F6, F6 Express
F9, F9 Express

Fetal & Maternal Monitor

Version 1.7

User Manual

CE 0123

EDAN

About this Manual

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Statement

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

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

Product Information

Product Name: Fetal & Maternal Monitor

Model: F6, F6 Express, F9, F9 Express

Responsibility of the Manufacturer

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

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

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

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

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other

information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

Table of Contents

Chapter 1 Safety Guide

CAUTION

Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

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.

3 The functions frequently used are marked with an asterisk *, for example *4.9* **Reviewing Alarms*.

1.1 Indications for Use/ Intended Use

F6/F9 Fetal & Maternal Monitor (hereinafter called F6/F9):

F6/F9 Fetal & Maternal Monitor is intended for non-invasive and invasive monitoring of fetus during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

F6/F9 Fetal & Maternal Monitor provides Non-Stress testing for pregnant women from the 28th week of gestation. It can externally monitor the FHRs using ultrasound and uterine activity via a TOCO transducer. Alternatively, it can internally monitor one of the FHRs with DECG and uterine activity with an IUPC.

F6 Express/F9 Express Fetal & Maternal Monitor (hereinafter called F6 Express/F9 Express):

F6 Express/F9 Express 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.

F6 Express/F9 Express Fetal & Maternal Monitor is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation. In addition, it provides a solution for maternal vital signs monitoring.

Contraindications:

They are not intended for use in intensive care units, operating rooms or for home use.

1.2 Features

The following table lists the measurements that **F6**, **F6 Express**, **F9** and **F9 Express** support.

Measurement \ Model	 F6, F9	 F6 Express	 F9 Express
Single-FHR	√	√	√
Dual-FHR	√	√	√
TOCO	√	√	√
FM	√	√	√
AFM	√	√	√
DECG/IUP	Opt	×	Opt
MECG	×	√	√
NIBP	×	√	√
MSpO2	×	√	√
TEMP	×	√	√
NOTE: √ = Standard Opt = Optional × = Not Available			

1.3 Instruction for Safe Operation

NOTE:

In this manual, **Monitor** refers to **F6, F6 Express, F9** and **F9 Express**, and is used where the information applies to all models.

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

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

◆ The protective degree against electric shock of the patient connections is:

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

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

a) The effects of high frequency currents

b) The interference of electrosurgery equipment

1.4 Ultrasound Safety Guide

◆ Fetal Use

The 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.

◆ Instructions for Use in Minimizing Patient Exposure

The acoustic output of the 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.

1.5 Safety Precautions

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

WARNING

For using safety:

1 The monitor or FTS-3 telemetry system (hereinafter called FTS-3) is provided for the use of qualified physicians or personnel professionally trained.

2 Only qualified service engineers can install this equipment. Only service engineers authorized by the manufacturer can open the shell.

3 The monitor is not intended for use in intensive care units (ICU), operating rooms or for home use.

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

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

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

7 **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.

8 Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously. Do not touch the signal input or output connector and the patient simultaneously.

9 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.

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

WARNING

11 **SHOCK HAZARD** – Do not connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.

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

13 Do not apply this monitor and other ultrasonic equipment simultaneously on a same patient, in case of possible hazard caused by leakage current superposition. Do not apply this monitor simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators, on the same patient.

14 The monitor can only be used on one patient at a time.

15 **SHOCK HAZARD** - Do not remove the top panel cover during operation or while power is connected. Only authorized service personnel could remove the unit cover.

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

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

18 The system should be operated by the doctor or under the doctor’s instructions.

19 Do not apply the monitor during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.

20 Only MECG, SpO2, NIBP and TEMP applied parts of the monitor are defibrillation-proof. When a defibrillator is applied, keep other accessories away from the patient. Otherwise it may result in damaging the monitor or harming the patient.

21 ECG cables may be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again.

22 After defibrillation, the screen display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers’ instructions.

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

WARNING

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

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

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

27 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:

28 The monitor is not intended for treatment.

29 Alarms must be set up according to different situations of patients. Make sure that audio sounds can be activated when an alarm occurs.

30 Do not perform NIBP measurements on patients with sickle-cell disease or under any condition where the skin is damaged or expected to be damaged.

31 Clinical decision making based on the output of the device is left to the discretion of the provider.

32 Do not put the sensor on extremities with arterial catheter or venous syringe.

33 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

34 The fetal spiral electrode and intrauterine pressure catheter are disposable. Discard them after use.

35 The disposable accessories are intended to be used only once. Dispose of them properly after use and do not reuse them.

36 The IUPC is neither intended nor approved for measuring intrauterine pressure extraovularly; attempting to do so may lead to maternal discomfort or injury.

For using the battery:

37 Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.

WARNING

38 Use the battery only in **F6 / F6 Express / F9 / F9 Express**.

39 Do not reverse the battery pole or it will cause explosion.

40 Do not unplug the battery when monitoring.

41 Do not heat or throw the battery into a fire.

42 Do not use or leave battery close to fire or other places where the temperature may be above +60 ºC (+140 ºF).

43 Do not immerse, throw, or wet the battery in water/ seawater.

44 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.

45 Do not short-circuit the battery by connecting the battery cable connector or battery socket with metal objects or solder.

46 If the liquid leak from the battery spills onto your skin or clothes, wash well with fresh water immediately.

47 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.

48 Do not solder the leading wire and the battery terminal directly.

49 Keep the battery away from fire immediately when leakage or foul odor is detected.

50 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.

51 Do not use a battery with serious scar or deformation.

52 Remove the battery and store it at a cool and dry environment if the monitor is not used for a long time.

53 Unplug the monitor before installing and removing the battery.

54 Do not connect the battery directly to an electric outlet or cigarette lighter charger.

55 Batteries have life cycles. If the time that the monitor using battery becomes much shorter than usual, the battery life is at an end. Replace the battery with a new one of the same specification as the one provided or recommended by the manufacturer.

56 If the battery is stored alone and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent overdischarge.

In addition, when you use the FTS-3 fetal telemetry system, please pay attention to the warnings as follows:

57 The system should be operated by the doctor or under the doctor’s instructions.

WARNING

58 SHOCK HAZARD – The base station and transducers for one patient must be supplied by the same power and do not change the power supply.

59 Please arrange a function test periodically for the system.

60 Do not move the system when it is powered on and do not soak it in any liquid.

61 Please check the transducer, cable and base station periodically. If the transducers are damaged, do not use them in water and repair them in time.

62 If the transducer has been beaten or knocked, please check whether the cover is airproof or damaged. If you have any doubt, please contact the manufacturer or local agent.

63 If the battery in the base station is stored alone and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent overdischarge.

64 The battery in the wireless transducer should be replaced by the serviceman authorized by EDAN.

65 The wireless transducer has priority over the wired transducer. When the wireless transducer is working, the wired transducer will be turned off automatically. Do not use the wireless transducer and the wired transducer at the same time.

CAUTION

1 The device is designed for continuous operation. Avoid liquid splashing on the device.

2 Refer servicing to qualified personnel.

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

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

5 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.

6 Do not sterilize the monitor or any accessory with autoclave or gas.

7 Switch off the system power before cleaning. Cleaning consists of removing all dust from the exterior surface of the equipment with a soft brush or cloth.

8 Only the sensor and cable of US/TOCO transducers are watertight. Pay attention not let any liquid enter the transducer plug.

CAUTION

9 **Electromagnetic Interference** - Ensure that the environment in which the monitor or FTS-3 is installed is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phone base stations, etc. Even though other devices are in accordance with national standard radiation requirements, the monitor or FTS-3 may be interfered.

10 **Electromagnetic Interference** - Do not use mobile phones nearby in the process of monitoring.

11 **Electromagnetic Interference** - Fetal parameters, especially ultrasound and ECG, are sensitive measurements involving small signals, and the monitoring equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.

12 **Electromagnetic Interference** - The monitor or FTS-3 system should not be used adjacent to or stacked with other equipment, refer to section A7.4 Recommended Separation Distances.

13 Electromagnetic interference is not unique to this system but is characteristic of fetal patient monitoring equipment in use today. This performance is due to very sensitive high gain front-end amplifiers required to process the small physiological signals from the patient. Among the various monitoring systems already in clinical use, interference from electromagnetic sources is rarely a problem.

14 The medical electrical equipment needs to be installed and put into service according to Appendix 7 EMC Information.

15 Portable and mobile RF communications equipment can affect medical electrical equipment, refer to section A7.4 Recommended Separation Distances.

16 Sterility cannot be guaranteed if package of the fetal spiral electrode is broken or opened.

17 The fetal spiral electrode has been sterilized by gamma radiation. Do not re-sterilize.

18 The device and reusable accessories could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

19 If the terminals of the battery become dirty, wipe with a dry cloth before using the battery.

20 For information on installing and removing the battery from the monitor, thoroughly read the user manual.

CAUTION

21 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.

22 Batteries have life cycles. If the time that the monitor and the FTS-3 system using battery becomes much shorter than usual, the battery life is at an end. Please contact the manufacturer to replace the battery with a new one of the same specifications as the one provided or recommended by the manufacturer.

In addition, when you use the FTS-3 fetal telemetry system, please pay attention to the cautions as follows:

1 The wireless transducers are IPX8 waterproof, but the base station should be kept non-soaked and non-condensing. The system may be condensing during transportation in high humidity or low temperature.

2 The water temperature must not exceed +60 ºC (+140 ºF) when you wash the belt.

3 The use of accessories and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.

4 This equipment generates, uses and radiates radio-frequency energy, and if it is not installed and used in accordance with its accompanying documentation, it may cause interference to radio communications.

5 When the battery is charged, used or stored, keep it away from objects or materials with static electric charges.

6 If the terminals of the battery become dirty, wipe with a dry cloth before using the battery.

7 The recommended charging temperature for the battery is between 0°C ~ +40°C. Please do not exceed the temperature range.

8 Batteries have life cycles. If the time that FTS-3 using battery becomes much shorter than usual, the battery life is at an end. Please contact the manufacturer to replace the battery with a new one of the same specification as the one provided or recommended by the manufacturer.

9 Remove the battery in the base station and store it at a cool and dry environment if the system is not used for a long time.

10 Please remove the battery out of the transducer at the end of their life.

11 Please read the user manual carefully when you install or remove the battery.

CAUTION

12 Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

13 Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

1.6 Definitions and Symbols

Socket for ultrasound transducer 1 (Type BF applied part)

Socket for ultrasound transducer 2 (Type BF applied part)

Socket for DECG cable (Type CF applied part)

Socket for TOCO transducer or IUP cable (Type BF applied part)

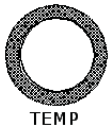
Socket for Remote Event Marker (Type BF applied part)

Reserved.

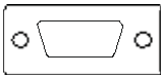
Socket for NIBP Cuff (Type BF applied part)

Socket for SpO_2 Sensor (Type BF applied part)

Socket for Maternal ECG Cable (Type CF applied part)



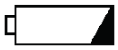
Socket for TEMP Sensor (Type CF applied part)



RS232 Interface (DB9 or D-Sub)

RJ45 Interface

Equipotential Grounding



Battery check

Alternating Current (a.c.)

Stand-by

Caution, consult ACCOMPANYING DOCUMENTS

Warning

Operating instructions

Follow instructions for use

Type BF applied part

Defibrillation-proof type BF applied part

Type CF applied part

Defibrillation-proof type CF applied part

IPX1 Protected against vertically falling water drops

IPX8 Protected against the effects of continuous immersion in water

CE marking

Disposal method

Part Number

Serial Number

Date Of Manufacture

Manufacturer

Authorized Representative in the European Community

General symbol for recovery/recyclable

Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician

With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1and CAN/CSA C22.2 No. 601.1

FTS-3 Fetal Telemetry System

Non-ionizing electromagnetic radiation

Serial Number

Wireless Transducer Working Indicator

USB Port (Reserved)

Ethernet Port (Reserved)

Channel Adjustment

Chapter 2 Installation Guide

NOTE:

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

2.1 Opening and Checking Package

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage.

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.
- Check all the cables and accessories.

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

2.2 Installing Battery

WARNING

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

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

(1) Battery Installation

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

3) Take the battery out from package. Put the battery and the cables into the battery compartment and insert the cable connector into the socket.

4) 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. To remove the battery, hold the two bands of the battery tight, shake it loose and pull it out with force.

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.

3 Do not pull the battery cables, or the battery may become damaged.

2.3 Installing Monitor

The monitor can be placed on a flat surface, or be installed on a wall or a trolley. The service engineer should install the monitor properly.

2.4 Connecting Power Cable

- Make sure the AC power supply of the monitor complies with the following specification: 100V-240V~, 50Hz/60Hz.
- Apply the power cable provided with the monitor. Plug one end of the power cable to the power socket of the monitor. Connect the other end to a three-slot power output special for hospital usage.
- The equipotential grounding terminal is provided for the connection of a potential equalization conductor. Therefore, it is recommended to connect the grounding terminal of the monitor and the power outlet with the grounding wire, making sure the monitor is grounded.

WARNING

If the protective grounding (protective earth) system is doubtful, the power of the monitor must be supplied by internal power supply only.

NOTE:

1 Make sure the monitor and the power outlet are placed at a place where it is easy to connect and disconnect the power cord.

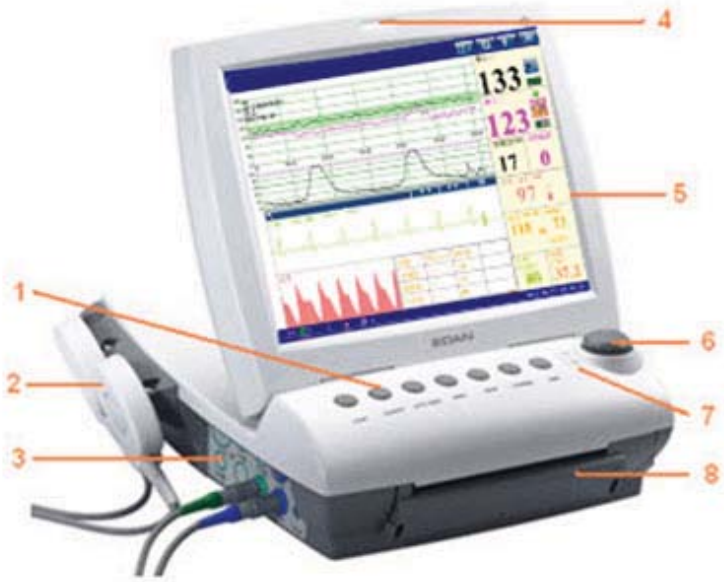
2 When the supply mains is interrupted, the device switches to internal power supply and operates normally if the battery is installed. If the battery is not installed, the monitor shuts down and resumes the previous settings at the subsequent operation.

Chapter 3 Monitor and Accessories

3.1 Overview

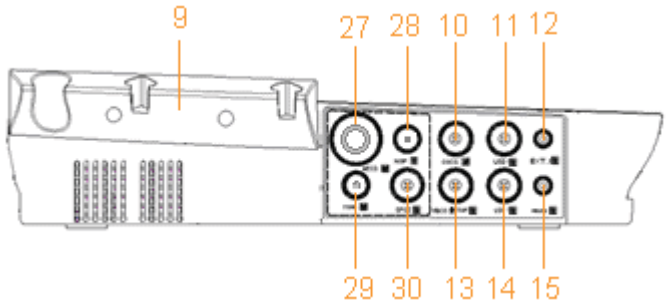
NOTE:

F6/F6 Express differs from **F9/F9 Express** in LCD size. This manual takes pictures and interfaces of **F9/F9 Express** as an example, and they may look slightly different from your model.



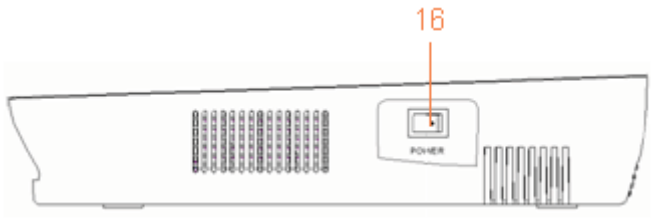
1 Keys
2 Transducer
3 Sockets
4 Alarm Indicator
5 Display Screen
6 Control Knob
7 Charge, AC, Power Indicator
8 Paper Drawer

Figure 3-1 Appearance (for reference only)



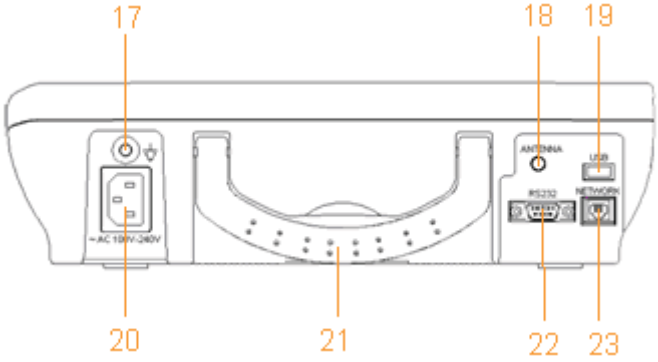
9 Transducer Holder
10 DECG Socket
11 US2 Socket
12 EXT.1 Socket
13 TOCO/IUP Socket
14 US1 Socket
15 MARK Socket
27 MECG Socket
28 NIBP Socket
29 TEMP Socket
30 SpO2 Socket

Figure 3-2 Left Panel



16 POWER Switch

Figure 3-3 Right Panel



17 Equipotential Grounding Terminal

18 Antenna (Not applicable)

19 USB Socket (Not applicable)

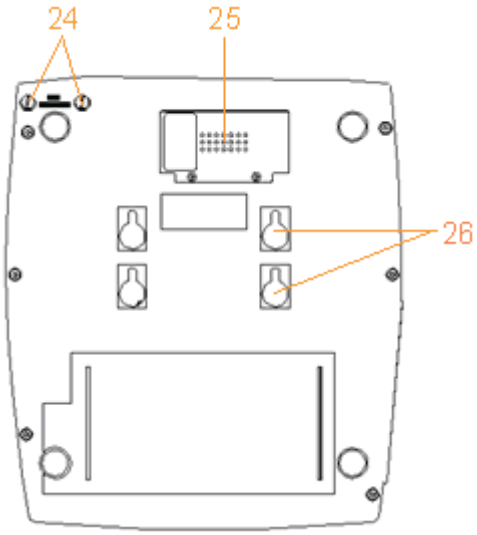
20 Power Socket

21 Handle

22 DB9 Socket

23 RJ45Socket

Figure 3-4 Rear Panel



24 Fuses

25 Battery Compartment

26 Wall-mounting Holes

Figure 3-5 Bottom Panel

3.1.1 Keys and Control Knob

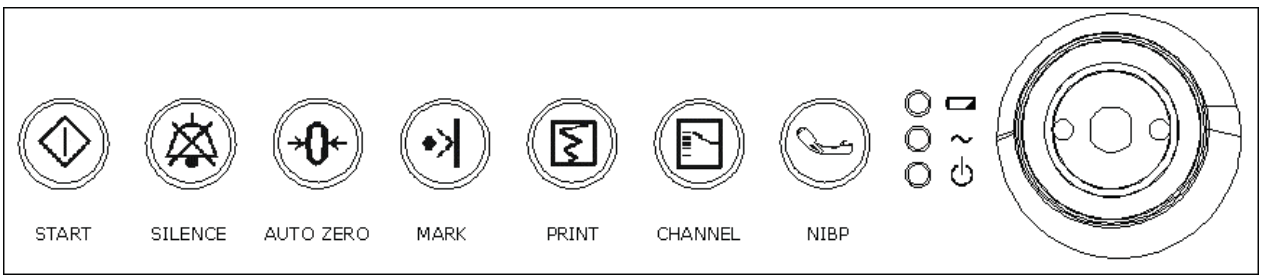


Figure 3-6 Keys and Control Knob

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: Silence/reset

Press this key to disable the current auditory alarm manifestation, and re-enable the monitor's response to new abnormal patient condition.

(3) AUTO ZERO 

Function: TOCO zero

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

(4) MARK 

Function: Record an event.
Press this key to make an event mark.

(5) PRINT 

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

(6) *CHANNEL 

Function: Switch the channels
Press this key to toggle the FH sound between US1 channel and US2 channel.

(7) NIBP 

Function: Start or stop a NIBP measurement.

Press this key to inflate the cuff and start a NIBP measurement. During the measuring process, press this key to cancel the measurement and deflate the cuff.

This function is only available on **F6 Express** and **F9 Express**.

(8) CONTROL KNOB

Function: Adjust volume, setup and review control.

It can be pressed like other keys and be rotated clockwise or counterclockwise. All the operations on the screen or in the menu are 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.

Operation Procedure:

a) Rotate the control knob to move the cursor to the item you want;

b) Press the control knob;

c) One of the following three results will be achieved:

- A menu pops up on the screen, or the menu is replaced by a new one;
- A submenu with several options appears on the right of the item. If this item has more than 8 options, they will be displayed in more than one page. Select **PREV** to switch to the previous page, or select **NEXT** to switch to the next page.
- The function operates immediately.

NOTE:

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

2 If the key sound is enabled, the monitor gives a normal key sound when the operation is valid, and gives a sharp “Di” sound when the operation is invalid.

CAUTION

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

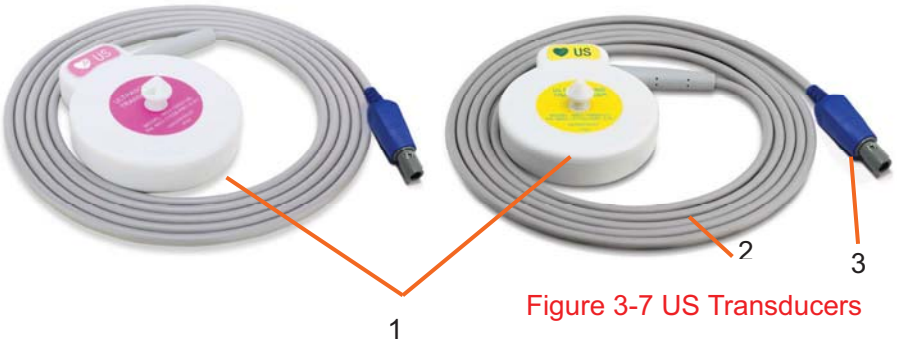
3.1.2 Indicators

There are four groups of indicator on top of the screen and the front panel. From the top down they are: alarm indicator, CHARGE indicator, AC indicator and Power indicator.

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

3.2 Accessories

3.2.1 Ultrasound (US) Transducers



1 US Transducer Sensor

2 Transducer Cable

3 Transducer Connector

Figure 3-7 US Transducers

3.2.2 TOCO Transducers

1 TOCOS Transducer Sensor (Blue Labeled)

2 Transducer Cable

3 Transducer Connector

Figure 3-8 TOCO Transducers

3.2.3 Belt

Figure 3-9 Belt

3.2.4 Remote Event Marker

Figure 3-10 Remote Event Marker

3.2.5 DECG Cable

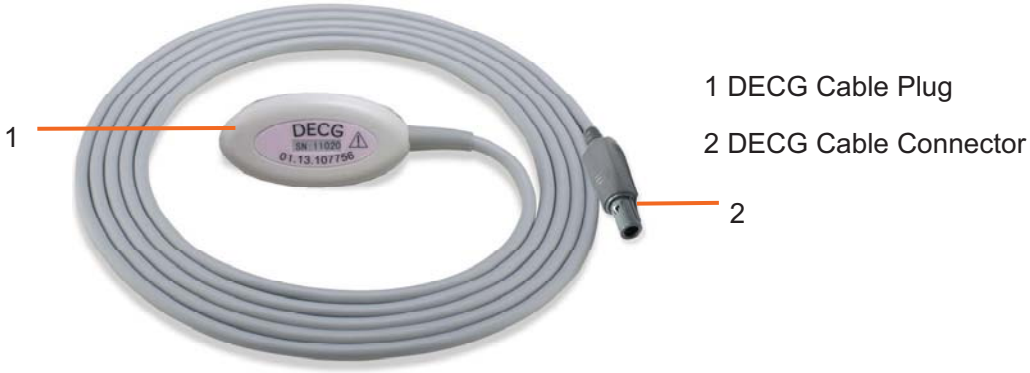


Figure 3-11 DECG Cable

3.2.6 Fetal Spiral Electrode

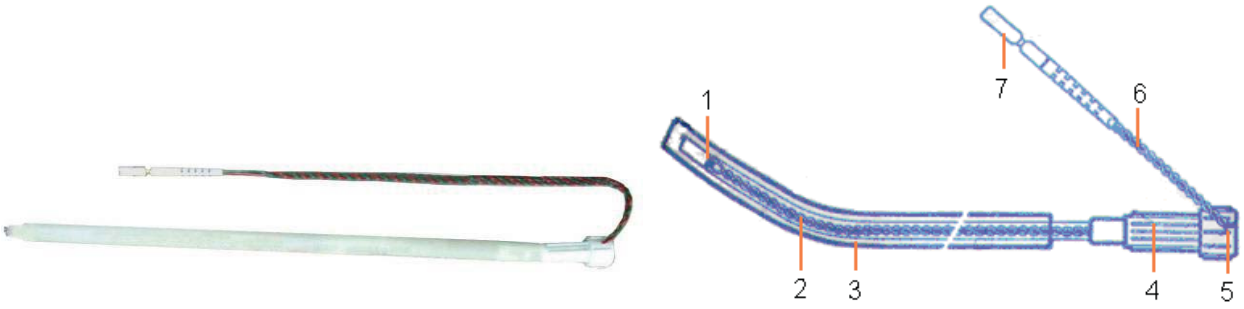


Figure 3-12 Fetal Spiral Electrode

1	Reference Electrode	2	Drive Tube	3	Guide Tube
4	Drive Handle	5	Handle Notch	6	Electrode Wire
7	Safety Cap				

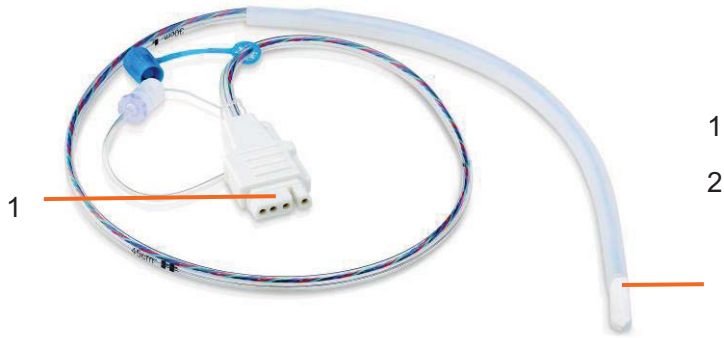
3.2.7 IUP Cable

Figure 3-13 IUP Connecting Cable

Figure 3-14 IUP Cable

1	Interface to IUP Cable	2	Connecting plug
3	Interface to IUP Catheter	4	Interface to Connecting Cable

3.2.8 IUP Catheter

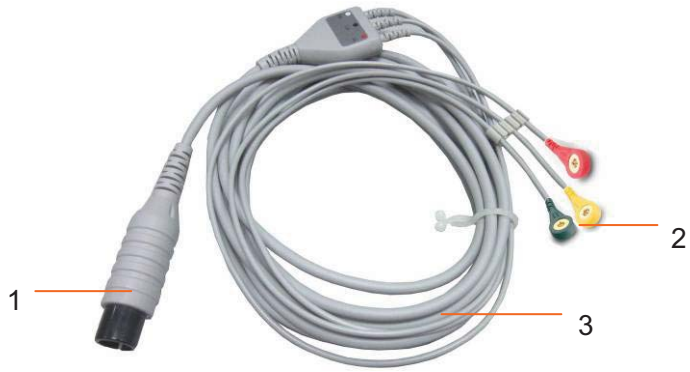


1 Interface to IUP Cable

2 Catheter

Figure 3-15 IUP Catheter

3.2.9 ECG Cable



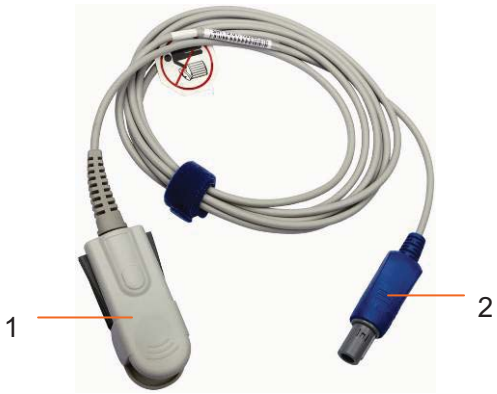
1 ECG Connector

2 ECG Fastener

3 Lead Wire

Figure 3-16 3-Lead ECG Cable

3.2.10 SpO_2 Sensor



1 SpO_2 Sensor

2 SpO_2 Connector

Figure 3-17 SpO2 Sensor

3.2.11 NIBP Cuff

Figure 3-18 NIBP Cuff

1 NIBP Cuff

2 Cuff Extension Tube

Figure 3-19 Cuff Extension Tube

3.2.12 TEMP Sensor

1 TEMP Sensor

2 TEMP Connector

Figure 3-20 TEMP Sensor

3.3 Screen

3.3.1 Main Interface

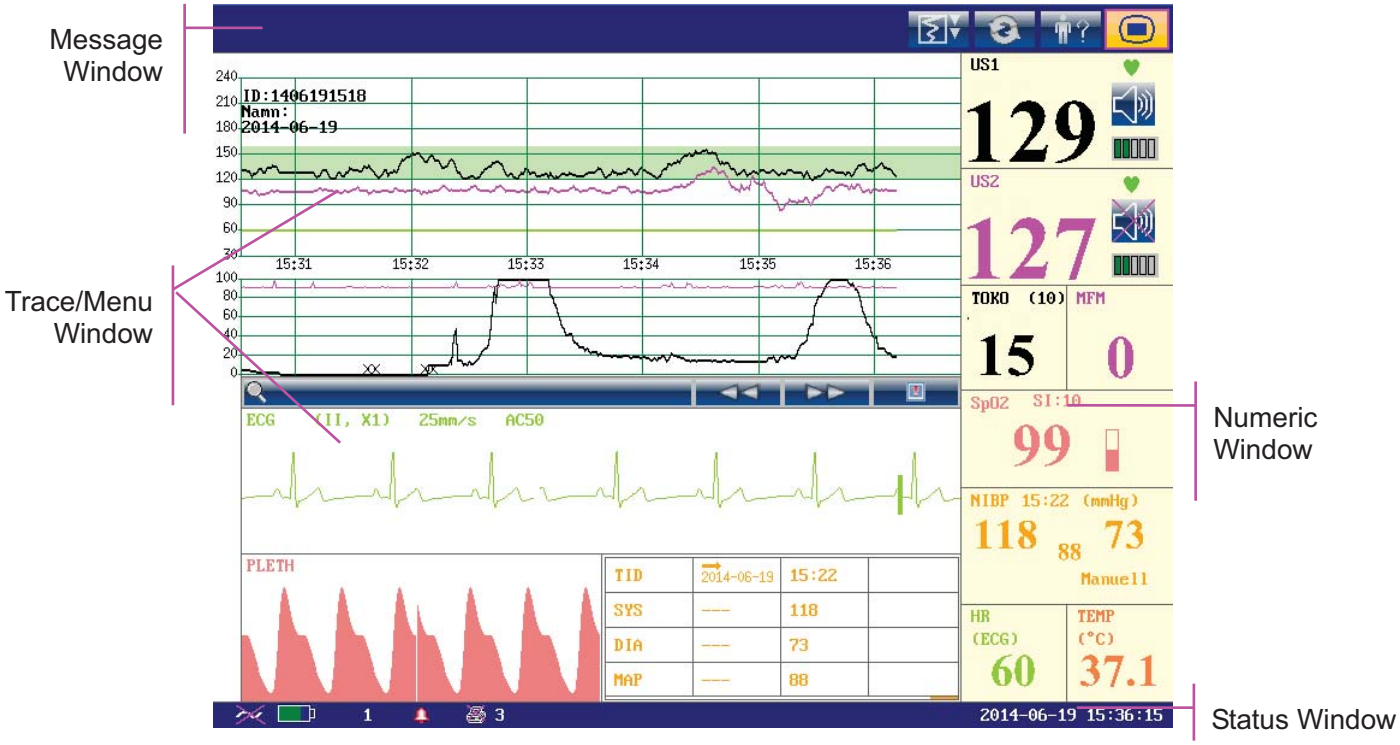


Figure 3-21 Main Interface

*Background Color Switch

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

To change the screen color,

1 Select the setup key  on the main interface.

2 Select **General > Screen Color**.

3 Select the required color.

4 Select **OK**.

According to the content, the main interface is divided into four windows:

