

WALACH FETAL²EMR

User Manual

Fetal Monitor

REF 902300



37474 • Rev B • 2/12

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- The electrical installation of the relevant room complies with national standards, and
- The instrument is used in accordance with the instructions for use.

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

 WARNING : This device is not intended for treatment.

Using This Label Guide

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

WARNING

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

CAUTION

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

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

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Chapter 1 Safety Guide

NOTE:

For Operator and Patient safety, please read through this instruction manual before using the Wallach Fetal2EMR Fetal Monitor.

1.1 Intended Use

The Wallach Fetal2EMR (Model F3) Fetal Monitor (hereinafter called Fetal2EMR) is intended for non-invasive monitoring of a single or twin fetuses 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 Fetal2EMR provides fetal monitoring. It can externally monitor the Fetal Heart Rates (FHRs) using ultrasound and uterine activity via a TOCO transducer.

Contraindications: The Fetal2EMR Monitor is not intended for use in intensive care units, operating rooms or for home use.

1.2 Instruction for Safe Operation

- ◆ The Fetal2EMR Monitor is designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- ◆ The Fetal2EMR Monitor operates within specifications at ambient temperatures between +5°C (+41°F) and +40°C (+104°F). Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 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 Fetal2EMR Monitor must be serviced only by authorized and qualified personnel. Wallach Surgical Devices does not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorized personnel. Identical replacement parts must be used.
- ◆ Perform periodic safety testing to ensure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.
- ◆ The protective categories against electric shock of the patient connections are:



- 1) Ultrasound (FHR1, FHR2) 2) External TOCO
3) Intrauterine Pressure (IUP) 4) Fetal Movement Mark (FM)

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



DECG (Direct Electrocardiography) (Not available in this model)

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

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

1.3 Ultrasound Safety Guide

Fetal Use

The monitor is designed for continuous fetal heart rate monitoring during pregnancy and labor. Clinical interpretation of fetal heart rate traces may be helpful in the diagnoses of fetal and/or maternal problems and complications.

Instructions for Use in Minimizing Patient Exposure

The acoustic output of the Fetal2EMR Monitor is internally controlled and cannot be varied by the operator in the course of the examination. The duration of exposure is, however, fully under the control of the operator. Mastery of the examination techniques described in the User Manual will facilitate obtaining the maximum amount of diagnostic information with the minimum amount of exposure. Exercising clinical judgment in monitoring low risk patients will avoid unnecessary insonation.

1.4 Safety Precautions

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

**Usage Safety Precautions:**


- 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 Only qualified service technicians can install this equipment. Only service technicians authorized by Wallach Surgical Devices can open the case.
- 3 This device is not intended for use in intensive care units, operating rooms or for home use.
- 4 **EXPLOSION HAZARD** - Do not use this device in the presence of flammable anesthetic mixture with air, with oxygen or with nitrous oxide.
- 5 **SHOCK HAZARD** –The power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.
- 6 Do not apply this monitor and other ultrasonic equipment simultaneously on a same patient, due to the potential of leakage current superposition.
- 7 Do not apply this monitor simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators.
- 8 Do not use the monitor with RF surgical equipment.
- 9 Do not switch on device power until all cables have been properly connected and verified.
- 10 Do not touch the signal input or output connector and the patient simultaneously.
- 11 Equipment and devices that connect to the Monitor should form an equipotential body to ensure effective grounding.
- 12 Disconnect power cord before changing fuses. Replace the fuses with those of the same specifications only.
- 13 **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.
- 14 **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.
- 15 The monitor is not protected against defibrillation. Do not apply it during electrosurgery or MRI; as it might result in harm to the patient or the operator.
- 16 Only connect accessories supplied or recommended by Wallach Surgical Devices to the device.
- 17 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). All configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Anyone who connects additional equipment to the signal input connector or signal output connector configures a medical system and therefore is responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our

technical service department or your local distributor.

Proper Monitoring Safety Precautions:

- 1 Clinical decision making based on the output of the device is left to the discretion of the provider.
- 2 Alarms may be set up based on different situations. Audio should be activated when monitor is in use.

Battery Safety Precautions:









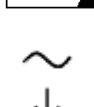






- 1 Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.
- 2 Do not connect the battery cable connector or battery socket with metal objects, which can result in short circuit.
- 3 Do not unplug the battery when monitoring.
- 4 Do not heat or throw the battery into a fire.
- 5 Do not use or leave battery close to fire or other places where the temperature may be above +60 °C (+140 °F).
- 6 Do not allow the battery to get wet.
- 7 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.
- 8 Use the battery only in this Monitor. Do not connect battery directly to an electrical outlet or cigarette lighter charger.
- 9 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.
- 10 Do not solder the leading wire and the battery terminal directly.
- 11 If the liquid leaks from the battery and spills onto your skin or clothes, wash well with fresh water immediately.
- 12 Keep battery away from flames. If leakage or foul odor is detected discontinue use.
- 13 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.
- 14 Do not use a battery that is visually damaged.
- 15  Proper disposal is required. Follow your Local Regulations for disposal.


















CAUTION

- 1 U.S. Federal law restricts this device to sale by or on the order of a physician.
- 2 Only qualified personnel shall service the unit.
- 3 The device is designed for continuous operation.

- 4 Keep the working environment clean. Avoid vibration. Keep it far from corrosive medicine, dust areas, high-temperature and humid environments.
 - 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 Do not sterilize the monitor or any accessory with autoclave or gas.
 - 8 Turn off the monitor and unplug it before cleaning. Cleaning consists of removing all dust from the exterior surface of the equipment with a soft brush or cloth. Use a brush to dislodge any dirt on or around the connectors and panel edges. Remove dirt with a soft cloth, slightly dampened with a mild detergent solution or 70% ethanol or isopropanol.
 - 9 When washing the belts, the water temperature must not exceed +60 °C (+140 °F).
 - 10 **Electromagnetic Interference** - Ensure that the environment in which the monitor is installed is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phone base stations, etc.
 - 11 Do not use mobile phones near monitoring.
 - 12 While the battery is charged, used or stored, keep it away from objects or materials with static electric charges.
 - 13 If the terminals of the battery become dirty, wipe with a dry cloth before using the battery.
 - 14 The recommended charge temperature range is from 0 °C (+32 °F) to +40 °C (+104 °F). Do not exceed this range.
 - 15 Batteries have life cycles. If the time that the monitor runs on the battery becomes 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 Wallach Surgical Devices.
 - 16 When not using battery for an extended period, remove it from the monitor and store it in a place with low humidity and low temperature.
 - 17 Remove a battery whose life cycle has expired from the monitor immediately.
 - 18 For information on installing and removing the battery from the monitor, thoroughly read the user manual.
 - 19 The device and accessories are to be disposed of in accordance with all applicable Federal, State and local medical/hazardous waste practices at the end of their useful lives. Alternatively, they can be returned to the manufacturer for recycling or proper disposal.
-

1.5 Definitions and Symbols

	Socket for ultrasound transducer 1 (Type BF applied part)
	Socket for ultrasound transducer 2 (Type BF applied part)
	Socket for DECG cable (Type CF applied part)
	Socket for TOCO transducer or IUP cable (Type BF applied part)
	Socket for Remote Event Marker (Type BF applied part)
	Reserved
	Type BF applied part
	Type CF applied part
	Charge Indicator
	AC (Alternating Current) Indicator
	Power Indicator
	ON/OFF switch for the device
	Start
	Alarm silence
	Auto-zero
	Event marker
	Print

	Channel selection
	Equipotential Grounding System
	Fuse
	Attention
	See Instructions for use
	Antenna
	USB (Universal Serial Bus) Connection
	Serial interface
	Network port
	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
	Reorder Number
	Serial Number
	Date of Manufacture
	Manufacturer
	General symbol for recovery/recyclable
Rx Only (U.S.)	U.S. Federal Law restricts this device to sale by or on the order of a physician.
	With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1, IEC 60601-2-37 and IEC 60601-2-49.

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 and file a claim for damage.

Open the package and 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 cables and accessories.

Packing List

Item	Quantity
Fetal Monitor	1
FHR Probe/Ultrasound Transducer	2
TOCO Transducer	1
Event Marker	1
Belt	Pack of 3
Ultrasound Gel	1
Recording Paper	Pack of 3
T1.6A Fuse	2
Power Cord	1
Screw Driver	1
User Manual	1
Quick Start Guide	1
Qualification Certificate	1

