



F9, F9 Express

Fetal & Maternal Monitor Version 1.5

CE₀₁₂₃

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.

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

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 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.
- \diamond 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: <u>http://www.edan.com.cn</u> 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.
- \diamond 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: <u>support@edan.com.cn</u>

Chapter 2 Overview

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.

2.1 Introduction

This service manual is a reference for periodic preventive maintenance and corrective service procedures for the **F9** and **F9 Express** 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.

2.2 General Information

- ◆ F9, F9 Express Fetal & Maternal Monitors (hereinafter called F9, F9 Express) are designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- The protective degree against electric shock of the patient connections is:

Ultrasound (FHR1, FHR2)		
External TOCO		
Intrauterine Pressure (IUP)	Type BF	I ↑
Fetal Movement Mark (FM)		
Fetal Stimulator ((FS)		
Non-invasive Blood Pressure (NIBP)	Type DE defibrillation proof	
Arterial Oxygen Saturation (SpO ₂)	Type BF, defibrillation-proof	י 🔨 ר
Direct Electrocardiography (DECG)	Type CF	

Electrocardiography (ECG)	Type CF, defibrillation-proof	-1 9 +	
Temperature (TEMP)		-	

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

- The effects of high frequency currents
- The interference of electrosurgery equipment

2.3 Safety Precautions

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

<u>WARNING</u>

- 1 **F9**, **F9 Express** 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.

WARNING

- 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.
- 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.

WARNING

- 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 60601-1-1. 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 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- 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 60601-1-1 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.

Chapter 3 Installation

<u>WARNING</u>

Only qualified service engineers should install this equipment.

3.1 Environment Requirements

Working Environment			
Temperature:	$+5 \text{ °C} \sim +40 \text{ °C} (+41 \text{ °F} \sim +104 \text{ °F})$		
Relative Humidity:	25% ~ 80% (non-condensing)		
Atmospheric Pressure:	860hPa ~ 1060hPa		
Transport and Storage			
Temperature:	-20 °C ~ +55 °C (-4°F ~ +131 °F)		
Relative Humidity:	25% ~ 93% (non-condensing)		
Atmospheric Pressure:	700hPa ~ 1060hPa		
Classification			
Anti-electric Shock Type:	Class I equipment with internal power supply		
	FHR1, FHR2, TOCO, IUP, FM BF		
Anti-electric Shock Degree:	SpO ₂ , NIBP BF (Defibrillating-proof)		
	DECG CF		
Degree of Protection against Harmful Ingress of Water:	ECG, TEMPCF (Defibrillating-proof)Main Unit: Ordinary equipment (sealed equipment without liquid proof)Wired US/TOCO Transducers: IPX8Other Accessories: No liquid ingress protection		
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.

3.2 Electrical Requirements

Operating Voltage:	$100V-240V \sim$
Operating Frequency:	50Hz/60Hz
Input Power:	110VA
Battery:	14.8V/4400mAh

3.3 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.

3.4 Installing the Monitor

3.4.1 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.

3.4.2 Mounting the Monitor on a Wall

To mount the monitor on a wall,

- 1 Order a wall mounting board (01.52.107983) and a connecting board (01.52.107984) from the manufacturer.
- 2 Turn the monitor over and fix the connecting board to the bottom panel using two pan head screws.



Figure 3-2 Fixing Wall Mounting Board

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



Figure 3-3 Securing Two Boards

<u>CAUTION</u>

- 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.

3.4.3 Installing the Monitor on a Roll Stand/Trolley

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



Figure 3-4 The Monitor on a Trolley (Sketch Map)

3.5 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 4 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.

4.1 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 8.1 Monitor Booting Failures for details.

4.2 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 8.1 Monitor Booting Failures for details.

4.3 Keys Check

Press the keys on the front panel to check if they work properly. When pressing a key, a normal key tone should be heard, unless its related function is disabled.

If any failure is detected, refer to section 8.2 Display Failures for details.

4.4 Touch Screen Check

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 you touch the center of a key but the monitor does not execute the right operation, calibrate the touch screen. Refer to section *5.5 Calibrating Touch Screen* for details.

If any operation failure is detected, refer to section 8.3 Touch Screen Failures for details.

4.5 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 8.5 Recorder Failures for details.

NOTE:

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

4.6 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 8.7 Alarm Failures for defective details.

Chapter 5 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.

5.1 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.

5.2 Entering Demo Mode

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

- 1 Open the System Setup menu.
- 2 Select Demo.
- 3 Select OK.

5.3 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.

5.4 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.

5.5 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.

5.6 Calibrating Touch Screen

NOTE:

Make sure the touch screen is enabled before trying to open the touch screen calibration menu.

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 "**W**" on the screen successively. This menu is closed when calibration finishes.

x			
	EXIT		

5.7 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 $1 \sim 99$.
- 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.

5.8 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
	MFM-CNS version is V3.0 or higher	RS485 V1.1
F9 connects to MFM-CNS via DB9 interface.	MFM-CNS version is V3.3 or higher	RS485 V1.2
	MFM-CNS version is V3.7 or higher	RS485 V1.3

F9 connects to Insight software via DB9 interface.						INSIGHT V1.2
F9 connects to MFM-CNS or Insight software via Ethernet.	MFM-CNS higher	version	is	V3.4	or	ETHERNET V1.2
F9 connects to MFM-CNS or Insight software via Wi-Fi wireless network.	MFM-CNS higher	version	is	V3.4	or	ETHERNET V1.3
F9 connects to OB TraceVue system of PHILIPS.						PHILIPS
F9 connects to FetalCare system.						FetalCare
F9 connects to QS system.						QS
F9 connects to MILOU system via DB9 interface.						MILOU-RS232
F9 connects to MILOU system via Ethernet.						MILOU-ETHERNET

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.

