FLUKE®

Biomedical

PS320

Fetal Simulator

Users Manual

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Fluke Biomedical warrants this instrument against defects in materials and workmanship for one full year from the date of original purchase. During the warranty period, we will repair or, at our option, replace at no charge a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty does not apply if the product has been damaged by accident or misuse or as the result of service or modification by other than Fluke Biomedical. IN NO EVENT SHALL FLUKE BIOMEDICAL BE LIABLE FOR CONSEQUENTIAL DAMAGES.

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Recalibration of instruments is not covered under the warranty.

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Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Technical Support

For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 648-7952 or 1-425-446-6945.

Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim. If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

Standard Terms and Conditions

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Please note that only serialized products and their accessory items (i.e., products and items bearing a distinct serial number tag) are eligible for partial refund and/or credit. Nonserialized parts and accessory items (e.g., cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. Only products returned within 90 days from the date of original purchase are eligible for refund/credit. In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the carrier chosen by the customer to return the goods, and the product must be returned complete (meaning with all manuals, cables, accessories, etc.) and in "as new" and resalable condition. Products not returned within 90 days of purchase, or products which are not in "as new" and resalable condition, are not eligible for credit return and will be returned to the customer. The Return Procedure (see below) must be followed to assure prompt refund/credit.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15 %. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20 %. Additional charges for damage and/or missing parts and accessories will be applied to all returns.

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double–walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-800-648-7952 or 1-425-446-6945.

Repair and calibration:

To find the nearest service center, goto www.flukebiomedical.com/service or

In the U.S.A.:
Cleveland Calibration Lab
Tel: 1-800-850-4606
Email: globalcal@flukebiomedical.com

Everett Calibration Lab
Tel: 1-800-850-4606
Email: service.status@fluke.com

In Europe, Middle East, and Africa:
Eindhoven Calibration Lab
Tel: +31-402-675300
Email: ServiceDesk@fluke.com

In Asia:
Everett Calibration Lab
Tel: +425-446-6945
Email: service.international@fluke.com

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

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Information in this document is subject to change and does not represent a commitment by Fluke Biomedical. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Fluke Biomedical for the use or reliability of software or equipment that is not supplied by Fluke Biomedical, or by its affiliated dealers.

Manufacturing Location

The PS320 Fetal Simulator is manufactured by Fluke Biomedical, Everett WA.

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PS320 Fetal Simulator

Introduction

The PS320 Fetal Simulator (hereafter called the Simulator) is a compact, lightweight, high-performance simulator for use by trained service technicians in fetal monitor testing.

Cardiotocographs or Electronic Fetal Monitoring (EFM) is a diagnostic tool used to identify a fetus at risk for neurological injury or death. The trained clinician can then carry out timely and appropriate intervention before the underlying condition causes irreversible damage. The goal of EFM is to detect fetal hypoxia at its earliest stage and to attempt to prevent asphyxia resulting from prolonged and severe hypoxia.

To gain a better overview of these clinical conditions, please refer your available clinical references, or as a suggested source, go to the Family Practice Notebook website: http://www.fpnotebook.com. This website clearly explains these clinical terms in Book: Obstetrics, Chapter: Fetus, Page: Fetus Index.

The Simulator provides comprehensive simulation of fetal and maternal ECG as well as uterine activity. It can simulate several fetal parameters, including twins, via such monitor modes as DECG and ultrasound. The Simulator offers an easy user interface providing a 2 x 16-character LCD display with adjustable contrast.

The Simulator runs on an internal 9-volt battery or is line operated via a battery eliminator. It provides an indication when the battery is low prior to shutting down. It also supplies RS-232 two-way data communication to control Simulator selections.

Safety

⚠⚠Warning. Read before using.

To avoid personal injury:

- **Do not use the Simulator in any manner not specified in the Users Manual. Otherwise, the protection provided by this product may be impaired.**
- **Always switch power Off and unplug the battery eliminator before cleaning.**
- **Inspect the product. If the Simulator appears damaged or appears to operate in a manner not specified in the manual, DO NOT CONTINUE USE. Return the product for service.**
- **Avoid spilling liquids on the Simulator; fluid seepage into internal components creates corrosion and a potential shock hazard. Do not operate if there is exposure of internal components to fluid.**
- **Do not open this product. There are no user replaceable parts.**

⚠Caution

Calibrate the Simulator annually. Only qualified technical personnel should perform troubleshooting and service procedures on the Simulator. Do not expose the Simulator to temperature extremes. Ambient operating temperatures should remain between 15 and 35 °C. Simulator performance may degrade if temperatures fluctuate above or below this range. Clean only with a damp, lint-free cloth, using a mild detergent; wipe down gently.

