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文件名称(Document Name)：iM50/M50维修手册_英文_老机型
文件编号(Number)：01.54.455510
版本(Version)：1.4
产品型号(Product Model)：M50;iM50
项目编码(Project Code)：2711I000

签批信息(Signature):

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iM50/M50

Patient Monitor

Version 1.4

Service Manual

CE 0123

EDAN

About this Manual

P/N: 01.54.455510

MPN: 01.54.455510014

Release Date: July, 2017

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) cannot be held liable.

EDAN owns the copyrights of this manual. Without prior written consent of EDAN, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

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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.

Table of Contents

Chapter 1 Warranty and Service 1

Chapter 2 Safety Guidance 4

2.1 Introduction 4

2.2 General Information 4

2.3 Safety Precautions 4

2.4 Explanation of Symbols on the Monitor 6

Chapter 3 Installation 10

3.1 Environment Requirements 10

3.2 Electrical Requirements 10

3.3 Safety Requirements 11

3.4 Installing the Monitor 11

3.5 Connecting to AC Power 12

Chapter 4 Test and Maintenance 13

4.1 Routine Test 13

4.1.1 Visual Inspection 13

4.1.2 Power- on Test 13

4.1.3 Key Test 13

4.1.4 Recording Test 13

4.1.5 Alarm Test 14

4.2 Functional Tests and Accuracy Tests 14

4.2.1 ECG Functional Test 14

4.2.2 SpO_2 Functional Test 15

4.2.3 NIBP Functional Test 15

4.2.4 NIBP Leakage Test 15

4.2.5 NIBP Accuracy Test 16

4.2.6 NIBP Calibration 17

4.2.7 TEMP Accuracy Test 18

4.2.8 CO_2 Functional Test 19

4.2.9 IBP Functional Test 19
4.3 Safety Test 19
4.3.1 Safety Test Procedures 19
4.3.2 Protective Earth Resistance 20
4.3.3 Enclosure Leakage Current 21
4.3.4 Patient Leakage current 22
4.3.5 Patient Leakage Current- Single Fault Condition (S.F.C) Mains on Applied Part . 23
4.4 Maintenance 24
4.4.1 Cleaning the Monitor and Accessories 25
4.4.2 Maintaining the Battery 25
Chapter 5 Configuration 26
5.1 Opening User Maintain Menu 26
5.2 Entering Demo Mode 26
5.3 Selecting Lead Style 26
5.4 Changing the Bed No. 27
5.5 Network Setup 27
Chapter 6 Principle Introduction 28
6.1 System Principle Block Diagram 28
6.1.1 Main Control Board 28
6.1.2 Key Board 30
6.1.3 Screen Drive Board 31
6.1.4 Interface Board 31
6.1.5 Power Module 31
6.2 Interfaces 32
Chapter 7 Troubleshooting 33
7.1 Monitor Booting Failures 33
7.2 Display Failures 34
7.3 Operation Failures 34
7.4 Recorder Failures 35
7.5 Alarm Failures 36

7.6 Parameter Monitoring Failures 37
7.7 Technological Alarms 39
Chapter 8 Disassembling the Monitor 40
8.1 Tools Required 40
8.2 Replacing Fuses 40
8.3 Disassembling the Main Unit 41
8.4 Disassembling the Front Housing Assembly 42
8.4.1 Replacing the Touch Screen or Protective Screen 42
8.4.2 Replacing the LCD 43
8.4.3 Replacing the Silicone Keys 43
8.4.4 Replacing the Key Board 43
8.4.5 Replacing the Knob 43
8.4.6 Replacing the Display Drive Board or Touch Screen Commutator 43
8.4.7 Replacing the Alarm Indicator Board 44
8.5 Disassembling the Main Frame Assembly 44
8.5.1 Replacing the Power Module 45
8.5.2 Replacing the Fan and Speaker 46
8.5.3 Replacing CO_2 Module, IBP Module and Nellcor Module 46
8.5.4 Replacing the Main Board 47
8.5.5 Replacing the Pump&Valve Assembly 47
8.5.6 Replacing the Battery Interface Board 48
8.5.7 Replacing the Main Unit Interface Board 49
8.5.8 Replacing the SD Card Commutator 49
8.5.9 Replacing the Recorder 49
8.5.10 Replacing EDAN EtCO_2 Module 50
Appendix 1 Replaceable Parts 51

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 iM50/M50 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 of doing so might result in damage to the monitor or personal injury.

2.2 General Information

iM50 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, Quick TEMP 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.

WARNING

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. 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. 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

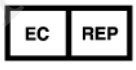
1 The device is designed for continuous operation. Avoid splashing water over the device.

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. 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		MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
5		Equipotential grounding
6		Alternating Current
7		Power Supply switch
8		SERIAL NUMBER
9		Network port
10		USB (Universal Serial Bus) Connection
11		Bell cancel – AUDIO OFF

12		NIBP measurement
13		Trend
14		Picture freeze
15		Graphical recorder
16		Menu
17		Video output
18		Write data into store
19		Defibrillator synchronization/Signal output port
20		Output
21		CE marking
22		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

23		Date of manufacture
24		MANUFACTURER
25	P/N	Part Number
26		General symbol for recovery/recyclable
27		Disposal method
28		Operating instructions
29		Refer to User Manual (Background: Blue; Symbol: White)
30		Warning (Background: Yellow; Symbol & outline: black)
31		Anti-theft lock
32		Gas inlet
33		Gas outlet (evac)

34	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
35	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
36	CLASSIFIED C UL US 3XM9	With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1and CAN/CSA C22.2 No. 601.1, IEC 60601-2-27, IEC 60601-2-30,IEC 60601-2-34, IEC 60601-2-49
37		DO NOT REUSE

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

Working	
Temperature	0 ℃ ~ 40 ℃(32 ℉~104 ℉)
Relative Humidity	15%RH ~ 95%RH (non-condensing)
Atmospheric Pressure	86 kPa ~ 106 kPa
Storage	
Temperature	-20 ℃ ~ 55 ℃(-4 ℉~131℉)
Relative Humidity	15%RH ~ 95%RH (non-condensing)
Atmospheric Pressure	70 kPa ~ 106 kPa

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	100 V-240 V ~
Operating Frequency	50 Hz/60 Hz
Input 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. 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.

iM50 on a Flat Surface

-

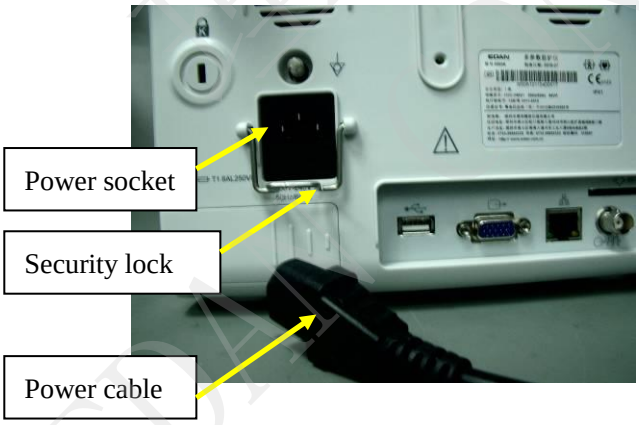
- M50 on a Flat Surface

- 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.



Disconnecting

Connecting

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 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, SpO_2 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=30 bpm.
4. Check the displayed HR value against the simulator configuration. The value should be 30 bpm ±1 bpm or ±1% (whichever is greater).

4.2.2 SpO_2 Functional Test

This test checks the function 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 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; (1mmHg=0.133kPa)
   - Diastolic pressure=195 mmHg;
   - Mean pressure=215 mmHg.

   And then start a NIBP measurement.
4. Check the displayed values against the simulator configuration. A tolerance of ±8 mmHg is reasonable.

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 **User Maintain > NIBP Maintain**.
5. Select **Leakage Test**. Then the prompt **Leak. Test Running** will appear indicating that the system has started the leakage test.
6. 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.
7. If the alarm information **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 leakage test. If the failure prompt still appears, please contact the manufacturer for repair.

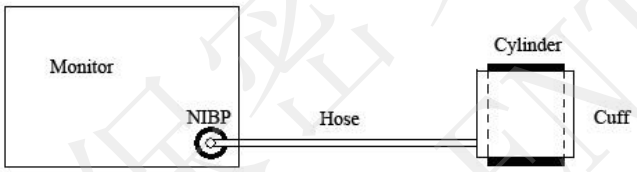


Figure 4-1 Diagram for NIBP Leakage Test

4.2.5 NIBP Accuracy Test

This test checks the performance of the NIBP system.

NOTE:

Manometer test is for checking the measurement accuracy and cannot change the measurement results.

Tools required:

- T-fitting
- NIBP extension tubes
- Cylinder (200 ml)
- Manometer (Its measurement range should be within the range of 0 mmHg to 300 mmHg; its accuracy should be more precise than the accuracy of ±0.3 mmHg.)

Procedure:

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

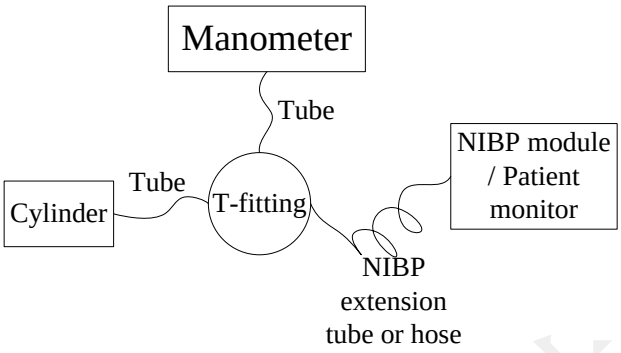


Figure 4-2 Diagram for Manometer Test

3. Select **NIBP Maintain** > **Manometer**.
4. Apply a fixed static pressure on the monitor with the help of the manometer.
5. Wait 10 s until the pressure stabilizes. Check the displayed values on the monitor against the manometer configuration.
6. A tolerance of ±3 mmHg is reasonable.