5.9 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 ($6 \sim 31$).
- 5 Select Wireless MOD.
- 6 Select a number $(0 \sim 31)$.
- 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.

5.10 Configuring for Ethernet Connecting

When connecting the monitor to a PC via Ethernet, you need to set the server IP 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 Ethernet Port.
- 6 Set the port number to be the same as that of the software.
- 7 Select **OK** in the Network Setup menu.
- 8 Select **OK** in the System Setup menu.

5.11 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 Setup.
- 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, AFM, TOCO, HR and SpO₂ traces in the same way.
- 6 Select **OK** in the Recorder Setup menu.
- 7 Select **OK** in the System Setup menu.

5.12 Changing Paper Style

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

- 1 Open the System Setup menu.
- 2 Select Recorder Setup.

- 3 Select the pane next to **Paper Style**.
- 4 Select the required style from USA and International.
- 5 Select **OK** in the Recorder Setup 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.

5.13 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.

5.14 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.

Chapter 6 Maintenance

6.1 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.

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

6.2 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 table environment is recommended.

Do not scratch or damage the screen.

Avoid high voltage and static charge.

6.3 Maintenance of the Transducers

Keep the transducers in a dry environment with the temperature lower than +45°C (+113°F).

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 movement. Contacting the transducers with hard or sharp objects should be avoided.

Do not excessively flex the cables.

6.4 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 70% Isopropyl alcohol-based solution.
- 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 7 Principle Introduction

7.1 System Principle Block Diagram

F9 monitor consists of the main control board, fetal monitor (FM) module, DECG module, print board, power module, key board, LCD and the corresponding interface boards. Besides that, F9 Express includes NIBP module, SpO₂ module and ECG module. Here is the system principle block diagram:



Figure 7-1 System principle block diagram

7.1.1 Main Control Board

The main control board applied is the 2410 main control board. It fulfills the following function: key input control, LCD display, process print, audio alarm and led indicate light alarm, data

memory and recall, time and date management, communication with the internal modules, ect. The parameters of this main control board are listed below:

Power	5V, 12V	
Processor	S3C2410A Work frequency: 266MHz / 200MHz External bus frequency: 1/2 or 1/4 of main frequency Dictate Cache: 16K bytes Data Cache: 16K bytes	
Net Port	10M Standard Ethernet port	
Parallel Port	1 parallel port, with CENTRONIX subclass interface definition	
EMS Memory	SDRAM: 64M byte Flash: program 8M bytes + data 64M bytes	
Serial Port	Configure in 5 serial ports and 9 serial ports way	
Headphone Interface	Loudspeaker output	
Touch Screen Interface	1 interface.	
USB	1 standard USB HOST interface, 1 standard DEVICE interface (1.1 specification)	
VGA	1 VGA output port	
LCD	1 TFT LCD interface, 1024*768 (highest resolution)	
Keyboard	1 PS/2 keyboard interface	
GPIO	At least 10	
Watchdog Timer	1.6s	
Power Consumption	700mA @ +5V (max)	
Size	142 mm×105 mm	
Operating System	Linux	

7.1.2 Fetal Monitor Module

The main function of the fetal monitor module is to detect FHR, AFM and TOCO, and a new function of collecting and playing back audio signals is added. As shown in figure 3, power, simulating front circuit, ADC, audio processing circuit and digital circuit are included. Signal detecting is divided into three branches: two fetal hearts and fetal movements detecting and one for TOCO (pressure on the pregnant woman's abdomen) detecting.





Figure 7-2 Fetal monitor module circuit block diagram

7.1.3 DECG Module

The DECG module fulfills the function of DECG detecting, TOCO and intrauterine pressure measuring, and then send the results to the main control board through serial port.

7.1.4 ECG (E3) Module

The ECG module includes ECG monitoring part and TEMP monitoring part. Their specifications are listed as follows:

(1) ECG

Lead Mode	3 Leads (R, L, F or RA, LA, LL),
Lead Selection	I, II, III, drive leads change accordingly
Waveform	1 channel
Measurement Range	30 bpm ~ 240 bpm
Accuracy	<u>+</u> 1% or <u>+</u> 1 bpm, whichever is larger
Resolution	1 bpm
Sensitivity	> 200 µV (peak to peak)
Differential Input Impedance	≥ 5 MΩ
Defibrillator Protection	Yes
ESU Protection	None

(2) **TEMP**

Channel Qty.	1
Measurement Range	0 °C ~ +50.0 °C
Resolution	0.1 °C
Accuracy	+25 °C ~ +45 °C: ±0.1 °C 0 °C ~ +25 °C, +45 °C ~ +50 °C: ±0.2 °C
Sensor Type	YSI (B series) and CF-FI
Update Time	Every 1 ~ 2 second(s)
Self-test	Every 5 ~ 10 minutes

7.1.5 NIBP (V6) Module

Method	Oscillometric	
Mode	Manual, Auto Circle, continuous measuring	
Auto Circle Mode Interval	1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 240, 480 minute(s)	
Continuous Measuring	5 minutes, 5s Interval	
Measuring Type	Systolic Pressure, Diastolic Pressure, Mean Artery Pressure	
Range	Systolic Pressure Range:40 mmHg ~ 270 mmHgDiastolic Pressure Range:10 mmHg ~ 215 mmHgMean Artery Pressure Range:20 mmHg ~ 235 mmHg	
Cuff Pressure Range	0 mmHg ~ 280 mmHg	
Pressure Resolution	1 mmHg	
Average Error	± 5 mmHg	
Standard Deviation	≤ 8 mmHg	
Cuff Autoinflation	120s	
Entire Measurement Period	30s ~ 45 s	
Overpressure Protection	(297 <u>+</u> 3) mmHg (double overpressure protection)	

7.1.6 SpO₂ (A6) Module

The SpO₂ module consists of two parts: sensor and measuring system. The measuring system includes SpO₂ signals collecting, amplified simulating circuit system and relative digital/analog converting, and signal processing systems.

