MEC-1200

Portable Multi-parameter Patient Monitor

Service Manual

For this Service Manual, the issued Date is 2010-05.

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- **Do not rely only on audible alarm system to monitor patient. When monitoring adjusting the volume to very low or completely muting the sound may result in the disaster to the patient. The most reliable way of monitoring the patient is at the same time of using monitoring equipment correctly, manual monitoring should be carried out.**
- **This multi-parameter patient monitor is intended for use only by medical professionals in health care institutions.**
- **To avoid electrical shock, you shall not open any cover by yourself. Service must be carried out by qualified personnel.**
- **Use of this device may affect ultrasonic imaging system in the presence of the interfering signal on the screen of ultrasonic imaging system. Keep the distance between the monitor and the ultrasonic imaging system as far as possible.**
- **It is dangerous to expose electrical contact or applicant coupler to normal saline, other liquid or conductive adhesive. Electrical contact and coupler such as cable connector, power supply and parameter module socket-inlet and frame must be kept clean and dry. Once being polluted by liquid, they must be thoroughly dried. If to further remove the pollution, please contact your biomedical department or Mindray.**
- **It is important for the hospital or organization that employs this equipment to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.**

NOTE

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

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

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Safety Precautions

1. Meaning of Signal Words

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

⚠DANGER

- **Indicates an imminent hazard that, if not avoided, will result in death or serious injury.**

⚠WARNING

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**

⚠CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**

2. Meaning of Safety Symbols

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

3. Safety Precautions

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

⚠DANGER

- **Do not use flammable gasses such as anesthetics, or flammable liquids such as ethanol, near this product, because there is danger of explosion.**

⚠WARNING

- **Do not connect this system to outlets with the same circuit breakers and fuses that control current to devices such as life-support systems. If this system malfunctions and generates an 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.**

⚠CAUTION

1. Malfunctions due to radio waves

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

- **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.

Contents

FOR YOUR NOTES

1 General

MEC-1200 is a flexible, portable patient monitor. MEC-1200 can monitor physiological signals including ECG, RESP. Rate, NIBP, SpO_2, and TEMP. MEC-1200 can convert these physiological signals into digital signals, which can be further processed and used to judge whether to trigger alarm. The user can control the operation of MEC-1200 via using the buttons on the front panel.

MEC-1200 uses ECG electrodes, SpO_2 finger sensor, blood pressure cuff and temperature probe to measure the physiological signals including ECG, NIBP, SpO_2, TEMP and RESP Rate. In the process of measurement no energy or substances are extracted from and/or delivered to the patient with the exception that sine wave signals are delivered to the patient during measuring RESP Rate. MEC-1200 converts the acquired physiological signals into digital signals, waveform and numerical values and displays all information on the screen. The user can also control the operation of the monitor via using the buttons on the front panel. The user can set alarm limits for each parameter. In this way once finding a physiological parameter exceed the pre-set alarm limits, MEC-1200 will activate its visual and audio alarm (the numerical display flashes or lights on) in order to raise the user's attention.

1.1 General

During treatment, it is highly important to continuously monitor the vital physiological signs of the patient to transmit the important information. Therefore patient monitor has always been occupying a very important position in the filed of medical devices. The continuous improvement of technologies not only helps us transmit the vital physiological signs to the medical personnel but also simplifies the measurement and as a result raise the monitoring efficiency. For inpatients, we need to measure those vital cardiac and pulmonary signs such as ECG, SpO_2, blood pressure and TEMP, etc. In recent years, the technological improvement pertaining to measurement and information transmission has led to more comprehensive performance and stable quality of the patient monitoring products. In the past, the dominant products manufactured by medical device manufacturers are mainly those for single parameter measurement. Nowadays however multi-parameter patient monitors are more widely and commonly used.

1.2 Intended Use

MEC-1200 patient monitor can measure physiological signals including ECG, RESP., NIBP, SpO_2 and TEMP. It can convert these physiological signals into digital signals and further display them on the screen. The alarm limits can be user-defined. Once finding a parameter reach or exceed its pre-set alarm limits, MEC-1200 can automatically activate the corresponding alarm. In addition, the user can operate the monitor by using the buttons on the front panel. In addition to outpatient department, monitors are generally used in some clinical areas such as ICU, CCU, operation room and emergency room because the monitor can provide many other physiological parameters of the patient to medical personnel. Only the qualified medical personnel shall use MEC-1200 patient monitor.

1.3 Environmental Conditions

1.3.1 Temperature

Operating	0 - 40 °C
Transportation and Storage	-20 - 60 °C

1.3.2 Humidity

Operating	15% - 95 % (noncondensing)
Transportation and Storage	10% - 95 %　(non-condensing)

1.3.3 Altitude

Operating	-500 to 4,600 meters
Transportation and Storage	-500 to 13,100 meters

1.3.4 Electrical specification

100-240 VAC, 50/60Hz，max. input power consumption 80VA

2 Principle

2.1 Principle

MEC-1200 portable patient monitor has been designed to measure physiological parameters including ECG, RESP, TEMP, NIBP and SPO2, etc. Figure 2-1 shows the structure of the whole monitor as well as the connection relationships between different parts. The board in the center of the figure is the core part of the monitor, i.e., integrated board for main control and parameter measurement, which, though being a single board, could realize the measurements of five said parameters, according uniform AD conversion and digital processing system is used.

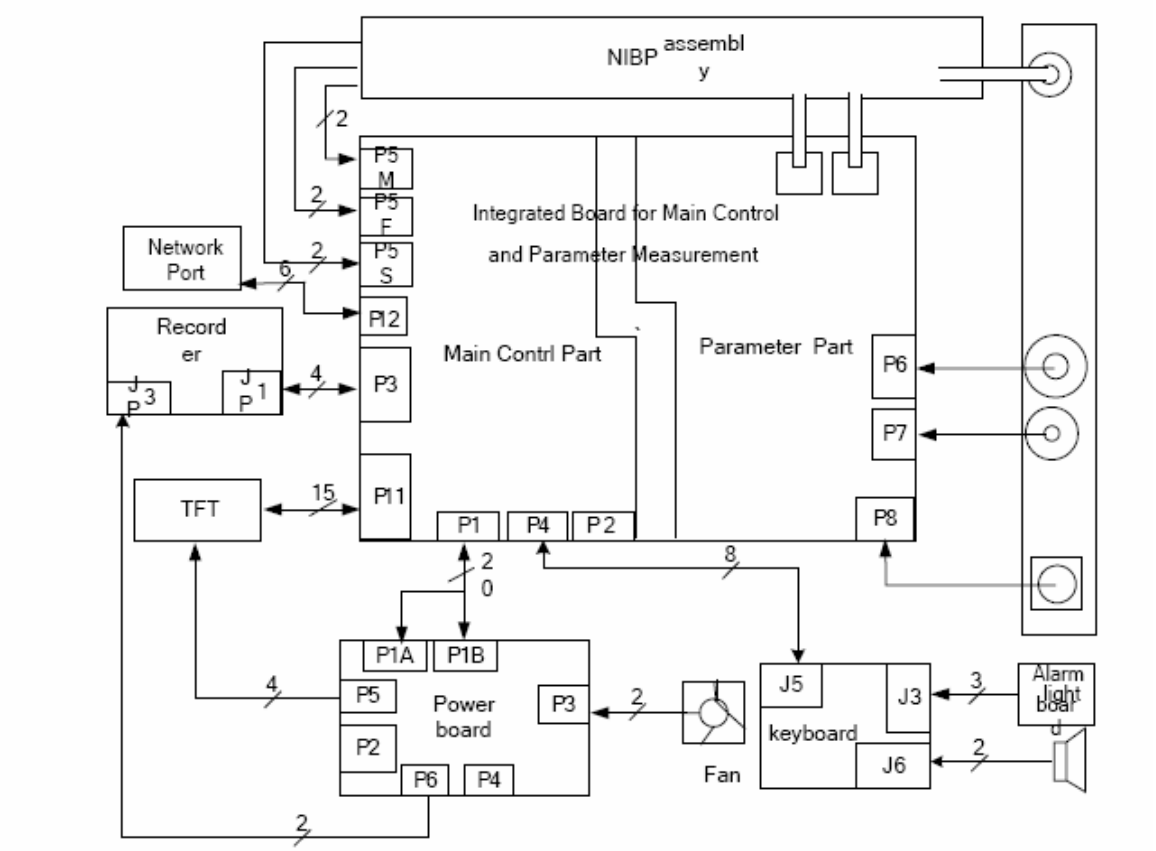


Figure 2-1 Patient monitor structure and part relationship

In terms of its functionality, MEC-1200 is made up of following parts.

Parameter measurement part

Main control part

Man-machine interface

Power supply

Other auxiliary part

Below is the detailed introduction to each part.

2.1.1 Parameter measurement part

Parameter measurement and monitoring are primary functions of the monitor. The parameter measurement part of the monitor consists of measurement probe (excluded in figure 2-1), parameter input socket assembly, NIBP assembly and the parameter part of the main control board. Its function is to convert the physiological signals into electronic signals, process them and execute calculations according to pre-set programs or the commands from the main control part, and then to send data of values, waveforms and alarms back to the main control part. The data will then be displayed via man-machine interface.

2.1.2 Main control part

The main control part of the integrated board is to drive man-machine interface, manage parameter measurement and provide other specific functions to the user such as configuration storage, waveform and data recall, etc.

2.1.3 Man-machine interface

The man-machine interfaces are TFT display, recorder, speaker, indicator, keys and knob.

The TFT display is the most primary output interface, displaying real-time or history data and waveforms, various patient information and alarm prompts on the screen for the user's observation.

Recorder is an auxiliary device to the display, which could print out various user-selected data for use and preservation.

Speaker gives audio alarm.

Indicator provides additional information about power supply, battery and alarm.

Keys and knob are user input interface of the system, by using which the user could input information and instructions into the monitor.

2.1.4 Power supply

Power supply is an important part of the system, consisting of power board, backlight board, battery and fan.

The main power board converts the AC mains input into 5V and 12V DC to energize other parts of the system. Similarly TFT display requires particular supply, for which case a backlight board is supplied. The battery could maintain the formal function of the system for a short period when AC mains is disconnected. A small fan requiring DC input is used to realize superior ventilation.

2.1.5 Other auxiliary part

Network port is available on MEC-1200, which allows the service engineer to upgrade the system software without necessarily opening the enclosure of the monitor. And can be connected to the Mindray Center Manage System.

2.2 Main Control Part

2.2.1 Functions of main control part

As the core part of the whole system, it finishes the following functions:

control, management and scheduling of parameter measurement part, recorder and keyboard;

display drive of TFT screen, AU screen and CRT screen

3-way expansion serial port realized by FPGA

alarm given for system fault;

storage of RTC, hardware WatchDog and relevant parameters

2.2.2 Schematic Diagram

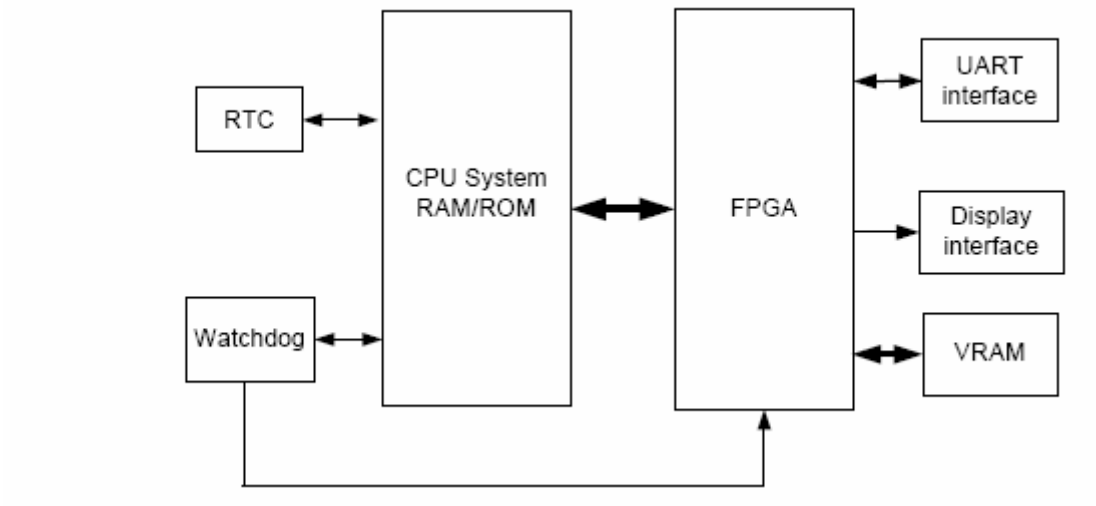


Figure 2-2 Schematic Diagram of Main Control Part

2.2.3 Introduction to Principle

The main control module, being the center part of the system, has serial ports to various modules, TFT display interface, CRT display interface. The BDM interface is reserved on the board for debugging or downloading software.

2.2.3.1 CPU System

CPU is the core element on the main control module. It connects peripheral modules through BUS and I/Os in order to finish data communication, data processing and logic control, etc.

2.2.3.2 RTC

RTC (real-time clock) provides time (hour, minute, second) and date (year, month, day) information. RTC information can be changed by CPU.

2.2.3.3 FPGA and VRAM

VRAM is used to save display data. CPU sends display data to VRAM via FPGA. The data in VRAM is a map of the real display device.

FPGA has various extended serial ports, which communicate with external Parameter Parts. CPU writes acquired data to FPGA and FPGA sends it to external Parameter Parts.

2.2.3.4 Watchdog

Upon power-up, Watchdog supplies Reset signals to CPU, FPGA, and Ethernet Controller. Provide functions of Waterdog Timer Output and voltage supervise.

2.2.3.5 Ethernet Controller

Ethernet Controller complies with IEEE802.3/IEEE802.3u LAN standard, supports 10Mbps and 100Mbps data rates, and realizes the data communication between CPU and Ethernet.

2.3 Parameter Part

2.3.1 Introduction to Principle

The parameter part collects, amplifies and filters the signals of the said five physiological parameters, executes A/D over the signals and processes the result signals. Figure 2-3 shows the structure of this part.

