FETALGARD Lite™

Fetal Monitor

OPERATOR'S MANUAL

MEDASONICS®

ANALOGIC®

The World Resource for Precision Signal Technology

Proprietary Material

16-400823 Revision 3
January 2001, May 2001, June 2001

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Printed in U.S.A.

Preface

The FETALGARD Lite Operator's Manual contains all of the information the operator needs to operate the FETALGARD Lite monitor system, including:

Monitor Software	Revision 1.xx
View Software	Revision 1.xx
Recorder Firmware	Revision 1.xx

If the software version of your product is not in the range from 1.00 to 1.99, please contact your sales representative to obtain addendum pages or a replacement manual that describes the operation of your version of the product.

The FETALGARD Lite Operator's Manual is intended for trained medical personnel (including midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

Table of Contents

Section 1
Safety

1.1 Instructions for the Safe Operation and Use of the FETALGARD Lite™ Family of Monitors

- Examine the monitor and any accessories periodically to ensure that the cables, line cords, transducers, and instruments do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the monitor if there is any visible sign of damage.
- Only the Battery Eliminator supplied with the device is approved for use in supplying external power for operation and recharging the internal batteries.
- Only the AC line cord supplied with the FETALGARD Lite Recorder, or its equivalent, is approved for use with the Recorder.
- Do not attempt to service the FETALGARD Lite monitor or recorder. Only qualified service personnel should attempt any needed internal servicing.
- The FETALGARD Lite is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.
- The FETALGARD Lite is not specified or intended for operation in the presence of electrosurgical equipment.
- The FETALGARD Lite is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.
- Perform periodic safety testing to insure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.
- Do not operate the FETALGARD Lite monitor if it fails to pass the power on self-test procedure.

1.2 Warnings

WARNING: EXPLOSION HAZARD — Do not use the FETALGARD Lite in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: SHOCK HAZARD — The power receptacle must be a three-wire grounded outlet. Never adapt the three-prong plug from the Battery Eliminator or accessory to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.

WARNING: Do not connect to an electrical outlet controlled by a wall switch.

WARNING: 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.

WARNING: Use only patient cables and transducers supplied with the monitor. Use of any other patient cables may result in out-of-specification performance and possible safety hazards.

1.3 Cautions

CAUTION: United States Law restricts this device to sale by or on the order of a physician.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The unit should be kept clean and free of transducer gel and other substances.

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

CAUTION: 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.

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.

CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices. The RS-232 connector on the FETALGARD Lite is electrically isolated to permit safe connections to non-medical devices, which should be connected with a cable of sufficient length to prevent the non-medical equipment from contacting the patient.

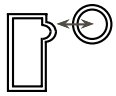
CAUTION: Do not autoclave or gas sterilize the monitor or any accessories. Follow cleaning and disinfection instructions in Section 12 of this manual.

CAUTION: Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer. Follow cleaning and disinfection instructions in Section 12 of this manual.

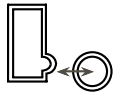
CAUTION: When washing the transducer belts, the water temperature must not exceed 60°C (140°F).

1.4 Definitions and Symbols

Ultrasound Transducer Input Connector

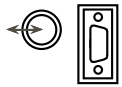


Toco Transducer Input Connector

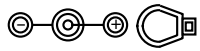


Remote Marker Input Connector

RS-232 Connector



Battery Eliminator Connector



Drip-proof Equipment Classification

Class II Equipment Symbol (double insulation)

Type BF Applied Part Symbol

Refer to Accompanying Documents

Protective Earth

Functional Earth

Section 2
Introduction

2.1 General

This chapter provides a general description of the FETALGARD Lite monitor including:

- Brief Device Description
- Product Features
- Model Configurations

2.2 Brief Device Description

The FETALGARD Lite is a family of microprocessor-based fetal monitors, providing continuous monitoring, display, and recording of fetal heart rate (FHR) and uterine activity (UA) for antepartum testing and monitoring.

2.3 Intended Use

The FETALGARD Lite is a Perinatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and optionally on a strip chart recorder. This data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy (Non-Stress Test). This device is for use only by trained medical personnel located in hospitals, clinics, doctors' offices and in the patient's home.

2.4 Product Features

The monitored data can be recorded continuously or intermittently on a strip-chart recorder at the operator's discretion. The recorded information includes graphic trend data and text information of monitor hardware and software configuration, date and time, patient identification, changes to operational settings, clinician and patient event marks, and recorder model and paper configurations.

2.5 Models, Options, and Accessories

There are four standard models in the FETALGARD Lite family.

- Model FGD01: Single-Fetus Monitoring
- Model FGD02: Twins-Fetus Monitoring
- Model FGDHC: Home Care Single-Fetus Monitoring
- Model FGDT: Home Care Twins-Fetus Monitoring

Table 2-1 defines the factory configurations of each of these models.

Table 2-1. FETALGARD Lite Configurations

Factory Configuration Monitoring Features and Included Items	Model FGD01	Model FGD02	Model FGDHC	Model FGDT
Fetal Heart Rate (FHR) – Single-Fetus monitoring	X	X	X	X
Fetal Heart Rate (FHR) – Twin-Fetus monitoring	No	X	No	X
Tocotonometer (TOCO) with belt	X	X	X	X
Recorder with line cord configured for country of intended use, I/O cable and 2 packs of paper	X	X	No	No
Factory-installed ultrasound cable and transducer (U/S1) for single monitoring with belt	X	No	X	No
Factory-installed ultrasound cable and transducer (U/S1) with belt and with connector for second transducer cable (U/S2) for twins monitoring	No	X	No	x
Second ultrasound cable and attached transducer (U/S2) with belt for twins monitoring	No	X	No	X
One tube of ultrasound gel	X	X	X	X
One Operator's manual	X	X	X	X
One table-top Battery Eliminator	X	X	X	X
One line cord for ordered U.S. or European use	X	X	X	X

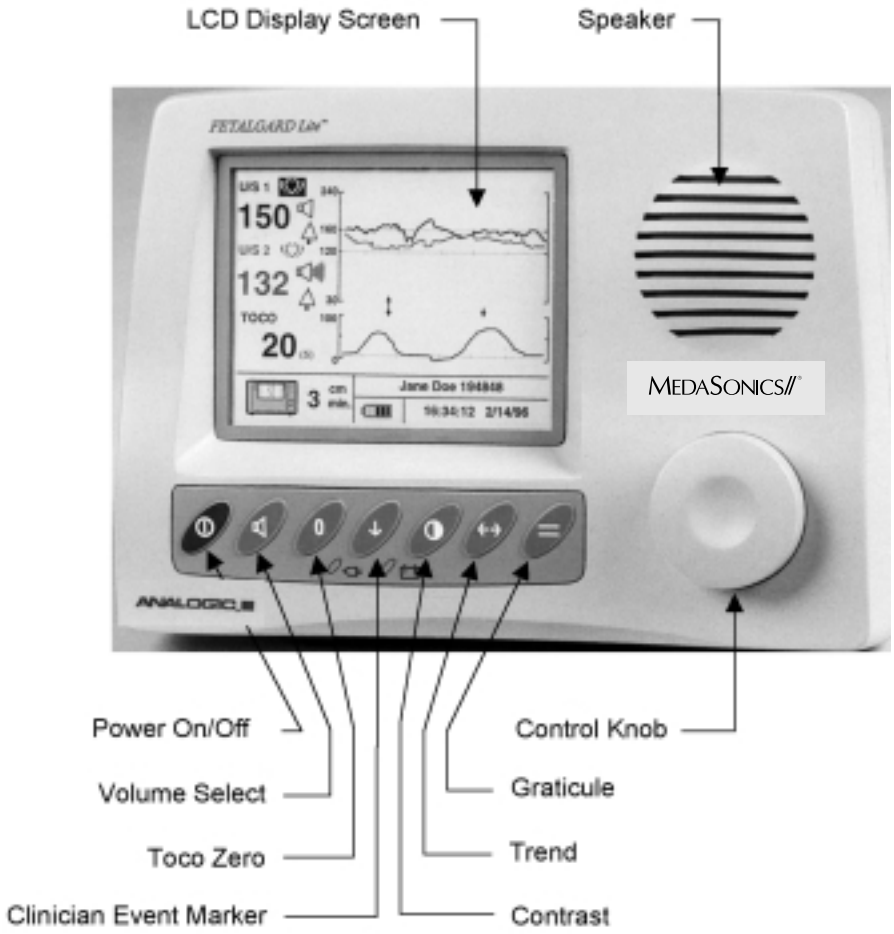
Table 2-2 indicates the Accessories that are designed for use with any of the models.

Table 2-2. FETALGARD Lite Accessories

Accessory Description	MedaSonics/I® Part Number
FG Lite Recorder w/cable 115V	FG REC-115
FG Lite Recorder Cable	REC
Single U/S Trans w/belt	UT
Single U/S Trans w/Y & belt	UTY
Second U/S Trans w/belt	UTYT
Tocotonometer w/belt	TOCO
Battery Eliminator 115V	BE-115
FG Lite Service Manual	FGSM
Remote Marker	RM01
FG Lite View Program	FGSP
GCX Adapter	FGGCX
FG Lite Carrying Case	FGCC

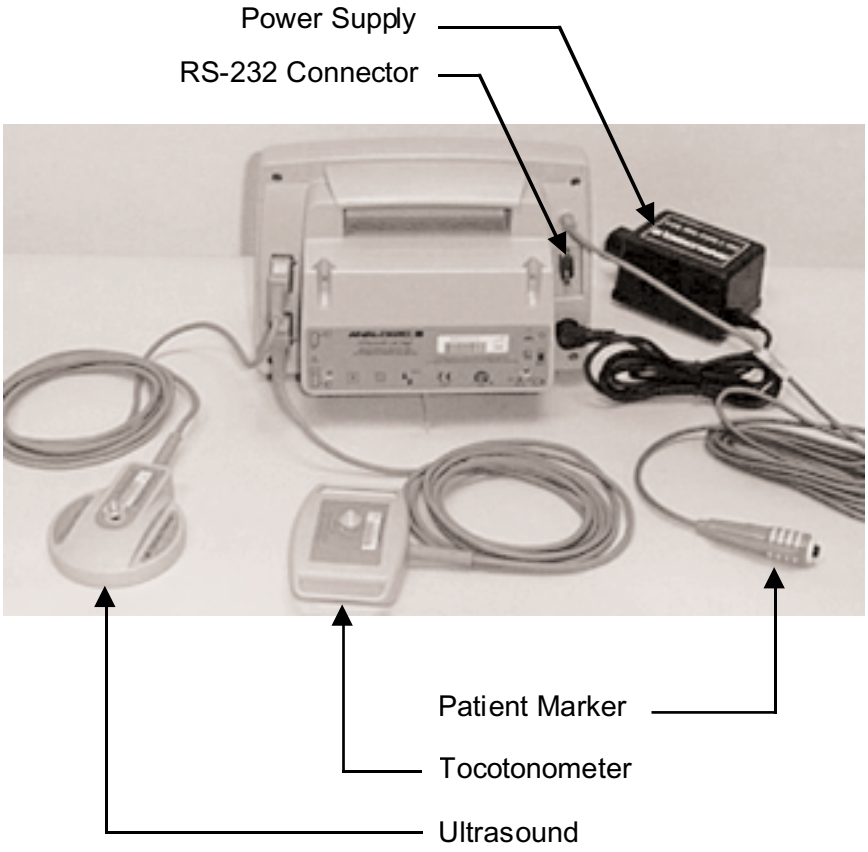
Section **3**
Installation, Setup, and Operation

3.1 Description of the Front Panel



This figure shows the location of the various parts and controls on the front of the FETALGARD Lite monitor.