The pulse extent of optical signal changes during monitoring. SpO_2 parameter, pulse rate signal and pleth wave will be acquired after calculation. These data will be transmitted to the position machine with special communication protocol. The specifications are listed as follows:

SpO ₂	
Measurement & Alarm Range	0% ~ 100%
Resolution	1%
Accuracy	<u>+</u> 2 (70% ~ 100%)
Pulse	
Measurement & Alarm Range	30 bpm ~ 240 bpm
Resolution	1 bpm
Accuracy	<u>+</u> 3 bpm; <u>+</u> 5 bpm (during movement)

7.1.7 Print Controlling Board

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



Figure 7-3 Print controlling board principle block diagram

The recorder module includes: microprocessor AT91SAM7S256 circuit, power switch and control, communicate interface, motor control part, recorder paper detecting circuit, time control for printing power and heating, paper lacking temperature control and thermosensitive head protecting circuit.

Definitions of print controlling board interfaces

(1) Interface connects to bottom interface board

	CON	6		
		9	PE	
		8	BUS	Y
		7	RXD	
		6	TXD	
		5		li.
		4		UCC .
		3		h
		2		lh.
		1		VDD
			_	
Se	erial	Port		

Pin No.	Symbol
1	VDD
2	VDD
3	GND
4	VCC
5	GND
6	TXD
7	RXD
8	BUSY
9	PE

(2) Interface connects to print head



Pin No.	Symbol
1	VH_+24V
2	VH_+24V
3	VH_+24V
4	GND
5	GND
6	GND
7	VCC
8	THERMISTOR
9	/STROBE_3
10	/STROBE_3
11	/STROBE_6
12	/STROBE_6
13	CLOCK
14	/LATCH
15	DATAIN

(3) Interface connects to stepper motor (gear assembly)



stepper motor interface

Pin No.	Symbol
1	VDD_MOTOR
2	VDD_MOTOR
3	/В
4	В
5	/A
6	А

(4) Interface connects to paper sensor (paper lack detecting)



paper lack detecting

Pin No.	Symbol
1	VDD_PS
2	GND
3	PS

7.1.8 Power Interface Board

The power interface board is used to transfer the power, its circuit is:



Figure 7-4 Power Interface board circuit

F1 and F2 are two containers for fuses, the specification of the fuse is: T2AH250V.

J1 is the equipotential grounding point that connects to the ground.

J2 is a 3-pin socket for outer power input.

J3 is the output port connecting to the power module in the machine.

C1, C2, C3 and C4 are Y capacitors, every capacitor resists 2300V voltage. Connecting a 10 Ω resistor and two Y capacitors in series between L-PE and N-PE will improve the fetal heart and solve the data jumping problem when measuring FH with EFT.

When laying out the PCB of this board, the creepage distances between L, N and PE must not be less than 8mm, the distance between L and N must not be less than 3mm.

7.1.9 Power Module

The power module outputs +12V, +5V voltage and manages charging.

When outer power (90-264VAC) is connected, the power module converts the alternative current into 12V and 5V direct current, providing power for monitor running and built-in battery charging. When outer power is disconnected, the power module converts the battery power into 12V and 5V direct current, providing power for monitor running.


Figure 7-5 Power module block diagram

7.1.10 Key Board

The key board codes the operation of keys and control knob with AT89C2051 singlechip processor, sends keycode to main control board using PS2 protocol, answers the corresponding keys and controls display of power indicator, AC indicator and Charge indicator. Its structure block diagram is as follows:



Figure 7-6 Key board principle block diagram

7.1.11 Bottom Interfaces Board

The bottom interface board consists of connect CNS interconnection circuit, voltage switching circuit, built-in wireless module power circuit and interfaces.

Interface definition

(1) Interface connects to power module



Pin No.	Symbol
1	VCC
2	GND
3	GND
4	GND
5	VDD
6	VEE

(2) Interface connects to power control board





Pin No.	Symbol
1	MB_TXD6
2	MB_RXD6
3	GND
4	CHARGE
5	AC_ON
6	Reserved

(3) Interface connects to FM board



Pin No.	Symbol	
1	GND	
2	MB_RXD1	
3	MB_TXD1	

(4) Interface connects to print controlling board



Pin No.	Symbol
1	+12V
2	+12V
3	GND
4	VCC
5	GND
6	MB_RXD2
7	MB_TXD2
8	BUSY
9	PE

(5) Interface connects to main control board



Pin No.	Symbol	Pin No.	Symbol	Pin No.	Symbol
1	VCC	15	ENERGY2	29	MB_RXD3
2	GND/BAT_V	16	ENERGY1	30	MB_TXD3
3	VCC	17	MB_RXD0	31	MB_RXD7
4	GND	18	MB_TXD0	32	MB_TXD7
5	+12V	19	MB_RTS	33	USB_DATA-
6	GND	20	GND	34	USB_DATA+
7	SOFT_CLOSE	21	BUSY	35	MB_RXD4
8	CLOSE_ASK	22	PE	36	MB_TXD4
9	BAT_ON	23	GND	37	MB_RXD5
10	CHARGE	24	CALL_CTRL	38	MB_TXD5
11	AC_ON	25	MB_RXD2	39	MB_RXD8
12	GND	26	MB_TXD2	40	MB_TXD8
13	ENERGY4	27	MB_RXD1		
14	ENERGY3	28	MB_TXD1		

(6) Interface connects to DECG module



Pin No.	Symbol
1	MB_RXD3
2	MB_TXD3
3	GND
4	+12V
5	VCC

(7) RJ45 Ethernet interface



Pin No.	Symbol
1	TD+
2	TD-
3	RD+
4	Reserved
5	Reserved
6	RD-
7	Reserved
8	Reserved