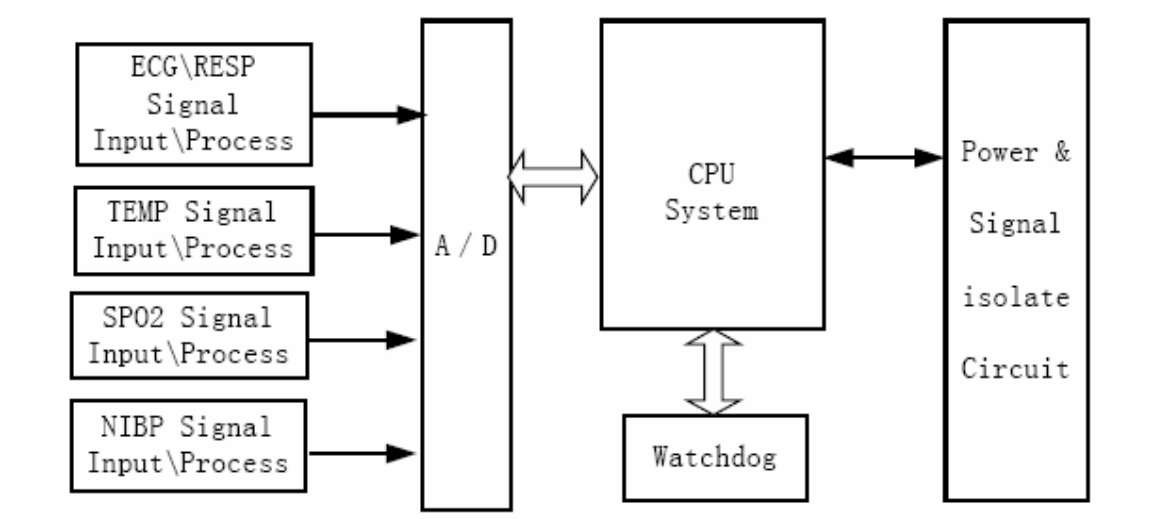


Figure 2-3 Schematic Diagram of Parameter Part

A/D and CPU in parameter part are shared for processing signals of the said five parameters, i.e., ECG, RESP, TEMP, NIBP and SPO2.

A/D

Convert analog signals output from parameter circuit into digital signals, and send them into CPU part to receive further processing.

CPU system

Realize logic control over all parameter parts and A/D part.

Process data of each parameter.

Communicate with main board.

Power and signal isolate Circuit

Realize isolation from external circuit in order to ensure human safety,

Provide power supplies for circuits;

Realize isolating communication between CPU System and main board.

Watchdog

Upon power-on, supply Reset signal to CPU;

Provides functions of Watchdog Timer Output and voltage detection.

2.3.2 ECG/RESP Module

2.3.2.1 General

This module is designed to measure two parameters including ECG, RESP.

2.3.2.2 Schematic Diagram

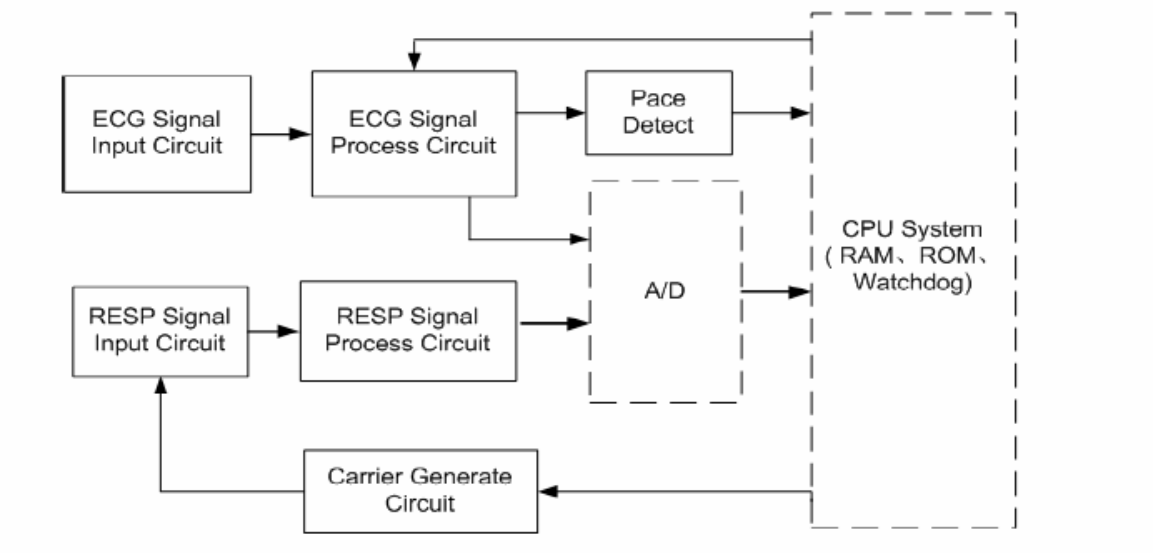


Figure 2-4 Schematic Diagram of ECG/RESP Module

2.3.2.3 Introduction to Principle

This module uses ECG cables to collect ECG, RESP signals, process them and transmit them to the main control part through serial port.

ECG Signal Input Circuit

Input protection and filter circuit: receives ECG signals from cables, removes high-frequency interference and prevents the circuit form being damaged by high voltage generated in defibrillation and ESD.

Right leg drive circuit: picks up 50/60Hz common-mode signals in lead wire and feeds them back to patient body, suppresses the common-mode interference in lead wire for the sake of better detecting ECG signals.

Lead Off detection circuit: detects if any ECG lead falls off and transmits relevant message to CPU.

ECG Signal Process Circuit

Differential Amplification circuit: first-order amplifies ECG signals and suppresses common-mode interference at the same time.

Low-pass filter circuit: removes high-frequency interference outside frequency band of ECG signals.

PACE signals are ECG packing signals, which greatly affect ECG detecting performance. Therefore PACE suppression circuit is designed to suppress PACE signals in order to better detect ECG signals.

Master AMP/Filter circuit: amplifies and filters ECG signals again and transmits them furthermore into A/D converter.

Pace Detect

Pick PACE signals out of ECG signals and transmit them to CPU.

Carrier Generate Circuit

RESP measurement is based on impedance method. Respiration causes the changes of thoracic impedances, which feature is taken advantage to modulate the amplitude of high frequency carriers. The modulated signals are then sent into the measuring circuit. This circuit is designed to generate high frequency carrier.

RESP Signal Input Circuit

Preamplifier circuit: amplifies and filters RESP signals;

Detection circuit: picks out the RESP wave modulated in excitation signals;

Level translation circuit: removes DC components in RESP signals;

Master AMP/Filter circuit: amplifies and filters RESP signals again and transmits them furthermore into A/D converter.

A/D and CPU System (Description in frame of dashed lines)

Refer to 2.3.1.

2.3.3 TEMP Module

2.3.3.1 General

This module uses sensors to collect TEMP signals, process them and transmit them to the main control part through serial port.

2.3.3.2 Schematic Diagram

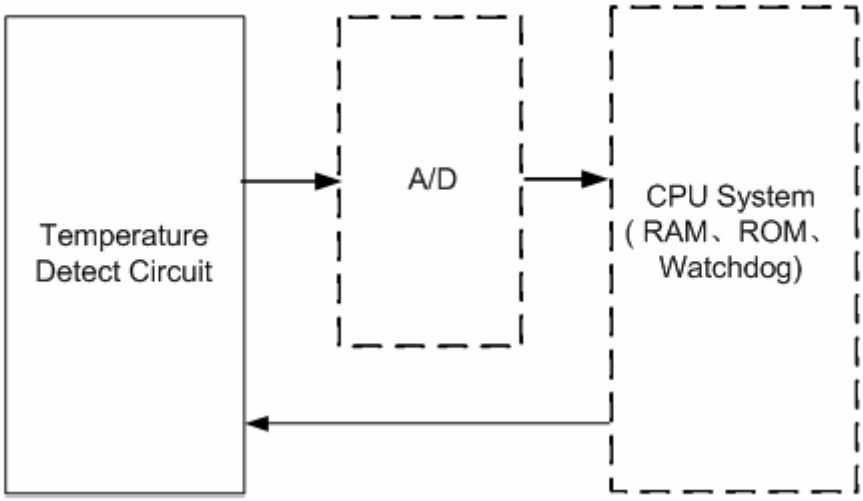


Figure 2-5 Schematic Diagram of TEMP Module

2.3.3.3 Introduction to Principle

Measurement temperature of body surface or endocavity by taking advantage of the characteristics of the thermal-sensitive resistor whose impedance varies with temperature of human body.

Temperature Detect Circuit

Receive the signal transmitted from TEMP sensor, amplify the signal and send it into A/D converter.

A/D and CPU system (Description in frame of dashed lines)

Refer to the 2.3.1

2.3.4 SPO2 Module

2.3.4.1 General

This module is designed to measure SPO2.

2.3.4.2 Schematic Diagram

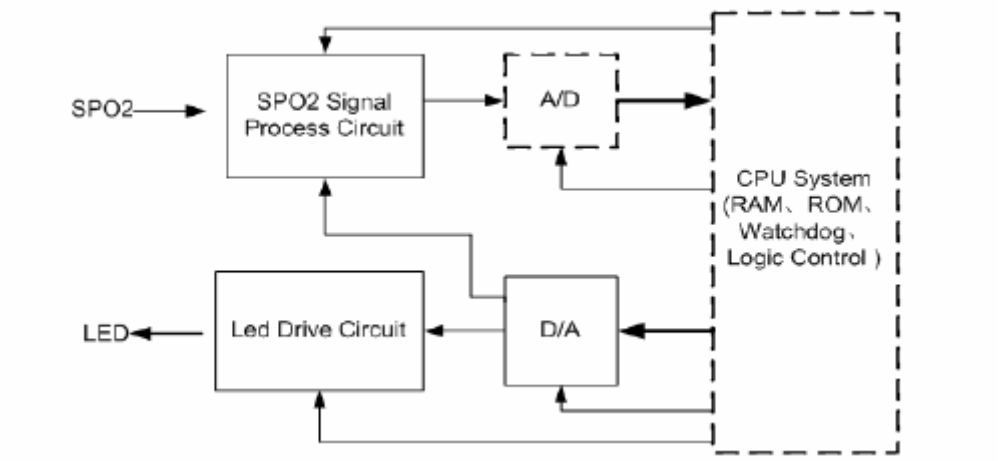


Figure 2-6 Schematic Diagram of SPO2 Module

2.3.4.3 Introduction to Principle

Sensor is used to collect the signals of red and infrared lights having penetrated human finger or toe. Relevant unit is designed to process the acquired signals and accordingly give the result. Driving current of LED and gain of AMP circuit are controlled to fit different patient.

LED Drive Circuit

Provide driving current to LED. The driving current is adjustable.

SPO2 Signal Process Circuit

Preamplifier circuit converts photocurrent signals into voltage signals and additionally first-order amplifies them;

Gain adjustment and amplification circuit amplifies the signals and adjusts their gain;

Bias circuit adjusts the dynamic range of the signals and then sends them into A/D converter.

D/A

Convert digital signals output from CPU into analog signals, supply control signals to LED Drive Circuit and SPO2 Signal Process Circuit.

A/D and CPU system (Description in frame of dashed lines)

Refer to the 2.3.1

2.3.5 NIBP Module

2.3.5.1 General

This module is designed to measure NIBP.

2.3.5.2 Schematic Diagram

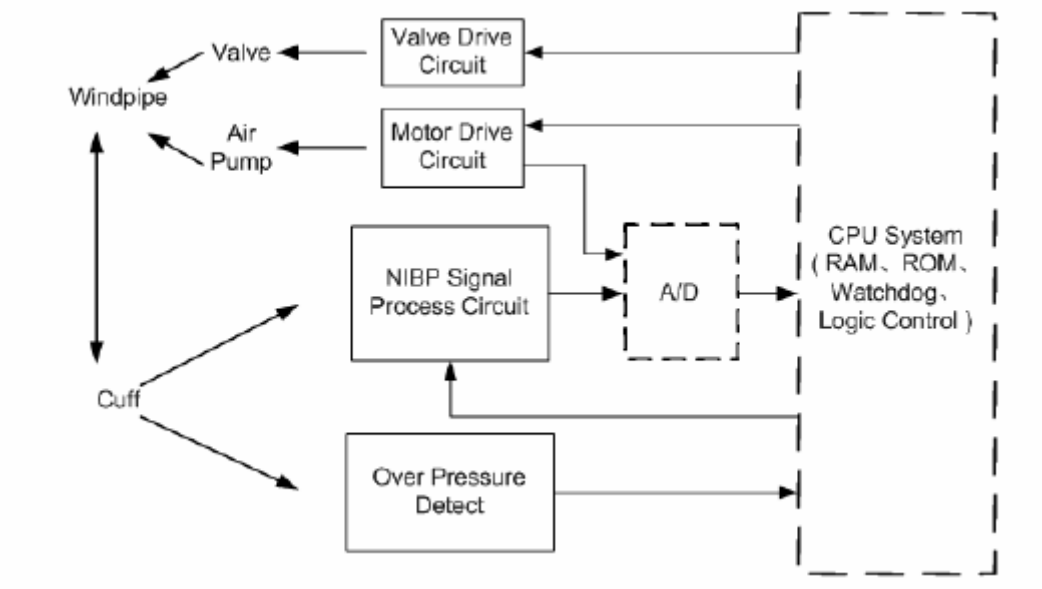


Figure 2-7 Schematic Diagram of NIBP Module

2.3.5.3 Introduction to Principle

Oscillometric method is adopted to measure NIBP. Inflate the cuff wrapped around the upper arm until the pressure makes the blood in the artery of the upper arm stops flowing. Then deflate the cuff according to the requirement of the algorithm. Blood flow in the artery resumes as the cuff pressure decreases, which will cause corresponding pulsation in the cuff. The pressure sensor connecting the inflating hose of the cuff will accordingly generate pulsating signals. The NIBP module can process these signals and give measuring resut.

Valve Drive Circuit

Control OPEN/CLOSE of the valve. This circui, together with Motor Drive Circuit, finishes the action of inflating and deflating cuff.

Motor Drive Circuit

Control the action of air pump. This circuit, together with Valve Drive Circuit, finishes the action of inflating and deflating cuff. Moreover, it supplies motor status signal to A/D converter for detection.

NIBP Signal Process Circuit

NIBP signals are differential signals. Differential Amplify circuit amplifies the differential signals and converts them into single ended signals and at the same time sends the signal of one way to A/D converter and the signal of the other way to the Blocking and AMP circuit.

Blocking and AMP circuit removes the DC components in the signals, amplifies the signals and then sends them into A/D converter.

Over Pressure Detect

Detect NIBP pressure signals. Once the pressure exceeds the protection limit, it sends the message to CPU System, which will accordingly control the Valve Drive Circuit to open the valve to deflate the cuff so as to reduce the pressure.

A/D and CPU system (Description in frame of dashed lines)

Refer to the 2.3.1

2.4 Power Board

2.4.1 General

This module provides DC supplies to other boards.

