



CooperSurgical
Fetal & Maternal Monitor
Models F9 and F9 Express
User Manual



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- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by CooperSurgical.
- The electrical installation of the relevant room complies with national standards, and
- The instrument is used in accordance with the instructions for use.

NOTE: This device is not intended for home use, Intensive Care Unit's or Operating Rooms.

⚠WARNING⚠: This device is not intended for treatment.

Upon request, CooperSurgical may provide necessary circuit diagrams, and other information to help qualified technicians to maintain and repair some parts, which CooperSurgical 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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Table of Contents

Chapter 1 Safety Guidance	1
1.1 Intended Use	1
1.2 Instructions for Safe Operation	1
1.3 Ultrasound Safety Guide	2
1.4 Safety Precautions	3
Chapter 2 Installation	7
2.1 Opening the Box and Checking	7
2.2 Installing the Battery	7
2.3 Loading the Recorder Paper	9
2.4 Connecting the Power Cable	11
2.5 Definitions and Symbols	11
2.6 Ordering Information	13
Chapter 3 Monitor and Accessories	14
3.1 Major Parts	14
3.1.1 Buttons	14
3.1.2 Indicators	16
3.1.3 Left Side Panel of the Monitor	17
3.1.4 Right Side Panel of the F9 Monitor	17
3.1.5 Rear Panel of the Monitor	17
3.1.6 Bottom Panel	18
3.2 Transducers and Cables	18
3.2.1 Ultrasound (US) Transducer	18
3.2.2 TOCO Transducer	19
3.2.3 Remote Event Marker	20
3.2.4 Fetal Spiral Electrode	20
3.3 Screen	21
3.3.1 Main Interface	21
3.3.2 Setup Interface	24
3.3.3 Touch screen	25
Chapter 4 Alarms	26
4.1 Alarm Classification	26
4.2 Audible Alarm	26
4.3 Visual Alarm	27
4.4 Choosing the Alarm Display Form	27
4.5 Changing the Alarm Volume	27
4.6 Reviewing Alarms	28
4.7 Alarm Treatment Measures	28
4.8 Testing Alarms	28
4.9 Patient Alarm Defaults	29
Chapter 5 Printing	30
5.1 Function Description	30
5.2 Printing Configuration	30
5.2.1 Switching Auto Start Printing On or Off	31
5.2.2 Choosing the Paper Speed	31
5.2.3 Changing the Print Timer	31
5.2.4 Switching Print Self-Check On or Off	31

5.3 Understanding the Recorder Paper Printout.....	32
Chapter 6 Pre-Monitoring Preparation.....	35
6.1 Switching On the Monitor.....	35
6.2 Checking the Recorder Paper.....	35
6.3 Adjusting the Screen Angle	36
6.4 Setting Date and Time.....	37
6.5 Connecting the Transducers.....	37
6.6 Adjusting the Volume	38
Chapter 7 Fetal Monitoring	40
7.1 Confirming Fetal Life	40
7.2 Monitoring Fetal Heart Rate (FHR) with Ultrasound.....	40
7.2.1 Parts Required.....	40
7.2.2 FHR Monitoring Procedure	41
7.2.3 Switching the FHR Alarm On or Off.....	42
7.2.4 Changing the FHR Alarm Limits.....	42
7.2.5 Changing the FHR Alarm Delay.....	42
7.3 Monitoring FHR with DECG (Optional).....	43
7.3.1 Contraindications	43
7.3.2 Parts Required.....	43
7.3.3 Preparing the Patient's Skin Prior to Placing Electrodes	43
7.3.4 Directions for Using Fetal Spiral Electrode.....	43
7.3.5 DECG Monitoring Procedure	44
7.3.6 Detaching the Fetal Spiral Electrode	44
7.4 Monitoring Twin FHRs.....	44
7.4.1 Monitoring Twins Externally.....	44
7.4.2 Monitoring Internally.....	44
7.4.3 Signals Overlap Verification (SOV).....	45
7.4.4 Changing FHR2/DFHR Offset.....	45
7.5 Monitoring Uterine Activity Externally.....	45
7.5.1 Parts Required.....	45
7.5.2 TOCO Monitoring Procedure	45
7.5.3 Changing the UA Baseline.....	46
7.6 Monitoring Uterine Activity Internally (Optional).....	46
7.6.1 Parts Required.....	46
7.6.2 Directions for Using IUPC.....	46
7.6.3 IUP Monitoring Procedure.....	47
7.6.4 Checking Intrauterine Pressure Cable Function.....	48
7.7 Monitoring Fetal Movement.....	48
7.7.1 Auto Fetal Movement (AFM) Monitoring.....	48
7.7.2 Enabling or Disabling AFM Trace.....	49
7.7.3 Changing AFM Gain.....	49
7.7.4 Manual Fetal Movement (MFM) Monitoring.....	49
7.8 Start Monitoring.....	49
7.9 Inputting Maternal Information (Mat. Info).....	50
7.9.1 Auto ID	50
7.9.2 Changing Maternal Information.....	50
7.9.3 Switching Mat. Info Entering On or Off.....	51
7.10 Fetal Monitoring Screen Display	51

7.10.1 Fetal Monitoring Traces.....	52
7.10.2 Changing the Time Scale.....	53
7.10.3 Changing the Trace Advancing Mode.....	53
7.10.4 Searching for a Patient.....	54
7.10.5 Reviewing.....	54
7.10.6 Making a Note.....	55
7.10.7 Fetal Monitoring Values.....	57
7.10.8 Changing Fetal Numeric Window Position.....	57
7.10.9 Fetal Monitoring Alarm Messages.....	58
Chapter 8 After Monitoring.....	60
8.1 Data Saving.....	60
8.2 Completing the Monitoring.....	60
8.3 Switching Off.....	60
Chapter 9 Maintenance and Cleaning.....	61
9.1 Maintenance.....	61
9.1.1 Maintenance Inspections.....	61
9.1.2 Maintenance of the Monitor.....	61
9.1.3 Maintenance of the Transducers.....	62
9.1.4 Storage of Recorder papers.....	62
9.1.5 Cleaning of the Recorder.....	62
9.2 Cleaning.....	63
9.2.1 Cleaning of the Monitor.....	63
9.2.2 Cleaning of the Accessories.....	64
9.4 Sterilizing.....	65
Chapter 10 Warranty and Service Policy.....	66
10.1 Warranty.....	66
10.2 After-Sales Service.....	66
Appendix 1 Product Specifications.....	67
A1.1 Monitor.....	67
A1.2 Transducers and Cables.....	71
A1.3 Rechargeable Lithium-ion Battery.....	71
Appendix 2 Signal Input/Output Connector.....	72
Appendix 3 Troubleshooting.....	73
A3.1 No Display.....	73
A3.2 Noise.....	73
A3.3 Recorder Error.....	73
A3.4 Trouble with Ultrasound FHR Monitoring.....	74
A3.5 Trouble with DECG FHR Monitoring.....	75
A3.6 Trouble with Contractions Monitoring (External).....	75
A3.7 Trouble with Contractions Monitoring (Internal).....	76
A3.8 Blown Fuses.....	76
Appendix 4 EMC Information – Guidance and Manufacture’s Declaration.....	77
A4.1 Electromagnetic Emissions – for all EQUIPMENT and SYSTEMS.....	77
A4.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS.....	78
A4.3 Electromagnetic Immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING.....	80
A4.4 Recommended Separation Distance.....	82

Chapter 1 Safety Guidance

NOTE: This User Manual is written to cover features of both the F9 and F9 Express Monitors. Therefore, your model may or may not have some of the parameters and functions described, depending on what you have ordered.

1.1 Intended Use

The CooperSurgical F9 Series Fetal & Maternal Monitor (hereinafter called F9 Monitor) is intended for non-invasive monitoring of a fetus during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

The F9 Monitor provides non-stress testing for pregnant women from the 28th week of gestation. It can externally monitor the Fetal Heart Rates (FHRs) using ultrasound and uterine activity via a TOCO transducer. Alternatively, it can internally monitor one of the FHRs with Direct Electrocardiography (DECG) and uterine activity with an Intrauterine Pressure Catheter (IUPC).

Contraindications: The F9 Monitor is not intended for use in intensive care units, operating rooms or for home use.

1.2 Instructions for Safe Operation

- The F9 Monitor is designed to comply with the international safety requirements IEC/EN 60601-1 for Medical Electrical Equipment. It is Class I equipment.
- The F9 Monitor operates within specifications at ambient temperatures between 5 °C (41 °F) and 40 °C (104 °F). 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 use. If damage is evident, replace.
- The F9 Monitor must be serviced only by authorized and qualified personnel. CooperSurgical 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.
- Perform periodic safety testing to ensure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.

- The protective categories against electric shock of the patient connections are:



- 1) Ultrasound (FHR1, FHR2)
- 2) External TOCO
- 3) Fetal Movement Mark (FM)
- 4) Fetal Stimulator (FS)

This symbol indicates that the protection against electric shock of this instrument is Type B.



IUP (Intrauterine Pressure)

This symbol indicates that the protection against electric shock of this instrument is Type BF.



DECG (Direct Electrocardiography)

This symbol indicates that the protection against electric shock of this instrument is Type CF.

The monitor described in this User Manual is not protected against:

- a) The effects of defibrillator shocks
- b) The effects of defibrillator discharge
- c) The effects of high frequency currents
- d) The interference of electrosurgery equipment

1.3 Ultrasound Safety Guide

Fetal Use

The F9 Monitor is designed for continuous fetal heart rate monitoring during pregnancy and labor. Clinical interpretation of the fetal heart rate traces can diagnose fetal and/or maternal problems and complications.

Instructions for Use in Minimizing Patient Exposure

The acoustic output of the F9 Monitor is internally controlled and can not be varied by the operator in the course of the examination. The duration of exposure is, however, fully under the control of the operator. Mastery of the examination techniques described in the User Manual will facilitate obtaining the maximum amount of diagnostic information with the minimum amount of exposure. Exercising clinical judgment in monitoring low risk patients will avoid unnecessary insonation.

1.4 Safety Precautions

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

WARNING :

Usage Safety Precautions:

- The F9 Monitor is provided for use by qualified physicians or professionally trained personnel. They should be familiar with the contents of this User Manual before operation.
- Only qualified service technicians can install this equipment. Only service technicians authorized by CooperSurgical can open the case.
- This device is not intended for home use, use in Intensive Care Units or Operating Rooms.
- **EXPLOSION HAZARD** - Do not use the F9 Monitor in a flammable atmosphere. Equipment is not suitable for use in the presence of flammable anesthetic mixture with air, with oxygen or with nitrous oxide.
- **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.
- Do not apply this Monitor and other ultrasonic equipment simultaneously on the same patient, due to the potential of leakage current superposition.
- Do not apply this Monitor simultaneously with other patient-connected equipment, such as a cardiac pacemaker or other electrical stimulators.
- Do not switch on device power until all cables have been properly connected and verified.
- 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.
- Disconnect power cord before changing fuses. Replace them with those of the same specifications only.
- **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.
- **SHOCK HAZARD** - Do not remove the top panel cover during operation or while power

is connected. Only authorized service personnel should remove the unit cover.

- The Monitor is not protected against defibrillation. Do not apply it during electro-surgery or MRI; as it might result in harm to the patient or the operator.
- Only connect accessories supplied or recommended by CooperSurgical to the device.
- 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. Anyone who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible 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 CooperSurgical representative.

Proper Monitoring Safety Precautions:

- This device is not intended for treatment.
- The fetal spiral electrode and intrauterine pressure catheter are single use only. Discard them after use.
- The IUPC is neither intended nor approved for measuring intrauterine pressure extra-ovularly; attempting to do so may lead to maternal discomfort or injury.
- Alarms must be set up based on different situations. Make sure that audio sounds can be activated when an alarm occurs.

Battery Safety Precautions:

- Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the User Manual and safety precautions thoroughly.
- Don't connect the battery cable connector or battery socket with metal objects, which can result in a short circuit.
- Do not unplug the battery when monitoring.
- Do not heat or throw the battery into a fire.
- Do not use or leave the battery close to fire or other places where the temperature may be above 60 °C (140 °F).
- Do not allow the battery to come in contact with water.
- Do not destroy the battery: Do not pierce battery with a sharp object such as a needle;

Do not hit with a hammer, step on, throw or drop to cause a strong shock; Do not disassemble or modify the battery.

- Use the battery only in the F9 Monitor. Do not connect battery directly to an electrical outlet or cigarette lighter charger.
- If the liquid from the battery gets into the eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.
- Don't solder the leading wire directly to the battery terminal.
- If the liquid leaks from the battery and spills onto your skin or clothes, wash well with fresh water immediately.
- Keep battery away from flames. If leakage or a foul odor is detected, discontinue use.
- Stop using the battery if abnormal heat, odor, discoloration, deformation or an abnormal condition is detected during use, charge, or storage. Keep it away from the Monitor.
- Do not use a battery with visual damage.



-  Proper disposal is required. Follow your Local Regulations for disposal.

 **CAUTION** :

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Only qualified personnel shall service the unit.
- The device is designed for continuous operation and is “ordinary” (i.e. not drip or splash-proof).
- Keep the working environment clean. Avoid vibration. Keep it far from corrosive medicine, dusty areas, high-temperature and humid environments.
- When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.
- Do not operate the unit if it is damp or wet caused by condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.
- Do not sterilize the Monitor or any accessory with an autoclave or gas.
- Turn off the system power before cleaning. Cleaning consists of removing all dust from the exterior surface of the equipment with a soft brush or cloth. Use a brush to dislodge

any dirt on or around the connectors and panel edges. Remove dirt with a soft cloth, slightly dampened with a mild detergent solution or 70% ethanol or isopropanol.

- When washing the belts, the water temperature must not exceed 60 °C (140 °F).
- **Electromagnetic Interference** - Ensure that the environment in which the F9 Monitor is installed is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phone base stations, etc.
- Do not use mobile phones while monitoring.
- While the battery is charged, used or stored, keep it away from objects or materials with static electric charges.
- If the terminals of the battery become dirty, wipe with a dry cloth before using the battery.
- The recommended charge temperature range is from 0° C to 40° C (32° F 104° F). Do not exceed this range.
- Batteries have life cycles. If the time span that the Monitor runs on the battery becomes much shorter than usual, the battery life is at an end. Replace the battery with a new one the same as the one provided or recommended by CooperSurgical.
- When not using the battery for an extended period of time, remove it from the Monitor and store it in a place with low humidity and low temperature.
- Remove a battery whose life cycle has expired from the Monitor immediately.
- For information on installing and removing the battery from the monitor, thoroughly read the User Manual.
- The device and accessories are to be disposed of in accordance with all applicable Federal, State, and local medical/ hazardous waste practices at the end of their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

Chapter 2 Installation

NOTE:

Installation must be carried out by qualified personnel authorized by CooperSurgical. In order to ensure the operator and patient's safety, read through this chapter before using this monitor.

2.1 Opening the Box and Checking

Open the box and take out the F9 Monitor and accessories carefully. Keep the packaging for possible future transportation or storage. Check the components according to the packing list.

- Check for any mechanical damage.
- Check all the cables and accessories.

If there is any problem, contact us or your local representative immediately.

2.2 Installing the Battery

If your Monitor is configured with the rechargeable lithium-ion battery, follow these steps to install the battery:

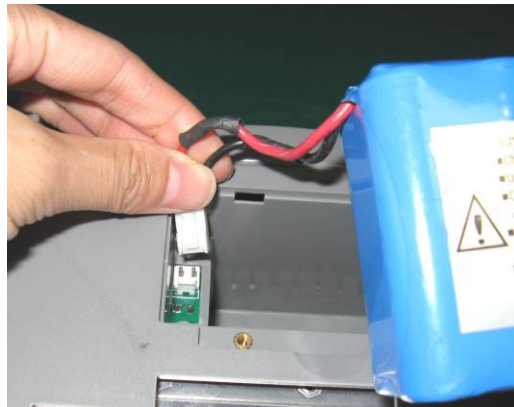
Battery Installation

1. Carefully place the F9 Monitor upside down on a flat surface covered with cloth or other type of protecting pad.
2. Remove the screws of the battery compartment using a Phillips-head screw driver. Remove the battery compartment cover.

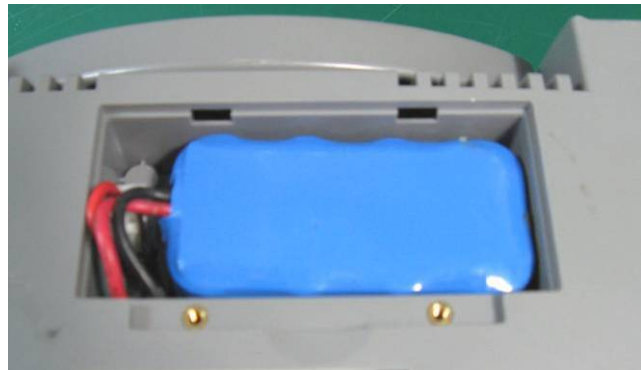


3. Take the battery out of its packaging. Place the battery into the battery compartment with the cable facing out.

4. Plug the cable connector into the socket.



5. Put the battery and the cables into the battery compartment.



6. Shut the battery compartment cover and secure the screws.



Battery Removal

Fold the LCD display completely flat before turning the F9 Monitor upside down. Remove the battery in reverse order.

