

Patient Monitor

Service Manual



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NOTE

• This equipment must be operated by skilled/trained medical professionals.

riangleWARNING

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.
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- 2. Freight policy: The customer is responsible for freight charges when this product is shipped to Mindray DS for service (this includes customs charges).
- 3. Return address: Please send the part(s) or equipment to the address offered by the Customer Service department

Company Contact

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Safety Precautions

1. Meaning of Signal Words

In this service manual, the signal words \(\text{\text{MARNING}}, \(\text{\text{CAUTION}} \) and NOTE are used to indicate safety and other important instructions The signal words and their meanings are defined as follows.

| Signal word | Meaning | |
|------------------|---|--|
| ≜ WARNING | 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 |
|----------|--|
| * | Type-BF applied part |
| <u> </u> | "Attention" (Refer to the operation manual.) |

Safety Precautions

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

MWARNING

- 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.

ACAUTION

- 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



See instructions



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 About the Product

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

SpO₂ Pulse Oxygen Saturation (SpO₂), Pulse Rate (PR)

SpO₂ Plethysmogram

NIBP Systolic pressure (NS), diastolic pressure (ND), mean pressure

(NM)

TEMP T1, T2, TD

IBP CH1: SYS, DIA

CH2: SYS, DIA

IBP waveform

CO₂ End-tidal carbon dioxide (EtCO₂)

Inspired minimum CO₂ (InsCO₂)

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 Principles

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.

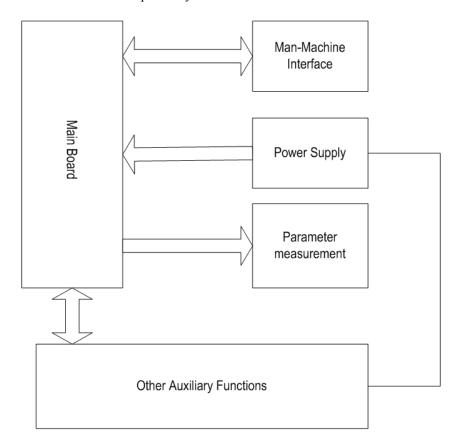


Figure 2-1 Structure of the DPM4

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.

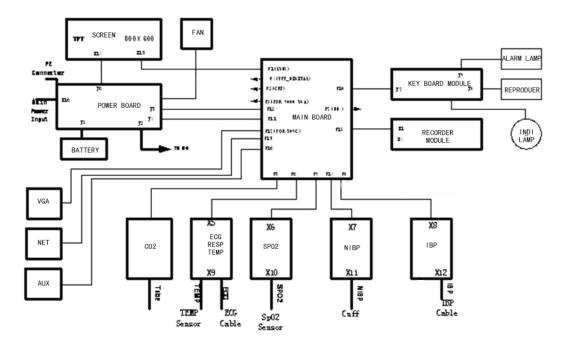


Figure 2-2 Functional structure of the DPM4

The DPM4 PCB connection is shown in the following figure.

