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iM8 M8 Series

Patient Monitor

Version 1.4

Service Manual

CE₀₁₂₃



About this Manual

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Release Date: January 2018

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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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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.

EDAN will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by EDAN as repairable by service personnel.

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 dismantled, 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 iM8&M8 series patient monitors. 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 of doing so might damage the monitor, invalidate the product warranty or lead to serious personal injury.

iM8&M8 series patient monitors include 6 models: iM8, iM8A, iM8B, M8, M8A and M8B.

2.2 General Information

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 BF ECG (RESP), TEMP, IBP 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

2.3 Safety Precautions

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

WARNING

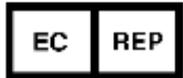
- 1 The monitor must be serviced only by authorized and qualified personnel. EDAN does not assume any responsibility for damage or injury if modifications or repairs are carried out by unauthorized personnel.
 - 2 Use and replace the substitutive parts provided or recommended by EDAN only.
 - 3 The service 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 tests should include leakage current measurement and insulation testing. It is recommended to perform the safety test every two years. You are responsible for any requirements specific to your country.
 - 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 Only connect the device with accessories supplied or recommended by EDAN.
 - 8 Do not remove the battery while AC power is on.
 - 9 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.
 - 10 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. Anybody that 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 60601-1. If you have any question, please consult our technical service department or your local distributor.
 - 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. If the monitor gets damp or liquid pours on the monitor, please contact the service personnel of EDAN.
- 3 While the battery is charged, used or stored, keep it away from objects or materials with static electric charges.

2.4 Explanation of Symbols on the Monitor

1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
3		Caution
4		Operating instructions
5		Equipotential grounding
6		USB (Universal Serial Bus) Connection
7		Video output
8		Power Supply switch

9		Gas inlet
10		DO NOT REUSE
11		SERIAL NUMBER
12		CE marking
13		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14		Date of manufacture
15		MANUFACTURER
16		Part Number
17		General symbol for recovery/recyclable
18		Disposal method
19		Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
20		Ingress Protection IPX1 (Protected against vertically falling water drops)

21		<p>Refer to User manual (Background: blue; Symbol :white)</p>
22		<p>Warning (Background: yellow; Symbol and outline: black)</p>
23		<p>Non-ionizing electromagnetic radiation</p>
24		<p>(This mark is optional.) Conforms to UL Std. 60601-1, IEC Std. 60601-2-27, IEC Std. 60601-2-30, IEC Std. 60601-2-34, IEC Std. 60601-2-49 Certified to CSA Std. C22.2 No 601.1, CSA Std. C22.2 No 60601-2-27, CSA Std. C22.2 No 60601-2-30, CSA Std. C22.2 No 60601-2-34, CSA Std. C22.2 No 60601-2-49</p>

NOTE:

The service manual is printed in black and white.

Chapter 3 Installation

WARNING

Only qualified service engineers should install this equipment.

3.1 Environment Requirements

Temperature	
Working	0 °C to +40 °C (32 °F ~104 °F)
Transport and Storage	-20 °C to +55 °C (-4 °F ~131 °F)
Humidity	
Working	15%RH to 95%RH (non-condensing)
Transport and Storage	15%RH to 95%RH (non-condensing)
Altitude	
Working	86 kPa to 106 kPa
Transport and Storage	70 kPa to 106 kPa

NOTE:

- 1 Do not install the monitor in the presence of 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:	100 V-240 V ~
Operating Frequency:	50 Hz/60 Hz
Current:	1.0 A -0.5 A

3.3 Safety Requirements

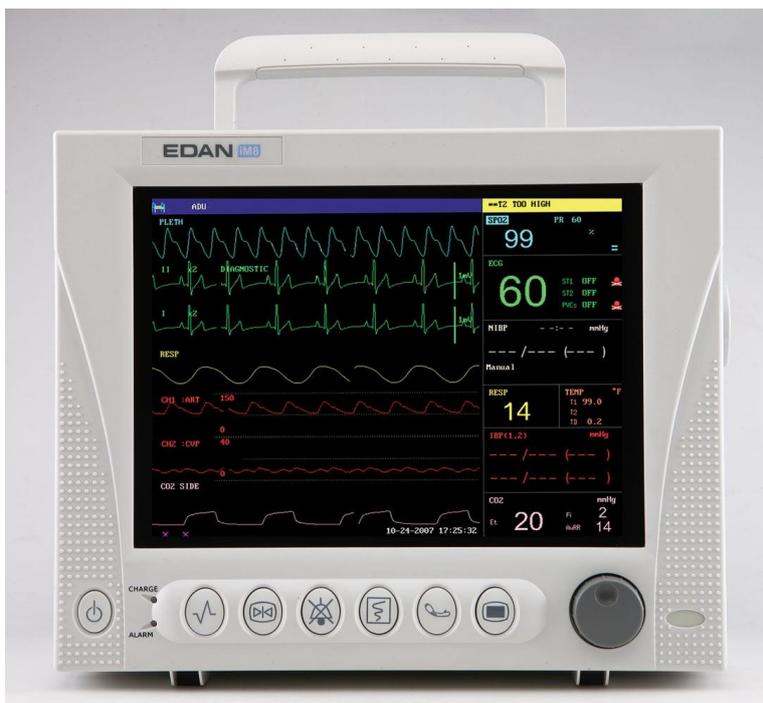
CAUTION

- 1 SHOCK HAZARD – To protect patients and medical staff, the power receptacle must be well grounded.
- 2 Do not simultaneously touch the signal input or output connector and the patient.
- 3 Devices connecting with monitor should be equipotential.
- 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.



Patient Monitor on a Flat Surface

- To install the monitor on a roll stand/trolley.

To install the monitor on a roll stand/ trolley, refer to the assembling instruction delivered with the roll stand/ 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, and 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 functional check, should be performed by qualified personnel every 24 months or after service.

4.1.1 Visual Inspection

Before using the monitor:

- ◆ 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 engineers 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. You can move the cursor by turning the trim knob clockwise or anticlockwise. Also, you can confirm the operation by pressing the trim knob.

4.1.4 Recording Test

Check if the recorder can perform printing without problem. Also, check if all the printed 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 printing.

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 Functional Tests and Accuracy Tests

WARNING

- 1 Functional tests and accuracy tests must only be carried out by qualified service personnel.
 - 2 If function of the monitor is in question, conduct an overall test on the function and accuracy of the monitor according to the instructions offered by the manufacturer.
 - 3 A functional tester, such as ECG simulator, SpO₂ simulator, NIBP simulator and IBP simulator, can only be used to assess the parameter consistency and function but not to be used to assess the clinical measurement accuracy.
-
-

A functional check should be performed once possible device malfunction emerges or after servicing the device.

It is unnecessary to open the device case for functional checks.

4.2.1 ECG Functional Test

This test checks the function 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 30 bpm ± 1 bpm or $\pm 1\%$ (whichever is greater).

4.2.2 SpO₂ Functional Test

This test checks the function of the SpO₂ measurement.

Tools required: SpO₂ simulator.

Procedure:

1. Connect the monitor and the SpO₂ simulator with a SpO₂ cable.
2. Switch on the monitor and the simulator.
3. Set the simulator to the following configuration:
 - SpO₂ = 70%.
4. Check the displayed SpO₂ value against the simulator configuration. The value should be 70% \pm 2%.

4.2.3 NIBP Functional Test

This test checks the function 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=255 mmHg;
 - Diastolic pressure=195 mmHg;
 - Mean pressure=215 mmHg.And then start a NIBP measurement.
4. Check the displayed values against the simulator configuration. The differences should be within the range of \pm 8 mmHg.

4.2.4 NIBP Leakage Test

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

Procedure:

1. Connect the cuff securely with the socket for NIBP air hole.
2. Wrap the cuff around the cylinder with an appropriate size.
3. Make sure the patient type has been set to **Adult**.
4. Access **SYSTEM MENU > MAINTAIN > 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 about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system will automatically open the deflating valve to stop the leak test and indicates NIBP Leak. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.

If the prompt of **Leak Test over** appears, it indicates that the airway is in good situation and no air leaks exist. However if the alarm information of **NIBP 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.

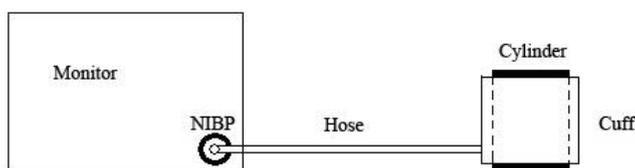


Figure 4-1 Diagram for NIBP Leakage Test

4.2.5 NIBP Calibration

NIBP calibration must be performed by professional personnel authorized by EDAN.

NOTE:

NIBP calibration can influence measurement results. Incorrect operation may influence measurement accuracy.

Tools required:

- T-fitting;
- NIBP extension tubes;
- Cylinder;
- Manometer.

Procedure:

1. Access **SYSTEM MENU > MAINTAIN > USER MAINTAIN** by inputting the password **ABC**.
2. Connect the equipment as shown below:

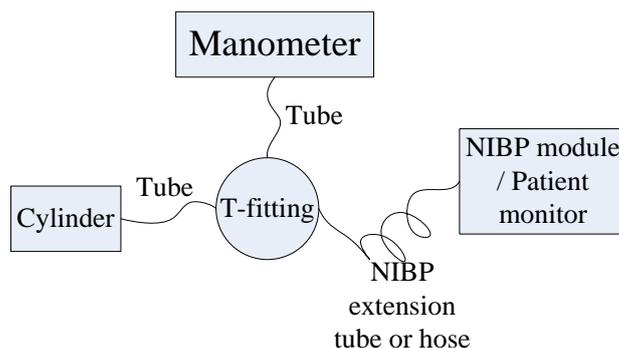


Figure 4-2 Diagram for NIBP Calibration

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 ± 3 mmHg is reasonable.

4.2.6 TEMP Accuracy Test

This test checks the accuracy 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°C in the resistance box.
4. A difference within the range of $\pm 0.1^\circ\text{C}$ is reasonable.

4.2.7 CO₂ Functional Test

This test checks the function of the CO₂ measurement.

Tools required: nasal cannula.

Procedure:

1. Switch on the monitor.
2. Access CO₂ setup menu, and set the **WORK MODE** to **MEASURE**.
3. Place the nasal cannula below the nose and normally breathe; check if the CO₂ measurement waveforms are available on the monitor.
4. The displayed CO₂ concentration is supposed to be 34~40 mmHg.

4.2.8 IBP Functional Test

This test checks the function 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; perform a zero calibration.
3. After completing the zero calibration, configure the simulator as P (static) = 200 mmHg.
4. Perform a dynamic pressure test. Set the simulator to the following configuration:
 - RADIALART 120/80
5. The tolerances for the measurement value provided by the monitor should be ± 4 mmHg or $\pm 4\%$.

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, and perform the test according to your local regulations, for example, in Europe according to IEC/EN60601-1, in USA according to UL60601-1. For the test setup, please refer to the Instructions for Use of the test equipment used.

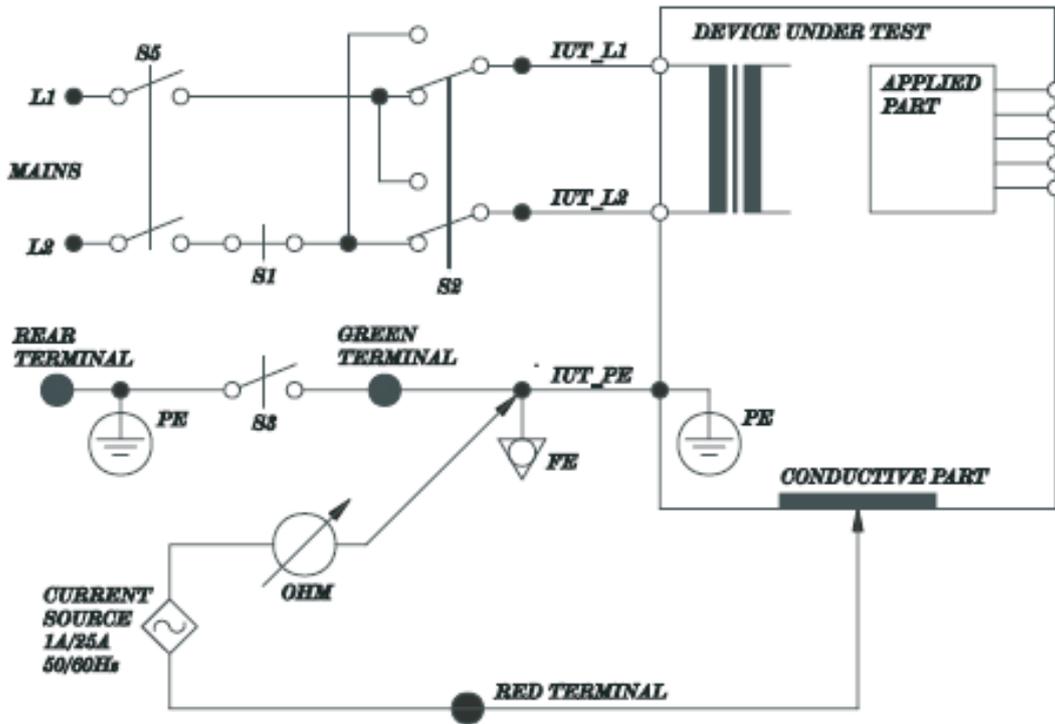
Additional test may be required by your local regulations.

