

User Manual English



Product Information

Product model: F-9 Fetal Monitor

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Edition

Second Edition: July 2013

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Statement

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

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

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

Responsibility of the Manufacturer

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

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

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

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

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

Using This Label Guide

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

AWARNING

A WARNING label advises against certain actions or situations that could result in personal injury or death.

(CAUTION (CAUTION)

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



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

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Revision History

Date	ECO#	Version	Description
2009/08/31		1.0	Completed edition
2010/01/14	ECR-F9-9016	1.1	According to the 2.4 software, Revised: alarm level of battery low, auto measuring function, position of mark editing key, self-check printout and trace querying. Added: extended soft keyboard and fetal heart signal quality indicating.



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Chapter 1 Safety Guidance

NOTE:

- 1) In order to ensure the operator and patient's safety, read through this chapter before using this monitor.
- 2) This user manual is written to cover the maximum configuration. Therefore, your model may not have some of the parameters and functions described, depending on what you have ordered.

1.1 Intended Use

The F9 fetal & maternal monitor is intended for monitoring physiological parameters of pregnant women 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. It is not intended for use in intensive care units, operating rooms or for home use.

F9 fetal & maternal monitor is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation.

1.2 Instruction for Safe Operation

- The F9 Fetal & maternal Monitor (hereinafter called F9 monitor) is designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- 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 each use. If damage is evident, replacement is recommended before use.
- F9 monitor must be serviced only by authorized and qualified personnel. The manufacturer does not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorized personnel. Identical replacement parts must be used.
- The protective categories against electric shock of the patient connections are:

1) Ultrasound (FHR1, FHR2) 2) External TOCO

3) Fetal Movement Mark 4) Fetal Stimulator (FS)





This symbol indicates that this is an IEC/EN 60601-1 Type B applied part.



IUP

This symbol indicates that this is an IEC/EN 60601-1 Type BF applied part.



This symbol indicates that this is an IEC/EN 60601-1 Type CF applied part.

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

G Fetal Use

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

C Instructions for Use in Minimizing Patient Exposure

The acoustic output of 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. The exercising of clinical judgment in the monitoring of 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.

For using safety:

1) F9 monitor is provided for the use of qualified physicians or personnel professionally





- trained. They should be familiar with the contents of this user manual before operation.
- 2) Installation and service should only be performed by qualified service engineers authorized by the manufacturer.
- 3) This device is not intended for home use.
- 4) **EXPLOSION HAZARD** Do not use the monitor in the presence of flammable anesthetics or other materials.
- 5) **SHOCK HAZARD** the power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.
- 6) Do not apply this monitor and other ultrasonic equipment simultaneously on a same patient, in case of possible hazard caused by leakage current superposition.
- 7) Do not apply this monitor simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators, on the same patient.
- 8) Do not switch on the monitor until all cables have been properly connected and verified.
- 9) Do not touch the signal input or output connector and the patient simultaneously.
- 10) Equipment and devices that connect to the monitor should form an equipotential body to ensure effective grounding.
- 11) Disconnect the power cord before changing fuses. Replace them with those of the same specifications only.
- 12) **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.
- 13) **SHOCK HAZARD** Do not remove the top panel cover during operation or while power is connected.
- 14) The 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.
- 15) Only connect accessories supplied or recommended by the manufacturer to the device.
- 16) Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- 17) Connect the grounding wire to the equipotential grounding terminal in the main system.



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

For proper monitoring:

- 18) This device is not intended for treatment.
- 19) The fetal spiral electrode and intrauterine pressure catheter are disposable. Discard them after use.
- 20) The IUPC is neither intended nor approved for measuring intrauterine pressure extraovularly; attempting to do so may lead to maternal discomfort or injury.
- 21) Alarms must be set up according to different situations of patients. Make sure that audio sounds can be activated when an alarm occurs.

For using the battery:

- 22) Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.
- 23) Unplug the monitor before installing and removing the battery.
- 24) Do not short-circuit the battery by connecting the battery cable connector or battery socket with metal objects or solder.
- 25) Do not connect the battery directly to an electric outlet or cigarette lighter charger.
- 26) Do not heat or throw the battery into a fire.
- 27) Do not use or leave battery close to fire or other places where temperatures may be above +60 °C (+140 °F).
- 28) Do not immerse, throw or wet the battery in water/ seawater.
- 29) 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 or throw or drop to cause strong shock; Do not disassemble or modify the battery.
- 30) Use the battery only in the F9 monitor.
- 31) If the liquid leak from the battery gets into eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.
- 32) If the liquid leak from the battery spills onto your skin or clothes, wash well with fresh water immediately.
- 33) Keep the battery away from fire immediately when leakage or foul odor is detected.
- 34) Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.
- 35) Do not use a battery with serious scar or deformation.

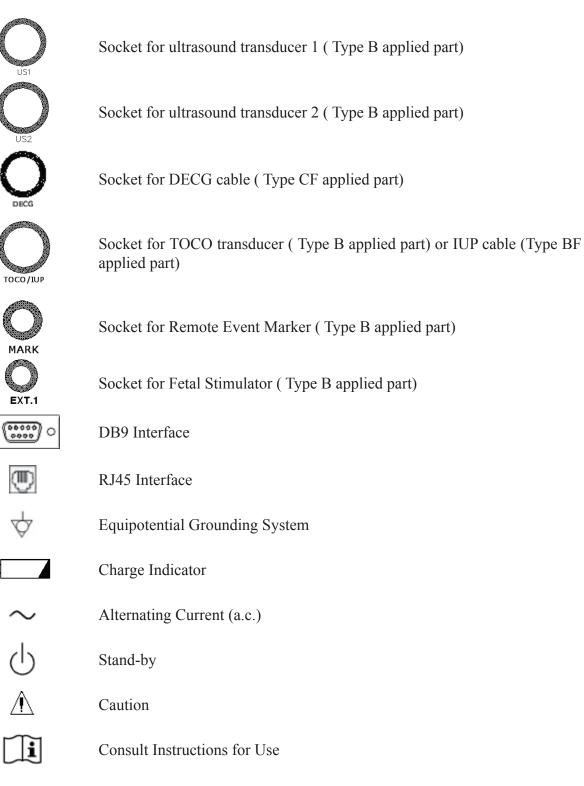


CAUTION :

- 1) Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
- 2) The device is designed for continuous operation and is "ordinary" (i.e. not drip or splashproof). Keep it far from corrosive medicine, dust area, high-temperature and humid environment.
- 3) When installing the unit into a cabinet, allow adequate room for ventilation and servicing accessibility.
- 4) Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.
- 5) Sterility can not be guaranteed if the package of the fetal spiral electrode is broken or opened.
- 6) The fetal spiral electrode has been sterilized. Do not re-sterilize.
- 7) Do not sterilize the monitor or any accessory.
- 8) Switch off the monitor and unplug it cleaning.
- 9) When washing the belts, the water temperature must not exceed +60 °C (+140 °F).
- 10) **Electromagnetic Interference** Ensure that the environment in which the F9 monitor is used is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phones base stations, etc.
- 11) Do not use mobile phones nearby in the process of monitoring.
- 12) When the battery is charged, used or stored, keep it away from objects or materials with static electric charges.
- 13) The recommended charge temperature range is from 0 °C (+32 °F) to +40 °C (+104 °F). Do not exceed this range.
- 14) Batteries have life cycles. If the time that the monitor uses the battery becomes much shorter than usual, the battery life is at an end. Replace it with a new one the same as the one provided or recommended by the manufacturer.
- 15) When not using the battery for an extended period, remove it from the monitor.
- 16) Remove a battery whose life cycle has expired from the monitor immediately.
- 17) The device and accessories are to be disposed of according to local regulations after 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.



1.5 Definitions and Symbols





F-9 Fetal Monitor Product Manual

Ŕ	Type B Applied Part Symbol
Ŕ	Type BF Applied Part Symbol
	Type CF Applied Part Symbol
X	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
P/N	Part Number
SN	Serial Number
M	Date Of Manufacture
	Manufacturer
E A	Recycle
-~ anhy (11 S)	Federal (U.S.) Law restricts this device to sale by or on the order of a

Rx only (U.S.) physician.



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Chapter 2 Installation Guidance

NOTE:

Installation must be carried out by qualified personnel authorized by the manufacturer.

2.1 Opening the Package and Checking

Open the package; take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

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

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

2.2 Installing Battery

If your monitor has been configured with the rechargeable lithium-ion battery, follow these steps to install the battery:

AWARNINGA:

Switch off the monitor and unplug the power cord before installing or removing the battery.

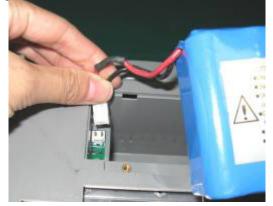
(1) Battery Installation

- 1) Carefully place the monitor upside down on a flat surface covered with a cloth or other types of protecting pad.
- 2) Remove the screws of the battery compartment using a cross-head screw driver. Remove the battery compartment cover.

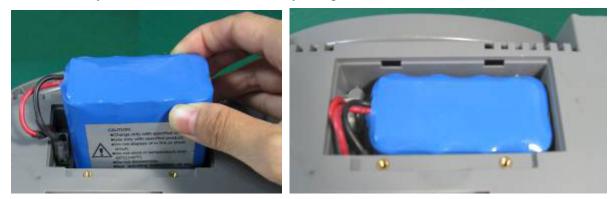




3) Take the battery out from package. Insert the cable connector into the socket.



4) Put the battery and the cables into the battery compartment.



5) Shut the battery compartment cover and fix the screws.



(2) Battery Removal

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

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NOTE:





- 1) If a rechargeable battery is outfitted, charge it fully each time after using the device to ensure the electric power is enough.
- 2) After the device is transported or stored for a long time, charge the battery fully before use. Connecting to power supply will charge the battery no matter if the monitor is powered on.

2.3 Connecting the Power Cable

- 1) Use the power cord provided with the monitor. Put the connector of the power cord into the power socket on the monitor. Put the plug of the power cord into a grounded 3-slot power output special for hospital usage.
- 2) Make sure the AC power supply complies with the following specification: 100V-240V~, 50Hz/60 Hz.

\triangle warning \triangle :

If the protective grounding (protective earth) system is doubtful, the monitor must be powered by inner power only.



