Equipment Packet: Fetal Doppler and Fetal Monitor

UMDNS #: 11692 & 535

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Equipment Packet Contents:

This is a two-part packet that contains information about the operation, maintenance, and repair of fetal monitors and fetal Doppler. Section A of this packet discusses fetal monitors and Section B of this packet discusses fetal Doppler.

Part I: External From the Packet:

1. **An Introduction to Fetal Monitors:** PowerPoint

Part II: Included in this Packet:

SECTION A:
Fetal Monitors

1. Operation and Use of Fetal Monitors

Featured in this Section:

Developing World Healthcare Technology Laboratory. “Fetal Monitors.” From the Publication: “Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment.” *Engineering World Health*, March 1, 2011, p. 115-159.

WHO. “Fetal Monitor.” From the publication: *Core Medical Equipment*. Geneva, Switzerland, 2011.

WHO. “Neonatal Physiological Monitor.” From the publication: “WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Fetal monitor Brief Overview: Fetal Heart Monitoring

UMDNS		GMDN	
18339	Monitors, Bedside, Fetal, Antepartum	43958	Foetal cardiac monitor
18340	Monitors, Bedside, Fetal, Intrapartum		

Other common names:
Cardiotocographs; fetal electrocardiogram (ECG) monitors; fetal heart rate monitors; ultrasonic fetal monitors; Monitor, cardiac, fetal; Monitor, heart valve movement, fetal, ultrasonic; Monitor, phonocardiographic, fetal.

Health problem addressed

Electronic fetal monitoring (EFM) provides graphic and numeric information on fetal heart rate (FHR) and maternal uterine activity (UA) to help clinicians assess fetal well-being before and during labor. FHR often exhibits decelerations and accelerations in response to uterine contractions or fetal movements; certain patterns are indicative of hypoxia. Examination of these patterns, the baseline level, and variability characteristics can indicate the need to alter the course of labor with drugs or perform an operative delivery.

Product description

Fetal monitors are bedside units that consist of a monitoring unit, cables, and electrodes. They are designed to measure, record, and display FHR, uterine contractions, and/or maternal blood pressure and heart rate before and during childbirth. These monitors may sense FHR and uterine contraction indirectly through the mother's abdomen and/or directly by placing an electrode on the fetal scalp (or other exposed skin surface) and measuring the change in pressure within the uterus. Antepartum fetal monitors are typically used in physician's offices and clinics long before the beginning of labor. Most hospital-based monitors have additional capabilities, including fetal and maternal ECG recording.

Principles of operation

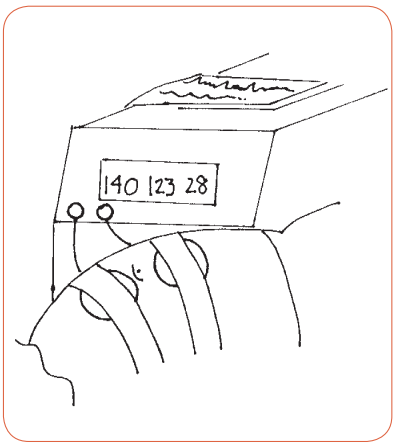
Fetal monitors detect FHR externally by using an ultrasound transducer to transmit and receive ultrasonic waves; the frequency (or Doppler) shift of the reflected signal is proportional to the velocity of the reflecting structure—in this case, the fetal heart. A transducer contains one or more piezoelectric elements that convert an electrical signal into ultrasonic energy that can be transmitted into tissues. When this ultrasonic energy is reflected back from the tissues, the transducer reconverts it to an electrical signal that can be used to create a waveform for display and recording and an audible FHR (sound created by the frequency shift of the ultrasonic signal).

Operating steps

Continuous electronic FHR monitoring can be performed indirectly, by applying an ultrasound transducer to the mother's abdomen, or directly, by attaching an electrode assembly to the fetus after rupture of the amniotic membranes. Uterine contractions can be recorded along with FHR by placing a pressure transducer on the mother's abdomen or by directly measuring the change in pressure in the uterus with a catheter.

Reported problems

Common errors include doubled or halved rates, masked fetal arrhythmias, and presentation of the maternal heart rate as the FHR. Another error is the report of false FHR decelerations during uterine contractions due to ultrasonic signal-processing circuits holding the last FHR on occasional signal peaks during noisy signals. Reported complications



of fetal scalp electrode application include infection, uterine perforation, and soft tissue injuries; mostly resulting from poor technique. Some investigators have expressed concern about the possible risks associated with fetal exposure to ultrasound.

Use and maintenance

User(s): Physicians, obstetric nurses, community midwives

Maintenance: Biomedical or clinical engineer/technician, medical staff, manufacturer/servicer

Training: Initial training by manufacturer, operator's manuals, user's guide

Environment of use

Settings of use: Obstetrics (hospital, OB/GYN practices), emergency medicine

Requirements: Uninterruptible power source, battery backup, appropriate transducer/electrodes/sensors

Product specifications

Approx. dimensions (mm): 100 x 150 x 200

Approx. weight (kg): 6

Consumables: Batteries, cables, electrodes/sensors, gel

Price range (USD): 1,200 - 15,000

Typical product life time (years): 8

Shelf life (consumables): NA

Types and variations

Tabletop, cart, some portable

WHO. "Fetal Monitor." From the publication: Core Medical Equipment. Geneva, Switzerland, 2011.

Fetal Monitors

Introduction

There are six types of measurements that can be made with the fetal monitor: four to measure fetal heart rate (FHR) and two for uterine activity (UA). The techniques selected for a particular patient depend on the clinical assessment of the needs of the patient and the personal preferences of the staff. The monitor also computes and records heart rate variability and uterine activity units from data obtained with direct modes. These modes can be further subdivided into two categories:

A. **External** – Patient connections are made on the material abdomen. The fetal heart rate (FHR) external modes include abdominal electrocardiogram (AFECG), phono, and ultrasound. A relative measure of uterine activity is obtained by means of a tocotransducer.

B. **Internal** --In the internal mode (FECG), FHR is determined from measurements obtained by electrodes attached to the fetal presenting part. Uterine activity is measured by means of an intrauterine catheter and strain gauge.

Each technique has advantages and disadvantages that must be weighed against the condition of the patient and the data desired.

Only properly trained and qualified personnel should be permitted access to any internal parts of this equipment.

WARNING: LIVE ELECTRICAL TERMINALS AND COMPONENTS CAN PRESENT A SHOCK HAZARD TO UNTRAINED PERSONNEL. FAILURE TO HEED THESE WARNINGS COULD RESULT IN SERIOUS ELECTRICAL SHOCK INJURIES.

Patient safety

As with all patient monitoring devices, reasonable caution must be exercised with equipment and patient connections. When properly followed, the following procedures will ensure maximum patient safety.

Leakage current

Leakage current, which flows from the frame of the equipment to ground, is present in all electronics equipment. Most monitors are equipped with isolated inputs, and leakage current is limited to a few microamperes even if full power-line voltage is applied to the patient leads. However, for maximum patient safety, the following procedures are recommended.

- Do not touch the patient while making adjustments on the monitor.

- Do not allow patient cables to come in contact with grounded items.
- Keep equipment clean and free of transducer gel, EKG electrode cream, and other lubricants.
- Do not operate if unit is wet due to spills or condensation. Condensation could occur if a monitor is moved from building to building.
- Monitors should be plugged into the same circuit as other equipment in use on the same patient. Your hospital engineering staff should identify outlets that are on the same circuit in patient areas.

Direct Measuring Hazards

When using direct measuring techniques, there are some potential hazards that must be considered.

Do not re-use any disposable product.

This equipment is not designed for use in an explosive atmosphere, in the presence of concentrations of inflammable anesthetics, or inside an oxygen tent. Use in such atmospheres may present an explosion hazard.

Repairs to this equipment should be made only by authorized personnel. All repairs or changes to equipment must be entered on a repair record form, along with the data and signature of repairer.