(8) USB interface



Pin No.	Symbol
1	USB_VCC
2	USB_DATA-
3	USB_DATA+
4	GND

(9) RS232 (485 network) interface

D-Sub interface:



DB9 interface:



Symbol
US2
ISOCNS_RXD
ISOCNS_TXD
485EN
0V Ref.
ТА
ТВ
RA
RB
DECG_SIGNAL
US1
+5V
ТОСО

Pin No.	Symbol
1	ISOVCC
2	ISOCNS_RXD
3	ISOCNS_TXD
4	EXT_MODEL_EN
5	GND
6	ТА
7	ТВ
8	RA
9	RB

(10) Interface connects to built-in wireless module

		CON4
\sum	WIMODE_VCC	- 1
7	ISORX	2
	ISOTX	- 4

(11) Ethernet interface

	Ethernet		
TD +			
TD -		1	
RD+		2	
RD-		3	
		4	

Pin No.	Symbol
1	WLMODE_VCC
2	GND
3	ISORX
4	ISOTX

Pin No.	Symbol
1	TD+
2	TD-
3	RD+
4	RD-

7.1.12 LVDS LCD

LCD applies a 12.1" screen with LCDS interface. Its main technical specifications are as follows:

Items	Unit	Specifications
Screen Diagonal	[mm]	310 (12.1")
Active Area	[mm]	246.0(H) x 184.5(V)
Pixel H x V		800(x3) x 600
Pixel Pitch	[mm]	0.3075(H) x 0.3075(V)
Pixel Arrangement		R.G.B. Vertical Stripe
Display Mode		Normally White
Typical White Luminance (ICFL= 6mA)	[cd/m ²]	200 Typ. (center)
Contrast Ratio		500:1 Typ.
Optical Rise Time / Fall Time	[msec]	10/25 Тур.
Nominal Input Voltage VDD	[Volt]	+3.3 Тур.
Typical Power Consumption (VDD line+VCFL line)	[Watt]	7.8 Тур.
Weight	[Grams]	640 <u>+</u> 10
Physical Size	[mm]	279.0(W) x 209.0(H) x 11(D)
Electrical Interface		LVDS
Support Color		Native 262K colors (RGB 6-bit driver)
Temperature Range:		
Operating	[°C]	-10 to +65
Storage(Shipping)	[°C]	-30 to +70

7.2 Interfaces

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

- DB9 interface or D-Sub interface
- RJ45 interface (NETWORK)
- Antenna

7.2.1 DB9/D-Sub Interface

All the monitors are configured with a DB9 interface or D-Sub interface.

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

7.2.2 RJ45 Interface

All the monitors are configured with an RJ45 interface.

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

7.2.3 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.

Chapter 8 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 *9 Modules' Malfunction Verification*. When replacement is needed, follow the procedures described in chapter *10 Dissembling the Monitor*.

8.1 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.
	The fuses are blown.	Replace the fuses.
	Main control board defective.	Replace the main control board.
The fuses blow when	Power board defective.	Replace the power board.
switching on the monitor.	Short circuit of other parts	Look for the short circuit source and fix it.
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.

8.2 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, power inverter board and the LCD are well connected. Check that the LCD backlight cable is well connected.
	LCD defective.	Replace the LCD.
	Power inverter board defective.	Replace the power inverter board.
	LCD backlight board defective.	Replace the LCD backlight board.
	Main control board defective.	Replace the main control board.
LCD displays improper characters.	LCD defective.	Replace the LCD.

8.3 Touch Screen Failures

Phenomenon	Possible Cause	Solution
	The touch screen is disabled.	Check if the touch screen is disabled in the system setup. If yes, enable it.
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 5.6 <i>Calibrating Touch Screen</i> .

8.4 Operation Failures

Phenomenon	Possible Cause	Solution
Kove pet functioning	Bad key board connection.	Check key board wire.
Keys not functioning	Key board is damaged.	Replace the key board.
When a key is pressed, no tone is heard.	Loudspeaker or wire has a failure.	Replace the loudspeaker or the wire.
Hoarse or odd sound from	Loudspeaker defective.	Replace the loudspeaker.
loudspeaker.	Main control board defective.	Replace the main control board.

8.5 Recorder Failures

Phenomenon	Possible Cause	Solution
	No paper in the drawer.	Load paper and close the drawer.
No paper advances.	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	Paper sensor dirty.	Clean the paper sensor with a dry clean cloth.
screen, but the drawer is not empty.	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.

8.6 Network Failures

Phenomenon	Possible Cause	Solution
The monitor can not connect	The RS232 or Ethernet socket defective.	Replace the RS232 or Ethernet socket.
to a network.	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.

8.7 Alarm Failures

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

8.8 Technique Alarms

Phenomenon	Possible Cause	Solution
Fetus EQUIP MALF	Bad connection between FM module, bottom interface board and main control board.	Check the connection.
	FM module defective.	Replace FM module.
	Main control board defective.	Replace main control board.

DECG EQUIP MALF	Bad connection between DECG module, bottom interface board and main control board.	Check the connection.
	DECG board defective.	Replace DECG board.
	Main control board defective.	Replace main control board.
NIBP EQUIP MALF	Bad connection between NIBP module, bottom interface board and main control board.	Check the connection.
	NIBP board defective.	Replace NIBP board.
	Main control board defective.	Replace main control board.
ECG EQUIP MALF	Bad connection between ECG module, bottom interface board and main control board.	Check the connection.
	ECG board defective.	Replace ECG board.
	Main control board defective.	Replace main control board.
SpO ₂ EQUIP MALF	Bad connection between SpO ₂ module, bottom interface board and main control board.	Check the connection.
	SpO ₂ board defective.	Replace SpO ₂ board.
	Main control board defective.	Replace main control board.

