## **EDAN Agile PLM Electronic Signature Information**

--Signatures related to this document and performed in EDAN Agile PLM.

文件名称(Document Name): iM3 维修手册\_英文

文件编号(Number): 01.54.457834

版本(Version): 1.1

产品型号(Product Model): iM3

项目编码(Project Code): 00004I002

## 签批信息(Signature):

作者(Originator): 陈艳娟 (chenyanjuan) 2018-02-07 10:15:49

审核人(Reviewers):程亮(chengliang) 2018-02-07 11:33:42

审核人(Reviewers): 史 洪华 (shihonghua) 2018-02-07 11:28:34

审核人(Reviewers): 韦 华彪 (weihuabiao) 2018-02-07 15:36:37

审核人(Reviewers): 陈 良款 (chenliangkuan) 2018-02-07 14:08:44

批准人(Approvers): 夏 欢欢 (xiahuanhuan) 2018-02-24 13:16:16

批准人(Approvers): 陈 浩杰 (chenhaojie) 2018-02-23 15:21:15

版权©深圳市理邦精密仪器股份有限公司 (Copyright©Edan Instrument,Inc.)

# iM3 Vital Signs Monitor Version 1.1

# Service Manual





## **About this Manual**

P/N: 01.54.457834

MPN: 01.54.457834011

Release Date: February 2018

© Copyright EDAN INSTRUMENTS, INC. 2017-2018. All rights reserved.

## **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.

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.

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

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

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

## Responsibility of the Manufacturer

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

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

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

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

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.

I

## **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	8
3.1 Environment Requirements	8
3.2 Electrical Requirements	
3.3 Safety Requirements	9
3.4 Installing the Monitor	9
3.5 Connecting to AC Power Supply	. 10
Chapter 4 Test and Maintenance	
4.1 Routine Test	. 11
4.1.1 Visual Inspection	. 11
4.1.2 Power- on Test	. 11
4.1.3 Key Test	. 11
4.1.4 Checking Touch Screen	. 11
4.1.5 Checking Internal Barcode Scanner	. 11
4.1.6 Recording Test	. 12
4.1.7 Alarm Test	. 12
4.2 Functional Tests and Accuracy Tests	. 12
4.2.1 SpO <sub>2</sub> Functional Test	. 12
4.2.2 NIBP Functional Test	. 13
4.2.3 NIBP Leakage Test	. 13
4.2.4 NIBP Calibration	. 14
4.2.5 NIBP Accuracy Test	. 15
4.2.6 TEMP Functional Test	. 16
4.3 Safety Test	. 17
4.3.1 Safety Test Procedures	. 17
4.3.2 Protective Earth Resistance	. 18
4.3.3 Enclosure Leakage Current	. 19
4.3.4 Patient Leakage current	. 20
4.3.5 Patient Leakage Current- Single Fault Condition (S.F.C) Mains on Applied Part	21
4.4 Maintenance	. 22
4.4.1 Maintenance of the Monitor	. 23
4.4.2 Maintenance of the Sensor	. 23
4.4.3 Maintenance of the Battery	. 23
4.4.4 Maintenance of the Recorder	
Chapter 5 System Configuration	. 24
5.1 Enter Factory Maintain	. 24
5.2 Enter Demo Mode	. 24
5.3 Default Configuration	. 25

5.4 Network Setup	25
5.5 Configure the System Time	25
Chapter 6 Principle Introduction	26
6.1 System Principle Block Diagram	26
6.1.1 Main Control Board	26
6.1.2 Parameter Board	27
6.1.3 Battery Module	27
6.2 Interface	28
Chapter 7 Troubleshooting	
7.1 Machine Failures	29
7.2 Display Failures	30
7.3 Operation Failures	31
7.4 Recorder Failures	32
7.5 Network Failures	33
7.6 Power Board Failures	33
7.7 Alarm Failures	34
7.8 Parameter Failures	34
Chapter 8 Disassembling the Monitor	36
8.1 Tools Required	36
8.2 Disassembling the Main Unit	36
8.3 Disassembling the Front Housing Assembly	40
8.3.1 Replacing the Touch Screen or Protective Screen	41
8.3.2 Replacing the LCD	42
8.3.3 Replacing the Main Control Board	43
8.3.4 Replacing the Wi-Fi Interface Board	44
8.3.5 Replacing the Alarm Indicator Board	44
8.3.6 Replacing the Rotary Knob	45
8.4 Disassembling the Rear Housing Assembly	45
8.4.1 Replacing the Power Module	45
8.4.2 Replacing SunTech Module	46
8.5 Disassembling the Middle Frame Assembly	47
8.5.1 Replacing the Pump/Valve Assembly	47
8.5.2 Replacing the Battery Interface Board	48
8.5.3 Replacing the Network Interface Board	49
8.5.4 Replacing Parameter Board	49
8.5.5 Replacing Sensor Board of Main Unit	51
8.6 Disassembling the Plug-in Module	
8.6.1 Replacing iM3 T2A Isolation Board/T2A Main Control Board	54
8.6.2 Replacing Quick TEMP Module/M3 Covidien TEMP Module Con	nmunication
Isolation Board	
8.6.3 Replacing the Isolation Board of M3 Infrared Ear TEMP	
8.6.4 Replacing the Recorder	
8.6.5 Replacing the Sensor Board of Recorder	
8.6.6 Replacing the Adapter Board of Recorder	
Chanter 9 Renlaceable Parts	62.

## **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.

#### NOTE:

- 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 iM3 monitor. It provides troubleshooting information, assembly procedures, instructions for functional testing and performance verification. It is intended for use only by technically qualified service personnel.

#### **WARNING**

When performing a service procedure, follow the instructions exactly as presented in this manual. Failure of doing so might damage the monitor, invalidate the product warranty or lead to serious personal injury.

#### 2.2 General Information

The iM3 Vital Signs 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	SpO <sub>2</sub> , NIBP, TEMP: BF
Ingress Protection	IPX1
	With T2A, TH or F3000 TEMP module: Ordinary equipment (Sealed equipment without liquid proof)
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 the possibility of injury, 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.

#### **WARNING**

- 3 The service personnel must be familiar with the operation of this monitor. Refer to *iM3 Vital Signs 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 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 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 6060-1. If you have any question, please consult our technical service department or your local distributor.
- 9 Do not directly solder the lead wire and the battery terminal.
- 10 The safe loads of the wall mounting bracket and the trolley are 7.5 kg and 11 kg respectively. Exceeding the safe load may cause bracket to fail and the device to fall.

#### **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	-  <b>*</b>	DEFIBRILLATION-PROOF TYPE BF APPLIED PART	
2	፟	TYPE BF APPLIED PART	
3	<u> </u>	Caution	
4	NR N	MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment	
5	$\Diamond$	Equipotential grounding	
6	<b>Ò∕</b> ⊙	Power Supply switch	
7	SN	SERIAL NUMBER	
8	뭚	Network port	
9	•	USB (Universal Serial Bus) Connection	
10	<b>C €</b> <sub>0123</sub>	CE marking	
11	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	
12		Date of manufacture	
13	**	MANUFACTURER	
14	P/N	Part Number	
15		General symbol for recovery/recyclable	

16		Disposal method
17	[]i	Operating instructions
18	<b>(3)</b>	Refer to User Manual (Background: Blue; Symbol: White)
19	<u>^</u>	Warning (Background: Yellow; Symbol & outline: black)
20	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
21	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
22	(( <u>(</u> )))	Non-ionizing electromagnetic radiation
23	$\rightarrow$	Output/ Nurse call
24	[+/←	Chargeable battery
25		Battery check

## NOTE:

The service manual is printed in black and white.

## **Chapter 3 Installation**

#### **WARNING**

Only qualified service engineers shall install this equipment.

## 3.1 Environment Requirements

Temperature		
Working	0 °C ~ +40 °C (32 °F ~104 °F)	
	With TEMP: +10 °C ~ +40 °C (50 °F ~104 °F)	
Transport and storage	-20 °C ~ +55 °C (-4 °F ~131 °F)	
	With TH module: -20 °C ~ +50 °C (-4 °F ~122 °F)	
Humidity		
Working	15% RH ~ 95% RH (non-condensing)	
Transport and storage	15% RH ~ 95% RH (non-condensing)	
Altitude		
Working	86 kPa ~ 106 kPa	
Transport and storage	70 kPa ~ 106 kPa	

#### NOTE:

- 1 If the monitor is installed in a cabinet, allow at least 2 inches (5 cm) clearance around the monitor for proper air circulation; allow adequate accessibility for servicing, and adequate room for visualization and operation.
- 2 Ensure the monitor is not subjected to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phones base stations, etc.
- 3 Do not install the monitor in the presence of flammable anesthetics.
- 4 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	0.7 A-0.35 A
Fuse	T2.5AH, 250VAC

## 3.3 Safety Requirements

#### **CAUTION**

- 1 SHOCK HAZARD- the power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.
- 2 Do not touch signal input or output connector and the patient simultaneously.
- 3 Devices connecting with monitor should be equipotential.
- 4 Do not switch on the monitor until all cables 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.



Figure 3-1 iM3 on a flat surface

#### To mount the monitor on wall

To mount the monitor on a wall, you need to order a Wall Mounting Bracket (02.04.243472). Please refer to that instruction for details of installation.

