F15 Series

Fetal & Maternal Monitor

Service Manual

CE 0123

EDAN

About this Manual

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Statement

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

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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 ME EQUIPMENT that are designated by EDAN as repairable by SERVICE PERSONNEL.

Using This Label Guide

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

WARNING

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

injury or death.

CAUTION

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

NOTE

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

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Chapter 1Safety Guidance

NOTE:

This service manual is written to cover the maximum configuration. Therefore, your model may not have some of the parameters/modules described, depending on what you have ordered.

1.1 Introduction

This service manual is a reference for periodic preventive maintenance and corrective service procedures for the **F15** and **F15 Air** fetal & maternal 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 to do so might damage the monitor, invalidate the product warranty or lead to serious personal injury.

1.2 General Information

NOTE:

In this manual, **Monitor** refers to both **F15** and **F15 air**, and is used where the information applies to both models.

- The monitor is designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- The monitor operates within specifications at ambient temperatures between 0℃ (+41 ℉) and +40 ℃ (+104 ℉). Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5 cm) clearance around the instrument for proper air circulation.
- You must check that the equipment, cables and transducers do not have visible evidence of damage that may affect patient safety or monitoring capability before each use. If damage is evident, replacement is recommended before use.
- The monitor must be serviced only by authorized and qualified personnel. The manufacturer

does not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorized personnel. Identical replacement parts must be used.

- The typical operator's position is in front of the monitor. Please position the device in a location where the operator can easily see the screen and access the operating controls.
- The protective degree against electric shock of the patient connections is:

Ultrasound (FHR1, FHR2, FHR3) External TOCO Fetal Movement Mark (FM) Fetal Stimulator (FS) Intrauterine Pressure (IUP) Maternal Electrocardiography (MECG) Direct Electrocardiography(DECG) Fetal Electrocardiography (FECG)	Type CF	
Non-invasive Blood Pressure (NIBP) Arterial Oxygen Saturation (SpO_2) Temperature (TEMP)	Type CF, defibrillation-proof	

The monitor described in this service manual is not protected against:

a) The effects of high frequency currents

b) The interference of electrosurgery equipment

1.3 Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the maintaining the instrument.

WARNING

1 The monitor must be serviced by authorized and qualified personnel only. EDAN do not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorized personnel. Identical replacement parts must be used.

2 The service personnel should be familiar with the operation of this monitor. Refer to *User Manual* of the monitor for details.

3 **EXPLOSION HAZARD** - Do not use the monitor in the presence of flammable anesthetics or other materials.

4 **SHOCK HAZARD** - the power receptacle must be a three-wire grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet. A hospital grade outlet is required. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.

5 Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).

6 Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.

7 If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.

8 Multiple portable socket-outlets shall not be placed on the floor.

9 Make sure that the power is turned off and the power cord is disconnected from the AC socket before connecting or disconnecting equipment. Otherwise, the patient or operator may receive electrical shock or other injury.

10 Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC 60601-1 approved to the monitor. The operation or use of non-approved equipment or accessories with the monitor is not tested or supported, and monitor operation and safety are not guaranteed.

11 **SHOCK HAZARD** - Don't connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.

WARNING

12 **SHOCK HAZARD** - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlets supplying the system.

13 Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.

14 Do not exceed the maximum permitted load when using multiple portable socket-outlets to supply the system.

15 Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.

16 Do not switch on the monitor until all cables have been properly connected and verified.

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

18 Equipment and devices that connect to the monitor should form an equipotential body to ensure effective grounding.

19 Disconnect the power cord before changing fuses. Replace them with those of the same specifications only.

20 **SHOCK HAZARD** - Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

21 **SHOCK HAZARD** - Do not remove the top panel cover during operation or while power is connected.

22 Only connect accessories supplied or recommended by the manufacturer to the device.

23 Accessory equipment connected to the analog and digital interfaces 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 60601-1. If in doubt, consult our technical service department or your local distributor.

WARNING

24 Parts and accessories used must meet the requirements of the applicable IEC 601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard.

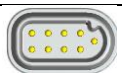
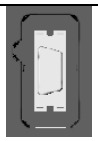
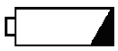
25 Connect the grounding wire to the equipotential grounding terminal in the main system. If it is not evident from the instrument specifications whether a particular instrument combination is hazardous or not, for example due to summation of leakage currents, you should consult the manufacturer or an expert in the field, to ensure that the necessary safety of all instruments concerned will not be impaired by the proposed combination.

26 Electromagnetic Interference - Ensure that the environment in which the monitor is installed is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phone base stations, etc.

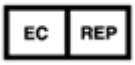
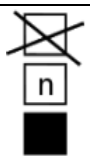
27 When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.

28 Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dust area, high-temperature and humid environment.

1.4 Definitions and Symbols

F15 Series Fetal & Maternal Monitor		
1		Fetal monitoring socket, ultrasound transducers, TOCO transducer and Fetal&Maternal Module can be connected to it(Type CF applied part)
2		Socket for Remote Event Marker (Type CF applied part)
3		Socket for Fetal Stimulator (Type CF applied part)
4		Socket for ECG cable (Type CF applied part)
5	 TEMP	Socket for TEMP Transducer (Type CF applied part)
6	 NIBP	Socket for NIBP Cuff (Type CF applied part)
7	 SpO_2 (EDAN)	Socket for SpO_2 Transducer (Type CF applied part)
8	 SPO_2 （Nellcor）	Socket for SpO_2 Transducer (Type CF applied part)
9		DB9 interface
10		RJ45 Interface
11		Battery check

12		Alternating Current
13		Direct Current
14		Stand-by
15		Power Supply switch
16		Warning (Background: Yellow; Symbol & outline: Black)
17		Caution
18		Operating instructions
19		Refer to User Manual (Background: Blue; Symbol: White)
20		TYPE CF APPLIED PART
21		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
22	IP68	Dust-tight and protected against the effects of continuous immersion in water
23	IPX2	Protected against vertically falling water drops when enclosure tilted up to 15°
24		CE marking
25		General symbol for recovery/recyclable
26	P/N	Part Number
27		Date Of Manufacture

28		Manufacturer
29		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
30		Disposal method
31		Non-ionizing electromagnetic radiation
32		USB Port
33		Ethernet Port
34		Serial Number
35		Catalogue number
36	Rx Only	Federal (U.S.) Law restricts this device to sale by or on the order of a physician
37		This way up
38		Fragile, handle with care
39		Keep dry
40		STACKING LIMIT BY NUMBER
41		HANDLE WITH CARE

42		DO NOT STEP ON

Chapter 2 Installation

WARNING

The system installation should be operated by serviceman authorized by the manufacturer.

2.1 Environmental Requirements

Working Environment		
Temperature:	0 ℃ ~ + 40 ℃ (+32 ℉ ~ +104 ℉)	
Relative Humidity:	15% ~ 95% (non-condensing)	
Atmospheric Pressure:	86 kPa ~ 106 kPa	
Transport and Storage		
Temperature:	-20 ℃ ~ +55 ℃ (-4 ℉ ~ +131 ℉)	
Relative Humidity:	15% ~ 93% (non-condensing)	
Atmospheric Pressure:	70 kPa ~ 106 kPa	
Classification		
Anti-electric Shock Type:	Class I equipment with internal power supply	
Anti-electric Shock Degree:	MECG,FHR1,FHR2,FHR3 ,TOCO,MARK,EXT.1, DECG, IUP,FECG	CF
	SpO2, NIBP , TEMP	CF (Defibrillating-proof)
Degree of Protection against Harmful Ingress of Water:	Main Unit: IPX2, protected against vertically falling water drops when enclosure tilted up to 15o (provided recorder drawer is shut and the monitor is not mounted on the wall vertically) US/TOCO/Fetal&Maternal Modules: IP68, dust-tight and protected against the effects of continuous emersion in water FT20 Telemetry Transmitter: IPX2	
Degree of Safety in Presence of Flammable Gases:	Equipment not suitable for use in presence of flammable gases	
Disinfection/Sterilizing Method:	Refer to *User Manual* for details	

EMC:	Group I Class A
Working System	Continuous running equipment

- 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.
- Ensure the monitor is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phones base stations, etc.
- Do not install the monitor in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dust area, high-temperature and humid environment.

2.2 Electrical Requirements

Operating Voltage:	100V-240V ~
Operating Frequency:	50Hz/60Hz
Input Power:	110VA
Battery:	10.8VDC/5100mAh

2.3 Safety Requirements

- **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. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.
- Do not touch signal input or output connector and the patient simultaneously.
- Equipment and devices that connect to the monitor should form an equipotential body to ensure effective grounding.
- Do not switch on the monitor until all cables have been properly connected and verified.

2.4 Installing the Monitor

2.4.1 Installing 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.

2.4.2 Mounting the Monitor on a Wall

CAUTION

1 The monitor should only be mounted on a solid concrete or brick wall.

2 Shut the display completely flat before mounting the monitor to the wall.

3 Make sure the wall mounting board is firmly fixed to the wall. If there is any doubt, do not hang the monitor to this board.

4 Make sure the monitor is safely hung on the posts of the board before releasing your hands from the monitor.

To mount the monitor on a wall,

1 Order a wall mounting board (01.52.107983), a retaining board (01.52.01983) and a connecting board (01.52.107984) from the manufacturer.

2 Turn the monitor over and fix the retaining board to the bottom panel using six pan head screws and then fix the connecting board to the retaining board with two pan head screws.

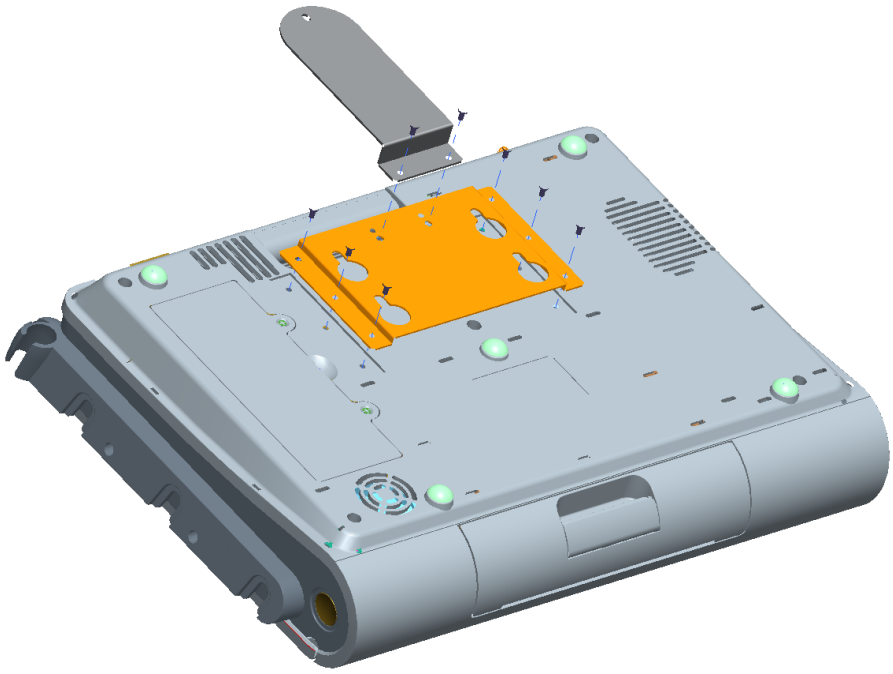


Figure 2-1 Fixing Retaining Board and Connecting Board

3 Fix the wall mounting board to the wall with six self-tapping screws.

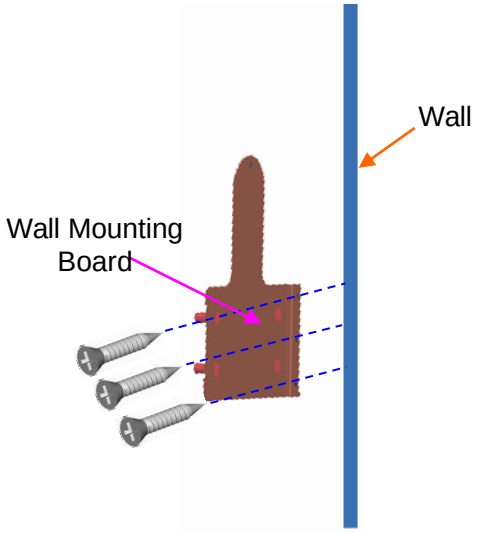
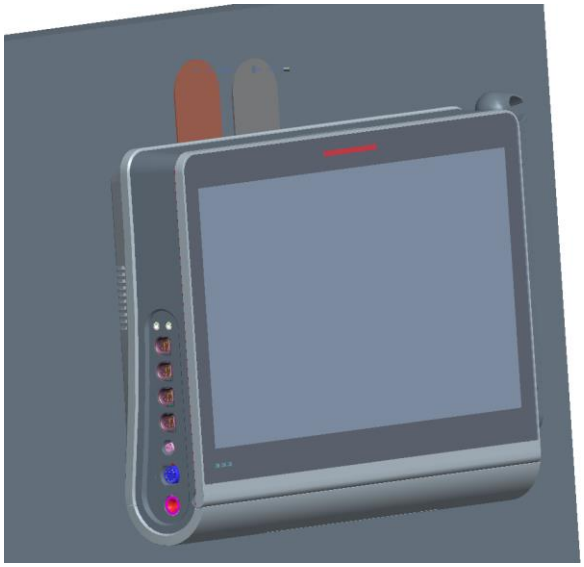


Figure 2-2 Fixing Wall Mounting Board

4 Lift the monitor with the bottom panel facing the wall. Let the four posts on the board stretch into wall-mounting holes and then release your hands from the monitor slowly.

5 Secure the connecting board to the wall mounting board with a pan head screw.



2.4.3 Installing the Monitor on Trolley

An Assembling Instruction will be delivered with the trolley. Refer to that instruction for details of installing the monitor on a trolley.

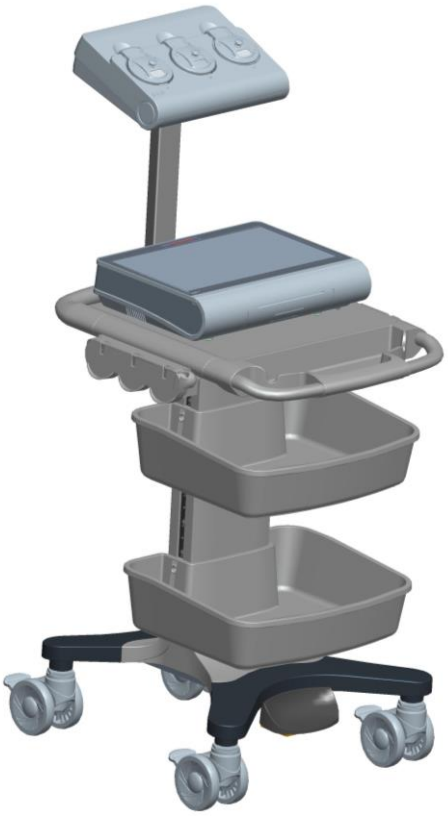


Figure 2-3 the Monitor on a Trolley (Sketch Map)

2.5 Connecting to AC Power

Apply the power cable provided with the monitor. Plug one end of the power cable to the power socket of the monitor. Connect the other end to a grounded 3-slot power output special for hospital usage.

Chapter 3 Functional Checks

This section describes the procedure of a complete functional test to support recommended preventive-maintenance schedules.

You are not required to open the device case for functional checks.

WARNING

Only qualified service personnel should perform a full functional check procedure.

Whenever the monitor is serviced or problems are suspected, the manufacturer recommends a full functional check procedure.

3.1 Switching on Check

Press the **POWER** switch on the right panel to switch on the monitor.

Check if the power indicator lights up, if a start-up tone is heard, and if the screen lights up in a few seconds.

If any failure is detected, refer to section *7.1 Monitor Booting Failures* for details.

3.2 LCD Screen Check

Observe if some characters are missing, or if there are bright spots and dark shadows on the LCD screen. Observe if the waveforms, fonts and symbols displayed on the LCD screen are normal.

If any failure is detected, refer to section *7.1 Monitor Booting Failures* for details.

3.3 Touch Screen Check

Touch any available keys on the screen to check if the screen is working properly.

If you touch the center of a key but the monitor does not execute the right operation, calibrate the touch screen. Refer to section 4.6 Calibrating Touch Screen for details.

If any operation failure is detected, refer to section 7.3 Touch Screen Failures for details.

3.4 Printing Check

Press the **PRINT** key to start printing. Check if the recorder starts printing.

Enable the **Print Self-Test** function. Restart the monitor and verify if the recorder prints a baseline.

Enter **DEMO** mode and print some traces and check if all the traces are clear on the paper.

If any failure is detected, refer to section *7.5 Recorder Failures* for details.

NOTE:

Please make sure the paper loading and setting are correct before the printing starts.

3.5 Alarms Check

Stimulate a signal that is higher than the upper limit or lower than the lower limit to activate a physical alarm. Disconnect one of the plugs off the monitor to activate a technical alarm. Check if the audible alarms and visible alarms are working properly.

