Service Manual

EDAN

iM80

Patient Monitor

Version 1.0

CE 0123

About this Manual

P/N: 01.54.455512-10

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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Materials protected by the copyright law, including but not limited to confidential information such as technical information and patent information are contained in this manual, the user shall not disclose such information to any irrelevant third party.

The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of EDAN.

EDAN holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

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Chapter 1 Warranty and Service

Standard Service

EDAN provides a one-year-warranty for the warranted products (accessories are included). The warranty period begins on the date the products are shipped to customers. If a customer promptly notifies EDAN of customer's warranty claim hereunder, EDAN will either repair, adjust or replace (with new or exchange replacement parts) EDAN's products. EDAN warrants that any service it provides to customers will be performed by trained individuals in a workmanlike manner.

Limitation of Warranty

Direct, indirect or final damage and delay caused by the following situations for which EDAN is not responsible may void the warranty:

- ✧ Groupware is dismounted, stretched or redebugged.
- ✧ Unauthorized modification or misuse.
- ✧ Damage caused by operating beyond the environmental specifications for the medical product.
- ✧ Change or remove original serial number label or Manufacturer symbol.
- ✧ Improper use.

Service Procedure

(1) Fill in the **Service Claim Form (SCF)**.

Fill in the SCF with detailed information including: **Model Name**, **Serial Number (SN)** and **Problem Phenomena**.

EDAN should not have any obligation to take over the case without this information. The form can be downloaded at: http://www.edan.com.cn or obtained from EDAN's Service Department.

(2) Send EDAN the SCF and Select a Solution.

Once the service department receives the fully filled SCF, EDAN's engineer will offer a solution in three working days. EDAN will follow out the case based on the two conditions below:

Within Warranty:

There are two options:

i) After receiving the **Return Material Authorization (RMA)** form from EDAN service department, the customer sends EDAN the defective parts and informs about the shipment tracking number. Then we will dispatch new part(s) to your confirmed address with confirmed shipping invoice.

ii) The customer signs the **Declaration Form** and sends it back by email or fax. This form is legally certificated to make sure the customer or end-user will return the defective parts to EDAN on time. We will, at this option, dispatch the replacement one(s) with confirmed shipping invoice.

NOTES:

(1) Both Return Material Authorization Form and Declaration Form are offered by EDAN service department once the SCF is confirmed by service engineer.
(2) The customer is responsible for freight & insurance charges when the equipment is shipped to EDAN for service, including custom charges. EDAN is responsible for the freight, insurance & custom charges from EDAN to the customer.

Out of Warranty:

After receiving the RMA form from the service department, the customer sends defective parts to EDAN in advance. We will analyze the problems and discuss with the customer about either repairing or replacing the part(s). Once the maintenance fee is invoiced and paid, we will make sure to dispatch good part(s) to the confirmed address.

NOTE: The customer is responsible for any freight & insurance charge for the returned product.

(3) Obtain the RMA Form.

Before the shipment of the materials, the customer must obtain an RMA form from our service department, in which the RMA number, description of returning parts and shipping instructions are included. The RMA number should be indicated on the outside of the shipping container.

NOTE:

EDAN should not have any obligation to the end-user or customer who returns the goods without the notification by EDAN's service department. The sender takes full responsibility for the accounted fee.

(4) Send the Parts to EDAN.

Follow these recommended instructions:

- ✧ Please disassemble the parts with anti-static facility, do not touch the parts with naked hand.
- ✧ Please pack the parts safely before return.
- ✧ Please put the RMA number on the parcel.
- ✧ Please describe the returned parts as ‘sample of *****’ and put the total value on the invoice, and note on the invoice as ‘sample, no commercial value’.
- ✧ Please confirm the invoice with EDAN before shipment.
- ✧ Please send back the parts after EDAN’s confirmation.

Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, do not hesitate to contact us.

EDAN Instruments, Inc.

TEL: +86-755-26898321, 26899221

FAX: +86-755-26882223, 26898330

E-mail: support@edan.com.cn

Chapter 2 Safety Guidance

2.1 Introduction

This service manual is a reference for periodic preventive maintenance and corrective service procedures for the iM80 patient monitor. It provides information on troubleshooting, assembly procedures, and instructions for functional testing as well as performance verification. The manual is intended for use only by technically qualified service personnel.

WARNING

Please follow the instructions exactly in accordance with this manual during service. Failure to do so might result in damage to the monitor or personal injury.

2.2 General Information

iM80 Patient Monitor (hereinafter called monitor) is designed in accordance with the international safety requirements in IEC/ EN 60601-1 for medical electrical equipment. Classification information of this equipment is as follows:

Anti-electroshock Type	Class I equipment and internal powered equipment
Anti-electroshock Degree	NIBP, SpO_2, CO_2, AG BF ECG, TEMP, IBP, C.O. CF
Ingress Protection	IPX1
Degree of Safety in Presence of Flammable Gases	Not suitable for use in presence of flammable gases
Working System	Continuous operation equipment
EMC Type	Group 1 Class A

2.3 Safety Precautions

To avoid possible injury, please observe the following precautions during the operation of the monitor.

WARNING

1 The monitor must be serviced only by authorized and qualified personnel. EDAN does not assume any responsibility for damage or injury if modifications or repairs are carried out by unauthorized personnel.

2 Use and replace the substitutive parts provided or recommended by EDAN only.

3 The service personnel must be familiar with the operation of this monitor. Refer to *Patient Monitor User Manual* for details.

4 Perform periodic safety test to ensure patient safety. Safety test should include leakage current measurement and insulation testing.

5 Disconnect the monitor from power before replacing the fuses which are with the identical specifications.

6 **SHOCK HAZARD** – Do not remove the top panel cover during operation or while power is on. The unit cover must be removed only by authorized service personnel.

7 **SHOCK HAZARD** – Do not attempt to connect or disconnect the power cord with wet hands. Make sure that your hands are clean and dry before touching the power cord.

8 Accessory equipment connected to the analog and digital interface must be certified according to the respective IEC/ EN standards (e.g. IEC/ EN 60950 for data processing equipment and IEC/ EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC/ EN 60601-1-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/ EN 6060-1-1-1. If you have any question, please consult our technical service department or your local distributor.

9 Do not remove the battery while AC power is on.

10 Do not directly connect the battery to an electric outlet.

11 Do not directly solder the lead wire and the batter terminal.

CAUTION

1 The device is designed for continuous operation. Avoid splashing water over the device.

2 Do not operate the device when it is damp or wet. Avoid using the device immediately after relocating it from a cold environment to a warm and humid environment.

3 While the battery is charged, used or stored, keep it away from objects or materials with static electric charges.

Chapter 3 Installation

WARNING

Only qualified service engineers should install this equipment.

3.1 Environment Requirements

Working	
Temperature	5 ºC ~ 40 ºC (41ºF ~ 104ºF)
Relative Humidity	25% ~ 80% (non-condensing)
Atmospheric Pressure	860hPa ~ 1060hPa
Storage	
Temperature	-20 ºC ~ 55 ºC
Relative Humidity	25% ~ 93% (non-condensing)
Atmospheric Pressure	700hPa ~ 1060hPa

NOTE:

1 Do not install the monitor in close proximity to flammable anesthetics.

2 Keep the environment clean and keep the device away from corrosive medicine. Prevent the device from vibration, high temperature, humidity and exposure to the sun.

3.2 Electrical Requirements

Operating Voltage	100V-240V ~
Operating Frequency	50Hz/60Hz
Current	1.4A-0.7A

3.3 Safety Requirements

CAUTION

1 **SHOCK HAZARD** – To protect patients and medical staff, the power receptacle must be well grounded. Never adapt the three-prong plug from the monitor to fit a two-socket outlet.

2 Do not simultaneously touch the signal input or output connector and the patient.

3 The monitor and equipment connected to the monitor should be equipotential to ensure effective grounding.

4 Do not switch on the monitor until all units and accessories have been properly connected and verified.

3.4 Installing the Monitor

- To install the monitor on a flat surface.

Place the monitor on a flat surface. Make sure the surface does not vibrate, and is free of corrosive medicine and dust.

iM80 on a Flat Surface

- To install the monitor on a trolley.

If the user wants to install the monitor on a trolley, please refer to the assembling instruction delivered with the trolley for details.

3.5 Connecting to AC Power

Apply the power cable offered with the monitor. Plug one end of the power cable to the power socket of the monitor before buckling the security lock to the plug as showed below. Then connect the other end to a grounded 3-prong power output special for hospital usage.

Chapter 4 Test and Maintenance

4.1 Routine Test

An overall check of the monitor, including safety check and performance check, should be performed by qualified personnel every 24 months or after service.

4.1.1 Visual Inspection

Before using the monitor, the user must:

- Inspect the monitor and accessories for obvious signs of damage.
- Check the external cables, power socket and power cable.

Do not use the monitor if any damage is detected until the monitor is repaired by the service personnel of EDAN or professional service personnel of the dealer.

4.1.2 Power- on Test

Switch on the monitor after it is connected to the power source and check:

- If the power indicator lights up;
- If the alarm indicators flicker and if the alarm tone is heard;
- If some images and characters are missing;
- If there are bright spots and dark shadows on the LCD screen;
- If the waveforms, fonts and symbols displayed on the LCD screen are normal.

If any failure is detected, refer to section *Monitor Booting Failures* and *Display Failures* for details.

4.1.3 Key Test

Press the keys on the front panel in turn to check if they work properly. When pressing a key, a corresponding functional display is supposed to be seen onscreen. Refer to *Patient Monitor User Manual* for details about the key function. The user can move the cursor by turning the trim knob clockwise or anticlockwise. Also, the user can confirm the operation by pressing the trim knob.

4.1.4 Recording Test

Check if the recorder can perform recording without problem. Also, check if all the recorded traces are correct and clear on the paper.

If any failure is detected, refer to section *Recorder Failures* for details.

NOTE:

Please make sure paper is well loaded and the setting is correct before recording.

4.1.5 Alarm Test

Trigger a signal that is higher than the upper limit or lower than the lower limit to activate a physical alarm. Disconnect one of the accessories from the monitor to activate a technical alarm. Check if the audible and visible alarms work properly.

If any failure is detected, refer to section *Alarm Failures* for defective details.

4.2 Performance Test

WARNING

1 Performance test must only be carried out by qualified service personnel.

2 If performance of the monitor is in question, conduct an overall performance test according to the instructions offered by the manufacturer.

A performance check should be performed once possible device malfunction emerges or after servicing the device.
It is unnecessary to open the device case for performance checks.

4.2.1 ECG Performance Test

This test checks the performance of the ECG measurement.

Tools required: ECG simulator.

Procedure:

1. Connect the ECG simulator to the monitor with an ECG cable.
2. Switch on the monitor and the simulator.
3. Set the simulator to the following configuration:

   - HR=30bpm.

4. Check the displayed HR value against the simulator configuration. The value should be 30bpm ±1bpm or ±1% (whichever is greater).

4.2.2 SpO_2 Performance Test

This test checks the performance of the SpO_2 measurement.

Tools required: SpO_2 simulator.