#### **WARNING**

- 1 The wall mounting bracket can be fixed only on a concrete wall.
- 2 Make sure the monitor is secure on the wall-mounting bracket before releasing your hands from the monitor.
- 3 Make sure the mounting bracket for the wall-mounting bracket is well attached to the monitor before fixing the monitor to the wall-mounting bracket.
- 4 Check and make sure all screws on the wall-mounting bracket are secure.
- 5 Make sure the wall-mounting bracket is firmly fixed to the wall.

#### • To install the monitor on trolley

An Assembling Instruction will be delivered with the Trolley (83.60.261116). Please refer to the instructions for details of installation.

## 3.5 Connecting to AC Power Supply

Apply the power cable provided with the monitor. Plug one end of the power cable to the power socket of the monitor and fasten the connector shoulder with the security lock. Connect the other end to a grounded 3-phase power output special for hospital use.

#### NOTE:

Do fasten the connector shoulder with the security lock after plugging the connector into the socket.

## **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 on/off 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 Machine 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 *iM3 Vital Signs 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.

If any failure is detected, refer to Section Operation Failures for details.

## 4.1.4 Checking Touch Screen

When the monitor is configured with a touch screen, touch any available keys on the screen to check if the screen is working properly.

If any failure is detected, refer to Section Operation Failures for details.

## 4.1.5 Checking Internal Barcode Scanner

When the monitor is configured with internal barcode scanner, switch on the function and scan barcode to check if monitor can normally display the contents.

If any failure is detected, refer to Section *Operation Failures* for details.

#### NOTE:

Prior to use, please ensure the scanner is normally installed and set.

## 4.1.6 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.

#### 4.1.7 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 SpO<sub>2</sub> simulator and NIBP 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 SpO<sub>2</sub> Functional Test

This test checks the function of the SpO<sub>2</sub> measurement. SpO<sub>2</sub> simulator is required for this test.

- 1. Connect the monitor and the SpO<sub>2</sub> simulator with a SpO<sub>2</sub> cable.
- 2. Switch on the monitor and the simulator.
- 3. Set the  $SpO_2$  output in the simulator to 70(%).
- 4. Check for the display on the monitor. A difference within the range of  $\pm 2\%$  is reasonable.

#### 4.2.2 NIBP Functional Test

This test checks the function of the NIBP measurement. Tools required for this test are: a NIBP simulator, a T-fitting, an extension tube and an artificial limb.

- 1. Connect the NIBP simulator to the monitor.
- 2. Switch on the monitor and the simulator. Perform calibration prior to using the simulator.
- 3. Set the patient type both on the monitor and in the simulator to adult; respectively set the systolic pressure and diastolic pressure (mean pressure) to 255/195(215) mmHg (1 mmHg=0.133 kPa). Start a NIBP measurement.
- 4. Check for the display on the monitor. A difference within the range of ±8 mmHg is reasonable.

## 4.2.3 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.

- 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 **Menu** > **User Maintain** by inputting the password **ABC**. Start a leakage test by selecting **NIBP** > **Leak Test**.

#### For EDAN module:

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.

#### For SunTech module:

#### NOTE:

When applying high pressures; take special care to increase the pressure at a rate that will not cause unwanted overpressure errors (300 mmHg).

Manually inflate the pneumatic system to approximately 250 mmHg. Start the timer and wait 60 seconds for the pneumatic system to reach its pressure equilibrium point. After the waiting period, record the pneumatic pressure level (P1) and wait another 60 seconds and record the pneumatic pressure level again (P2). Safety circuitry on the module only allows the pressure in the pneumatic system to remain above 10mmHg for 180 seconds. When this safety time limit is exceeded, the valves will open releasing the pressure. Subtract P2 from P1 and this is the leak rate per minute.

5. 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.

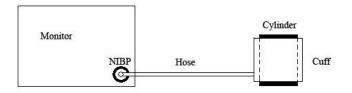


Figure 4-1 Diagram for NIBP Leakage Test

#### 4.2.4 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 to 300 mmHg; its accuracy should be more precise than the accuracy of ±0.3 mmHg.)

#### Procedure:

1. Connect the equipment as shown below.

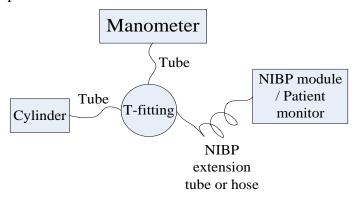


Figure 4-2 Diagram for NIBP Calibration

- 2. Access **Menu** > **Factory Maintain** by inputting the password 998.
- 3. Select **NIBP Calibration** 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  $\pm 3$  mmHg is reasonable.

## 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 to 300 mmHg; its accuracy should be more precise than the accuracy of ±0.3 mmHg.)

#### Procedure:

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

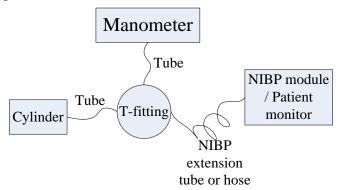


Figure 4-3 Diagram for Manometer Test

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

#### 4.2.6 TEMP Functional Test

This test checks the function of the TEMP measurement.

#### For T2A TEMP module:

- 1. Switch on the monitor and the resistance box.
- 2. Connect the probe with the resistance box.
- 3. Set the resistance value to  $(9571\Omega)$  26 °C in the resistance box.
- 4. Set the resistance value to  $(6014\Omega)$  37 °C in the resistance box.
- 5. Set the resistance value to  $(4542\Omega)$  44 °C in the resistance box.
- 6. A tolerance of  $\pm 0.1$  °C is reasonable.

#### For TH TEMP module:

- 1. Place the thermometer in the calibration mode follow the steps below:
  - a Press the ON/MEM button to turn the thermometer on. The display of the thermometer shows symbols and functions.
  - b Keep pressing the ON/MEM button for five seconds and you will see the "OFF" symbol on the display. Do not release the button until you see a dot onscreen.
  - c The thermometer is now in the Calibration Mode and the display is flashing and showing the "CAL" symbol.
- 2. Apply a new probe cover.
- 3. Position the thermometer making the end of the probe against the cavity inside the thermostatic water bath whose temperature is set to 37 °C. Press the "Scan" button for 1 second until you hear a long beep sound. The measurement is completed. You can read the result from LCD.
- 4. The displayed value should be 37  $^{\circ}$ C  $\pm 0.1$   $^{\circ}$ C.

#### For F3000 TEMP module:

- 1. Remove the isolation chamber/probe from the monitor unit.
- 2. Install the calibration plug into the visible connector.
- 3. Switch on the monitor.
- 4. Insert the probe into the opening in the top of the unit until the tip of the probe reaches the bottom and three beeps are sounded.
- 5. The displayed value should be 37  $^{\circ}$ C  $\pm 0.1 ^{\circ}$ C

## 4.3 Safety Test

## 4.3.1 Safety Test Procedures

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

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

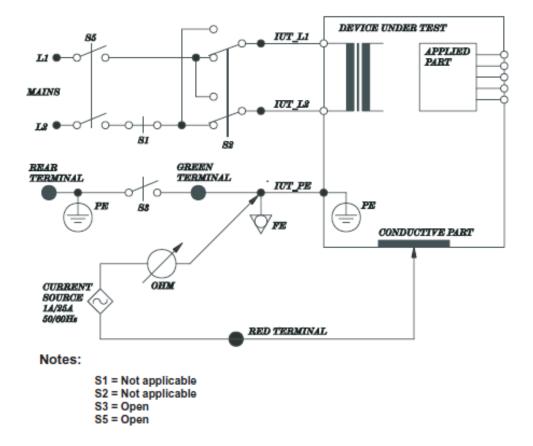
Additional test may be required by your local regulations.

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

#### NOTE:

- 1 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



#### NOTE:

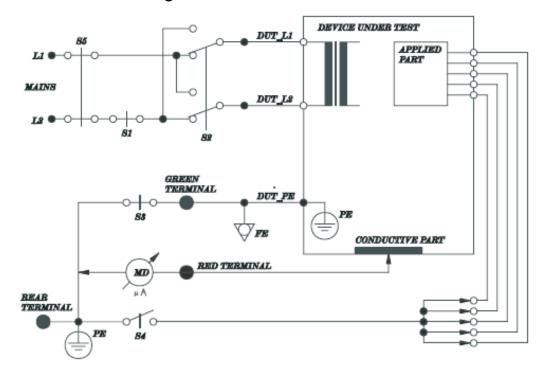
The circuit diagram is based on the Fluke 601Pro series safety analyzer.