3.2 Description of the Rear Panel



This figure shows the location of the various connectors on the rear of the FETALGARD Lite monitor, with accessories attached.

3.3 Patient Cables

The ultrasound transducer and TOCO transducer are attached to the rear of the monitor. Each cable has a tab located on the connector housing to insure proper insertion into the appropriate connector on the monitor. The location of the connectors is shown on the label located on the rear of the monitor.

The cables are inserted or removed by squeezing the narrow ends of the connector housing. This releases the connector locking mechanism.

A second ultrasound transducer and cable are supplied with the version of the FETALGARD Lite capable of monitoring two fetuses. This second transducer comes with a shorter cable that inserts into a connector located on the primary ultrasound transducer cable. To install the second transducer, remove the protective cover from the connector on the primary cable and insert the second transducer cable.

> ***WARNING***: Use only patient cables and transducers supplied with the monitor. Use of any other patient cables may result in out-of-specifications performance and possible safety hazards.

3.4 Remote Marker Cable

The remote marker cable is inserted into a connector on the rear. The rear label shows the location of the connector. The cable connector is inserted into the connector firmly until it is fully engaged.

3.5 Battery Eliminator

The battery eliminator is used to charge the monitor's internal battery. The battery can be charged either during normal fetal monitoring or when off. The battery eliminator consists of a tabletop box with a permanently attached cable and a separate AC line cord. The attached cable is inserted into its mating connector located on the rear of the monitor.The label on the rear of the monitor shows the location of this mating connector. Insert the cable into this connector firmly until it is fully engaged.

Insert the AC line cord into the three-pronged IEC receptacle on the battery eliminator. The other end of the AC line cord is then inserted into an appropriate wall outlet.

WARNING: SHOCK HAZARD — The power receptacle must be a three-wire grounded outlet. Never adapt the three-prong plug from the Battery Eliminator or accessory to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.

WARNING: Do not connect to an electrical outlet controlled by a wall switch.

WARNING: 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.

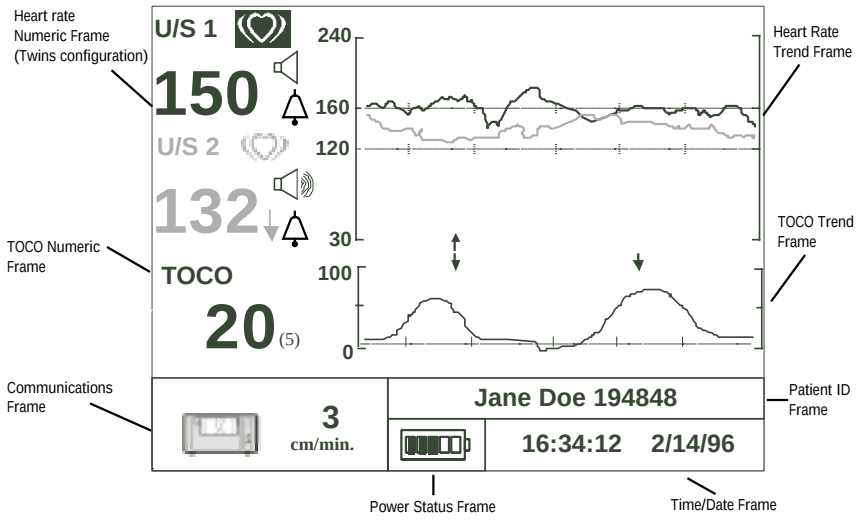
3.6 GCX Mounting Plate

The GCX mounting plate attaches to the bottom of the monitor by sliding the narrow piece of the mounting plate into the slot on the bottom of the monitor. The spring loaded plunger will snap into place when the GCX mounting plate is fully engaged. To remove the mounting plate simply pull on the spring loaded plunger until the plate is free to slide out.

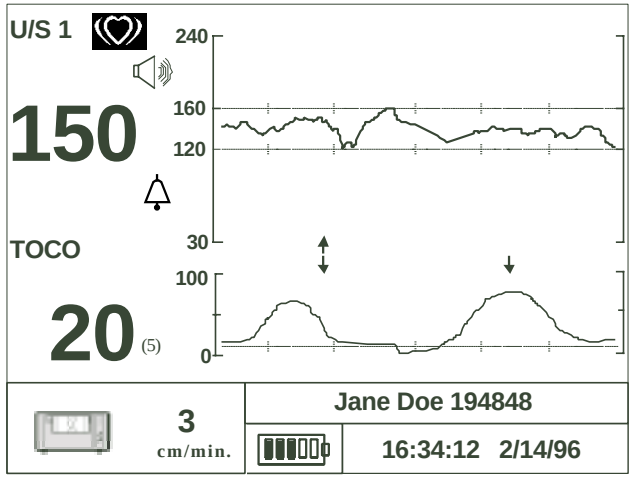
The monitor and GCX plate is attached to a standard GCX roll stand (GCX part number ANA-0001064).

3.7 FETALGARD Lite Monitor Display Screen

Main Monitoring Screen (Twins Configuration)



Main Monitoring Screen (Single Configuration)



3.7.1 Heart Rate Numeric

The heart rate numeric frame displays the fetal heart rate, a heart icon, alarm status icon, and a speaker volume icon. This channel is labeled “U/S 1.” The heart rate value shows the most recent calculated fetal heart rate. The heart rate icon blinks at the measured heart rate interval when a valid rate is present.

The volume icon provides an indication of the speaker volume setting for the fetal echo sounds. This icon changes when the speaker volume setting is adjusted. The alarm icon is a bell. A diagonal line through the bell indicates alarms are disabled. A bell missing a diagonal line indicates alarms are enabled.

When the second ultrasound transducer is installed, the heart rate frame will include additionally the fetal heart rate, a heart rate icon, alarm status icon, and a speaker volume icon for the second ultrasound channel. These function identically as described above. This channel is labeled "U/S 2."

The trace-offset icon will also appear in the heart rate frame if two ultrasound transducers are installed and ultrasound trace offset has been enabled. The trace-offset icon is a downward pointing arrow.

3.7.2 Heart Rate Trend

The Heart Rate Trend Frame displays a graphical representation of the fetal heart rate. The vertical scale is labeled and corresponds to the selection of recorder paper (30 to 240 BPM for U.S. style paper, 50 to 210 BPM for international style paper). The graph displays 6 minutes of data if the monitor is set for a print speed of 3 cm per minute, 9 minutes of data when set for 2 cm per minute, and 18 minutes when set to 1 cm per minute.

This frame will show two heart rate trends when two ultrasound transducers are installed.

Two horizontal graticules are included to make it easier for the caregiver to observe heart rate trend or heart rates that exceed limits. The position of these two graticules is 120 BPM and 160 BPM.

This graphical frame is also used to display heart rate data when scrolling through historical patient data.

3.7.3 TOCO Numeric

This frame contains the numeric value from the TOCO transducer representing uterine activity. This frame also shows the present TOCO baseline value. The TOCO baseline is user adjustable.

3.7.4 TOCO Trend

The TOCO Trend Frame displays uterine activity trend data. The scale is from zero to 100 in relative units. The graph displays 6 minutes of data if the monitor is set for a print speed of 3 cm per minute, 9 minutes of data when set for 2 cm per minute, and 18 minutes when set to 1 cm per minute. This graphical frame also displays uterine activity data when scrolling through patient data.

3.7.5 Power Status

This frame contains either a battery icon or an AC power connector icon. If the unit is operating on AC power then an AC power connector icon is displayed. If the monitor is operating on internal battery power then a battery icon is displayed. The battery icon also includes a scale indicating battery charge status.

The battery icon will flash when the battery is low (less than 30 minutes of remaining time). The battery eliminator should be connected to the monitor to charge the battery. The monitor will operate normally while the battery eliminator is charging the battery. The battery will be fully recharged in 8 hours if the monitor is not in use, or in 14 hours while in normal use.

3.7.6 Communications

This frame shows the status of devices connected to the monitor's serial interface port.

Icon	*Description*
	This phone icon appears if the monitor is connected to an external modem and no call is in process.
	This icon appears when the connected modem is making a call to another modem. The call is in process and an attempt is being made to connect to another device.
	This icon appears when the attached modem is transferring patient data files.
	This icon appears when the monitor is connected directly to an external computer and they are able to communicate with each other.
	This icon appears when the monitor is connected to the FETAL-GARD Lite Recorder. This icon is accompanied by the present setting for print speed.

3.7.7 Patient ID

This section displays the patient identification. The monitor uses a time and date encoded identification scheme that insures no duplication of names. The user may also enter a different name if desired.

3.7.8 Time and Date

This frame shows the current time and date for the monitor. These settings can be changed as needed. The format for time and date is also user configurable.

3.7.9 Error Display

The error screen will be displayed when the monitor is unable to operate properly. If this screen appears, discontinue use of monitor. Refer to the service manual for appropriate action.

3.8 FETALGARD Lite Monitor Controls and Indicators

There are seven buttons located on the front panel. The buttons are activated by pushing with the finger until an audible click is heard.