4.2.6 NIBP Calibration

NOTE:

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

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

Tools required:

- T-fitting
- NIBP extension tubes
- Cylinder (200 ml)
- Manometer (Its measurement range should be within the range of 0 mmHg to 300 mmHg; its accuracy should be more precise than the accuracy of ±0.3 mmHg.)

Procedure:

1. Connect the equipment as shown below:

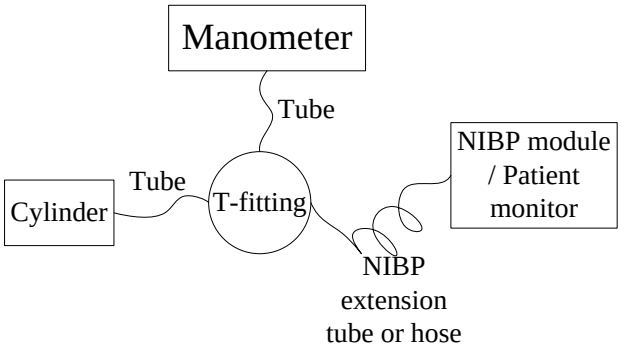


Figure 4-3 Diagram for NIBP Calibration

2. Access **Menu** > **Maintenance** > **Factory Maintain** by inputting the password 998.
3. Select **NIBP Calibration (Xm)** from the menu.
4. Select **Calibrate Initialization** to start calibration.
5. Adjust the manometer value to 50 mmHg (If different values are required for calibration, keep the value of the manometer consistent with the one displayed on the monitor). After the value of the manometer stabilizes, select **Calibrate Low**.
6. Adjust the manometer value to 250 mmHg (If different values are required for calibration, keep the value of the manometer consistent with the one displayed on the monitor). After the value of the manometer stabilizes, select **Calibrate High**.
7. Select **Calibrate Confirm**.
8. Select **Calibrate Protection Unit**.
9. Apply a fixed static pressure on the monitor with the help of the manometer. Check the displayed values on the monitor against the manometer configuration.
10. A tolerance of ±3 mmHg is reasonable.

4.2.7 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 ℃ in the resistance box.
4. The displayed value should be 37 ℃ ±0.1 ℃.

4.2.8 CO_2 Functional Test

This test checks the function 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 (34~40) mmHg.

4.2.9 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
   The tolerances for the measurement value provided by the monitor should be ±4 mmHg or ±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:

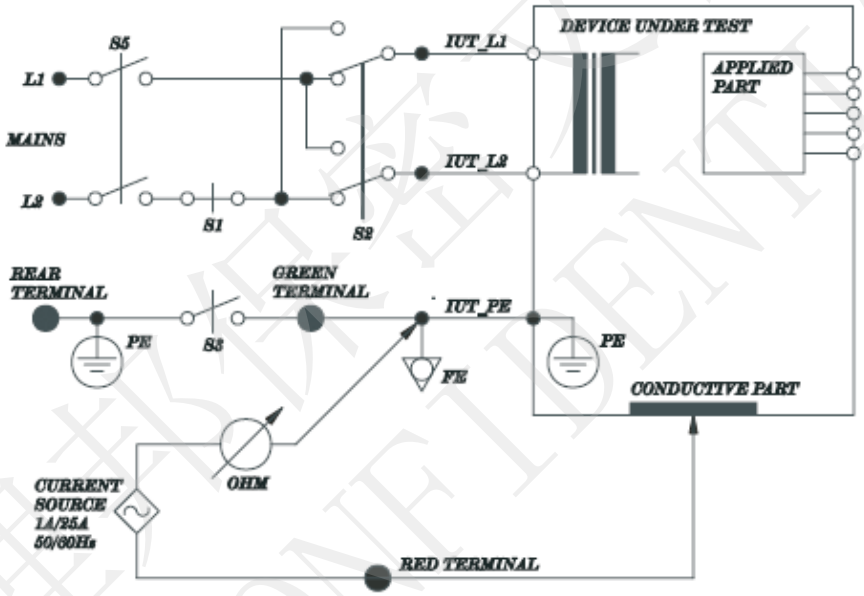
1 When testing according to IEC 60601-1, system must be tested and not individual devices.

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



NOTE:

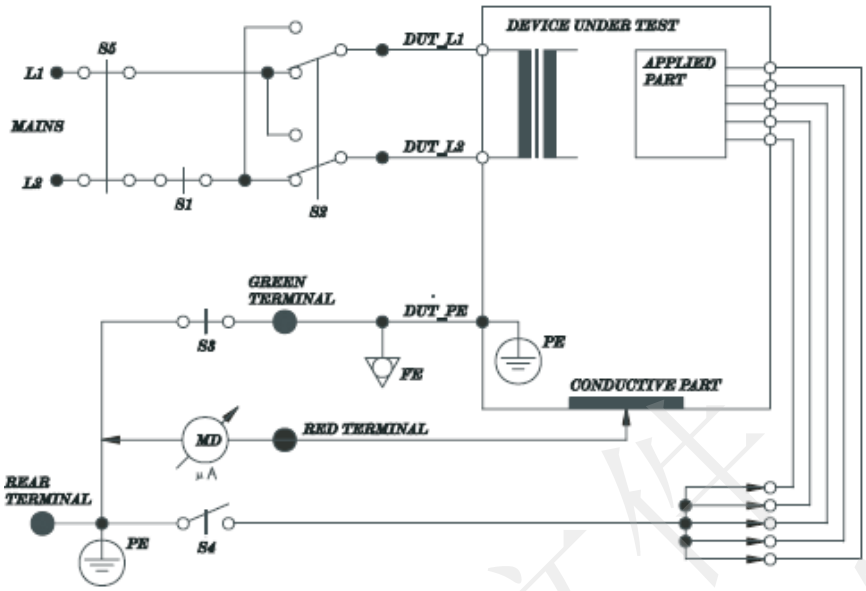
The circuit diagram is based on the Fluke 601Pro series safety analyzer.

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:

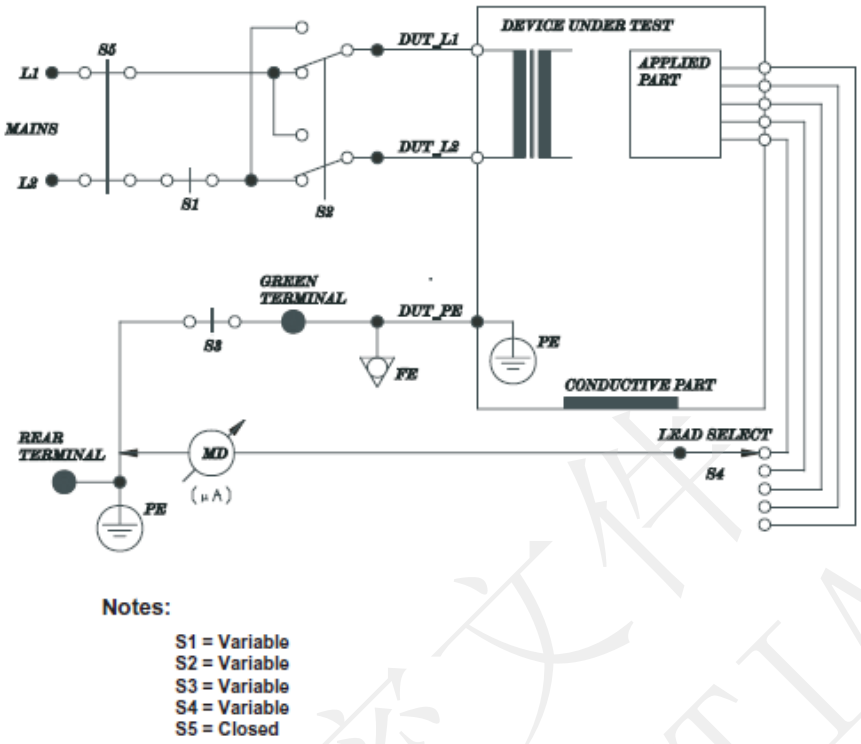
Normal condition: 100 μA (IEC/EN60601-1)

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

Normal condition: 100 μA (UL60601-1)

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

(IEC/EN60601-1, UL60601-1)

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

(IEC/EN60601-1, UL60601-1)

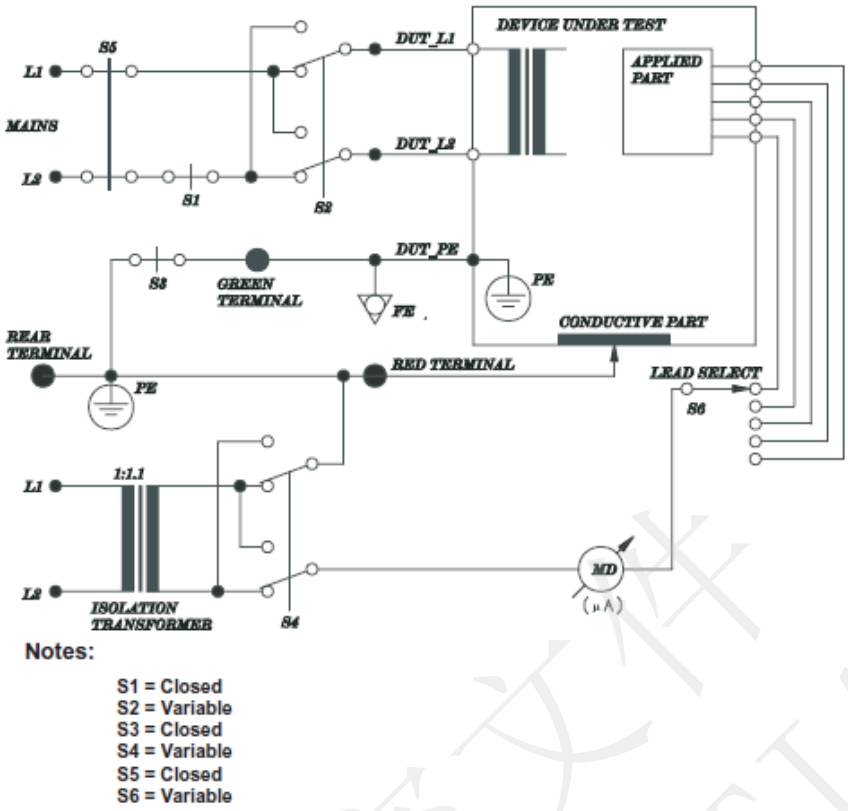
Leakage Current

	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.