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 mOhm

(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:

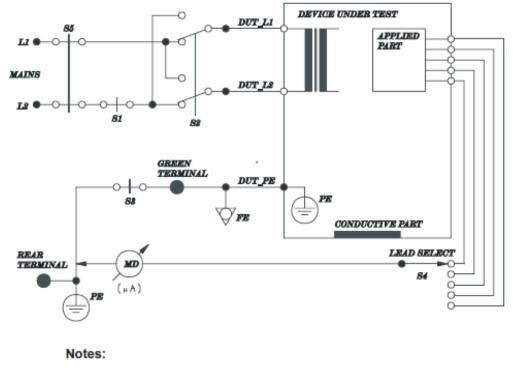
Normal condition: 100 µA (IEC/EN60601-1)

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



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: 100  $\mu A$  a.c., 10uA d.c. (BF applied part), 10  $\mu A$  a.c., 10uA d.c. (CF applied part)

(IEC/EN60601-1, UL60601-1)

Single fault condition:  $500\,\mu\text{A}$  a.c., 50uA d.c. (BF applied part),  $50\,\mu\text{A}$  a.c., 50uAd.c. (CF applied part)

(IEC/EN60601-1, UL60601-1)

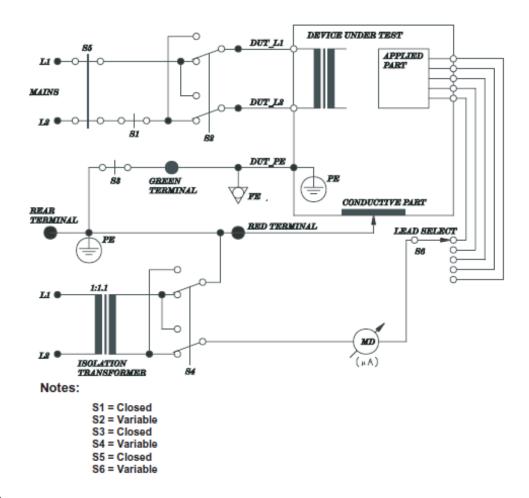
#### **Leakage Current**

	Applied Part	Normal Condition	Single Fault Condition
Earth Leakage Current		<0.5 mA	<1 mA
Enclosure Leakage Current		<0.1 mA	<0.5 mA
	CF	AC: <0.01 mA	AC: <0.05 mA
Patient Leakage Current	CI	DC: <0.01 mA	DC: <0.05 mA
1 attent Leakage Current	BF	AC: <0.1 mA	AC: <0.5 mA
		DC: <0.01 mA	DC: <0.05 mA
Patient Leakage Current (Mains on	CF		<0.05 mA
Applied Parts)	BF		<5 mA
	CF	AC: <0.01 mA	AC: <0.05 mA
Patient Auxiliary Current	CI	DC: <0.01 mA	DC: <0.05 mA
1 attent Auxinary Current	BF	AC: <0.1 mA	AC: <0.5 mA
	DI	DC: <0.01 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 *iM3 Vital Signs 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 Maintenance of the Monitor

A stable working environment is recommended. The gathering of dew on the screen may occur with abrupt temperature or humidity changes.

Keep the exterior surface of the monitor clean, free of dust and dirt. Do not scratch or damage the screen.

#### 4.4.2 Maintenance of the Sensor

Generally, sensors should be stored in dry environment with the temperature lower than 45 °C. Despite the durability of the sensors, you should use them carefully. Using the sensor with violence will damage the shell, the piezoelectric crystals and the parts. The shell of the sensor is made of soft plastic; thus, keep it away from hard or tined objects. Besides, do not over bend the cable of the sensor.

## 4.4.3 Maintenance of the Battery

Refer to relevant sections in iM3 Vital Signs Monitor User Manual for details.

#### 4.4.4 Maintenance of the Recorder

The platen, thermal print head and printing paper sensor should be cleaned at least once per year or whenever needed (e.g. the graph is blurred).

Clean the recorder following the steps below:

- 1. Clean the platen of the recorder with a piece of soft cloth dipped with suds or water.
- 2. Clean the thermal array with a piece of cotton swab dipped with 70% isopropyl alcohol.
- 3. Remove the dust over the printing paper inductor and the sensor with a piece of a dry cloth.

#### **CAUTION**

Only use the printing paper supplied by EDAN, or damage may happen to the recorder. Warranty is void in case of damage caused by this.

## **Chapter 5 System Configuration**

The end users cannot change the system configuration of the monitor. As a service engineer, the users need to change the configuration for them after the monitor is installed and checked properly.

#### NOTE:

Restart the monitor after changing the settings.

## 5.1 Enter Factory Maintain

Enter **Menu > Factory Maintain >** input password 998 and confirm.

Factory maintenance is only available for the service engineers of EDAN or representatives authorized by EDAN.

- ◆ **Module Select**: to select NIBP, Quick TEMP and SpO₂ module, and to switch the functions on/off, including recorder, Wi-Fi, encrypt and e-link.
- ◆ NIBP Calibration (X2): for NIBP calibration.
- ◆ Update (X2) U-disk: for X2 module (NIBP/SpO<sub>2</sub>) update by U-disk.
- ◆ **Update** (**X2**) **PC**: for X2 module (NIBP/SpO<sub>2</sub>) update through the network connection with PC.
- ◆ **LED Test**: for physiological/technical alarm indicator test.
- ◆ **Software Update**: for Logo/system software update by U-disk or TFTP server.
- ◆ Language Update: for language update by U-disk or TFTP server.
- ◆ **Wi-Fi Power**: to set the power dissipation of Wi-Fi module.
- ◆ System: to check device SN and the version information of software & hardware.

#### 5.2 Enter 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 Default Configuration

Press the **Menu > Default Setup** to display the default setup menu.

#### NOTE:

Select any item in this submenu to cancel the current setup and use the selected default setup.

- ◆ **Default**: to choose a factory configuration (adult, pediatric or neonate) based on the patient category, choose a user configuration saved in the monitor if it is available, or check the configuration currently used. The one labeled with is current configuration. If there's no labeled configuration, it means the currently used configuration is not one of them.
- ◆ User Configure: to save the current monitor's configuration, delete the saved user configuration or rename it. Three pieces of user configuration can be saved in the monitor. User can select as desire. The one labeled with is current configuration.

## 5.4 Network Setup

The monitor is provided with two network connection methods: wired network and Wi-Fi. The IP address in wired network and Wi-Fi 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** > **User Maintain** > input password **ABC**;
- 2 Select **Network**:
- 3 Set Network Type as Wired or Wi-Fi, access Config;
- 4 Set **Mode** as **Static**, and set the network **IP** as desired.

## 5.5 Configure the System Time

- 1. Select **Menu** > **System Setup** > **Date/Time**.
- 2. Adjust the date display format based on the user's habit.
- 3. Set the correct time of year, month, day, hour, min and sec.
- 4. Set **Display Second** to on/off. The current time can display or not display seconds.
- 5. Set **Sync Time** to on/off. If network is in good condition, the monitor will or won't accept time synchronization from MFM-CMS.

#### NOTE:

The system time should be reset under following circumstances:

- The monitor is not used for a long period of time.
- The main control board of the monitor is changed.
- The cell on the main control board is changed.

## **Chapter 6 Principle Introduction**

## 6.1 System Principle Block Diagram

The system consists of three parts: main control board, parameter board and power module.

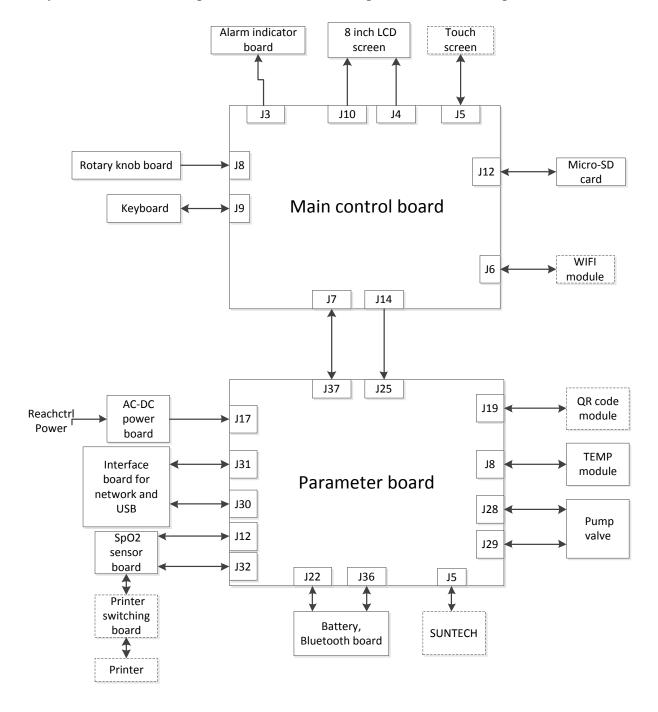


Figure 6-1 iM3 System Principle Block Diagram

#### 6.1.1 Main Control Board

Using the digital platform of 9G45, the main control board achieves the machine control, display,

network, and print functions, with focus on the communication and signal processing functions between the modules, and the realization of human-computer interaction. The module directly connected with the main control board includes the button, knob, alarm indicator, 8 inch LCD screen, touch screen (optional), Micro-SD card, and Wi-Fi (optional), while other modules communicate with main control board through the parameter transferred board.

#### 6.1.2 Parameter Board

The parameters board is mainly responsible for the power supply management and the measurement parameters collection; it exports 5V power supply to the main control board, and simultaneouslycontrolssome module's power supply. The measured parameters include noninvasive blood pressure (NIBP), pulse oxygen saturation (SpO<sub>2</sub>), pulse rate (PR), quick temperature (Quick TEMP) and infrared temperature (Infrared TEMP). The parameter board controls these monitoring data and communicates with main board after processing.