Procedure:

1. Connect the monitor and the SpO_2 simulator with a SpO_2 cable.
2. Switch on the monitor and the simulator.
3. Set the simulator to the following configuration:

   - SpO_2 = 70%.

4. Check the displayed SpO_2 value against the simulator configuration. The value should be 70% ±2%.

4.2.3 NIBP Performance Test

This test checks the performance of the NIBP measurement.

Tools required:

- NIBP simulator;
- T-fitting;
- Extension tube;
- Artificial limb.

Procedure:

1. Connect the NIBP simulator to the monitor.
2. Switch on the monitor and the simulator. Calibrate the simulator before using it.
3. Set the patient type on the monitor to adult; set the simulator to the following configuration:

   - Patient type: adult;

   - Systolic pressure=255mmHg;

   - Diastolic pressure=195mmHg;

   - Mean pressure=215mmHg.

   And then start a NIBP measurement.

4. Check the displayed values against the simulator configuration. The differences should be

within the range of ±8mmHg.

4.2.4 NIBP Leakage Test

This test checks leakage of the airway. See Figure 4-1 for details about tools required.

1. Connect the cuff securely with the socket for NIBP air hole.
2. Wrap the cuff around the cylinder with an appropriate size.
3. Access **Menu** > **Maintenance** > **User Maintain** by inputting the password **ABC**. Start a leakage test by selecting **NIBP Maintain** > **Leak Test**.

The system will automatically inflate the pneumatic system to 180 mmHg. After 20 seconds, the system will automatically open the deflating valve, which marks the completion of a pneumatic measurement.

If the prompt of **Leak Test OK** appears, it indicates that the airway is in good situation and no air leaks exist. However if the alarm information of **NIBP Cuff Leak** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the pneumatic test. If the failure prompt still appears, please contact the manufacturer for repair.

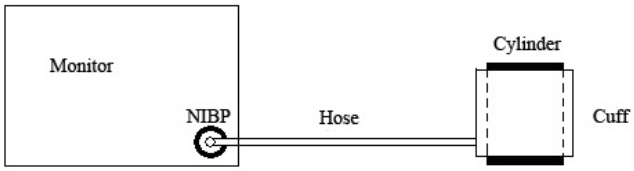


Figure 4-1 Diagram for NIBP Leakage Test

4.2.5 NIBP Calibration

NIBP calibration must be performed by professional personnel authorized by EDAN. Access **Menu** > **Maintenance** > **User Maintain** by inputting the password **ABC**.

NOTE:

NIBP calibration is for checking the measurement accuracy and cannot change the measurement results.

Tools required:

- T-fitting;
- NIBP extension tubes;

- Cylinder;
- Manometer.

Procedure:

1. Access **Menu** > **Maintenance** > **User Maintain** by inputting the password **ABC**.
2. Connect the equipment as shown below:

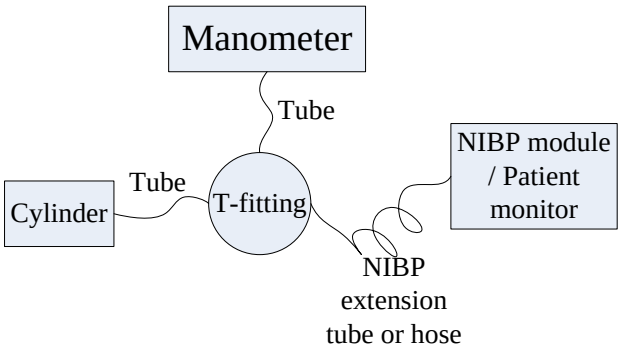


Figure 4-2 Diagram for NIBP Calibration

3. Select **NIBP Maintain** > **Calibrate**.
4. Apply fixed static pressure on the monitor with the help of the manometer. Compare the displayed values on the monitor with the manometer values.
5. A difference within the range of ±3mmHg is reasonable.

4.2.6 TEMP Performance Test

This test checks the performance of the TEMP measurement.

Tools required: resistance box.

Procedure:

1. Switch on the monitor and the resistance box.
2. Set the probe type on the monitor to YSI-10K, and respectively connect the probes to channel T1 and T2 connectors. And then connect the probes with the resistance box.
3. Set the resistance value to (6017Ω) 37℃ in the resistance box.
4. A difference within the range of ±0.1℃ is reasonable.

4.2.7 CO_2 Performance Test

This test checks the performance of the CO_2 measurement.

Tools required: nasal cannula.

Procedure:

1. Switch on the monitor.
2. Access CO_2 setup menu, and set the **Work Mode** to **Measure**.
3. Place the nasal cannula below the nose and normally breathe; check if the CO_2 measurement waveforms are available on the monitor.
4. The displayed CO_2 concentration is supposed to be 34~40mmHg.

4.2.8 IBP Performance Test

This test checks the performance of the IBP measurement.

Tools required: patient simulator

Procedure:

1. Connect the IBP cable to the connector for channel BP2 on the patient simulator and to the IBP connector on the monitor.
2. Set the simulator to 0 pressure and perform a zero calibration.
3. After completing the zero calibration, configure the simulator as P (static) = 200mmHg.
4. Perform a dynamic pressure test. Set the simulator to the following configuration:

   - RADIALART 120/80

   The tolerances for the measurement value provided by the monitor should be ±4 mmHg or ±4%.

4.2.9 C.O. Performance Test

This test checks the performance of the C.O. measurement.
Tools required: patient simulator
Procedure:
1. Connect the simulator to the C.O. module using the patient cable.
2. Configure the patient simulator as follows:
   - Injection temperature: 0℃
   - Computation Const: 0.542

(Edward's Catheter)

- Flow: 5 l/min

3. Check displayed value against the simulator configuration.
4. Expected test result: C.O.= 5+/－1 l/min

4.3 Safety Test

4.3.1 Safety Test Procedures

Use the test procedures outlined here only for verifying safe installation or service of the product. These tests are not a substitute for local safety testing where it is required for an installation or a service event.

When performing a safety test, you must use a standard safety analyzer such as Fluke 601Pro Series safety analyzer or equivalent, perform the test according to your local regulations, for example, in Europe according to IEC/EN60601-1, IEC/EN60601-1-1, in USA according to UL60601-1. For the test setup, please refer to the Instructions for Use of the test equipment used.

Additional test may be required by your local regulations.

You are recommended to document the result of the safety test.

NOTE:

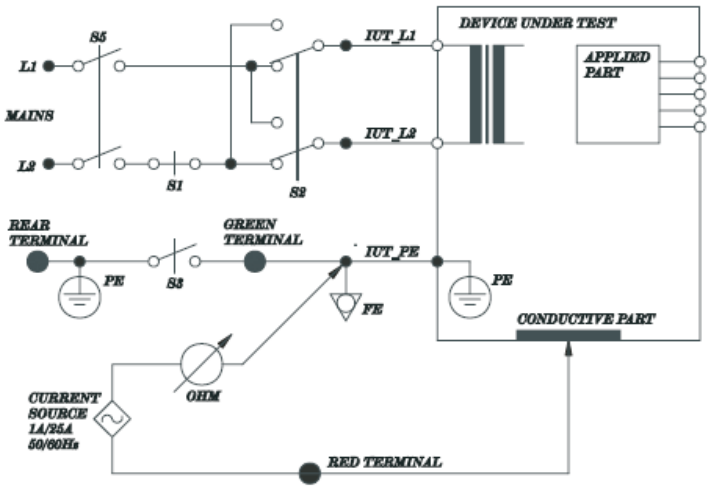
1 When testing according to IEC 60601-1, system must be tested and not individual devices.

2 Systems must be handled as devices.

3 A system is a combination of several devices of which at least one is a medical electrical device which is connected to other devices by functional connections or by a transportable multiple socket outlet.

4 With devices that are connected to other devices by means of a data cable, this connection must be disconnected prior to performing the electrical safety check, in order to avoid incorrect measurements.

4.3.2 Protective Earth Resistance



Notes:

S1 = Not applicable
S2 = Not applicable
S3 = Open
S5 = Open

NOTE:

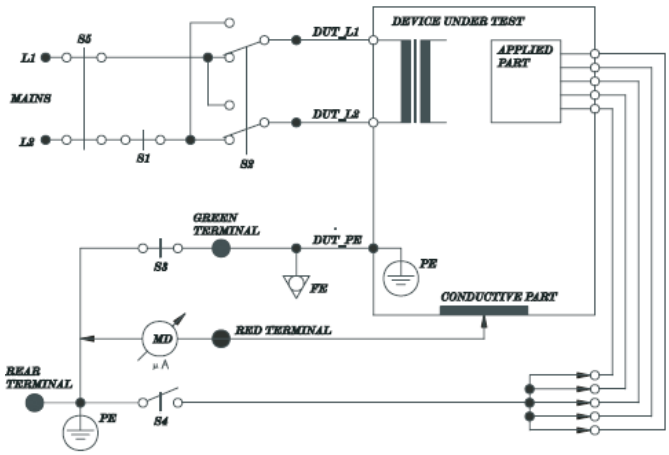
The circuit diagram is based on the Fluke 601Pro series safety analyzer.

This measures impendence of Protective Earth (PE) terminal to accessible metal part of Device under test (DUT) which is protectively earthed. A current of 25A is passed for 5s to 10s through the protective terminal and each accessible metal part which is protectively earthed.

Allowable value: without mains cable, maximum impendence: 100 mOhms

(IEC 60601-1 and UL60601-1)

4.3.3 Enclosure Leakage Current



Notes:

S1 = Variable
S2 = Variable
S3 = Variable
S4 = Variable
S5 = Closed

NOTE:

The circuit diagram is based on the Fluke 601Pro series safety Analyzer.

This measures leakage current of exposed metal parts of Device under test (DUT) and parts of the system within the patient environment; normal and reversed polarity using S2 test performed both in normal condition and single fault conditions.

Normal condition (NC): with S1, S3, S5 closed, S2, S4 variable.

Single fault condition (SFC): S1, S3 open (one for each time) and S5 closed, S2, S4 variable.

Allowable value:

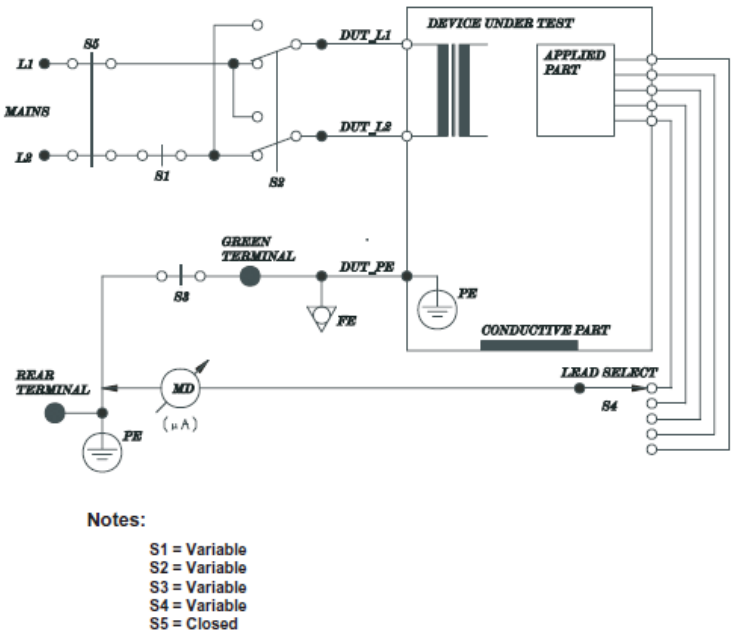
Normal condition: 100μA (IEC/EN60601-1)

Single fault condition: 500μA (IEC/EN60601-1)

Normal condition: 100μA (UL60601-1)

Single fault condition: 300μA (UL60601-1)

4.3.4 Patient Leakage current



Notes:

S1 = Variable
S2 = Variable
S3 = Variable
S4 = Variable
S5 = Closed

NOTE:

The circuit diagram is based on the Fluke 601Pro series safety Analyzer.