If any failure is detected, refer to section *7.7 Alarm Failures* for defective details.

Chapter 4 System Configuration

The end users can not change the system configurations of the monitor. As a service engineer, you need to change these configurations for them after the monitor is installed and checked properly.

NOTE:

Restart the monitor after changing the settings.

4.1 Opening System Setup Menu

The system configurations of the monitor are to be changed in the system setup menu. To open this menu,

1 Select the setup key  on the main interface.

2 Select System.

3 Input the password 9999 on the soft keyboard.

4 Select Enter on the soft keyboard.

4.2 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 Open the System Setup menu.

2 Select **Demo**.

3 Select **OK**.

4.3 Reloading Default Settings

The default settings are predefined in the factory. Users can change the monitor setup, but this default configuration stays the same. To reload this default,

1 Open the System Setup menu.

2 Select **Default**.

3 Select **OK**.

4.4 Clearing Data

The auto-saved data is saved in the monitor memory. In order to delete this data,

1 Open the System Setup menu.

2 Select **Clear Data**.

3 Select **OK**.

4.5 Checking Product Information

The product information menu lists the hardware and software information of this monitor. This information can be very helpful when contacting the manufacturer for service.

To check the product information,

1 Open the System Setup menu.

2 Select **Product Information**.

4.6 Calibrating Touch Screen

When the monitor does not react to each touch on the touch screen properly, calibrate the touch screen by performing the following steps:

1 Open the System Setup menu.

2 Select **Touch Screen Calibration**.

3 Touch the cross mark "X" on the screen successively. This menu is closed when calibration finishes.



Figure 4-1 Touch Screen Calibration Interface

NOTE:

If the touching function fails and cannot enter the calibrating interface, please use a USB keyboard. Connect the USB keyboard to the USB interface of the monitor, and use the

up/left/right key and ENTER key to enter the calibrating interface. If the touching function still fails or calibration cannot be performed, please refer to section 7.3 for service.

4.7 Changing the Device No.

This device No. determines the bedside monitor ID on the data receiving software, such as MFM-CNS central monitoring system of EDAN.

1 Open the System Setup menu.

2 Select **Network Setup**.

3 Select the pane next to **Device No.**.

4 Select a device number from 1 ~ 99.

5 Select **OK** in the Network Setup menu.

6 Select **OK** in the System Setup menu.

CAUTION

Make sure the device numbers of the monitors in the same system do not overlap.

4.8 Changing Net Version

This Net version determines the network protocol of monitor when it is connecting to a PC.

Connecting Mode	Other Requirements	Net Version
F15 connects to MFM-CNS via 485 RF module	MFM-CNS version is V3.93 or higher	RS485 V1.3 RS485 V1.4
F15 connects to MFM-CNS via WIFI or network cable.	MFM-CNS version is V3.93 or higher	Ethernet V1.2 Ethernet V1.3 Ethernet V1.4

1 Open the System Setup menu.

2 Select **Network Setup**.

3 Select the pane next to **Net Version**.

4 Select a net version.

5 Select **OK** in the Network Setup menu.

6 Select **OK** in the System Setup menu.

4.9 Configuring 485 Wireless Network

When connecting the monitor to MFM-CNS via 485 wireless network, you need to set wireless

channel number and wireless module number:

1 Open the System Setup menu.

2 Select **Network Setup**.

3 Select **Wireless CH**.

4 Select a number (6 ~ 31).

5 Select **Wireless MOD**.

6 Select a number (0 ~ 31).

7 Select **OK** in the Network Setup menu.

8 Select **OK** in the System Setup menu.

NOTE:

Refer to *MFM-CNS Wireless Network Installation Guide* for details of setting 485 wireless network.

4.10 Configuring for Ethernet Connecting

NOTE:

Only when you have selected one of the Ethernet protocols for Net Version, such as Ethernet V1.2 or Ethernet V1.3, can you proceed to Ethernet connecting settings. Ethernet V1.3 and Ethernet V1.4 can be used for WIFI connection.

When connecting the monitor to a PC via Ethernet, you need to set the server IP, monitor IP, subnet mask, default gateway and Ethernet port:

1 Open the System Setup menu.

2 Select **Network Setup**.

3 Select **Server IP**.

4 Set the IP address to be the same as that of the PC.

5 Select **Monitor IP**.

6 Set the IP address of the monitor for Ethernet connection.

7 Select **Subnet Mask**.

8 Set the subnet mask of the monitor for Ethernet connection.

9 Select **Default Gateway**.

10 Set the default gateway of the monitor for Ethernet connection.

11 Select **Ethernet Port**.

12 Set the port number according to the Ethernet protocol. For Ethernet V1.2, Ethernet V1.3, select 5510 and for Ethernet V1.4, select 5525. Set Security configuration-Network encryption to off.

13 If the Ethernet protocol uses wireless connection, then WiFi setup is required. Input the WiFi name and password, and set WiFi connection setup to ON. Besides, the setup IP address of the monitor in Step 6 and WiFi dynamically assigned IP address should not be within the same network segment. For example, if the WiFi dynamically assigned IP address is 192.168.1.100, then in Step 6, the IP address of the monitor should not be

192.168.1.X.

14 Select **OK** in the Network Setup menu.

15 Select **OK** in the System Setup menu and then restart the monitor.

4.11 Changing Trace Width

In order to differentiate the traces clearly, you may assign different widths for different traces.

1 Open the System Setup menu.

2 Select **Recorder Configuration**.

3 Select **FHR1**.

4 Select a number from **1**, **2**, **3** and **4**. The width of the trace increases by degrees from **1** to **4**.

5 Set width of FHR2, FHR3, AFM, TOCO, HR and SpO_2 traces in the same way.

6 Select **OK** in the Recorder Configuration menu.

7 Select **OK** in the System Setup menu.

4.12 Changing Paper Style

The paper style determines the range of FHR trace background pane bar. Observe the recorder paper that the user has ordered, 30 ~ 240 is USA style; 50 ~ 210 is International style.

1 Open the System Setup menu.

2 Select **Recorder Configuration**.

3 Select the pane next to **Paper Style**.

4 Select the required style from **USA** and **International**.

5 Select **OK** in the Recorder Configuration menu.

6 Select **OK** in the System Setup menu.

CAUTION

To avoid inconsistency between FHR traces on the recorder paper and those on the screen, the paper style must comply with the style of the recorder paper being used.

4.13 Changing the Language

The software supports several languages.

1 Open the System Setup menu.

2 Select **Language**.

3 Select the required language.

4 Select **OK**.

4.14 Changing FHR Algorithm

The **Beat-to-beat** FHR algorithm provides vivid short-term variation information of the fetal heart rate. The **Average** FHR algorithm provides a smoothened FHR trace.

1 Open the System Setup menu.

2 Select **Beat-to-beat** or **Average**.

3 Select **OK**.

4.15 Pressure Verification

Pressure Verification enables the ***Pressure Verif mode***, in which you can verify whether there is a problem with the NIBP measurement.

1 Open the System Setup menu.

2 Select **Pressure Verif**.

NOTE:

Make sure neither NIBP measuring nor NIBP leak test is being performed before you enable pressure verification. If you need to disable pressure verification, please open the System Setup menu and press **Pressure Verif** again. In addition, you should restart the system after the pressure verification is finished.

4.16 NIBP Leak Test

NIBP Leak Test checks whether there is leak during NIBP measuring.

1 Open the System Setup menu.

2 Select NIBP Leak Test.

NOTE:

Make sure neither NIBP measuring nor pressure verification is being performed before you enable NIBP leak test. Once the leak test is enabled, it can't be stopped manually. It will automatically stop after it is finished and a message box will prompt out to inform you whether the test has passed or not. In addition, you should restart the system after the NIBP leak test is finished.

4.17 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.

3 NIBP calibration can only be performed when none of NIBP measuring, pressure verification and NIBP leak test is being performed.

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:

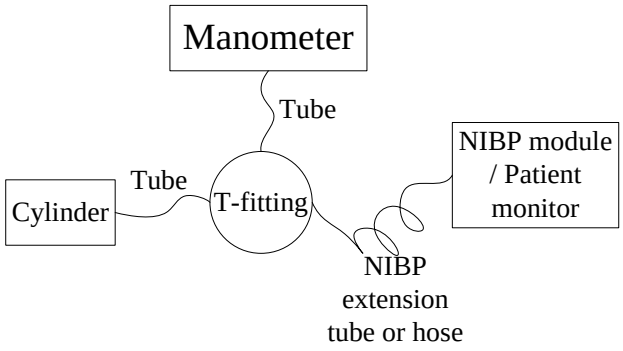


Figure 5-2 Diagram for NIBP Calibration

2 Open the **System** setup menu.

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 Main Sensor**.

8 Select **Calibrate Overpressure Unit**.

9 Exit **NIBP Calibration**. After the system is restarted, enter the **System** setup menu again and select **Pressure Verif**. 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.

Chapter 5 Maintenance

5.1 Maintenance Inspection

(1) Visual Inspection

- Check the monitor and accessories to see if there is any visible damage that may affect patient's safety.
- Check all the outer cables, power socket and power cables.
- Check if the monitor functions properly.

If any damage is detected, replace the damage part(s) or contact EDAN immediately.

(2) Routine Inspection

The overall check of the monitor, including the safety check and functional check, should be performed by qualified personnel every 6 to 12 months, and each time after service.

The equipment should undergo periodic safety test to insure proper patient isolation from live parts. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

		N.C.	S.F.C.
Patient Leakage Current (Limit) (CF applied part)	d.c.	10μA	50μA
	a.c.	10μA	50μA
Patient Leakage Current (Limit) (BF applied part)	d.c.	10μA	50μA
	a.c.	100μA	500μA
Patient Auxiliary Current (Limit) (CF applied part)	d.c.	10μA	50μA
	a.c.	10μA	50μA
Patient Auxiliary Current (Limit) (BF applied part)	d.c.	10μA	50μA
	a.c.	100μA	500μA

(3) Mechanical Inspection

Make sure all exposed screws are tightly fixed.

Check the external cables for splits, cracks or signs of twisting.

Pay particular attention to the supply socket. Replace any cable that shows serious damage.

5.2 Maintenance of the Monitor

Keep the exterior surface of the monitor clean, free of dust and dirt.

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

Do not scratch or damage the screen.

Avoid high voltage and static charge.

5.3 Maintenance of the Transducers

Wipe off coupling gel from the ultrasound transducer after use to prolong its life.

Handle the transducers with care. Rough handling could damage the cover, piezoelectric crystals and mechanical parts. Contacting the transducers with hard or sharp objects should be avoided.

Do not excessively flex the cables.

5.4 Maintenance of the Recorder

The recorder platen, thermal printhead and paper sensing mechanism must be cleaned at least once a year or when needed (when traces become faint).

To clean the recorder:

1) Clean the recorder platen with a lint-free cloth dampened in soap/water solution.

2) Wipe the thermal array using a cotton swab moistened with mild near neutral detergent, or ethanol 75%.

3) Remove the dust from the paper sensing mechanism and paper sensor with a dry clean cloth.

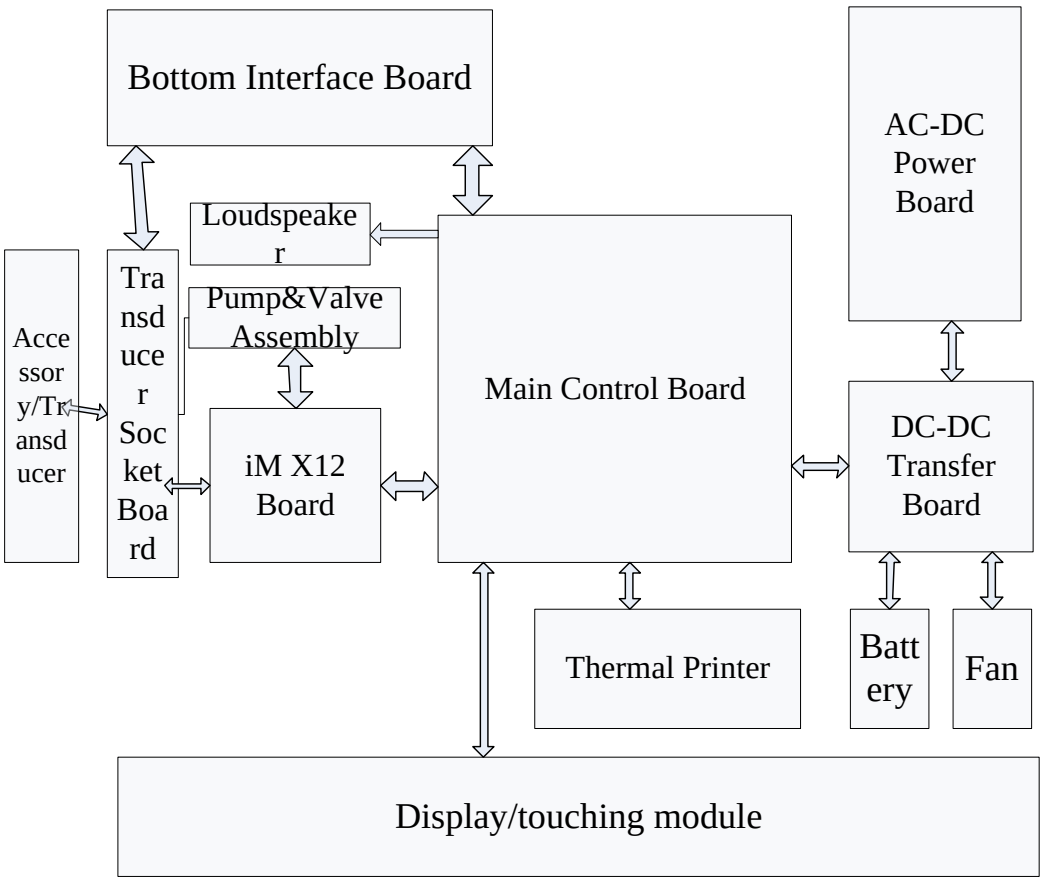
CAUTION

Only use the recorder paper provided by EDAN, or it may damage the recorder. This kind of damage is not covered by warranty.

Chapter 6 Principle Introduction

6.1 System Principle Block Diagram

F15 series fetal&maternal monitor consists of the AC-DC power board, DC-DC transfer board, battery, fan, main control board, thermal printer, display/touching module, bottom interface board, loudspeaker, pump&valve assembly, iM X12 parameter board, transducer socket board and wired transducer/all parameter accessories. Here is the system principle block diagram:



F15 Air series fetal&maternal monitor consists of the AC-DC power board, DC-DC transfer board, battery, fan, main control board(with AP module), thermal printer, display/touching module, bottom interface board, loudspeaker, wireless transducer/NBIP&SpO2 fetal&maternal module/all parameter accessories. Here is the system principle block diagram:

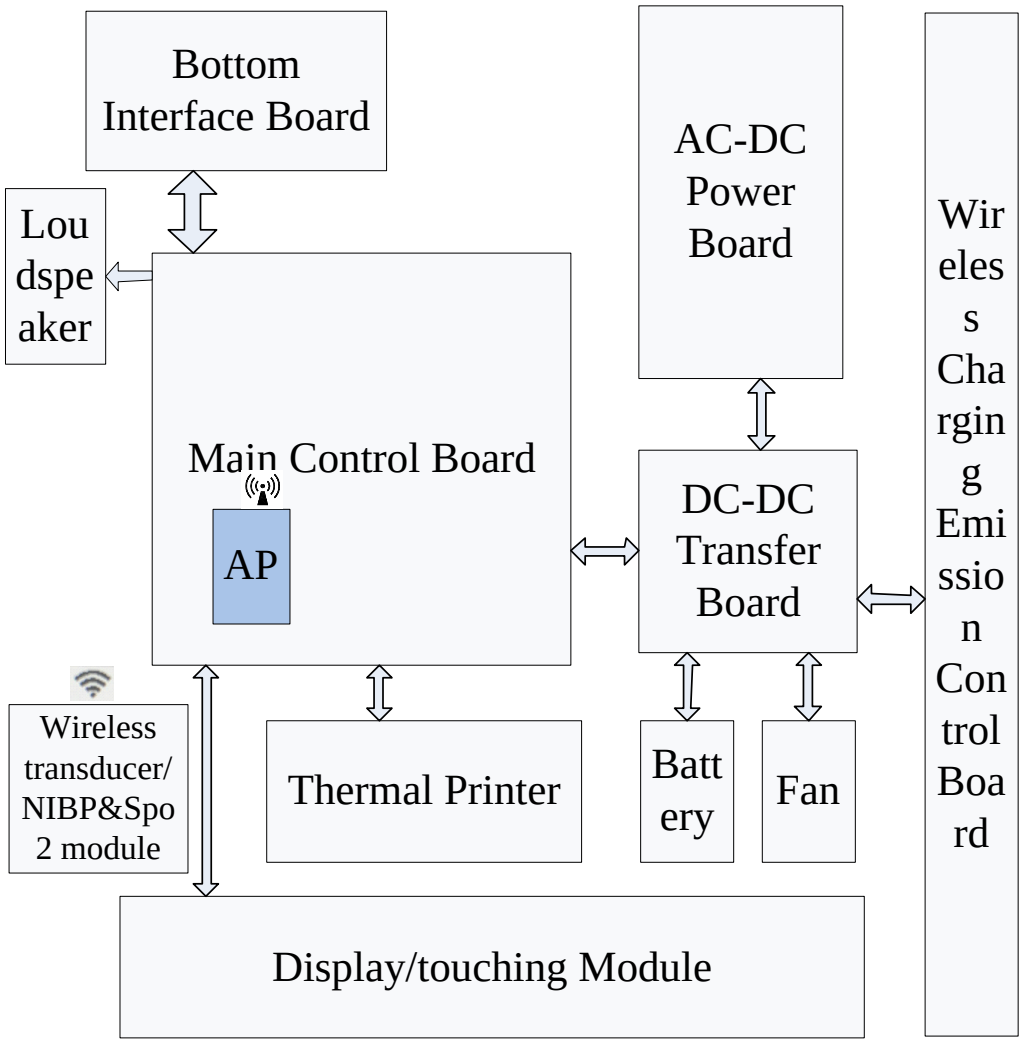


Figure 6-1. F15 System principle block diagram

6.1.1 Main Control Board

The main control board applied in F15 includes communication interfaces like USB, Ethernet, HDMI, UART, SPI, I2C, and SDIO. It fulfills the following function: control of WIFI communication module, wireless AP module, battery charging, and power control when switching on/off the monitor, audio playing, and control of thermal printer. The parameters of this main control board are listed below:

Power	24V, +12V, +5V
Processor	Kernel: ARM Cortex A9 Work frequency: 400MHz External bus frequency: 133MHz Dictate Cache: 32K bytes Data Cache: 32K bytes
Net Port	10/100M Standard Ethernet port
EMS Memory	DDRIII: 1G byte Flash: program + data 4G bytes

Serial Port	8 serial port ways
Touch Screen Interface	1 interface.
USB	1 standard USB HOST interface, 1 standard DEVICE interface (1.1 specification)
HDMI	1 HDMI output port
LCD	eDP interface, 1920*1080@60Hz (highest resolution)
Loudspeaker Interface	1 interface.
Stepping Motor Interface	1 interface.
Printer Head Interface	1 interface.
Out of Paper Checking Interface	1 interface.
Paper Darwer Checking Interface	1 interface.
Power Consumption	8.5W
Size	180 mm×155 mm
Operating System	Linux

6.1.2 Bottom Interface Board

The bottom interface board locates at the left rear side of the lower case. It fulfills the following function: communicate with external USB interface, network interface, HDMI, serial port (RS-485*1，FTS-3 serial port*2）and bridging signals of transducer accessory serial port, MARK, EXT to the main control board.

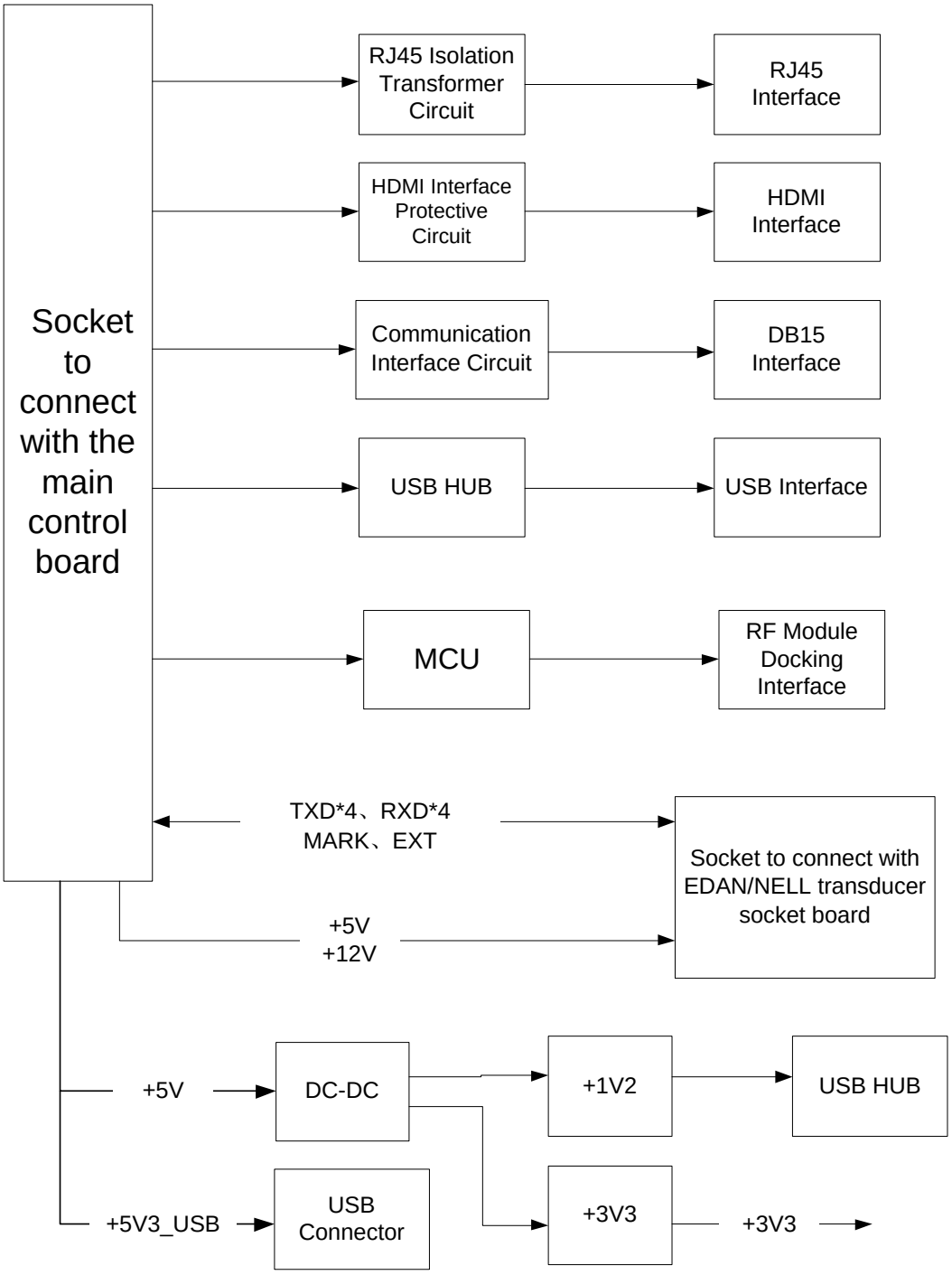


Figure 6-2 Bottom Interface Board Circuit Block Diagram

6.1.3 AC-DC Power Board

The AC-DC power module assembly provides voltage to F15 main unit and DC-DC transfer board, i.e realizing the power supply of the main unit and charging function of the batteries.

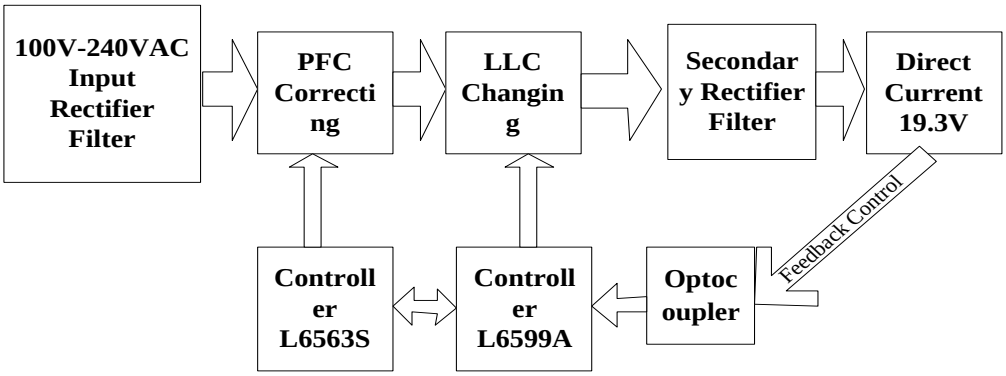


Figure 6-3 AC-DC Power Board Principle Block Diagram

The parameters of this power board are listed below:

Item	Parameter
Input Voltage Range	100-240VAC ±10%
Input Frequency Range	50Hz-60Hz ±3Hz
Input Max.Current	1.2A(110VAC)，0.7A(230VAC)
Input Surge Current	60A MAX（220VAC input）
Input Fuse	3.15A/250V（L、N Line）
PF Value	≥0.98（110VAC，rated load），≥0.94（230VAC，rated load）

6.1.4 DC-DC Transfer Board

F15 DC-DC transfer board connects to the 100w AC-DC power board and batteries, and mainly transfers the 19.3V voltage outputted by the 100w AC-DC power board to direct current required by F15 main control board and wireless transducer charging board, and controls the transfer between the batteries and 19.3V voltage, ensuring normal operation of the product and realizing power supply of the wireless transducer, main control board, multi-parameter module and LCD display.

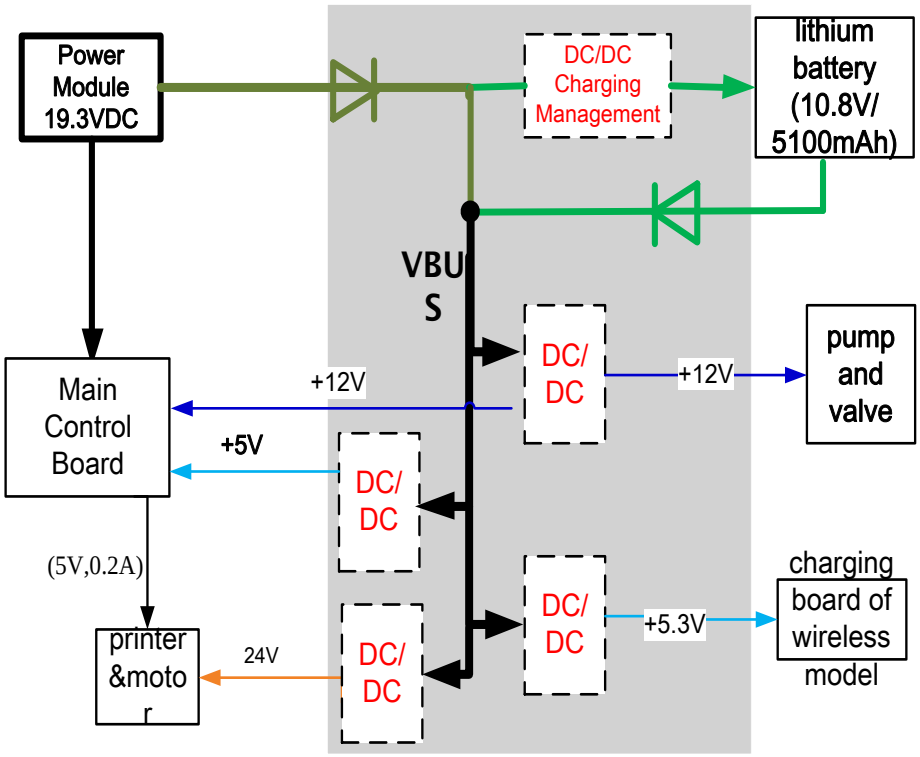


Figure 6-4 DC-DC Transfer Board Principle Block Diagram

6.1.5 iM X12 Parameter Board（wired model only）

iM X12 parameter board is located on the left of the main control board of F15 wired model, providing parameters like NIBP, SpO2（EDAN or Nellcor）, TEMP. The ECG function of the board is not used. Its main specifications are as below.

(1)（NIBP）

Method	Oscillometric
Mode	Manual Auto Circle
Auto Circle Mode Interval	1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 240, 480 minute(s)
Measuring Content	Systolic Pressure, Diastolic Pressure, Mean Artery Pressure
Range	Systolic Pressure Range: 40 mmHg ~ 270 mmHg Diastolic Pressure Range: 10 mmHg ~ 215 mmHg Mean Artery Pressure Range: 20 mmHg ~ 235 mmHg
Cuff Pressure Range	0 mmHg ~ 300 mmHg
Pressure Resolution	1 mmHg (0.1 kPa)

Measurement Time Span	120 Seconds (Maximum)
Software Overpressure Protection	(297 ±3) mmHg [(39.6 0.4) kPa]
Hardware Overpressure Protection	(320 ±10)mmHg [(41.3±1.3) kPa]

（2）SpO2（EDAN）

SpO_2	
Measurement Range	50% ~ 100%
Resolution	1%
Accuracy	70% ~ 100%： ± 2% 50% ~ 69%： Not Defined
Pulse	
Measurement Range	30 bpm ~ 240 bpm
Resolution	1 bpm
Accuracy	± 3 bpm

3）SpO2（Nellcor）

SpO_2	
Measurement Range	50% ~ 100%
Resolution	1%
Accuracy	70% ~ 100%： ± 2% 50% ~ 69%： Not Defined
Pulse	
Measurement Range	30 bpm ~ 240 bpm
Resolution	1 bpm
Accuracy	± 3 bpm

4） TEMP

Channel Qty.	1
Measurement Range	0 ºC ~ +50.0 ºC (+32ºF ~ +122ºF)
Resolution	0.1 ºC (±0.18ºF)
Accuracy (Sensor inaccuracy not included)	+25ºC ~ +45ºC (+77ºF ~ +113ºF): ± 0.2ºC (±0.36ºF) Other measurement range: ± 0.3ºC

Sensor Type	YSI-10K
Refresh Time	Every 1 ~ 2 second(s)

6.1.6 Edan Transducer Socket Board (wired model only)

The EDAN transducer socket board locates on the left of the lower case, i.e. the left of the monitor. It communicates between the main control board and external transducer accessories. Its function is to isolate the signal of accessories, power supply and ground, and transfers collected SpO2 and TEMP signals to iM X12 parameter board.

Here is the principle block diagram:

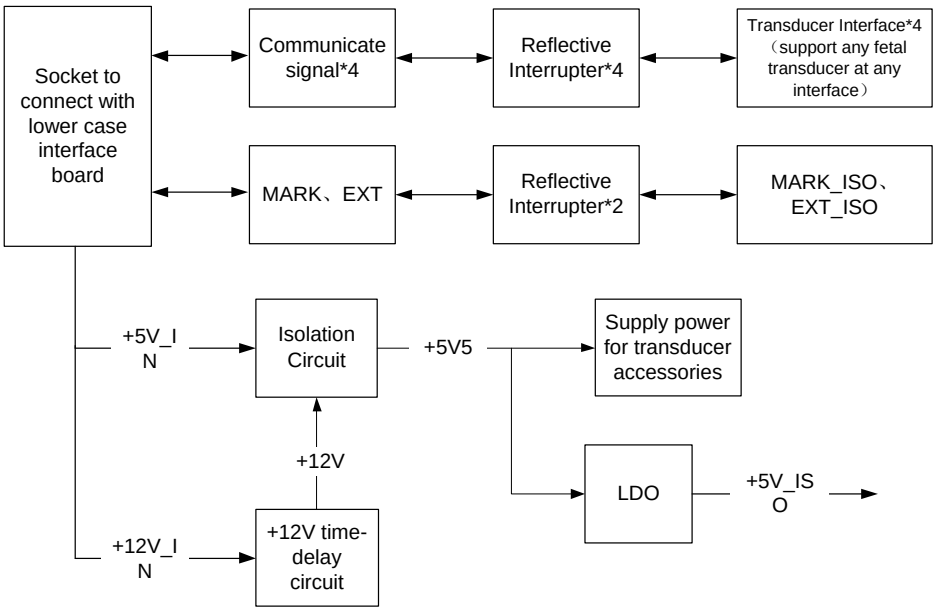


Figure 6-5 EDAN Transducer Socket Board Principle Block Diagram

Note:

The US, TOCO&MECG and DECG&IUP transducer can be plugged in and out at any of the 4 transducer interface.

6.1.7 NELL Transducer Socket Board (wired model only)

The NELL transducer socket board locates at left side of the lower case, i.e. the left of the monitor. The NELL transducer socket board communicates between the main control board and external transducer accessories. Its function is to isolate the signal of accessories, power supply and ground, and transfers collected SpO2 and TEMP signals to iM X12 parameter board.