2.4.2 Schematic Diagram

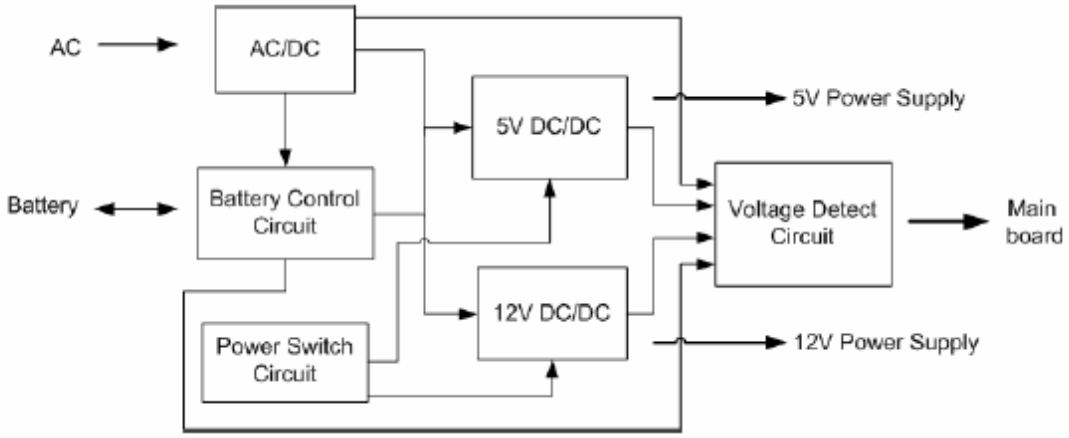


Figure 2-8 Schematic Diagram of Power Board

2.4.3 Introduction to Principle

This module converts 220V AC mains or battery power into 5V and 12V DC supplies to power other boards. If AC mains and battery coexist, the former take the priority to power the system and charge the latter at the same time.

AC/DC

Convert high-voltage AC supply into low-voltage DC supplies to power subsequent circuits and charge the battery.

Battery Control Circuit

If AC mains and battery coexist, this circuit controls the output from AC/DC part to charge the battery. If AC mains is disconnected, this circuit controls the battery to power the subsequent circuit.

5V DC/DC

Convert the DC supply from the previous circuit into stable 5V DC supply to power other boards.

12V DC/DC

Convert the DC supply from the previous circuit into stable 12V DC supply to power other boards.

Power Switch Circuit

Control the working status of 5V DC/DC and 12V DC/DC in order to control ON/OFF action of the patient monitor.

Voltage Detect Circuit

Detect the output voltages of various parts of the circuits; convert the analog signals into digital signals and send them into main board for further processing.

2.4.4 Testing key points

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

Test before power on the monitor.

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

Use oscillograph to measure between the PIN1 of Q1 and the negative electrode of C12, a driving waveform with the frequency being about 110KHz should exist.

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

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

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

Tests after powering on the monitor:

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

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

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

2.5 Keyboard

2.5.1 General

This module acts as the man-machine interface.

2.5.2 Schematic Diagram

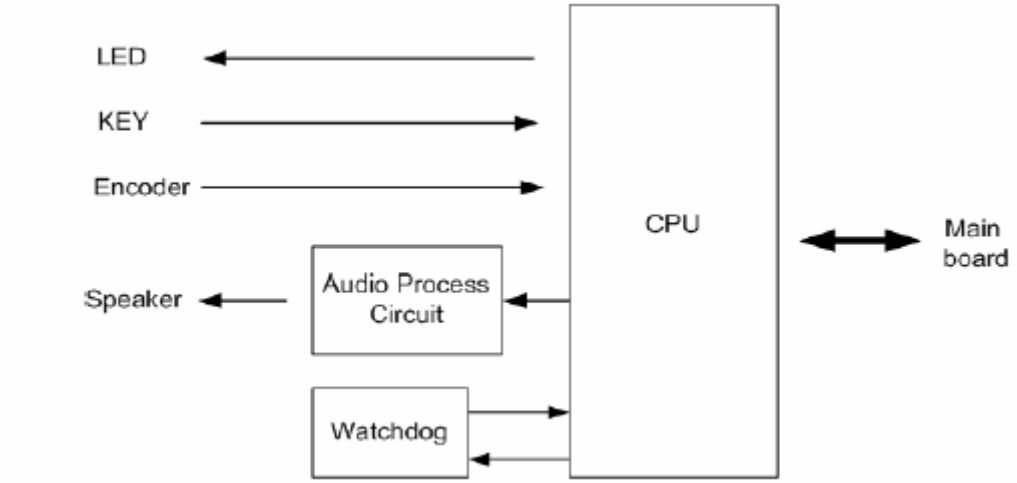


Figure 2-9 Schematic Diagram of Keyboard

2.5.3 Introduction to Principle

This module detects key and encoder input signals, converts them into codes and sends to the main board. The main board sends command to the keyboard and the latter accordingly control indicator and audio process circuit to act so as to realize audio and visual alarm.

CPU

Detect key and encoder input signals;

Control LED status

Control Audio Process Circuit

Regularly zero Watchdog Timer;

Communicate with main board.

Audio Process Circuit

Generate audio signals to drive the speaker to give sound.

Watchdog

Upon power-up, supply Reset signal to CPU;

Provide functions of Waterdog Timer Output and voltage detection.

2.6 Recorder Module

2.6.1 General

This module is designed to drive line thermal printer.

2.6.2 Schematic Diagram

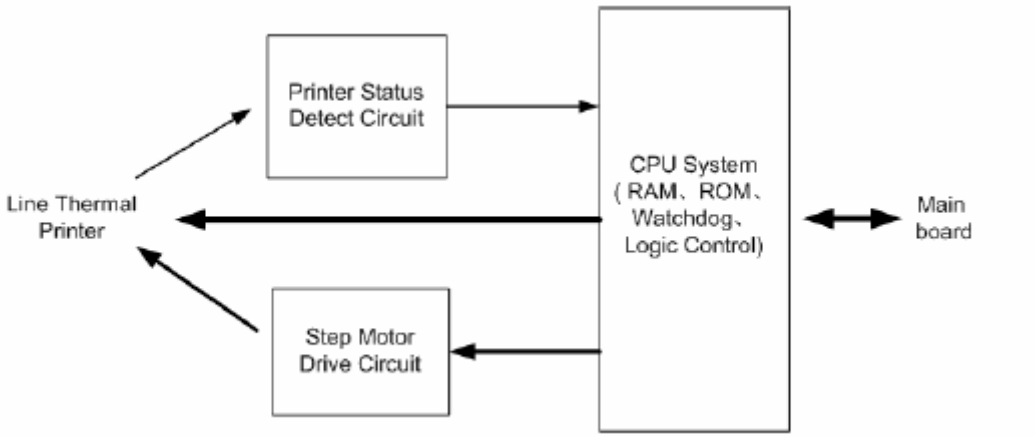


Figure2-10 Schematic Diagram of Recorder Module

2.6.3 Introduction to Principle

This module receives printing data from the main board. At the same time of converting the data into dot matrix data and sending them to the printer, It also drives the printer to start printing action.

2.6.4 Step Motor Drive Circuit

A step motor is used in the printer to feed paper. This circuit is designed to drive the step motor to act.

Printer Status Detect Circuit

Detect the status of the printer, including the position of paper platen, if there is paper, and temperature of thermal head and send the information to CPU system.

CPU System

- Process printing data;
- Control printer and step motor;
- Collect printer status information and realize corresponding control;
- Communicate with main board;

3 Product Specification

3.1 Classification

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

3.2 Specifications

3.2.1 Size and Weight

Size	258(W) x 118(D) x 244(H) mm
Weight（Max）	5.0 kg

3.2.2 Environment

Temperature

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

Humidity

Working	15% - 95 % (noncondensing)
Transport and Storage	10% - 95 % (noncondensing)

Altitude

Working -	500 to 4,600m
Transport and Storage	-500 to 13,100m
Power Supply	100~240 VAC, 50/60 Hz, Pmax=80 VA FUSE T 3.15A

3.2.3 Display

Screen	8.4 in. TFT display , 800×600 Resolution
Messages	
	4 Waveforms Maximum
	1 Alarm LED (Yellow/Red)
	1 Working LED (Green)
	1 Charge LED (Green)
	3 Sound Modes corresponding to Alarm Modes

3.2.4 Battery(option)

Rechargeable 2.3 A/Hr 12V Lead-Acid battery

Operating time	120 minutes under the normal use and full charge;
	More than 5 minutes after the first alarm of low battery
Charge time	a maximum of 8h in the running status

3.2.5 Recorder(option)

Record Width	48 mm
Paper Speed	25/50 mm/s
Trace	2

Recording types:

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

3.2.6 Recall

Trend Recall	
Short	1 hrs, 1 s or 5 s. Resolution
Long	72 hrs, 1 Min. Resolution
Alarm Event Recall	60 alarm events of all parameters and 8/16/32seconds of corresponding waveform.
NIBP Measurement Recall	400 NIBP measurement data
Power-off Storage	72 hours of trend data, 400 NIBP measurement data, 60 alarm events and 60 Arr. Events

3.2.7 ECG

Lead Mode	3 Leads (R, L, F or RA, LA, LL)
Lead selection	I, II, III
Waveform	1 ch
Gain	×2.5mm/mV, ×5.0mm/mV, ×10mm/mV, ×20mm/mV, AUTO
HR and Alarm	
Range	
Adult	15 ~ 300 bpm
Neo/Ped	15 ~ 350 bpm
Accuracy	±1% or ±1bpm, use the greater
Resolution	1bpm
Sensitivity	≥200 (uV_{P-P})
Differential Input Impedance	> 5 MΩ
CMRR	
Monitor	≥ 105 dB
Surgery	≥ 105 dB
Diagnostic	≥ 90 dB
DC offset voltage	±300mV
Patient leakage current	< 10 uA
Recovery time after defibrillation	< 3 s
ECG Signal Range	±5 m V (Vp-p)
Frequency Response (Bandwidth)	
Surgery	1 ~ 15 Hz
Monitor	0.5 ~ 35 Hz
Diagnostic	0.05 ~ 100 Hz
Calibration Signal	1 m V (Vp-p), Accuracy: ±5%
ST Segment Monitoring	
Measure and Alarm Range	-2.0 ~ +2.0 mV
Precision	–0.8 ~ +0.8mV: ±0.02mV or ±10%, whichever is greater.
Beyond this range:	Undefined

Update period	10s
ARR Detecting	
Type	ASYSTOLE, VFIB/VTAC, VPB, COUPLET, VT>2, BIGEMINY, TRIGEMINY, R ON T, MISSED BEATS, TACHY, BRADY, PNC, PNP
Alarm	Available
Review	Available

3.2.8 RESPARATION (RESP)

Method	Impedance between R-F (RA-LL)
Measuring Impedance Range:	0.3~5.0 Ω
Base line Impedance Range:	200 ~ 1500 Ω
Bandwidth	0.2 ~ 2 Hz
Resp. Rate	
Measuring and Alarm Range	
Adult	0 ~ 120 BrPM
Neo/Ped	0 ~ 150 BrPM
Resolution	1 BrPM
Accuracy	0 to 6 BrPM: Undefined
	7 to 150 BrPM: ±2 BrPM or ±2%, whichever is greater
Apean Alarm delay	10 ~ 40 s

3.2.9 NIBP

Method	Oscillometric
Mode	MANUAL, AUTO, CONTINUOUS
Measuring Interval in AUTO Mode	
	1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240,480 (Min)
Measuring Period in CONTINUOUS Mode	
	5 Min
Alarm Type	SYS, DIA, MEAN
Measuring range	
Adult Mode	
SYS	40 ~ 270 mmHg
DIA	10 ~ 210 mmHg
MEAN	20 ~ 230 mmHg
Pediatric Mode	
SYS	40 ~ 200 mmHg
DIA	10 ~ 150 mmHg
MEAN	20 ~ 165 mmHg

Neonatal Mode	
SYS	40 ~ 135 mmHg
DIA	10 ~ 100 mmHg
MEAN	20 ~ 110 mmHg
Resolution	
Pressure	1mmHg
Accuracy	
Pressure	
Maximum Mean error	±5mmHg
Maximum Standard deviation	8mmHg
Overpressure Protection	
Adult Mode	297±3 mmHg
Pediatric Mode	240±3 mmHg
Neonatal Mode	147±3 mmHg

3.2.10 SpO_2

Measuring Range	0 ~ 100 %
Alarm Range	0 ~ 100 %
Resolution	1 %
Accuracy	70% ~ 100%: ±2 %
	0% ~ 69%: unspecified
Update period	about 1 s
Pulse Rate	
Measuring Range	20~254bpm
Resolution	1bpm
Accuracy	±3bpm

3.2.11 TEMPERATURE (TEMP)

Channel	1
Measuring and Alarm Range	0 ~ 50 °C
Resolution	0.1°C
Accuracy	±0.1°C
Update period	about 1 s

FOR YOUR NOTES

4 Structure and Part List

4.1 MEC-1200 Explosive view

4.1.1 MEC-1200 Explosive view

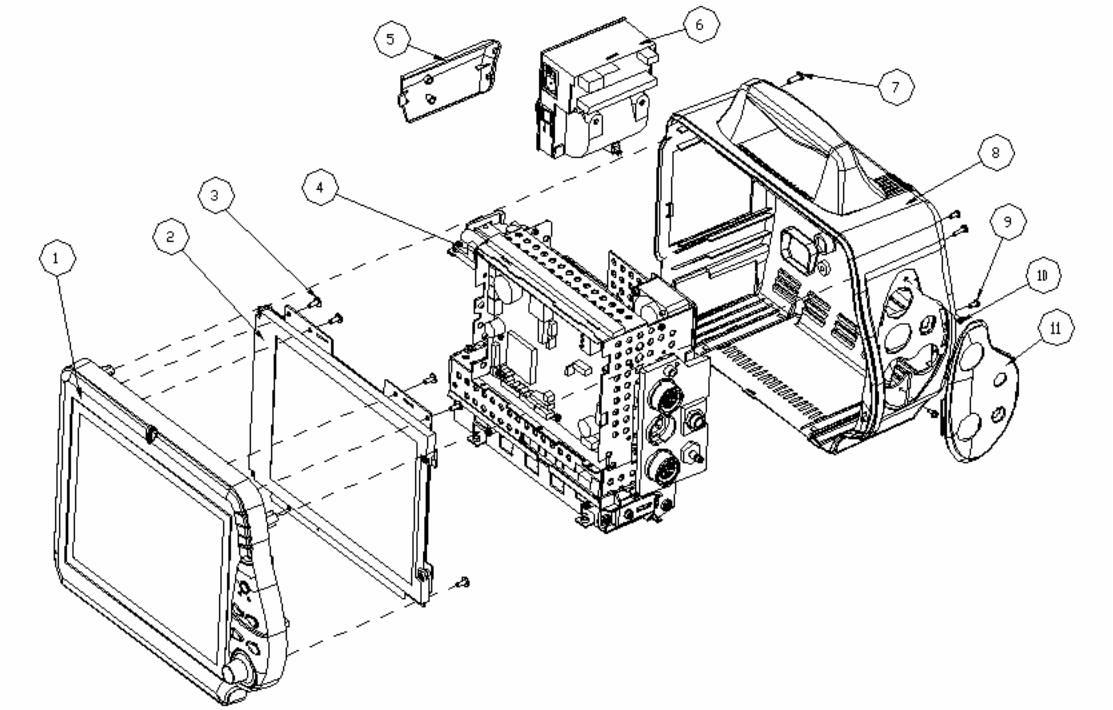


Figure 4-1 Graphics, exploded

11	8000-20-10171-51	4-hole socket cover	1		
10	M04-004012---	Cross phoned screw with washer M3x6	2		
9	M04-002505---	Screw GB818-86 M3x6	4		
8	M1K3-30-57768	Rear housing assembly	1		
7	M04-051079-00	Cross panhead tapping screw PT3x12	2		
6	8100-20-14152	Cover board of Recorder	1		
5	8100-20-14151	Battery door	1		
4	M1K3-30-57764	Main frame assembly	1		
3	M04-003905---	Screw GB845-85 M3x6	6		
2	M1K3-30-57774	screen assembly	1		
1	M1K3-30-57767	Front panel assembly	1		
SN	Standard Code	Name & SPEC.	QTY.	Material	Remarks

