F3
Fetal Monitor

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

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

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.

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

NOTE:

1 In order to ensure the operator and the patient's safety, read through this chapter before using the 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 *4.8 *Reviewing Alarms*.

The monitor mainly consists of the main unit, built-in recorder, thermosensitive paper, ultrasound transducer, TOCO transducer, remote event marker, fetal stimulator and other accessories.

The monitor can monitor FHR, twin FHRs, TOCO, fetal movement (FM), automatic fetal movement (AFM), and fetal stimulation continuously during perinatal period and send alarm messages when abnormality is detected.

1.1 Intended Use/Indications for Use

F3 Fetal 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.

The 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.

Contraindications:

F3 Fetal Monitor is not intended for use in intensive care units, operating rooms or for home use.

1.2 Configuration

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

Optionally you can add DECG module to them, providing DFHR (direct fetal heart rate) and IUP (Intra-uterine Pressure) monitoring.

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

A DB9 interface and an RJ45 interface are built in the monitor. With them, the monitor can be

connected to a computer or the MFM-CNS central monitoring system via 485 network or Ethernet. Optionally, you can order a built-in wireless network module to connect the monitor via wireless network.

The monitor adopts a 5.6" LCD, on which the collected data, traces, and numerics are displayed. The built-in thermal recorder prints the fetal traces. Rechargeable lithium-ion batteries are provided for options.

1.3 Instruction for Safe Operation

- 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 +5℃ (+41℉) and +40℃ (+104℉). Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 5 cm (2 inches) 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.
- 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.
- Perform periodic safety testing to ensure proper patient safety. This should include leakage current measurement and insulation testing. It is recommended that the periodic safety testing should be performed once a year and be in accordance with the related regulations recognized by the public organizations.
- The protective categories against electric shock of the patient connections are:

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

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

This symbol indicates that the electric shock defend grade of this applied part is Type BF.

IUP

This symbol indicates that the electric shock defend grade of this applied part is Type BF.

DECG

This symbol indicates that the electric shock defend grade of this applied part t is Type CF.

- The monitor described in this user manual is not protected against:
  a) The effects of defibrillator shocks
  b) The effects of defibrillator discharge
  c) The effects of high frequency currents
  d) The interference of electrosurgery equipment

1.4 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 is provided for the use of qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.

2 Installation and service should be performed by qualified and authorized service engineers.

3 This device is not intended for home use.

4 **EXPLOSION HAZARD** - Do not use the device in the presence of flammable anesthetics due to explosion risk.

WARNING

5 **SHOCK HAZARD** – In order to protect the patient and the operator, the monitor case should be grounded. When connecting or disconnecting the grounding wire, be careful not to damage the equipotential grounding terminal.

6 The equipment and devices that connect to the monitor should form an equipotential body to ensure effective grounding.

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

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

9 Additional multiple socket-outlet or extension cord can't be connected to the system.

10 The multiple portable socket-outlet provided with the system shall be only used for supplying power to equipment which is intended to form part of the system. If the electrical device that does not belong to the system plug in the socket, the total power may exceed the maximum load of the separating transformer and cause high temperature and fire. Enclosure leakage current within the system exceeds the standard limit, which may lead an electric risk.

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

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

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

14 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard I IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.

15 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.

16 **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.

WARNING

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

18 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.

19 Connecting any accessory (such as external printer) or other device (such as the computer) to this monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:

a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and

b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

20 Using accessories other than those specified by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

21 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

22 The monitor should be operated by the doctor or under the doctor’s instructions.

23 The monitor is not protected against defibrillation. Do not apply it during HF electro-surgery or MRI; otherwise it might result in harming the patient or the operator.

24 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.

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

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

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

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

WARNING

29 Do not apply this monitor simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators, on a same patient.

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

31 Do not service or maintain the monitor or any accessory which is in use with the patient.

32 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

For proper monitoring:

33 The monitor cannot be used for treatment.

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

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

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

37 The spiral electrode and IUP catheter are disposable and should not be reused.

38 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:

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

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

41 Before using the battery, make sure to read the user manual and safety precautions thoroughly. Improper operations may lead to battery overheat, fire, explosion, damage and battery capacity reduction.

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

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

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

45 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.

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

WARNING

47 Use the battery only in this Monitor. Do not connect battery directly to an electric outlet or cigarette lighter charger.

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

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

50 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.

51 Keep away from fire immediately when leakage or foul odor is detected.

52 If the battery is not used for a long time, charge it at least once every six months to avoid over discharge.

53 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.

54 Do not connect the battery cable connector or battery socket with metal objects, which can result in short circuit.

55 Do not unplug the battery when monitoring.

56 Do not use a battery with serious damage or deformation.

57 Only authorized personnel should perform the replacement of button cell.

58 Only rechargeable button cell supplied or recommended by EDAN can be used.

CAUTION

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

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

3 Refer servicing to qualified personnel.

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

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

6 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.

7 The appliance coupler or mains plug is used as isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.

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

9 When washing the belts, the water temperature must not exceed +60 ºC (+140 ºF).

CAUTION

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

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

12 **Electromagnetic Interference** - Fetal parameters, especially ultrasound 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.

13 **Electromagnetic Interference** - The monitor should not be used adjacent to, or stacked with, other equipment unless otherwise specified.

14 Electromagnetic interference is not unique to the monitor 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.

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

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

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

18 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 the battery with a new one the same as the one provided or recommended by the manufacturer.

19 Remove a battery whose life cycle has expired from the monitor immediately. For information on installing and removing the battery from the monitor, thoroughly read the user manual.

20 Switch off the monitor and unplug it before cleaning.

CAUTION

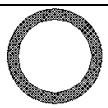
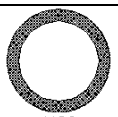
21 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At 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 Portable and mobile RF communications equipment can affect medical electrical equipment, refer to section A7.4 Recommended Separation Distances.

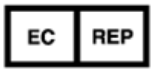
23 Sterility cannot be guaranteed if package of the fetal spiral electrode is broken or opened.

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

1.6 Definitions and Symbols

1		Socket for ultrasound transducer 1 (Type BF applied part)
2		Socket for ultrasound transducer 2 (Type BF applied part)
3		Socket for DECG cable (Type CF applied part)
4		Socket for TOCO transducer (Type BF applied part) or IUP cable (Type BF applied part)
5		Socket for Remote Event Marker (Type BF applied part)
6		Socket for Fetal Stimulator (Type BF applied part)
7		TYPE BF APPLIED PART
8		TYPE CF APPLIED PART
9		Battery check

10		Alternating Current
11		Stand-by
12		ON/OFF switch for the device
13		Start (of action)
14		Bell cancel –AUDIO OFF
15		Zero-point adjustment
16		Marker
17		Graphical recorder
18		Channel selector with logic control
19		Equipotentiality
20		Fuse
21		Caution
22		Warning (Background: Yellow; Symbol & outline: Black)
23		Operating instructions
24		Refer to instruction manual/ booklet (Background: Blue; Symbol: White)
25		Aerial; antenna
26		USB (Universal Serial Bus) Connection
27		Serial interface
28		Computer network

29		CE marking
30		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
31		Disposal method
32	P/N	Part number
33		Serial number
34		Date of manufacture
35		Manufacturer
36		General symbol for recovery/recyclable
37	Rx Only	Federal (U.S.) Law restricts this device to sale by or on the order of a physician

NOTE:

The user manual is printed in black and white.

Chapter 2 Monitor and Accessories

2.1 Opening and Checking Package

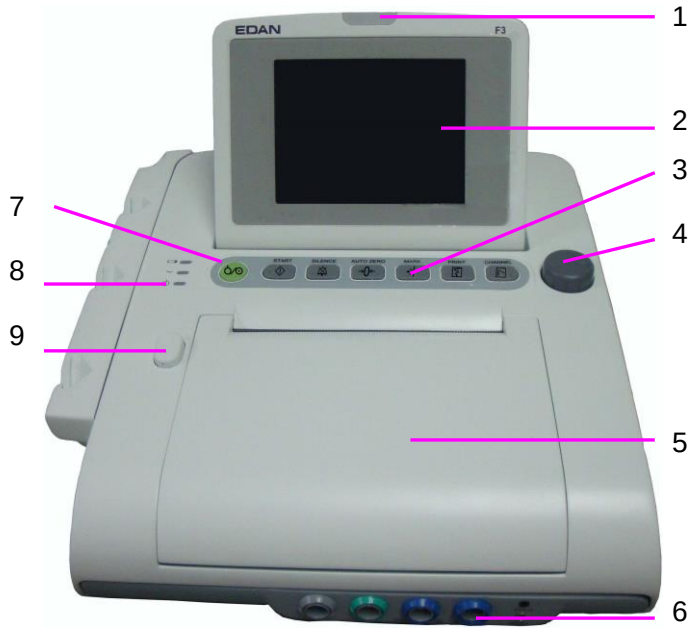
Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage.

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 the manufacturer or your local distributor immediately.

2.2 Overview



1 Alarm Indicator
2 LCD
3 Keys
4 Control Knob
5 Paper Drawer
6 Accessory Sockets
7 Power Switch
8 Indicators
9 Paper Drawer Latch

Figure 2-1 Appearance

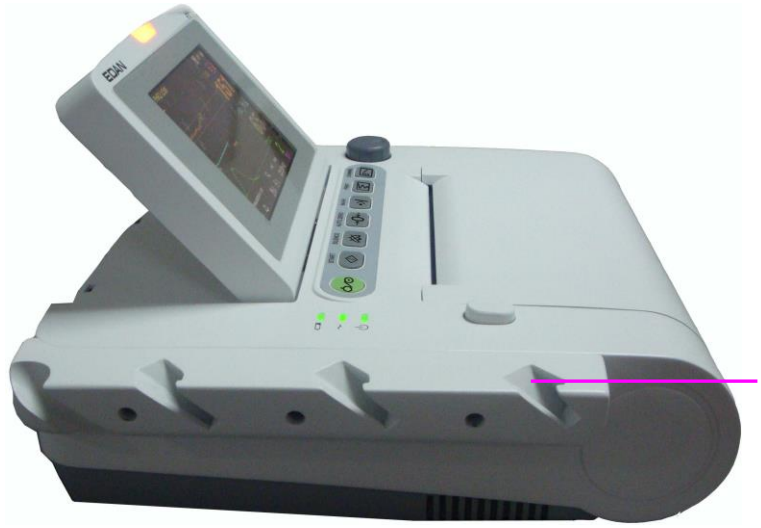


Figure 2-2 Left Panel

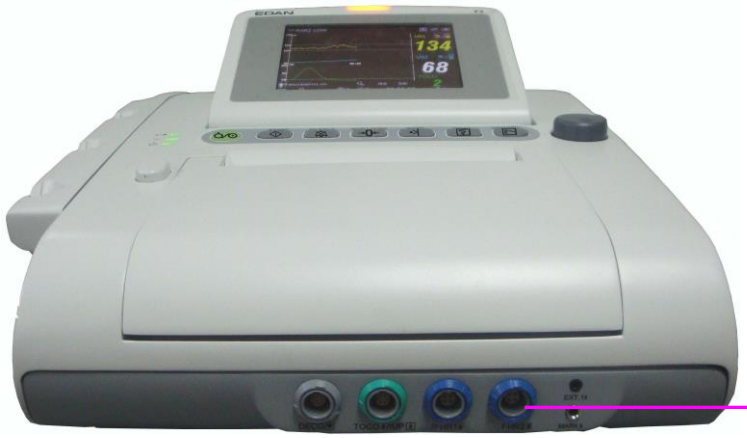


Figure 2-3 Front Panel

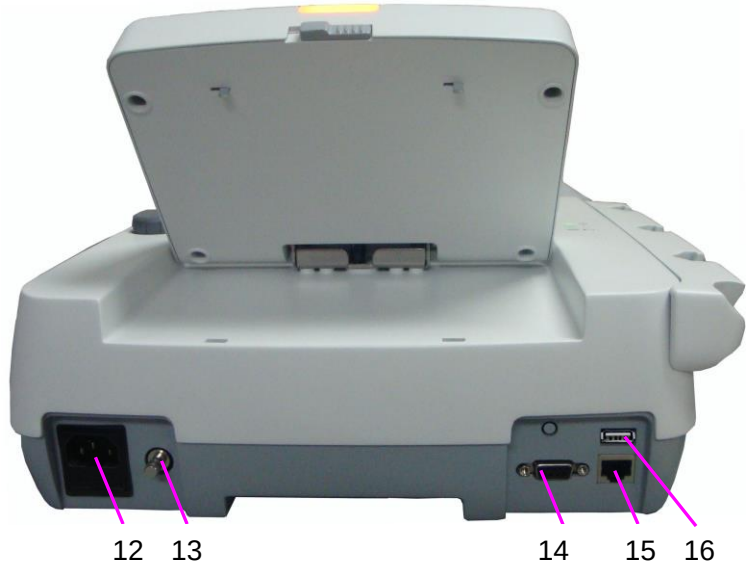


Figure 2-4 Rear Panel

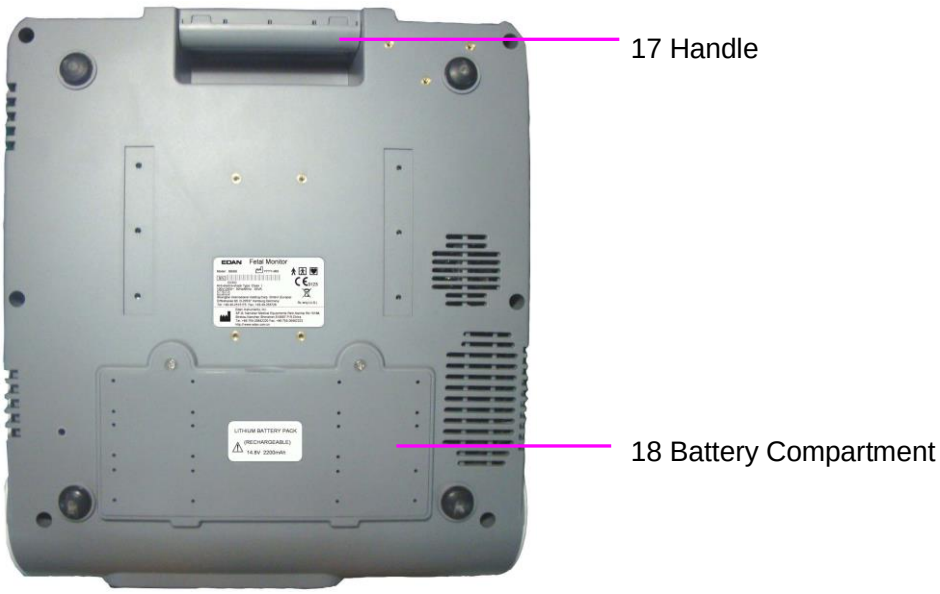


Figure 2-5 Bottom Panel

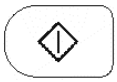
2.2.1 Keys and Control Knob

Figure 2-6 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) POWER switch 

Function: Switch on or off the monitor.

(2) *START key 

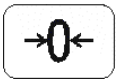
Function: Start monitoring or return to the main interface

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

(3) SILENCE key 

Function: Switch on off the alarm sound

Press this key to switch on or off the alarm sound.

(4) AUTO ZERO key 

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).

(5) MARK key 

Function: Make record of an event.
Press this key to make an event mark.

(6) *PRINT key 

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

(7) CHANNEL key 

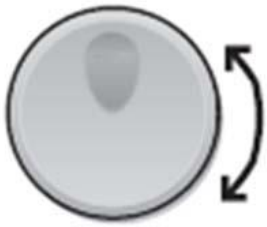
Function: Switch the channels
Press this key, the fetal heart sound toggles between US1 channel and US2 channel.

(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:

1) Rotate the control knob to move the cursor to the item you want;
2) Press the control knob and one of the following three results will be achieved:
    a) A menu pops up on the screen, or the menu is replaced by a new one;
    b) A submenu with several options appears. If this item has more than 6 options, they will be displayed on more than one page. Select **Prev** to switch to the previous page, or select **Next** to switch to the next page.

c) The function operates immediately.

NOTE:

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

2.2.2 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. Table 2-1 lists their meanings:

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

Table 2-1 Indicator description

2.3 Accessories

The US transducer, TOCO transducer, remote event marker and fetal stimulator should be plug in the socket of the top panel accordingly.

2.3.1 Ultrasound (US) Transducer

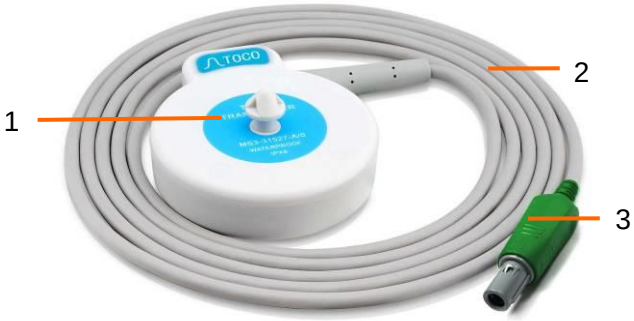
1 US Transducer (Pink Labeled)

2 Transducer Cable

3 Transducer Connector

Figure 2-7 US Transducer

2.3.2 TOCO Transducer



1 TOCOS Transducer (Blue Labeled)

2 Transducer Cable

3 Transducer Connector

Figure 2-8 TOCO Transducer

CAUTION

Degree of protection against harmful ingress of water of the US transducer and TOCO transducer is IPX8. They can be continuously immersed in water to a depth of 1.1 meter for 24 hours and remain safe, but they are not allowed to be immersed in organic solvent, such as ethanol.