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

2.2 Overview

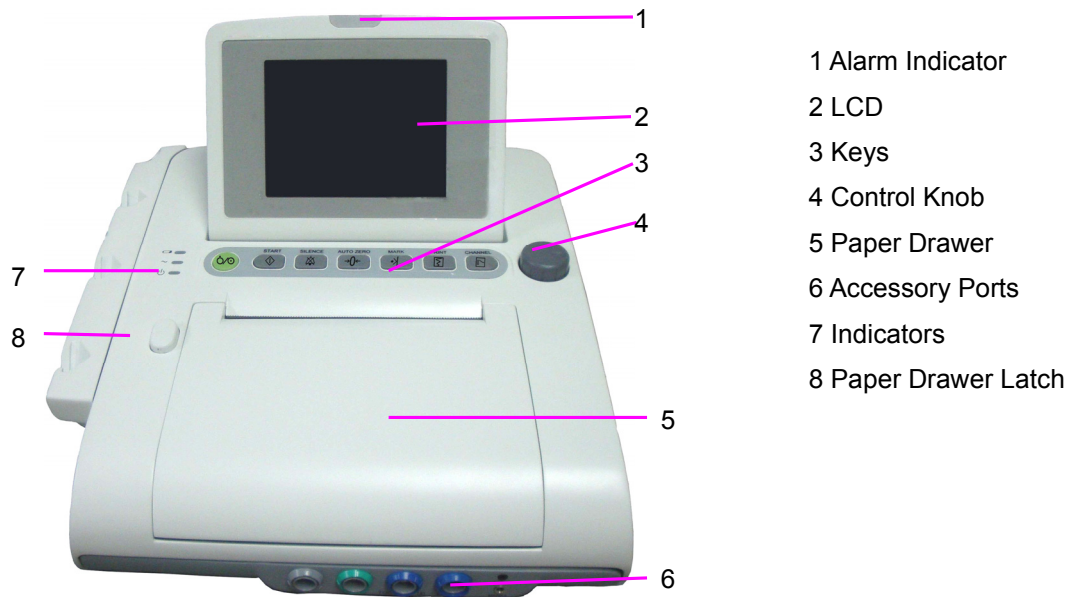


Figure 2-1 Front View

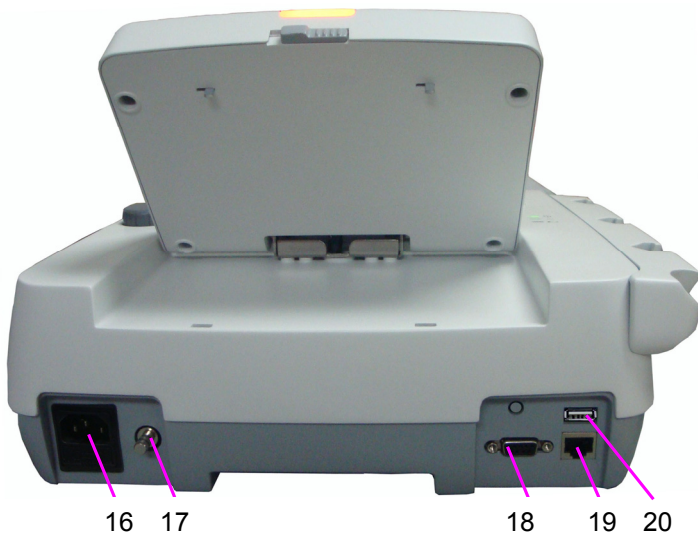


Figure 2-2 Left Panel



- 10 DECG Socket
- 11 TOCO/IUP Socket
- 12 FHR1 Socket
- 13 FHR2 Socket
- 14 MARK Socket
- 15 EXT.1 Socket

Figure 2-3 Front Panel



- 16 Power Socket
- 17 Equipotential
Grounding Terminal
- 18 DB9 Socket
- 19 RJ45Socket
- 20 USB Socket

Figure 2-4 Rear Panel

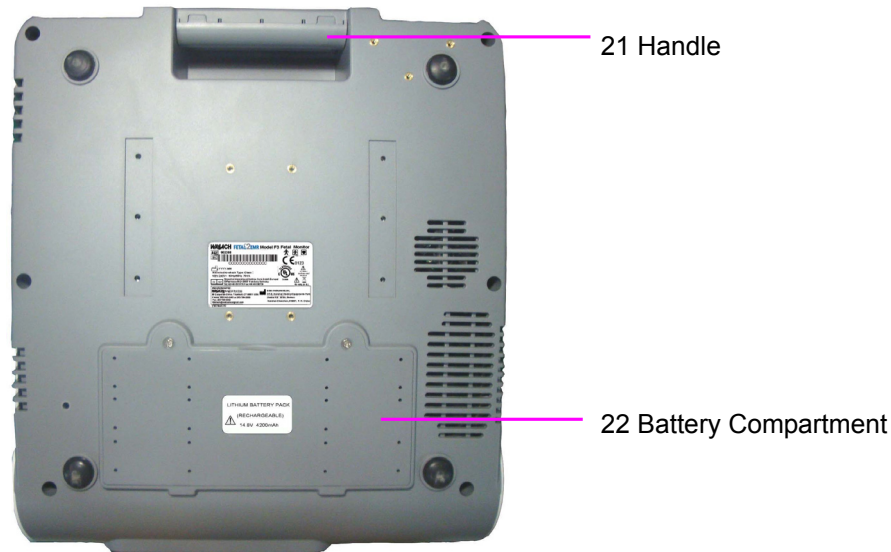


Figure 2-5 Bottom Panel

2.2.1 Keys and Control Knob



Figure 2-6 Keys and Control Knob

The Fetal2EMR monitor is a user-friendly device with operation controlled 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

Press this key to start monitoring (the monitor automatically stops printing data of the last monitoring, checks transducer connection, clears the MFM count and the monitoring timer, zeroes the pressure).

When inputting maternal information, or when changing the monitor settings, press this key to return to the main interface.

(3) SILENCE key 

Function: Switch on/off the alarm sound
 Press this key to switch on/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 and the fetal heart sound toggles between US1 channel and US2 channel.

(8) CONTROL KNOB

Function: Adjust volume, setup and review control.

The control knob 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 the “cursor”. Operations can be performed in the position on the screen indicated by cursor placement. When the cursor is located on a particular function, press the control knob to open the 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 select an item with the cursor.
- 2) Press the control knob and one of the following will happen:



- a) A menu pops up on the screen, or the menu is replaced by another 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 and then pressing the knob.
- 2 If the key sound is enabled, the monitor gives a normal key sound when the operation is valid, and gives a sharp “Di” sound when the operation is invalid.



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

2.2.2 Indicators

There are four groups of indicator lights 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 orange	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

2.3.1 Ultrasound (US) Transducer

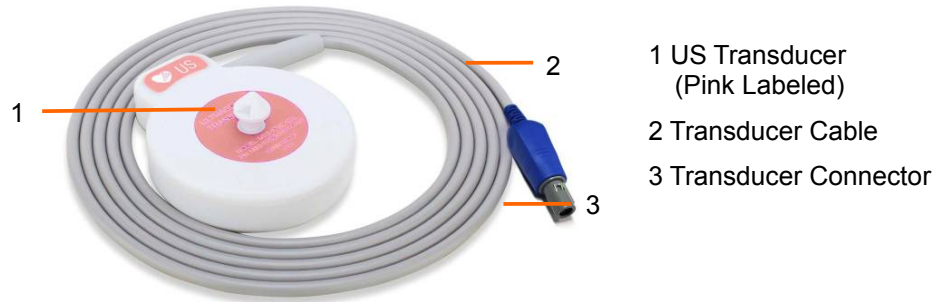


Figure 2-7 US Transducer

2.3.2 TOCO Transducer



Figure 2-8 TOCO Transducer

2.3.3 Belt



Figure 2-9 Belt

2.3.4 Remote Event Marker



Figure 2-10 Remote Event Marker

2.4 Screen

2.4.1 Main Interface

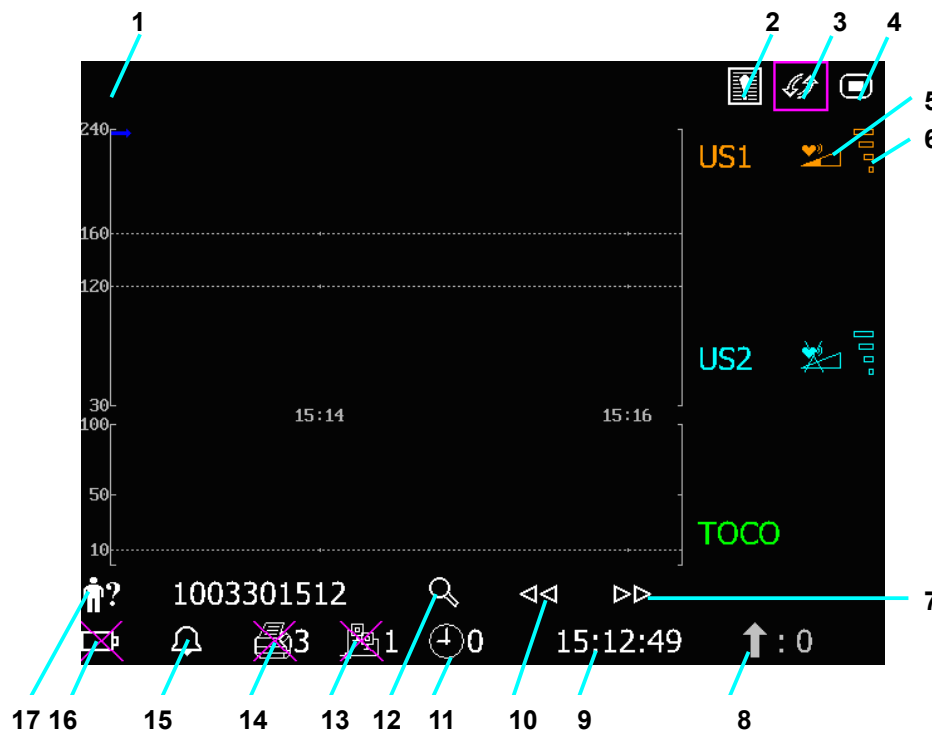
























Figure 2-11 Main Interface

Item	Screen element	Description
1		Alarm messages displaying area
2		Alarm reviewing key

3		Display mode switch
4		Setup key
5	<p>Fetal heart sound volume adjust/indicator:</p> <p>: the current fetal heart sound comes from this channel.</p> <p>: the fetal heart sound of this channel is mute.</p>	
6	<p>Fetal heart signal quality indicator:</p> <p> poor  acceptable  optimum</p>	
7, 10		Trace review keys
8		FM count
9		System time
11		Monitoring timer, the number on the right indicates the duration of the current monitoring.
12		Patient searching / File managing key
14	<p>Recorder status/speed indicator:</p> <p> No printing in progress  Printing in progress (3 stands for the printing speed: 3 cm/min.)</p>	
15	<p>Alarm sound status indicator:</p> <p> Alarm sound on  Alarm sound is disabled  Alarm sound pause and the remaining time</p>	
16	<p>Battery status indicator.</p> <p> Battery not installed  Battery installed (the vertical strips indicate the electric charge)</p>	
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.

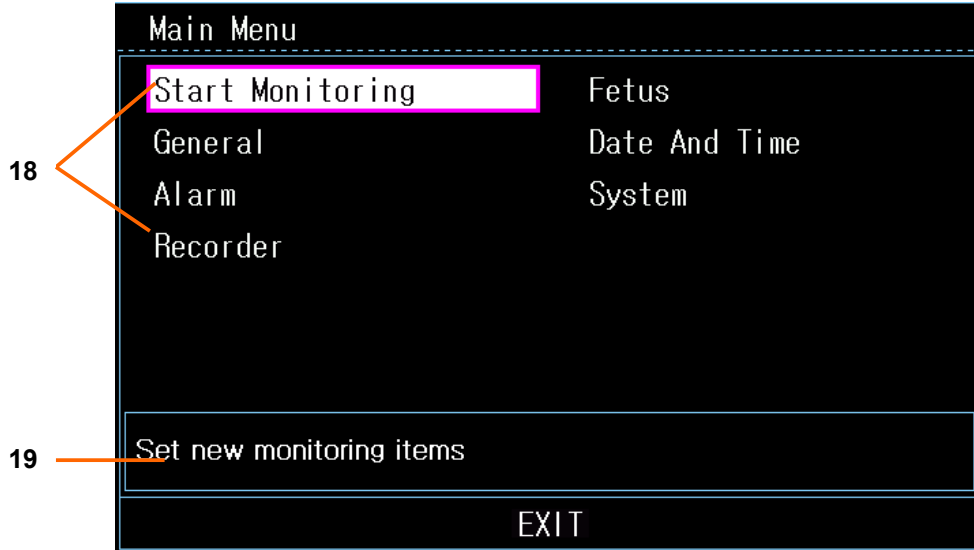


Figure 2-12 Setup Menu

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 within 30 seconds, the menu will return to the upper level 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 **Start Monitoring** in the illustration above. Correspondingly, its function **Set new monitoring items** is shown in the blue frame pane.