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) 

:

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)  : **Paper advancing key**. Select this key to advance the paper for 8 cm (PHILIPS paper) or 7 cm (GE paper).

c)  : **Display mode switch. F6 Express** and **F9 Express** monitors have three display modes: maternal-fetal display mode, fetal display mode and maternal display mode. Select this key, and the display mode will switch to the next one in order.

d)  : **Mat. Info key.** Select this key to open maternal information menu for inputting or changing the patient's ID and name.

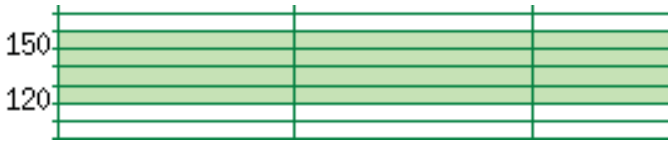
e)  : **Setup key.** Select this key to open setup main menu.

(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 ~ 240 (American standard) and 50 ~ 210 (International standard).

The green band in between the fetal heart rate panes indicates the preset alarm range (the top edge is not higher than 180 and the bottom edge is not lower than 100). It makes it easy to observe if the FHR exceeds the normal range. So you can easily tell if the fetal heart rate is too low or too high.



(3) Numeric Window

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

When the monitor is connected to the FTS-3 system, the signal strength and battery level of the wireless transducers are displayed.

(4) Status Window

f) Power indicator

- AC power supplied.
- no AC power supplied.

g) Battery indicator

The battery is loaded into the monitor with 100% capacity

75% capacity

50% capacity

25% capacity

The battery is almost depleted and needs to recharge immediately.

No battery is loaded.

h) Network connection indicator and device no.

- the monitor is online.
- the monitor is offline.

NOTE:

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

i) Audio alarm indicator

- the audible alarm is switched on.

 - the current audible alarm is switched off infinitely.

 - the current audible alarm is switched off temporarily.

j) Recorder status indicator

 - the recorder is in the process of printing.

 - no printing is going on.

k)  - Print speed.

l)  - Print remaining time.

m)  - Monitoring timer. It indicates the duration of the current monitoring, and zeroes when the **START** key is pressed.

n)  - FTS-3 system working channel

o) FTS-3 Base Station Battery indicator

 The battery is loaded into the base station with 100% capacity

 75% capacity

 50% capacity

 25% capacity

 The battery is almost depleted and needs to recharge immediately.

When there is no battery indicator, it indicates that no battery is installed in the base station.

p) The date and time of the monitor.

3.3.2 Setup Interface

The setup menu is provided to change the monitor configurations and monitoring settings. Press the Setup key  on the main interface to open this menu.

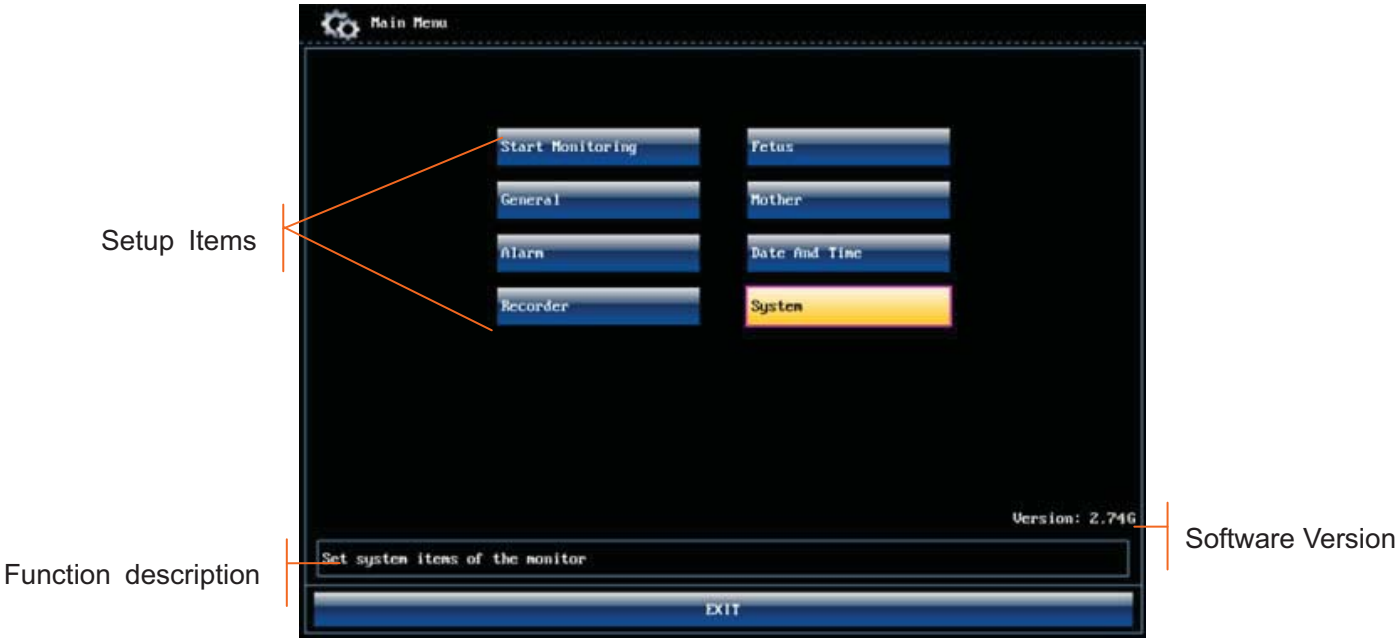


Figure 3-22 Main Setup Menu (**F9 Express**)

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 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. The setting does not take effect if the system exits automatically or is shutdown before **OK** is selected.

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 "System" in the illustration above. Correspondingly, its function "Set system items of the monitor" is issued in the blue frame pane.

3.3.3 Touch Screen

As an option, some of **F9** and **F9 Express** may have been configured with a 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 the  symbol to increase the numeric, move to the previous item or move leftwards. While touching 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.

Chapter 4 Alarms

4.1 Alarms 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. Audible alarms and visual alarms can be disabled excluding ASYSTOLE alarm. 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. They cannot be disabled.

In terms of severity, the alarms are divided into three levels: high, medium and low. High level alarm indicates the condition where the patient's life is endangered; it is a severe warning, labeled with the symbol ***; Medium level alarm is a moderate warning, labeled with the symbol **; low level alarm is a general warning.

The high level alarms have highest priority, and the medium level alarms take the second place. If more than one type of alarms is active at the same time, the monitor sounds an audible indicator for the higher level alarms.

The alarm levels are preset, and can not be changed.

4.2 Audible Alarm

If the audible alarm is not disabled, the alarm indicator displays  . When an alarm is active, the monitor gives out an alarm sound (the sound pressure range is 45dB ~ 85dB).

High level alarm: a "Do" tone is repeated three times, and then pauses for 3 seconds.

Medium level alarm: a "Do" tone is repeated three times, and then pauses for 5 seconds.

Low level alarm: a "Do" tone is issued, and then pauses for 20 seconds.

Press the **SILENCE** key, the current audible alarm toggles between on and off (temporarily or infinitely, you can change the setting).

If the current audible alarm is temporarily disabled, the alarm indicator displays  , with a remaining time on the right. The audible alarm is enabled again when the time is out, or when the **SILENCE** key is pressed.

If the current audible alarm is infinitely disabled, the alarm indicator displays  (flashing). The audible alarm is enabled again when the **SILENCE** key is pressed.

If Alarm Reset is enabled (see *4.8 Pausing or Resetting the Alarm*), and you press the **SILENCE** key to disable an audible alarm, the alarm indicator will display  . When other alarms present, the monitor will enable the audible alarm again automatically.

During the silence period, the alarm messages are displayed and the alarm indicator lights up as usual. You can press the **SILENCE** key again to enable the audible alarm.

WARNING

1 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

2 When the sound pressure of audible alarm is equivalent to the ambient noise, it may be difficult for the operator to distinguish the audible alarm.

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

NOTE:
After you enable the audible alarm again, whether the alarm sound still exists depends on whether the alarm persists.

4.3 Visual Alarm

When an alarm is active,

- **Alarm indicator:** the alarm indicator lights up:

Alarm Category	Indicator Color	Flashing Frequency	Duty Cycle
High level alarm	red	1.4Hz to 2.8Hz	20% to 60% on
Medium level alarm	yellow	0.4Hz to 0.8Hz	20% to 60% on
Low level alarm	yellow	Constant (on)	100% on

- **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:

- 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".

WARNING

Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.

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**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **Message Form**.

4 Select **Text** (default) or **Numeric**.

5 Select **OK**.

4.5 Changing the Alarm Volume

You can change the alarm volume,

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **Alarm Volume**.

4 Select **Low** (default), **Medium** or **High**.

5 Select **OK**.

4.6 *Choosing Alarm Silence Duration

You can change the alarm silence duration,

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **Silence Duration**.

4 Select **Infinite**, **1 min** (default), **2 min** or **3 min**.

5 Select **OK**.

4.7 Choosing Signal Loss Delay

When the fetal signal is lost and this condition continues for a certain time, the monitor issues a technical alarm. This time (signal loss delay) is adjustable. To change the signal loss delay,

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **Signal Loss Delay**.

4 Select **0** (default) ~ **300** seconds.

5 Select **OK**.

4.8 Pausing or Resetting the Alarm

You can enable the function of pausing or resetting audible alarms.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **Audio Alarm**.

4 Select **Alarm Pause** (default) or **Alarm Reset**.

If **Alarm Pause** is selected: When the monitor gives out alarm sound and you press the **SILENCE** key, the alarm indicator displays  , and the alarm sound is muted.

If **Alarm Reset** is selected: When the monitor gives out alarm sound and you press the **SILENCE** key, the alarm indicator displays  , and the alarm sound is muted. When other alarms present, the monitor will enable the audible alarm again automatically.

5 Select **OK**.

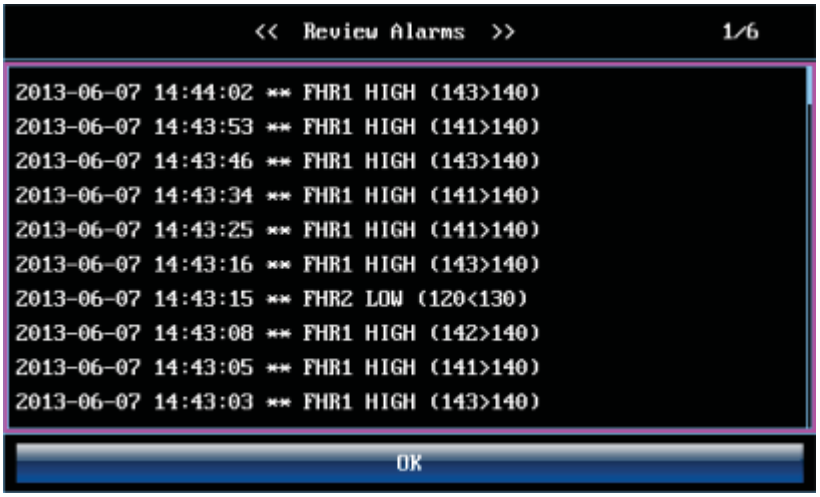
4.9 *Reviewing Alarms

An alarm reviewing menu cannot only record the immediate alarm messages with date and time information, but also record the historically physiological alarm and signal overlap alarm messages with date and time information.

The monitor can display a maximum of 100 immediate alarm messages. When the storage is full, it will delete the earliest alarm message automatically to store the new one.

The monitor can display a maximum of 800 historically physiological alarm and signal overlap alarm messages. When the total number exceeds 800, the alarms messages cannot be stored.

Select the alarm reviewing key  in the message window to open this menu. When you review the traces with the word **REVIEW** shown in the background, the alarm reviewing menu displays historic alarm review. Otherwise, it displays the immediate alarm review.



Each page displays 10 alarm records. The page mark “1/6” informs you that there are 6 pages and the present one is page 1.

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

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

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

NOTE:

You can select **Main Menu** > **General** > **Review Alarms** to set up **On** (by default) or **OFF**. When the alarm review is enabled, the icon will appear in the main interface.

4.10 Alarm Treatment Measures

During monitoring, make sure there is at least one physician in the area where the alarm sound can be heard or the alarm messages can be seen, so necessary measures can be taken when an emergency occurs.

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.

When the monitored parameter(s) come(s) back within the adjusted limits, or if the abnormal technical condition does not exist any longer, the monitor stops giving out the alarm.

4.11 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.

5 Verify if the visible and audible alarms are working properly.

4.12 Patient Alarm Defaults

Alarm Setting	Options	Default
High Level		
ASYSTOLE	On (not adjustable)	On
Asystole Alarm Delay	0 second (not adjustable)	0 second
Asystole Alarm Level	High (not adjustable)	High
Medium Level		
FHR1/FHR2 Alarm	On, Off	On
FHR1/FHR2 Low Alarm Limit	60 bpm ~ 205 bpm, in increments of 5	110 bpm
FHR1/FHR2 High Alarm Limit	65 bpm ~ 210 bpm, in increments of 5	160 bpm
FHR1/FHR2 Alarm Delay	0 ~ 30 second(s), in increments of 5	10 seconds
FHR1/FHR2 Alarm Level	Medium, not adjustable	Medium
HR Alarm	On, Off	On
HR Low Alarm Limit	30 bpm ~ 239 bpm, in increments of 1	50 bpm
HR High Alarm Limit	31 bpm ~ 240 bpm, in increments of 1	120 bpm
HR Alarm Delay	0 second, not adjustable	0 second
HR Alarm Level	Medium, not adjustable	Medium
SpO_2 Alarm	On, Off	On
SpO_2 Low Alarm Limit	50% ~ 99%, in increments of 1	90%
SpO_2 High Alarm Limit	51% ~ 100%, in increments of 1	100%

SpO_2 Alarm Delay	0 second, not adjustable	0 second
SpO_2 Alarm Level	Medium, not adjustable	Medium
SYS Alarm	On, Off	On
SYS Low Alarm Limit	40 mmHg ~ 269 mmHg, in increments of 1	90 mmHg
SYS High Alarm Limit	41 mmHg ~ 270 mmHg, in increments of 1	160 mmHg
SYS Alarm Delay	0 second, not adjustable	0 second
SYS Alarm Level	Medium, not adjustable	Medium
DIA Alarm	On, Off	On
DIA Low Alarm Limit	10 mmHg ~ 214 mmHg, in increments of 1	50 mmHg
DIA High Alarm Limit	11 mmHg ~ 215 mmHg, in increments of 1	90 mmHg
DIA Alarm Delay	0 second, not adjustable	0 second
DIA Alarm Level	Medium, not adjustable	Medium
TEMP Alarm	On, Off	On
TEMP Low Alarm Limit	0 ºC ~ +49.9 ºC, in increments of 0.1	+36.0 ºC
TEMP High Alarm Limit	+0.1 ºC ~ +50.0 ºC, in increments of 0.1	+39.0 ºC
TEMP Alarm Delay	0 second, not adjustable	0 second
TEMP Alarm Level	Medium, not adjustable	Medium

NOTE:

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

Chapter 5 Printing

5.1 *Function Description

The built-in thermal recorder 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:

- **Auto start printing:** If the function is enabled, the recorder starts printing automatically when new monitoring starts (the **START** key is pressed). Otherwise you have to press the **PRINT** key to start printing.
- **Printing timer:** The printing timer determines the elapsed time for each print. This time is adjustable. Refer to *5.2.3 Changing the Print Timer*.
- **Remaining time indicating:** If the printing timer is set, a process indicator 

appears in the status window after printing starts, with the remaining time shown in it. When the time is up, the monitor gives three “Do” tones and flashes the indicator.
- **Fast printing:** The recorder prints the data saved in the monitor at a high speed (up to 15mm/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:

  1 When the monitor is switched off, the data in the internal memory will be lost.

  2 If a printing timer is set, and the time is out when the paper runs out, the CTG analysis result may disaccord with the printout. Therefore, reload the paper in time to avoid paper lack.
- **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 *7.4.4 Changing FHR2 Offset.*
- **Print self-check:** The recorder prints a baseline for self checking when the monitor is switched on.
- **Paper advance:** When printing stops, press the paper advancing key  to advance the paper, making sure the paper has a perforation outside the drawer and is easy to be torn off.

  NOTE:

  The paper advancing key is invalid in the process of printing and paper advancing.

5.2 Printing Configuration

NOTE:

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 Monitoring > PRINT**.

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  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**.

NOTE:

Different paper speed setting causes different FHR trace appearance on the record paper. To avoid misinterpretation, we recommend you to set all monitors in your institution to the same paper speed.

5.2.3 *Changing the Print Timer

You can choose different time lengths for the print timer:

1 Select the setup key  on the main interface.

2 Select **Recorder > Timer**.

3 Set timer to **10 ~ 90** (minutes, the step is 5) or **Infinite** (default). For a fixed time, the recorder stops when the time is up. For **Infinite**, there is no time limit. Whatever the setting is, the recorder stops when this patient's traces come to the end or if the **PRINT** key is pressed in midway.

4 Select **OK**.

5.2.4 Switching Print Self-Check On or Off

You can switch on or off the print self-check feature:

1 Select the setup key  on the main interface.

2 Select **Recorder > Print Self-Check**.

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

4 Select **OK**.

5.2.5 Changing Printing End Volume

The monitor gives a tone when printing ends, and this tone volume is adjustable.

1 Select the setup key  on the main interface.

2 Select **Recorder > Print Ending Beep**.

3 Select **High**, **Low** (default) or **OFF**.

4 Select **OK**.

5.3 Understanding the Recorder Paper Printout

WARNING

1 If there is any discrepancy between the display and the printout, the printout should prevail.

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:

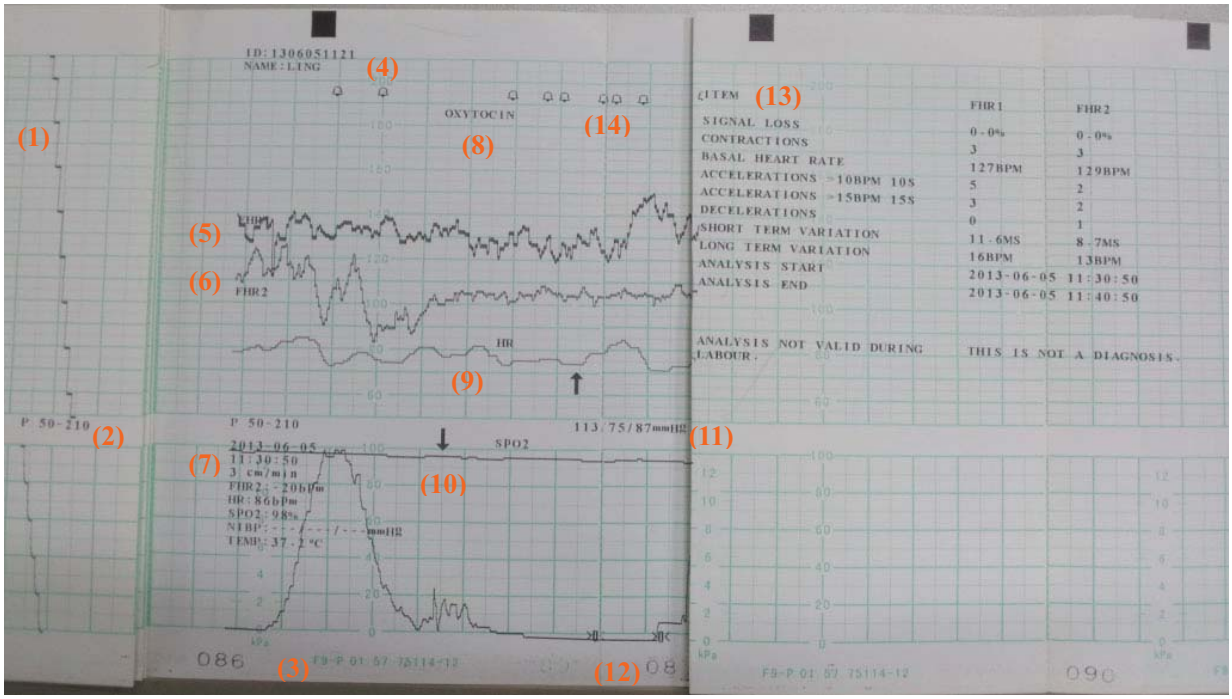


Figure 5-1 An example of recorder paper with traces

Item	Information	Description
1.	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.
2.	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. It is printed out to check if the proper recorder paper is used.
3.	Paper Type	There are two types of paper: F9-G and F9-P.
4.	Paper Style	The FHR pane range indicates the paper style. American style: 30 ~ 240 International style: 50 ~ 210
5.	FHR1 Mark	The trace marked with “FHR1” is the FHR1 trace.
6.	FHR2 Mark	The trace marked with “FHR2” is the FHR2 trace.
7.	Trace Information List	A list of current date, time, print speed, ID, Name, FHR2 offset, HR, SpO_2, NIBP (including SYS and DIA) and TEMP is printed at the start of the monitoring and every ten minutes afterwards.
8.	Smart Note	The annotation of the event mark below.
9.	HR Mark	The trace marked with “HR” is the maternal HR trace.

10.	SpO_2 Mark	The trace marked with "SpO_2" is the maternal SpO_2 trace.
11.	NIBP	In the real-time printing mode, each NIBP measurement result is printed on the paper in the order of SYS/DIA.
12.	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.
13.	CTG Analysis Result	The CTG analysis results of FHR1 and FHR2.
14.	Alarm Message	It indicates the physiological alarm message and signal overlap alarm message.

Chapter 6 Pre-Monitoring Preparation

6.1 Loading Recorder paper

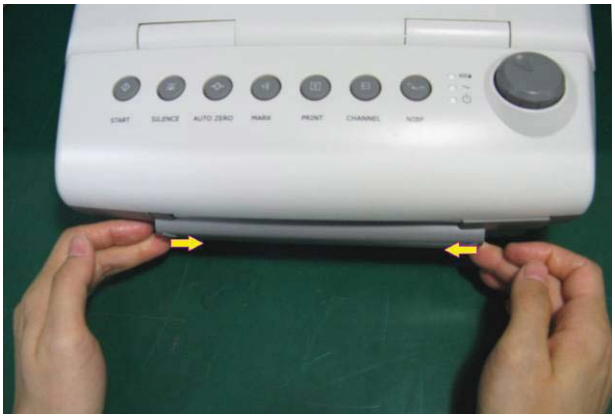
CAUTION

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

2 Configured with different hardware, the monitor is compatible with both GE and Philips recorder paper. However, the monitor is configured with only one type of paper in the shipment. If you want to use the other type of paper, contact the manufacturer for service first, otherwise trace excursion or paper jam may occur.

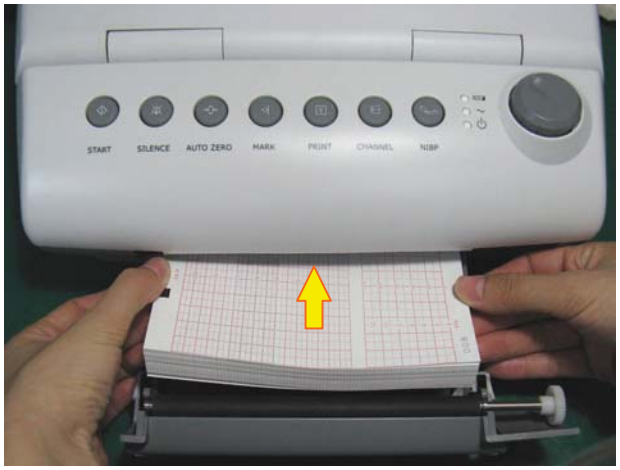
If the monitor is used for the first time or when the paper runs out, you should load paper.

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



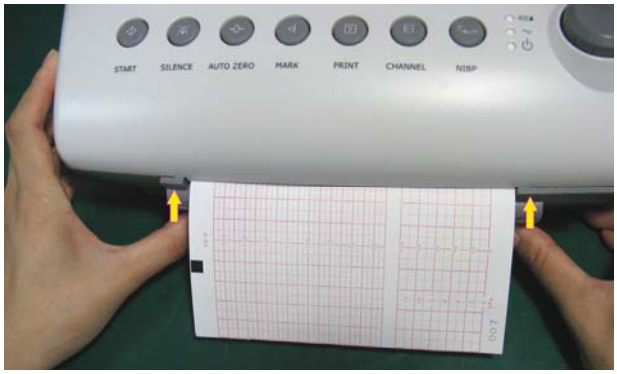
2) Take out the Z-fold thermosensitive paper and remove the wrapper.

3) Place the pack in the drawer, with the pane facing up and the FHR trace 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 providing a service.