#### **NIBP**

This monitor uses the oscillometric method for measuring NIBP. It inflates the cuff around the upper arm, until the cuff pressure blocks the brachial artery blood flow, and then gradually deflates according to a certain algorithm. With the decrease of cuff pressure, the arterial blood will bring pressure pulsation in the cuff. Through the pressure sensor connecting with cuff inflating pipe, a voltage fluctuation signal will be generated with pulse beat.

#### SpO<sub>2</sub>& PR

Based on the pleth of finger pulse, etc.,  $SpO_2$  is calibrated through certain algorithm and clinical data.  $SpO_2$  sensor measures with two built-in luminous diodes and one photocell component. The two luminous diodes are separately red light and infrared diode, which are light alternately with certain time order. When hyperemia of the finger capillary occurs repeatedly with the heart pump, luminous diode light passes through the blood and tissues, and projects onto the photocell. Photocell can sense the light strength which changes with the pulse blood and whose form is the changeable optical signals. The ratio of the DC and AC components of the two photoelectric signals corresponds to the oxygen content in the blood, and the correct oxygen saturation value can be obtained by a specific algorithm, at the same time, pulse rate can be calculated according to  $SpO_2$  wave.

#### **Quick TEMP& Infrared TEMP**

Quick TEMP uses measurement sensor to measure oral/axillary/rectal temperature. When measured value is beyond the limit, the monitor will prompt alarm signals; Infrared TEMP uses infrared detection method to measure ear temperature. iM3 is configured with three temperature modules including F3000, T2A and TH.

## 6.1.3 Battery Module

The battery module is mainly responsible for switching AC/DC power. It switches the network input into +19 V DC power supply to parameter board. The maximum output power is 45W. It also can charge the battery when parameter board is connected.

## 6.2 Interface

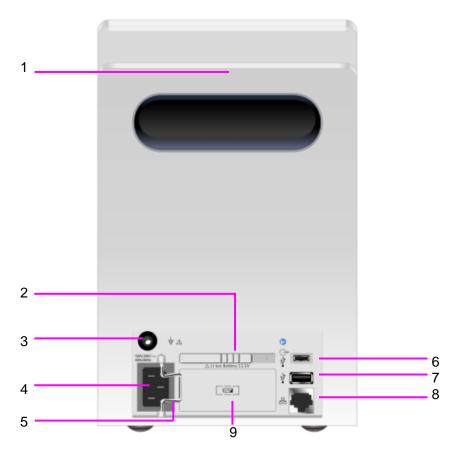


Figure 6-2

No	Interface Description	
1	Portable handle/Accessory collecting	
2	Battery compartment latch	
3	Equipotential grounding terminal.	
4	AC power input	
5	Power cable safety latch.	
6	OTG interface/nurse call port	
7	USB interface	
8	Network interface	
9	Battery	

## **Chapter 7 Troubleshooting**

In transportation, storage and use of monitor, various factors such as unstable network voltage, changing environmental temperature, falling-down or impact, component aging may all result in monitor failures and therefore affect normal application of the device. In failure conditions, professional personnel with the experience of repairing electronic medical devices should perform component-level service for the failure classification listed in the table below. Component-level service means based on analyzing, replacing or trial-operating the component, we can pinpoint the failure on a certain component of the device, such as power board, main control board, TFT assembly, measuring cable or parameter module, etc. Component maintenance means component-level maintenance, which must be conducted by a service engineer with abundant experience and with the assistance of special equipment and in specific environment and conditions. When the monitored parameter has malfunction (such as no parameters, no waveforms, etc), the service engineer should first check whether the operator's operation method is appropriate, so as to avoid unnecessary maintenance.

#### 7.1 Machine Failures

Phenomenon	Possible Cause	Solution
After switching on, LCD has no display; the power indicator is off.	<ol> <li>Fuse damage (If it has fuse on).</li> <li>Power board damage.</li> <li>Component short-circuits.</li> </ol>	<ol> <li>Replace fuse.</li> <li>Replace power board.</li> <li>Anchor the short-circuited component.</li> </ol>
No display after power-on or black screen during operation, however, power indicator lights.	Main control board failure or display failure.	Refer to Section 6.2 Display Failure.
Operation or measurement function is disabled.	Main control board or corresponding component damage.	Examine the main control board and the corresponding components.
Accidental crash.	<ol> <li>Instantaneous intensive interference of network.</li> <li>Poor performance of power board.</li> <li>Poor performance of main control board.</li> <li>Bad connection of power board or main control board.</li> </ol>	<ol> <li>Check power supply and grounding system.</li> <li>Replace power board.</li> <li>Replace main control board.</li> <li>Replace or repair connectors.</li> </ol>

Shut down suddenly	If the monitor is powered by battery and shuts down suddenly, maybe the battery is too low.	Please connect AC to the monitor and charge the battery.
	The monitor is stricken by sudden high voltage, e.g. lightning strike.	Check the power supply and grounded system.
	Bad connection of power input.	Check the power input.
Power failure.		Replace the power supply.
	Main control board failure.	Replace the main control board.

# 7.2 Display Failures

Phenomenon	Possible Cause	Solution
Characters are displayed normally, however waveforms are displayed intermittently.	Data communication error between main control board and parameter module.	Replace the main control board or parameter module based on the error prompt.
When powering on the device, power supply is in normal operation, however,	Malfunction in the display driver circuit of the main control board.	Replace the main control board.
there is no display or the screen turns black during normal operation.	Wire malfunction for LCD backlight power supply.	Check the connection. Reconnect the connecting wire.
	Damage of main control board.	Replace main control board.
	Power board failure.	Replace the power board.
Wrong characters are displayed on screen.	Bad connection of LCD display screen wire	Check the connection wire of LCD connection and main control board.
	LCD display screen failure.	Replace the LCD screen.

# 7.3 Operation Failures

Phenomenon	Possible Cause	Solution			
Buttons are disabled.	Button damage or main control board damage.	Replace the button or main control board.			
	The edge of the touch screen is pressed.	Check the assembling of the front cover and the touch screen.			
Touch screen has no reaction.	Bad connection of touch screen wire.	Check the connection. Reconnect the connecting wire.			
	Touch screen damage.	Replace the touch screen.			
	Main control board failure.	Replace the main control board.			
Turn the rotary knob, but there's no reaction.	Bad connection of the wire between the rotary knob and main control board.	Check the connection. Reconnect the connecting wire.			
	Rotary knob switch damage.	Replace the rotary knob.			
	Main control board failure.	Replace the main control board.			
Built-in scanner has no emitting light or is unable to scan.	Bad connection of the wire between the scanner and parameter board.	Check the connection. Reconnect the connecting wire.			
	The malfunction of the scanner leads to the communication failure with the main control board.	Replace the scanner.			
	The malfunction of the main control board leads to the communication failure with the scanner.	Replace the main control board.			
Insert the USB flash	USB flash disk damage.	Try another USB flash disk.			
disk, and there's no reaction.	Parameter board failure.	Replace the parameter board.			
	Main control board failure.	Replace the main control board.			
Hoarse sound or no sound from the speaker.	Malfunction in the audio subassembly of the main control board.	Replace the main control board.			
	Malfunction in the speaker or connecting wire.	Replace the speaker or connecting wire.			

# 7.4 Recorder Failures

Phenomenon	Possible Cause	Solution		
Press <b>Record</b> but no	No paper in the drawer.	Load paper and close the drawer.		
paper is out.	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.		
	The correct printer module category was not selected.	Set in <b>Factory Maintain</b> . Turn of the printer mode. If the printer i Unicode, select U, otherwise E.		
Alarm is displayed onscreen as "out of paper", but there is	The detector of recording paper is contaminated.	Clean the detector of recording paper.		
still paper in the drawer.	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	Inexact loading of the recording paper.	Load the recording paper exactly.		
is blank on the paper.	The two screw nuts on the print head are not adjusted to balance.	Adjust the screw nuts.		
	Recording head failure.	Replace the recording head.		

## 7.5 Network Failures

Phenomenon	Possible Cause	Solution				
	① Malfunction in network linking wire.	① Check and repair network linking wire or the HUB.				
Unable to connect to	② Network Bed No. conflict.	② Change Bed No				
the network.	③ Main control board failure.	③ Replace the main control board.				
	The antenna is not connected to Wi-Fi board.	Check the connection. Reconnect the connecting wire.				
Unable to connect Wi-Fi.	Wi-Fi board failure.	Replace the Wi-Fi board.				
	Main control board failure.	Replace the main control board.				

# 7.6 Power Board Failures

Phenomenon	Possible Cause	Solution
The fuses are burnt when the monitor is switched on.	Short circuit of the power or other parts.	Switch on the monitor for further check.
The fuses are still burnt after disconnecting all loads.	Power board failure.	Replace the power board.
The fuses are burnt when certain part is connected.	Short circuit of the specific part.	Replace the specific part.

## 7.7 Alarm Failures

Phenomenon	Possible Cause	Solution
No audio alarm is activated.	<ul><li>① Audio alarm is temporarily disabled.</li><li>② Speaker and its connecting wire have failure.</li></ul>	① Switch on the audio alarm. ② Replace the speaker or the wire.
The alarm indicator stays off.	Alarm indicator has failure.	Replace the alarm indicator board.
No audio alarm or visual alarm is activated.	Program failure.	Update the software.