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.~~ After the system is installed or set up, safety test must be performed according to IEC 60601-1.
- 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:

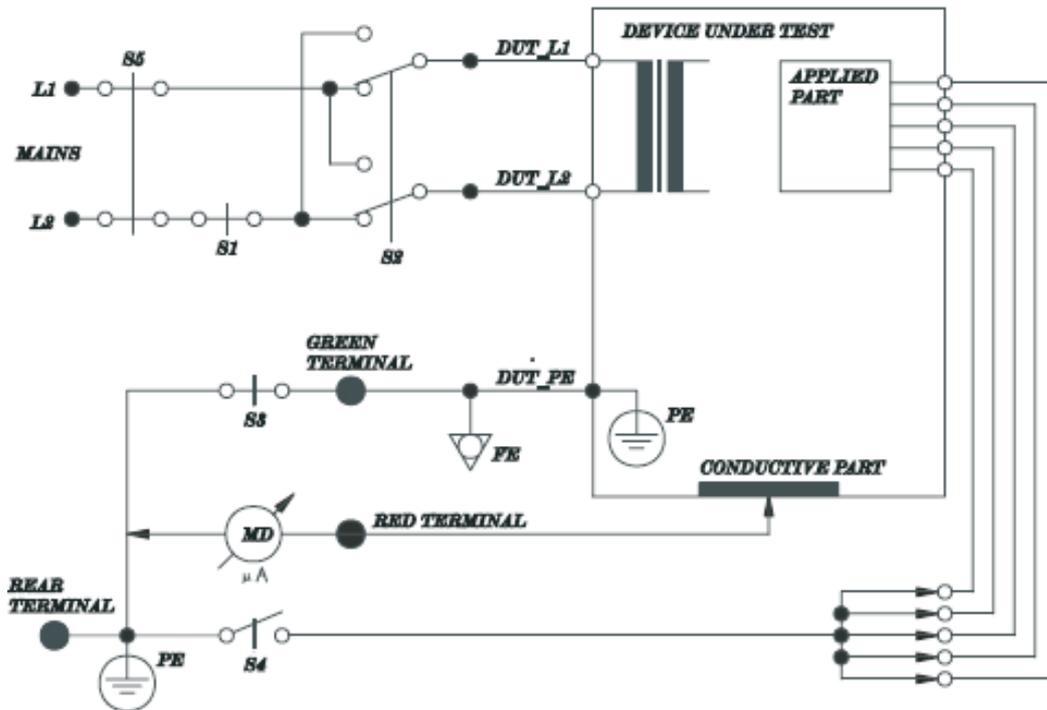
The circuit diagram is based on the Fluke 601Pro series safety analyzer.

This measures impedance 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 impedance: 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:

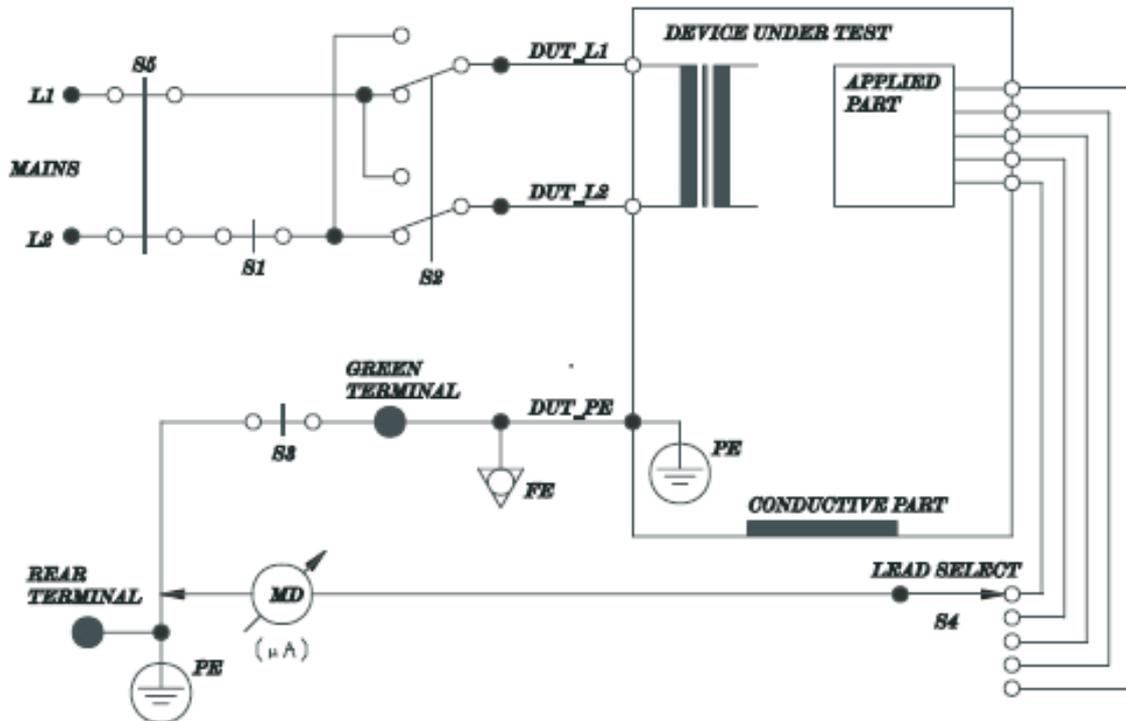
Normal condition: 100 μ A (IEC/EN60601-1)

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

Normal condition: 100 μ A (UL60601-1)

Single fault condition: 300 μ A (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: 10 μ A (BF applied part), 10 μ A (CF applied part)

(IEC/EN60601-1, UL60601-1)

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

(IEC/EN60601-1, UL60601-1)

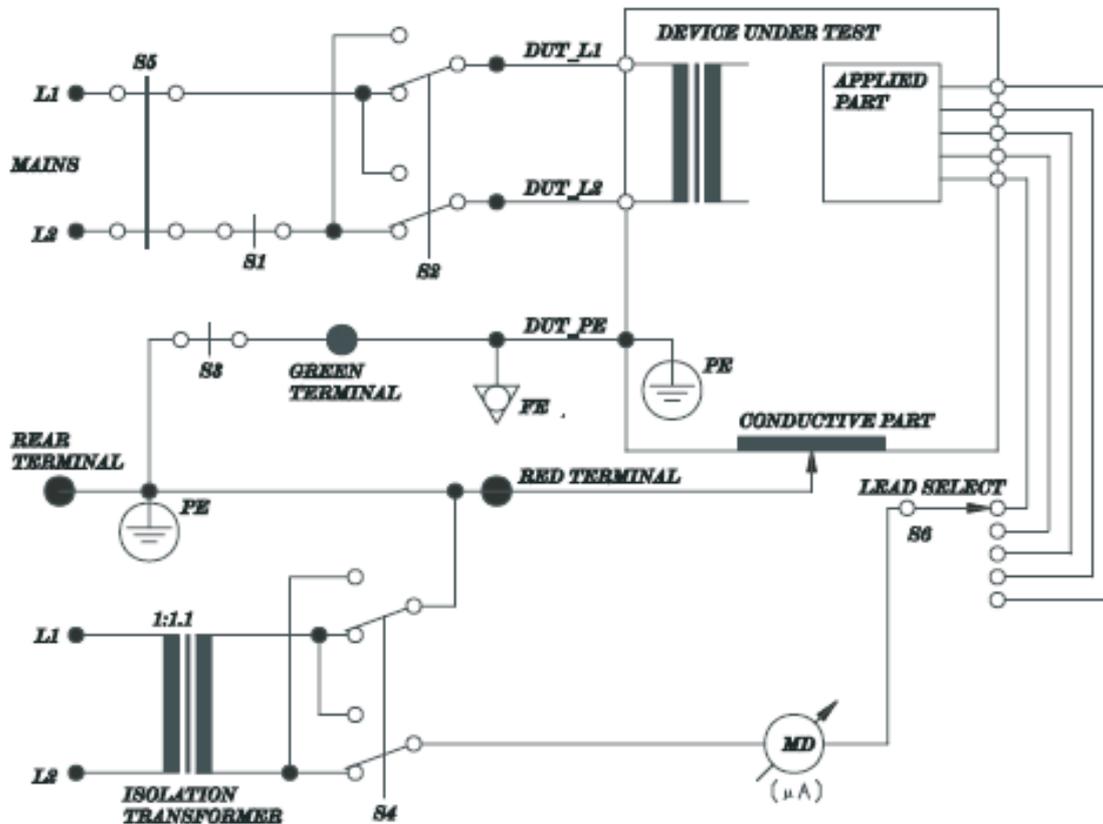
Leakage Current

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



Notes:

- S1 = Closed
- S2 = Variable
- S3 = Closed
- S4 = Variable
- S5 = Closed
- S6 = Variable

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):

5000 μ A (BF applied part), 50 μ A (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 Principle Introduction

5.1 System Principle Block Diagram

Here is the system principle block diagram of the monitor:

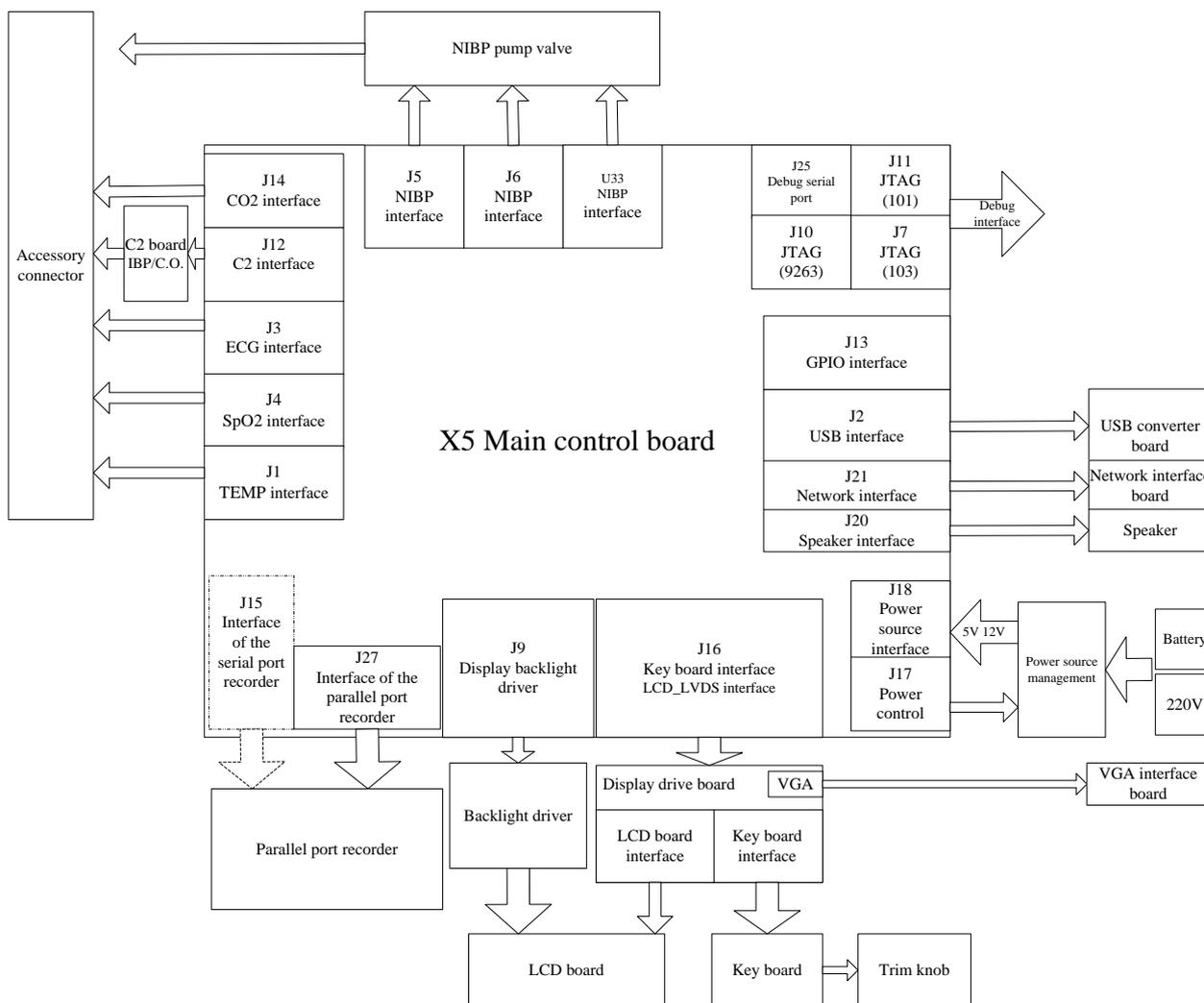


Figure 5-1 System Principle Block Diagram

5.1.1 Main Control Board

X5 main control board is integrated with multiple parameters. It includes digital part and parameter part.