Chapter 3 Installation Guide

Note: Installation must be carried out by qualified personnel authorized by Wallach Surgical Devices. In order to ensure the operator and patient safety, read through this chapter before using this monitor.

3.1 Installing Battery



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

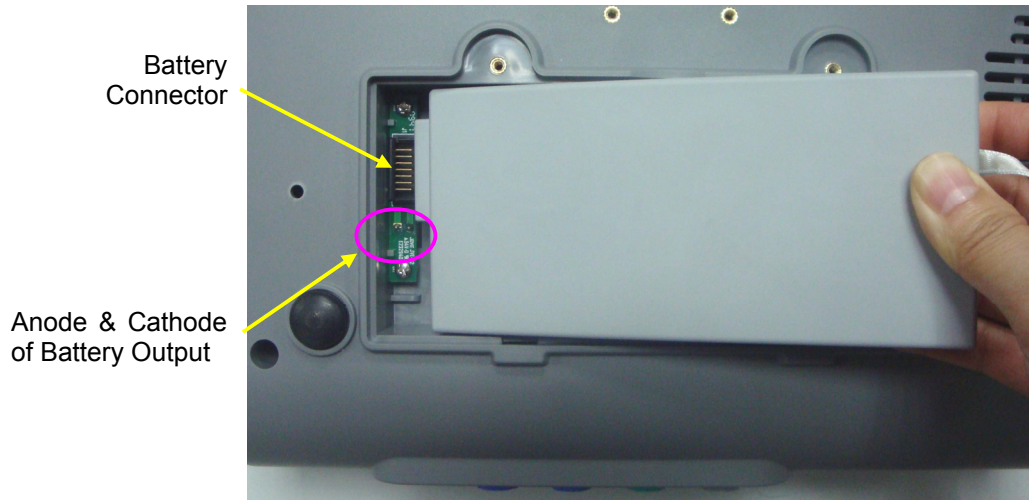
If the monitor is purchased with the optional rechargeable lithium-ion battery, follow these steps to install the battery:

(1) Battery Installation

- 1) Fold the LCD flat and then place the monitor upside down on a flat surface covered with cloth or other type of protective pad.
- 2) Remove the screws of the battery compartment using a Philips-head screwdriver. 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 with fingers or metal materials, to avoid hazards caused by the short-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 replace 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 adequate.

- 2 When the battery configuration is provided, after the device is transported or stored, the battery must be charged. Connecting the Fetal2EMR to a power supply will charge the battery even if the monitor is not turned on.

3.2 Installing Monitor

The monitor should be placed on a flat surface.

Alternatively, it can be installed on an optional cart. Consult the sales representative for more information.



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

3.3 Loading Recorder Paper

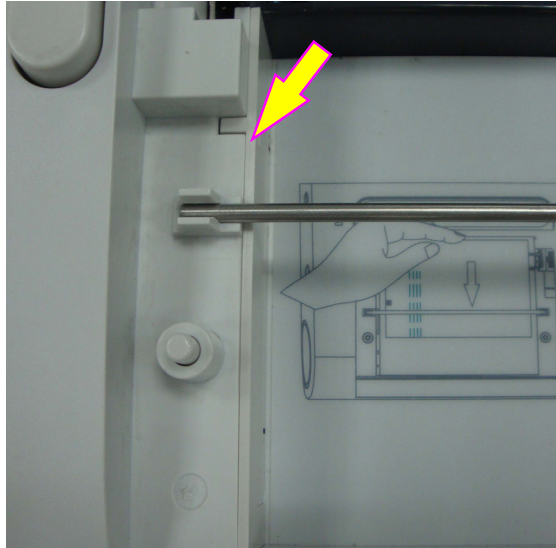


Use only the recorder paper provided by the manufacturer, otherwise the printer may be damaged. This kind of damage is not covered by warranty.

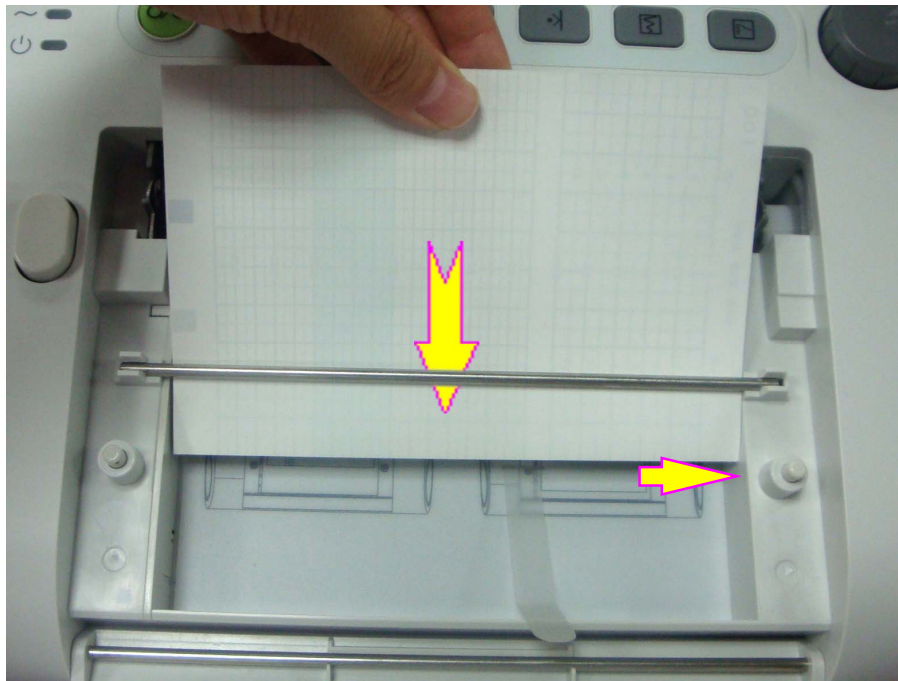
If the monitor is used for the first time or when the paper runs out, you should load paper.

- 1) Press the drawer latch on the front panel to flick open the paper drawer cover.

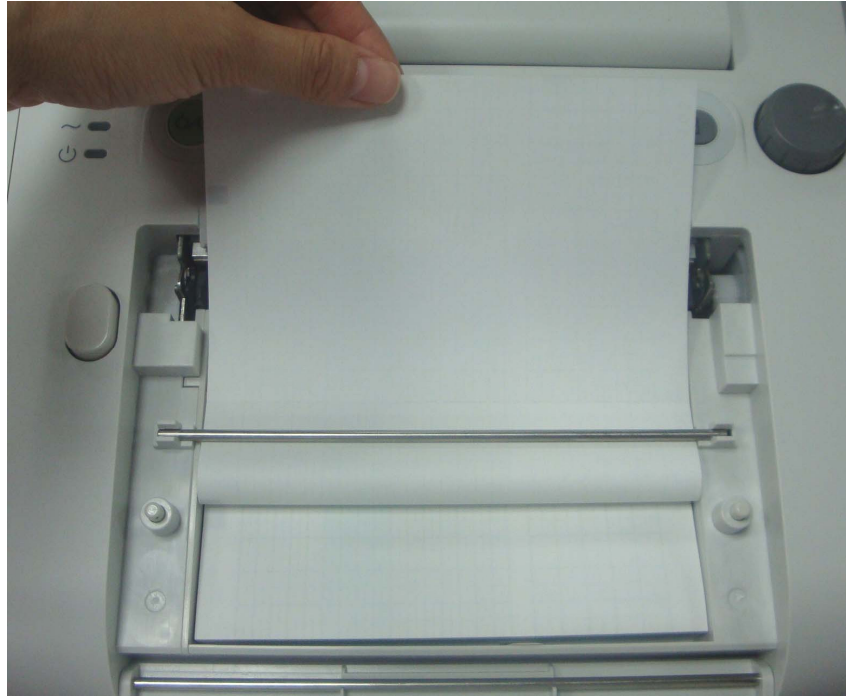




- 2) Take out the thermosensitive paper; remove the wrapper.
- 3) Guide the pack into the drawer underneath the retaining rod, abutting it against the right edge. Make sure the blank side of the paper faces you and the FHR trace area is on the left.



- 4) 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).



- 5) Put the paper drawer cover down and press the top until it clicks shut.




CAUTION

- 1 Be careful when inserting paper. Do not touch the thermosensitive print head or the paper sensor by hand as damage may be caused 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 paper jam. Use only paper provided by Wallach Surgical Devices to avoid printing problems.
 - 3 Keep the drawer closed except when loading paper or servicing.
 - 4 Be careful not to trap 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 force to tear paper 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.

3.5 Adjusting Screen Angle

The Fetal2EMR screen can lie completely flat, or tilt to an appropriate angle.

To tilt or to fold the screen,

- 1) Push the tab 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.



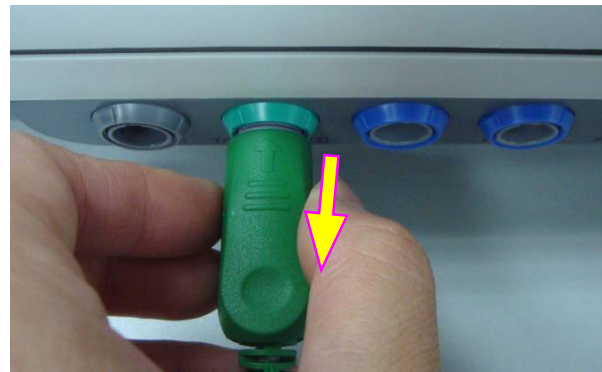
3.6 Connecting Transducers

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

When plugging transducers into the monitor, make sure the arrow symbol of the connector is facing up.