Here is the principle block diagram:

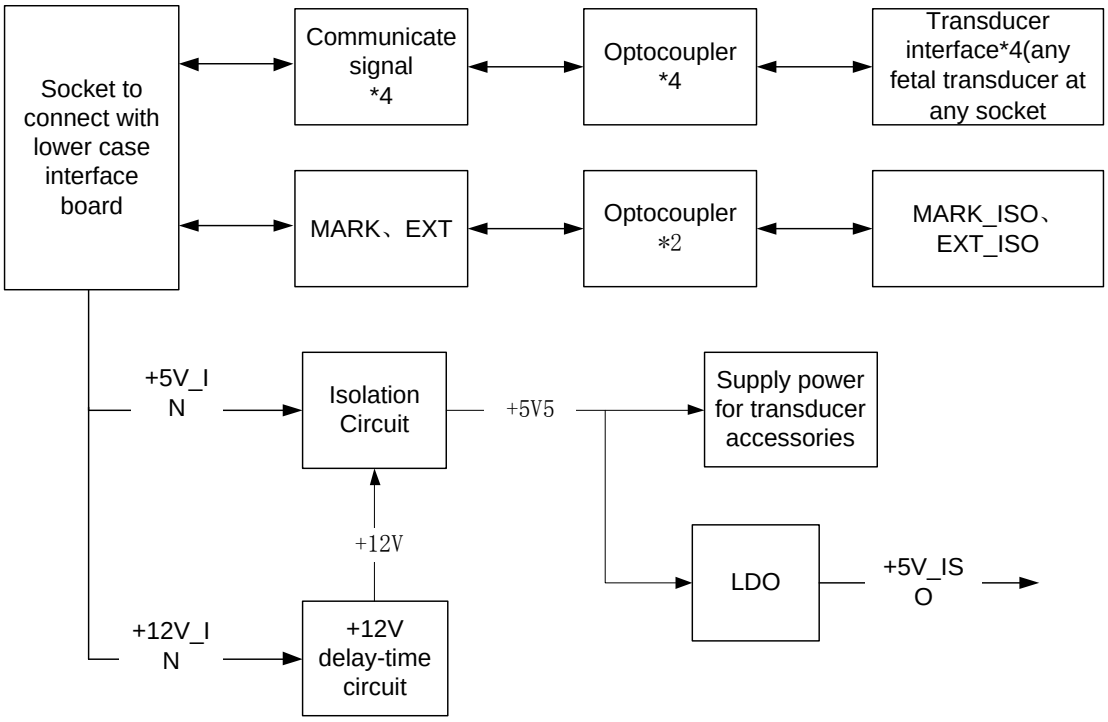


Figure 6-6 Nell Transducer Socket Board Principle Block Diagram

Note:

The US, TOCO&MECG and DECG&IUP transducer can be plugged in and out at any of the 4 transducer interface.

6.1.8 Wireless Charging Board (wireless model only)

The wireless charging board is only applicable in wireless model. It fulfills the following function: charging of wireless transducer, NFC communication and fan's control. When the transducer is docked properly, the main unit will charge the transducer and finishes NFC communication with transducer, at the same time, the fan will start to work.

Here is the principle block diagram:

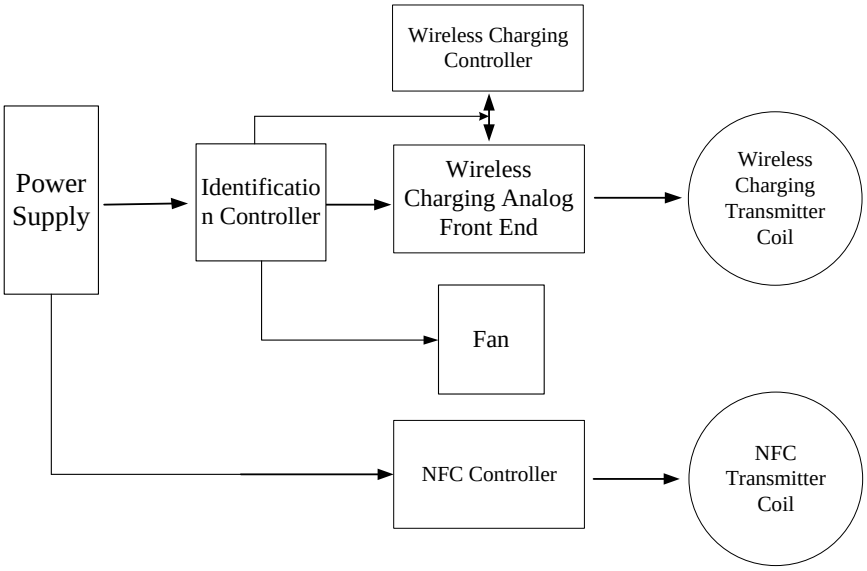


Figure 6-7 Wireless Charging Board Principle Block Diagram

6.2 Interface

On the rear panel of the monitor, there are two interfaces and an antenna:

- USB *2
- RJ45 interface (NETWORK)
- HDMI interface
- DB15 interface
- 485 Antenna (optional for domestic sales)

6.2.1 DB15 Interface

All the monitors are configured with a DB15 interface. It is used to connect the monitor to a computer for monitoring information collection, or to an obstetrical monitoring system such as MFM-CNS.

6.2.2 Antenna

If the monitor has a built-in wireless module, an antenna will be configured.

It is used to send signals of the bedside monitor to the obstetrical monitoring system.

6.2.3 RJ45 Interface

All the monitors are configured with a RJ45 interface.

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

6.2.4 HDMI Interface

All the monitors are configured with a HDMI interface. It is used to project the display of the monitor to an external display, the output resolution is 1080P.

Chapter 7 Troubleshooting

This troubleshooting guide introduces the suitable actions for correcting the problems or replacing the accessory or calling the service person. It can also help you to have more exact descriptions of the fault symptoms when calling for service.

EDAN supports replacement of PCBs and major subassemblies for this product. Verify the malfunction of the PCBAs/Modules prior to disassembling with the method described in chapter *8 Modules' Malfunction Verification*. When replacement is needed, follow the procedures described in chapter *9 Dissembling the Monitor*.

7.1 Monitor Booting Failures

Phenomenon	Possible Cause	Solution
After switching on, LCD has no display; the power indicator is off; the fan doesn't run.	No AC mains connected.	Check if the power cord is damaged. Check if the power cord is well connected to the power socket of the monitor and hospital AC outlet.
	Main control board defective.	Replace the main control board.
Abrupt switching off.	The monitor is stricken by strong high voltage, such as lighting strike.	Check the power supply and earth system.
	Bad power supply performance.	Replace power supply.
	Main control board defective.	Replace the main control board.
	Bad connection.	Check all the connectors.

7.2 Display Failures

Phenomenon	Possible Cause	Solution
The LCD has no display.	The LCD related cable(s) is (are) disconnected.	Check that the LCD related cables between the main control board and the LCD are well connected. Check that the LCD backlight cable is well connected.
	LCD defective.	Replace the LCD.
	Main control board defective.	Replace the main control board.

LCD displays improper characters.	LCD defective.	Replace the LCD.

7.3 Touch Screen Failures

Phenomenon	Possible Cause	Solution
The touch screen is not functioning.	The touch screen related cable(s) is (are) disconnected.	Check that the touch screen related cables between the main control board, touch screen controlling board and the touch screen are well connected.
	The touch screen is damaged.	Replace the touch screen.
The touch position invalid.	The touch screen is not calibrated.	Calibrate the touch screen using procedures described in section *4.6 Calibrating Touch Screen*.

7.4 Sound Failures

Phenomenon	Possible Cause	Solution
Hoarse or odd sound from loudspeaker.	Loudspeaker defective.	Replace the loudspeaker.
	Main control board defective.	Replace the main control board.

7.5 Recorder Failures

Phenomenon	Possible Cause	Solution
No paper advances.	No paper in the drawer.	Load paper and close the drawer.
	Paper drawer is open.	Close the drawer.
	Paper jam.	Open the drawer and remove the paper jam. Re-load paper then close the drawer.
	Print controlling board defective.	Replace the print controlling board.
	Recorder connection failure.	Check all the connectors.
	Gear assembly defective.	Replace the gear assembly.
	Main control board defective.	Replace the main control board.
The “Check paper” alarm message appeared on the screen, but the drawer is not empty.	Paper sensor dirty.	Clean the paper sensor with a dry clean cloth.
	Paper sensor defective.	Replace the paper sensor.

	The paper drawer is not closed properly.	Push the drawer back in position.
Blank, blurry or incorrect traces.	Paper is not correctly loaded.	Reload paper correctly.
	The printhead adjusting nuts are lopsided.	Adjust the printhead adjusting nuts.
	Print head defective.	Replace the printhead.
	Improper paper settings of the monitor.	Set paper style according to section *5.12 Changing Paper Style*.

7.6 Network Failures

Phenomenon	Possible Cause	Solution
The monitor can not connect to a network.	The bottom interface board defective.	Replace the bottom interface board.
	Bad connection between the bottom interface board and main control board.	Check the connection.
	Main control board defective.	Replace main control board.
	Overlapped device no. in the network.	Change device no. of the monitor.
	Incorrect sever IP setting.	Set server IP correctly.

7.7 Alarm Failures

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

7.8 Alarm Failures

Phenomenon	Possible Cause	Solution
FETUS 302 MODULE MALF or Extend 302 MODULE MALF or FETUS 417 MODULE MALF.	Wired and wireless model is selected by mistake.	Re-set the model type.
	Main control board defective.	Replace the main control board.
SpO2 EQUIP MALF	Bad connection between iM X12 parameter board and main control board.	Check the connection.
	iM X12 parameter board defective.	Replace the iM X12 parameter board.
	Main control board defective.	Replace the main control board.

7.9 FHR/TOCO Monitoring Failures

Phenomenon	Possible Cause	Solution
No FHR/TOCO trace or numeric value.	Bad connection of the transducers.	Check the connection.
	US Transducer defective.	Replace the transducer.
	Transducer socket board defective.	Replace the transducer socket board.
	Bad connection between the transducer socket board, bottom interface board and main control board.	Check the connection.
	Main control board defective.	Replace the main control board.
Lower heart beat or no sound.	Loudspeaker defective.	Replace the loudspeaker.
	US transducer defective.	Replace the US transducer.
	Main control board defective.	Replace the main control board.
Inaccurate measurement values.	US Transducer defective.	Replace the transducer.
	Main control board defective.	Replace the main control board.

7.10 ECG Monitoring Failures

Phenomenon	Possible Cause	Solution
No ECG trace.	Bad connection of ECG cable.	Check the connection.
	Cables defective.	Replace the cables.

	Bad connection of electrodes.	Check the connection.
	TOCO&MECG Transducer defective.	Replace the TOCO&MECG Transducer.
	Main control board defective.	Replace the main control board.

7.11 SpO2 Monitoring Failures

Phenomenon	Possible Cause	Solution
No SpO_2 waveform or numeric value.	SpO_2 transducer defective.	Replace the SpO_2 transducer.
	Bad connection of SpO_2 cable.	Check the connection.
	iM X12 parameter board defective.	Replace the iM X12 parameter board.
	Main control board defective.	Replace the main control board.

7.12 NIBP Monitoring Failures

Phenomenon	Possible Cause	Solution
The cuff fails to be inflated.	Bad connection of the cuff, the air hose and the NIBP socket.	Check the connection from outside.
	Bad connection of the iM X12 board to the NIBP socket.	Check the connection from inside.
	Cuff or extension tube defective.	Replace the damaged part(s).
	Air pump, air valve leak.	Replace pump valve module.
	iM X12 parameter board defective.	Replace the iM X12 parameter board.
	Main control board defective.	Replace the main control board.
No NIBP numeric values.	iM X12 parameter board defective.	Replace the iM X12 parameter board.
	Air pump, air valve leak.	Replace pump valve module.
	Main control board defective.	Replace the main control board.

7.13 TEMP Monitoring Failures

Phenomenon	Possible Cause	Solution
No TEMP numeric value.	TEMP transducer defective.	Replace the TEMP transducer.
	Bad connection of TEMP transducer.	Check the connection.
	iM X12 parameter board defective.	Replace the iM X12 parameter board.
	Main control board defective.	Replace the main control board.

Chapter 8 Modules' Malfunction Verification

When a module is suspected of malfunction, verify it with the method described in this chapter.

NOTE:

For all the interfaces, the first pin is the one with a square solder pad.

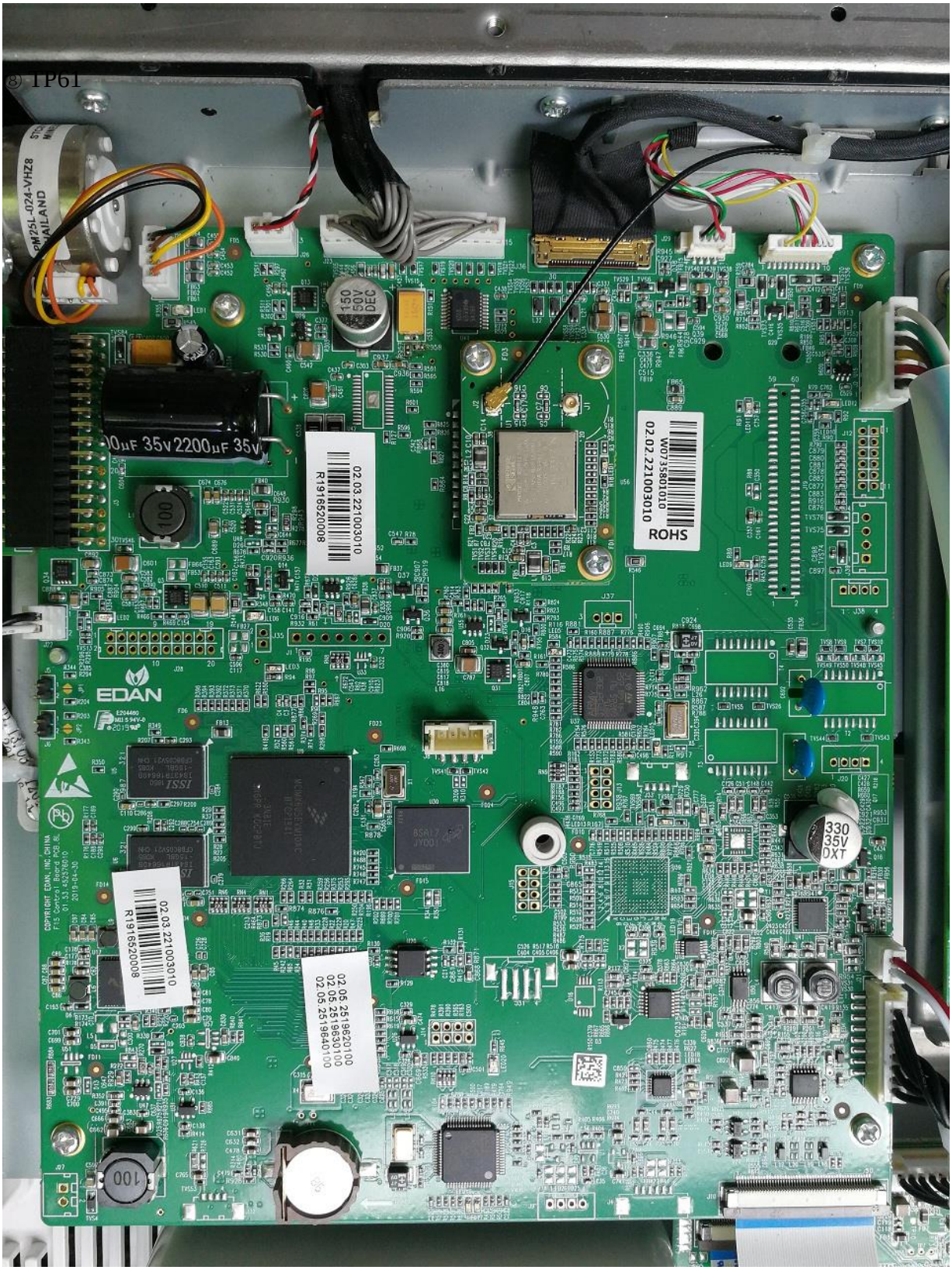
8.1 Verifying Malfunction of the Main Control Board