This test measure the leakage current flowing between the selected applied part and the mains PE; the test with normal and reverse polarity, in normal condition and single fault condition.

Normal condition (NC): with S1, S3, S5 closed, S2, S4 variable.

Single fault condition (SFC): S1, S3 open (one for each time) and S5 closed, S2, S4 variable.

Allowable value:

Normal condition: 10µA (BF applied part), 10µA (CF applied part)

(IEC/EN60601-1, UL60601-1)

Single fault condition: 500µA (BF applied part), 50µA (CF applied part)

(IEC/EN60601-1, UL60601-1)

Leakage Current

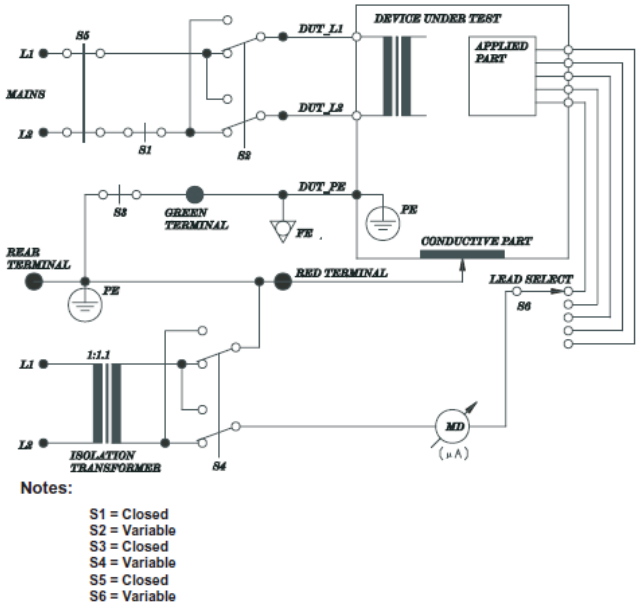
	Applied Part	**Normal Condition**	**Single Fault Condition**
Earth Leakage Current		<0.5 mA	<1 mA
Enclosure Leakage Current		<0.1 mA	<0.5 mA

	Applied Part	Normal Condition	Single Fault Condition
Patient Leakage Current	CF	AC: <0.01 mA DC: <0.01 mA	AC: <0.05 mA DC: <0.05 mA
	BF	AC: <0.1 mA DC: <0.01 mA	AC: <0.5 mA DC: <0.05 mA
Patient Leakage Current (Mains on Applied Parts)	CF		<0.05 mA
	BF		<5 mA
Patient Auxiliary Current	CF	AC: <0.01 mA DC: <0.01 mA	AC: <0.05 mA DC: <0.05 mA
	BF	AC: <0.1 mA DC: <0.01 mA	AC: <0.5 mA DC: <0.05 mA

4.3.5 Patient Leakage Current- Single Fault Condition (S.F.C) Mains on Applied Part

NOTE:

The following test is based on test with the Fluke 601 pro series safety analyzer. This device allows applying a 110% mains voltage between the applied part and the device PE. When testing with other device, you may need to apply the 110% mains voltage manually.



NOTE:

The circuit diagram is based on the Fluke 601Pro series safety Analyzer.

This test measure the current flowing between the applied part and the mains PE in response to an isolate mains voltage (110% of the mains voltage) applied to applied part. This test is performed with normal and reverse polarity of the mains voltage using S2, and normal and reverse polarity of the isolate voltage using S4.

Single fault condition: S1, S3, S5 closed, S2, S4, S6 variable.

Allowable value:

Single fault condition (110% mains voltage on applied part):

5000μA (BF applied part), 50μA (CF applied part)

(IEC/EN 60601-1 UL 60601-1)

4.4 Maintenance

For details about basic cleaning and maintenance methods, refer to relevant sections in *Patient Monitor User Manual*. For further technical support, contact service engineers of EDAN.

Users are responsible for preventive maintenance and periodic inspection for the monitor.

4.4.1 Cleaning the Monitor and Accessories

Refer to relevant sections in *Patient Monitor User Manual* for details.

4.4.2 Maintaining the Battery

Refer to relevant sections in *Patient Monitor User Manual* for details.

Chapter 5 Configuration

The users have no access to changing the system configuration of the monitor. As a service engineer, the users need to change the configuration after the monitor is installed and checked.

5.1 Opening User Maintain Menu

1 Select **Menu** on the main interface;

2 Select **Maintenance > User Maintain**;

3 Input the password **ABC** by using the soft keyboard;

4 Select **OK** to enter the **User Maintain** menu.

5.2 Entering Demo Mode

The monitor works in real-time monitoring mode when monitoring a patient. If you want to show the traces and parameters for a demonstration, you need to enter the **Demo** mode.

1 Select **Menu** > **Common Function**.

2 Select **Demo Mode**, and input the password **3045** by using the soft keyboard.

3 Select **OK** to enter the Demo mode.

WARNING

Demonstration function is for performance demonstrating and training usage. It is forbidden in clinical applications in case medical staff mistake what displays on the monitor as the waveforms and parameters of the patient, which will affect patient monitoring and delay diagnosis and treatment.

5.3 Selecting Lead Style

Two styles of ECG lead name are available: American standard and European standard. Users can set it according to the condition.

1 Select **User Maintain** > **Lead Placement**.

2 Select **AHA** or **EURO** from the list and press the knob to confirm it.

5.4 Changing the Bed No.

The bed No. determines the bedside monitor ID on the data receiving software, such as

MFM-CMS central monitoring system by EDAN. To set the device No., the user should:

1 Enter **User Maintain**;

2 Select **Network Maintain > Bed No.**;

3 Select a device No. from 1 to 254 and press the knob to confirm it.

CAUTION

Make sure the device No. of the monitors in the same system do not overlap.

5.5 Changing Network Bed No.

This network bed No. is the physical device No. of the monitor in the network and used for setting the IP address of the device. It needs to be set if the device connects to the CMS network.

Chapter 6 Principle Introduction

6.1 System Principle Block Diagram

iM80 patient monitor consists of the main board, IBP module, CO_2/AG module, ECG module, NIBP module, SpO_2 module, print board, power module, key board, and the corresponding interface boards.

Here is the system principle block diagram.

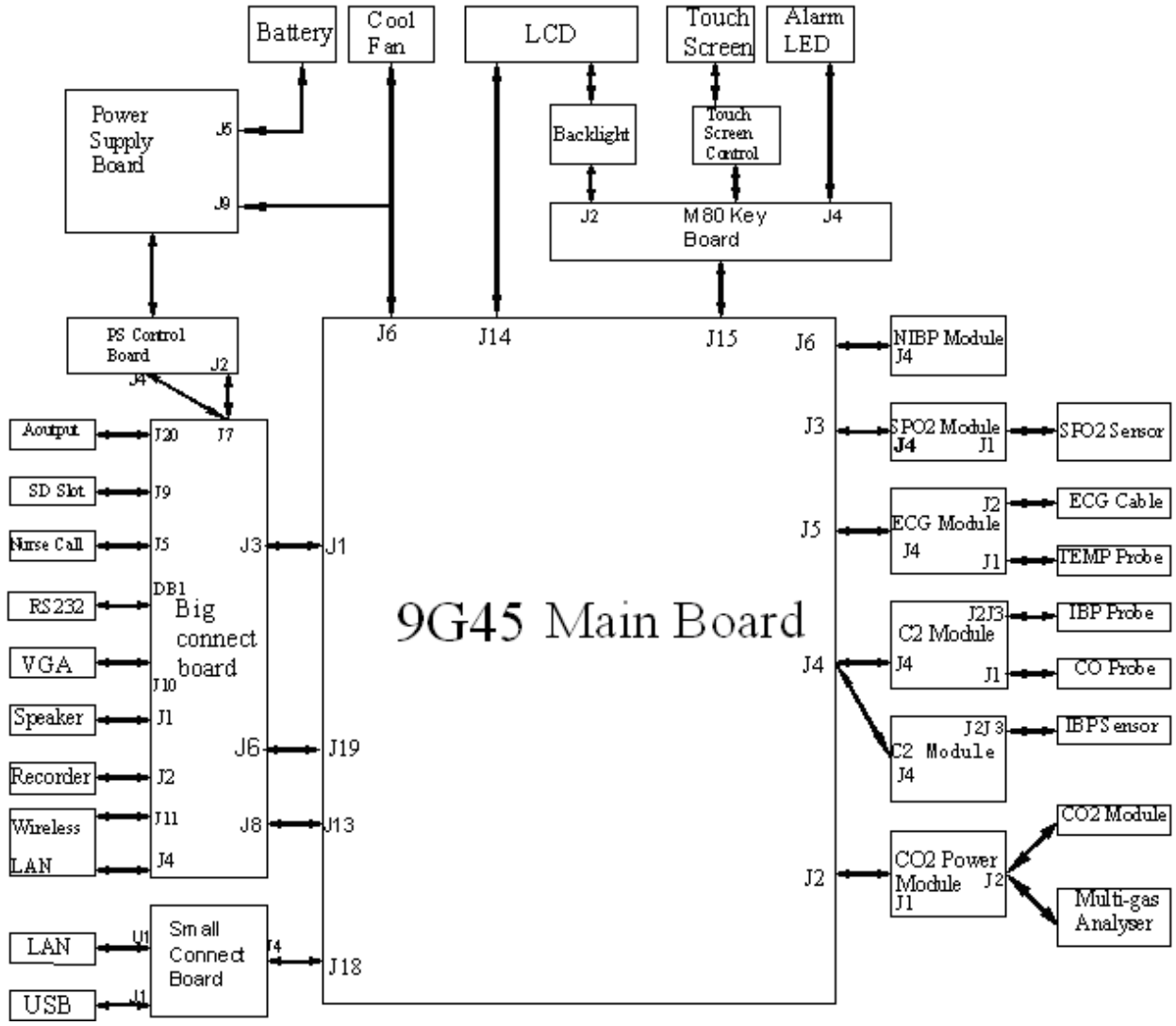


Figure 6-1 iM80 System Principle Block Diagram

6.1.1 Main Board

The main board applied in iM80 monitor is 9G45 main board developed by EDAN. The operating system is embedded. As the core of the system, the main control board fulfills the following functions: key input control, LCD display, recording, audio alarm and led indicator light alarm, data memory and recall, time and date management, module control, etc.