Connecting the transducer



Disconnecting the transducer

When disconnecting a transducer, pinch the body 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 other 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 produce 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 specifications:
100V-240V~, 50Hz/60Hz.
- ◆ Connect the power cable provided with the monitor to the monitor's power socket. Connect the other end to a hospital grade grounded 3-wire AC outlet.

⚠ WARNING ⚠

If the protective grounding (protective earth) system is in question, the monitor must be powered only by the battery.

NOTE:

1. Make sure the monitor and the power outlet are placed where it is easy to connect and disconnect the power cord.
2. When the power is interrupted, the device switches to inner power and operates normally if a battery is installed. If a 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 that the vital signs are exceeding its configured limit. They can be disabled. The adjustable alarm limits determine the conditions that trigger the alarm.


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

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

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


The system sets all patient alarm levels, and these settings cannot be changed.


4.2 Audible Alarm


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

Medium level alarm: a “Do” tone is repeated three times, and then pauses for 4 seconds.

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

Press the **SILENCE** key  on the front panel and the audible alarm toggles between on and off. Settings can be changed to make this temporary or indefinite.

If the current audible alarm is temporarily disabled, the alarm indicator displays , with a remaining time on the right. When the time is out, or when other alarms present, the monitor enables the audible alarm automatically.

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

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

4.3 Visual Alarm

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

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

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

- ◆ **Alarm message:** the alarm message appears in the alarm message area of the main interface in yellow.
- ◆ **Flashing numeric:** the numerical value of the measurement flashes in grey with a frequency of 2Hz.

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


The patient alarm messages are displayed either:

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

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


4.4 Choosing Alarm Silence Duration

To 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 Display Form

To change the patient alarm display form:

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


4.6 Changing Alarm Volume

To change the alarm volume:

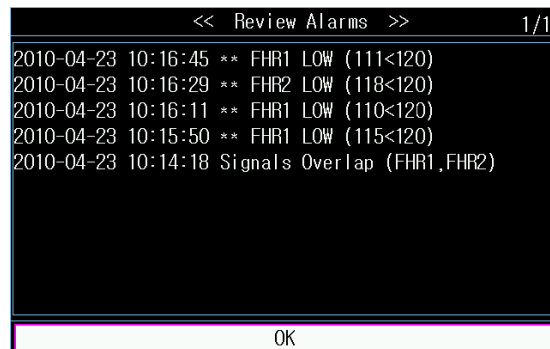
- 1 Select the setup key  on the main interface.
- 2 Select **Alarm > Alarm Volume**.
- 3 Select **Low** (default), **Medium** or **High**.
- 4 Select **OK**.

4.7 Reviewing Alarms

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

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

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



To review more records, select the alarm list and then rotate the control knob.

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

4.8 Alarm Treatment Measures

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

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

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

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

4.9 Testing Alarms

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

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

4.10 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 ~ 300 second(s), in increments of 5	10 seconds
FHR1/FHR2 Alarm Level	Medium, not adjustable	Medium

NOTE:

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

Chapter 5 Printing

5.1 Function Description

The built-in thermal recorder applied in the monitor supports both the American and international standard width 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 configured correctly before printing starts. You cannot change the configuration in the process of printing.


5.2.1 Switching Auto Start Printing On or Off

Switch auto start printing on or off as follows:

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

Paper speed choices are 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 use to the same paper speed.

5.2.3 Changing Print Timer

Different time lengths can be chosen 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 increment is 5) **Present ID** or **Infinite**.


For a fixed time, the recorder stops when the time is up.

For **Present ID and Infinite**, the recorder will only print the traces of the patient with the present ID, and stops automatically when her traces come to an end. 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 timing 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

To switch print self-check on or off:

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

5.3 Understanding Recorder Paper Printout



- 1 If there is any difference between the display and the printout, the printout should prevail.
- 2 If the data is ambiguous, clinicians should make diagnoses based on the clinical assessment.

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 the printed recording:

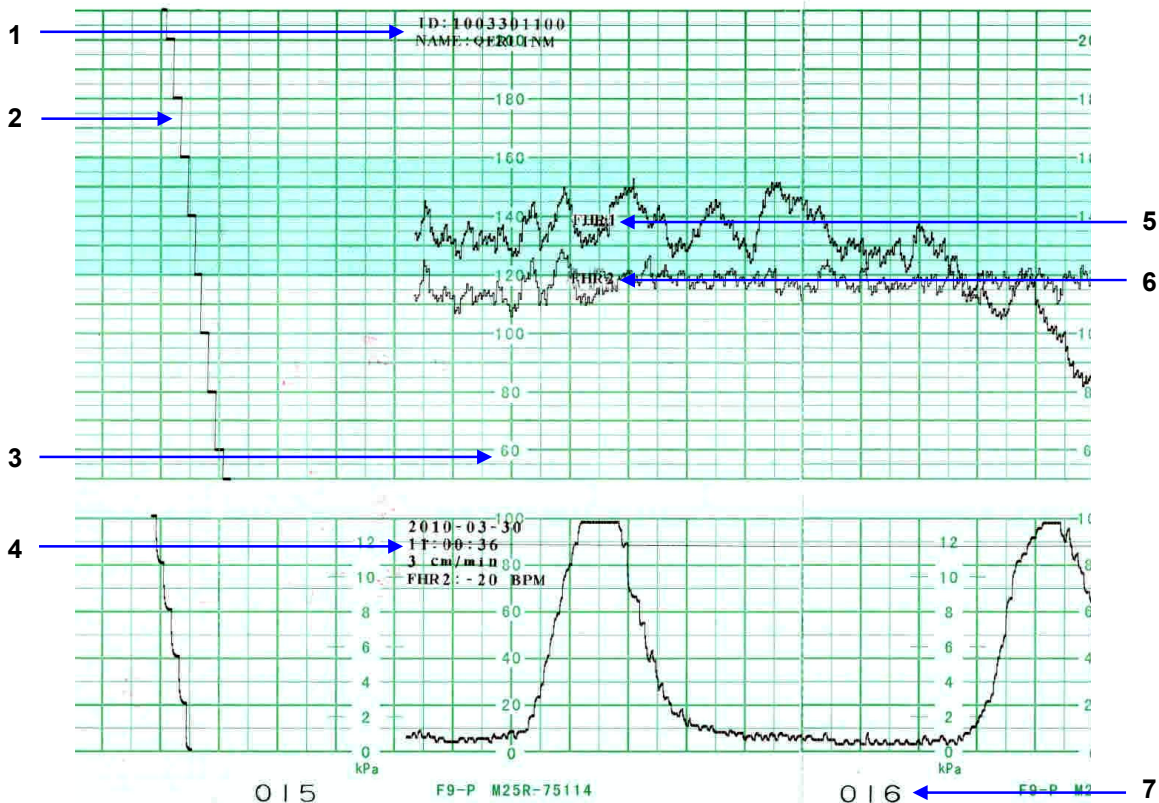


Figure 5-1 Example of recorder paper with traces

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	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.
5	FHR1 Mark	The trace marked with "FHR1" is the FHR1 trace.
6	FHR2 Mark	The trace marked with "FHR2" is the FHR2 trace.
7	Page Mark	Each recorder paper pack has 150 pages. When you notice the page mark comes to the end, remember to load new paper.

Chapter 6 Pre-Monitoring Preparation

6.1 Confirming Fetal Life

Fetal monitoring with ultrasound cannot differentiate a fetal heart rate signal source from a maternal heart rate source in all situations. There are some signal sources that might be mistaken as an FHR signal source as follows:


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

Confirm fetal life by other methods before starting to use the fetal monitor.


6.2 Switching On

 **WARNING** 

- Check that all the metal parts are linked to the protective earth cord and the cord is in good condition before switching on the monitor.
 - If any sign of damage is detected, or the monitor displays some error messages, do not use it on a patient. Contact biomedical engineer in the hospital or the Wallach 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**.

NOTE:

Check all the functions to make sure that the monitor is in good condition. If the monitor has a large amount of data saved in its long-term memory, it will take a few seconds to load them after start-up. When you notice the message “Loading data, please wait...” On the screen, do not operate the monitor until the main interface appears. A message “Load failed!” indicates that the data has been damaged and therefore cannot be loaded.

6.3 Checking Recorder Paper

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

The recorder prints a baseline after start-up (if **Print Self-Check** in the menu is ON). Observe the borders of the printed baselines (illustrated with the arrow). The borders should be printed exactly on the margins of the pane if the recorder paper is correctly loaded and set. If they do not comply with the margins, reload paper or ask the service technician to change the paper setup 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 to print.

6.4 Setting Date and Time



You can change the date and time on the monitor,

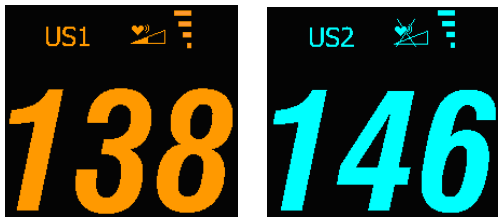
1. Select the setup key  on the main interface.
2. Select **Date and Time**.
3. Set the year, month, date, hour, minute and second. The first three numbers are used to set the year, month and date. Their orders vary with the preset Date Format below.
4. Select **Date Format** for the format of the date: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


⚠ CAUTION ⚠

Set date and time information in advance. After this information is changed, the monitor starts new monitoring with an auto ID. Therefore, it is advisable to restart the monitor after changing date or time information. Do not perform this operation when monitoring is in process.


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 one step and the volume increases by one level. There are ten levels. The volume level indicator  increases by one bar for every two steps; rotate the knob counterclockwise to decrease the volume.
3. Press the knob again to confirm the selection.

Adjust the key volume:

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

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

Chapter 7 Fetal Monitoring

⚠️ WARNING ⚠️

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

7.1 Monitoring Fetal Heart Rate (FHR) with Ultrasound

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

⚠️ WARNING ⚠️

Confirm fetal life by other means before using this monitor for FHR monitoring.

7.1.1 Parts Required

1. Ultrasound transducer
2. Ultrasound coupling gel
3. Belt

7.1.2 FHR Monitoring Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belts will reach around the patient's abdomen and be able to be fastened. Lay the patient on the bed.

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

2) Determining the Transducer Position

To acquire the FH signal, search for the location of the fetal heart using a handheld doppler or a fetoscope. The best fetal heart signal can be obtained through the fetal back.