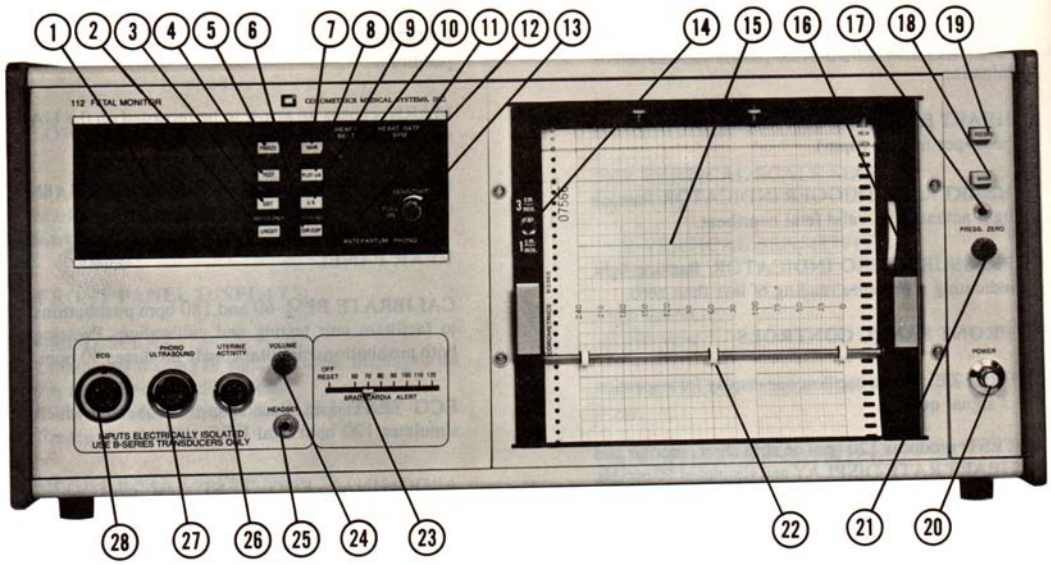
In all cases, should questions arise, consult the operator's manual for your particular monitor.

Figures 1 and 2 on the following pages show the front and back panel displays of a fetal monitor. A wide variety of accessories is available for fetal monitors. These are featured in figures 3 and 4.

Figure 0-1: Front panel, fetal monitor

ILLUSTRATED DESCRIPTION

FRONT PANEL



1 CRT DISPLAY
2 UNEDIT PUSHBUTTON
3 EDIT PUSHBUTTON
4 TEST PUSHBUTTON
5 FREEZE PUSHBUTTON
6 DIRECTIONAL DOPPLER PUSHBUTTON
7 MHR PUSHBUTTON
8 PLOT UA PUSHBUTTON
9 US (CONVENTIONAL) PUSHBUTTON
10 VALID FECG INDICATOR
11 HEART RATE (BPM) DISPLAY
12 ANTEPARTUM PHONO INDICATOR
13 ANTEPARTUM PHONO SENSITIVITY CONTROL
14 CHART SPEED SWITCH
15 RECORDER ASSEMBLY
16 MANUAL ADVANCE WHEEL
17 PRESSURE ZERO INDICATOR
18 MARK PUSHBUTTON
19 RECORD PUSHBUTTON
20 POWER PUSHBUTTON
21 PRESSURE ZERO CONTROL
22 GUIDE ROLLERS
23 BRADYCARDIA ALERT CONTROL
24 VOLUME CONTROL
25 HEADSET INPUT
26 UTERINE ACTIVITY TRANSDUCER INPUT
27 PHONO AND ULTRASONIC TRANSDUCER INPUT
28 ECG INPUT

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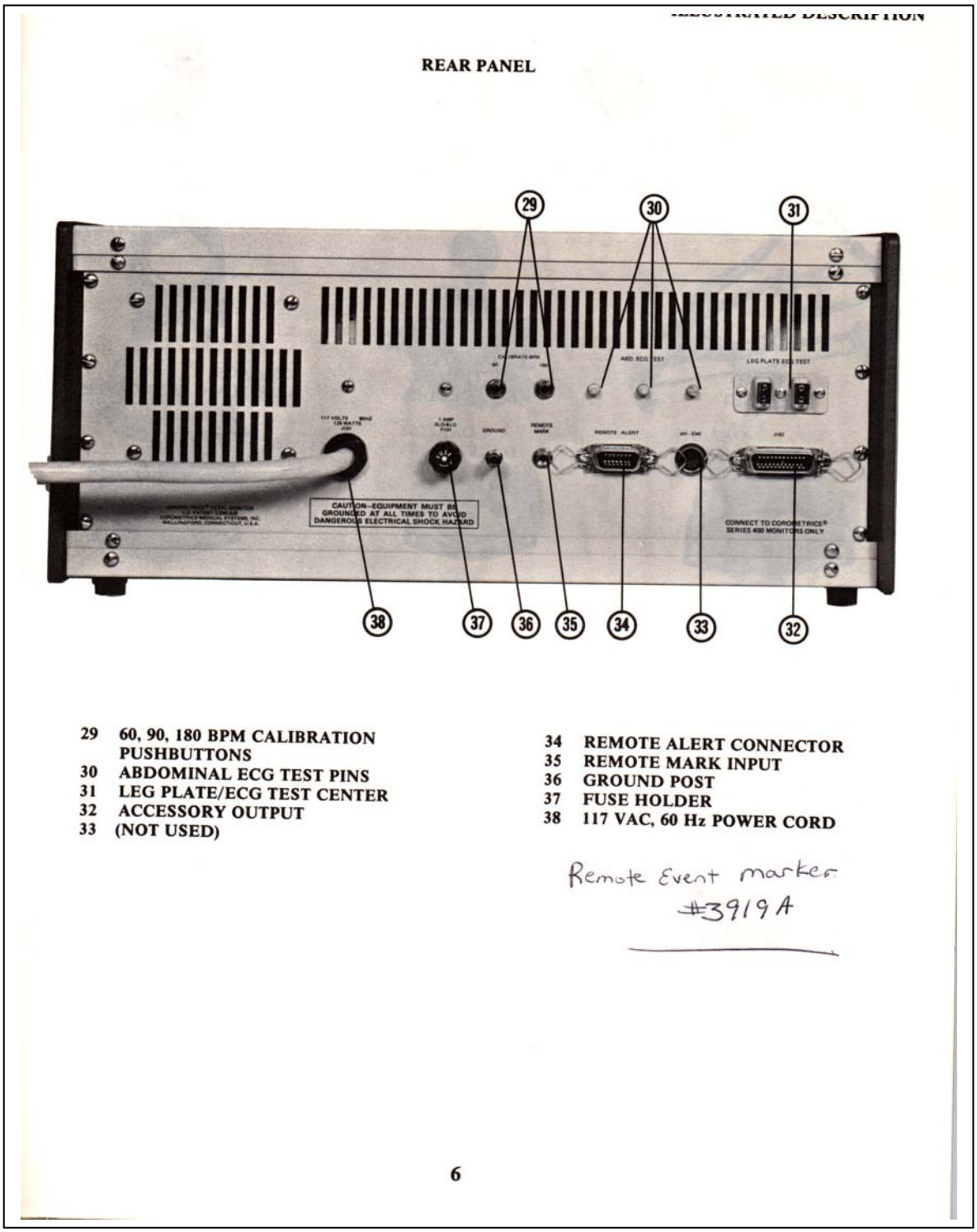
Developing World Healthcare Technology Laboratory. "Fetal Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 115-159.

Figure 0-2: Rear panel, fetal monitor



Developing World Healthcare Technology Laboratory. "Fetal Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 115-159.

Figure 0-3: Accessories for fetal monitor

Developing World Healthcare Technology Laboratory. "Fetal Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 115-159.

Figure 0-4: Additional accessories for fetal monitor

Developing World Healthcare Technology Laboratory. "Fetal Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 115-159.