The parameters of this main board are listed below:

Power	5V, 12V
Processor	ARM926EJ-S Work frequency: 400MHz External bus frequency: 133MHz Dictate Cache: 32K bytes Data Cache: 32K bytes
Net Port	10M/100M standard Ethernet port
Parallel Port	1 parallel port
EMS Memory	SDRAM: 64M byte Flash: program 8M bytes + data 64M bytes
Serial Port	Configure in 4 serial ports and 6 serial ports way
Headphone Interface	Loudspeaker output
Touch Screen Interface	1 interface.
USB	2 standard USB HOST interfaces, 1 standard DEVICE interface (2.0 specification)
VGA	1 VGA output port, standard VGA outputting
LCD	1 TFT LCD interface, 1024*768 (highest resolution)
Keyboard	1 PS/2 keyboard interface
GPIO	10
Watchdog Timer	1.6s
Power Consumption	5.934 W (max)/1.775W(typical)
Size	134 mm×107 mm
Operating System	Linux

6.1.2 ECG Module

The ECG module fulfills the functions of ECG detection and measurement, and then sends the results to the main control board through serial port. The ECG module includes ECG monitoring part and TEMP monitoring part. Please refer to *Patient Monitor User Manual* for the ECG specification.

6.1.3 SpO_2 Module

The SpO_2 module consists of two parts: sensor and measuring system. The measuring system includes SpO_2 signals collecting, amplified simulating circuit system and relative digital/analog converting, and signal processing systems.

The pulse extent of optical signal changes during monitoring. SpO_2 parameter, pulse rate signal and pleth wave will be acquired after calculation. These data will be transmitted to the PC by special communication protocol. Please refer to *Patient Monitor User Manual* for the SpO_2 specification.

6.1.4 Print Controlling Board

The print controlling board is in charge of receiving data from main board and driving the thermo sensitive print head to print. Its structure block diagram is as follows:

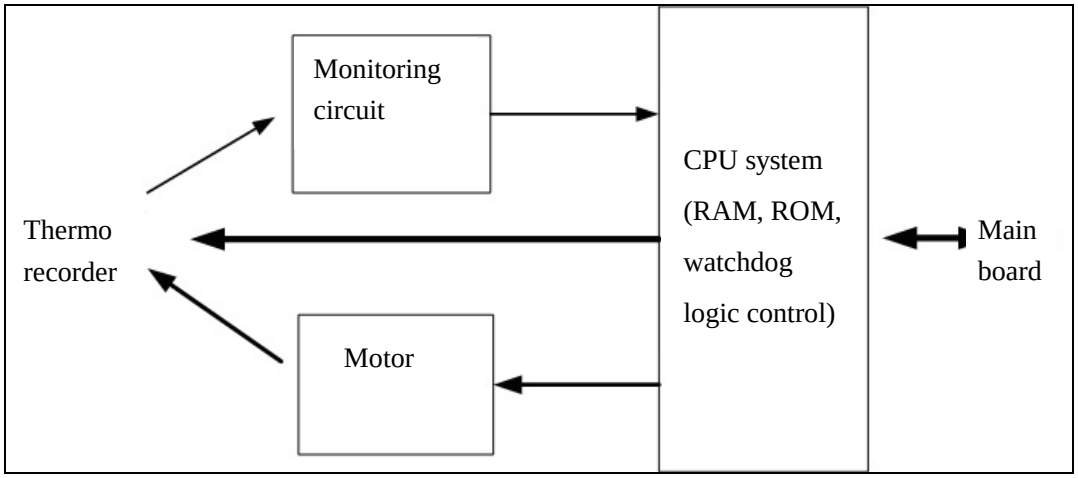


Figure 6-2 Print controlling board principle block diagram

The iM80 printer module includes: microprocessor circuit, power switch and control, communication interface, motor control part, recorder paper detecting circuit, time control for printing power and heating, paper lacking temperature control and thermo sensitive head protecting circuit.

6.1.5 Power Module

The power module is EDAN PS900Q. It outputs +5V, +12V and bus voltage (13V~19V) and manages charging. It converts 220V AC power or battery power to 5V and 12V DC power, and then supplies power to other boards. When AC power and battery power exist at the same time, the system is powered by AC power which meanwhile charges the battery. When battery power is used independently, the corresponding indicator lights on the front board of monitor.

PS900Q power module mainly consists of PS900Q power board, PS900Q power control board, and PS900K DC output board.

6.1.6 Key Board

The key board codes the operation of keys and control knob with ATMEGA16L singlechip processor, sends keycode to main control board using PS2 protocol, answers the corresponding keys. The touch screen communicates with the main control board through a set of independent serial ports. Its structure block diagram is as follows:

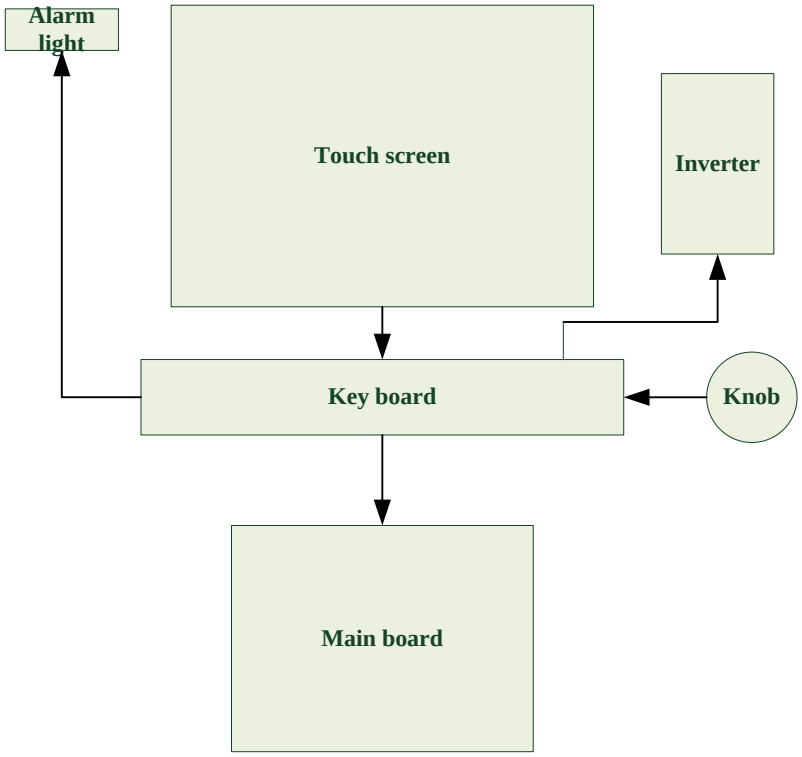


Figure 6-3 Key Board Principle Block Diagram

6.1.7 Interface Board (big)

Interface board includes SD card interface, analog output/synchronous defibrillation interface, nurse call interface, RS232 interface, VGA visual signal interface, audio interface, power control board interface, printer interface, and the second network interface.

6.1.8 Interface Board (small)

Interface board mainly includes USB interface and network interface.

6.1.9 LVDS LCD

Its main technical specifications are as follows:

Items	Unit	Specifications
Screen Diagonal	[mm]	380 (12.1”)

Active Area	[mm]	304.128(H) x 228.096(V)
Pixel H x V		1024 x 768
Pixel Pitch	[mm]	0.297(H) x 0.297(V)
Pixel Arrangement		R.G.B. Vertical Stripe
Display Mode		Normally White
Typical White Luminance (ICFL= 6mA)	[cd/m2]	250 Typ. (center)
Contrast Ratio		500:1 Typ.
Nominal Input Voltage VDD	[Volt]	+3.3 Typ.
Typical Power Consumption (VDD line + VCFL line)	[Watt]	8.6 Typ.
Weight	[Grams]	1200
Physical Size	[mm]	326.5(W) x 253.5(H) x 11.4(D)
Electrical Interface		LVDS
Support Color		Native 16,196,227 colors (RGB 6-bit driver)
Temperature Range: Operating Storage(Shipping)	 [°C] [°C]	 0 to +50 -20 to +60

6.2 Interfaces

Figure 6-4 Interface Diagram

On the rear panel of the monitor, there are 7 interfaces:

- DB 9 interface (RS232)
- RJ45 interface (Network)
- USB interface
- DB15 interface (VGA visual signal interface)
- BNC interface (synchronous defibrillation/analog output interface)
- SD card interface (data storage interface)
- Nurse call interface

6.2.1 DB9 Interface

All monitors are configured with a DB9 interface.

It is used to connect the monitor to a computer for monitoring information collection, or to a monitoring system such as MFM-CMS.

6.2.2 RJ45 Interface

All monitors are configured with an RJ45 interface.

It is used to connect the monitor to a computer for updating or monitoring information collection, or to a monitoring system such as MFM-CMS.

6.2.3 USB Interface

All monitors are configured with a USB interface.

It is used to connect external devices that support USB protocol to the monitor.

6.2.4 DB15 Interface

All monitors are configured with a DB15 interface.

It is used to output the VGA visual signals of monitor to the external display device that supports VGA signals.

6.2.5 BNC Interface

All monitors are configured with a BNC interface.

It is used to output synchronous defibrillation and analog output signals.

6.2.6 SD Card Interface

All monitors are configured with an SD interface.

It is used to store the data of the monitor in external SD card.

6.2.7 Nurse Call Interface

All monitors are configured with a nurse call interface.

It is used to carry out the function of nurse call.

Chapter 7 Troubleshooting

EDAN supports replacement of PCB and major subassemblies for this monitor. When replacement is needed, follow the procedures described in chapter *8 Disassembling the Monitor*.

7.1 Monitor Booting Failures

Phenomenon	Possible Cause	Solution
After switching on, LCD has no display; the power indicator is off; the fan doesn't run.	The fuses are blown.	Replace the fuses.
	Power board defective.	Replace the power board.
	Short circuit of other parts.	Look for the short circuit source and fix it.
After switching on, LCD has no display or is black when working; the power indicator is lit; the fan runs normally.	Main control board defective.	Check whether the keys sound properly. If yes, examine the LCD.
	LCD defective.	If the keys don't sound, it may be the fault of the main control board. Replace the main control board.
Characters display correctly, but waveforms display intermittently.	Faulty data communication between main control board and parameter module.	Replace the main control board, link board or parameter module to verify the fault according to the prompt.
Some operation or measurement function invalid.	Main control board or corresponding parts defective.	Further examine the main control board and corresponding parts.
Abrupt switching off.	The monitor is struck by strong high voltage, such as lightning strike.	Check the power supply and earth system.
	Bad power supply performance.	Replace power supply.
	Main control board defective.	Replace the main control board.
	Bad connection.	Replace or repair connectors.

7.2 Display Failures

Phenomenon	Possible Cause	Solution
After switching on, LCD has no display or is black when working.	LCD backlight board defective.	Replace the LCD backlight board.
	LCD cable defective	Repair or replace the LCD cable.
	Main board defective.	Replace the main control board.
	Power board defective.	Replace the power board.