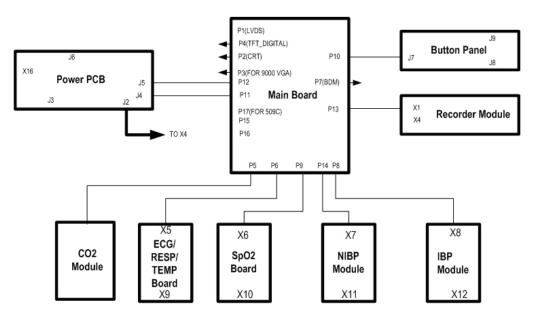


Figure 2-3 PCB connection

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

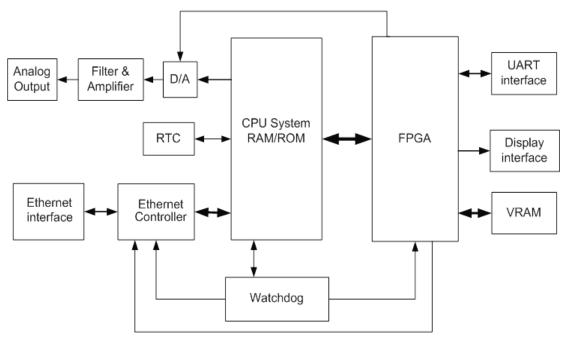


Figure 2-4 Working principle of the main board

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

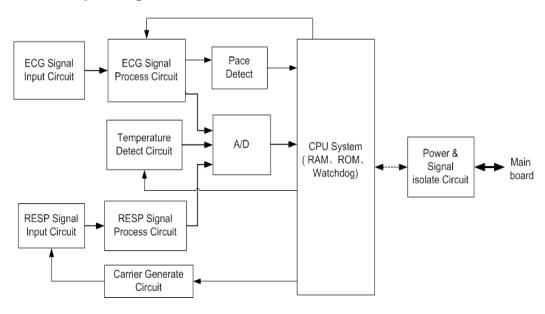


Figure 2-5 Working principle of the ECG/RESP/TEMP module

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

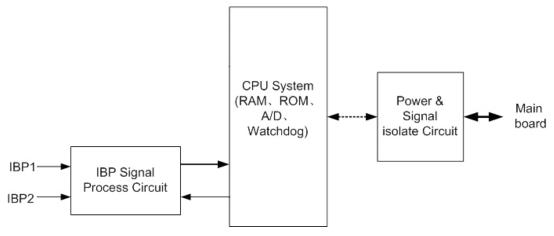


Figure 2-6 Working principle of the IBP module

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

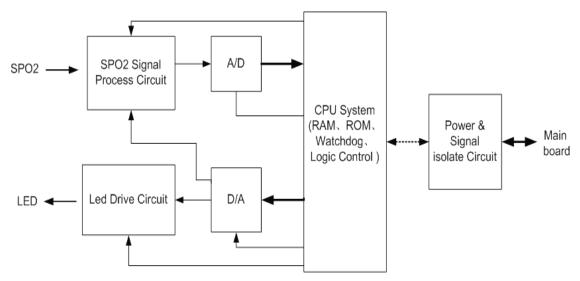


Figure 2-7 Working principle of the SpO2 module

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

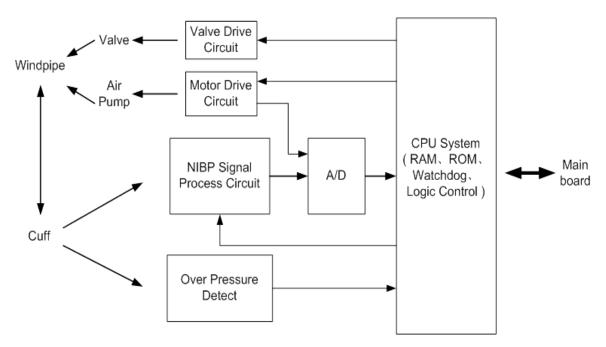


Figure 2-8 Working principle of the NIBP module

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

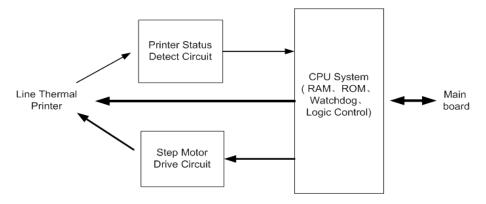


Figure 2-9 Working principle of the recorder module

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

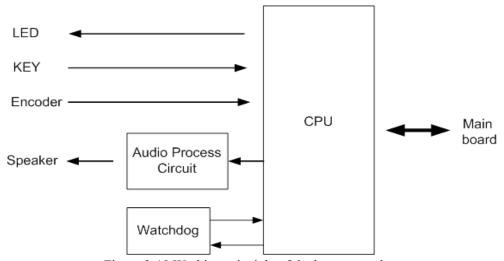


Figure 2-10 Working principle of the button panel

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

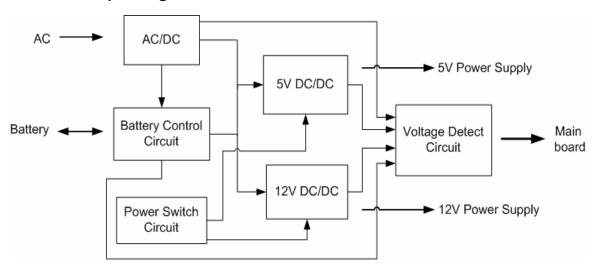


Figure 2-11 Working principle of the power PCB

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

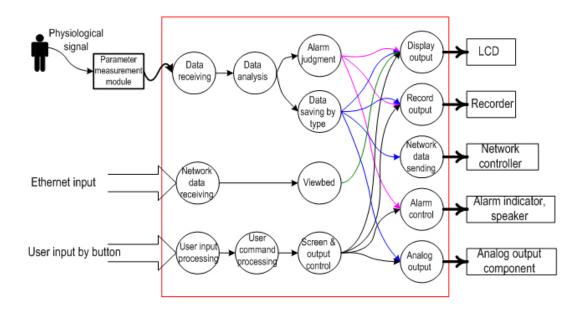


Figure 2-12 System function

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.