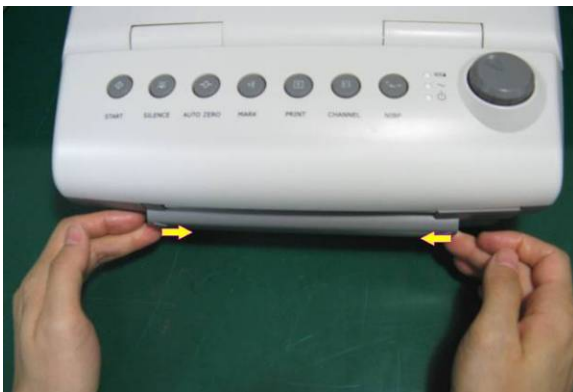
NOTES:

- 1) If a rechargeable battery is supplied, charge it fully every time after using the device to ensure the electric power is adequate.
- 2) When the battery configuration is provided, after the device is transported or stored, the battery must be charged. Connecting the F9 Monitor to a power supply will charge the battery even if the Monitor is not turned on.
- 3) Turn off the F9 Monitor and unplug the power cord before installing or removing the battery.

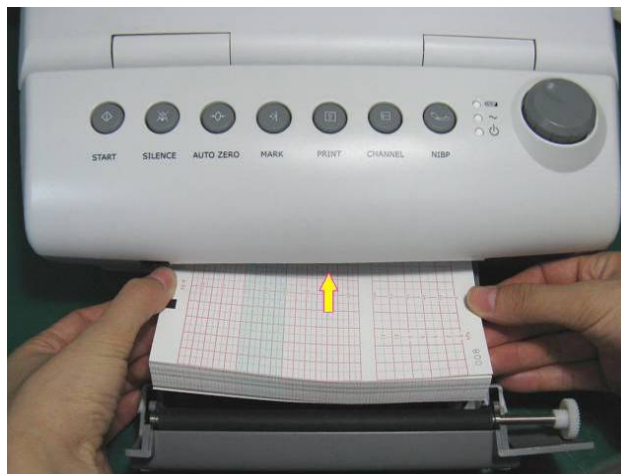
2.3 Loading the Recorder Paper

Use the following procedure to load Recorder the paper.

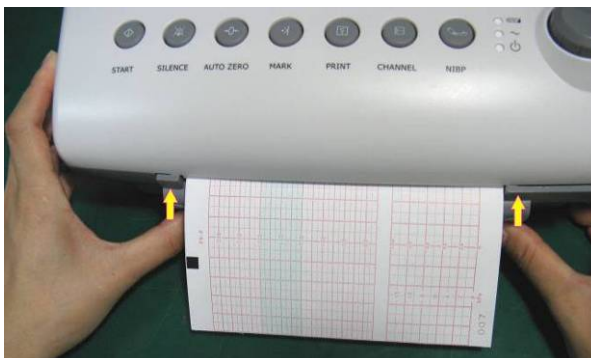
1. Press the two latches on each side of the paper drawer at the same time and slide the drawer out carefully.



2. Remove the wrapper from the “Z” type thermosensitive paper.
3. Place the paper in the drawer, with the pane facing up and the green safety area on the left.



4. Unfold two sheets from the top of the pack and pull the end of the paper out of the drawer (make sure the pack in the drawer remains flat).
5. Slide the drawer in until both the latches are locked.



NOTES:

- 1) Be careful when inserting paper. Avoid damaging the thermosensitive print head.
- 2) The paper going out from the drawer should be aligned. Otherwise the data will be inaccurate or a paper jam will occur.
- 3) Only use the paper CooperSurgical approved to avoid poor printing quality, deflection, or a paper jam.
- 4) Keep the drawer closed except when loading paper or servicing.

Removing a Paper Jam

When the recorder does not function properly, open the drawer to check for a paper jam. Remove the paper jam as follows:

1. Cut the recorder paper from the paper drawer edge.
2. Push the recorder paper up with one finger through the hole on the bottom panel of the paper drawer. Remove the paper.
3. Reload the paper and then close the drawer.



2.4 Connecting the Power Cable

- Make sure the AC power supply of the Monitor complies with the following specifications: 100 V - 240 VAC, 50/60 Hz.
- Connect the power cable provided with the F9 Monitor to the Monitor's power socket (see Figure 3-5 in Chapter 3). Connect the other end to a hospital grade grounded 3-wire AC outlet.

⚠️WARNING⚠️: If the protective grounding (protective earth) system is in question, the F9 Monitor must be powered only by the battery.

2.5 Definitions and Symbols



Socket for Channel 1 Ultrasound Transducer (for connection with ultrasound transducer, Protection Category B)



Socket for Channel 2 Ultrasound Transducer (for connection with ultrasound transducer, Protection Category B)



DECG Socket (for connection with DECG cable, Protection Category CF)



TOCO/IUP Socket (TOCO input socket-for connection with external contractions (TOCO) transducer, Protection Category B/ IUP input socket, for connection with intrauterine pressure connector, Protection Category BF)



Socket for Remote Event Marker (for connection with the marker, Protection Category B)



Socket for Fetal Stimulator (reserved)



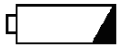
DB9 Interface



RJ45 Interface



Equipotential Grounding System



Charge Indicator



Alternating Current (a.c.)



Stand-by



Attention, See instructions for use



Type B Applied Part Symbol



Type BF Applied Part Symbol



Type CF Applied Part Symbol



Symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life and that this unit was put on the market after August 13, 2005.



Reorder Number



Serial Number



Date of Manufacture



Manufacturer



Recycle

Rx Only

US Federal law restricts this device to sale by or on the order of a physician

2.6 Ordering Information

The following table describes the accessories that are supplied by or approved by CooperSurgical to be used with the F9 Monitor. The accessories used, such as the rechargeable battery (P/N: HYL B, manufactured by HENGYU) have passed the CE authentication, and have the characteristics specified by their manufacturers. Call CooperSurgical Customer Service at 800-243-2974 or 203-601-9818 for part numbers and pricing.

Accessory (Spare Part) List	
US Transducer 1 (pink label)	Intrauterine Pressure Connecting Cable
US Transducer 2 (yellow label)	Intrauterine Pressure Cable
TOCO Transducer	Disposable Intrauterine Pressure Catheter
Remote Event Marker	Thermosensitive Paper (GE-American)
Belt	Thermosensitive Paper (GE-International)
Aquasonic Coupling Gel (0.25ltr bottle)	Thermosensitive Paper (Philips-American)
Fetal Stimulator	Thermosensitive Paper (Philips-International)
DECG Cable	Power Cord (American Standard)
Disposable Fetal Spiral Electrode	Fuse T1.6AL 250V
Disposable Maternal Attachment Pad Electrode	Rechargeable Lithium-ion Battery

⚠️ WARNING ⚠️: Only connect the accessories supplied or recommended by CooperSurgical to the F9 Monitor.

Chapter 3 Monitor and Accessories

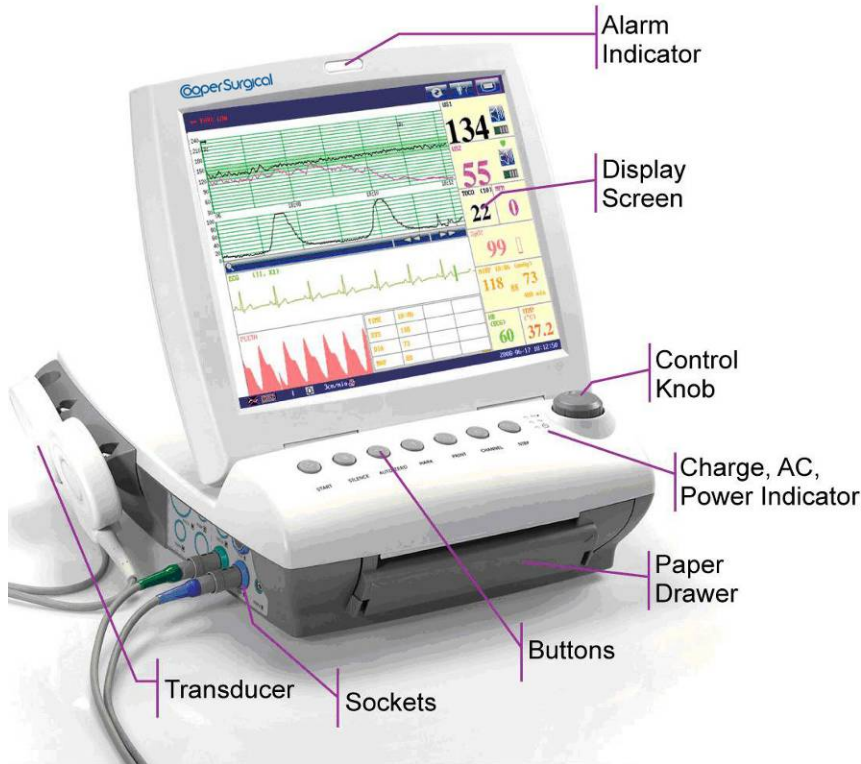


Figure 3-1: The CooperSurgical F9 Fetal Monitor

3.1 Major Parts

3.1.1 Buttons

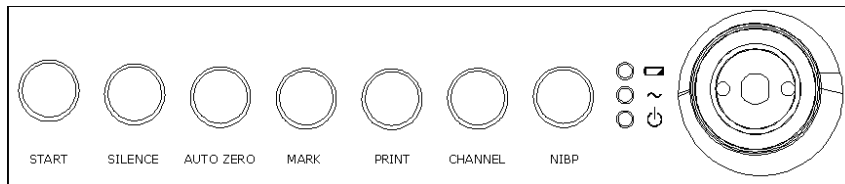


Figure 3-2: Buttons and Control Knob

The F9 Monitor is a user-friendly device that is controlled by a few buttons on the front panel and the Control Knob. Their functions are as follows:

START

Function: Start monitoring, return to main interface

Press this button to start monitoring (on main interface) or return to main interface (in maternal information inputting menu or setup menus).

SILENCE

Function: Disable/Enable audio alarm

Press this button once to switch the alarm sound off, but the alarm information displays and indicator flashes as normal; press this button again to switch the sound on again.

AUTO ZERO

Function: TOCO/IUP zero

Adjust the external TOCO contractions trace/value to preset unit (external monitoring contractions) or the IUP trace/ value to reference point 0 (internal monitoring contractions).

MARK

Function: Record an event

Press this key to mark a patient event or open the smart note list.

PRINT

Function: Start / stop printing

Press this button to toggle between starting and stopping printing.

CHANNEL

Function: Switch the channels

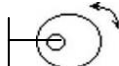
The default fetal heart audio is US1. When two ultrasound transducers are connected to the monitor, press this button to switch the audio to US2; press it again to switch the audio back to US1.

NIBP (Non-Invasive Blood Pressure)

Function: Start or stop a NIBP measurement.

This button is not active unless the optional NIBP feature is enabled.

CONTROL KNOB

Press Control Knob  Rotate Control Knob

Function: Adjust volume, setup and playback control.

The knob can be rotated clockwise or counterclockwise and be pressed like other buttons. All operations on the screen or in the menu can be completed by using the control knob.

The rectangular mark on the screen that moves with the rotation of the control knob is referred to as the “cursor”. Operations can be performed in the position on the screen where the cursor stays. When the cursor is located on a certain item, you can press the control knob to open its submenu or confirm the operation. Press the control knob again and the cursor will be able to move around on

the interface/menus.

Control Knob Operating Procedure:

- a) Rotate the control knob to move the cursor to the required item.
- b) Press the control knob.
- c) One of the following three results will be achieved:
 - A new menu pops up. Operate the control knob in the new menu in the same way.
 - A submenu with several options appears on the right of the item. If this item has more than 8 options, they will be displayed in more than one page. Select **PREV** to switch to the previous page, or select **NEXT** to switch to the next page.
 - The function operates immediately.

Note: The word “select” hereinafter stands for rotating the control knob cursor to an item and then pressing the knob.

⚠ CAUTION ⚠: This F9 Monitor is a “normal” medical device. Please avoid violent operations such as continuously pressing the buttons or control knob.

3.1.2 Indicators

There are four groups of indicators on top of the screen and the front panel. From the top to bottom they are: Alarm Indicator, Charge Indicator, AC indicator and Power indicator. Table 3-1 lists their meanings:

Indicator	Status of Indicator	Meaning
Alarm Indicator	Flash or light up in orange	An alarm is active
	Off	No alarm is active
Charge Indicator	On	The battery is being charged
	Off	No battery or the battery is fully charged
AC Indicator	On	The Monitor is connected to AC power supply.
	Off	The Monitor is not connected to AC power supply.
Power Indicator	On	The Monitor is powered on.
	Off	The Monitor is powered off.

Table 3-1: Indicator Descriptions

3.1.3 Left Side Panel of the Monitor

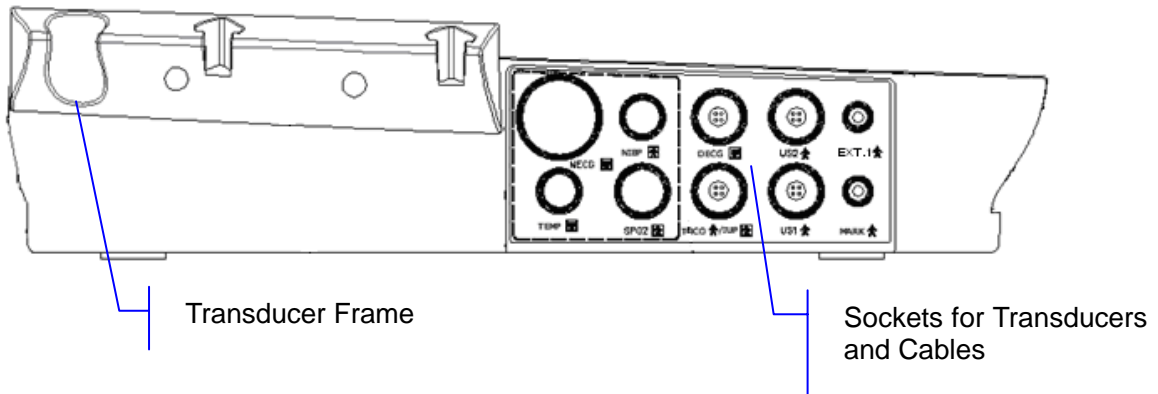


Figure 3-3: Sockets on the left side of the Monitor

NOTE: Sockets for MECG, NIBP, TEMP and SpO2 are only used when these optional features are enabled.