Symbol	Description
	See Users Manual.
	Caution risk of electric shock
	Manufacturer's declaration of product compliance with applicable EU directives
	Battery Eliminator Port
	Do not dispose of this product as unsorted municipal waste. Go to Fluke's website for recycling information.

Specifications

General

Display.....2 x16 alphanumeric characters
Interface.....RS232 bi-directional interface. Baud rate 9600
Power.....9-V alkaline battery or battery eliminator
Case.....High impact plastic
Weight.....0.4 kg / 0.9 lb.
Dimensions
Height.....15.6 cm / 6.1 in.
Width.....9.4 cm / 3.7 in.
Depth.....3.4 cm / 1.3 in.
Temperature, Operating.....15 °C to 35 °C (59 °F to 95 °F)
Temperature, Storage.....0 °C to 50 °C (32 °F to 122 °F)
Maximum Humidity, Operating.....80 % relative humidity up to 31 °C (88 °F), decreasing linearly to 50 % relative humidity at 40 °C (104 °F).
Maximum Humidity, Storage.....95 %
Altitude.....Up to 2000 m
Part No.....PS320 Fetal Simulator (PN 2583030)

Accessories

Item	Part Number
Standard Accessories	
Users Manual CD-ROM	2631717
Users Manual (printed)	2631693
9 VDC Battery Eliminator	2647372
Optional Accessories	
Mechanical Fetal Heart (MFH-1). Includes interconnecting MFH-1 Cable (PN 2462123)	2462114
Interface cables are available for various brands of electronic fetal monitors: • Ultrasound (Fetal ECG) Simulation Cables * • External TOCO (Uterine Pressure) Simulation Cables * • IUP (Intrauterine Pressure) Simulation Cables *	
* Contact your local Fluke Biomedical Sales Agent for further details	

Fetal ECG

Primary fetal cardiac activity is presented simultaneously in both direct/internal scalp-electrode-derived and indirect/external, ultrasound-derived (US-1) signal formats. Another indirect/external, ultrasound-derived (US-2) signal provides secondary fetal cardiac activity for either independent "normal" or "twins" simulation.

The US-1 channel also provides the electrical drive signal to operate the Mechanical Fetal Heart (MFH-1). The MFH-1 mimics the physical movement of the fetal heart and tests the indirect/external ultrasound transducer and the electronic fetal monitor.

Fetal ECG static rates ..... 30, 60, 90, 120, 150, 180, 210, 240 BPM
Fetal ECG sensitivity (amplitude) ..... 50 µV, 100 µV, 200 µV, 500 µV, 1 mV, 2 mV
US-1 ..... Tracks the primary direct fetal activity
US-2 ..... Secondary fetal cardiac activity for either independent “normal” or “twins” simulation.

Fetal Patterns

The dynamic fetal ECG patterns listed in Table 1 are interactive with uterine activities described in Table 2 and represent a wide range of clinical conditions encountered during the labor and delivery process. These selections illustrate the fetal response to the uterine pressure. To gain a better overview of these clinical conditions, please refer to your available clinical references, or as a suggested source, go to the Family Practice Notebook website: http://www.fpnotebook.com. This website clearly explains these clinical terms in Book: Obstetrics, Chapter: Fetus, Page: Fetus Index.

Table 1. Fetal ECG Patterns

Pattern	Description
TREND#1 – TWIN FETAL PATTERNS	
NORMAL	Normal pattern
TACHYCARDIA	Tachycardia pattern
BRADYCARDIA	Bradycardia pattern
ARRHYTHMIAS	Arrhythmia pattern
LATE DECELERATION	Late deceleration
EARLY DECELERATION	Early deceleration
MODERATE DECELER.	Moderate variable deceleration
ACCELERATION #1	Acceleration wave #1
ACCELERATION #2	Acceleration wave #2
SINUSOIDAL (HIGH)	Sinusoidal pattern, large change
SINUSOIDAL (LOW)	Sinusoidal pattern, small change
SEVERE VAR. DEC. #1	Severe deceleration wave #1
SEVERE VAR. DEC. #2	Severe deceleration wave #2
PROLONGED DECELER.	Prolonged deceleration
BIPHASIC DECELERAT.	Biphasic deceleration

Table -1. Fetal ECG Patterns (cont.)