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:

1) Cut the recorder paper from the paper drawer edge.

2) Through the hole on the bottom panel of the paper drawer, push the recorder paper up with one finger. Remove the paper.

3) Reload paper and then close the drawer.

6.2 Switching On

WARNING

1 Check if all the metal parts are linked to the protective earth cord and the cord is in good condition before switching 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,

1 Select the setup key  on the main interface.

2 Select **General > Start-up Music**.

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

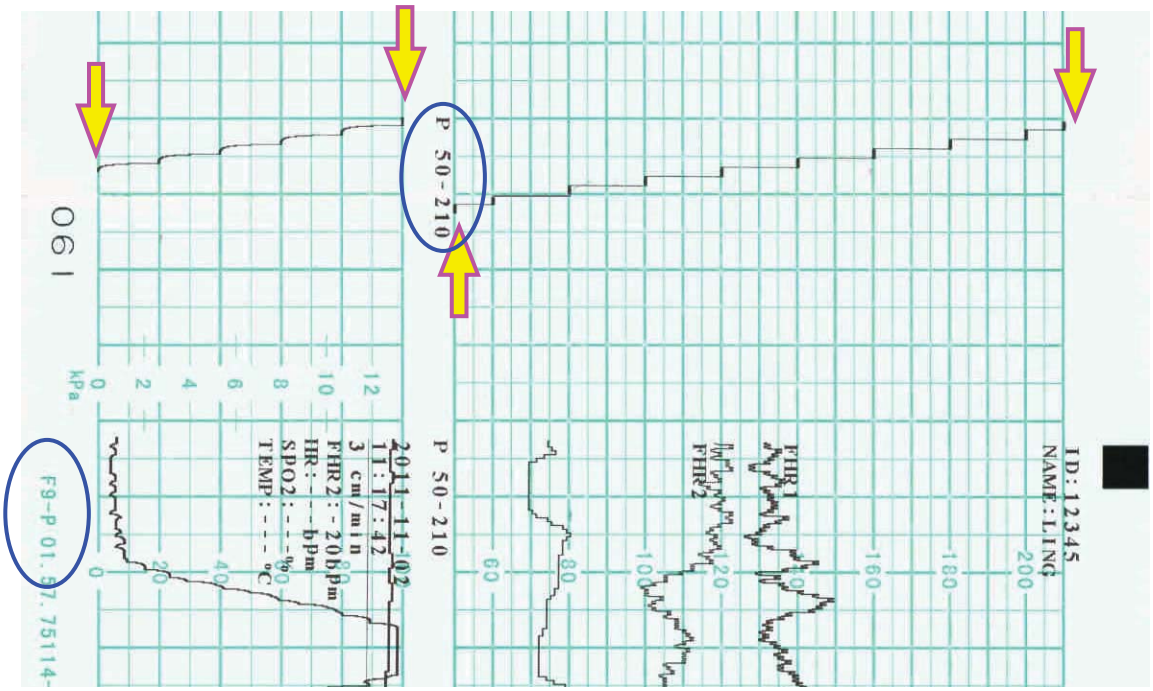
4 Select **OK**.

6.3 Checking 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 match the paper being used (in the circled area below, **P** should correspond to **F9-P**, and **G** to **F9-G**), 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** function and then restart the monitor.

NOTE:

Make sure the paper is correctly loaded before the printing starts.

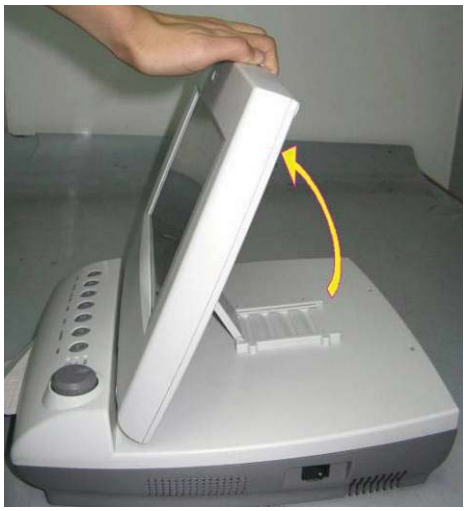
6.4 Adjusting Screen Angle

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 one of the preset screen angles.

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**.

CAUTION

You should set date and time information in advance. After this information is changed, the monitor starts new monitoring with an auto ID. Therefore, we advise you to restart the monitor after changing date or time information, and do not perform this operation when monitoring is in process.

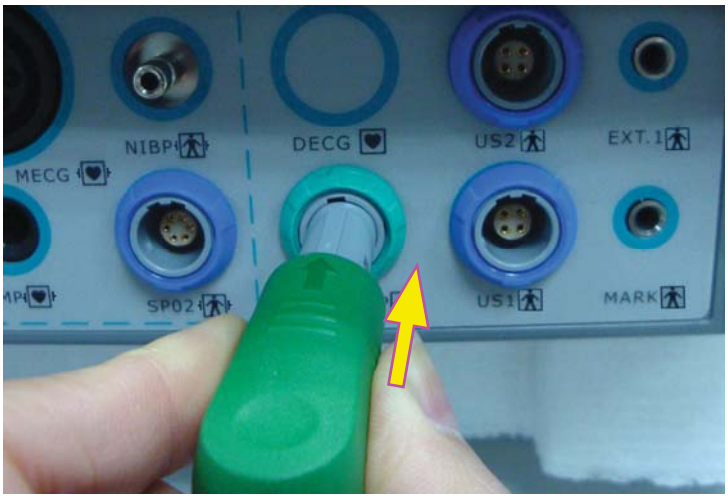
NOTE:

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 faces up and put it into the socket.



When disconnecting a transducer, pinch the afterbody of the transducer plug and pull it out slightly.

NOTE:

Never try to disconnect the transducer by pulling the cable directly.

6.7 Placing Accessories in the Holder

In order to protect the accessories, place the not-in-use accessories in the holder. The accessory holder is on the left of the front panel. The first hole from the top is for the remote event marker, and the rest two are for the transducers.

To place a transducer into the holder, hold the transducer on the edge, and then place the buckle all the way into one of the holes on the holder. Make sure that the transducer cable is on the bottom.

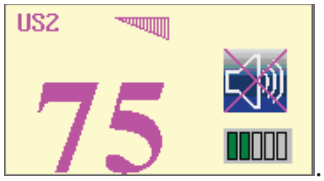
To place the remote event marker, put the small end of the marker into the hole as far as it can go.

NOTE:

In the process of monitoring, the transducer that is placed in the holder may be affected and thereby produces interfering signals. Therefore, when monitoring a patient, it is recommended to remove or disconnect the transducer that is not in use.

6.8 Adjusting the Volume

The monitor automatically detects which channel the transducer is connected to. The corresponding volume adjustment key of this channel displays  , indicating the FH sound is coming out from this channel; while the other one displays  , for example: 



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

Adjust the default monitoring volume:

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

1 Select the setup key  on the main interface.

2 Select **Start Monitoring > Volume**.

3 Select the volume from 1 ~ 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 satisfactory during monitoring, you can adjust the real-time volume of each channel.

1 Select the volume adjustment key  on the main interface.

2 Rotate the control knob clockwise for one step, the volume increases by one level, there are ten levels for your choice; the green pane of the volume level indicator  increases by one at every two steps; rotate the knob anticlockwise to decrease the volume.

3 Press the knob again 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**.

Chapter 7 Fetal Monitoring

WARNING

1 The monitor is not intended for use in intensive care units (ICU), operating rooms or for home use.

2 Do not apply the monitor 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.

7.1 Confirming Fetal Life

Fetal monitoring with ultrasound or DECG can not differentiate a fetal heart rate signal source from a maternal heart rate source in all situations. 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.

7.2 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.

WARNING

Make sure you have confirmed the fetal life by other means before using this monitor for FHR monitoring.

7.2.1 Parts Required

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

7.2.2 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) Determining the Transducer Position

- Determine the fetal position using Leopold's maneuvers.
- Search for the location of the fetal heart using a stethoscope or a fetoscope. The best fetal heart signal can be obtained through the fetal back.
- Place the transducer below the navel for head presentation and place the transducer above the navel for breech presentation.
- During parturition, the fetal heart moves downward as the labor progresses. It is recommended to move the transducer along with the fetus.

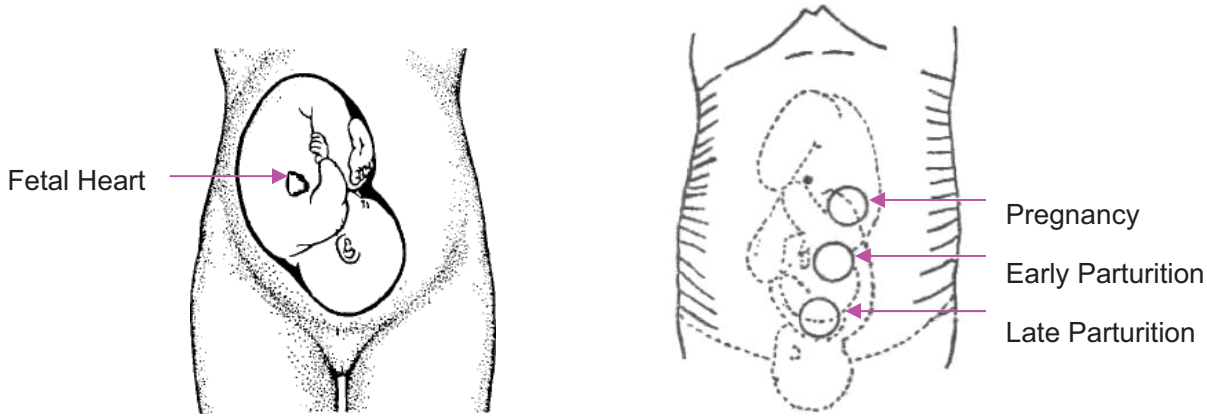


Figure 7-1 Positioning Ultrasound Transducer (single fetus)

3) Acquiring Fetal Heart Signal

Apply a certain amount of acoustic gel on the transducer and move the transducer slowly around the fetus site to even the gel. The best fetal heart signal can be obtained through the fetal back. Find at least 2 or 3 sites, and choose the one where the clearest, most sonorous and steady fetal heart sound is heard. When the transducer is connected correctly and communicated well, the fetal heart signal indicator is full. If the signal is poor, the signal indicator shows as it is and no FHR data are displayed. When you move the transducer on the abdomen, adjust the speaker volume so that it can be clearly heard.

4) Fixing the Transducer

When you find clearest and most steady fetal heart sound, 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. During long-time monitoring, the gel may dry out as the transducer moves around. Add more gel in time if it is inadequate.

5) Confirming that the Fetus is the Signal Source

Ultrasound Doppler technology is utilized to observe the fetal heart rate externally, there are possibilities that maternal heart rate signal is mistaken for FHR signal. It is highly recommended to confirm that the fetus is the signal source continuously. You can feel the maternal pulse at the same time.

If the maternal heart signal is misidentified as the fetal heart signal, Repositioning of the transducer is needed.

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. Positions with strong placental sounds or umbilical blood flow sound should be avoided.

3 If the fetus is in the cephalic presentation and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During monitoring, the patient'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.

4 It is impossible to examine FHR unless a clear fetal heart signal is detected.

5 During long-time monitoring, the gel may dry out as the transducer moves around. Add more gel in time if it is inadequate.

6 When applied to the patient, the ultrasound transducer may warm slightly (less than 1°C (1.8ºF) above ambient temperature). When NOT applied, the ultrasound transducer may warm slightly (less than 2°C (3.6ºF) above ambient temperature).

7.2.3 Switching 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 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**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **FHR**.

4 Select **ON** (default) or **OFF** for **Alarm**.

5 Select **OK**.

When the alarm is switched off, an alarm switched-off symbol appears in the numeric window. For example:

WARNING

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

7.2.4 Changing 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**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **FHR**.

4 Select a value from 60 ~ 205 for **Low Alarm Limit**. (The step is 5, and the default value is 110 bpm.)

5 Select a value from 65 ~ 210 for **High Alarm Limit**. (The step is 5, and the default value is 160 bpm.)

6 Select **OK**.

7.2.5 Changing 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 on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **FHR**.

4 Select a value from 0 ~ 30 second(s) for **Alarm Delay**. (The step is 5, and the default value is 10 seconds.)

5 Select **OK**.

WARNING

The FHR alarm delay is adjustable between 0 and 30 seconds.

7.2.6 Testing US Transducers

To test a US transducer:

1) Switch on the monitor.

2) Connect the US transducer to the fetal monitor.

3) Hold the transducer with one hand, and gently touch the center of the transducer with the other hand in the frequency of 2 times per second.

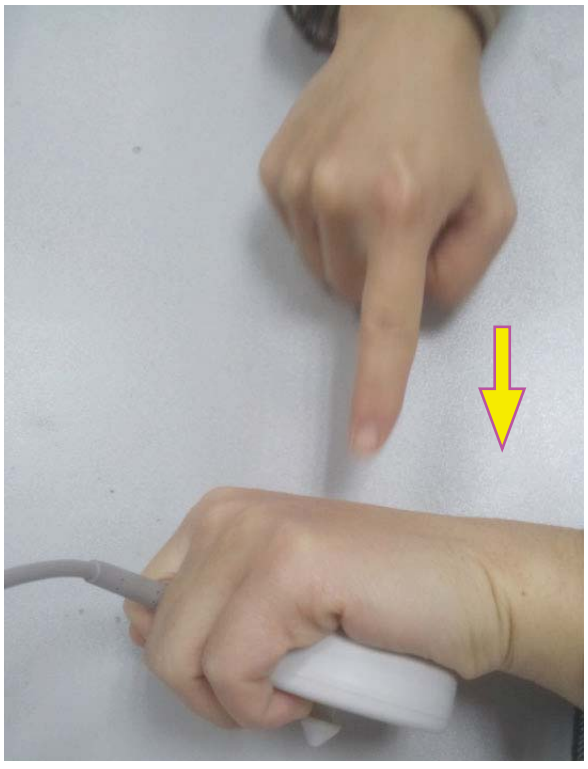


Figure 7-2 Testing a US Transducer

4) Check that the value on the display shows this change in FHR.

If a US transducer fails the test, repeat this test with another transducer. If the second one passes the test, defect of the first transducer is confirmed. Replace it with a good one. If the second transducer fails the test as well, contact the manufacturer for service.

7.3 Monitoring FHR with DECG

7.3.1 Contraindications

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

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

7.3.2 Parts Required

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

The following illustration shows how these parts should be connected:

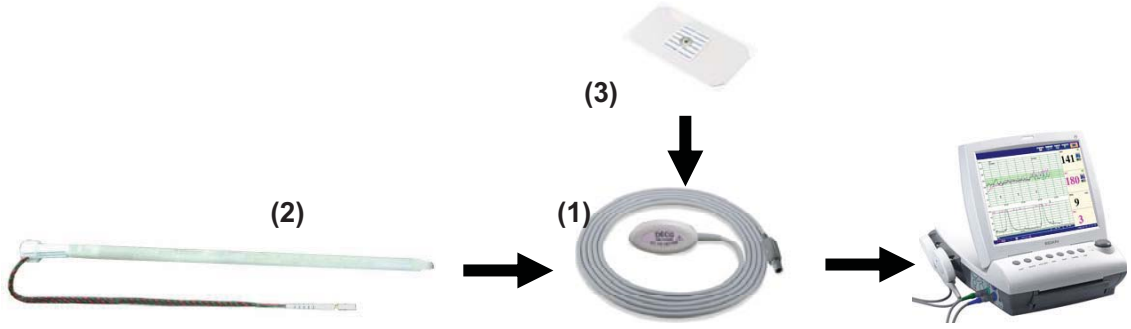


Figure 7-3 Connection for DECG Monitoring

7.3.3 Preparing 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.

1) Shave hair from electrode sites, if necessary.

2) Wash the sites thoroughly with soap and water. (Do not use ether or pure alcohol, which will increase skin impedance)

3) Rub the skin briskly to increase capillary blood flow in the tissues.

4) Remove skin scurf and grease.

7.3.4 Changing DECG Beep Volume

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

To change the DECG beep volume,

1 Select the setup key  on the main interface.

2 Select **Fetus > DECG Beep**.

3 Select **0** (default) ~ **9**.

4 Select **OK**.

NOTE:

1 The DECG beep and HR beep share the same audio channel. Once the DECG beep is switched on, the HR beep is disabled (set to level 0) automatically.

2 Once the DECG/HR beep volume is changed, the sound switches to channel 1 automatically. Therefore, it is advised against changing DECG/HR beep volume in the monitoring process.

7.3.5 Switching the Artifact Suppression On or Off

When monitoring FHR with DECG, artifacts may occur due to bad connection of the spiral electrode, excessive motion of the mother, electromyographic interference etc.. The **Artifact Suppression** feature is designed to eliminate the interference. When artifact suppression is on, artifacts are suppressed and not recorded. When it is off, the artifacts are shown as well as the fetal heartbeats.

You can choose to switch the artifact suppression on or off.

1 Select the setup key  on the main interface.

2 Select **Fetus > Artifact Suppression**.

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

4 Select **OK**.

WARNING

When artifact suppression is on, fetal arrhythmia will also be suppressed. Therefore, if fetal arrhythmia is suspected, switch artifact suppression off.

7.3.6 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.

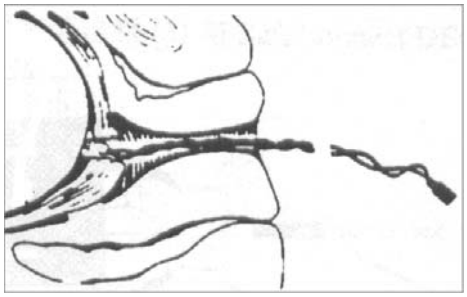


Figure 7-4 The well-attached fetal spiral electrode

7.3.7 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 *7.3.3 Preparing Patient's Skin Prior to Placing Electrodes.*

3 Attach the fetal spiral electrode to the fetal presenting part using the procedures described in section *7.3.6 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.

WARNING

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

CAUTION

Do not mistake the higher maternal heart rate for DECG.

NOTE:

1 If there is any doubt as to the presence of a fetal heart signal with ECG, check with the US transducer on the patient's abdomen or with a separate diagnostic instrument. The presence of an audible heart sound at a rate distinct from that of the maternal pulse is unequivocal evidence of the fetal life.

2 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.

7.3.8 Detaching 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.

7.4 Monitoring Twin FHRs

7.4.1 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 *7.2 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.

NOTE:

To ensure that both transducers stay at the optimum location, each transducer should be fixed with a separate belt.

7.4.2 Monitoring Internally

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

Connect the US transducer to US2 socket; connect DECG cable to DECG socket.

Monitor one twin with a US transducer using the procedures described in Section *7.2 Monitoring FHR with Ultrasound*.

Monitor the other twin with a DECG cable using the procedures described in Section *7.3 Monitoring FHR with DECG*.

CAUTION

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

7.4.3 Signals Overlap Verification (SOV)

When monitoring twins, there are possibilities that one twin's FHR signal is mistaken for the other one's signal. The 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/DFHR, FHR2)" will appear on the screen to warn you. Checking the patient and reposition of transducers might be needed.

7.4.4 Changing FHR2 Offset

In order to distinguish FHR1/DFHR trace from FHR2 trace, FHR2 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,

1 Select the setup key  on the main interface.

2 Select **Recorder > FHR2 Offset**.

3 Select **-20 bpm** (default), **0 bpm** or **+20bpm**.

4 Select **OK**.

This preset FHR2 offset will be printed on the recorder paper every 10 minutes.

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

"FHR2: 0bpm": the FHR2 trace is in its real position.

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

7.5 Monitoring Uterine Activity Externally

7.5.1 Parts Required

1) TOCO transducer 2) Belt

7.5.2 TOCO Monitoring Procedure

1) 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

Wipe any gel remaining on abdomen around the fundus area.

Place the TOCO transducer on the patient's abdomen, which is flat and approximately 3 cm away from the fundus, e.g. slightly above the umbilicus on the left or on the right. The position should be different for different purposes: place the transducer close to the fetal buttocks for NST, and place it on fetal back in delivery.

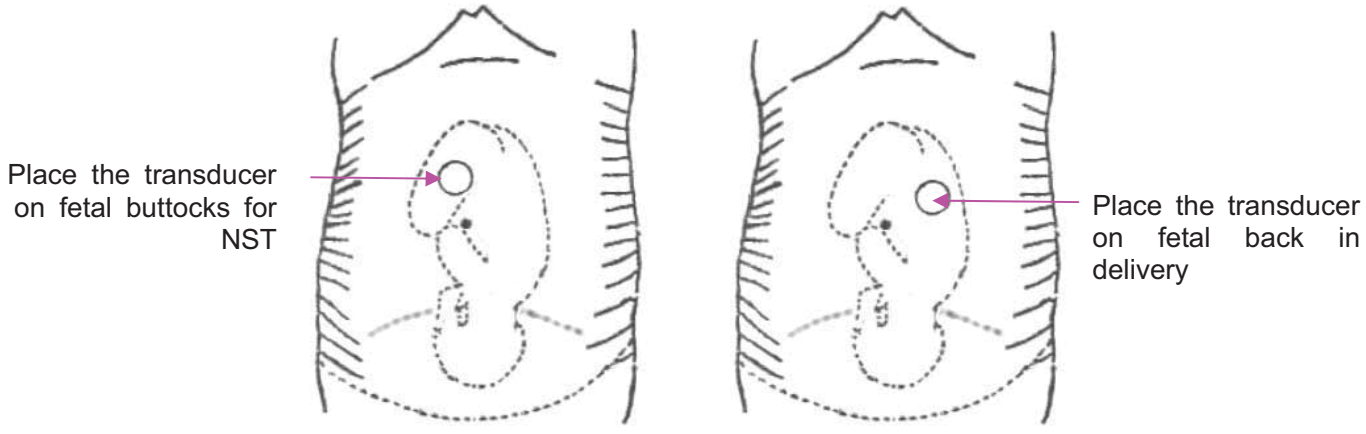


Figure 7-5 Positioning TOCO Transducer

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.

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 ~ 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.

7.5.3 Changing UA Baseline

You can change the UA baseline,

1 Select the setup key  on the main interface.

2 Select **Fetus > UA Baseline**.

3 Select **5**, **10** (default), **15** or **20**.

4 Select **OK**.

NOTE:

If the monitor has been configured with IUP, the IUP baseline is 0 and it is not adjustable. The TOCO baseline is adjustable.

7.5.4 Testing TOCO Transducers

To test a TOCO transducer:

1) Switch on the monitor.

2) Connect the TOCO transducer to the fetal monitor.

3) Gently press the center of the transducer.

Figure 7-6 Testing a TOCO Transducer

4) Check that the value on the display shows this change in pressure.

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

7.6 Monitoring Uterine Activity Internally

7.6.1 Parts Required

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

The following illustration shows how these parts should be connected:

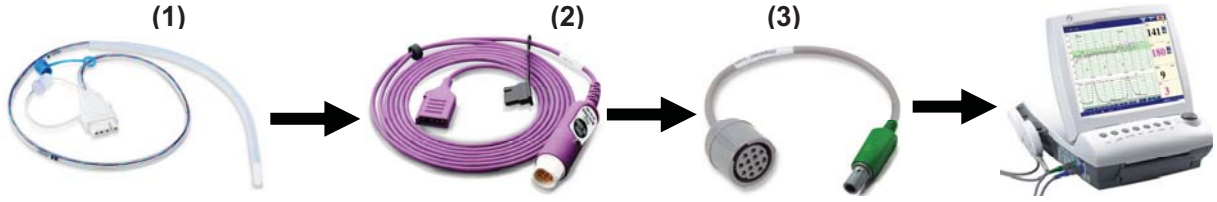


Figure 7-7 Connection for IUP Monitoring

7.6.2 Directions for Use of IUPC

Preparation

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

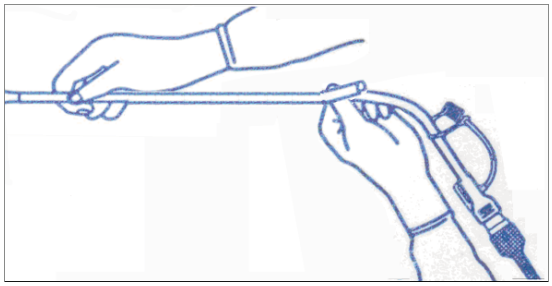


Figure 7-8 Separate the introducer

9) Anchor the catheter in place with one hand, and pull the introducer straight back off the catheter.

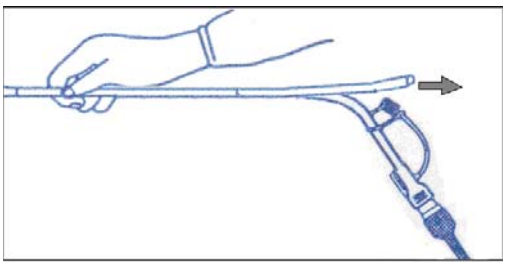


Figure 7-9 Remove the introducer

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.

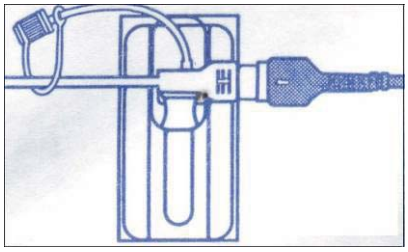


Figure 7-10 Secure the adhesive pad to mother

Rezeroing the System During Monitoring

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

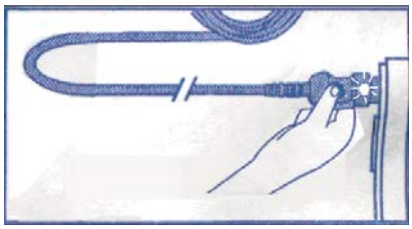


Figure 7-11 Rezeroing the system

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

WARNING

1 Before insertion of IUPC, 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

1 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.

2 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.

7.6.3 IUP Monitoring Procedure

1) Insert IUPC using the procedure described in section *7.6.2 Directions for Use of IUPC*.
2) Connect the IUPC to the IUP cable.

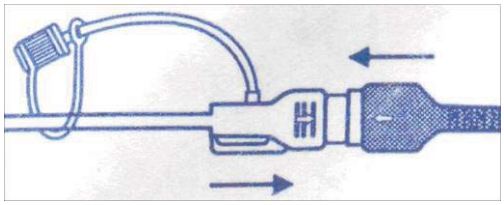


Figure 7-12 Connect catheter to pressure cable

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.

7.6.4 Checking Intrauterine Pressure Cable Function

To test an IUP cable's function:

1) Disconnect the catheter from the cable. Insert the cable check plug into the catheter end of the cable.

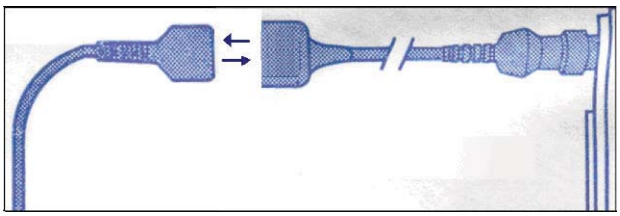


Figure 7-13 Test the pressure cable

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

NOTE:

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

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

7.7 Monitoring Fetal Movement

7.7.1 Auto Fetal Movement (AFM) Monitoring

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.

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

NOTE:

AFM monitoring is not available when FHR is monitored by DECG.

7.7.2 Enabling or Disabling AFM Trace

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

1 Select the setup key  on the main interface.

2 Select **Fetus > AFM**.

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

4 Select **OK**.

7.7.3 Changing AFM Gain

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

1 Select the setup key  on the main interface.

2 Select **Fetus > AFM Gain**.

3 Select **1**, **2**, **3** (default) or **4**.

4 Select **OK**.

7.7.4 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  on the main interface.

2 Select **Fetus > AFM Mode**.

3 Select **Trace** (default) or **Blackmark**.

4 Select **OK**.

7.7.5 Choosing FM Source

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

To choose the FM source,

1 Select the setup key  on the main interface.

2 Select **Fetus > FM Source**.

3 Select **MFM** (default) or **AFM**.

4 Select **OK**.

7.7.6 Manual Fetal Movement (MFM) Monitoring

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.

7.7.7 Changing MFM Volume

The monitor gives a sound when the FM marker key is pressed, and the volume is adjustable.

To change the MFM volume,

1 Select the setup key  on the main interface.

2 Select **Fetus > MFM Volume**.

3 Select **Low** or **High** (default).

4 Select **OK**.

7.8 *Start Monitoring

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

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

7.9 *Inputting Maternal Information (Mat. Info)

7.9.1 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.