The parameter part applying floating ground technology includes parameters such as ECG, SpO₂, NIBP, RESP and TEMP. This part adopts a CPU to control the front-end analog signals, collect data, simply process the data and deliver it.

The digital part applying chassis ground is a digital platform consisting of ARM chipset as the core. This part will receive the data delivered from the floating ground and process the data.

Besides, it performs the functions including controlling, displaying, networking, recording and so on. The main board contains a main CPU and an extended CPU. The main CPU, with its abundant resources, can realize extension of the main storage system, networking (10 M/ 100 M self-adaptable), audio output; additionally, and offers display interface. The extended CPU is able to realize interface extension, to collect and control valve signals of NIBP, and to offer sufficient I/O ports which enable key board scanning.

Parameter Part

The parameter part of X5 includes five physiological parameters such as ECG, SpO₂, NIBP, RESP and TEMP. With control of the monitor, X5 module is able to work in the mode of 3-lead and 5-lead, and maximumly realize 7-lead ECG monitoring. X5 offers SpO₂ as well as NIBP measurement function and supports I/ II lead respiration measurement (respiration lead can be switched by the monitor). Also, X5 supports 2-channel TEMP with YSI sensors available. The main control part of X5 performs the functions of display, networking, recording and so on.

ECG

X5 supports 3/5 leads ECG monitoring. In 3-lead mode, three electrodes used are RA, LA and LL. 3-lead ECG measurement can be realized by controlling conversion of the drive electrodes.

In 5-lead mode, five electrodes in used are RA, LA, LL, RL and V1; four ECG channels are available; four channels of ECG signal are amplified; and RL is the drive electrode. In the mode of 5 leads, seven leads (I, II, III, AVR, AVL, AVF and V1) of ECG signal can be collected.

Summarily, the ECG module can perform the following functions:

In 3-lead mode: RA, LA and LL are available, I/ II/ III are optional and the drive lead alter accordingly.

In 5-lead mode: RA, LA, LL, RL and V1 are available, two channels among I, II, III, AVR, AVF, AVL and V1 are optional and the drive lead is RL.

SpO₂

By outputting the control pulse via DA, MCU controls red ray and illumination of the infrared illuminators of the SpO₂ sensors. The ray measuring system amplifies the minute measured signal. Subsequently, the amplified signal is delivered for AD sampling. Measurements of SpO₂ and PR will be calculated based on the corresponding algorithm. To adapt the difference between the strong and weak signal, the receiving circuit is outfitted with a program control amplifier. If the measured signal is weak, the system will enhance the gain; if the measured signal is strong, the system will lessen the gain.

NIBP

NIBP module can measure the pressure via the pressure transducer and then convert the pressure signal into electric signal which is subsequently amplified and delivered to AD; after AD detects

and measures the pressure and pulse wave signal, BP can be calculated based on the related algorithm.

The pressure protection unit of NIBP will protect the patient when individual malfunction occurs. Once the pressure protection unit detects that the value of pressure exceeds the normal one, it will activate the valve and deflate.

RESP

The respiratory carrier wave of 62.8 kHz will act on the body via the resistance-capacitance network. The change of celiac impedance during respiration a minute amplitude modulated wave can be obtained on the front end of the respiratory amplifying circuit. By amplifying, demodulating and reamplifying the amplitude modulated wave, a real respiratory wave can be attained. X5 supports I and II lead selection which can switch between each other by the host system sending instruction.

TEMP

The mode utilizing steady voltage source is adopted to collect the body temperature. Compared with utilizing constant current source, using steady voltage source is relatively simple. There are two channels in the TEMP circuit, supporting YSI sensor.

5.1.2 Key Board

The key board is the indispensable part of the device. iM8&M8 series patient monitors adopt free-standing key board. The key board works with the trim knob to perform information communication between the user and the device. The module circuit connected with the key board includes the trim knob and display drive board which are connected to X5 after converted. Six functional keys on the key board are alarm pause, NIBP, trend graph, freeze, recording and menu. Besides, two LED with different colors are on the board. One LED indicates the status of AC and the other indicates the status of battery charging.

The structure of the key board is shown in Figure 5-2. The key board communicates with the host system via the serial interface USART, transmitting information from key sets and trim knob to the host system. The switch-on key and two power status LEDs are connected to the host system via another connector.

In Figure 5-2, KJ2 and KJ3, the interfaces for linking the key board and host system, are connected to the display drive board with wires and then to the X5 main board.

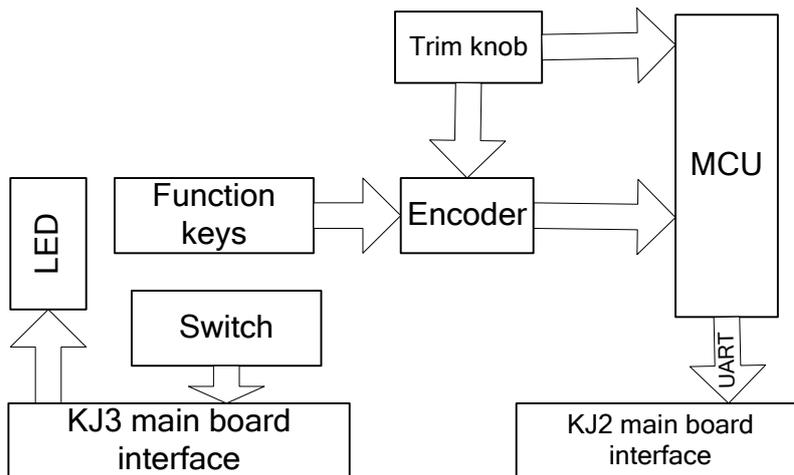


Figure 5-2 Key Board Principle Block Diagram

5.1.3 Display Drive Board

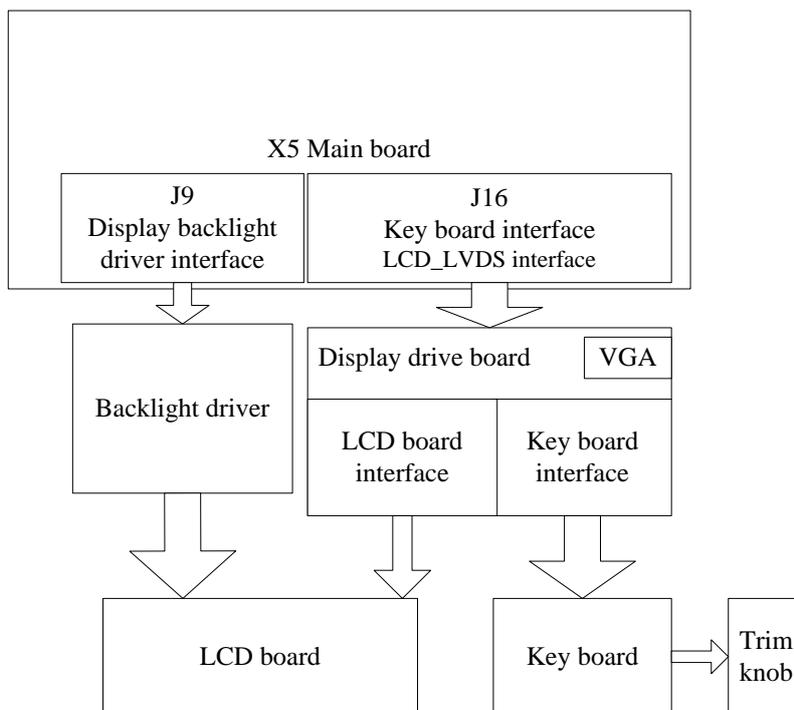


Figure 5-3 Display Drive Board Block Diagram

Different models of iM8&M8 series patient monitors are outfitted with screens of different sizes: iM8 patient monitor is outfitted with a 12.1-inch screen; iM8A 10.4-inch; iM8B 10.1-inch; M8 12.1-inch; M8A 10.4-inch; M8B 10.1-inch. They share the same operation principle.

As shown in Figure 5-3, the LCD realizes backlight source drive with a backlight board. The display drive board realizes transmission of key board signal and conversion of video signal. The video signal is transmitted through J16 on the X5 main board to the display drive board and video signal conversion will be completed on the board. On the one hand, the signal drives the LCD

board so as to realize screen display; on the other hand, the converted VGA signals are transmitted to the VGA converter board in the rear housing assembly and exported to peripheral equipment via the VGA interface.

5.1.4 Interface Board

Network interface (nurse call), USB interface and VGA interface are available on iM8&M8 series patient monitors. Three interface boards are installed in the rear housing assembly.

The network interface board is connected with the main board which controls the relay on the interface and controls the switch-on-and-off of the outlying nurse call indicator. Ethernet signals, which are insulated by the transformer on the interface board, are transmitted through the network interface; consequently, the monitor is able to be networked via network cable.

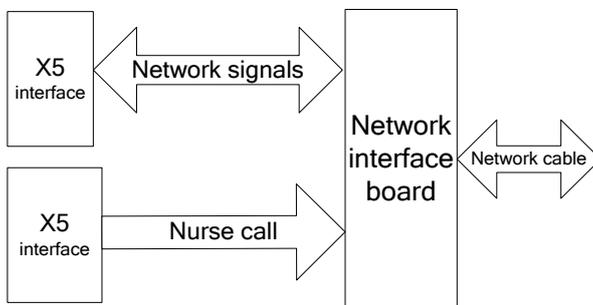


Figure 5-4 Network Interface Board Block Diagram

USB signal transformation is realized on the USB interface board which is connected to the main board via the connector, and a USB port is reserved for external connection.

The one end of the VGA interface board is linked to the display drive board, the other end is reserved as the VGA port (DB15) for external connection.

5.1.5 Power Module

The power module is developed by EDAN. It outputs +12 V and +5 V voltage and manages battery charging.

Interface	Pin Definition					
J1	1		2		3	
	AC_IN		N/A		AC_IN	
J9	1	2	3	4	5	6
	+12V	+5V	GND	GND	GND	NC
J5	1			2		
	BAT			GND		

J4	1		2	
	POWR_ON/OFF		GND	
J2	1	2	3	4
	POWR_UP	CHARGE	RXD	TXD

5.1.6 LCD

A 10.1-inch/ 10.4-inch/ 12.1-inch LCD is adopted as the display screen.

5.2 Interfaces



Interfaces on the rear panel of the monitor include:

- ◆ 1 USB port
- ◆ VGA interface
- ◆ Network / Nurse call interface

5.2.1 USB Port

Via the USB port, external devices which support USB protocols can be connected to the monitor.

5.2.2 VGA Interface

Via the VGA interface, VGA signals from the monitor can be outputted to external display devices which support VGA signals.

5.2.3 Network / Nurse Call Interface

This interface enables networking and nurse call. Ethernet and nurse call share the same RJ-45 interface. PIN7 and PIN8 are used for nurse call. When there is alarm, PIN7 and PIN8

Chapter 6 Troubleshooting

EDAN supports replacement of PCBs and major subassemblies for this product. When replacement is needed, follow the procedures described in Chapter 7 *Disassembling the Monitor*.