4.1.2 MEC-1200 TFT Screen Assembly

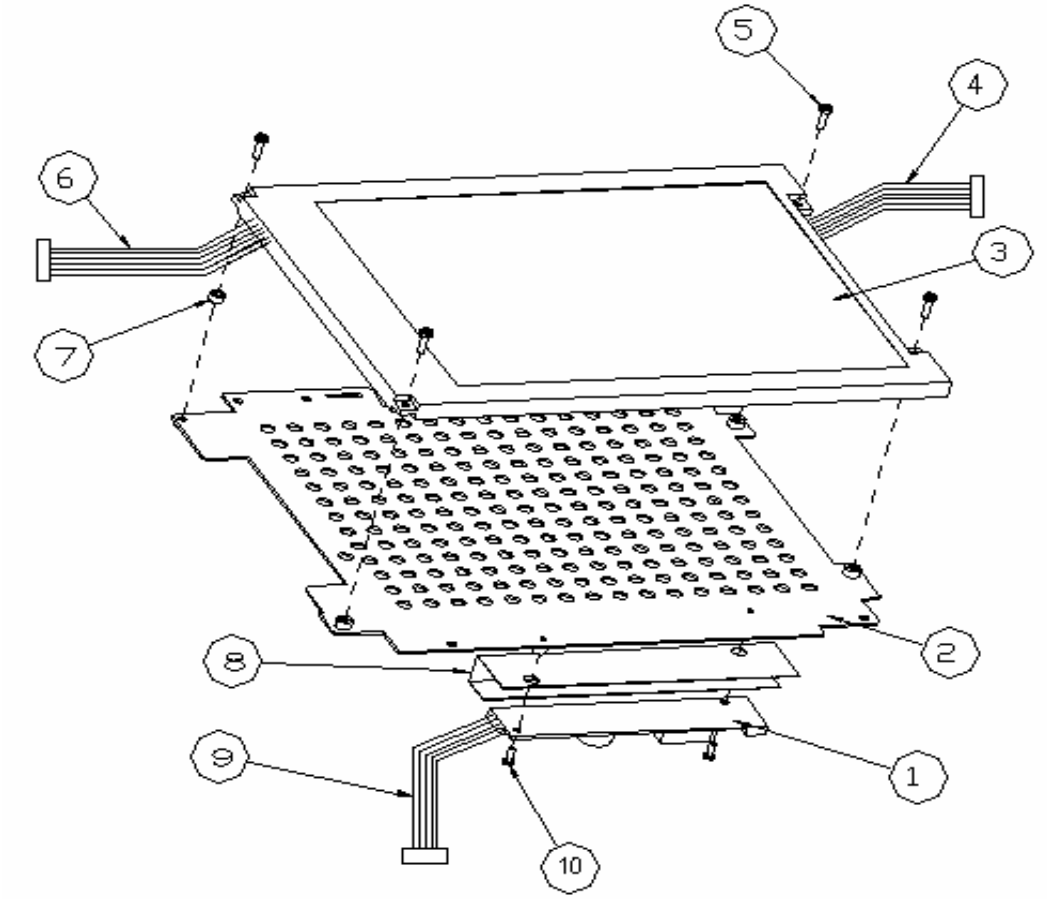


Figure 4-2 MEC-1200 TFT screen assembly

10	M04-002405---	SCREW GB818-86 M2X6	2		
9	8000-21-10142	Connecting wire of backlight board	1		
8	9300-20-13901	Insulation of TPI invertor	1	PC	
7	8000-20-10217	SCREW of screen	1		
6	8000-21-10153	Connecting wire of TFT screen	1		
5	M04-051121---	Cross panhead screw M2.5X8	4		
4	8000-21-10239	Connecting wire of backlight board of TFT screen	1		
3	0010-10-12358	TFT Screen 8.4 B084SN03 800x600	1		
2	8000-20-10183	Display bracket	1	SPCC	
1	0010-10-12096	INVERTOR TPI-01-0207-M ‘TAMURA’	1		
SN	Standard Code	Name & Specification	QTY.	Material	Remarks

4.1.3 MEC-1200 Bracket Assembly

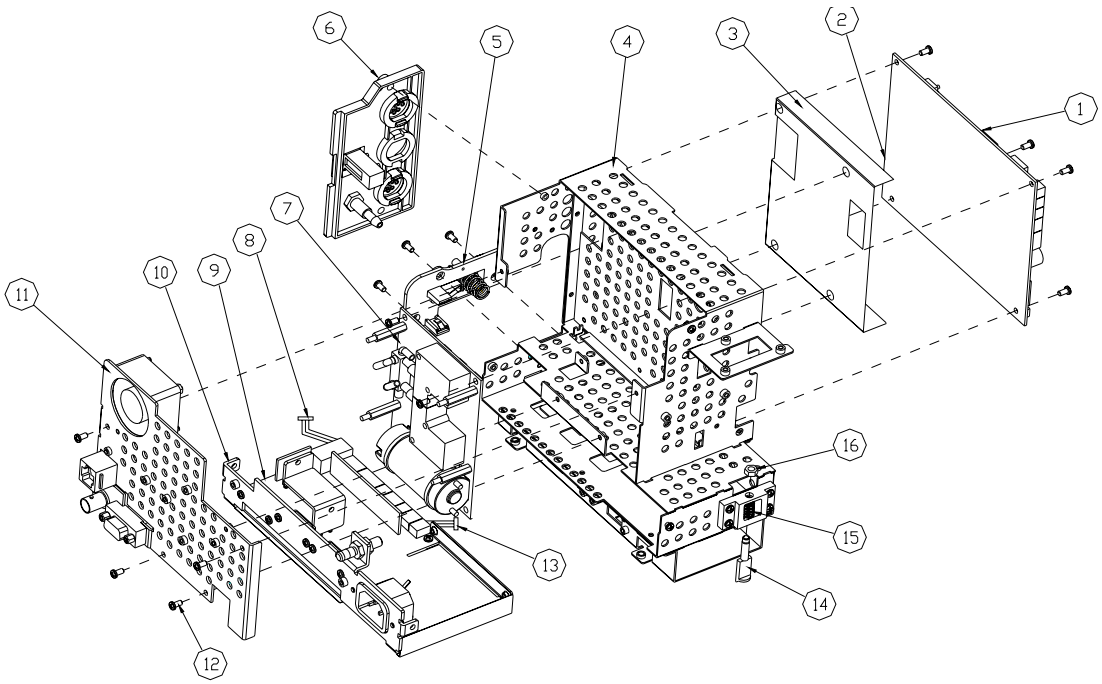


Figure 4-3 MEC-1200 bracket assembly

16	M04-000401---	Hexagon nut-M4	1		
15	8000-20-10299	Battery lever	1		
14	8000-20-10298	Battery lever spring	1		
13	M1K3-20-57750	Connecting cable of main board to power board			
12	M04-002505---	Cross panhead Screw M3x6	26		
11	M1K3-30-57766	Back board Subassembly	1		
10	8200-30-19902	Power board	1		
9	8000-20-10215	Insulating pad of power board	1		
7	8100-30-14117	NIBP pump subassembly	1		
6	8000-30-10174	Parameter Socket Assembly	1		
5	8000-30-10173	Charge subassembly	1		
4	8000-20-10175	Main bracket	1		
3	8100-20-14125	Insulation pad of main board	1		
2	M05-010R03---	CR1220 button battery 3v lithim	1		
1	5100-30-26870	Integrated parameter main control board	1		
SN	Standard Code	Name & SPEC.	QTY.	Material	Remarks

4.1.4 Back Board Assembly

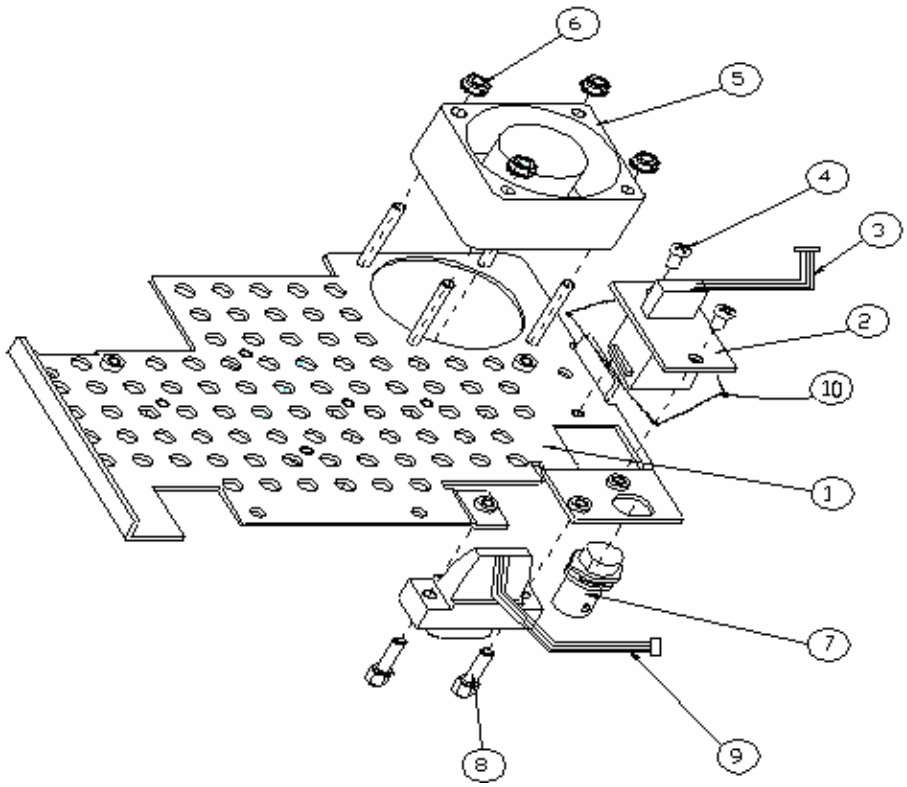


Figure 4-6 Back board assembly

10	9210-20-30175	Insulating pad of network	1		
9	8000-21-10152	VGA connecting Cable	1		
8	8000-20-10213	VGA connecting stud screw	2		
7	509b-10-05973	BNC pin(BNC-50KY-5)	1		
6	M04-011002---	M3 nut with toothed washer	4		
5	8000-20-10315	Fan(SUNNON KD2404PKb2)	1		
4	M04-002505---	Screw GB818-86 M3x6	2		
3	9201-20-36015	Connecting cable of network	1		
2	9210-30-30152	Network connecting plate	1		
1	8000-20-10184	Back board	1	SPCC	
SN	Standard Code	Name & SPEC.	QTY.	Material	Remarks

4.1.5 NIBP Pump Assembly

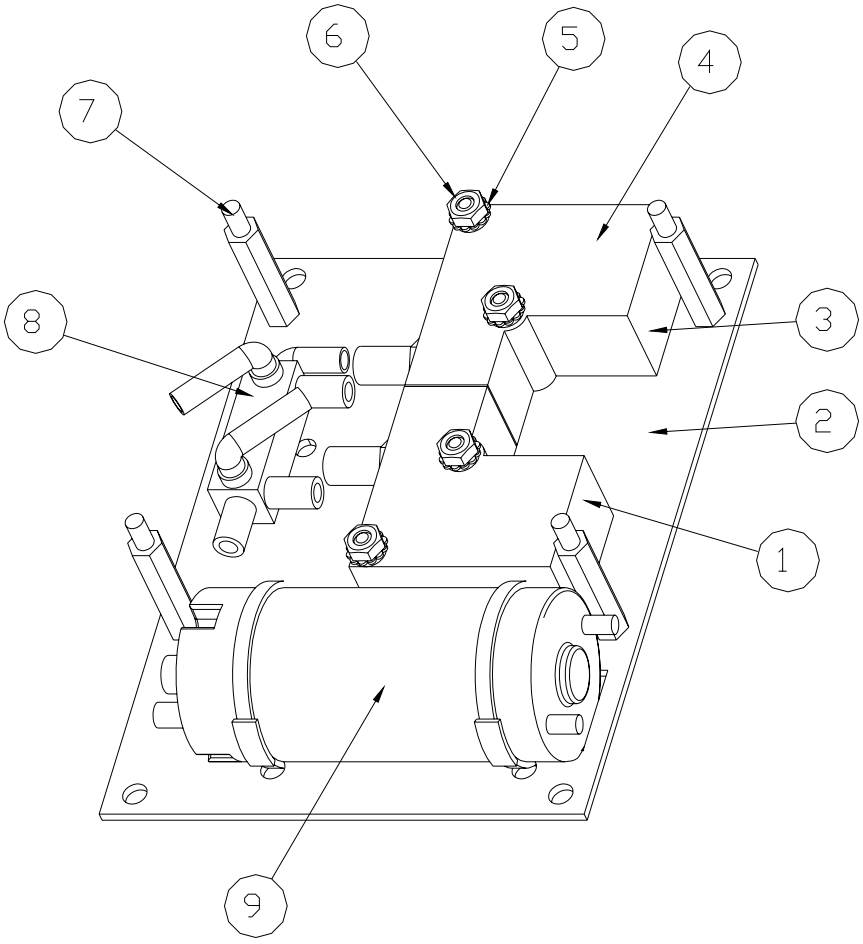


Figure 4-7 NIBP pump assembly

9	5000-10-14656	PUMP KPM27C-12E	1		
8	0010-20-12114	Cavity	1		
7	M04-000018-00	Stud screw M3x20	4		Screw length 6mm
6	M04-011002---	M3 nut with toothed washer	4		
5	M90-000002---	Insulation Washer Φ3x1mm	4		
4	0530-20-00416	Electromagnetic cover Subassembly	2	SPCC	
3	630D-30-09115	quick deflate valve subassembly	1		
2	630A-21-05395	630A bottom plate	1		
1	630D-30-09116	slow deflate valve subassembly			
SN	Standard Code	Name & SPEC.	QTY.	Material	Remarks