7.9.2 Changing Maternal Information

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

1 Select Mat. Info key  on the main interface.

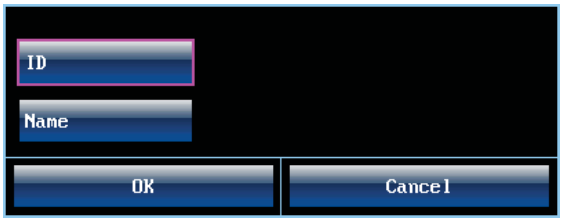


Figure 7-14 Mat. Info Inputting Menu

2 Select **ID**.

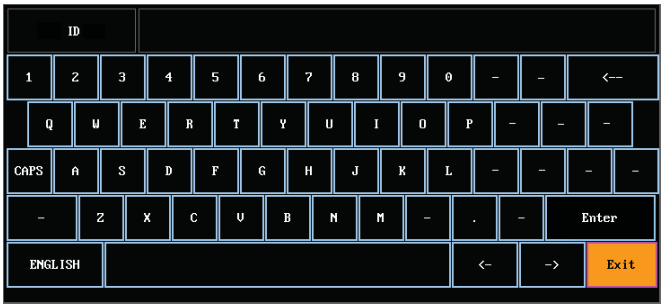


Figure 7-15 Soft Keyboard

3 Select the required character for patient's ID on the soft keyboard.

4 Select **Enter**.

5 Select **Name**.

6 Select the required letter for patient's name on the soft keyboard.

7 Select **Enter**.

8 Select **OK**.

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 The ID and name are shown on the screen, the paper printout and the archive list.

4 For the non-English system, more letters are provided for inputting the name. Select the key on the bottom left corner to toggle between them.

7.9.3 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 Monitoring > Mat. Info**.

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

4 Select **OK**.

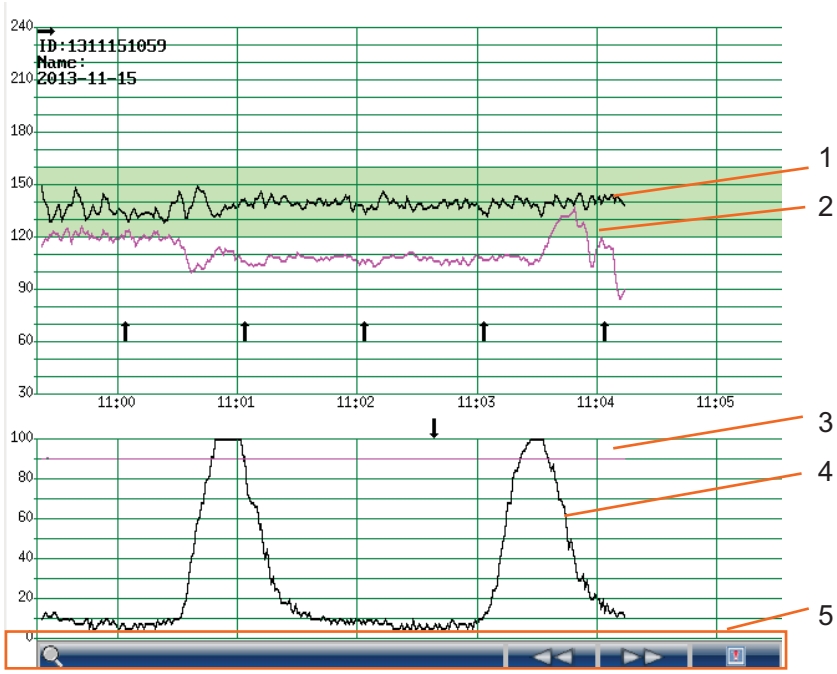
Chapter 8 Fetal Monitoring Display (F6/F9)

8.1 Traces

WARNING

1 Due to the LCD size, resolution and system settings, the traces displayed on the screen may look different from the recorder printout. The printout should prevail when making diagnoses.

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



1 FHR1 Trace

2 FHR2 Trace

3 AFM Trace

4 TOCO Trace

5 Trace Control Tools

Figure 8-1 Traces

During monitoring or reviewing, the trace window displays four traces: 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 bpm ~ 240 bpm (American standard) or 50 bpm ~ 210 bpm (International standard).

AFM trace

The y-axis indicates the scope of fetal movement.

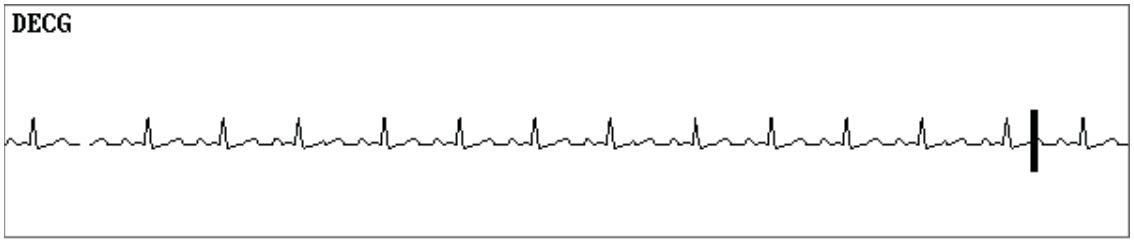
NOTE:

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% ~ 100%.

If FHR is monitored using DECG, and the DECG trace is switched on in the hardware setup (only service engineers have access to it), a DECG trace is shown underneath other traces on the screen.



Besides, some other symbols appear among the traces:

- This symbol indicates the new monitoring starts.
- This symbol indicates a manual fetal movement, and it appears after the patient presses the 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.

8.1.1 Changing Time Scale

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

To change this time format:

1 Select the setup key  on the main interface.

2 Select **Date And Time > Time Scale**.

3 Select **Real Time** (default) or **Relative Time**.

4 Select **OK**.

NOTE:

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

8.2 Trace Control Tools

Figure 8-2 Trace Control Tools

1	Searching Key	2	Reviewing Keys
3	Alarm Reviewing Key	4	CTG Analyzing Key

8.2.1 Data Saving

When the **START** key is pressed, the monitor saves data of the previous ID in a file, and then clears it from the main interface. The main interface only displays the new patient's data. During monitoring, the data is saved every 10 minutes. All data of the same patient is saved in a file (the maximum duration is 24 hours, the rest data is saved in another file.)

The files are stored in the monitor. When the data amount reaches the maximum capacity (300 files or approximately 60-hour), the monitor deletes the oldest file(s) automatically.

8.2.2 *Searching for a File

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

To search for a patient,

1 Select the searching key to open the file list. It contains six sets of most recent patient's ID, name and start time of monitoring. Select the required item, this file is loaded to the main interface immediately.

Figure 8-3 File List

If the required file is not in this list,

2 Select **MORE** to open the **Patient Searching** window.

Figure 8-4 Patient Searching

3 Select **ID**, input the patient ID with the soft keyboard and select **Enter**.

4 Select **Name**, input the patient's name with the soft keyboard and select **Enter**.

NOTE:

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

5 Select **Search**. The files with the matched information are listed in the window.

6 Select the required item, this file is loaded to the main interface immediately. You can review the traces backward or forward.

8.2.3 *Reviewing

The reviewing keys  (backward key) and  (forward key) are used to review the traces. The word **REVIEW** is shown in the background when reviewing 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  symbol to increase the speed until it reaches the maximum. Rotate the knob clockwise or touch the  symbol to decrease the speed until it reaches the minimum. Press the knob or touch any place on the screen to pause.

Select the forward key to review the next traces. The traces start to advance. The amount of the progress symbol ">" on top of the traces indicates the advancing speed. Rotate the control knob clockwise or touch the  symbol to increase the speed until it reaches the maximum. Rotate the knob 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. If no operation is performed in 10 seconds, the monitor switches to real-time interface automatically, unless the printing is in process.

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

WARNING

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

NOTE:

1 The main interface only displays traces and patient information of one file. If you want to review another file you should search for the file and load it.

2 For a real-time monitoring patient, you can print all her traces, including SpO2 trace. However, when printing traces in a file, the SpO2 trace cannot be printed.

3 You must pause before printing starts. Printing in the process of playback might result in failure information on the paper.

4 After the reviewed data has been printed out, the recorder does not switch back to real-time printing automatically.

8.2.4 *CTG Analysis

CTG analysis aims at a real-time trace, providing some reference data for the physicians. It only analyzes the real-time trace after it's been printed for 10 minutes, and the longest duration is 60 minutes.

WARNING

1 CTG analysis is used for the surveillance of pregnancies and not in delivery room of childbirth.

2 CTG analysis 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 analysis 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.

8.2.4.1 Enabling/Disabling CTG analysis

1 Select the setup key  on the main interface.

2 Select **General Setup > CTG Analysis**.

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

4 Select **OK**.

A CTG analysis key  appears on the main interface, indicating that CTG analysis is enabled.

8.2.4.2 CTG analyzing

NOTE:

1 CTG analyze starts after the real-time trace has been printed for 10 minutes.

2 The CTG analysis result is for reference only.

After the real-time trace is printed for 10 minutes, select the CTG analysis key  on the main interface. The analysis result window opens.

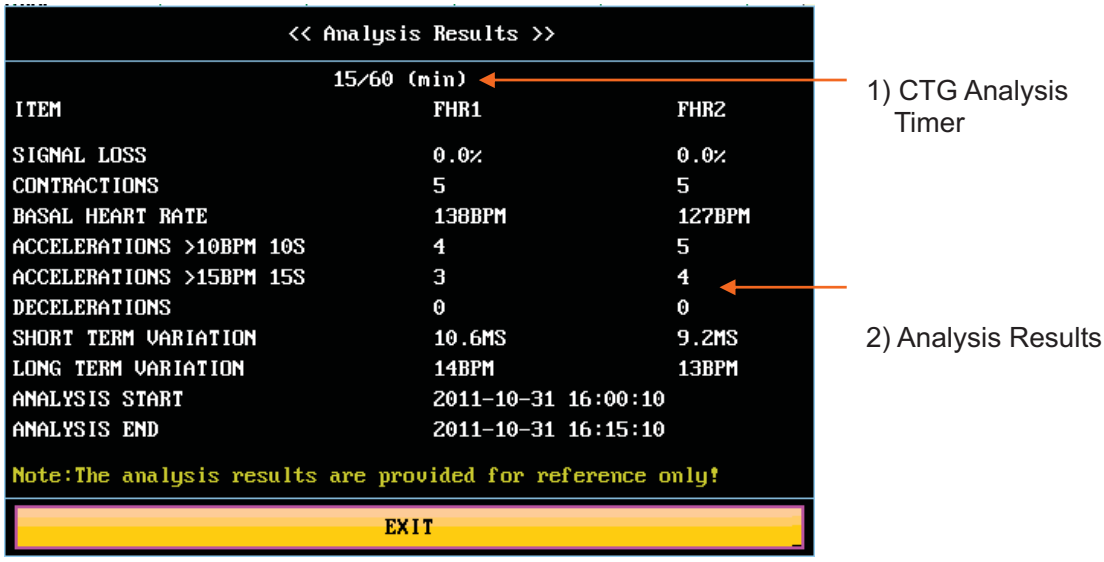


Figure 8-5 CTG Analysis Results

Refer to figure 8-5, the CTG analysis results on the screen include:

1) CTG Analysis Timer:

The CTG 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) CTG Analysis Results:

SIGNAL LOSS:	the proportion of the signal loss. If it is larger than 10%, analysis results cannot be acquired.
CONTRACTIONS:	the contraction time during analysis.
BASAL HEART RATE:	the average FHR in 10 minutes when it is not influenced by fetal movement or contractions.
ACCELERATIONS:	the acceleration time, including the acceleration with amplitude larger than 10bpm and lasts more than 10 seconds, and the acceleration with amplitude larger than 15bpm and lasts more than 15 seconds.
DECELERATIONS:	the deceleration time.
SHORT TERM VARIATION:	the short-term variation analysis result.
LONG TERM VARIATION:	the long-term variation analysis result.
ANALYSIS START:	the start time of the analysis.
ANALYSIS END:	the finishing time of the analysis.

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

At the end of the printing, the recorder prints the CTG analysis results of this moment on the recorder paper.

Be aware that CTG 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:

Do not disconnect the ultrasound transducer(s) before the printing stops, otherwise the analysis results will not be printed.

8.2.5 *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 ⬇ 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. This feature is only available on **F9** and **F9 Express**.

8.2.5.1 Enabling/disabling Smart Notes

To enable or disable **Smart Notes**,

1 Select the setup key  on the main interface.

2 Select **General Setup** > **Smart Notes**.

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

4 Select **OK**.

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

8.2.5.2 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 during real-time printing.

8.2.5.3 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 **Enter**.

8 Select **OK**.

8.3 Numerics

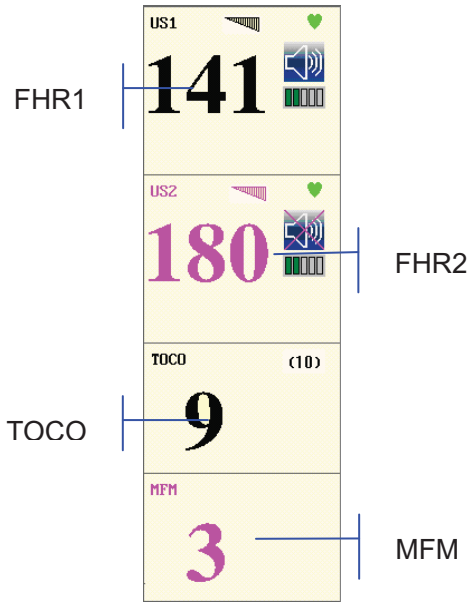


Figure 8-6 Fetal Monitoring Numerics

The fetal monitoring values in the numeric window include FHR1/DFHR value, FHR2 value, TOCO/IUP value and FM count:

FHR1/DFHR 	: FHR signal quality. When the quality is poor, it turns into .
	: FH refreshing rate
	: FH sound volume adjusting key.
	: FH sound volume indicator

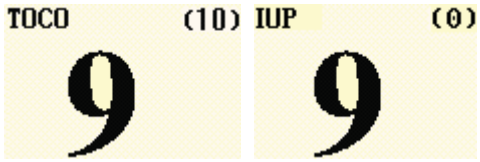
<table>
<tr><td> 

FHR2

</td><td>141: FHR1/DFHR measurement numeric.

If the US1 socket is not connected with a US transducer and DECG socket is not connected with a DECG cable, nothing displays here; if the transducer/cable is connected but no monitoring is going on, it displays ---.

180: FHR2 measurement numeric.

If the US2 socket is not connected with a US transducer when switching on, it displays OFF but no numeric here; if the transducer is connected but no monitoring is going on, it displays ---.</td></tr>
<tr><td rowspan="2">TOCO/IUP
 
</td><td>(10)/(0): UA baseline</td></tr>
<tr><td>9: current UA measurement numeric</td></tr>
<tr><td>FM
 
</td><td>MFM/AFM: FM source

3: FM count</td></tr>
</table>

When F9, F9 Express Fetal/Maternal Monitor is connected to FTS-3 Telemetry System, the wireless US transducer and TOCO transducer signal strength and battery level are displayed in the numeric window.

Figure 8-7

8.3.1 Changing Numeric Window Position (F9)

Especially for **F9**, the numeric window can be located either on the right of the traces or on top of them. To change its position,

1 Select the setup key  on the main interface.

2 Select **General > Numeric Window**.

3 Select **Top** or **Right** (default).

4 Select **OK**.

8.4 Fetal Monitoring Alarm Messages

During fetal monitoring, the monitor gives alarms for the situations that need the physicians to pay attention to. The alarm messages are listed below.

8.4.1 Patient Alarm Messages

Alarm Message	Source	Cause	Countermeasure
Medium Level			
**FHR1 HIGH or ** FHR1 xxx > yyy, **FHR2 HIGH or ** FHR2 xxx > yyy	US	FHR1 or FHR2 measuring result (xxx) is higher than the set upper limit (yyy) over the alarm delay time.	Check if the alarm limits are suitable; check the patient's condition.
**FHR1 LOW or ** FHR1 xxx < yyy, **FHR2 LOW or ** FHR2 xxx < yyy	US	FHR1 or FHR2 measuring result (xxx) is lower than the set lower limit (yyy) over the alarm delay time.	

8.4.2 Technical Alarm Messages

Alarm Message	Source	Cause	Countermeasure
Medium Level			
**Battery Low	Monitor	The battery power is too low to support further work of the monitor.	Connect the monitor to AC power supply.
Low Level			

Check Paper	Monitor	There is no paper in the paper drawer or the drawer is open.	Load paper and/ or close the drawer.
US1 UNPLUGGED or US2 UNPLUGGED	US	US transducer 1 or US transducer 2 is not well connected. Or wireless US signal is not detected.	Check the connection of the transducer.
US1 SIGNAL LOSS or US2 SIGNAL LOSS	US	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 patient's condition.
Fetus EQUIP MALF	US	The fetus board can not communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
TOCO UNPLUGGED	TOCO	TOCO transducer is not well connected. Or wireless TOCO signal is not detected.	Check the connection of both TOCO transducer and US transducer.
DECG LEADS OFF	DECG	The spiral electrode is not well connected.	Check the connection of the spiral electrode.
DECG UNPLUGGED	DECG	The DECG lead is not well connected to the monitor.	Check the connection of the DECG cable.
DECG SIGNAL LOSS	DECG	DECG signal is too weak for the system to analyze.	Check if the spiral electrode is well attached to the fetus; check the patient's condition.
DECG EQUIP MALF	DECG	The DECG board can not communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
Signals Overlap (FHR1, FHR2)	US	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 (DFHR, FHR2)	US + DECG	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.

Chapter 9 Maternal Monitoring (F6 Express/F9 Express)

WARNING

1 Do not apply the monitor during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.

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

3 Check for any fault of the transducers before applying them to the patient.

NOTE:

This feature is only available on **F6 Express** and **F9 Express**.

9.1 Maternal ECG Monitoring

9.1.1 Introduction

ECG monitoring produces a continuous wave form of the patient's cardiac electric activity to enable an accurate assessment of current physiological state. Only proper connection of ECG cables can ensure a satisfactory measurement.

The parts needed are ECG lead and electrodes.

A 20-second monitor stabilization period shall be allowed before testing. The monitor has Tall T-wave rejection capability.

The response time of heart rate meter to change in heart rate is less than 10s.

The minute heart rate display is updated at an interval of 1s.

Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals. If each of three consecutive RR intervals is greater than 1200ms, then the four most recent RR intervals are averaged to compute the HR.

The monitor does not have capability of detecting or rejecting pacemaker pulse, nor does it provide a pulse to synchronize a defibrillator discharge.

The monitor does not give alarm for tachycardia and cardiac arrhythmia.

The d.c. offset voltage tolerance of the monitor is from -500mV to +500mV. If the d.c. offset voltage of the detected ECG signal is out of this range, the monitor issues a high level alarm: ECG SINGNAL EXCEEDS LIMIT.

WARNING

1 When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient.

2 The electrodes should be made of the same metal materials.

WARNING

3 ECG accessories are not suitable for DIRECT CARDIAC APPLICATION (Refer to IEC60601-1 for more information about the definition of DIRECT CARDIAC APPLICATION).

CAUTION

A different type of electrodes may produce higher offset voltage. Therefore, only use the ECG leads supplied by the manufacturer when using the monitor for ECG monitoring.

NOTE:

Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

A good ECG signal should be –

1) With normal QRS wave.
2) Tall and narrow with no notches.
3) With tall R-wave completely above the baseline.
4) With T-wave less than one-third of the R-wave height.
5) With P-wave much smaller than the T-wave.

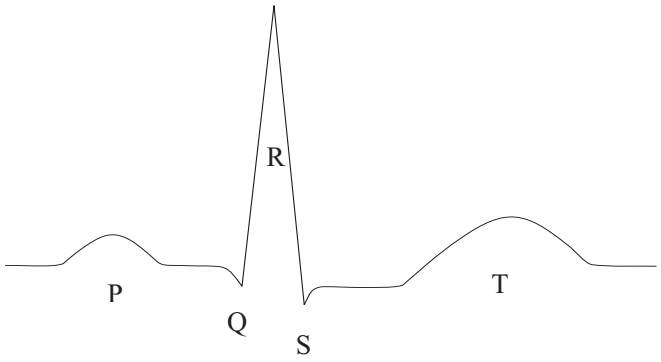


Figure 9-1 Standard ECG Waveform

9.1.2 How to Place 3-lead ECG Cables

The table below lists the names and position of 3-lead ECG cable in America and Europe.

America		Europe		Position
Name	Color	Name	Color	
RA	White	R	Red	Near the right shoulder, right below the clavicle
LA	Black	L	Yellow	Near the left shoulder, right below the clavicle
LL	Red	F	Green	On the left hypogastrium

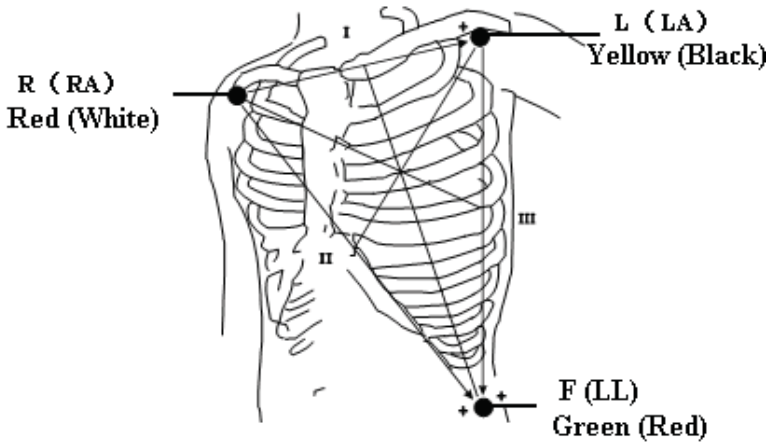


Figure 9-2 Placing 3-lead ECG Cable

NOTE:

1 To ensure patient's safety, all leads must be attached to the patient.

2 Check everyday if the skin is irritated from ECG electrodes, if so, change for new electrodes or change their sites every 24 hours.

3 Recycle or dispose the used electrodes properly to protect the environment.

9.1.3 ECG Monitoring Procedure

1) Prepare the skin for ECG monitoring. Refer to section *7.3.3 Preparing Patient's Skin Prior to Placing Electrodes*.

2) Insert the ECG cable connector into the MECG socket on the monitor.

3) Connect ECG electrodes with an ECG cable.

4) Peel the protection membrane off the back of ECG electrodes and attach electrodes to the patient. Refer to section *9.1.2 How to Place 3-lead ECG Cables* for electrodes' sites.

NOTE:

After the monitor is switched on, if electrodes are not well attached or fell off, alarm message "ECG LEADS OFF" will appear on the screen to draw your attention.

9.1.4 Changing ECG Source

Refer to figure 9-2, the ECG signal can come from channel I, II or III. In the ECG trace area of the main interface, **ECG (II, X1)** indicates the ECG source and gain.

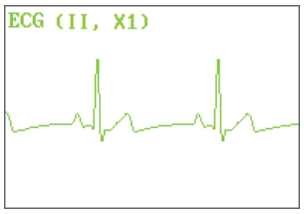
If the electrodes are tightly attached to the patient but ECG waveform is not accurate, switch ECG source to another lead by performing the following procedures:

1 Select the setup key on the main interface.

2 Select **Mother > Lead**.

3 Select **I**, **II** (default) or **III**.

4 Select **OK**.



9.1.5 Changing ECG Gain

You can change the ECG gain. The ECG gain affects overall numeric and scope of the ECG waveform.

1 Select the setup key on the main interface.

2 Select **Mother > Gain**.

3 Select **X1/4**, **X1/2**, **X1** (default), **X2** or **Auto**.

'Auto' means the monitor adjusts the gain automatically. The system displays a 1mv scale at the left side of the ECG waveform. The height of 1mv bar is directly proportional to the waveform amplitude.

4 Select **OK**.

9.1.6 Enabling ECG Calibration

When windage of the ECG waveform is suspected, enable ECG calibration to validate the wave.

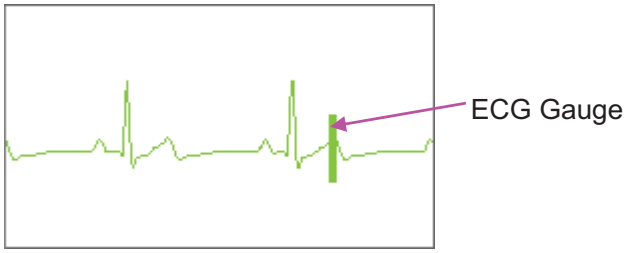
1 Select the setup key on the main interface.

2 Select **Mother > ECG Calibration**.

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

4 Select **OK**.

The monitor creates a square wave in the ECG area. Compare the square wave with the ECG gauge. If the error is larger than 0.5mm, change the ECG gain.



When the error is smaller than 0.5mm, calibration is completed. Disable ECG calibration in the same directory.

9.2 Maternal SpO_2 Monitoring

9.2.1 Introduction

The monitor provides continuous monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate(PR) for pregnant women.

SpO_2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the monitor will read 97% .The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

SpO_2 Plethysmogram Measurement Principle:

- Pulse oximetry is a continuous and noninvasive monitoring technique used to estimate the measurement of arterial oxygen saturation. It measures the amount of light penetrating the patient tissue and reaching the receiver. The reading, obtained through pulse oximetry, uses a light sensor containing two sources of light (red and infrared) that are absorbed by hemoglobin and transmitted through tissues to a photodetector.
- The amount of light penetrated depends on multiple factors and most of them are constant. However, the arterial blood flow changes with time passing by as is pulsative. The arterial oxygen saturation can be obtained through testing the absorbed light during pulsation. Plethysmogram wave and pulse rate signal can be also provided during pulsation testing.

The sensor contains LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 900 nm. Information about wavelength range can be especially useful to clinicians.

The monitor is compatible with the SpO_2 sensors supplied by the manufacturer only, and the provided SpO_2 sensor can only be used with this monitor.

Compatibility should be checked prior to use. Otherwise the monitor performance can be degraded.

They have been tested and found to comply with the limits for medical device in IEC/EN60601-1-2 (International standard for EMC testing of Medical Electrical Equipment, second edition). These limits are designed to provide reasonable protection against harmful interference in typical medical installation.

WARNING

1 Before monitoring, check whether the sensor cable is normal. If any sign of damage in the SpO_2 sensor is detected, do not use the sensor. Return it to the manufacturer for service.

2 Do not put the SpO_2 sensor on the extremities with arterial catheter or venous syringe.

WARNING

3 Do not perform SpO_2 measuring and NIBP measuring on the same arm at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO_2 numeric.

4 Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin.

5 The maximum application time of the SpO_2 sensor at a single site is 4 hours. Check the sensor placement every 2 to 3 hours and move it when the skin deteriorates. More frequent examinations may be required for different patients.

6 Setting the SpO_2 higher alarm limit to 100% is equivalent to switching off the alarm on higher limit. High oxygen levels may predispose a premature infant to retrolental fibroplasia. Therefore, the higher alarm limit for oxygen saturation must be carefully selected in accordance with commonly accepted clinical practices.

CAUTION

Compatibility between the monitor and sensor should be verified before use to avoid injuring the patient or operator.

NOTE:

1 The monitor is calibrated to display functional oxygen saturation.

2 A functional tester cannot be used to assess the accuracy of the SpO_2 sensor or the monitor.

3 The monitor does not have specific SpO_2 calibration baselines.

4 SpO2 waveform is not proportional to the pulse volume.

5 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

Measurement Limits -

In operation, the accuracy of oximetry readings can be affected by:

1) Magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.

2) Excessive patient movement.

3) Low perfusion.

4) High-frequency electrical noise, including noise created by the host system, or noise from external sources, such as electrosurgical apparatus, which is admitted by the host system.

5) Intravascular dye injections.

6) Improper sensor application.

7) Sensor temperature. (Maintain the temperature between +28 °C (+82.4 °F) and +41 °C (+105.8 °F) for best operation)

8) Placement of the sensor, such as on an extremity that has a NIBP cuff, arterial catheter, or intravascular line.

9) Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin.

10) External illumination more than 5,000 lumens/square meter (typical office lighting). (Cover the sensor site with opaque materials is recommended.)

11) Venous pulsations.

To use the sensor:

a) Select an appropriate sensor. Use an SpO_2 sensors approved by the manufacturer.

b) Apply the sensor as directed, and observe all warnings and cautions presented in the sensor user manual.

c) Clean and remove any substances, such as nail polish, from the application site.

d) Periodically check to ensure that the sensor remains properly positioned on the patient.

e) Cover the sensor site with opaque material.