## 7.8 Parameter Failures

Phenomenon	Possible Cause	Solution		
NIBP function communication stops.	<ol> <li>Bad connection between the parameter board and main control board.</li> <li>NIBP module function of parameter board has failure.</li> <li>Main control board failure.</li> </ol>	<ol> <li>Check the connection between boards.</li> <li>Replace the parameter board.</li> <li>Replace the main control board.</li> </ol>		
NIBP cuff can not be inflated.	Airway is folded or has leakage.	Adjust or repair the airway.		
Blood pressure can not be measured occasionally.	Cuff becomes loose or patient is moving.	Keep the patient quiet; bind the cuff correctly and safely.		
Great error in NIBP measurement.	①Cuff size does not fit the patient. ②Parameter board failure.	①Use the cuff of appropriate size. ②Replace the parameter board.		
SpO <sub>2</sub> function communication stops.	① Bad connection between parameter board and main control board.	<ol> <li>Check the connection between boards.</li> <li>Replace the parameter board.</li> </ol>		

	<ul><li>② Parameter board failure.</li><li>③ Main control board failure.</li></ul>	③ Replace the main control board.		
No SpO <sub>2</sub> waveform	Sensor or parameter board is damaged. Replace the sensor and contains the malfunction.			
SpO <sub>2</sub> waveform has strong interference.	<ol> <li>Patient is moving.</li> <li>Environment light is very intensive.</li> </ol>	<ol> <li>Keep the patient quiet.</li> <li>Weaken the light intensity in the environment.</li> </ol>		
SpO <sub>2</sub> value is inaccurate	Coloring agent has been injected into patient body.	Remove the coloring agent before measurement.		
No TEMP value (for T2A, F3000 and TH module)	<ol> <li>Bad connection of the wire between the TEMP module (T2A, F3000 and TH module) and the monitor.</li> <li>TEMP module (T2A, F3000 and TH module) is damaged.</li> <li>The TEMP probe is damaged.</li> <li>The main control board is damaged.</li> </ol>	<ol> <li>Check the connection.         Reconnect the connecting wire. If the malfunction continues, replace the connecting wire.</li> <li>Replace the TEMP module (T2A, F3000 and TH module).</li> <li>Replace the TEMP probe.</li> <li>Replace the main control board.</li> </ol>		

## **Chapter 8 Disassembling the Monitor**

#### **WARNING**

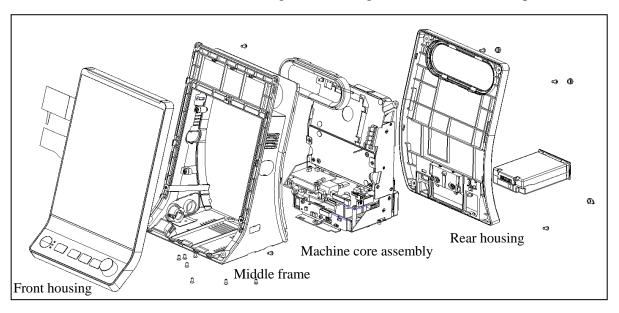
- 1 Only qualified service personnel can open the monitor case.
- 2 Switch off the monitor and disconnect it from the AC mains before disassembling the monitor. (If batteries are used, also take the batteries out from the monitor.)
- 3 After any repair of the monitor, perform safety tests prior to use.

## 8.1 Tools Required



#### 8.2 Disassembling the Main Unit

The main unit consists of the front housing, rear housing, main frame and other parts

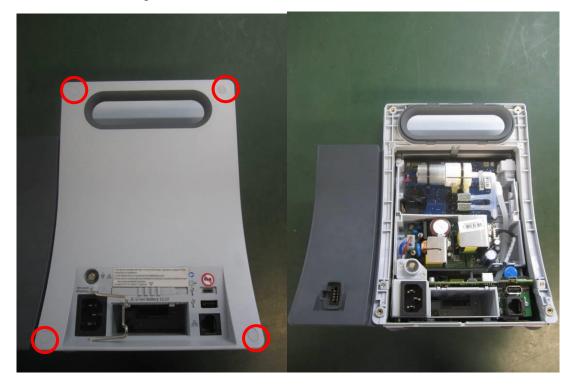


To disassemble the main unit:

1 Disassemble the external plug-in assembly from the main unit with a cross-head screwdriver.



2 Take out the rubber plug with knife, and unscrew the screws securing the rear housing to unfold the rear housing with a cross-head screwdriver.



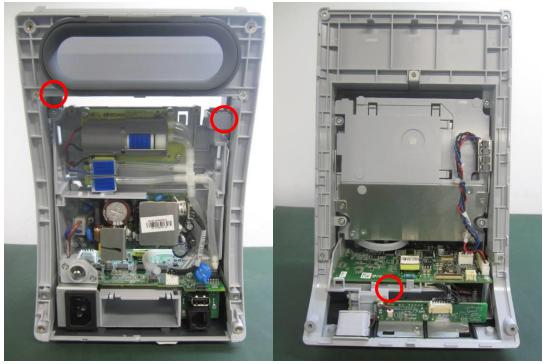
Unscrew the screws securing the front housing to unfold front housing. Pull out the wires linking the main board and parameter board to separate the front housing and rear housing. (When you start to separate the front and rear housing, use your body against the front housing and then separate them with your hands.)



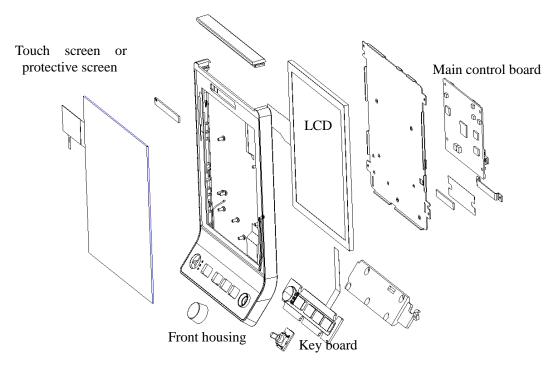


To separate the middle frame and rear housing, unscrew the screws securing middle frame on the bottom and inside the unit with cross head screw driver.



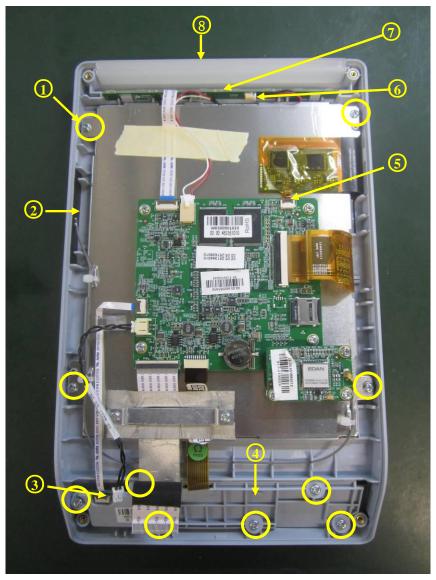


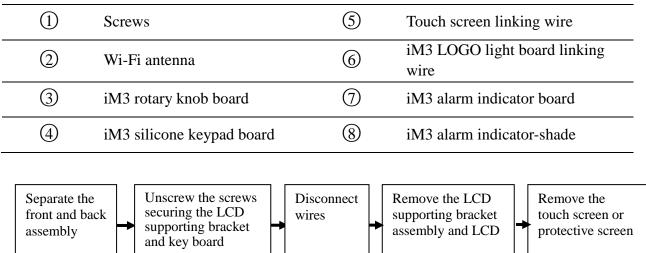
# 8.3 Disassembling the Front Housing Assembly



iM3 Front Housing Structure Block Diagram

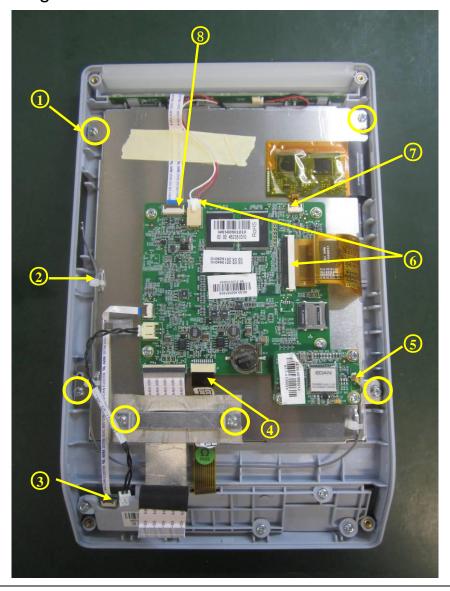
#### 8.3.1 Replacing the Touch Screen or Protective Screen

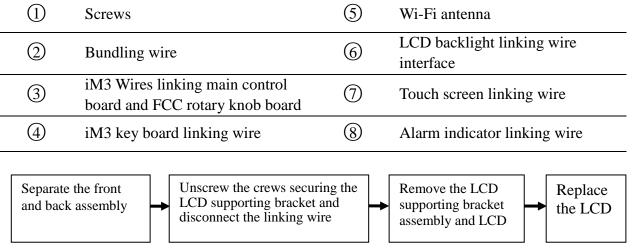




Assemble the touch screen or protective screen in the reversed order. Connect the wires and fix the main unit.