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 μA (BF applied part), 50 μA (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 **IEC** 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 Select **Menu** > **Patient Setup** ;

2 Select **Patient Info** > **Bed No.** ;

3 Select a device No. from 1 to 254 as the Bed No..

CAUTION

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

5.5 Network Setup

The monitor is provided with two network connection methods: wired network and wireless network. The IP address in wired network and wireless network can be chosen as static and dynamic, and only if in static, it can be set up. To set the device IP:

1 Select **Menu** > **Maintenance**;

2 Select **User Maintain > Network Maintain**;

3 Set **Network Type** as **Wired** or **Wi-Fi**, access **Config**;

4 Set **Mode** as **Static**, and set the network **IP** as desired.

Chapter 6 Principle Introduction

6.1 System Principle Block Diagram

Here is the system principle block diagram:

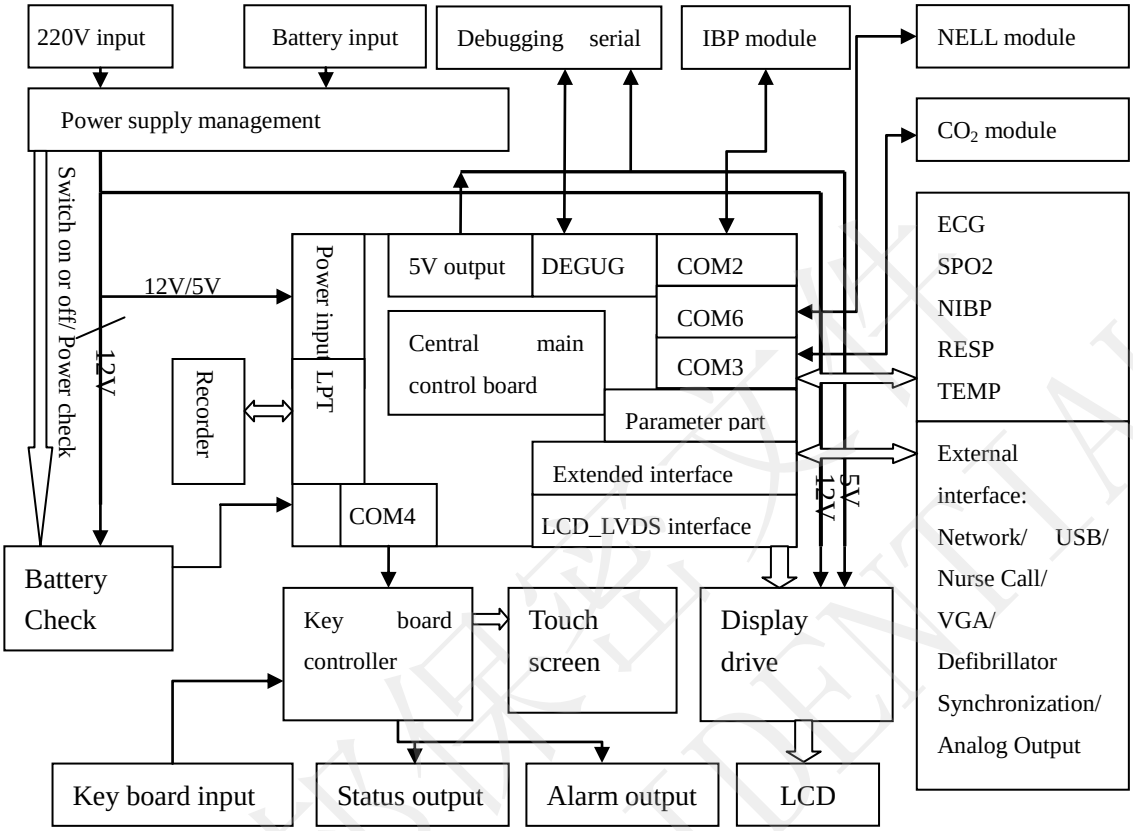


Figure 6-1 iM50/M50 System Principle Block Diagram

6.1.1 Main Control Board

X5V(9G45) main control board is a main control board integrated with multiple parameters. It includes digital part and parameter part. The system principle is shown above.

The system working principle is shown above. The main board contains two CPU; one is the main CPU, the other is the extended CPU. SPI is adopted as the communication mode between the two CPU. With the abundant resources from the unit, the main CPU can realize extension of the main storage system, networking (10M/ 100M self-adaptable) and audio output; additionally, it offers two types of display interface (LVDS and VGA interface). The extended CPU is able to complete the extension of two serial interfaces and one LPT, to collect and control valve signals of NIBP, and to offer sufficient I/O ports which can perform the function of keyboard scanning.

Parameter part applying floating ground technology includes parameters such as ECG, SpO_2, NIBP, RESP and TEMP. This part adopts STM32F103VD to control the front-end analog signals, collect data, simply process the data and deliver it.

ECG

X5V(9G45) supports 3/ 5 leads ECG. In the mode of 3 leads, three electrodes used are RA, LA and LL. 3-lead ECG measurement can be realized by controlling conversion of the drive electrodes.

In the mode of 5 leads, 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 the mode of 3 leads: RA, LA and LL are available, I/ II/ III are optional and the drive lead alter accordingly.

In the mode of 5 leads: 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.

SpO_2

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 SpO_2 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. X5V（9G45） supports I and II lead selection which can switch between each other by the host computer 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 CY and YSI sensor.

IBP

IBP can monitor parameters such as arterial BP, vein BP, and pulmonary arterial BP.

IBP is measured by means of a catheter inserted directly into the circulatory system. A pressure transducer connected to the catheter converts the mechanical force exerted by the blood into an electrical signal, which is displayed graphically as pressure versus time on a monitor screen or numerically on digital display. The monitor measures direct blood pressure of one selected blood vessel through two channels or four channels, and displays waveforms and pressure of measured direct blood pressure (SYS, DIA and MAP).

6.1.2 Key Board

The key board is the indispensable part of the device. At present, free-standing key board is adopted in iM50/M50 Patient Monitor. The key board works with the knob to perform information communication between the user and the device. The module circuit connected with the key board includes the knob, alarm indicator, touch screen and main control board. 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.

Key board hardware diagram is shown below.

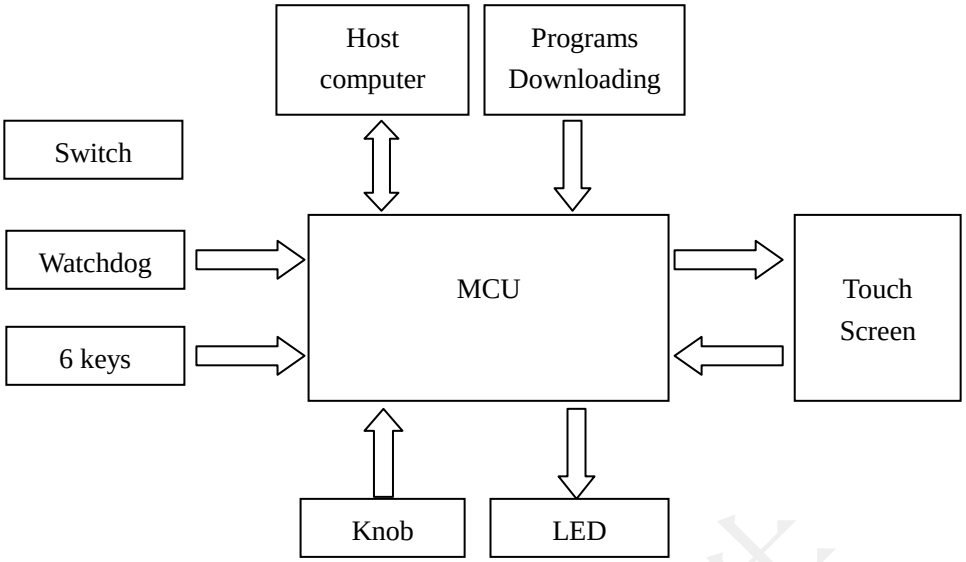


Figure 6-2 Key Board Hardware Block Diagram

6.1.3 Screen Drive Board

The screen drive board of iM50/M50 is to drive display of the 8.4" LCD. Through voltage to current converted circuit, it offers LCD back light with constant current source, and it adjusts LCD luminance. Besides, it converts the LVDS display signal from the main board into the LVTTL signal, and it drives the LCD to display via FPC wires.