2. Diagrams and Schematics of Fetal Monitors

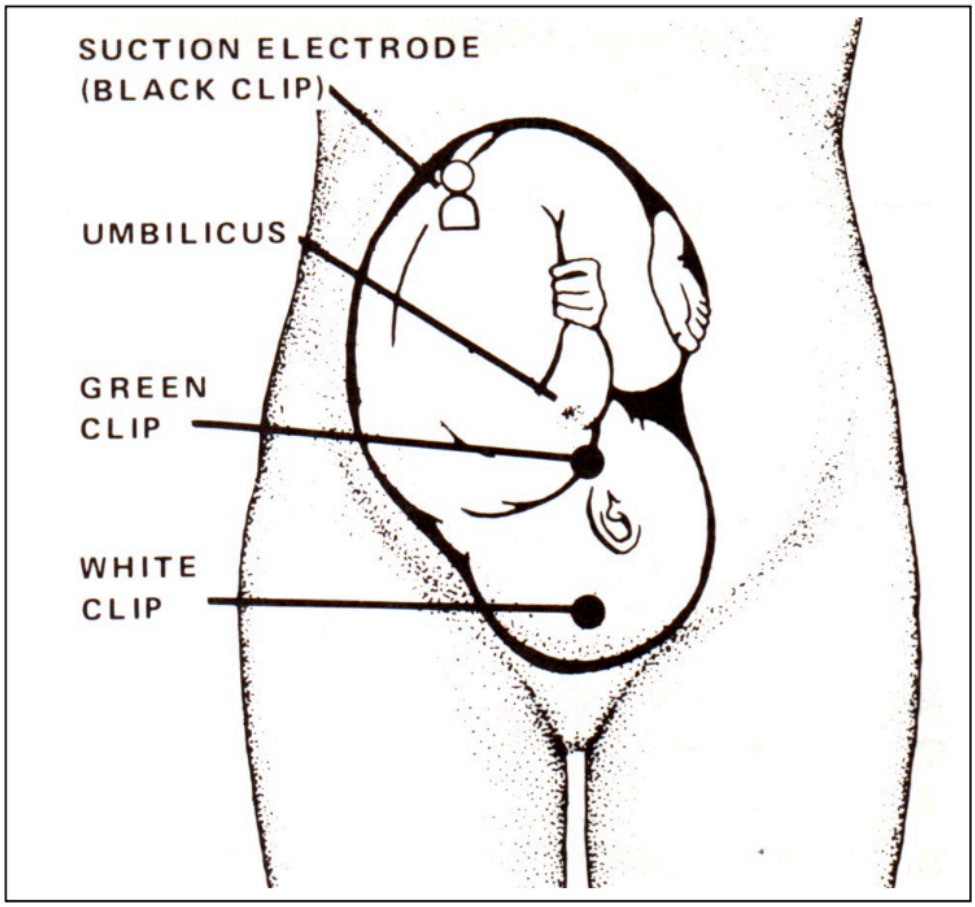
Featured in this Section:

Developing World Healthcare Technology Laboratory. “Fetal Monitors.” From the Publication: “Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment.” *Engineering World Health*, March 1, 2011, p. 115-159.

Figure 1: Proper Placement of Fetal Monitor Electrodes

Proper placement of electrodes is crucial in obtaining a good reading.

Figure 0-8: Position of electrodes



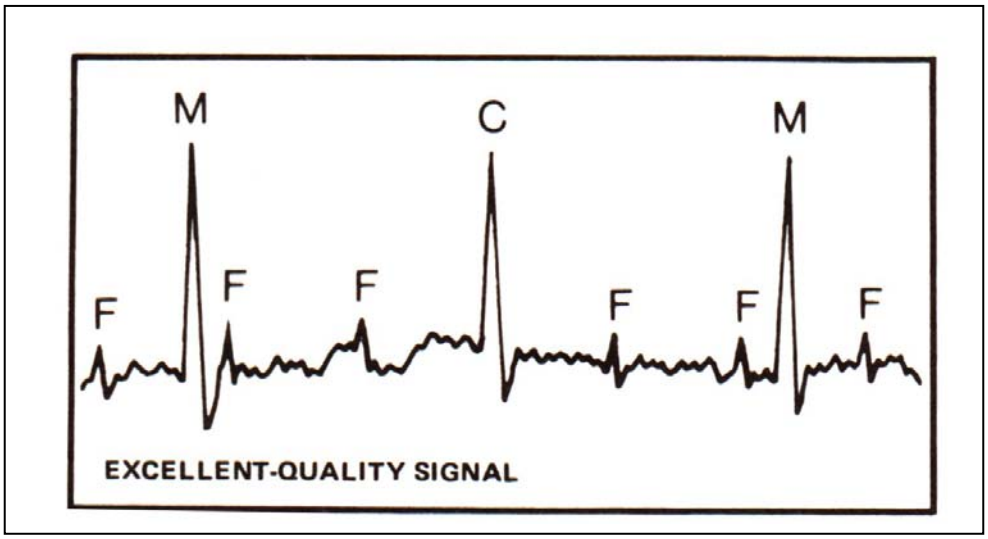
Developing World Healthcare Technology Laboratory. "Fetal Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 115-159.

Figure 2: Examples of Output from Fetal Monitors

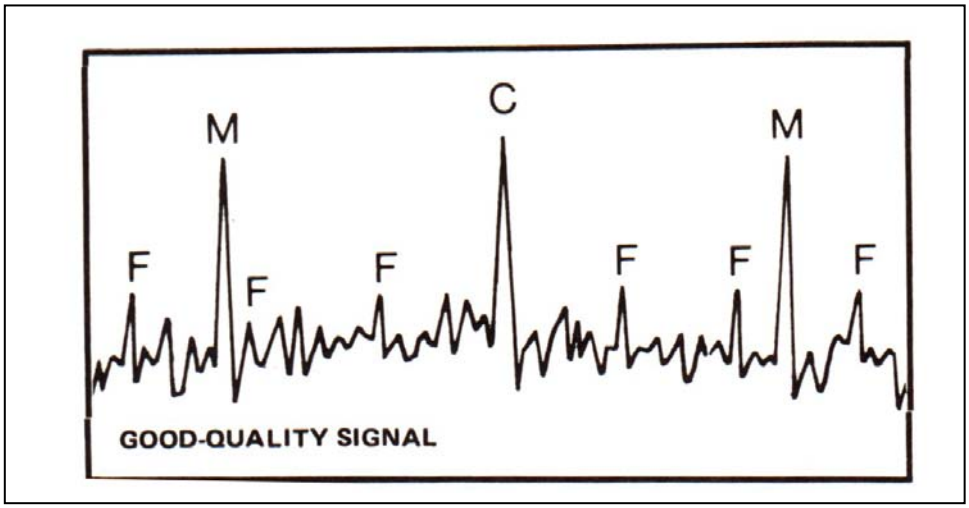
Waveform Examples

The following waveform examples illustrate various patterns that may be presented on the CRT.

1. EXCELLENT-QUALITY SIGNAL. FECG/MECG pattern where FECG is clearly defined. FECG (F) is clearly distinguished from noise signals and from much larger MECG. FECG/MECG signals that are coincident © are also illustrated.

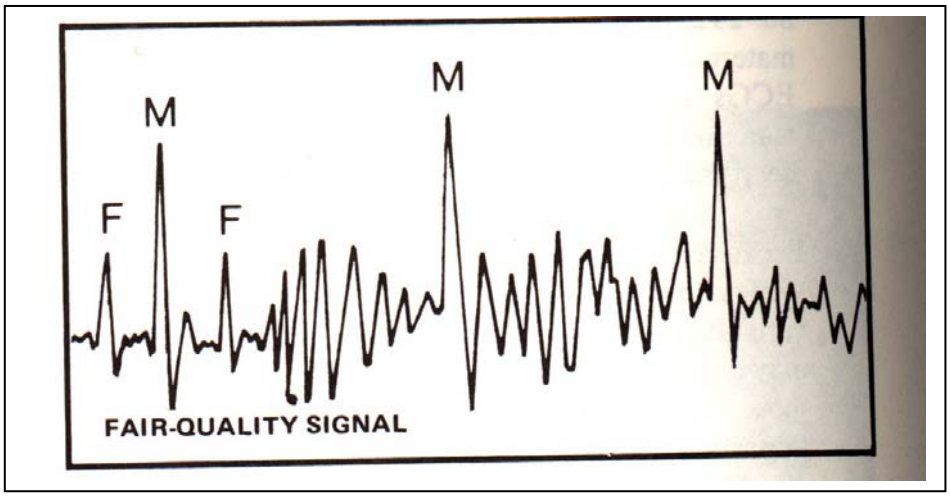


2. GOOD QUALITY SIGNAL. Noise signals are more evident. FECG (F) is still clearly distinguishable.

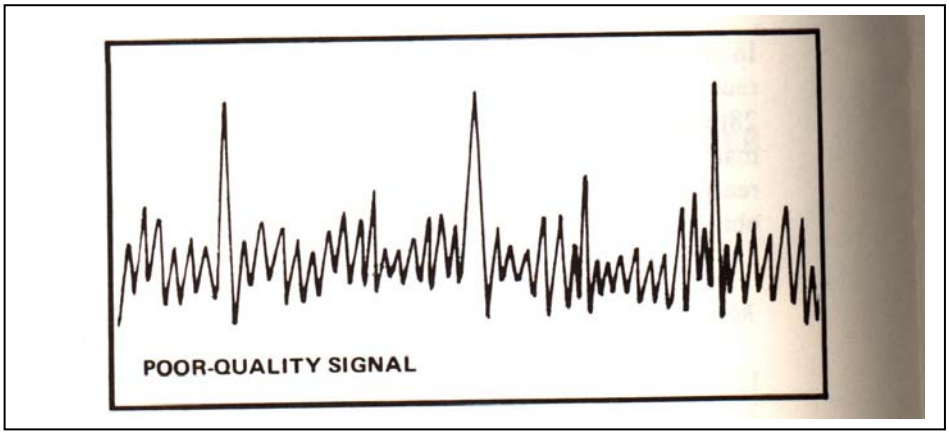


Developing World Healthcare Technology Laboratory. "Fetal Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 115-159.