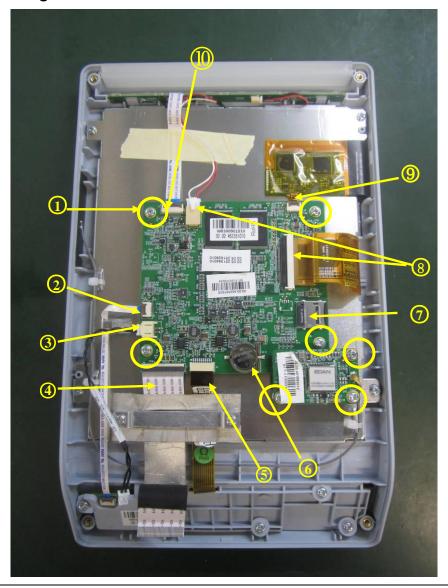
#### 8.3.2 Replacing the LCD





Assemble the LCD in the reversed order. Connect the wires and fix the main unit.

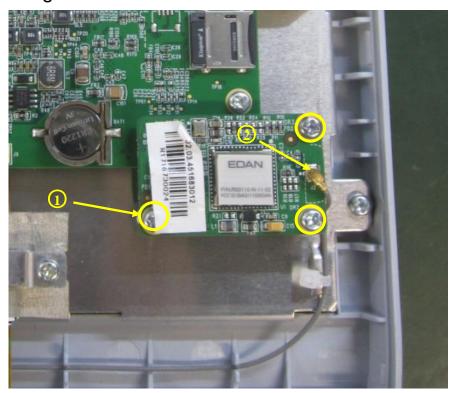
## 8.3.3 Replacing the Main Control Board

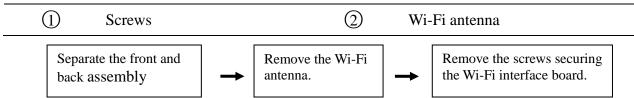


1	Screws	6	Lithium-manganese button battery		
2	iM3 Wires linking main control board and FCC rotary knob board	7	Micro SD card		
3	iM3 power linking wire of interface board	8	LCD backlight linking wire interface		
4	iM3 Wires linking main control board and FCC interface board	9	Touch screen linking wire		
(5)	iM3 key board linking wire	10	Alarm indicator linking wire		
	Disconne related w		Remove the screws securing the main control board.		

Assemble the main control board in the reversed order. Connect the wires and fix the main unit.

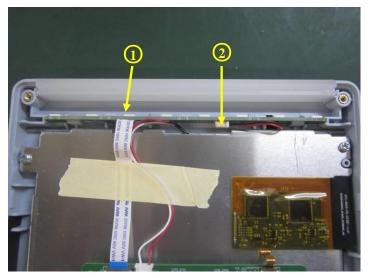
## 8.3.4 Replacing the Wi-Fi Interface Board



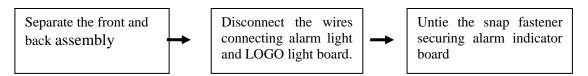


Assemble the Wi-Fi interface board in the reversed order. Connect the wires and fix the main unit.

## 8.3.5 Replacing the Alarm Indicator Board

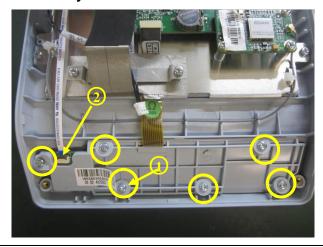


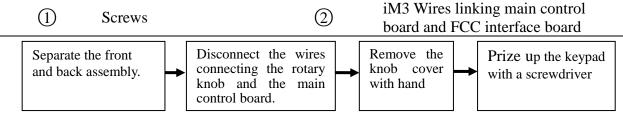
iM3 alarm indicator FCC linking wire iM3 LOGO light board linking wire



Assemble the alarm indicator board in the reversed order. Connect the wires and fix the main unit.

#### 8.3.6 Replacing the Rotary Knob



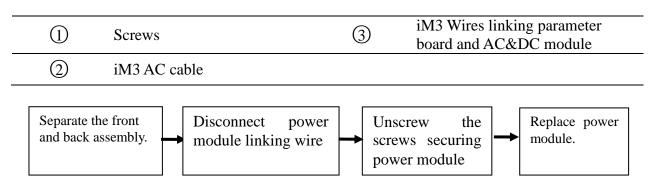


Assemble the knob in the reversed order. Connect the wires and fix the main unit.

#### 8.4 Disassembling the Rear Housing Assembly

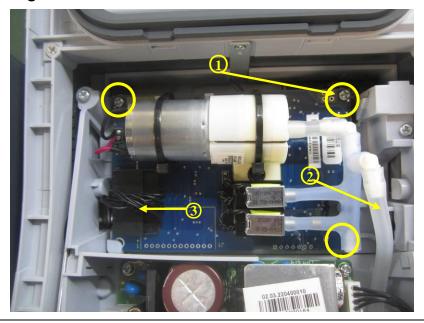
## 8.4.1 Replacing the Power Module

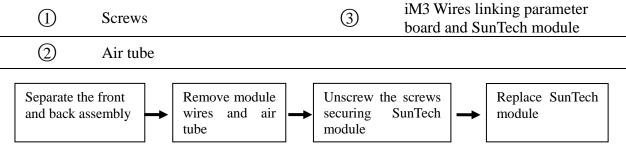




Assemble the power module in the reversed order. Connect the wires and fix the main unit.

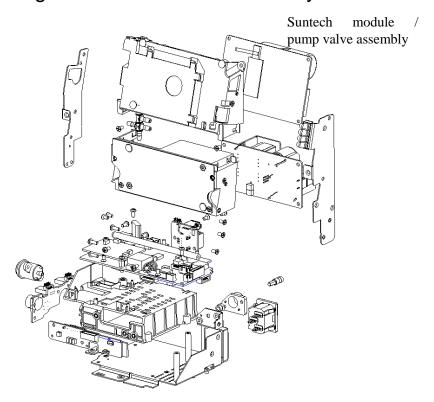
#### 8.4.2 Replacing SunTech Module



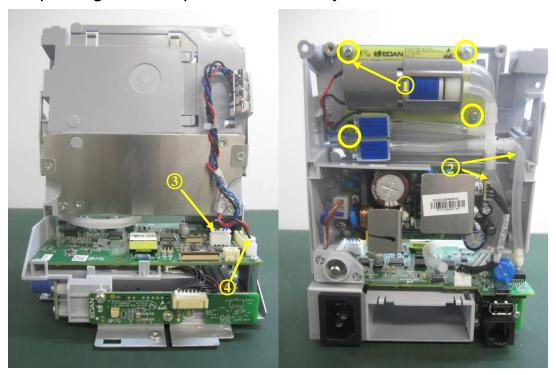


Assemble SunTech module in the reversed order. Connect the wires and air tube, and then fix the main unit.

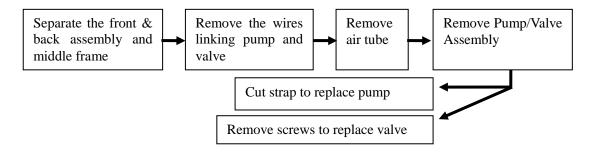
## 8.5 Disassembling the Middle Frame Assembly



# 8.5.1 Replacing the Pump/Valve Assembly

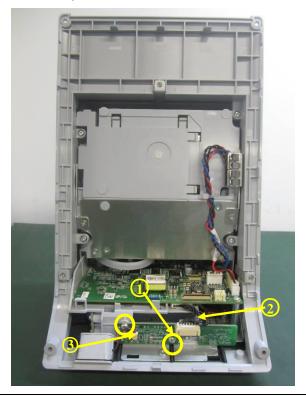


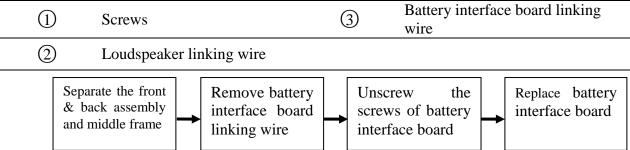
1	Screws	3	Valve linking wire
2	Air tube	4	Pump linking wire



Assemble the pump/valve assembly in the reversed order. Connect the wires and fix the main unit.

#### 8.5.2 Replacing the Battery Interface Board

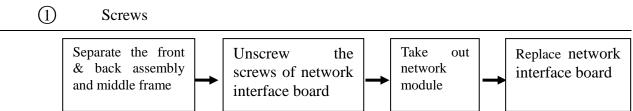




Assemble the battery interface board in the reversed order. Connect the wires and fix the main unit.