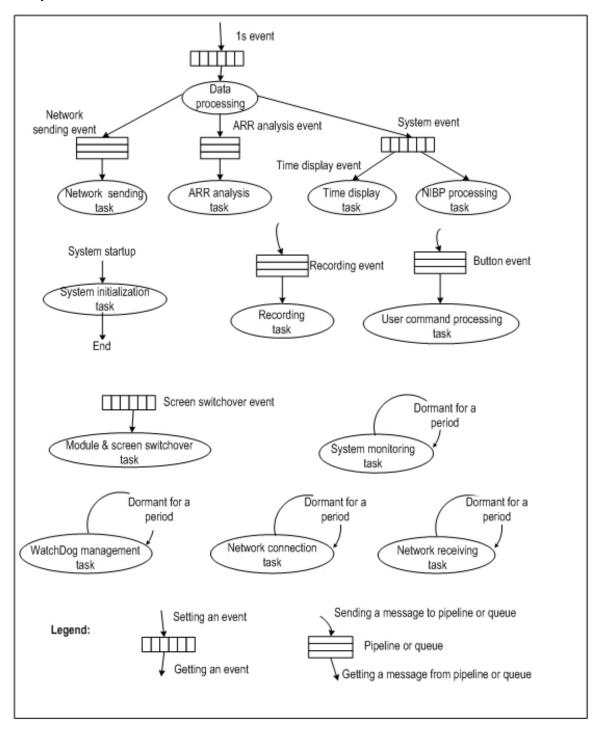


Figure 2-13 System task

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.

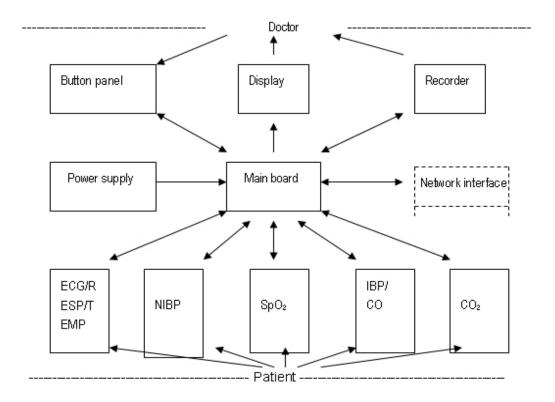


Figure 2-14 System Structure

As shown in Figure 2-14, the five modules and measurement cables monitor and measure NIBP, SpO₂, ECG/RESP/TEMP, IBP and CO₂ 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 Product Specification

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 to 35°C (With Sidestream CO2 module) | | |
| | 5 to 35°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℃ | | |
| Storage humidity | 10 to 95%, noncondensing | | |
| G. 1. | -500 to 13100 m (-1640 to 42979 feet) | | |
| Storage and transportation altitude | -305 to 6096 m (-1000 to 20000 feet) (with CO2, Masimo or | | |
| unnude | Nellcor SpO2 module) | | |

3.3 Power Source Specifications

| AC Power Supply Specifications | | |
|--------------------------------|---|--|
| Input voltage | 100 to 240 V∼ | |
| 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) | |

3.4 Hardware Specifications

| Physical | | |
|------------------------------|---|--|
| Size | 261 × 240 × 171mm (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. Supporting PITCH TONE and multi-level volume. | |
| | Audio alarms comply with EN 60601-1-8 and IEC60601-1-8. | |
| Connectors | 1 * 2 | |
| 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 | |
| | 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. | |
|-------------------|--|--|
| Trend data | 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 V/mV± 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 | $< 1\Omega$ | |
| Isolation voltage | > 1500 VAC | |
| Signal type | Normally open or normally closed, selectable | |
| Defibrillator synchronization p | ulse | |
| 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 μF capacitor, it will not cause a lead fault condition. For 3/5-lead, differential offsets \leq ±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 turne | d off.) | |
| 50/60Hz Notch | The monitor provides so | oftware filtering against the 50/60HZ | |
| Filtering | industrial frequency. | | |
| | In monitor and surgery rautomatically. | modes, the 50/60HZ filter will be turned on | |
| | In diagnostic mode, the | 50/60HZ filter will be turned off. | |
| Input offset current | ≤0.1µA (except currents | to drive leads) | |
| Differential input impedance | $\geq 5M\Omega$ | | |
| Input signal range | ±8mV (peak-to-peak val | lue) | |
| Accuracy of input | Methods A and D were u | used to establish overall system error and | |
| signal reproduction | frequency response acco | ording to EC11. | |
| Auxiliary current | Active electrode: $< 0.1 \mu A$ | | |
| (Leads off detection) | Reference electrode: < 1 μA | | |
| 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: 100V | N | |
| | Restore time: ≤10s | | |
| | • | ith 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 | | 2 | |
| | 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 | |
| Response time to heart rate changes | Meets the requirement of ANSI/AAMI EC13 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 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 | |
| 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 | |
| | 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 | | |
| Precision | -0.8 to +0.8 mV: ± 0.02 mV or $\pm 10\%$, whichever is greater | | |
| | 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 μF 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 | | |
| | Diagnostic mode: | 0.05 to 150 Hz (M08A module) | |
| Bandwidth (-3 dB) | Monitor mode: | 0.5 to 40 Hz | |
| | Surgery mode: | 1 to 20 Hz | |