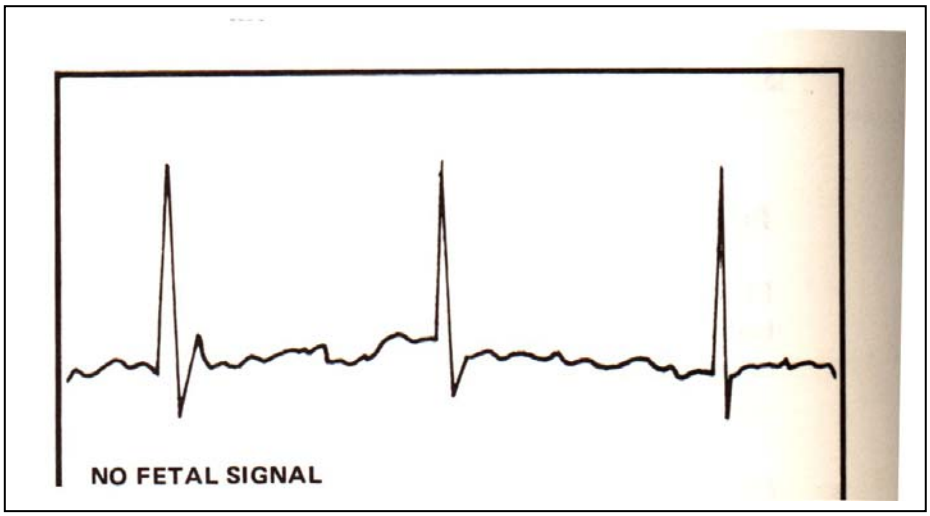
3. FAIR-QUALITY SIGNAL. FECG sometimes obliterated by sporadic electrical noise. Some monitors edit these signals (in EDIT) mode and obtain and display FECG.



4. POOR-QUALITY SIGNAL. FECG/MECG patterns, where excessive noise completely obliterates the fetal signal on the monitor display. Some monitors may still obtain and present FHR on the strip chart recorder, but normally a visibly discernible fetal signal is required.



5. NO FETAL SIGNAL. No discernible FECG. Perform search process until acceptable FECG is obtained, or use alternate method to obtain FHR recording.



Search Procedure

If a good recording is not obtained with original electrode positions, a search procedure must be performed.

Each time the electrode is positioned, wait for AGC to optimize the signal.

If the signal is still not acceptable after the three electrodes have been moved, another measurement technique should be used.

Edit/unedit modes of operation

The use of electronic logic and pulse insertion makes the FHR record cosmetically acceptable. However, the actual proportion of accurate event-to-event FHR data may be quite small. It is difficult to separate precise from imprecise event-to-event FHR data on a record so treated.

To aid the medical staff in their evaluation of edited and unedited FHR records, the EDIT and UNEDIT modes of operation are described.

Figure 3: WHO Specification for Neonatal Physiological Monitors

MEDICAL DEVICE SPECIFICATION		
i	Version No.	1
ii	*Date of initial version*	8/27/12
iii	*Date of last modification*	7/4/14
iv	*Date of publication*	
v	*Completed / submitted by*	WHO working group
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	Neonatal physiological monitor
3	Specific type or variation (optional)	
4	GMDN name	Neonatal physiologic monotoring systems
5	GMDN code	35569
6	GMDN category	Anaesthetic and respiratory devices , Electro mechanical medical devices
7	UMDNS name	Monitors, Bedside, Physiologic, Neonatal
8	UMDNS code	15791
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Physiologic monitoring system; Neonatal patient monitor; Physiologic monitoring system, neonatal
11	Alternative code/s (optional)	MS 12636; S 34379; S 15791
12	Keywords (optional)	patient monitor, ECG, EKG, vital signs, physiological
13	GMDN/UMDNS definition (optional)	A device assembly designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care. It is typically capable of monitoring parameters such as electrocardiogram (ECG), respiration rate, heart rate, blood pressure, and body temperature; it may also assess haemoglobin oxygen saturation (SpO2) through transcutaneous sensors that measure both transcutaneous oxygen (tcpO2) and transcutaneous carbon dioxide (tcpCO2) saturation. The system typically includes sensors with appropriate size and design for infant use.
PURPOSE OF USE		
14	Clinical or other purpose	Designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care.
15	Level of use (if relevant)	district hospital, provincial hospital, specialized hospital
16	Clinical department/ward(if relevant)	Neonatal intensive care unit (NICU), Emergency room (ER), Operating Theatre
17	Overview of functional requirements	Continuous display on screen of neonatal or infant ECG, respiration and heart rates, invasive / non-invasive blood pressure, body temperature and SpO2.
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	Hard copy printout of traces will not be required. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. SpO2 measurement range at least 70 to 99 %, with accuracy better than ± 3% and minimum gradation 1%. NIBP blood pressure monitoring range at least 30 to 300 mmHg, minimum gradation 1 mmHg. Respiration rate measurement range at least 0 to 100 bpm, minimum gradation 1 bpm Temperature range at least 30 to 40 deg C, minimum gradation 0.1 deg C.
19	Displayed parameters	Multichannel (up to 12 leads) ECG measurement and selectable display. Allows display of single, 3 lead ECG or simultaneous display of at least 3 waves selected from up to 12 points. Unwanted parameters can be deselected from display. Display to be digital of all active parameters and trace display of at least three selectable parameters. Trend display of each parameter over at least previous 24 hours to be selectable Display must allow easy viewing in all ambient light levels.
20	User adjustable settings	Operator can set audio visual alarm levels for low or high levels of each parameter independently. User operated 1mV ECG test marker function required Alarm override and temporary silence facility to be included. Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor / wire / probe disconnected, low battery
PHYSICAL/CHEMICAL CHARACTERISTICS		

WHO. "Neonatal Physiological Monitor." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

21	Components(if relevant)	Case is to be hard and splash proof. Cable connectors to be designed so as fit correct socket only Wired patient cable connections will be preferred above wireless connection
22	Mobility, portability(if relev	Supplied in protective case for clean storage and safe transport
23	Raw Materials(if relevant)	
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Power input to be ********** fitted with ********** compatible mains plug Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Battery powered, silenceable alarm for power failure. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure. Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. Electrical protection provided by fuses in both live and neutral supply lines Mains cable to be at least 3m length
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	12 lead ECG cable. ECG patient connectors that are sterilisable and reusable are preferred, though reusable cables that attach to disposable connection patches are also acceptable. 5 sets of ECG connection electrodes (if reusable type), 100 sets of ECG connection electrodes (if disposable type) shall be supplied. 5 tubes electrode gel (if required). 5 lead ECG cable (if option offered). Two reusable SpO2 probes each for neonatal and infant use. Blood pressure – invasive: one sensor for each channel offered; non-invasive: two reusable neonatal cuffs. Two reusable, external skin temperature probes.
26	Sterilization process for accessories (if relevant)	
27	Consumables / reagents (if relevant)	
28	Spare parts (if relevant)	Two sets of spare fuses (if non-resettable fuses used). List to be provided of other important spares and accessories, with their part numbers and cost.
29	Other components (if relev	An extra option for simple five lead connection would be preferred.
PACKAGING		
30	Sterility status on delivery (if relevant)	
31	Shelf life (if relevant)	
32	Transportation and storage (if relevant)	
33	Labelling (if relevant)	Unit shall be supplied protectively packed for safe onward shipping
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	
36	Requirements for commissioning (if relevant)	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided.
38	User care(if relevant)	The case is to be cleanable with alcohol or chlorine wipes.
WARRANTY AND MAINTENANCE		
39	Warranty	Duration of warranty to be stated, minimum one year. Specific inclusions and exclusions to be listed. One service visits shall be made under warranty. Contact details of manufacturer, supplier and local service agent to be provided