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.

The operation of the buttons is summarized below.

Icon	*Description*
	Power On/Off button — turns monitor power on and off.
	U/S Volume Select button — selects an ultrasound channel in order to adjust its audio volume. The control knob is then used to increase or decrease volume settings. This button is also used to silence the audible warning indicator that accompanies a heart rate alarm condition.
0	TOCO Zero button — resets the TOCO baseline.
	Clinician Event Marker button — inserts a nurse event mark on the display and strip chart paper when pressed.
	Contrast Adjust button — changes the operation of the control knob for adjusting the display contrast.

Trend Scroll button — this button puts the monitor into trend scroll mode. The trend frames shows historical patient data and the control knob provides navigation capability.

Graticule button — displays a pair of horizontal level lines, 15 BPM apart, on the FHR trend frame. Rotating the control knob moves these lines up or down on the display.

The keypad has two LED indicators. The indicator next to the battery symbol is on whenever the monitor is powered from the internal battery. The indicator next to the power cord connector symbol is on whenever the monitor is powered from AC mains via the external battery eliminator.

3.9 FETALGARD Lite Monitor Control Knob

The Control Knob is the primary method of adjusting parameters and navigating through the menu system. Rotating the knob while in the main monitoring screen moves a selection frame to each of the frames in the display. When the knob is pressed, a menu appears that contains monitor settings that are relevant to the display frame that was selected.

If the knob is rotated while in a menu, the cursor moves throughout the items within the menu. This process is used to select a menu item for modification. The knob is then pressed to select this item for editing.

Once a menu item has been selected for editing, the knob is rotated to scan through the available choices for this parameter. Pressing the knob stores the new value.

Pressing the knob when “Return” is selected will exit the present menu. In some cases this action will return the monitor to the main monitoring screen. In other cases the monitor will display the previous menu.

Specific Control Knob procedures are included in the chapters describing setup, monitoring, recording and viewing patient data.

3.10 Startup

3.10.1 Power-on Self-test

The monitor performs a self-test each time it is turned on. This process allows the monitor to check various systems for proper operation. The monitor displays the startup screen during the power-on self-test. When the test is successfully completed the FETALGARD Lite displays the monitoring screen.

If a malfunction is detected an error screen appears and an error tone is sounded. The error tone will continue until the power is turned off. If this occurs, remove the monitor from service until appropriate action is taken.

3.10.2 Configuration Settings

The monitor has several configuration settings that the user can change. Some of these settings are reset to the default value each time the monitor is powered down. Other parameter settings are saved in the monitor until the next time they are changed. These parameters are unaffected when the monitor is powered down. A complete list of these parameters is shown below.

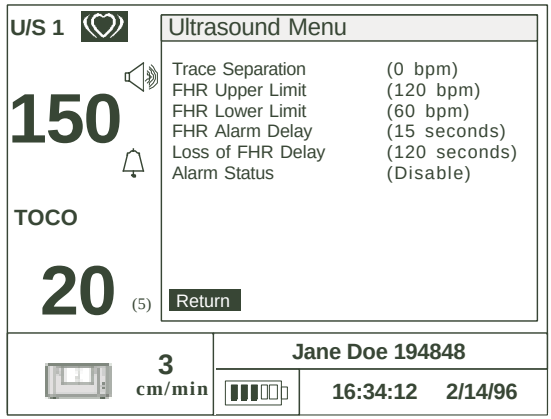
Configuration Parameter	Factory Default	Saved Until Changed
U/S Trace Separation	0 BPM	No
TOCO Baseline Set Point	10	Yes
Time Format	12-hour	Yes
Date	"today"	Yes
Date Format	mm/dd/yy	Yes
Patient Id	Time/Date encoded	No
Language	English	Yes
Modem Initialization String	—	Yes
Modem Phone Number	—	Yes
Recorder Paper Speed	3 cm/min	Yes
Recorder Paper Vendor	Analogic	Yes
Recorder Paper Style	U.S.A.	Yes
Alarms	Disabled	Yes
U/S Heart Rate Upper Alarm Limit	120 BPM	Yes
U/S Heart Rate Lower Alarm Limit	60 BPM	Yes
Heart Rate Alarm Delay	15 seconds	Yes
Loss of Heart Rate Alarm Delay	120 seconds	Yes
Display Contrast	—	Yes
Speaker Volume	—	Yes

3.10.3 Setting U/S Trace Separation

When ultrasound trace separation is enabled, the trend data for ultrasound channel 2 is shifted down by 20 BPM. This feature is provided to clearly see separate heart rate trends when both heart rates are similar. The heart rate value shown in the numeric frame is not affected.

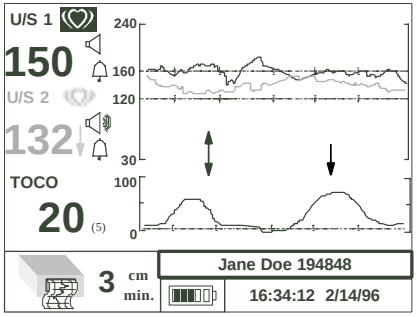
Follow the steps below to change the heart rate separation setting.

Knob Activity	**Desired Result**
Rotate	To highlight the heart rate frame.
Press	To view the ultrasound menu (shown below).



Rotate	To select Trace Separation.
Press	To select this parameter for change.
Rotate	To select “0 BPM,” or “20 BPM.”
Press	To keep this selection.
Rotate	To select “Return.”
Press	To exit this submenu and return to the main monitoring screen

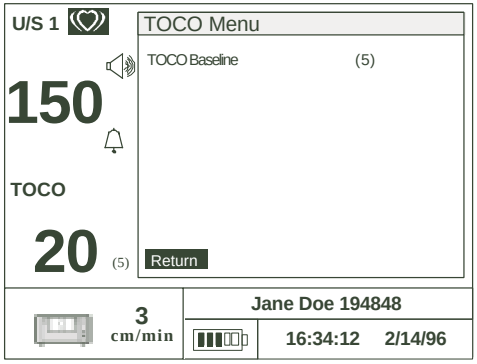
When trace separation is activated, it is indicated on the monitoring display by an arrow pointing downward next to the U/S 2 numeric value. This indicator will flash at a 1 Hz rate.



0 *3.10.4 Setting TOCO Baseline*

This section describes the procedure for setting the TOCO baseline.

Knob Activity	Desired Result
Rotate	To highlight the TOCO numeric frame.
Press	To view the TOCO menu (shown below).



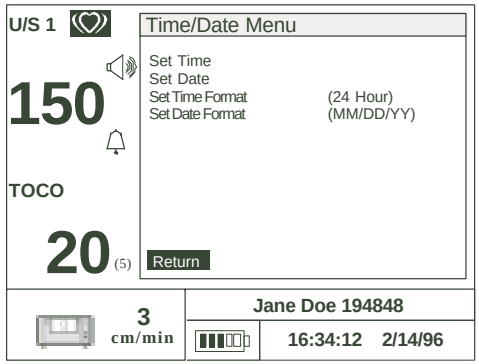
Rotate	To highlight "TOCO Baseline."
Press	To select this parameter for change.
Rotate	To highlight the desired baseline value ("5," "10," "15," or "20").
Press	To keep this selection.
Rotate	To select "Return."
Press	To exit this submenu and return to the main monitoring screen.

The new baseline value is displayed in parentheses in the TOCO numeric frame.

3.10.5 Setting Time, Date, and Display Format

This section describes the procedure used to change the time and date settings of the monitor.

Knob Activity	Desired Result
Rotate	To highlight the Time and Date Frame with a heavy border.
Press	To view the Time/Date menu (shown below). Next to each parameter is the present setting in parentheses.



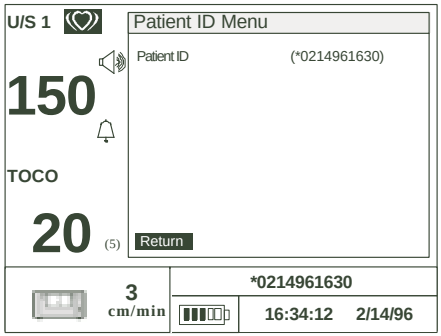
Rotate	To highlight the item you want to change ("Set Time," "Set Time Format," "Set Date," or "Set Date Format").
Press	To select this item for editing.
Rotate	To highlight the parameter value for editing. The options for each parameter in the submenu are: Time {hours, minutes, seconds} Date {month, day, year} Time Format {12 Hour, 24 Hour} Date Format {MM/DD/YY, DD/MM/YY}
Press	To select the parameter value for editing.
Rotate	To choose new values for the parameter.
Press	To keep the displayed value for this parameter. Repeat the previous steps for each parameter you wish to change.
Rotate	To select "Return."
Press	To exit this menu.

The new time, date, and format selections are displayed on the main monitoring screen.

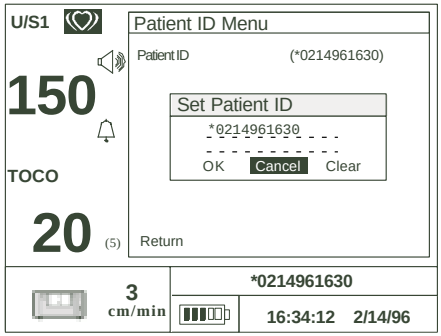
3.10.6 Setting Patient ID

This section describes the procedure used to change the patient ID. When the monitor is turned on a default patient ID is created by the monitor based upon the present time and date. When this default patient ID is changed, the new patient ID will be incorporated into the stored patient record within the monitor and presented on the display. If the patient ID is changed a second time the monitor assumes a new patient and automatically creates a new patient record.

Knob Activity	**Desired Result**
Rotate	To highlight the Patient ID Frame with a heavy border.
Press	To view the Patient ID menu (shown below). The present patient ID is displayed in parentheses.



Rotate	To highlight "Patient ID."
Press	To select "Patient ID" for editing. The Set Patient ID submenu will appear (shown below).



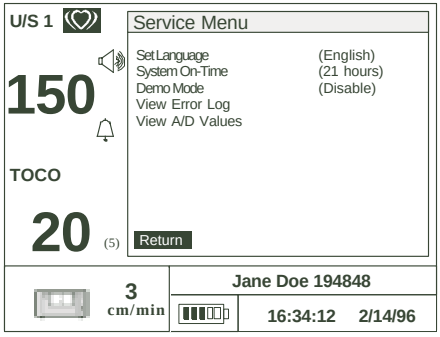
Rotate	To highlight a character in the patient ID for edit or to highlight "Clear," "OK," or "Cancel."