Chapter 3 Monitor and Accessories

3.1 Configuration

The standard configuration of F9 monitor includes FHR1 (fetal heart rate 1), FHR2 (fetal heart rate 2), TOCO, MFM and AFM monitoring.

That is to say, F9 = FHR1 + FHR2 + TOCO + MFM + AFM

Optionally you can add DECG module to F9, providing DFHR (direct fetal heart rate) and IUP (Intrauterine Pressure) monitoring.

That is to say, $F9_{optional} = F9 + DFHR + IUP$

A fetal stimulator can be provided to give a mild vibrating stimulation to the fetus. Refer to *FS-1 Fetal Stimulator User Manual* for details.

A DB9 interface and an RJ45 interface are built in the monitor. With them, F9 monitor can be connected to a computer or the MFM-CNS central monitoring system via 485 network or Ethernet. Optionally, you can order a built-in wireless network module to connect the monitor via wireless network.

F9 monitor adopts a 12.1" LCD, on which the collected data, traces, and numerics are displayed. The built-in thermal recorder prints the fetal traces. Touch screen and rechargeable lithium-ion battery are provided for options.



3.2 Major Parts

NOTE:

The pictures and interfaces in this manual are for reference only.



Figure 3-1 Appearance

3.2.1 Keys

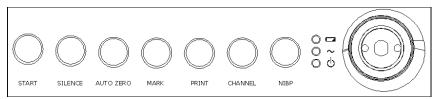


Figure 3-2 Keys and Control Knob

The Monitor is a user-friendly device with operation conducted by a few keys on the front panel and the control knob. Their functions are as follows:

(1) START

Function: Start monitoring or return to the main interface

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



(2) SILENCE

Function: Disable/Enable the audio alarm

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

(3) AUTO ZERO

Function: TOCO/IUP zero

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

(4) MARK

Function: Record an event. Press this key to make an event mark or open the smart note list.

(5) PRINT

Function: Start/stop printing Press this key to toggle between starting and stopping printing.

(6) CHANNEL

Function: Switch the channels

The monitor has two separate ultrasonic channels (US1 and US2). The default fetal heart sound comes from US1. When two ultrasound transducers are connected to the monitor, press this key to switch the sound to US2; press it again to switch the sound back to US1.

(7) NIBP

Function: Start or stop a NIBP measurement.

Reserved.

(8) CONTROL KNOB



Press Control Knob, Rotate Control Knob

Function: Adjust volume, setup and playback control.

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

The highlighted rectangular mark on the screen that moves with the rotation of the control knob is called "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.

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.
 - **C** The function operates immediately.

NOTE:

The word "select" hereinafter means rotating the control knob cursor to an item and then pressing the knob.

This monitor is a normal medical device. Please avoid violent operations such as continuously pressing the keys or control knob.

3.2.2 Indicators

There are four indicators on the top of the screen and the front panel. From the top down they are: alarm indicator, CHARGE indicator, AC indicator and Power indicator. Table 3-1 lists their meanings:

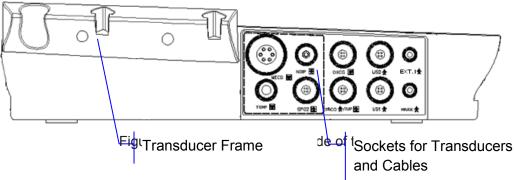
Indicator		Status of Indicator	Meaning
	Alarm Indicator	Flash or light up in orange	An alarm is active.
		Off	No alarm is active.
• -	Charge Indicator	On	The battery is being charged.
In The second se		Off	No battery or the battery is fully charged.
AC Indicator		On	The monitor is connected to AC power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

Table 3-1 Indicator description



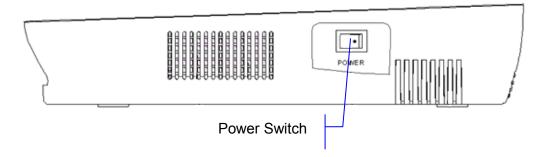
3:2.3 Left Side Panel of the Monitor

Accessory sockets and transducer frame are located on the left side panel of the monitor.



3.2.4 Right Side Panel of the Monitor

The power switch is located on the right side panel of the monitor.





3.2.5 Rear Panel of the Monitor

The equipotential grounding terminal, power socket, handle, DB9 interface, RJ45 interface, USB interface and antenna are located big the sear part of the monitor

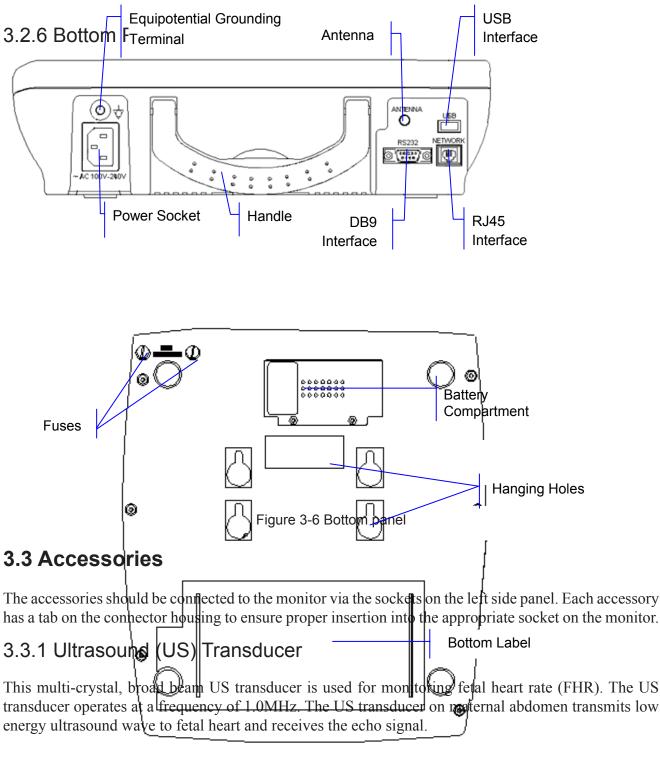






Figure 3-7 Ultrasound transducer

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

U:xxxxx: Series 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 stands for pulsed wave, 1.0 means the 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-metre 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.

3.3.2 TOCO Transducer

TOCO transducer is a tocotonometer 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. It gives a subjective indication of contraction pressure.





Figure 3-8 TOCO transducer

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

T:xxxxx: Series 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 for the TOCO transducer.

WATERPROOF: means this transducer is waterproof.

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

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.

3.3.3 Remote Event Marker

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





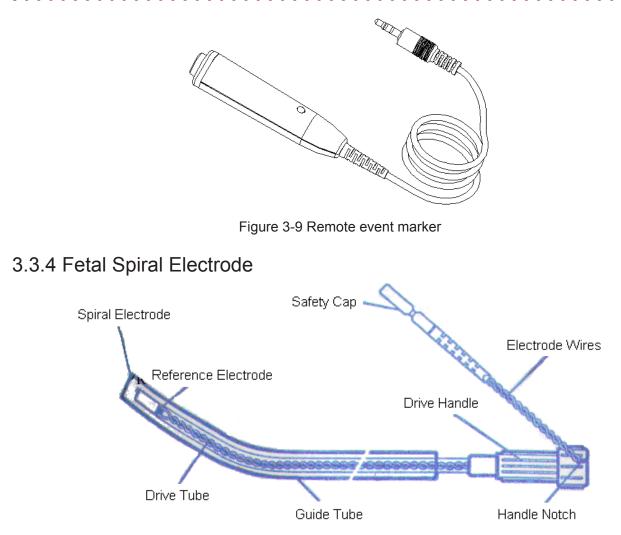


Figure 3-10 Fetal spiral electrode

3.3.5 Fetal Stimulator

FS-1 Fetal Stimulator is a hand-held device. In order to reduce the time required for the NST when the fetus is asleep, it can be used to give a mild vibrating stimulation to the fetus through the maternal abdomen.

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





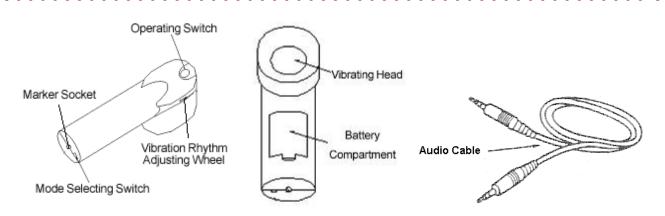
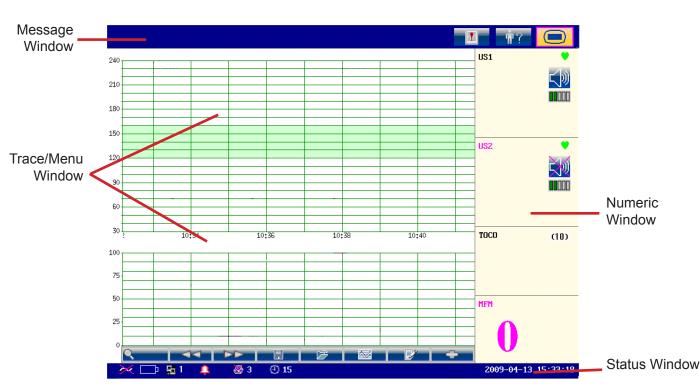


Figure 3-11 Operating control of fetal stimulator

3.4 Screen



3.4.1 Main Interface

Figure 3-12 Main interface

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



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.

(1) Message Window

a	b	c	d
** FHR2 HIGH			?
a) ** FHR2 HIGH			

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

- b) **Alarm reviewing key.** Select this key to open the alarm reviewing menu.
- c) **Mat. Info key.** Select this key to open maternal information menu for inputting or changing the patient's ID and name.
- d) **Setup key.** Select this key to open setup main menu.

(2) Trace/Menu Window

The trace/menu window occupies most space of the screen. During monitoring or reviewing, it displays traces; during setting, it displays setup menus.

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

The $120 \sim 160$ (bmp) area with the green band in between the fetal heart rate pane makes it easy to observe if the FHR exceeds this range. So you can easily tell if the fetal heart rate is too low or too high.

