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Performance verification of HP/Agilent/Philips fetal monitors with the PS320 Fetal Simulator

Application Note

By Dennis McMahon, Dennis McMahon Consulting

Theory

The role of the electronic fetal monitor is to detect and record both the heart rate of the fetus and the uterine activity of the mother in labor. In this respect, these monitors should properly be called fetal-maternal monitors. Assessing the heart rate of the fetus synchronously with uterine contractions is a valuable means of detecting fetal distress, and allows timely intervention when necessary. These monitors are used in the majority of births in most countries.

The least invasive and most often utilized fetal heart rate detection method is the use of ultrasound: high-frequency sound waves are emitted and received like echoes with a slight shift in frequency. The amount of shift indicates the amount of movement of the target (in this case the fetal heart). The heart rate is derived from the received signal and displayed numerically, along with an audible tone. In the event of twin fetuses, most monitors are capable of detecting and discriminating two distinct heartbeats.

If, for any reason, the fetal heart cannot be reliably detected with ultrasound, the fetus's electrocardiogram (ECG), and thereby the heart rate, can be accessed directly by the use of a disposable electrode attached to the fetus' scalp while in the normal inverted position in the uterus. The electrode for this direct ECG (DECG) method interfaces with a cable to the monitor, which detects and displays the fetal heart rate, again including an audible tone.

In most cases, uterine contractions are detected by the attachment of a strain gauge (tocodynamometer) to the abdomen of the mother, secured with slight tension by a strap. When applied between contractions, the output of the strain gauge is referenced as zero strain. When a contraction occurs, the strain gauge creates a voltage that is read on a relative scale at the monitor. This external detection of uterine activity is used in the majority of cases.

If clinical conditions require direct detection of uterine contractions, a fluid-filled catheter is inserted into the uterus and connected to a cable that includes an integrated strain gauge. The intra-uterine pressure (IUP) is referenced to zero between contractions, and each contraction creates an increase in pressure that is detected and displayed at the monitor.

Regardless of the source of signal, both the fetal heart rate and relative uterine pressure are also recorded graphically on a thermal printer with a paper speed slow enough to provide a visual trend: typically 1 cm/min to 3 cm/min. Current monitors also provide inputs for maternal ECG, indirect blood pressure, and oxygen saturation.

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The simulator

The Fluke Biomedical PS320 provides signals to simulate fetal heartbeat by ultrasound as well as by a direct ECG signal, and provides signals to simulate uterine activity externally and internally by a strain gauge signal. Dual heart rates simulating twin fetuses are also available, as well as a maternal ECG signal. Signals for normal as well as abnormal conditions and trends can be selected. (See the product data sheet for specifications.)

List of tests:

Fetal Heart Rate by external ultrasound sensor (Monitor only)	Test #1
Fetal Heart Rate by external ultrasound sensor (Monitor and sensor)	Test #2
Fetal Heart Rate by direct electrocardiogram (DECG)	Test #3
Maternal Heart Rate by maternal electrocardiogram	Test #4
Uterine Contractions electronically by external strain gauge	Tests #1, #3, #4
Uterine Contractions by Intra-Uterine Pressure (IUP)	Test #5
Uterine Contractions by Intra-Uterine Pressure, manometrically	Test #6

Directory of simulation cables for HP/Agilent/Philips Monitors		
HP 8040		
Parameter	**Fluke Cable #**	
Uterine activity (Toco)	17489	2462543
Uterine activity (IUP)	17487	2462528
Fetal Heart Rate (Ultrasound)	17488	2462537
For the HP/Agilent/Philips 80- series:		
Parameter	**Fluke Cable #**	
Uterine activity (Toco)	17484	2462491
Uterine activity (IUP)	17487	2462528
Fetal Heart Rate (Ultrasound)	17482	2462478

The Toco port on the PS320 provides the same simulated pressure signal for uterine contractions, by either the Fluke Biomedical interface cable or by the manufacturer's IUP cable.