Press	To activate the highlighted selection. If the knob is pressed when “Clear” is highlighted, characters within the Patient ID field will be set to blanks. If the knob is pressed when a character in the Patient ID is highlighted, this character is selected for editing.
Rotate	To select new values for this character in the patient ID. The characters available are 0-9, A-Z, and “space.”
Press	To keep the displayed value. Repeat the previous steps for each character you wish to change.
Rotate	To highlight “Return,” “OK,” or “Cancel.”
Press	If the knob is pressed when “OK” is highlighted, the patient ID will be updated with the displayed characters and the Set Patient ID dialog box will be removed. If the patient ID contains all spaces when “OK” is pressed, the monitor will sound the invalid beep tone and not close the dialog box. If the knob is pressed when “Cancel” is highlighted, the Set Patient ID dialog box will be removed with the original patient ID unchanged.
Rotate	To highlight “Return.”
Press	To exit the Patient ID menu and return to the main monitoring screen.

3.10.7 Setting the Language Configuration

This section describes the procedure used to change Language displayed on the display.

Knob Activity	Desired Result
Rotate	To highlight the Power Status Frame with a heavy border.
Press	To view the Service menu shown below. The present language setting is displayed in parenthesis.



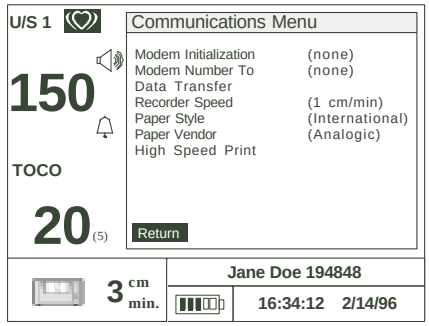
Rotate	To highlight "Language."
Press	To select a new language setting.
Rotate	To highlight the desired language. Available options are English, German, French, Russian, Spanish, Portuguese, and Italian.
Press	To select the highlighted language.
Rotate	To highlight "Return."
Press	To exit the Service menu and return to the main monitoring screen.

Caution: Selecting an unfamiliar language may make it difficult to resume normal operations.

3.10.8 Setting Modem Parameters

This section describes the procedure used to establish the correct modem settings for proper operation. These settings control the operation of the external modem.

Knob Activity	Desired Result
Rotate	To highlight the Communications Frame with a heavy border.
Press	To view the Communications menu (shown below).

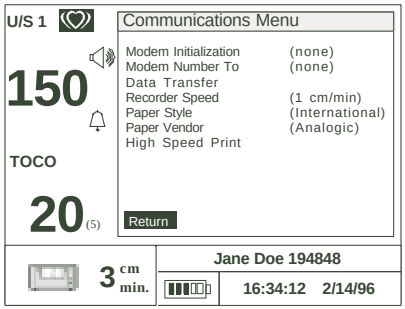


Rotate	To highlight "Modem Initialization."
Press	To select "Modem Initialization" for editing.
Rotate	To highlight the desired character.
Press	To select this character for editing.
Rotate	To choose a new value for this character.
Press	To keep the new value for this character. Repeat the previous four steps until the initialization string has the desired changes.
Rotate	To highlight "OK."
Press	To exit the modem initialization dialog box and return to the Communications Menu. Repeat the previous steps to set the "Modem Number to Dial."
Rotate	To highlight "Return."
Press	To exit the Service Menu and return to the main monitoring screen.

3.10.9 Setting Recorder Parameters

This section describes the procedure used to set the paper speed, paper vendor, and paper style.

Knob Activity	Desired Result
Rotate	To highlight the Communications Frame with a heavy border.
Press	To display the communications Menu shown below.



Rotate	To highlight "Recorder Speed," "Recorder Paper Style," or "Recorder Paper Vendor."
Press	To select the highlighted parameter for editing. A dialog box will appear with the available options for this parameter.
Rotate	To highlight the desired value. The list below shows the values that are available for each parameter. Recorder speed {1 cm/minute, 2 cm/minute, 3 cm/minute} Recorder paper style {U.S., International} Recorder paper vendor {Analogic, Coro, HP}
Press	To keep the highlighted value and exit the dialog box. Repeat the previous steps until "Recorder Speed,"Recorder Paper Style," and "Recorder Paper Vendor" are properly configured.
Rotate	To highlight "Return" in the Service Menu.
Press	To exit the Service Menu and return to the main monitoring screen.

3.10.10 Understanding and Setting Alarms

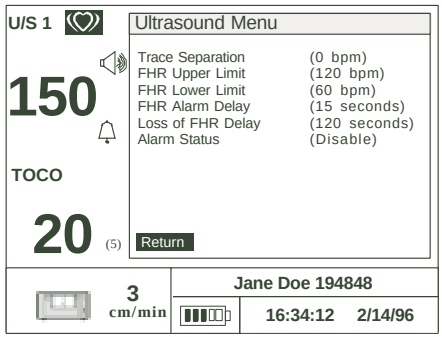
The FETALGARD Lite monitor has the capability to alert the caregiver in the event a heart rate goes above or below an alarm limit for a preset time delay. The limit values and the delay from onset to alert are configurable. An alarm event results in an audible tone and blinking of the heart rate value on the display. Pressing the speaker key on the monitor's keypad can silence the alarm tone. The blinking heart rate will continue as long the alarm condition persists or until alarms are disabled.

The monitor also has the capability of alerting the clinician if a loss of heart rate detection occurs. This alert occurs if a valid heart rate is followed by no measurable heart rate for a preset time delay. The heart rate frame will display blinking dashes and the audible warning tone will sound if this condition happens. The audible warning tone can be silenced by pressing the speaker button on the monitor's keypad. The display of blinking dashes will continue as long as the alarm condition persists or until alarms are disabled. The loss of heart rate alarm delay time is adjustable by the user.

Alarms are enabled or disabled by accessing the selection in the Ultrasound menu. If alarms are disabled then all alarms are off. If alarms are enabled then all alarms are on.

The following section describes the procedure used to set alarm parameters for ultrasound heart rates.

Knob Activity	**Desired Result**
Rotate	To highlight the Ultrasound Frame with a heavy border.
Press	To view the Ultrasound menu (shown below).



Rotate	To highlight "Heart Rate Upper Limit," "Heart Rate Lower Limit," "Heart Rate Alarm Delay," or "Loss of Heart Rate Delay."
Press	To select the highlighted parameter for editing. A dialog box will appear with the available options for this parameter.
Rotate	To highlight the desired value. The list below shows the values that are available for each parameter. Heart Rate Upper Limit {120–220 BPM, 5 BPM increments} Heart Rate Lower Limit {60–120 BPM, 5 BPM increments} Heart Rate Alarm Delay {15–120 sec., 15 sec. increments} Loss of Heart Rate Delay {30–120 sec., 30 sec. increments}
Press	To keep the highlighted value and exit the dialog box. Repeat the previous steps until "Heart Rate Upper Limit," Heart Rate Lower Limit," "Heart Rate Alarm Delay," or "Loss of Heart Rate Delay" are properly configured.
Rotate	To highlight "Alarm Status."
Press	To select "Alarm Status" for a new setting.
Rotate	To highlight "Enabled," or "Disabled." "Enabled" activates the alarm system, "Disable" deactivates the alarm system.
Press	To keep the highlighted selection.
Rotate	To highlight "Return."
Press	To exit the Ultrasound Menu and return to the main monitoring screen.

3.10.11 Adjusting the Display Contrast

Display contrast is set to a default value at the factory. This setting is adjustable to optimize the display for best viewing. The contrast button and the control knob are used for this adjustment.

Pressing the contrast button initiates the process and resets the contrast to the factory default. This is done to ensure the display contrast is centered and the display is reasonably viewable. The knob is rotated clockwise to lighten the contrast or counterclockwise to darken the contrast.

Pressing the contrast button a second time completes the adjustment process. The new contrast setting is saved until the next time it is changed. Knob inactivity for more than 10 seconds will also complete the adjustment process as if the button were pressed a second time.

3.10.12 Adjusting Speaker Volume

Speaker volume can be increased or decreased by pressing the speaker volume button followed by clockwise or counterclockwise rotation of the knob. This volume adjustment affects only the amplitude of the ultrasound heart sounds. A volume icon, located in the ultrasound heart rate frame of the display, changes with knob rotations to provide visual feedback of the volume setting.

Pressing the volume button a second time completes the adjustment process. The new volume setting is saved until the next time it is changed. Knob inactivity for more than 10 seconds also completes the adjustment process.

The adjustment process varies slightly for a monitor with two ultrasound channels. The first press of the volume button followed by knob rotation adjusts the volume for ultrasound channel one. The second press of the volume button completes the adjustment for channel one and enables the adjustment of channel two. Knob rotation will now change the volume setting for ultrasound channel two. A volume indicator icon for channel two, located in the heart rate frame for channel two, operates the same as described above for channel one. Pressing the volume button a third time completes the adjustment process for channel two and saves the desired setting. Knob inactivity for more than 10 seconds also completes the adjustment process.

3.11 FETALGARD Lite Recorder

3.11.1 Installation and Loading Paper

Unpack the recorder and accessories and place the recorder on a solid table surface. Connect the communications cable to the connector on the rear of the recorder. The other end of the cable connects to its mating connector on the rear of the monitor.

Attach the AC line cord to the IEC receptacle on the rear of the recorder and to an appropriate AC outlet.

WARNING: The power receptacle must be a three-wire grounded outlet. Never adapt the three-prong plug from the Battery Eliminator or accessory to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the recorder.