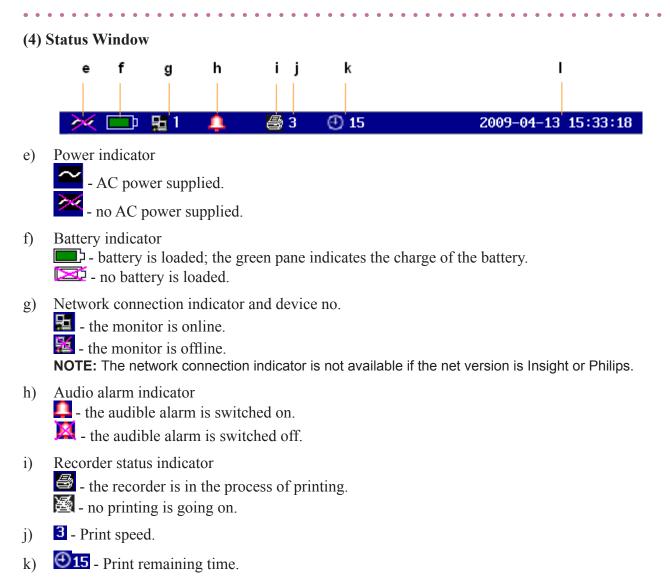


(3) Numeric Window

The fetal monitoring numerics are displayed here.



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1) The date and time of the monitor.

3.4.2 Setup Interface

Setup menus are provided to change the monitor configurations and monitoring settings. Press the setup key on the main interface to open the main menu.



	Ô				
Setup Items		Start Monitoring	Fetus		
Setup items		Genera l	Date And Time		
		Alarm	System		
		Recorder			
				Version: 2.3	Software Version
	Set fetal monit	toring items			
Function description -		E	XIT		

In the setup main menu, you have access to all the items other than System. You can select EXIT to exit from this menu.

The items in this main menu all have submenu(s). To confirm the setting changes in the submenus, you need to 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 operation is performed 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 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 located at an item in this menu, the monitor provides a brief function description of this item in a pane with blue frame under the items. For example, the cursor is located at "Fetus" in the illustration above. Correspondingly, its function "Set fetal monitoring items" is issued in the blue frame pane.

3.4.3 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 item is equal to 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 highlighted item. Touch

symbol to increase the numeric, move to the previous item or move leftwards. While touching the



the will decrease the numeric, move to the next item or move rightwards.

To exit from the 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 ensure the operating validity. A key sound is heard corresponding to every valid touch, if the key sound is enabled.

3.5 Ordering Information

Accessories supplied or approved by the manufacturer can be used with the F9 Express monitor. See the following table for details.

Accessory (Spare Part)	Part Number
US Transducer 1 (pink label)	MS3-31528
US Transducer 2 (yellow label)	MS3-107705
TOCO Transducer	MS3-31527
Remote Event Marker	MS3-31112
Belt	MS1-02264
Aquasonic Coupling Gel (0.25ltr bottle)	M50-78001
Fetal Stimulator	MS9-17660
DECG Cable	MS2-02148
Disposable Fetal Spiral Electrode	MS0-02145
Disposable Maternal Attachment Pad Electrode	MS0-02146
Intrauterine Pressure Connecting Cable	MS1R-107796
Intrauterine Pressure Cable	MS1-104152
Disposable Intrauterine Pressure Catheter	MS1-104153
Thermosensitive Paper (GE-American)	M25R-75111



Thermosensitive Paper (GE-International)	M25R-75112
Thermosensitive Paper (Philips-American)	M25R-75113
Thermosensitive Paper (Philips-International)	M25R-75114
Fuse T1.6AL 250V	M21-64010
Rechargeable Lithium-ion Battery	M21R-064118

The accessories employed by the manufacturer, such as the rechargeable battery (model No.: HYLB) manufactured by HENGYU are products having passed the authentication of CE, and they have the characteristics specified by their manufacturers. The materials with which the patient or any other person can come into contact conform with the standard of ISO 10993.

CAUTION :

Only connect the accessories supplied or recommended by the manufacturer to the monitor.

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Chapter 4 Alarms

4.1 Alarm Classification

The monitor has two types of alarm: patient alarm and technical alarm.

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

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

In terms of severity, the alarms are divided into two levels: medium and low. Medium level alarm is a severe warning, labeled with the symbol ******; 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 alarm levels are preset, and you can not change them.

4.2 Audible Alarm

When an alarm condition is active, the monitor gives out an alarm sound (the sound pressure range is 45dB ~ 85 dB).

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

Low level alarm: a "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 main interface will toggle between \square and \bowtie . However, the alarm messages will still be displayed and the alarm indicator will still be lit up when an alarm is active.

Do not disable the audible alarm in the condition where the patient's safety may be endangered.

4.3 Visual Alarm

When an alarm is active,

- Alarm indicator: the alarm indicator flashes in orange with a frequency of 0.5Hz 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 yellow, with patient alarms on the left and technical alarms in the middle.





- Flashing numeric: the numeric of the measurement flashes in grey with a frequency of 2Hz.

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

The patient alarm messages are displayed either:

- C 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

You can 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

You can change the alarm volume,

1 Select the setup key **up** 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 reviewing menu records a list of up to 50 of the most recent patient and technical alarm messages with date and time information.

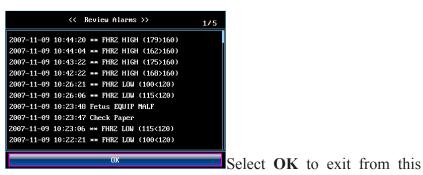
Select the alarm reviewing key **E** in the message window to open this menu.

Each page displays 10 alarm records. The page mark "1/5" informs you that there are 5 pages and the present one is page 1.

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







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 monitor gives out an alarm and catches your attention, 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 solved.

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 small range.
- 4 Stimulate a signal that is higher than the upper limit or lower than the lower limit. Or disconnect one of the plugs.

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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 bpm ~ 205 bpm, in increments of 5	120 bpm
FHR1/FHR2 Upper Limit	55 bpm ~ 210 bpm, in increments of 5	160 bpm





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FHR1/FHR2 Alarm Delay	0 ~ 300 second(s), in increments of 5	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.

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Chapter 5 Printing

5.1 Function Description

The built-in thermal recorder applied in the monitor supports both the American and international standard wide recorder paper. It prints continuous traces synchronously along with marks.

The monitor supports some other functions listed below:

- **C** 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.
- **C Printing timer:** The printing timer determines the elapsed time for each print. This time is adjustable. Refer to *5.2.3 Changing the Print Timer*.
- Remaining time indicating: A print remaining time 🕑 appears in the status window, unless the timer is set as Infinite or Present ID.
- **C** Fast printing: The recorder prints the data saved in the monitor at a high speed (up to 25mm/s).
- Data Caching: When the paper drawer runs 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 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 8.4.4 Changing FHR2/DFHR Offset.
- Print self-check: The recorder prints a baseline for self checking when the monitor is switched on.

5.2 Printing Configuration

CAUTION :

All the parameters should be well configured before printing starts. You can not change the configuration in the process of printing.

5.2.1 Switching Auto Start Printing On or Off

You can switch auto start printing on or off:



1 Select the setup key on the main interface.

- 2 Select Start Monitor > Printing.
- 3 Select **ON** or **OFF** (default).
- 4 Select OK.

5.2.2 Choosing the Paper Speed

You can choose a paper speed of 1 cm/min, 2cm/min or 3cm/min:

- 1 Select the setup key **O** on the main interface.
- 2 Select **Recorder > 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

You can choose different time length for the print timer:

- 1 Select the setup key **Output** on the main interface.
- 2 Select **Recorder > Timer**.
- 3 Set timer to **Infinite** (default), **Present ID** or 10 ~ 90 (minutes, the step is 5). **Infinite** means the recorder will not stop printing until the **PRINT** key is pressed. **Present ID** means 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 end of the page will be the printed.
- 4 Select **OK**.

5.2.4 Switching Print Self-Check On or Off

You can switch print self-check on or off:

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

5.3 Understanding the Recorder Paper Printout

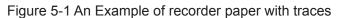
WARNING:

1) If there is any difference between the display and the printout, take the printout as criterion.



2) If the data is doubtful, clinicians should make diagnoses based on the real condition.

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



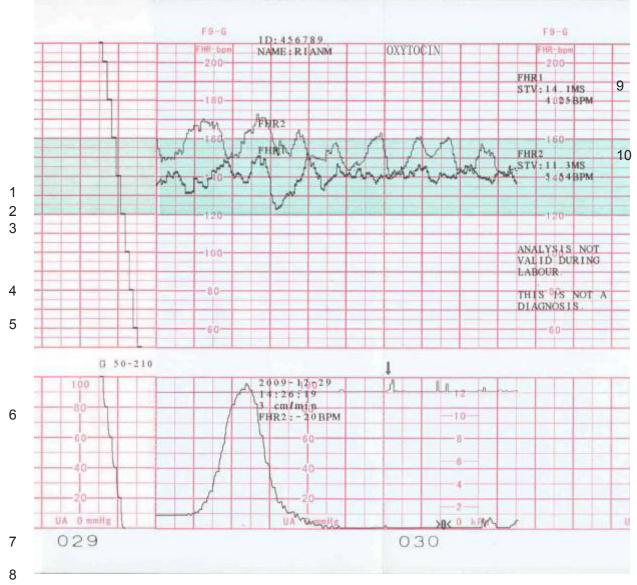


Figure 5-1 An Example of recorder paper with traces

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ltem	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	FHR2 Mark	The trace marked with "FHR2" is the FHR2 trace.
5	FHR1 Mark	The trace marked with "FHR1" is the FHR1 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	STV	The STV results of FHR1 and FHR2.
11	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.

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Chapter 6 Pre-Monitoring Preparation

6.1 Loading Recorder paper

CAUTION :

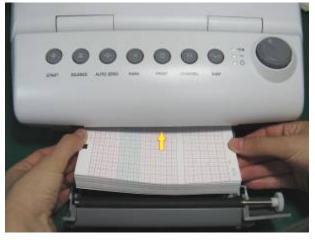
Only use the recorder paper provided by the manufacturer, otherwise the recorder may be damaged. This kind of damage is not covered by warranty.

If the monitor is used for the first time or when the paper runs out, you should load paper.