8.9 FHR/TOCO Monitoring Failures

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

8.10 DECG/IUP Monitoring Failures

Phenomenon			Possible Cause	Solution		
No DECG/IUP numeric value.	trace	or	Bad connection of cables.	Check the connection.		
			Cables defective.	Replace the cables.		
			DECG module defective.	Replace the DECG module.		
			Main control board defective.	Replace the main control board.		

8.11 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.		
	ECG module defective.	Replace the ECG module.		
	Main control board defective.	Replace the main control board.		

8.12 SpO₂ Monitoring Failures

Phenomenon	Possible Cause	Solution		
	SpO ₂ transducer defective.	Replace the SpO ₂ transducer.		
	Bad connection of SpO ₂ cable.	Check the connection.		
No SpO ₂ waveform or numeric value.	Cables defective.	Replace the cables.		
	SpO ₂ module defective.	Replace the SpO ₂ module.		
	Main control board defective.	Replace the main control board.		

8.13 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 NIBP module to the NIBP socket.	Check the connection from inside.	
	Cuff or extension tube defective.	Replace the damaged part(s).	
	NIBP module defective.	Replace the NIBP module.	
	Main control board defective.	Replace the main control board.	
	NIBP module defective.	Replace the NIBP module.	
No NIBP numeric values.	Main control board defective.	Replace the main control board.	

8.14 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.		
	ECG module defective.	Replace the ECG module.		
	Main control board defective.	Replace the main control board.		

Chapter 9 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.

9.1 Verifying Malfunction of the Main Control Board

To verify the main control board,

- 1) Open the main unit using the procedures described in section 10.3.
- 2) Switch on the monitor. (Powered by AC or battery.)
- 3) Measure the voltage to earth of the pins listed below, using a multimeter:

ltem	Pin	Reference result
1	J8's first pin	VCC+5V (5.0±5%) V
2	J31's first pin	VCC33 (3.3±5%) V
3	TP1	+12V (12.0±5%) V
(4)	TP2	PVCC (3.3±5%) V
(5)	C35's positive pole	VDDARM (1.9±5%) V
6	C16's positive pole	VDDALIVE (1.9±5%) V
7	J2's first pin	VBB33 (3.3±5%) V
8	C59	VDD_RTC (1.8±5%) V
9	C61	Li_BAT (≥2.75V)



TP2







TP1

J2





C16



Rear of the Main control board



 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.

9.2 Verifying Malfunction of the FM Module

To verify the FM module,

- 1) Open the main unit using the procedures described in section 10.3.
- 2) Measure the voltage to earth of the pins listed below, using a multimeter:

ltem	Pin	Reference result
1	TP19	(+6±10%) V
2	TP18	(+6.8±10%) V
3	TP10	(+2.5±10%) V
4	TP22	(-5±10%) V
5	TP15	(+3.3±10%) V
6	TP20	(+5±10%) V



FM Module

- 6 TP20
- 3) Compare the measurement results with the reference results in the list. If all the results are in

the allowance	range.	Switch	on	the	monitor	and	measure	the	voltage	to	earth of the	pins
listed below.												

ltem	Pin	Reference result
$\overline{7}$	TP3	(0.45±20%) V
8	TP13	(3.30±20%) V
9	TP9	(0.9±20%) V
10	TP8	(0.9±20%) V
1	TP11	(3.30±20%) V
	TP2	(0.45±20%) V
13	TP4	(0.40±20%) V



4) If any one of the results exceeds the reference range, the FM module defection is confirmed. Replacement of the module is recommended.

9.3 Verifying Malfunction of the DECG Module

To verify the DECG module,

- 1) Open the main unit using the procedures described in section 10.3.
- 2) Disconnect the DECG cable connector from the bottom interface board.
- 3) Switch on the monitor.
- 4) Measure the voltage to earth of the following pins on the bottom interface board, using a multimeter:

ltem	Pin	Reference result
1	1 st pin of J9	MB_RXD3
2	2 nd pin of J9	MB_TXD3
3	5 th pin of J9	(+5 ±5%) V



- 5) Measure the 1^{st} pin of J9 with an oscillograph. A $0V \sim 5V$ pulse string signal should be detected.
- 6) If all the results are in the reference range, reconnect the DECG cable and measure the voltage to earth of the following pins on the DECG board.

ltem	Pin	Reference result
4	TP7	(+3.3±5%) V
5	TP5	(+8±5%) V
6	TP6	(-8±5%) V



7) Compare the measurement results with the reference results in the list. If any one of the results exceeds the reference range, the DECG module defection is confirmed. Replacement of the module is recommended.

9.4 Verifying Malfunction of the NIBP Module

To verify the NIBP module,

- 1) Make sure the malfunction of NIBP measurement is not caused by other defects, such as bad connection or defective cuff, extension tube, main control board, etc.
- 2) Open the main unit using the procedures described in section 10.3.
- 3) Disconnect the NIBP cable connector from the bottom interface board.
- 4) Switch on the monitor.
- 5) Measure the voltage to earth of the following pins on the bottom interface board, using a multimeter: (Refer to section 9.3 for J5's location.)

Item	Pin	Reference result
1)	1 st pin of J5	MB_RXD5
2	3 rd pin of J5	MB_TXD5

3	6 th pin of J5	(+5±5%) V
4	7 th pin of J5	(+12±5%) V

- 6) Use an oscillograph to measure the 1^{st} pin of J5. A 0 ~5V pulse string signal should be detected.
- 7) If all the results are in the reference range, reconnect the NIBP plugs. Measure the following pins on the NIBP board.

ltem	Pin	Reference result
5	2 nd pin of J4	(+5±5%) V
6	3 rd pin of J4	(+12±5%) V
0	5 th pin of J4	Serial port signal with 9600bps baud rate
8	6 th pin of J4	Serial port signal with 9600bps baud rate



8) If any one of the results exceeds the reference range, the NIBP module defection is confirmed. Replacement of the module is recommended.