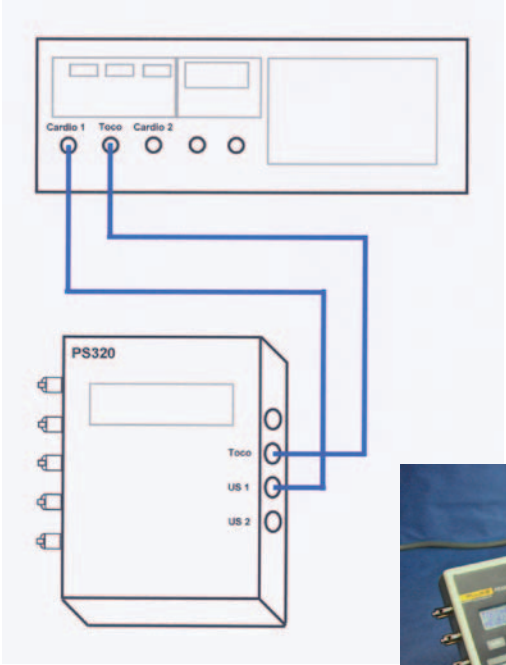
Test #1: Simulation of fetal heartbeat by ultrasound and uterine contraction (Toco) by external strain gauge

Required

- PS320
- Model-specific simulation cable for indirect fetal ECG*
- Model-specific simulation cable for uterine activity externally*

*See directory of cables above, or visit http://www.flukebiomedical.com/Biomedical/usen/Support/PS320-Cables.htm

1. Connect the Toco simulation cable to the Toco port of the PS320.
2. In the Toco button group on the PS320, select Toco. Select the 40 µV button (all HP/Agilent/Philips monitors have a sensitivity factor of 40 µV per volt of excitation per mmHg of pressure.)
3. With a Toco pressure of zero on the PS320, zero the Toco channel on the monitor, then select increasing values of pressure on the PS320, and verify each on the monitor.
4. Connect the fetal heart simulation cable to the US1 port of the PS320.
5. The PS320 will default to a fetal heart rate of 150 BPM. Select various rates to verify accuracy and alarms.

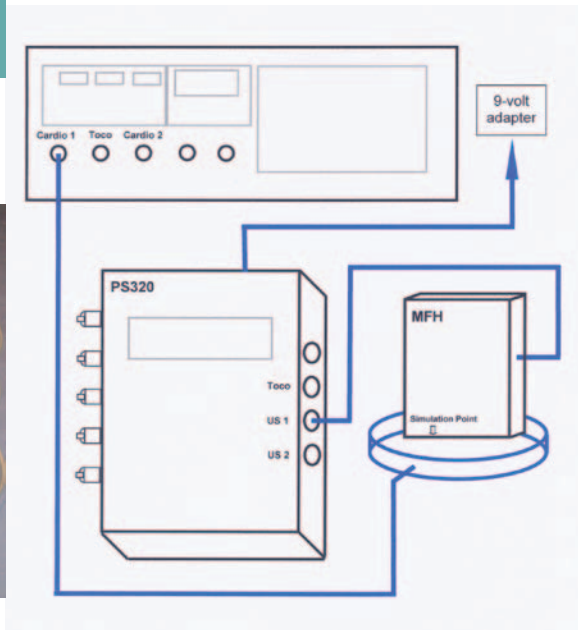


Test #2: Testing an ultrasound fetal heart transducer with the mechanical fetal heart

Required
- PS320
- 9-volt ac/dc adapter (Fluke Biomedical item # 2647372)*
- Mechanical Fetal Heart MFH-1 (Fluke Biomedical item # 2651757)
- Manufacturer-provided ultrasonic transducer

*The 9-volt power adapter must be used when testing with the MFH-1.

1. Slowly move the MFH-1 around the transducer surface to obtain an optimum signal.



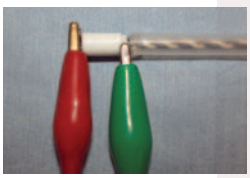
Test #3: Simulation of fetal heartbeat by direct ECG and uterine activity (Toco) by external strain gauge