9.2.2 SpO_2 Monitoring Procedure

1) Insert the SpO_2 sensor plug into the SpO_2 socket on the monitor.

2) Place the forefinger, middle finger or third finger into the SpO_2 sensor, refer to figure 9-3.

Figure 9-3 Placement of the Finger for SpO_2 Measuring

NOTE:

1 The nail should cover the light but not too long.

2 The cable should be placed on the backside of the hand.

3 Avoid external light sources such as radiated rays or ultrared rays.

9.2.3 Enabling SpO_2 Trace Printing

The real-time SpO_2 measurement result is displayed in the parameter area of the main interface. You can choose to print them as a continuous trace on the recorder paper (refer to figure 5-1).

To enable or disable SpO_2 trace printing,

1 Select the setup key  on the main interface.

2 Select **Recorder > SpO_2 Trace**.

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

4 Select **OK**.

9.2.4 Assessing the Validity of a SpO2 Reading

You can check the quality of the pleth wave and the stability of the SpO2 values to assess whether the sensor functions properly and whether the SpO2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO2 reading.

NOTE:

1 The SpO_2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies composed of local healthy men and women from age 19 to 37, with variations of skin pigmentations. The SpO_2 accuracy is as follows: ±2% for 90%-100% and ±4% for 70%-90%.

2 The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).

3 Generally, the quality of the SpO_2 pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors, unstable SpO_2 readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO_2 readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

9.2.5 SI (Signal Intensity)*

*Only applicable to the EDAN module

The signal intensity (SI) shows perfusion in numeric, and it reflects the pulse intensity of the measurement site. The SI ranges from 0 to 10, with a larger value indicating the more intense signal. When the SI value reaches 10, the signal quality is optimal. If the SI value is less than 2, it indicates that the pulse at the current site is weak, and you should change the measurement site.

The SI value is displayed in the SpO_2 parameter area.

9.2.6 Switching the SpO_2 Alarm On or Off

You can choose to switch the SpO_2 alarm on or off.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **SpO_2**.

4 Select **ON** (default) or **OFF** for **Alarm**.

5 Select **OK**.

9.2.7 Changing SpO_2 Alarm Limits

You can change the SpO_2 alarm limits.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **SpO_2**.

4 Select a value from 50 ~ 99 for **Low Alarm Limit**. (The step is 1, and the default value is 90%.)

5 Select a value from 51 ~ 100 for **High Alarm Limit**. (The step is 1, and the default value is 100%.)

6 Select **OK**.

9.3 Maternal HR Monitoring

9.3.1 Introduction

Maternal heart rate (HR) monitoring does not need an extra accessory. When you perform ECG or SpO_2 (Pulse) monitoring, the HR result can be acquired at the same time.

When monitoring ECG and SpO_2 at the same time, you can choose the HR source. If only one of them is being performed, the source will automatically switch to the available one (the screen reading should prevail).

9.3.2 Choosing HR Source

You can change the HR source.

1 Select the setup key  on the main interface.

2 Select **Mother > HR Source**.

3 Select **ECG** (default) or **Pulse** (during SpO_2 monitoring).

4 Select **OK**.

9.3.3 Changing HR Beep Volume

When the HR beep is enabled, the monitor gives a beep sound of maternal heart.

To change the HR beep volume,

1 Select the setup key  on the main interface.

2 Select **Mother > HR Beep**.

3 Select **OFF** (default), **Low** or **High**.

4 Select **OK**.

NOTE:

1 The DECG beep and HR beep share the same audio channel. Once the HR beep is switched on, the DECG beep is disabled (set to **OFF**) automatically.

2 Once the DECG/HR beep volume is changed, the sound switches to channel 1 automatically. Therefore, it is advised against changing DECG/HR beep volume in the monitoring process.

9.3.4 Enabling HR Trace

The real-time HR measurement result is displayed in the parameter area of the main interface. Also, you can choose to display and print those as a continuous trace on the recorder paper (refer to figure 5-1).

To enable or disable HR trace printing,

1 Select the setup key  on the main interface.

2 Select **Recorder > HR Trace**.

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

4 Select **OK**.

9.3.5 Switching the HR Alarm On or Off

You can choose to switch the HR alarm on or off.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **HR**.

4 Select **ON** (default) or **OFF** for **Alarm**.

5 Select **OK**.

9.3.6 Changing HR Alarm Limits

You can change the HR alarm limits.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **HR**.

4 Select a value from 30 ~ 239 for **Low Alarm Limit**. (The step is 1, and the default value is 50 bpm.)

5 Select a value from 31 ~ 240 for **High Alarm Limit**. (The step is 1, and the default value is 120 bpm.)

6 Select **OK**.

9.3.7 Signals Overlap Verification

When monitoring maternal heart rate and fetal heart rate at the same time, there are possibilities that maternal HR signal is mistaken for FHR signal. The SOV function of the monitor can also reduce these possibilities.

In the process of monitoring, if the SOV detects signals overlapping, an alarm message “Signals Overlap (FHR1/FHR2, HR)” will appear on the screen to warn you. Checking the patient and reposition of sensors might be needed.

9.4 Maternal NIBP Monitoring

9.4.1 Introduction

The monitor measures blood pressure using the oscillometric method.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

There are two modes available: Manual and Auto. In manual mode, NIBP is measured once on each demand. In auto mode, NIBP is measured repeatedly after a preset time interval. This interval is adjustable. You can perform a manual measurement during an Auto measurement interval.

In both modes, systolic pressure (SYS) and diastolic pressure (DIA) are measured and displayed.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI/ISO 81060-2:2009, ANSI/AAMI SP10:2002) in relation to mean error and standard deviation.

WARNING

1 Check for any fault of the cuff before start monitoring.

2 Do not perform NIBP measurements on patients with sickle-cell disease or under any condition where the skin is damaged or expected to be damaged, such as on the arm on the side of a mastectomy.

3 Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitor on the same limb.

4 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.

5 For a thrombasthemia patient, it is important to determine whether the measurement of blood pressure shall be done automatically. The determination should be based on clinical evaluation.

6 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place frequently. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

7 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.

NOTE:

The monitor is intended to measure NIBP for adults only.

Measurement Limitations -

To different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances where the patient's condition makes it difficult to detect, the measurement becomes unreliable and the measuring time increases. You should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

1) Patient Movement

Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

2) Cardiac Arrhythmia

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus will be prolonged.

3) Heart-lung Machine

Measurements will not be possible if the patient is connected to a heart-lung machine.

4) Pressure Changes

Measurements will be unreliable and may not be possible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

5) Severe Shock

If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

6) Heart Rate Extremes

Measurements can not be done to a patient whose heart rate is lower than 40 bpm or higher than 240 bpm.

9.4.2 How to Apply NIBP Cuff

WARNING

Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and choose the proper cuff size. If you find something is wrong with the cuff size, please replace it immediately.

1) Select appropriate cuff for the patient.

The table below lists the reference size:

Type	Limb Perimeter	Cuff Size	Air Hose Length
Upper Arm (Adult 1)	27 cm ~ 35 cm	14.5 cm	3 m
Upper Arm (Adult 2)	34 cm ~ 43 cm	18 cm	

2) Squeeze the cuff to discharge the air.

3) Apply the cuff to the patient; make sure that the index line is placed in the appointed range and the symbol ⇧ is over the appropriate artery (Refer to figure 9-4). If the index line is not in the appointed range, please replace for a proper one. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.

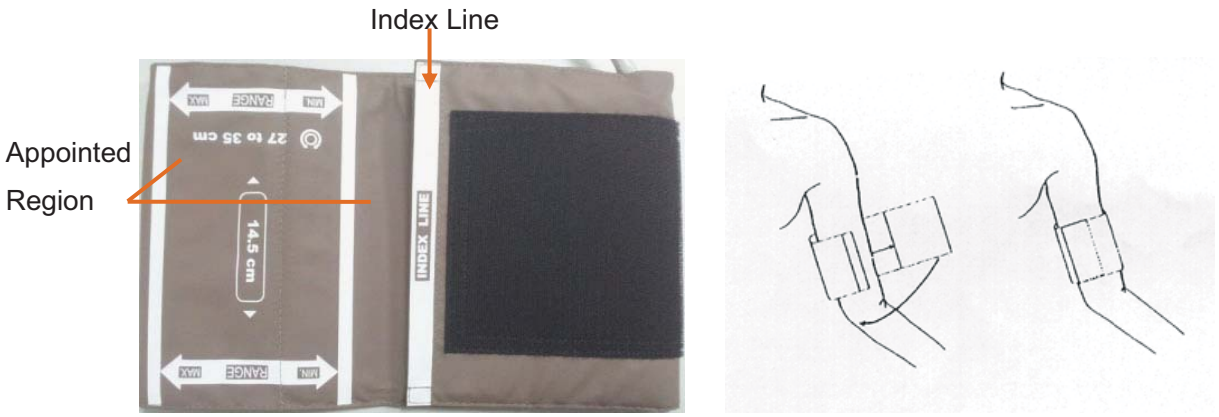


Figure 9-4: Applying the Cuff

9.4.3 Preparation for NIBP Monitoring

To obtain accurate measurements, the following operating steps need to be observed:

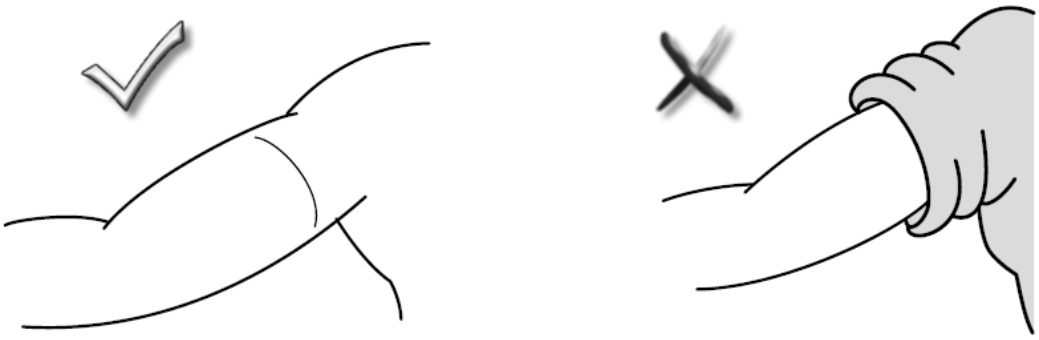
1. Ensure the patient position in normal use, including
   - comfortably seated
   - legs uncrossed
   - feet flat on the floor
   - back and arm supported
   - middle of the cuff at the level of the right atrium of the heart
2. Relax as much as possible and do not talk during the measurement.

3. Wait for five minutes until the first reading is taken.

NOTES:

Please roll up the sleeve and keep the patient's arm bare or it will cause the inaccurate measurements.

1) Wrap the cuff on a bare arm.



2) Insert the cuff plug into NIBP socket on the monitor.

3) Apply the NIBP cuff to the patient's arm or leg following the instructions described in section *9.4.2 How to Apply NIBP Cuff*.

4) Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible, correct the measurement using the formula described in section *9.4.6 Correcting the Measurement*.

Figure 9-5 Connection for NIBP measurement

9.4.4 *Auto Measurement

To perform an auto measurement,

1 Select the setup key  on the main interface.

2 Select **Mother > Cycle**.

3 Select a time interval from 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240 and 480 minutes.

4 Select **OK**.

5 Press **NIBP** key on the front panel to start an Auto measurement.

NOTE:

The monitor checks uterine contract (UC) pressure when the **NIBP** key is pressed. If the UC is over 50, a prompt “Intense UC, can't measure NIBP now.” is issued, and the monitor will check the UC every 30 seconds. The monitor will measure NIBP only when the UC is lower than 50, and it will then start timing for the Auto measurement.

To stop the current measurement,

Press the **NIBP** key anytime during the current measurement to stop it. Another measurement will start after the time interval.

WARNING

Prolonged NIBP measurements in automatic mode may be associated with purplish patches, ischemia and neurologic damage in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the NIBP measurement.

9.4.5 *Manual Measurement

To perform a manual measurement,

1 Select the setup key  on the main interface.

2 Select **Mother > Cycle**.

3 Select **Manual**.

4 Select **OK**.

5 Press **NIBP** key on the front panel to start a manual measurement.

To stop the manual measurement,

Press the **NIBP** key anytime during the measurement to stop it.

To perform a manual measurement during an auto measurement interval,

1 Press the **NIBP** key to start the manual measurement.

2 Press the **NIBP** key again anytime to stop it.

The monitor will restart timing for the Auto measurement and resume measuring after the time interval.

NOTE:

1 If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the monitor.

2 The monitor checks uterine contract (UC) pressure when the **NIBP** key is pressed. If the UC is over 50, a prompt “Intense UC, can't measure NIBP now.” is issued. Please wait and do not attempt to measure NIBP until the UC is lower than 50.

CAUTION

1 Do not squeeze the rubber tube on the cuff.

2 If liquid is inadvertently splashed on the equipment or its accessories, or may enter the conduit or inside the monitor, contact local service center.

9.4.6 Correcting the Measurement

To correct the measurement if the limb is not at heart level,

- add 0.75 mmHg (0.10 kPa) for each inch higher.
- deduct 0.75 mmHg (0.10 kPa) for each inch lower.

9.4.7 Changing NIBP Unit

You can change the NIBP unit.

1 Select the setup key  on the main interface.

2 Select **Mother > Unit** (NIBP Setup).

3 Select **mmHg** (default) or **kPa**.

4 Select **OK**.

9.4.8 Switching the NIBP Alarm On or Off

You can choose to switch the NIBP alarm on or off. The SYS alarm and DIA alarm are related. Once one of them is switched off, the rest will be switched off as well.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **SYS** or **DIA**.

4 Select **ON** (default) or **OFF** for **Alarm**.

5 Select **OK**.

9.4.9 Changing SYS Alarm Limits

You can change the SYS alarm limits.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **SYS**.

4 Select a value from 40 ~ 269 for **Low Alarm Limit**. (The step is 1, and the default value is 90 mmHg.)

5 Select a value from 41 ~ 270 for **High Alarm Limit**. (The step is 1, and the default value is 160 mmHg.)

6 Select **OK**.

9.4.10 Changing DIA Alarm Limits

You can change the DIA alarm limits.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **DIA**.

4 Select a value from 10 ~ 214 for **Low Alarm Limit**. (The step is 1, and the default value is 50 mmHg.)

5 Select a value from 11 ~ 215 for **High Alarm Limit**. (The step is 1, and the default value is 90 mmHg.)

6 Select **OK**.

9.4.11 *Choosing NIBP Printing Mode

When the recorder is printing real-time fetal traces, the NIBP result is also recorded on the paper whenever NIBP measurement is performed. After the paper stops advancing, you can choose to keep recording NIBP results on the paper.

To enable or disable NIBP printing after paper advancing stops,

1 Select the setup key  on the main interface.

2 Select **Recorder > NIBP**.

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

4 Select **OK**.

NOTE:

The NIBP measurement results during the period of paper lacking and fast printing after new paper is loaded will not be saved or printed. Therefore, do not perform NIBP measurements during this period.

9.4.12 *Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure sensors must be verified and calibrated, if necessary, at least once every two years by a qualified service professional.

9.5 Maternal TEMP Monitoring

9.5.1 TEMP Monitoring Procedure

1) Insert the TEMP plug into the TEMP socket on the monitor.

2) Apply the sensor firmly underneath the patient's axilla. It takes 5 minutes for the temperature measurement to stabilize.

WARNING

1 Check if the TEMP sensor functions properly prior to use.

2 Do not apply the TEMP sensor to the mouth or the rectum.

CAUTION

Be cautious when taking and putting the TEMP sensor. Do not pull the cable too tight or it might cause mechanical damage.

The transient response time for the continuous TEMP sensor is not larger than 30s. The laboratory method used to test the response time is as follows:

1. Prepare two reference temperature sources. The first one with a constant temperature of 25ºC (77ºF) and the second one with a constant temperature of 27ºC (80.6ºF).
2. Put the TEMP sensor to the first reference temperature source until the temperature reading reaches 25ºC (77ºF).
3. Move the TEMP sensor to the second reference temperature source. Note the time (t1) from the TEMP sensor being moved in to the temperature reading reaching 27ºC (80.6ºF).
4. When the temperature reading is stable, move the TEMP sensor back to the first reference temperature source. Note the time (t2) from the TEMP sensor being moved in to the temperature reading falling to 25ºC (77ºF).
5. The larger value of t1 and t2 is the response time.

9.5.2 Changing TEMP Unit

You can change the TEMP unit.

1 Select the setup key  on the main interface.

2 Select **Mother > Unit** (TEMP Setup).

3 Select **ºC** (default) or **ºF**.

4 Select **OK**.

9.5.3 Switching the TEMP Alarm On or Off

You can choose to switch the TEMP alarm on or off.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **TEMP**.

4 Select **ON** (default) or **OFF** for **Alarm**.

5 Select **OK**.

9.5.4 Changing TEMP Alarm Limits

You can change the TEMP alarm limits.

1 Select the setup key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter **9999**, then select **Enter**.

3 Select **TEMP**.

4 Select a value from 0.0 ~ 49.9 for **Low Alarm Limit**. (The step is 0.1, and the default value is 36.0 ºC.)

5 Select a value from 0.1 ~ 50.0 for **High Alarm Limit**. (The step is 0.1, and the default value is 39.0 ºC.)

6 Select **OK**.

Chapter 10 Maternal Monitoring Display (F6 Express/F9 Express)

10.1 *Display Mode

F6 Express and **F9 Express** have three display modes: maternal-fetal display (figure 10-1), fetal display (figure 10-2) and maternal display (figure 10-3).

To change the display mode, select the display mode switch  on the main interface. The display mode will switch among the three modes.

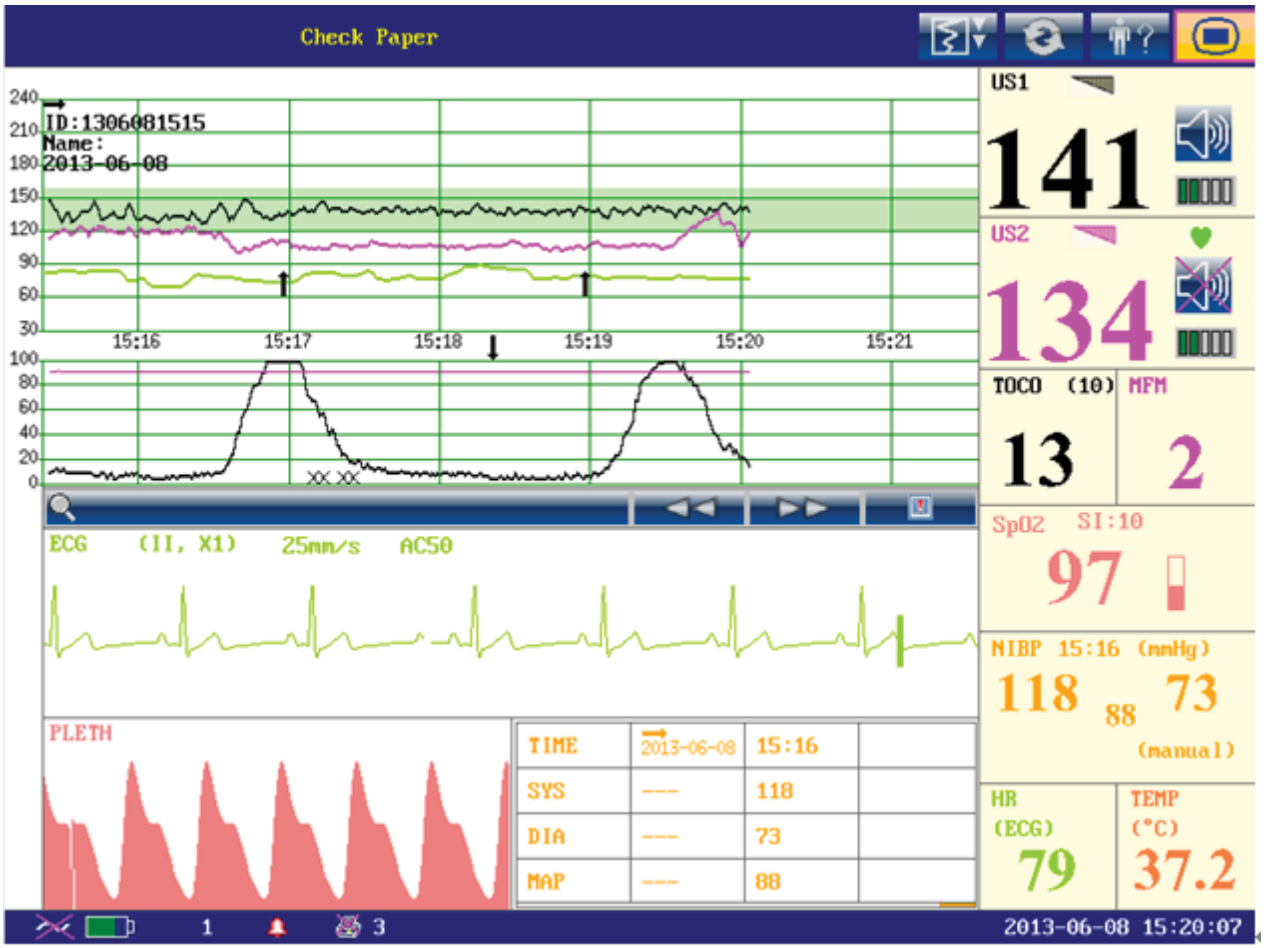


Figure 10-1 Maternal-Fetal Display mode

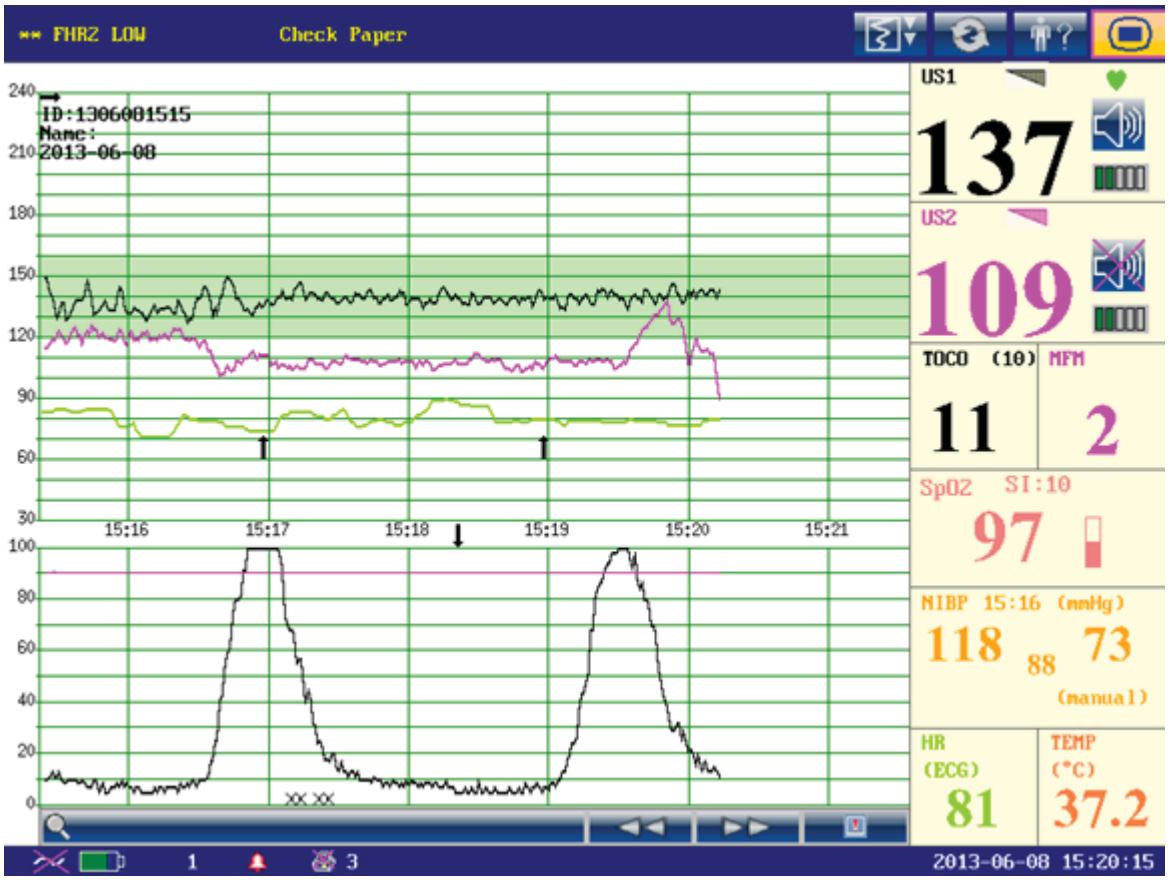


Figure 10-2 Fetal Display Mode

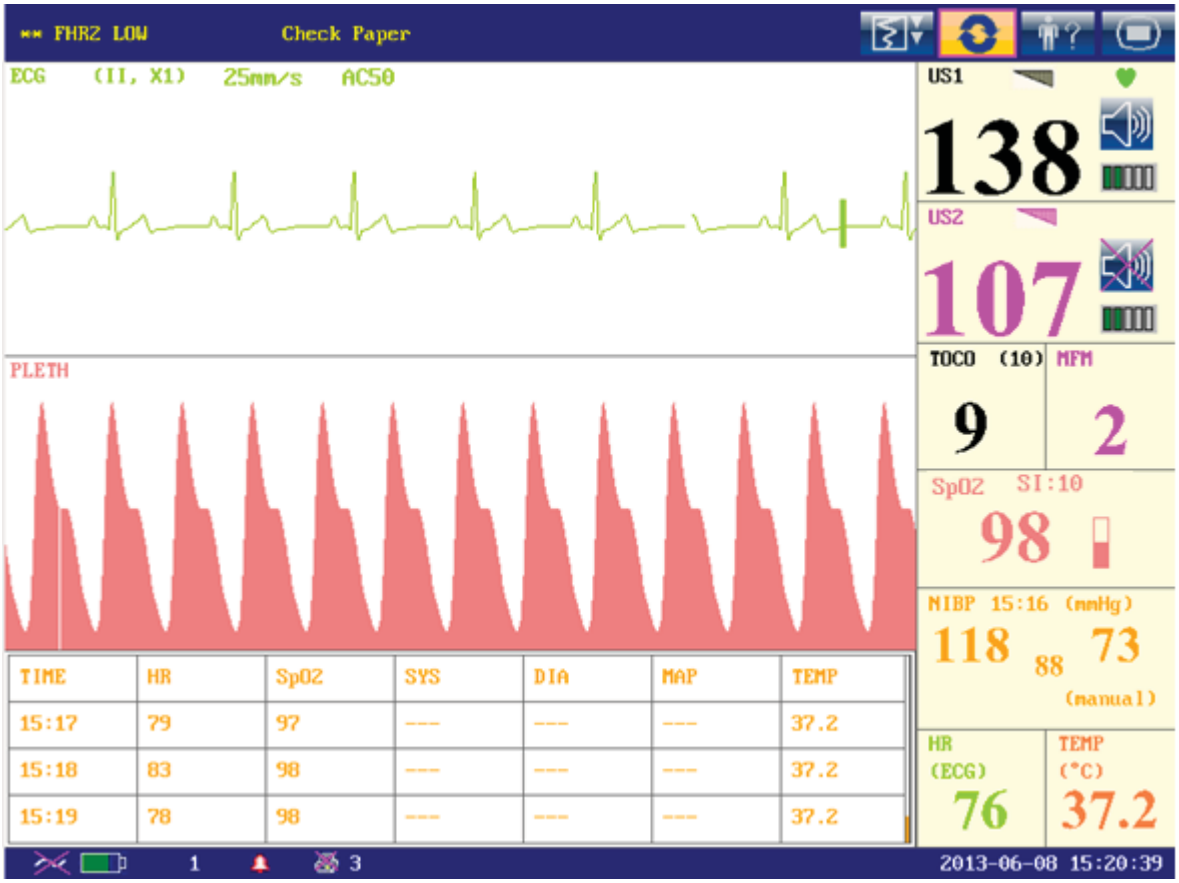


Figure 10-3 Maternal Display Mode

10.2 Maternal Monitoring Traces

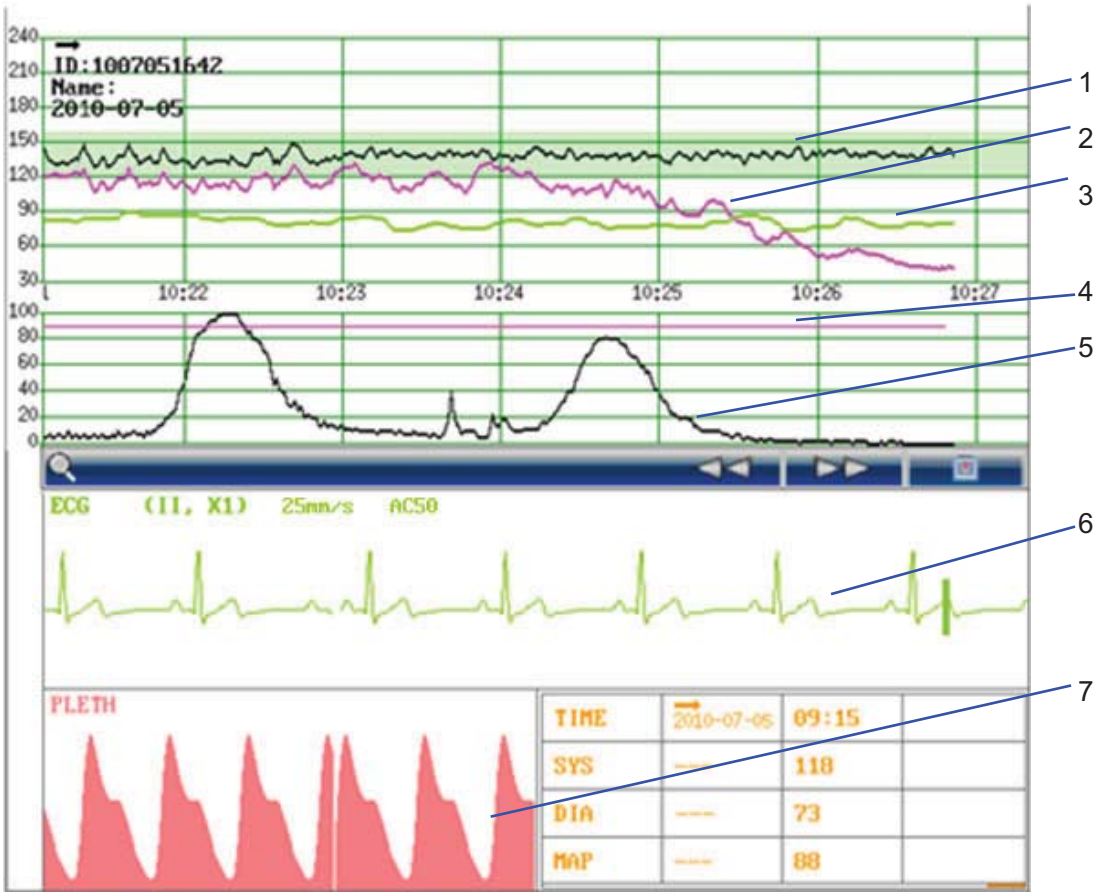


Figure 10-4 Maternal Monitoring Traces

1	FHR1 Trace	2	FHR2 Trace	3	HR Trace	4	AFM Trace
5	TOCO Trace	6	ECG Trace	7	SpO_2 Waveform		

F6 Express and **F9 Express** display both maternal monitoring traces and fetal monitoring traces on the same screen. The maternal monitoring traces include ECG waveform and SpO_2 waveform. The fetal monitoring traces are the same as traces of **F6/F9**, refer to *8.1 Fetal Monitoring Traces* for more information.