3.1.4 Right Side Panel of the F9 Monitor

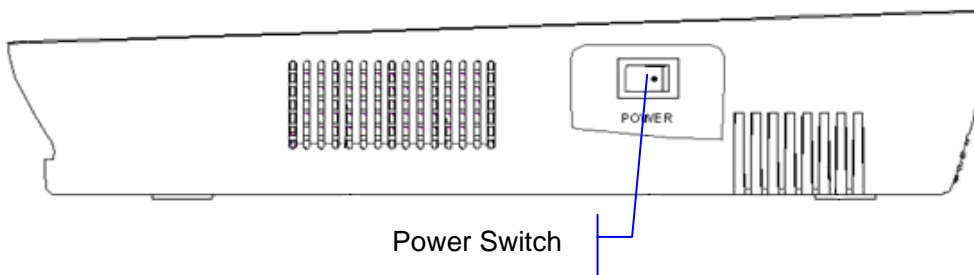


Figure 3-4: Right side of the Monitor

3.1.5 Rear Panel of the Monitor

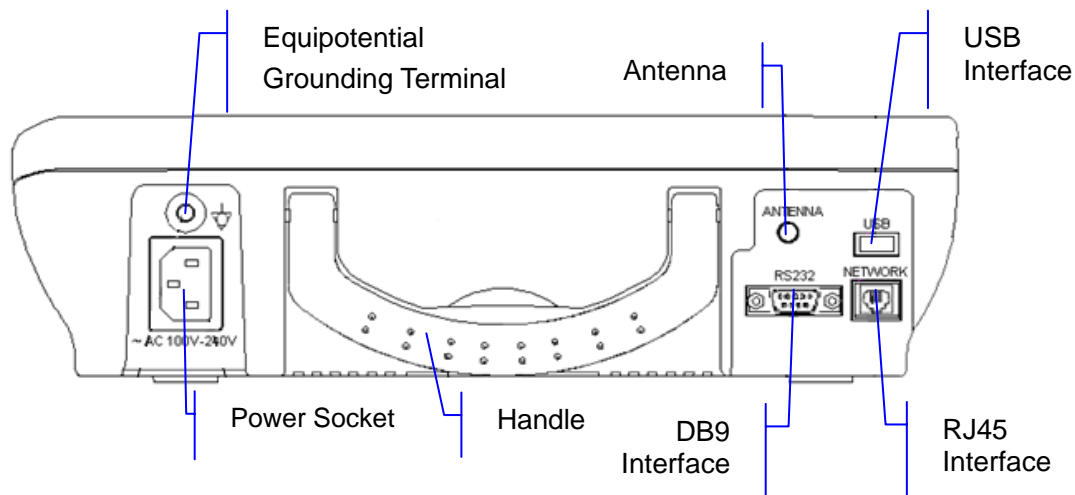


Figure 3-5: Rear panel of the monitor

3.1.6 Bottom Panel

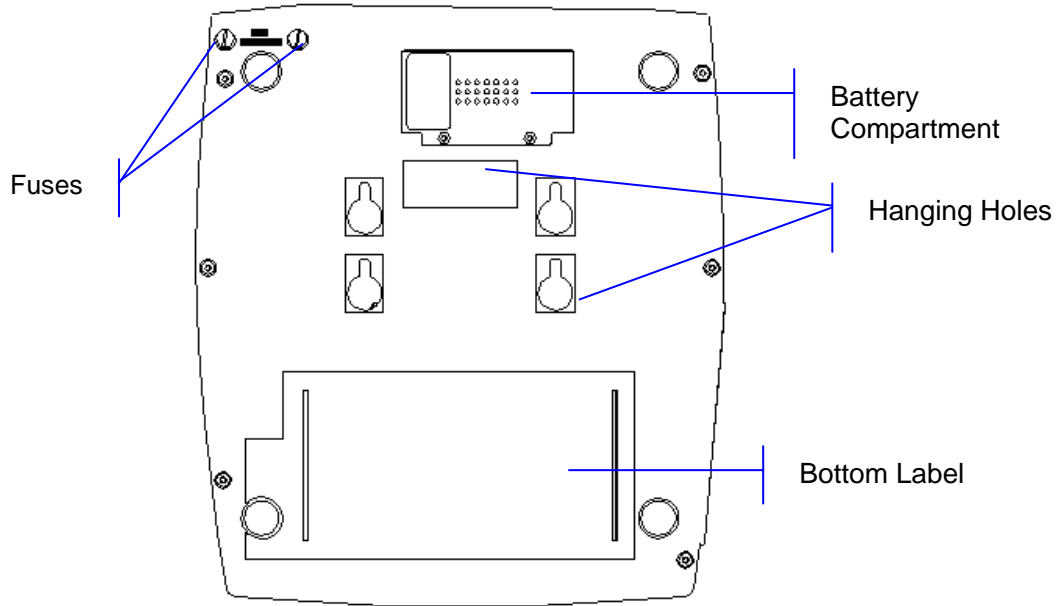


Figure 3-6: Bottom panel

3.2 Transducers and Cables

The ultrasound transducer(s), TOCO transducer, IUP cable and remote event marker should be connected to the left side panel of the monitor. Each cable has a tab on the connector housing to insure proper insertion into the appropriate socket on the monitor.

3.2.1 Ultrasound (US) Transducer

This multi-crystal, broad beam US transducer is used for monitoring fetal heart rate (FHR). The US transducer operates at a frequency of 1.0 MHz. The FHR transducer on the maternal abdomen transmits a low energy ultrasound wave to the fetal heart and receives the echo signal. The F9 Monitor then calculates the fetal heart rate.

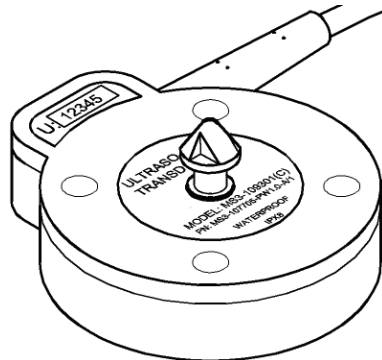


Figure 3-7: Ultrasound transducer

US transducer 1 has two pink labels; US transducer 2 has two yellow labels. This information is shown on the labels:

U:xxxxx: number of this US transducer.

MODEL: MS3-109301: Model of this US transducer.

PN: MS3-31528: Part number of the US transducer 1.

PN: MS3-107705: Part number of the US transducer 2.

PW 1.0: PW means pulsed wave, 1.0 means central frequency is 1.0 MHz.

A/1: Version number of the ultrasound transducer.

WATERPROOF: means this transducer is waterproof.

IPX8: means this transducer can work continuously for 5 hours under 1-meter of water without being waterlogged.

⚠ CAUTION ⚠: The waterproof parts of the ultrasound transducer are restricted to the main body and the cable. Do not immerse the plug into water during the process of monitoring or cleaning.

3.2.2 TOCO Transducer

This transducer is a toco tonometer whose central section is depressed by the forward displacement of the abdominal muscles during a contraction. It is used for assessment of frequency and duration of uterine contractions.

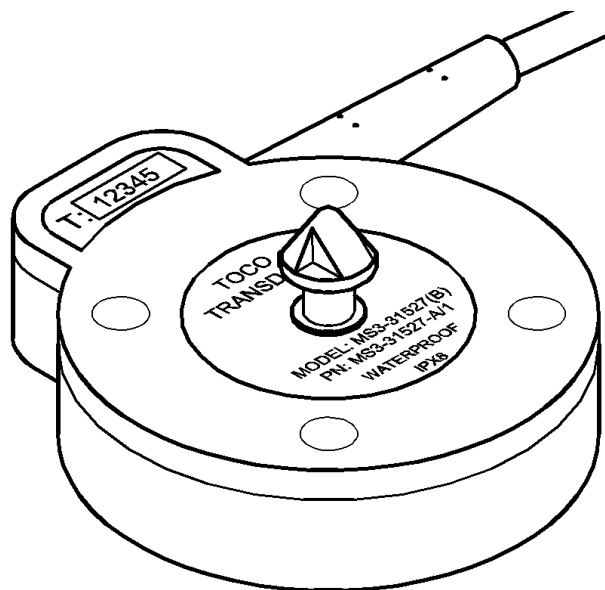


Figure 3-8: TOCO transducer

There are two blue labels on the TOCO transducer. They include the following information:

T:xxxxx: number of this TOCO transducer.

MODEL: MS3-31527: Model of this TOCO transducer.

PN: MS3-31527: Part number of this TOCO transducer.

A/1: Version number of the TOCO transducer.

WATERPROOF: means this transducer is waterproof.

IPX8: means this transducer can work continuously for 5 hours under 1-meter of water without being waterlogged.

⚠ CAUTION ⚠: The waterproof parts of the TOCO transducer are restricted to the main body and the cable. Do not immerse the connector into water during the process of monitoring or cleaning.

3.2.3 Remote Event Marker

The remote event marker is a hand-held device used by the pregnant woman to detect and mark fetal movement from the mother's perspective.

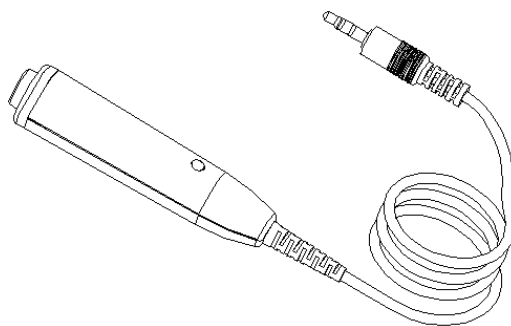


Figure 3-9: Remote Event Marker

3.2.4 Fetal Spiral Electrode

Please refer to manufactures instructions when using a fetal spiral electrode.

3.2.5 Fetal Stimulator

The FS-1 Fetal Stimulator is a hand-held device. It can be used to observe changes in the fetal heart rate by giving a mild vibrating stimulation to the fetus through the maternal abdomen. This can reduce the time required for the NST.

During NST, the vibrating operation marks can be displayed /printed on CTG trace when the fetal stimulator is connected to the F9 Monitor by an audio cable.

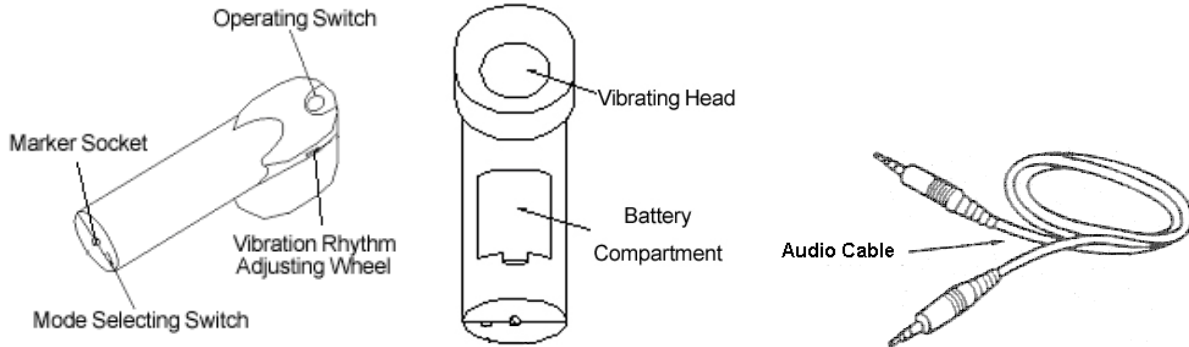


Figure 3-10: Operating control of fetal stimulator

3.3 Screen

3.3.1 Main Interface

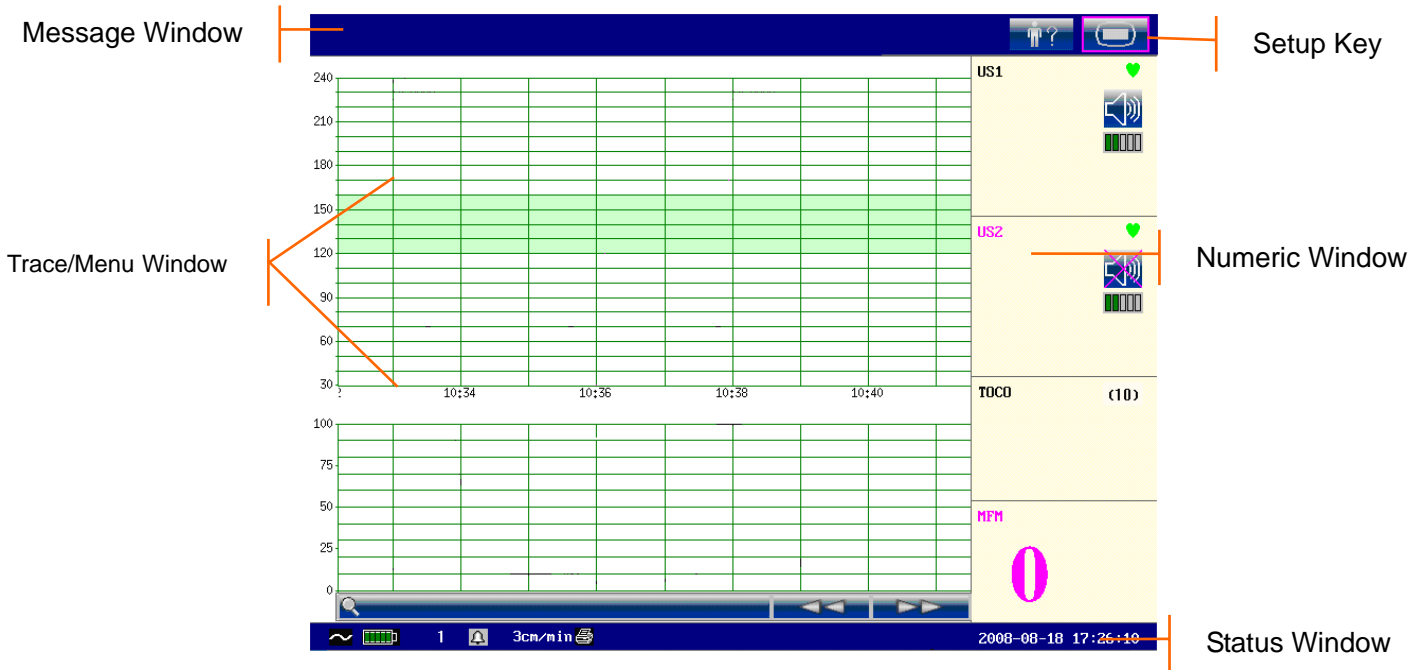



Figure 3-11: Main Interface

The main interface of the F9 Monitor displays traces, numeric information menus and monitor status information. The screen background color has four color options: black, green (default), orange and blue.

To change the screen color:

- 1) Select the Setup key  on the main interface.
- 2) Select **General** ⇌ **Screen Color**.
- 3) Select the required color.
- 4) Select **OK**.

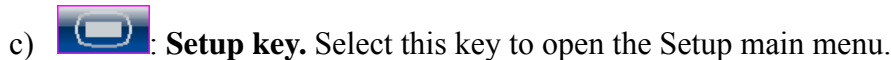
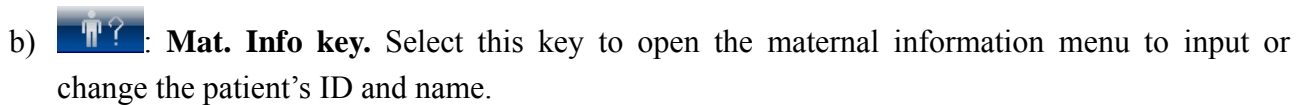
According to the content, the main interface is divided into four windows: (1) Message Window (2) Trace/ Menu Window (3) Numeric Window (4) Status Window.

Message Window



Alarm messages displaying area. When an alarm is active, the message will be displayed here in red. Patient alarms will be displayed on the left and technical alarms in the center.

Alarm reviewing key. Select this key to open the alarm review menu.



Trace/Menu Window

The trace/menu window occupies the main portion of the screen. During monitoring or reviewing, it displays traces; during system configuration, it displays Setup menus.

The background pane bar supports two standards: 30 ~ 240 (American standard) and 50 ~ 210 (International standard).

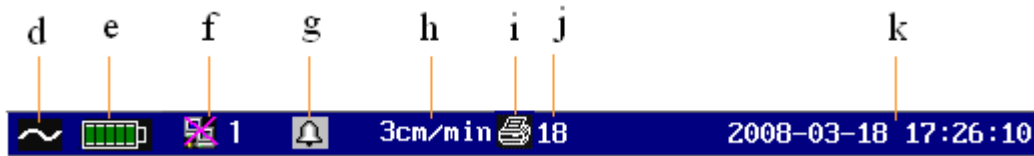
The 120 ~ 160 bpm area with the green background in between the fetal heart rate pane makes it easy to observe if the FHR exceeds this range.



Numeric Window

The fetal monitoring values and maternal vital signs are displayed here.

Status Window



d) Power indicator



- AC power supplied.



- no AC power supplied.

e) Battery indicator



- the battery is loaded; the green pane indicates the charge of the battery.



- no battery is loaded.

f) Network connection indicator and device no.



- the Monitor is online.



- the Monitor is offline.

NOTE: The network connection indicator is not available if the net version is Insight or Philips.

g) Audio alarm indicator



- the audible alarm is switched on.



- the audible alarm is switched off.

h) **3cm/min** - Print speed.

i) Recorder status indicator



- the recorder is in the process of printing.




- the printer is off line.

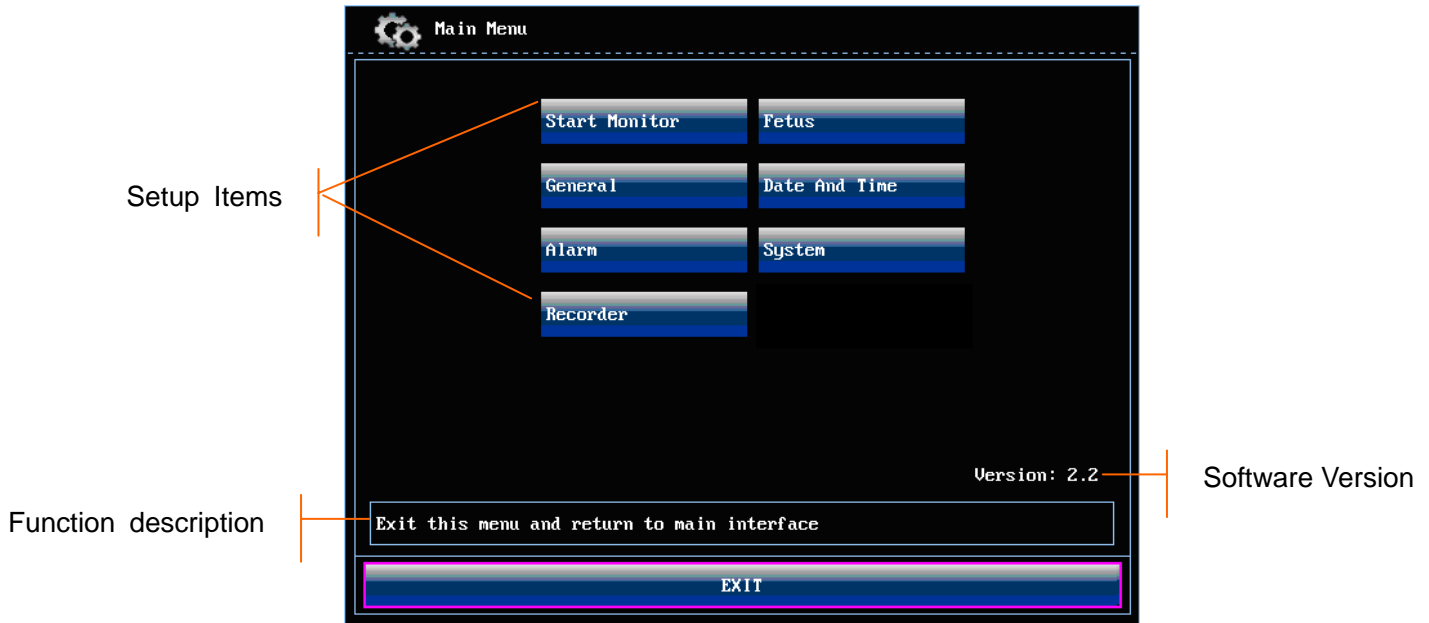
j) Print time remaining.

k) The current date and time.