40	Maintenance tasks	List shall be provided of equipment and procedures required for local calibration and routine maintenance Advanced maintenance tasks required shall be documented
41	Type of service contract	Costs and types of post-warranty service contract available shall be described.
42	Spare parts availability po	Guaranteed time period of availability of spare parts post-warranty shall be described.
43	Software / Hardware upgr	Guaranteed time period of support and software upgrade (if relevant) availability post-warranty shall be described.
DOCUMENTATION		
44	Documentation requirements	User, technical and maintenance manuals to be supplied in ********** language. Supplier to describe any materials contained in the device that are classified as hazardous under local regulations.
DECOMMISSIONING		
45	Estimated Life Span	7 years
SAFETY AND STANDARDS		
46	Risk Classification	Class B (GHTF Rule 10); Class II (USA); Class II (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	Shall be FDA, CE or UL approved product.
48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-8 :2012 (Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems) IEC 60601-2-49:2011 (Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment) Optional: IEC 60601-2-23:2011 (Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment) IEC 60601-2-26:2012 (Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs) IEC 60601-2-27:2011 (Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment) IEC 60601-2-34:2011 (Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment) IEC 60601-2-40:1998 (Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment) IEC 60601-2-47:2012 (Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems) IEC 80601-2-30:2009 (Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers) ISO 80601-2-55:2011 (Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors) ISO 80601-2-61:2011 (Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment)
49	Reginal / Local Standards	AAMI/ANSI EC38:2007 (Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems) IEEE Std 11073-10406-2011 (Health informatics - Personal health device communication Part 10406: Device specialization - Basic electrocardiograph) EN 12470-4:2000 Clinical thermometersPerformance of electrical thermometers for continuous measurement JIS T 1115:2005 Non-invasive Automated Sphygmomanometers JIS T 3323:2008 Pressure transducers
50	Regulations	**US regulations** 21 CFR part 820 21CFR section 870.1025 monitor, physiological, patient(with arrhythmia detection or alarms) **JP regulations** MHLW Ordinance No.169 35569000 Neonatal monitor

3. Preventative Maintenance and Safety of Fetal Doppler

Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. “Fetal Monitor Preventative Maintenance.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

EQUIPMENT

Fetal Doppler Preventative Maintenance

Preventive Maintenance

Fetal Doppler/Monitor Preventative Maintenance

1. Clean the probe before every use to disinfect.
2. Clean the probe and cable after every use with a damp cloth to remove gel.
3. Check the batteries periodically to ensure no corrosion and proper charge.

Fetal Doppler Proper usage guidelines

1. Remove the battery if not in use for an extended period.
2. When cleaning the probe prior to use, use a sort non-abrasive cloth or disposable wipe soaked in disinfectant. Avoid aerosol disinfectants or solutions containing organic solvents or alcohol. Then wipe the probe with a non-abrasive cloth soaked in water. Finally dry the probe and package in a clean bag, covered tray or other way or careful storage and transport.
3. To sterilize the Fetal Doppler or probes, use cold gas sterilization such as ethylene oxide at less than 140 ^{0}F or the Sterad System.
4. Store at a temperature between -10^{0}C and 60^{0}C with a humidity of between 15 and 90%.

Printer Usage

- For Thermal Paper (must use company provided paper)
    - Thermal side facing up
    - Make sure plastic cover and sticky tab are removed
    - Printer door must be closed correctly
    - 30-240 BPM (USA) scale or 50-210 BPM scale (foreign)

4. Troubleshooting and Repair of Fetal Monitors

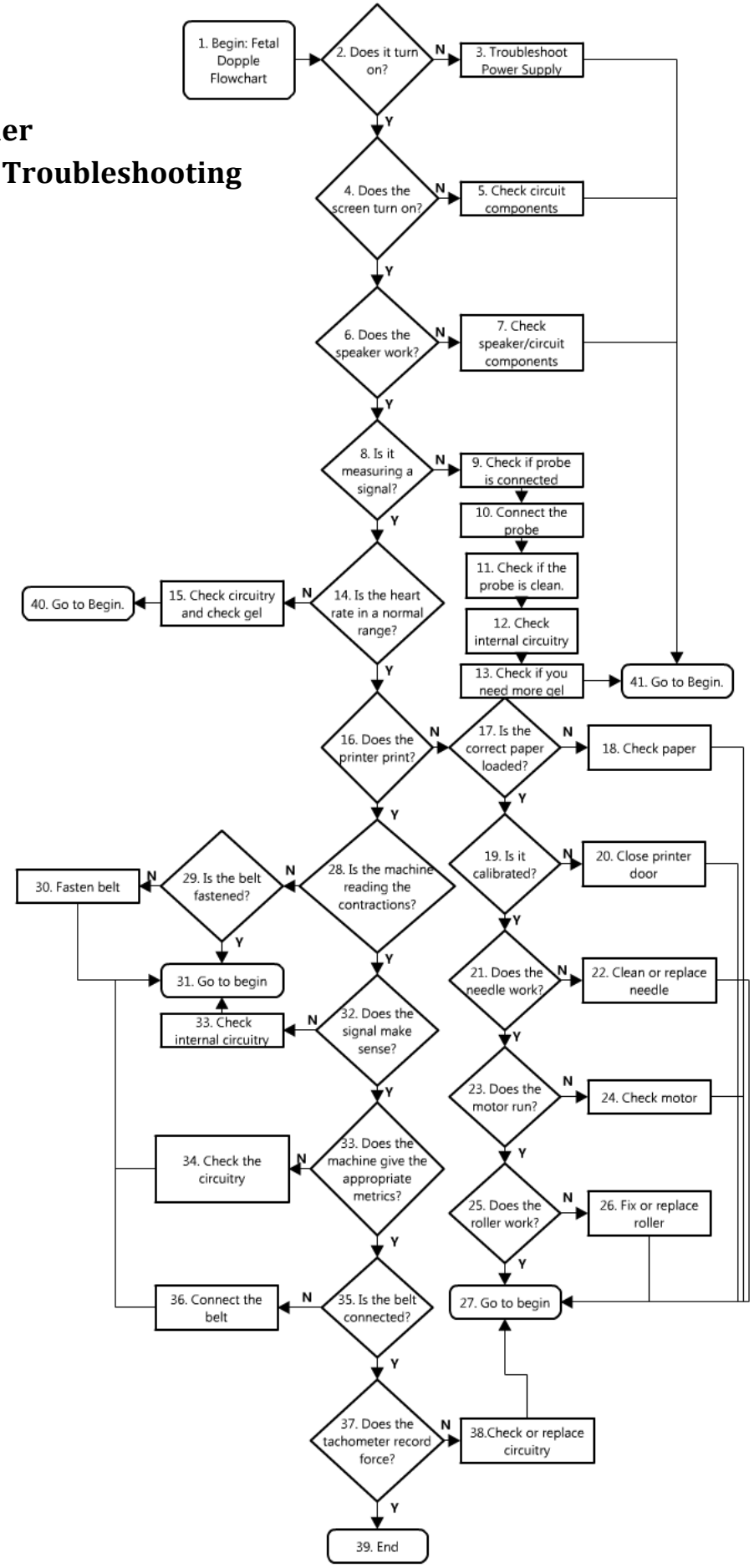
Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. “Fetal Monitor Troubleshooting Flowchart.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Fetal Doppler Troubleshooting Flowchart

Fetal Doppler
Repair and Troubleshooting

Flowchart



Cooper, Justin and Alex Dahinten for EWH. "Fetal Doppler Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Description

	Textbox	Explanation
1	Begin Fetal Doppler Flow Chart	Begin diagnostic process for a work order on Fetal Doppler
2	Does it turn on?	Does it turn on?
3	Trouble shoot Power Supply	See Flowchart on Power Supply, and BTA skills on Power Supply.
4	Does the screen turn on?	Does the screen turn on?
5	Check circuit components	Troubleshoot the electrical components. See BTA skills on Electrical Simple.
6	Does the speaker work?	Is sound audible?
7	Check speaker/ circuit components	Troubleshoot the electrical components. See BTA skills on Electrical Simple.
8	Is it measuring a signal?	Is the monitor/Doppler producing HR sound?
9	Check if probe is connected	Check if the probe is connected to the fetal doppler/monitor.
10	Connect the probe	Connect the probe. See BTA skills on Mechanical – Attachments.
11	Check if probe is clean	Clean the probe. See BTA skills on Cleaning.
12	Check internal circuitry,	Troubleshoot the electrical components. See BTA skills on Electrical Simple.
13	Check if you need more gel	Apply ultrasound gel to the probe.
14	Is the heart rate in a normal range?	Is the heart rate in a normal range?
15	Check circuitry and check gel	Troubleshoot the electrical components and apply ultrasound gel to the probe as necessary. See BTA skills on Electrical Simple.
16	Does the printer print?	Is there a marking on the paper?
17	Is the correct paper in>	Do you have the proper thermal paper?
18	Check paper	Check to see whether paper is full.
19	Is it calibrated?	Is the proper Heart Rate, timing, and contraction output? Is the proper calibration signal upon start?
20	Close printer door	Close door.