10.3 Maternal Vital Sign List

The maternal vital sign list keeps records of the recent maternal vital signs and the measuring time. A start mark ➞ and the date appear when a new monitoring begins.

In maternal-fetal display mode, the list contains the time, SYS and DIA numerics of every measurement.

TIME	11:02	11:03	11:04
SYS	117	117	117
DIA	77	77	77

Figure 10-5 Maternal NIBP List

In maternal display mode, the list contains the time, HR, SpO_2, SYS, DIA and TEMP numerics. The numerics are recorded every minute.

TIME	HR	SPO2	SYS	DIA	TEMP
11:02	60	99	117	77	37.2
11:03	60	99	117	77	37.2
11:04	60	99	117	77	37.2

Figure 10-6 Maternal Vital Sign List

The maternal vital sign list can be reviewed: select the list and then rotate the control knob to review the previous lists.

10.4 Numerics

Besides the fetal numerics, the numeric window of **F6 Express** / **F9 Express** includes maternal vital signs: SpO_2, NIBP, HR and TEMP:

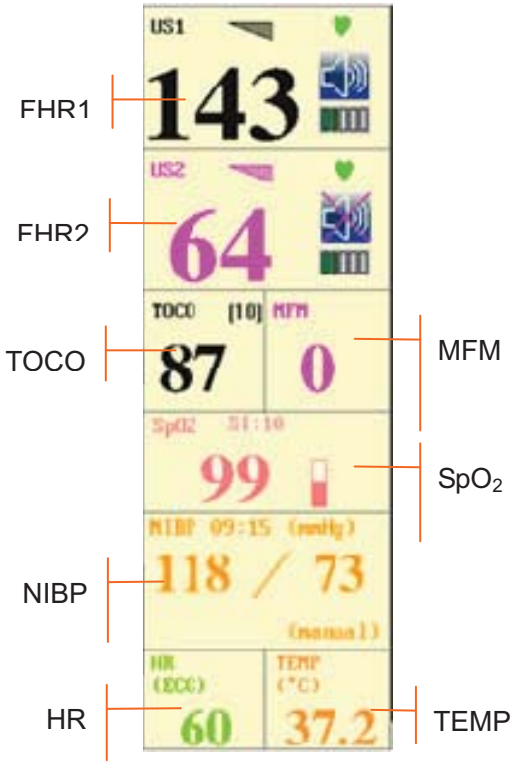
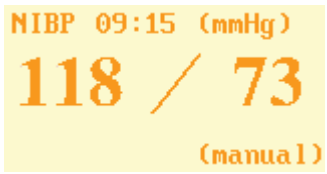


Figure 10-7 Numeric Window

SpO_2 	99: Current SpO_2 measurement numeric.
	: SpO_2 indicator. SI: Signal intensity.
NIBP 	09:15: Time when the NIBP measurement starts.
	mmHg/kPa: NIBP unit.
	From left to right in turn: systolic pressure (118) and diastolic pressure (73).
	(manual)/(Auto): The current NIBP measurement mode.
HR 	(ECG)/(Pulse): The current HR source.
	60: Current maternal heart rate measurement numeric.
TEMP 	(ºC)/(ºF): TEMP unit.
	37.2: Current TEMP measurement numeric.

10.5 Maternal Monitoring Alarm Messages

Besides the fetal monitoring alarms, **F6 Express**/**F9 Express** also gives alarms for the situations that occur during maternal monitoring. The alarm messages are listed below.

10.5.1 Patient Alarm Messages

Alarm Message	Source	Cause	Countermeasure
High Level			
***ASYSTOLE	ECG	No QRS wave is detected in 4 seconds	Check the patient's condition and take necessary measures.
Medium Level			
**HR HIGH or **HR xxx > yyy	ECG/ Pulse	Maternal HR result (xxx) is higher than the upper limit (yyy).	Check if the alarm limits are suitable; check the patient's condition.
**HR LOW or **HR xxx < yyy	ECG/ Pulse	Maternal HR result (xxx) is lower than the upper limit (yyy).	
** SpO_2 HIGH or ** SpO_2 xxx > yyy	SpO_2	SpO_2 result (xxx) is higher than the upper limit (yyy).	
** SpO_2 LOW or ** SpO_2 xxx < yyy	SpO_2	SpO_2 result (xxx) is lower than the upper limit (yyy).	

**SYS HIGH or **SYS xxx > yyy	NIBP	SYS result (xxx) is higher than the upper limit (yyy).	Check if the alarm limits are suitable; check the patient's condition.
**SYS LOW or **SYS xxx < yyy	NIBP	SYS result (xxx) is lower than the upper limit (yyy).	
**DIA HIGH or **DIA xxx > yyy	NIBP	DIA result (xxx) is higher than the upper limit (yyy).	
**DIA LOW or **DIA xxx < yyy	NIBP	DIA result (xxx) is lower than the upper limit (yyy).	
**TEMP HIGH or **TEMP xxx > yyy	TEMP	TEMP result (xxx) is higher than the upper limit (yyy).	
**TEMP LOW or **TEMP xxx < yyy	TEMP	TEMP result (xxx) is lower than the upper limit (yyy).	

10.5.2 Technical Alarm Messages

Alarm Message	Source	Cause	Countermeasure
High Level			
***ECG SINGNAL EXCEEDS LIMIT	ECG	ECG signal exceeds the measurement limits.	Check the connection of the leads and the patient's condition.
Low Level			
Signals Overlap (FHR1, HR)	US+ECG /Pulse	US transducer 1 has picked up the maternal heart signal; the signals overlap.	Reposition the US transducer 1 until the fetal heart signal is detected.
Signals Overlap (FHR2, HR)	US+ECG /Pulse	US transducer 2 has picked up the maternal heart signal; the signals overlap.	Reposition the US transducer 2 until the fetal heart signal is detected.
Signals Overlap (FHR1, FHR2, HR)	US+ECG /Pulse	US transducer 1 and US transducer 2 have picked up the maternal heart signal; the signals overlap.	Reposition the US transducers until the fetal heart signals are detected.
ECG LEADS OFF	ECG	ECG leads are not well connected.	Check the connection of ECG leads.
ECG SIGNAL LOSS	ECG	ECG signal is too weak for the system to analyze.	Check if the ECG leads are well attached; check the patient's condition.

ECG EQUIP MALF	ECG	The ECG board can not communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
HR EXCEEDS MEASUREMENT RANGE	ECG/ Pulse	The heart rate exceeds the measurement limits.	Check the connection of the ECG leads/SpO_2 sensor and the patient's condition.
NIBP EQUIP MALF	NIBP	The NIBP board can not communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
NIBP SYSTEM FAILURE	NIBP	The NIBP module defective.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
NIBP CUFF LOOSE or OFF	NIBP	The cuff is loose or not connected.	Wrap the cuff properly.
NIBP OVER PRESSURE	NIBP	The pressure has exceeded the specified upper safety limit.	Measure again, if failure persists, stop using the monitor for NIBP measuring and contact the manufacturer for service.
NIBP CUFF TYPE ERROR	NIBP	A different cuff other than the one supplied by the manufacturer is used.	Use the cuff supplied by the manufacturer.
NIBP LEAK	NIBP	The cuff, hose and (or) connector are (is) damaged.	Check and replace the leaking part(s). Contact the manufacturer for service if required.
NIBP SIGNAL LOSS	NIBP	Cuff is too loose or the patient pulse is too weak.	Use other methods to measure NIBP.
NIBP SIGNAL INTERFERED	NIBP	Large signal noise or irregular pulse rate caused by excessive motions of the patient.	Keep the arm that is wrapped with the cuff still.
NIBP EXCEEDS MEASUREMENT RANGE	NIBP	The blood pressure exceeds the measurement limits.	Check the connection of the cuff and the patient's condition.
NIBP TIME OUT	NIBP	Measuring time has exceeded 120 seconds.	Start measuring again, or use other measuring methods.
SpO_2 LOW PERFUSION	SpO_2	The signal received by SpO_2 sensor is too weak, or the measurement part has low perfusion, and therefore the result may be inaccurate.	Check the patient's condition and reposition the SpO_2 sensor. Contact the manufacturer for service if the problem persists.

SpO_2 SENSOR OFF	SpO_2	SpO_2 sensor is not well connected.	Check the connection of SpO_2 sensor and finger placement.
SpO_2 EQUIP MALF	SpO_2	The SpO_2 board can not communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
TEMP UNPLUGGED	TEMP	TEMP sensor is not well connected.	Check the connection of TEMP sensor.
TEMP Calibration Failed	TEMP	Calibration of the TEMP sensor failed.	Restart the monitor and try again. Contact the manufacturer for service if the problem persists.

Chapter 11 FTS-3 Fetal Telemetry System

11.1 Brief Introduction

FTS-3 Fetal Telemetry System (hereinafter called FTS-3) provides non-invasive monitoring for the fetal heart rate (FHR) and testing TOCO for the pregnant women from the 28th week of gestation. When connected to a compatible fetal monitor, FTS-3 provides wireless patient monitoring in the antepartum period and during 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.

FTS-3 is used with F6, F9 series fetal/maternal monitor and connects to the monitor by signal cable. The wireless transducers monitor the FHR, TOCO parameters within certain distance, and then the base station sends them to the monitor through signal cable, and the monitor can display, alarm, print or review the parameters.

FTS-3 consists of the wireless US transducers, the wireless TOCO transducer and the base station.

The wireless signal can be transmitted in the Industrial Scientific Medical Band (ISM) according to the local regulations. The transmission range depends on where the system is used. It is recommended to use in hospital for better transmission. The transmission range is smaller in water than that in the air.

Device	FCC ID
Base Station	SMQFTS3BEDAN
US Transducer	SMQFTS3UEDAN
TOCO Transducer	SMQFTS3TEDAN

11.1.1 Base Station

Figure 2-1 Top Panel

	Name	Description
1	Docking Slot	Place, charge and manage the transducer.
2	Power Indicator	When you turn the power supply, the indicator is on.
3	AC Indicator	When AC power is supplied, the indicator is on.
4	Battery Indicator	When the base station battery is charging, the indicator is on. When the battery is in low level, it is flashing.
5	Wireless Connection Indicator	When the transducer connects to the base station successfully, the green light is on.
6	Charging Point	When you place the transducer in the docking slot, you can charge the transducer by these points.

WARNING

The charging point is specially used for charging the medical equipment and please do not touch the charging point and the patient at the same time.

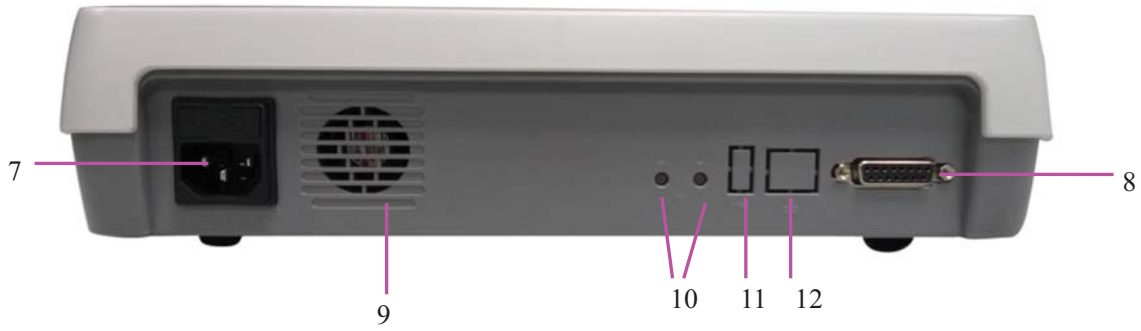


Figure 2-2 Rear Panel

	Name	Description
7	AC Outlet	AC outlet.
8	Communication Socket	Communicate to the bedside monitor.
9	Emission Slot	Emit the heat.
10	Channel Adjustment Button	Adjust the channel.
11	USB port	Reserved
12	Ethernet port	Reserved

Figure 2-3 Right Panel

	Name	Description
13	Power Switch	Turn on or turn off the base station.

CAUTION

1. This monitor is a normal medical device. Please avoid violent operations such as continuously pressing the power switch.
2. When the transducer is taken up, please do not power off the base station.

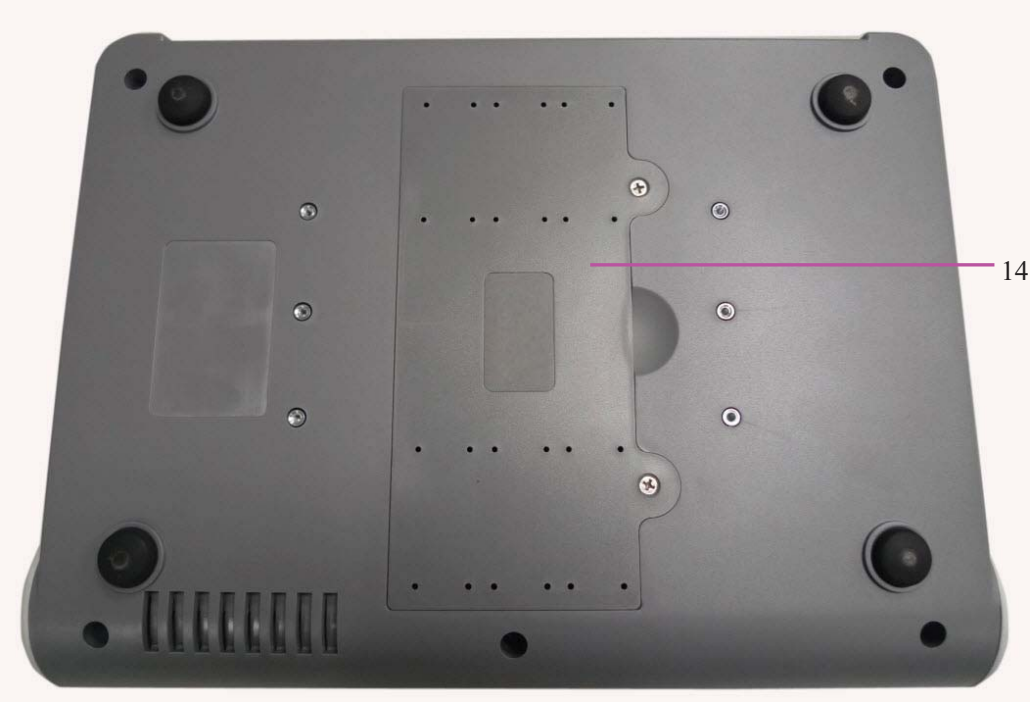


Figure 2-4 Bottom

	Name	Description
14	Battery Compartment	Install the battery.

11.1.2 US Transducer and TOCO Transducer

US transducer

TOCO transducer

	Name	Description
15	Transducer	Tied to the pregnant women.
16	Transducer Type	Indicate the transducer type.
17	System Working Channel	Indicate the system working channel.
18	Signal Indicator	Indicate wireless signal strength.
19	Battery Indicator	Indicate battery level.

11.1.3 Features

- Long work distance and free to walk in a great range
- Wireless transducers
- Low power consumption and working for long time
- Rechargeable transducers
- Cabinet, portable and waterproof transducers
- Provide rechargeable battery for base station

11.2 Installation Guide

WARNING

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

11.2.1 Opening the Package and Checking

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage.

Open the package; take out the base station 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.
- Check all the cables and accessories.

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

11.2.2 Installing Battery

WARNING

Switch off FTS-3 and unplug it before installing or removing the battery.

NOTE:

1 If the system is provided with a rechargeable base station battery, please charge the battery after each transportation and storage.

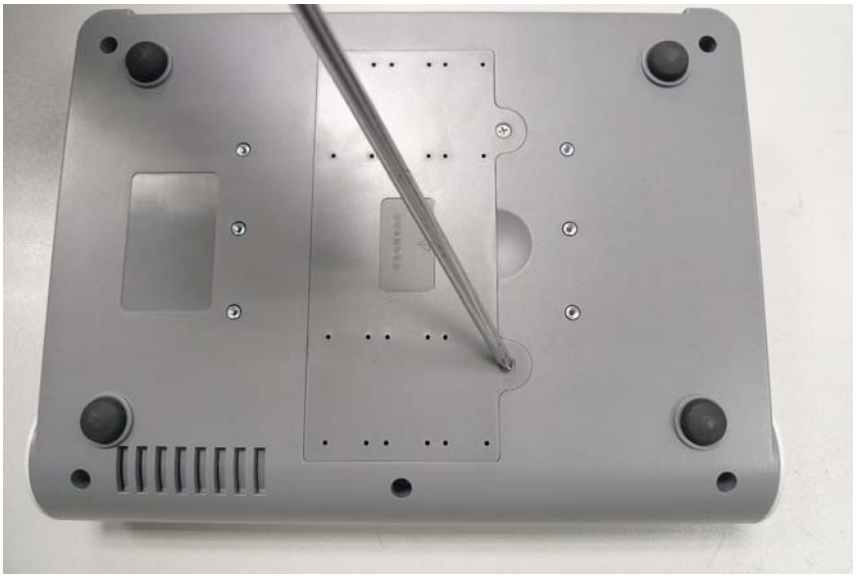
2 Please charge the battery to the full after each use. When the system is powered on with the AC power supply, the battery is charging. Please do not interrupt the charging and wait until the battery is fully charged.

If the system is provided with a rechargeable lithium-ion battery, follow these steps to install the battery:

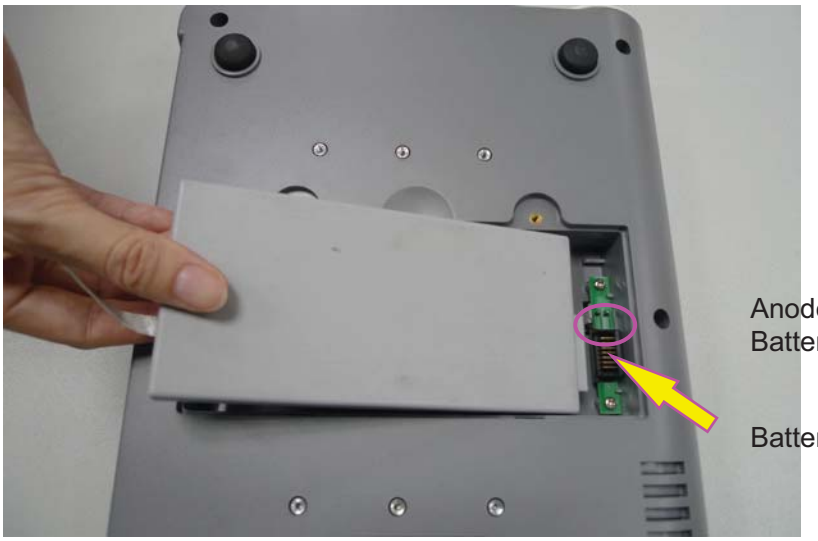
(1) Battery Installation

a) Place FTS-3 upside down on a flat surface covered with cloth or another type of protecting pad.

b) Remove the screws of the battery compartment using a cross-head screw driver. Remove the battery compartment cover.



c) Take the battery out from package and put it into the compartment. Make sure the battery connector is on the left and the battery label faces down.



WARNING

Do not touch the anode and cathode of the battery output together with fingers or metal materials, avoiding hazards to you and the battery caused by the short-circuit.

d) Arrange the battery flat in the compartment, and push the strip at the end of the battery into the gap.

e) Shut the battery compartment cover and fix it with the screws.

(2) Battery Removal

Remove the battery in reverse order. You can pull the strip at the end to take the battery out from the compartment.

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 When the battery configuration is provided, after the device is transported or stored, the battery must be charged.

11.2.3 Installing the System

FTS-3 should be placed on a flat surface. It should be placed far from the device with strong radiation and avoid being in the shielded room. More than 2 similar systems should be kept at a distance of over 1.5m.

Alternatively, provided with proper devices, it can be installed on a wall or a trolley. Consult the sales representative for more information.

CAUTION

1. Installation must be carried out by qualified personnel authorized by the manufacturer.
2. If you choose to install FTS-3 on the wall, the ceiling or other locations, it is the user's responsibility to ensure their integrity and solidity evaluated by a registered, professional structural or mechanical engineer and compliance with all local regulations. The manufacturer will not be responsible for the failure and loss of any improper installation.

CAUTION

3. This equipment has been tested and found to comply with the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

   -Reorient or relocate the receiving antenna.
   -Increase the separation between the equipment and receiver.
   -Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
   -Consult the dealer or an experienced radio/TV technician for help.

4. Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

11.2.4 Connecting Power Cable

- Make sure the AC power supply of the system complies with the following specification: 100V-240V~, 50Hz/60Hz.
- The equipotential grounding terminal is provided for the connection of a potential equalization conductor. Therefore, it is recommended to connect the grounding terminal of the system and the power outlet with the grounding wire, making sure FTS-3 is grounded.

WARNING

If the protective grounding (protective earth) system is doubtful, the power of the system must be supplied by internal power supply only.

NOTE:

1 Make sure the system and the power outlet are placed at a place where it is easy to connect and disconnect the power cord.

2 When the supply mains are interrupted, the device switches to internal power supply and operates normally if the battery is installed. If the battery is not installed, the system shuts down and resumes the previous settings at the subsequent operation.

3 After the AC power supply is connected, please wait for at least 2 seconds before pressing the POWER switch to turn on the system.

11.2.5 Connect to the Base Station

1. Power on the base station.
2. Connect one end of the signal cable to the base station and the other end to the monitor input socket.
3. Put the transducer back into the docking slot. The system can support 2 US transducers and 1 TOCO transducer at most. Please do not exceed the maximum number of the transducer.

NOTE:

If the system is provided with transducer protection cover, please do not take up the cover during monitoring.

11.2.6 Configure the Monitor

1. Charge the transducer battery.
2. Power on the monitor.
3. Achieve the fetal heart signal.

   Take the transducer up and keep the transducer at a distance of over 30cm from the base station. The wireless connection indicator is on, and it indicates the transducer is taken out. If you want to power off the transducer, put it back in the docking slot. If the transducer connects to the base station successfully, the wireless connection indicator is always on and do not put back the inactivated transducer in the docking slot.
4. Place the transducer on the patient.

NOTE:

1. Detailed operations please refer to *7.2.2 FHR Monitoring Procedure.*
2. If the working status indicator is on, please do not put the uncharged transducer in the docking slot.
3. The transducer has been taken first displays US1 on the screen, and that taken later displays US2. Please do not take two US transducers simultaneously and wait at 2 seconds to take the other one.

11.2.7 Adjusting the Working Channel

If the fetal heart sound is with interference or it cannot be played smoothly, the working channel is probably interfered. Put all the transducers back in the docking slots and press the adjustment button  in back of the base station. The channel range is 1-32.

Restart the system when it enters the charging interface.

NOTE:

The working channel number used by a system cannot be duplicate with that used by a device of the same type.

11.3 Technical Alarm Messages

When FTS-3 is connected to F9 series fetal/maternal monitor, the monitor gives technical alarms for the situations that need the physicians to pay attention to during wireless monitoring, The alarm messages are listed below.

Alarm Message	Cause	Countermeasure
Medium Level		
**Wireless US1 Transducer Battery Low	The battery power is too low to support further work of the transducer.	Please charge the US1 transducer immediately.
** Wireless US2 Transducer Battery Low	The battery power is too low to support further work of the transducer.	Please charge the US2 transducer immediately.
** Wireless TOCO Transducer Battery Low	The battery power is too low to support further work of the transducer.	Please charge the TOCO transducer immediately.
** Base Station Battery Low	The battery power is too low to support further work of the base station.	Connect the base station to AC power supply.
Low Level		
Wireless US1 SIGNAL LOSS	FHR1 signal is too weak for the system to analyze.	Check if the Wireless US1 transducer is aimed at the fetal heart; check if the patient moves out of the base station RF range, if the transducer is well

		connected to the base station.
Wireless US2 SIGNAL LOSS	FHR2 signal is too weak for the system to analyze.	Check if the Wireless US2 transducer is aimed at the fetal heart; check if the patient moves out of the base station RF range, if the transducer is well connected to the base station.
Wireless TOCO SIGNAL LOSS	TOCO signal is too weak for the system to analyze.	Check if the Wireless TOCO transducer is placed correctly; check if the patient moves out of the base station RF range, if the transducer is well connected to the base station.

11.4 Basic Operation

11.4.1 Charge the Transducer

Place the transducer in the docking slot and it displays the charging state on the transducer screen.

Caution

Please wait for 2 minutes to use the transducers after charging.

11.4.2 Charge the Battery

Please pay attention to the battery level during monitoring process. The battery symbol displays in the top right corner of the screen. The low battery level may influence the monitoring.

 : It is fully charged.

 : It is less fully charged.

 : It is in low level. Please charge the battery. There is alarm information on the screen.

 : It is out of power. Please charge the battery immediately.

Caution

When in indicates the power is low, please charge the battery immediately or the monitoring will be interrupted.

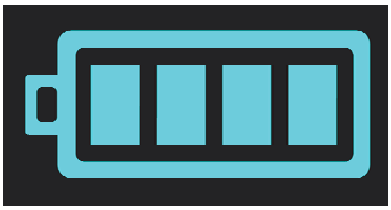
Please wipe the transducer and the charging point with a dry cloth before charging the transducer. Please do not scratch the charging point.

The battery is installed in the transducer. If the base station is supplied by AC, the battery will be charged automatically when it is placed in the docking slot. Please keep the transducer free of

water and coupling gel during charging.

When you charge the battery, the screen will display as follows:

- Full charging icon: fully charged.