7.3 Touch Screen Failures

Phenomenon	Possible Cause	Solution
The touch screen is not functioning.	The touch screen is disabled.	Check if the touch screen is disabled in the system setup. If yes, enable it.
	The touch screen related cable(s) is (are) disconnected.	Check that the cables between the key board and the touch screen are well connected.
	The touch screen is damaged.	Replace the touch screen.
The touch position invalid.	The touch screen is not calibrated.	Calibrate the touch screen using procedures described in section *To Calibrate Touch Screen* of the user manual.

7.4 Operation Failures

Phenomenon	Possible Cause	Solution
Keys or rotary coder not functioning	Bad key board connection.	Replace or repair key board wire.
	Key board or rotary coder is damaged.	Replace the key board or rotary coder.
Hoarse sound from loudspeaker or no tone is heard when a key is pressed.	Loudspeaker or wire defective.	Replace the loudspeaker or wire.
	key board defective.	Replace the key board.

7.5 Recorder Failures

Phenomenon	Possible Cause	Solution
No paper advances.	No paper in the drawer.	Load paper and close the drawer.

	Paper bail is not pressed down.	Press down the paper bail.
	Recorder defective.	Replace the recorder.
	Recorder power supply defective.	Replace the power supply.
	Recorder connection failure.	Replace or repair the connecting wire.
Paper advances lopsidedly.	The assembly or location of recorder is bad.	Calibrate the assembly of recorder.

7.6 Network Failures

Phenomenon	Possible Cause	Solution
The monitor can not connect to a network.	Network connection defective.	Check and repair the network wire and HUB box.
	Overlapped device no. in the network.	Change device no. of the monitor.
	Main control board defective.	Replace main control board.

7.7 Alarm Failures

Phenomenon	Possible Cause	Solution
No audible alarm is activated.	The audible alarm is temporarily disabled.	Switch on the audible alarm.
	Loudspeaker or wire defective.	Replace the loudspeaker or the wire.
The alarm indicator stays off.	Alarm indicator defective.	Replace alarm indicator.
	Alarm indicator board defective.	Replace alarm indicator board.
No audible alarm or visual alarm is activated.	Program defective.	Update the software.

7.8 Power Board Failures

Phenomenon	Possible Cause	Solution
Fuses are blown after switching on.	Short circuit of power or other parts.	Further examination after switching on.
Fuses are still blown after all programs are cut out.	Power defective.	Replace the power.
Fuses are blown after	Short circuit of the part.	Replace the part.

connecting to some part.		
Power indicator and main control board indicator are on, but the fan doesn't run and the link board indicator stays off.	+12V AC power defective.	Replace the power.
Power indicator and main control board indicator stay off, but the fan runs properly and the link board indicator is on.	+5V AC power defective.	Replace the power.

7.9 Data Storage

Phenomenon	Possible Cause	Solution
The data in the U disk can't be saved.	The file format of U disk is incorrect, it may be NTFS.	Format the U disk into FAT.
	The U disk is not inserted properly.	Insert the U disk once again or replace it.

7.10 ECG Monitoring Failures

Phenomenon	Possible Cause	Solution
No ECG trace.	Bad connection of electrodes.	Use new electrodes and ensure good connection.
	ECG waveform is disabled.	Enable ECG waveform in system menu. See the user manual.
	RL electrode hangs in the air.	Connect RL electrode well.
	No CAL self-test?	Replace the module.
	ECG module defective.	Replace the module.
ECG waveform abnormality or interference.	Incorrect connection of electrodes.	Connect measurement electrode well.
	Electrodes hang in the air.	Remove unused electrodes.
	No earth wire for AC power.	Use 3-wire power.
	Incorrect filter method.	Select proper filter method.
	ECG module defective.	Replace ECG module.
No RESP waveform or RESP waveform abnormal.	Incorrect connection of electrodes.	Use RL-LL electrode.

	Frequent patient activity.	Quiet the patient.
	RESP waveform is disabled.	Enable the RESP waveform in system menu.
	RESP waveform amplitude faint.	Adjust waveform amplitude multiple in RESP menu.
	ECG module defective.	Replace ECG module.
HR inaccurate, HR abnormal, and ST analysis incorrect.	Measurement waveforms defective.	Adjust the connection.

7.11 SpO_2 Monitoring Failures

Phenomenon	Possible Cause	Solution
No SpO_2 waveform.	SpO_2 transducer or module defective.	Replace the SpO_2 transducer.
Strong SpO_2 waveform interference.	Patient activity.	Quiet the patient.
	Extremely strong ambient light.	Weaken ambient light.
SpO_2 value is inaccurate.	The patient is injected with dye.	Eliminate dye before measurement.

7.12 NIBP Monitoring Failures

Phenomenon	Possible Cause	Solution
The cuff fails to be inflated.	The cuff is folded or air leak occurs.	Repair the cuff.
No NIBP numeric value.	Loose cuff or patient activity.	Tie up the cuff or quiet the patient.
Big error in NIBP numeric value.	Cuff size unsuitable for patient.	Use appropriate cuff.
	NIBP module defective.	Replace NIBP module.

7.13 TEMP Monitoring Failures

Phenomenon	Possible Cause	Solution
TEMP numeric value incorrect.	Bad connection of TEMP transducer.	Connect and fix the TEMP transducer well.

7.14 CO_2 Monitoring Failures

Phenomenon	Possible Cause	Solution
No CO_2 waveform.	Bad connection of CO_2 module.	Power off, reconnect CO_2 module.
	CO_2 module defective.	Replace CO_2 module.
The CO_2 waveform is smooth.	CO_2 module stays in Standby mode.	Change the working mode of CO_2 module to Measurement.
	The CO_2 sampling tube is jammed or not connected well.	Unplug the sampling tube and clear foreign matters, and then connect it again. Or replace the sampling tube.
CO_2 waveform looks a mess, and the numeric value has obvious errors.	CO_2 module has not been zeroed for a long time, thus the measurement is inaccurate.	Open CO_2 setup menu and zero CO_2.
CO_2 waveform is smooth and the numeric value displays - - -.	CO_2 module stays in standby mode.	Change the working mode of CO_2 module to Measurement.
Tube jam displays on the interface in CO_2 measurement.	CO_2 sampling tube has a jam.	Unplug the sampling tube and clear foreign matters, and then connect it again. Or replace the sampling tube.
CO_2 waveform is normal, but data measurement has an error.	CO_2 module has not been zeroed for a long time, thus the measurement is inaccurate.	Open CO_2 setup menu and zero CO_2.
	The settings of compensation gas and air pressure are inaccurate.	Open CO_2 setup menu and set compensation gas and air pressure correctly.

7.15 IBP Monitoring Failures

Phenomenon	Possible Cause	Solution
The IBP waveform is available, yet IBP measurement value is unavailable.	The IBP module has not been zeroed or zero drift occurs.	Zero the IBP module.
The IBP waveform appears and disappears time after time.	Bad connection of the IBP cable and sensor	Check the connection of IBP cable and sensor.
The IBP waveform is flat and there is no apparent	An unsuitable selection of the ruler	Check whether the IBP label is consistent with the measured site of

fluctuation.		the patient; adjust the ruler.
The monitor indicates an IBP communication failure.	Failure in the PCBA of IBP module or disconnection of the IBP module and communication board	Check the connection of IBP module and communication board or change the IBP module.

7.16 AG Monitoring Failures

Phenomenon	Possible Cause	Solution
No waveform	Bad connection of GAS module.	Power off, and reconnect GAS module.
	GAS module defective.	Replace GAS module.
AG waveform is smooth.	GAS module is in Standby mode.	Change Standby mode to Measurement mode.
	The tube is jammed or not connected well.	Power off, and clean or replace the tube.
	The module is zeroed automatically.	Normal phenomenon.
AG measurement numeric value has an error.	GAS module has not been zeroed for a long time, thus the measurement is inaccurate.	Zero the GAS module.
	The system is not in measurement mode.	Measure again when the system enters measurement mode after 10 minutes of warm-up.

7.17 Technological Alarms

For details on technological alarms, please refer to relevant section in the user manual.

Chapter 8 Disassembling the Monitor

WARNING

1 Only qualified service personnel shall open the monitor housing.

2 Switch off the monitor and disconnect it from AC power before disassembling the monitor.

3 After any repair of the device, perform safety tests prior to use.

8.1 Tools Required

1 – A cross-head screwdriver

2 – A flat-head screwdriver

3 – A M3 nut driver

4 – A pair of pliers

8.2 Replacing Fuses

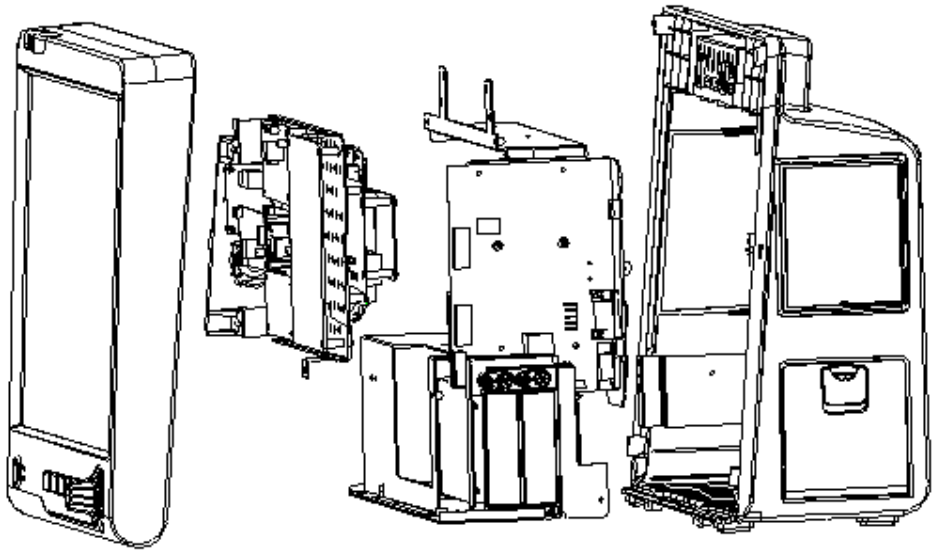
To replace the melted fuses,

1. Switch off the monitor and disconnect it from power.
2. The back of the monitor should face the operator.
3. Pull out the fuse box and pick the inside fuse up with a flat-head screwdriver.

4. Replace the old fuse with a new one that is supplied by EDAN or with the same specifications. (Dimensions: Φ5mm*20mm; model: T1.6AL 250V)
5. Put back the fuse box.

8.3 Disassembling the Main Unit

The main unit consists of the front housing, back housing, main frame, CO_2 assembly, TEMP assembly and recorder.