4.1.6 Front Panel Assembly

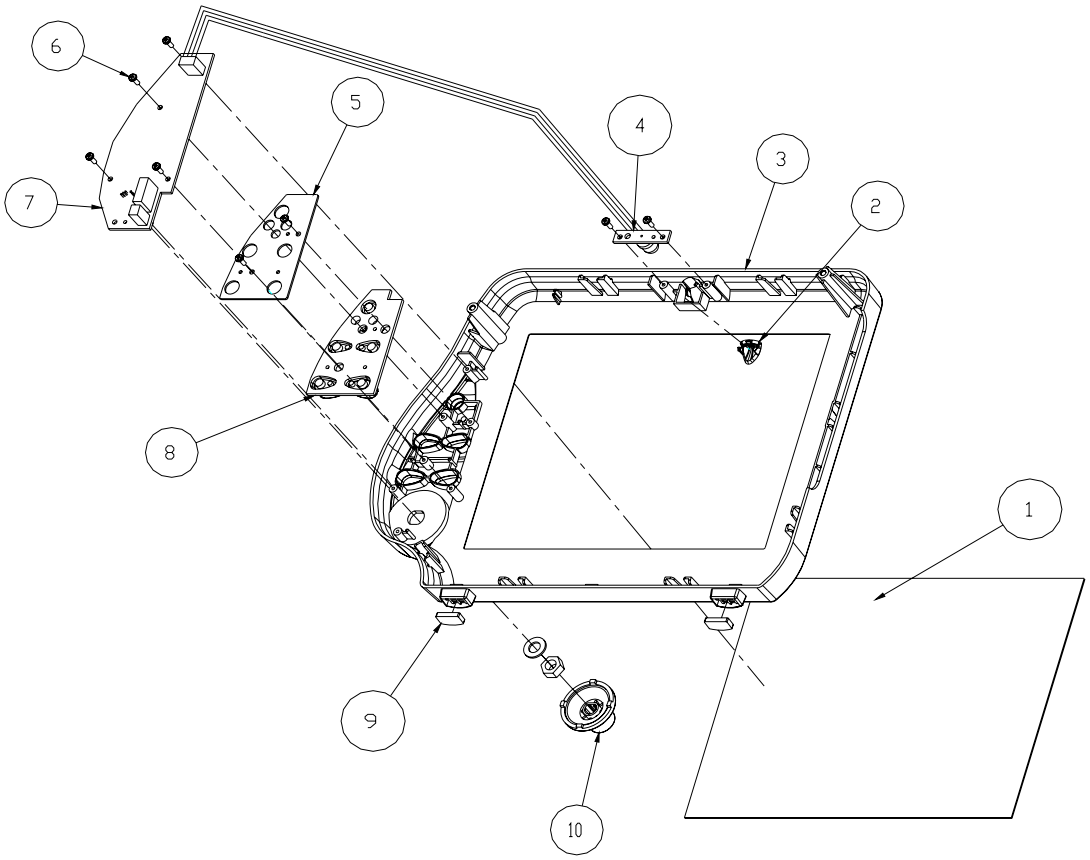


Figure 4-8 Front panel assembly

10	8000-20-10205	Encoder	1		
9	8000-20-10220	Rubber foot	2		
8	8000-20-10194	Rubber button	1		
7	8002-30-36165	Keyboard	1		
6	M04-051003---	Cross panhead tapping Screw PT2x6	9		
5	8000-20-10193	Fixing board of Keyboard	1		
4	8001-30-25667	Alarm indication board	1		
3	8000-20-10192-51	Front panel	1		
2	8000-20-10195	Alarm lamp cover	1		
1	8000-20-10196	anti-Screen	1		
SN	Standard Code	Name & SPEC.	QTY.	Material	Remarks

4.1.7 Rear Panel Assembly

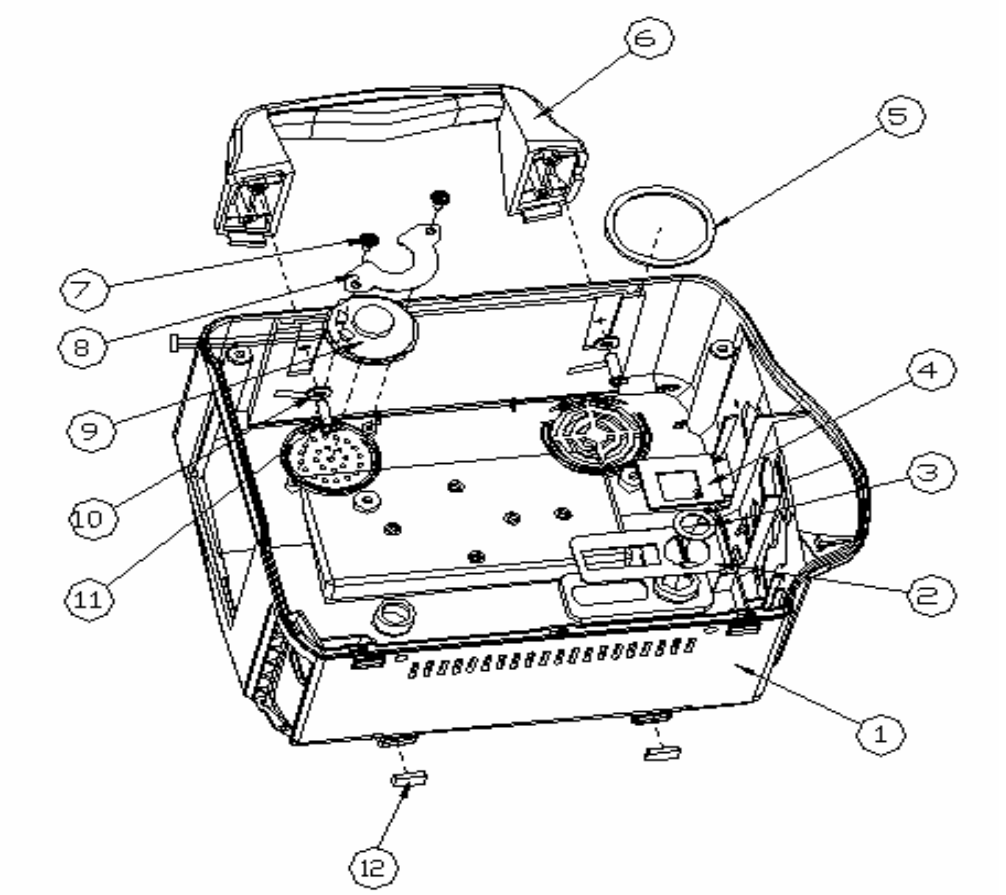


Figure 4-9 Rear panel assembly

12	8000-20-10220	Rubber foot	2		
11	M04-051085---	Cross panhead tapping screw PT4X14	2		
10	M04-004702---	WASHER GB97.2 4	2		
9	8000-21-10292	38mm speaker and its connecting wire	1		
8	8000-20-10296	Press flake of speaker	1	SPCC	
7	M04-003105--	SCREW GB845-85 M3X8	2		
6	5000-20-14620	Handle	1	ABS	
5	8000-20-10219	Fan pad	1		
4	8000-20-10339	Sealing pad 2 of rear panel	1		
3	DA8k-20-14544	Sealing pad 1 of rear panel	1		
2	8000-20-10340	Sealing pad 3 of rear panel	1		
1	8100-20-14140	Rear panel	1	ABS	

4.2 Use of Battery

4.2.1 Assembly/disassembly

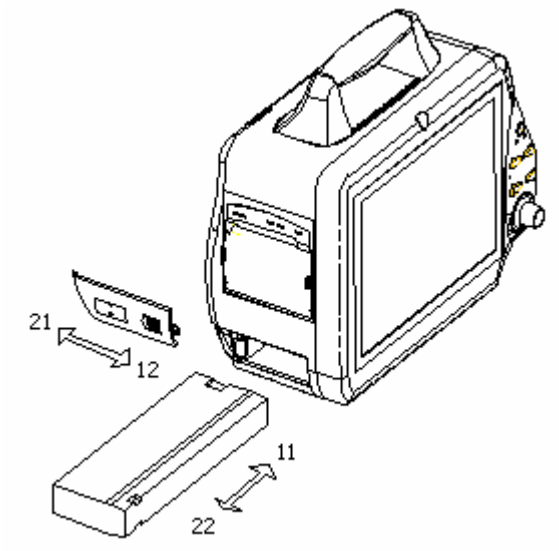


Figure 4-10 Assembly/disassembly of battery

4.2.2 Precautions

1. Battery specification: Lead-Acid 12V rechargeable battery
2. Charging time: 8 hours
3. Discharging time: if the monitor works to measure ECG/RESP/TEMP, SPO2,and NIBP parameters and NIBP is in the mode of one measurement per fifting minutes, a battery with full capacity can power the monitor continuously for 120 minutes. Five minutes before the battery runs out of its capacity, the monitor will give audio and visual prompt.
4. To extend the lifespan o the battery, it is recommended to use it at least once monthly. Besides, the battery shall be charged after its capacity is completely exhausted.

5 Tests

5.1 Introduction

To ensure the patient monitor always functions normally, qualified service personnel should perform regular inspection, maintenance and test. This chapter provides a checklist of the testing procedures for the patient monitor with recommended test equipment and frequency. The service personnel should perform the testing and maintenance procedures as required and use appropriate test equipment.

The testing procedures provided in this chapter are intended to verify that the patient monitor meets the performance specifications. If the patient monitor or a module fails to perform as specified in any test, repairs or replacement must be done to correct the problem. If the problem persists, contact our Customer Service Department.

⚠CAUTION

- **All tests should be performed by qualified service personnel only.**
- **Care should be taken to change the settings in [USER MAINTAIN] and [FACTORY MAINTAIN] menus to avoid loss of data.**
- **Service personnel should acquaint themselves with the test tools and make sure that test tools and cables are applicable.**

5.1.1 Test Equipment

See the following sections.

5.1.2 Test Report

Upon completion of the tests, the table of preventative maintenance test reports and the table of maintenance test reports in this chapter should be kept properly.

5.1.3 Preventative Maintenance

Below are preventative maintenance tests which need to be performed on the monitor. See the following sections for detailed maintenance procedures.

- Visual inspection
- NIBP test and calibration

5.1.4 . Recommended Frequency

Check/Maintenance Item		Frequency
Preventative Maintenance Tests		
Visual inspection		1. When first installed or reinstalled.
NIBP test	Accuracy test	1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of relevant module. 3.At least once a year is recommended for NIBP..
	Leakage test	
Performance Tests		
ECG test	Performance test	1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of relevant module. 3. At least once every two years. Note: At least once a year is recommended for NIBP, CO2 and AG.
	Calibration	
Resp performance test	/	
SpO2 test	/	
NIBP test	Pressure check	
	Leakage test	

Temp test	/	
Electrical Safety Tests		
Electrical safety tests	Refer to ***A Electrical Safety Inspection.***	1. Following any repair or replacement 2. After the monitor drops. 3. At least once every two years.
Other Tests		
Power on test		1. When first installed or reinstalled. 2. Following any maintenance or the replacement of any main unit parts.
Recorder check	/	Following any repair or replacement of the recorder.
Battery check	Functionality test	1. When first installed. 2. Whenever a battery is replaced.

5.2 Preventative Maintenance Procedures

5.2.1 Visual Inspection

Inspect the equipment for obvious signs of damage. The test is passed if the equipment has no obvious signs of damage. Follow these guidelines when inspecting the equipment:

- Carefully inspect the case, the display screen and the buttons for physical damage.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect all external connections for loose connectors, bent pins or frayed cables.
- Inspect all connectors on the equipment for loose connectors or bent pins.
- Make sure that safety labels and data plates on the equipment are clearly legible.

5.2.2 NIBP Tests

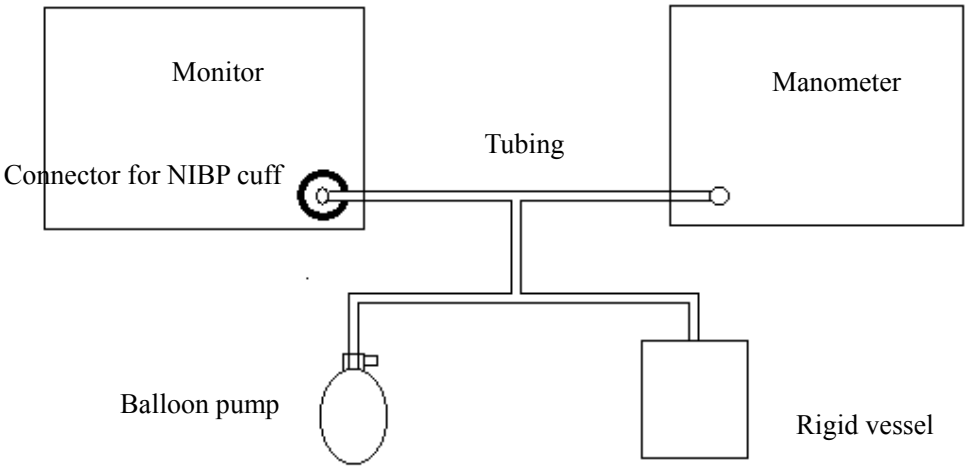
NIBP Accuracy Test

Tools required:

- T-shape connector
- Appropriate tubing
- Balloon pump
- Rigid Vessel with volume 500 ± 25 ml
- Reference manometer (calibrated with accuracy equal to or greater than 1 mmHg)

Follow this procedure to perform the test:

1. Connect the equipment as shown below.



2. Before inflation, the reading of the manometer should be 0. If not, turn off the balloon pump to let the whole airway open to the atmosphere. Turn on the balloon pump after the reading is 0.
3. Select NIBP from NIBP parameter window to access [**NIBP SETUP**] and select [**CALIBRATE**].
4. Check the manometer values and the monitor values. Both should be 0mmHg.
5. Raise the pressure in the rigid vessel to 50 mmHg with the balloon pump. Then, wait for 10 seconds until the measured values become stable.
6. Compare the manometer values with the monitor values. The difference should be 3 mmHg.
7. Raise the pressure in the rigid vessel to 200 mmHg with the balloon pump. Then, wait for 10 seconds until the measured values become stable and repeat step 6.

NOTE

- **You can use an NIBP simulator to replace the balloon pump and the reference manometer to perform the test.**
- **You can use an appropriate cylinder and a cuff instead of the rigid vessel.**

NIBP Leakage Test

NOTE

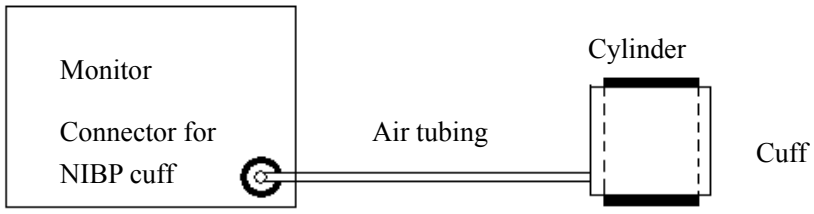
- **You should perform NIBP accuracy test and make sure the test result is pass prior to NIBP leakage test.**

Tools required:

- NIBP cuff for adult patient
- Appropriate tubing
- Cylinder

Follow this procedure to perform the test:

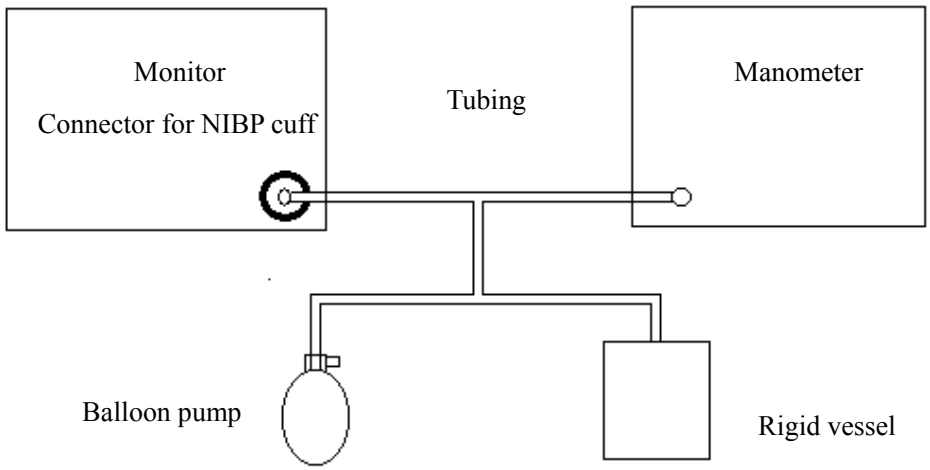
1. Set [**PAT TYPE**] to [**ADU**].
2. Connect the NIBP cuff with the NIBP connector on the monitor.
3. Apply the cuff to the cylinder as shown below.