| Common mode rejection Diagnostic mode: ≥90 dB Monitor mode: ≥105 dB Surgery mode: ≥105 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 ≤0.1μA (except currents to drive leads) Differential input impedance ≥ 5MΩ Input signal range ±8mV (peak-to-peak value) | | |
|--|------------------------|--|
| Common mode rejection $ \begin{array}{c} Surgery\ mode: \\ \ge 105\ dB \\ \hline (The\ notch\ filter\ is\ turned\ off.) \\ \hline \\ S0/60Hz\ Notch\ Filtering \\ \hline \\ Surgery\ mode: \\ \hline \\ Surgery\ mode: \\ \ge 105\ dB \\ \hline \\ The\ monitor\ provides\ software\ filtering\ against\ the\ 50/60HZ\ industrial\ frequency. \\ \hline In\ monitor\ and\ surgery\ modes,\ the\ 50/60HZ\ filter\ will\ be\ turned\ on\ automatically. \\ \hline In\ diagnostic\ mode,\ the\ 50/60HZ\ filter\ will\ be\ turned\ off. \\ \hline \\ Surgery\ mode: \\ \hline \\ In\ put\ offset\ current \\ \hline \\ Surgery\ mode: \\ \ Surg$ | | |
| $(The notch filter is turned off.)$ $50/60Hz Notch Filtering$ $The monitor provides software filtering against the 50/60HZ industrial frequency.$ $In monitor and surgery modes, the 50/60HZ filter will be turned on automatically.$ $In diagnostic mode, the 50/60HZ filter will be turned off.$ $Input offset current$ $\leq 0.1 \mu A \text{ (except currents to drive leads)}$ $Differential input impedance$ $\geq 5M\Omega$ $Input signal range$ $\pm 8mV \text{ (peak-to-peak value)}$ | | |
| | | |
| $\begin{tabular}{ll} 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. \\ \hline Input offset current & $\leq 0.1 \mu A (except currents to drive leads) \\ \hline Differential input impedance & $\geq 5 M\Omega$ \\ \hline Input signal range & $\pm 8 mV (peak-to-peak value) \\ \hline \end{tabular}$ | | |
| | | |
| 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 $\pm 8mV$ (peak-to-peak value) | 1 | |
| | | |
| | | |
| Input signal range ±8mV (peak-to-peak value) | | |
| | | |
| Assume of investment Makeda Assul Dominion 12.1 and 12.1 | | |
| Accuracy of input signal Methods A and D were used to establish overall system error and | d | |
| reproduction frequency response according to EC11. | | |
| Auxiliary current (Leads off Active electrode: < 0.1 μA | | |
| detection) Reference electrode: < 1 µA | | |
| Patient leakage current < 10uA | < 10uA | |
| Recovery time after defibrillation <5s | <5s | |
| Calibration signal 1 mV (peak-to-peak value), precision: ±5% | | |
| ESU protection Incision mode: 300W | | |
| Congelation mode: 100W | Congelation mode: 100W | |
| Restore time: ≤10s | | |
| The monitor complies with the requirements of ANSI/AAMI EC13 Section 4.2.9.14. | | |
| ESU noise control | | |
| 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 | | |
| 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: | | |
| | The average heart rate is calculated on the basis of the mean | | |
| | RR-interval of the last 16 beats, unless the heart rate calculated using the last 4 beats is less than or equal to 48, then this rate is | | |
| | used. | | |
| | The displayed Heart Rate is updated once per second. | | |
| Heart Rate Meter Accuracy | When tested in accord | ance with the ANSI/AAMI EC13 Section | |
| and Response to Irregular Rhythm | 4.1.2.1 e), the indicate period is: | d heart rate after a 20 second stabilization | |
| Tany timi | 1 | Bigeminy) -80±1 bpm | |
| | | nating Ventricular Bigeminy) -60±1 bpm | |
| | | rnating Ventricular Bigeminy) -120±1 bpm | |
| | | nal Systoles) -90±2 bpm | |
| | Meets the requirement | of ANSI/AAMI EC13 Section 4.1.2.1 f). | |
| Response time to heart rate | 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: | 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 | |
| | Figure 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 | | ance with the ANSI/AAMI EC13 Section | |
| | , · | te meter will reject all T-waves with | |
| | amplitudes less than 1 180ms and a Q-T inter | .2 mV, 100 ms QRS, a T wave duration of | |
| Dago mulgo | 100ms and a Q-1 men | vai 01 330 iiis. | |
| Pace pulse | D 1 | C. H | |
| | Pace pulses meeting the following conditions are marked by the PACE indicator. | | |
| Pulse indicator | Amplitude: | ±4 to ±700 mV (3/5-lead) | |
| 1 uise muicatoi | | ±2 to ±700 mV (12-lead) | |
| | Width: | 0.1 to 2 ms | |
| | Rise 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 | | |
| Dragicion | -0.8 to +0.8 mV: ± 0.02 mV or $\pm 10\%$, whichever is greater | | |
| Precision | Beyond this range: Undefined | | |
| 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 | in ECG cable with $1k\Omega$ resistance) |
| Differential input impedance | $> 2.5 \text{ M}\Omega$ | |
| 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 | | |
| Management | Adult: | 0 to 120 BrPM |
| Measurement range | Pediatric/neonate: | 0 to 150 BrPM |
| Resolution | 1 BrPM | |
| Precision | 7 to 150 BrPM: | ±2 BrPM or ±2%, whichever is greater. |
| FICCISIOII | 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.