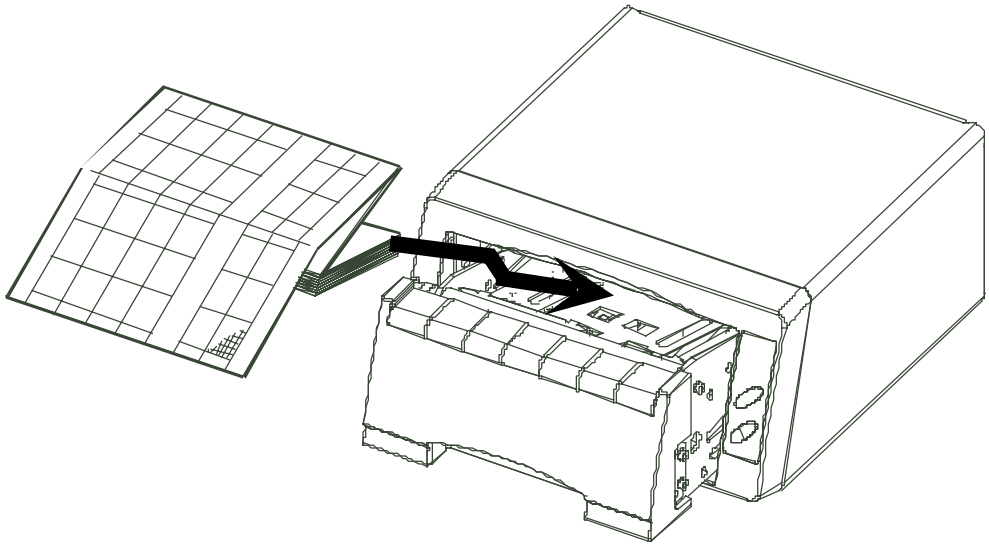
WARNING: Do not connect to an electrical outlet controlled by a wall switch.

WARNING: 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.

The paper is loaded by first sliding the paper drawer forward as shown below.

A spacer is required in the paper tray when HP paper is used. This spacer is supplied with the monitor and is installed into the left side of the paper tray. This spacer must be installed to properly align the paper to the print head. Make sure this spacer is installed properly prior to proceeding with loading paper.

Unwrap a pack of paper and slide it into the paper tray as shown below.



Several pages from the top of the pack of paper should drape forward over the top of the paper drawer. The orientation of the paper is with the printed grid facing up (unfolding from the top of the pack) and the TOCO grid area closest to the recorder keypad.

Slide the paper drawer into the recorder. The recorder is now ready for use.

Turn the recorder on using the AC mains switch on the rear of the recorder. An indicator LED on the front of the recorder will confirm the unit is attached to an AC source and the unit is powered on.

3.11.2 Controls and Indicators

This section describes the fixed function buttons and indicator lights on the recorder.

Icon	Description
	**Paper Advance button —** This button is used to fast-forward the recorder paper. A press and hold of this button will advance the recorder paper at high speed until the button is released. The recorder will resume its original activity when the button is released. Any text and graphics in the process of being printed during a paper advance event will be lost. When the button is released, printing will resume normally.
	**Printing Enable/Disable button —** A single press and release of this button will toggle the recorder mode between printing and non-printing. The indicator LED next to the icon at the left will be on when printing is enabled and off when disabled. At power-on, the unit will default to printing enabled. If the recorder is connected to an active monitor, the recorder will automatically begin printing as instructed by the monitor.
	**Power-on Indicator —** This indicator will be on whenever the unit is connected to an AC line source and the AC mains switch on the rear of the recorder is on.

Section 4
Monitoring Fetal Heart Rate

Electromagnetic Interference

Certain strong electromagnetic fields can interfere with the ultrasound transducer and cause a false heart rate reading that does not originate from the patient. This interference is rare, and usually found in the vicinity of large machinery. In order to avoid the possibility of these interfering signals being misinterpreted as fetal heart rates, the following procedure should be followed whenever the monitor is to be used in a new location, or if it is known that electrical machinery is being operated in the vicinity.

After connecting the ultrasound transducer(s), turn on the monitor and observe the heart rate indications on the screen for 30 seconds. Intermittent display of random heart rates is acceptable. However, if there is a constant display of a physiological heart rate lasting more than 5 seconds, this is an indication that there is a source of electromagnetic interference in the vicinity. The following steps should be taken to determine if it is possible to use the monitor in this environment.

- Move all line cords and line-powered equipment at least 6 feet away from the FETALGARD Lite. Check for extension cords running behind or under the bed and equipment in adjacent rooms. If the artifact heart rate indication ceases, the monitor may be used normally.
- Remove the line cord from the monitor's power supply. If the artifact heart rate indication ceases, the monitor may be used normally.
- Unplug the FETALGARD Lite recorder and move it out of the vicinity. If the artifact heart rate indication ceases, the monitor may be used normally.

If these measures do not result in cessation of the heart rate artifact, the monitor cannot be safely used in this environment.

Fetal heart rate is measured by placing an ultrasound transducer on the maternal abdomen and processing the Doppler echo signal to produce a heart rate and an audio representation of the echo signal.

Step 1: Preparing the Monitor

Turn the monitor on and verify that the normal monitoring screen appears on the display. Remove the monitor from service if an error occurs.

Determine whether the monitor is powered from the internal battery or the battery eliminator. If operating on the internal battery, check the power status frame on the display to determine whether the battery has sufficient charge to complete the monitoring session. Use the battery eliminator if the battery is too low.

Check the ultrasound transducer to verify proper attachment to the monitor. For twins monitoring, make sure the second ultrasound transducer is properly connected.

Adjust heart rate channel one speaker volume to mid level. Adjust channel two speaker volume to off if monitoring twins.

Apply ultrasound gel to the face of the transducer.

Step 2: Acquiring the Fetal Heart Signal

Determine the location of the fetal heart using palpation or a fetoscope.

Place the transducer on the maternal abdomen and listen for the fetal heart signal. Reposition the transducer for the loudest fetal heart signal and verify the indicator LED on the transducer is blinking at the fetal heart rate.

Secure the ultrasound transducer with the elastic belt. Make sure the transducer is still positioned for the loudest fetal heart signal.

Verify the monitor is displaying fetal heart rate values and that the heart rate indicator on the ultrasound transducer is blinking at the measured heart rate.

Step 3: Acquiring Twins' Heart Rates

Follow the steps outlined in step 2 above to acquire the heart rate for the first fetus.

Adjust the ultrasound audio volume for channel one down and channel two up so that the second heart sounds can be heard.

Determine the location of the second fetal signal using palpation or fetoscope.

Apply gel to the second ultrasound transducer and place it on the maternal abdomen where the second fetal signal was located. Adjust the position of the transducer to find the fetal signal and to maximize its loudness.

Secure the ultrasound transducer with the elastic belt. Make sure the transducer is still positioned for the loudest fetal heart signal. Also verify the position of transducer one has not changed.

Verify the monitor is displaying fetal heart rate values for both fetuses and that the heart rate indicators in both ultrasound transducers are blinking at the measured heart rate.

Step 4: Monitor Adjustments
Readjust the volume settings for the desired loudness.

Section 5
Monitoring Uterine Activity (UA)

Uterine activity is measured externally by placing a pressure sensitive device (Tocotonometer) on the maternal abdomen and recording relative pressure changes.

Step 1: Preparing the Monitor
Turn the monitor on and verify that the normal monitoring screen appears on the display. Remove the monitor from service if an error occurs.

Determine whether the monitor is powered from the internal battery or the battery eliminator. If operating on the internal battery, check the power status frame on the display to determine whether the battery has sufficient charge to complete the monitoring session. Use the battery eliminator if the battery is too low.

Check the TOCO transducer to verify proper attachment to the monitor.

Check for the proper setting for TOCO baseline. Adjust as needed.

Step 2: Acquiring Uterine Activity Data
Place the face (button side) of the Tocotonometer on the fundus of the uterus when contractions are not occurring. No gel is required.

Secure the Tocotonometer with the belt. The uterine activity reading at this point should be greater than 30 and less than 90 units. If the readings fall outside this range, the belt may be too tight or too loose. If the belt is over tightened, the contraction peaks may have a flat-top at less than 100 on the TOCO scale. If the belt is under tightened, the position of the transducer may wander and cause unusable readings. Readjust the belt pressure as needed.

Step 3: Monitor Adjustments
Press the TOCO Zero button on the front panel to adjust the values to the baseline. This must be done during non-contraction intervals.

Section 6
Remote Patient Marker and Clinician Marker

6.1 Clinician Marker

The nurse's marker arrow is provided so that the nurse can record the time of important events. The clinician merely presses the marker button located on the front-panel keypad at the time an event occurs. This marker time is recorded in the patient record in the monitor.

The nurse marker icon is a downward pointing arrow. The monitor will display this downward pointing arrow in the information frame of the display. A strip chart printout of the patient record will also show this mark accompanied by the time and date.

6.2 Remote Patient Marker

The patient marker arrow is provided so that the patient can record the time of important events. The patient merely presses the marker button located on the end of the marker cable at the time an event occurs. This marker time is recorded in the patient record in the monitor.

The patient marker icon is an upward pointing arrow. The monitor will display this upward pointing arrow in the information frame of the display. A strip chart printout of the patient record will also show this mark.

Section 7
Using Graticules

Graticules are reference lines on a chart that are used to aid in interpreting the plotted data. The FETALGARD Lite has two horizontal graticule lines in the ultrasound trend frame located at 120 BPM and 160 BPM. These graticule lines provide a reference for estimating heart rate.

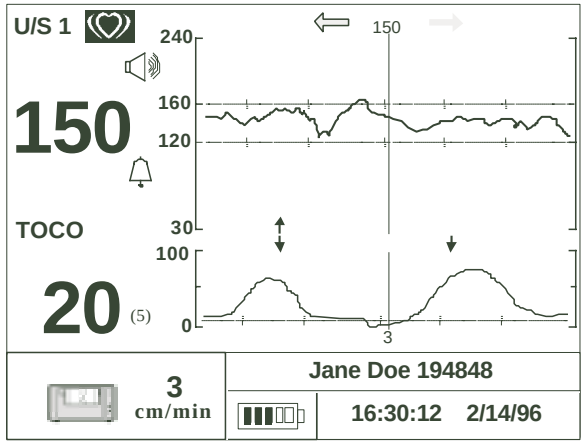
The TOCO trend frame also has a graticule reference line. It is located at the TOCO baseline value. This graticule line is relocated when the baseline value is changed to one of the other values.

When the operator presses the graticule button on the keypad, the two reference graticule lines in the ultrasound trend frame are replaced with two new graticule lines. These lines are 15 BPM apart and can be moved up and down by rotating the control knob. This pair of moveable graticule lines will stay on the screen until there is 20 seconds of knob inactivity at which point they will change back to the fixed lines at 120 BPM and 160 BPM. The purpose for these moveable graticule lines is to aid in establishing heart rate variability, particularly when performing a non-stress test, NST. For example, the lower line can be placed on a reference heart rate baseline and the other line used to locate the reference point where the heart rate change equaled 15 BPM. Timing marks are spaced 1 minute apart to provide a simple time scale.