Pattern	Description
EXAGGERATED DECELE.	Exaggerated deceleration
NON_UNIFORM DECELE.	Non-uniform deceleration (2 different shapes)
VAR. DECELERATION (U)	Variable deceleration “U” shaped
VAR. DECELER. TACH	Variable deceleration with high rate BPM
VAR. DECELER (V)	Variable deceleration “V” shaped
VAR. DECEL. (POST)	Variable deceleration post exaggerated
VAR. DECELERATION	Variable deceleration
DECELER. (POSITION)	Variable deceleration with position changes
LONG DECELERATION	Long deceleration
COMPENSATORY ACCEL.	Compensatory acceleration

Maternal ECG

Maternal ECG static rates.....60, 80, 100, 120, 140, 160 BPM

Maternal ECG sensitivity (amplitude).....0.5 mV, 1 mV, and 2 mV

Select pattern during Trend #1 selection

Uterine Activity

Note

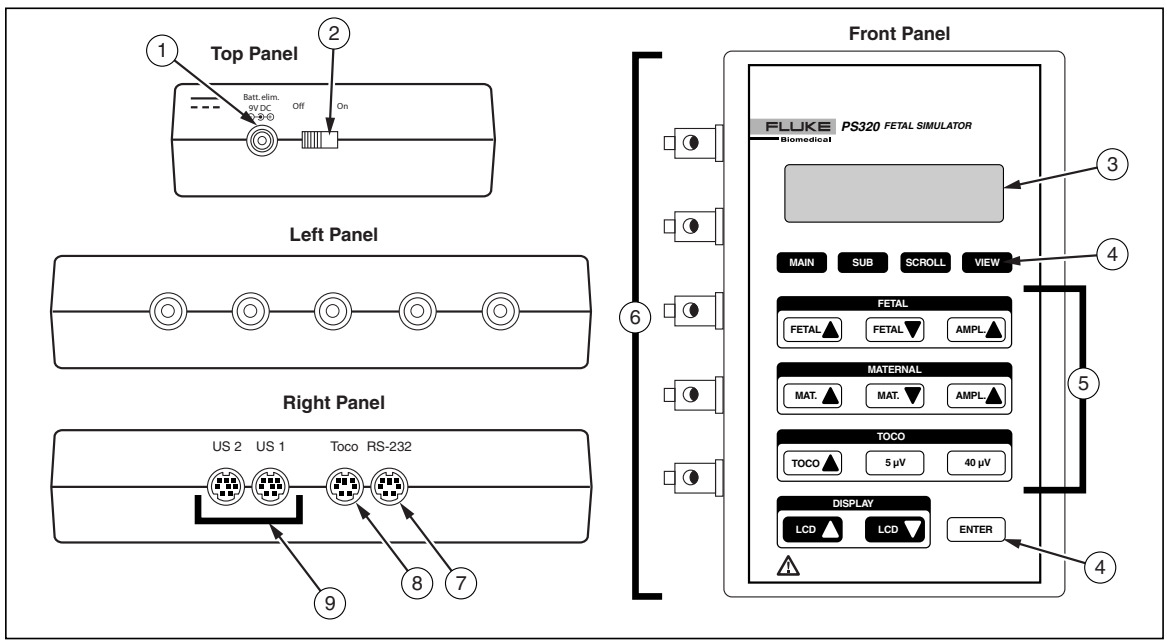
TOCO waveform selection is not available during TREND #1.

Table 2. Uterine Activity

Activity	Description
EXECUTE WAVEFORM	Start TOCO waveform
UTERINE WAVE OFF	Stop TOCO waveform
ANALOG 0 TO +1 VOLT	Analog range 0 to +1 V (1 V=100 mmHg)
ANALOG 0 TO -1 VOLT	Analog range 0 to -1 V (-1 V=100 mmHg)
UTERINE WAVE 0-25	Range of TOCO waveform
UTERINE WAVE 0-50	Range of TOCO waveform
UTERINE WAVE 0-100	Range of TOCO waveform
SHORT DURATION	TOCO waveform of short duration
NORMAL DURATION	Normal duration of TOCO waveform
INCREASED DURATION	Long duration of TOCO waveform
UTERINE LEVEL =ZERO	Zero TOCO channel (automatic on power up)
UTERINE STATIC +20	Increase TOCO static level by 20 mmHg (0-100 mmHg)
INCR. RESTING TONE	Resting tone increases
COUPLING	2 close TOCO waves
TRIPLING	3 close TOCO waves
UTERINE PRESSURE SENSIVITY	5 or 40 µV on power up