To verify the main control board,

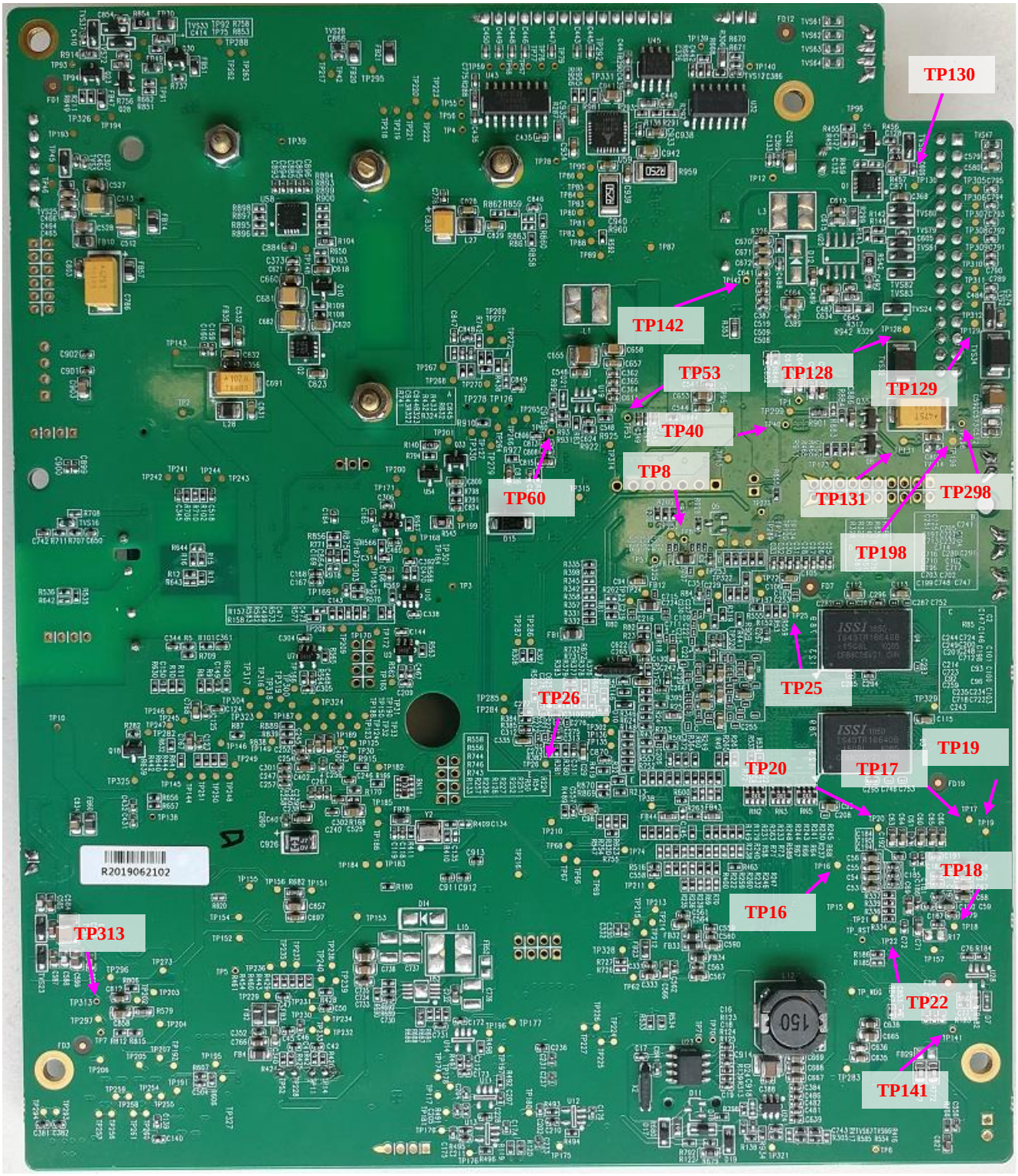
1) Open the main unit using the procedures described in section 9.3.
2) Switch on the monitor. (Powered by AC or battery.)
3) Measure the voltage to earth of the pins listed below, using a multimeter:

Item	Test Pin	Reference Result	Remark
1	TP198 (19V3_IN)	18.7~19.9VDC	Voltage outputted from power supply to main control board
2	TP128 (+5V_IN)	4.75~5.25V	
3	TP129 (+12V_IN)	11.40~12.60V	
4	TP130 (V_PRT_IN,24V)	22.80~25.20V	
5	TP131 (VBUS)	8.25~12.60VDC (batteries supply power) or 18.7~19.9VDC (AC supply power)	
6	TP25 (3.3V)	3.14~3.46V	Working pressure of U9 (iMX6) main control chip
7	TP26 (3.3V)	3.14~3.46V	
8	TP22 (1.5V)	1.40~1.60V	
9	TP16 (1.375V@default; 1.425V@1GHz)	1.20~1.57V	
10	TP17 (3V)	2.85~3.15V	
11	TP18 (3V)	2.85~3.15V	
12	TP19 (1.5V)	1.42~1.58V	
13	TP20 (1.8V)	1.71~1.89V	
14	TP8 (1.375V@default;	1.20~1.57V	

	1.425V@1GHz)		
15	TP60	3.14~3.46V	DC-DC power output on the main control board
16	TP141	3.14~3.46V	
17	TP142	3.14~3.46V	
18	TP53	3.14~3.46V	
19	TP313	5.04~5.56V	
20	TP40	4.75~5.25V	
21	TP298	11.40~12.60V	



Main control board



Back of the Main control board

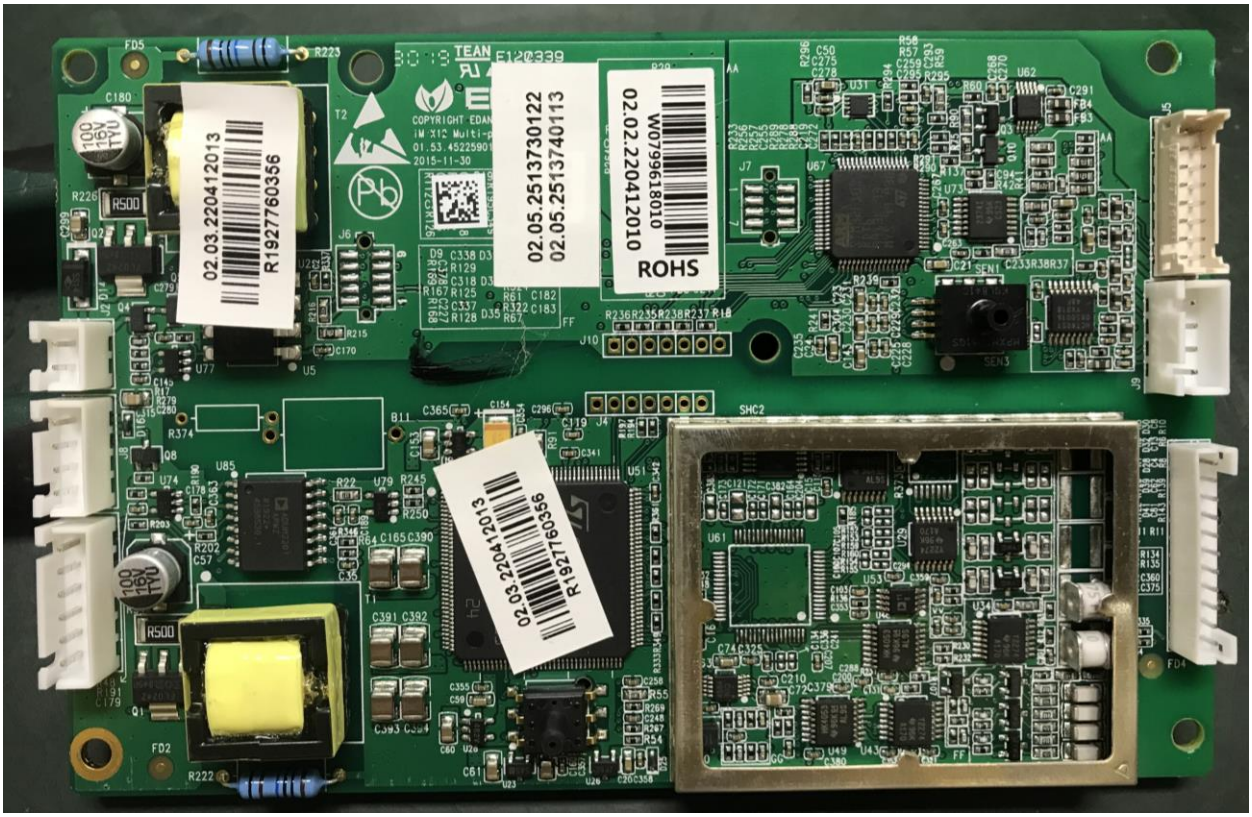
4) Compare the measurement results with the reference results in the list. If any one of the results exceeds the reference range, the main control board defection is confirmed. Replacement of the main control board is recommended.

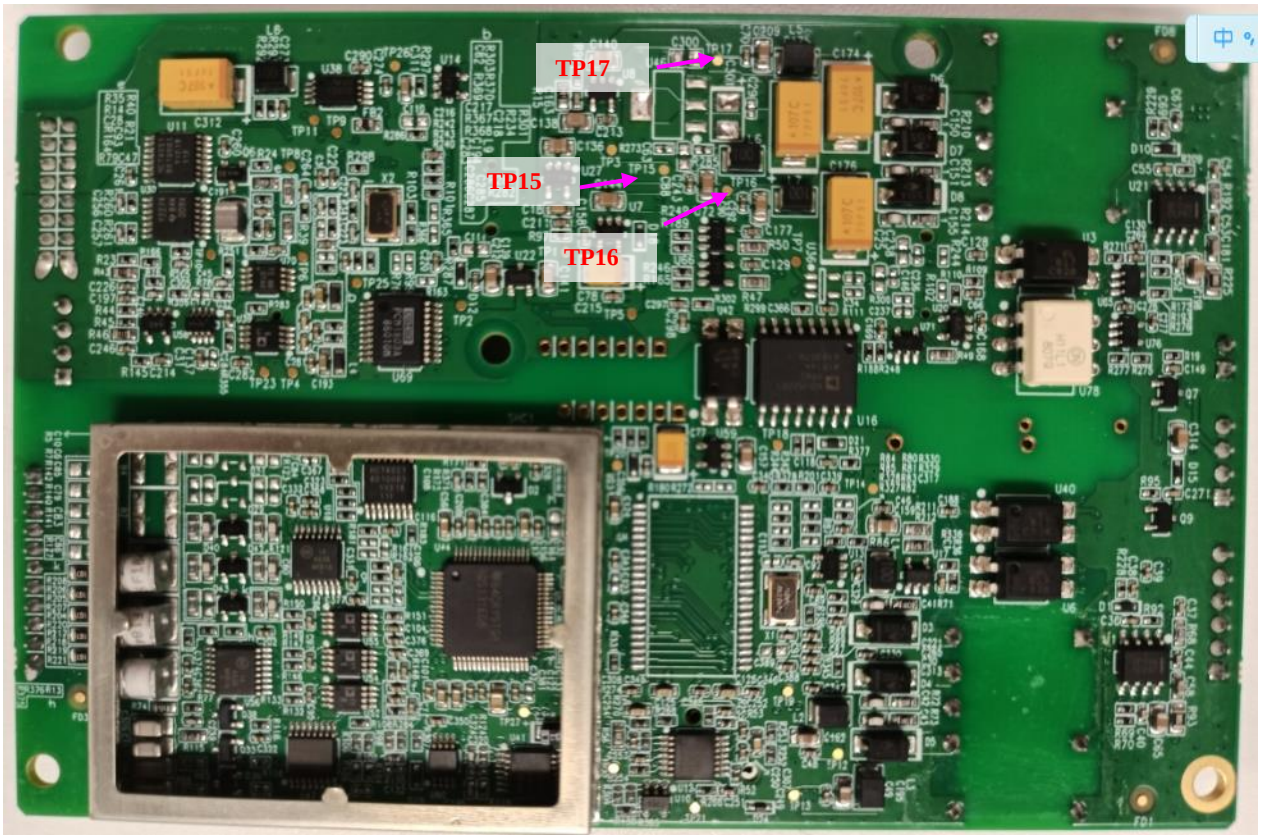
8.2 Verifying Malfunction of the iM X12 Parameter board

To verify the iM X12 parameter board,

1) Open the main unit using the procedures described in section 9.3.
2) Switch on the monitor. (Powered by AC or battery.)
3) Measure the voltage to earth of the pins listed below, using a multimeter:

Item	Reference Pin	Test Pin	Reference Result
①	R223.2(FGND2)	TP15	+4.9V±5%
②	R223.2 (FGND2)	TP16	-6.4V±5%
③	R223.2 (FGND2)	TP17	+6.4V±5%





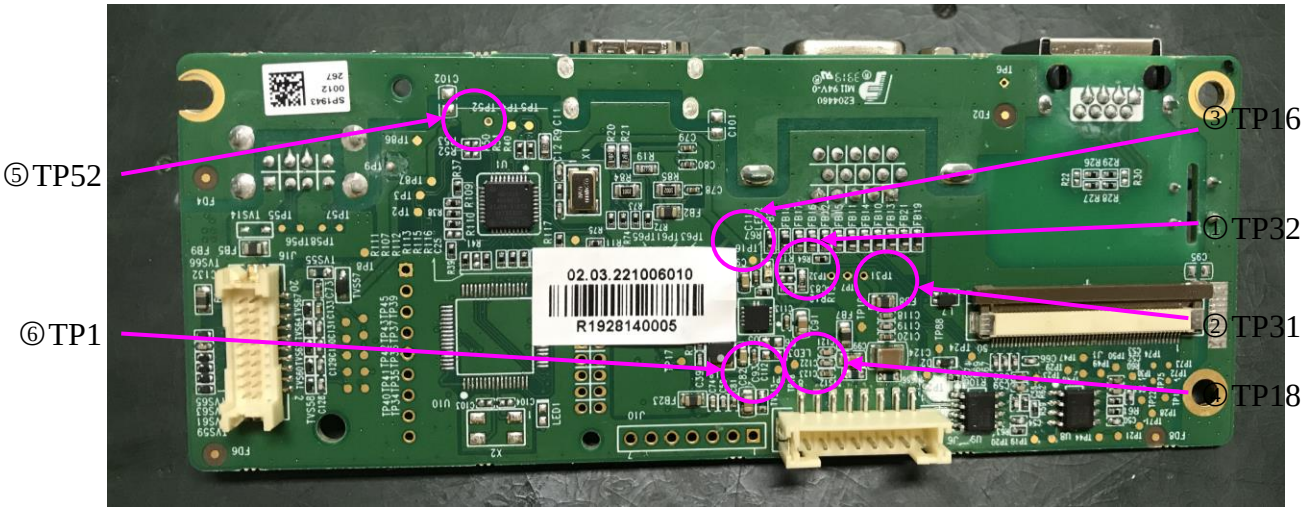
4) If any one of the results exceeds the reference range, the iM X12 parameter board defection is confirmed. Replacement of the iM X12 parameter board is recommended.

8.3 Verifying Malfunction of Lower Case Interface Board

To verify the lower case interface board,

1) Open the main unit using the procedures described in section 9.3.
2) Switch on the monitor. (Powered by AC or battery.)
3) Measure the voltage to earth of the pins listed below, using a multimeter:

Item	Test Pin	Reference Result	Remark
①	TP32	4.75~5.25V	
②	TP31	11.40-12.60V	
③	TP16	3.14-3.46V	
④	TP18	4.75~5.25V	
⑤	TP52	4.75~5.25V	
⑥	TP1	3.14-3.46V	Test only when connected with 485 module



Lower case interface board

5) If any one of the results exceeds the reference range, the lower case interface board defection is confirmed. Replacement of the module is recommended.

8.4 **Verifying Malfunction of AC-DC Power Board**

To verify the AC-DC power board,

1) Open the main unit using the procedures described in section 9.3.
2) Switch on the monitor. (Powered by AC or battery.)
3) Measure the voltage to earth of the pins listed below, using a multimeter:

Item	Reference Pin	Test Pin	Reference Result
①	1st and 2nd pin of J3	3rd and 4th pin of J3	18.70-19.90V

4) If any one of the results exceeds the reference range, the AC-DC power board defection is confirmed. Replacement of the board is recommended.

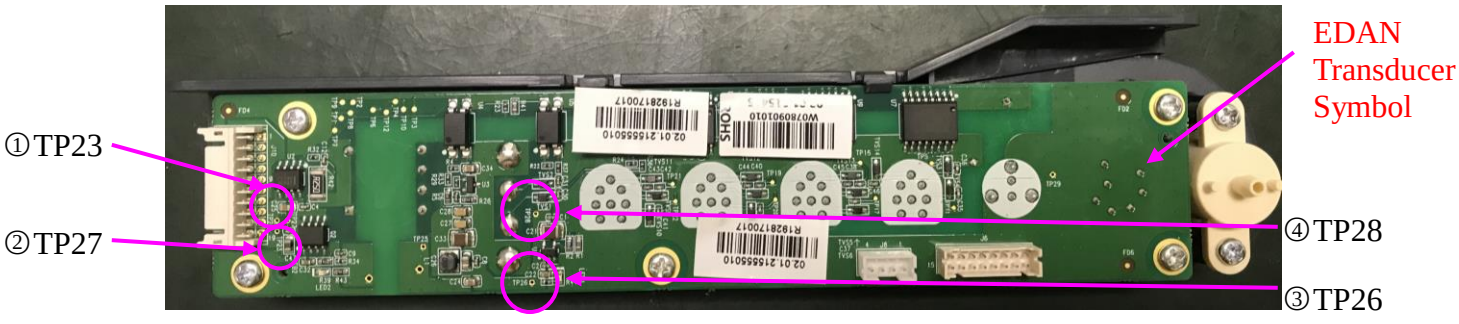


8.5 Verifying Malfunction of EDAN Transducer Socket Board (wired model only)

To verify the EDAN transducer socket board,

1) Open the main unit using the procedures described in section 9.3.
2) Switch on the monitor. (Powered by AC or battery.)
3) Measure the voltage to earth of the pins listed below, using a multimeter:

Item	Reference Pin	Test Pin	Reference result
①	TP24(GND)	TP23	4.75~5.25V
②	TP24(GND)	TP27	11.4~12.6V
③	TP25(FGND)	TP26	5.23-5.78V
④	TP25(FGND)	TP28	4.75-5.25V



EDAN Transducer Socket Board

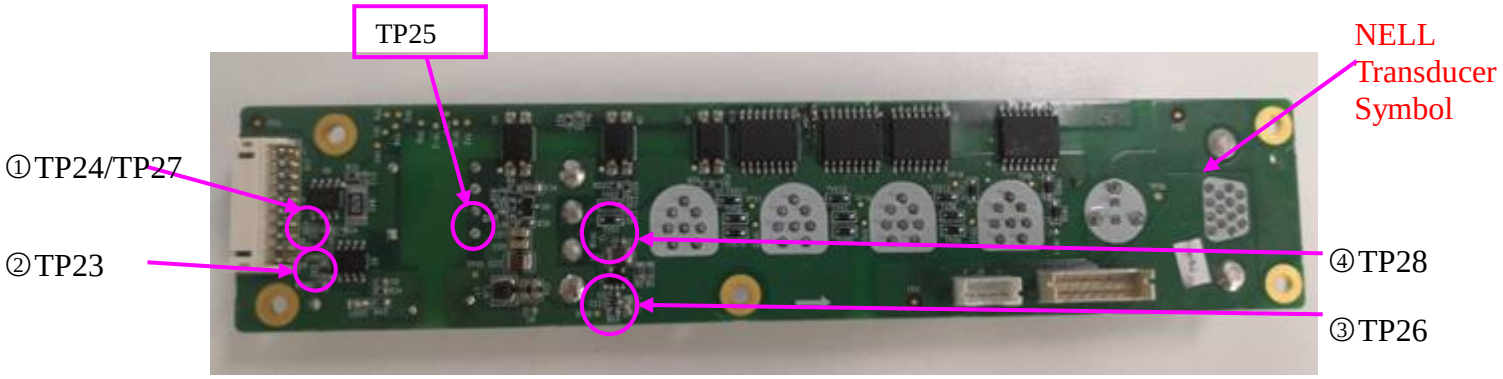
4) If any one of the results exceeds the reference range, the EDAN transducer socket board defection is confirmed. Replacement of the board is recommended.