2.3.3 Belt

Figure 2-9 Belt

2.3.4 Remote Event Marker

Figure 2-10 Remote Event Marker

2.3.5 DECG Cable

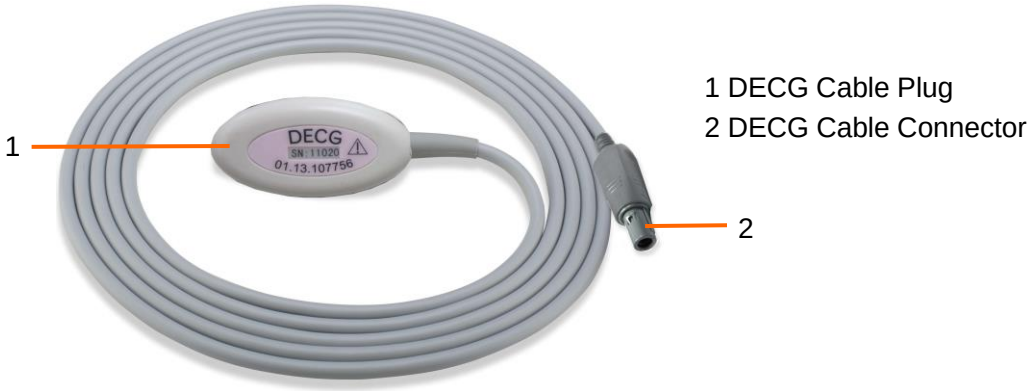


Figure 2-11 DECG Cable

2.3.6 Fetal Spiral Electrode

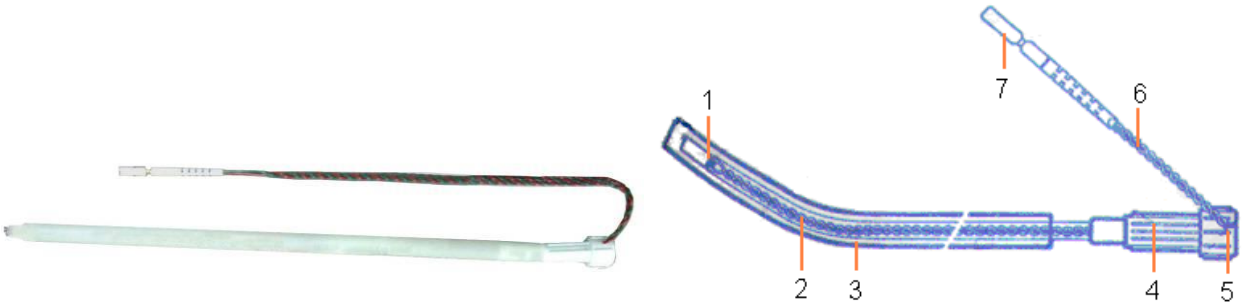


Figure 2-12 Fetal Spiral Electrode

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

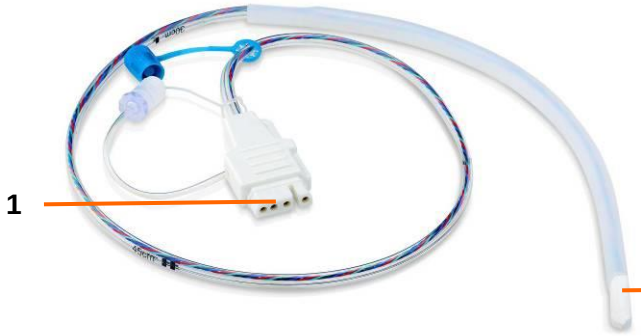
2.3.7 IUP Cable and Catheter(Kendall)

Figure 2-13 IUP Connecting Cable

Figure 2-14 IUP Cable

1 Interface to IUP Cable 2 Connecting plug

3 Interface to IUP Catheter 4 Interface to Connecting Cable



1 Interface to IUP Cable
2 Catheter

Figure 2-15 IUP Catheter

2.3.8 IUP Cable and IUP Catheter(Koala)

Figure 2-16 IUP Connecting Cable

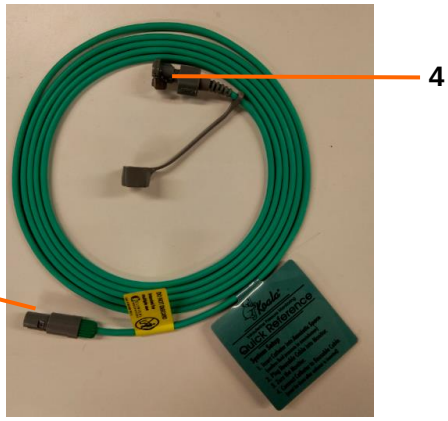
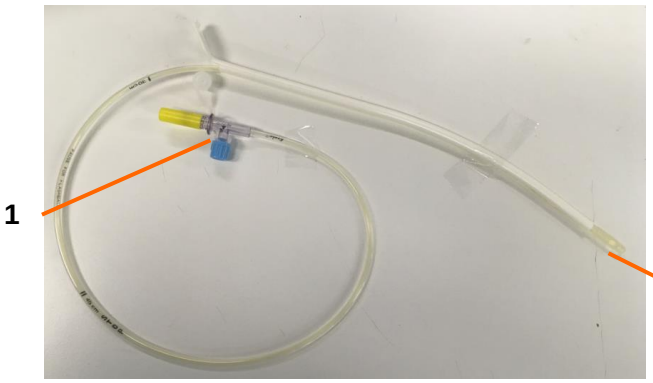


Figure 2-17 IUP Cable

1 Interface to IUP Cable 2 Connecting plug

3 Interface to IUP Catheter 4 Interface to Connecting Cable



1 Interface to IUP Cable
2 Catheter

Figure 2-18 IUP Catheter

2.3.9 Fetal Stimulator

Figure 2-19 Fetal Stimulator

NOTE:

1. The fetal stimulator is not available in the USA.
2. Refer to User Manual of the fetal stimulator for operation instructions.

2.4 Screen

2.4.1 Main Interface

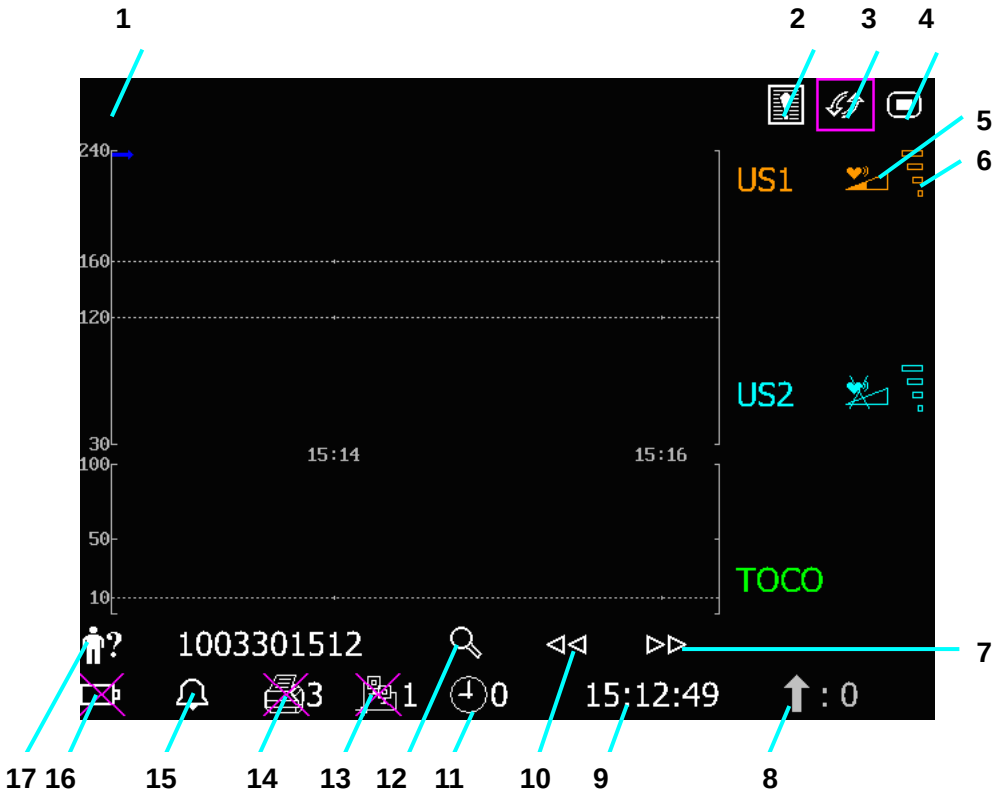


Figure 2-20 Main Interface

Item	Screen element	Description
1	Alarm messages displaying area	
2		Alarm reviewing key
3		Display mode switch
4		Setup key
5	Fetal heart sound volume adjust/indicator:  : the current fetal heart sound comes from this channel.  : the fetal heart sound of this channel is mute.	
6	Fetal heart signal quality indicator:  poor  acceptable  optimum	
7, 10		Trace review keys
8		MFM/AFM count
9	15:12:49	System time

11		Monitoring timer, the number on the right indicates the duration of the current monitoring.
12		Patient searching / File managing key
13	Network connection/device no. indicator:   Online Offline (1 stands for the device number.) **NOTE:** The network connection indicator is not shown if the net version is **Insight** or **Philips**.	
14	Recorder status/speed indicator:   No printing in progress Printing in progress (**3** stands for the printing speed: 3 cm/min.)	
15	Alarm sound status indicator:    Alarm sound on Alarm sound is disabled infinitely Alarm sound pause and the remaining time	
16	Battery status 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.	
17		Patient ID (identification)

2.4.2 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.

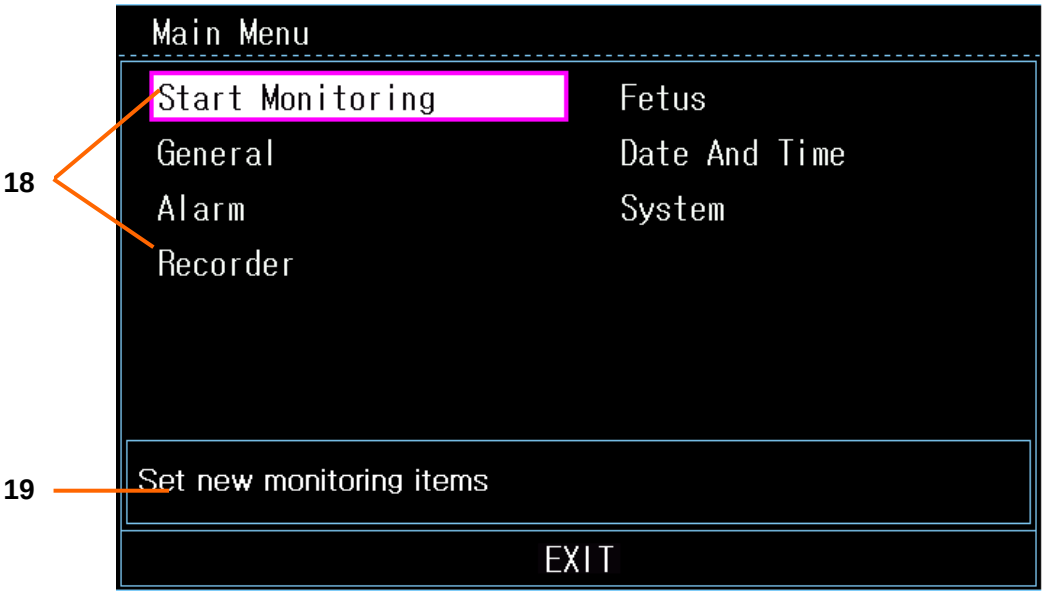


Figure 2-21 Setup Menu

Item	Screen element
18	Setup Items
19	Function Description

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.

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 **Star Monitoring** in the illustration above. Correspondingly, its function **Set new monitoring items** is issued in the blue frame pane.

Chapter 3 Installation Guide

3.1 Installing Battery

WARNING

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

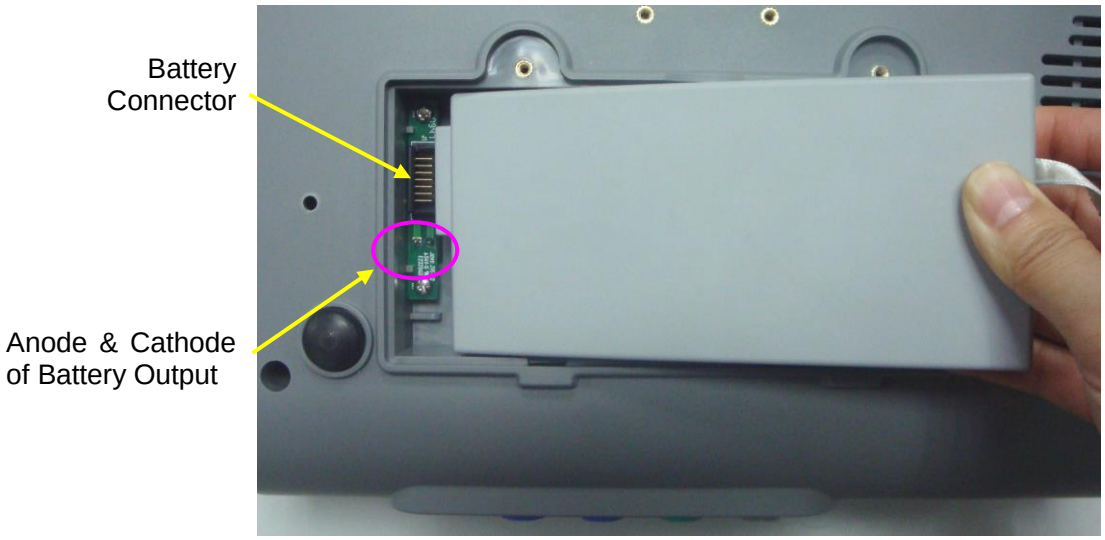
2 When in indicates the power is low, please change for a new battery or charge the rechargeable battery in time, or the monitoring will be interrupted.

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

(1) Battery Installation

1) Fold the LCD flat and then place the monitor upside down on a flat surface covered with cloth or another 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 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 shirt-circuit.

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

5) 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. Connecting to power supply will charge the battery no matter if the monitor is powered on.

3.2 Installing Monitor

The monitor should be placed on a flat surface.

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 the monitor on the wall, MT-803 trolley, MT-503 trolley 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.

3.3 Loading Recorder paper

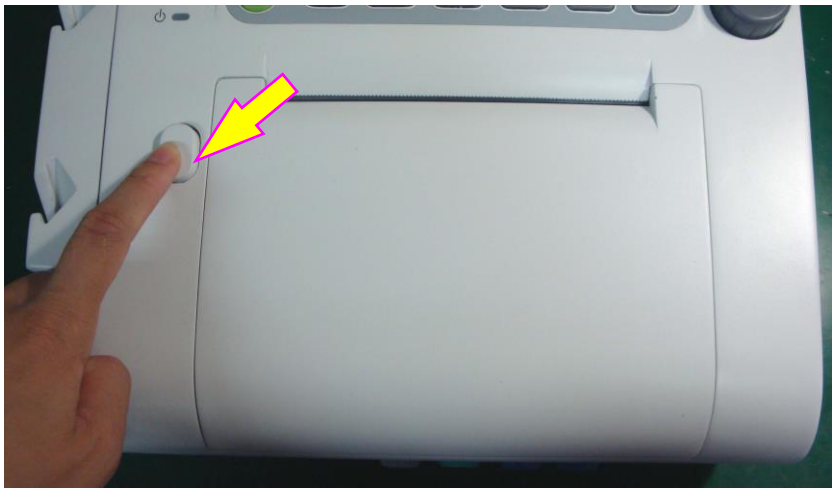
CAUTION

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.