Front housing	Module bracket assembly	Main bracket assembly	Rear housing

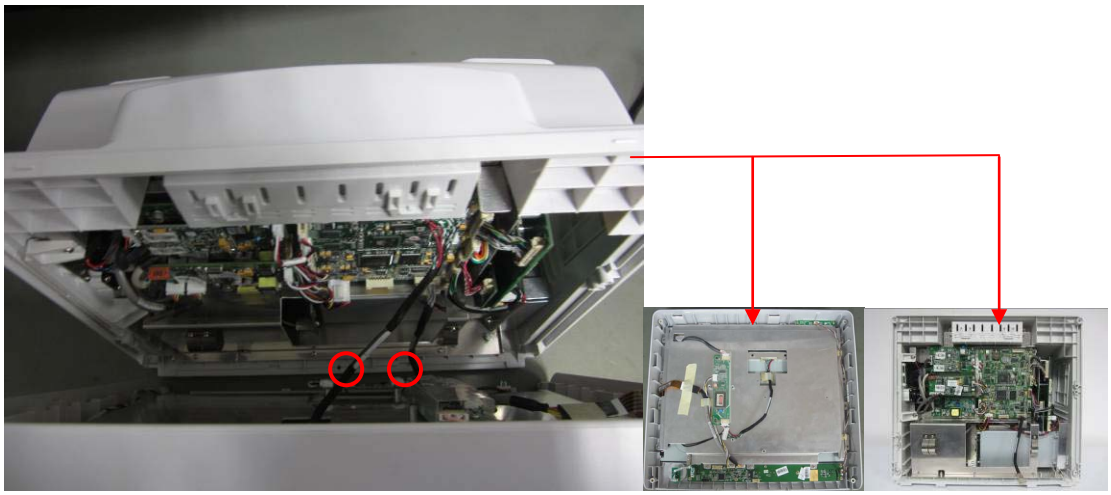
Figure 8-1 Main Unit Structure Block Diagram

To disassemble the main unit:

1 Place the monitor on the protective pad on a flat surface.

2 Unscrew the screws securing the front and back housings and the front and back assemblies are unfolded.

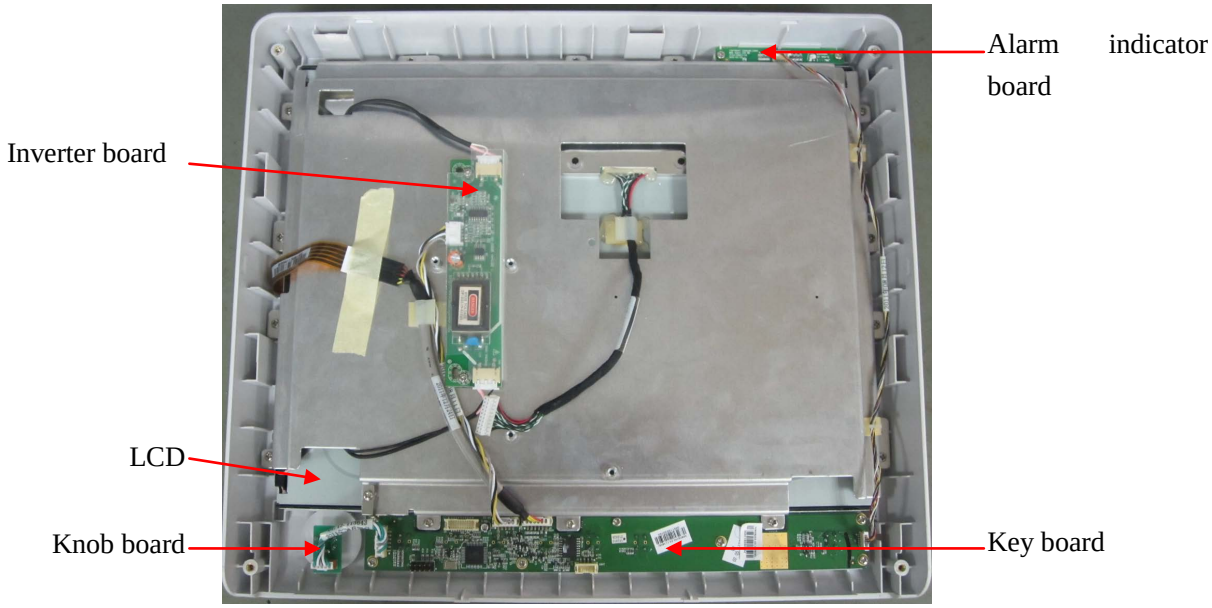
3 Put the monitor upward and slightly pull the front and back housings, and disconnect the wires to LCD and key board to separate the front housing and back housing assemblies, shown in circle in the figure below;



4 Place the back assembly on a flat surface, and unscrew the screws securing the module bracket assembly and disconnect the wires to separate the module bracket assembly;

5 Unscrew the screws securing the main frame on the bottom and inside the unit, and the main frame are separated from the back assembly.

8.4 Disassembling the Front Housing Assembly



8.4.1 Replacing the Alarm Indicator Board

To disassemble the alarm indicator board:

Separate the front and back assembly	→ Disconnect wire to alarm indicator board	→ Unscrew the screws securing alarm indicator board

Assemble the alarm indicator board in the reverse order.

8.4.2 Replacing the Key Board

1	Wire connecting knob board
2	Wire connecting main board
3	Wire connecting inverter board
4	Wire connecting touch screen
5	Screw

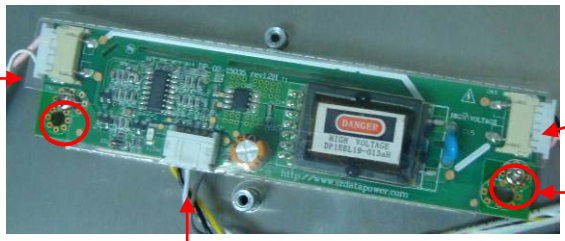
6	Wire connecting alarm indicator board

To disassemble the key board:

Separate the front and back assembly → Disconnect all wires on key board → Unscrew the screws on key board

Assemble the key board in the reverse order.

8.4.3 Replacing the Power Inverter Board



To disassemble the power inverter board:

Separate the front and back assembly → Disconnect all wires on power inverter board → Unscrew the screws on power inverter board

Assemble the power inverter board in the reverse order.

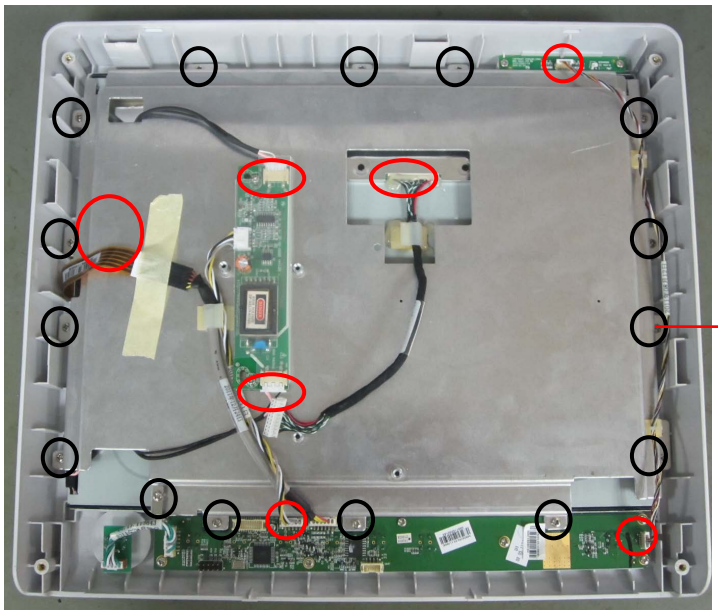
8.4.4 Replacing the Knob

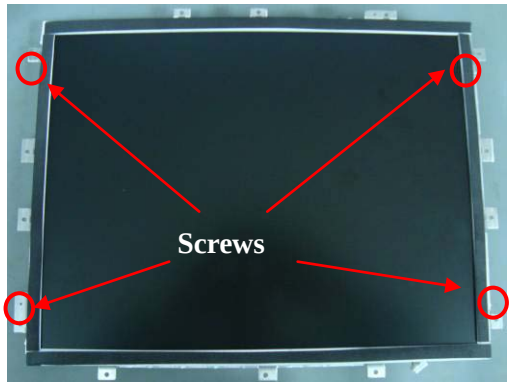
To disassemble the knob:

Separate the front and back assemblies → Remove the knob cap by using pliers → Loosen nut securing the knob cap by using pliers

Assemble the knob in the reverse order.

8.4.5 Replacing the LCD



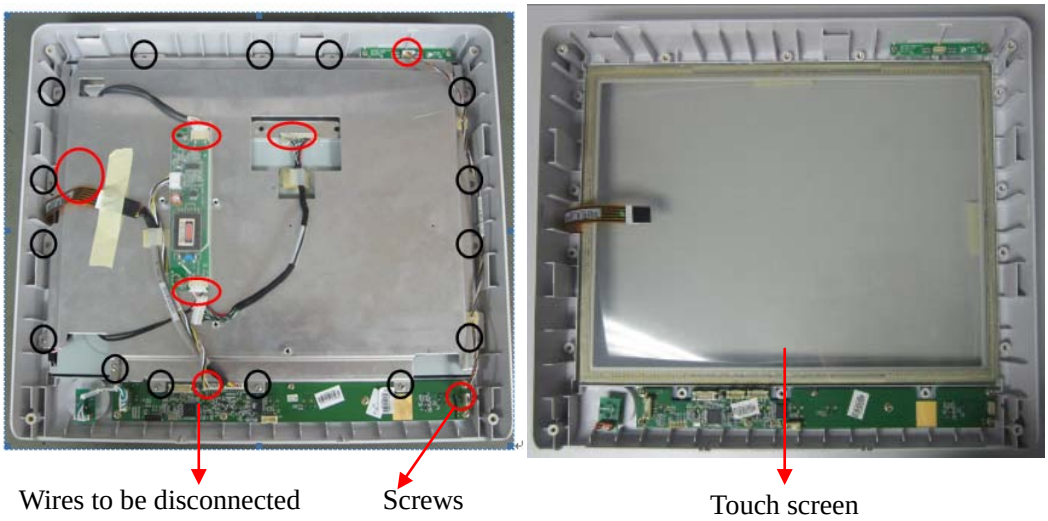


To disassemble LCD:

Separate the front and back assemblies → Disconnect wires on LCD → Unscrew the screws on LCD → Unscrew the screws on display assembly stander

Assemble LCD in the reverse order.