8.6 Verifying Malfunction of NELL Transducer Socket Board (wired model only)

To verify the NELL transducer socket board,

1) Open the main unit using the procedures described in section 9.3.
2) Switch on the monitor. (Powered by AC or battery.)
3) Measure the voltage to earth of the pins listed below, using a multimeter:

Item	Reference Pin	Test Pin	Reference result
①	TP24(GND)	TP23	4.75~5.25V
②	TP24(GND)	TP27	11.4~12.6V
③	TP25(FGND)	TP26	5.23-5.78V
④	TP25(FGND)	TP28	4.75-5.25V



NELL Transducer Socket Board

4) If any one of the results exceeds the reference range, the NELL transducer socket board defection is confirmed. Replacement of the board is recommended.

8.7 Verifying Malfunction of Wireless Charging Board

To verify the wireless charging board,

1) Open the main unit using the procedures described in section 9.3.
2) Switch on the monitor. (Powered by AC or battery.)
3) Measure the voltage to earth of the pins listed below, using a multimeter:

Item	Test Pin	Reference result
①	TP7	4.7V~5.6 V
②	TP8	3.135V~3.46 V



4) If any one of the results exceeds the reference range, the wireless charging board defection is confirmed. Replacement of the board is recommended.

Chapter 9 Disassembling the Monitor

WARNING

1 Only qualified service personnel should open the monitor case.

2 Switch off the monitor and remove the AC power cable before disassembling the monitor.

3 After any repair of the monitor, perform safety tests before using the monitor again.

9.1 Tools Required

1 – A cross-head screwdriver

2 – A flat-head screwdriver

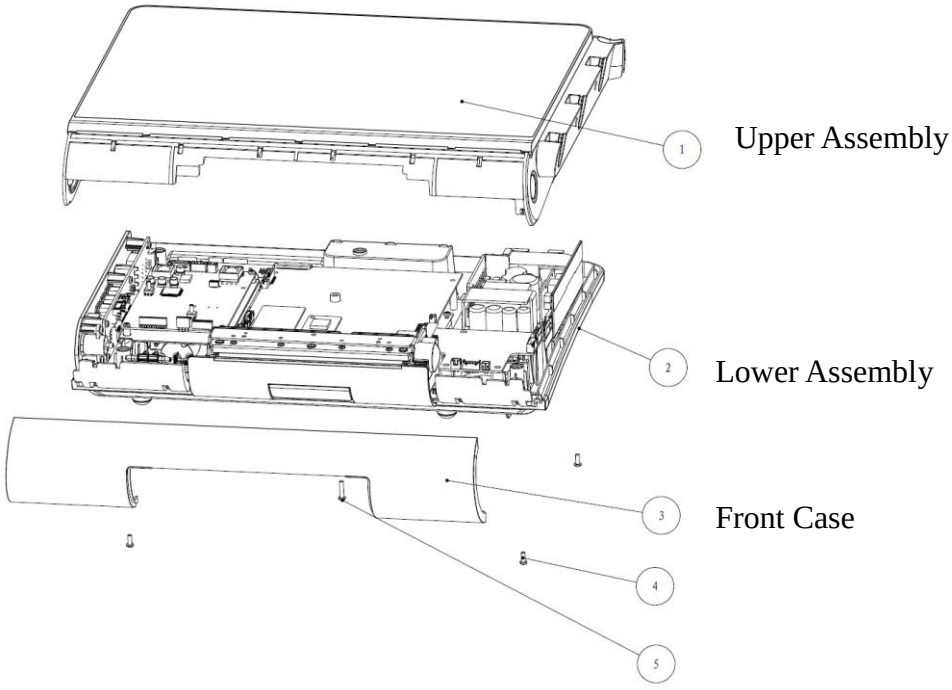
3 – A M3 nut driver

4 – A pair of pliers



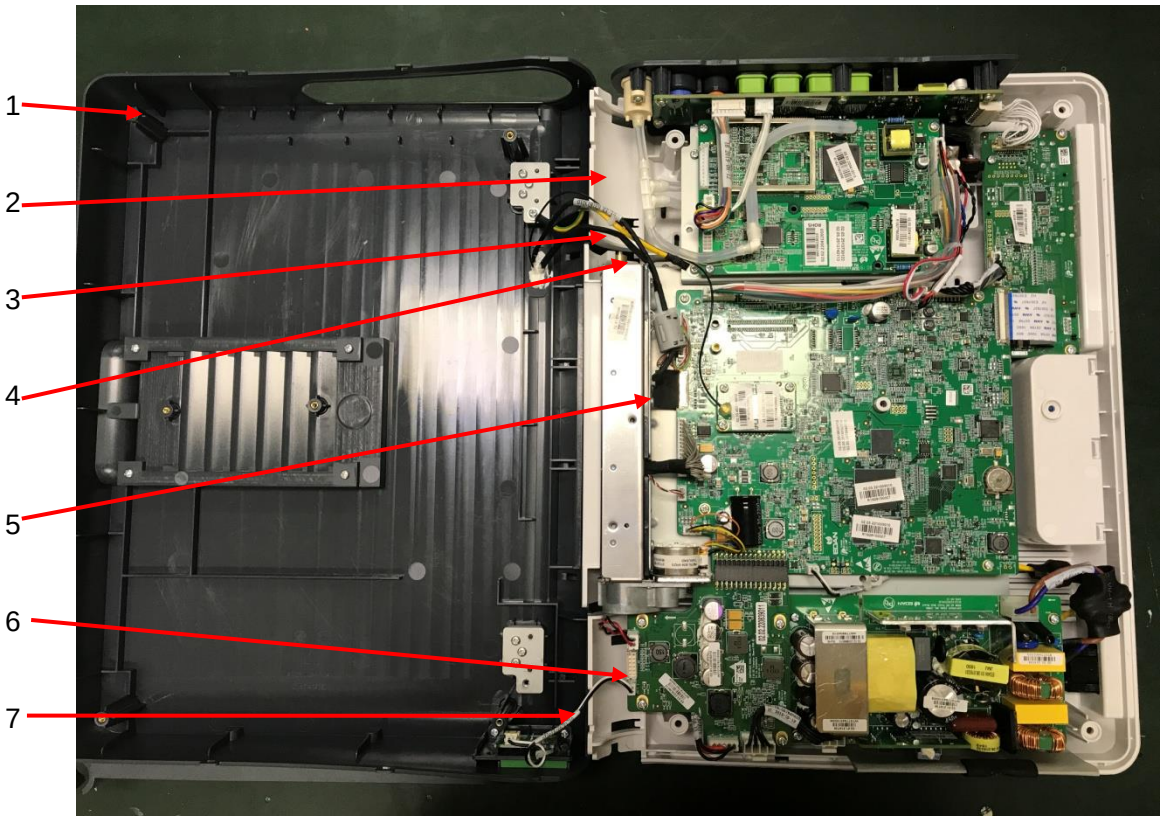
9.3 Disassembling the Main Unit

The main unit consists of two major parts: upper assembly and lower assembly.



To disassemble the main unit,

1) Fold the LCD display completely flat.
2) Carefully place the monitor upside down on a flat surface covered with cloth or other protecting pad.
3) Take off the front case.
4) With a cross-head screw driver, remove the six screws securing the upper assembly to the lower assembly.
5) Hold both upper and lower assemblies together, place the monitor upright again.
6) Carefully lift up the upper assembly and place it upside down on the left side of the lower assembly.



1 –Upper assembly

2 –Lower assembly

3 –Ground Wire

4 –Touching/Alarm Indicator/Indicator Connection Cable

5 –Display Connection Wire

6 –Charging Stand Connection Wire (wireless model only)

6 –Switch Connection Wire

7) Disconnect the cables/wires to separate the two parts.

9.4 Disassembling the Lower assembly

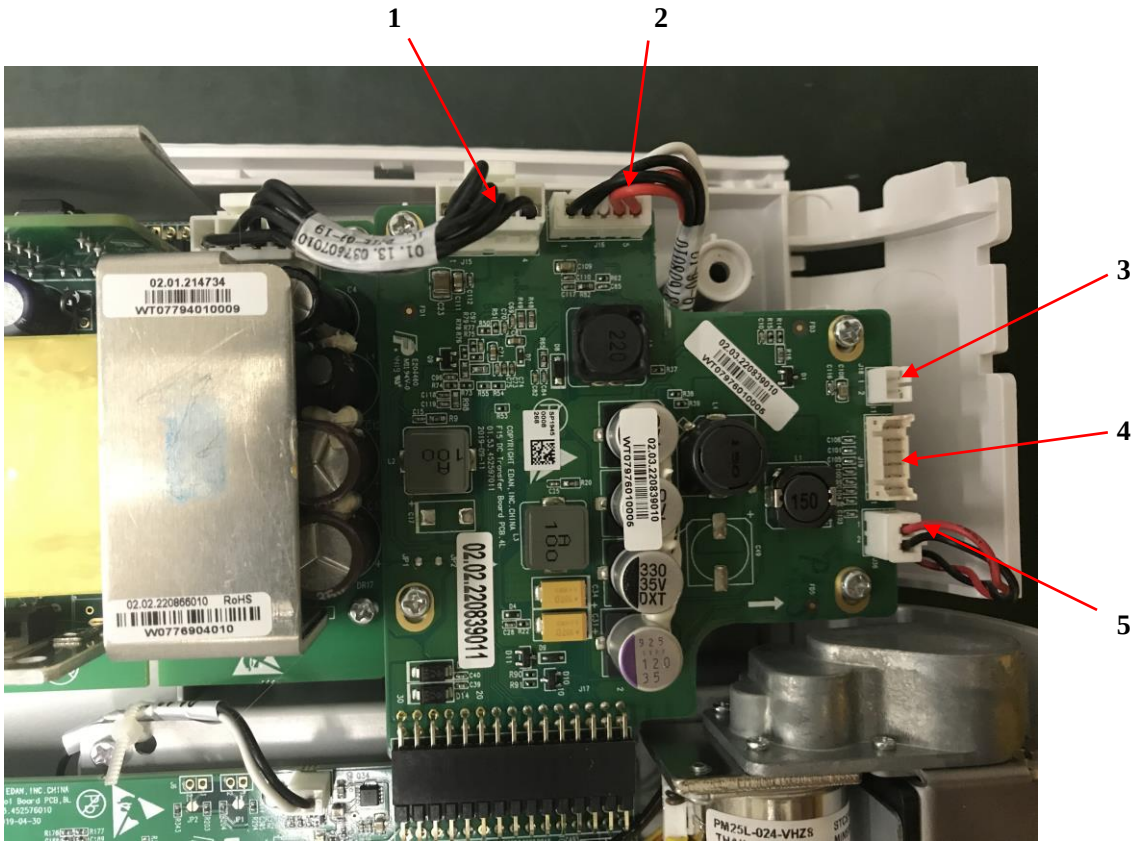
9.4.1 Replacing the DC-DC Transfer Board

To remove the DC-DC transfer board,

1) Separate the upper assembly and the lower assembly.
2) Remove the four screws on the DC-DC transfer board.
3) Disconnect all the wires.
4) Remove the studs/screw securing the DC-DC transfer board.

To replace the DC-DC transfer board,

Replace the DC-DC transfer board in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



1： Power Output Cable Socket

2： Battery Charging Cable Socket

3： Switch Connection Cable Socket

4： NFC Connection wire socket

5： Fan connection socket

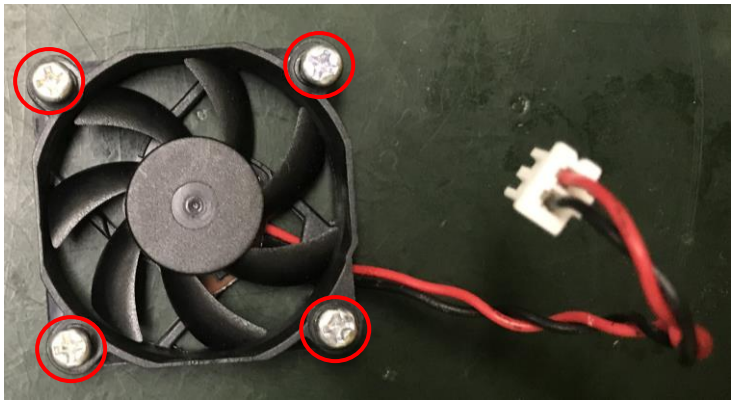
9.4.2 Replacing the Fan

To remove the fan,

1) Separate the DC-DC transfer board per section 9.4.1.
2) Remove the four screws on the fan.
3) Disconnect all the wires.

To replace the fan,

Replace the fan in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



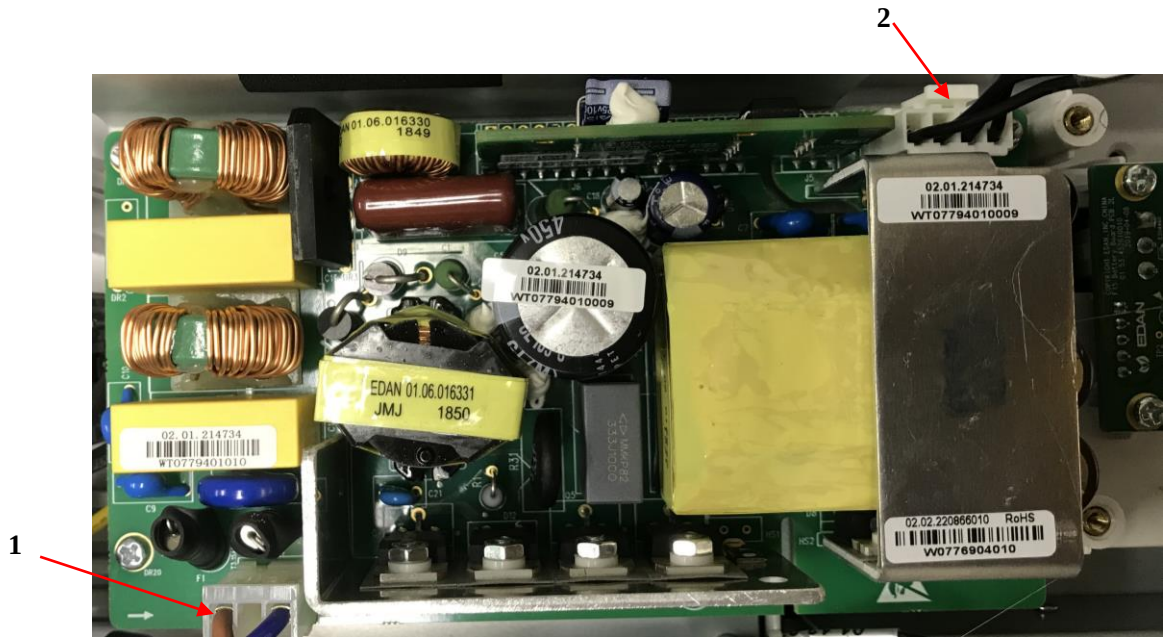
9.4.3 Replacing the Power Module

To remove the power module,

1) Separate the upper assembly and the lower assembly.
2) Disconnect all the wires.
3) Remove the4 screws securing the power module.