| SpO2 | | | |
|-------------------|-----------------|---|--|
| Measurement range | 0 to 100% | | |
| Resolution | 1% | | |
| | 70 to 100%: | ±2 % (adult/pediatric, non-motion conditions) | |
| Precision | 70 to 100%: | ±3% (neonate, non-motion conditions)* | |
| | 0% to 69%: | Undefined. | |
| Refreshing rate | 1 s | | |
| | 7 s (When the s | 7 s (When the sensitivity is set to High) | |
| Averaging time | 9 s (When the s | 9 s (When the sensitivity is set to Medium) | |
| | 11 s (When the | 11 s (When the sensitivity is set to Low) | |
| PR | | | |
| Measurement range | 20 to 254 bpm | 20 to 254 bpm | |
| Resolution | 1 bpm | 1 bpm | |
| Precision | ±3 bpm (non-m | ±3 bpm (non-motion conditions) | |
| Refreshing rate | 1 s | 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 SpO_2 sensors specified in the section *Masimo SpO2 Accessories* meets the following specifications when used with Masimo SpO_2 module.

| SpO2 | | |
|--------------------------|---|---|
| Measurement range | 1 to 100% | |
| Resolution | 1% | |
| Precision | 70 to 100%: 70 to 100%: 70 to 100%: 0% to 69%: | ±2% (adult/pediatric, non-motion conditions) ±3% (neonate, non-motion conditions) ±3% (in motion conditions) Undefined. |
| Refreshing rate | 1 s | |
| Averaging time | 2-4 s, 4-6 s, 8 s | s. 10 s. 12 s. 14 s. 16 s |
| Low perfusion conditions | Pulse amplitude: >0.02% Light penetration: >5% | |
| Low perfusion accuracy | ±2% | |
| PR | | |
| Measurement range | 25 to 240 bpm | |
| Resolution | 1 bpm | |
| Precision | ±3 bpm (non-motion conditions) ±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, | 70 to 100% | ±2% |
| | MAX-P, MAX-I and MAX-FAST | 0% to 69% | Undefined |
| SpO2 measurement range | OxiCliq A, OxiCliq N, OxiCliq P, | 70 to 100% | ±2.5% |
| and precision | OxiCliq I | 0% to 69% | Undefined |
| F | D-YS, DS-100A, OXI-A/N and | 70 to 100% | ±3% |
| | OXI-P/I | 0% to 69% | Undefined |
| | MAV D D VCF I D VCDD | 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 | 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 co | 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 |

| Mangurament practicion | Maximum average error: ±5mmHg | | |
|--------------------------------------|-----------------------------------|-------------------------------------|--|
| Measurement precision | Maximum standard deviation: 8mmHg | | |
| Resolution | 1mmHg | | |
| Static pressure measurement range | 0 to 300mmHg | | |
| Static accuracy | ± 3 mmHg | | |
| 0 | Adult: | 297±3 mmHg | |
| Over-pressure protection by software | Pediatric: | 240±3 mmHg | |
| by software | Neonate: | 147±3 mmHg | |
| 0 | Adult: | 330 mmHg | |
| Over-pressure protection by hardware | Pediatric: | 330 mmHg | |
| | Neonate: | 165 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 | 40 to 240 bpm | |
| Precision | ±3 bpm or ±3%, | ±3 bpm or ±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 | 2 | |
|--------------------|--|---|--|
| Pressure readings | Systolic, diastolic, mean pressures and PR | | |
| Pressure labels | ART, PA, CVP, RAP, LA | ART, PA, CVP, RAP, LAP, ICP, P1 and P2 | |
| Linear input range | will be -50 to + 300 mm | will be -50 to + 300 mmHg, after zeroing. | |
| | ART | 0 to 300 mmHg | |
| Maggiramant ranga | PA | -6 to 120 mmHg | |
| Measurement range | CVP/RAP/LAP/ICP | -10 to 40 mmHg | |
| | P1/P2 | -50 to 300 mmHg | |
| Resolution | 1 mmHg | | |
| Precision | ±2% or ±1mmHg, which | never is greater | |
| Excitation | will be 5 Volts DC, ± 2% | | |
| Excitation | Minimum load resistance | Minimum load resistance will be 300Ω per transducer. | |
| Update period | 1s | 1s | |
| Zero offset range | ± 200 mmHg | ± 200 mmHg | |
| Zero accuracy | ± 1 mmHg | ± 1 mmHg | |
| Noise | <0.5 mmHg RTI, DC to 12.5 Hz, 300Ω source impedance. | | |
| Drift | <0.15 mmHg/°C; will no | <0.15 mmHg/°C; will not exceed ± 1 mmHg in 24 hours. | |
| Frequency Response | DC-12.5Hz ±1 Hz, -3db | DC-12.5Hz ±1 Hz, -3db | |
| PR from IBP | | | |
| Measurement range | 25 to 350 bpm | 25 to 350 bpm | |
| Precision | 25 to 350 bpm: ±1 or ±1 | 25 to 350 bpm: ±1 or ±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