6.1 Monitor Booting Failures

Phenomenon	Possible Cause	Solution
After switching on, no display is on the LCD; the power indicator is off; the fan doesn't run.	None AC power inputs.	Check whether the cable is intact and whether it is well connected with the monitor as well as the AC output.
	The fuses melt and break.	Replace the fuses.
	Main control board failure.	Replace the main control board.
The fuses melt and break during switching.	Power failure.	Replace the power board.
	Short circuit of other parts.	Retry after checking the short circuit source and fixing it.
Abrupt switching off.	The monitor is stricken by strong high voltage, e.g. lightning strike.	Check the power supply and grounded system.
	Power failure.	Replace the power supply.
	Bad connection of power input.	Check the power input.
	Main control board failure.	Replace the main control board

6.2 Display Failures

Phenomenon	Possible Cause	Solution
After switching on, the power indicator and fan run normally; but no display is on the screen.	LCD failure.	Replace the display screen.
	LCD is disconnected.	Check the connection of X5 main control board, display drive board and the screen.

Phenomenon	Possible Cause	Solution
After switching on, the power indicator and fan run normally; but no display is on the screen.	Display drive board failure.	Replace the display drive board. Refer to the principle diagram and repair the replaced one
	Main control board failure.	Replace the main control board. Refer to the principle diagram and repair the replaced one.
Wrong characters are displayed onscreen.	Display drive board failure.	Replace the display drive board. Refer to the principle diagram and repair the replaced one.
	LCD failure.	Replace display screen.

6.3 Operation Failures

Phenomenon	Possible Cause	Solution
Keys are not functioning.	Key board failure.	Replace the key board.
	Key board connection failure.	Check the connection of the key board.
It is mute when a key is pressed.	Speaker or wire failure.	<ol style="list-style-type: none"> 1. Replace the speaker or wire. 2. Check the settings of key volume. Refer to the section <i>Key Volume</i> in the <i>Patient Monitor User Manual</i>.
Hoarse sound comes from the speaker or it is mute of the speaker.	Speaker failure.	Replace the speaker.
	Main control board failure.	Replace the main control board.

6.4 Recorder Failures

Phenomenon	Possible Cause	Solution
Press Record but no paper is out.	No paper in the drawer	Load paper and close the drawer.
	The drawer is open.	Close the drawer.
	Paper is jammed.	Open the drawer and check if the paper is well loaded. Reload paper and close the drawer.
	Recording control board failure.	Replace the recording control board.
	Recorder connection failure.	Check all the connections.
	Gear box/ gear failure.	Replace the gear box or the gear.
	Main control board failure.	Replace the main control board.
The alarm indicating “out of paper” is onscreen, but there is paper in the drawer.	The detector of recording paper is contaminated.	Clean the detector of recording paper.
	Detector of recording paper failure.	Replace the detector of recording paper.
	The drawer is not fastened up.	Fasten up the drawer.
Trace on the recording paper is blurred or tilts; or it is blank on the paper.	Inexact loading of the recording paper.	Load the recording paper exactly.
	The two screw nuts on the print head are not adjusted to balance.	Adjust the screw nuts.
	Print head failure.	Replace the print head.

6.5 Alarm Failures

Phenomenon	Possible Cause	Solution
Inaction of audible alarm.	The audible alarm is temporarily disabled.	Activate the audible alarm.

	Speaker or wire failure.	Replace the speaker or the wire.
Alarm indicator stays off.	Alarm indicator failure.	Replace the alarm indicator.
	Alarm indicator board failure.	Replace the alarm indicator board.
Inaction of audible or visual alarm.	Program failure.	Update the software.

6.6 Parameter Monitoring Failures

Phenomenon	Possible Cause	Solution
No ECG trace.	Bad connection of ECG cable.	Check the connection of the ECG cable.
	The ECG cable is damaged.	Replace the ECG cable.
	Bad connection of the electrodes.	Check the connection.
	Circuit failure of ECG on the main control board.	Replace the main control board.
No SpO ₂ trace or measurements.	SpO ₂ sensor failure.	Replace the SpO ₂ sensor.
	Bad connection of the cable of the SpO ₂ sensor.	Check the connection.
	Circuit failure of SpO ₂ on the main control board.	Replace the main control board.
The cuff fails to be inflated.	Bad connection of the cuff, the pump and the NIBP connector.	Check the connection outside the monitor.

Phenomenon	Possible Cause	Solution
	Bad connection of NIBP module and connector.	Check the connection inside the monitor.
	The cuff or the extended cable is damaged.	Replace the damaged parts.
	Circuit failure of NIBP on the main control board.	Replace the main control board.
No NIBP measurements.	Circuit failure of NIBP on the main control board.	Replace the main control board.
No TEMP measurements.	TEMP sensor failure.	Replace the TEMP sensor.
	Bad connection of TEMP sensors.	Check the connection.
	Circuit failure of TEMP on the main control board.	Replace the main control board.
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 .

Phenomenon	Possible Cause	Solution
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.
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 fluctuation.	An unsuitable selection of the ruler	Check whether the IBP label is consistent with the measured site of 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.

6.7 Dust-proof System Failure

Phenomenon	Possible Cause	Solution
During inflation, the motor is extremely noisy, and the inflation time is longer than usual	The battery box is full of dust.	Clean the filter base as the user manual described.
During inflation, the cuff has abnormal sound, but no abnormal thing is found in cuff	There is abnormal thing in the filter assembly between front and back housing.	Clean the filter assembly between front and back housing as the user manual described.
During deflation, the residual air in cuff can't be exhausted	There is abnormal thing in the filter assembly between front and back housing.	Clean the filter assembly between front and back housing as the user manual described.

6.8 Technological Alarms

For details on technological alarms, please refer to relevant sections in *Patient Monitor User Manual*.

Chapter 7 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 device.
- 3 After any repair of the device, perform safety tests prior to use.

7.1 Tools Required

1 – A cross-head screwdriver



2 – A flat-head screwdriver



3 – A M3 nut driver



4 – A pair of pliers



7.2 Replacing Fuses

To replace the melted fuses,

- 1) Switch off the monitor and disconnect it from power.
- 2) The back of the device should face the operator.
- 3) Press and turn the cartridge anticlockwise with a flat-head screwdriver; take out the fuse from the released cartridge.



- 4) Replace the old fuse with a new one that is supplied by EDAN or with the same specifications. (Dimensions: $\Phi 5\text{mm} \times 20\text{mm}$; model: T3.15AH 250VP)
- 5) Put back the cartridge and turn it clockwise until it is secured.

7.3 Disassembling the Main Unit

The main unit consists of the front housing assembly, rear housing assembly, main frame and recorder.

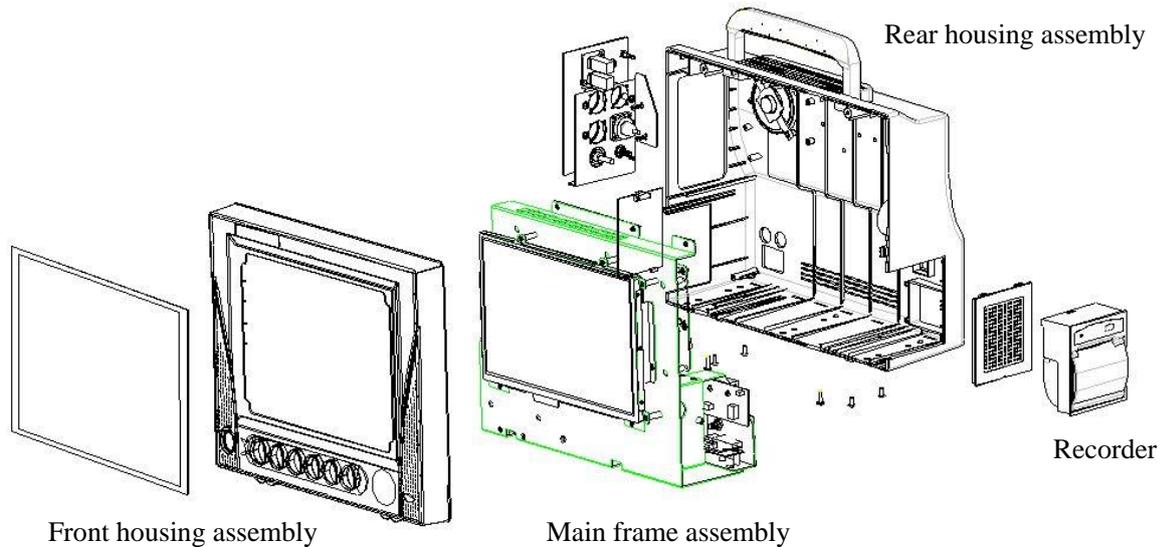
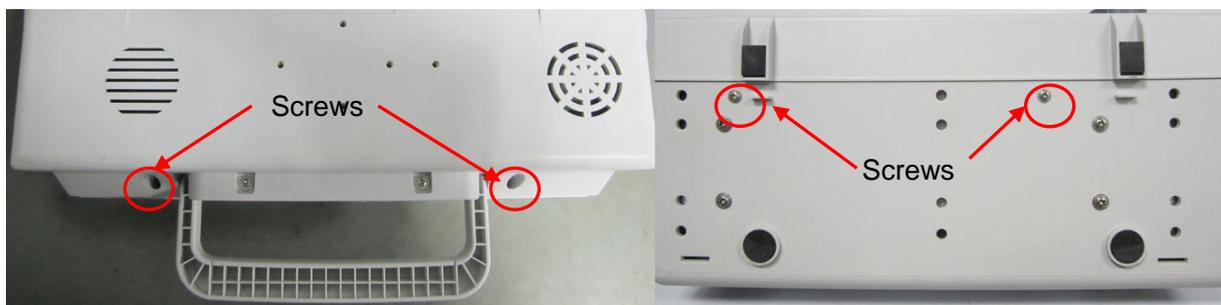


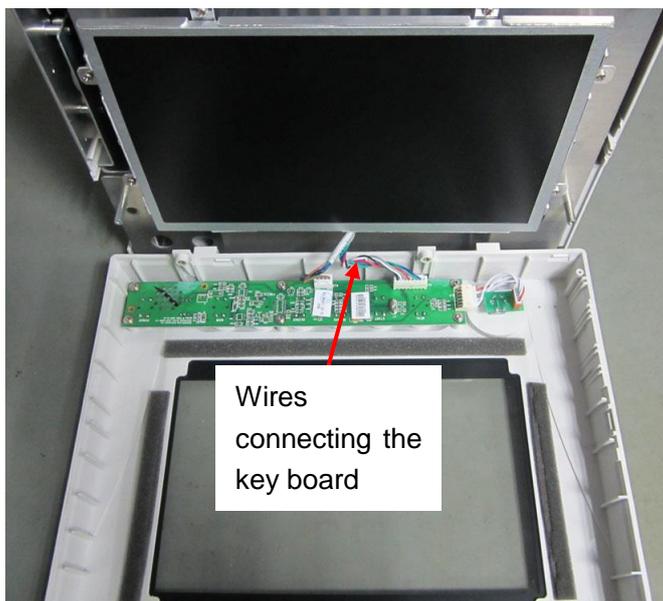
Figure 7-1 Main Unit Structure Block Diagram

To disassemble the main unit,

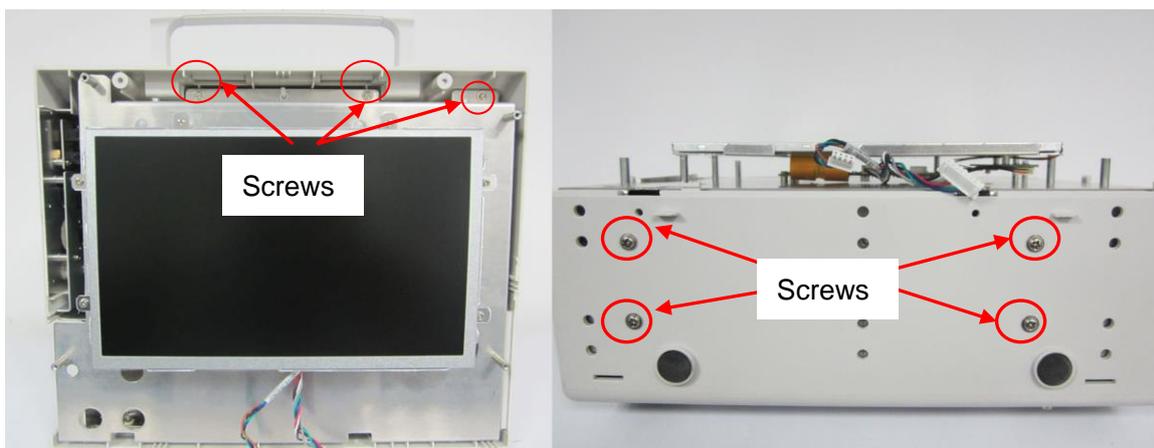
- 1) Disassemble the recorder assembly from the main unit with a screwdriver.
- 2) Remove the screws securing the front and rear housings as well as the bottom panel; the front and back assemblies are unfolded.