3.3.2 Setup Interface

The Setup main menu is provided to change the Monitor configurations and monitoring settings.

Press the Setup key  on the main interface to open this menu. Using F9 Monitor Setup main menu as an example:



In the Setup main menu, you have access to all the items other than **System**. You can select **EXIT** to close this menu.

The items in this main menu all have submenus. To confirm the setting changes in the submenus, you must select **OK** to exit. If you don't want to store the new settings, select **Cancel**, or press the **START** key (or touch setup key with touch screen) to return to the main interface. If no action is taken in 30 seconds, the menu will return to the upper directory. The change will not be stored.




Once you select **OK** to confirm the setting changes, the new settings will be stored in the monitor's long-term memory. If the F9 Monitor is switched on again after being switched off or a power loss, it will restore the new settings.


For your reference, when the cursor is placed over an item in this menu, the F9 Monitor provides a brief function description of this item in a pane with a blue frame under the items. For example, if the cursor is located at "Fetus", its function "Set fetal monitoring items" is visible in the blue frame pane.

3.3.3 Touch screen

The touch screen is easy to use and operate. It works as a smart Control Knob. All the operations of the Control Knob can be done by gently touching the corresponding position on the screen.

When the touch screen is configured, touching the corresponding menu items is the same as rotating the Control Knob to this item and then pressing it. In the same way, one of the three results with the Control Knob will be achieved.

On the main interface, the symbols  and  might appear right next to the pane. Touch the  symbol to increase the numeric value, move to the previous item or move to the left.

Touching the  will decrease the numeric value, move to the next item or move to the right.

To exit from the selecting submenu, you should touch the item again or touch any place outside the area of the options.

NOTE: When touching an item, place the finger or the stylus pen within this item's cursor pane to insure the operating validity.

Chapter 4 Alarms

4.1 Alarm Classification

The F9 Monitor has two types of alarms: a patient alarm and a technical alarm.

Patient alarms indicate that the vital signs are exceeding its configured limit. They can be disabled. The adjustable alarm limits determine the conditions that trigger the alarm.

Technical alarms indicate that the F9 Monitor can not measure and therefore can not reliably detect critical patient conditions. When a patient alarm is switched off, its related technical alarms will be disabled as well.

According to the degree of severity, the alarms are divided into two levels: medium and low. A medium level alarm is a severe warning, labeled with the symbol **; a low level alarm is a general warning.

The medium level alarms have higher priority than the low level alarms. If both types of alarms are active at the same time, the Monitor sounds an audible indicator for the medium level alarms.



The system sets all patient alarms as medium level and all technical alarms as low level, and these settings can not be changed.


4.2 Audible Alarm

When an alarm is active, the F9 Monitor gives out an alarm sound.

Medium level alarm: a “Do” tone is repeated three times, followed by a pause.

Low level alarm: a single “Do” tone is issued, followed by a pause.

Press the **SILENCE** key on the front panel to toggle between audible alarm **on** and **off**. Meanwhile, the audible alarm indicator on the main interface will toggle between  and . However, the alarm messages will still be displayed and the alarm indicator will still be lit up when an alarm is active.

 **WARNING** : **Do not disable the audible alarm for the condition where the patient’s safety may be endangered.**

4.3 Visual Alarm

When an alarm is active, the following 3 visuals occur:

- **Alarm indicator:** the alarm indicator flashes in orange with a frequency of 0.5 Hz if it is a medium level alarm; the alarm indicator lights up continuously in orange if it is a low level alarm.
- **Alarm message:** the alarm message appears in the message window of the main interface in red, with patient alarms on the left and technical alarms in the middle.
- **Flashing number:** the numerical value of the measurement flashes in grey with a frequency of 2 Hz.

When more than one alarm is active, the alarm messages appear in the same area in succession.


The patient alarm messages are displayed either:

- in text form, for example “** FHR2 LOW”; or
- in numeric form, for example “** FHR2 115 < 120”; ** indicates this is a medium level alarm event; the first number is the current measurement result; the second number is the preset alarm limit.

The technical alarm messages are displayed in text form, for example “Fetus EQUIP MALF”.


4.4 Choosing the Alarm Display Form

To change the patient alarm display form,

- 1) Select the Setup key  on the main interface.
- 2) Select **Alarm** ⇨ **Message Form**.
- 3) Select **Text** (default) or **Numeric**.
- 4) Select **OK**.

4.5 Changing the Alarm Volume

To change the alarm volume,


- 1) Select the Setup key  on the main interface.
- 2) Select **Alarm** ⇨ **Alarm Volume**.
- 3) Select **Low** (default), **Medium** or **High**.
- 4) Select **OK**.

4.6 Reviewing Alarms

An alarm review menu records a list of up to 50 of the most recent patient and technical alarm messages with date and time information.

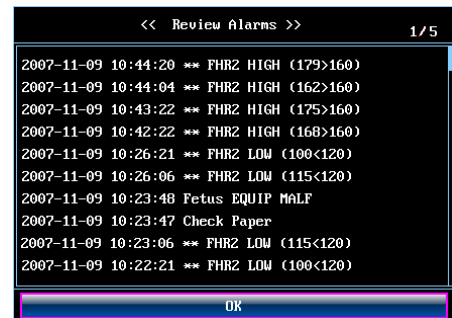
Select the alarm review key in the message window to open this menu.

Each page displays 10 alarm records. The page mark “1/5” informs you that there are five pages and the present one is page one (1).

To review more records, select the alarm list and then rotate the control knob or touch the  symbol to switch to the previous or next page.

Select **OK** to exit from this menu.

When a new monitoring starts, or after the monitor is switched off, the alarm messages will be cleared.



4.7 Alarm Treatment Measures

When the F9 Monitor gives out an alarm, you should:

- Check the patient’s condition.
- Identify the cause of the alarm.
- Silence the alarm if necessary.
- Check if the alarm is terminated when the alarm condition is cleared.

4.8 Testing Alarms

To test the functions of visible and audible alarms, do the following:

- 1) Switch on the monitor.
- 2) Enable the alarm.
- 3) Set the alarm limits to a narrow range.
- 4) Simulate a signal that is higher than the upper limit or lower than the lower limit. Or disconnect one of the plugs.
- 5) Verify if the visible and audible alarms are working properly.

4.9 Patient Alarm Defaults

Alarm Setting	Options	Default
FHR1/FHR2 Alarm	On, Off	On
FHR1/FHR2 Lower Limit	50 ~ 205 bpm, adjustable in 5 bpm steps	120 bpm
FHR1/FHR2 Upper Limit	55 ~ 210 bpm, adjustable in 5 bpm steps	160 bpm
FHR1/FHR2 Alarm Delay	0 ~ 300 second(s), adjustable in 5 second steps	10 seconds
FHR1/FHR2 Alarm Level	Medium, not adjustable	Medium


NOTE: The upper limit must be higher than the lower limit. When setting the upper limit, you do not have access to the options that are lower than the preset lower limit, and vice versa.

Chapter 5 Printing

5.1 Function Description

The built-in thermal recorder in the F9 Monitor supports both the American and International standard width recorder paper. It prints continuous FHR1/ FHR2 /TOCO /AFM traces synchronously along with the FHR1 mark, FHR2 mark, FM marks, event marks and zeroing marks.



The F9 Monitor supports some other functions as listed below:

- **Auto start printing:** If the function is enabled, the recorder starts printing automatically when a new monitoring starts (the **START** key is pressed). Otherwise you have to press the **PRINT** key to start printing.
- **Printing timer:** The printing timer determines the elapsed time for each print. This time is adjustable. Refer to Section 5.2.3 *Changing the Print Timer*.
- **Remaining time indicating:** A print remaining time appears next to the recorder status indicator  in the status window, unless the timer is set to **Infinite** or **Present ID**.
- **Fast printing:** The recorder prints the data saved in the F9 Monitor at a high speed (up to 25 mm/s).
- **Data Caching:** When the paper drawer is out of paper or when it is open, the recorder stops printing. The data from this time on (at most 60 minutes) will be temporarily saved in the internal memory. When new paper is loaded and/or the drawer is closed, the saved data will be printed out at a high speed. When the saved trace has been printed out, the recorder switches back to continue printing the current data at the normal speed automatically.


NOTE: When the F9 Monitor is switched off, the data in the internal memory will be lost.

- **FHR2 offset:** You can set the offset of the FHR2 trace to separate the two FH traces on the screen and the recorder paper. Refer to Section 7.4.4 *Changing FHR2/DFHR Offset*.
- **Print self-check:** The recorder prints a baseline for self checking when the F9 Monitor is switched on.


5.2 Printing Configuration

 **WARNING** : All the parameters should be configured correctly before printing starts. You can not change the configuration in the process of printing.


5.2.1 Switching Auto Start Printing On or Off

- 1) Select the Setup key  on the main interface.
- 2) Select **Start Monitor** \Rightarrow **Printing**.
- 3) Select **ON** (default) or **OFF**.
- 4) Select **OK**.

5.2.2 Choosing the Paper Speed

- 1) Select the Setup key  on the main interface.
- 2) Select **Recorder** \Rightarrow **Print Speed**.
- 3) Select **1 cm/min**, **2 cm/min** or **3 cm/min** (default).
- 4) Select **OK**.

5.2.3 Changing the Print Timer


- 1) Select the Setup key  on the main interface.
- 2) Select **Recorder** \Rightarrow **Timer**.
- 3) Set the timer to **Infinite** (default), **Present ID** or 10 ~ 90 (minutes, the increment is 5).

Infinite means that the recorder will not stop printing until the **PRINT** key is pressed.

Present ID means that the recorder will only print the traces for the patient with the present ID. It will stop when her traces come to the end. If the current page of the screen display includes more than one patient, traces of the one on the right side of the page will be the one printed.

- 4) Select **OK**.

5.2.4 Switching Print Self-Check On or Off

- 1) Select the Setup key  on the main interface.
- 2) Select **Recorder** \Rightarrow **Print Self-Check**.
- 3) Select **ON** or **OFF** (default).
- 4) Select **OK**.

5.3 Understanding the Recorder Paper Printout

CAUTION :

1. If there is any discrepancy between the display and the printout, the printout should have priority.
2. If the data is ambiguous, clinicians should make diagnoses based on the clinical assessment.

Figure 5-1 below is an example of the recorder paper with traces. Comparing it with the Monitor screen, you can find this extra information on the printed recording:

Paper vendor – “F9-G” indicates the paper vendor is GE. “F9-P” indicates the paper vendor is Philips.

Paper Style – The FHR pane range 30 ~ 240 bpm indicates the paper style is American Standard. The FHR pane range 50 ~ 210 bpm indicates the paper style is International Standard.

Self-Check Trace – The F9 Monitor prints a self-check trace after being switched on. It is used to check if the recorder paper is properly loaded.

FHR1 Mark – The thick FHR trace marked with “FHR1” indicates this trace is FHR1 trace.

FHR2 Mark – The thin FHR trace marked with “FHR2” indicates this trace is FHR2 trace.

Numeric List – A list of the current date, time, print speed, ID and FHR2 offset is printed at the start of a monitoring and every ten minutes afterwards.

Page Mark – Each recorder paper pack has 150 pages. When you notice the page mark comes to the end, remember to load new paper in time.

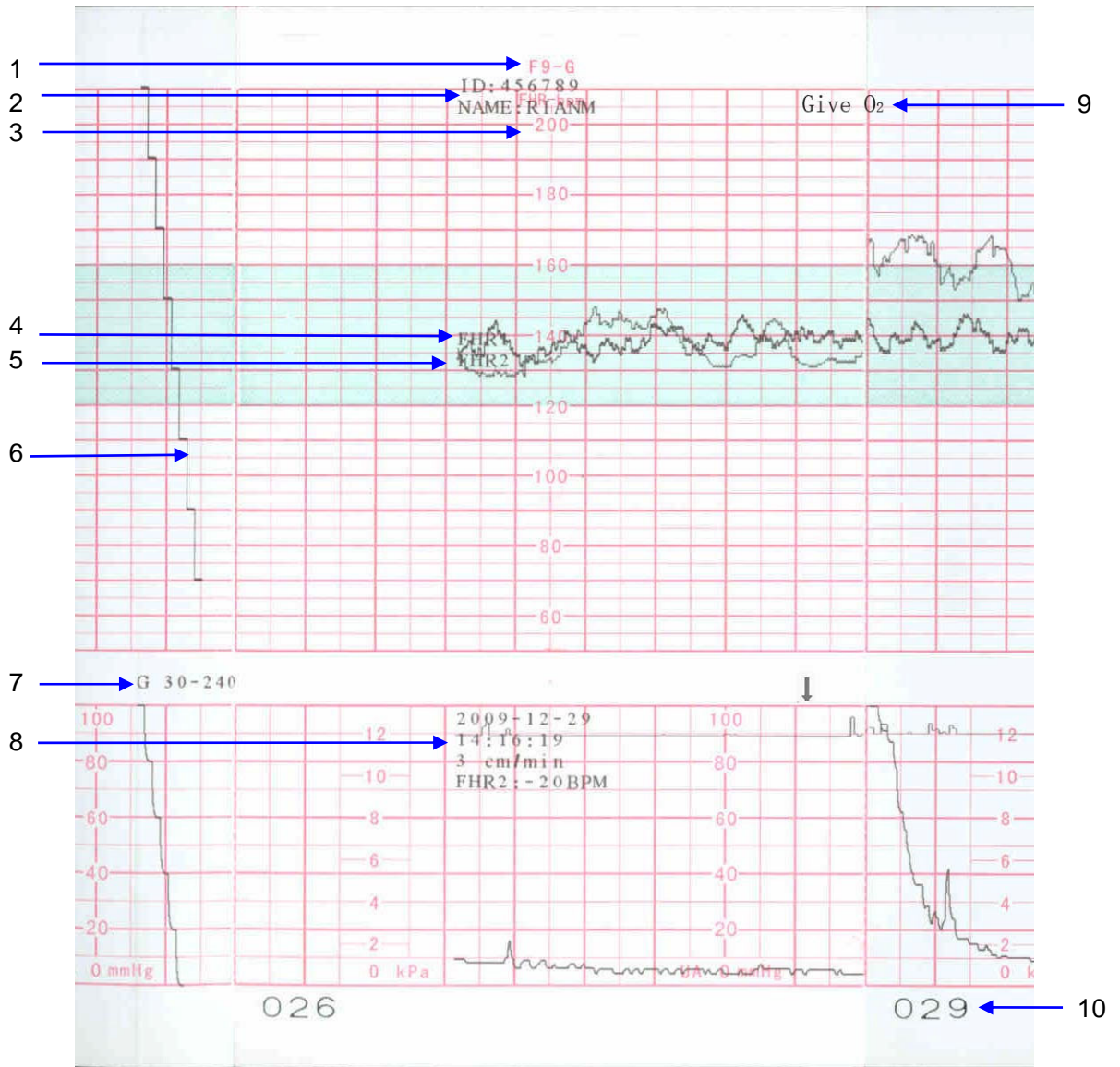


Figure 5-1: An Example of Recorder Paper with Traces

Item	Information	Description
1	Paper Type	There are two types of paper: F9-G and F9-P.
2	Patient Information	The patient's ID and name.
3	Paper Style	The FHR pane range indicates the paper style. American style: 30 ~ 240 International style: 50 ~ 210
4	FHR1 Mark	The trace marked with "FHR1" is the FHR1 trace.
5	FHR2 Mark	The trace marked with "FHR2" is the FHR2 trace.

6	Self-Check Trace	The monitor prints a self-check trace after being switched on. It is used to check if the recorder paper is properly loaded.
7	Paper Settings	The paper settings of the monitor. It consists of the paper type and paper style, e.g. "G 50-210", indicating that the paper type is "F9-G", and the paper style is International.
8	Trace Information List	A list of current date, time, print speed, ID, FHR2 offset, HR, SpO ₂ , and TEMP is printed at the start of the monitoring and every ten minutes afterwards. In the NIBP timer printing mode, the list also includes SYS, DIA and MAP.
9	Smart Note	The annotation of the event mark below.
10	Page Mark	Each recorder paper pack has 150 pages. When you notice the page mark comes to the end, remember to load new paper in time.