| CO2 measurement range | 0 to 99mmHg | | |
|-----------------------------|--|--|--|
| | 0 to 40 mmHg: ±2 mmHg | | |
| Precision* | 41 to 76 mmHg: ±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 | ±15% or 15 ml/min, whichever is great | | |
| Start-up time of CO2 | < 1min, the module enters the warming up status after the startup. | | |
| module | One minute later, it enters the ready-to-measure status. | | |
| AwRR measurement range | 0 to 120 BrPM | | |
| Precision | 0 to 70 BrPM: ±2 BrPM | | |
| Precision | > 70 BrPM: ±5 BrPM | | |
| | When measured with a neonatal watertrap and a 2.5 m-long | | |
| | neonatal sampling line: | | |
| | <3.5 s @ 100 ml/min | | |
| Response time | <4 s @ 70 ml/min | | |
| Response time | 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 | | |
| | When measured with a neonatal watertrap and a 2.5m-long | | |
| | neonatal sampling line: | | |
| Delay time | <3 s @ 100 ml/min | | |
| Delay time | <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: ± 4 mmHg (0 to 40mmHg) or $\pm 12\%$ of the reading (41 to 99 mmHg)

Oridion CO₂ Specifications

| CO2 measurement range | 0 to 99mmHg | |
|----------------------------|--|-----------------------------------|
| D * | 0 to 38 mmHg: | ±2 mmHg |
| Precision* | 39 to 99 mmHg: | ±5% + 0.08% × (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 | |
| A DD | 0 to 70 BrPM: | ±1 BrPM |
| AwRR measurement precision | 70 to 120 BrPM: | ±2 BrPM |
| | 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 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 Section Eleven, Part 101.

4 Disassembling/Assembling & Troubleshooting

4.1 DPM4 Disassembling/Assembling

4.1.1 Exploded View of DPM4

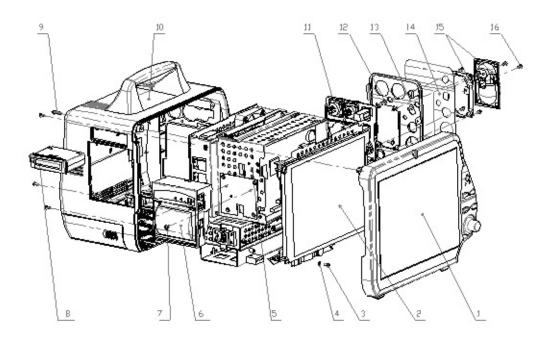


Figure 4-1 Exploded view of DPM4

| NO | Material code | Part & Specification | Quantity |
|----|---------------|--------------------------------|----------|
| 1 | 115-001437-00 | Front bezel assembly | 1 |
| 2 | 8002-30-36161 | 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 | 115-000121-00 | TR60 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

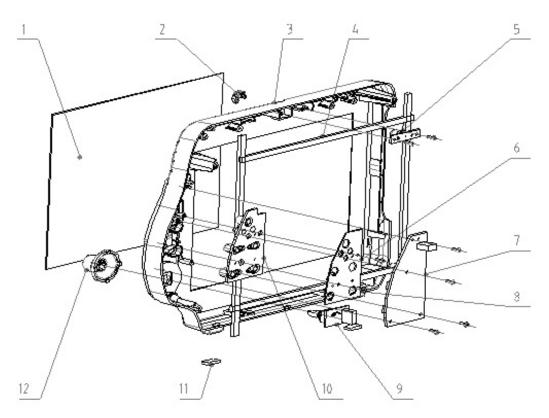


Figure 4-2 DPM4 display front bezel assembly

| 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)