8.4.6 Replacing the Touch Screen

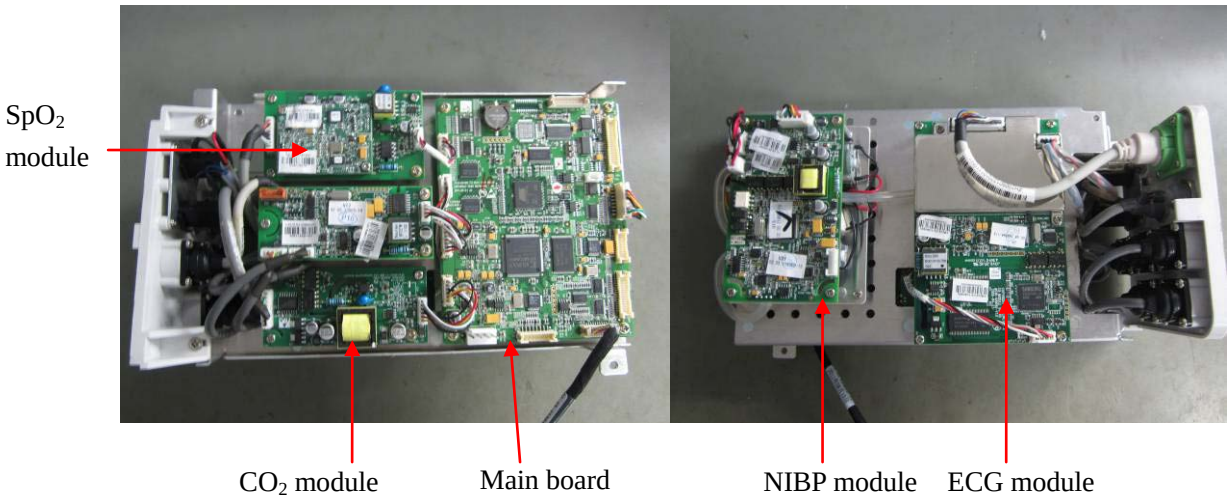


To disassemble touch screen:

Separate the front and back assemblies	→ Disconnect wires on touch screen	→ Unscrew the screws on touch screen	→ Remove LCD assembly and replace touch screen

Assemble touch screen in the reverse order.

8.5 Module Bracket Assembly

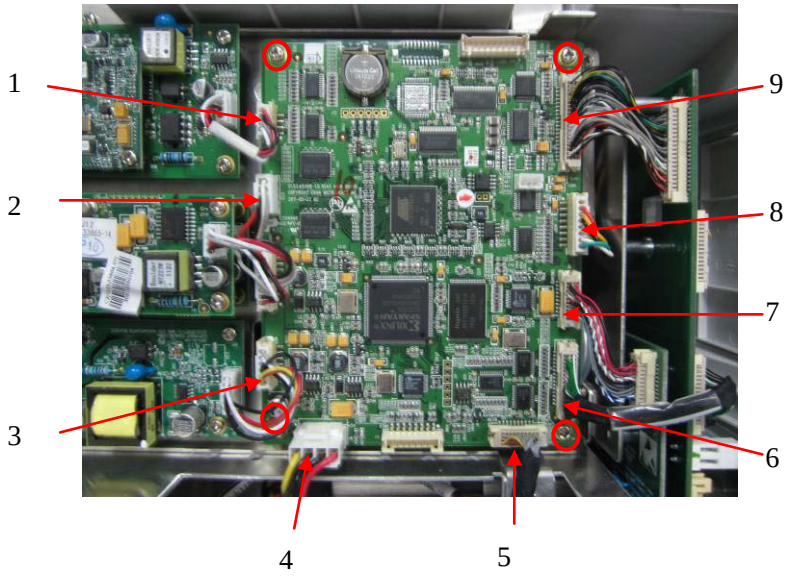


8.5.1 Replacing the Main Board

To disassemble main board:

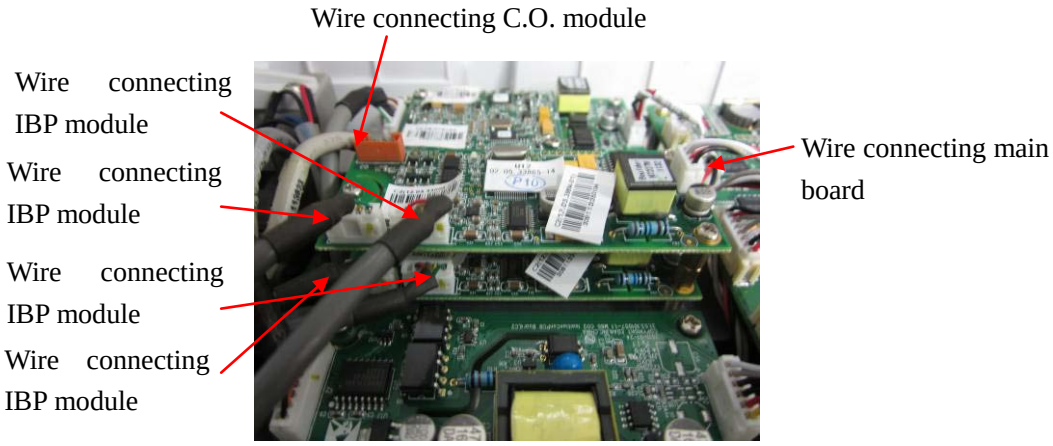
Separate the front and back assemblies → Disconnect wires on main board → Unscrew the screws securing main board

Assemble the main board in the reverse order.



1	Wire connecting SpO_2 module
2	Wire connecting ECG module
3	Wire connecting CO_2 module
4	Wire connecting power module
5	Wire connecting key board
6	Wire connecting interface board (big)
7	Wire connecting interface board (small)
8	Wire connecting NIBP module
9	Wire connecting interface board (big)

8.5.2 Replacing the IBP-C.O. Module



To disassemble IBP module:

Separate the front and back assemblies as described in section 8.3	→ Disconnect wires connecting IBP module	→ Unscrew the screws securing IBP module

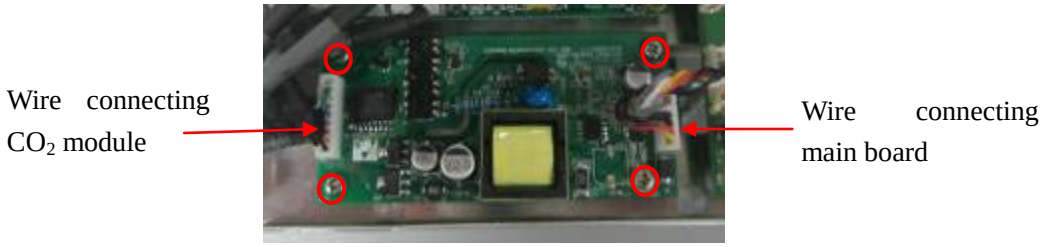
8.5.3 Replacing the SpO_2 Module

To disassemble SpO_2 module:

Separate the front and back assemblies	→ Disconnect wires connecting SpO_2 module	→ Unscrew the screws securing SpO_2 module

Assemble the SpO_2 module in the reverse order.

8.5.4 Replacing the CO_2 Module

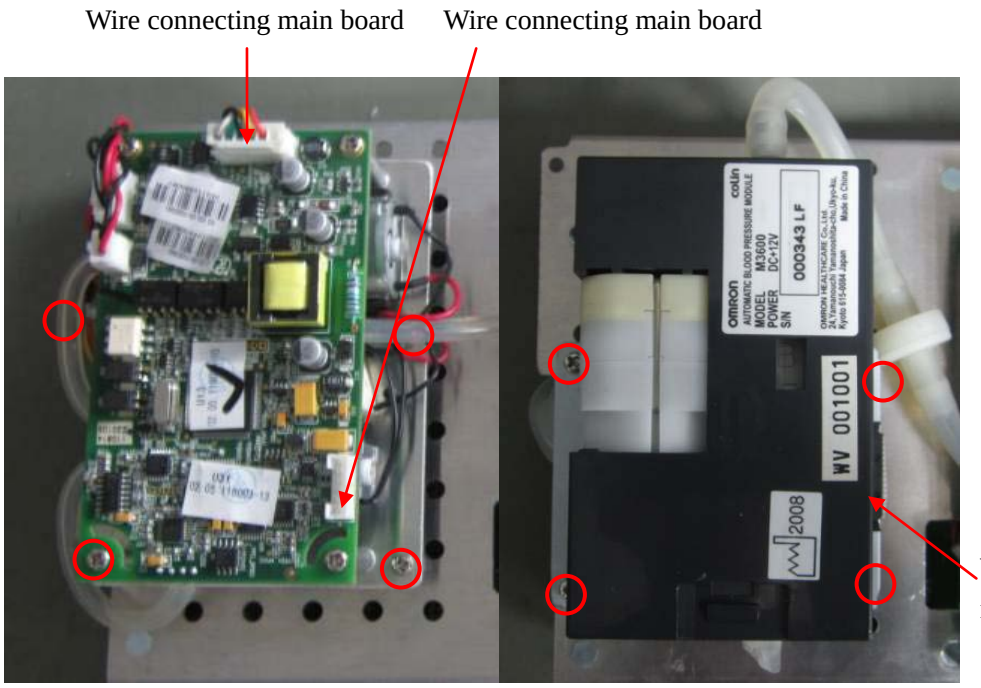


To disassemble the CO_2 module:

Separate the front and back assemblies → Disconnect wires connecting CO_2 module → Unscrew the screws securing CO_2 module

Assemble the CO_2 module in the reverse order.

8.5.5 Replacing NIBP Module

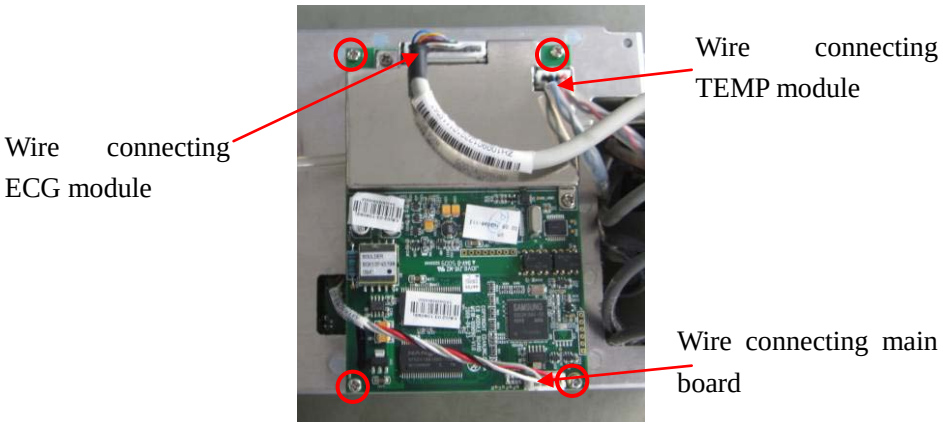


To disassemble the NIBP module:

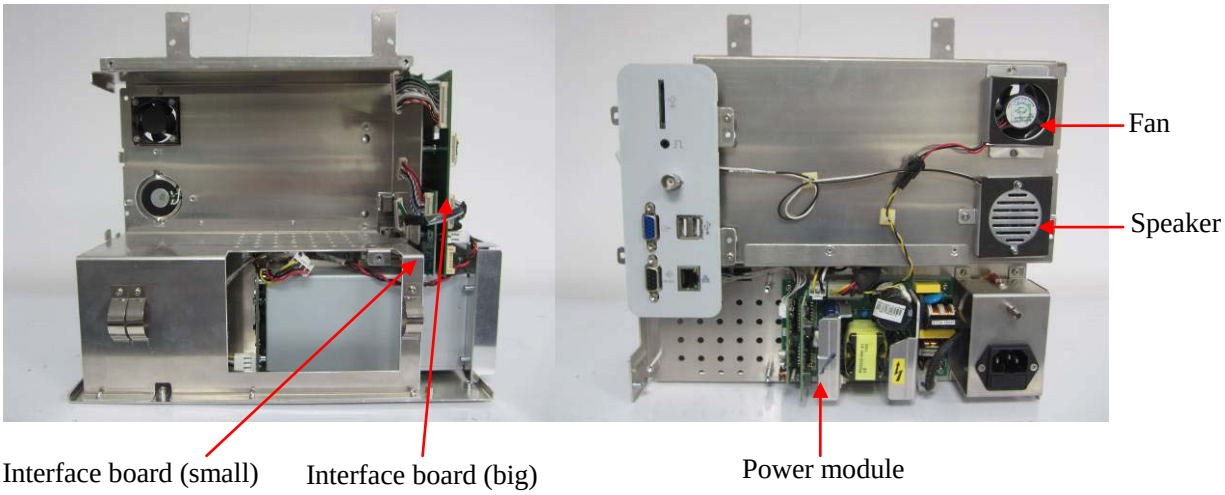
Separate module bracket assembly as described in section 8.3 → Disconnect wires connecting NIBP module → Unscrew the screws securing NIBP module

Assemble the NIBP module in the reverse order.