6.1.4 Interface Board

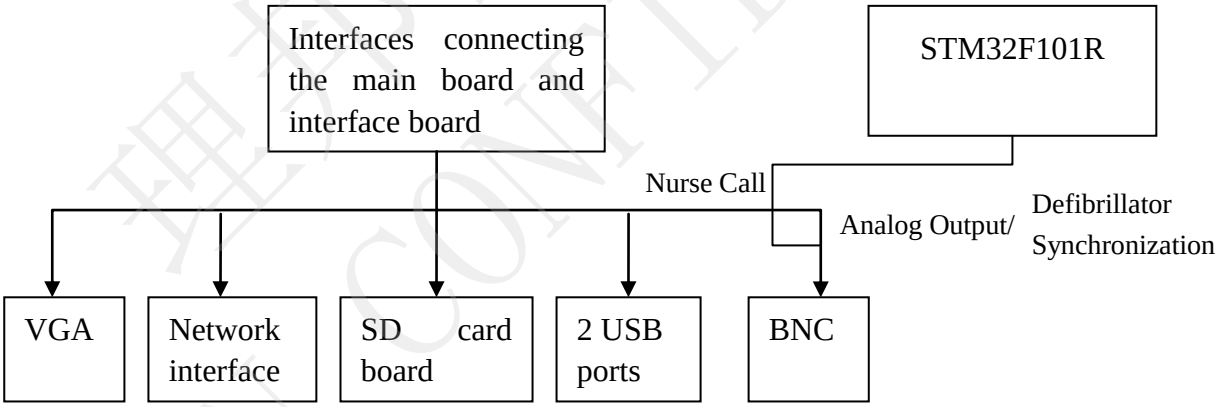


Figure 6-3 Interface Board Diagram

6.1.5 Power Module

The power module is EDAN PS900K. It outputs +12V, +5V voltage and manages 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	

6.2 Interfaces

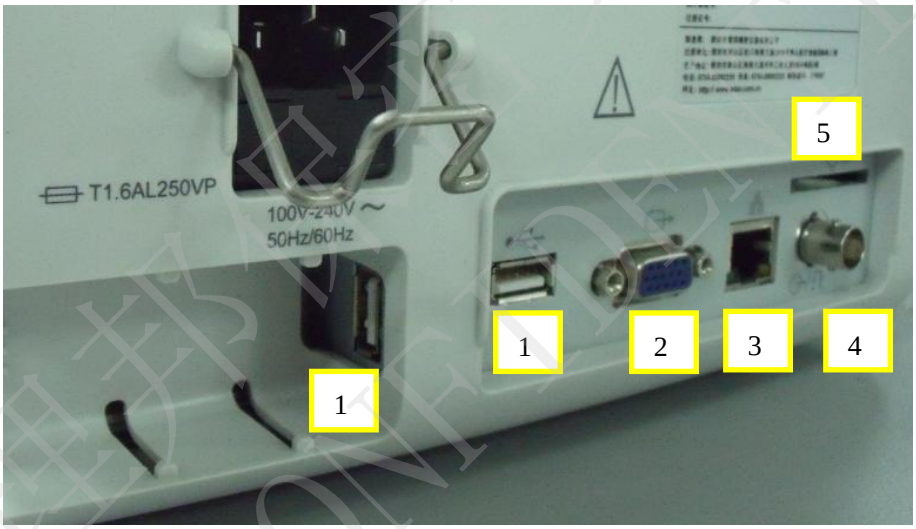


Figure 6-4 Interface Diagram

Interfaces on the rear panel of iM50/M50 include:

1 USB port

2 VGA interface

3 Network / Nurse call interface

4 Analog output/ Defibrillator Synchronization interface

5 SD card interface

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, 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.
	Keyboard failure.	Replace the keyboard.
	Power board failure.	Replace the power board.
	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.	If the monitor is powered by battery and switch off suddenly, maybe the battery is too low.	Please charge the battery and connect AC to the monitor.
	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.
	The power supply button on keyboard failure.	Replace the keyboard.
	Bad connection of power input.	Check the power input.
	Main control board failure.	Replace the main control board

7.2 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 X5V main control board, screen drive board and the screen.
	Display drive board failure.	Replace the display drive board. Refer to the principle diagram and repair the replaced one
	Keyboard failure.	Replace the keyboard.
	Main control board failure.	Replace the main control board. Refer to the principle diagram and repair the replaced one.
Wrong characters are displayed onscreen.	LCD bad connection.	Check the LCD connection to main control board, screen drive board and keyboard.
	Display drive board failure.	Replace the display drive board. Refer to the principle diagram and repair the replaced one.
	LCD failure.	Replace display screen.

7.3 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.
	The edge of the touch screen is pressed.	Check the assembling of the front cover and the touch screen.

Phenomenon	Possible Cause	Solution
It is mute when a key is pressed.	Speaker or wire failure.	Replace the speaker or wire.
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.
Inaction of the touch screen.	The touch screen calibration failure.	Please calibrate touch screen twice.
	The touch screen is disconnected.	Check the connection of the main control board, the touch screen control board and the screen.
	The touch screen is damaged.	Replace the touch screen.
Deflection of the touch positions	The edge of the touch screen is pressed.	Check the assembling of the front cover and the touch screen.
	The touch screen has not been calibrated.	Calibrate the touch screen.

7.4 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 remove the paper. 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.

Phenomenon	Possible Cause	Solution
Alarm is displayed onscreen as “out of paper”, but there is still 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 recording head are not adjusted to balance.	Adjust the screw nuts.
	Recording head failure.	Replace the recording head.

7.5 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.

7.6 Parameter Monitoring Failures

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

Phenomenon	Possible Cause	Solution
NIBP cuff pressure value has no obvious change.	Circuit failure of BP on the main control board.	Replace the main control board.
	NIBP tube leakage.	Please perform leakage test and change the tube or valve.
No NIBP measurement values or no alarm information.	Cuff or extension tube abnormal.	Please replace the cuff or extension tube.
	Circuit failure of BP on the main control board.	Replace the main control board.
No TEMP measurement value.	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	Poor connection of the CO_2 module.	Turn off the monitor and reconnect the CO_2 module.
	The CO_2 module is damaged.	Replace the CO_2 module.
The CO_2 waveform is a beeline	The CO_2 module is in standby mode	Change work mode from standby to measure.
	The sample line is blocked or disconnected	Draw off the sample line, clear it or replace it to another one.
The CO_2 waveform is abnormal, values are incorrect.	Long time no zero calibration, the measured values are incorrect	Enter **Menu > CO_2 Setup**, and perform **Zero Calibration**.

Phenomenon	Possible Cause	Solution
The measured CO_2 values are displayed as "---"	The CO_2 module is in STANDBY mode	Change work mode from standby to measure.
Prompts for CO_2 catheter is blocked on screen	The CO_2 sample line is blocked	Draw off the CO_2 sample line, clear it or replace it to another one.
The CO_2 measured value has error	No zero calibration for a long time; the measured value is incorrect	Enter **Menu > CO_2 Setup**, and perform **Zero Calibration**.
	The compensatory gas and barometric is set incorrectly	Enter **Menu > CO_2 Setup > Other Setup**, and set the **Baro Press** and **O_2 Compens** items in menu for compensatory gas and barometric 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 PCB 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.

7.7 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

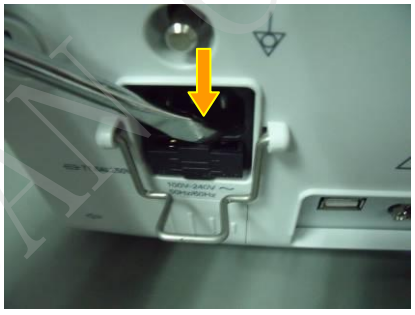
3 – A M3 nut driver

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 to 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: T3.15AH 250VP)

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.

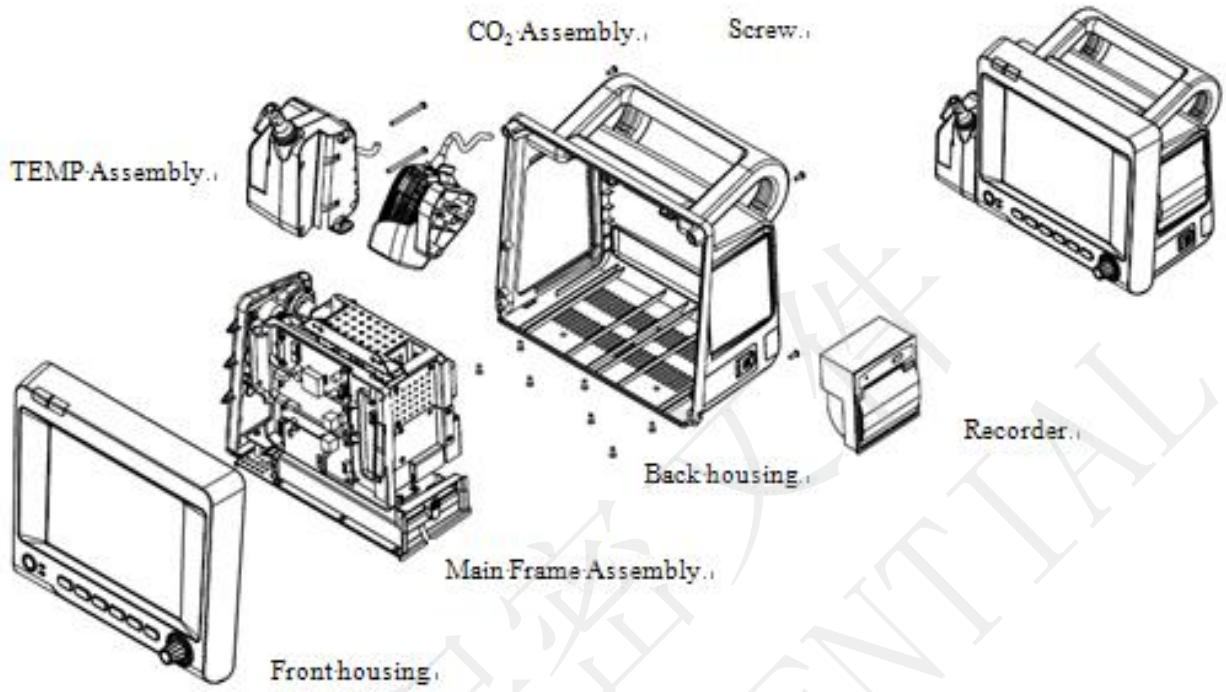


Figure 8-1 Main Unit Structure Block Diagram

To disassemble the main unit:

1 Disassemble the recorder, CO_2 assembly and temperature assembly from the main unit with a screwdriver.

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

3 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

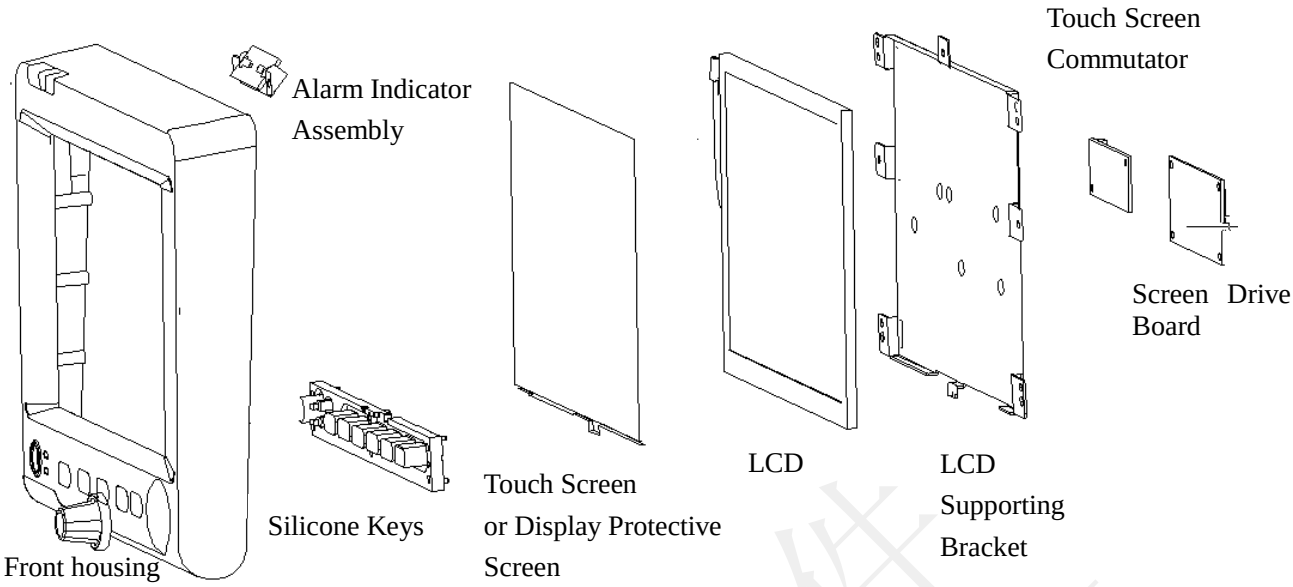
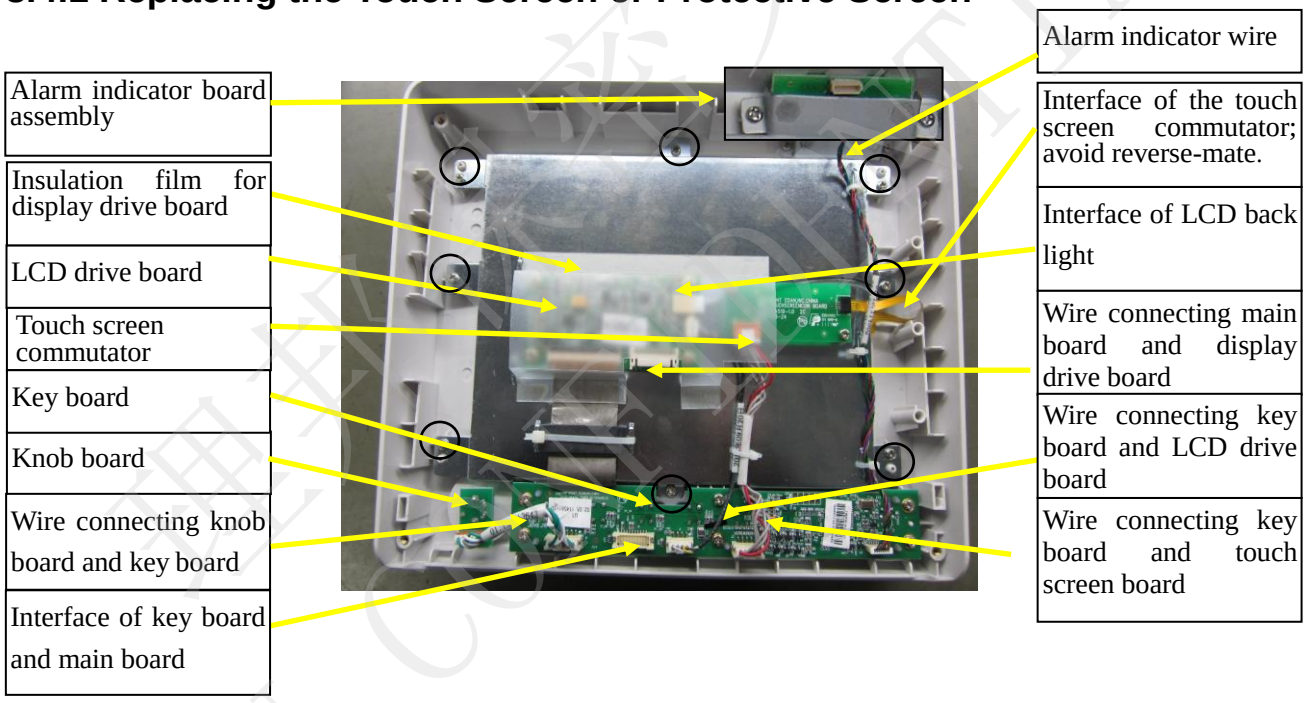


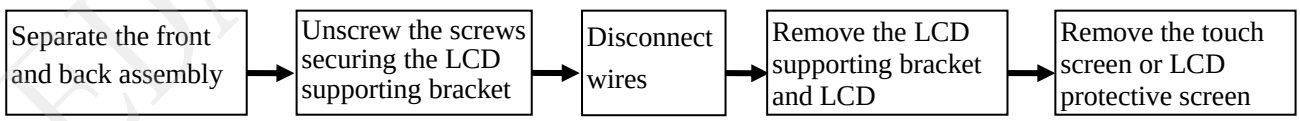
Figure 8-2 Front Shell Structure Block Diagram

8.4.1 Replacing the Touch Screen or Protective Screen



NOTE: Gently pull out the security lock and do not overexert.

Figure 8-3 Replacing touch screen or protective screen

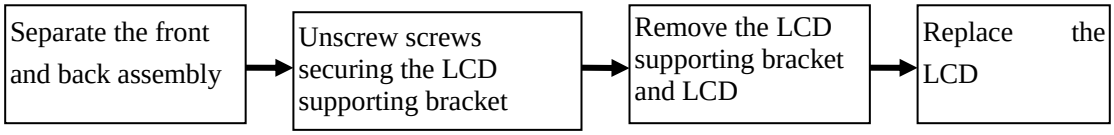


Assemble the touch screen or protective screen in the reversed order. Check whether the sponge around the LCD is damaged. If so, please replace a new one.

NOTE:

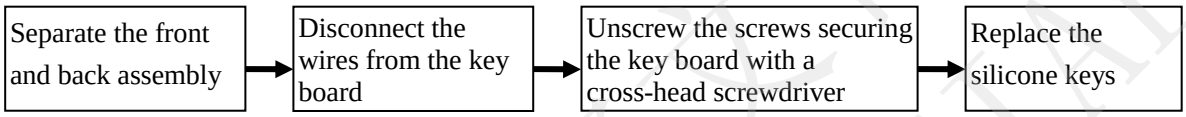
The user can only choose one from the touch screen and protective screen to assemble in the main unit.

8.4.2 Replacing the LCD



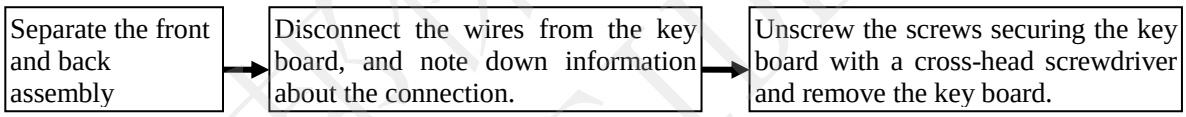
Assemble the LCD in the reversed order. Please refer to the diagram on the section 8.4.1.

8.4.3 Replacing the Silicone Keys



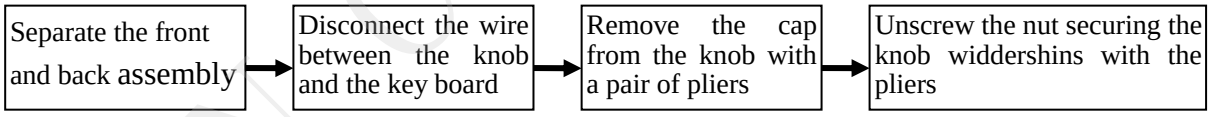
Assemble the silicone keys in the reversed order, and connect the wire of the key board. Please refer to the figure in the section 8.4.1 for more information.

8.4.4 Replacing the Key Board



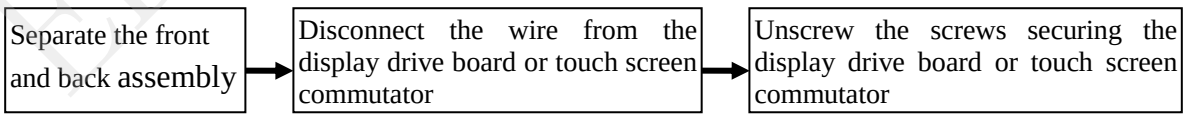
Assemble the key board in the reversed order. Please refer to the figure in the section 8.4.1 for more information.

8.4.5 Replacing the Knob



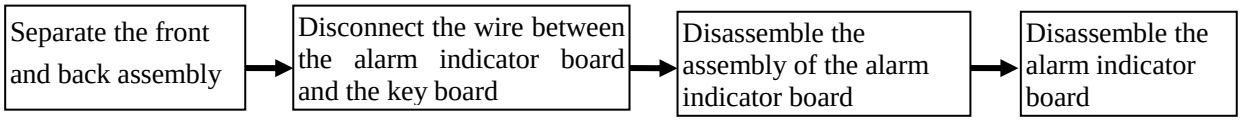
Please refer to the figure in the section 8.4.1 for more information.