Section **8**
Using Trend Scroll

The FETALGARD Lite can store up to 12 hours of patient data. Only the most recent 6, 12, or 18 minutes of this data is observable on the display at any point in time (depending on the print speed setting). Scrolling capability is a feature that enables viewing stored data from the present session or historical data from previous monitoring sessions.

Pressing the scroll-mode button on the keypad enters scroll mode. This button is labeled with an image of two opposing arrows. Two opposing arrows will be displayed above the ultrasound trend frame indicating the monitor is in scroll mode. A second press of this button or knob inactivity for 30 seconds will exit scroll mode.



The monitor will display a vertical reference line centered in the ultrasound trend frame and a vertical reference line centered in the TOCO trend frame. TOCO and heart rate values pass the vertical reference line as the data is scrolled through the display. The heart rate values at the reference line are displayed above the vertical reference line in the ultrasound trend frame and the TOCO values at the reference line are displayed below the vertical reference line in the TOCO trend frame.

The heart rate numeric frames, TOCO numeric frame, power status frame, and the communications frame are unaffected when in scroll mode and continue displaying the most current data and status information pertinent to the present monitoring session.

The patient ID frame displays the appropriate ID for the stored data. The ID will be for the current patient when scrolling through the data from the current monitoring session. When scrolling further back into previous records, the displayed ID will reflect the record being viewed. The Patient ID will change after the present record has scrolled fully off the display and the next record begins to scroll onto the display.

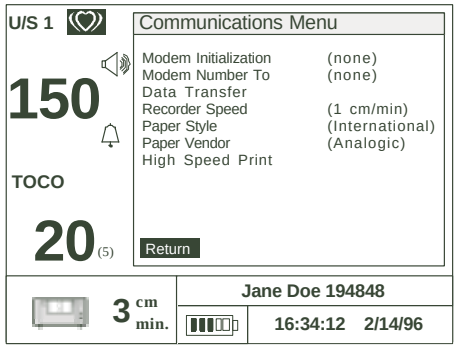
The time and date frame will display the time and date when the data values were recorded as they pass the vertical reference lines.

Rotating the control knob slides the heart rate and TOCO values synchronously left and right. Clockwise rotation views older data and counterclockwise rotation views more recent data. Rotating the knob slowly slides the values through the display at the rate that is convenient for viewing. Rotating the knob quickly slides the data through the display at a faster rate. This provides a quicker way to move ahead or back.

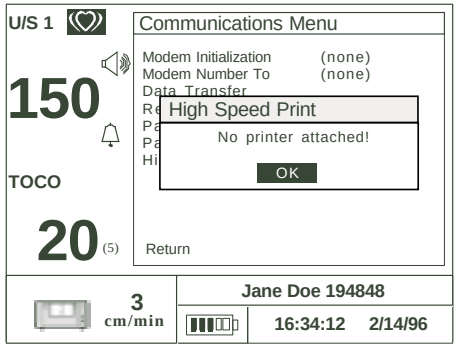
Section **9**
Printing Patient Files

This section describes the procedure used to print stored patient files. Printing stored files occurs at a faster rate than printing during a monitoring session and is referred to as “batch printing” or “high speed printing.”

Knob Activity	**Desired Result**
Rotate	To highlight the Communications Frame with a heavy border.
Press	To view the Communications menu (shown below).



Rotate	To highlight “High Speed Print.”
Press	To select “High Speed Print.” The “High Speed Print” dialog box will appear.



	The most recent patient file is shown at the top of the dialog box as the first choice for printing.
Rotate	To highlight "Yes," "No," "All," or "Cancel."
Press	To select "Yes," "No," "All," or "Cancel."
	File prints with % complete status message. Selecting "Yes" will cause the patient file shown to be printed and the next patient file to be displayed.
	Selecting "No" will result in not printing of the displayed file and the next patient file to be displayed.
	Selecting "All" causes all stored patient files to be printed.
	Selecting "Cancel" closes the dialog box and returns to the Communications menu.
	Repeat the selection process until all desired patient files have been chosen for printing.
Rotate	To highlight "Cancel."
Press	To select "Cancel" and close the dialog box.
Rotate	To highlight "Return."
Press	To exit the Communications menu and return to the main monitoring screen.

High speed printing of the patient files will occur at a rate of approximately 30 cm per minute until all selected files have been printed.

Section 10
Transferring Patient Data

In order to transfer patient data files from the monitor to a remote computer, the monitor must be configured with the correct modem setup string and dialing phone number (see the chapter entitled *Installation, Setup, and Operation* for details). Additionally, the remote computer must have a modem installed and be running the FETALGARD Lite View applications program. Installation and operation of FETALGARD Lite View is discussed in another chapter within this operator's manual.

The user must purchase an approved modem in order for file transfers to work properly. Please contact the factory for the list of approved modem vendors and model numbers. Follow the installation procedure supplied by the modem vendor prior to connecting to the FETALGARD Lite monitor.

The communications port on the rear of the monitor is connected to a tabletop modem using an RS-232 cable with a female DB9 connector and a male DB25 connector. The cable supplied with the FETALGARD Lite Recorder will work.

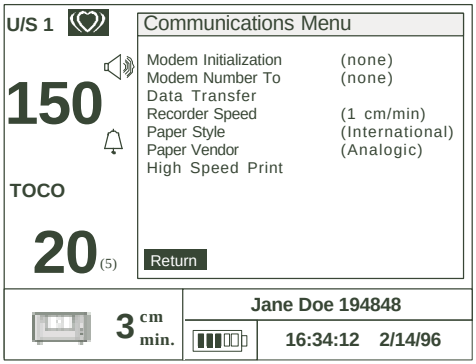
CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices. The RS-232 connector on the FETALGARD Lite is electrically isolated to permit safe connections to non-medical devices, which should be connected with a cable of sufficient length to prevent the non-medical equipment from contacting the patient.

Make sure the cable is attached properly and the connectors are fully engaged. The monitor will display the telephone icon shown below when properly attached to a modem.

The following section describes the procedure used at the monitor to complete a transfer of all patient records in the monitor to a remote computer. Make sure the remote PC is properly configured and running the FETALGARD Lite View application program before starting.

When connecting the monitor directly to a computer, use a null modem PC cable no longer than 3 meters in length having a female DB9 connector at both ends. The conductor shield must be tied to the metal shells of the DB connectors.

Knob Activity	Desired Result
Rotate	To highlight the Communications frame with a heavy border.
Press	To view the Communications menu (shown below).
Rotate	To highlight "Transfer Data."



Press — To select "Data Transfer."

The dialog box will show the dialing number and commence dialing. You will hear the dial tone and dialing process from the modem speaker. The Communications frame will display a two-phone icon with one dark and one light (shown below). This icon means the monitor is attempting to connect to the remote computer.

Transferring patient data files occurs automatically when the monitor and remote computer are connected. The Data

Transfer dialog box will show the record number being transferred, the total number of files to be transferred, and percent complete. The Communications frame will display a two-phone icon with both dark (shown below). This means files are being transferred.

When all files have successfully transferred the Data Transfer dialog box will display a message confirming completion.

Press	To exit the Data Transfer dialog box and display the Communications menu.
Rotate	To highlight “Return.”
Press	To exit the Communications menu and return to the main monitoring screen.

10.1 Troubleshooting

Here are some comments that may help when the process doesn’t go smoothly.

Behavior	Reason	Possible Remedy
The monitor dialed a number but did make a connection to the remote computer.	Remote Modem did not answer.	Check that the remote modem is connected and turned on.
	Dialed number was busy.	Check the number by calling using the phone. Wait for current call to complete.
	Remote Modem connected but Data Transfer timed out before any data was transferred.	Check that the FETALGARD View Receiver is running and that the modem is selected to receive data on the remote computer.
No dial tone or dialing was heard when the monitor dialed the remote computer.	The modem may be set to disable the speaker.	Examine the modem documentation and initialization strings to enable the the modem speaker during dialing.
	Faulty modem or faulty connection to the modem.	Watch the modem lights for activity during dialing. If the modem lights show no activity then check the cable connections between the monitor and the modem. Check the modem operation.
	Modem not connected to the phone jack.	Check the modem connection to the to the phone jack.
File transfers were cut off/terminated before completion.	Disconnect from modem or phone line @ monitor or remote computer.	Check the phone line connections between the modem and phone jack on the local and remote computers.
	Poor phone connection.	Check the phone connection. Poor or noisy phone lines will cause the transfer of data to be terminated.
	Insufficient remote processor.	Check that the computer running the FETALGARD Receiver software meets the minimum system requirements.
	Extension was taken off hook.	Check that another extension on the same phone line was not used.

Section 11
FETALGARD Lite View

11.1 Overview

FETALGARD Lite View is an application program that is used to view, annotate, and store patient data files originating from the FETALGARD Lite monitor. The program runs on a personal computer with either Windows 95/98™ or WindowsNT™ operating systems.

Patient data files are transferred to the computer using either a serial port hook-up between the monitor and computer or via a modem connection.

The program uses a Windows-like user interface with pull-down menus and mouse operation.

11.2 Installation

System Requirements:

- IBM-compatible personal computer
- Standard VGA graphics
- CD-ROM drive
- 2 megabytes (minimum) available hard drive free space
- Windows 95, 98 or NT operating system

Procedure

- Insert View CD in the CD-ROM drive.
- Follow the on-screen instructions.
- The View program will be installed in the default directory or in one selected by the operator during the installation process.
- The Help Files are supplied in Adobe Acrobat pdf format. To access these files, the system needs Adobe Acrobat Reader which is available at www.adobe.com. This is free of charge.