21	Does the needle work?	Does the needle work?
22	Clean or replace needle	Clean or replace needle. See BTA skills on Mechanical.
23	Does the motor run?	Does the motor rotate?
24	Check motor	See motor guide and BTA skills on Motors.
25	Does the roller work?	Does the roller move the paper at the correct rate without slipping? Are there cracks or damage to the roller? Is the roller hard and showing signs of age?
26	Fix or replace Roller	Fix or replace Roller.
27	Go to begin.	Go to begin.
28	Is the machine reading the contractions?	Does the machine show numbers for the uterine contractions?
29	Is the belt fastened?	Is the belt fastened?
30	Fasten belt.	Fasten belt.
31	Go to begin.	Go to begin.
32	Does the signal make sense?	Does the uterine contraction signal correlate with the contractions the mother is having?
33	Does the machine give the appropriate metrics?	Does the machine output sensible numbers for contraction force and frequency?
34	Check the circuitry.	Troubleshoot the electrical components. See BTA skills on Electrical Simple.
35	Is the belt connected?	Is the belt connected to the fetal monitor?
36	Connect the belt.	Connect the belt.
37	Does the tachometer record force?	Does the tachometer record force numbers?

38	Replace or check circuitry.	Replace the contraction belt or troubleshoot the circuit (see troubleshooting guide)
39	End	End the flow chart.
40	Go to begin.	Go to begin.
41	Go to begin.	Go to begin.

SECTION B:
Fetal Doppler

5. Operation and Use of Fetal Doppler

Featured in this Section:

Malkin, Robert. “Fetal Monitor and Fetal Doppler: Use and Operation.” From the publication: *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

WHO. “Fetal Heart Detector, Ultrasonic.” From the publication: *Core Medical Equipment*. Geneva, Switzerland, 2011.

Wikipedia. “Doppler Effect.” *Wikipedia,* p. 1-8. Retrieved from: https://en.wikipedia.org/wiki/Doppler_effect

Fetal Heart Detector, Ultrasonic

Brief Introduction: Fetal Heart Monitoring

UMDNS	GMDN
11696 Detectors, Fetal Heart, Ultrasonic	35068 Foetal heart detector, ultrasonic

Other common names:
Ultrasonic stethoscopes; fetal Dopplers; Monitor, heart rate, fetal ultrasonic; Monitor, heart sound, fetal, ultrasonic; monitor, hemic sound, ultrasonic.

Health problem addressed

Ultrasonic fetal heart detectors are low-cost devices used in a variety of healthcare settings to provide audible and visual information about the fetus. The unit provides quick reassurance of fetal well-being to both the mother and the healthcare worker. Fetal heart detectors can easily detect fetal heart sounds throughout the pregnancy, starting as early as 8 weeks. The ability of most units to accurately calculate the fetal heart rate has also made these devices valuable diagnostic tools.

Product description

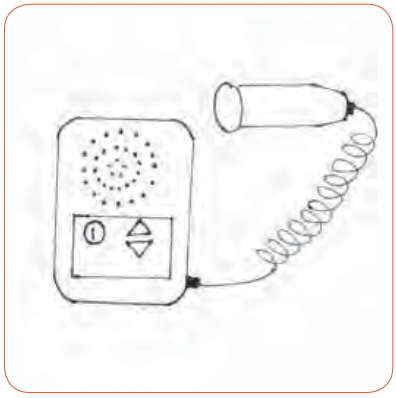
Fetal heart detectors are devices that use ultrasonic waves to provide audible and/or visual information. They consist of an ultrasound-frequency electrical generator and appropriate ultrasound transducers housed in a probe that is placed on the maternal abdomen. Ultrasonic heartbeat detectors amplify the audible frequency shift signal of the returned ultrasonic waves and deliver it to speakers or headphones; the heart rate is determined either by measuring the timing of the peaks in the Doppler signal or, more accurately, by using automated autocorrelation procedures. These devices can detect fetal heart activity as soon as 10 weeks after conception. Advanced units can even detect bidirectional blood flow, allowing the clinician to evaluate maternal vessels, such as the uterine artery.

Principles of operation

Fetal heart detectors transmit high-frequency sound waves either continuously or in pulses. In continuous-wave (CW) units, a crystal vibrates as an electrical current passes through it, creating and transmitting acoustic energy, while a second crystal detects echoes from structures in the body. In pulsed-Doppler systems, a single crystal alternately transmits periodic bursts of ultrasonic waves and senses the echoed energy. In both systems, the reflected wave is reconverted to an electrical signal that can be used to create an audible sound or a waveform. Ultrasonic heartbeat detectors amplify the audible frequency shift signal of the returned ultrasonic waves and deliver it to speakers or headphones; the heart rate is determined either by measuring the timing of the peaks in the Doppler signal or by using automated autocorrelation procedures.

Operating steps

An acoustic coupling gel is spread over the skin to facilitate the efficient transmission of ultrasound waves into and out of the body. The probe is placed against the mother's abdomen. If the scanned structures are in motion, the frequency of the returning sound waves changes in proportion to the velocity and direction of the moving structures. Fetal heart detectors amplify this audible frequency change, known as Doppler shift, and channel it to speakers or headphones.



Reported problems

Although researchers have yet to establish whether a significant risk exists, there is some concern about whether exposure to ultrasonic energy during diagnostic procedures is safe. Many factors can affect the ability of the unit to detect the fetal heartbeat (i.e., body fat and blood flow can absorb acoustic energy). Since pathogens may be present on the patient's skin, transmission of these organisms to the transducer head commonly occurs.

Use and maintenance

User(s): Physicians, obstetric nurses, community midwives

Maintenance: Biomedical or clinical engineer/ technician, medical staff, manufacturer/servicer

Training: Initial training by manufacturer, operator's manuals, user's guide

Environment of use

Settings of use: Obstetrics (hospital, OB/GYN practices), emergency medicine

Requirements: Battery, uninterruptible power source (recharge batteries), appropriate transducer with gel

Product specifications

Approx. dimensions (mm): 100 x 150 x 200

Approx. weight (kg): 1

Consumables: Batteries, gel

Price range (USD): 350 - 800

Typical product life time (years): 8

Shelf life (consumables): NA

Types and variations

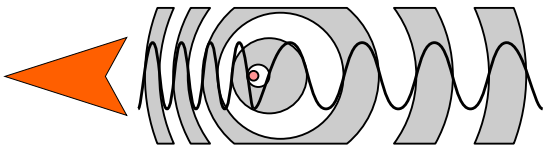
Portable, handheld, tabletop units

WHO. "Fetal Heart Detector, Ultrasonic." From the publication: Core Medical Equipment. Geneva, Switzerland, 2011.

World Health Organization http://www.who.int/medical_devices/en/index.html

Overview of the Doppler Effect

Doppler effect



Change of wavelength caused by motion of the source

An animation illustrating how the Doppler effect causes a car engine or siren to sound higher in pitch when it is approaching than when it is receding. The pink circles represent sound waves.

Doppler effect of water flow around a swan

The **Doppler effect** (or **Doppler shift**) is the change in frequency of a wave (or other periodic event) for an observer moving relative to its source. It is named after the Austrian physicist Christian Doppler, who proposed it in 1842 in Prague. It is commonly heard when a vehicle sounding a siren or horn approaches, passes, and recedes from an observer. Compared to the emitted frequency, the received frequency is higher during the approach, identical at the instant of passing by, and lower during the recession.