Chapter 6 Pre-Monitoring Preparation


6.1 Switching On the Monitor

⚠️WARNING⚠️: Check if all the metal parts are linked to the grounded power cord and the cord is working correctly before powering on the monitor.

⚠️WARNING⚠️: If any sign of damage is detected, or the F9 Monitor displays some error messages, do not use it on a patient. Contact a biomedical engineer in the hospital or our service technicians immediately.

Press the power switch located on the right panel to turn on the Monitor. The power indicator lights up and start-up music will be heard. You can operate the F9 Monitor after the main interface appears.

You can choose to switch the start-up music on or off,

- 1) Select the Setup key  on the main interface.
- 2) Select **General** ⇌ **Start-up Music**.
- 3) Select **ON** (default) or **OFF**.
- 4) Select **OK**.

NOTE: Check all the functions to make sure that the F9 Monitor is in good condition.

NOTE: If the F9 Monitor has a large amount of data saved in its long-term memory, it will take a few seconds to load them after start-up. When you notice the message “Loading data, please wait.....” on the screen, do not operate the F9 Monitor until the main interface appears. A message “Load failed!” indicates that the data has been damaged and therefore can not be loaded.

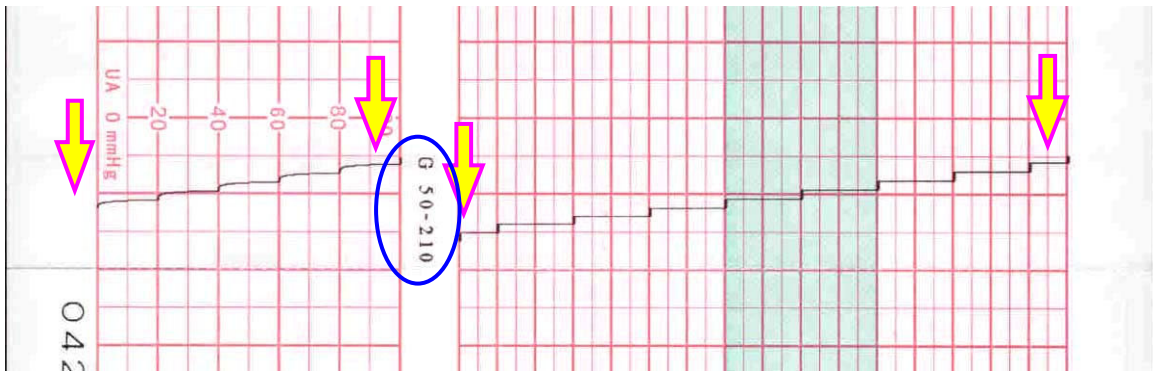
6.2 Checking the Recorder Paper

The monitor provides a **Print Self-Check** function to check if the recorder paper is loaded correctly and set.

The recorder prints a baseline and paper settings after start-up (if **Print Self-Check** is ON).

Check if the paper settings (circled in the illustration below) match the paper being used, and then observe the starts and ends of the printed baselines (illustrated with the arrow). The starts and ends should be printed exactly on the edges of the pane if the recorder paper is correctly loaded and set. If

they do not comply with the edges, reload paper or ask the service engineer to check the paper settings of the monitor.



If the F9 Monitor does not print the baseline, switch on the **Print Self-Check** and then restart the Monitor.

NOTE: Make sure the paper is correctly loaded before starting to print.

6.3 Adjusting the Screen Angle

The angle between the screen and the top cover of the F9 Monitor is adjustable as needed, allowing it to be mounted on a wall or placed on a flat surface.

Adjustment method:


Slide the hook latch on the left side of the screen to open it. Pull the screen forward and adjust it to the preset screen angles of 31, 44 or 53 degrees.



To bring the screen back to flat, pull it all the way forward and then push it back.



6.4 Setting Date and Time

- 1) Select the Setup key  on the main interface.
- 2) Select **Date and Time**.
- 3) Set the year, month, date, hour, minute and second. The first three numbers are used to set the year, month and date. Their orders vary with the preset Date Format below.
- 4) Select **Date Format** for the format of the date;
 yyyy-mm-dd,
 mm/dd/yyyy (default), or
 dd/mm/yyyy.
- 5) Select **OK**.

NOTE: The date and time remain in the F9 Monitor after it is switched off for at least two months. You do not have to reset the date and time before each usage.

6.5 Connecting the Transducers

Check for visible damage to the transducers each time before connecting them to the monitor. Pay special attention to the seams on the transducers and cables before immersing them into conductive fluid. If damage is found, replace them.

When plugging transducers into the Monitor, make sure the arrow symbol of the connector is facing up. Refer to Figure 6-2.

When disconnecting a transducer, hold the body of the transducer collar (the shaded part shown in Figure 6-3) with fingers, push it in slightly, then pull it out.

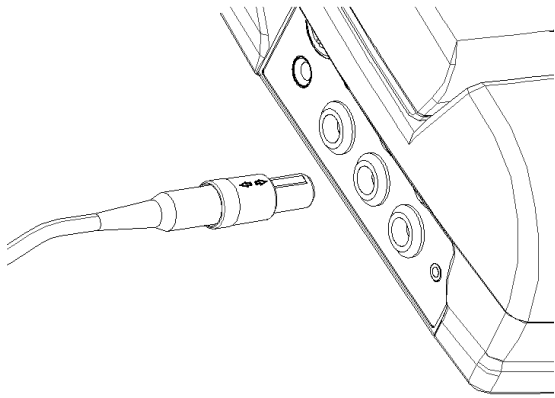


Figure 6-2: Connecting the transducer

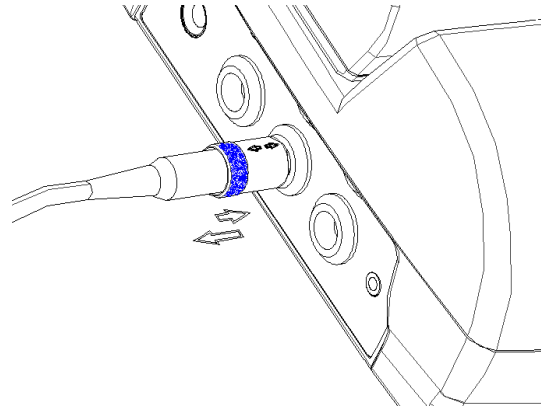







Figure 6-3: Disconnecting the transducer

6.6 Adjusting the Volume



The F9 Monitor automatically detects which channel the ultrasound transducer is connected to. The corresponding volume adjustment key of this channel displays , indicating the FH sound is

coming out from this channel, for example:  **141** ; while the other one displays , for

example:  **180** . Press the **CHANNEL** key to switch the FH sound to the other channel.




Adjust the default monitoring volume:


The FH volume returns to the default level after the **START** key is pressed. This default level is adjustable. To change this level,

- 1) Select the Setup key  on the main interface.
- 2) Select **Start Monitor**  **Volume**.
- 3) Select the volume from 1 ~ 10; the increment is 1 and the default level is 3.
- 4) Select **OK**.

Adjust the real-time monitoring volume:

If the default volume level is not satisfactory when monitoring, you can adjust the real-time volume of each channel.


- 1) Select the volume adjustment key  on the main interface.
- 2) Rotate the control knob clockwise or touch the  symbol for one step, the volume increases by one level. There are ten levels. The green volume level indicator  increases one bar for every two steps. Rotate the Control Knob counter-clockwise or touch

the  symbol to decrease the volume.

3) Press the Control Knob again or touch any other place on the screen to confirm the volume level.

Adjust the F9 Monitor Event Sound volume:

The volume of the sound emitted when pressing keys, and rotating/pressing the control knob is also adjustable.

- 1) Select the Setup key  on the main interface.
- 2) Select **General** \rightleftarrows **Key Volume**.
- 3) Select **Low** (default), **High** or **OFF**.
- 4) Select **OK**.

Chapter 7 Fetal Monitoring

⚠️WARNING⚠️:

- **The F9 Monitor is not intended for use in intensive care units (ICU), operating rooms or for home use.**
- **The F9 Monitor is not protected against defibrillation. Do not apply it during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.**
- **Always check if the alarm settings are appropriate for your patient before starting monitoring.**

7.1 Confirming Fetal Life

Fetal monitoring with ultrasound or DECG can not differentiate a fetal heart rate signal source from a maternal heart rate source in all situations. Following are some of the signal sources that might be taken as FHR signal source by mistake:

- High maternal heart rate signal.
- Maternal aorta or other large vessels signals.
- Electrical impulse from the maternal heart transmitted through a recently deceased fetus.
- Movement of a deceased fetus during or following maternal movement.

So you need to confirm fetal life by other means before starting to use the Fetal Monitor, such as using a fetoscope, stethoscope, Pinard stethoscope or visual obstetric ultrasound.

7.2 Monitoring Fetal Heart Rate (FHR) with Ultrasound

Ultrasound monitoring is a method used to obtain FHR through the maternal abdominal wall, which can be used for antepartum monitoring. By placing the FHR transducer on the maternal abdomen, it will transmit a low energy ultrasound wave to the fetal heart, and receive the echo signal.

7.2.1 Parts Required

- 1) Ultrasound transducer
- 2) Ultrasound coupling gel
- 3) Belt

7.2.2 FHR Monitoring Procedure

- 1) Place the transducer belts across the bed. Lay the patient on the bed and draw the belts over her abdomen.
- 2) To acquire the FH signal, search for the location of the fetal heart using a stethoscope or a fetoscope. Apply ultrasonic gel on the transducer and move it slowly around the abdomen until a clear heartbeat sound of the fetal heart is heard. Refer to Figure 7-1 for the transducer position.

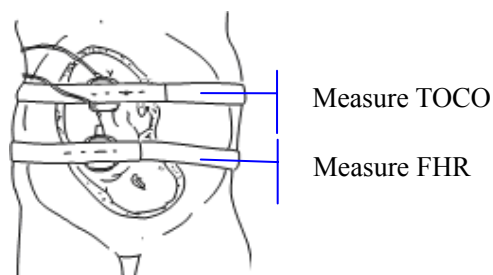


Figure 7-1: Ultrasound transducer & TOCO transducer positioning (single fetus)

- 3) To secure the Transducer, wrap the abdomen with the belt over the transducer. Secure the transducer by pushing its buckle through the overlapping section of the belt.

Make sure the belt is neither too tight nor too loose and the patient is monitored comfortably. When the fetal heart beat sound is detected, the FHR trace and numeric value are displayed on the screen.


NOTES:


- 1) Do not mistake high maternal heart rate for fetal heart rate.
- 2) The best quality records will only be obtained when the transducer is placed in the optimum position.
- 3) Positions with strong placental sounds (swishing) or fetal cord pulse (indistinct pulse at fetal rate) should be avoided.
- 4) If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During the monitoring, prolonged lying in the supine position should be avoided due to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable to the mother.
- 5) It is not possible to measure FHR unless an audible fetal heart signal is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.

7.2.3 Switching the FHR Alarm On or Off

Always check if the alarm settings are appropriate for your patient before starting to monitor.

If the fetal heart alarm is switched off, the F9 Monitor will no longer give any audible or visual warning for this monitoring item.

- 1) Select the Setup key  on the main interface.
- 2) Select **Alarm** \Rightarrow **FHR1** or **FHR2** \Rightarrow **Alarm**.
- 3) Select **ON** (default) or **OFF**.
- 4) Select **OK**.


If the FHR1 or FHR2 alarm is switched off, an alarm switched-off symbol  will appear in the numeric window. For example:



⚠️WARNING⚠️: Do not disable the alarm for the condition where the patient's safety may be endangered.


7.2.4 Changing the FHR Alarm Limits

The alarm limits you set determine the parameters that trigger the alarm.

- 1) Select the Setup key  on the main interface.
- 2) Select **Alarm** \Rightarrow **FHR1** or **FHR2**.
- 3) Select a value from 50 ~ 205 bpm for the **Lower Limit**; the increment is 5 and the default is 120 bpm.
- 4) Select a value from 55 ~ 210 bpm for the **Upper Limit**; the increment is 5 and the default is 160 bpm.
- 5) Select **OK**.

7.2.5 Changing the FHR Alarm Delay

The alarm delay indicates how long the measured result continues exceeding its limit before the alarm is triggered.

- 1) Select the Setup key  on the main interface.
- 2) Select **Alarm** \Rightarrow **FHR1** or **FHR2** \Rightarrow **Alarm Delay**.
- 3) Select a value from 0 ~ 300 second(s); the increment is 5 and the default is 10 seconds.
- 4) Select **OK**.

7.3 Monitoring FHR with DECG (Optional)

7.3.1 Contraindications

The fetal spiral electrode can be used when amniotic membranes are adequately ruptured and sufficient cervical dilatation is ensured. The fetal electrode tip is designed to penetrate the epidermis of the fetus; therefore, trauma, hemorrhage and/or infection can occur. The electrode should be used with strict adherence to aseptic technique.

The fetal spiral electrode should not be applied to the fetal face, fontanelles or genitalia.

Do not apply when placenta previa is present; when the mother has visible genital herpes lesions or reports symptoms of prodromal lesions; when the mother is HIV sero-positive; when mother is a confirmed carrier of hemophilia and the fetus is affected or of unknown status; or when it is not possible to identify fetal presenting part where application is being considered. This method is not recommended when the fetus is extremely premature, or in the presence of a maternal infection such as Hepatitis B, Group B hemolytic strep, syphilis or gonorrhea, unless a clear benefit to the fetus or mother can be established.

7.3.2 Parts Required

1) DECG cable 2) Fetal spiral electrode 3) Disposable maternal attachment pad electrode

7.3.3 Preparing the Patient's Skin Prior to Placing Electrodes

The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Shave hair from electrode sites, if necessary.
- Wash the sites thoroughly with soap and water. (Do not use ether or pure alcohol, which will increase skin impedance)
- Rub the skin briskly to increase capillary blood flow in the tissues.
- Remove skin oil.

7.3.4 Directions for Using Fetal Spiral Electrode

Please refer to the manufacturer's directions for the Fetal Spiral Electrode.

7.3.5 DECG Monitoring Procedure

Please refer to the manufactures directions for the Fetal Spiral Electrode.

⚠️ WARNING ⚠️: Do not plug the fetal spiral electrode wire in to the power socket.

⚠️ CAUTION ⚠️: Do not mistake the higher maternal heart rate for DECG.

NOTE:

- 1) If there is any doubt as to the presence of a fetal heart signal with ECG, check using the US transducer on the patient's abdomen or with a separate diagnostic instrument. The presence of an audible Doppler heart sound at a rate distinct from that of the maternal pulse is unequivocal evidence of the fetal life.
- 2) After the electrode is securely attached, allow a few minutes for the electrode and fetal tissue to become stabilized. It is essential that the ECG signal electrode is in good contact with the fetal presenting part.

7.3.6 Detaching the Fetal Spiral Electrode

To detach the fetal spiral electrode, rotate it counterclockwise until it is free from the fetal presenting part. Do not pull the electrode from the fetal skin forcefully.

Dispose of the used fetal spiral electrode in accordance with all applicable Federal, State and local medical/hazardous waste practices. Do not use it again.

7.4 Monitoring Twin FHRs

7.4.1 Monitoring Twins Externally

To monitor twin FHRs externally, you need to connect a US transducer to the US1 socket and the second US transducer to the US2 socket of the monitor. Follow the instructions described in Section 7.2 to acquire FHR signals for both channels. Press the **CHANNEL** button to switch the FH sound from one channel to the other.

When the two US transducers are in place, make sure the FH sounds from both channels are clear. Two FHR traces and two FHR values are displayed on the screen.

7.4.2 Monitoring Internally

Alternatively, you can monitor a FH using ultrasound externally, and monitor the second FH using DECG internally.

Connect the US transducer to the US1 socket; connect the DECG cable to the DECG socket.

Monitor one twin with a US transducer using the procedures described in Section 7.2.

Monitor the second twin with a DECG cable using the procedures supplied by the manufacture.

⚠ CAUTION ⚠: **The US transducer must be connected to the US1 socket. If the US transducer connects to the US2 socket while the DECG cable is connected to the DECG socket, the FHR trace and numeric from US2 will not be displayed.**


7.4.3 Signals Overlap Verification (SOV)

When monitoring twins, there are possibilities that one twin's FHR signal is mistaken for the other one's signal. The F9 Monitor provides a signal overlap verification (SOV) function to reduce these possibilities.

In the process of monitoring, if the SOV detects signals overlapping, an alarm message "Signals Overlap (FHR1, FHR2/DFHR)" will appear on the screen to warn you. It may be necessary to check the patient and reposition the transducers.

7.4.4 Changing FHR2/DFHR Offset

In order to distinguish the FHR1 trace from the FHR2/DFHR trace, FHR2/DFHR offset is provided to help you separate the two traces by an offset of -20 bpm or +20 bpm.

- 1) Select the Setup key  on the main interface.
- 2) Select **Recorder** ⇌ **FHR2 Offset**.
- 3) Select **-20 bpm** (default), **0 bpm** or **+20bpm**.
- 4) Select **OK**.

The following preset FHR2/DFHR offset will be printed on the recorder paper every 10 minutes.