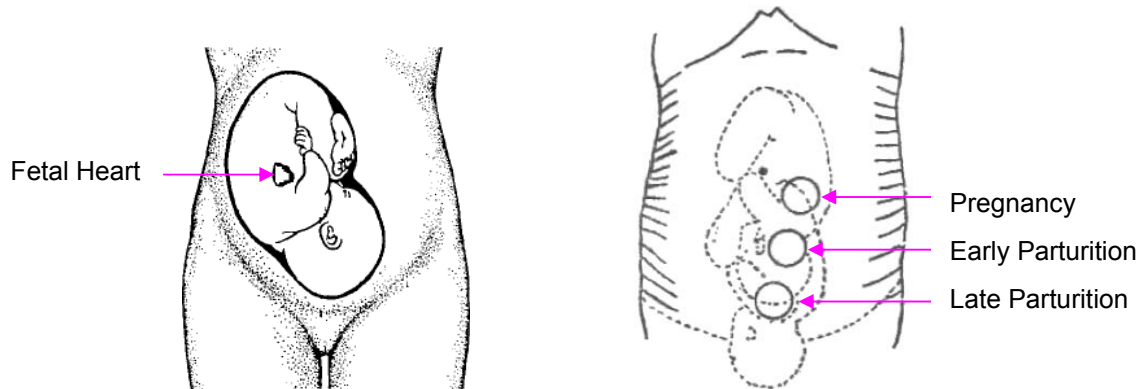


Figure 7-1 Positioning Ultrasound Transducer (single fetus)

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 acoustic gel on the transducer and move it slowly around the abdomen. Find at least 2 or 3 sites, and choose the one where the clearest, most sonorous and steady fetal heart sound is heard.

4) Fixing the Transducer

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

Make sure the belt fits the patient snugly but comfortably. When the fetal heart beat sound is detected; the FHR trace and numeric value 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 the maternal heart rate signal can be mistaken for the FHR signal. It is highly recommended to confirm that the fetus is the signal source continuously, for example checking the maternal pulse.

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.
- 2 The best quality records will only be obtained if the transducer is placed in the optimum position. Positions with strong placental sounds (swishing) or fetal cord pulse (indistinct pulse at fetal rate) should be avoided.
- 3 If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During the monitoring, prolonged lying in the supine position should be avoided due to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable.


- 4 During long-time monitoring, the gel may dry out as the transducer moves around. Add more gel if necessary.
- 5 It is not possible to examine FHR unless an audible fetal heart signal is present.

7.1.3 Switching the FHR Alarm On or Off

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

If the fetal heart alarm is switched off, the 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 any condition where the patient's safety may be endangered.


7.1.4 Changing FHR Alarm Limits

The alarm limits set determine the parameters 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 **lower alarm limit**.
4. Select a value from 65 ~ 210 for **higher alarm limit**.
5. Select **OK**.

7.1.5 Changing 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 ~ 300 seconds.
4. Select **OK**.



The FHR alarm delay is adjustable between 0 and 300 seconds. If there is a condition to which attention should be directed, the alarm delay should be set properly.

7.2 Monitoring Twin FHRs

7.2.1 Monitoring Twins Externally

To monitor twin FHRs externally, you need to connect a US transducer to the US1 socket and the second US transducer to 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** button to switch the fetal heart sound from one channel to the other.

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

NOTE:

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

7.2.2 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 a signal overlap verification (SOV) function to reduce these possibilities.

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

7.2.3 Changing FHR2/DFHR Offset

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

To change the FHR2/DECG offset,

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/DFHR offset will be printed on the recorder paper every 10 minutes.

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

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

7.3 Monitoring Uterine Activity Externally

7.3.1 Parts Required

1. TOCO transducer
2. Belt

7.3.2 TOCO Monitoring Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the patient's 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 away any gel remaining on abdomen around this area.

Place the TOCO transducer on the patient's abdomen on the uterine fundus.

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 Value to Zero

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


The uterine activity reading at this point should be 30 ~ 90. A flat-top aligned with 100 on the TOCO scale indicates the belt is too tight, and needs adjustment.

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.

7.3.3 Changing UA Baseline

The UA baseline can be changed.

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**.

7.4 Monitoring Fetal Movement

7.4.1 Auto Fetal Movement Monitoring (AFM)

During fetal heart monitoring with ultrasound, 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 due to the bigger scope of moving areas (e.g., the fetal arms or legs); lower frequency is due to the lower velocity of the fetal movements compared with those of the fetal heart.


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

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

AFM monitoring can be switched off and is gain adjustable.


7.4.2 Enabling or Disabling AFM Trace

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

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

7.4.3 Changing AFM Gain

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

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

7.4.4 Manual Fetal Movement Monitoring (MFM)


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

1. Insert the remote event marker connector into the **MARK** socket on the monitor.
2. Let the patient hold the remote event marker 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 the patient should be instructed to press the key only once.



7.4.5 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**.

7.5 Starting Monitoring

After the **START** key  is pressed, the monitor automatically zeroes the pressure, checks transducer connections, clears the MFM count and the monitoring timer. A start symbol  is presented on the screen.


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

NOTE:

Pressing the **START** key indicates a new patient is being monitored. Therefore, please remember to press the **START** key when monitoring a new patient.

7.6 Inputting Maternal Information (Mat. Info)

7.6.1 Auto ID


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

NOTE:

Do not press the **START** button continuously in a short period of time as the system will not accept the command to indicate a new patient each time.

7.6.2 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 **OK**.
5. Select **Name**.
6. Enter the required letters for patient’s name on the soft keyboard.
7. Select **OK**.
8. Select **OK**.

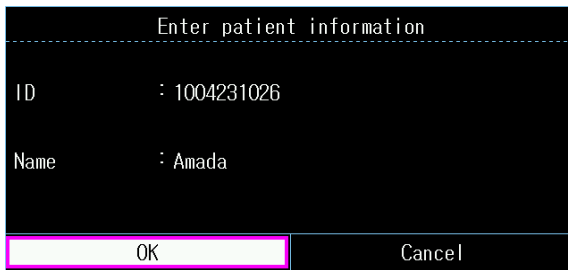


Figure 7-2 Mat. Info inputting menu

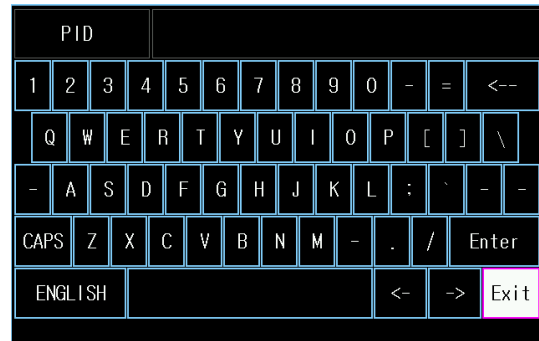


Figure 7-3 Soft keyboard

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.


 **CAUTION** 

- 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.

7.6.3 Switching Mat. Info Inputting On or Off

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

To switch the **Mat. Info Inputting** function 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 simultaneously, choose the trace-numeric mode (figure 8-1).

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

If you want to observe the numerics in large 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.