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

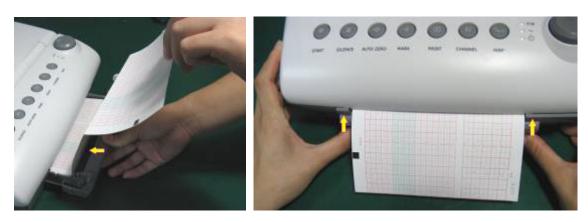


- 2) Take out the Z-fold thermosensitive paper and remove the wrapper.
- 3) Place the pack in the drawer, with the pane facing up and the green safety area on the left.



- 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.





NOTE:

- 1) Be careful when inserting paper. Avoid damaging the thermosensitive print head.
- 2) Make sure the paper is evenly loaded in the drawer. Otherwise the data will be inaccurate or paper jam will happen.
- 3) Only use the paper the manufacturer approved to avoid poor printing quality, deflection, or paper jam.
- 4) Keep the drawer closed unless when loading paper or servicing.

Removing Paper Jam

When the recorder does not function or sound properly, open the drawer to check for a paper jam. Remove the paper jam in this way:

- Cut the recorder paper from the paper drawer edge.
- Through the hole on the bottom panel of the paper drawer, push the recorder paper up with one finger. Remove the paper.
- **C** Reload paper and then close the drawer.





6.2 Switching On the Monitor

AWARNINGA:

- 1) Check if all the metal parts are linked to the protective earth cord and the cord is working well before powering on the monitor.
- 2) If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or our service engineer immediately.

Press the **POWER** switch on the right panel to switch on the monitor. The power indicator lights up and a start-up music will be heard. You can operate the monitor after the main interface appears.

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

Select the setup key on the main interface.
 Select General > Start-up Music.
 Select ON (default) or OFF.
 Select OK.

NOTE:

- 1) Check all the functions to make sure that the monitor is in good condition.
- 2) If the monitor has a great 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 monitor until the main interface appears. The message "Load failed!" indicates that the data have been damaged and therefore can not be loaded.

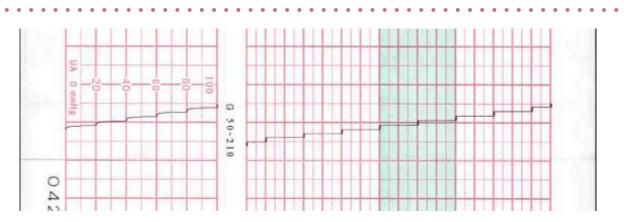
6.3 Checking the Recorder Paper

The monitor provides the print self-check function to check if the recorder paper is correctly loaded 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 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 printing.

6.4 Adjusting the Screen Angle

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

Adjustment method:

Push the hook on top of the screen left to spring it open. Pull the screen forward to adjust 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.





6.5 Setting Date and Time

You can change the date and time of the monitor,

- 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; there are three options: yyyy-mm-dd (default), mm/dd/yyyy and dd/mm/yyyy.
- 5 Select OK.

NOTE:

The date and time remain in the monitor for at least two months after it is switched off. You do not have to set date and time before monitoring each time.

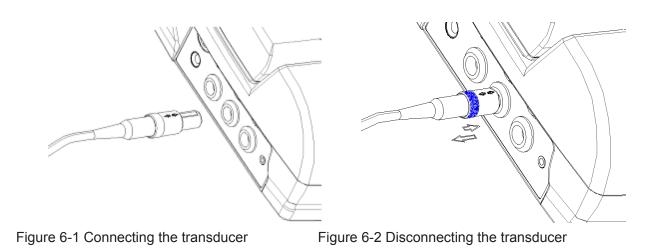
6.6 Connecting Transducers

Check for visible damages of the transducers every time before connecting them to the monitor. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid. If damage is found, replace them with good ones at once.

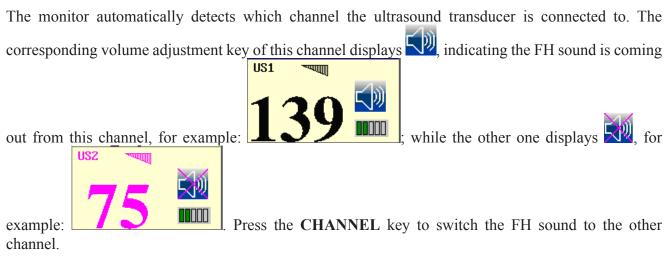
When plugging transducers into the monitor, make sure the arrow symbol of the connector is facing up, refer to figure 6-1.

When disconnecting a transducer, hold the afterbody of the transducer outshell (the shaded part shown in figure 6-2) with fingers and push it in slightly, then pull it out. Refer to figure 6-2.





6.7 Adjusting the Volume



Adjust the default monitoring volume:

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

- 1 Select the setup key **O** on the main interface.
- 2 Select **Start Monitor > Volume**.
- 3 Select the volume from $1 \sim 10$; the step is 1 and the default level is 3.
- 4 Select **OK**.

Adjust the real-time monitoring volume:

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



- 1 Select the volume adjustment key $\overbrace{}^{1}$ 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 in all; the green pane of the volume level indicator increases

by one at every two steps; rotate the knob anticlockwise or touch the was symbol to decrease the volume.

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

Adjust the key volume:

The volumes of pressing keys, rotating and pressing the control knob are also adjustable.

1 Select the setup key on the main interface.

- 2 Select General > Key Volume.
- 3 Select Low (default), High or OFF.
- 4 Select OK.





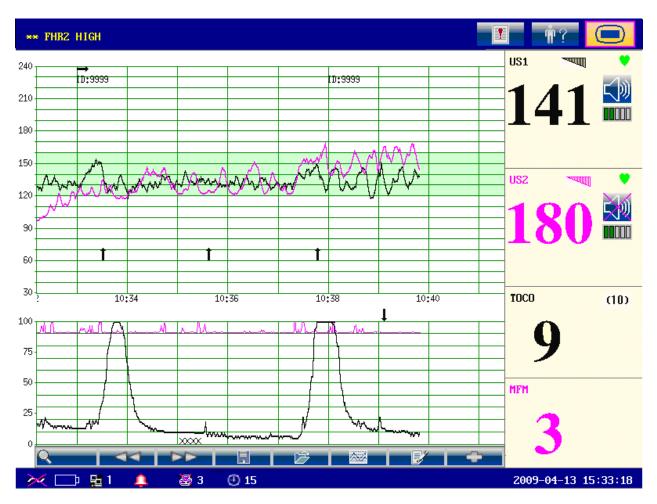


Figure 7-1 F9 screen display



7.1 Traces

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.

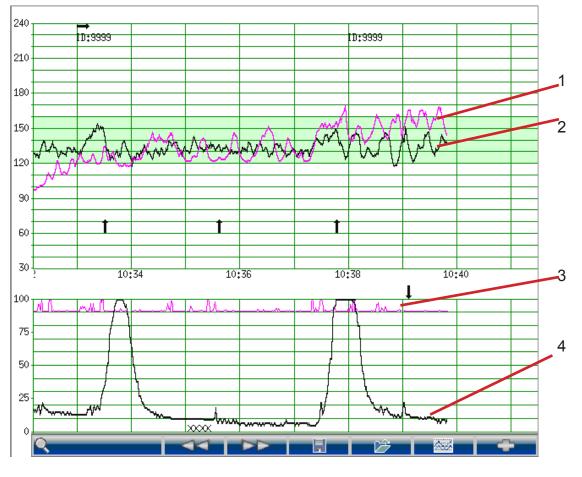


Figure 7-2 Traces

1 FHR2 Trace 2 FHR1 Trace 3 AFM Trace 4 TOCO Trace

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

FHR1/FHR2 trace

The y-axis of the trace indicates the numerics of FHR. The range is $30 \sim 240$ (American standard) or $50 \sim 210$ (International standard).

AFM trace

The y-axis indicates the scope of fetal movement.



NOTE:

The AFM trace is only for reference, please take the MFM marks as criterion.

TOCO trace

The y-axis indicates the numeric of TOCO. The range is $0\% \sim 100\%$.

Besides, some other symbols appear among the traces:

- \rightarrow This symbol indicates the new monitoring starts.
- **†** This symbol indicates a manual fetal movement, and it appears after the patient presses the FM marker when she feels a fetal movement.
- This symbol indicates the **MARK** key is pressed to record an event, such as the patient turning around, taking injection.
- ** This symbol indicates the monitor is zeroed by pressing AUTO ZERO key.

7.1.1 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 **O** 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 $0 \sim 59$ th second of the system time. Do not mistake the time scale for the exact time.

7.1.2 Changing the Trace Advancing Mode

Trace advances as time passes by when the 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 has received for 30 seconds. It will advance again when valid data is received.

To change the screen advancing mode:



1 Select the setup key on the main interface.

- 2 Select Fetus > Trace Advancing.
- 3 Select Auto (default) or Valid.
- 4 Select OK.

7.2 Trace Control Tools

Q		$\neg \neg$			i 🖻		+
	1	2	3	4	5	6	7
			Figure 7-3	Trace cont	trol tools		
1	Searching Key	2, 3	Reviewing	Keys	4	Archiving Key	
5	Archive Loading Key	6	Auto Measuring Key		7	STV Analyzing	Key

7.2.1 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.

66	; Susan	
55	; Nancy	
44	;	
33	;	
22		
11	;	
MORE		
Q		

		((query muces //		
ID		Name		Query
	ID		Name	
(912310857			
(9912310857			
(912310856			
(912121758			
(912121623			
(912110948			
(912110843			
		EXIT		



Figure 7-5 Query Traces

If the patient is not in this list,

2 Select MORE to open the Query Traces 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 Query. The patients with the matched information are listed in the window.

6 Select the required item, and the main interface will switch to the most current data of this patient.

7.2.2 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

anticlockwise or touch the <u>symbol</u> to increase the speed until it reaches the maximum. Rotate the

knob clockwise or touch the **v** 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 <u>symbol</u> to increase the speed until it reaches the maximum. Rotate the knob anticlockwise

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** key 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 whole reviewable traces.

Move the cursor away from the trace control tools, or touch any place out of the trace window on the screen to return to the real-time main interface.

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

\triangle warning \triangle :

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 start printing. Printing in the process of playback might result in failure information on the paper.
- 2) After the reviewed data has been printed out, the recorder does not switch back to realtime printing automatically.

7.2.3 Archive Managing

By default, the monitor saves the most recent 24-hour data in its memory. (Refer to section 9.1 Data Saving for details.) However, when the memory is full, the anterior data would be cleared. There are possibilities that some important data is cleared. The monitor provides the archive storage to reduce these possibilities.