8.4.6 Replacing the Display Drive Board or Touch Screen Commutator



Assemble the display drive board or the touch screen commutator in the reversed order. Please refer to the figure in the section 8.4.1 for more information.

8.4.7 Replacing the Alarm Indicator Board



Assemble the alarm indicator board in the reversed order. Please refer to the figure in the section 8.4.1 for more information.

8.5 Disassembling the Main Frame Assembly

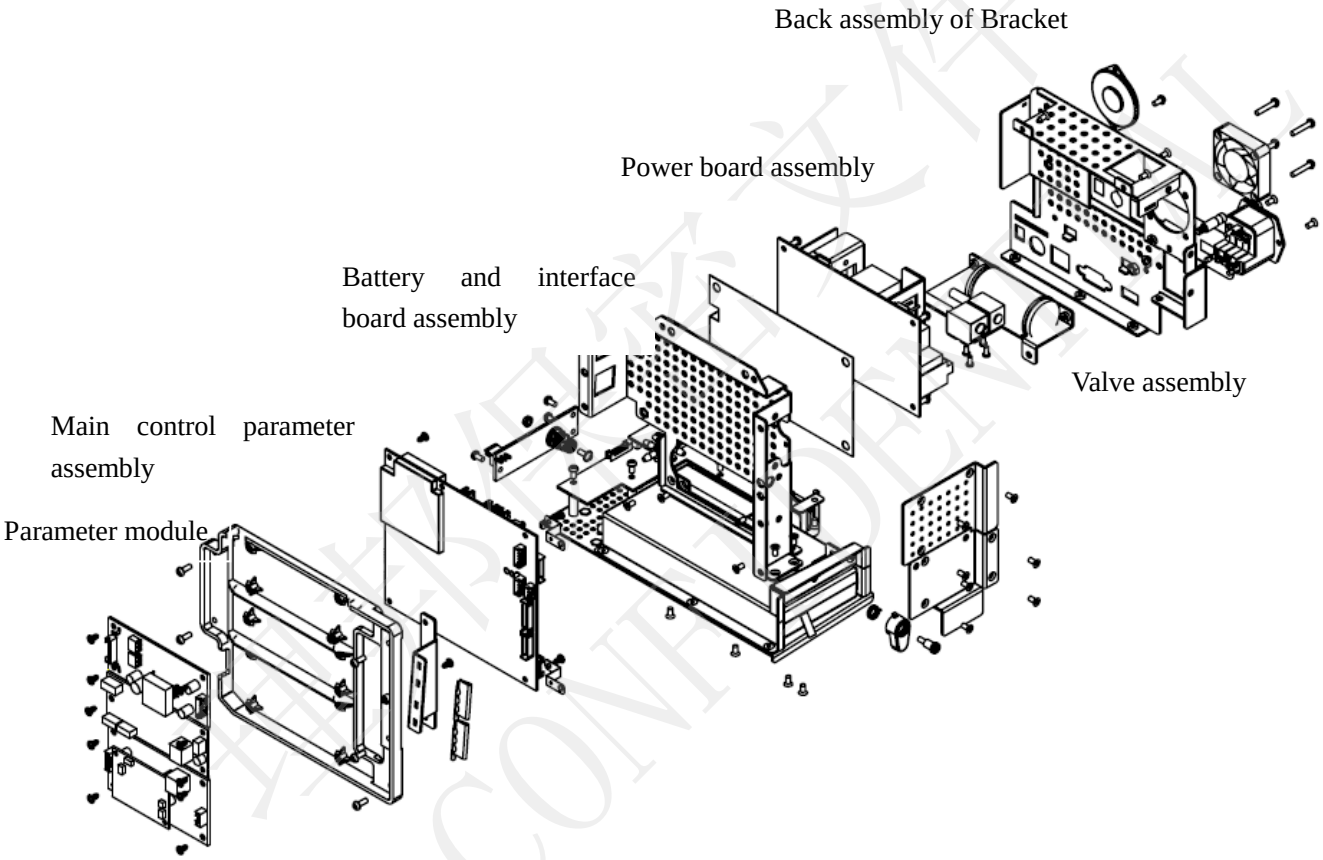


Figure 8-4 Main Frame Assembly

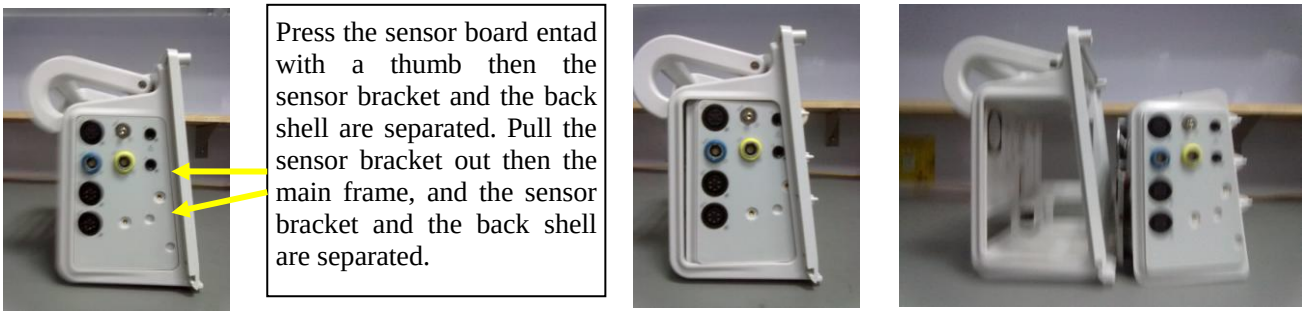


Figure 8-5 Sensor Board Removal

Separate the front and back assembly → Unscrew the screws securing the main frame insides the main unit → Press the sensor board to separate the main frame and the sensor bracket assembly and remove them

NOTE:

During disassembling the monitor, please note down the information about all connections of the wires and the interfaces.

8.5.1 Replacing the Power Module

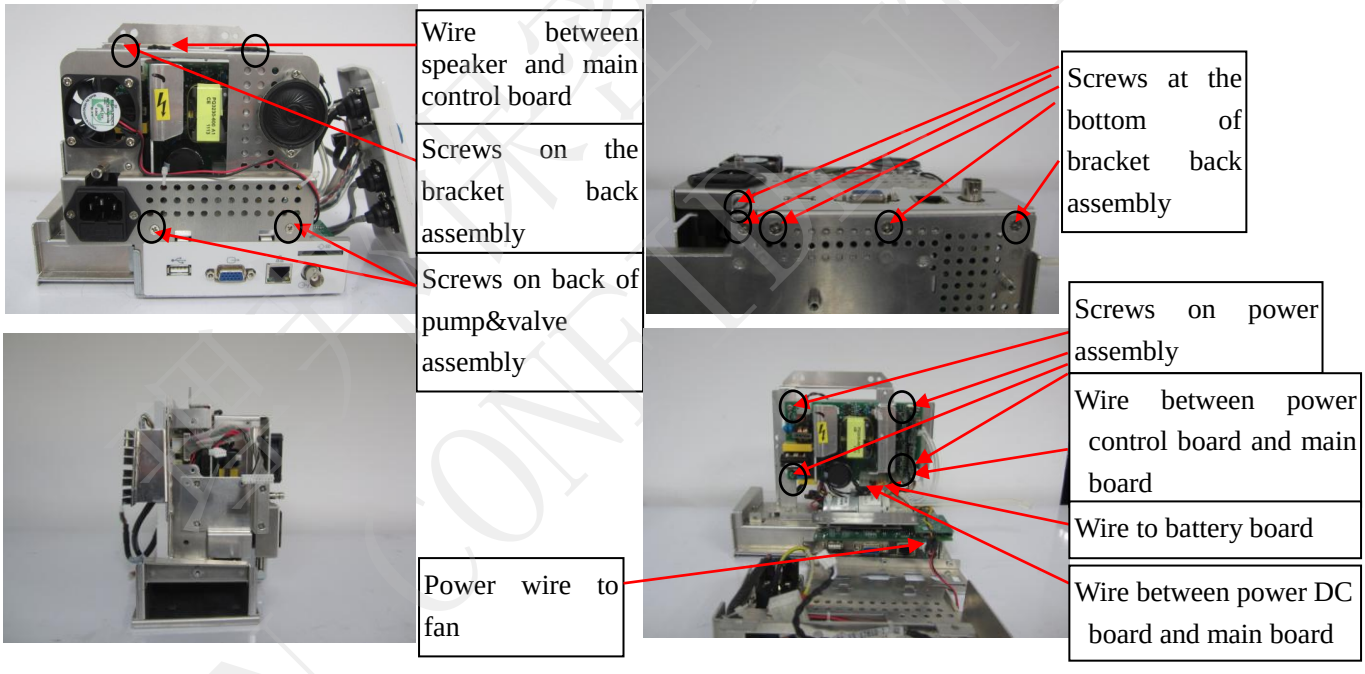


Figure 8-6 Replacing Power Module

Separate the front and back assembly → Separate the main frame and back assembly → Remove bracket back assembly → Disconnect wire from power module → Replace power module

Assemble the power module in the revered order.