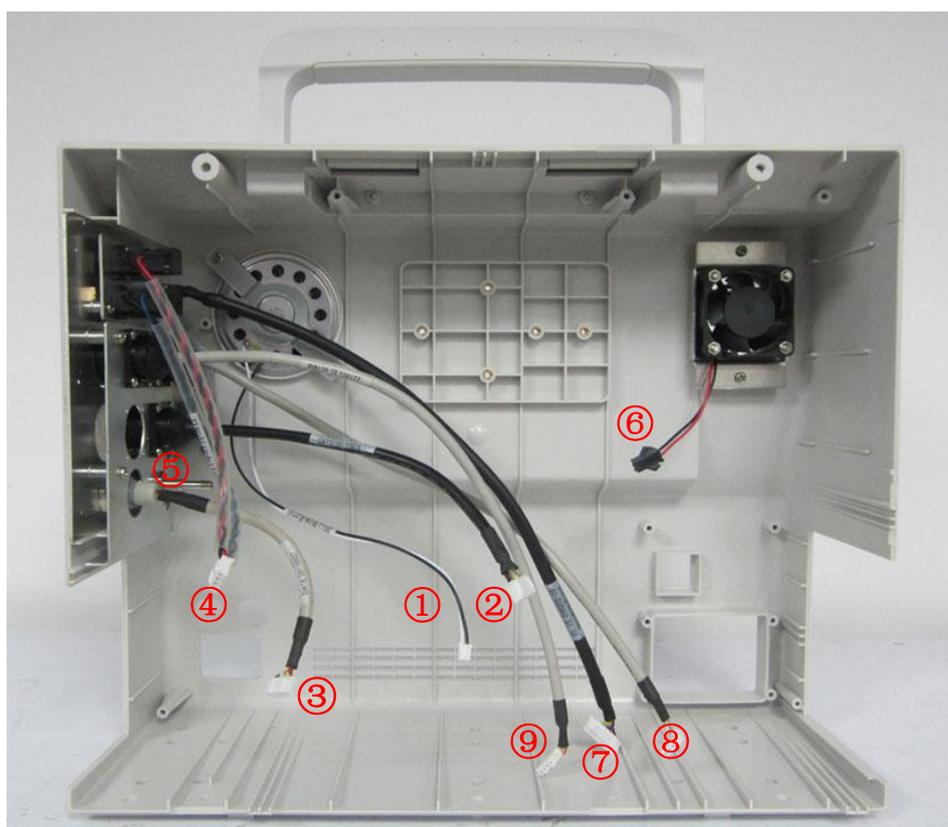
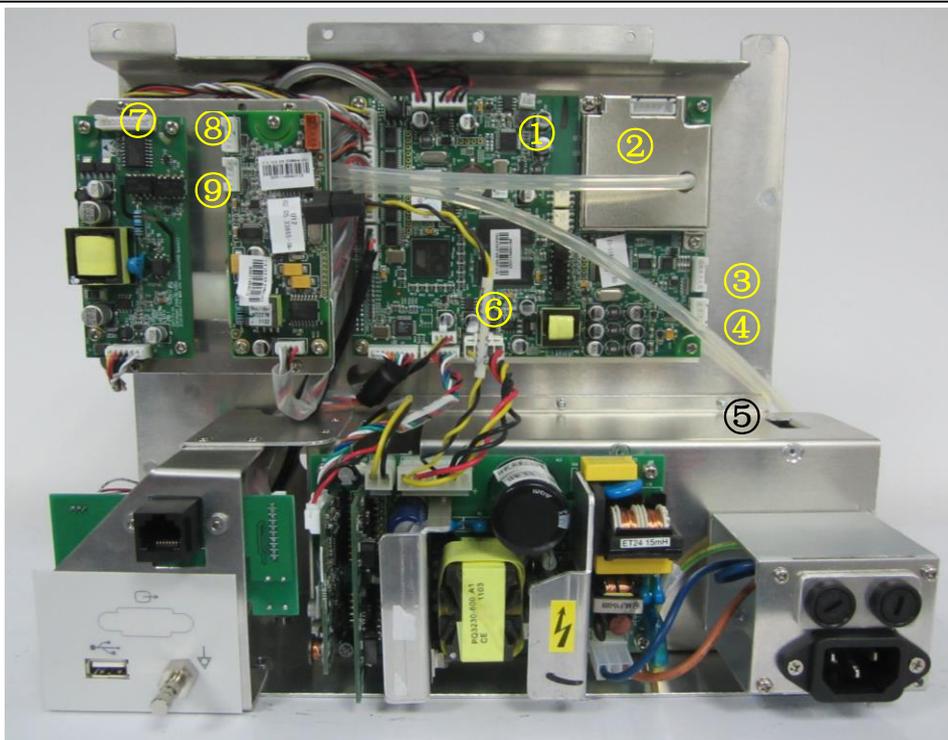
- 3) Disconnect the wires between the front and rear shells; the front and rear housing assembly are separated.



- 4) Remove the screws securing the main frame on the bottom panel and inside the unit; the main frame are separated from the rear housing assembly.



- 5) Disconnect the wires between the main frame and rear housing; the main frame and rear housing assembly are separated.



- ① Speaker wire and connector
- ② ECG wire and connector
- ③ SpO₂ wire and connector
- ④ TEMP wire and connector
- ⑤ Air tube
- ⑥ Fan wire
- ⑦ CO₂ wire and connector
- ⑧ IBP 1 wire and connector
- ⑨ IBP 2 wire and connector

7.4 Disassembling the Front Assembly

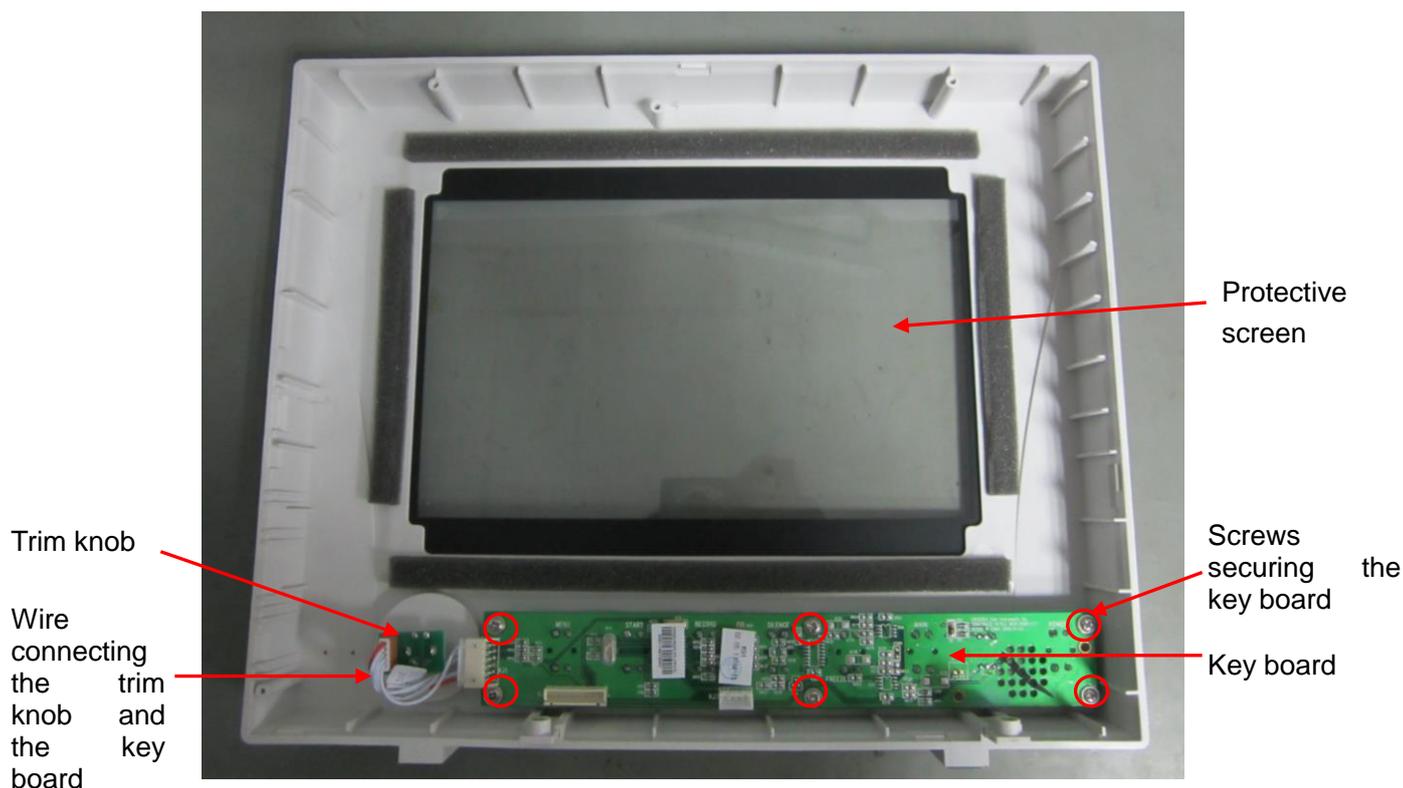
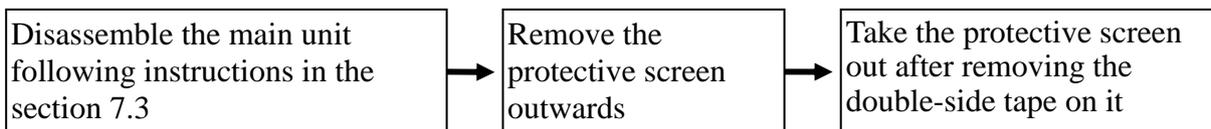


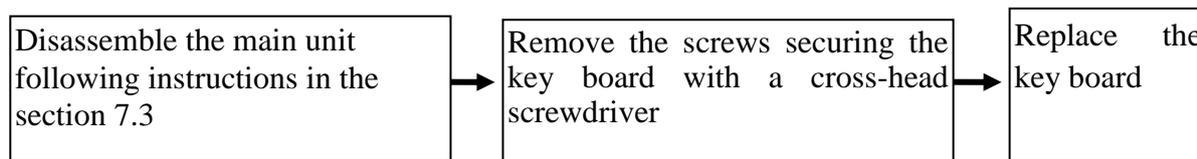
Figure 7-2 Front Assembly Diagram

7.4.1 Replacing the Protective Screen



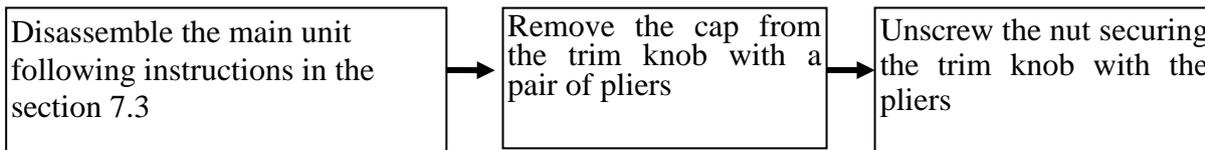
Assemble the protective screen in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.4.2 Replacing the Key Board



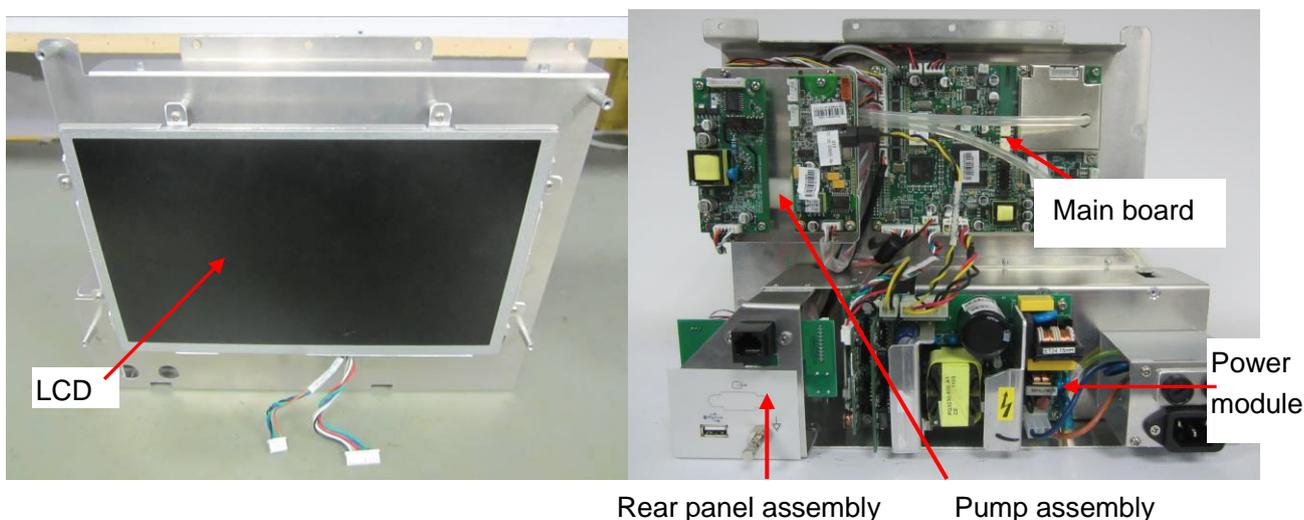
Assemble the key board in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.4.3 Replacing the Trim Knob