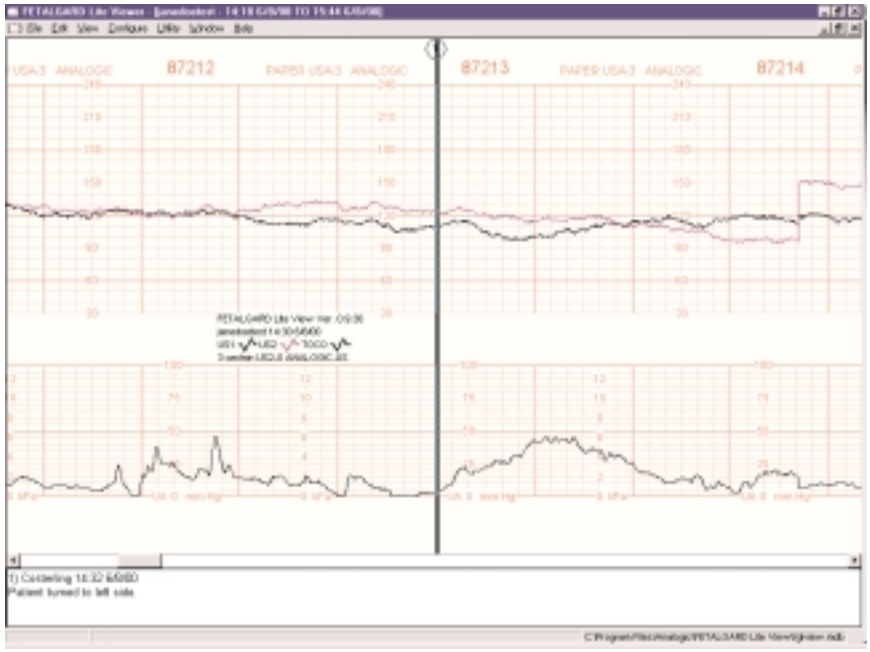
- In order to install FETALGARD Lite View, administrative rights to the system are needed. If an error message is displayed during the installation process, contact the system administrator.

11.3 Starting FETALGARD Lite View

Running the View program is accomplished by clicking on the "Viewer" contained in the Program selection of the Start menu.

11.4 Display Screen

The picture below shows the FETALGARD Lite View program with a patient record open. The Main menu selections are shown at the top of the screen.



Each patient file is identified at the top of the window by its file name and location. The patient data is displayed in a format similar to the strip chart printout from the recorder. All graphical data and text information is included. Annotations made within the View program are displayed in the bottom section of the window.

Elevator controls are used to scroll left and right, or up and down to view the desired section of the patient record.

11.5 Menu System

The main menu system contains the following selections:

File…Open…
Starts the dialog box used for opening patient records. This dialog shows a multi-column list box containing all of the records in the currently selected FETALGARD Lite Viewer database. Patient ID, start time, duration, and monitor serial number are shown for each file.

The records can be sorted (ascending or descending) by any of the headings by clicking on the heading.

The user can select one or more records in the list box by left clicking on it, select a group of records with Shift-Left click, or select/de-select a record with Control-Left-click.

The "•••" button allows the user to select another database via a Windows File dialog box. The user can select a file and then click Open.

File…Close
Closes the window containing the currently active patient data.

File…Delete…
Starts the dialog used for deleting patient records. This menu entry provides a mechanism for removing all records corresponding to a specific patient from the currently selected database. Deletes are final. There will be no way to undelete.

The File Delete dialog will list all patients in the currently selected database. Entries will be sorted alphabetically by user ID.

The user would initiate the file delete by selecting a patient name and clicking the "DELETE" button.

If the user tries to delete patient records which have not been backed up, then the application will inform the user of this and allow the operation to be cancelled.

File…Backup…
Starts the dialog used for storing patient records to other media. This menu entry provides a mechanism for copying all records corresponding to one or more patients to backup media such as a zip drive.

The File Backup dialog will list all patients in the currently selected database. Entries will be sorted alphabetically by user ID.

The user must select a destination file. If the destination file already exists then the user will be prompted to overwrite the file.

The user would initiate the file archive by selecting one or more patient IDs and clicking the "BACKUP" button.

File…Page Setup…
The page setup dialog enables the user to specify the display format.

The user can select from Analogic, HP or Corometrics style paper, U.S. or International format, and print speed (1, 2 or 3 cm/min.).

To change the display format, the user must select one of the six paper types or one of the print speeds from the pull-down menu.

File…Print…
This will bring up the standard Windows print dialog for selecting the printer. By default, the printed output will be the entire trend data set. The user can choose to print just the highlighted portion by clicking on "Selection" in the Print Menu. If a FETALGARD Lite Recorder has been installed, it will appear as an option.

Note: Original chart paper numbers will not coincide with FETALGARD Lite Viewer numbers.

File…Purge FGLite Recorder
This will cancel the current printing job. (Note: The Recorder will finish with a few pages of blank paper.)

File…Exit
Ends the program.

Edit…Annotate…
Starts the Enter Annotation dialog. The Edit Menu provides tools for annotating the patient record and for searching within the patient record. The user can add annotations, search for markers and annotations, jump to specific times during the test and change the patient ID to fix data entry errors.

When Annotate is selected, an annotation marker (a circled number) will be superimposed on the patient data to show the location of the annotation. It will show who made the annotation and when it was made. To enter the annotation, the user must type their annotation text and click OK.

Annotations are stored immediately and cannot be deleted or modified.

Edit…Find…
Starts the Find dialog box for finding markers and annotations. The Find dialog allows the user to re-center the display around markers and annotations in the patient data.

This dialog box has three radio buttons that can be used to set the type of data being searched: Annotation, Patient Marker, and Clinician Marker.

The dialog box has a “PREVIOUS” button, a “NEXT” button and a “CLOSE” button.

Edit… Find Next
Finds the next object in the record. The type of object is the same as the last “Find.”

Edit…Find Previous
Finds the previous object in the record. The type of object is the same as the last “Find.”

Edit… Go To…
Starts the Go To dialog box for re-centering the data to specific times. The dialog has an edit control for entering the time. This edit control is initialized to the time of the current cursor position and will display time in either 12/24-hour format. The user can enter the desired time and click the “Go” button. The program will find the specified time and redraw the display centered on that data.

Edit…Patient ID
This dialog box provides a way to edit the patient ID to handle the case where it was incorrectly entered when the test was originally performed. If the patient ID has been modified from what was originally in the record it will be displayed followed by an asterisk and an annotation will be displayed indicating a change was made.

Configure…Language
This item opens a language selection dialog box to allow the user to select the language of all menus and dialogs from a list of supported languages. The dialog box displays a list of the available languages with the currently selected language checked. Language selection is the fourth pull-down menu and the first option.

Configure…Add Patient Records to…
When new patient records are transferred from a monitor to the PC, they will be added to the database file specified in this dialog box. If the file does not exist, FETALGARD Lite Viewer will create it.

Once specified, the name of this database will appear in the lower right corner of the FETALGARD Lite Viewer screen.

Configure…Time Format
This menu entry allows the user to set the time and date formats for the application. Choices for time format are 12 hour or 24 hour. Choices for date format are MM/DD/YY or DD/MM/YY.

Utility…Database Compact
Compacts the database. This command is used to remove deleted files from the database and compact the database to the smallest size possible.

Utility…Database Repair
Repairs a corrupted database.

Window…Tile
Splits the data window so that two or more records can be viewed simultaneously.

Window…Cascade
Cascade the windows so that one patient record dominates the window and the top window mostly obstructs other open patient records.

Window… "Patient ID"
Allows the user to switch between opened patient files by selecting the "Patient ID" of interest.

Help…FETALGARD Lite Viewer Help
Starts the help subsystem.

Help…Contact Info
Phone number and email address for tech support.

Help…About…
This menu entry will display a dialog containing revision and copyright information.

Section 12
FETALGARD Lite Receiver and Recorder

12.1 Overview

The FETALGARD Lite Receiver is a Windows application that is used to transfer data from the FETALGARD Lite monitor to a database on a PC. The Receiver runs as an application on Windows 95/98 or Windows NT. An icon representing the FETALGARD Lite Receiver will appear in the System Tray.

This program must be installed on the computer which has the patient data base files. This can be the same computer that has the FETALGARD Lite View program or a separate computer.

The FETALGARD Lite Recorder program is a Windows application for adding the FETALGARD Lite Recorder to the printer menu. This enables the FETALGARD Lite Viewer user to print to the FETALGARD Lite Recorder.

12.2 Installation

System Requirements:

- IBM-compatible personal computer (200 MHz Pentium or equivalent)
- Standard VGA graphics
- CD-ROM drive
- 2 megabytes (minimum) available hard drive free space
- Windows 95, 98, or NT operating systems

Procedure:

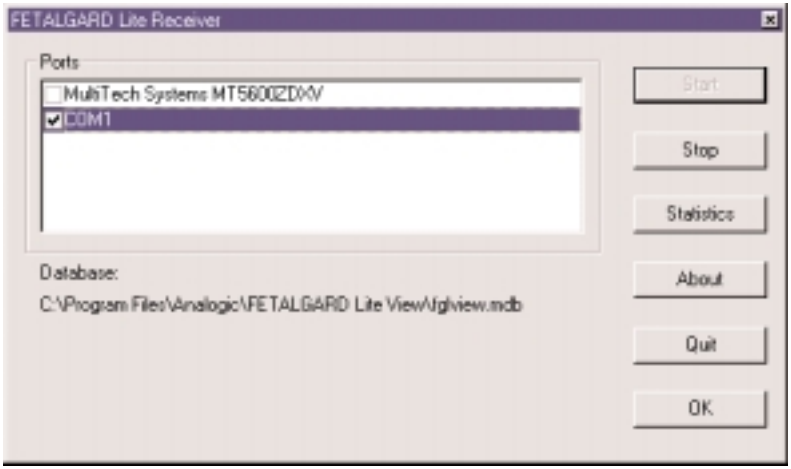
- All applications will be installed when FETALGARD Lite Viewer is installed.
- The Receiver program will be installed in the default directory or in one selected by the operator during the installation process.
- The Recorder program will be installed in the system folder.

12.3 Starting FETALGARD Lite Receiver

The FETALGARD Lite Receiver can be started from the desktop icon or the Start menu.

12.4 User Interface

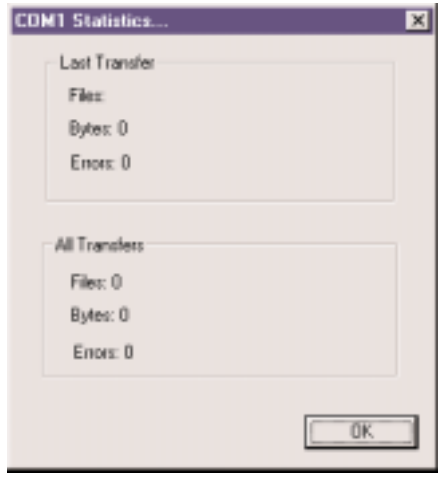
The user interface allows the user to select which TAPI communication ports will be answered by this program. The user interface screen is shown below.