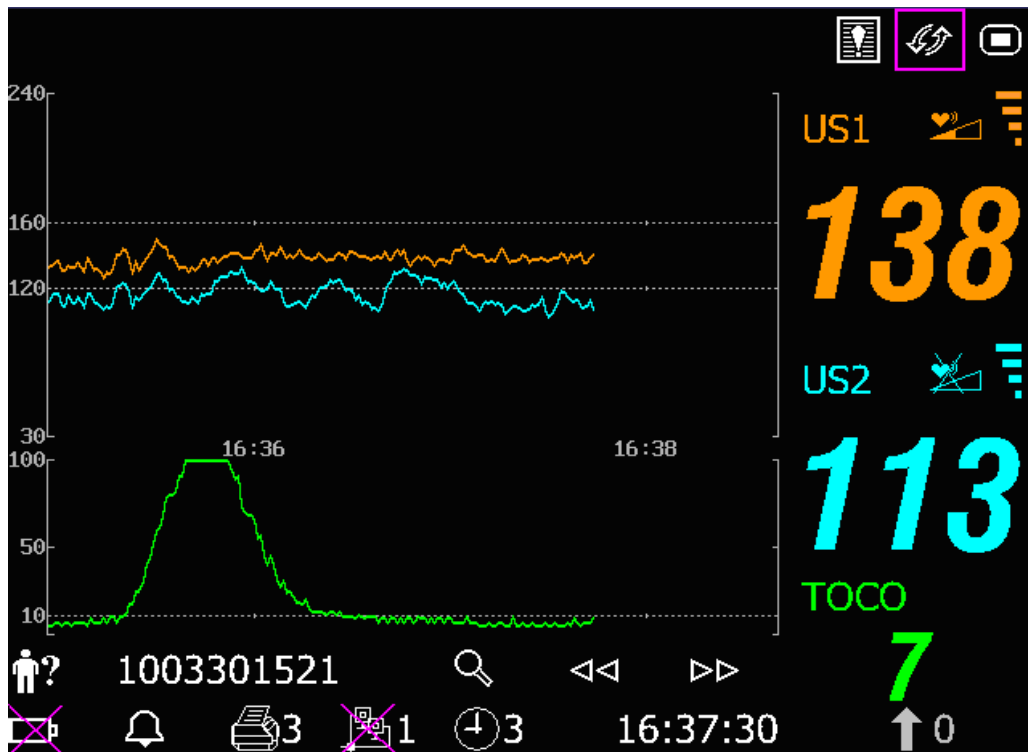


Figure 8-1 Trace-Numeric Mode

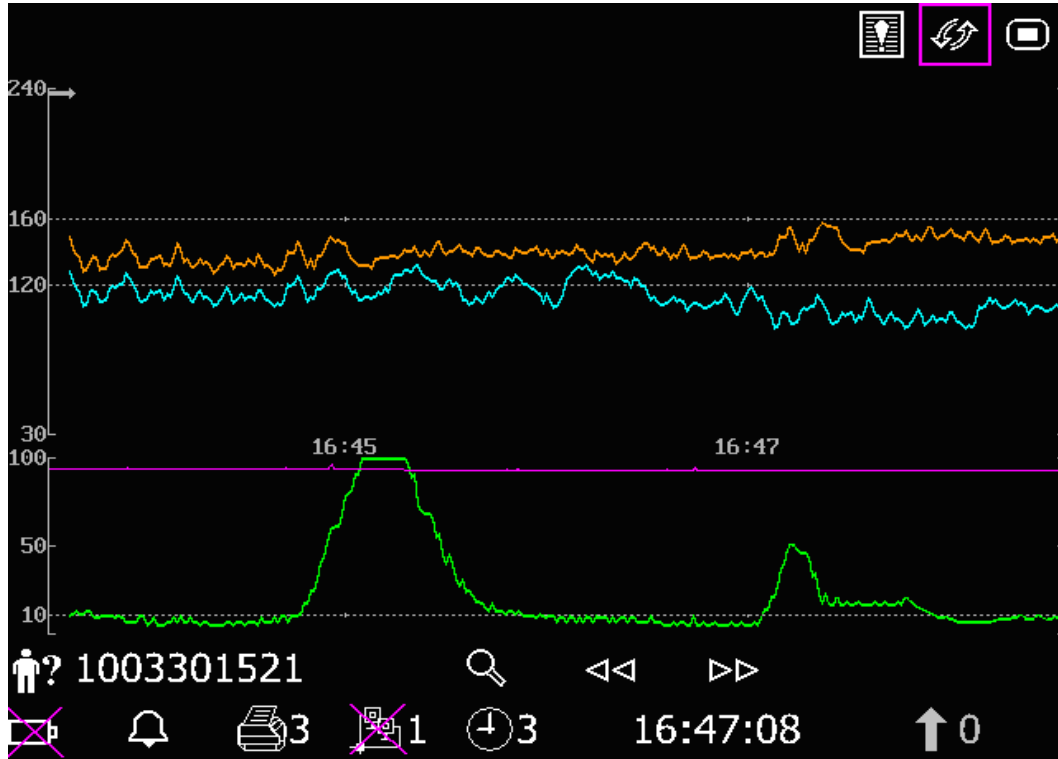


Figure 8-2 Trace Mode

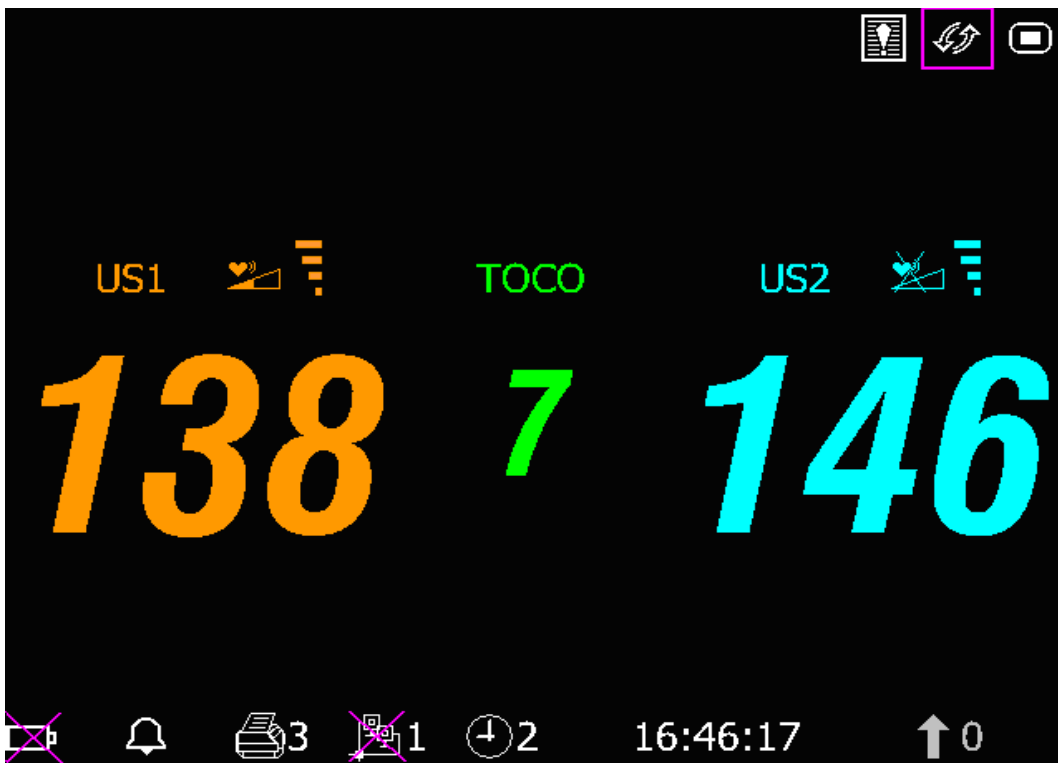


Figure 8-3 Numeric Mode

8.2 Traces



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.

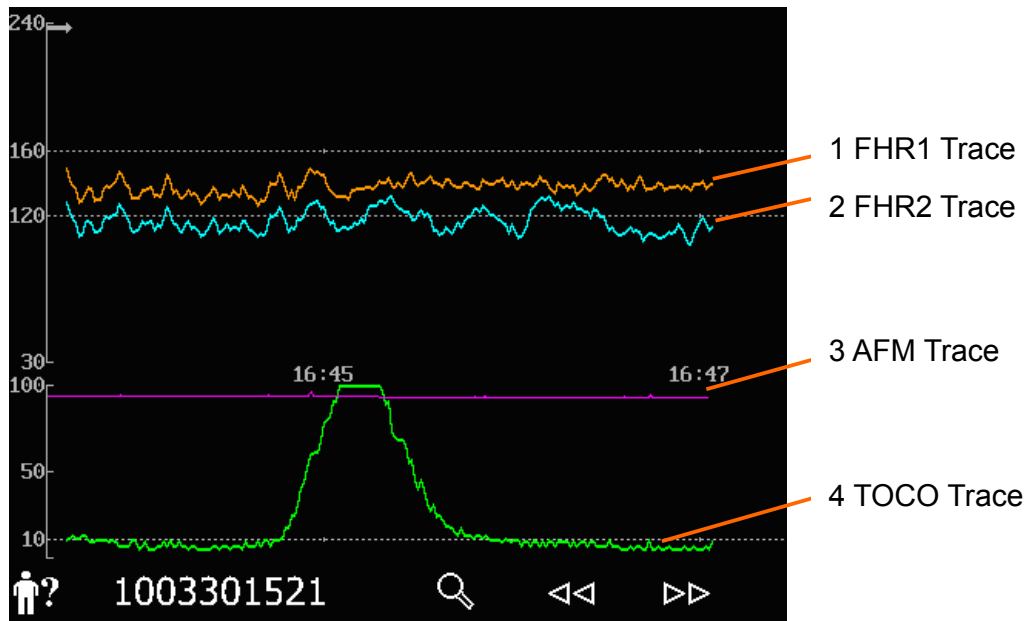



Figure 8-4 Traces

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). 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, and it appears after the patient presses the FM marker when she feels a fetal movement.
↓	This symbol indicates the MARK key is pressed to record an event, such as the patient turning around.
xx	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 not seconds. 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 search key  on the main interface to open the **Patient Searching** interface, which records a list of up to 50 most recent patients’ ID and name (When the USB feature is disabled, the interface is shown as follows).

Patient Searching	
ID	Name
1101201800	Rose
1101201450	Jone
1101201249	Julia
1101201148	Elva
1101201117	Hebe
1101201045	Lili
1101201014	Linda
	Next
EXIT	

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 disabled 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 connection 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 connection.
3. Select the file managing key  on the main interface to open the **File Management** interface, which records a list of up to 50 most recent monitoring records (patients’ ID, name and date) and a few operation items.

File Management		
ID	Name	Date
1101201800	Rose	2011-01-20
1101201450	Jone	2011-01-20
1101201249	Julia	2011-01-20
1101201148	Elva	2011-01-20
1101201117	Hebe	2011-01-20
1101201045	Lili	2011-01-20
1101201014	Linda	2011-01-20
Next		
Export All	Delete All	Remove Disk
EXIT		

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 through the USB connection. Or you can select **Export All** to export all the records through the USB connection.

NOTE:

1. When the monitor is in the process of printing or is connected to the network, the files cannot be exported.
2. The manufacturer advises against plugging in the USB connection and exporting the data during the process of monitoring.
3. A USB thumb drive is not an appropriate tool for long-term data storage. Save the

exported files on a PC.

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 12-hour data). You should export and save the files in a timely manner.
- 4 When there are more than 100 files, it may take an extended period of time for the monitor to load them.

8.2.4 Reviewing

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

Select the backward key to review the previous traces. The traces start to retreat. The amount of the progress symbol “<” on top of the traces indicates the retreating speed. Rotate the control knob counterclockwise 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 counterclockwise 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** button  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 entire reviewable traces.

Move the cursor to any item other than 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 number values are all real time information of the current patient.

 **WARNING** 


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




 **CAUTION** 

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


8.3 Number Values

The fetal monitoring number values in the numeric window include FHR1, FHR2/DECG, TOCO/IUP and MFM.

	<p>FHR1 measurement numeric display area.</p> <p>If the US1 socket is not connected with a US transducer, nothing displays here.</p> <p>If the transducer is connected but no valid signal is received, it displays ---.</p>
---	--

	<p>TOCO or IUP measurement numeric display area.</p> <p>If the TOCO socket is not connected with a transducer/catheter, nothing displays here.</p> <p>If the TOCO socket is connected with a transducer/catheter, it displays the value.</p>
	<p>FHR2 or DFHR measurement numeric display area.</p> <p>If the transducer/cable is connected but no monitoring is going on, it displays ---.</p>
	<p>MFM count display area.</p>

NOTE:

The monitor detects the transducers automatically. If no US transducer or DECG cable 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 the 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	FHR1 or FHR2 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 patient's condition.
**FHR1 LOW or ** FHR1 xxx < yyy, **FHR2 LOW or ** FHR2 xxx < yyy	FHR1 or FHR2 measuring result (xxx) is lower than the set low alarm limit (yyy) over the alarm delay time.	Check if the alarm limits are suitable; check the patient'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 patient's condition.
TOCO UNPLUGGED	TOCO transducer is not well connected.	Check the connection of the transducer.
Fetus EQUIP MALF	The monitor 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 positioned at the same fetal heart; the signals overlap.	Adjust one of the US transducers until another fetal heart signal is detected.
Signals Overlap (FHR1, DFHR)	US transducer 1 is aimed at the fetus that the spiral electrode is attached to; the signals overlap.	Adjust the US transducer until another fetal heart signal is detected.

Chapter 9 After Monitoring

9.1 Saving Data

The monitor automatically saves the data every five minutes and prior to shutdown, including fetal monitoring traces and maternal information. The maximum capacity is 12-hour data.