4. Select NIBP from NIBP parameter window to access [**NIBP SETUP**] menu and select [**PNEUMATIC]**. Then the message "Pneum testing…" is displayed at the lower left corner of the NIBP parameter window.
5. The cuff automatically deflates after 20s, which means NIBP leakage test is completed.

If no message is displayed in the NIBP parameter area, it indicates that the system has no leakage. If the message "PNEUMATIC LEAK" is displayed, it indicates that the system may have a leakage. In this case, check if all connections are good and the cuff and tubing have no leakage. Perform the test again after making sure all connections are good and the cuff and tubing have no leakage.

You can either perform a manual leakage test:
Connect the equipment as shown below.



2. Before inflation, the reading of the manometer should be 0. If not, turn off the balloon pump to let the whole airway open to the atmosphere. Turn on the balloon pump after the reading is 0.

3. Select NIBP from the parameter windows to access [**NIBP SETUP**] menu and select [**PNEUMATIC]**.

4. Check the manometer values and the monitor values. Both should be 0mmHg..

5. Raise the pressure in the rigid vessel to 250 mmHg with the balloon pump. Then, wait for 5 seconds to let the measured values becoming stable.

6. Record the current pressure value and meanwhile use a time counter to count time. Then, record the pressure value after counting to 60s.

7. Compare the two values and make sure the difference should not be greater than 6 mmHg.

5.2.3 Preventative maintenance test report

Customer name		
Customer address		
Servicing person		
Servicing company		
Equipment under test (EUT)		
Model of EUT		
SN of EUT		
Hardware version		
Software version		
Test equipment	Model/No.	Effective date of calibration

Test items	**Test records**	**Test results(Yes/No)**
Visual inspection		
The case, display screen, buttons, knob, modules, power cord, and accessories have no obvious signs of damage.		Yes No
The external connecting cables are not frayed and the connector pins are not loose and bent.		Yes No
The external connectors are not loose or their pins are not bent.		Yes No
The safety labels and data plate are clearly legible.		Yes No
NIBP test		
The difference is within ±3 mm when 0, 50 or 200 mmHg is set for NIBP accuracy test.		Yes No
There is no leakage with NIBP, or the manual leakage test result does not exceed 6mmHg/min.		Yes No

5.3 Power On Test

This test is to verify that the patient monitor can power up correctly. The test is passed if the patient monitor starts up by following this procedure:

1. Insert a battery in the battery chamber and connect the patient monitor to the AC mains, the AC mains LED and battery LED light.
2. Press the power on/off switch to switch on the patient monitor.
3. The alarm lamp turns yellow and then red and then turns off. This indicates that the self test on the alarm lamp is passed. The system sounds a beep indicating the self-test on alarm sounds is passed. Then the start-up screen is displayed.
4. The patient monitor enters the main screen and start-up is finished.

5.4 Module Performance Tests

5.4.1 ECG Tests

ECG Performance Test

Tool required:

- Fluke Medsim 300B patient simulator recommended

Follow this procedure to perform the test:

1. Connect the patient simulator with the ECG module using an ECG cable.
2. Set the patient simulator as follows: ECG sinus rhythm, HR=80 bpm with the amplitude as 1mV.
3. Check the ECG waves are displayed correctly without noise and the displayed HR value is within 80 ± 1 bpm.
4. Disconnect each of the leads in turn and observe the corresponding lead off message displayed on the screen.
5. Set that the simulator outputs paced signals and set [**PACE**] to [**ON**] on the monitor. Check the pace pulse marks on the monitor screen.

ECG Calibration

Tool required:

- Vernier caliper

Follow this procedure to perform a calibration:

1. Select the ECG parameter window or waveform area and set the filter mode to DIAGNOSTIC.
2. Select [**ECG SETUP**]→ [**OTHER SETUP>>**].
3. Select [**ECG CAL**]. A square wave appears on the screen and the message “When CAL, can’t monitor”is displayed.
4. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%.
5. After completing the calibration, select [**STOP ECG CAL**].

If necessary, you can print out the square wave and wave scale through the recorder and then measure the difference.

5.4.2 Resp Performance Test

Tool required:

- Fluke Medsim 300B patient simulator recommended

Follow this procedure to perform the test:

1. Connect the patient simulator to the module using a non ESU-proof cable and set lead II as the respiration lead.
2. Configure the simulator as follows: lead II as the respiration lead, base impedance line as 1500 Ω; delta impedance as 0.5 Ω, respiration rate as 40 rpm.
3. Check the Resp wave is displayed without any distortion and the displayed Resp value is within 40 ± 2 rpm.

5.4.3 SpO_2 Test

Tool Required:

- None.

Follow this procedure to perform the test:

1. Connect SpO2 sensor to the SpO_2 connector of the monitor. Set [**PAT TYPE**] to [**ADU**].
2. Measure SpO2 on your finger. (Assume that you stay healthy)
3. Check the Pleth wave and PR reading on the screen and make sure that the displayed SpO2 is within 95%-100%.
4. Remove the SpO2 sensor from your finger and make sure that an alarm of SpO2 Sensor Off is triggered.

NOTE

- **A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor. However, it can be used to demonstrate that a particular pulse oximeter monitor reproduces a calibration curve that has been independently demonstrated to fulfill a particular accuracy specification.**

5.4.4 NIBP Tests

See section ***5.2.2 NIBP Tests***.

5.4.5 Temp Test

Tool required:

- Resistance box (with accuracy above 0.1Ω)

Follow this procedure to perform the test:

1. Connect the two pins of any Temp connector of a module to the two ends of the resistance box using 2 wires.
2. Set the resistance box to 1354.9Ω (corresponding temperature is 37ºC).
3. Verify each Temp channel of the monitor and make sure that the displayed value is within 37 ± 0.1ºC.

You can also use a patient simulator to perform the Temp test.

5.5 Electrical Safety Test

See ***A Electrical Safety Inspection*** for electrical safety tests.

5.6 Recorder Check

Tools required:

- None.

1. Print ECG waveforms. The recorder should print correctly and the printout should be clear.
2. Set the recorder to some problems such as out of paper, etc. the patient monitor should give corresponding prompt messages. After the problem is removed, the recorder should be able to work correctly.
3. Switch automatic alarm recording for each parameter ON and then set each parameter's limit outside set alarm limits. Corresponding alarm recordings should be triggered when parameter alarms occur.

5.7 Battery Check

Tools required:

- None.

Function Test

1. If the patient monitor is installed with a battery, remove the battery first.
2. Verify that the patient monitor works correctly when running powered form an AC source.
3. Insert a battery per the procedures provided in the Operator's Manual.
4. Remove the AC power cord and verify that the patient monitor still works correctly.

Performance Test

Perform the test by referring to the ***Battery*** section in the Operator's Manual and verify the operating time of the battery meets the product specification.

Maintenance and Test Report

(See the above sections for detailed test procedures and contents)

Customer name		
Customer address		
Servicing person		
Servicing company		
Equipment under test (EUT)		
Model of EUT		
SN of EUT		
Hardware version		
Software version		
Test equipment	Model/No.	Effective date of calibration
Test items	Test records	Test results(Yes/No)
Visual inspection		
The case, display screen, buttons, knob, modules, power cord, and accessories have no obvious signs of damage.		Yes No
The external connecting cables are not frayed and the connector pins are not loose and bent.		Yes No
The external connectors are not loose or their pins are not bent.		Yes No
The safety labels and data plate are clearly legible.		Yes No
Power-on test		
The power-on test is passed. The power indicator and alarm system work correctly and the monitor start up properly.		Yes No
Performance test		
ECG performance test		
ECG waves are displayed correctly without noise and the HR value is within 80±1 bpm.		Yes No
ECG Lead Off alarm behaves correctly.		Yes No

Paced signals are detected and pace pulse marks are displayed when [PACE] is set to [ON].		Yes No
The difference between the amplitude of the ECG calibration square wave and that of the wave scale is not greater than 5%.		Yes No
Resp test		
The Resp wave is not distorted and the Resp value is within 40±2 rpm.		Yes No
SpO2 test		
Measure SpO2 on a healthy person's finger and a Pleth wave and PR value are displayed. The displayed SpO2 value is within 95%-100%		Yes No
NIBP test		
The difference is within ±3 mm when 0, 50 or 200 mmHg is set for NIBP accuracy test.		Yes No
There is no leakage with NIBP, or the manual leakage test result does not exceed 6mmHg/min.		Yes No
Temp test		
The value displayed for each Temp channel of the monitor is within 37±0.1ºC.		Yes No
Electrical safety tests		
Refer to ***A Electrical Safety Inspection***. All the electrical safety tests should be passed.		Yes No
Recorder check		
The recorder can print ECG waves correctly and the printout is clear.		Yes No
Set the recorder to some problems such as out of paper, paper jam, etc. the monitor gives corresponding prompt messages. After the problem is removed, the recorder is able to work correctly.		Yes No
Automatic alarm recording for each parameter functions correctly when parameter alarms occur.		Yes No
Battery check		
The monitor can operates correctly from battery power when an AC power failure accidentally occurs.		Yes No
The patient monitor can operate independently on a single battery.		Yes No
The operating time of the battery meets the product specification.		Yes No

FOR YOUR NOTES

6 Maintenance and Cleaning

6.1 System Checks

6.1.1 Checks Before Using MEC-1200

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

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or Mindray Customer Service Department immediately.

6.1.2 Routine Check

The overall check of the monitor, including the functional safety check, must be performed by qualified personnel once every 6 to 12 month or each time after fix up. All checks that need to open the monitor enclosure must be performed by qualified service personnel.

⚠WARNING

- **If the hospital or agency that is responding to using the monitor does not follow a satisfactory maintenance schedule, the monitor may become invalid, and the human health may be endangered.**

6.2 General Cleaning

⚠WARNING

- **Turn off the power and disconnect the line power before cleaning the monitor or the sensor/probe.**

The MEC-1200 Multi-Parameter Patient Monitor must be kept dust-free.

It is recommended that you should clean the outside surface of the monitor enclosure and the display screen regularly. Only use non-caustic detergents such as soap and water to clean the monitor enclosure.

⚠CAUTION

Pay special attention to avoid damaging MEC-1200 monitor:

- **Avoid using ammonia-based or acetone-based cleaners such as acetone.**
- **Most cleaning agents must be diluted before use. Dilute the cleaning agent as per the manufacturer's direction.**
- **Do not use the grinding material, such as steel wool etc.**
- **Do not let the cleaning agent enter the monitor. Do not immerse any part of the system into liquid.**
- **Do not leave the cleaning agents at any part of the equipment.**

6.3 Cleaning Agents

Use any of the solutions listed below as the cleaning agent.

1. Diluted Sodium Hyoichlo (Bleaching agent)
2. Diluted Formaldehyde 35% -- 37%
3. Hydrogen Peroxide 3%
4. Alcohol
5. Isopropanol

6.4 Sterilization

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

Recommended sterilization materials: Ethylate, and Acetaldehyde.

Appropriate sterilization materials for ECG lead and blood pressure cuff are introduced in relevant chapters of MEC-1200 operation manual.

6.5 Disinfection

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

Appropriate disinfection materials for ECG lead, SpO2 sensor, blood pressure cuff and TEMP probe are introduced in relevant chapters of MEC-1200 operation manual.

FOR YOUR NOTES

7 Troubleshooting

7.1 Back display with white or blurring screen

1. Check if TFT connecting wire is well contacted；
2. If changing connecting wire cannot solve the problem, replace the TFT screen;
3. If fault still exists, replace the main control board.

7.2 Encoder fault

1. If other functions of the keypad run correctly (indicator, alarm light and key), go to the second step; otherwise, replace the keypad;
2. Check if the bonding pad of the encoder is short-circuit connected or abnormal open circuit;
3. Replace the encoder.

7.3 No alarm sound

1. Check if the sound is switched off in the software setups;
2. Replace the speaker;
3. Replace the keypad.

7.4 Can not print

1. Check if the software has alarm related to recorder; if yes, remove the corresponding alarm;
2. Check if the indicator of the recorder is lighted on;
3. If not, check the connecting wire of signal input of the recorder;
4. Check if the recorder module is set to ON in the MAINTAIN menu;
5. Check the connecting wire of the power input of the recorder (including power board of the recorder);
6. Replace the recorder.

7.5 Abnormal paper feeding

1. Check if foreign objects are attached to the paper bail of the recorder;
2. Check if foreign objects are attached to the gears of the thermal head of the recorder;
3. Check if the power voltage of the recorder is >17.8V.

System Alarm Prompt

Prompt	**cause**	**Measure**
"XX TOO HIGH"	XX value exceeds the higher alarm limit.	Check if the alarm limits are appropriate and the current situation of the patient.
"XX TOO LOW"	XX value is below the lower alarm limit.	
XX represents the value of parameter such as HR, ST, RR, SpO2, NIBP, etc in the system.		
"ECG WEAK SIGNAL"	The ECG signal of the patient is too small so that the system can not perform ECG analysis.	Check if the electrodes and lead wires are connected correctly and the current situation of the patient.
“NO PULSE”	The pulse signal of the patient is too small so that the system can not perform pulse analysis.	Check the connection of the sensor and the current situation of the patient.
"RESP APNEA"	The respiration signal of the patient is too small so that the system cannot perform RESP analysis.	Check the connection of the linking wire and the current situation of the patient.
"ASYSTOLE"	Patient suffers from Arr. Of ASYSTOLE.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"VFIB/VTAC"	Patient suffers from Arr. of VFIB/VTAC.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"BIGEMINY"	Patient suffers from Arr. Of BIGEMINY.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"TRIGEMINY"	Patient suffers from Arr. of TRIGEMINY.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"R ON T"	Patient suffers from Arr. of R ON T.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"PVC"	Patient suffers from Arr. of PVC.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"COUPLET"	Patient suffers from Arr. of COUPLET.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.