Controls, Indicators, and Connectors

Refer to Figure 1 and Table 3 for views and descriptions of Simulator features.



ebv001f.eps

Figure 1. Controls, Indicators, and Connectors

Table 3. Controls, Indicators, and Connectors

Item	Name	Description
①	Battery Eliminator Connection	For use in operating the Simulator from any standard electrical outlet. To ensure safe operation, use only the Fluke Biomedical Battery Eliminator (PN 2647372). **⚠⚠Warning** **Caution risk of electric shock, use only the battery eliminator specified in this manual or the protection provided may be impaired.**
②	Power Switch	Switches the power On and Off.
③	LCD Display	15 mm x 60 mm (0.58 in. x 2.37 in.) window displaying up to two lines of 20-point font.
④	Control Keys	
	ENTER	Enters the selected code line value into memory.
	MAIN	Selects the main headings or groupings.
	SUB	Selects the functions within the main menu.
	SCROLL	Scrolls selections back whether within the main menu or sub menu.
	VIEW	Pressing **VIEW** scrolls through the currently active functions.
	LCD▲ / LCD▼	Changes the contrast of the display.

Table 3. Controls, Indicators, and Connectors (cont.)

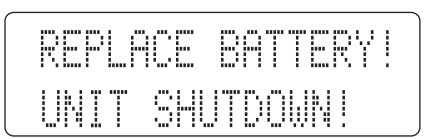
Item	Name	Description	
⑤	Soft Keys	These keys provide one-step selection of Simulator functions.	
	FETAL▲ / FETAL▼	Scrolls through available fetal heart rate parameters.	
	MAT.▲ / MAT.▼	Scrolls through available maternal heart rate parameters.	
	AMPL▲	Scrolls through available amplitude parameters.	
	TOCO▲	Scrolls through available TOCO parameters.	
	5 µV	Selects sensitivity of 5 µV.	
	40 µV	Selects sensitivity of 40 µV.	
⑥	ECG Connectors	Five snap and multi-banana connectors for ECG output, allowing for connection to any ECG. These labeled terminals and on the left side panel. Labels and their definitions are as follows:	
		Label	Definition
		Fetal	Fetal ECG signal
		Fet/Mat	Fetal and Maternal ECG signal. Fetal signal is approximately ½ of the maternal amplitude selected.

Table 3. Controls, Indicators, and Connectors (cont.)

Item	Name	Description	
⑥	ECG Connectors	Maternal	Maternal ECG signal
		Reference	Ground reference lead
⑦	RS-232	6-pin mini-DIN plug connector for the serial connection.	
⑧	Toco	6-pin mini-DIN connector for the Toco signal cable.	
⑨	US 1 & US 2	8-pin mini-DIN plug connector for ultrasound cable plugs.	

Powering the Simulator

The Simulator uses a 9-V alkaline battery. When it detects less than about 5.6 volts, it goes into a shutdown mode, sounds a continuous tone alarm, and displays the following message:



The battery resides in the base of the instrument. Use a 9-volt alkaline battery (Duracell® MN1604 or equivalent). Do not use mercury, air, or carbon-zinc batteries.

⚠ Warning

The 9-volt alkaline battery provided with the Simulator may explode or leak if recharged, inserted improperly, or disposed of in a fire. Dispose of the battery in accordance with any applicable state or local regulations.

As an alternative to a battery, you can power the Simulator with the supplied battery eliminator. Use only the Fluke Biomedical Battery Eliminator (PN 2647372) to ensure safe operation.

⚠⚠Warning

Caution risk of electric shock, use only the battery eliminator specified in this manual or the protection provided may be impaired.

Note

Remove the 9-V battery and disconnect the Battery Eliminator if you do not intend to use the Simulator for an extended period.

You must use the Battery Eliminator when using the Mechanical Fetal Heart (MFH-1).

Operating the Simulator

Connect the Simulator to the device-under-test. First, connect the ECG leads. The active lead goes on the Fetal, Fet/Mat, or Maternal points as appropriate. The reference lead connects to the reference point.