To replace the power module,

Replace the power module in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



No.	Connect to
1	Power supply socket
2	DC-DC transfer board

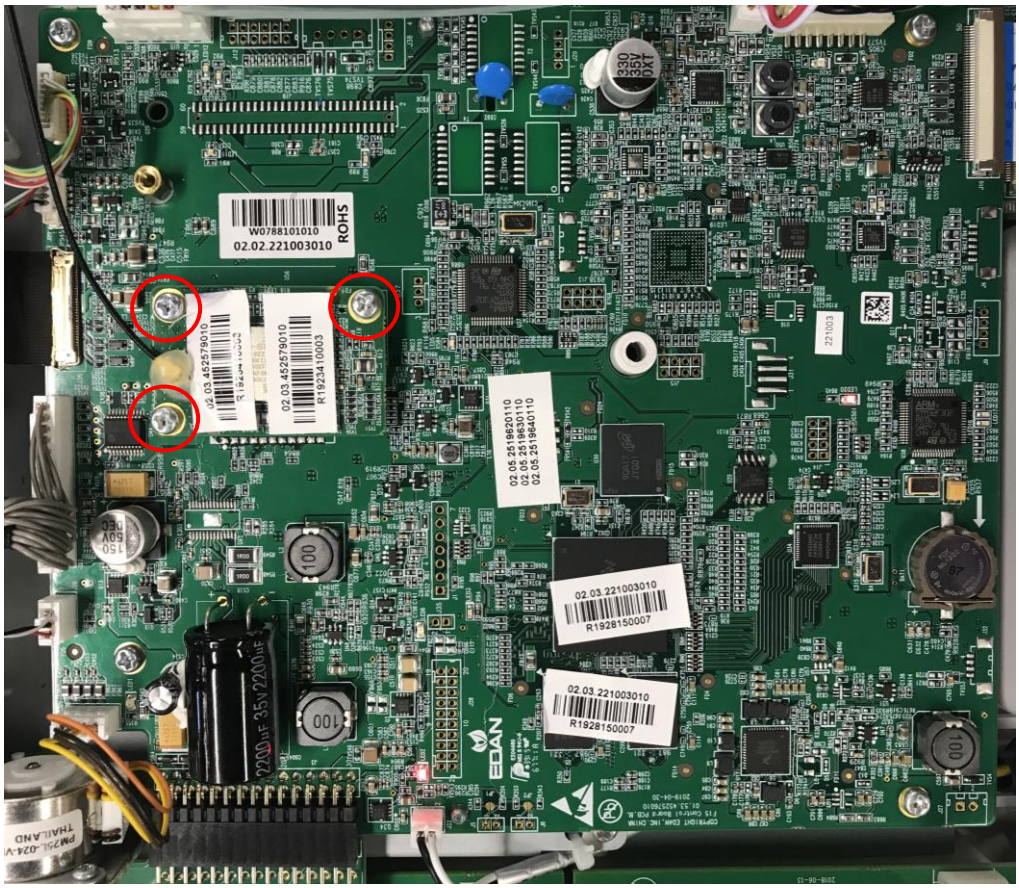
9.4.4 Replacing the WIFI Module

To remove the WIFI module,

1) Separate the upper assembly and the lower assembly.
2) Remove the 3 screws on the WIFI module.

To replace the WIFI module,

Replace the WIFI module in a reverse procedure.



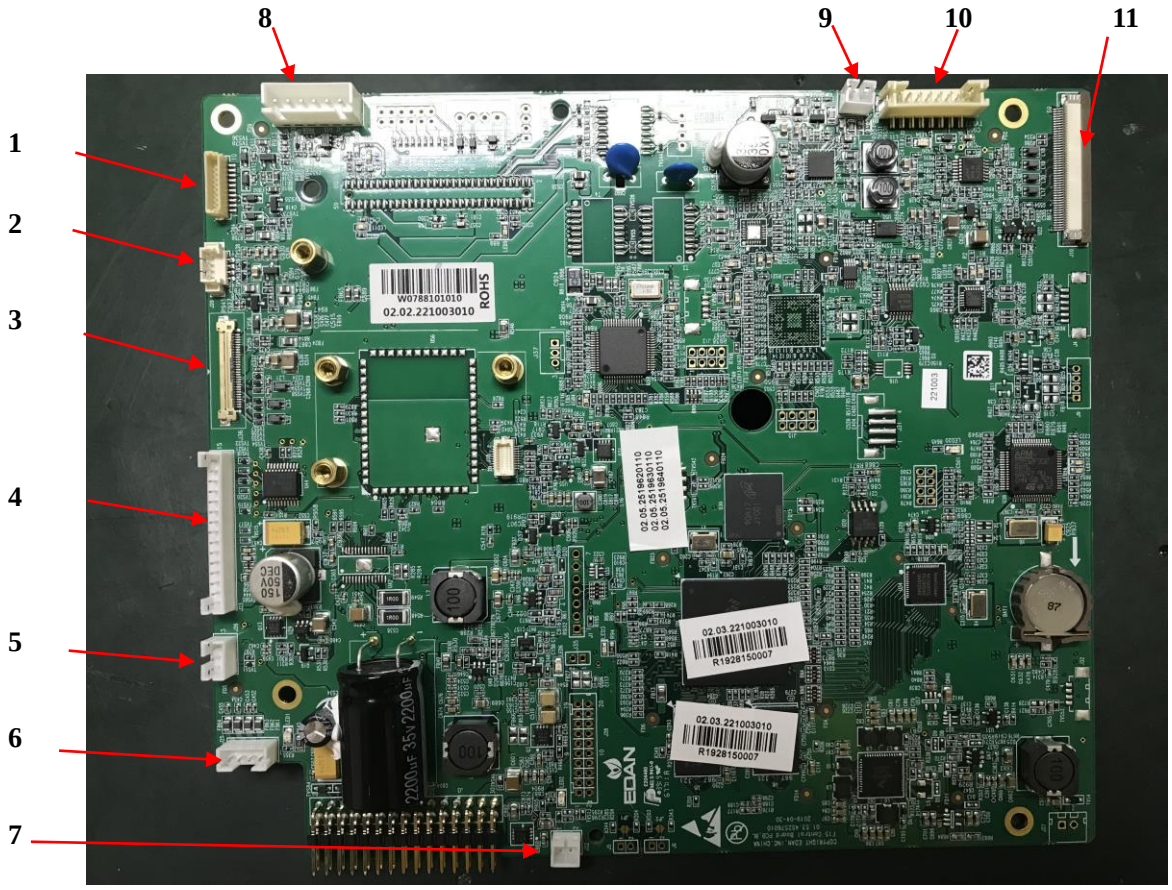
9.4.5 Replacing the Main Control Board

To remove the main control board,

1) Separate the upper assembly and the lower assembly.
2) Disconnect all the wires.
3) Remove the 4 screws securing the main control board.

To replace the main control board,

Replace the main control board in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



No.	Connect to
1	alarm indicator/indicator board
2	touchscreen
3	screen
4	printer head
5	out-of paper checking board
6	motor
7	paper drawer in place checking switch
8	maternal parameter board
9	loudspeaker
10	bottom interface board
11	top interface board

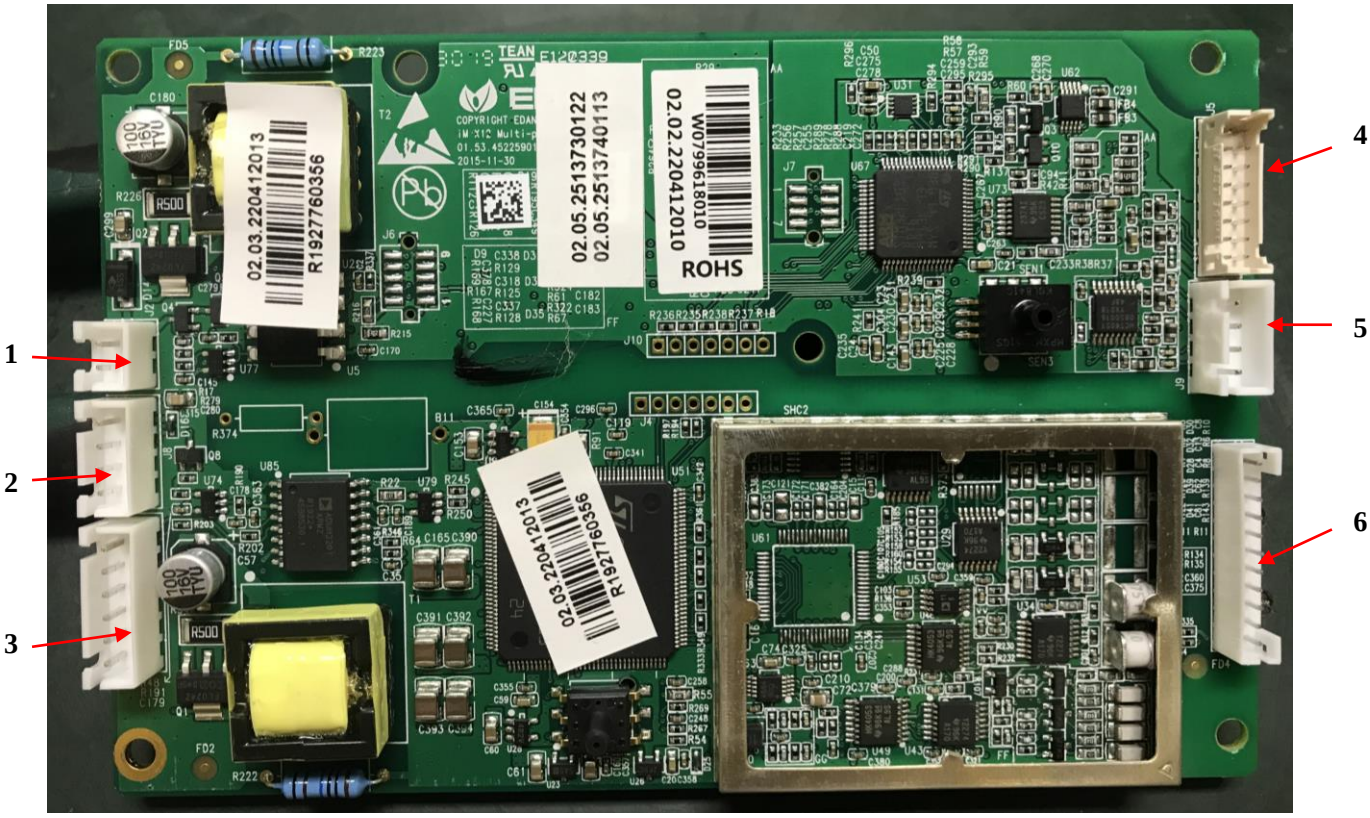
9.4.6 Replacing the iM X12 Parameter Board (wired model only)

To remove the iM X12 parameter board,

1) Separate the upper assembly and the lower assembly.
2) Disconnect all the wires.
3) Remove the four screws on the iM X12 parameter board.

To replace the iM X12 parameter board,

Replace the iM X12 parameter board in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



No.	Connect to
1	pump connection wire
2	air valve connection wire
3	main control board
4	SpO2 connection wire
5	TEMP connection wire
6	NA

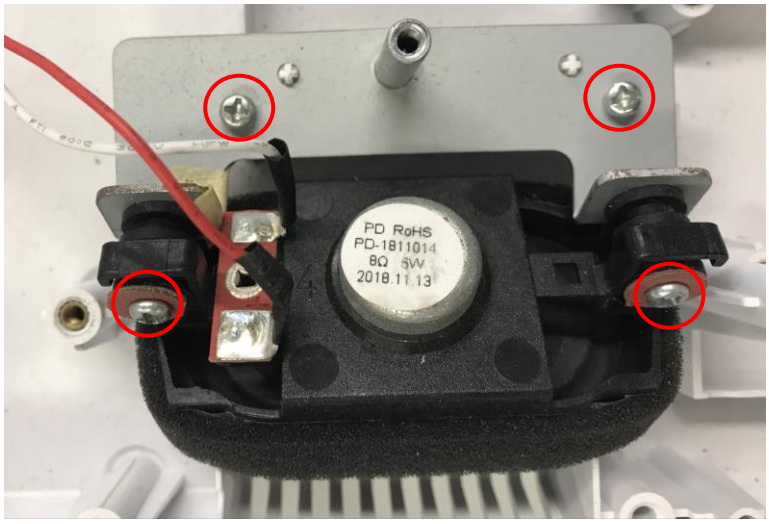
9.4.7 Replacing the Loudspeaker

To remove the loudspeaker,

1) Remove the iM X12 parameter board per section 9.4.6.
2) Remove the loudspeaker cable interface.
3) Remove the two screws on the loudspeaker supporting bracket.
4) Remove the studs/screw securing the loudspeaker.

To replace the loudspeaker,

Replace the loudspeaker in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



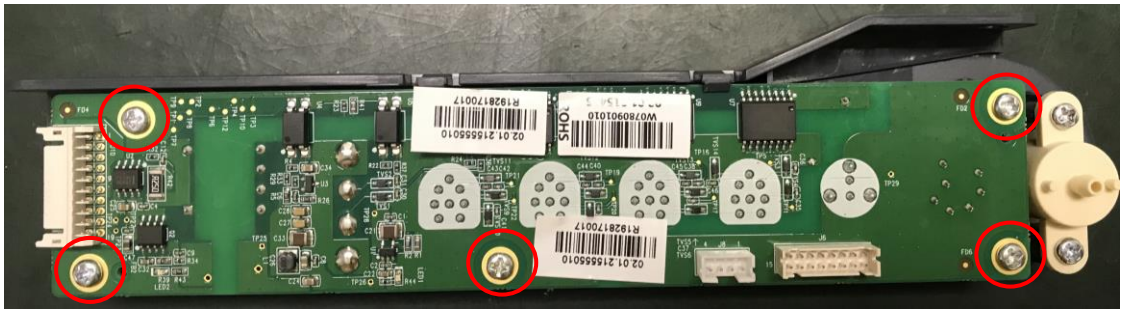
9.4.8 Replacing the Transducer Socket Board (wired model only)

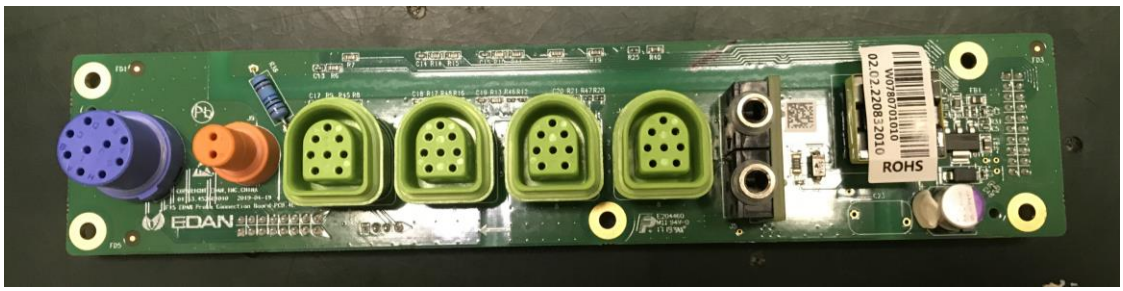
To remove the transducer socket board,

1) Separate the upper assembly and the lower assembly.
2) Remove the five screws on the transducer socket board.
3) Remove the rubber gaskets on the sockets.

To replace the transducer socket board,

Replace the transducer socket board in a reverse procedure.





9.4.9 Replacing the Bottom Interface Board

To remove the bottom interface board,

1) Separate the upper assembly and the lower assembly.
2) Remove all the cables on the bottom interface board.
3) Remove the four screws on the bottom interface board.

To replace the bottom interface board,

Replace the bottom interface board in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



No.	Connect to
1	bottom interface board
2	main control board
3	main control board

9.4.10 Replacing the Printhead

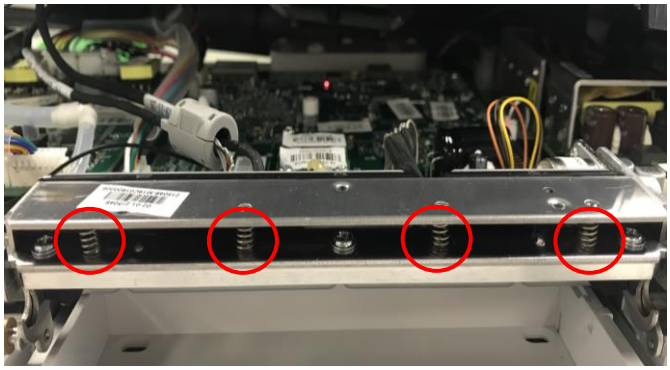
To remove the printhead,

1) Separate the upper assembly and the lower assembly.
2) Remove all the cables on the printhead assembly.
3) Remove the three screws on the printhead assembly.
4) Remove the four springs on the printhead assembly.
5) Take out the printhead.

To replace the printhead,

Replace the printhead in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.





CAUTION

The thermal printhead is a fragile part. Handle it with care.

9.4.11 Replacing the AP Module (wireless model only)

To remove the AP module,

1) Separate the upper assembly and the lower assembly.
2) Remove all the cables on the AP module.
3) Remove the screw on the AP module.