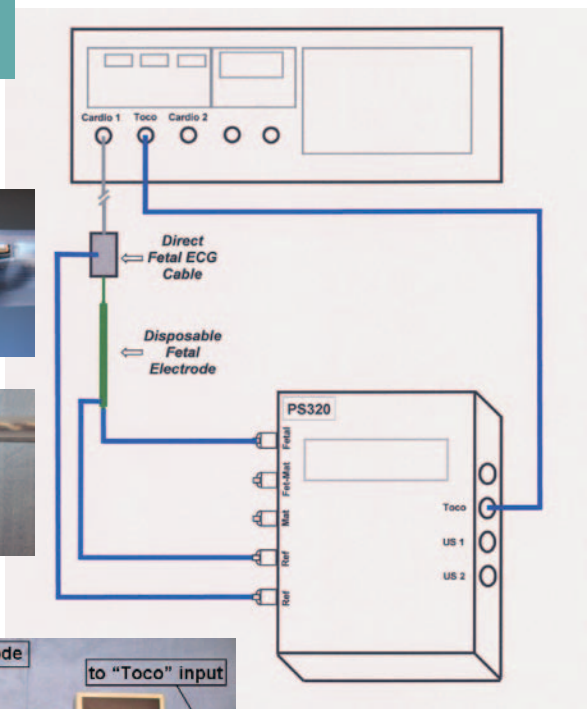
Required
- PS320
- Model-specific simulation cable for uterine activity externally*
- Model-specific Direct ECG (DECG) interface cable**
- Disposable fetal scalp electrode***
- 3 each: 25–30 cm test lead, with alligator clips

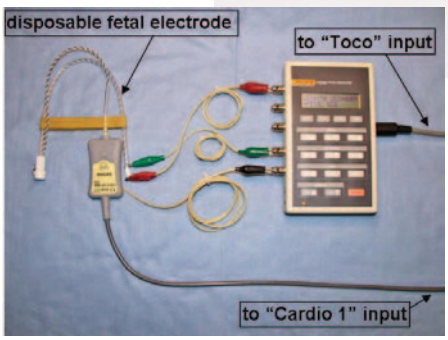
*See the directory of cables above, or visit http://www.flukebiomedical.com/Biomedical/usen/Support/PS320-Cables.htm
**Provided by the manufacturer of the monitor.
***Obtain from the user department.

1. Attach one test lead to the spiral contact of the disposable fetal scalp electrode, and to the fetal connector of the PS320.
2. Attach another test lead to the side connector of the disposable fetal scalp electrode, and to a Ref connector of the PS320.
3. Connect a third test lead from the ground point (or plate) of the DECG cable junction, and connect it to the other Ref connector of the PS320.

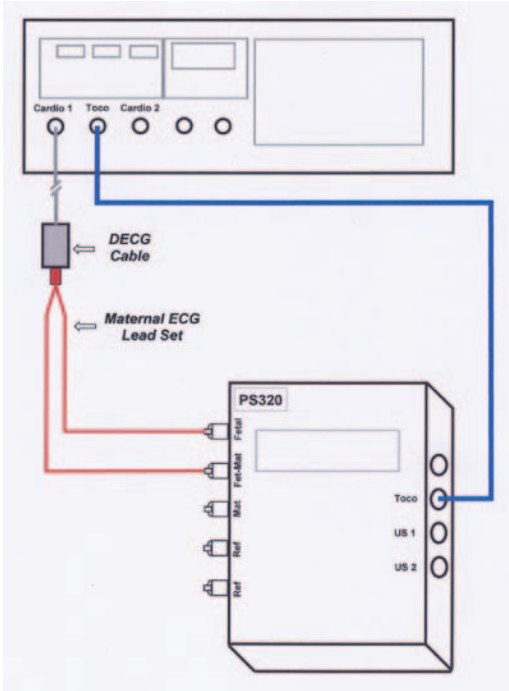
   (Alternatively, you can improvise connections directly from the two wires from a scalp electrode to the PS320, and keep the assembly for future testing.)







Test #4: Simulation of maternal heartbeat by direct ECG and uterine activity (Toco) by external strain gauge



Required

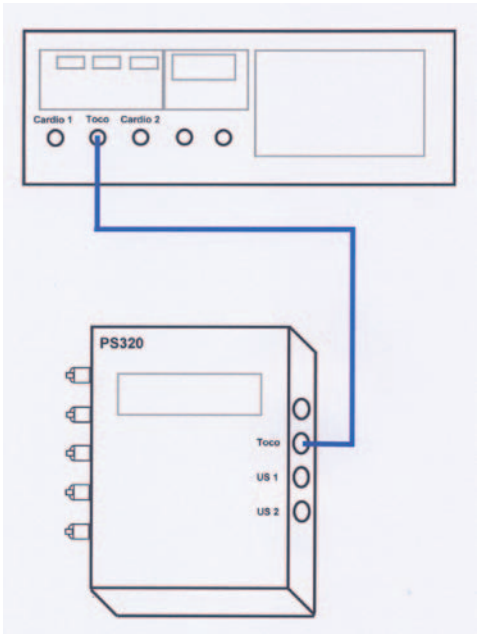
- PS320
- Model-specific simulation cable for uterine activity externally*
- Model-specific Direct ECG (DECG) interface cable**
- Model-specific maternal ECG lead set**