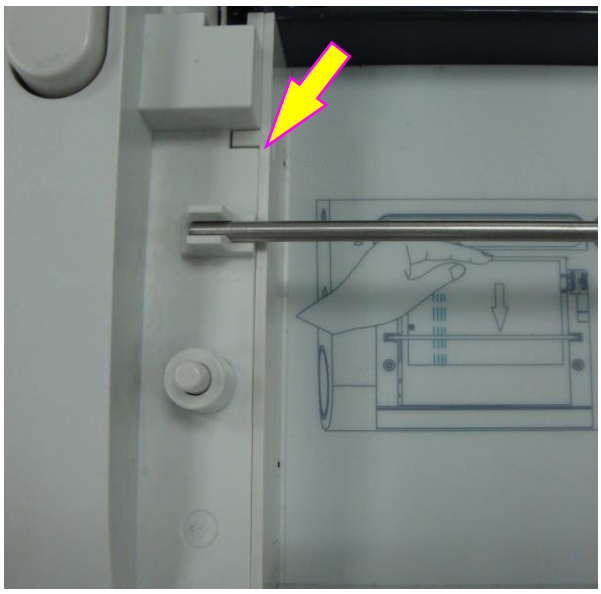
2 Configured with different hardware, the monitor is compatible with both GE and Philips recorder paper. However, only one type of paper is configured with the monitor in the shipment. If you want to use the other type of paper, contact the manufacturer for service first, otherwise trace excursion or 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 drawer latch on the front panel to flick open the paper drawer cover.

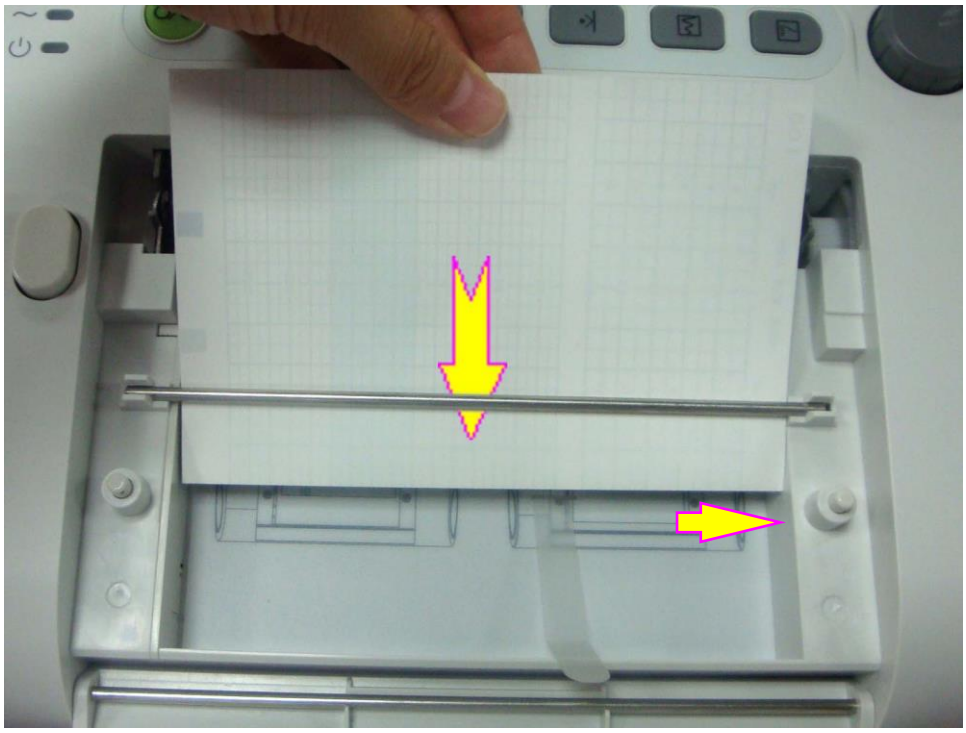


2) Check if there is a paper baffle installed in the left of the drawer. If the baffle is installed, you can only use PHILIPS record papers otherwise you can use GE record papers.

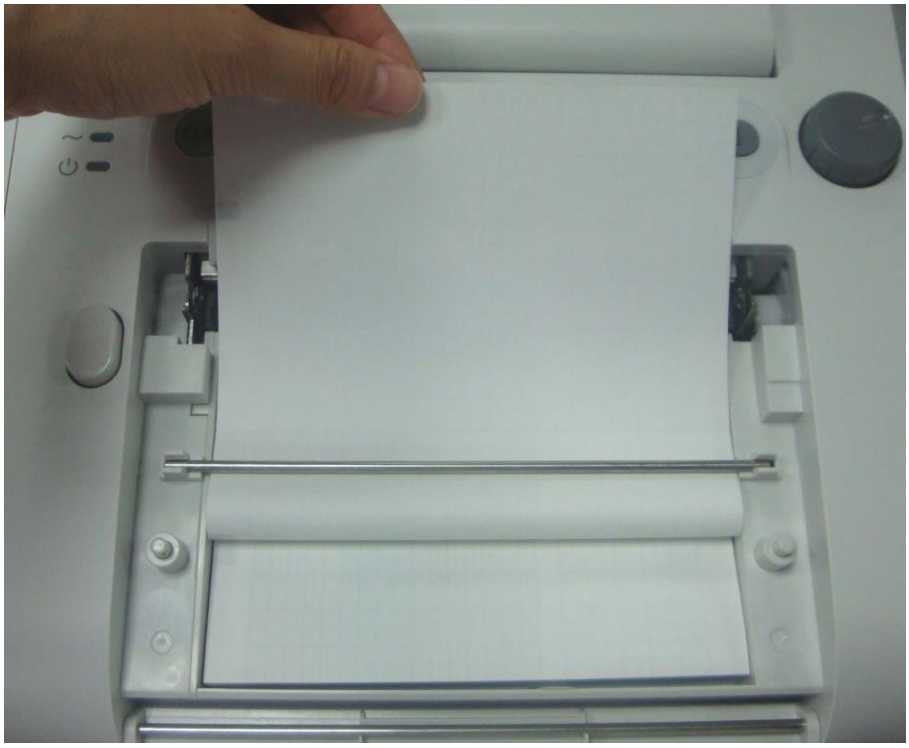


3) Take out the Z-fold thermosensitive paper, remove the wrapper and check if it is the correct paper type.

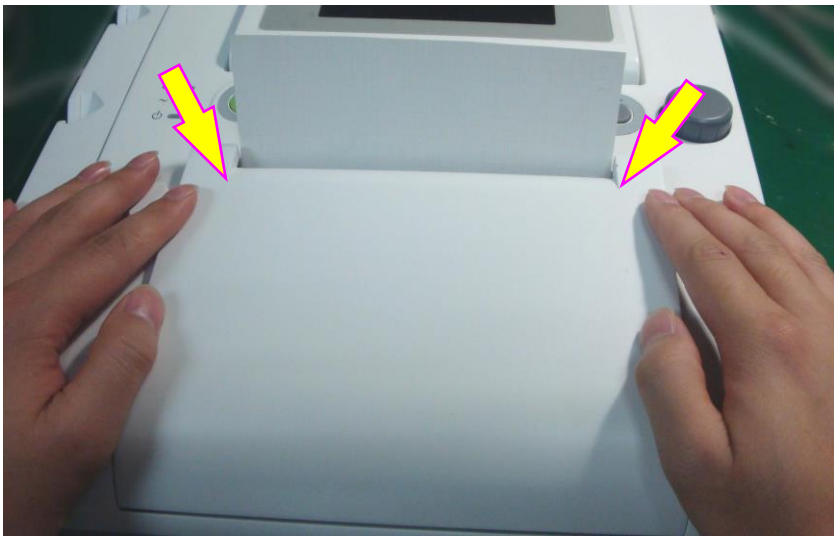
4) Guide the pack into the drawer underneath the retaining rod, abutting it against the right edge. Make sure the blank side of the paper faces you and the FHR trace area is on the left.



5) Unfold a sheet from the top of the pack and pull its end out of the drawer (make sure the pack in the drawer remains flat).



6) Put the paper drawer cover down and press its end until it clicks locked properly.



CAUTION

1 Be careful when inserting paper. Do not touch the thermosensitive print head or the paper sensor by hand, in case they are damaged by static electricity.

2 Make sure the paper pack in the drawer remains flat when the top sheets are pulled out of the drawer. If paper deflection is detected after the drawer cover is closed, reload paper to prevent trace excursion or paper jam.

3 Keep the drawer closed except when loading paper or providing servicing.

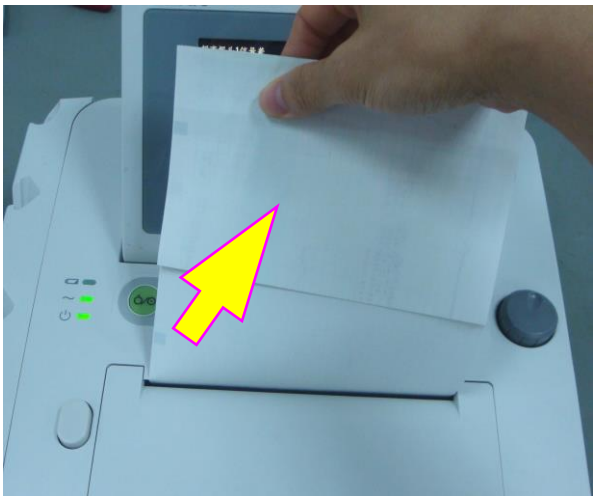
4 Be careful not to trap your fingers when closing the paper drawer cover.

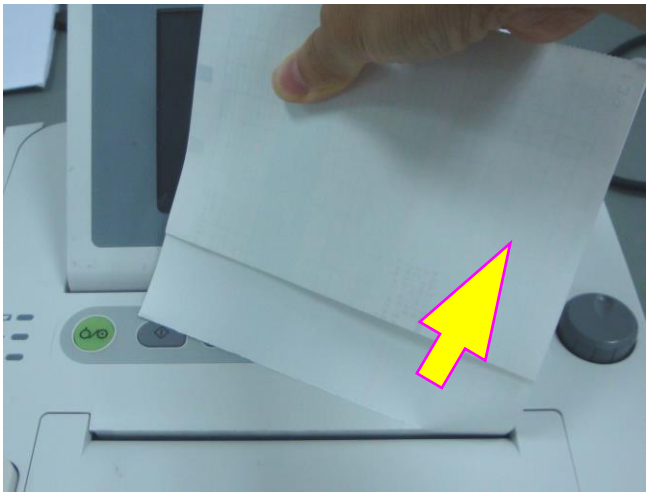
3.4 Tearing Off Recorder paper

Perform the following procedure to tear off the recorder paper:

1) Press the **PRINT** key on the front panel if the recorder is running.

2) Pull up the end of the paper (fold the paper if it is very long), and use moderate power to tear it off in an upward motion along the paper-cutting edge.





CAUTION

Always tear off the paper along the paper-cutting edge or the perforation. Pulling the paper fiercely may damage the printhead or cause misalignment of the paper in the drawer.

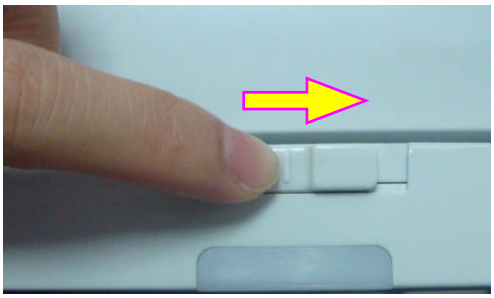
If you wish to tear off the paper at the perforation all the time, please use the **F9-P** paper and enable the **Paper Advance**.

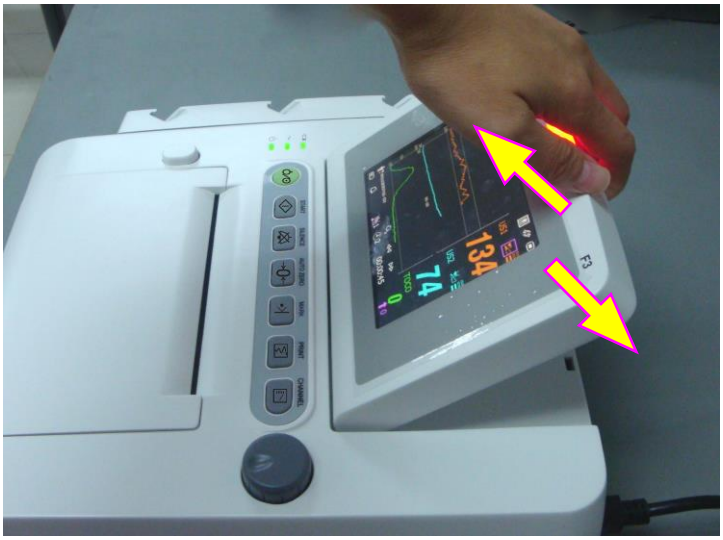
3.5 Adjusting Screen Angle

You can fold the screen completely flat, or tilt it to an appropriate angle, allowing the monitor to be placed on a flat surface or mounted on a wall.

To tilt or to fold the screen,

1) Push the hook on top of the screen right to spring it open.
2) Hold the centre part of the screen on the top edge and push it forward or backward to the required angle.

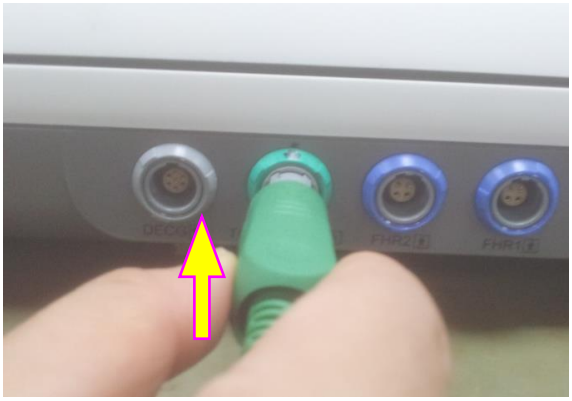




3.6 Connecting Transducers

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 symbols of the connector is facing up.



Connecting the transducer

Disconnecting the transducer

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

NOTE:

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

3.7 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 three 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.

Placing the transducer

Placing the marker

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.

3.8 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.

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

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. The adjustable alarm limits determine the conditions that trigger the alarm. They can be disabled.

Technical alarms indicate that the monitor cannot measure and therefore cannot detect critical patient conditions reliably. They cannot be disabled.

The alarms have two levels: medium and low. Medium level alarm is a serious warning, whose symbol is **; low level alarm is a general warning.

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

The system sets all alarm levels, and you cannot change them.

4.2 Audible Alarm

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

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 audible alarm toggles between on and off (temporarily or infinitely, you can change the setting).

If the audible alarm is temporarily disabled, the alarm indicator displays  , with a remaining time on the right. When the time is out, the audible alarm is enabled again automatically.

If the audible alarm is infinitely disabled, the alarm indicator displays  , which is flashing in the manner of lighting for one second and pausing for one second. It will not be enabled again until the **SILENCE** key  is pressed.

However, the alarm messages will still be displayed and the alarm indicator will still be lighted up when an alarm is active.

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.

4.3 Visual Alarm

When an alarm is active,

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

Alarm Category	Indicator Color	Flashing Frequency	Duty Cycle
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 alarm message area of the main interface in yellow.

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

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

When more than one alarm of different levels are active, only the alarms of the highest level are displayed in the message window.

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 Alarm Silence Duration

You can choose the alarm silence duration,

1 Select the setup key on the main interface.
2 Select **Alarm > Silence Duration**.
3 Select **Infinite** (default), **1 min**, **2 min** or **3 min**.
4 Select **OK**.

4.5 Choosing Alarm Message Form

You can change the patient alarm display form,

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

4.6 Changing Alarm Volume

You can change the alarm volume,

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

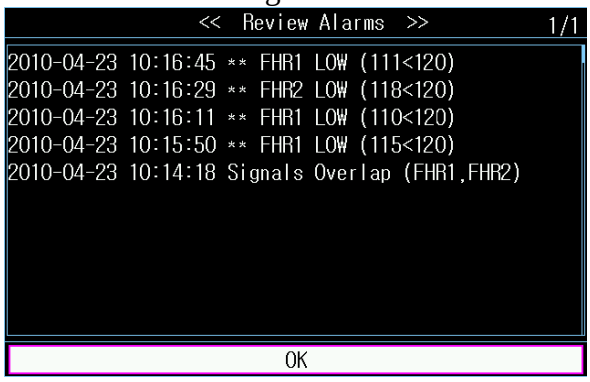
4.7 Choosing Signal Loss Delay

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 > Signal Loss Delay**.
3 Select **0** (default) ~ **300** seconds, in steps of 10s.
4 Select **OK**.

4.8 *Reviewing Alarms

An alarm reviewing menu can record the immediate 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.



Select the alarm reviewing key in the

message window to open this menu.

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

You can select the alarm list and then rotate the control knob to review more alarms.

When the monitor is switched off, the power supply is cut off accidentally, or a new monitoring starts, the immediate alarm messages will be cleared.

4.9 Alarm Treatment Measures

When the monitor gives out an alarm and catches your attention, you should:

- Recognize which functional parameter alarms or what the alarm is.

- Check the patient’s condition.

- Identify the cause of the alarm.

- Silence the alarm if necessary.

Check if the alarm is terminated when the alarm condition is solved.

4.10 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 high alarm limit or lower than the low alarm limit. Or disconnect one of the plugs.
5 Verify if the visible and audible alarms are working properly.