When the source of the waves is moving toward the observer, each successive wave crest is emitted from a position closer to the observer than the previous wave. Therefore, each wave takes slightly less time to reach the observer than the previous wave. Hence, the time between the arrival of successive wave crests at the observer is reduced, causing an increase in the frequency. While they are travelling, the distance between successive wave fronts is reduced, so the waves "bunch together". Conversely, if the source of waves is moving away from the observer, each wave is emitted from a position farther from the observer than the previous wave, so the arrival time between successive waves is increased, reducing the frequency. The distance between successive wave fronts is then increased, so the waves "spread out".

For waves that propagate in a medium, such as sound waves, the velocity of the observer and of the source are relative to the medium in which the waves are transmitted. The total Doppler effect may therefore result from motion of the source, motion of the observer, or motion of the medium. Each of these effects is analyzed separately. For waves which do not require a medium, such as light or gravity in general relativity, only the relative difference in velocity between the observer and the source needs to be considered.

1 Developments

Doppler first proposed this effect in 1842 in his treatise "*Über das farbige Licht der Doppelsterne und einiger anderer Gestirne des Himmels*" (On the coloured light of the binary stars and some other stars of the heavens).[1] The hypothesis was tested for sound waves by Buys Ballot in 1845.[2] He confirmed that the sound's pitch was higher than the emitted frequency when the sound source approached him, and lower than the emitted frequency when the sound source receded from him. Hippolyte Fizeau discovered independently the same phenomenon on electromagnetic waves in 1848 (in France, the effect is sometimes called "effet Doppler-Fizeau" but that name was not adopted by the rest of the world as Fizeau's discovery was six years after Doppler's proposal).[3] In Britain, John Scott Russell made an experimental study of the Doppler effect (1848).[4]

2 General

In classical physics, where the speeds of source and the receiver relative to the medium are lower than the velocity of waves in the medium, the relationship between observed frequency f and emitted frequency f_0 is given by:[5]

$$f = \left(\frac{c + v_\mathrm{r}}{c + v_\mathrm{s}}\right) f_0$$

where

c

v_r

v_s

The frequency is decreased if either is moving away from the other.

The above formula assumes that the source is either directly approaching or receding from the observer. If the source approaches the observer at an angle (but still with a constant velocity), the observed frequency that is first heard is higher than the object's emitted frequency. Thereafter, there is a monotonic decrease in the observed frequency as it gets closer to the observer, through equality when it is coming from a direction perpendicular to the relative motion (and was emitted at the point of closest approach; but when the wave is received, the source and observer will no longer be at their closest), and a continued monotonic decrease as it recedes from the observer. When the observer is very close to the path of the object, the transition from high to low frequency is very abrupt. When the observer is far from the path of the object, the transition from high to low frequency is gradual.

If the speeds v_s and v_r are small compared to the speed of the wave, the relationship between observed frequency f and emitted frequency f_0 is approximately[5]

where

$\Delta f = f - f_0$

$\Delta v = v_\mathrm{r} - v_\mathrm{s}$

Proof

Given $f = \left(\frac{c+v_\mathrm{r}}{c+v_\mathrm{s}}\right) f_0$

we divide for c

$f = \left(\frac{1+\frac{v_\mathrm{r}}{c}}{1+\frac{v_\mathrm{s}}{c}}\right) f_0 = \left(1 + \frac{v_\mathrm{r}}{c}\right)\left(\frac{1}{1+\frac{v_\mathrm{s}}{c}}\right) f_0$

Since $\frac{v_\mathrm{s}}{c} \ll 1$ we can substitute the geometric expansion:

$\frac{1}{1+\frac{v_\mathrm{s}}{c}} \approx 1 - \frac{v_\mathrm{s}}{c}$

3 Analysis

To understand what happens, consider the following analogy. Someone throws one ball every second at a man. Assume that balls travel with constant velocity. If the thrower is stationary, the man will receive one ball every second. However, if the thrower is moving towards the man, he will receive balls more frequently because the balls will be less spaced out. The inverse is true if the thrower is moving away from the man. So it is actually the *wavelength* which is affected; as a consequence, the received frequency is also affected. It may also be said that the velocity of the wave remains constant whereas wavelength changes; hence frequency also changes.

With an observer stationary relative to the medium, if a moving source is emitting waves with an actual frequency f_0 (in this case, the wavelength is changed, the transmission velocity of the wave keeps constant -- note that the *transmission velocity* of the wave does not depend on the *velocity of the source*), then the observer detects waves with a frequency f given by

$$f = \left(\frac{c}{c + v_\mathrm{s}}\right) f_0$$

A similar analysis for a moving *observer* and a stationary source (in this case, the wavelength keeps constant, but due to the motion, the rate at which the observer receives waves -- and hence the *transmission velocity* of the wave [with respect to the observer] -- is changed) yields the observed frequency:

$$f = \left(\frac{c + v_\mathrm{r}}{c}\right) f_0$$

These can be generalized into the equation that was presented in the previous section.

$$f = \left(\frac{c + v_\mathrm{r}}{c + v_\mathrm{s}}\right) f_0$$

An interesting effect was predicted by Lord Rayleigh in his classic book on sound: if the source is moving at twice the speed of sound, a musical piece emitted by that source would be heard in correct time and tune, but *backwards*.[6] The Doppler effect with sound is only clearly heard with objects moving at high speed, as change in frequency of musical tone involves a speed of around 40 meters per second, and smaller changes in frequency can easily be confused by changes in the amplitude of the sounds from moving emitters. Neil A Downie has demonstrated [7]how the Doppler effect can be made much more easily audible by using an ultrasonic (eg. 40kHz) emitter on the moving object. The observer then uses a heterodyne frequency converter, as used in many bat detectors, to listen to a band around 40 kHz. In this case, with the bat detector tuned to give frequency for the stationary emitter of 2000 Hz, the observer will perceive a frequency shift of a whole tone, 240 Hz, if the emitter travels at 2 meters per second.

World War II, relies upon Doppler radar to detonate explosives at the correct time, height, distance, etc.

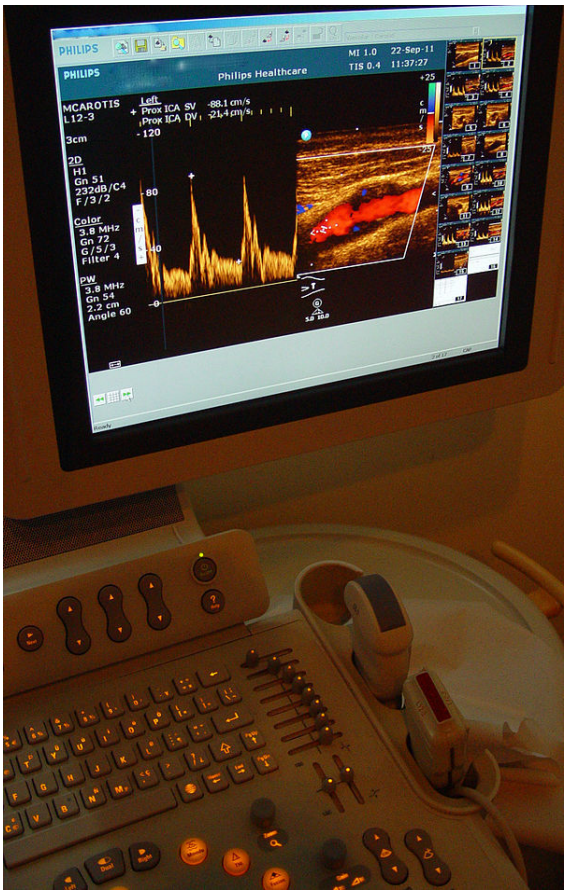
Because the doppler shift affects the wave incident upon the target as well as the wave reflected back to the radar, the change in frequency observed by a radar due to a target moving at relative velocity Δv is twice that from the same target emitting a wave:

$$\Delta f = \frac{2\Delta v}{c} f_0 \,.$$ [9]

4.4 Medical imaging and blood flow measurement

Main article: Medical_ultrasonography § Doppler_ultrasonography

An echocardiogram can, within certain limits, produce



Colour flow ultrasonography (Doppler) of a carotid artery - scanner and screen

an accurate assessment of the direction of blood flow and the velocity of blood and cardiac tissue at any arbitrary point using the Doppler effect. One of the limitations is that the ultrasound beam should be as parallel to the blood flow as possible. Velocity measurements allow assessment of cardiac valve areas and function, any abnormal communications between the left and right side of the heart, any leaking of blood through the valves (valvular regurgitation), and calculation of the cardiac output. Contrast-enhanced ultrasound using gas-filled microbubble contrast media can be used to improve velocity or other flow-related medical measurements.