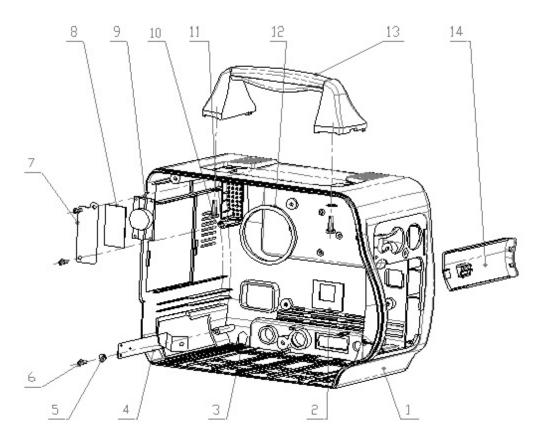


Figure 4-3 DPM4 back housing assembly

| 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

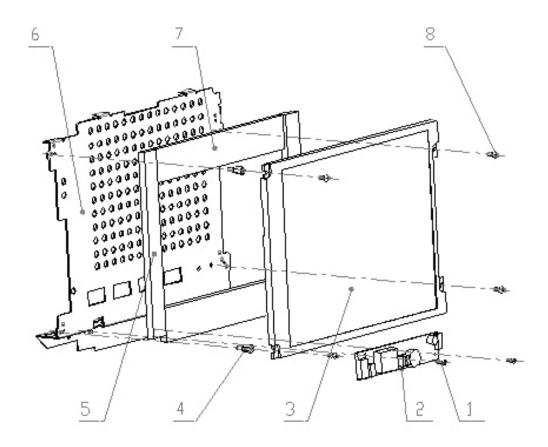


Figure 4-4 Screen assembly

| NO | Material code | Part & Specification | Quantity |
|-----|---------------|--------------------------|----------|
| 110 | Waterial code | 1 art & Specification | Quantity |
| 1 | M04-002405 | Cross-head screw M2X6 | 2 |
| 2 | 900E-10-04913 | INVERTOR 'TDK" | 1 |
| 3 | 0010-10-12358 | TFT screen 8.4"(800X600) | 1 |
| 4 | 8000-20-10217 | Stud screw for screen | 4 |
| 5 | 8000-20-10231 | Sponge cushion1 | 2 |
| 6 | 8002-20-36175 | Screen supporter | 1 |
| 7 | 8000-20-10232 | Sponge cushion2 | 2 |
| 8 | M04-051045 | Cross-head screw M2.5X6 | 4 |

4.1.5 Battery Connector Assembly

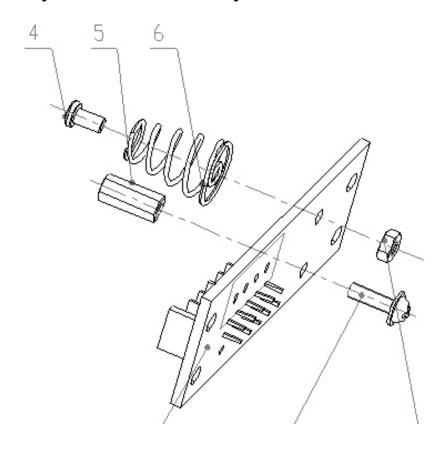


Figure 4-5 Battery Connector assembly

| 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

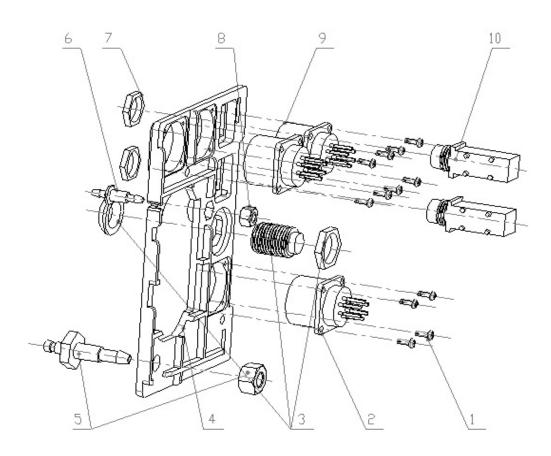


Figure 4-6 Parameter connector assembly

| 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

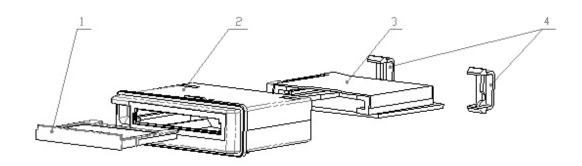


Figure 4-7 CF card assembly

| 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 4.2.1 Black Screen, Startup Failure