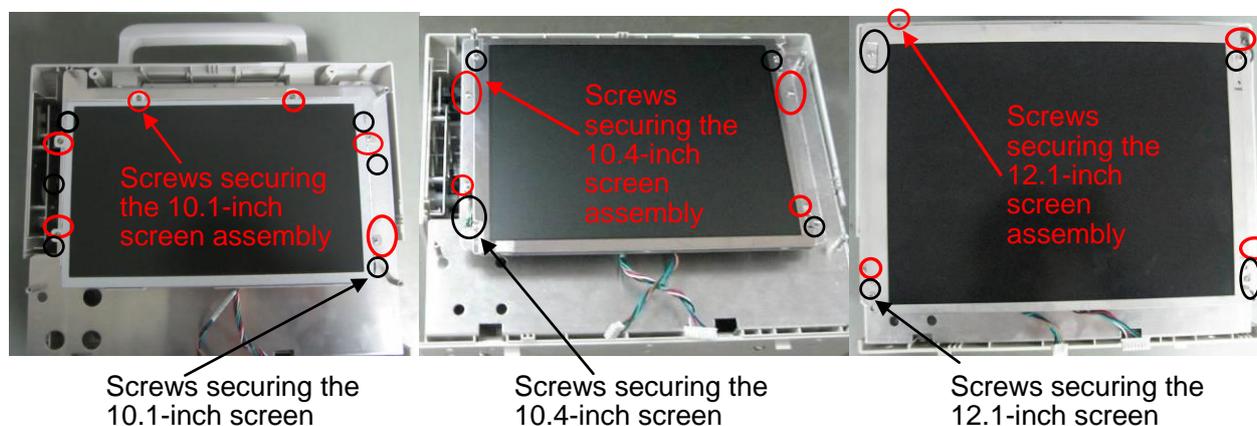
Assemble the trim knob in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

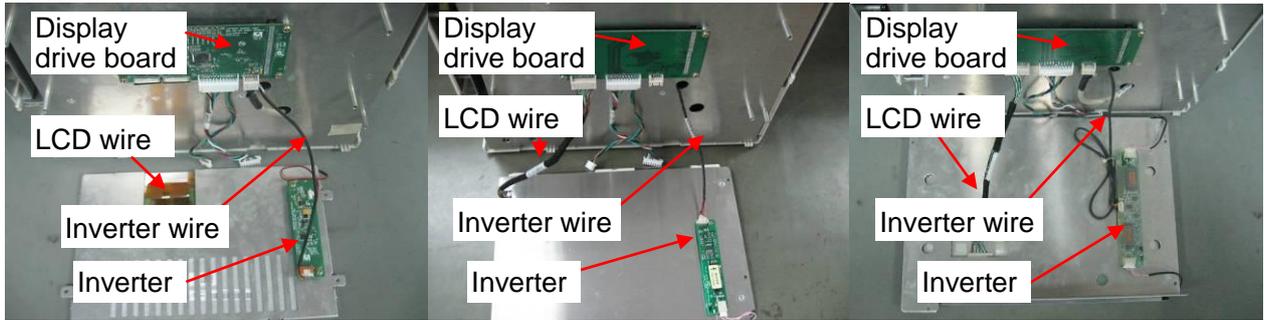
7.5 Disassembling the Main Frame Assembly



NOTE:
During disassembling the main frame, make notes about connection information for reference.

7.5.1 Replacing the LCD

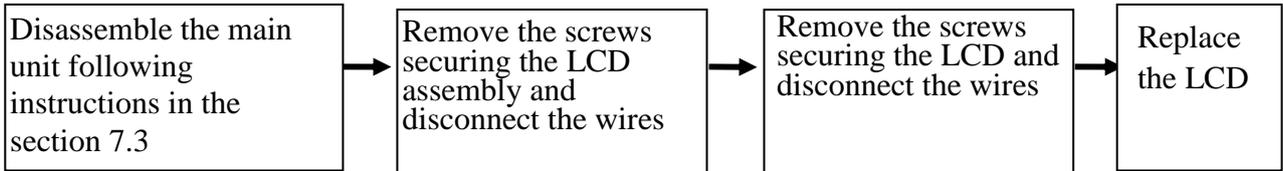




10.1-inch screen assembly

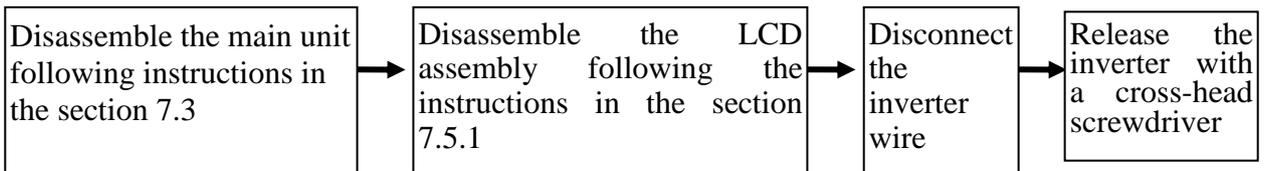
14.1-inch screen assembly

12.1-inch screen assembly



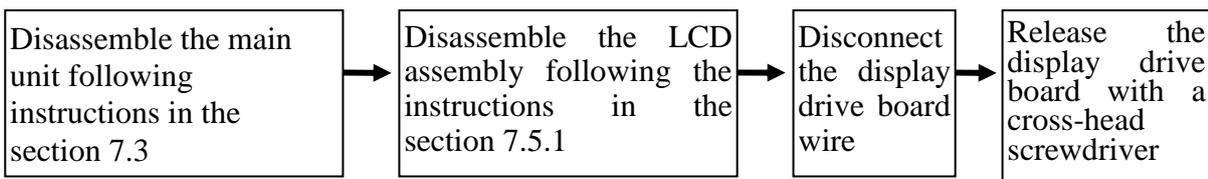
Assemble the LCD in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.2 Replacing the Inverter



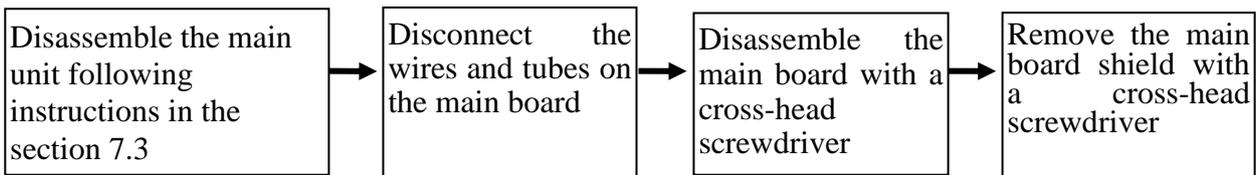
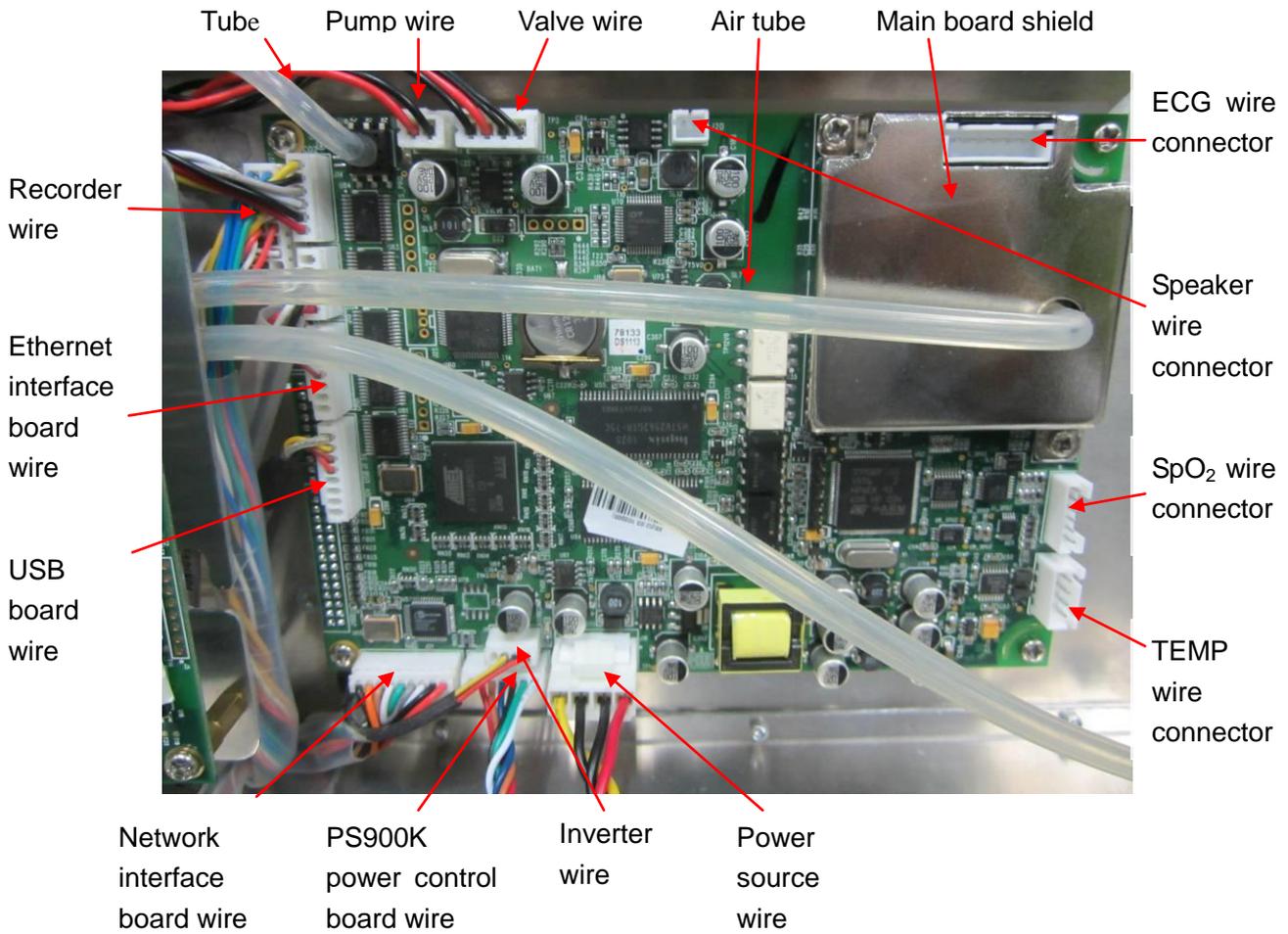
Assemble the inverter in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.3 Replacing the Display Drive Board



Assemble the display drive board in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.4 Replacing the Main Board

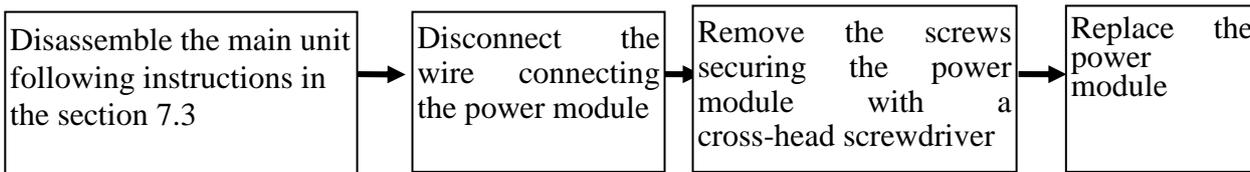


Assemble the main board in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

NOTE:

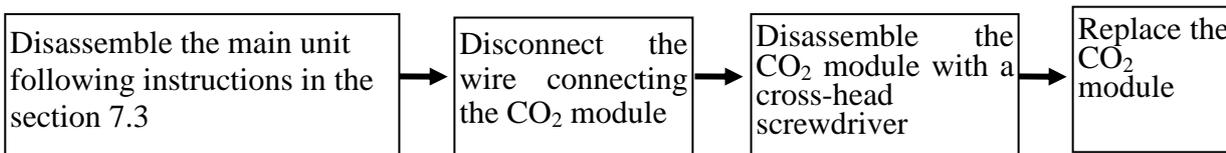
When assembling the main board, make the double-row pins on the main board precisely inserted into the connector on the display drive board.