"TACHY"	Patient suffers from TACHY.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
" BRADY"	Patient suffers from BRADY.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"VT>2"	Patient suffers from Arr. of VT>2.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
“MISSED BEATS”	Patient suffers from Arr. of MISSED BEATS.	Check the current situation of the patient. Check the connection of the electrodes and lead wires.
"PNP"	The pacemaker is not paced.	Check the connection of the pacemaker. Check the connection of electrodes and lead wires. Check the current situation of the patient.
"PNC"	No pacemaker signal is captured.	Check the connection of the pacemaker. Check the connection of electrodes and lead wires. Check the current situation of the patient.
"ECG LEAD OFF"	ECG lead is not connected correctly.	Check the connection of ECG lead wire.
"ECG LL LEAD OFF";	The LL lead wire of ECG is not connected correctly.	Check the connection of LL lead wire.
"ECG LA LEAD OFF";	The LA lead wire of ECG is not connected correctly.	Check the connection of LA lead wire.
"ECG RA LEAD OFF";	The RA lead wire of ECG is not connected correctly.	Check the connection of RA lead wire.
"ECG F LEAD OFF";	The F lead wire of ECG is not connected correctly.	Check the connection of F lead wire.
"ECG L LEAD OFF";	The L lead wire of ECG is not connected correctly.	Check the connection of L lead wire.
"ECG R LEAD OFF";	The R lead wire of ECG is not connected correctly.	Check the connection of R lead wire.
"SPO2 SENSOR OFF"	SPO2 sensor is not connected correctly.	Check the connection of SpO2 sensor.
"SEARCH PULSE"	SPO2 sensor is not connected correctly or the patient arm moves.	Check the connection of SpO2 sensor. Check the current situation of the patient.
"TEMP SENSOR OFF"	TEMP sensor is not connected correctly.	Check the connection of TEMP sensor.
"ECG NOISE"	Rather large interference signals appear in the ECG signals.	Check the connection of ECG lead wire. Check the current situation of the patient. Check if the patient moves a lot.

"XX INIT ERR X"	XX has error X during initialization.	Re-start up the monitor or re-plug in/out the module. If the error still exists, contact the manufacturer.
"XX COMM STOP"	XX cannot communicate with the host.	
"XX COMM ERR"	XX cannot communicate normally with the host.	
XX represents all the parameter modules in the system such as ECG, NIBP, SpO2, , etc.		
"XX ALM LMT ERR"	The alarm limit of XX parameter is modified by chance.	Contact the manufacturer for repair.
"XX RANGE EXCEEDED"	The measured value of XX parameter has exceeded the measuring range of the system.	Contact the manufacturer for repair.
XX represents the parameter name in the system such as HR, ST, RR, SpO2, NIBP, etc.		
"REAL CLOCK NEEDSET"	When the system displays 2000-1-1, the system gives this prompt reminding the user that the current system time is not right.	Re-set up the system time. It is better to set up the time just after the start-up and prior to monitoring the patient. After modifying the time, the user had better re-start up the monitor to avoid storing error time.
"REAL CLOCK NOT EXIST"	The system has no cell battery or the battery has run out of the capacity.	Install or replace the rechargeable battery.
"SYSTEM WD FAILURE"	The system has serious error.	Re-start up the system. If the failure still exists, contact the manufacturer.
"SYSTEM SOFTWARE ERR"		
"SYSTEM CMOS FULL"		
"SYSTEM CMOS ERR"		
"SYSTEM EPGA FAILURE"		
"SYSTEM FAILURE2"		
"SYSTEM FAILURE3"		
"SYSTEM FAILURE4"		
"SYSTEM FAILURE5"		
"SYSTEM FAILURE6"		
"SYSTEM FAILURE7"		
"SYSTEM FAILURE8"		
"SYSTEM FAILURE9"		
"SYSTEM FAILURE10"		
"SYSTEM FAILURE11"		
"SYSTEM FAILURE12"		
"KEYBOARD NOT AVAILABLE";	The keys on the keyboard cannot be used.	Check the keys to see whether it is pressed manually or by other object. If the key is not pressed abnormally, contact the

		manufacturer for repair.
"KEYBOARD COMM ERR";	The keyboard has failure, which cannot be used.	Contact the manufacturer for repair.
"KEBOARD ERROR";		
"KEYBOARD ERR1";		
"KEYBOARD ERR2";		
"5V TOO HIGH"	The power part of the system has failure.	If the prompt appears repeatedly, contact the manufacturer for repair.
"5V TOO LOW"		
"POWER ERR3"		
"POWER ERR4"		
"12V TOO HIGH"		
"12V TOO LOW"		
"POWER ERR7"		
"POWER ERR8"		
"3.3V TOO HIGH"		
"3.3V TOO LOW"		
"RECORDER SELFTEST ERR"	During the selftest, the system fails connecting with the recorder module.	Execute ‘Clear Record Task’ function in the recorder setup menu to re-connect the host and the recorder. If the failure still exists, contact the manufacturer for repair.
"RECORDER VLT HIGH"	The recorder module has voltage failure.	Contact the manufacturer for repair.
"RECORDER VLT LOW"		
"RECORDER HEAD HOT"	The continuous recording time may be too long.	After the recorder becomes cool, use the recorder for output again. If the failure still exists, contact the manufacturer for repair.
"REC HEAD IN WRONG POSITION"	The handle for pressing the paper is not pressed down.	Press down the recorder handle for pressing the paper.
"RECORDER OUT OF PAPER"	No paper is in the recorder.	Place the paper into the recorder.
"RECORDER PAPER JAM"	The paper in the recorder is jammed.	Place the recorder correctly and try again.
"RECORDER COMM ERR"	The communication of the recorder is abnormal.	In the recorder setup menu, execute the function of clearing record task. The function can make the host and the recorder connect again. If the failure still exists, contact the manufacturer for repair.
"RECORDER S. COMM ERR"		
"RECORDER PAPER W.P."	The paper roll of the recorder is not placed in the correction position.	Place the paper roll in the correct position.
"REC NOT AVAILABLE"	Cannot communicate with the recorder.	In the recorder setup menu, execute the function of clearing

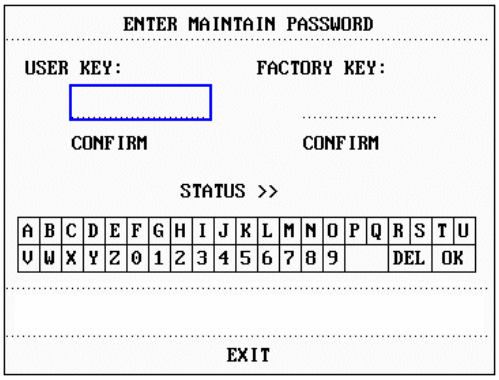
		record task. The function can make the host and the recorder connect again. If the failure still exists, contact the manufacturer for repair.
"NIBP INIT ERR"	NIBP initialization error	Execute the reset program in the NIBP menu. If the failure still exists, contact the manufacturer for repair.
"NIBP SELFTEST ERR"		
"NIBP ILLEGALLY RESET"	During NIBP measurement, illegal reset occurs.	Check the airway of NIBP to see if there are clogs. Then measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP COMM ERR"	The NIBP communication part has problem.	Execute the reset program in the NIBP menu. If the failure still exists, contact the manufacturer for repair.
"LOOSE CUFF"	The NIBP cuff is not connected correctly.	Re-connect the NIBP cuff.
"AIR LEAK"	The NIBP cuff is not connected correctly or there are leaks in the airway.	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"AIR PRESSURE ERROR"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"WEAK SIGNAL"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check if the setup of patient type is correct. Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair
"RANGE EXCEEDED"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"EXCESSIVE MOTION"	The patient arm moves.	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"OVER PRESSURE"	Perhaps folds exist in the airway.	Check for the smoothness in the airway and patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"SIGNAL SATURATED"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.

"NIBP TIME OUT"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"CUFF TYPE ERR"	Perhaps the used cuff does not fit the setup patient type.	Check if the patient type is set up correctly. Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"PNEUMATIC LEAK"	NIBP airway has leaks.	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"MEASURE FAIL"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP SYSTEM FAILURE"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.

FOR YOUR NOTES

8 Maintenance Menu

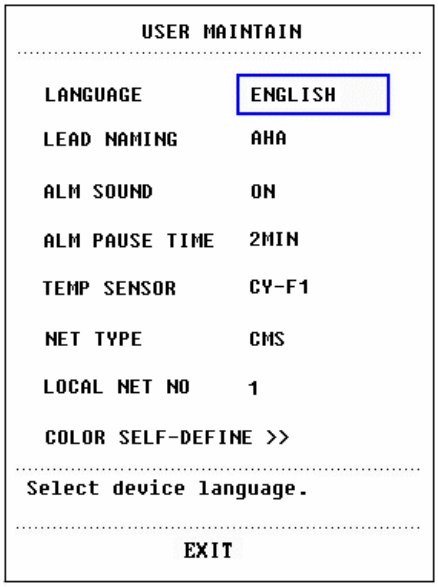
Select the [**MAINTAIN**] item in the SYSTEM MENU to call up the ENTER MAINTAIN PASSWORD dialog box as shown below, in which you can enter password and then customize maintenance settings.

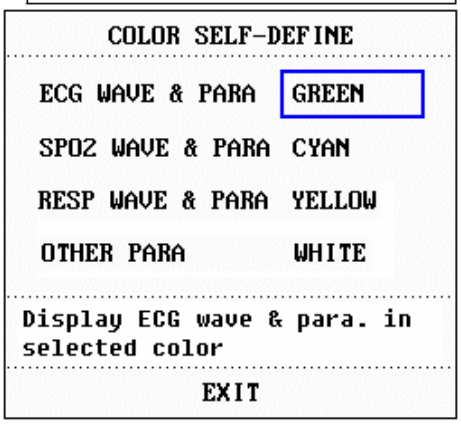


8.1 Password

1. user key: MINDRAY
2. Factory key: 332888
3. DEMO key: 2088

8.2 User Maintain menu





Enter[**USER MAINTAIN**]menu, you can do the follow thing

For the **[LANGUAGE**] language, you can set the screen language you need.

For the [**LEAD NAMING**] item, you can select “AHA” or “EURO”. To know the difference between these two styles, refer to ***Chapter: ECG/RESP Monitoring***.

For the [**ALM SOUND**] item, you can set the alarm volume to “ON” or “OFF”.

For the [**ALM PAUSE TIME**] item, you can set up the duration of Alarm Pause status. Three options are available, 1 minute, 2 minutes and 3 minutes.

In the [**TEMP SENSOR**] item, you can choose either “YSI” or “CY-F1”. “YSI” is for imported

TEMP probe and “CY-F1” is for homemade TEMP probe (i.e., made in China).

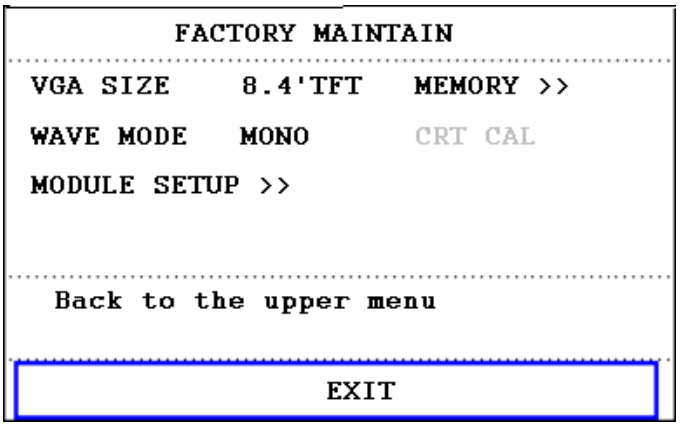
In the [**NET TYPE**] item, you can choose “HYPER III” or “CMS”.

In the [**LOCAL NET NO**] item, It refers to the net No.

[**COLOR SELF-DEFINE**]: This is used to define the color of the waveform displayed on the screen. Five colors can be chosen from: green, cyan, red, yellow and white.

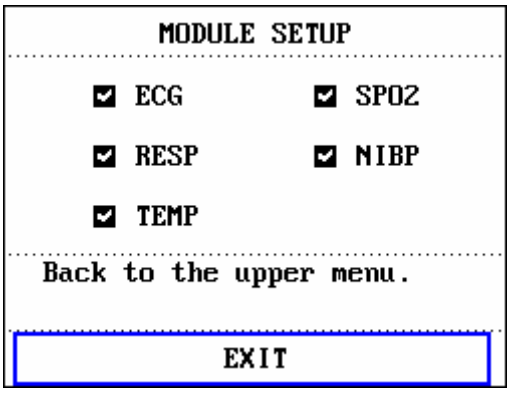
8.3 Factory Maintain

Enter [**FACTORY MAINTAIN]** menu, you can do the follow thing



For the [**VGA SIZE**] item, you can set the screen size when the screen size is not right.
For the [**MEMORY**] item, you can check the used memory.
For the [**VGA SIZE**] item, you can set the screen size when the screen size is not right.
For the [**WAVE MODE**] item, you can choose “MONO” or “COLOR”.

For the [**MODULE SETUP**] item, you can choose the parameter module on or off.



A Electrical Safety Inspection

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed using commercially available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers complying with IEC 60601-1 used in Europe such as Fluke, Metron, or Gerb may require modifications to the procedure. Follow the instructions of the analyzer manufacturer.

The consistent use of a safety analyzer as a routine step in closing a repair or upgrade is emphasized as a mandatory step if an approved agency status is to be maintained. The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

A.1 Power Cord Plug

- The Power Plug

Test Item		Acceptance Criteria
The power plug	The power plug pins	No broken or bent pin. No discolored pins.
	The plug body	No physical damage to the plug body.
	The strain relief	No physical damage to the strain relief. No plug warmth for device in use.
	The power plug	No loose connections.
The power cord		No physical damage to the cord. No deterioration to the cord.
		For devices with detachable power cords, inspect the connection at the device.
		For devices with non-detachable power cords, inspect the strain relief at the device.

A.2 Device Enclosure and Accessories

- Visual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No physical damage to the enclosure and accessories.
	No physical damage to meters, switches, connectors, etc.
	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).

- Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., a rattle inside the case).
	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).
	No taped notes that may suggest device deficiencies or operator concerns.

A.3 Device Labeling

Check the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

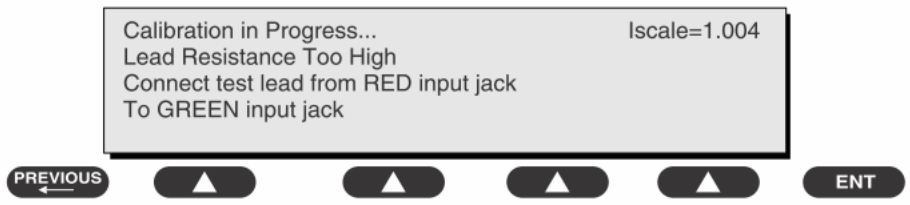
A.4 Protective Earth Resistance

Protective Earth Resistance is measured using the RED test lead attached to the DUT Protective Earth terminal or enclosure. Select the test current by pressing SOFT KEY 3 to toggle between 1AMP, 10AMP, and 25AMP. The front panel outlet power is turned off for this test.

The following conditions apply: L1 and L2 Open.