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



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

9.2 Completing the Monitoring

After monitoring is completed,

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

NOTE:

- 1 The remaining coupling gel on the ultrasound transducer may cause the monitor to create noise. Therefore, the gel should be wiped off the transducer after monitoring.
- 2 After the fetus is delivered, the monitor may pick up signals of the umbilical cord and display a trace/numeric value. To avoid misinterpretation, it is recommended the transducers be removed from the patient and the monitor switched off 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.



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, perform 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 seams 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. Replace the damage part(s) or contact Wallach Surgical Devices for service before reusing it.

(2) Routine Inspection

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

The equipment should undergo periodic safety testing to ensure proper patient isolation from live parts. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

(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.



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

10.1.2 Maintenance of Monitor

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

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

Avoid scratching and damaging the screen.

10.1.3 Maintenance of Transducers

Keep the transducers in a dry environment, where the temperature should be lower than +45°C (+113 °F).

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

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 save the monitoring data to 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 °C (+104 °F).

Do not exceed a relative humidity of 80%.

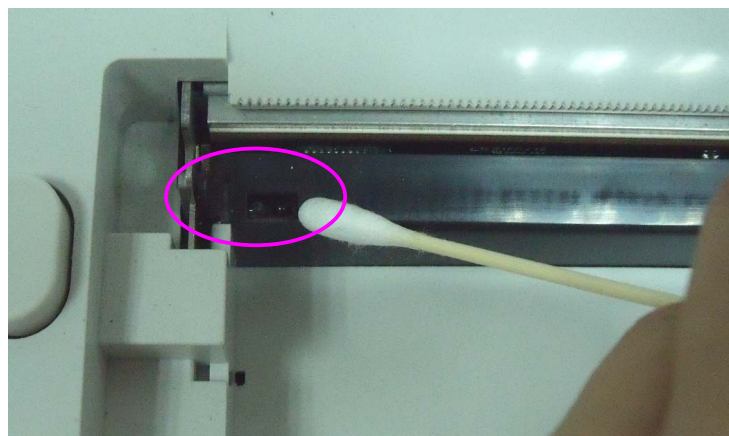
Storage conditions outside these limits may distort the paper and adversely affect the accuracy of grid lines or make the trace unreadable.

10.1.5 Maintenance of Recorder



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

Check to see if the paper sensor is covered with dust. If it is dirty, gently wipe it clean with a dry cloth or a cotton swab.



The recorder plate, thermal print head and paper sensing mechanism must be cleaned at least once a year or when needed (when trace becomes faint). The following procedure may be used:

1. Switch off the monitor and open the paper drawer.
2. Wipe the printhead with a cotton swab or a soft cloth moistened with isopropyl alcohol.
3. Air-dry the printhead surface and then close the drawer.



CAUTION

Use only paper provided by Wallach Surgical Devices or damage to the recorder may occur. This type of damage is not covered by warranty.

10.2 Cleaning

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

10.2.1 Cleaning of the 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 soapy water, Tensides, Ethylate and Acetaldehyde.

Clean the screen with a dry soft cloth. If necessary the screen may be cleaned with a neutral detergent or isopropyl alcohol. Do not use chemical solvents, acidic or alkali solutions.

⚠ 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 liquid.
- 6 Avoid pouring liquids on the monitor while cleaning.
- 7 Do not leave any cleaning solution on the surface of the monitor.

10.2.2 Cleaning of Accessories

(1) Cleaning of Transducers

To clean the US transducer and TOCO transducer:

- ◆ 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	BURATON LIQUID MIKROZID ETHANOL 70% SPORACIDIN CIDEX

⚠ CAUTION ⚠

- 1 Do not immerse accessories in liquid. Only clean the outer surface of the connectors, making sure no liquid goes into the connectors.
- 2 Be sure the temperature of cleaning solutions does not exceed +45 °C (+113 °F).
- 3 After cleaning accessories, confirm that no remaining cleanser is on the surface.

(2) Cleaning of Belt

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

10.3 Disinfecting

Clean the equipment before disinfecting.

The table below lists the allowed disinfectant bases:

Type	Ethylate	Acetaldehyde	Recommended
Transducers	√	√	Ethanol 70% Isopropanol 70%

⚠ 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, confirm there is no remaining disinfectant on the surface.
- 5 Check that the monitor and accessories are in good condition. If any aging or damage is detected (e.g. the belt loses its elasticity), replace the damaged part(s) or contact Wallach Surgical Devices 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.

Chapter 11 Warranty and Service Policy

Warranty

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

Material and Manufacture

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

Software or Firmware

Wallach software and firmware products, which are designated by Wallach for use with a hardware product, when properly installed on that hardware product, are warranted not to fail to execute their programming instructions due to defects in materials and workmanship. If Wallach receives notice of such defects during the warranty period that begins on the date of shipment, Wallach shall repair or replace software media or firmware which does not execute their programming instructions due to such defects. However, Wallach does not warrant that operating of the hardware, software, or firmware shall be uninterrupted or free from error. This unit has no parts can be repaired by users themselves. All the service should be performed by Wallach technical personnel.

Limit of Warranty

The warranty is void in the case of

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

If you have any question about maintenance, technical specifications or malfunctions of devices, contact: Wallach at (800) 243-2463 or (866) 928-3211. An email may also be sent to wallach@wallachsurgical.com.

Appendix 1 Product Specifications

A1.1 Environmental Specifications

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

A1.2 Physical Specifications

Monitor		
Dimensions and Weight	Size (depth x width x height) :	350mm x 300mm x 104mm 13.78” x 11.81” x 4.09”
	Weight:	Approx. 3.5 kg/ 6.6 lbs.
Power Supply	Operating Voltage:	100V-240V~
	Operating Frequency:	50Hz/60Hz
	Input Power :	70VA
	Battery:	14.8V/4200mAh
Standards Compliance	UL/IEC/EN 60601-1, IEC/EN 61157, IEC/EN 60601-2-37, IEC/EN 60601-1-2, IEC 60601-2-49.	
Anti-electric Shock Type	Class I equipment with internal power supply	
Anti-electric Shock Degree	FHR1, FHR2, TOCO, FM, IUP DECG	BF CF
Degree of Protection against Harmful Ingress of Water for the Transducers	IPX 8	
Degree of Safety in Presence of Flammable Gases	Equipment not suitable for use in presence of flammable gases	
Disinfection/Sterilizing Method	Refer to this user manual for details	
EMC	Group I Class A	

Working System		Continuous running equipment
Earth Leakage Current (Limit)		N.C. 300µA S.F.C. 300µA
Enclosure Leakage Current (Limit)		N.C. 100µA S.F.C. 300µA
Patient Leakage Current (Limit)		N.C. 10µA S.F.C. 50µA d.c. 10µA a.c. 10µA
Patient Auxiliary Current (Limit)		N.C. 10µA S.F.C. 50µA d.c. 10µA a.c. 10µA
Display	LCD Size:	5.6"
	Active Area:	112.9 mm (W) x 84.7 mm(H)
	Resolution:	640 (RGB) x 480
	Display Mode	Normally White, Transmissive
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	Ultrasound Frequency:	(1.0±10%) MHz
	p-	<1 MPa
	I_{ob}	<10 mW/cm ²
	I_{spta}	<100 mW/cm ²
	FHR Measurement Range:	50 bpm ~ 240 bpm
	Resolution:	1 bpm
	Accuracy:	±2 bpm
	Dielectric Strength:	> 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%
TOCO	TOCO Range:	0% ~ 100%,
	Non-linear Error:	±10%
	Resolution:	1%
	Zero Mode:	Automatic/ Manual
	Dielectric Strength:	> 4000Vrms
AFM	Technique:	Pulsed Doppler ultrasound
	Range:	0% ~ 100%,
	Resolution:	1%
Marking	Manual fetal movement mark	

A1.4 Recorder Specifications

Paper:	Z-fold, thermosensitive
Paper width:	152mm (GE)
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, fetal movement mark, event mark, AUTO-zero symbol, date, time, printing speed, ID, name, FHR2 Offset etc.

A1.5 Rechargeable Lithium-ion Battery Specifications

Part Number	902350
Nominal Capacity	4200mAh
Charge Current (Standard)	0.2C ₅ A(1200mA)
Continual Working Time	7 hours
Nominal Voltage	14.8V
Charge Voltage (Standard)	(16.8±0.1) V
Cycle Life	≥300 times
Charge Temperature	0°C ~ +50°C (+32°F ~ +122°F)
Operating Temperature	-20°C ~ +60°C (-4°F ~ +140°F)
Relative Humidity	45% ~ 75%
Charge Mode	Constant current/ constant voltage

Storage	Short Term (within 1 month): -20 °C ~ +60 °C (-4 °F ~ +140 °F) Middle Term (within 3 months): -20 °C ~ +45 °C (-4 °F ~ +113 °F) Long Term (within 1 year): -20 °C ~ +20 °C (-4 °F ~ +68 °F) During storage, recharge the battery at least every six months.
Charge State When Leaving Factory	20% ~ 50%

A1.6 Low Output Summary Table

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0)

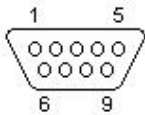
System: Fetal Monitor

Transducer Model	$I_{spta.3}$ (mW/cm ²)	TI Type	TI Value	MI	$I_{pa.3@MI_{max}}$ (W/cm ²)
PW 1.0 MHz	2.77	TIS	0.055	0.029	0.01
		TIB	0.629		

Appendix 2 Signal Input/Output Connector

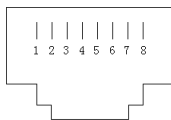
Accessory equipment connected to these interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN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

DB9 Interface



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

RJ45 Interface



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

Appendix 3 Troubleshooting

A3.1 No Display

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

A3.2 Noise

Error Condition	Possible Cause	Corrective Action
Noise	Volume set too high	Turn down the volume.
	Interference from mobile phone or other source.	Turn off or remove the interference source.
		Move the monitor to a place with less interference.

A3.3 Recorder Error

Error Condition	Possible Cause	Corrective Action
Paper jam	Paper is loaded incorrectly or paper is damp.	Load paper correctly and keep paper away from moisture.
	Wrong paper is being used.	Use the paper that is provided by the manufacturer, or contact the manufacturer for service.
Recorder does not work.	The recorder is not turned on.	Press the PRINT key.
	Out of paper.	Load paper.
	The paper drawer is not locked.	Close the drawer cover and press it until both latches are locked in position.
	Wrong paper is being used.	Use the paper that is provided by the manufacturer, or contact the manufacturer for service.