8.5.2 Replacing the Fan and Speaker

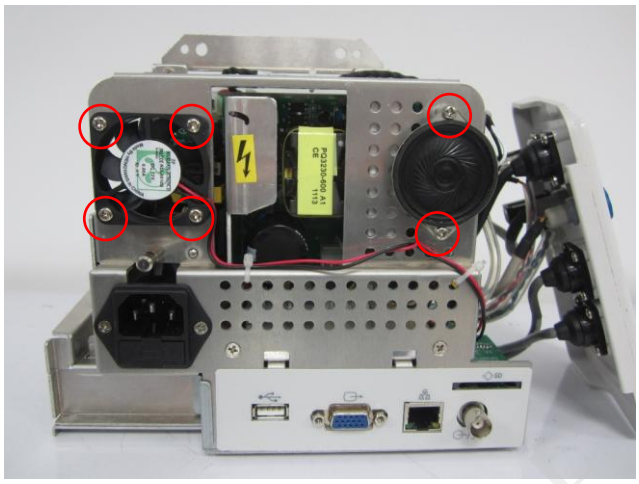
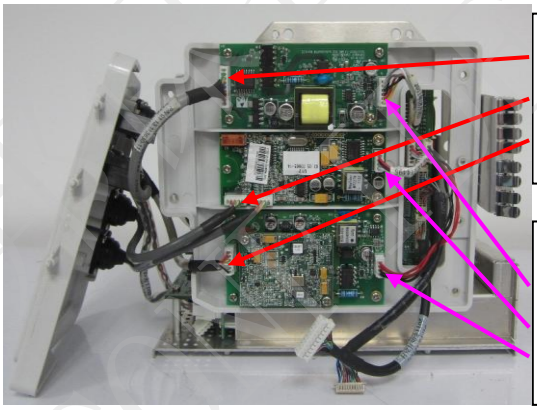


Figure 8-7 Replacing the Fan and the Speaker

Separate the front and back assembly → Separate the main frame and back assembly → Cut the strap → Replace the fan and speaker

Assemble the fan and speaker in the revered order.

8.5.3 Replacing CO_2 Module, IBP Module and Nellcor Module



From top to bottom, wires between sensor board and CO_2 module, sensor board and IBP module, sensor board and Nellcor module

From top to bottom, wires between main board and CO_2 module，main board and IBP module, main board and Nellcor module.

Figure 8-8 Replacing CO_2 Module, IBP Module and Nellcor Module

Separate the front and back assembly → Disconnect wire from CO_2 module, IBP module and Nellcor module → Replace CO_2 module, IBP module and Nellcor module

Assemble the CO_2 module, IBP module and Nellcor module in the reversed order.

8.5.4 Replacing the Main Board

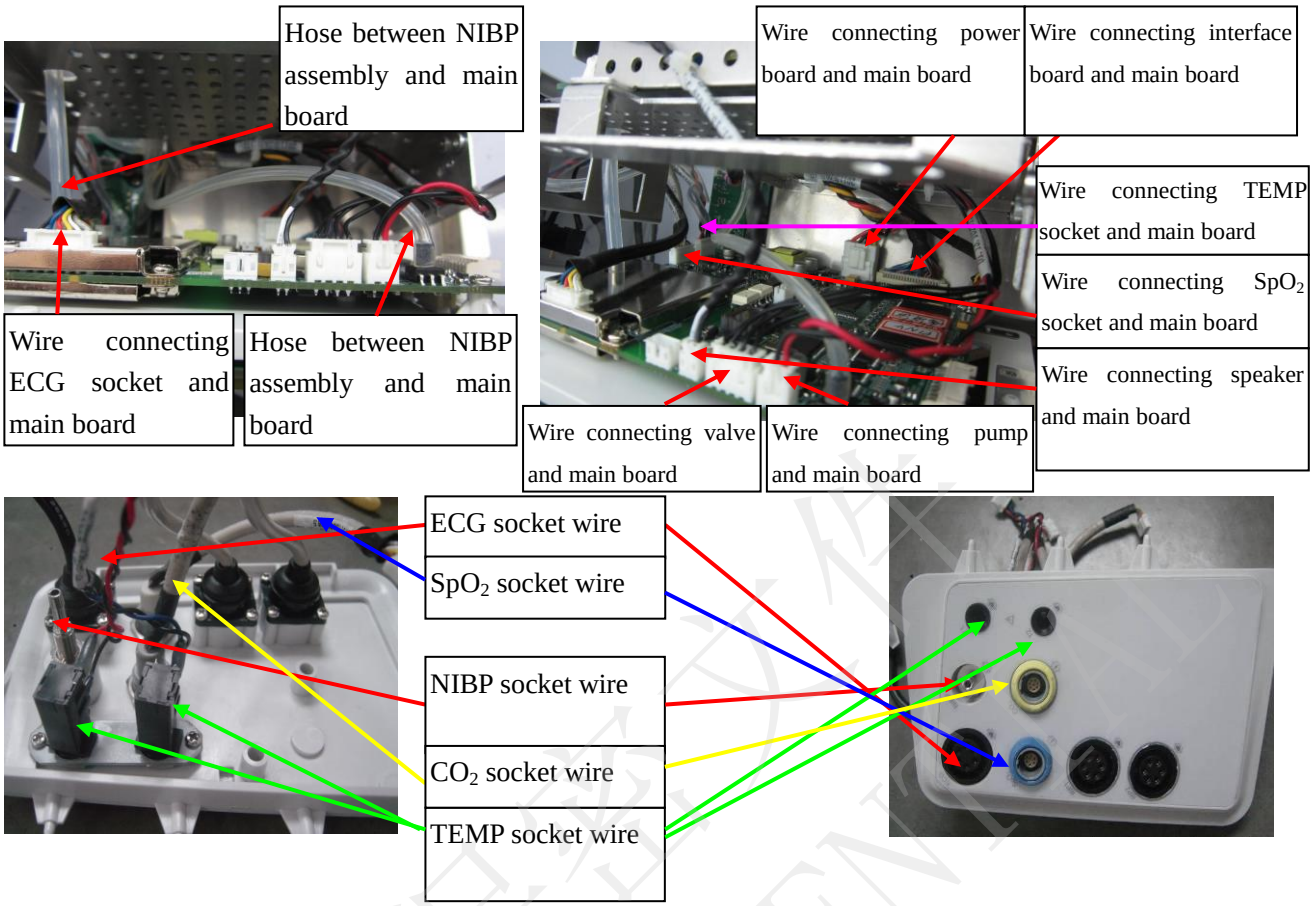


Figure 8-9 Replacing Main Board

Separate front and back assembly → Separate the main frame and the back assembly → Disconnect wire from main board → Remove main board → Replace main board

Assemble the main board in the reversed order.

8.5.5 Replacing the Pump&Valve Assembly

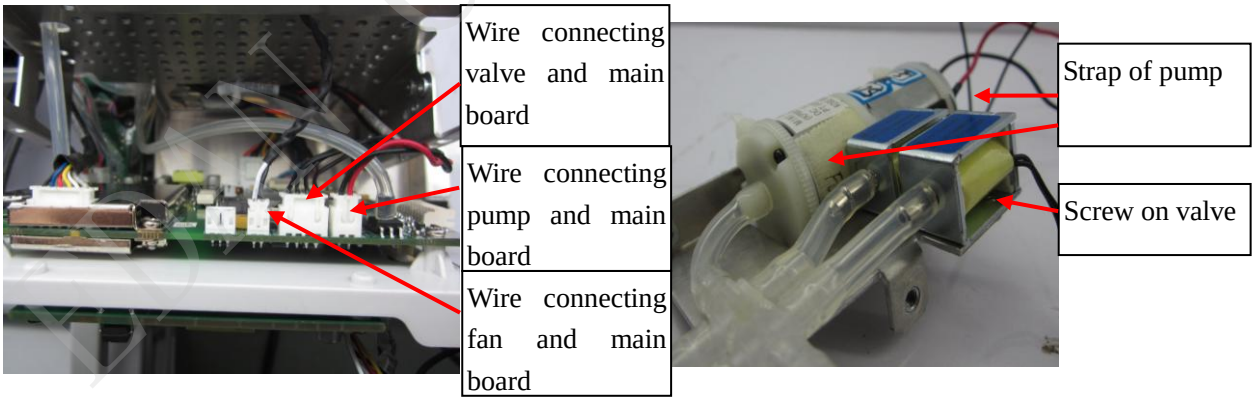
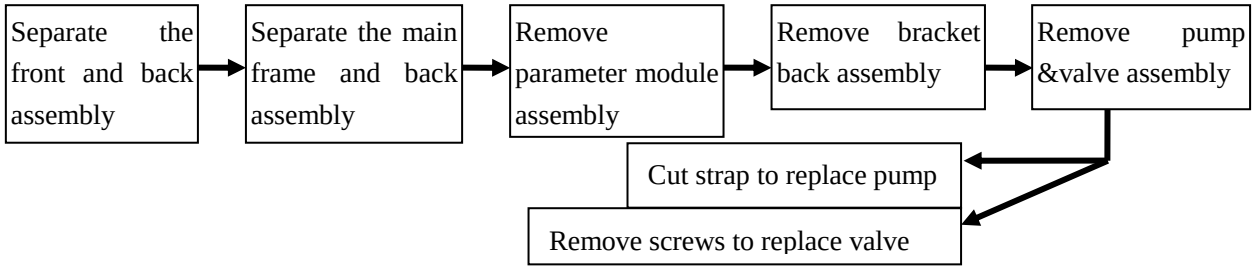


Figure 8-10 Replacing Pump&Valve



Assemble the pump&valve in the reversed order.