4.11 Patient Alarm Defaults

Alarm Setting	Options	Default
FHR1/FHR2 Alarm	On, Off	On
FHR1/FHR2 Low alarm limit	60 bpm ~ 205 bpm, in increments of 5	120 bpm
FHR1/FHR2 High alarm limit	65 bpm ~ 210 bpm, in increments of 5	160 bpm
FHR1/FHR2 Alarm Delay	0 ~ 20 second(s), in increments of 5	10 seconds

FHR1/FHR2 Alarm Level	Medium, not adjustable	Medium

NOTE:

The high alarm limit must be higher than the low alarm limit. When setting the high alarm limit, you do not have access to the options that are lower than the preset low alarm 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 a new monitoring starts (the **START** key is pressed). Otherwise you have to press the **PRINT** key to start printing.
- **Printing timer:** The printing timer determines the elapsed time for each print. This time is adjustable. Refer to *5.2.3 Changing the Print Timer*.
- **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. After the saved trace has been printed out, the recorder switches back to printing the current data at the normal speed automatically.

  NOTE:

  When the monitor is switched off, the data in the internal memory will be lost.
- **FHR2 offset:** You can set the offset of the FHR2 trace to separate the two fetal heart traces on the screen and the recorder paper. Refer to *7.3.4 Changing FHR2/DFHR Offset.*
- **Print self-check:** The recorder prints a baseline for self checking when the monitor is switched on.
- **Paper advance:** When printing stops, the paper advances to the next perforation, making it easy to be torn off. Refer to *5.2.5 Switching Paper Advance On or Off*.

5.2 Printing Configuration

NOTE:

All the parameters should be well configured before printing starts. You cannot 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 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 appearances 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 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) **Present ID** or **Infinite**. For a fixed time, the recorder stops when the time is up. For **Present ID** and **Infinite**, it prints the traces of the present patient, and stops automatically when another patient's traces come up. If there is no ID on the current reviewing screen, the recorder with **Present ID** setting starts printing from the beginning of this ID, and with a fixed timer or **Infinite** setting, it starts printing from the left border of the screen. Whatever the setting is, the recorder stops when the **PRINT** key is pressed in midway.
4 Select **OK**.

5.2.4 Switching Print Self-Check On or Off

You can switch print self-check on or off:

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

5.2.5 Switching Paper Advance On or Off

You can switch paper advance on or off:

1 Select the setup key  on the main interface.
2 Select **Recorder** > **Paper Advance**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

NOTE:

This option is available only when the paper type is **PHILIPS**.

5.3 Understanding Recorder Paper Printout

WARNING

1 If there is any difference 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:

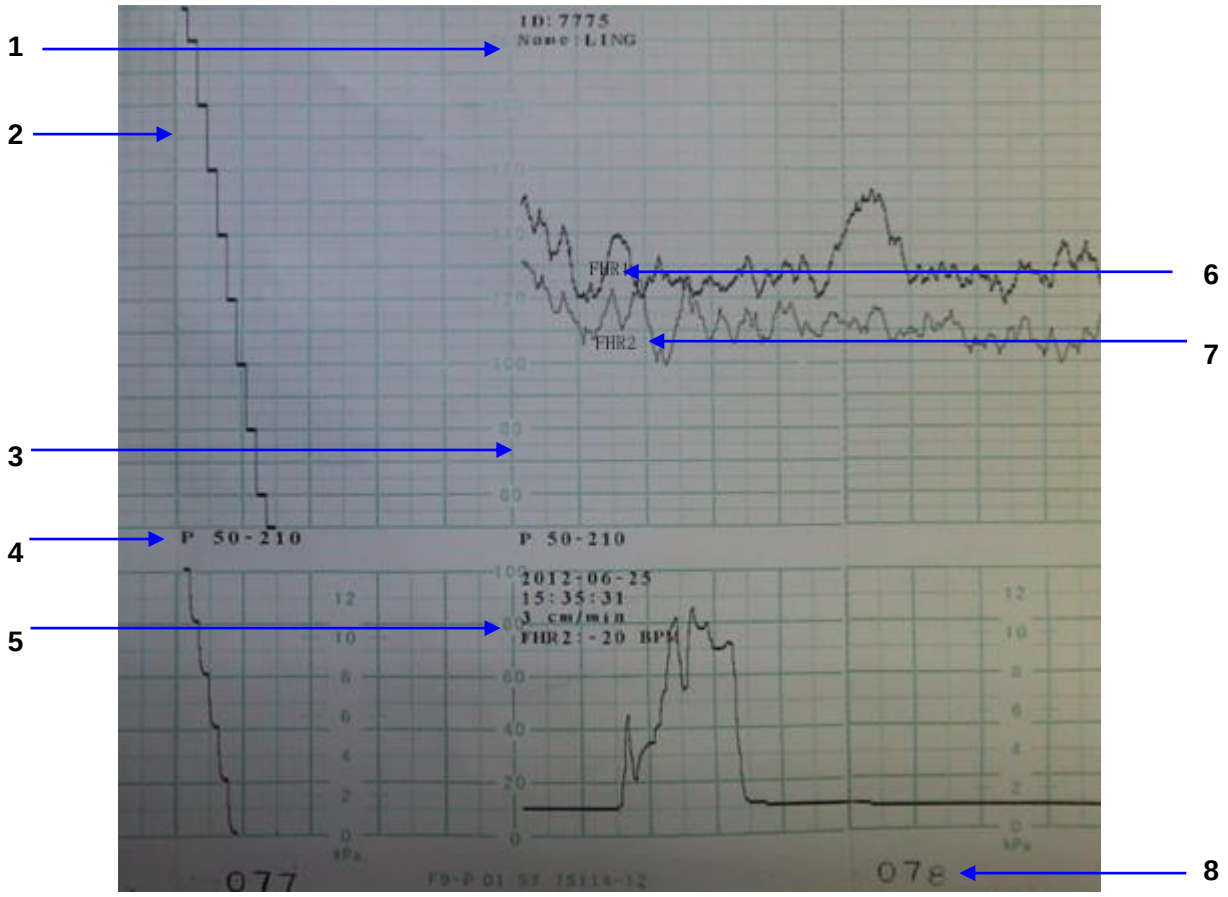


Figure 5-1 An example of recorder paper with traces

Item	Information	Description
1	Patient Information	The patient's ID and name.
2	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.
3	Paper Style	The FHR pane range 30 bpm ~ 240 bpm indicates the paper style is American Standard. The FHR pane range 50 bpm ~ 210 bpm indicates the paper style is International Standard.
4	Paper Type	There are two types of paper: F9-G and F9-P.
5	Trace Information List	A list of current date, time, print speed and FHR2 offset is printed at the start of the monitoring and every ten minutes afterwards.
6	FHR1 Mark	The trace marked with "FHR1" is the FHR1 trace.
7	FHR2 Mark	The trace marked with "FHR2" is the FHR2 trace.
8	Page Mark	Each recorder paper pack has 150 pages. When you notice the page mark comes to the end, remember to load new paper in time.

Chapter 6 Pre-Monitoring Preparation

6.1 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.

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 front 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.

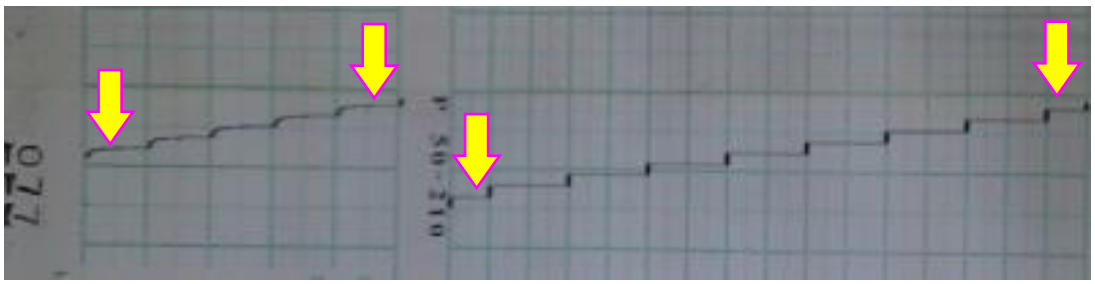
You can choose to switch the start-up music on or off,

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 after start-up (if **Print Self-Check** in the menu is ON). Observe the starts and ends of the printed baselines (illustrated with the arrow). The starts and ends should be printed exactly on the edges of the pane if the recorder paper is correctly loaded and set. If they do not comply with the edges, reload paper or ask the service engineer to check the paper settings of the monitor.



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

NOTE:

Make sure the paper is correctly loaded before starting printing.

6.4 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 From left to right, the figures are used to set the year, month, date, hour, minute and second.

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

1 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.

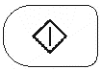
2 If date and time cannot be saved, it is probably the battery has reached the end of its service life. Please contact the service personnel or your local distributor.

6.5 Adjusting Volume

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

Press the **CHANNEL** key  to switch the fetal heart sound to the other channel.

Adjust the default monitoring volume:

The fetal heart 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 in increments of 1. 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 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 selection.

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**.

6.6 Relocation of the Transducers

Transducers may be belted on the patient for a long time without stop. In rare cases, this may lead to irritations to the patient skin. To avoid skin irritations, please inspect the application site at least every three hours. If the skin quality changes, you should move the transducer to another site.

US transducers need to change application site frequently to track fetal heart. It is normal during a monitoring process. But TOCO transducers are different. Please periodically inspect the application site (between contractions) of TOCO transducer at least every three hours.

To reduce the risk of skin irritations, do not allow residual cleaning agent or disinfecting agent on the surface of transducers. Before using cleaning agent and/or disinfecting agent, refer to the cleaning and disinfecting sections in this user manual. Wipe the transducer surface with a cloth dampened with water before applying to the patient.

Chapter 7 Fetal Monitoring

WARNING

1 The monitor is intended for use in antenatal care room, predelivery room and delivery room, but not for use in intensive care units (ICU), operating rooms or for home use.

2 The monitor is not protected against defibrillation. Do not apply it during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.

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

7.1 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

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

2 FHR should not be monitored until a clear fetal heart signal is detected.

3 If FHR reduces more than 10 bpm suddenly, or the beat of fetal heart sounds slower abruptly, please check if it is the MHR that is being monitored by the transducer. If so, relocate the transducer for the best fetal heart signal.

4 The sphere of activity for the fetus is much larger during mid-trimester of gestation (from 24th week to 28th week). When fetal heart moves away from the US transducer, please redetermine the fetal heart position and relocate the transducer.

5 Inspect patient skin before applying the transducer for monitoring. If the skin quality is poor, especially when the skin is damaged or irritated, please change a site to apply the transducer.

CAUTION

It is recommended to start printing FHR trace after clear fetal heart signal is detected and FHR computing has stabilized.

7.1.1 Parts Required

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

7.1.2 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 above the navel for head presentation and place the transducer below the navel for breech presentation.

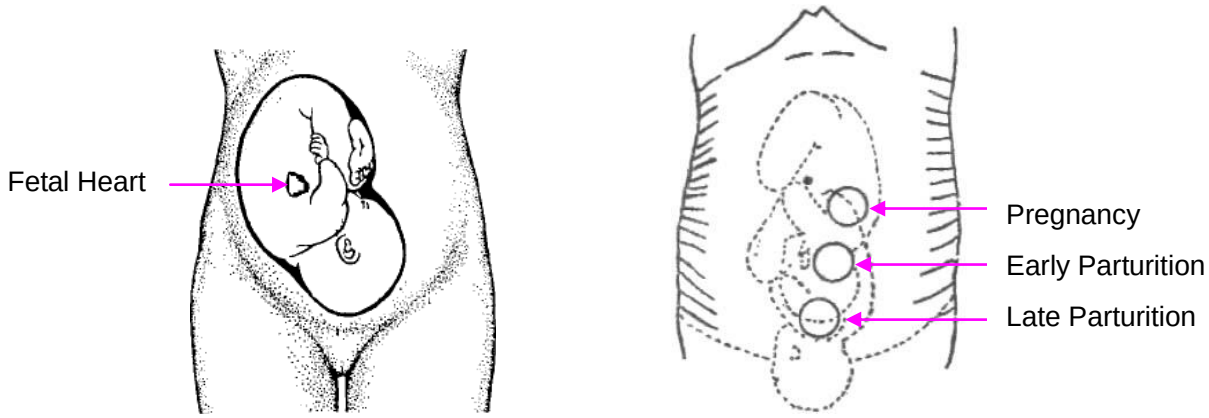


Figure 7-1 Positioning Ultrasound Transducer (single fetus)

- During parturition, the fetal heart moves downward as the labor progresses. It is recommended to move the transducer along with the 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

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt.

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

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 pregnant woman's prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable.

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

5 When applied to the patient, the ultrasound transducer may warm slightly (less than 2°C (3.6ºF) above ambient temperature). When NOT applied, at the ambient temperature of 40°C (104ºF), the ultrasound transducer may reach the highest temperature of 43°C (109.4ºF).

7.1.3 Switching the FHR Alarm On or Off

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 > FHR > Alarm**.
3 Select **ON** (default) or **OFF**.
4 Select **OK**.

If FHR alarm is switched off, an alarm switched-off symbol  will appear in the alarm message area on the main interface. For example:

WARNING

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

7.1.4 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 > FHR**.
3 Select a value from 60 ~ 205 for **low alarm limit**.
4 Select a value from 65 ~ 210 for **high alarm limit**.
5 Select **OK**.

7.1.5 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 > FHR > Alarm Delay**.
3 Select a value from 0 ~ 20.
4 Select **OK**.

WARNING

The FHR alarm delay is adjustable between 0 and 20 seconds.

7.1.6 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.

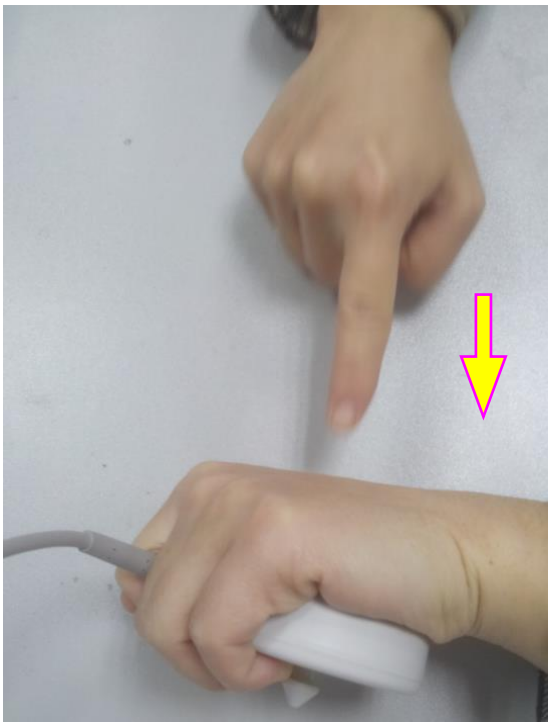


Figure 7-2 Testing a US Transducer

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.

7.2 Monitoring FHR with DECG

7.2.1 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.

7.2.2 Parts Required

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

The following illustration shows how these parts should be connected:

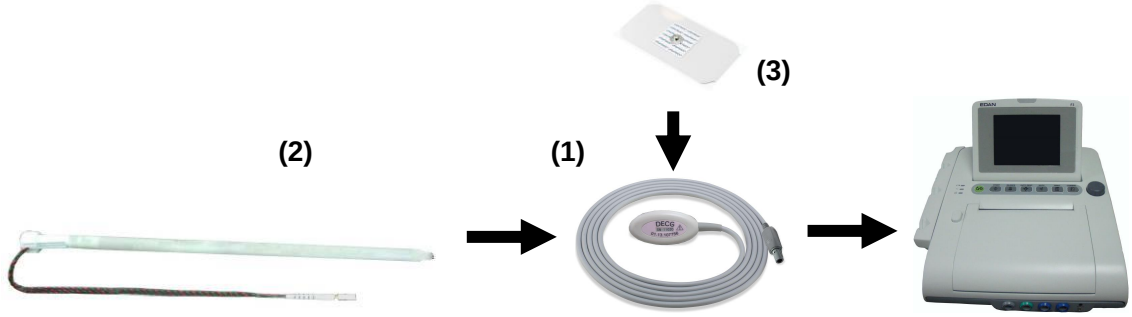


Figure 7-3 Connection for DECG Monitoring

7.2.3 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.

7.2.4 Changing DECG Beep Volume

When the DECG beep is enabled, the monitor gives a beep sound of DECG. The frequency of DECG beep corresponds to the fetal heart rate, but occasionally it may differ due to weak DECG signal.

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:

Once the DECG beep volume is changed by selecting the volume adjustment key on the main interface and rotating the control knob, the sound switches to channel 1 automatically. Therefore, it is advised against changing DECG beep volume in the monitoring process.

7.2.5 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.

7.2.6 DECG Monitoring Procedure

1 Perform a vaginal examination to identify the fetal presenting part.

2 Prepare the patient's skin using the procedures described in section *7.2.3 Preparing the Patient's Skin Prior to Placing Electrodes*.