7.5.5 Replacing the Power Module



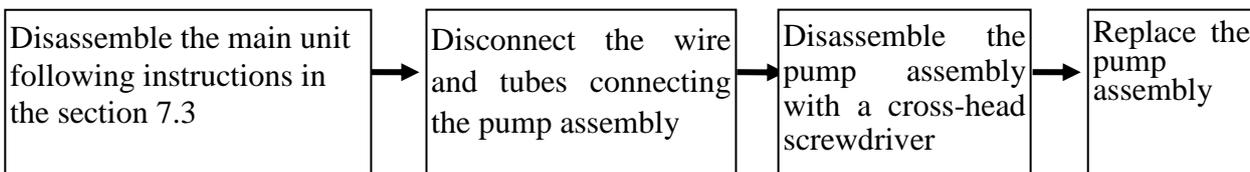
Assemble the power module in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.6 Replacing the CO₂ Insulated Power Module



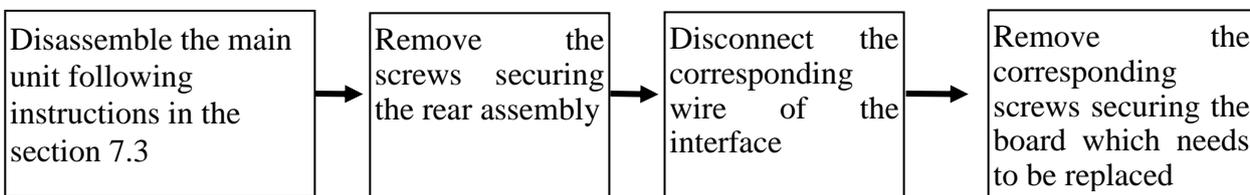
Assemble the CO₂ module in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.7 Replacing the Pump Assembly



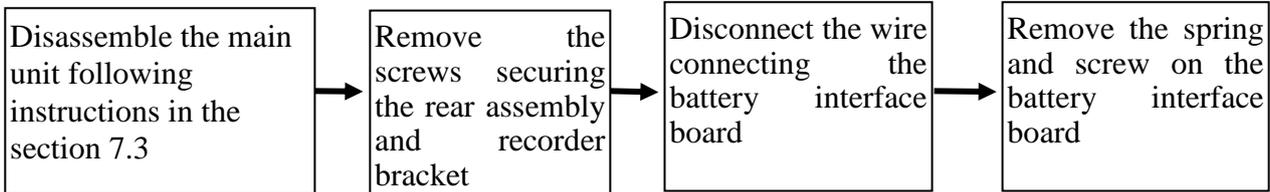
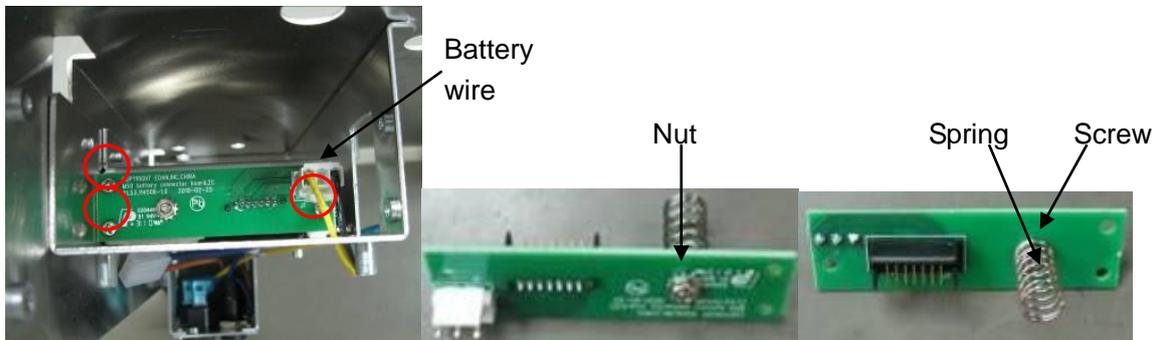
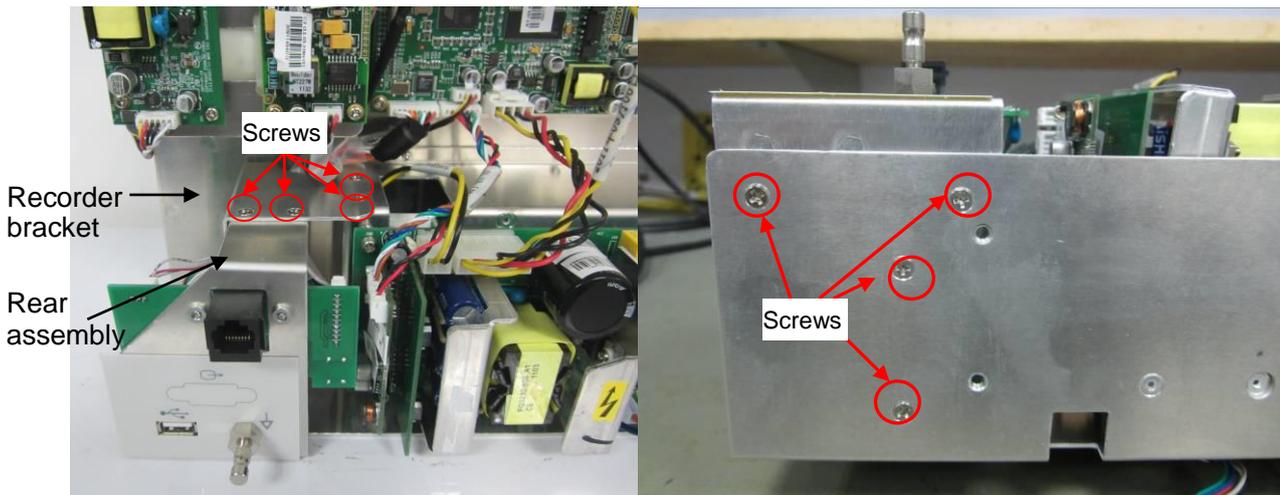
Assemble the pump assembly in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.8 Replacing the USB Interface Board, Ethernet Interface Board and VGA Board (Smaller)



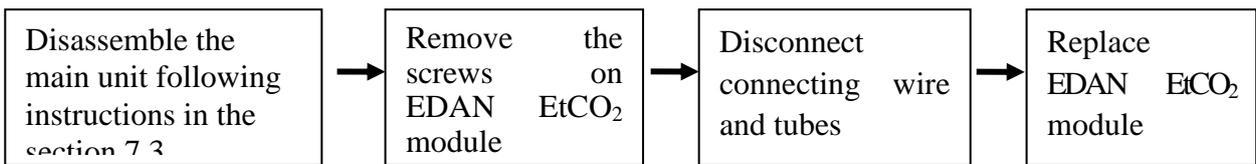
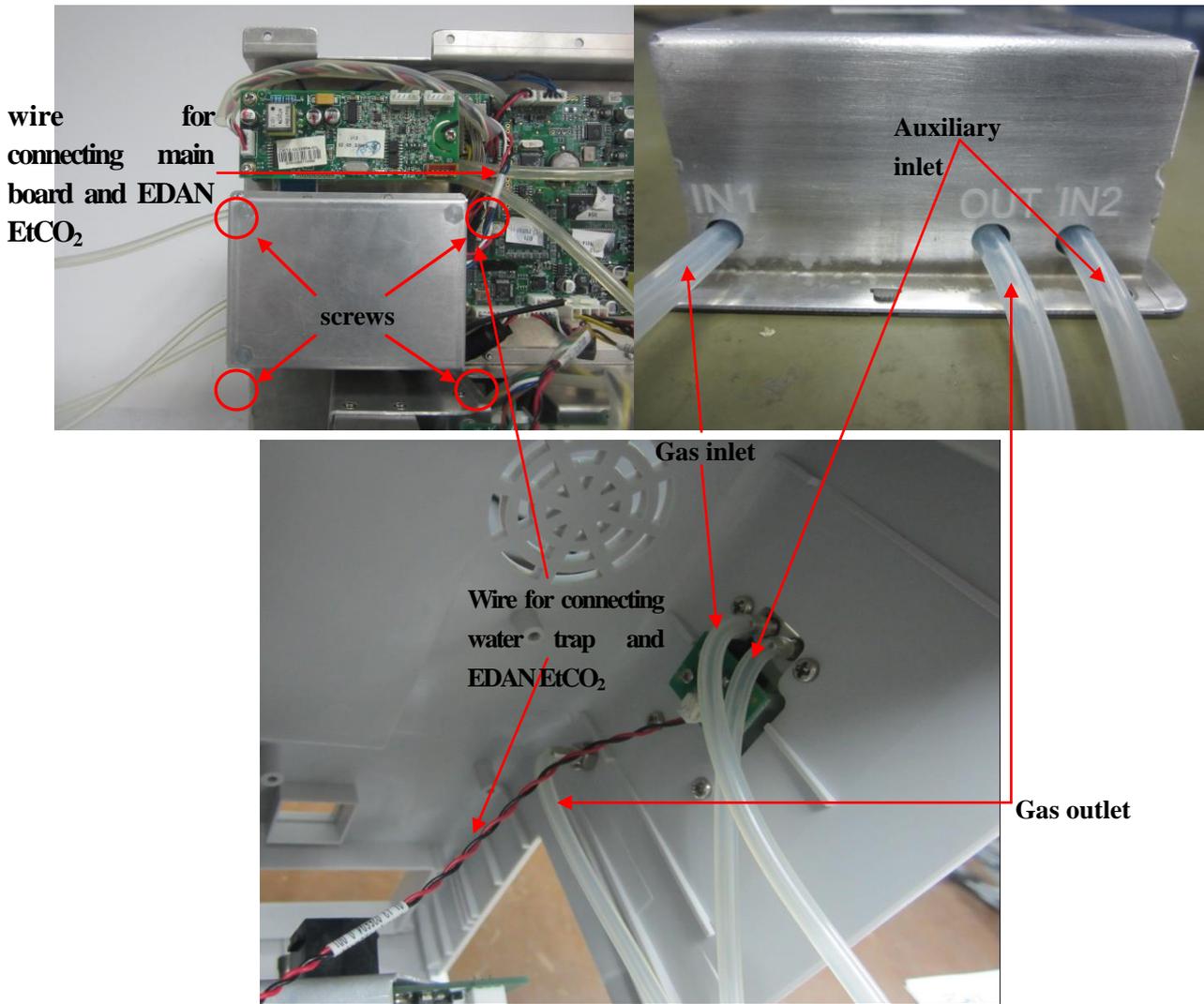
Assemble the boards in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.9 Replacing the Battery Interface Board



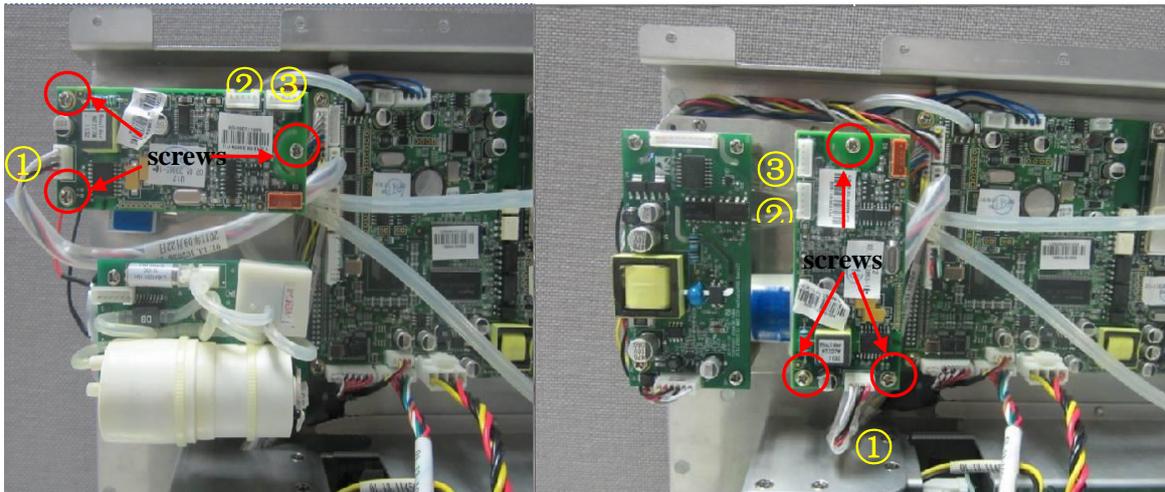
Assemble the battery interface board in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.10 Replacing EDAN EtCO₂ Module