- Increasing charging icon: charging
- No charging icon: the transducer place in the docking slot incorrectly.
- If the screen displays ERROR, it indicates that the transducer is not connected well or you place the transducer from the other system by mistake.

It takes about 3.5 hours to charge the battery. It is recommended to place the transducer in the docking slot when the transducer is not used for a long time.

Install the transducer in the base station and the transducer icon will display on the screen.

At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. If the battery charging time decreases sharply, the battery is considered as obsolete battery. Please use the battery provided by the manufacturer and disposes the battery according to the local regulations.

11.4.3 Basic Function Test

Please test the system after each service.

1. Power on the base station and connect it to the fetal monitor.
2. Charge the transducer.
3. Power on the monitor.
4. Take up the US transducer and test the following function:
   - The US transducer screen displays the standard start interface.
   - The US transducer indicator is green.
   - The fetal monitor screen displays US.
5. Simulate the audio frequency signal:
   - The fetal monitor displays FHR.
6. Take up the TOCO transducer and test the following function:
   - The TOCO transducer screen displays the standard start interface.
   - The TOCO transducer indicator is green.
   - The monitor screen displays TOCO.

7. Touch the measuring area of the TOCO transducer gently:
   - The fetal monitor displays TOCO value change.
8. Install the US transducer to charge:
   - The US transducer screen displays charging interface and charging state.
   - The US transducer indicator is off.
   - The fetal monitor screen is no display.
9. Install the TOCO transducer to charge:
   - The TOCO transducer screen displays charging interface and charging state.
   - The TOCO transducer indicator is off.
   - The fetal monitor screen is no display.
10. It takes about 3.5 hours to charge the US transducer and TOCO transducer.

11.5 Patient Application

11.5.1 General Application

Take out the US transducer from the docking slot and it will power on automatically. The transducer screen displays the signal strength, battery level and working channel. After the transducer is successfully connected to the base station, it will also display the transducer type. The indicators are yellow and blue.

NOTE:

1. Fix the US transducer and TOCO transducer tightly to ensure that they will not shift during movement.
2. It is recommended that the transducer should be placed when the patient stands for better monitoring.
3. Excessive coupling gel may slide the transducer.
4. Instruct the patient to move in the prescriptive area and distance for obtaining better signal.

WARNING

If the patient is monitored underwater, please place the transducer when she is ready.

11.5.2 US Transducer

Apply the coupling gel to the transducer:

- Underwater monitoring requires less coupling gel or no coupling gel.
- Move the transducer to get the desire fetal heart and belt it to the belly.

NOTE:

1. When applied to the patient, the wireless ultrasound transducer may warm slightly

(less than 3°C (5.4ºF) above ambient temperature).

2. When NOT applied, the wireless ultrasound transducer may warm slightly (less than 3°C (5.4ºF) above ambient temperature).

11.5.3 Monitor the Ambulatory Patient

FTS-3 is suitable for ambulatory patients. You can take out the transducer from the docking slot and fix the transducer on the location where the best fetal heart signal is received.

Please pay attention to the following during the monitoring.

- Ensure the transducer is tied up well.
- Record the effective FHR.
- The patient should not walk in strong tramps.
- The patient should move in the prescriptive area.
- The patient should be under monitoring when the wireless signal is good.

When the transducer is placed in the docking slot, the system stops transmission. It starts when the monitor is connected to the transducer.

When the patient moves during monitoring, the interference may occur. The artificial interference may influence the signal transmission quality. It will cause drop out or other interference if the transducer works in the changing environment. Some kind of the artificial interference can be anticipated and others can be discovered by observing the signal.

Some artificial interference may be caused by certain place. You can leave the place such as the elevator or the window in iron for the place with signal reception.

The FHR may not be detected clearly when the patient moves in virtue of artificial interference. The transducer is easy to shift underwater and it may lead to temporary signal loss.

No matter how good a telemetry system design is, the occasional US/TOCO dropouts are inevitable. If it is not acceptable for certain patients, please connect the wired the transducer to the bedside monitor.

The manufacturer has no control over the RF environment in the places where the system is used. If interference exists at operating frequencies, the system performance will be affected. You can change the working channel or move the system away from the interference to solve the problem.

Caution

Please do not mistake the patient's steps for the fetal heartbeats.

11.5.4 Underwater Monitoring

Most wireless signal can be absorbed by water. Wireless transmission distances are shorter when monitoring under water. If you have any question, just contact the manufacturer or the local agent.

Caution

1. Please avoid flushing the transducer during underwater monitoring, or it may cause wireless signal interference.
2. The transducers are watertight to a depth of 1.1 meter for 24 hours, but base station is not waterproof. Please do not splash water about the station or soak it into any liquid.
3. Underwater monitoring may influence the TOCO baseline in virtue of water temperature and depth or other reasons. Please adjust the TOCO baseline until the pressure of the transducer in water is steady and keep checking it.
4. A metal bath tub and underwater monitoring both reduce the operating range.

RF Exposure statement

The devices has been tested and meets applicable limits for Radio Frequency (RF) exposure.

FCC statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1)This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Chapter 12 After Monitoring

12.1 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) Press the **PRINT** key to stop printing, and press the paper advancing key  to advance the paper.
3) Wait the paper to stop and then tear it off along the perforation.

NOTE:

After the fetus is delivered in the labor, the monitor may pick up signals of the umbilical cord and display a trace/numeric. To avoid misinterpretation, it is recommended to remove the transducers from the patient and switch off the monitor immediately after the fetus is delivered.

12.2 Switching Off

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

CAUTION

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

Chapter 13 Maintenance and Cleaning

13.1 Maintenance

13.1.1 Maintaining Inspection

(1) Visual Inspection

Prior to using the monitor or FTS-3 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 or FTS-3 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 and the accessories, 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.

WARNING

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

CAUTION

Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.

13.1.2 Maintenance of Monitor and Base Station

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

The gathering of dew on the screen may occur with abrupt temperature or humidity changes. A stable environment is recommended. Stop using the monitor or the base station and contact the service personnel immediately if accidental wetting occurs.

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.

13.1.3 Maintenance of Wired and Wireless Transducers

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.

The transducers must be cleaned before docking in the base station after each use. Make sure that there is no residual coupling gel. Besides, the transducers must be thoroughly cleaned and disinfected at least once a month. When cleaning, please firstly use a lint-free cloth moistened with mild near neutral detergent, ethanol 75% solution or isopropanol 70% alcohol-based solution to clean the transducers. Then use a cotton cloth moistened with clear water to clean again. At last, use a dry, soft cloth to dry them.

In case of unsuccessful charge or poor contact, please use detergent with abrasive effect to rub the electrodes of the transducers in order to clear away the oxide of coupling gel.

Charge and discharge the wireless transducer battery every 3 months.

13.1.4 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.

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

13.1.5 Cleaning of 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.

WARNING

Switch off the monitor and remove the power cord prior to recorder cleaning.

13.1.6 Maintaining the Battery

It is required to follow the instructions in this user manual during installation, storage and maintenance of the battery.

When the battery is charged, used or stored, keep it away from objects or materials with static electric charges.

The recommended charge temperature range is from 0 ºC (+32 ºF) to +40 ºC (+104 ºF). Do not exceed this range.

When not using battery for an extended period, remove it from the monitor and store it in a place with low humidity and low temperature.

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.

13.2 Cleaning

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

13.2.1 Cleaning of Monitor and Base Station

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

WARNING

1 Unplug the monitor and the base station 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.

The solutions recommended for monitor cleaning are: mild near neutral detergent, ethanol 75% and isopropanol 70%.

Clean the monitor and the base station enclosure with soft cloth and diluent non-caustic detergents recommended above.

Clean the screen and the charging point in the docking slot with a dry soft cloth.

CAUTION

1 Although the monitor and the base station are chemically resistant to most common hospital cleaners and non-caustic 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 and the base station.

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 allow any remaining 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.

2 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.

13.2.2 Cleaning of Accessories

(1) Cleaning of Transducers

To clean the transducers and leads, follow these steps:

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

The recommended cleansers for accessories are listed below:

Accessory	Cleansers
Ultrasound Transducer TOCO Transducer (Including the wireless)	Mild near neutral detergent Ethanol 75% Isopropanol 70%
DECG Leads	Mild near neutral detergent Ethanol 75% Isopropanol 70%
IUP Cable	Mild near neutral detergent Ethanol 75% Isopropanol 70%
ECG Leads	Mild near neutral detergent Ethanol 75% Isopropanol 70%
SpO_2 Sensor	Mild near neutral detergent Ethanol 75% Isopropanol 70%
TEMP Sensor	Mild near neutral detergent Ethanol 75% Isopropanol 70%

CAUTION

1 The waterproof parts of the transducer are restricted to the main body and the cable. Do not immerse the plug into water during the process of monitoring or cleaning.
2 Be sure the temperature of cleaning solutions does not exceed +45 ºC (+113 ºF).
3 Only wipe the outer surface of accessories. Do not immerse them in any liquid.
4 Make sure no liquid enters the connector.
5 When you clean the TEMP transducer, take the head in one hand and clean with the soft cloth in the other hand.
6 After cleaning, no remaining cleanser is allowed on the surface.
7 Please clean the charging point periodically or it will not be charged.

(2) Cleaning of Belt

Wash soiled belts with soap and water. The water temperature must not exceed +60 ºC (+140 ºF).

(3) Cleaning of NIBP Cuff

The cuff can also be machine-washed or hand-washed. Hand-washing will prolong the life of the cuff.

Remove the latex rubber bag before washing; for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing; then reinsert the rubber bag.

Replace the Rubber Bag in the Cuff

To replace the rubber bag in the cuff, first place the bag on the top of the cuff so that the rubber tubes line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the complete cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

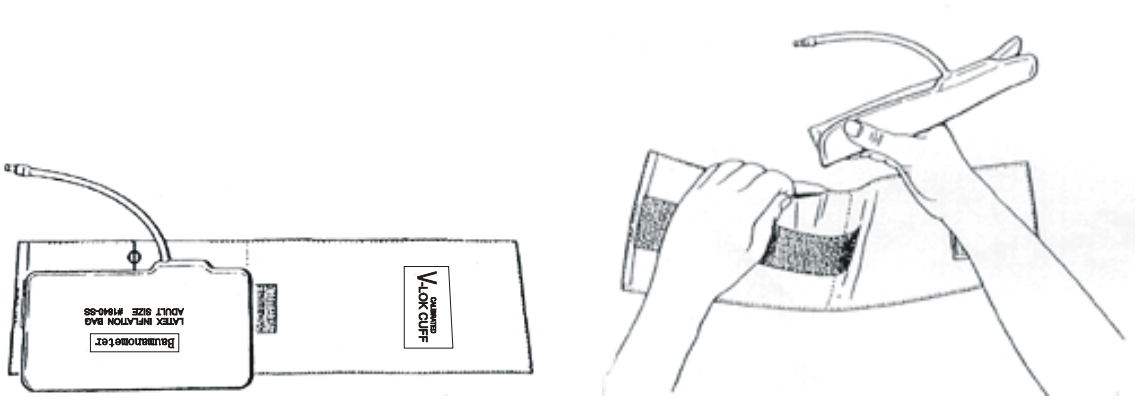


Figure 12-1 Replace the Rubber Bag in the Cuff

CAUTION

1 Do not squeeze the rubber tube on the cuff.
2 Do not dry-clean the cuff.
3 Only clean the outer surface of the connectors, make sure no liquid goes into the connector.
4 When the reusable cuff is not connected with the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.

13.3 Disinfecting

To disinfect the transducers and leads, follow these steps:

1) Clean the accessories.
2) Wipe them with a soft cloth dampened in the recommended disinfectant.
3) Wipe them clean with a soft cloth dampened in water.
4) Air-dry them or wipe the remaining moisture with a soft dry cloth.

The table below lists the allowed disinfectant bases:

Type	Recommended
Fetal/Maternal Monitor	Ethanol 75% Isopropanol 70%
Base Station	
US and TOCO Transducers (the wired and wireless)	
Remote Event Marker	
DECG Cable	
IUP Cable	
ECG Leads	
SpO_2 Transducer	
TEMP Transducer	
NIBP Cuff	Ethanol 75% Isopropanol 70%
NIBP Cuff Extension Tube	

CAUTION

1 Do not use any disinfectant containing additional active ingredients other than those listed.

2 Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.

3 Do not immerse any part of the 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 (e.g. the belt loses its elasticity), replace the damage part(s) or contact the manufacturer for service before reusing them.

6 Please do not light the TOCO transducer with ultraviolet light for a long time.

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.

13.4 Sterilizing

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

NOTE:

Check if the monitor, the base station, cables and accessories function well. If any problem is detected, please contact the manufacturer for service before reusing them.

Checking Item	Checking Method
Visual	Inspect the monitor, base station and cables etc. for any damage.
Power On	Power on the monitor. Does it boot up successfully without errors and enter the main menu?
Functionality Test	After power up, check whether the AC power indicator and battery status indicator in the bottom left of the screen display as stated in *3.3.1* section.
Performance	Please check the US transducer and TOCO transducer according to *7.2.6 Testing US Transducers* and *7.5.4 Testing TOCO Transducers.* FTS-3 wireless transducers also can be tested accordingly.
System	When the monitor is connected to FTS-3, please check whether the base station working channel and its battery status indicator in the bottom right of the screen display as stated in *3.3.1* section.

Chapter 14 Warranty and Service

14.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) damage caused by mishandling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by EDAN.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

14.2 Contact information

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

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix 1 Product Specifications

A1.1 Environmental Specifications

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

Working	Temperature:	+5 ºC ~ + 40 ºC (+41 ºF ~ +104 ºF)
	Relative Humidity:	15% ~ 93% (non-condensing)
	Atmospheric Pressure:	860hPa ~ 1060hPa
Transport and Storage	Temperature:	-20 ºC ~ +55 ºC (-4ºF ~ +131 ºF)
	Relative Humidity:	15% ~ 93% (non-condensing)
	Atmospheric Pressure:	700hPa ~ 1060hPa

A1.2 Physical Specifications

Monitor		
Dimensions and Weight	Size (depth x width x height): 347mm × 330mm × 126mm	
	Weight:	F6: Approx. 5.3 kg F6 Express: Approx. 6.1kg F9: Approx. 5.5 kg F9 Express: Approx. 6.3 kg
Power Supply	Operating Voltage:	100V-240V~
	Operating Frequency:	50Hz/60Hz
	Input Power :	1.0A-0.5A
	Battery:	14.8VDC/5000mAh
Standards Compliance	IEC 60601-1:2005, EN 60601-1:2006/AC:2010, IEC 60601-1-2:2007, EN 60601-1-2:2007/AC:2010, IEC/EN 60601-2-27, IEC/EN 60601-2-37, IEC/EN 60601-2-49,	

	IEC 80601-2-30, ISO 80601-2-61, ISO 80601-2-56, EN 12470-4, AAMI/ANSI EC13	
Anti-electric Shock Type	Class I equipment with internal power supply	
Anti-electric Shock Degree	FHR1, FHR2, TOCO, FM, IUP SpO_2, NIBP DECG ECG, TEMP	BF BF (Defibrillating-proof) CF CF (Defibrillating-proof)
Degree of Protection against Harmful Ingress of Water	Main Unit: IPX1, protected against vertically falling water drops(provided recorder drawer is shut and the monitor is not mounted on the wall vertically) US/TOCO Transducers: IPX8, protected against the effects of continuous emersion in water	
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	CISPR11 Group 1 Class A	
Working System	Continuous running equipment	
Display (F6/F6 Express)		
LCD Size:	10.1” (Diagonal)	
Resolution:	800 × 480	
Display (F9/F9 Express)		
Screen Diagonal:	12.1”	
Pixel:	800(H) × 600(V)	
Signal Interface		
DB9 network interface, RJ45 interface		
Ultrasound Transducer		
Cable Length:	2.5m	
Weight:	190 g	

Dimension:	88 mm × 35 mm
TOCO Transducer	
Cable Length:	2.5 m
Weight:	180 g
Dimension:	88 mm × 35 mm
Remote Event Marker	
Length:	2.5 m
Weight:	56 g
ECG	
Cable Length:	3 m
Weight:	213 g
SpO2	
Cable Length:	2.4 m
Weight:	68 g
NIBP	
Cable Length:	3.3 m
Weight:	194 g
TEMP	
Cable Length:	3 m
Weight:	55 g

A1.3 Performance Specifications

Ultrasound	Technique:	Ultrasound Pulse Doppler with autocorrelation
	Pulse Repetition Rate:	2 KHz
	Pulse Duration:	92 μs
	Ultrasound Frequency:	(1.0±10%) MHz
	Ultrasound Signal Range:	3.5uV Vpp~350 uV Vpp
	p- <1 MPa	
	I_{ob} <10 mW/cm^2	
	I_{spta} <100 mW/cm^2	
	I_{sata}<20 mW/cm^2	

	$I_{sppa.3}$<190W/cm^2	
	$I_{spta.3}$<94mW/cm^2	
	Max Output Power <15mW	
	Effective Radiating Area:	942 mm^2 ± 15%
	FHR Measurement Range:	50 bpm ~ 240 bpm
	Resolution:	1 bpm
	Accuracy:	±2 bpm (F6/F6 Express) ±1 bpm (F9/F9 Express)
	Dielectric Strength:	4000Vrms
	Maximum transducer temperature rise during use:	Less than 5 °C (9ºF)
	Expanded uncertainty of temperature test:	U=0.4°C (0.72ºF), k=2
DECG	Technique:	Peak-peak detection technique
	DFHR Measurement Range:	30bpm ~ 240bpm
	Resolution:	1bpm
	Accuracy:	±1bpm
	Input Impedance:	> 10M (Differential, DC50/60Hz)
	Input Impedance:	> 20M (Common Mode)
	CMRR:	> 110dB
	Noise:	< 4μVp
	Skin Voltage Tolerance:	±500mV
	Fetal Input Voltage Current:	20μVp-3mVp
TOCO	TOCO Range:	0% ~ 100%
	Non-linear Error:	±10%
	Baseline Drift due to Temperature Changes	1 unit/min/°C (free air)
		5 units/min/°C (underwater)
	Resolution:	1%
	Zero Mode:	Automatic(TOCO value becomes zero or below lasting for 30 seconds)/ Manual
	Dielectric Strength:	4000Vrms
IUP	Pressure Range:	0 ~ 100mmHg
	Sensitivity:	5μV/V/mmHg

	Non-linear Error:	± 3mmHg
	Resolution:	1%
	Zero Mode:	Manual
Fetal Movement		
Technique:	Pulsed Doppler ultrasound	
FM Mode	Automatic/Manual	
AFM Mode	Trace or blackmark	
Display Range	0-999	
ECG	HR Measurement Range:	30 bpm ~ 240 bpm
	Input Signal Range:	±8 mV PP
	HR Measuring Accuracy:	±2 bpm
	ECG Waveform:	Manual control ECG waveform display
	ECG falls off:	Detect automatically
	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
	Differential Input Impedance	>5MΩ
	Display Sensitivity	2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2), AUTO gain
	Sweep speed	25mm/s
	d.c. Offset Voltage Tolerance	±500mV
	Auxiliary Current (Leads off detection)	Active electrode: < 100 nA Reference electrode: < 900 nA

ECG	Accuracy and Response to Irregular Rhythm	According with ANSI/AAMI EC13-2002 Sect.4.1.2.1 e) The HR value displays after a stable period of 20s: Ventricular bigeminy: 80bpm±1bpm Slow alternating ventricular bigeminy: 60bpm±1bpm Rapid alternating ventricular bigeminy: 120bpm±1bpm Bidirectional systoles: 91bpm±1bpm
	Response time to Change in HR	HR range: 80bpm ~ 120bpm Range: 7s ~ 8s (average: 7.5s) HR range: 80bpm ~ 40bpm Range : 7s ~ 8s (average: 7.5s)
	Accuracy of HR Alarm Limit	1 bpm
	Tall T-wave Rejection	Exceeds ANSI/AAMI EC13-2002 Sect. 4.1.2.1 (C) minimum recommended 1.2mV T-Wave amplitude
	HR averaging method	Heart rate is computed by averaging the 12 most recent RR intervals.
SpO_2	Measurement Range:	50% ~ 100%
	Resolution:	1%
	Measuring Accuracy (EDAN):	90% ~ 100% ± 2% 70% ~ 90% ± 4% < 70% unspecified
	Measuring Accuracy (Nellcor):	70% ~ 100% ± 2% < 70% unspecified
	Data Update Period:	2 seconds (typically) 10 seconds (in extreme condition)
	PR Measurement Range:	30 bpm ~ 240 bpm
	PR Measuring Accuracy:	±3 bpm
	Data update period (EDAN)::	1s
	Data update period (Nellcor):	2s
	Wave length	
	Red light	(660±3) nm

	Infrared light	(905±10) nm
	Emitted light energy	< 15 mW
	Information about the wave length range can be especially useful to clinicians (for instance, when photodynamic therapy is performed.)	
NIBP (for adult)	Measurement Range:	
	Systolic pressure:	40mmHg ~ 270mmHg
	Diastolic pressure:	10mmHg ~ 215mmHg
	Measuring Time:	≤ 120 seconds
	Software Over Voltage Protection:	(297 ± 3) mmHg
	Hardware Over Voltage Protection:	(320 ± 10) mmHg
	Cuff pressure measuring range:	0 mmHg ~ 300 mmHg
	Resolution:	1 mmHg
	Measuring Accuracy	
	Max. average deviation:	≤ ±5mmHg
	Max. standard deviation:	≤ 8mmHg
TEMP	Channel:	1
	Measuring Mode:	Direct Mode
	Position:	Axilla
	Measurement Range:	0ºC ~ +50ºC (+32ºF ~ +122ºF)
	Accuracy: (sensor error excluded)	0ºC ~ +25ºC (+32ºF ~ +77ºF): ± 0.2ºC (±0.36ºF) +25ºC ~ +45ºC (+77ºF ~ +113ºF): ± 0.1ºC (±0.18ºF) +45ºC ~ +50ºC (+113ºF ~ +122ºF): ± 0.2ºC (±0.36ºF)
	Refresh Time:	Every 1s to 2s
	Accessory:	TEMP sensor

A1.4 Recorder Specifications

Paper:	Z-fold, thermosensitive (compatible with GE and PHILIPS recorder paper)
Paper width:	152mm (GE), 150mm (PHILIPS)

Effective printing width:	110mm (American Standard) 120mm (International Standard)
FHR printout width:	70mm (American Standard) 80mm (International Standard)
FHR scaling:	30bpm/cm (American Standard) 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 15mm/sec
Accuracy of data:	± 5% (X axis) ± 1% (Y axis)
Resolution:	8 dots/mm
Record Information:	FHR1 trace/mark, FHR2 trace/mark, TOCO trace, AFM trace/black mark, fetal movement mark, event mark (and annotation), AUTO-zero symbol, alarm indicator, date, time, printing speed, ID, name, FHR2 Offset, HR, SpO_2, SYS, DIA, TEMP, CTG analysis results etc.

A1.5 Rechargeable Lithium-ion Battery

Type:	Rechargeable Lithium-ion Battery
Continual Working Time:	>2 hours
Necessary Charge Time:	<7hours
Nominal Capacity:	5000mAh
Nominal Voltage:	14.8V
Cycle Life:	> 300 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)	TI Type	TI Value	MI	$Ipa.3@MI_{max}$ (W/cm^2)
PW1.0MHz (**F6/F6 Express** US Transducer)	1.288	TIS	0.006149	0.01405	0.007225
		TIB	0.04687		
PW1.0MHz (**F9/F9 Express** US Transducer)	1.817	TIS	0.008761	0.01567	0.01025
		TIB	0.05723		

B FTS-3 Fetal Telemetry System

B1.1 Environmental Specifications

Working	Temperature:	+5 ºC ~ +40 ºC (+41ºF ~ +104ºF)
	Relative Humidity:	15% ~ 93% (non-condensing)
	Atmospheric Pressure:	860hPa ~ 1060hPa
Transport and Storage	Temperature:	-20 ºC ~ +55 ºC (-4ºF ~ +131 ºF)
	Relative Humidity:	15% ~ 93% (non-condensing)
	Atmospheric Pressure:	700hPa ~ 1060hPa

B1.2 Physical Specifications

Size:	250x200x85mm	
Weight:	Approximately 1.8 kg	
Power Supply	Operating Voltage:	100V-240V~
	Operating Frequency:	50Hz/60Hz
	Input Power :	0.8A-0.3A
	Battery:	14.8VDC/5000mAh
Standards Compliance	IEC 60601-1:2005, EN 60601-1:2006/AC:2010, IEC 60601-1-2:2007, EN 60601-1-2:2007/AC:2010, IEC/EN 60601-2-37. FCC 47 CFR Part 95	
Anti-electric Shock Type	Class I equipment with internal power supply	
Anti-electric Shock Degree	FHR1, FHR2, TOCO BF	
Degree of Protection against Harmful Ingress of Water	IPX8	
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	CISPR11 Group 1 Class A
Ground 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. 100μA 500μA
Patient Auxiliary Current (Limit):	N.C. S.F.C. d.c. 10μA 50μA a.c. 100μA 500μA
Base Station	
Weight:	1.8 kg
Size:	310mm x 235mm x81mm
US Transducer	
Weight:	About 150 g
Size:	Ø81 mm × 35 mm
TOCO Transducer	
Weight:	About 150 g
Size:	Ø81 mm × 35 mm

B1.3 Performance Specifications

Ultrasound	
Technique:	Ultrasound Pulse Doppler with autocorrelation
Pulse Repetition Rate:	2 KHz
Pulse Duration:	92 μs
Ultrasound Frequency:	(1±10%) MHz

$p_- < 1$ MPa	
I_{ob}<10 mW/cm^2	
I_{spta}<100 mW/cm^2	
FHR Measurement Range:	50 bpm ～ 240 bpm
Resolution:	1 bpm
Accuracy:	±2 bpm
Dielectric Strength:	4000 Vrms
TOCO	
TOCO Range:	0% ~ 100%
Non-linear Error:	±10%
Baseline Drift due to Temperature Changes	1 unit/min/°C (free air)
	5 units/min/°C (underwater)
Resolution:	1%
Zero Mode:	Automatic/ Manual
Dielectric Strength:	4000 Vrms
RF Index	
Transmission Power:	< 10mW e.r.p
Frequency Range:	608.00MHz~614.00MHz
Transmission Range (line of sight):	>110m
Modem Mode:	FSK
Transmission Rate:	About 25kbps
Channel Range:	1~32
Transducer Antenna:	FM antenna
Base Station Antenna:	Internal antenna

B1.4 Rechargeable Lithium-ion Battery

Base Station Battery	
Nominal Capacity:	5000 mAh
Continuous Work Time:	≥40 Hours
Nominal Voltage:	14.8 V
Necessary Charge Time:	≤14 Hours
Cycle Life:	>300 times
Transducer Battery	
Nominal Capacity:	1600 mAh
Charge Current (Standard):	700 mA
Continuous Work Time:	>16 Hours
Nominal Voltage:	3.7 V
Charge Voltage (Standard):	(4.2±0.1) V
Cycle Life:	≥500 times

B1.5 Low Output Summary Table

Low Output Summary Table

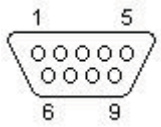
(for systems with no transducers having global maximum index values exceeding 1.0)
System: Fetal Telemetry System

Transducer Model	$I_{spta.3}$ (mW/cm^2)	TI Type	TI Value	MI	Ipa.3@MI_{max} (W/cm^2)
PW1.0MHz	0.6186	TIS	0.002949	0.01087	0.003412
		TIB	0.01939		

Appendix 2 Signal Input/Output Connector

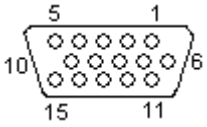
Accessory equipment connected to these interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 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



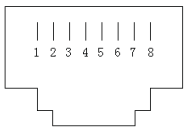
Pin	Signal	Input/Output
1	+5V	Output
2	Rx	Input
3	Tx	Output
4	485EN	Input
5	0V Ref.	
6	TA	Output
7	TB	Output
8	RA	Input
9	RB	Input

D-Sub Interface



Pin	Signal	Input/Output
1	US2	Input
2	ISOCNS_RXD	Input
3	ISOCNS_TXD	Output
4	485EN	Input
5	0V Ref.	
6	TA	Output
7	TB	Output
8	RA	Input
9	RB	Input
10	DECG_SIGNAL	Input
11	US1	Input
12	+5V	Output
13	TOCO	Input
14	DECG_GND	
15	EN	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	

CAUTION

Only the PC recommended by the manufacturer can be connected to the signal input/output interface of the monitor. Other equipment is forbidden.