To replace the AP module,

Replace the AP module in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



9.4.12 Replacing the Wireless Transducer Bracket (wireless model only)

To remove the wireless transducer holder bracket,

1) Remove the two screws securing the wireless transducer holder bracket.

2) Remove all the cables on the wireless transducer holder bracket.

3) Remove the rubber gasket on the fan.

To replace the wireless transducer holder bracket,

Replace the wireless transducer holder bracket in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.





9.5 Disassembling the Upper Assembly

9.5.1 Replacing the LCD Assembly

To remove the LCD assembly,

1) Separate the upper assembly and the lower assembly.

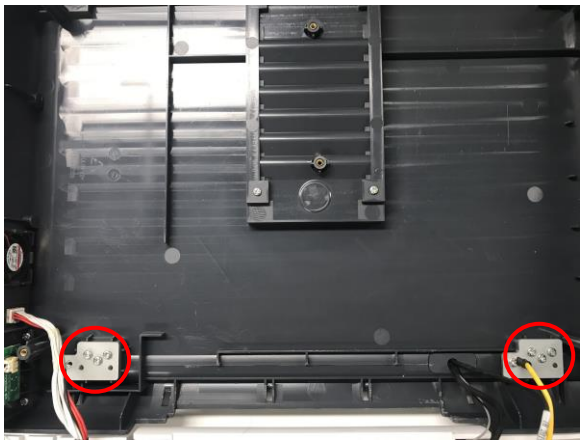
2) Carefully lift up the upper assembly and place it right side up. Remove the six screw securing the screen retaining plate.

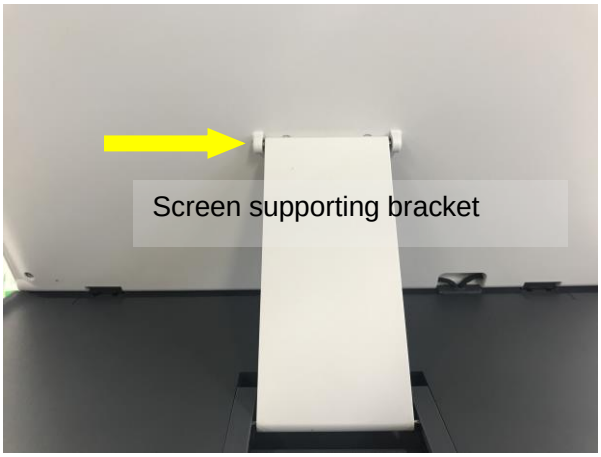
3) Use a slender tool and hold it against the spring in the hole of screen supporting bracket, and then remove the screen supporting bracket.

4) Remove the LCD assembly.

To replace the LCD assembly,

Replace the LCD assembly in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.





Chapter 10 Periodic Tests

10.1 Safety Tests

Safety tests should be performed by qualified personnel every 6 to 12 months, and each time after service.

Use a standard safety tester to perform safety tests. The tester must comply with IEC/EN 60601-1 or the local standards and statutes.

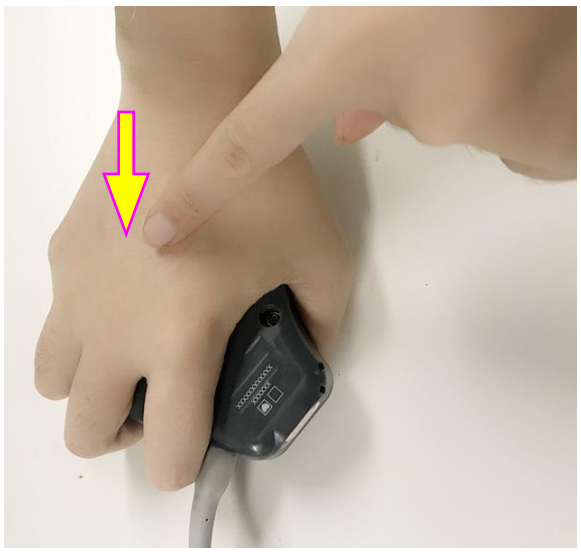
Refer to the accompanying operation instructions of the tester for test procedure details.

10.2 Performance Tests

The performance test should be done once every 12 months or when you suspect the measurement is incorrect.

10.2.1 FHR Performance Test

1) Switch on the monitor.
2) Connect the ultrasound transducer to the monitor.
3) Select the fetal heart sound for this channel.
4) Increase the loudspeaker volume to an audible level.
5) Open the palm of one hand and hold still while the other hand holding a US transducer moves back and forth facing the open palm, as illustrated in the picture below. The fetal heart sound should be heard during the whole process.



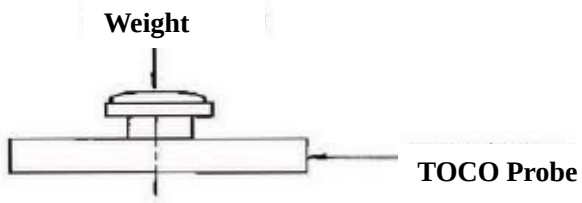
10.2.2 TOCO Performance Test

This test checks the performance of TOCO measurement.

1) Connect the TOCO transducer to the fetal monitor, adjust the pressure test tool to balance and lay the transducer horizontally on the tool surface so that the pressure spot of the tool is right in the middle of the transducer. Press **AUTO ZERO** to return to zero and the value on the monitor display is 10.

2) Add a weight of 50 grams and check if the value on the display is 34±8. Press **AUTO ZERO** to return to zero.

3)Add another weight of 50 grams and check if the value on the display is 34±8.



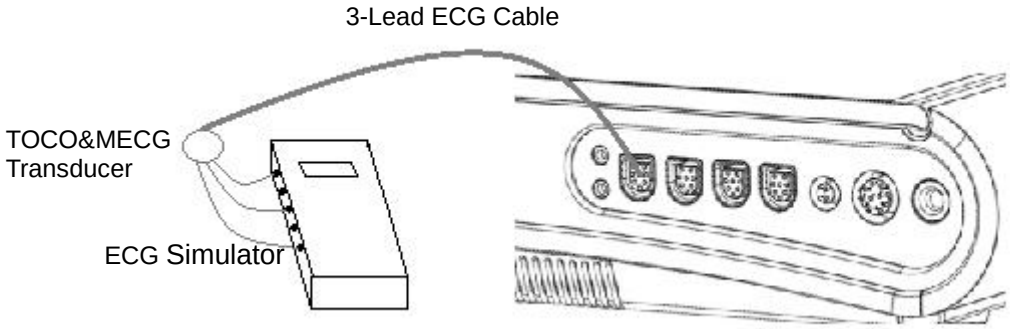
If a TOCO transducer fails the test, repeat this test with another transducer. If the second one passes the test, defect of the first transducer is confirmed. Replace it with a good one. If the second transducer fails the test as well, check the monitor.

10.2.3 ECG Performance Test

This test checks the performance of ECG measurement.

Required Equipment: ECG Simulator

1) Connect the equipment and the monitor as shown below:



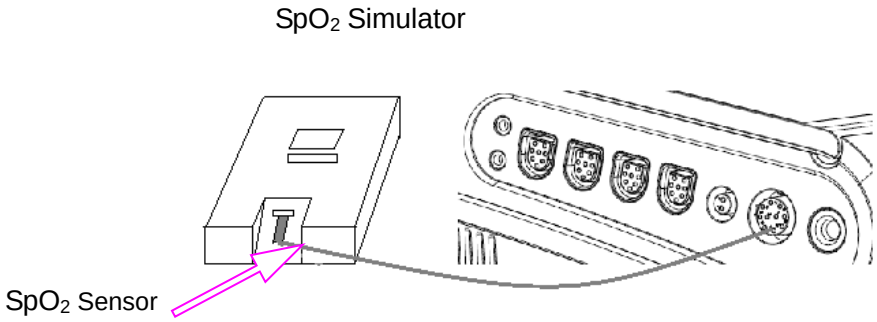
2) Switch on the monitor.
3) Generate the heart rate 30 bpm, 120 bpm and 240 bpm in turn.
4) Check if the HR value displayed on the screen is accurate. Error within 2 bpm is acceptable.

10.2.4 SpO2 Performance Test

This test checks the performance of SpO_2 measurement.

Required Equipment: SpO_2 Simulator

1) Connect the equipment and the monitor as shown below:



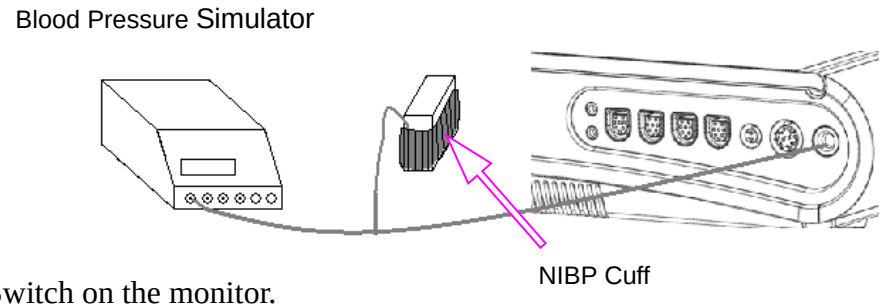
2) Switch on the monitor.
3) Generate the SpO2 signal 98% and 100% in turn.
4) Check if the SpO2 value displayed on the screen is accurate. Error within 2% is acceptable.

10.2.5 NIBP Performance Test

This test checks the performance of NIBP measurement.

Required Equipment: Blood Pressure Simulator

1) Connect the equipment and the monitor as shown below:



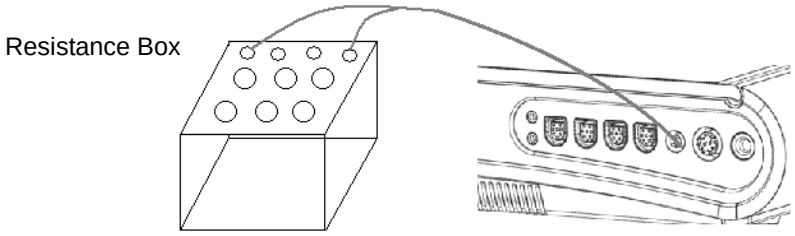
2) Switch on the monitor.
3) Generate the NIBP signal 270/215 (235) and 40/10(20) in turn.
4) Check if the NIBP value displayed on the screen is accurate. Error within 8 mmHg is acceptable.

10.2.6 TEMP Performance Test

This test checks the performance of TEMP measurement.

Required Equipment: Resistance Box

1) Connect the equipment and the monitor as shown below:



2) Switch on the monitor.

3) Adjust the resistance value to 32657Ω, 6017Ω and 3602.4Ω in turn.

4) The TEMP numeric value displayed on the screen correspond to 0 ℃, 37 ℃ and 50 ℃. Error within 0.2 ℃ is acceptable.

Remark：The test methods of the above parameters are the same for wireless and wired models. The only difference is that the connection method between the transducer and the main unit is wireless for wireless model.

10.2.7 FECG Performance Test（Wireless Model Only）

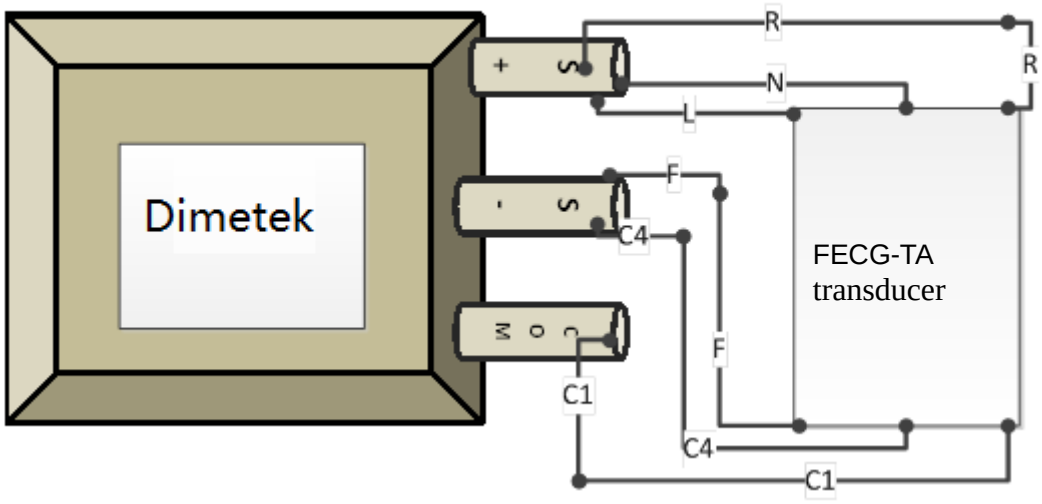
This test checks the performance of FECG measurement.

Required Equipment: interactive biomedical universal signal source (Dimetek)

1) Switch on the monitor.

2) Take up the FECG-TA transducer from the monitor and connect it to the monitor.

3) Connect the FECG-TA transducer to the test equipment as shown below.



4) Set the MECG amplitude to 1mV and FECG amplitude to 0.2mV on the pop-up maternal &fetal ECG signal setup interface of Dimetek.

5) Set the MRH/FHR to 30BPM/30BPM, 150BPM/150BPM, and 240BPM/240BPM respectively, wait for 10s after finishing the setup.

6) Check whether the HR value is accurate on the screen, error within 1 bpm can be

accepted.

Appendix 1 Renewal Parts

CAUTION

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

Repair Part	Part Number
F15 bottom interface board (not configured with RF module)	02.03.221006
F15 bottom interface board	02.03.220833
Power module	02.01.214734
F15 DC-DC transfer board	02.03.220839
Loudspeaker	01.14.104873
Fan	01.58.472174
Wireless AP module	02.03.221158
Printhead	01.17.114392
Main control board（wireless model）	02.03.452576
Main control board	02.03.221003
Screen assembly	02.04.244389
Wireless transducer bracket assembly	02.04.244394
AP/IP transducer socket board PCBA assembly	02.01.215557
EDAN transducer socket board PCBA assembly	02.01.215555
NELL transducer socket board PCBA assembly	02.01.215556

Appendix 2 Connecting to OB TraceVue System

Preparation

Prior to connecting **F15/F15Air** to the OB TraceVue obstetrical documentation and surveillance system of Philips, make sure that:

1) **Net Version** of **F15/F15Air** on the **Network Setup** interface has this option: **PHILIPS**.

2) The OB TraceVue system of Philips has a network interface (DB9 or RJ45) available.

3) You have the proper connecting cable.

If a DB9 interface is available, you need a Serial Port Cable (01.13.107702):



Figure A2-1 Serial Port Cable

If an RJ45 interface is available, you need a Serial Port to RJ45 Cable (01.13.107974 or 01.13.036124). The part numbers are shown on the labels attached to the cables.



Figure A2-2 Serial Port to RJ45 Cable

Besides, you need a DB9 head Y shape cable



Check other bedside monitors in the OB TraceVue system to see if protocol converters (as shown in the following illustrations) are used.



Figure A2-3 Protocol Converter

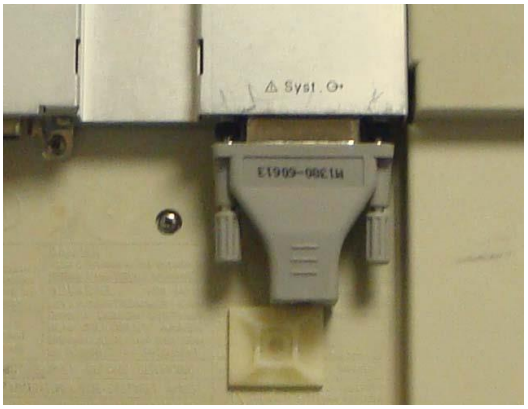


Figure A2-4 A Protocol Converter Used on a Monitor

If protocol converters are used on other bedside monitors, connect **F15/F15Air** with the Serial Port to RJ45 Cable #2 (01.13.036124). Otherwise use the cable #1 (01.13.107702).

Connection

Connect the DB15 interface of the DB9 head Y shape cable to the monitor,

Connect the convex plug of the serial port connection wire to the DB9 interface of the DB9 head Y shape cable; connect the concave plug to the DB9 interface of the OB TraceVue system.

Or

Connect the convex plug of the Serial Port to RJ45 Cable to the DB9 interface of the DB9 head Y shape cable; connect the RJ45 plug of the Serial Port to RJ45 Cable to the free RJ45 interface of the OB TraceVue system.





Figure A2-5 Connecting DB9 and RJ45 interfaces of the OB TraceVue system

Setting

Set the Net Version of F15/F15Air to **PHILIPS**. (Refer to *5.8 Changing Net Version*)

Restart F15/F15Air.

Validation

1) Switch F15/F15Air to Demo mode.

2) Observe the surveillance window of the OB TraceVue system. If data from F15/F15Air is transferred to the system, the connection succeeds. Otherwise check the connection or try on another interface of the system.

NOTE:

The identity number of this interface is preset. The device No. of F15/F15Air does not take effect in this system.

P/N: 01.54.458569
MPN: 01.54.458569010

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