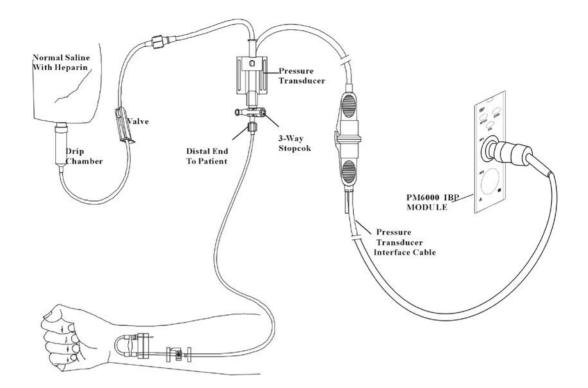


Figure 5-3 IBP Zero

IBP Calibration

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

IBP PRESSURE CALIBRATE		
CH1 CAL VALUE 200 🗢 CALIBRATE		
200 (200) 08-10-2001 00:07:00		
CH2 CAL VALUE 200 🗢 CALIBRATE		
200 (144) 08-10-2001 00:00:00		
Back to the upper menu.		
EXIT		

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 DPM4:

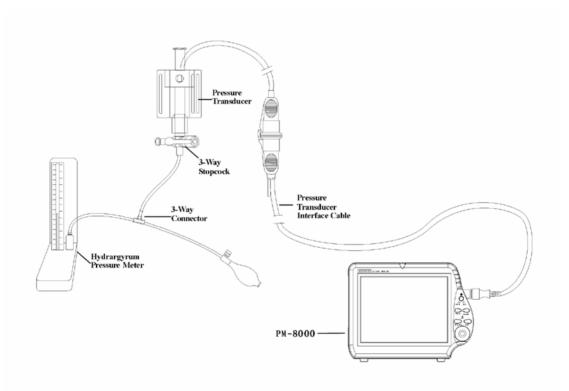


Figure 5-5 IBP Calibration

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 DPM4 Material List

Material Code	Name & Specification
115-001437-00	Front bezel assembly
043-000087-00	Front bezel
8002-30-36342	Back housing assembly
8002-30-36378	Back housing assembly (supporting wireless network adapter)
8002-20-36167-51	Back housing
8002-20-36167-52	Back housing (supporting wireless network adapter)
021-000166-00	TFT Screen 8.4"(800X600)
009-005261-00	Cable MB to LCD
009-005260-00	Cable BP to LCD
8002-30-36209	CF Card Module
9210-30-30150	9210 Host Board
051-000007-00	812B ECG module
630D-30-09121	630D NIBP module
051-000058-00	9008 SpO2 module
M03A-30-26050	IBP board
115-031392-00	Screen assembly
8002-30-36165	Keyboard
0010-30-43089	Encoder board
8001-30-25667	Alarm indicators board
8002-20-36175	Screen supporter
8002-20-36195	Fan
115-031469-00	TR6F Recorder
8000-20-10290	Anti-glare mask
9211-30-87429	Water trap assembly
0000-10-11020	Inverter TPI-01-0207-M
8002-30-36204	Parameter connector assembly
8002-30-36155	Power board
9201-30-35910	Battery charger board

FOR YOUR NOTES

6.1 Maintenance

6.1.1 Checking 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 DS 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 DS engineers. The local office of Mindray DS 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 patient monitor 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.

- Do not use strong solvent, such as acetone;
- Most cleaning agents must be diluted before being used, so conduct dilution under the instruction of manufacturers;
- Do not use any erosive material (such as steel wool or polishing agent);
- Prevent the ingress of any liquid to the enclosure and any part of the device;
- 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 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;

For the disinfections of ECG leads, SpO₂ sensor, blood pressure cuffs and temperature sensor, refer to relevant chapters in *Operation Manual*.

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

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