8.5.6 Replacing the ECG Module



8.6 Main Bracket Assembly



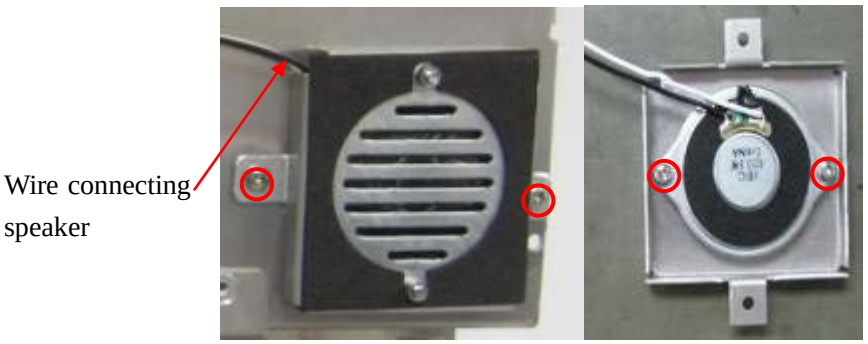
8.6.1 Replacing the Recorder

To disassemble the recorder:

Open the paper casing → Unscrew the two screws → Disconnect wires connecting recorder

Assemble the recorder in the reverse order.

8.6.2 Replacing the Speaker

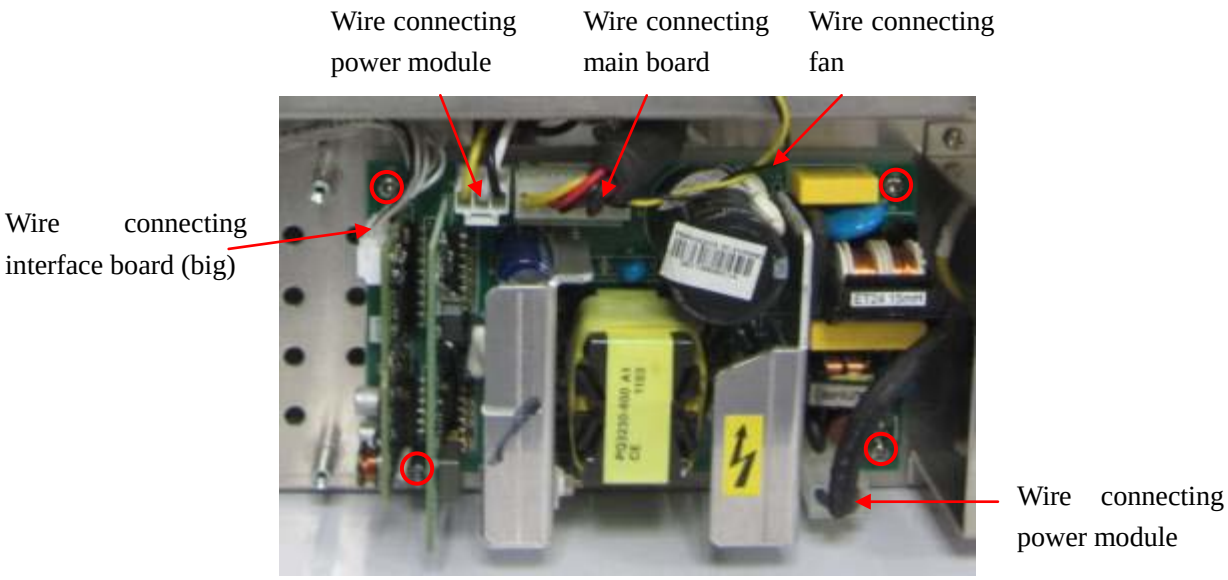


To disassemble the recorder:

Separate main bracket assembly as described in section 8.3 → Disconnect wires connecting speaker → Unscrew the screws securing speaker assembly → Unscrew the screws securing speaker

Assemble the speaker in the reverse order.

8.6.3 Replacing the Power Module

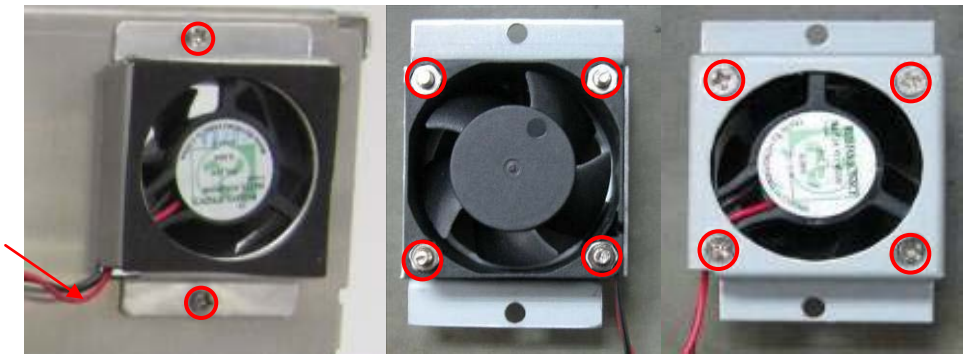


To disassemble the power module:

Separate main bracket assembly as described in section 8.3 →	Disconnect wires connecting power module →	Unscrew the screws securing power module

Assemble the power module in the reverse order.

8.6.4 Replacing the Fan

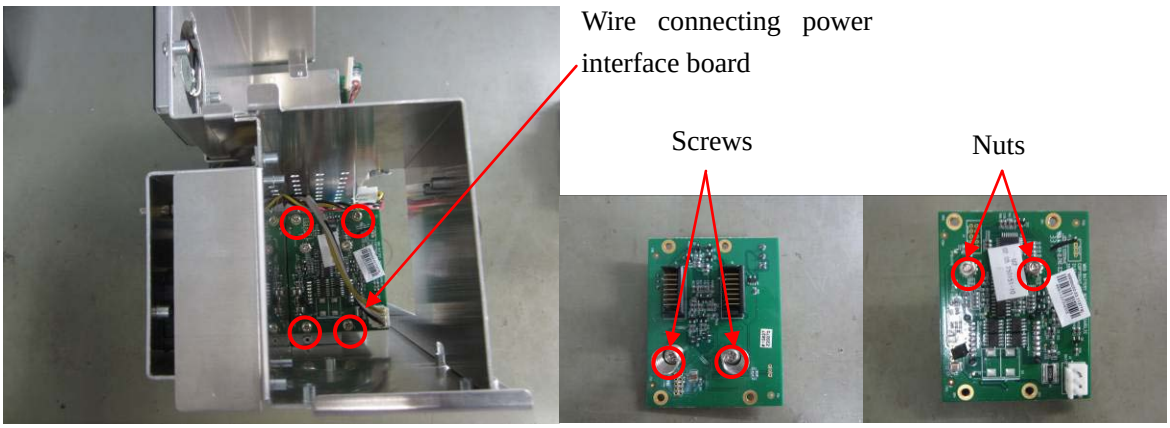


To disassemble the fan:

Separate main bracket assembly as described in section 8.3 →	Unscrew the screws securing fan assembly and disconnect wires connecting it →	Unscrew the screws and nuts securing fan assembly

Assemble the fan in the reverse order.

8.6.5 Replacing the Power Interface Board

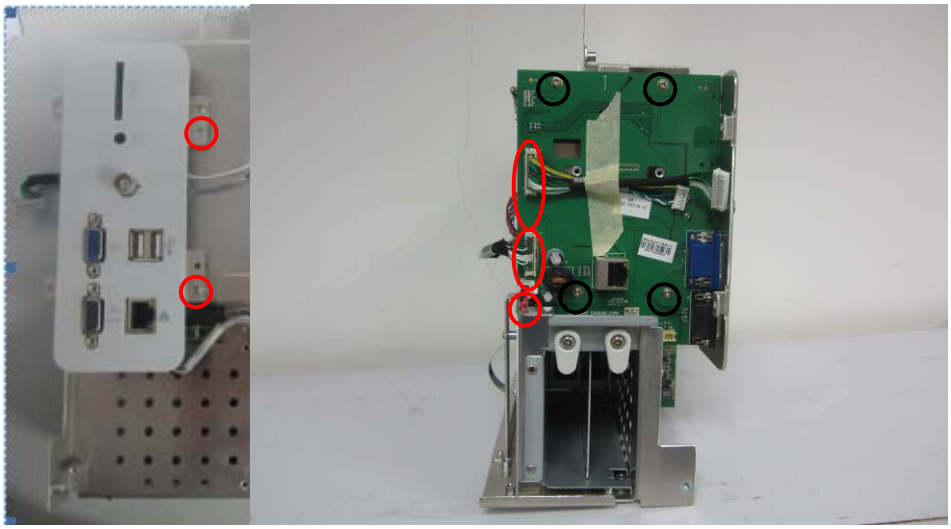


To disassemble the power interface board:

Separate main bracket assembly as described in section 8.3 → Disconnect wires connecting power interface board and unscrew the screws → Unscrew the screws and nuts securing power interface board

Assemble the power interface board in the reverse order.

8.6.6 Replacing the Interface Board (big)



To disassemble the Interface Board (big):

Separate main bracket assembly as described in section 8.3 → Unscrew the screw securing back board → Disconnect wires connecting interface board (big) → Unscrew the screws and nuts securing power interface board (big)

Appendix 1 Replaceable Parts

WARNING

Only connect the replaceable parts supplied by EDAN to the monitor.

Parts	Part Number
Speaker	01.14.038010
Fan	01.58.47066-11
LCD	01.16.078208
Touch Screen	01.16.078211
Alarm Indicator Board	02.02.113653
Interface Board (big)	02.03.113609-11
Interface Board (small)	02.02.113607
iM80 Key Board	12.03.220070
Power Module Assembly	02.01.210066
Inverter	02.08.113741
Main Board	12.03.451109-10
X2 Module	22.01.210444
M80 CO_2 Isolation Power Plug Board	12.02.101058-11
E8 Module	02.01.109095
E6 Module	12.03.451487
Recorder	22.01.210443
Knob Board	12.02.16803-11
Battery Interface Board	02.03.113778

P/N: 01.54.455512-10

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