*See the directory of cables above, or visit http://www.flukebiomedical.com/Biomedical/usen/Support/PS320-Cables.htm

**Provided by the manufacturer of the monitor.

1. Connect the maternal ECG cable to either of the "Cardio" inputs on the monitor.
2. Connect the two ECG connectors to the "Fet" and "Fet-Mat" connector of the PS320.
3. Power-on the PS320 and touch "Mat". Maternal ECG will default at a rate of 100.
4. Adjust the maternal ECG rate with the "Mat" up or down keys.

Test #5: Simulation of Intra-Uterine Pressure by IUP cable and catheter



Required

- PS320
- Model-specific simulation cable for Intra-uterine pressure*

*See the directory of cables above, or visit http://www.flukebiomedical.com/Biomedical/usen/Support/PS320-Cables.htm

1. Connect the IUP simulation cable to the "Toco" port of the PS320.
2. In the Toco button group on the PS320, select "Toco". Select the "40 µV" button (All HP-Agilent-Philips monitors have a sensitivity factor of 40 µV per volt of excitation per mmHg of pressure.)
3. With a Toco pressure of zero on the PS320, zero the Toco channel on the monitor, then select increasing values of pressure on the PS320, and verify each on the monitor.

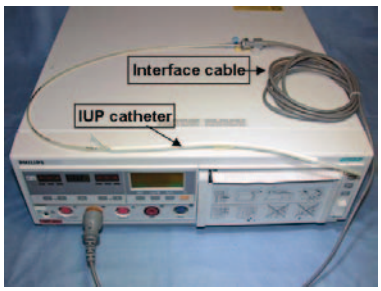
Test #6: Alternate test for accuracy of intra-uterine pressure measurements

Required

- Calibrated digital manometer (Fluke Biomedical DPM-4 or equivalent)
- Blood pressure bulb with bleed valve
- Model-specific intra-uterine pressure (IUP) cable
- Model-specific disposable intra-uterine pressure (IUP) catheter

The IUP and Toco share the same connectors on the monitor and the PS320.

1. Improvise a test setup including the manometer, the bulb, and the connector cut from the intra-uterine catheter. See image below.
2. Connect the interface cable to the test setup, and to the monitor.
3. With the system open to atmospheric pressure, zero the pressure reading on the monitor.
4. Gently pump the bulb to create a pressure in the system, and compare the pressure value on the monitor with that on the manometer. See image below.



References:

Chan, A: Biomedical Device Technology: Principles and Design C Thomas. 2008 ISBN 978-0-398-07700-6

Fluke Biomedical PS320 Users Manual, # 2631693, Rev. 1, 12/07

About Fluke Biomedical

Fluke Biomedical is the world's leading manufacturer of quality biomedical test and simulation products. In addition, Fluke Biomedical provides the latest medical imaging and oncology quality-assurance solutions for regulatory compliance. Highly credentialed and equipped with a NVLAP Lab Code 200566-0 accredited laboratory, Fluke Biomedical also offers the best in quality and customer service for all your equipment calibration needs.

Today, biomedical personnel must meet the increasing regulatory pressures, higher quality standards, and rapid technological growth, while performing their work faster and more efficiently than ever. Fluke Biomedical provides a diverse range of software and hardware tools to meet today's challenges.

Fluke Biomedical Regulatory Commitment

As a medical test device manufacturer, we recognize and follow certain quality standards and certifications when developing our products. We are ISO 9001 and ISO 13485 medical device certified and our products are:

- CE Certified, where required
- NIST Traceable and Calibrated
- UL, CSA, ETL Certified, where required
- NRC Compliant, where required

Fluke Biomedical.
Better products. More choices. One company.

Fluke Biomedical
6045 Cochran Road
Cleveland, OH 44139-3303 U.S.A.

Fluke Biomedical Europe
Science Park Eindhoven 5110
5692EC Son, The Netherlands

For more information, contact us:
In the U.S.A. (800) 850-4608 or
Fax (440) 349-2307
In Europe/M-East/Africa +31 40 267 5435 or
Fax +31 40 267 5436
From other countries +1 (440) 248-9300 or
Fax +1 (440) 349-2307
Email: sales@flukebiomedical.com
Web access: www.flukebiomedical.com