- Enabling/disabling archive storage

To enable or disable archive storage,

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

To archive the data of a patient, locate them using the reviewing keys first. When the data is displayed on the main interface, select the archiving key **Example**. The data of this monitoring is stored in the monitor as a separate archive.

NOTE:

If more than one patient is present on the main interface, the data of the patient on the right is archived.

The archives are stored in the long-term memory of the monitor. When the storage is full, you need to delete some archives before storing new data.

- Loading an archive

You can load an archive by selecting the archive opening key in the main interface. A list of the archives pops up, including the time and duration of the monitoring, the patient's name and ID. Select the required one and then select **Load** to load the archive to the main interface. The loaded data starts from the left end of the screen. You can review the data by using reviewing keys.

Move the cursor away from the trace control tools, or touch any place out of the trace window on the screen to return to the real-time main interface.



- Deleting an archive

To delete an archive, select the archive opening key on the main interface. Select the Archive and then choose **Delete** to delete the archive.

7.2.4 Auto Measuring

The auto measurement feature of the monitor provides baseline, acceleration peak and deceleration peak of a FHR trace.

NOTE:

- 1) When operating the monitor with the touch screen, you need to double click on the key to start auto measuring.
- 2) The auto measurement results are provided for reference only.

- Measuring the FHR1 trace,

Load the traces to the main interface by using reviewing keys and then select the auto measuring key

The following information is shown on the trace (figure 7-6):

- Baseline. A line is drawn in the central section of FHR1 trace, indicating FHR1 baseline.
- Acceleration peak. If the acceleration is larger than 15 bpm and lasts longer than 15 seconds, its amplitude and duration is marked above the peak in the format of +X[xs].
- Deceleration peak. If the deceleration is larger than 15 bpm and lasts longer than 20 seconds, its amplitude and duration is marked under the peak in the format of -X[xs].
- Measuring the FHR2 trace,

Press the auto measuring key again, the monitor measures the FHR2 trace.



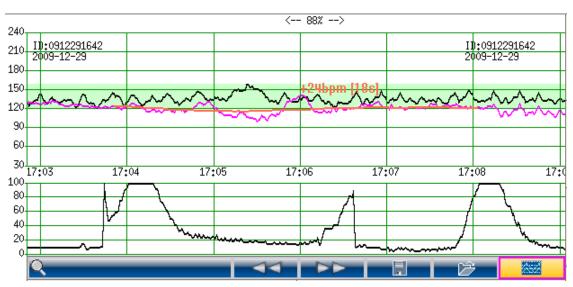


Figure 7-6 Auto measuring FHR2

The auto measuring feature can only be applied to the reviewed FHR traces. The information disappears when you exit from the reviewing status.

7.2.5 STV Analysis

STV (short-term variation) analysis is an advanced function. It is available only by special order.

AWARNINGA:

- 1) STV analysis is used for the surveillance of pregnancies and not in delivery room of childbirth.
- 2) The STV is just an analysis intended to assist the physicians in interpreting the waveforms. Conclusions should be drawn on the basis of the physicians' diagnosis.
- 3) This analyze describes the fetal heart rate, the tocography and the fetal movements. It's the responsibility of qualified medical staff to do the diagnostic interpretation of the waveform.

- How is STV measured?

The monitor measures STV by dividing each minute of the trace into 16 sections. Each section is 3.75 seconds long and typically contains about 7-10 fetal heartbeats, or 6-9 pulse intervals. The average pulse interval in each section is calculated, and the change in these average values from one section to the next determines the STV. The use of 3.75 seconds is not a magic number; it is simply that division by 2, 4, 8, 16, etc., is very fast on a computer, and 3.75 seconds is 1/16th of a minute.

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- Enabling/Disabling STV analysis



Make sure your monitor has been configured with STV analysis, and then enable or disable it by performing the following steps:

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

An STV analysis key appears on the main interface, indicating that STV analysis is enabled.

- STV analyzing

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The monitor performs STV analyzing when:

- the monitor is working in real-time monitoring mode, and
- the recorder has printed at least 10-minute (less than 60-minute) traces.

Select the STV analysis key **Example** on the main interface to view the STV results.

- Understanding STV results

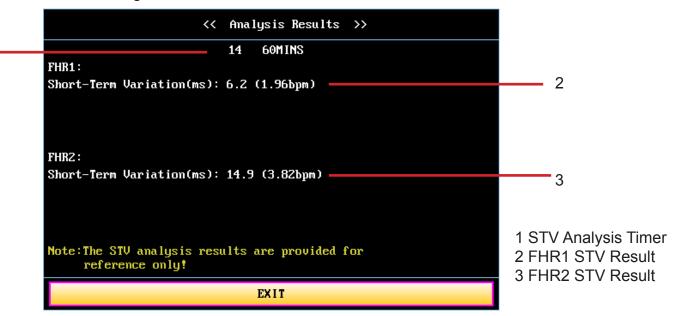


Figure 7-7 STV analysis results on the screen

Refer to figure 7-7, the STV analysis results on the screen include:

1 STV Analysis Timer:



The STV analysis timer starts when the recorder starts printing; it stops when the timer reaches 60 minutes (the timer turns into >60) and resets when the recorder stops printing.

2-3 STV analysis results:

During 10 to 60-minute of the timer, the monitor gives STV analysis results every two minutes.

The STV results are displayed in the format of two numerics, e.g. 6.2 (1.96bpm). The unit of the first numeric is millisecond (ms).

At the end of the printing, the recorder prints the STV analysis results of this moment on the recorder paper (figure 7-8).

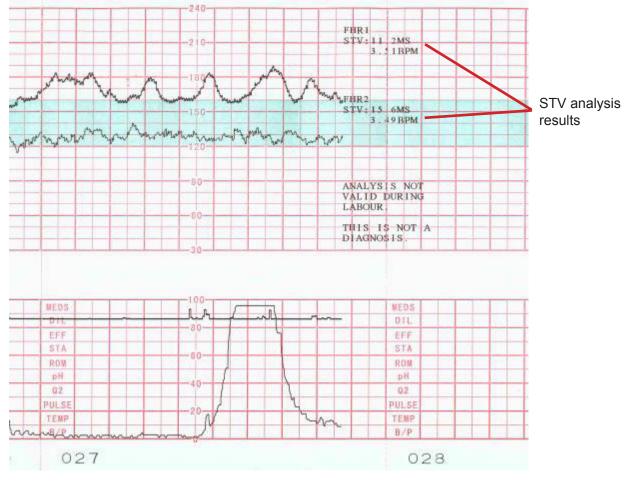


Figure 7-8 STV analysis results on the recorder paper

Be aware that STV analysis result is a calculation output. It can be used as a reference to assist medical personnel in making correct diagnosis, instead of replacing it.

NOTE:

STV analysis results are not available during the first 10 minutes and after 60 minutes of the timer.



7.2.6 Marking 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 \downarrow 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 **EVEN** 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.

7.3 Numerics

The numeric window includes FHR1, FHR2/DECG, TOCO/IUP and MFM.



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FHR1	FHR signal quality. When the quality is poor, it turns into		
1/1	FH refreshing rate		
	EH sound volume adjusting key		
	FH sound volume indicator		
	141: FHR1 measurement numeric.		
	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		
FHR2/DECG	180: FHR2/DFHR measurement numeric.		
180	If the US2/DECG socket is not connected with a US transducer/DECG cable when switching on, it displays OFF but no numeric here; if the transducer/cable is connected but no monitoring is going on, it displays		
	(10): UA baseline		
9	9: current UA measurement numeric		
MFM 3	3: MFM count		

7.3.1 Changing Numeric Window Position

The numeric window can be located either on the right of the traces or on top of them. To change its position,

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1 Select the setup key on the main interface.

- Select the setup key solution the main intern
- 2 Select General > Numeric Window.
- 3 Select **Top** or **Right** (default).
- 4 Select **OK**.

7.4 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 woman'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 (M	edium Level)				
Battery Low	The battery power is too low to support further work of the monitor.	Connect the monitor to AC power supply.			
Technical Alarm (L	ow Level)				
US1 UNPLUGGED or US2 UNPLUGGED	US transducer 1 or US transducer 2 is not well 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 aimed at the fetal heart; check if the alarm limits are suitable; check the woman's condition.			
TOCO UNPLUGGED	TOCO transducer is not well connected.	Check the connection of the transducer.			

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Fetus EQUIP MALF	The fetus board can not communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.	
Check Paper	There is no paper in the paper drawer or the drawer is open.	Load paper and/ or close the drawer.	
Signals Overlap (FHR1, FHR2)	US transducer 1 and US transducer 2 are aimed 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 aimed 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 well connected.	Check the connection of the spiral electrode.	
DECG UNPLUGGED	The DECG lead is not well 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 well attached to the fetus; check the woman's condition.	

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Chapter 8 Fetal Monitoring

AWARNINGA:

- 1) The monitor is not intended for use in intensive care units (ICU), operating rooms or for home use.
- 2) The 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.
- 3) Always check if the alarm settings are appropriate for your patient before starting monitoring.

8.1 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. These 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 the 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 obstetric ultrasonography.

8.2 Monitoring FHR with Ultrasound

The ultrasound monitoring is a method to obtain FHR on maternal abdominal wall. Place a US transducer (Ultrasound transducer) on maternal abdomen. It transmits low energy ultrasound wave to the fetal heart, and receives the echo signal.

8.2.1 Parts Required

1) US transducer 2) Aquasonic coupling gel 3) Belt

8.2.2 FHR Monitoring Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the abdomen when it is fastened. Lay the patient on the bed.

Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

2) Acquiring FH Signal



Search for the location of the fetal heart using a stethoscope or a fetoscope.

Apply a certain amount of acoustic gel on the transducer and move it slowly around the fetus site until a clear characteristic hoof-beat sound of the fetal heart is heard. Refer to figure 8-1 for the transducer position.

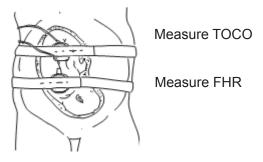


Figure 8-1 Ultrasound transducer & TOCO transducer positioning (single fetus)

3) Fixing the Transducer

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 fits the patient snugly but comfortably. Meanwhile, fetus heart beat sound is heard; the FHR trace and numeric are displayed on the screen.