3 Attach the fetal spiral electrode to the fetal presenting part using the procedures described on the package.

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 Doppler heart sound at a rate distinct from that of the maternal pulse is unequivocal evidence of the fetal life.

2 After the electrode is 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.

7.2.7 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.

7.3 Monitoring Twin FHRs

7.3.1 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 *7.1 Monitoring FHR with Ultrasound* to acquire FHR signals for both channels. Press **CHANNEL** key to switch the fetal heart sound from one channel to the other.

When the two US transducers are fixed, make sure fetal heart 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.

7.3.2 Monitoring Internally

Alternatively, you can monitor one fetal heart using ultrasound externally, and monitor the other fetal heart 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 *7.1 Monitoring FHR with Ultrasound*.

Monitor the second twin with a DECG cable using the procedures described in Section *7.2 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.

7.3.3 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.

7.3.4 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 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.

7.4 Monitoring Uterine Activity Externally

WARNING

1 Inspect patient skin before applying the transducer for monitoring. If the skin quality is poor, especially when the skin is damaged or irritated, please change a site to apply the transducer.

2 During long-time monitoring, please inspect the application site (between contractions) of TOCO transducer at least every three hours. If the skin quality changes, you should move the transducer to another site.

7.4.1 Parts Required

1) TOCO transducer 2) Belt

7.4.2 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 this 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.

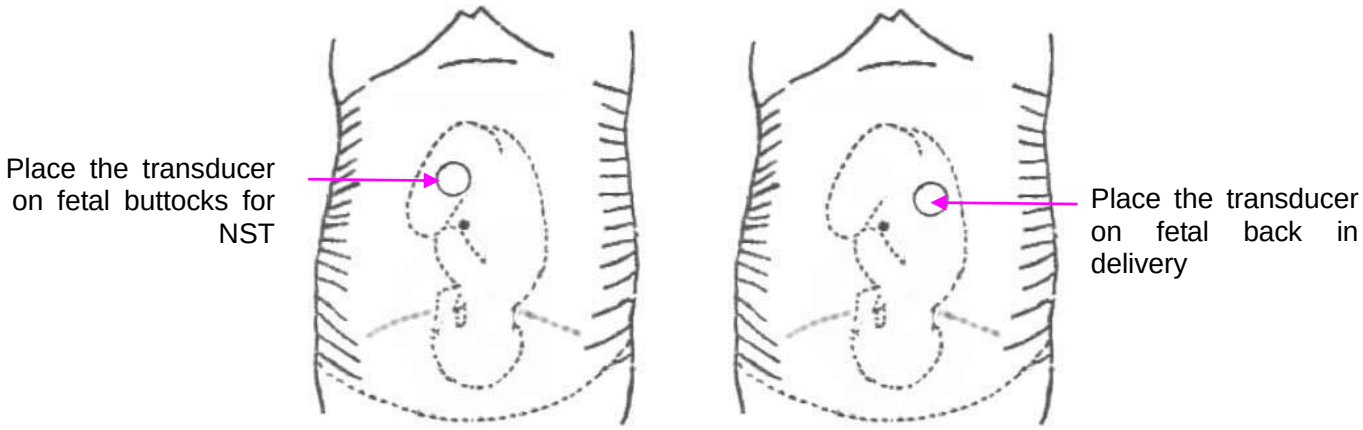


Figure 7-4 Positioning TOCO Transducer

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 and 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.

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.

7.4.3 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 your monitor has been configured with IUP, the baseline will be 0 and not adjustable.

7.4.4 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 7-5 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.

7.5 Monitoring Uterine Activity Internally

7.5.1 Parts Required

1) Disposable intrauterine pressure catheter (“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:

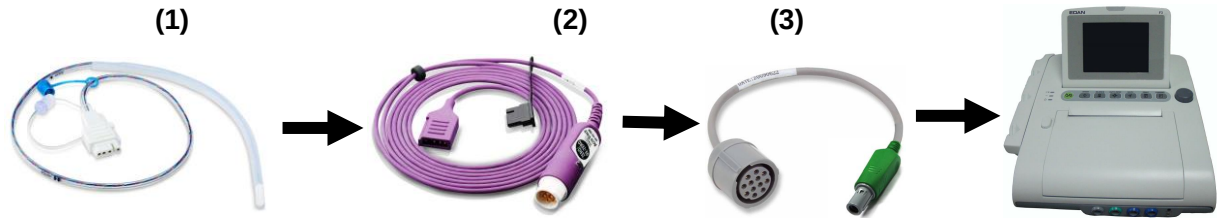


Figure 7-6 Connection for IUP Monitoring (Kendall)

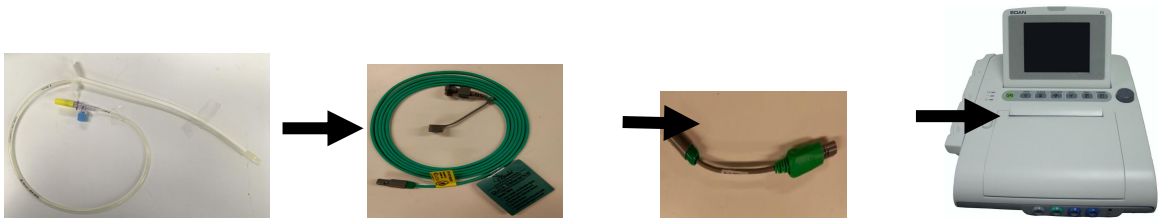


Figure 7-7 Connection for IUP Monitoring (Koala)

7.5.2 IUP Monitoring Procedure

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.

4 Do not catheterize if placenta previa is diagnosed, or if uterine bleeding from an undetermined source is present.

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:

Read the instructions that accompany the intrauterine catheter and the adapter cable before you start monitoring. Zero the monitor when instructed.

Prepare for IUP monitoring using the list below. The standard procedures in use in your facility determine the sequence of actions.

1) Perform a complete clinical evaluation.
2) Catheterize after membrane rupture.

➢ **Kendall Procedures:**

1) Insert IUPC using the procedures described on the package.
2) Plug the IUP cable to the TOCO/IUP socket of the monitor.
3) 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".
4) Connect the IUPC to the IUP cable.

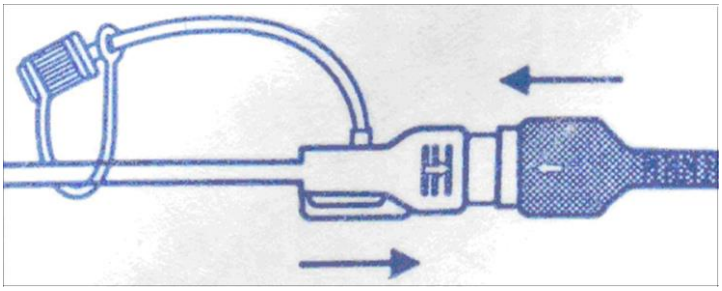


Figure 7-8 Connect catheter to pressure cable

5) Ask the mother to cough. A spike on the trace in response to the cough indicates proper positioning and function of the IUPC.
6) Wash timely during monitoring. A spike on the trace will respond to the washing.

➢ **Koala Procedures:**

1) Insert IUPC using the procedures described on the package.
2) Plug the IUP cable to the TOCO/IUP socket of the monitor.
3) Connect the IUPC to the IUP cable.

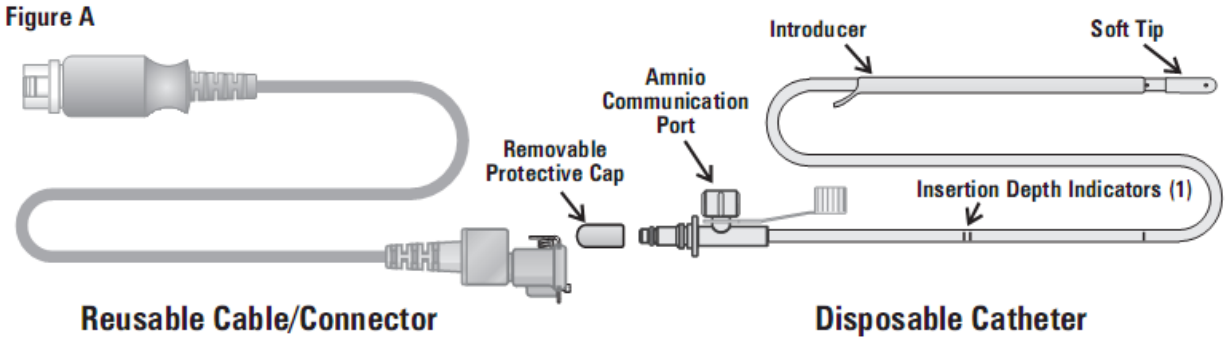


Figure 7-9 Connect catheter to pressure cable

4) Zero the monitor by pressing the **AUTO ZERO** key. Make sure the display numeric and trace are both "0".

5) Ask the mother to cough. A spike on the trace in response to the cough indicates proper positioning and function of the IUPC.
6) Wash timely during monitoring. A spike on the trace will respond to the washing.

7.6 Monitoring Fetal Movement

Fetal movement situation derives from auto fetal movement (AFM) and manual fetal movement (MFM) monitoring.

7.6.1 Auto Fetal Movement Monitoring (AFM)

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

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

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

AFM monitoring can be switched off.

7.6.2 Enabling or Disabling AFM Monitoring

To enable or disable AFM monitoring,

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

7.6.3 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**.

7.6.4 Manual Fetal Movement Monitoring (MFM)

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

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

7.6.5 Changing MFM Volume

The monitor gives a sound when the remote 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**.

7.7 *Starting Monitoring

After the **START** key  is pressed, the monitor starts new monitoring automatically after performing these operations: stops printing data of the last monitoring, checks transducer connection, clears the FM count and the monitoring timer, and zeroes the pressure. A start symbol ➞ is presented on the screen.

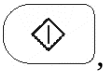
If the Auto start printing is disabled, press the **PRINT** key  to start printing.

NOTE:

Pressing the **START** key separates two patients. Therefore, please remember to press the **START** key when monitoring a new patient.

7.8 *Inputting Maternal Information (Mat. Info)

7.8.1 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.

NOTE:

The auto IDs created in a minute are the same. The manufacturer advises against pressing the **START** key continuously in a short time.

7.8.2 Changing Maternal Information

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

1 Select the patient ID area next to the **Mat. Info** key  on the main interface.
2 Select **ID**.
3 Select the required number 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**.

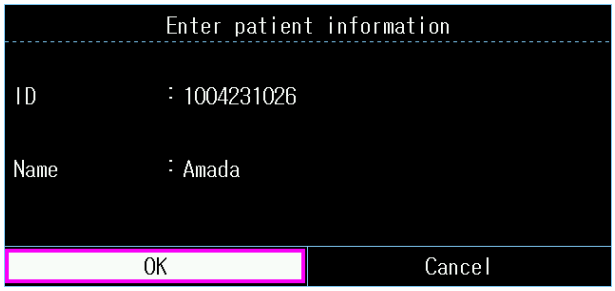


Figure 7-10 Mat. Info inputting menu

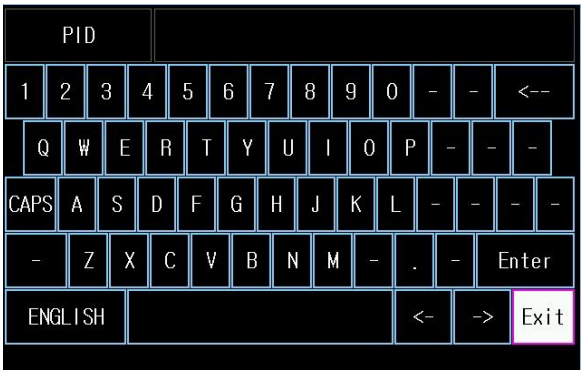


Figure 7-11 Soft keyboard

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

NOTE:

1 The monitor only saves the most recent inputted maternal information.

2 If the maternal information is changed in the printing process, the monitor prints the new ID and name immediately.

7.8.3 Switching Mat. Info Inputting On or Off

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

To switch **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 Understanding Measurement Results

8.1 Changing Screen Display Mode

The monitor has three display modes: trace-numeric mode, trace mode and numeric mode.

If you want to observe the traces (FHR, TOCO and AFM) and numerics synchronously, choose the trace-numeric mode (figure 8-1).

If you want to observe more traces on the screen, choose the trace mode (figure 8-2).

If you want to observe the numerics in big typeface, choose the numeric mode (figure 8-3).

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

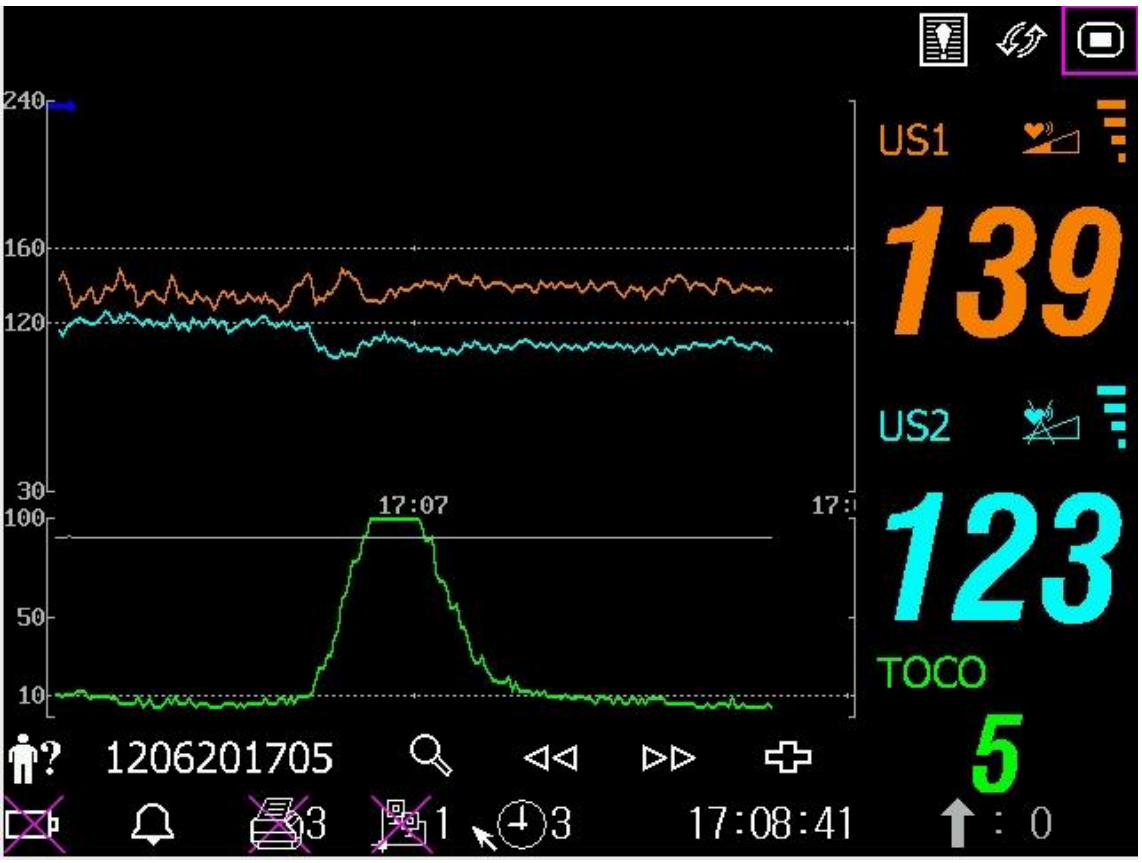


Figure 8-1 Trace-Numeric Mode

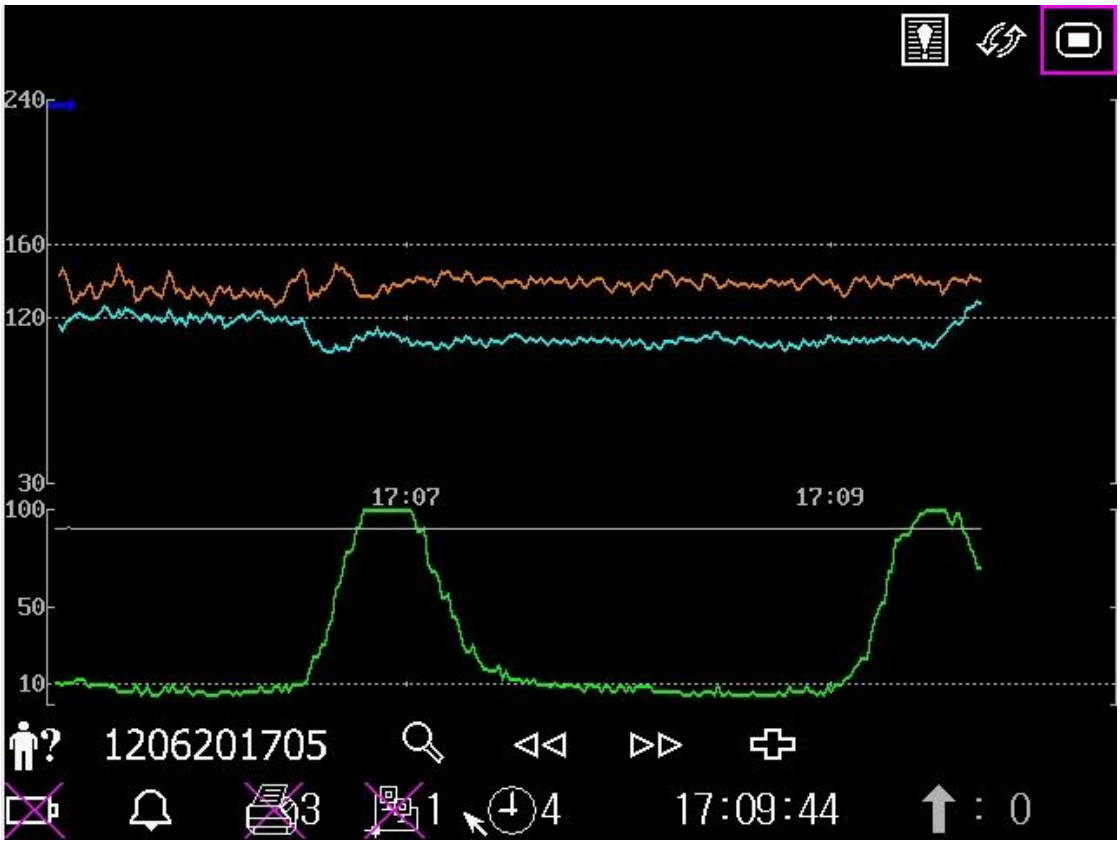


Figure 8-2 Trace Mode

Figure 8-3 Numeric Mode

8.2 Traces

WARNING

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.