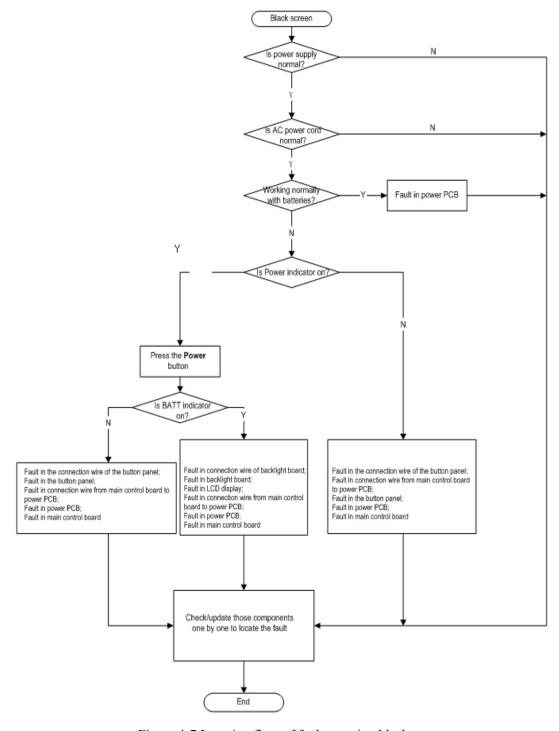


Figure 4-7 Location flow of faults causing black screen

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

Test and Material List

5.1 Test Procedure

5.1.1 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 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 ±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: $2K\Omega$, 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 $35\pm0.1^{\circ}\text{C}$, $37\pm0.1^{\circ}\text{C}$ and $39\pm0.1^{\circ}\text{C}$.

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

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.
- 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 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 SpO₂ sensor. The screen should display the PR and SpO₂ values normally. The normal SpO₂ 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%mmHg. 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.

②When 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

- 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.
- 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

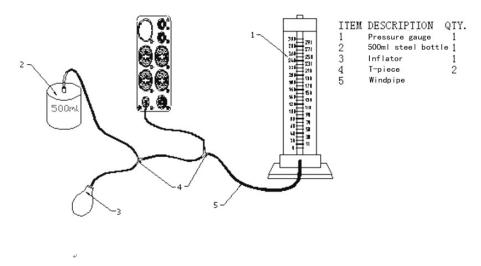


Figure 5-1 NIBP Calibration

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 ± 3 mmHg (± 0.4 kPa). 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 ± 3 mmHg (± 0.4 kPa).

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:

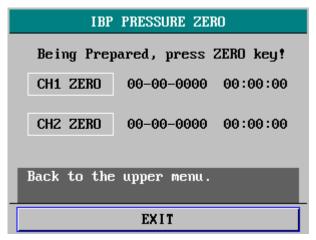


Figure 5-2 IBP PRESSURE ZERO

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.

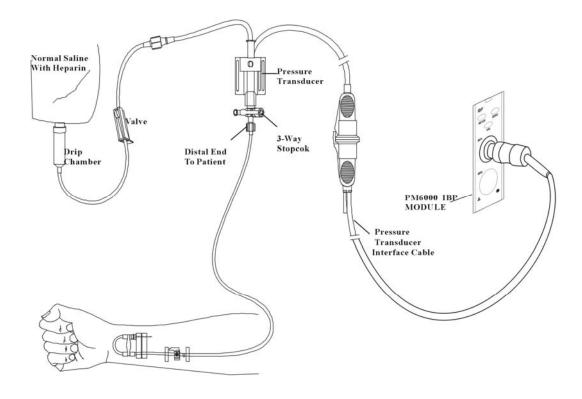


Figure 5-3 IBP Zero

IBP Calibration

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

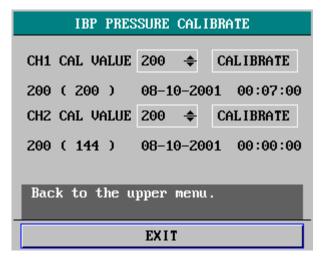


Figure 5-4 IBP Calibration Menu

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:

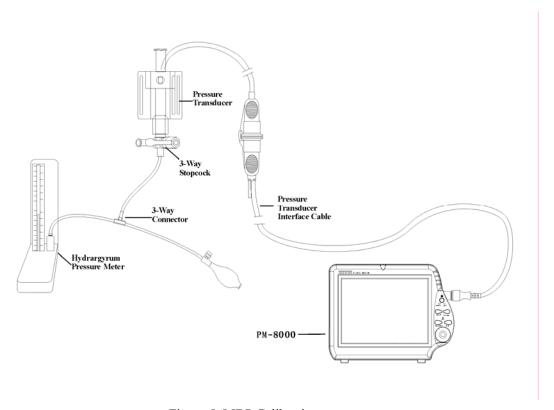


Figure 5-5 IBP Calibration

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) | | |
| 0010-10-12358 | TFT Screen 8.4"(800X600) | | |
| 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 | | |
| 8002-30-36161 | 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 | | |
| 115-000121-00 | TR60 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 Maintenance and Cleaning

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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