8.5.6 Replacing the Battery Interface Board

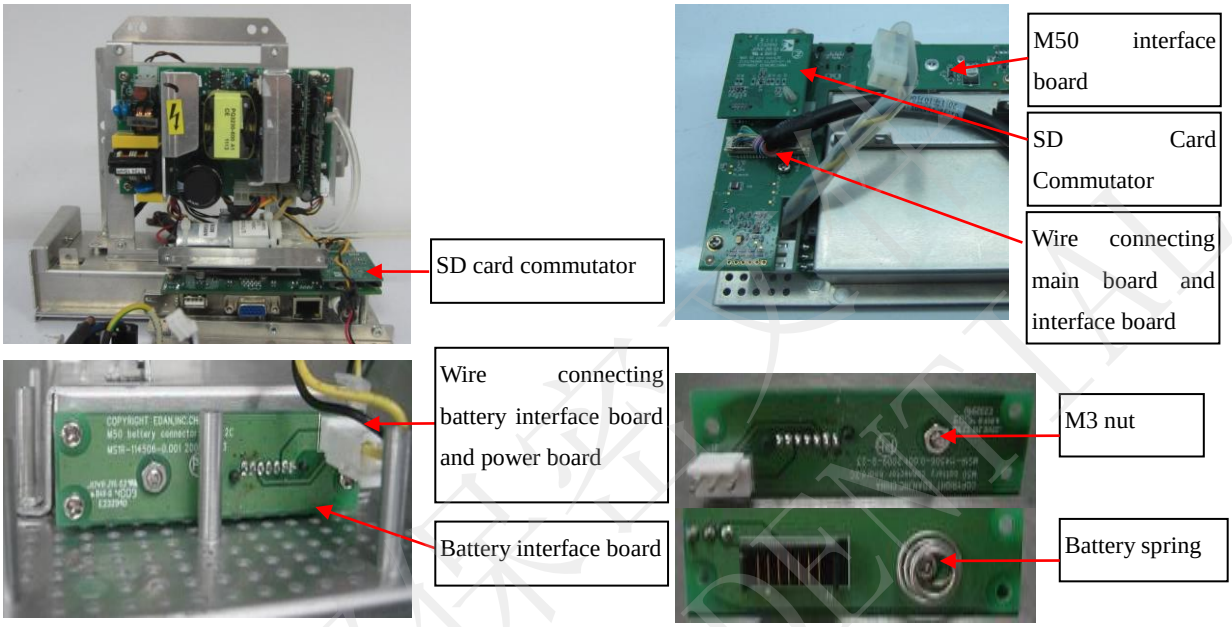
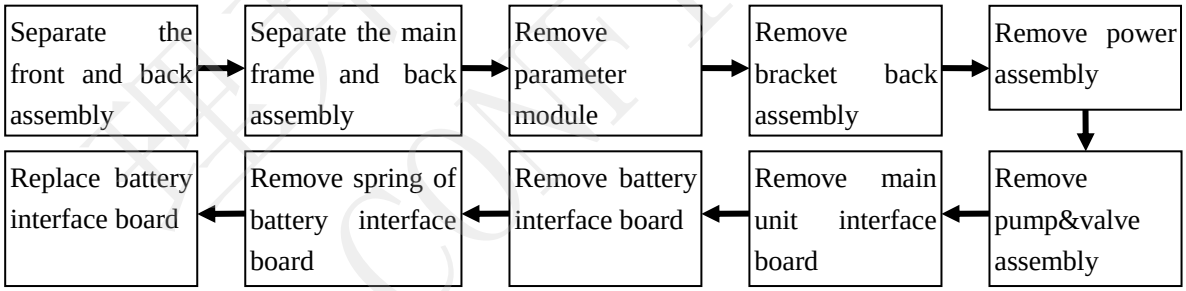
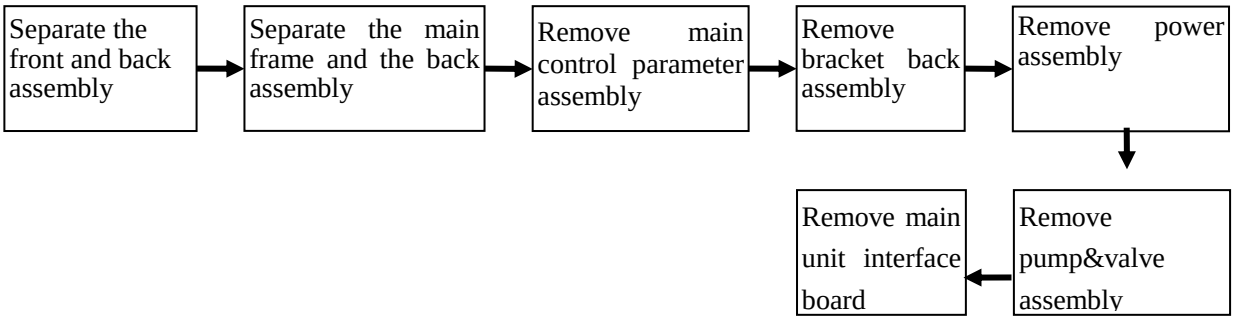


Figure 8-11 Replacing Battery Interface Board



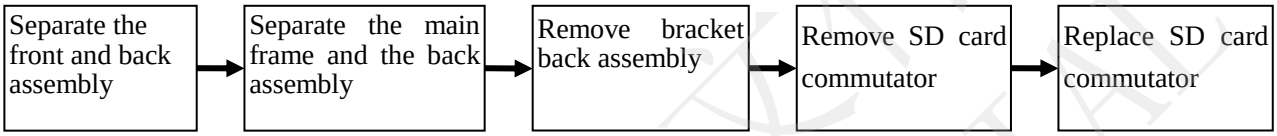
Assemble the battery interface board in the reversed order.

8.5.7 Replacing the Main Unit Interface Board



For detailed information, please refer to section 8.5.5.

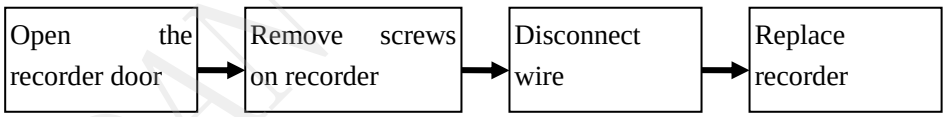
8.5.8 Replacing the SD Card Commutator



Assemble the SD card commutator in the reversed order. For detailed information, please refer to section 8.5.5.

8.5.9 Replacing the Recorder

Figure 8-12 Replacing Recorder



Assemble the SD card commutator in the reversed order.

8.5.10 Replacing EDAN $EtCO_2$ Module

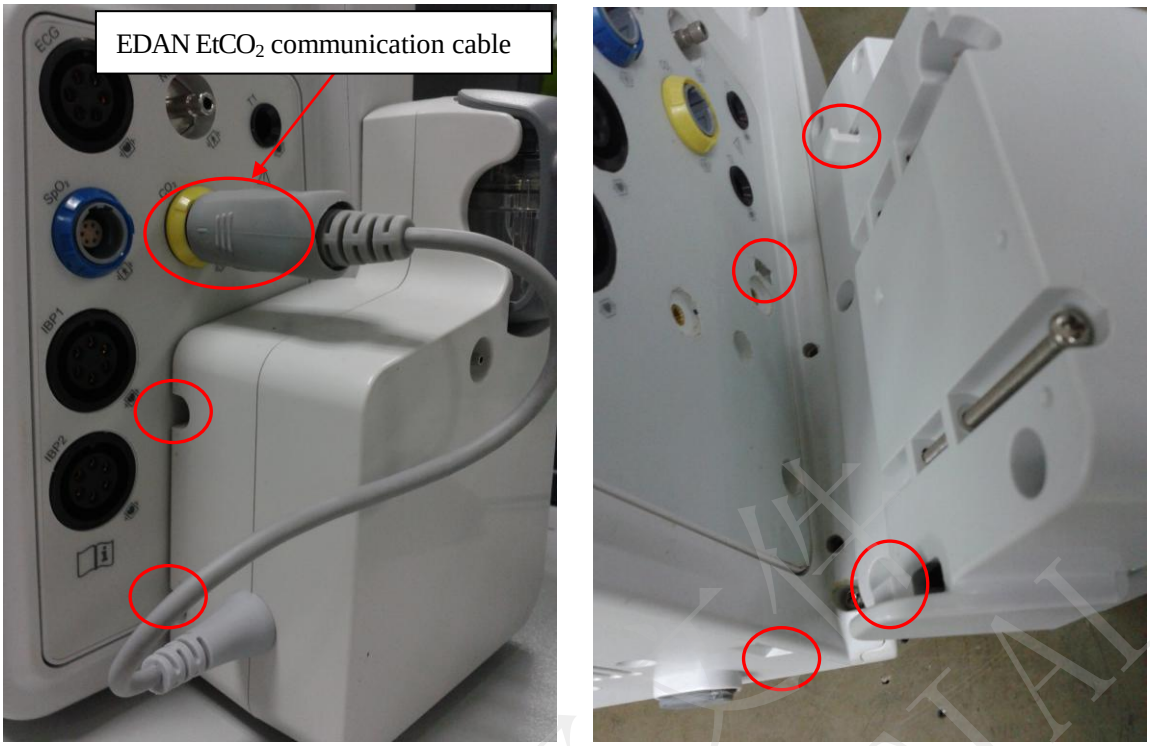


Figure 8-13 Replacing EDAN $EtCO_2$ Module

Disconnect the EDAN $EtCO_2$ communication cable → Remove screws on EDAN $EtCO_2$ module → Remove EDAN $EtCO_2$ module → Replace EDAN $EtCO_2$ module

Assemble the EDAN $EtCO_2$ module in the reversed order.

Appendix 1 Replaceable Parts

WARNING

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

Section	Parts	Part Number
8.4.1	Touch Screen	01.16.78122
	LCD Protective Screen	01.51.114533
8.4.2	LCD	01.16.045102
8.4.3	Silicone Keys	01.60.410174
8.4.4	Key Board	02.03.114455
8.4.5	Knob Board	02.02.16803
8.4.6	Display Drive Board	02.03.451757
	Touch Screen Commutator	02.02.114511
8.4.7	Alarm Indicator Board	02.02.114461
8.5.1	Power Module Assembly	02.01.112205
8.5.2	Speaker	01.14.038010
	Fan	21.58.472030
8.5.3	CO_2 Commutator	02.02.114575
	IBP-CO module	12.03.33864
8.5.4	X5V (9G45) Main Board	02.03.451245
8.5.5	Pump	01.58.472008
	Measurement Valve	01.58.472009
	Safety Valve	01.58.472010
8.5.6	Battery Interface Board	02.02.114507
8.5.7	Interface Board	02.03.451449
8.5.8	SD Card Commutator	02.02.114509
8.5.9	Recorder	02.01.210633
8.5.10	EDAN $EtCO_2$ Module Assembly	02.01.211360
Others	Lithium-Ion Battery	01.21.064142
	Lithium-Manganese Button Cell	01.21.064095

NOTE:

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

P/N: 01.54.455510
MPN: 01.54.455510014

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