"FHR2/DFHR: -20bpm": the FHR2/DFHR trace is 20bpm lower than it really is.

"FHR2/DFHR: +20bpm": the FHR2/DFHR trace is 20bpm higher than it really is.

7.5 Monitoring Uterine Activity Externally

7.5.1 Parts Required

- 1) TOCO transducer
- 2) Belt

7.5.2 TOCO Monitoring Procedure

- 1) Place the transducer belt across the bed. Lay the patient on the bed with her abdomen positioned over the belts.

- 2) Set the TOCO baseline. Place the transducer on the patient's fundus to get an optimum recording of uterine activity. Refer to Figure 7-1 for the TOCO transducer position.


Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt. Make sure the belt is neither too tight nor too loose and the patient is monitored comfortably.

- 3) To adjust the value to zero, press the **AUTO ZERO** button to adjust the value to the baseline. Make sure this is not done during a contraction. The uterine activity reading at this point should be <30 on the TOCO scale indicates the belt is too tight, and you need to adjust it. Wipe off any gel present on the abdomen around this area.

NOTES:

- 1) Do not apply ultrasound coupling gel on a TOCO transducer or its contact area.
- 2) Check the function of the TOCO transducer by applying pressure to it to see if this is displayed on the screen.

7.5.3 Changing the UA Baseline

- 1) Select the Setup key  on the main interface.
- 2) Select **Fetus** ⇌ **UA Baseline**.
- 3) Select **5**, **10** (default), **15** or **20**.
- 4) Select **OK**.

NOTE: If your Monitor has been configured with IUP, the baseline will be 10 and is not adjustable.

7.6 Monitoring Uterine Activity Internally (Optional)

7.6.1 Parts Required

- 1) Disposable intrauterine pressure catheter IUPC (“IUPC” for short)
- 2) Reusable intrauterine pressure connecting cable (“connecting cable” for short)
- 3) Reusable intrauterine pressure cable (“IUP cable” for short)

7.6.2 Directions for Using IUPC

See the manufactures instructions for insertion.

Rezeroing the System During Monitoring

- 1) Attach the IUPC cable.

- 2) With the catheter connected to the IUP cable, momentarily press the re-zero button on the pressure cable (See Figure 7-2). The green light on the cable will flash for five seconds.

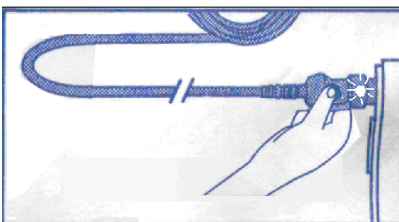


Figure 7-2: Rezeroing the system

- 3) During that time, adjust the F9 Monitor to zero by pressing the **AUTO ZERO** button.

⚠WARNING⚠:

- **Before insertion, the placental position should be confirmed, amniotic membranes are adequately ruptured and sufficient cervical dilatation is assured.**
- **Try to insert the catheter opposite the placental site. Do not insert the introducer beyond the cervical OS. Use with caution when a uterine infection is present.**
- **If resistance is met at any time during insertion, withdraw the catheter slightly and try at a different angle. Forced insertion may result in patient's discomfort or injury.**

⚠CAUTION⚠:

- **Since procedures vary according to hospital needs/ preferences, it is the responsibility of the hospital staff to determine exact policies and procedures for both monitoring and amnioinfusion. The safe and effective use of the IUPC depends on the skill of the clinician who applies /uses it.**
- **Read the manufactures Directions For Use of the IUPC prior to insertion.**

7.6.3 IUP Monitoring Procedure

- 1) Insert the IUPC according to the manufactures instructions for use.
- 2) Connect the IUPC to the IUP cable. (See Figure 7-3)

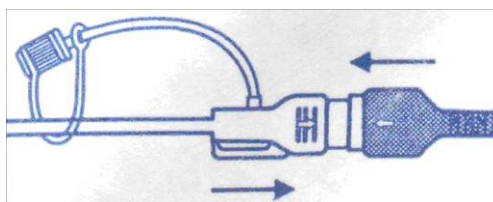


Figure 7-3: Connect catheter to pressure cable

- 3) Connect the IUP cable to the connecting cable. (They might have already been securely connected in the package.)
- 4) Plug the connecting cable to the TOCO/IUP socket of the monitor.
- 5) Momentarily pressing the re-zero button on the IUP cable. The green light on the cable will flash for five seconds. During that time, zero the F9 Monitor by pressing the **AUTO ZERO** button. Make sure the display value and the trace are both “0”.
- 6) Ask the mother to cough. A spike on the trace in response to the cough indicates proper positioning and function of the IUPC.
- 7) Flush as needed during monitoring. A spike on the tracing will appear during flushing.

7.6.4 Checking Intrauterine Pressure Cable Function

To test an IUP cable’s function:

- 1) Disconnect the catheter from the cable. Insert the cable check plug into the catheter end of the cable. (See Figure 7-4).

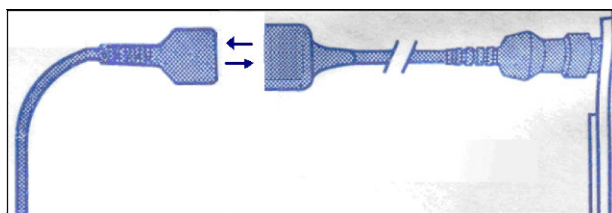


Figure 7-4: Test the Pressure Cable

- 2) Verify that the green light is continuously lit (not flashing).
- 3) If the light does not illuminate, replace the cable.

NOTE: If the light is flashing, verify that the cable check plug is inserted completely into the cable.

⚠️WARNING⚠️: The cable test function is not intended to check the accuracy of the system, only to confirm cable function.

7.7 Monitoring Fetal Movement

7.7.1 Auto Fetal Movement (AFM) Monitoring

Auto fetal movement is also detected from the ultrasound Doppler signal. The fetal movement signals differ from the Doppler heart rate signal in that they have larger extent and lower frequency. The larger extent is due to the bigger scope of moving areas (e.g., the fetal arms or legs); lower frequency is due to the lower velocity of the fetal movements compared with those of the fetal heart.


Only the US1 channel can monitor AFM. Be aware that when monitoring twins, the AFM detected by US1 may also be caused by the second fetus's movement.

The movement of the fetus will be detected and displayed in the form of a trace on the screen and the recorder paper.

AFM monitoring can be switched off; and is gain adjustable.


7.7.2 Enabling or Disabling AFM Trace

The AFM trace on the screen can be enabled or disabled.

- 1) Select the Setup key  on the main interface.
- 2) Select **Fetus** \rightleftarrows **AFM**.
- 3) Select **ON** or **OFF** (default).
- 4) Select **OK**.

7.7.3 Changing AFM Gain

The AFM gain affects overall number values and the scope of the AFM trace.

- 1) Select the Setup key  on the main interface.
- 2) Select **Fetus** \rightleftarrows **AFM Gain**.
- 3) Select **1**, **2**, **3** (default) or **4**.
- 4) Select **OK**.

7.7.4 Manual Fetal Movement (MFM) Monitoring

The MFM monitoring result comes from the patient's feeling of fetal movement. The count will be displayed on the screen in the MFM numeric window area.

- 1) Insert the remote event marker connector into the **MARK** socket on the monitor.
- 2) Let the patient hold the Remote Event Marker and ask her to press the top button when a fetal movement is felt. Continuous movements in 5 seconds are considered to be one movement and instruct patient to press the button only once.

7.8 Start Monitoring

After pressing the **START** button, the F9 Monitor automatically zeroes the pressure, clears the MFM count and starts monitoring.

If the Auto start printing function is disabled, press the **PRINT** button to start printing.


7.9 Inputting Maternal Information (Mat. Info)

7.9.1 Auto ID

After you press the **START** button, the system creates an auto-ID for the present patient (if the Mat. Info inputting function is turned off). The auto-ID consists of the date and time when the monitoring starts.

7.9.2 Changing Maternal Information

You can change the patient’s information after the monitoring starts:

- 1) Select the Mat. Info key  on the main interface.
- 2) Select **ID**.
- 3) Enter the required numbers for the patient’s ID on the touch-screen keyboard.
- 4) Select **Ok**.
- 5) Select **Name**.
- 6) Enter the required letters for the patient’s name on the touch-screen keyboard.
- 7) Select **Ok**.
- 8) Select **OK**.

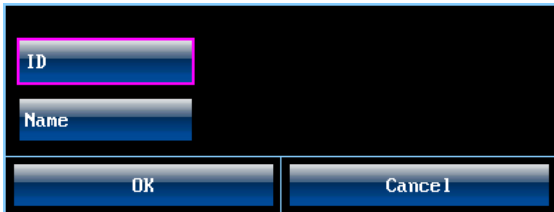
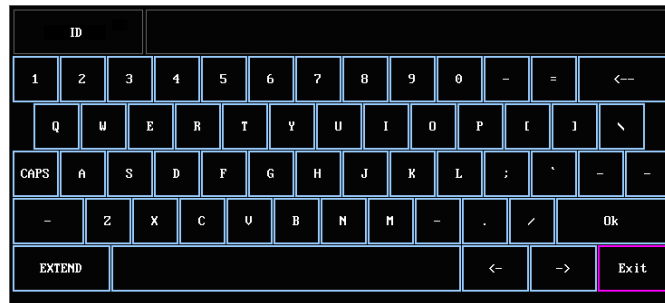


Figure 7-5: Mat. Info inputting menu



7-6: Touch-Screen Keyboard

The monitoring does not stop when you change the maternal information. After selecting **OK** to exit, the new ID takes the place of the old one for this patient.

CAUTION :

1. Pressing the **START** key separates two patients. The F9 Monitor only displays the most recent ID for the same patient.
2. If printing starts automatically with the monitoring, the first ID printed on the recorder paper will be the auto-ID. The new ID will be printed 10 minutes later.
3. Both the ID and name are shown on the printout.


- For the non-English system, more letters are provided for inputting the name.

Select the key **ENGLISH** and **EXTEND** on the bottom left corner to toggle between them.

7.9.3 Switching Mat. Info Entering On or Off

If the Mat. Info entering function is switched on; the menu will pop up for you to input the ID and name for the patient after the **START** key is pressed. The monitoring starts immediately after you exit from the menu.

To switch the Mat. Info Inputting function on or off:

- Select the Setup key  on the main interface.
- Select **Start Monitor** \Rightarrow **Mat. Info**.
- Select **ON** or **OFF** (default).
- Select **OK**.

7.10 Fetal Monitoring Screen Display

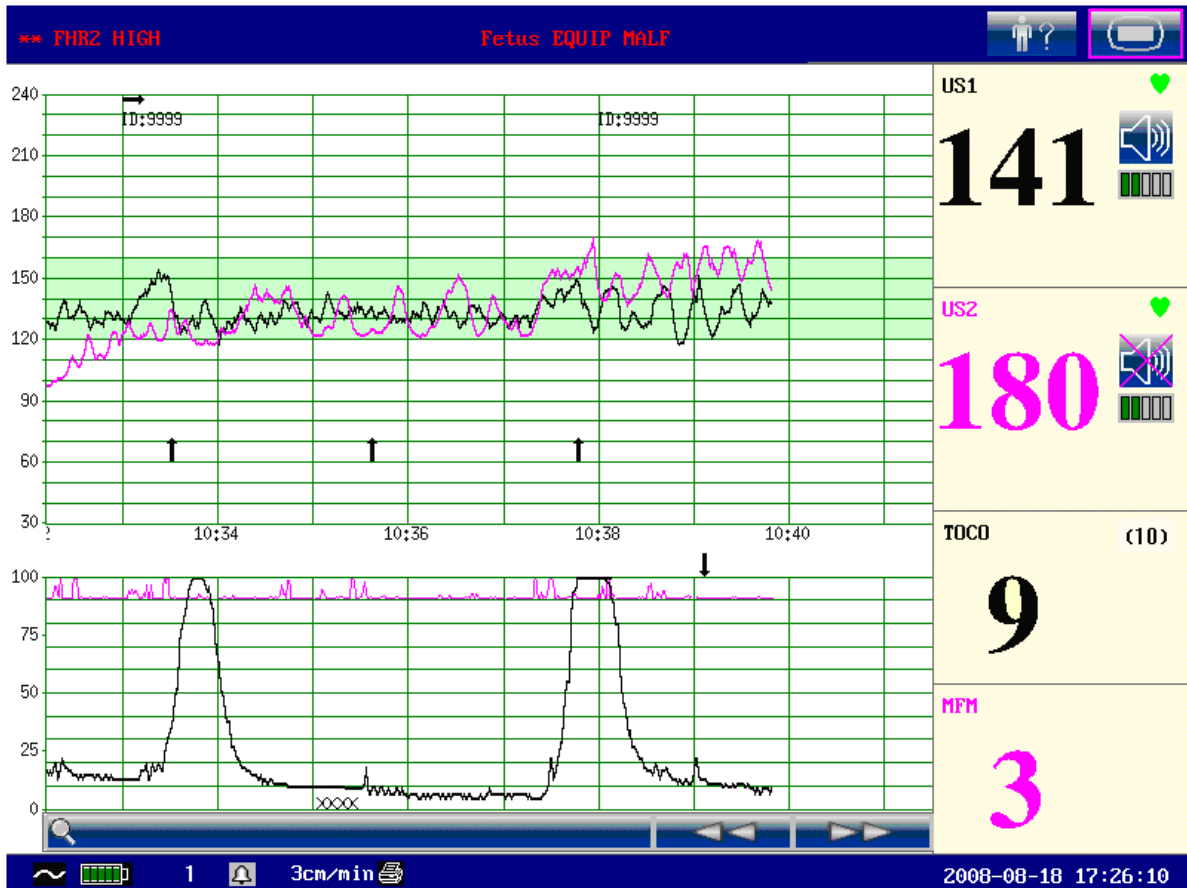


Figure 7-7: Fetal monitoring screen display

7.10.1 Fetal Monitoring Traces

⚠️ WARNING ⚠️: Due to the LCD size, resolution and system settings, the traces displayed on the screen may look different from the recorder printout. Take the printout as criterion when making diagnoses.

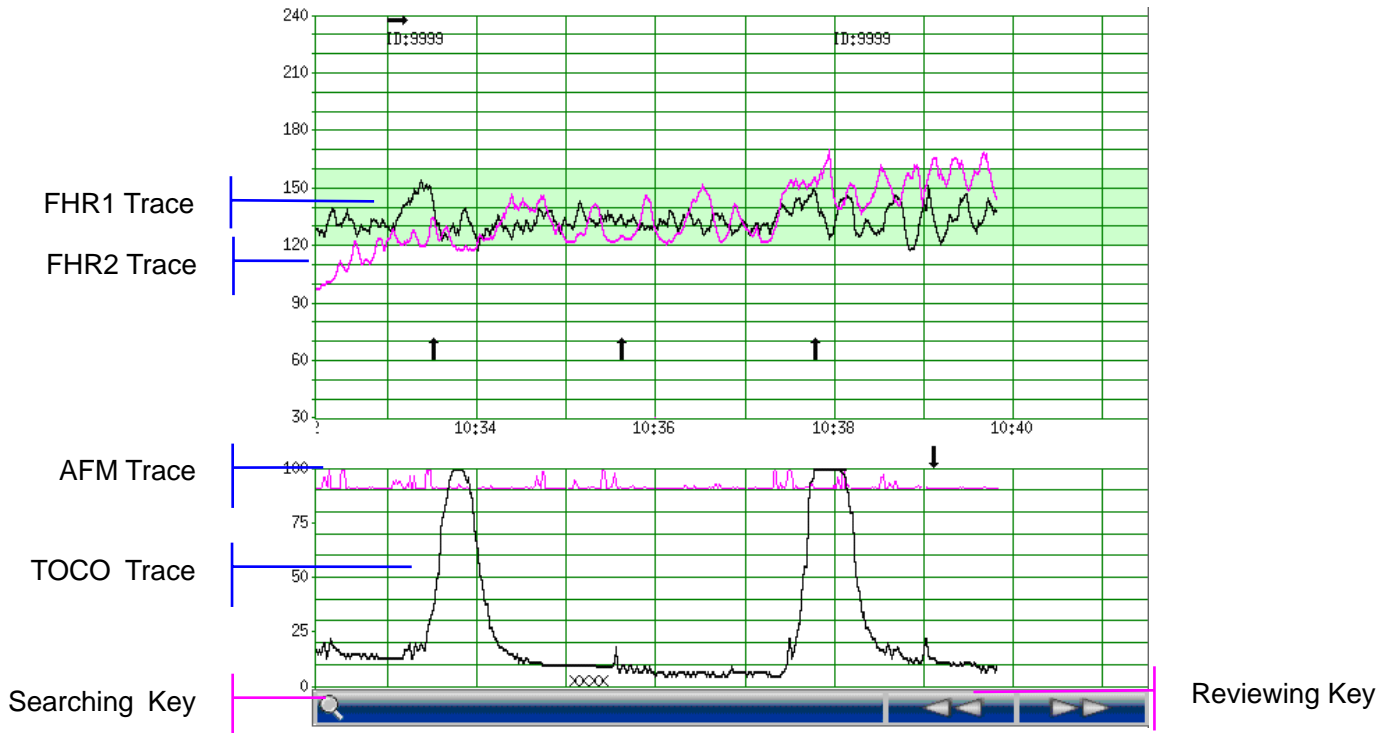


Figure 7-8: Fetal monitoring traces

During monitoring or reviewing, the trace window displays four traces at most (refer to Figure 7-8): FHR1 trace, FHR2 trace (dual configuration), AFM trace, and TOCO trace.