Appendix 3 Troubleshooting

A3.1 No Display

Phenomenon	Possible Cause	Solution
Power indicator is off.	Power cable is loose.	Tighten the power cable.
	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
Noise	Too high volume setup.	Turn down the volume.
	Interfered by mobile phone or other electromagnetic interference source.	Turn off or move the interference source.
		Move the monitor to a place with less interference.

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

A3.4 Trouble with Ultrasound FHR Monitoring

Phenomenon	Possible Cause	Solution
Inconstant trace / display	The patient is overweighted.	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.
	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 the 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.

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
Bad trace quality or fluctuant TOCO baseline	The belt is too tight or too loose.	Adjust the belt.
	The belt has no elasticity.	Renew the belt.
	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.

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 Big ECG Signal Interference or Thick Baseline

Phenomenon	Possible Cause	Solution
Big ECG signal interference or thick baseline	Abnormal electrodes placing or electrodes invalidation.	Check the electrodes placing and the period of validity of electrodes.
	The cable connector is not well connected.	Check the connection of cable connector.
	Power socket has no standard ground wire.	Check if power socket has standard ground wire.
	The special ground wire connecting with monitor is not properly earthed.	Check if the special ground wire connecting with monitor is earthed.

A3.9 NIBP and SpO2 No Results

Phenomenon	Possible Cause	Solution
NIBP and SpO_2 have no results	The NIBP cuff is not properly wrapped to the position of patient's arm.	Check if the NIBP cuff is properly wrapped to the position of patient's arm.
	The NIBP can not be inflated.	Extend catheter, and check the connection.
	Hose connector plug is not connected well with the NIBP socket.	Check if the hose connector plug is connected well with the NIBP socket.
	SpO_2 sensor is not connected well with the SpO_2 socket.	Check if the SpO_2 sensor is connected well with the SpO_2 socket.
	Abnormal working condition.	Shut off the power, then switch it on again.

A3.10 Blown Fuses

WARNING

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: Φ5mm*20mm; Model: T2AH250V.

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.

B FTS-3 Fetal Telemetry System

B3.1 Troubleshooting

Phenomenon	Possible Cause	Solution
Take out the US transducer, but it cannot power on.	① It runs out of power. ② The base station cannot communicate with the transducer by RF.	① Recharge the transducer. ② Put it back in the docking slot and take it up again. If the problem persists, restart the base station.
The wireless connection indicator is green but the fetal monitor shows no signal.	① Loose or damaged cable to the monitor socket	① Tighten or repair the cable.
FHR or TOCO record interrupts.	① Transducer is placed incorrectly. ② Transducer slides. ③ The patient walks in strong tramps. ④ RF interference or out of prescriptive area.	① Check the transducer position. ② Tighten the transducer and apply little coupling gel. ③ Ask the patient to walk slightly. ④ Ask the patent to walk in the prescriptive area.
The battery icon does not display when charging the battery.	① The transducer does not connect to the charging point tightly. ② The base station is not supplied by AC power.	① Press the transducer to touch the charging point. ② Ensure the base station is not supplied by AC power.
The charging board or charging point is corrosive.	① It is wet or polluted by the coupling gel.	① Clean the transducer before charging. Replace the charging point if necessary.

B3.2 Blown Fuses

WARNING

Switch off the base station and remove the power cord before changing the fuse.

Replace the fuse when it is blown.

The two fuses of the base station are located on the rear panel, their specifications are:

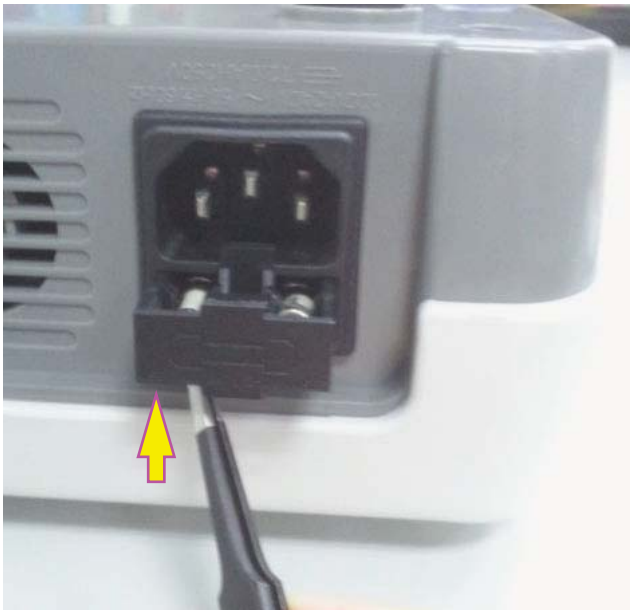
Size: Φ5mm*20mm; Model: T2AH250V.

To replace a fuse:

1) Place the base station on a flat surface and remove the power cord.

2) Reverse the base station and pull the fuse container out as far as it can go.

3) Use a screw driver or a pair of pliers to push the fuse up from the bottom of the container.



4) Take the fuse out and replace it with a new one that is supplied by the manufacturer or of the same specifications.

5) Push the fuse container all the way back in position.

Appendix 4 Ultrasound Intensity and Safety

A4.1 Ultrasound in Medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. Given its known benefits for non-invasive investigations and medical diagnosis, including investigation of the human fetus, the question of clinical safety with regards to ultrasound intensity arises.

There is no easy answer to the question of safety surrounding the use of diagnostic ultrasound equipment. Application of the ALARA (As Low As Reasonably Achievable) principle serves as a rule-of-thumb that will help you to get reasonable results with the lowest possible ultrasonic output.

The American Institute of Ultrasound in Medicine (AIUM) states that given its track record of over 25 years of use and no confirmed biological effects on patients or instrument operators, the benefits of the prudent use of diagnostic ultrasound clearly outweigh any risks.

A4.2 Ultrasound Safety and the ALARA Principle

Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. Although this effect is extremely low with Doppler, it is important to know how to control and limit patient exposure. Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound, however, exposure levels should always be limited to As Low As Reasonably Achievable (the ALARA principle).

A4.3 Explanation of MI/TI

A4.3.1 MI (Mechanical Index)

Cavitations will be generated when ultrasound wave passes through and contacts tissues, resulting in instantaneous local overheating. This phenomenon is determined by acoustic pressure, spectrum, focus, transmission mode, and factors such as states and properties of the tissue and boundary. This mechanical bioeffect is a threshold phenomenon that occurs when a certain level of ultrasound output is exceeded. The threshold is related to the type of tissue. Although no confirmed adverse mechanical effects on patients or mammals caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported, the threshold for cavitation is still undetermined. Generally speaking, the higher the acoustic pressure, the greater the potential for mechanical bioeffects; the lower the acoustic frequency, the greater the potential for mechanical bioeffects.

The AIUM and NEMA formulate mechanical index (MI) in order to indicate the potential for mechanical effects. The MI is defined as the ratio of the peak-rarefactional acoustic pressure (should be calculated by tissue acoustic attenuation coefficient 0.3dB/cm/MHz) to the acoustic frequency.

$$MI = \frac{P_{r,\ \alpha}}{f_{awf} \times C_{MI}}$$

$$C_{MI} = 1\ (\text{MPa} / \text{MHz})$$

A4.3.2 TI (Thermal Index)

Heating of tissues is caused by absorption of ultrasound when the ultrasound energy is applied. The temperature rise is determined by the acoustic intensity, exposed area and thermophysical properties of the tissue.

In order to indicate the potential for temperature rise caused by thermal effects, the AIUM and NEMA formulate thermal index (TI). It is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1ºC (1.8ºF).

According to different thermophysical properties of the tissue, TI is divided into three kinds: TIS, TIB and TIC.

TIS (Soft Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.

TIB (Bone Thermal Index): It provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

TIC (Cranial Bone Thermal Index): It provides an estimate of potential temperature rise in the cranial bones or superficial bones.

A4.3.3 Measurement Uncertainty

The uncertainties in the measurements were predominantly systematic in origin; the random uncertainties were negligible in comparison. The overall systematic uncertainties were determined as follows:

1. Hydrophone Sensitivity

Based on the HNP-0400 hydrophone calibration certificate, the hydrophone measurement uncertainty for 1-15MHz is 1 dB, which is equivalent to an uncertainty of ±12.20% for intensity and ±6.10% for pressure. This uncertainty is used in PW measurement uncertainty assessment.

2. Digitizer

Based on the oscilloscope calibration certificate, the oscilloscope uncertainty is ±1.16% for intensity and ±0.58% for pressure.

3. Temperature

Based on the temperature variation of the water bath, the uncertainty is ±1.6% for intensity and ±0.8% for pressure.

4. Spatial Averaging

±10.2% for intensity, and ±6.1% for pressure.

5. Non-linear Distortion:

N/A. No effects of nonlinear propagation were observed.

Since all the above error sources are independent, they may be added on an RMS basis, giving a total uncertainty of ± 26.62 percent for all intensity values reported, ± 13.31 percent for all the

pressure values and ± 14.52 percent for the Mechanical Index.

A4.4 Prudent Use Statement

Although no confirmed bioeffects on patients caused by exposure from present diagnostic ultrasound equipment have ever been reported, the potential exists that such bioeffects may be identified in the future. Therefore, the ultrasound should be used prudently. High levels of acoustic output and long exposure time should be avoided while acquiring necessary clinical information.

A4.5 References for Acoustic Output and Safety

1. “Bioeffects and Safety of Diagnostic Ultrasound” issued by AIUM in 1993
2. “Medical Ultrasound Safety” issued by AIUM in 1994
3. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" issued by AIUM/NEMA in 2004
4. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004
5. "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in 2008.
6. “Medical electrical equipment—Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2007.

A4.6 Probe Acoustic Output Parameters List

A4.6.1 Test of Wired Probe

Acoustic Output Reporting Table (F9/F9 Express)

Operating Mode: PW mode

Working Frequency: 1.0MHz

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt≤1	Aaprt>1		
Global Maximum Index Value			0.01567			0.008761	0.05723	N/A
Associated Acoustic Parameters	$P_{r.a}$ (MPa)		0.01567					
	P (mW)						11.52	N/A
	Min of $[P_a(Z_s),I_{ta.a}(Z_s)]$ (mW)					1.84		
	Z_s (cm)					13.95		
	Z_{bp} (cm)					5.188		
	Z_b (cm)					13.60		
	Z at max $I_{pi.a}$ (cm)		13.80				13.80	
	deq(Z_b) (cm)						1.75	
	f_{awf} (MHz)		1.00			1.00	1.00	N/A
	Dim of Aaprt	X (cm)				Φ3.46	Φ3.46	N/A
		Y (cm)				Φ3.46	Φ3.46	N/A
Other Information	td (usec)		88.72					
	prr (Hz)		2000					
	P_r at max I_{pi} (MPa)		0.02930					
	Deq at max I_{pi} (cm)						1.73	
	$I_{pi.3}$ at max MI (W/cm^2)		0.01025					
	Focal Length	Flx (cm)				N/A		
		Fly (cm)				N/A		
Operating Control Conditions	Focus(mm)		Fixed					
	Depth(mm)		Fixed					
	Freq(MHz)		1.0					

Operating Mode: PW mode

Working Frequency: 1.0MHz

Acoustic Output			MI	$I_{spta.3}$ (mW/cm^2)	$I_{sppa.3}$ (W/cm^2)
Global Maximum Value			0.01567	1.817	0.01025
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.01567		
	W_0 (mW)			11.52	11.52
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		13.65	13.65	13.65
	Beam dimensions	X_{-6} (cm)		0.5795	0.5795
		Y_{-6} (cm)		0.6061	0.6061
	PD (usec)		88.72		88.72
	PRF (Hz)		2000		2000
	EDB	A_z (cm)		Φ3.46	
		E_{le} (cm)		Φ3.46	
Operating Control Conditions	Fixed				

Acoustic Output Reporting Table (F6/F6 Express)

Operating Mode: PW mode

Working Frequency: 1.0MHz

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt≤1	Aaprt>1		
Global Maximum Index Value			0.01405			0.006149	0.04687	N/A
Associated Acoustic Parameters	$P_{r.a}$ (MPa)		0.01405					
	P (mW)						10.70	N/A
	Min of $[P_a(Z_s),I_{ta.a}(Z_s)]$ (mW)					1.29		
	Z_s (cm)					13.45		
	Z_{bp} (cm)					4.236		
	Z_b (cm)					13.35		
	Z at max $I_{pi.a}$ (cm)		13.45				13.45	
	deq(Z_b) (cm)						2.04	
	f_{awf} (MHz)		1.00			1.00	1.00	N/A
	Dim of Aaprt	X (cm)				Φ2.83	Φ2.83	N/A
		Y (cm)				Φ2.83	Φ2.83	N/A
Other Information	td (usec)		89.36					
	prr (Hz)		2000					
	P_r at max I_{pi} (MPa)		0.0229					
	Deq at max I_{pi} (cm)						2.04	
	$I_{pi.3}$ at max MI (W/cm^2)		0.007225					
	Focal Length	Flx (cm)				N/A		
		Fly (cm)				N/A		
Operating Control Conditions	Focus(mm)		Fixed					
	Depth(mm)		Fixed					
	Freq(MHz)		1.0					

Operating Mode: PW mode

Working Frequency: 1.0MHz

Acoustic Output			MI	$I_{spta.3}$ (mW/cm^2)	$I_{sppa.3}$ (W/cm^2)
Global Maximum Value			0.01405	1.288	0.007225
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.01405		
	W_0 (mW)			10.70	10.70
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		13.30	13.30	13.30
	Beam dimensions	X_{-6} (cm)		0.7092	0.7092
		Y_{-6} (cm)		0.7766	0.7766
	PD (usec)		89.36		89.36
	PRF (Hz)		2000		2000
	EDB	A_z (cm)		Φ2.83	
		E_{le} (cm)		Φ2.83	
Operating Control Conditions	Fixed				

A4.6.2 Test of Wireless Probe (FTS-3)

Acoustic Output Reporting Table

Operating Mode: PW mode

Working Frequency: 1.0MHz

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt≤1	Aaprt>1		
Global Maximum Index Value			0.01087			0.002949	0.01939	N/A
Associated Acoustic Parameters	$P_{r.a}$ (MPa)		0.01087					
	P (mW)						3.496	N/A
	Min of $[P_a(Z_s),I_{ta.a}(Z_s)]$ (mW)					0.62		
	Z_s (cm)					12.50		
	Z_{bp} (cm)					5.188		
	Z_b (cm)					11.95		
	Z at max $I_{pi.a}$ (cm)		12.10				12.10	
	deq(Z_b) (cm)						1.77	
	f_{awf} (MHz)		1.00			1.00	1.00	N/A
	Dim of Aaprt	X (cm)				Φ3.46	Φ3.46	N/A
		Y (cm)				Φ3.46	Φ3.46	N/A
Other Information	td (usec)		90.65					
	prr (Hz)		2000					
	P_r at max I_{pi} (MPa)		0.01743					
	Deq at max I_{pi} (cm)						1.74	
	$I_{pi.3}$ at max MI (W/cm^2)		0.003412					
	Focal Length	Flx (cm)				N/A		
		Fly (cm)				N/A		
Operating Control Conditions	Focus(mm)		Fixed					
	Depth(mm)		Fixed					
	Freq(MHz)		1.0					

Operating Mode: PW mode

Working Frequency: 1.0MHz

Acoustic Output			MI	$I_{spta.3}$ (mW/cm^2)	$I_{sppa.3}$ (W/cm^2)
Global Maximum Value			0.01087	0.6186	0.003412
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.01087		
	W_0 (mW)			3.496	3.496
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		11.80	11.80	11.80
	Beam dimensions	X_{-6} (cm)		0.5663	0.5663
		Y_{-6} (cm)		0.5437	0.5437
	PD (usec)		90.65		90.65
	PRF (Hz)		2000		2000
	EDB	A_z (cm)		Φ3.46	
		E_{le} (cm)		Φ3.46	
Operating Control Conditions	Fixed				

Appendix 5 Abbreviation

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

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
DIA	Diastolic Blood Pressure
ECG	Electrocardiogram
FH	Fetal Heart
FHR	Fetal Heart Rate
FM	Fetal Movement
FS	Fetal Stimulator
HR	Heart Rate
ICU	Intensive Care Unit
ID	Identity
IUP	Intra-Uterine Pressure
IUPC	Intra-Uterine Pressure Catheter
LCD	Liquid Crystal Display
MAP	Mean Artery Blood Pressure
MECG	Maternal ECG
MFM	Manual Fetal Movement [Detection]
MRI	Magnetic Resonance Imaging
NIBP	Non-Invasive Blood Pressure
NST	Non Stress Test
PR	Pulse Rate
SOV	Signals Overlap Verification
SpO_2	Pulse Oximetry

STV	Short-Term Variation
SYS	Systolic Blood Pressure
TEMP	Temperature
TOCO	Tocotonometer
UA	Uterine Activity [TOCO]
US	Ultrasound [Transducer]

Appendix 6 Ordering Information

Accessories (standard and optional configuration) supplied or approved by the manufacturer can be used with the monitor. See the following table for details. The accessories employed by us, such as the rechargeable battery, are products having passed the authentication of CE, and they have the characteristics specified by their manufacturers. The materials with which the patient can come into contact conform to the standard of ISO 10993.

Accessory (Spare Part)	Part Number
US Transducer 1 (purple label, for **F9/F9 Express**)	02.01.31528
US Transducer 2 (yellow label, for **F9/F9 Express**)	02.01.107705
US Transducer (pink label, for **F6/F6 Express**)	02.01.109301
Wireless US Transducer (American Standard)	02.01.000925
Wireless TOCO Transducer (American Standard)	02.01.000926
FTS-3 Overall Unit	83.62.001974
FTS-3 Overall Unit (Singleton Pregnancy)	83.62.002459
TOCO Transducer	02.01.31527
TOCO Transducer (IUP)	02.01.107791
Remote Event Marker	02.01.210095
Belt	01.57.471447
DECG Cable	01.13.036358
Disposable Fetal Spiral Electrode	01.57.02145
Disposable Attachment Pad Electrode	01.57.02146
IUP Cable	01.13.104152
IUP Connecting Cable	01.13.036357
Disposable Intrauterine Pressure Catheter	01.57.104153
3-lead ECG Cable (Grabber style, IEC)	01.57.471098
3-lead ECG Cable (Grabber style, AHA)	01.57.471095

Disposable ECG Electrode (US)	01.57.471276
SpO_2 Sensor	02.01.109069
NIBP Cuff (Upper Arm Perimeter 27cm-35cm, for Adult)	01.57.471330
NIBP Cuff Extension Tube	01.57.471005
TEMP Sensor	01.15.040187
Thermosensitive Recorder Paper (GE-American)	01.57.75111
Thermosensitive Recorder Paper (GE-International)	01.57.75112
Thermosensitive Recorder Paper (Philips-American)	01.57.75113
Thermosensitive Recorder Paper (Philips-International)	01.57.75114
Power Cord (American Standard)	21.13.036384
Fuse T2AH250V	21.21.064181
Rechargeable Lithium-ion Battery	21.21.064150
Rechargeable Lithium-ion Battery (FTS-3)	01.21.064143

CAUTION

Replacement of all above accessories can be performed by the operator. But only the accessories supplied or recommended by the manufacturer are allowed connected to the monitor.

Appendix 7 EMC Information

A7.1 Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacture’s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The F Series Fetal & maternal Monitor is intended for use in the electromagnetic environment specified below. The customer of the user of the F Series Fetal & maternal Monitor should assure that it is used in such and environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The F Series Fetal & maternal Monitor 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.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The F Series Fetal & maternal Monitor is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

A7.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The *F Series Fetal & maternal Monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *F Series 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 ± 1 kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) 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.

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

A7.3 Electromagnetic Immunity

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The F Series Fetal & maternal Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of F Series Fetal & maternal Monitor should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V_{rms}
150 kHz to 80 MHz</td><td>3 V_{rms}</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the F Series Fetal & maternal Monitor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td><td>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 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:
  </td></tr>
</table>

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

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

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *F Series Fetal & maternal Monitor* is used exceeds the applicable RF compliance level above, the *F Series 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 *F Series Fetal & maternal Monitor*.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A7.4 Recommended Separation Distances

Recommended separation distances between

portable and mobile RF communications equipment and the

F Series Fetal & maternal Monitor

The *F Series 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 *F Series Fetal & maternal Monitor* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *F Series Fetal & maternal Monitor* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

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.

Appendix 8 Limitations of Ultrasonic Monitoring

A8.1 How Does Ultrasound Work

When the ultrasound waves strike an object, they bounce back and create an echo. If the object moves toward the sound source, the frequency of the echo increases. If the object moves away from the sound source, the frequency of the echo decreases. This is called “Doppler Effect”. In the 1960's, the ultrasonic technique was first applied to medical diagnostic imaging.

The ultrasound process involves placing a small device called a transducer, against the skin of the patient near the region of interest. The ultrasound transducer combines functions of emitting and receiving ultrasounds in one device. This transducer produces a stream of inaudible, high frequency sound waves which penetrate into the body and bounce off the organs inside. It detects sound waves as they bounce off or echo back from the internal structures and contours of the organs. The movement of the organs produces the Doppler Effect, and this movement can be measured and described by measuring the echo.

In fetal monitoring, the ultrasound transducer produces a stream of sound waves which penetrate into the maternal abdomen and bounce off the fetal heart. Then the transducer receives the echoes and transfers them to the monitor, which turns the signal into fetal heart beating sound and fetal heart rate trace.

Therefore, placement of the transducer is critical to ultrasound fetal heart monitoring.

A8.2 Artifacts in Fetal Heart Monitoring

(1) How does artifact happen?

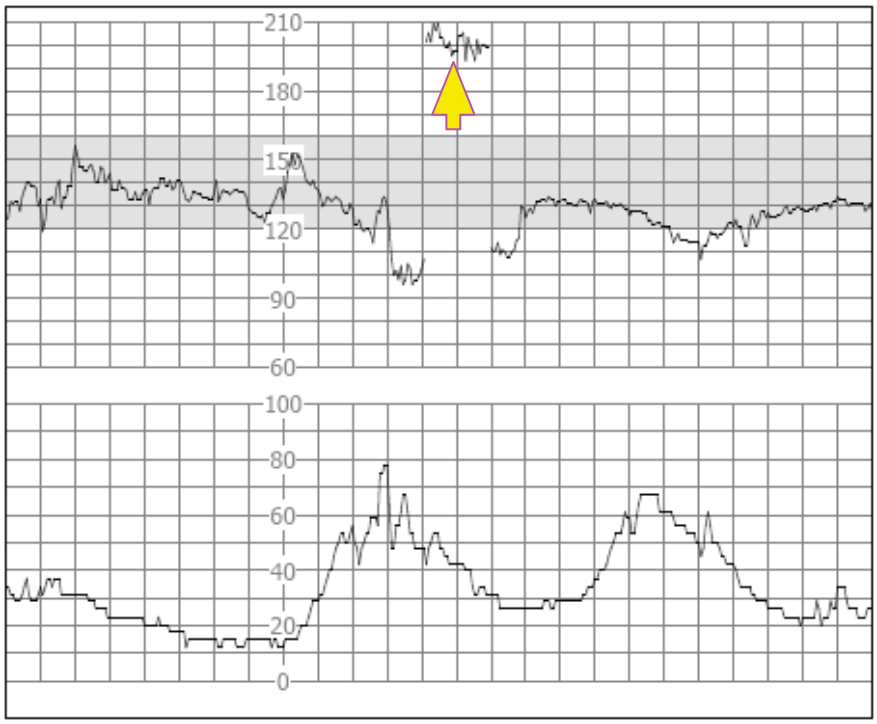
The transducer detects sound waves as they bounce off or echo back from the fetal heart. However, the sound waves bouncing off from maternal blood vessels may be detected by the transducer and then be processed by the monitor as well. As a result, artifacts may be produced.

The artifacts, if not correctly interpreted, may cause the physicians to perform unnecessary interventions, or to fail to detect the fetal distress and the need for interventions.

The most common artifacts are doubling and halving.

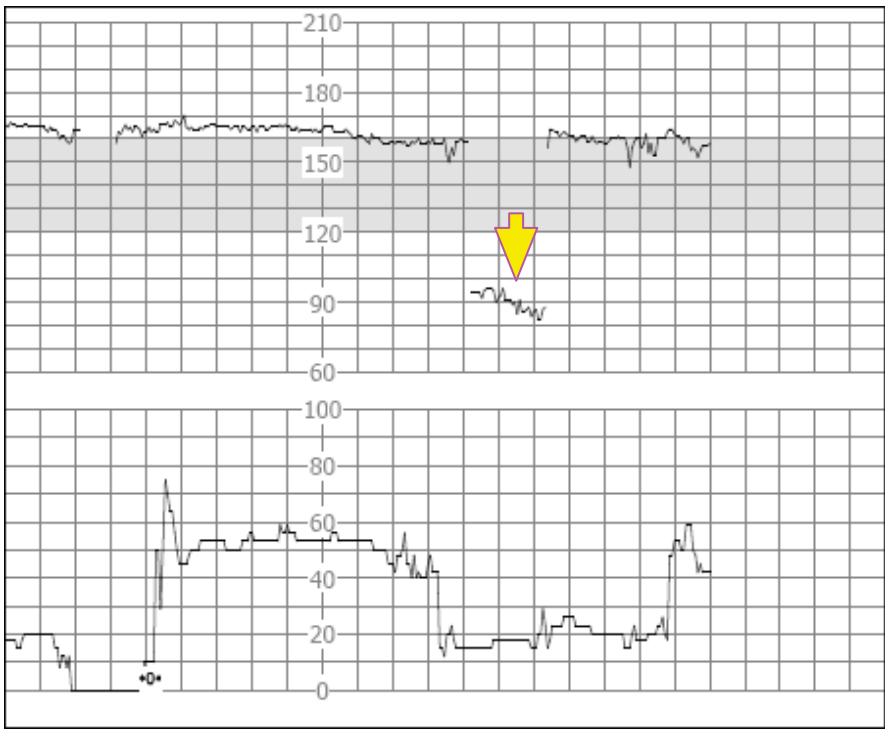
(2) Doubling:

When the FHR drops to 120 bpm or lower, the diastole and systole become far apart, thereby the monitor may mistake these two movements of a single heartbeat for two separate heartbeats. As a result, a heart rate trace that is double the actual heart rate is produced. This often happens during severe decelerations and bradycardia, representing an abrupt switch of the trace to double the actual heart rate.



(3) Halving:

When the FHR increases to 180 bpm or higher, it is possible for the monitor to mistake the two separate hearbeats for the diastole and systole of a single heartbeat. As a result, a heart rate trace that is half the actual heart rate is produced. This often happens during tachycardia, representing an abrupt switch of the trace to half the actual heart rate. The clinicians may interpret it as a "deceleration".



However, the heart beat sound from the monitor speaker is still reliable even when doubling or halving is occurring.

Stethoscopy should be applied when sudden changes in baseline are detected.

If the amniotic membrane rupture and cervical dilatation are sufficient, consider using a spiral electrode to obtain precise FHR with direct fetal ECG as the signal source.

(4) Erratic Traces / Drop out

When the fetal heart moves partially out of the ultrasound wave path, the transducer receives mixed or weak signals, and thereby the monitor presents erratic traces. When the fetal heart moves fully out of the path, inadequate consecutive and periodic signals are received, and no trace is represented.

Erratic traces and transitory episodes of drop out are common, especially when the fetus or/and mother move(s). If they exist for an extended period, it indicates that the transducer is not aimed at the fetus. Repositioning of the transducer is needed.

A8.3 Audio Output and Screen Reading

In most instances, the audio output from the monitor speaker corresponds to the readings presented on the monitor screen. But occasionally the fetal heart sound may differ from the trace and numeric.

When the fetal heart moves partially out of the ultrasound wave path, the transducer receives weaker FHR signal and other stronger signals (usually maternal heart/pulse rate). After the signals are transmitted to the monitor, the audio system and the video system of the monitor process the signals separately. On one hand, the audio circuit filters the low-frequency signals and gives audio output of the high-frequency signals, so fetal heart sound is heard. On the other hand, the autocorrelation algorithm computes the stronger signal source and thereby the maternal heart/pulse rate is displayed. As a result, the audio output differs from the screen reading.

If this situation occurs, it can be dismissed by repositioning the transducer.

In a word, the abnormalities listed above (artifacts, sound and reading differences) are caused by the limitations of ultrasonic monitoring technique. Fortunately they rarely occur. But a good understanding of how to detect them and what countermeasures should be taken will help obtain better fetal monitoring effect.

We hope you find this information useful. If you have any questions about fetal monitoring, please contact our sales representatives and perinatal specialists.

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