1. Switch the Simulator On. The LCD window displays the program version for about two seconds. The window then displays the default code entry display.
2. Use the keypad to increase or decrease fetal ECG rate and amplitude, increase or decrease maternal ECG rate and amplitude, select TOCO level and amplitude, and adjust display contrast. Then press **ENTER**.
3. To select a simulation, repeatedly press **MAIN** to select FETAL ECG, MATERNAL ECG, UTERINE ACTIVITY, FETAL PATTERNS, or AUXILIARY. Then press **SUB** to access the next level of available selections. Press **SCROLL** to move through these selections. Press **ENTER** to activate the selection.
4. At any point, you can view the Simulator's current parameter settings by pressing **VIEW**. Repeatedly press **VIEW** to scroll through all of the settings.

Note

*Only use the **ENTER** key when scrolling through the current settings. Using a menu scroll or change key interrupts the scrolling operation.*

5. The first parameter setting is "**TOCO=00 5µV**". Thereafter, each time you press **VIEW**, current settings appear in the following sequence:

   TOCO=00 5µV

   MAT SENS. @ 1mV

   FET SENS. @ 1mV

   US1=150 US2=NORM

   FETHR=150 STATIC

   MATERNAL HR=100

Operating the MFH-1

The Mechanical Fetal Heart (MFH-1) is an accessory to the Simulator. Connect the MFH-1 to the US 1 port on the Simulator via the cable supplied with the MFH-1. Set the rate and rhythm of the mechanical heart by adjusting the US 1 output on the Simulator. For the MFH-1 to function, you must power the Simulator through the Battery Eliminator. The MFH-1 will not function on battery power.

Place the ultrasound transducer face up on your work surface and coat it with an appropriate ultrasound conductive gel. The MFH-1 outputs the mechanical signal via the simulation window. Place this window over each transducer crystal in turn to verify each crystal's function. See Figure 2.

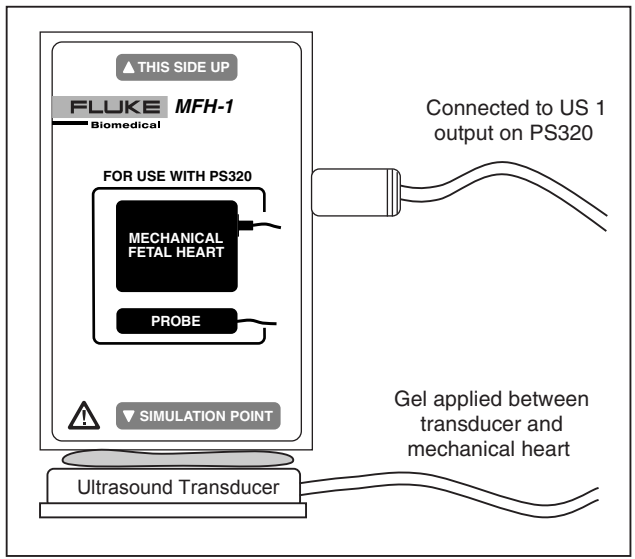


Figure 2. Mechanical Fetal Heart (MFH-1)

When you are finished, clean the MFH-1 with normal soap and water, and then dry.

Simulating Functions

Refer to Table 4 for a list of simulating functions. An arrow indicates a main menu grouping of selections. An asterisk (*) indicates a sub menu selection.

Table 4. Simulating Functions

Main Menu	Sub Menu	Function
→FETAL ECG	*FETAL RATE +30	Increases fetal rate up by 30 bpm
	*FETAL RATE -30	Decreases fetal rate up by 30 bpm
	*FET SEN. 50µV	Sets fetal ECG amplitude to 50 µV
	*FET SEN. 100µV	Sets fetal ECG amplitude to 100 µV
	*FET SEN. 200µV	Sets fetal ECG amplitude to 200 µV
	*FET SEN. 0.5mV	Sets fetal ECG amplitude to 0.5 mV
	*FET SEN. 1 mV	Sets fetal ECG amplitude to 1 mV
	*FET SEN. 2 mV	Sets fetal ECG amplitude to 2 mV

Table 4. Simulating Functions (cont.)

Main Menu	Sub Menu	Function
→MATERNAL ECG	*MAT SEN. 0.5mV	Sets maternal ECG amplitude to 0.5 mV
	*MAT SEN. 1 mV	Sets maternal ECG amplitude to 1 mV
	*MAT SEN. 2 mV	Sets maternal ECG amplitude to 2 mV
	*MAT RATE +20	Increases maternal rate by 20 bpm
	*MAT RATE –20	Decreases maternal rate by 20 bpm
→UTERINE ACTIVITY	*SENS @ 5μV mmHg	Sets pressure sensitivity to 5 μV
	*SENS @40μV mmHg	Sets pressure sensitivity to 40 μV
	*UTERINE LVL =0	Sets uterine level to 0 (zero)
	*ANALOG TO +1 V	Sets analog uterine output from 0 to +1V. 1V=100 mmHg
	*ANALOG TO –1V	Sets analog uterine output from 0 to –1V. -1V = 100 mmHg
	*UTERINE STATIC	Sets uterine output in steps of 20 mmHg
	*EXECUTE TOCO WA	Starts a TOCO wave, not valid during trend selection
	*UTERINE WVF OFF	Stops TOCO wave, not valid during trend selection
	*UTERINE WV 0-25	Sets standard TOCO wave from 0 to 25 units

Table 4. Simulating Functions (cont.)