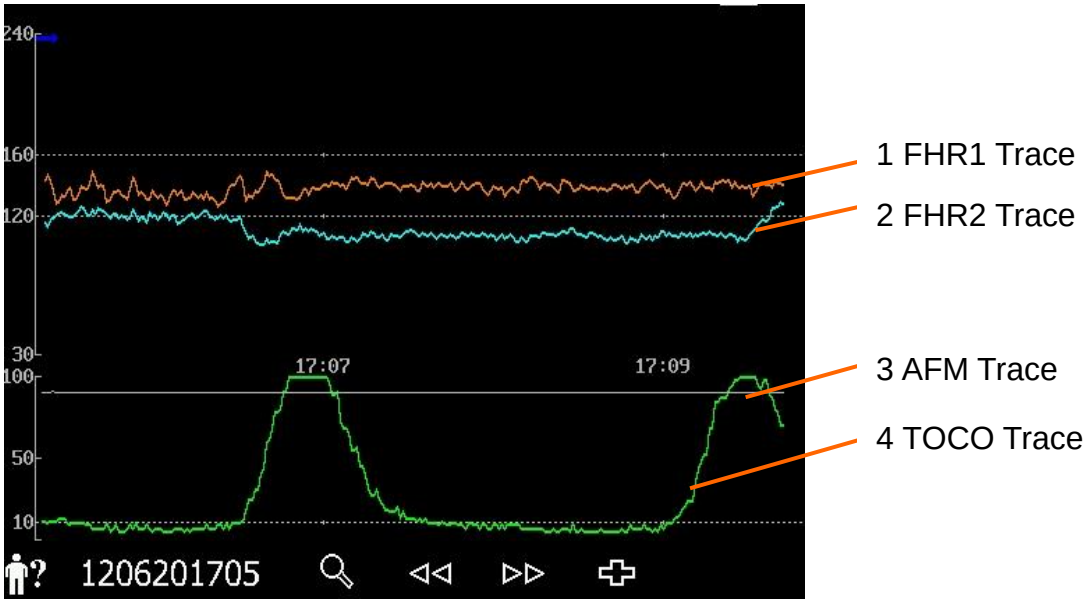


Figure 8-4 Traces

Main traces	
1, 2 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). The positions of the two broken lines in between the fetal heart rate pane vary with the alarm limits (with the lowest at 100 and highest at 180). So you can easily tell if the fetal heart rate is too low or too high.
3 AFM trace	The y-axis indicates the scope of fetal movement. **NOTE:** The AFM trace is only for reference, please take the MFM marks as criterion.
4 TOCO trace	The y-axis indicates the numeric of TOCO. The range is 0 ~ 100.
Other elements:	
➞	This symbol indicates the new monitoring starts.
↑	This symbol indicates a manual fetal movement, which 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.

8.2.1 Changing Time Scale

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

To change this time format:

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

NOTE:

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

8.2.2 Searching for a Patient's Record

The auto-saved data of every monitoring is stored as a separate file in the monitor. With the searching key  , you are able to find a patient's monitoring record easily.

1 Select the searching key  on the main interface to open the **Patient Searching** interface, which records a list of up to 200 most recent patients' ID and name (When the USB feature is disabled, the interface is shown as follows).

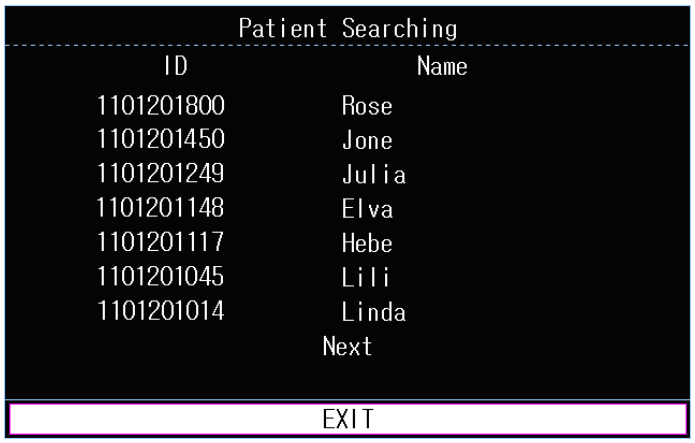


Figure 8-5 Patient Searching

2 If the required record is not on the current page, select **Next** to view more records.

3 Move the cursor to select the required item (if the USB feature is enabled, you should select **Load** in the pop-up item), and the monitor loads the traces of this record to the main interface for review.

8.2.3 File Management (Optional)

The USB feature of the monitor allows you to export the auto-saved files into a USB disk, and then you can save the files in a PC or open them in a data managing system.

Once the monitor is configured with the relevant hardware, the USB feature can be enabled or disable by the service personnel of the manufacturer.

8.2.3.1 Exporting Files

1 Make sure the USB feature is enabled. Stop printing and disconnect the network.

2 Plug the USB disk into the USB socket on rear panel of the monitor (figure 2-4). A message "Ready to use USB disk" in the message area indicates the proper insertion of the disk.

3 Select the file managing key  on the main interface to open the **File Management** interface, which records a list of up to 200 most recent monitoring records (patients' ID, name and date) and a few operation items.

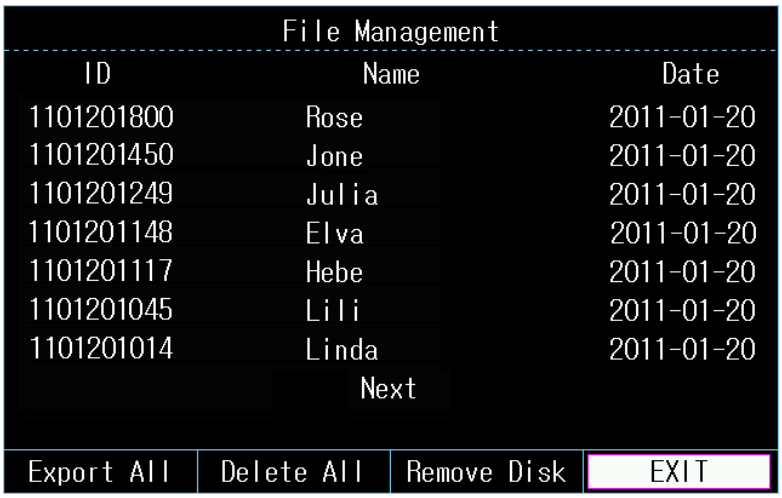


Figure 8-6 File Management

4 If the required record is not on the current page, select **Next** to view more records.

5 Move the cursor to select the required item, and then select **Export** in the pop-up item, and the monitor exports this record to the USB disk. Or you can select **Export All** to export all the records to the USB disk.

NOTE:

1 When the monitor is in the process of printing or is connected to the network, the files cannot be exported.

2 To avoid influence caused to the real-time monitoring, the manufacturer advises against plugging in the USB disk and exporting the data in the process of monitoring.

3 The USB disk is not a tool for long-term data storage. You should save the exported files in a PC in time and clear the USB disk termly.

4 The monitor only supports those USB disks with **FAT** or **FAT32** (recommended) format, and with capacity not larger than 8G. You are advised to use the USB disk provided by the manufacturer.

In the **FetusData** folder of the USB disk, a sub-folder named after the export date and time is created when the export is performed. The exported records are saved in this sub-folder as .trc files, named after the monitor started date, time and ID, e.g. "20100120-124936-12345.trc".

8.2.3.2 Removing USB Disk

After the export finishes, select **Remove Disk** on the **File Management** interface. Do not unplug the USB disk until a message "The USB can now be safely removed." is prompted.

If the message "Failure" is prompted, you should perform the above procedures again.

NOTE:

1 Make sure you perform the **Remove Disk** procedure, otherwise data lose or USB disk damage may be caused.

2 You should unplug the USB disk after performing the **Remove Disk** procedure; otherwise the monitor cannot identify the USB disk.

8.2.3.3 Deleting Files

After the files are saved, you can delete them.

1 Select the file managing key  on the main interface to open the **File Management** interface.

2 Select **Delete All** > **Yes**. All the files in the monitor are deleted.

3 Select **Exit**.

NOTE:

1 When the monitor is in the process of printing, the files cannot be deleted.

2 File deleting should be performed with caution since the deleted files cannot be restored.

3 The monitor automatically erases the earliest files when the memory is full (the maximum capacity is 60-hour data). You should export and save the files in time.

4 When there are more than 200 files, it may take extended time for the monitor to load them. You should export the files in time and then delete them from the monitor.

8.2.4 *CTG Analysis (Optional)

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 **System > Function**.

3 Activate CTG function and enter the password on the pop-up interface.

4 Select **OK**.

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

8.2.4.2 CTG analyzing

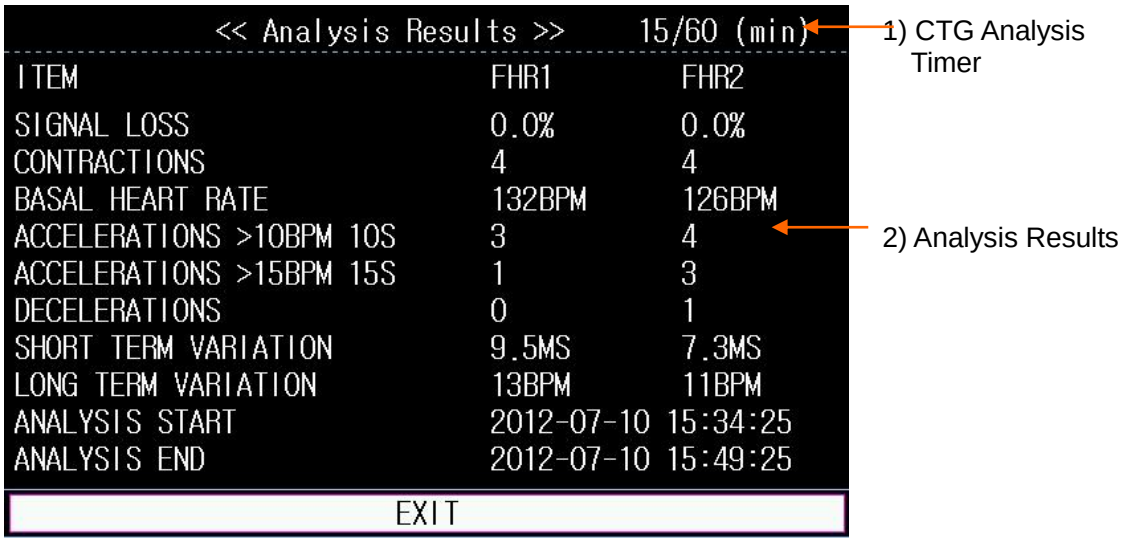
NOTE:

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

2 The CTG analysis result is for reference only.

3 As an advanced optional function, CTG analysis can't be closed once opened. If you want to purchase it, you can ask local dealers or marketing personnel for the activation password.

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



<< Analysis Results >> 15/60 (min)

ITEM	FHR1	FHR2
SIGNAL LOSS	0.0%	0.0%
CONTRACTIONS	4	4
BASAL HEART RATE	132BPM	126BPM
ACCELERATIONS >10BPM 10S	3	4
ACCELERATIONS >15BPM 15S	1	3
DECELERATIONS	0	1
SHORT TERM VARIATION	9.5MS	7.3MS
LONG TERM VARIATION	13BPM	11BPM
ANALYSIS START	2012-07-10 15:34:25	
ANALYSIS END	2012-07-10 15:49:25	

EXIT

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： <32 weeks, including the acceleration with amplitude larger than 10bpm and lasts more than 10 seconds, ⩾32 weeks 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 *Reviewing

The reviewing keys  (backward key) and  (forward key) under the traces 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 to increase the speed until it reaches the maximum. Rotate the knob clockwise to decrease the speed until it reaches the minimum. Press the knob 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 to increase the speed until it reaches the maximum. Rotate the knob anticlockwise to decrease the speed until it reaches the minimum. Press the knob to pause.

When the reviewing is paused, the progress symbol turns to <--X%-->. If the **PRINT** key  is pressed at this moment, the recorder prints the traces of the patient on the current screen at a high speed according to the settings.

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

Move the cursor away from the reviewing and searching keys to return to the real-time main interface.

When reviewing the traces, the monitor does not stop. The fetal heart 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 You must pause before start printing. Printing in the process of playback might result in failure information on the paper.

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

3 The reviewed data cannot be printed if the net version is set to **PHILIPS**.

8.3 Numerics

The numerics include FHR1/DECG, FHR2, TOCO/IUP and MFM/AFM.

	FHR1 or DFHR measurement numeric display area. If the US1 or DECG socket is not connected with a US transducer, nothing displays here. If the transducer is connected but no valid signal is received, it displays ---.
	TOCO or IUP measurement numeric display area. If the TOCO or IUP socket is not connected with a transducer/catheter, nothing displays here. If the TOCO or IUP socket is connected with a transducer/catheter, it displays the value.
	FHR2 measurement numeric display area. If the US2 socket is not connected with a US transducer, nothing displays here. If the transducer is connected but no valid signal is received, it displays ---.
	MFM/AFM count display area.

NOTE:

The monitor detects the transducers automatically. If no US transducer is connected to the US2 socket, the US2 numeric area is not displayed. However, if they are unplugged midway, the monitor gives alarm for the disconnection. At this time, press the **START** key  to let the monitor check transducer connection again.

8.4 Alarm Messages

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

Alarm Message	Cause	Countermeasure
Patient Alarm (Medium Level)		
**FHR1 HIGH or ** FHR1 xxx > yyy, **FHR2 HIGH or ** FHR2 xxx > yyy **DFHR HIGH or **DFHR xxx > yyy	FHR1, FHR2 or DECG measuring result (xxx) is higher than the set high alarm limit (yyy) over the alarm delay time.	Check if the alarm limits are suitable; check the woman's condition.

**FHR1 LOW or ** FHR1 xxx < yyy, **FHR2 LOW or ** FHR2 xxx < yyy **DFHR LOW or **DFHR xxx > yyy	FHR1, FHR2 or DECG measuring result (xxx) is lower than the set low alarm limit (yyy) over the alarm delay time.	Check if the alarm limits are suitable; check the woman's condition.
Technical Alarm (Medium Level)		
**Battery Low	The battery power is too low to support further work of the monitor.	Connect the monitor to AC power supply.
Technical Alarm (Low Level)		
US1 UNPLUGGED or US2 UNPLUGGED	US transducer 1 or US transducer 2 is not well connected.	Check the connection of the transducer.
US1 SIGNAL LOSS or US2 SIGNAL LOSS	FHR1 or FHR2 signal is too weak for the system to analyze.	Check if the US transducer is aimed at the fetal heart; check if the alarm limits are suitable; check the woman's condition.
TOCO UNPLUGGED	TOCO transducer is not well connected.	Check the connection of the transducer.
IUP UNPLUGGED	IUP cable is not well connected to the monitor.	Check the connection of the IUP cable.
Fetus EQUIP MALF	The fetus board cannot communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
Check Paper	There is no paper in the paper drawer or the drawer is open.	Load paper and/ or close the drawer.
Signals Overlap (FHR1, FHR2)	US transducer 1 and US transducer 2 are aimed at the same fetal heart; the signals overlap.	Adjust one of the US transducers until another fetal heart signal is detected.
Signals Overlap (DFHR, FHR2)	US transducer 2 is aimed at the fetus that the spiral electrode is attached to; the signals overlap.	Adjust the US transducer until another fetal heart signal is detected.
DECG LEADS OFF	The spiral electrode is not well connected.	Check the connection of the spiral electrode.
DECG UNPLUGGED	The DECG lead is not well connected to the monitor.	Check the connection of the DECG cable.
DECG SIGNAL LOSS	DECG signal is too weak for the system to analyze.	Check if the spiral electrode is well attached to the fetus; check the woman's condition.
DECG EQUIP MALF	The DECG board cannot communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.