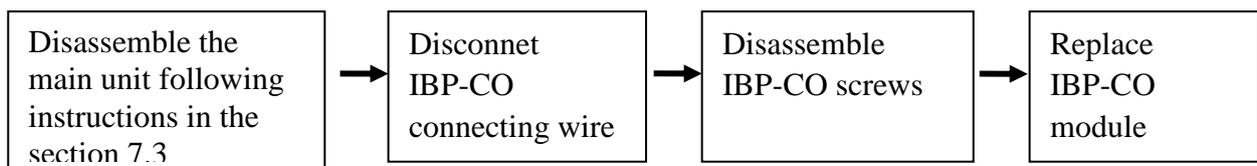


Assemble the EDAN EtCO₂ module in the reversed order; connect the wires and tubes, and fix the screws. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.11 Replace IBP-CO Module



- ① Wire for connecting IBP module and mainboard
- ② IBP 2 adapter connector
- ③ IBP 1 adapter connector

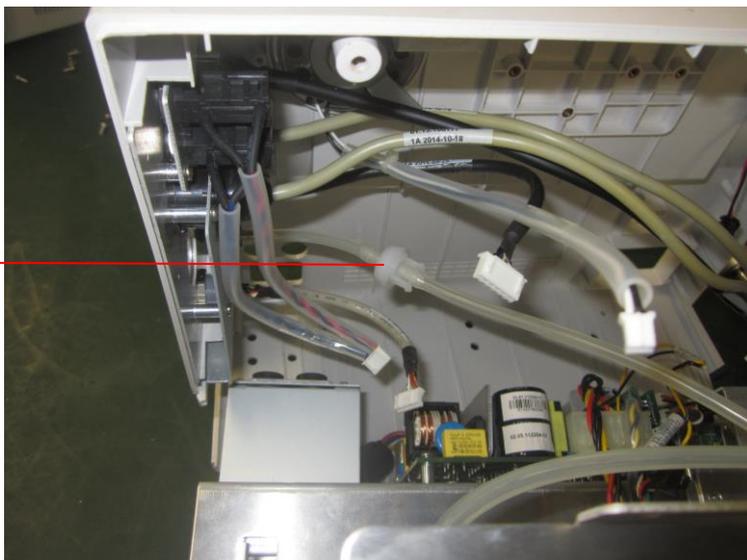


Assemble the IBP-CO module in the reversed order; connect the wires and fix the mainboard. Refer to 7.3 *Disassembling the Main Unit* for details.

7.5.12 Replace the Dust-proof Filter Assembly

1. Separate the front and rear assemblies according to Section 7.3.1 *Separating Front Housing and Rear Housing*.
2. Remove the tube in filter assembly, replace new tube.

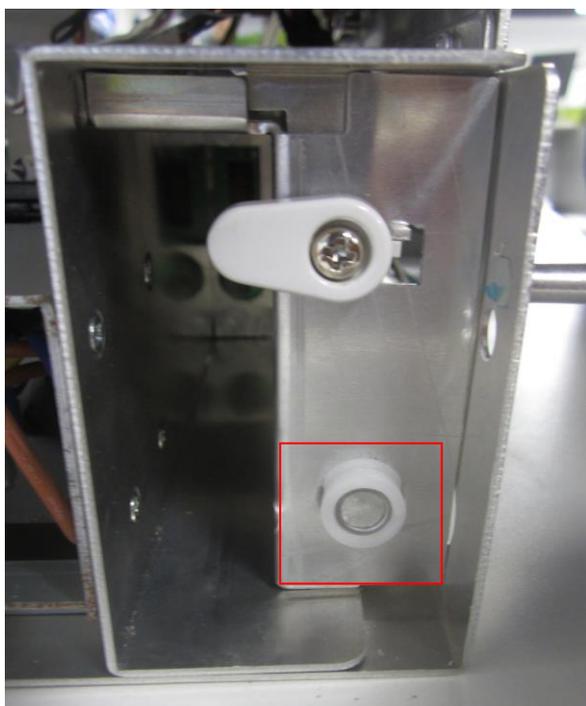
Dust-proof Filter Assembly



7.5.13 Replacing Filter Base

To replace the filter base:

1. Separate front panel and rear panel assemblies, and take out the main frame as described in Section 7.3 *Disassembling the Main Unit*.
2. Using pliers to clip the plastic knob of filter base as below shown, remove the filter base, replace new base, connect the silicon tube, and then fix the base well.



7.6 Disassembling the Rear Assembly

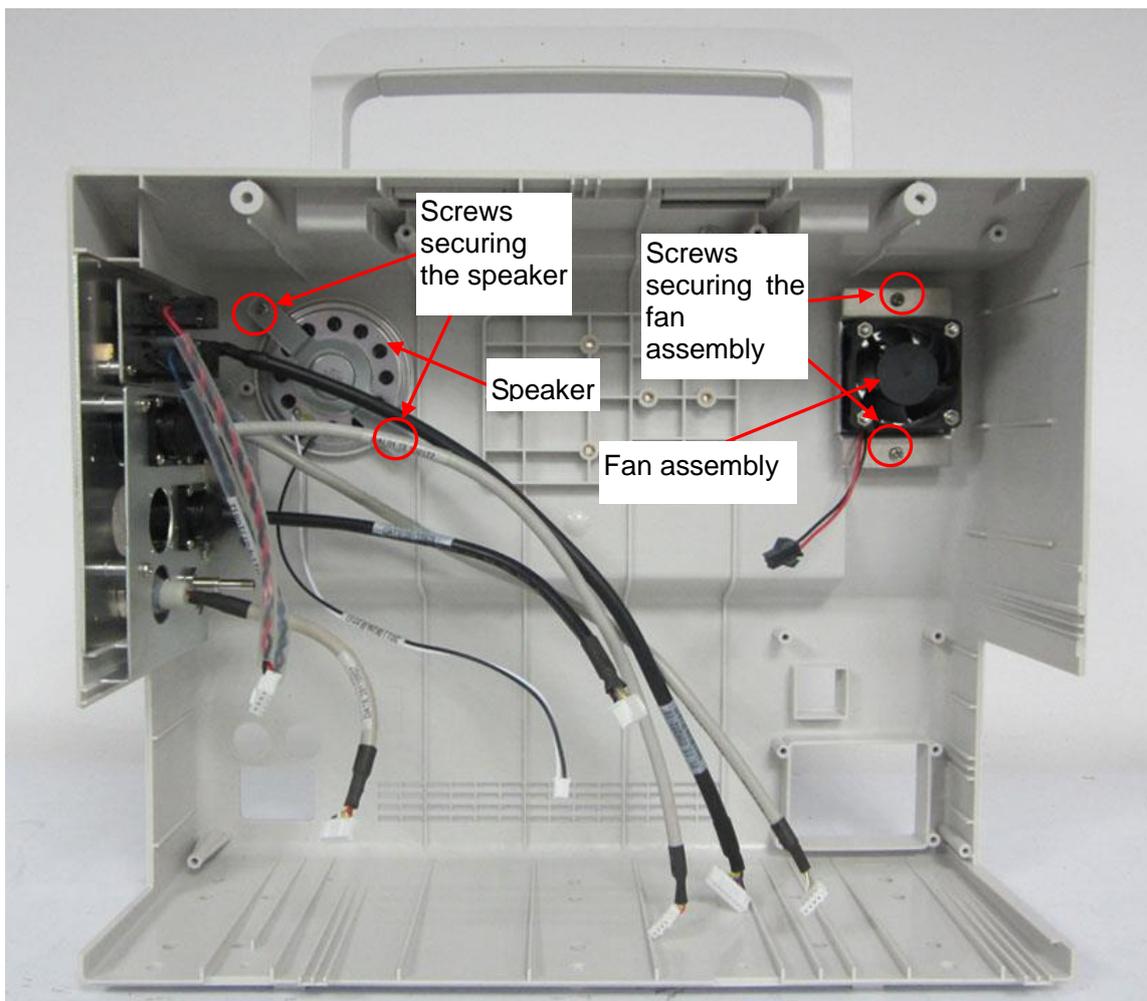
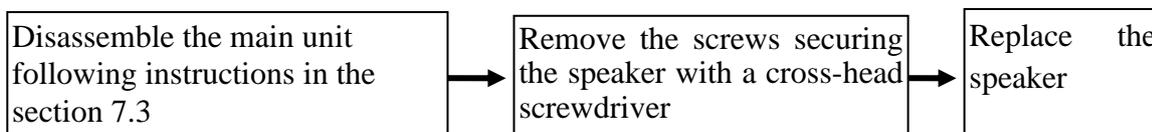


Figure 7-4 Rear Assembly Diagram

7.6.1 Replacing the Speaker

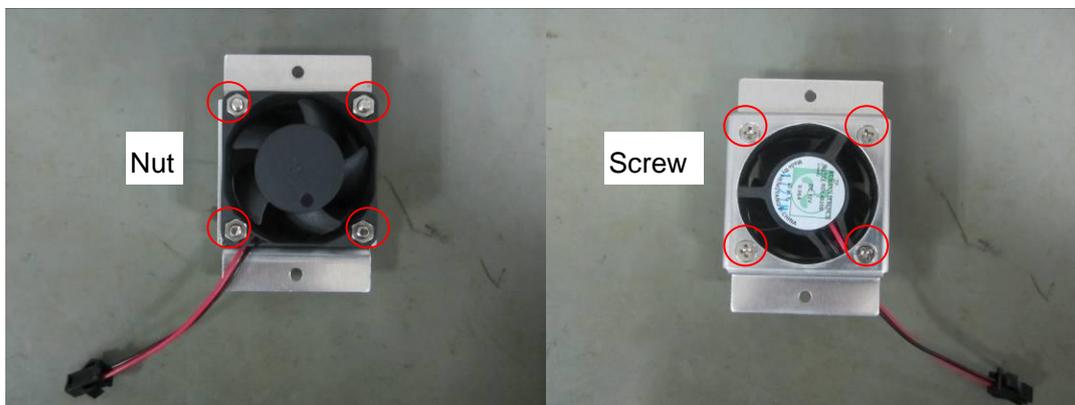


Assemble the speaker in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

7.6.2 Replacing the Fan

NOTE:

If the monitor is not equipped with the fan, please ignore this section.



Disassemble the main unit following instructions in the section 7.3

Remove the screws securing the fan assembly with a cross-head screwdriver

Remove the screws and nuts securing the fan with a cross-head screwdriver

Assemble the fan assembly in the reversed order; connect the wires and assemble the main unit. Refer to 7.3 *Disassembling the Main Unit* for details.

Appendix 1 Renewal Parts

WARNING

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

Parts	Part Number
Lithium-Manganese Button Cell	01.21.064095
X5 Main Board PCBA for iM8&M8 Series	12.03.203080
PS900K Power Board	02.03.112196
PS900K DC Converter Board	02.03.112198
PS900K Power Control Board	12.03.112200
Air valve assembly	01.58.472153
iM8B Support board	02.01.213382
Unicode recorder assembly kit, Serial/parallel port	02.04.241047
Pump	01.58.472008
Speaker	01.14.38007
Fan	01.58.47066
Battery Interface Board	02.02.114507
USB Interface Board	02.02.100516
Ethernet Interface Board	12.02.102042
VGA Board (Smaller)	02.02.451164
12.1-inch LCD	01.16.002468
10.4-inch LCD	01.16.045133
10.1-inch LCD	01.16.045058
M9D Narrow Key Board	02.03.19037
Backlight Board	02.02.102019
Single Light Inverter	12.02.100405
10-inch Wide Screen Drive Board	12.03.102005
Display Drive Board	02.02.102007
M9D Key Board	02.03.19013
IBP-C.O. Module	02.03.33864
CO ₂ sidestream module	02.08.208008
CO ₂ Isolating Power Converter Board	02.02.114575

Trim Knob Board	12.02.16803
Lithium-Ion Battery 2500mAh	01.21.064142
Lithium-Ion Battery 5000mAh	01.21.064143
Fuse	21.21.064172
10.4-inch LCD driver	02.02.451989
Dust-free filter assembly	02.01.214392

NOTE:

The part name may vary depending on context, but the part number is constant.

P/N: 01.54.455514
MPN: 01.54.455514014



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