FHR1/FHR2 trace

The y-axis of the trace indicates the values of FHR, whose range is 30 ~ 240 bpm (American standard) or 50 ~ 210 bmp (International standard).

AFM trace

The y-axis indicates the range of fetal movement.

NOTE: The AFM trace is only for reference, and must be taken in context with MFM marks.

TOCO trace

The y-axis indicates the values of TOCO, whose range is 0% ~ 100%.


In addition, some other symbols appear among the traces:

- This symbol indicates the new monitoring starts.
- ↑ This symbol indicates a manual fetal movement, and it appears after the patient presses the remote event marker when she feels a fetal movement.
- ↓ This symbol indicates the **MARK** button is pressed to record an event, such as the patient turning around, taking injection.
- xx This symbol indicates the Monitor is zeroed by pressing the **AUTO ZERO** button.

7.10.2 Changing the Time Scale

The fetal monitoring traces share the same time scale, which displays the time every two minutes. This scale is either in real time format or relative time format. Real time is the time of the monitor. Relative time records the elapsed time for the current monitoring.

To change this time format:


- 1) Select the Setup key  on the main interface.
- 2) Select **Date And Time** ⇌ **Time Scale**.
- 3) Select **Real Time** (default) or **Relative Time**.
- 4) Select **OK**.

NOTE: The real time contains only the hour and minute, but no second. As a result, the time scale may correspond to the 0 ~ 59th second of the system time. Do not mistake the time scale for the exact time.


7.10.3 Changing the Trace Advancing Mode

Trace advances as time passes by when the F9 Monitor receives valid data. If no valid data is received, the screen will either advance with Auto or Valid. **Auto** means the screen keeps advancing as time passes by; **Valid** means the screen advances when valid data is received, and it will stop after no valid data is received for 30 seconds. The screen will advance again when valid data is received.

To change the screen scroll mode:

- 1) Select the Setup key  on the main interface.
- 2) Select **Fetus** ⇌ **Trace Advancing**.
- 3) Select **Auto** (default) or **Valid**.
- 4) Select **OK**.

7.10.4 Searching for a Patient

The searching key  under the traces is used to search for a patient's data saved in the monitor.

To search for a patient,

- 1 Select the searching key to open the patient list. It contains six sets of most recent patient's ID and name. Select the required item, and the main interface will switch to the most current data of this patient.



Figure 7-9 Patient List



Figure 7-10 Patient Searching

If the patient is not in this list,



- 2 Select **MORE** to open the **Patient Searching** window.
- 3 Select **ID**, input the patient ID with the soft keyboard and select **Ok**.
- 4 Select **Name**, input the patient's name with the soft keyboard and select **Ok**.

NOTE:


You can input only a part of the patient ID or name. However, the more information you input, the more accurate result you will get.


- 5 Select **Search**. The patients with the matched information are listed in the window.
- 6 Select and confirm the required item, and the main interface will switch to the most current data of this patient.

7.10.5 Reviewing



The reviewing keys  (backward key) and  (forward key) under the traces are used to review the traces.

Select the backward key to review the previous traces. The traces start to retreat. The amount of the

progress symbol “<” on top of the traces indicates the retreating speed. Rotate the control knob counter-clockwise or touch the  symbol to increase the speed until it reaches the maximum.

Rotate the knob clockwise or touch the  symbol to decrease the speed until it reaches the minimum. Press the knob or touch any place on the screen to pause.

Select the forward key to review the next traces. The traces start to advance. The amount of the progress symbol “>” on top of the traces indicates the advancing speed. Rotate the control knob

clockwise or touch the  symbol to increase the speed until it reaches the maximum. Rotate the knob counter-clockwise or touch the  symbol to decrease the speed until it reaches the minimum. Press the knob or touch any place on the screen to pause.

When the reviewing is paused, the progress symbol turns to <--X%-->. If the **PRINT** button is pressed at this moment, the recorder will print the traces starting from the left edge of the screen at a high speed.

X% indicates the proportion of current traces positioned in the entire reviewable traces.

Move the cursor to any item other than reviewing keys/ searching key, or touch any place outside the range of trace window on the screen to return to the real time main interface.

When reviewing, the monitor does not stop. The FH sound and values are all real time information of the current patient.


 **WARNING** :

The reviewing printout is provided for reference only. Please take the real-time printout as criterion when making diagnoses.

 **CAUTION** :

- 1) **You must pause before starting to print. Attempting to print while in playback mode might result in missing data on the paper.**
- 2) **After the reviewed data has been printed out, the recorder does not switch back to real-time printing automatically.**

7.10.6 Making a Note


When there is a significant event, you can press the **MARK** key on the front panel to add a note. An event mark  will appear on both the main interface and the recorder paper.

However, an event mark cannot clearly indicate an event. **Smart Notes** provides a list of annotation for the events, including events that relate to drugs, positions, membranes, procedures, antenatal,

reasons and others.

- Enabling/disabling Smart Notes

To enable or disable **Smart Notes**,

- 1) Select the setup key  on the main interface.
- 2) Select **General Setup > Smart Notes**.
- 3) Select **ON** or **OFF** (default).
- 4) Select **OK**.

A smart note editing key  appears next to the **Smart Notes** item.



- Annotating an event

Once **Smart Notes** is enabled, press the **MARK** key on the front panel to open the smart note list, choose an event catalog and then choose an annotation from the list.

The annotation of this event will be printed in the top area of recorder paper.

- Changing smart note content

You can change the smart note content in the smart note list by performing the following steps:

- 1) Select the setup key  on the main interface.
- 2) Select **General Setup**.
- 3) Select the smart note editing key .
- 4) Select a catalog.
- 5) Select a note.
- 6) Use the soft keyboard to edit the note content.
- 7) Select **Ok**.
- 8) Select **OK**.


7.10.7 Fetal Monitoring Values

The fetal monitoring values in the numeric window include FHR1, FHR2/DECG, TOCO and MFM count:

	FHR1	<p>FHR1</p>	<p> : FH refreshing rate</p> <p> : FH sound volume adjustment key</p> <p> : FH sound volume indicator</p> <p>141: FHR1 measurement value.</p> <p>If the US1 socket is not connected with a US transducer, nothing displays here; if the transducer is connected but no monitoring is going on, it displays ---.</p>
	FHR2	<p>FHR2/DECG</p>	<p>180: FHR2/DFHR measurement value.</p> <p>If the US2/DECG socket is not connected with a US transducer/DECG cable when switched on, it displays OFF (no numeric value); if the transducer/cable is connected but no monitoring is going on, it displays ---.</p>
	TOCO	<p>TOCO/IUP</p>	<p>(10)/(0): UA baseline</p> <p>9: current UA measurement value</p>
	MFM	<p>MFM</p>	<p>3: MFM count</p>

7.10.8 Changing Fetal Numeric Window Position

For the F9 Monitor, the fetal numeric value window can be located either on the right of the traces or on top of them. To change its position,

- 1) Select the Setup key  on the main interface.
- 2) Select **General** \Rightarrow **Numeric Window**.
- 3) Select **Top** or **Right** (default).
- 4) Select **OK**.

7.10.9 Fetal Monitoring Alarm Messages

This table lists the alarm information that might appear during fetal monitoring, their respective causes and countermeasures.

Alarm Message	Cause	Countermeasure
Patient Alarm (Medium Level)		
**FHR1 HIGH or ** FHR1 xxx > yyy, **FHR2 HIGH or ** FHR2 xxx > yyy	FHR1 or FHR2 measuring result (xxx) is higher than the set upper limit (yyy) over the alarm delay time.	Check if the alarm limits are suitable; check the patient's condition.
**FHR1 LOW or ** FHR1 xxx < yyy, **FHR2 LOW or ** FHR2 xxx < yyy	FHR1 or FHR2 measuring result (xxx) is lower than the set lower limit (yyy) over the alarm delay time.	
Technical Alarm (Low Level)		
US1 UNPLUGGED or US2 UNPLUGGED	US transducer 1 or US transducer 2 is not securely connected.	Check the connection of the transducer.
US1 SIGNAL LOSS or US2 SIGNAL LOSS	FHR1 or FHR2 signal is too weak for the system to analyze.	Check if the US transducer is positioned at the fetal heart; check if the alarm limits are suitable; check the patient's condition.
TOCO UNPLUGGED	TOCO transducer is not securely connected.	Check the connection of the transducer.
Fetus EQUIP MALF	The monitor board can not communicate with the system successfully.	Restart the F9 Monitor and try again, contact CooperSurgical if the connection still fails.
Battery Low	The battery power is too low to support continued working of the monitor.	Connect the F9 Monitor to AC power supply.
Check Paper	There is no paper in the paper drawer or the drawer is open.	Load paper and/ or close the drawer.

Alarm Message	Cause	Countermeasure
Signals Overlap (FHR1, FHR2)	US transducer 1 and US transducer 2 are positioned at the same fetal heart; the signals overlap.	Adjust one of the US transducers until another fetal heart signal is detected.
Signals Overlap (FHR1, DFHR)	US transducer 1 is positioned at the fetus that the spiral electrode is attached to; the signals overlap.	Adjust the US transducer until another fetal heart signal is detected.
DECG LEADS OFF	The spiral electrode is not securely connected.	Check the connection of the spiral electrode.
DECG UNPLUGGED	The DECG lead is not securely connected to the monitor.	Check the connection of the DECG cable.
DECG SIGNAL LOSS	DECG signal is too weak for the system to analyze.	Check if the spiral electrode is securely attached to the fetus; check the patient's condition.

Chapter 8 After Monitoring

8.1 Data Saving

The F9 Monitor automatically saves the data every 2 hours and prior to shutdown. The maximum capacity is 24-hour data.

When the F9 Monitor is turned on again, the saved data will be loaded. You can review them or print them at a high speed.

⚠CAUTION⚠: Turn off the F9 Monitor as described in Section 8.3, otherwise the unsaved data will be lost.

8.2 Completing the Monitoring

After monitoring is completed,

- 1) Remove transducers or electrodes from the patient. Wipe the remaining gel off the patient and the transducer with a clean soft cloth or tissue.
- 2) Tear off the printed recorder paper along the perforation.

8.3 Switching Off

- 1) Press and hold the **POWER** switch for at least 3 seconds to switch off the monitor.
- 2) Unplug the power cord.

⚠WARNING⚠: Do not press the POWER switch continuously. Allow at least 10 seconds between switching the F9 Monitor on and off.

Chapter 9 Maintenance and Cleaning

9.1 Maintenance

9.1.1 Maintenance Inspections

Visual Inspection

Prior to using the Monitor, perform the following inspections:

- Check the F9 Monitor and accessories to see if there is any visible evidence of damage that may affect patient safety. Pay special attention to the seams on the transducers and cables before immersing them into conductive fluid.
- Check all the outer cables, power socket and power cables.
- Check if the F9 Monitor functions properly to make sure it is in good condition.

If any damage is detected, stop using the F9 Monitor on the patient. Replace the damage part(s) or contact CooperSurgical for service before reusing it.

Routine Inspection

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

The equipment should undergo periodic safety testing to ensure 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.

Mechanical Inspection

Make sure all exposed screws are tight.

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

Replace any cable that shows serious damage.

Pay particular attention to the supply socket.

⚠️ WARNING ⚠️: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

9.1.2 Maintenance of the Monitor

Keep the exterior surface of the F9 Monitor clean and free of dust and dirt.

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

Scratching and damaging the screen should be avoided.

Operate the touch screen with the special stylus pen or finger. Sharp edged or hard items like ball point pens are not recommended.

Keep the touch screen surface clean. No adhesives should come in contact with the screen.

Avoid high voltage and static charges.

9.1.3 Maintenance of the Transducers

Keep the transducers in a dry environment, where the temperature should be lower than 45°C (113 °F). Gel must be wiped from the US transducer after use. These precautions will prolong the life of the transducer.

Although transducers are designed for durability, they should be handled 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.

9.1.4 Storage of Recorder papers

When storing recorder paper (including the printed paper with traces):

Do not store in plastic envelopes.

Do not leave exposed to direct sunlight or ultraviolet light.

Do not exceed a storage temperature of 40 °C (104 °F).

Do not exceed a relative humidity of 80%.

Storage conditions outside these limits may distort the paper and adversely affect the accuracy of the grid lines or make the trace unreadable.

9.1.5 Cleaning of the Recorder

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

To do this:

- 1) Clean the recorder plate with a lint-free cloth dampened with a soap and water solution.
- 2) Wipe the thermal array using a cotton swab moistened with a 70% Isopropyl alcohol-based solution.
- 3) Check that the paper sensing mechanism is free of dust.

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

9.2 Cleaning

In order to avoid contamination, clean and disinfect the F9 Monitor and accessories after each use.

9.2.1 Cleaning of the Monitor

Regular cleaning of the F9 Monitor casing and the screen is strongly recommended.

The solutions recommended for F9 Monitor cleaning are: mild soapy water, Tensides, Ethylate and Acetaldehyde.

⚠️ WARNING ⚠️: Unplug the F9 Monitor from the AC power source and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

Clean the F9 Monitor casing with a soft cloth and a diluted non-caustic detergent recommended above.

Clean the screen with a dry soft cloth.

Clean the touch screen with a soft cloth and neutral detergent or isopropyl alcohol. Do not use chemical solvents, acidic or alkali solutions.

⚠️ CAUTION ⚠️:

- 1) Although the F9 Monitor is chemically resistant to most common hospital cleaners and non-caustic detergents, different cleaners are not recommended and may stain the monitor.**
- 2) Many cleaners must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.**
- 3) Don't use strong solvents, for example, acetone.**
- 4) Never use an abrasive such as steel wool or metal polish.**
- 5) Do not allow any liquid to enter the monitor, and do not immerse any part of the F9 Monitor into liquid.**
- 6) Avoid pouring liquids on the F9 Monitor while cleaning.**
- 7) Don't leave any cleaning solution on the surface of the monitor.**

NOTES:

- 1) The F9 Monitor surface can be cleaned with hospital-grade ethanol and air-dried or with a clean cloth.
- 2) CooperSurgical has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

9.2.2 Cleaning of the Accessories

Cleaning of Transducers and ECG Leads

To clean the US transducer, TOCO transducer, IUP Probe and DECG Lead, follow these steps:

- 1) Wipe them with a soft cloth dampened in cleaning solution;
- 2) Clean them with a soft cloth dampened in water;
- 3) Air-dry them or wipe off the remaining moisture with a soft dry cloth.

The recommended cleansers for accessories are listed below:

Accessory	Cleansers
Ultrasound Transducer TOCO Transducer	BURATON LIQUID MIKROZID ETHANOL 70% SPORACIDIN CIDEX
DECG Cable	Mild alcohol-free soapy water
IUP Cable	Mild alcohol-free soapy water

CAUTION :

- 1) **Be sure the temperature of the cleaning solution does not exceed 45 °C (113 °F).**
- 2) **Do not immerse them in any liquid.**
- 3) **Only clean the outer surface of the connectors, make sure no liquid goes into the connector.**
- 4) **After cleaning, confirm that no remaining cleanser is on the surface.**

Cleaning the Belt

Wash soiled belts with soap and water. The water temperature must not exceed 60 °C (140 °F).

9.3 Disinfecting

Clean the equipment before disinfecting.

The table below lists the allowed disinfectant bases:

Type	Base
Instrument Disinfectant	Glutaraldehyde up to 3.6%
Surface Disinfectant	Ethanol 1- and 2- Propanol

⚠ CAUTION ⚠:

- 1) Do not use any disinfectant containing additional active ingredients other than those listed.
- 2) Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.
- 3) Do not immerse any part of the F9 Monitor or any accessory into liquid.
- 4) After disinfection, confirm that no remaining disinfectant is on the surface.
- 5) Check that the F9 Monitor and accessories are in good condition. If any aging or damage is detected, replace the damaged part(s) or contact CooperSurgical for service before reusing them.

NOTE: CooperSurgical has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

9.4 Sterilizing

Do not sterilize the F9 Monitor or the accessories, unless this is necessary according to your hospital regulation.

Chapter 10 Warranty and Service Policy

10.1 Warranty

CooperSurgical's obligation under this warranty is limited to repairing, at CooperSurgical's option, any part, which upon CooperSurgical's examination proves defective. If the product doesn't function as warranted during the 1 year warranty period, we will repair or replace it without charge.

Material and Manufacture

CooperSurgical warrants that there is no defect in material and manufacture. During the 1 year warranty period, CooperSurgical will repair or replace the defective part free if the defect has been confirmed as material or manufacture defect.