To enable or disable a port, the user must select the port by clicking its description in the list box. Then, if a port is disabled, it can be enabled with the "Start" button. If a port is enabled, it can be disabled with the "Stop" button. Enabled ports are indicated by a check mark next to the port description. Only one of the "Start" and "Stop" buttons will be enabled at any time.

The "quit" button closes the Receiver program. When the program is closed, the FETALGARD Lite Receiver will answer no incoming data calls. This leaves the port available for other modem transfers such as Internet access.

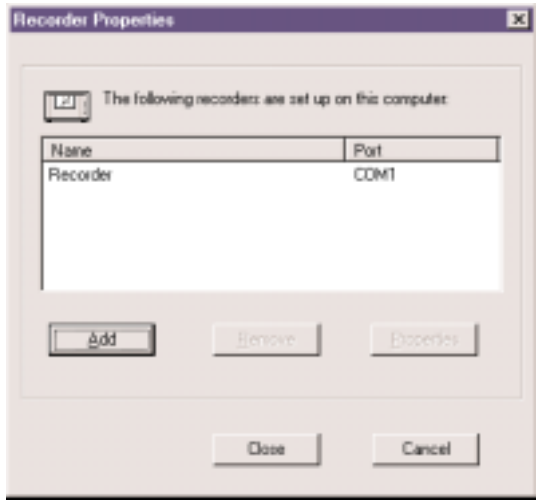
If the user clicks the Statistics button while a port is selected, the statistics summary will be shown for that port. The statistics screen is shown below.



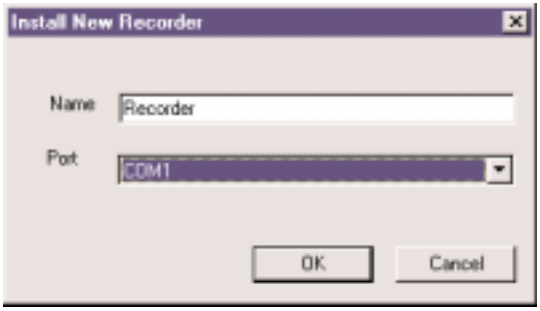
12.5 Installation of the Recorder

Adding the FETALGARD Lite Recorder to the printer menu is accomplished by running the FETALGARD Lite Recorder program.

Select the FETALGARD Lite Recorder icon in the Control Panel. The Control Panel is found by using the start button and the settings menu. The "Recorder Properties" box will appear and click on "Add."



The "Install New Recorder" box will appear. Type the name of the Recorder. Then select the port to which the Recorder is connected and click on "OK."



Then select "close" in the "Recorder Properties" box.

Section 13
Cleaning

This chapter contains instructions for the care and cleaning of the FETALGARD Lite unit and its accessories.

The FETALGARD Lite requires proper care and preventive maintenance. This ensures consistent operation and maintains the high level of performance necessary in monitoring procedures.

13.1 Monitor

Keep the external surface clean and free of dust, dirt, and residual liquids. Clean with a damp cloth using mild soap and water or hospital approved, non-abrasive disinfectants.

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

CAUTION: Take extra care when cleaning the display surfaces, which are sensitive to rough handling. Rub the lens that covers them with a soft, dry cloth.

13.2 Recorder

Maximum time between printhead cleaning is one year, more frequent cleaning may be required depending on operating environments.

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

To clean, wipe the printhead and roller with a Q-tip soaked in isopropyl alcohol while lifting the head, or run 6" x 6" cleaning paper pre-soaked in isopropyl alcohol through the recorder. Pre-saturated thermal printer cleaning cards are available in boxes of 25 cards or in bulk. They may be ordered directly from:

Clean Team Company™
960 Enchanted Way Building 108
Simi Valley, California 93065
Phone: 805-581-1000
Fax: 805-581-1058

13.3 Transducers

Cleaning and Disinfecting the Tocotonometer and Ultrasound Transducer

To avoid damage to the transducers, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the Tocotonometer label and the Tocotonometer cable label. DO NOT remove, conceal or deface Tocotonometer labels.

CAUTION: Do not autoclave. Do not gas sterilize.

1. Wipe the device with a sterile wipe soaked in enzymatic detergent safe for use with metal instruments. Wipe the exterior of the device three times. Prepare the detergent according to the manufacturer's transducer recommendations.
2. Scrub the transducer with enzymatic detergent using soft bristled brush for five (5) minutes. DO NOT IMMERSE THE TRANSDUCER.

CAUTION: Do not immerse in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.

3. Wipe the transducer three (3) times with sterile water to remove soap residue.
4. Wipe the transducer with a sterile wipe soaked in Cidex™. Wipe all exterior surfaces of the transducer three (3) times.

5. Wipe the transducer three (3) times with sterile water to remove Cidex residue.
6. Dry the device thoroughly with a sterile soft towel or gauze surgical sponge.
7. Wrap the dry device in a fresh sterile soft towel or transparent sterile wrap for storage until next use.

13.4 Belts

Wash soiled belts with soap and water.

> ***CAUTION***: The water temperature must not exceed 60°C (140°F).

Section 14
Specifications

FETALGARD Lite Monitor Specifications:

Physical Characteristics

Dimensions — 18 cm H x 24.2 cm W x 13 cm D
Weight — approx. 1.9 kg

Safety

Complies with EN60601-1, EN60601-1-1, En60601-2
Class II Equipment, double insulated
Continuous Operation
Type BF applied parts

Power

Internal:	Lead-acid, rechargeable 2-hours operation fully charged at 10°C 14 hours to full recharge during monitoring 8 hours to full recharge when monitor is off.
External:	AC-powered Battery Eliminator, two models: P/N 21-615116, 100-120V~, 50-60 Hz, 0.15A P/N 21-615115, 220-240V~, 50-60 Hz, 0.08A
Power Dissipation:	
Battery-powered:	6 watts, maximum
AC-powered	10 watts, maximum

Environmental

Operating Temperature:	10°C to 45°C (50°F to 110°F)
Storage Temperature:	–20°C to 60°C (–4°F to 140°F)
Relative Humidity:	20% to 90% non-condensing
Altitude:	0—3048m (0—10,000 ft)

Doppler Ultrasound FHR Monitoring

Parameter	Value
I(SATA) at the transducer face:	0.766 mW/cm^2 +27.8/–23.6%
Entrance beam dimensions:	19.95 cm^2, circular
Ultrasonic frequency:	1024 MHz ±0.5%
Pulse duration:	97.65625 microseconds
Pulse repetition frequency:	3.2 kHz
Ultrasonic power:	15.28 mW +27.8/–23.6%
BPM Range:	
USA Paper	50-240 BPM
International Paper	50-210 BPM
Accuracy:	±1% ±1 BPM
Leakage:	<10 µA @ 264 VAC applied to transducer
Isolation:	>4 kV RMS, Type BF applied part

Tocotonometer Uterine Activity (TOCO) Monitoring

Parameter	Value
TOCO Range:	0-100 relative units
Resolution:	1 Count
Accuracy:	±1% ±1 relative unit
Leakage:	<10 µA @ 264 VAC applied to transducer
Isolation:	>4 kV RMS, Type BF applied part

FETALGARD Lite Recorder Specifications:

Physical Characteristics

Dimensions — 11.5 cm H x 24.2 cm W x 20.4 cm D
Weight — approx. 3.4 kg

Safety

Complies with EN60601-1, EN60601-1-1, En60601-2
Class I Equipment, requires 3-prong outlet with protective earth
Continuous Operation

Power

100-120V~, 50-60 Hz, 0.4A
220-240V~, 50-60 Hz, 0.2A
Power consumption: 20 watts maximum at nominal supply voltage

Environmental

Operating Temperature:	10°C to 45°C (50°F to 110°F)
Storage Temperature:	–20°C to 60°C (–29°F to 175°F)
Relative Humidity:	20% to 90% non-condensing
Altitude:	0—3048m (0—10,000 ft)

Paper

Pack Style:	Z-Fold. USA or International
Pack Size:	152 mm x 90 mm
End-of-Pack:	Mark along paper edge
Loading:	Front-door, drop-in, self aligning
Paper Detectors:	Paper Out
	Loading Door Open

Paper Speeds

Normal:	1, 2, and 3 cm/min ±1%
High-Speed:	30 cm/min

Paper Tracking Accuracy: ±1% (exclusive of paper accuracy)

Section 15
Troubleshooting and Maintenance

15.1 Self Test

The monitor performs a self test each time the unit is turned on.

1. Make sure the recorder and monitor are properly interconnected.

2. Check the recorder for paper.

3. Connect the monitor to the battery eliminator.

4. Turn on the monitor and recorder.

Check that the monitor successfully powered on and is displaying the main monitoring screen. If an error occurs the monitor will display the error screen. The unit should be removed from service if this occurs.

Check that the recorder is feeding paper and the power on test pattern printed properly. Remove from service if this does not occur.

15.2 Ultrasound Transducer Test

To test an ultrasound transducer:

1. Properly connect the transducer to the rear of the monitor.

2. Turn on the monitor and recorder.

3. Adjust the speaker volume to an audible level.

4. Hold the transducer on one hand and tap on the transducer face with the other hand. The tapping should be heard from the monitor.

The transducer is operating properly if you can hear noise from the speaker. Remove from service if no noise is heard or until the proper cause is identified and repaired.

15.3 TOCO Test

To test the TOCO transducer:

1. Properly connect the transducer to the rear of the monitor.

2. Turn on the monitor and recorder.

3. Gently apply pressure to the button centered on the face of the transducer.

The display and printout should show a change in pressure if the transducer is operating properly. Remove from service if this does not occur.

15.4 Battery Disposal and Handling

Caution when disposing of internal lead acid battery. Adhere to all applicable laws regarding recycling. Avoid storing battery above 140°F. If clothing or skin comes in contact with material from inside the battery, immediately wash with plenty of clean water.

15.5 Maintenance

The FETALGARD Lite monitor, recorder and accessories require no periodic calibration or adjustment.

The recommended interval for performing hipot and leakage testing is once per year.

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