Main Menu	Sub Menu	Function
→UTERINE ACTIVITY	*UTERINE WV 0-50	Sets standard TOCO wave from 0 to 50 units
	*UTERINE WV 0-100	Sets standard TOCO wave from 0 to 100 units
	*SHORT DURATION	Selects short duration TOCO waveform, not valid during trend
	*NORMAL DURATION	Selects norm duration TOCO waveform, not valid during trend
	*INCREASED DURAT	Selects long duration TOCO waveform, not valid during trend
	*TRIPLING	Selects tripling TOCO waveform, not valid during trend
	*INCR. REST TONE	Selects TOCO waveform with increased baseline level, not valid during trend
	*COUPLING	Selects coupling TOCO waveform, not valid during trend
	*TRIPLING	Selects tripling TOCO waveform, not valid during trend
→FETAL PATTERNS	*TREND #1	Selects real patient trend of fetal heart rate and TOCO, other TOCO selections not valid during this selection
	*NORMAL	Selects normal pattern
	*BRADYCARDIA	Selects bradycardia pattern
	*TACHYCARDIA	Selects tachycardia pattern

Table 4. Simulating Functions (cont.)

Main Menu	Sub Menu	Function
→FETAL PATTERNS	*ARRHYTHMIAS	Selects arrhythmia pattern
	*LATE DECELERATI	Selects late deceleration pattern
	*EARLY DECELERAT	Selects early deceleration pattern
	*MODERATE DECELE	Selects moderate deceleration pattern
	*ACCELERATION #1	Selects acceleration pattern #1
	*ACCELERATION #2	Selects acceleration pattern #2
	*SINUSOIDAL, HIGH	Selects high level sinusoidal pattern
	*SINUSOIDAL, LOW	Selects low level sinusoidal pattern
	*COMPENS ACCEL.	Selects compensatory acceleration pattern
	*LONG DECELERATI	Selects long deceleration pattern
	*PROLONGED DEC.	Selects prolonged deceleration pattern
	*DEC. (POSITION)	Selects position deceleration pattern
	*VAR. DECELERATI	Selects variable deceleration pattern

Table 4. Simulating Functions (cont.)

Main Menu	Sub Menu	Function
→FETAL PATTERNS	*VAR. DEC. (POST)	Selects post variable deceleration
	*VAR. DECEL. (V)	Selects “v” shaped variable deceleration pattern
	*SEV VAR. DEC.#1	Selects severe variable deceleration pattern
	*VAR. DECEL TACH	Selects variable deceleration tachycardia pattern
	*VAR. DECEL. (U)	Selects “u” shaped variable deceleration pattern
	*NON-UNIFORM DEC	Selects non-uniform deceleration pattern
	*EXAGGERATED DEC	Selects exaggerated deceleration pattern
	*BIPHASIC DECEL.	Selects biphasic deceleration pattern
	*ABSENT VARIABIL	Selects no variability in the fetal heart rate pattern
	*LOW VARIABILITY	Selects low variability in the fetal heart rate pattern
	*MILD VARIABILIT	Selects mild variability in the fetal heart rate pattern
	*HIGH VARIABILIT	Selects high variability in the fetal heart rate pattern
	*SEVERE VARIABIL	Selects severe variability in the fetal heart rate pattern
	*LONG TERM VARIB	Selects long term variability in the fetal heart rate pattern

Table 4. Simulating Functions (cont.)

Main Menu	Sub Menu	Function
→AUXILIARY	*REVISION n.nn	Displays software revision
	*POWER ON 40μV	Enables 40 μV uterine pressure on power up
	*POWER ON 5μV	Enables 5 μV uterine pressure on power up
	*LCD ADJUST+	Adjusts LCD contrast high
	*LCD ADJUST-	Adjusts LCD contrast low
	*ECG SQ .125Hz	Selects .125 Hz ECG square wave