NOTE:

- 1) Do not mistake the high maternal heart rate for fetal heart rate. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.
- 2) The best quality records will only be obtained if the probe is placed in the optimum position.
- 3) Positions with strong placental sounds or umbilical blood flow sound 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 monitoring, the pregnant woman's prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable.
- 5) It is impossible to examine FHR unless an audible fetal heart signal is detected.

8.2.3 Switching the FHR Alarm On or Off

Always check if the alarm settings are appropriate for your patient before starting a monitoring.

You can choose to switch the FHR alarm on or off. If the fetal heart alarm is switched off, the monitor

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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 > FHR1 or FHR2 > Alarm.
- 3 Select **ON** (default) or **OFF**.

4 Select OK.

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



AWARNINGA:

Do not switch the alarm off for the condition where the patient's safety maybe endangered.

8.2.4 Changing the FHR Alarm Limits

You can change the FHR alarm limits. The alarm limits you set determine the conditions that trigger the alarm.

1 Select the setup key on the main interface.

2 Select Alarm > FHR1 or FHR2.

- 3 Select a value from $50 \sim 205$ for Lower Limit.
- 4 Select a value from $55 \sim 210$ for Upper Limi.
- 5 Select OK.

8.2.5 Changing the FHR Alarm Delay

You can change 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 **O** on the main interface.
- 2 Select Alarm > FHR1 or FHR2 > Alarm Delay.
- 3 Select a value from $0 \sim 300$ second(s).
- 4 Select **OK**.

8.3 Monitoring FHR with DECG

8.3.1 Contraindications

The fetal spiral electrode can be used when amniotic membranes are adequately ruptured and sufficient

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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, fontanels or genitalia.

Do not apply the fetal spiral electrode 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 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.

8.3.2 Parts Required

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

8.3.3 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 scurf and grease.

8.3.4 Switching DECG Beep On or Off

When the DECG beep is enabled, the monitor gives a beep sound of DECG.

To switch DECG beep on or off,

- 1 Select the setup key **O** on the main interface.
- 2 Select Fetus > DECG Beep.
- 3 Select Off (default), Low or High.
- 4 Select OK.

8.3.5 Directions for Using Fetal Spiral Electrode

- 1 With the patient in the dorsal lithotomy position, perform a vaginal examination and clearly identify the fetal presenting part.
- 2 Remove the spiral electrode from the package; leave the electrode wires locked in the handle



notch.

- 3 Gently bend the guide tube to the desired angle.
- 4 Hold the drive handle, ensure the spiral electrode is retracted about one inch (2.5 cm) from the distal end of the guide tube.
- 5 Place the guide tube firmly against the identified presenting part.
- 6 Maintain pressure against the fetal presenting part with guide and drive tubes. Rotate the drive tube by rotating the drive handle clockwise until gentle resistance is encountered. Resistance to further rotation and recoil of the drive handle indicates that the spiral electrode is well attached to the fetus.
- 7 Release the electrode wires from the handle notch and straighten them. Slide the drive and guide tubes off the electrode wires.
- 8 Insert the safety cap into DECG cable.

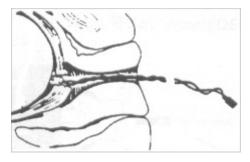


Figure 8-2 The well attached fetal spiral electrode

8.3.6 DECG Monitoring Procedure

- 1 Perform a vaginal examination to identify the fetal presenting part.
- 2 Prepare the patient's skin using the procedures described in section 8.3.3 Preparing the *Patient's Skin Prior to Placing Electrodes*.
- 3 Attach the fetal spiral electrode to the fetal presenting part using the procedures described in section *8.3.4 Directions for Using Fetal Spiral Electrode*.
- 4 Fix an attachment pad electrode to DECG cable.
- 5 Remove the film on the back of the electrode and place the electrode on maternal thigh; press it firmly in place.
- 6 Connect the fetal spiral electrode to the DECG cable.
- 7 Insert connector of DECG cable into the DECG socket of the monitor.

AWARNINGA:

Do not plug the fetal spiral electrode wire into the power socket.



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 with 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.
- After the electrode is well 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.

8.3.7 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 a proper way. Do not use it again.

8.4 Monitoring Twin FHRs

8.4.1 Monitoring Twins Externally

To monitor twin FHRs externally, you need to connect a US transducer to US1 socket and the second US transducer to US2 socket of the monitor. Follow the instructions described in Section 8.2 Monitoring FHR with Ultrasound to acquire FHR signals for both channels. Press CHANNEL key to switch the FH sound from one channel to the other.

When the two US transducers are fixed, make sure FH sounds from both channels are clear, two FHR traces and two FHR numerics are displayed on the screen.

8.4.2 Monitoring Internally

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

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

Monitor one twin with a US transducer using the procedures described in Section 8.2 *Monitoring FHR with Ultrasound*.

Monitor the second twin with a DECG cable using the procedures described in Section 8.3 *Monitoring FHR with DECG*.

CAUTION :

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



8.4.3 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 monitor provides signals 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. Checking the patient and reposition of transducers might be needed.

8.4.4 Changing FHR2/DFHR Offset

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

To change the FHR2/DECG offset,

Select the setup key on the main interface.
 Select Recorder > FHR2 Offset.
 Select -20 bpm (default), 0 bpm or +20bpm.
 Select OK.

This 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.

8.5 Monitoring Uterine Activity Externally

8.5.1 Parts Required

1) TOCO transducer 2) Belt

8.5.2 TOCO Monitoring Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the abdomen when it is fastened. Lay the patient on the bed.

Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

2) Fixing the Transducer

Refer to figure 8-1 for the TOCO transducer position. Wipe any gel remaining on abdomen around this area.

Place the transducer on the patient's fundus to get optimum recording of uterine activity.

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 fits the patient snugly but comfortably.



3) Adjusting the Numeric to Zero

Press the AUTO ZERO key to adjust the numeric to the baseline. Make sure this is not done during a contraction.

The uterine activity reading at this point should be $30 \sim 90$. A flat-top aligned with 100 on the TOCO scale indicates the belt is too tight, and you need to adjust it.

Wipe off any gel presents on abdomen around this area.

NOTE:

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

8.5.3 Changing the UA Baseline

You can change the UA baseline,

1 Select the setup key **Or an end of 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 not adjustable.

8.6 Monitoring Uterine Activity Internally

8.6.1 Parts Required

- 1) Disposable intrauterine pressure catheter ACCU-TRACE[™] IUPC ("IUPC" for short)
- 2) Reusable intrauterine pressure connecting cable ("connecting cable" for short)
- 3) Reusable intrauterine pressure cable ("IUP cable" for short)

8.6.2 Directions for Use of IUPC

Preparation

1) Gather supplies: ACCU-TRACE IUPC, reusable cable, and amnioinfusion supplies if needed.

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2) Open the sterile ACCU-TRACE IUPC package.

Insertion



NOTE: This product is designed for use with the introducer.

- 3) Using aseptic technique, remove the catheter from the package.
- 4) Perform vaginal exam to ensure ruptured membranes and adequate dilation.
- 5) Advance the catheter tip to the cervical os along the examination hand, using the hand as a guide. Do not advance the introducer through the cervix.
- 6) Continue to gently advance the catheter tip through the cervical os and feed the catheter into the intra-amniotic cavity until the 45cm mark is at the introitus. If the 45cm mark is not clearly visible, stop advancing when the symbol on the catheter meets the introducer.
 NOTE: For easier insertion, do not twist the catheter in the introducer.
- 7) The IUPC may be spontaneously filled with amniotic fluid. This can be seen in the clear lumen of the catheter. The filter cap will prevent the amniotic fluid from leaking.
- 8) Slide the introducer out of the vagina along the catheter. When the introducer is completely out of the vagina, slide thumb between catheter and introducer tab, which will begin to separate the introducer from the catheter. (See figure 8-3)

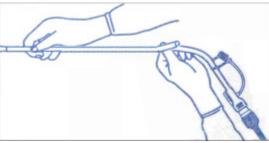


Figure 8-3 Separate the introducer

9) Anchor the catheter in place with one hand, and pull the introducer straight back off the catheter. (See figure 8-4)

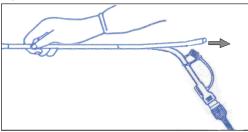


Figure 8-4 Remove the introducer

10) Remove the liner from the adhesive pad, and then adhere the pad to the patient's skin. Secure the catheter by placing the catheter attachment strap to the adhesive pad. (See figure 8-5).





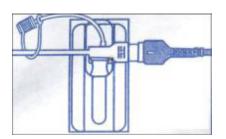


Figure 8-5 Secure the adhesive pad to mother

Rezeroing the System During Monitoring

1) With the catheter connected to the IUP cable, momentarily pressing the re-zero button on the pressure cable (See figure 8-6). The green light on the cable will flash for five seconds.

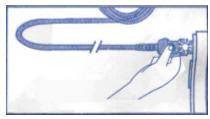


Figure 8-6 Rezeroing the system

2) During this period, adjust the monitor to zero by pressing AUTO ZERO key.

AWARNINGA:

- 1) Before insertion, placental position should be confirmed, amniotic membranes are adequately ruptured and sufficient cervical dilatation is assured.
- 2) Try to insert the catheter opposite the placental site. Do not insert the introducer beyond the cervical OS. Use it with caution when uterine infection is present.
- 3) 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 Directions For Use of IUPC prior to insertion. The Product has been sterilized by gamma radiation and is sterilized and non-pyrogenic unless package is broken or open. Do not re-sterilize it.

NOTE:

Refer to the instruction on the package for more information about using the IUPC.





8.6.3 IUP Monitoring Procedure

- 1) Insert IUPC using the procedure described in section 8.6.2 Directions for Use of IUPC.
- 2) Connect the IUPC to the IUP cable. (See figure 8-7)

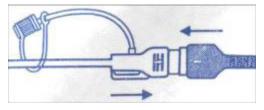


Figure 8-7 Connect catheter to pressure cable

- 3) Connect the IUP cable to the connecting cable. (They might have already been well 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 this period, zero the monitor by pressing the **AUTO ZERO** key. Make sure the display numeric and 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) Wash timely during monitoring. A spike on the tracing will respond to the washing.

8.6.4 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 8-8).

