

FLUKE®

Biomedical

PS320

Fetal Simulator

Users Manual

PN 2631693

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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.

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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

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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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: | |
| <ul style="list-style-type: none"> • 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 μ V, 100 μ V, 200 μ V, 500 μ V, 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: This website clearly explains these clinical terms in Book: Obstetrics, Chapter: Fetus, Page: Fetus Index.

Table 1. Fetal ECG Patterns

| Pattern | Description |
|--------------------------------------|----------------------------------|
| <i>TREND#1 – TWIN FETAL PATTERNS</i> | |
| 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 μ V on power up |

Controls, Indicators, and Connectors

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

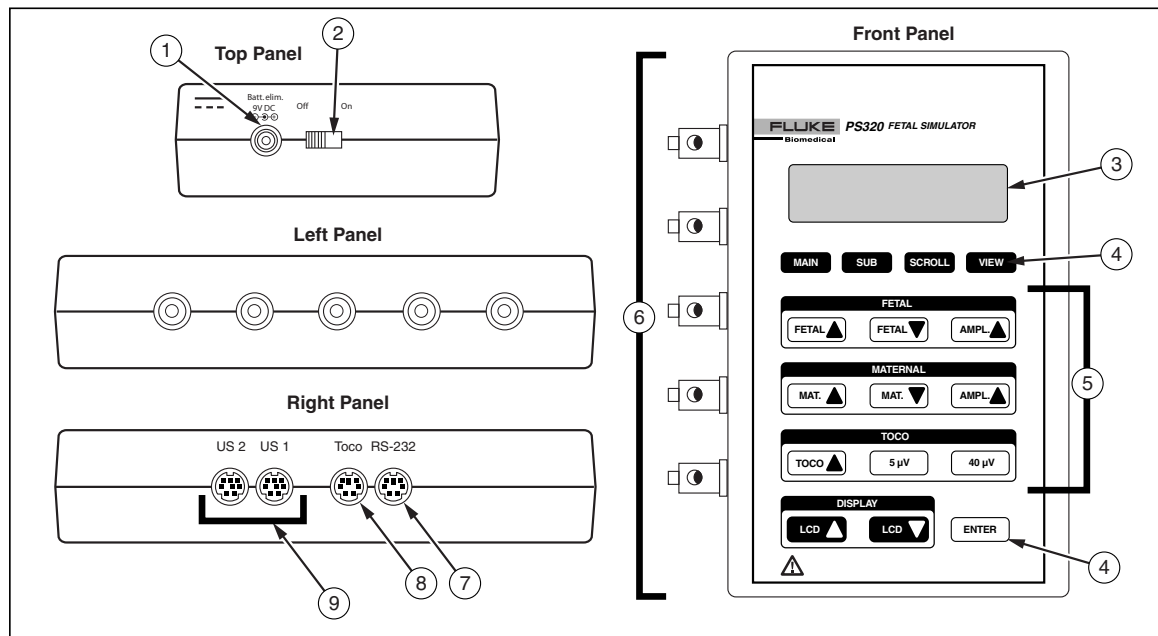


Figure 1. Controls, Indicators, and Connectors

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Table 3. Controls, Indicators, and Connectors

| Item | Name | Description |
|------|-------------------------------|--|
| ① | Battery Eliminator Connection | <p>For use in operating the Simulator from any standard electrical outlet. To ensure safe operation, use only the Fluke Biomedical Battery Eliminator (PN 2647372).</p> <p style="text-align: center;">⚠⚠Warning</p> <p style="text-align: center;">Caution risk of electric shock, use only the battery eliminator specified in this manual or the protection provided may be impaired.</p> |
| 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 are 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:

REPLACE BATTERY!
 UNIT SHUTDOWN!

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 5 μ V**”. Thereafter, each time you press **VIEW**, current settings appear in the following sequence:

TOCO=00 5 μ V

MAT SENS. @ 1mV

FET SENS. @ 1mV

US1=150 US2=NORM

FETHR=150 STATIC

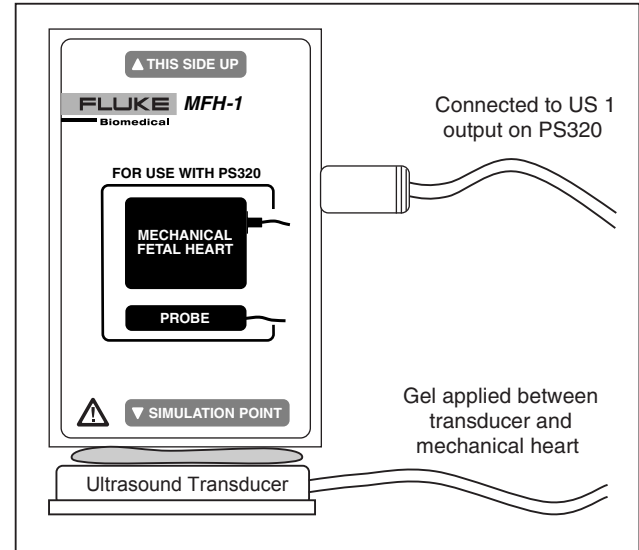
MATERNAL HR=100

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.



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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. 50 μ V | Sets fetal ECG amplitude to 50 μ V |
| | *FET SEN. 100 μ V | Sets fetal ECG amplitude to 100 μ V |
| | *FET SEN. 200 μ V | Sets fetal ECG amplitude to 200 μ V |
| | *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 40 μ V | Enables 40 μ V uterine pressure on power up |
| | *POWER ON 5 μ V | Enables 5 μ V 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 |