Chapter 9 After Monitoring

9.1 Saving Data

The monitor automatically saves the data every two minutes and prior to shutdown, including fetal monitoring traces and maternal information. The maximum capacity is 60-hour data.

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

CAUTION

Switch off the monitor in a normal way as described in section 9.3 Switching Off. Interrupted power-off may cause data loss and failure in data reloading.

9.2 Completing Monitoring

After monitoring,

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

NOTE:

1 The remaining coupling gel on the ultrasound transducer may cause the monitor to give some noise. Therefore, the gel should be wiped off the transducer after monitoring.

2 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.

9.3 Switching Off

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

CAUTION

After the monitor is switched off, please wait for at least 10 seconds before switching it on again.

Chapter 10 Maintenance and Cleaning

10.1 Maintenance

10.1.1 Maintaining Inspection

(1) Visual Inspection

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

1) 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.
2) Check all the outer cables, power socket and power cables.
3) Check if the monitor functions properly.

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

(2) Routine Inspection

The overall check of the monitor and 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.

10.1.2 Maintenance of Monitor

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

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

Avoid scratching and damaging the screen.

10.1.3 Maintenance of Transducers

WARNING

1 The transducers must be cleaned before docking in the base station after each use. Make sure that there is no residual coupling gel.

2 The transducers are delicate and sensitive. Please handle them with care and try to avoid dropping on to the ground or any hard surfaces.

Gel must be wiped off the US transducer after use. These precautions will prolong the life of the transducer.

Avoid contacting the transducers with hard or sharp objects. Although transducers are designed for durability, they should be handled with care. Rough handling could damage the cover, piezoelectric crystals and mechanical movement.

Do not excessively flex the cables.

10.1.4 Storage of Recorder Paper

The thermosensitive recorder paper is not intended to be used as a long-term storage medium. We recommend you to save the monitoring data with another medium.

When storing recorder paper (including used paper with traces):

Do not store in plastic envelopes.

Do not leave exposed to direct sunlight or ultraviolet light.

Do not exceed a storage temperature of +40 ℃ (+104 ℉).

Do not exceed a relative humidity of 80%.

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

10.1.5 Maintenance of Recorder

WARNING

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

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.

10.2 Cleaning

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

10.2.1 Cleaning of Monitor

WARNING

1 Unplug the monitor from the AC power source, remove the battery and detach all accessories before cleaning.

2 Do not immerse the unit in water or allow liquids to enter the case. 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.

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

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

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

Clean the screen with a dry soft cloth.

CAUTION

1 Although the monitor is chemically resistant to most common hospital cleaners and non-caustic detergents, different cleaners are not recommended and may stain the monitor.

2 Many cleansers must be diluted before use. Follow the manufacturer’s directions carefully to avoid damaging the monitor.

3 Do not use strong solvent, for example, acetone.

4 Never use an abrasive such as steel wool or metal polish.

5 Do not allow any liquid to enter the product, and do not immerse any part of the monitor into any liquid.

CAUTION

6 Avoid pouring liquids on the monitor while cleaning.

7 Do not allow any remaining solution on the surface of the monitor.

NOTE:

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

10.2.2 Cleaning of Accessories

(1) Cleaning of Transducers

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

- Wipe them with a soft cloth dampened in cleaning solution;
- Clean them with a soft cloth dampened in water;
- 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	Mild near neutral detergent Ethanol 75% Isopropanol 70%
DECG Cables	Ethanol 75% Isopropanol 70%
IUP Cable	Ethanol 75% Isopropanol 70%

CAUTION

1 The waterproof parts of the US/TOCO transducer are restricted to the main body and the cable. Do not immerse the plug into any liquid in the process of monitoring or cleaning.

2 Only clean the outer surface of the connectors, make sure no liquid goes into the connector.

3 Be sure the temperature of cleaning solutions does not exceed +45 ºC (+113 ºF).

4 After cleaning, no remaining cleanser is allowed on the surface.

(2) Cleaning of Belt

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

10.3 Disinfecting

Clean the equipment before disinfecting.

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
Transducers	Ethanol 75% Isopropanol 70%
DECG Cable	
IUP Cable	

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.

10.4 Sterilizing

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

NOTE:

Check if the monitor, 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 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 *2.4.1* section.
Performance	Please check the US transducer and TOCO transducer according to *7.1.6 Testing US Transducers* and *7.4.4 Testing TOCO Transducers.*

Chapter 11 Warranty and Service

11.1 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.

11.2 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 ℃ ~ + 40 ℃ (+41 ℉ ~ +104 ℉)
	Relative Humidity:	15% ~93% (non-condensing)
	Atmospheric Pressure:	86 kPa ~ 106 kPa
Transport and Storage	Temperature:	-20 ℃ ~ +55 ℃ (-4 ℉ ~ +131 ℉)
	Relative Humidity:	15% ~ 93% (non-condensing)
	Atmospheric Pressure:	70 kPa ~ 106 kPa

A1.2 Physical Specifications

Monitor		
Dimensions and Weight	Size (depth x width x height) :	350mm x 300mm x 104mm
	Weight:	Approx. 3.5 kg
Power Supply	Operating Voltage:	100V-240V~
	Operating Frequency:	50Hz/60Hz
	Input Power :	70VA
	Battery:	14.8VDC/5000mAh
Standards Compliance	IEC 60601-1:2005/A1:2012, EN 60601-1:2006/A1:2013, IEC 60601-1-2:2014, EN 60601-1-2:2015, IEC/EN 60601-2-37	

Anti-electric Shock Type	Class I equipment with internal power supply
Anti-electric Shock Degree	FHR1, FHR2, TOCO, FM, FS BF IUP BF DECG CF
Degree of Protection against Harmful Ingress of Water for the Transducers	IPX 8 (FHR1,FHR2,TOCO)
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		CISPR 11 Group 1 Class A
Working System		Continuous running equipment
Earth Leakage Current (Limit)		N.C. S.F.C. 500μA 1000μA
Enclosure Leakage Current (Limit)		N.C. S.F.C. 100μA 500μA
Patient Leakage Current (Limit)		N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Patient Auxiliary Current (Limit)		N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Display	LCD Size:	5.6”
	Resolution:	640 (RGB) x 480
Signal Interface	DB9, RJ45 network interface	
Ultrasound Transducer		
Weight:		190g
Cable Length:		2.5m
Dimension:		88mm×35mm
TOCO Transducer		
Weight:		180g
Cable Length:		2.5m
Dimension:		88mm×35mm
Remote Event Marker		
Length:		2.5m
Weight:		56g

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	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:	628 mm^2 ± 15%
	*FHR Measurement Range:	50 bpm ~ 240 bpm
	*Resolution:	1 bpm
	*Accuracy:	±2 bpm
	*Temperature Rise	When applied to the patient, the ultrasound transducer may warm slightly (less than 2℃ (3.6℉) above ambient temperature). When NOT applied, at the ambient temperature of 40℃ (104℉), the ultrasound transducer may reach the highest temperature of 43℃ (109.4℉).
	Dielectric Strength:	> 4000Vrms
	ISATA@ the transducer face: 1.865 mW/cm^2	
	Entrance beam: 6.08 cm^2	
	Measurement uncertainties for ISATA: ±26.6%	
	Measurement uncertainties for ultrasonic power: ±26.6%	
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 Range:	0 ~ 100
	*Non-linear Error:	±10%

TOCO	Baseline Drift due to Temperature Changes	≤ 1 unit/min/ ℃ (free air)
		≤ 5 units/min/ ℃ (underwater)
	*Resolution:	1
	Zero Mode:	Automatic/ Manual
IUP	*Pressure Range:	0mmHg ~100mmHg (0.0 kPa~13.3 kPa)
	Sensitivity:	5 μV/V/mmHg
	*Non-linear Error:	±3mmHg (±0.4 kPa)
	*Resolution:	1mmHg (0.1 kPa)
	Zero Mode:	Manual
AFM	Technique:	Pulsed Doppler ultrasound
Marking	Manual fetal movement mark	

NOTE:
The essential performance is marked with an asterisk *.

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)
Accuracy of data:	±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, fetal stimulation mark, AUTO-zero symbol, date, time, printing speed, ID, name, FHR2 Offset etc.

A1.5 Lithium-ion Battery Specifications

Battery / Specification	01.21.064143
Nominal Capacity	5000mAh
Working Time	>7 hours (depending on configuration)
Nominal Voltage	14.8V
Charge Time	<6 hours
Cycle Life	≥300 times

NOTE:

Operation of the equipment below the minimum amplitude may cause inaccurate results.

A1.6 Low Output Summary Table

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0)
System: F3 Fetal Monitor

Transducer: 8 Ultrasound Crystal

Transducer Model	$I_{spta.3}$ (mW/cm^2)	TI Type	TI Value	MI	$Ipa.3@MI_{max}$ (W/cm^2)
MS3-109301(D) (8 ultrasound crystals)	1.16	TIS	0.0054	0.010	0.0064
		TIB	0.033		

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0)
System: F3 Fetal Monitor

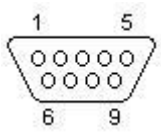
Transducer: 7 Ultrasound Crystal

Transducer Model	$I_{spta.3}$ (mW/cm^2)	TI Type	TI Value	MI	$Ipa.3@MI_{max}$ (W/cm^2)
MS3-109301(D) (7 ultrasound crystals)	4.63	TIS	0.020	0.030	0.030
		TIB	0.020		

Appendix 2 Signal Input/Output Connector

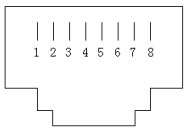
Accessory equipment connected to these interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). If in doubt, contact our technical service department or your local distributor.

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

RJ45 Interface



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

Appendix 3 Troubleshooting

A3.1 No Display

Phenomenon	Possible Cause	Solution
Power 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.
	Rather than the provided paper, another type of paper is used.	Use the paper that is provided by the manufacturer, or contact the manufacturer for service.
Recorder does not work.	The recorder is not started.	Press the **PRINT** key.
	The drawer runs out of paper.	Load paper.
	The paper drawer is not locked.	Close the drawer cover and press it until both latches are locked in position.
	Wrong type of paper is used.	Use the identical type of paper as that provided by the manufacturer. Or contact the manufacturer for service.

Feint trace or no trace	Improper paper is used.	Use paper recommended by manufacturer
The monitor gives “check paper” warning when there is paper in the drawer.	The paper sensor is dirty.	Clean the paper sensor with a dry cloth gently.
Incorrect time and date	Time incorrectly set	Reset time and date and note the difference between Daylight Saving Time and Winter Standard Time(See 6.5)
	Battery fault	The battery needs service. Call the service personnel.

A3.4 Trouble with Ultrasound FHR Monitoring

Phenomenon	Possible Cause	Solution
Inconstant trace / display	The pregnant woman is overweight.	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.
The channel from unused transducer displays numerics.	The transducer is affected.	Unplug the unused transducer.

A3.5 Troubles with DECG FHR Monitoring

Phenomenon	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.	Ensure favorable contact for patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

A3.7 Troubles with Contractions Monitoring (Internal)

Phenomenon	Possible Cause	Solution
No trend	The intrauterine catheter is jammed	Wash with disinfector
No pressure change when uterine contraction	“Dry” environment or the tip of intrauterine catheter is placed extraovularly	Wash with disinfector or change the position of transducer
Only see the IUP peak but no baseline	Zero adjustment is wrong	Zero the system

The trend is a beeline	The connector failure.	Move or contact catheter. If trend no fluctuation, change intrauterine cable.

A3.8 Blown Fuses

WARNING

Switch off the monitor and remove the power cord before changing the fuse.

Replace the fuse when it is blown.

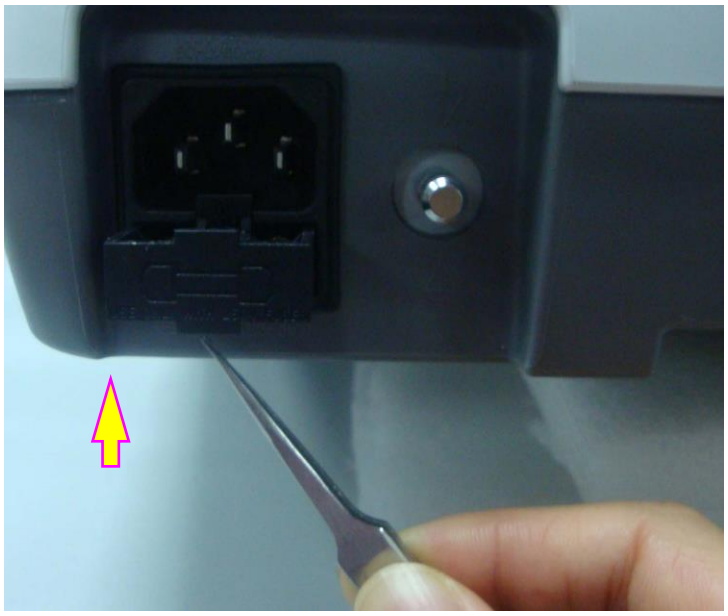
The two fuses of the monitor are located on the rear panel, their specifications are:

Size: Φ5mm*20mm; Model: T2AH250V.

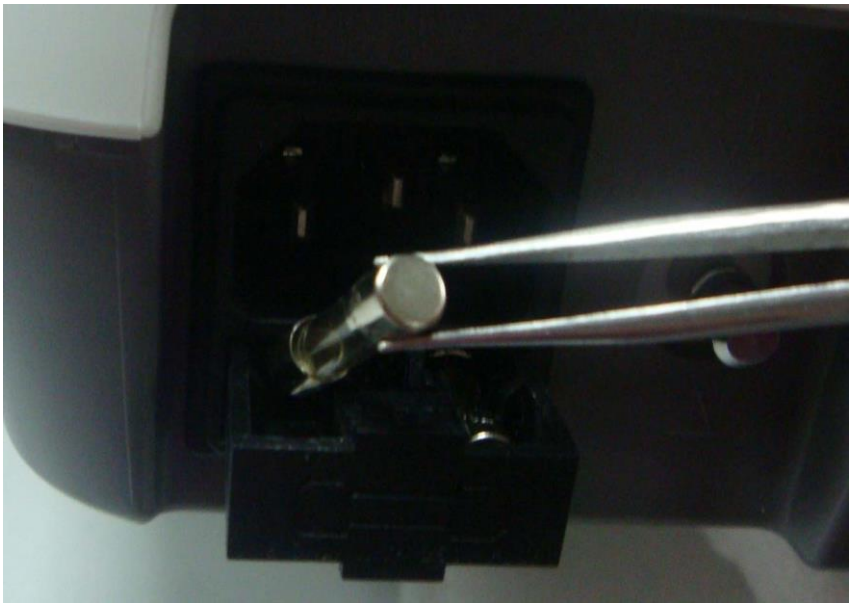
To replace a fuse:

1) Place the monitor on a flat surface and remove the power cord.
2) 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.

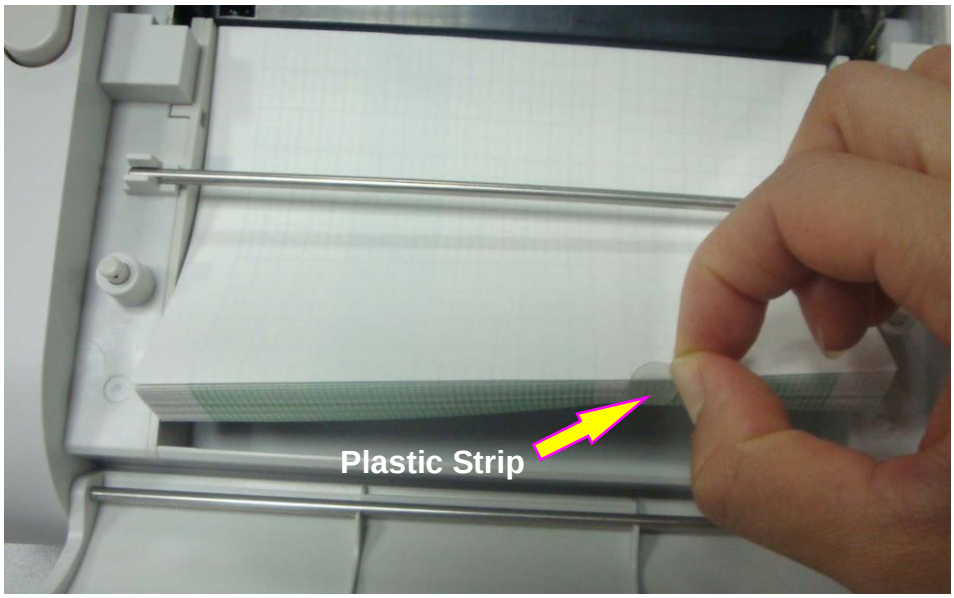


5) Push the fuse container all the way back in position.