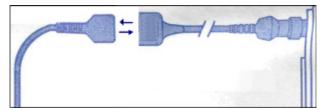


Figure 8-8 Test the pressure cable

- 2) Verify that the green light is continuously lit (no flashing).
- 3) If the light does not illuminate, replace the cable.





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

AWARNINGA:

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

8.7 Monitoring Fetal Movement

8.7.1 Auto Fetal Movement Monitoring (AFM)

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

Only US1 channel can perform AFM. But be aware that when monitoring twins, the movements 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.

8.7.2 Enabling or Disabling AFM Monitoring

To enable or disable AFM monitoring,

Select the setup key on the main interface.
 Select Fetus > AFM.
 Select ON or OFF (default).
 Select OK.

8.7.3 Changing AFM Gain

You can change the AFM gain. The AFM gain affects overall numeric and scope of the AFM trace.

Select the setup key on the main interface.
 Select Fetus > AFM Gain.
 Select 1, 2, 3 (default) or 4.
 Select OK.

8.7.4 Choosing AFM Mode

When AFM monitoring is enabled, the AFM monitoring result is displayed either in the form of a trace or black marks.



To choose AFM mode,

- 1 Select the setup key **O** on the main interface.
- 2 Select Fetus > AFM Mode.
- 3 Select Trace (default) or Blackmark.
- 4 Select OK.

8.7.5 Changing AFM Threshold

When AFM monitoring is enabled, you can change the AFM threshold.

To change the AFM threshold,

1 Select the setup key **O** on the main interface.

- 2 Select Fetus > AFM Threshold.
- 3 Select a value from $0 \sim 100$ for **AFM Threshold**.
- 4 Select OK.

8.7.6 Choosing FM Source

When AFM monitoring is enabled, the FM has two sources: AFM and MFM.

To choose the FM source,

- Select the setup key on the main interface.
 Select Fetus > FM Source.
 Select MFM (default) or AFM.
- 4 Select **OK**.

8.7.7 Manual Fetal Movement Monitoring (MFM)

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

- 1) Insert the FM marker connector into the MARK socket on the monitor.
- 2) Let the patient hold the marker in hand; ask her to press the top key of it when a fetal movement is felt. Continuous movements in 5 seconds are considered to be one movement and only press the key once.

8.8 Start Monitoring

After the **START** key is pressed, the monitor automatically zeroes the pressure, clears the MFM count and starts monitoring.

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



8.9 Inputting Maternal Information (Mat. Info)

8.9.1 Auto ID

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

8.9.2 Changing Maternal Information

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

- 1 Select the Mat. Info key **T**? on the main interface.
- 2 Select ID.
- 3 Select the required number for patient's ID on the soft keyboard.
- 4 Select ok.
- 5 Select Name.
- 6 Select the required letter for patient's name on the soft keyboard.
- 7 Select ok.
- 8 Select OK.

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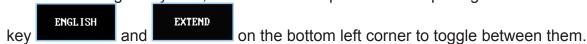
Figure 8-9 Mat. Info inputting menu

Figure 8-10 Soft keyboard

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

NOTE:

- 1) Pressing the START key separates two patients. The 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 in the archive list and the printout.
- 4) For the non-English system, more letters are provided for inputting the name. Select the







Exit

8.9.3 Switching Mat. Info Inputting On or Off

The **Mat. Info inputting** function allows the menu to pop up automatically after the **START** key is pressed. After you input the mother's information and exit from the menu, the monitoring starts immediately.

To switch the Mat. Info Inputting on or off:

1 Select the setup key on the main interface.

2 Select Start Monitor > Mat. Info.

3 Select **ON** or **OFF** (default).

4 Select OK.





Chapter 9 After Monitoring

9.1 Data Saving

The monitor automatically saves the data every 2 hours and prior to shutdown, including fetal monitoring traces and maternal information. The maximum capacity is 24-hour data.

When the monitor is switched on again, those data will be loaded. You can review them or print them at a high speed.

CAUTION :

Switch off the monitor in a normal way as described in section *9.3 Switching Off*, otherwise the data that is not saved will be lost.

9.2 Completing Monitoring

After monitoring,

- 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.

9.3 Switching Off

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

Do not press the POWER switch continuously. Allow at least 10 seconds between switching the monitor on and off.

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Chapter 10 Maintenance and Cleaning

10.1 Maintenance

10.1.1 Maintaining Inspection

(1) Visual Inspection

Prior to using the monitor every time, do the following inspections:

- Check the monitor and accessories to see if there is any visible evidence of damage that may affect patient safety. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid.
- Check all the outer cables, power socket and power cables.
- Check if the monitor functions properly.

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

(2) 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 leakage currents. 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.

(3) 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.

AWARNINGA:

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.

10.1.2 Maintenance of the Monitor

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

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

Scratching and damaging the screen should be avoided.



Operate the touch screen with special stylus pen or finger. Sharp edged or hard particles like ball pen or propelling pencil are prohibited.

Keep the touch screen surface clean, and no adhesive should be applied.

Avoid high voltage and static charge.

10.1.3 Maintenance of the Transducers

Keep the transducers in a dry environment, where the temperature had better be lower than 45°C.

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.

10.1.4 Storage of Recorder Paper

When storing recorder paper (including used 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 grid lines or make the trace unreadable.

10.1.5 Cleaning of the Recorder

The recorder platen, 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 platen with a lint-free cloth dampened in soap/ water solution.

2) Wipe the thermal array using a cotton swab moistened with 70% Isopropyl alcohol-based solution.

3) Check that the paper sensing mechanism is free of dust.

AWARNINGA:

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

10.2 Cleaning

In order to avoid infection, clean and disinfect the monitor and accessories after each use.



10.2.1 Cleaning of the Monitor

Regular cleaning of the monitor enclosure and the screen is strongly recommended.

The solutions recommended for monitor cleaning are: soft soap water, Tensides, Ethylate and Acetaldehyde.

AWARNINGA:

- 1) Unplug the 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.
- 2) If liquid is splashed on or into the main unit inadvertently, or enters the conduit, stop using the monitor and contact the manufacturer for service immediately.

Clean the monitor enclosure with soft cloth and diluent non-caustic detergents 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 CAUTION

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

NOTE:

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

10.2.2 Cleaning of the Accessories

(1) Cleaning of Transducers



Follow these steps to clean the US transducer, TOCO transducer and IUP cable:

- 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 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 Leads	Mild alcohol-free soap water
IUP Cable	Mild alcohol-free soap water

CAUTION :

- 1) Be sure the temperature of cleaning solutions 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, no remaining cleanser is allowed on the surface.

(2) Cleaning of Belt

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

10.3 Disinfecting

Clean the equipment before disinfecting.

The table below lists the allowed disinfectant bases:

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

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 monitor or any accessory into liquid.
- 4) After disinfection, no remaining disinfectant is allowed on the surface.
- 5) Check if the monitor and accessories are in good condition. If any aging or damage is detected, replace the damage part(s) or contact the manufacturer for service before reusing them.

NOTE:

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

10.4 Sterilizing

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



Chapter 11 After-Sales Service

If you have any question about maintenance, technical specifications or malfunctions of devices, contact the manufacturer or distributor.

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Appendix 1 Product Specifications

A1.1 Environmental Specifications

Working	Temperature:	$+5 \text{ °C} \sim +40 \text{ °C} (+41 \text{ °F} \sim +104 \text{ °F})$		
	Relative Humidity:	$25\% \sim 80\%$ (non-condensing)		
	Atmospheric Pressure:	860hPa ~ 1060hPa		
	Temperature:	-20 °C ~ +55 °C (-4°F ~ +131 °F)		
Transport and Storage	Relative Humidity:	25% ~ 93% (non-condensing)		
	Atmospheric Pressure:	700hPa ~ 1060hPa		

A1.2 Physical Specifications

Monitor					
Dimensions and Weight	Size (depth x width x height):		347mm x 330mm x 126mm		
Dimensions and Weight	Weight:		Approx. 6 kg		
Power Supply	Operating	Voltage:	100V-240V~		
	Operating	Frequency:	50Hz/60Hz		
	Input Powe	er :	110VA		
	Battery:		14.8V/4400mAh		
Standards Compliance	IEC/EN 61	-1:1988+A1+A2, EN 6060 1157, IEC/EN 60601-2-37, 0601-1-2:2001+A1	-		
Anti-electric Shock Type		Class I equipment with internal power supply			
Anti-electric Shock Degree		FHR1, FHR2, TOCO, FM IUP BI DECG G	, ,		
Degree of Protection agair Ingress of Water	nst Harmful	Ordinary equipment (sea proof)	aled equipment without liquid		



Degree of Safety in Presence of Flammable Gases	Equipment not suitable for use in presence of flammable gases
Disinfection/Sterilizing Method	Refer to this user manual for details
EMC	Group I Class A
Working System	Continuous running equipment
Earth Leakage Current (Limit)	N.C. S.F.C. 500μA 1000μA
Enclosure Leakage Current (Limit)	N.C. S.F.C. 100µA 500µA
Patient Leakage Current (Limit)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Patient Auxiliary Current (Limit)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Display	
Screen Diagonal:	310mm(12.1")
Display Size:	246.0 mm (H) × 184.5mm(V)
Pixel:	$800(H) \times 600(V)$
Pel Pitch:	0.3075 mm × 0.3075 mm
Pel Array:	RGB vertical stripe
Display Mode:	Normal White
Contrast Ratio:	500:1 (Typ.)
Brightness:	200 cd/m ² (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



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Angle of View:	Horizontal K=10 Right 70° \[K: Contrast Ratio] Left 70°
	Vertical K=10 Top 60° \Box K: Contrast Ratio)
	Bottom 50°
Signal Interface	
DB9 network interface, RJ45 in	terface
Ultrasound Transducer	
Weight:	190g
Cable Length:	2.5m
Dimension:	88mm × 35mm
TOCO Transducer	
Weight:	180g
Cable Length:	2.5m
Dimension:	88mm × 35mm
Remote Event Marker	
Length:	2.5m
Weight:	56g

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A1.3 Performance Specifications