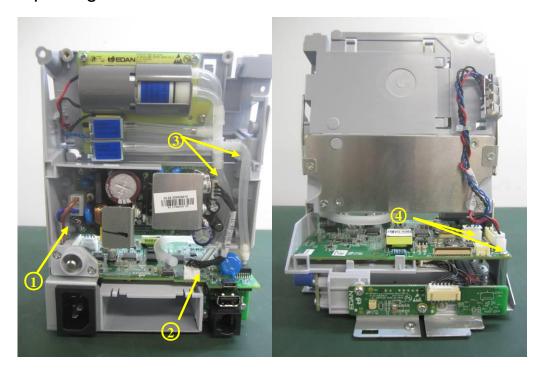
## 8.5.3 Replacing the Network Interface Board

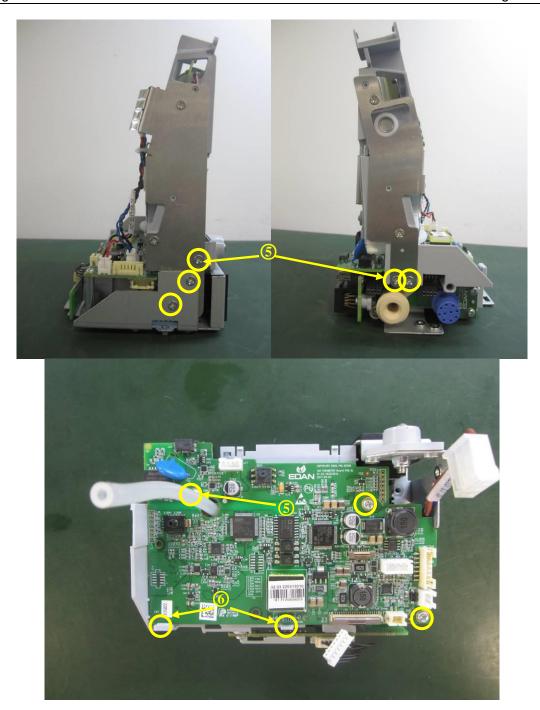




Assemble the network interface board in the reversed order and fix the main unit.

## 8.5.4 Replacing Parameter Board

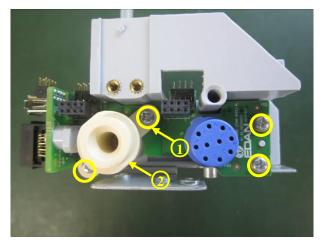


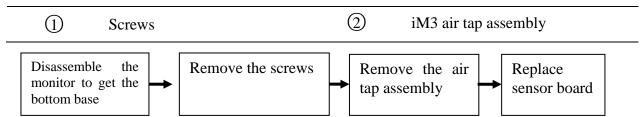


1	iM3 AC	cable		4	Pump/va	lve	linking wire
2		linking parameter AC&DC module		(5)	Screws		
3	Air tube			6	Snap fast	ten	er
1 -	e the front & assembly and frame	Remove air tube and linking wire	<b>→</b>	Remove the and remove fastener outv	the snap	<b>→</b>	Replace parameter board

Assemble parameter board in the reversed order. Connect the wires, air tube and fix main unit.

#### 8.5.5 Replacing Sensor Board of Main Unit

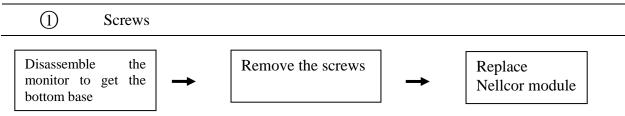




Assemble sensor board in the reversed order. Install air tap assembly and fix main unit.

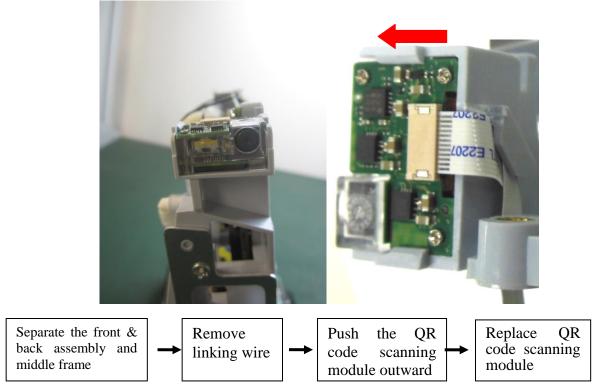
## 8.5.6 Replacing Nellcor Module





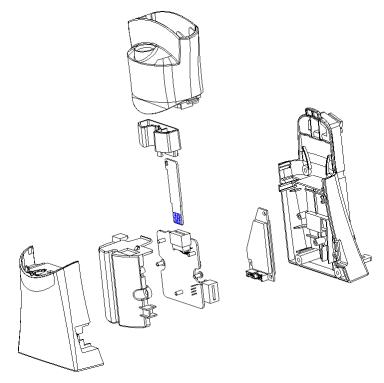
Assemble Nellcor module in the reversed order. Install air tap assembly and fix main unit.

## 8.5.7 Replacing QR Code Scanning Module

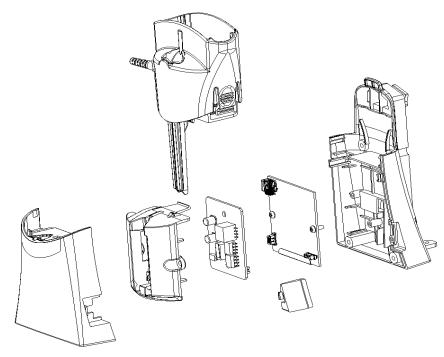


Assemble QR code scanning module in the reversed order and fix main unit.

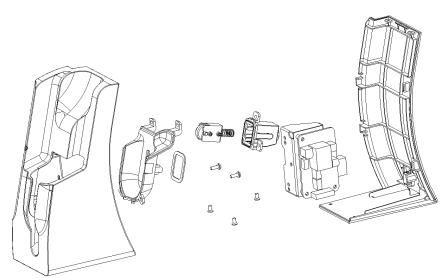
## 8.6 Disassembling the Plug-in Module



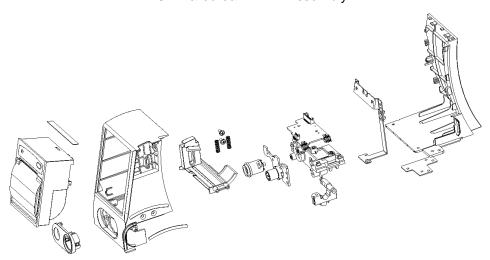
iM3 Quick TEMP Assembly



iM3 Covidien F3000 Quick TEMP Assembly

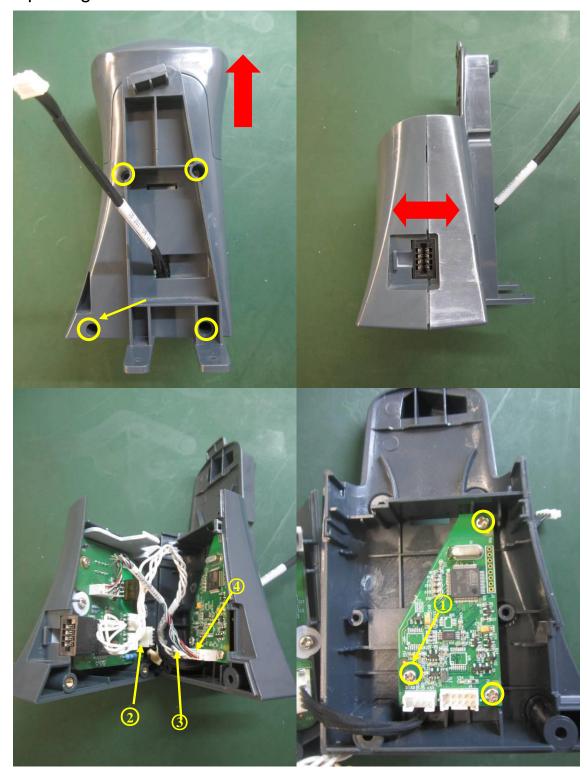


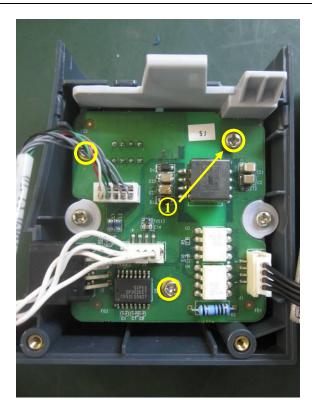
iM3 Infrared ear TEMP Assembly

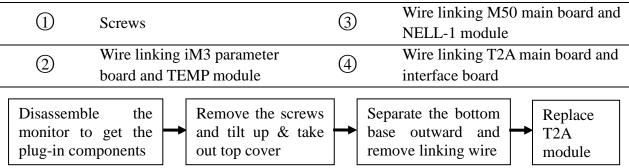


iM3 Recorder Assembly

# 8.6.1 Replacing iM3 T2A Isolation Board/T2A Main Control Board



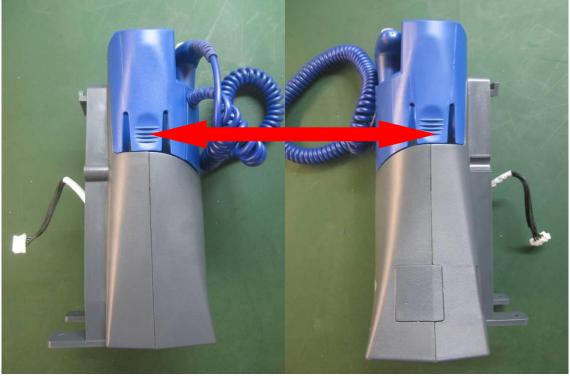


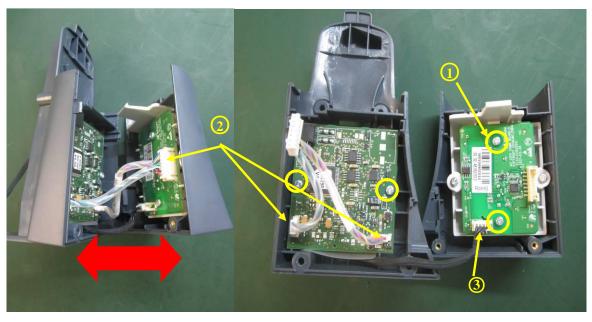


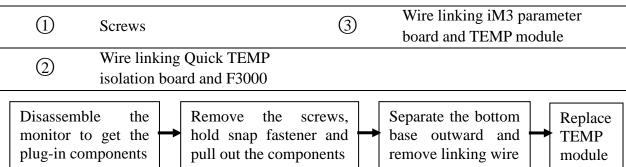
Assemble iM3 isolation board or T2A main control board in the reversed order, and fix the module components.