Faint trace or no trace	Wrong paper is being 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 gently with a dry cloth.

A3.4 Trouble with Ultrasound FHR Monitoring

Error Condition	Possible Cause	Corrective Action
Inconstant trace / display	The pregnant woman is too obese.	Monitor FHR with DECG, if applicable.
	Improper ultrasound transducer position.	Adjust the position of the transducer until a better signal is received.
	Loose belt.	Tighten the belt.
	Excess ultrasound coupling gel.	Wipe off excess ultrasound coupling gel.
	Frequent fetal movements.	Delay the monitoring.
	Maternal movement.	Request the patient to reduce movements.
	Inadequate ultrasound coupling gel.	Add ultrasound aquasonic coupling gel.
Questionable FHR	Recording maternal heart rate inadvertently.	Change the position of the ultrasound transducer.
	The transducer is not securely placed in position, and the mixed noise has been recorded.	Adjust the position of the transducer.
The channel from the unused transducer displays numeric values.	Inadvertently left unused transducer connected while monitoring.	Unplug the unused transducer.

A3.5 Trouble with Contractions Monitoring (External)

Error Condition	Possible Cause	Corrective Action
Bad trace quality or	The belt is too tight or too loose.	Adjust the belt.

fluctuant TOCO baseline	The belt has no elasticity.	Replace the belt.
	Maternal movement.	Request that the patient reduce movement.
	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.	Confirm good contact to patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

A3.6 Blown Fuses



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

Replace the blown fuse when needed.

The two fuses of the monitor are located on the rear panel; Their specifications are:

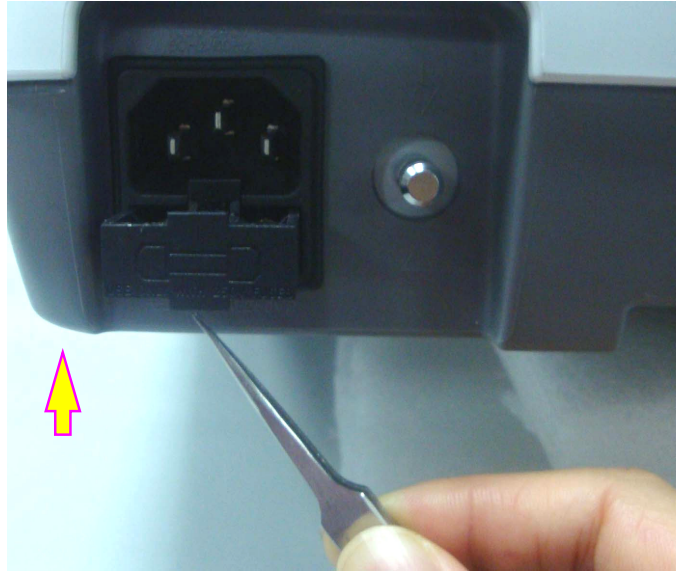
Size: $\Phi 5\text{mm} \times 20\text{mm}$; Model: T2AH250V.

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.

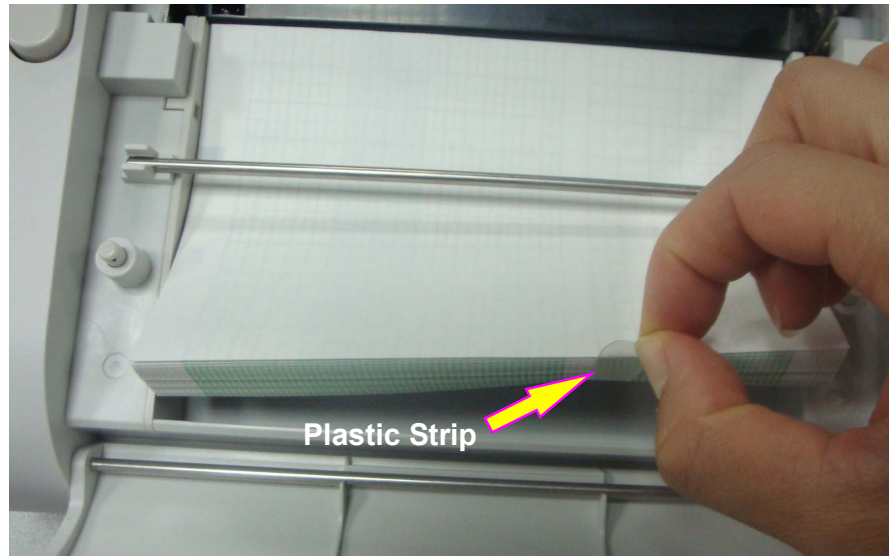


5. Push the fuse container all the way back in position.

A3.7 Paper Jam

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

1. Cut the recorder paper from the paper drawer edge.
2. 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 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
DFHR	Direct FHR
ECG	Electrocardiogram
FHR	Fetal Heart Rate
FM	Fetal Movement
ICU	Intensive Care Unit
ID	Identity
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 5 Ordering Information

The following accessories can be used with the monitor. The accessories all carry the CE mark.

Accessory (Spare Part)	Part Number
FHR Probe/Ultrasound Transducer	902302
TOCO Transducer	902303
Remote Event Marker	902307
Belt (pack of 3)	902308
Rolling cart with tray	902340
Thermosensitive Paper (GE-American)	902304
Fetal2EMR Software	902320
Rechargeable Lithium-ion Battery (4200mAh)	902350



Only accessories supplied or recommended by Wallach Surgical Devices may be connected to the monitor.

Appendix 6 EMC Information – Guidance and Manufacturer’s Declaration

A6.1 Electromagnetic Emissions – for all EQUIPMENT and SYSTEMS


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

A6.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer’s declaration – electromagnetic immunity			
The <i>Fetal Monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Fetal Monitor</i> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ±2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

A6.3 Electromagnetic Immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

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

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 *Fetal Monitor* is used exceeds the applicable RF compliance level above, the *Fetal Monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Fetal Monitor*.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A6.4 Recommended Separation Distance

Recommended separation distance between portable and mobile RF communications equipment and the <i>Fetal Monitor</i>			
The <i>Fetal Monitor</i> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the <i>Fetal Monitor</i> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <i>Fetal Monitor</i> as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.2	1.2	2.3
10	3.7	3.7	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 7 Limitations of Ultrasonic Monitoring

A7.1 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.

A7.2 Artifacts in Fetal Heart Monitoring

(1) How does artifact happen?

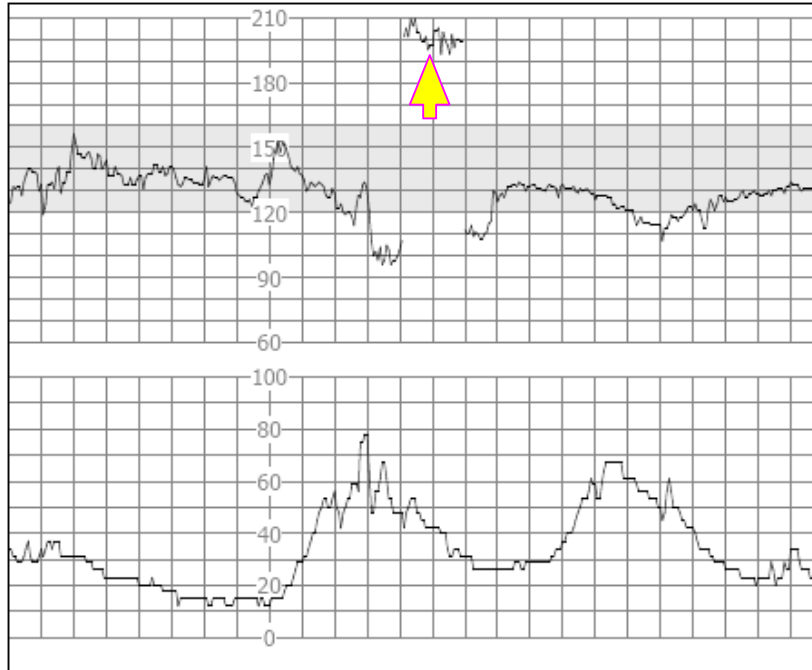
The transducer detects sound waves as they bounce off or echo back from the fetal heart. However, the sound waves bouncing off from maternal blood vessels may be detected by the transducer and then be processed by the monitor as well. As a result, artifacts may be produced.

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.

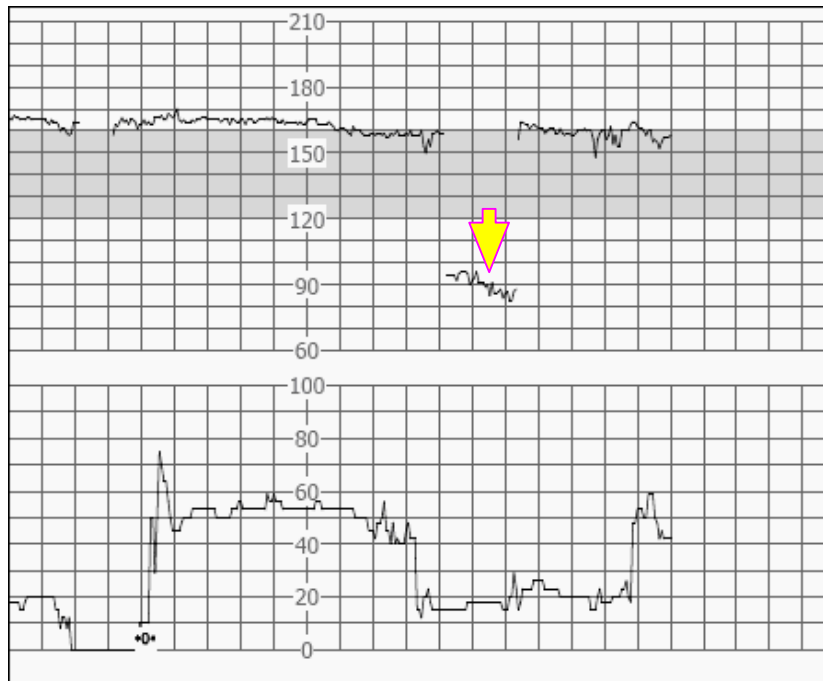
(2) Doubling:

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 heartbeats 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.

Auscultation 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.

A7.3 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 corrected by repositioning the transducer.

In summary, 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.

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