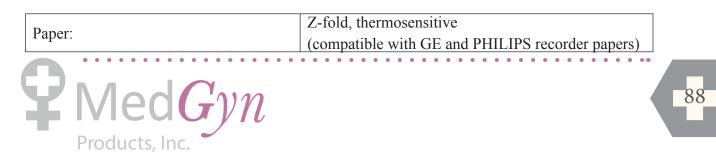




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	Technique:	Ultrasound Pulse Doppler with autocorrelation			
Pulse Repetition Rate:		2 KHz			
	Pulse Duration:	92 μs			
	Ultrasound Frequency:	(1.0±10%) MHz			
	p- <1 MPa				
Ultrasound	$I_{\rm ob}$ <10 mW/cm ²				
	$I_{\rm spta}$ <100 mW/cm ²				
	FHR Measurement Range:	50 bpm ~ 240 bpm			
	Resolution:	1 bpm			
	Accuracy:	±1 bpm			
	Dielectric Strength:	> 4000Vrms			
	TOCO Range:	0%~100%,			
	Non-linear Error:	10%			
тосо	Resolution:	1%			
	Zero Mode:	Automatic/ Manual			
	Dielectric Strength:	> 4000Vrms			
	Technique:	Pulsed Doppler ultrasound			
AFM	Range:	0% ~ 100%,			
Resolution:		1%			
Marking	Manual fetal movement mark				
Momory	Auto data saving:	24-hour data			
Memory	Archive storage:	35-hour data			

A1.4 Recorder Specifications



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Paper width:	152mm (GE), 150mm (PHILIPS)
Effective printing width:	110mm (American Standard)
Effective printing width:	120mm (International Standard)
FHR printout width:	70mm (American Standard)
FHK printout width.	80mm (International Standard)
	30bpm/cm (American Standard)
FHR scaling:	20bpm/cm (International Standard)
TOCO printout width:	40mm
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 25mm/sec
Accuracy of data:	± 5% (X axis)
Accuracy of data:	± 1% (Y axis)
Resolution:	8 dots/mm
Record Information:	FHR1 trace/mark, FHR2 trace/mark, TOCO trace, AFM trace, fetal movement mark, event mark (and annotation), AUTO-zero symbol, date, time, printing speed, ID, name, FHR2 Offset, STV analysis results etc.

A1.5 Rechargeable Lithium-ion Battery

Туре	Rechargeable Lithium-ion Battery	
Continual Working Time	2 hours ~ 4 hours (depending on the configuration)	
Necessary Charge Time	9 hours ~ 10 hours	
Nominal Capacity	4400mAh	
Nominal Voltage	14.8V	



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Charge Mode	Constant current/ constant voltage
Charge Current (Standard)	0.2C ₅ A (880mA)
Charge Voltage (Standard)	$(16.8 \pm 0.1) \mathrm{V}$
Maximum Continuous Charge Current	2000mA
Storage Temperature	Short Term ($\leq 1 \text{ month}$): -20 °C ~ +60 °C (-4 °F ~ +140 °F) Medium Term ($\leq 3 \text{ months}$): -20 °C ~ +45 °C (-4 °F ~ +113 °F) Long Term ($\leq 1 \text{ year}$): -20 °C ~ +20 °C (-4 °F ~ +68 °F) During storage, recharge the battery at least every six months.
Cycle Life	\geq 500 times

A1.6 Low Output Summary Table

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0) System: Fetal & maternal Monitor

Transducer Model	I _{spta.3} (mW/cm ²)	ТІ Туре	TI Value	MI	Ipa <u>.3@MI_{max}</u> (W/cm ²)
PW1.0MHz	4.29	TIS	0.085	0.030	0.048
	4.29	TIB	0.160	0.030	0.048

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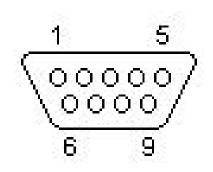


Appendix 2 Signal Input/Output Connector

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. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, contact our technical service department or your local distributor.

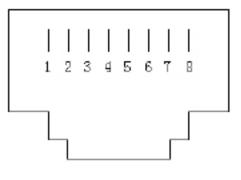
DB9 Interface

Pin	Signal	Input/Output
1	+5V	Output
2	Rx	Input
3	Tx	Output
4	485EN	Input
5	0V Ref.	
6	TA	Output
7	ТВ	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

Phenomenon	Possible Cause	Solution
	Power cable is loose.	Tighten the power cable.
Power indicator is off.	The fuse is blown.	Change the fuse.
	The battery runs out of power.	Connect to AC power supply.

A3.2 Noise

Phenomenon	Possible Cause	Solution
	Too high volume.	Turn down the volume.
Noise	Interfered by mobile phone or other interfering source.	Keep the interfering source far away from the monitor.

A3.3 Recorder Error

Phenomenon	Possible Cause	Solution
Paper jam	Wrong loading paper or paper is dampened.	Load paper correctly and keep paper from moist.



	The recorder is not started.	Press the PRINT key.
	Run out of paper.	Load paper.
Recorder does not work.	The paper drawer is not locked.	Slide the paper drawer in until both latches are locked in position.

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A3.4 Trouble with Ultrasound FHR Monitoring

Phenomenon	Possible Cause	Solution
	The pregnant woman is too fat.	Monitor FHR with DECG.
	Improper ultrasound transducer position.	Adjust the position of the transducer till the better signal is received.
	Loose belt.	Tighten the belt.
Inconstant trace / display	Superfluous aquasonic coupling gel.	Wipe off superfluous aquasonic coupling gel.
	Frequent fetal movements.	Delay the monitoring.
	Maternal movement.	Request the patient to calm down and stay still.
	Inadequate aquasonic coupling gel.	Use recommended aquasonic coupling gel quantity.
Doubtful FHR	Record maternal heart rate wrongly.	Change the position of the ultrasound transducer.
	The transducer is not well placed in position, and the mixed noise has been recorded.	Adjust the position of the transducer.
Feint 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 the manufacturer for service.

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A3.5 Troubles with DECG FHR Monitoring

Symptom	Possible Cause	Solution
Inconstant trend Inconstant 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 fixed firmly	Fix an attachment pad at the DECG cable.

A3.6 Troubles with Contractions Monitoring (External)

Phenomenon	Possible Cause	Solution
	The belt is too tight or too loose.	Adjust the belt.
Bad trace quality or	The belt has no elasticity.	Renew the belt.
fluctuant TOCO baseline	Maternal movement.	Request the patient to calm down and stay still.
	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 numeric.	Insure favorable contact for patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

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A3.7 Troubles with Monitoring Contractions (Internal)

Symptom	Possible Cause	Solution
No trend	The intrauterine catheter is jammed	Wash with disinfector
No pressure change when uterine contraction	"Dry" environment or the tip of intrauterine catheter is placed extraovularly	Wash with disinfector or change the position of transducer
Only see the IUP peak but no baseline	Zero adjustment is wrong	Zero the system
The trend is a beeline	The connector failure.	Move or contact catheter. If trend no fluctuation, change intrauterine cable.

A3.8 Blown Fuses

AWARNINGA:

Switch off the monitor and unplug it before changing the fuse.

Replace the fuse when it is blown.

The two fuses of the monitor are located on the bottom panel, their specifications are:

Size: Ф5mm*20mm; Model: T1.6AL 250V.

To replace a fuse:

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



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Appendix 4 Abbreviation

Abbreviation	Full Name
AC	Alternative Current
AFM	Automatic Fetal Movement [Detection]
BPM	Beat(s) Per Minute
CTG	Cardiotocography
DC	Direct Current
DECG	Direct ECG
DFHR	Direct FHR
ECG	Electrocardiogram
FH	Fetal Heart
FHR	Fetal Heart Rate
FM	Fetal Movement
FS	Fetal Stimulator
ICU	Intensive Care Unit
ID	Identity
IUP	Intra-Uterine Pressure
IUPC	Intra-Uterine Pressure Catheter
LCD	Liquid Crystal Display
MFM	Manual Fetal Movement [Detection]
NST	Non Stress Test
SOV	Signals Overlap Verification
STV	Short-Term Variation
тосо	Tocotonometer
UA	Uterine Activity [TOCO/IUP]
US	Ultrasound [Transducer]

The abbreviations used in this manual and their full names are listed below:





Appendix 5 EMC Information – Guidance and Manufacture's Declaration

A5.1 Electromagnetic Emissions – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration - electromagnetic emission

The *F9 Fetal & maternal Monitor* is intended for use in the electromagnetic environment specified below. The customer of the user of the *F9 Fetal & maternal Monitor* should assure that it is used in such and environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>F9 Fetal & maternal 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 F9 Fetal & maternal Monitor is suitable for
Harmonic emissions IEC 61000-3-2	Class A	use in all establishments, other than domestic and those directly connected to the public low-
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	voltage power supply network that supplies buildings used for domestic purposes.



A5.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity

The *F9 Fetal & maternal Monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *F9 Fetal & maternal Monitor* 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 are 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.

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Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 $< 5\% U_{T}$ (> 95% c for 0.5 cy $40\% U_{T}$ (60% dip for 5 cyc $70\% U_{T}$ (30% dip for 25 cy $< 5\% U_{T}$ (> 95% c for 5 sec	lip in U_{τ}) /cle(> 95% dip in U_{τ}) for 0.5 cyclein U_{τ}) les40% U_{τ} (60% dip in U_{τ}) for 5 cyclesin U_{τ}) cles70% U_{τ} (30% dip in U_{τ}) for 25 cycleslip in U_{τ}) cles< 5% U_{τ} (> 95% dip in U_{τ}) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <i>F9 Fetal & maternal</i> <i>Monitor</i> requires continued operation during power mains interruptions, it is recommended that the F9 Fetal & maternal Monitor be powered from an uninterruptible power supply or a battery.		
NOTE: U_{τ} is the a.c. mains voltage prior to application of the test level.				





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A5.3 Electromagnetic Immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity

The *F9 Fetal & maternal Monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *F9 Fetal & maternal Monitor* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3V _{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the <i>F9 Fetal & maternal Monitor</i> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1}\right]\sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz}$
			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). 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 Interference may occur in the vicinity of equipment marked with the following symbol:

absorption and reflection from structures, objects and people.

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- 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 Fetal & maternal Monitor* is used exceeds the applicable RF compliance level above, the *F9 Fetal & maternal 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 & maternal Monitor*.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.





A5.4 Recommended Separation Distance

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

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

	Separation distance	e according to frequency	rding to frequency of transmitter (m)		
Rated maximum output power of	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz		
transmitter (W)	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$		
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.



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