# 8.6.2 Replacing Quick TEMP Module/M3 Covidien TEMP Module Communication Isolation Board





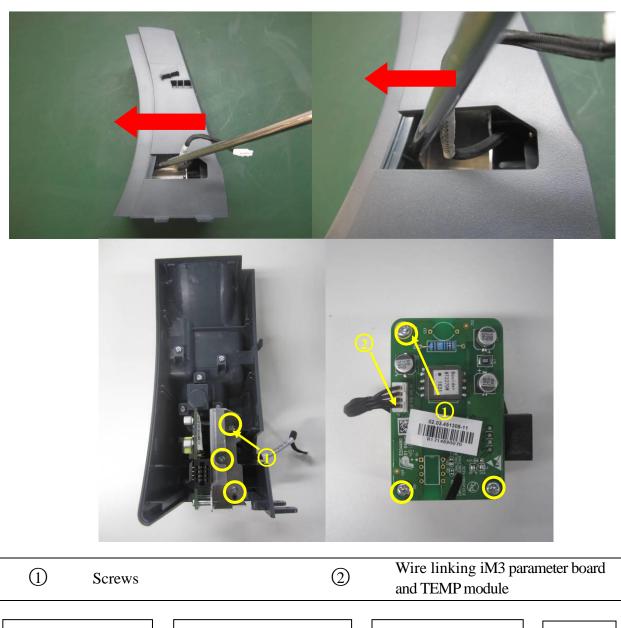




Assemble Quick TEMP Module/M3 Covidien TEMP Module Communication Isolation Board in the reversed order, and fix the module components.

#### 8.6.3 Replacing the Isolation Board of M3 Infrared Ear TEMP





Disassemble the monitor to get the plug-in components

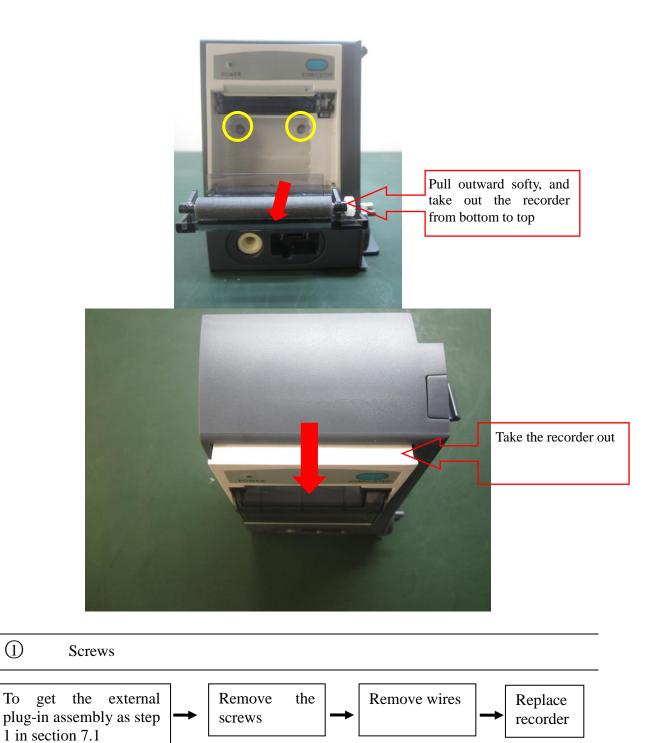
Remove the screws and prize up rear cover leftward with a screwdriver

Remove screws and wires

Remove screws and prize up rear cover leftward with a screwdriver

Assemble the Isolation Board of M3 Infrared Ear TEMP in the reversed order, and fix the module components.

## 8.6.4 Replacing the Recorder



#### Installing the recorder:

1

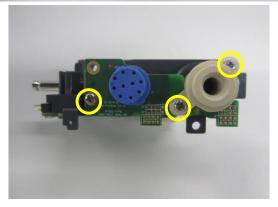
Install the recorder in the reverse order and fix the external plug-in assembly.

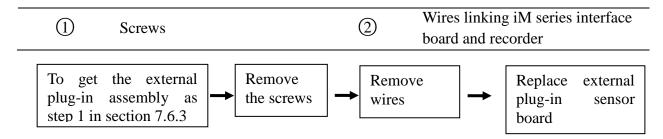
# 8.6.5 Replacing the Sensor Board of Recorder







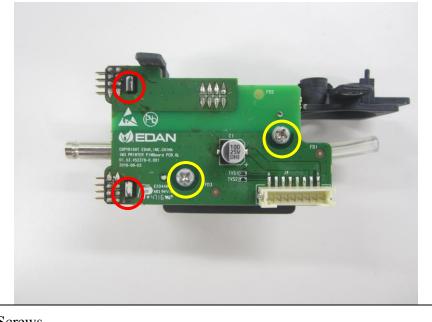


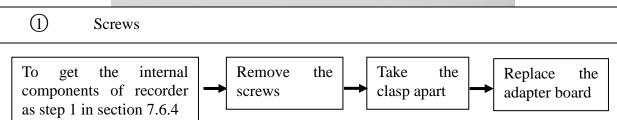


Install external plug-in sensor board:

Install the sensor board in the reverse order, fix the water tray and fix the external plug-in assembly.

#### 8.6.6 Replacing the Adapter Board of Recorder





Install the adapter board of recorder:

Install the adapter board in the reverse order, fix the water tray and fix the external plug-in assembly.

# **Chapter 9 Replaceable Parts**

#### **WARNING**

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

Parts	Part Number
iM3 main board PCBA (debugged)	02.03.452351
iM series power module main board PCBA (debugged)	02.03.220400
SunTech Advantage HT TEMP module	01.48.000636
Wi-Fi interface board PCBA (debugged))	02.03.451683
iM3 battery and Bluetooth interface board PCBA (not debugged)	02.02.220524
iM3 battery interface board (without Bluetooth) PCBA (not debugged)	02.02.220587
X2 air valve components	01.58.472153
Lithium-Manganese Button Cell	01.21.064095
Air pump	01.58.472151
iM3 parameter board (EDAN SpO <sub>2</sub> ) PCBA (debugged)	02.03.220513
iM3 parameter board (NELLCOR SpO <sub>2</sub> ) PCBA (debugged)	02.03.220516
iM3 sensor board of main unit (EDAN SpO <sub>2</sub> ) PCBA (not debugged)	02.02.220519
iM3 sensor board of main unit (NELLCOR SpO <sub>2</sub> ) PCBA (not debugged)	02.02.220521
SpO <sub>2</sub> module	02.08.208106
Speaker	01.14.038040
8-inch LCD screen	01.16.045272
Micro SD card	01.17.052452
iM3 alarm indicator board PCBA	02.02.220577
iM3 Rotary knob PCBA	02.02.452353
iM3 key board	02.48.027329
iM3 Pressure screen components (EDAN, touch screen)	02.01.213973
iM3 Pressure screen components (EDAN, Acrylic)	02.01.213974
iM3 Pressure screen components (Neutral, touch screen)	02.01.213975
iM3 Pressure screen components (Neutral, Acrylic)	02.01.213976
QR code scanning module	01.48.099051
iM3 network and USB interface board PCBA (not debugged)	02.02.220523
M3 Infrared Ear TEMP communication isolation board PCBA	02.03.451308

Parts	Part Number
(debugged)	
iM3 T2A isolation board	02.02.220569
T2A main control board	02.03.114524
M3 Covidien TEMP communication isolation board	02.02.451627
Quick TEMP module	02.03.203123
Lithium battery	02.21.064365
Unicode serial and parallel interface Recorder Assembly	02.01.210633
iM3 recorder adapter board	02.02.220531

#### NOTE:

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

P/N: 01.54.457834

MPN: 01.54.457834011







#### EC REPRESENTATIVE

Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, D-20537 Hamburg Germany TEL: +49-40-2513175 FAX: +49-40-255726

E-mail: shholding@hotmail.com

#### EDAN INSTRUMENTS, INC.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District Pingshan District, 518122 Shenzhen, P.R.China

Email: info@edan.com.cn

TEL: +86-755-2689 8326 FAX: +86-755-2689 8330

www.edan.com.cn