Software or Firmware

CooperSurgical software and firmware products, which are designated by CooperSurgical for use with a hardware product, when properly installed on that hardware product, are warranted not to fail to execute their programming instructions due to defects in materials and workmanship. If CooperSurgical receives notice of such defects during the warranty period that begins on the date of shipment, CooperSurgical shall repair or replace software media or firmware which does not execute their programming instructions due to such defects. However, CooperSurgical does not warrant that operating of the hardware, software, or firmware shall be uninterrupted or free from error.

This unit has no parts can be repaired by users themselves. All the service should be performed by CooperSurgical personnel.

Limit of Warranty

The warranty is void in the case of

- Assembly, extensions, readjustments of any parts;
- Modification and repair by unauthorized persons;
- Subsequent damage caused by improper use or maintenance.

10.2 After-Sales Service

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor or CooperSurgical service department.

Call us at: 1-203-601-5200, 1-800-444-8456

Fax us at: 1-203-601-1946

Or send e-mail to: technicalsupport@coopersurgical.com

Appendix 1 Product Specifications

A1.1 Monitor

Physical Characteristics	Dimensions: 347 mm x 330 mm x 126 mm (13.7" x 13" x 5") Weight: about 6 kg (13 lbs)																	
Safety	Complies with: IEC 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 61157, IEC/EN 60601-2-37, IEC/EN 60601-1-2:2001+A1 Anti-electric Shock Type: Class I equipment with internal power supply Anti-electric Shock Degree: <table border="0" style="width: 100%;"> <tr> <td style="width: 80%;">FHR1, FHR2, TOCO, FM, FS</td> <td style="width: 20%; text-align: right;">B</td> </tr> <tr> <td>IUP</td> <td style="text-align: right;">BF</td> </tr> <tr> <td>DECG</td> <td style="text-align: right;">CF</td> </tr> </table> Degree of Protection against Harmful Ingress of Water: Ordinary equipment (sealed equipment without liquid proof) Degree of Safety in Presence of Flammable Gases: Equipment not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide. Disinfection/Sterilizing Method: Refer to this User Manual for details EMC: Group I Class A Working System: Continuous running equipment		FHR1, FHR2, TOCO, FM, FS	B	IUP	BF	DECG	CF										
FHR1, FHR2, TOCO, FM, FS	B																	
IUP	BF																	
DECG	CF																	
Power Supply	<table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Operating Voltage:</td> <td>100V-240V AC</td> </tr> <tr> <td>Line Frequency:</td> <td>50/60 Hz</td> </tr> <tr> <td>P_{max} :</td> <td>110VA</td> </tr> <tr> <td>Fuse:</td> <td>T1.6AL 250V</td> </tr> </table>		Operating Voltage:	100V-240V AC	Line Frequency:	50/60 Hz	P_{max} :	110VA	Fuse:	T1.6AL 250V								
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Environment	Monitor	<table border="0" style="width: 100%;"> <tr> <td colspan="2">Working</td> </tr> <tr> <td>Temperature:</td> <td>5 °C ~ 40 °C (41 °F ~ 104 °F)</td> </tr> <tr> <td>Relative Humidity:</td> <td>25% ~ 80% (non-condensing)</td> </tr> <tr> <td>Atmospheric Pressure:</td> <td>860hPa ~ 1060hPa</td> </tr> <tr> <td colspan="2">Transport and Storage</td> </tr> <tr> <td>Temperature:</td> <td>-20 °C ~ 55 °C (-4°F ~ 131 °F)</td> </tr> <tr> <td>Relative Humidity:</td> <td>25% ~ 93% (non-condensing)</td> </tr> <tr> <td>Atmospheric Pressure:</td> <td>700hPa ~ 1060hPa</td> </tr> </table>	Working		Temperature:	5 °C ~ 40 °C (41 °F ~ 104 °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
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<p>Environment (con't)</p>	<p>Transducers</p>	<p>Working Temperature: 0 °C ~ 40 °C (32 °F ~ 104 °F) Relative Humidity: < 95% @ 40 °C Altitude: -500m ~ 3000m Transport and Storage Temperature: -40 °C ~ 60 °C (-40°F ~ 140 °F) Relative Humidity: < 90% @ 60 °C Altitude: -500m ~ 3000m</p>
<p>Display</p>	<p>Screen Diagonal: 310 mm(12.1") Display Size (H × V): 246.0 × 184.5 mm (9.7" x 7.3") Pixel: 800(H) × 600(V) Pel Pitch: 0.3075 mm × 0.3075 mm Pel Array: RGB vertical stripe Display Mode: Normally White Contrast Ratio: 500:1 (typ.) Brightness: 200 cd/m² (typ.) Response Time: TrR = 10ms (typ.) / TrD = 25ms (typ) Support Color: 262,144 (RGB 6 bit Driver) Input Voltage: 3.3V Power: 7.8 Watt (typ.) Electric Interface: LVDS Angle of View: Horizontal K=10 Right 70° (K: Contrast Ratio) Left 70° Vertical K=10 Top 60° (K: Contrast Ratio) Bottom 50°</p>	
<p>Recorder</p>	<p>Paper: Z-fold, thermosensitive (compatible with GE and PHILIPS recorder papers) Paper width: 152 mm (GE), 150 mm (PHILIPS) Effective printing width: 110 mm (American Standard) 120 mm (International Standard) FHR printout width: 70 mm (American Standard) 80 mm (International Standard) FHR scaling: 30 bpm/cm (American Standard) 20 bpm/cm (International Standard) TOCO printout width: 40 mm TOCO scaling: 25% / cm Printing speed: Standard Speed (Real-Time Traces): 1 cm/min, 2 cm/min, 3 cm/min Fast Print Speed (Stored Traces): Up to 25 mm/sec</p>	

Recorder (con't)	Accuracy of data: $\pm 5\%$ (X axis) Accuracy of data: $\pm 1\%$ (Y axis) Resolution: 8 dots/mm Record Information: FHR1 trace/mark, FHR2/DECG trace/mark, TOCO/IUP trace, AFM trace, fetal movement mark, doctor event mark (and annotation), AUTO-zero symbol, date, time, printing speed, ID, name, FHR2 Offset etc.
Signal Interface	DB9 network interface, RJ45 interface
Ultrasound	Technique: Ultrasound Pulse Doppler with autocorrelation Mode: PW Doppler Mode Pulse Repetition Rate: 2 KHz Pulse Duration: 92 μ s Ultrasound Frequency: 1.0MHz \pm 10% p- < 1 MPa $I_{ob} < 10 \text{ mW/cm}^2$ $I_{spta} < 100 \text{ mW/cm}^2$ FHR Measurement Range: 50 bpm ~ 240 bpm Resolution: 1 bpm Accuracy: ± 1 bpm Earth Leakage Current: < 10 uA @ 264 VAC applied to transducer Dielectric Strength: > 4000Vrms ISATA@ the transducer face: 1.902 mW/cm ² Entrance beam dimensions: 9.42 cm ² Measurement uncertainties for ISATA: $\pm 26.6\%$ Measurement uncertainties for ultrasonic power: $\pm 26.6\%$ Global Maximum Value: MI = 0.030 $I_{SPTA.3} = 4.29 \text{ (mW/cm}^2)$ $I_{SPPA.3} = 48 \text{ (mW/cm}^2)$

<p>DECG (Direct Electro-cardiography)</p>	<p>Technique: Peak-peak detection technique DFHR Measurement Range: 30 bpm ~ 240 bpm Resolution: 1 bpm Accuracy: ±1 bpm Input Impedance: > 10 M (Differential, DC50/60Hz) Input Impedance: > 20 M (Common Mode) CMRR: > 110 dB Noise: < 4 uVp Skin Voltage Tolerance: ±500 mV Fetal Input Voltage Current: 20 uVp-3mVp Earth Leakage Current: < 10 uA @ 264 VAC applied to transducer</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;"></td> <td style="width: 15%; text-align: center;">N.C</td> <td style="width: 15%; text-align: center;">S.F.C</td> </tr> <tr> <td>Patient Leakage Current (Limit) /</td> <td style="text-align: center;">d.c.</td> <td style="text-align: center;">10 uA</td> </tr> <tr> <td>Patient Auxiliary Current (Limit):</td> <td style="text-align: center;">a.c.</td> <td style="text-align: center;">10 uA</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">50 uA</td> </tr> </table>		N.C	S.F.C	Patient Leakage Current (Limit) /	d.c.	10 uA	Patient Auxiliary Current (Limit):	a.c.	10 uA			50 uA
	N.C	S.F.C											
Patient Leakage Current (Limit) /	d.c.	10 uA											
Patient Auxiliary Current (Limit):	a.c.	10 uA											
		50 uA											
<p>TOCO</p>	<p>TOCO Range: 0% ~ 100%, Sensitivity: 3.7 uV/V/g Non-linear Error: 10% Resolution: 1% Zero Mode: Automatic/ Manual Earth Leakage Current: < 10 uA @ 264 VAC applied to transducer Dielectric Strength: > 4000Vrms</p>												
<p>IUP</p>	<p>Pressure Range: 0 ~ 100 mmHg Sensitivity: 5uV/V/mmHg Non-linear Error: ± 3 mmHg Resolution: 1% Zero Mode: Automatic / Manual</p>												
<p>AFM</p>	<p>Technique: Pulsed Doppler ultrasound Range: 0 ~ 100 (%) Resolution: 1%</p>												
<p>Marking</p>	<p>Manual fetal movement mark</p>												

A1.2 Transducers and Cables

Ultrasound Transducer	Weight: 190 g (6.7 oz) Cable Length: 2.5 m (8 ft) Dimension: 88 mm×35 mm (3.5" x 1.4")
TOCO Transducer	Weight: 180 g (6.35 oz) Cable Length: 2.5 m (8 ft) Dimension: 88 mm×35 mm (3.5" x 1.4")
Remote Event Marker	Length: 2.5 m (8 ft) Weight: 56 g (2 oz)

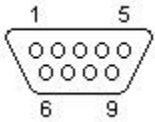
A1.3 Rechargeable Lithium-ion Battery

Type	Rechargeable Lithium-ion Battery
Continual Working Time	2 ~ 4 hours (depending on the configuration)
Nominal Capacity	4400 mAh
Nominal Voltage	14.8V
Charge Mode	Constant current/ constant voltage
Charge Current (Standard)	0.2 C ₅ A (800 mA)
Charge Voltage (Standard)	(16.8 ± 0.1V)
Maximum Continuous Charge Current	2000 mA
Necessary Charge time	8 hours
Storage Temperature	Short Term (within 1 month): -20 °C ~ 60 °C (-4 °F ~ 140 °F) Medium Term (within 3 months): -20 °C ~ 45 °C (-4 °F ~ 113 °F) Long Term (within 1 year): -20 °C ~ 20 °C (-4 °F ~ 68 °F) During storage, recharge the battery at least every six months.
Cycle Life	≥ 500 times

Appendix 2 Signal Input/Output Connector

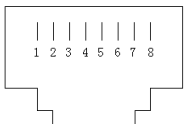
Accessory equipment connected to these interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, contact our technical service department or your local CooperSurgical representative.

DB9 Interface



Pin	Signal	Input/Output
1	+5V	Output
2	Rx	Input
3	Tx	Output
4	485EN	Input
5	0V Ref.	
6	TA	Output
7	TB	Output
8	RA	Input
9	RB	Input

RJ45 Interface



Pin	Signal	Input/Output
1	TD+	Output
2	TD-	Output
3	RD+	Input
4	Reserved	
5	Reserved	
6	RD-	Input
7	Reserved	
8	Reserved	

Appendix 3 Troubleshooting

A3.1 No Display

Error Condition	Possible Cause	Corrective Action
Power indicator is off	Power cable is loose	Tighten the power cable
	The fuse is blown	Change the fuse
	The battery has run out of power	Connect to AC power supply

A3.2 Noise

Error Condition	Possible Cause	Corrective Action
Noise	Volume set too high	Turn down the volume
	Interference from mobile phone or other source	Keep the interfering source far away from the monitor

A3.3 Recorder Error

Error Condition	Possible Cause	Corrective Action
Paper jam	Paper loaded incorrectly or paper is damp	Load paper correctly and keep paper away from moisture
Recorder does not work	The recorder is not turned on	Press the PRINT key
	Out of paper	Load paper
	The paper drawer is not locked	Slide the paper drawer in until both latches are locked in position

A3.4 Trouble with Ultrasound FHR Monitoring

Error Condition	Possible Cause	Corrective Action
Inconstant trace / display	The pregnant woman is too obese	Monitor FHR with DECG, if applicable
	Improper ultrasound transducer position	Adjust the position of the transducer until the better signal is received
	Loose belt	Tighten the belt
	Excess ultrasound coupling gel	Wipe off excess ultrasound coupling gel
	Frequent fetal movements	Delay the monitoring
	Maternal movement	Request the patient to reduce movements
	Inadequate ultrasound coupling gel	Add ultrasound coupling gel
Doubtful FHR	Recording maternal heart rate inadvertently	Change the position of the ultrasound transducer
	The transducer is not securely placed in position and the mixed noise has been recorded	Adjust the position of the transducer
Faint trace or no trace	Improper paper	Use paper recommended by manufacturer
	The paper drawer is not locked	Slide the paper drawer in until both latches are locked in position
	Adjusting nuts of the print head are unbalanced	Contact CooperSurgical for service

A3.5 Trouble with DECG FHR Monitoring

Error Condition	Possible Cause	Corrective Action
Inconsistent trend Inconsistent display	No ECG signal	Use a new spiral electrode
	Bad contact of reference electrode and patient	Use a new spiral electrode
Inconstant trend	The DECG cable has not been attached firmly	Connect an attachment pad at the DECG cable

A3.6 Trouble with Contractions Monitoring (External)

Error Condition	Possible Cause	Corrective Action
Bad trace quality or fluctuating TOCO baseline	The belt is too tight or too loose	Adjust the belt
	The belt has no elasticity	Replace the belt
	Maternal movement	Request the patient to reduce movements
	Frequent fetal movements	Delay the monitoring
Too high TOCO sensitivity (higher than 100 unit)	The body pressure from uterus to TOCO transducer is far higher than the average value	Confirm good contact to patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

A3.7 Trouble with Contractions Monitoring (Internal)

Error Condition	Possible Cause	Corrective Action
No tracing	The intrauterine catheter is jammed	Wash with disinfectant
No pressure change when uterine contraction	“Dry” environment or the tip of intrauterine catheter is placed extra-ovularly	Wash with disinfectant or change the position of transducer
Only see the IUP peak but no baseline	Zero adjustment required	Zero the system
The tracing is a straight line	Connector failure	Move or contact catheter. If trend is not fluctuating, change intrauterine cable.

A3.8 Blown Fuses

Replace the blown fuse when needed.

The two fuses of the F9 Monitor are located on the bottom panel. Their specifications are:

Size: $\Phi 5$ mm*20 mm; Model: T1.6AL 250V.

NOTE: Switch off the F9 Monitor and unplug it before changing the fuses.

To replace a fuse:

- 1) Fold the LCD display completely flat.
- 2) Carefully place the F9 Monitor upside down on a flat surface covered with cloth or other protecting pad.
- 3) With a flat-head screw driver, push the fuse in for about 1 mm then unscrew it counter-clockwise.
- 4) Remove the old fuse and replace it with a new fuse that is supplied by CooperSurgical or of the same specifications.
- 5) Push the new fuse into the socket for about 1 mm, then screw it clockwise back in to position.

Appendix 4 EMC Information – Guidance and Manufacture’s Declaration

A4.1 Electromagnetic Emissions – for all EQUIPMENT and SYSTEMS


Guidance and manufacture’s declaration – electromagnetic emission		
<p>The <i>F9 Monitor</i> is intended for use in the electromagnetic environment specified below. The customer of the user of the <i>F9 Monitor</i> should assure that it is used in such and environment.</p>		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>F9 Monitor</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The <i>F9 Monitor</i> is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

A4.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture’s declaration – electromagnetic immunity			
The <i>F9 Monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of <i>F9 Monitor</i> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2V for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <i>F9 Monitor</i> requires continued operation during power mains interruptions, it is recommended that the F9 Monitor be powered from an uninterruptible power supply or a battery.
<p>NOTE: U_T is the a.c. mains voltage prior to application of the test level.</p>			

A4.3 Electromagnetic Immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacture’s declaration – electromagnetic immunity			
The <i>F9 Monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of <i>F9 Monitor</i> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	1V _{rms}	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <i>F9 Monitor</i> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^{a)} should be less than the compliance level in each frequency range.^{b)}</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *F9 Monitor* is used exceeds the applicable RF compliance level above, the *F9 Monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *F9 Fetal Monitor*.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE: During the test of inject current, when the test level is 3 Vrms, the heart rate parameter displaying on the screen changes and has great difference with setting level, when reduce the test level to 1 Vrms, all parameters and functions are working properly. So the compliance level is 1 Vrms.

A4.4 Recommended Separation Distance

**Recommended separation distances between
portable and mobile RF communications equipment and the
F9 Fetal Monitor**

The *F9 Monitor* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *F9 Monitor* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *F9 Monitor* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTES:

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