9.5 Verifying Malfunction of the SpO₂ Module

To verify the SpO₂ module,

- Make sure the malfunction of SpO₂ measurement is not caused by other defects, such as bad connection or defective transducer, main control board, etc.
- 2) Open the main unit using the procedures described in section 10.3.
- 3) Disconnect the SpO_2 cable connector from the bottom interface board.
- 4) Switch on the monitor.
- 5) Measure the voltage to earth of the following pins of the bottom interface board, using a multimeter: (Refer to section 9.3 for J14's location.)

Item	Pin	Reference result
1	1 st pin of J14	(+12±5%) V
2	3 rd pin of J14	MB_TXD4
3	4 th pin of J14	MB_RXD4
4	5 th , 6 th pin of J14	(+5±5%) V

- 6) Use an oscillograph to measure the 4th pin of J14. A 0 5V pulse string signal should be detected.
- If all the results are in the reference range, reconnect the SpO₂ plugs. Measure the following pins on the SpO₂ board.

ltem	Pin	Reference result
(5)	1 st pin of J2	4.75V ~ 5.25V
6	3 rd pin of J2	Serial port signal with 4800bps baud rate
0	4 th pin of J2	Serial port signal with 4800bps baud rate



8) If any one of the results exceeds the reference range, the SpO2 module defection is confirmed. Replacement of the module is recommended.

9.6 Verifying Malfunction of the ECG Module

To verify the ECG module,

- 1) Make sure the malfunction of ECG measurement is not caused by other defects, such bad connection or defective electrodes, main control board, etc.
- 2) Open the main unit using the procedures described in section 10.3.
- 3) Disconnect the ECG cable connector from the bottom interface board.
- 4) Switch on the monitor.
- 5) Measure the voltage to earth of the following pins of the bottom interface board, using a multimeter: (Refer to section 9.3 for J16's location.)

Item	Pin	Reference result
1	1 st pin of J16	MB_RXD7
2	2 nd pin of J16	MB_TXD7
3	4 th pin of J 16	(+5±5%) V

- Measure the 1st pin of J16 by using an oscillograph, a 0V ~ 5V pulse string signal should be detected.
- 7) If all the results are in the reference range, reconnect the ECG plugs. Measure the following pins on the ECG board.

	ltem	Pin	Reference result
ſ	4	1 st pin of J4	4.75V ~ 5.25V
	5	3 rd pin of J4	Serial port signal with 115000bps baud rate
	6	4 th pin of J4	Serial port signal with 115200bps baud rate



 If any one of the results exceeds the reference range, the ECG module defection is confirmed. Replacement of the module is recommended.

9.7 Verifying Malfunction of the Power Module

To verify the power module,

- 1) Open the main unit using the procedures described in section 10.3.
- 2) Disconnect the power board connector from the bottom interface board.
- 3) Switch on the monitor.
- Measure the voltage to earth of the following pins on the bottom interface board, using a multimeter: (Refer to section 9.3 for J3's location.)

ltem	Pin	Reference result
1	1 st pin of J3	(+5±5%) V
2	5 th pin of J3	(+12±5%) V

5) If any one of the results exceeds the reference range, the power module defection is confirmed. Replacement of the module is recommended.

Chapter 10 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.

10.1 Tools Required

- 1 A cross-head screwdriver
- 2 A flat-head screwdriver
- 3 A M3 nut driver
- 4 A pair of pliers



10.2 Replacing Fuses

To replace the blown fuse,

- 1) Switch off the monitor and unplug it.
- 2) Fold the LCD display completely flat.
- 3) Carefully place the monitor upside down on a flat surface covered with cloth or other protecting pad.
- 4) Place a flat-head screw driver in the gap of the fuse. Apply a certain amount of pressure on the screw driver to sink the fuse for about 1 mm. Unscrew the fuse anticlockwise.



- Remove the old fuse. Take out a new fuse supplied by EDAN or of the same specification: Size: Φ5mm*20mm; Model: T2AH250V.
- 6) Place the new fuse in the fuse socket. Press it in and screw it clockwise back in position.

10.3 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) With a cross-head screw driver, remove the six screws securing the upper assembly to the lower assembly.
- 4) Hold both upper and lower assemblies together, place the monitor upright again.
- 5) Carefully lift up the upper assembly and place it upside down on the left side of the lower assembly.



1 – Upper assembly 2 – Network Cable 3 – Main control board Power Cable

- 4 Ground Wire (connecting the upper assembly and the lower assembly)
- 5 Main Control Board & Bottom Interfaces Board Connecting Cable

- 6 Lower assembly
- 6) Disconnect the cables/wires to separate the two parts.

10.4 Disassembling the Lower assembly

10.4.1 Replacing the FM Module

To remove the FM module,

- 1) Separate the upper assembly and the lower assembly.
- 2) Remove the four screws on the FM module shield cover.
- 3) Disconnect all the wires.
- 4) Remove the studs/screw securing the FM module.

To replace the FM module,

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



No. Connect to

- i Toco Socket
- ii US2 Socket
- iii Bottom Interfaces Board (J18)
- iv US1 Socket
- v Mark Socket
- vi Speaker
- vii Bottom Interfaces Board (J4)
- viii Power Module

10.4.2 Replacing the DECG Module

To remove the DECG module,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires.
- 3) Remove the four screws securing the DECG module.

To replace the DECG module,

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



No. Connect to

- i Bottom Interfaces Board
- ii IUP Socket
- iii DECG Socket

10.4.3 Replacing the Print Controlling Board

To remove the print controlling board,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires on the PCBA.
- 3) Remove the three screws securing the PCBA.