Preparation

1. First select the test current that will be used for performing the Protective Earth Resistance test by pressing AMPERES (SOFT KEY 3).
2. Connect the test lead(s) between the RED input jack and the GREEN input jack.
3. Press CAL LEADS. The 601PRO will measure the lead resistance, and if less than 0.150 Ohms, it will store the reading and subtract it from all earth resistance readings taken at the calibrated current.



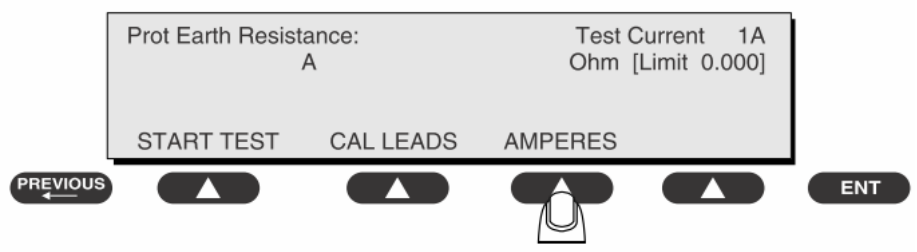
If the calibration fails, the previously stored readings will be used until a passing calibration has occurred.:

⚠WARNING

- **During Earth Resistance testing, the DUT must be plugged into the 601PRO front outlet. If the DUT fails Earth Resistance, discontinue tests and label the device defective.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet.
2. Attach the 601PRO RED input lead to the device's Protective Earth terminal or an exposed metal area.
3. Press shortcut key 3. The Protective Earth Resistance test is displayed.
4. Press SOFT KEY 3 to select a test current (1AMP, 10AMP, or 25AMP). The selected test current is displayed in the upper right corner of the display.



5. Press START TEST to start the test. The test current is applied while resistance and current readings are taken. This takes approximately 5 seconds.
6. Press the print data key at any time to generate a printout of the latest measurement(s).

NOTE

- **When "Over" is displayed for Ohms, this signifies that a valid measurement was not obtained because either an open connection was detected or that the measurement was not within range. Readings greater than 9.999 Ohms will be displayed as Over.**

In Case of Failure

Once it reaches the limitation, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

ALL COUNTRIES R = 0.2Ω Maximum

A.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

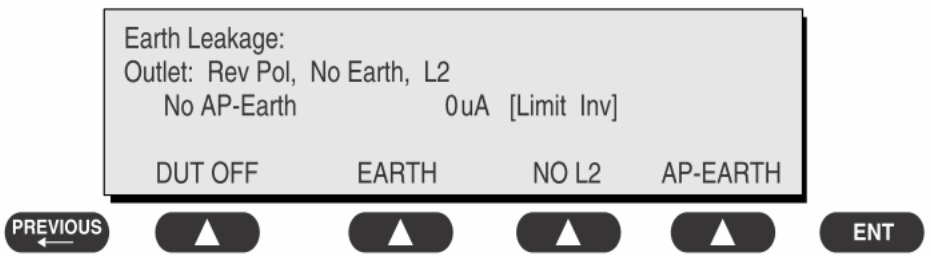
Leakage current is measured the following ways:

- Earth Leakage Current, leakage current measured through DUT outlet Earth
- Earth Leakage Current AP-EARTH (ALL Applied Parts connected to Earth), leakage current measured through DUT outlet Earth

There is no need to attach a test lead; the 601PRO automatically connects the measuring device internally.

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the device's applied parts to the 601PRO applied part terminals if applicable.
3. Press shortcut key 4.The Earth Leakage test appears on the display, and the test begins immediately:



- SOFT KEY 1 toggles the DUT outlet Polarity from Normal to Off to Reverse.
- SOFT KEY 2 toggles the DUT outlet from Earth to No Earth.
- SOFT KEY 3 toggles the DUT outlet from L2 to No L2.
- SOFT KEY 4 toggles the AP to Earth to No AP to Earth.

4. Press the print data key at any time to generate a printout of the latest measurement.

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- Inspect wiring for bad crimps, poor connections, or damage.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

USA:	300 μA Normal Condition
	1000 μA Single Fault Condition
OTHER COUNTRIES:	500 μA Normal Condition
	1000 μA Single Fault Condition

A.6 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements may have either a true RMS or a DC-only response.

Preparation

Perform a calibration from the Mains on Applied Part menu.

The following outlet conditions apply when performing this test:

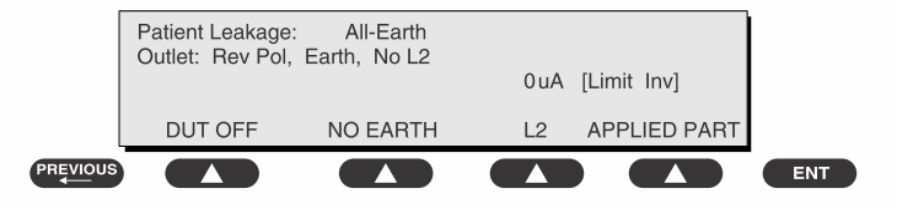
- Normal Polarity, Earth Open, Outlet ON Normal Polarity, Outlet ON
- Normal Polarity, L2 Open, Outlet ON Reversed Polarity, Outlet ON
- Reversed Polarity, Earth Open, Outlet ON Reversed Polarity, L2 Open, Outlet ON

⚠WARNING

- **If all of the applied parts correspond to the instrument type, the applied parts will be tied together and one reading will be taken. If any of the applied parts differ from the instrument type, all applied parts will be tested individually, based on the type of applied part. This applies to Auto and Step modes only.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the applied parts to the 601PRO's applied part terminals.
3. Press shortcut key 6. The Patient Leakage test is displayed, and the test begins immediately.



4. Press APPLIED PART (SOFT KEY 4) at any time to select the desired applied part leakage current.
5. Modify the configuration of the front panel outlet by pressing the appropriate SOFT KEY on the 601PRO.
6. Press the print data key at any time to generate a printout of the latest measurement.

NOTE

- **If the current test standard being used does not include Patient Leakage DC readings, or the DC option is not enabled, then DC readings will not be available through the APPLIED PART SOFT KEY selections. Refer to Chapter 8, Standards and Principles.**

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.

- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- Inspect wiring for bad crimps, poor connections, or damage.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

USA:

For ECG Input and ECG Input and other applied parts

- 10μA Normal Condition
- 50μA Single Fault Condition

OTHER COUNTRIES:

For ECG Input (Defibrillator proof)

- 10μA Normal Condition
- 50μA Single Fault Condition

For ECG Input and other applied part

- 100μA Normal Condition
- 500μA Single Fault Condition

A.7 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage, through a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) to applied parts in the normal and reverse polarity conditions as indicated on the display.

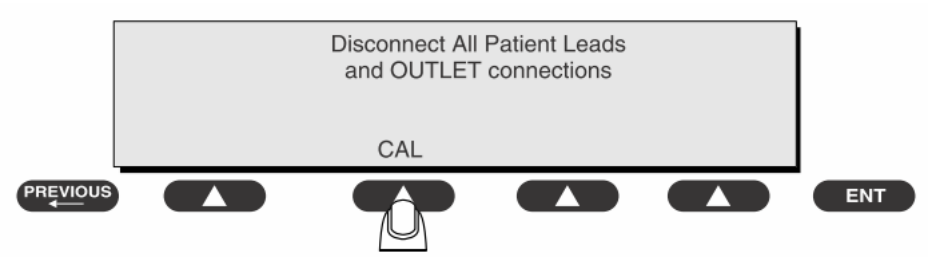
The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity

Preparation

To perform a calibration from the Mains on Applied Part test, press CAL (SOFT KEY 2).

1. Disconnect ALL patient leads, test leads, and DUT outlet connections.
2. Press CAL to begin calibration, as shown:



If the calibration fails, the previously stored readings will be used until a passing calibration has occurred. Also, the esc/stop key has no effect during calibration.

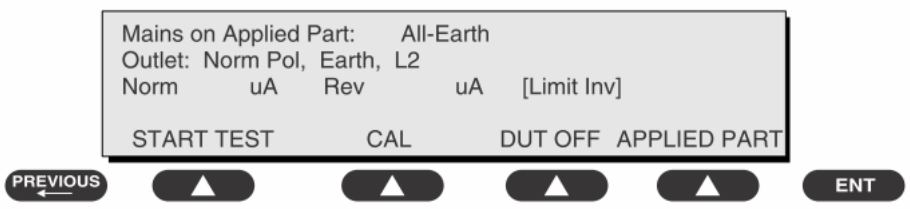
3. When the calibration is finished, the Mains on Applied Part test will reappear.

⚠WARNING

- **A 2-beep-per-second signal indicates high voltage present at the applied part terminals while a calibration is being performed.**
- **High voltage is present at applied part terminals while measurements are being taken.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601
2. Attach the applied parts to the 601PRO applied part terminals.
3. Attach the red terminal lead to a conductive part on the DUT enclosure.
4. Press shortcut key 7. The Mains on Applied Part test is displayed.



5. Select the desired outlet configuration and applied part to test using the appropriate SOFT KEYS:
6. Press START TEST (SOFT KEY 1) to begin the test.
7. Press the print data key to generate a printout of the latest measurement.

NOTE

- **If all of the applied parts correspond to the instrument type, the applied parts will be tied together and one reading will be taken. If any of the applied parts differ from the instrument type, all applied parts will be tested individually, based on the type of applied part. This applies to Auto and Step modes only.**

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- Inspect wiring for bad crimps, poor connections, or damage.

- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

USA

For ECG Input and ECG Input and other applied parts
50μA

OTHER COUNTRIES:

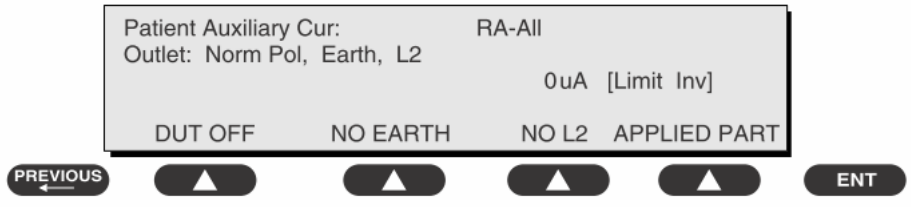
For ECG Input
50μA
For ECG Input and other applied parts
5000μA

A.8 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected ECG jack and the remaining selected ECG jacks. All measurements may have either a true RMS or a DC-only response.

Preparation

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the patient leads to the 601PRO ECG jacks.
3. Define the Lead Types from the View Settings Option (refer to: Lead Type Definitions in Section 5 of this chapter).
4. Press shortcut key 8. The Patient Auxiliary Current test is displayed, and the test begins immediately. Display values are continuously updated until another test is selected.



5. Press SOFT KEYS 1-4 to select leakage tests

6. Press APPLIED PART (SOFT KEY 4) at any time to select the desired applied part leakage current:

7. Modify the configuration of the front panel outlet by pressing the appropriate SOFT KEY on the 601PRO:

8. Press the print data key at any time to generate a printout of the latest measurement.

NOTE

- **If the current test standard being used does not include Patient Auxiliary Current DC readings, or the DC option is not enabled, then DC readings will not be available through the APPLIED PART SOFT KEY selections.**

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- Inspect wiring for bad crimps, poor connections, or damage.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

USA

For ECG Input and ECG Input and other applied part

- 10μA Normal Condition
- 50μA Single Fault Condition

OTHER COUNTRIES:

For ECG Input

- 10μA Normal Condition
- 50μA Single Fault Condition

For ECG Input

- 100μA Normal Condition
- 500μA Single Fault Condition

A.9 Functional test

For functional test items, please refer to relevant functional tests in ***5 Tests***.

FOR YOUR NOTES

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ELECTRICAL SAFETY INSPECTION FORM

American version

Overall assessment:

□ Scheduled inspection — Test item: 1, 2, 3, 9

□ Unopened repair type — Test item: 1, 2, 3, 9

□ Opened repair type, not modify the power part including transformer or patient circuit board — Test item: 1, 2, 3, 4, 5, 9

□ Opened repair type, modify the power part including transformer or patient circuit board — Test item: 1, 2, 3, 4, 5, 6, 7, 8, 9

Location				Technician	
Equipment				Control Number	
Manufacturer		Model		SN	
Measurement equipment /SN				Date of Calibration	
INSPECTION AND TESTING				Pass/Fail	Comments
1	Power Cord Plug				
2	Device Enclosure and Accessories				
3	Device Labeling				
4	Protective Earth Resistance	Ω			Max 0.2 Ω
5	Earth Leakage	—		—	Max
	Normal condition(NC)	μA			NC:300μA
	Single Fault condition(SFC)	μA			SFC:1000μA
6*	Patient Leakage Current	—		—	Max
	Normal condition(NC)	μA			NC:10μA,
	Single Fault condition(SFC)	μA			SFC: 50μA
7*	Mains on Applied Part Leakage				Max 50μA
8*	Patient Auxiliary Current	—		—	Max
	Normal condition(NC)				NC:10μA,
	Single Fault condition(SFC)				SFC: 50μA
9	Functional test (parameters tested):				

Note: The test items marked "*" are needed only for incoming inspections and after repairs or modifications that may have affected lead leakage [NFPA 99 (2005)8.5.2.1.3].

Deficiency / Note:

Name: _____ Date / Signature:_____

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ELECTRICAL SAFETY INSPECTION FORM

International version

Overall assessment:

□ Scheduled inspection — Test item: 1, 2, 3, 9

□ Unopened repair type — Test item: 1, 2, 3, 9

□ Opened repair type, not modify the power board and patient circuit board — Test item: 1, 2, 3, 4, 5, 9

□ Opened repair type, modify the power board or patient circuit board — Test item: 1, 2, 3, 4, 5, 6, 7, 8, 9

Location			Technician	
Equipment			Control Number	
Manufacturer	Model		SN	
Measurement equipment /SN			Date of Calibration	
INSPECTION AND TESTING			Pass/Fail	Comments
1	Power Cord Plug			
2	Device Enclosure and Accessories			
3	Device Labelling			
4	Protective Earth Resistance	Ω		Max 0.2 Ω
5	EARTH Leakage	—	—	Max NC:500μA SFC:1000μA
	Normal condition(NC)	μA		
	Single Fault condition(SFC)	μA		
6*	Patient Leakage Current	—	—	Max CF AP NC:10μA, SFC: 50μA BF AP NC:100μA, SFC: 500μA
	Normal condition(NC)	μA		
	Single Fault condition(SFC)	μA		
7*	Mains on Applied Part Leakage			Max CF AP: 50μA BF AP: 5000μA
8*	Patient Auxiliary Current	—	—	Max CF AP NC:10μA,SFC: 50μA BF AP NC:100μA, SFC: 500μA
	Normal condition(NC)			
	Single Fault condition(SFC)			
9	Functional test (parameters tested):			

Note: The test items marked "*" are needed only for incoming inspections and after repairs or modifications that may have affected lead leakage [NFPA 99 (2005)8.5.2.1.3].

Deficiency / Note:

Name: _____ Date / Signature: _____