A3.9 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) Pull up the plastic strip in the drawer to lift the remaining paper. Remove the paper.



3) Reload paper and then close the drawer.

Appendix 4 Ultrasound Intensity and Safety

A4.1Ultrasound 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.

A4.2Ultrasound 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).

A4.3Explanation of MI/TI

A4.3.1MI (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 (MPa / MHz)

A4.3.2TI (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 1 ℃.

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.

A4.3.3Measurement 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 and the difference in mean temperatures between the hydrophone calibration lab and our facility, the uncertainty is ±1.6% for intensity and ±0.8% for pressure.

4. Spatial Averaging

The maximum spatial averaging correction factor in this submission is reported as 1.17 for HNP-0400 hydrophone. According to [6], the uncertainty is assumed to be one-half of the value of the correction value; therefore the uncertainty for spatial averaging is ±10.2% for intensity and ±6.1% for pressure for the HNP-0400 hydrophone.

5. Non-linear Distortion:

N/A.

6. Total Uncertainty for HNP-0400 Hydrophone

Since all the above error sources are independent, they may be added on an root sum square basis, giving a total uncertainty of ±26.62% for all intensity values reported, and ±13.31% for all the pressure values.

Since the total power is based on the intensity, the uncertainty for power is also ±26.62%. The center frequency estimate is depended upon the digital oscilloscope and is therefore given as

±0.3%.
Since the MI is based on the pressure and the square root of the center frequency, the uncertainty for the MI is therefore reported as ±14.52%.

A4.4Prudent 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.

A4.5References 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.
7. “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 Transducer Acoustic Output Parameters List

A4.6.1 8 Ultrasound Crystal Transducer

Acoustic Output Reporting Table for Track1(Non-autoscanning Mode)

Transducer Model: MS3-109301(D)(8 ultrasound crystals)
Working 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			0.010	1.16	0.0064
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.010		
	W_0 (mW)			5.60	5.60
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		12.45	12.45	12.45
	Beam dimensions	X_{-6} (cm)		0.75	0.75
		Y_{-6} (cm)		0.83	0.83
	PD (usec)		90.72		90.72
	PRF (Hz)		2000.00		2000.00
	EBD	A_z (cm)		Φ2.83	
		E_{le} (cm)		Φ2.83	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		1.00		

Acoustic output reporting table for IEC60601-2-37
(IEC60601-2-37, Edition 2.1, 2015-06, table 201.103)

System:F3
Transducer Model: MS3-109301(D)(8 ultrasound crystals)
Working Mode: PW mode
Working Frequency:1.0MHz

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.010	0.0054		0.033		N/A
Index component value			N/A	0.0054	N/A	0.033	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	0.010					
	P (mW)		5.60		5.60		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			13.95			
	z_b (cm)					13.95	
	z_{MI} (cm)	12.45					
	$z_{PII.\alpha}$ (cm)	12.45					
	f_{awf} (MHz)	1.00	1.00		1.00		N/A
Other Information	*prr* (Hz)	2000.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	0.0064					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$ (mW/cm^2)	1.16					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	2.73					
	p_r at z_{PII} (MPa)	0.016					

Operating control conditions	Focus(mm)	Fixed					
	Depth(mm)	Fixed					
	Frequency(MHz)	1.00					

A4.6.2 7 Ultrasound Crystal Transducer

Acoustic Output Reporting Table for Track1(Non-autoscanning Mode)

Transducer Model: MS3-109301(D)(7 ultrasound crystals)
Working 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			0.030	4.63	0.030
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.030		
	W_0 (mW)			12.44	12.44
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		1.79	1.79	1.79
	Beam dimensions	X_{-6} (cm)		3.12	3.12
		Y_{-6} (cm)		3.12	3.12
	PD (usec)		87.17		87.17
	PRF (Hz)		2000.00		2000.00
	EBD	A_z (cm)		Φ3.12	
		E_{le} (cm)		Φ3.12	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		1.00		

Acoustic Output Reporting Table for IEC60601-2-37
(IEC60601-2-37, Edition 2.1, 2015-06, table 201.103)

System:F3
Transducer Model: MS3-109301(D)(7 ultrasound crystals)
Working Mode:PW mode
Working Frequency:1.0MHz

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.030	0.020		0.020		N/A
Index component value			N/A	0.020	N/A	0.020	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	0.030					
	P (mW)		12.44		12.44		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			1.79			
	z_b (cm)					1.79	
	z_{MI} (cm)	1.79					
	$z_{PII.\alpha}$ (cm)	1.79					
	f_{awf} (MHz)	1.00	1.00		1.00		N/A
Other Information	*prr* (Hz)	2000.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	0.030					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$	4.63					

	(mW/cm^2)						
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	5.24					
	$p_{r.}$ at z_{PII} (MPa)	0.030					
Operating control conditions	Focus(mm)	Fixed					
	Depth(mm)	Fixed					
	Frequency(MHz)	1.00					

A4.7 Standard Parameter Equal Contrast List

IEC60601-2-37 standard parameter equal contrast list	
IEC60601-2-37 parameter	**NOTE**
$p_{r.\alpha}$	Attenuated Peak-rare-factional Acoustic Pressure
p_r	Peak-rare-factional Acoustic Pressure
P	Output Power
z_s	Depth for Soft Tissue Thermal Index
$P_\alpha(Z_s)$	Attenuated Output Power
$I_{ta.\alpha}(Z_s)$	Attenuated Temporal-average Intensity
z_{bp}	Break-point Depth
z_b	Depth for Bone Thermal Index
$I_{pi.\alpha}$	Attenuated Pulse-intensity Integral
I_{pi}	Pulse-intensity Integral
$d_{eq}(Z_b)$	Equivalent Beam Diameter at the point of Z_{sp}
f_{awf}	Center Frequency, Acoustic Working Frequency
X	-12dB Output Beam Dimensions
Y	
t_d	Pulse Duration
prr	Pulse Repetition Frequency (Pulse Repetition Rate)
d_{eq}	Equivalent Beam Diameter
FL_x	Focal Length
FL_y	
$I_{pi.\alpha}$ at max MI	Attenuated Pulse-average Intensity at the point of Maximum MI
A_{aprt}	-12dB Output Beam Area
MI	Mechanical Index
TIS	Soft Tissue Thermal Index
TIB	Bone Thermal Index

TIC	Cranial-bone Thermal Index

parameter specified in TRACK1 of FDA Guidance	
TRACK1 parameter	**NOTE**
$p_{r.3}$	Derated Peak-rare-factional Acoustic Pressure
W_0	Output Power
z_{sp}	$z_{sp} = z_{B.3}$, Depth for Bone Thermal Index
f_c	Center Frequency, Acoustic
x_{-6}	-6dB Beamwidth
y_{-6}	
PD	Pulse Duration
PRF	Pulse Repetition Frequency
MI	Mechanical Index
$I_{SPTA.3}$	Derated Spatial-peak Temporal-average Intensity
$I_{SPPA.3}$	Derated Spatial-peak Pulse-average Intensity
Az.	Aperture X width Y Dimeter
Ele.	
EDS	Entrance Dimensions Of The Scan
EBD	Entrance Beam Dimensions

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
ECG	Electrocardiogram
FHR	Fetal Heart Rate
FM	Fetal Movement
FS	Fetal Stimulator
ICU	Intensive Care Unit
ID	Identity
IUP	Intra-Uterine Pressure
IUPC	Intra-Uterine Pressure Catheter
LCD	Liquid Crystal Display
MFM	Manual Fetal Movement [Detection]
NST	Non Stress Test
SOV	Signals Overlap Verification
TOCO	Tocotonometer
UA	Uterine Activity [TOCO/IUP]
US	Ultrasound [Transducer]

Appendix 6 Ordering Information

The accessories employed by the manufacturer, 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 with the standard of ISO 10993.

Part Number	Accessory	Specification
02.01.109301	US Transducer	8 ultrasound crystals, 1MHz, pink label
02.01.212662	US Transducer	7 ultrasound crystals, 1MHz, pink label
02.01.31527	TOCO Transducer	Blue label
02.01.107791	TOCO Transducer	Cyan label
01.13.104152	IUP Cable	PN:56321,Kendall
01.57.472052	IUP Cable	PN:IPC-5090,Koala
01.57.002145	Disposable Fetal Spiral Electrode	PN:31479549
01.57.002146	Disposable Maternal Attachment Pad Electrode	PN:50000095
01.57.104153	Disposable Intrauterine Pressure Catheter	PN:56300,Kendall
01.57.472051	Disposable Intrauterine Pressure Catheter	PN: IPC-5000E,Koala
01.13.036358	DECG Cable	TPU, L=2200mm
01.13.036477	DECG Cable	TPU, L=2200mm DECG-Q
01.13.036478	DECG Cable	TPU, L=2200mm DECG-P
01.13.036357	IUP Connecting Cable	L=150mm ,Kendall
01.13.037841	IUP Connecting Cable	L=80mm ,Koala
02.01.210095	Remote Event Marker	/2.5m
01.57.471447	Belt	/1400mm*58mm
83.62.17692	Fetal Stimulator	
01.57.78001	Ultrasound Gel	/PARKER
01.57.78008	Aquasonic Coupling Gel	/Shenfeng
01.57.471865	Thermosensitive Paper	GE, American Standard, with green safe range
01.57.471869	Thermosensitive Paper	GE, American Standard, without green safe range
01.57.471857	Thermosensitive Paper	GE, European Standard
01.57.471867	Thermosensitive Paper	Phillips, American Standard
01.57.471868	Thermosensitive Paper	Phillips, European Standard
01.13.036667	Power Cord	Domestic Standard
01.13.037122	Power Cord	American Standard
01.13.036638	Power Cord	European Standard
01.21.064143	Rechargeable Lithium-ion Battery	5000 mAh
21.21.064181	Fuse	T2AH250V
01.13.036770	Signal Cable	USB TO DB9
01.13.20096	Signal Cable	Downloading cable/ Ethernet
01.13.036124	Signal Cable	F9 to OB TraceVue cable (DB9 to RJ45, For OB TraceVue with adapter)
01.13.107974	Signal Cable	F9 to OB TraceVue cable (DB9 to RJ45)

01.13.107702	Signal Cable	F9 to OB TraceVue cable (DB9 to DB9)
02.01.210517	Wireless AP module	WL-330N
01.18.052246	Wireless AP	DWL-3200AP
01.57.471026	Dust Cover	890mm*740mm
01.24.070019	Screwdriver	Φ4
01.18.052245	Flash Disk	Netac, U180, 4G, USB2.0
01.13.114114	Ground Cable	Domestic Sales
01.13.114214	Ground Cable	Foreign Sales
83.62.002271	Trolley	MT-803
02.04.240301	Tablet	MT-803
02.01.210926	Basket	MT-803
83.62.328035	Trolley	MT-503N plus laptop holder, provided with F3
83.62.328020	Trolley	MT-503
02.04.101976	Basket	MT-503
02.04.240184	Wall Mounting Package	Provided with F3
02.01.210115	Wall-Mounting Bracket	Provided with F3/ With basket
01.56.465631	Carry Bag	

NOTE:

The part name may vary depending on documents, but the part number is constant.

CAUTION

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

Appendix 7 EMC Information

A7.1 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
The Monitor is intended for use in the electromagnetic environment specified below. The customer of the user of the Monitor should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The 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.
RF emission CISPR 11	Class A	The 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

A7.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	± 8 kV contact ±15 kV air	± 8 kV contact ±15 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 N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ±2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	30 A/m	30 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	0 % $U_{T;}$ 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	0 % $U_{T;}$ 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Monitor requires continued operation during power mains interruptions, it is recommended that the 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 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the 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
6Vrms[c)]in ISM bands between
0,15 MHz and 80 MHz</td><td>3V_{rms}
6Vrms[c)]in ISM bands between
0,15 MHz and 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the 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 ~ 80 MHz
$d = 1.2\sqrt{P}$ 80 MHz ~ 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz ~ 2.7 GHz
d=6 /E at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer).
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>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>3 V/m
80 MHz to 2.7 GHz</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 Monitor is used exceeds the applicable RF compliance level above, the Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Monitor.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz,21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table-Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Brand [a] (MHz)	Service [a]	Modulation [b]	Maximum Power(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Brand 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation[b] 217 Hz	2	0.3	28

5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case						

A7.4 Recommended Separation Distance

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

The Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 2.7 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?

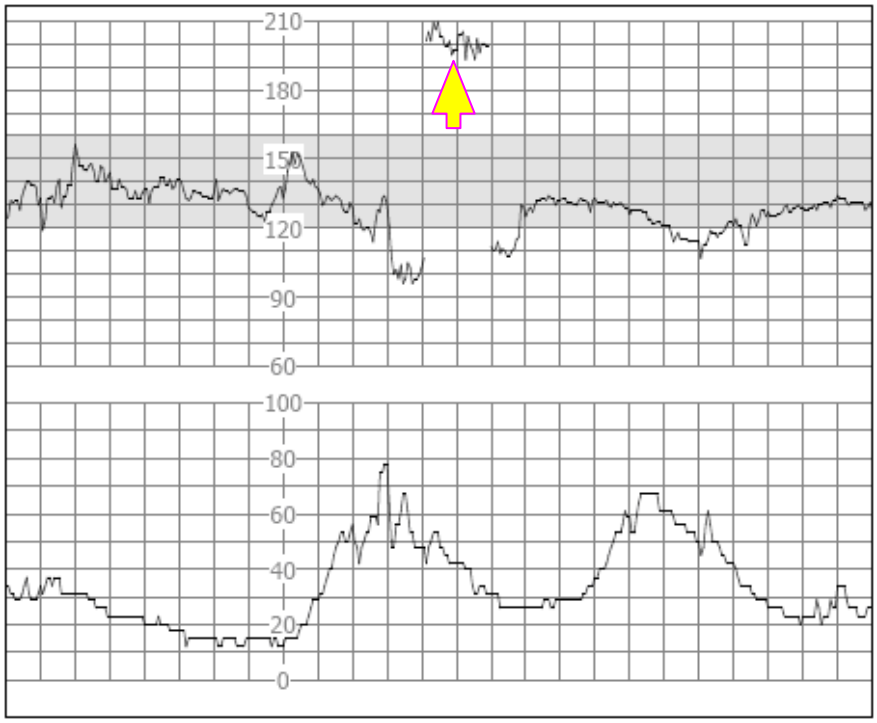
The transducer detects sound waves as they bounce off or echo back from the fetal heart. However, the sound waves bouncing off from maternal blood vessels may be detected by the transducer and then be processed by the monitor as well. As a result, artifacts may be produced.

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.

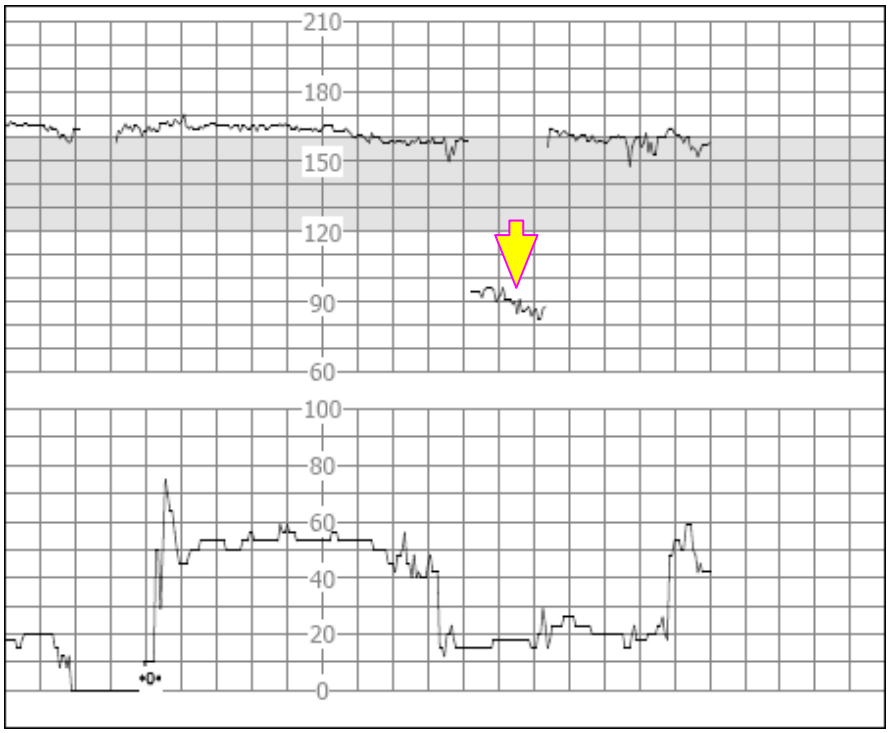
(2) Doubling:

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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