To replace the print controlling board,

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

F9, F9 Express Fetal & Maternal Monitor Service Manual



No. Connect to

- ii Paper Sensor
- iii Paper Drawer Detector
- iv Bottom Interfaces Board
- v Print head
- vi Gear Assembly

10.4.4 Replacing the Gear Assembly

To remove the gear assembly,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect the wires' connector from the print controlling board.
- 3) Remove the three screws securing the gear assembly.

To replace the gear assembly,

Replace the gear assembly in a reverse procedure. Ensure the wires' connector is correctly connected to the print controlling board.



10.4.5 Replacing the Speaker

To remove the speaker,

- 1) Separate the upper assembly and the lower assembly.
- 2) Unplug the speaker wires' connector from the FM module.
- 3) Remove the three screws securing the speaker frame.
- 4) Remove the four screws securing the speaker to the frame.

To replace the speaker,

Replace the speaker in a reverse procedure. Ensure the wires' connector is correctly connected to the FM module.



10.4.6 Replacing the Power Module

To remove the power module,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires on the module.
- 3) Remove the four screws securing the 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.



10.4.7 Replacing the Fan

To remove the fan,

- 1) Separate the upper assembly and the lower assembly.
- 2) Unplug the fan wires connector from the power cable bundle.
- 3) Remove the two screws securing the fan frame.
- 4) Remove the four screws securing the fan to the frame.



To replace the fan,

Replace the fan in a reverse procedure. Ensure the wires' connector is correctly connected to connector on the power cable bundle.

No. Connect to

- i Power Switch
- ii Battery Interface Board
- iii FM module , Print Control Board and Bottom Interface Board
- iv Power Interface Board

v

Green/Yellow Ground Wire (connects to power interface board)

10.4.8 Replacing the Power Interface Board

To remove the power interface board,

- 1) Separate the upper assembly and the lower assembly.
- 2) Unplug the power wires connector from the power interface board. Using pliers to release the ground wire.
- 3) Remove the three screws securing the power interface board.

To replace the power interface board,

Replace the power interface board in a reverse procedure. Ensure the wires are correctly connected.



No. Connect to

- i Power Module
- ii Grounding Wires of the Power Module

10.4.9 Replacing the NIBP Module

To remove the NIBP module,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect the wire connecting the module to the bottom interface board. Detach the plastic tube from the NIBP socket.
- 3) Remove the four screws securing the NIBP module.

To replace the NIBP module,

Replace the module in a reverse procedure. Ensure the wires are correctly connected.



10.4.10 Replacing the SpO₂ Module

To remove the SpO₂ module,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires on the SpO_2 module.
- 3) Remove the two studs/screws securing the module.

To replace the SpO₂ module,

Replace the SpO_2 module in a reverse procedure. Refer to the following illustration when connecting wires. Ensure they are all correctly connected.



No. Connect to

- i SpO₂ Socket
- ii Bottom Interface Board

10.4.11 Replacing the ECG Module

To remove the ECG module,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires on the ECG module.
- 3) Remove the two studs/screws securing the module.

To replace the ECG module,

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



No. Connect to

- i Bottom Interface Board
- ii TEMP Socket
- iii ECG Socket

10.4.12 Replacing the Bottom Interface Board

To remove the bottom interface board,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires on the board.
- 3) Remove the five screws securing the 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

i Network Wire

- ii Power Control
 - Board
- iii Battery
- iv Signal Cable
- v SpO2 Module
- vi ECG Module
- vii NIBP Module
- viii FM Module (P2)
- ix Print Control Board
- x Power Board + Fan
- xi FM Module (J28)

10.4.13 Replacing the Printhead

To remove the printhead,

- 1) Separate the upper assembly and the lower assembly.
- 2) Loosen the FM module by removing its fixing screws.
- 3) Remove the DECG module.
- 4) Unplug the connectors of the printhead signal cable and paper sensor cable from the print control board, and then loosen the print control board by removing its fixing screws.



Paper sensor cable Printhead signal cable

- 5) Remove the film that separates the boards and the metal piece (paper drawer cover).
- 6) Remove the screws (3-6), loose the screws (1-2) and then rotate the metal retainers

sideward to release the printhead connecting board.



Printhead connecting board

7) Take the printhead connecting board out from the monitor and then remove the four screws that fix the printhead.



To replace the printhead,

Replace the printhead in a reverse procedure. The connector of the paper sensor cable is supposed to be connected to J2 socket of the print control board. The connector of the printhead signal cable is supposed to be connected to J5 socket of the print control board.

CAUTION

The thermal printhead is a fragile part. Handle it with care.
10.5 Disassembling the Upper Assembly

10.5.1 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 on the main control board.
- 3) Remove the four screws securing the board.

To replace the main control board,

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



10.5.2 Replacing the Touch Screen Controlling Board

To remove the touch screen controlling board,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires on the touch screen controlling board.
- 3) Remove the four screws securing the board.

To replace the touch screen controlling board,

Replace the board in a reverse procedure. Refer to the following illustration when connecting

wires. Ensure they are all correctly connected.

(i)

No. Connect to

- i Main Control Board
- ii Touch Screen Signal Cable

10.5.3 Replacing the Key Board

To remove the key board,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires on the key board.
- 3) Remove the four screws securing the board.

To replace the key board,

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



No. Connect to

- i Main Control Board
- ii Control Knob

10.5.4 Replacing the Power Inverter Board

To remove the power inverter board,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect all the wires on the power inverter board.
- 3) Remove the four screws securing the board.

To replace the power inverter board,

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



10.5.5 Replacing the LCD

To remove the LCD,

- 1) Separate the upper assembly and the lower assembly.
- 2) Disconnect the five wires from the power inverter board, main control board and touch screen controlling board (shown with arrows).



3) Remove the four screws shown with the arrows.



4) Place the upper assembly upright. Open the display assembly completely. Remove four screws securing the display assembly stander.

No. Connect to

- i LCD Backlight Wire (Short)
- ii Main Control Board
- iii LCD Backlight Wire (Long)



5) Remove seven screws on the back of display assembly and the two roll shaft covers.



- 6) Pull out the wires then open the display assembly with care.
- 7) Remove the touch screen signal cable from the LCD.
- 8) Remove the six screws securing the LCD to the case.



LCD

Touch screen signal cable

No. Connect to

- i Power inverter (left)
- ii Power inverter (right)
- iii Main control board (vi socket)
- iv Main control board (vii socket)
- v Touch screen controller

To replace the LCD,

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

Chapter 11 Periodic Tests

11.1 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.

11.2 Performance Tests

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

11.2.1 FHR Performance Test

This test checks the performance of FHR measurement.

Required Equipment: Ultrasonic Doppler FHR Accuracy Tester System

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

Ultrasonic Doppler FHR Accuracy Tester



Ultrasound Transducer

- 2) Switch on the monitor.
- Generate the heart rate 50 bpm, 90 bpm, 120 bpm, 150 bpm, 180 bpm and 210 bpm in turn.
- 4) Check if the FHR value displayed on the screen is accurate. Error within 2 bpm is acceptable.
- 5) Connect the ultrasound transducer to the other US socket and perform the same test.

11.2.2 TOCO Performance Test

This test checks the performance of TOCO measurement.

- 1) Switch on the monitor.
- 2) Connect the TOCO transducer to the fetal monitor.
- 3) Gently press the center of the transducer.



- 4) Check that the value on the display shows this change in pressure.
- 5) Lay the transducer face up on a hard, flat surface for a few seconds.
- 6) Press the AUTO ZERO key to zero the TOCO displays 10.
- 7) Find a flat thing, such as a coin, whose diameter is less than 2.7cm.
- 8) Turn the transducer over so that the transducer is resting on the coin. The TOCO numeric should read between **35** and **50**.



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.

11.2.3 ECG Performance Test

This test checks the performance of ECG measurement.

Required Equipment: ECG Simulator

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



ECG Simulator

- 2) Switch on the monitor.
- Generate the heart rate 40 bpm, 80 bpm, 120 bpm, 160 bpm, 200 bpm and 240 bpm in 3) turn.
- Check if the HR value displayed on the screen is accurate. Error within 2 bpm is 4) acceptable.

11.2.4 SpO₂ Performance Test

This test checks the performance of SpO₂ measurement.

Required Equipment: SpO₂ Simulator

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



SpO₂ Sensor

- 2) Switch on the monitor.
- Generate the SpO2 signal 70%, 76%, 86%, 92%, 96% and 100% in turn. 3)
- 4) Check if the SpO2 value displayed on the screen is accurate. Error within 2% is acceptable.

11.2.5 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:

Blood Pressure Simulator



- 2) Switch on the monitor.
- 3) Generate the NIBP signal 120/80 (93), 200/150 (166), 60/30 (40) and 80/50(60) in turn.
- 4) Check if the NIBP value displayed on the screen is accurate. Error within 8 mmHg is acceptable.

11.2.6 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 8773.0Ω , 6013.8Ω and 5326.0Ω in turn.
- The TEMP numeric value displayed on the screen correspond to 28 °C, 37 °C and 40 °C. Error within 0.2 °C is acceptable.

Appendix 1 Renewal Parts

CAUTION

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

Repair Part	Part Number	Repair Part	Part Number
FM Module	02.03.451221 (cordless system)/ 02.03.110440	Main control board	02.03.107965
DECG Module	02.03.451003	Touch screen control board	11.16.31092
Print Controlling Board	12.03.451277	Key Board	02.03.451013
Power Module	12.01.112205	Power Inverter Board	12.08.30102
NIBP Module	12.01.107855	LCD	01.16.045051
ECG Module	12.01.110422	Touch screen	11.16.31091
SpO ₂ Module	02.03.30384	Alarm Indicator Board	02.02.114346
Bottom Interfaces Board	12.03.451227 (cordless system)/ 02.03.109259	Serial Port Cable	01.13.107702
Speaker	02.01.210047	Serial Port to RJ45 Cable #1	01.13.107974
Fan	21.58.047299	Serial Port to RJ45 Cable #2	01.13.036124
Power Interface Board	12.02.114139	Y-Shape Signal Cable	01.13.036301
Printhead	11.17.02385		

Appendix 2 Connecting to OB TraceVue System

Preparation

Prior to connecting **F9/F9 Express** to the OB TraceVue obstetrical documentation and surveillance system of Philips, make sure that:

- 1) Net Version of F9/F9 Express 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.



RJ45 Plug

Figure A2-2 Serial Port to RJ45 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 ConverterFigure A2-4 A Protocol Converter Used on a MonitorIf protocol converters are used on other bedside monitors, connect F9/F9 Express with theSerial Port to RJ45 Cable #2 (01.13.036124). Otherwise use the cable #1 (01.13.107702).

Connection

- 1) Connect the T840 telemetry system to F9/F9 Express using the Y-shape signal cable.
- Put the convex plug of the Serial Port to RJ45 Cable into the DB9 socket of the signal cable; put the concave plug of the Serial Port Cable into the free DB9 interface of the OB TraceVue system.

OR

Put the convex plug of the Serial Port to RJ45 Cable into the DB9 socket of the signal cable; put the RJ45 plug of the Serial Port to RJ45 Cable into 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 F9/F9 Express to **PHILIPS**. (Refer to 5.8 *Changing Net Version*)

Restart F9/F9 Express.

Validation

- 1) Switch F9/F9 Express to Demo mode.
- Observe the surveillance window of the OB TraceVue system. If data from F9/F9 Express 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 F9/F9 Express does not take effect in this system.