Although "Doppler" has become synonymous with "velocity measurement" in medical imaging, in many cases it is not the frequency shift (Doppler shift) of the received signal that is measured, but the phase shift (*when* the received signal arrives).

Velocity measurements of blood flow are also used in other fields of medical ultrasonography, such as obstetric ultrasonography and neurology. Velocity measurement of blood flow in arteries and veins based on Doppler effect is an effective tool for diagnosis of vascular problems like stenosis.[10]

4.5 Flow measurement

Instruments such as the laser Doppler velocimeter (LDV), and acoustic Doppler velocimeter (ADV) have been developed to measure velocities in a fluid flow. The LDV emits a light beam and the ADV emits an ultrasonic acoustic burst, and measure the Doppler shift in wavelengths of reflections from particles moving with the flow. The actual flow is computed as a function of the water velocity and phase. This technique allows non-intrusive flow measurements, at high precision and high frequency.

4.6 Velocity profile measurement

Developed originally for velocity measurements in medical applications (blood flow), Ultrasonic Doppler Velocimetry (UDV) can measure in real time complete velocity profile in almost any liquids containing particles in suspension such as dust, gas bubbles, emulsions. Flows can be pulsating, oscillating, laminar or turbulent, stationary or transient. This technique is fully non-invasive.

4.7 Satellite communication

Fast moving satellites can have a Doppler shift of dozens of kilohertz relative to a ground station. The speed, thus magnitude of Doppler effect, changes due to earth curvature. Dynamic Doppler compensation, where the frequency of a signal is changed multiple times during transmission, is used so the satellite receives a constant frequency signal.[11]

4.8 Audio

The Leslie speaker, associated with and predominantly used with the Hammond B-3 organ, takes advantage of the Doppler Effect by using an electric motor to rotate an acoustic horn around a loudspeaker, sending its sound in

a circle. This results at the listener's ear in rapidly fluctuating frequencies of a keyboard note.

4.9 Vibration measurement

A laser Doppler vibrometer (LDV) is a non-contact method for measuring vibration. The laser beam from the LDV is directed at the surface of interest, and the vibration amplitude and frequency are extracted from the Doppler shift of the laser beam frequency due to the motion of the surface.

5 Inverse Doppler effect

Since 1968 scientists such as Victor Veselago have speculated about the possibility of an Inverse Doppler effect. An experiment that claimed to have detected this effect was conducted by Nigel Seddon and Trevor Bearpark in Bristol, United Kingdom in 2003.[12]

Researchers from Swinburne University of Technology and the University of Shanghai for Science and Technology showed that this effect can be observed in optical frequencies as well. This was made possible by growing a photonic crystal and projecting a laser beam into the crystal. This made the crystal act like a super prism and the Inverse Doppler Effect could be observed.[13]

6 See also

- Relativistic Doppler effect
- Dopplergraph
- Doppler cooling
- Fizeau experiment
- Fading
- Photoacoustic Doppler effect
- Differential Doppler effect
- Rayleigh fading
- Redshift

7 References

[1] Alec Eden *The search for Christian Doppler*,Springer-Verlag, Wien 1992. Contains a facsimile edition with an English translation.

[2] Buys Ballot (1845). "Akustische Versuche auf der Niederländischen Eisenbahn, nebst gelegentlichen Bemerkungen zur Theorie des Hrn. Prof. Doppler (in German)". *Annalen der Physik und Chemie* **11**: 321–351. Bibcode:1845AnP...142..321B. doi:10.1002/andp.18451421102.

[3] Fizeau: "Acoustique et optique". *Lecture, Société Philomathique de Paris*, 29 December 1848. According to Becker(pg. 109), this was never published, but recounted by M. Moigno(1850): "Répertoire d'optique moderne" (in French), vol 3. pp 1165-1203 and later in full by Fizeau, "Des effets du mouvement sur le ton des vibrations sonores et sur la longeur d'onde des rayons de lumière"; [Paris, 1870]. *Annales de Chimie et de Physique*, 19, 211-221.

- Becker (2011). Barbara J. Becker, *Unravelling Starlight: William and Margaret Huggins and the Rise of the New Astronomy*, illustrated Edition, Cambridge University Press, 2011; ISBN 110700229X, 9781107002296.

[4] Scott Russell, John (1848). "On certain effects produced on sound by the rapid motion of the observer". *Report of the Eighteenth Meeting of the British Association for the Advancement of Science* (John Murray, London in 1849) **18** (7): 37–38. Retrieved 2008-07-08.

[5] Rosen, Joe; Gothard, Lisa Quinn (2009). *Encyclopedia of Physical Science*. Infobase Publishing. p. 155. ISBN 0-8160-7011-3., Extract of page 155

[6] Strutt (Lord Rayleigh), John William (1896). MacMillan & Co, ed. *The Theory of Sound* **2** (2 ed.). p. 154.

[7] Downie, Neil A, 'Vacuum Bazookas, Electric Rainbow Jelly and 27 other projects for Saturday Science', Princeton (2001) ISBn 0-691-00986-4

[8] The distinction is made clear in Harrison, Edward Robert (2000). *Cosmology: The Science of the Universe* (2nd ed.). Cambridge University Press. pp. 306*ff*. ISBN 0-521-66148-X.

[9] http://www.radartutorial.eu/11.coherent/co06.en.html

[10] Evans, D. H.; McDicken, W. N. (2000). *Doppler Ultrasound* (2nd ed.). New York: John Wiley and Sons. ISBN 0-471-97001-8.

[11] Qingchong, Liu (1999), "Doppler measurement and compensation in mobile satellite communications systems", *Military Communications Conference Proceedings / MILCOM* **1**: 316–320, doi:10.1109/milcom.1999.822695

[12] Kozyrev, Alexander B.; van der Weide, Daniel W. (2005). "Explanation of the Inverse Doppler Effect Observed in Nonlinear Transmission Lines". *Physical Review Letters* **94** (20): 203902. Bibcode:2005PhRvL..94t3902K. doi:10.1103/PhysRevLett.94.203902. PMID 16090248. Lay summary – *Phys.org* (May 23, 2005).

[13] *Scientists reverse Doppler Effect*, physorg.com, March 7, 2011, retrieved 2011-03-18

8 Further reading

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- "Doppler and the Doppler effect", E. N. da C. Andrade, *Endeavour* Vol. XVIII No. 69, January 1959 (published by ICI London). Historical account of Doppler's original paper and subsequent developments.
- Adrian, Eleni (24 June 1995). "Doppler Effect". NCSA. Retrieved 2008-07-13.

9 External links

- Doppler Effect, [ScienceWorld]
- Java simulation of Doppler effect
- Doppler Shift for Sound and Light at MathPages
- Flash simulation and game of Doppler effect of sound at Scratch (programming language)
- The Doppler Effect and Sonic Booms (D.A. Russell, Kettering University)
- Video Mashup with Doppler Effect videos
- Wave Propagation *from John de Pillis.* An animation showing that the speed of a moving wave source does not affect the speed of the wave.
- EM Wave Animation *from John de Pillis.* How an electromagnetic wave propagates through a vacuum
- Doppler Shift Demo - Interactive flash simulation for demonstrating Doppler shift.
- Interactive applets at Physics 2000

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10.1 Text

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Hammer, OrphanBot, Cwy, Joshua0527~enwiki, Aldaron, Aqnguyen, Spectrogram, Hgilbert, Bogsat, Kukini, L337p4wn, Srikeit, Loodog, Even248, JohnWittle, Hvn0413, Stwalkerster, Owlbuster, Basmandude, Iadistar, P199, Cbuckley, Homeycat, Xionbox, Pejman47, Iridescent, Az1568, Tawkerbot2, Chetvorno, JForget, Rodneysmall, BeenAroundAWhile, Ninetyone, GHe, Dgw, ONUnicorn, Johnjohnston, Tzaphkiel, Cahk, MC10, Shadwstalkr, Wikipediarules2221, Odie5533, Michael C Price, Omicronpersei8, Pinky sl, Thijs!bot, Epbr123, Bill Nye the wheelin' guy, Decorian, N5iln, 24fan24, CarrotMan, Headbomb, WilliamH, Marek69, Vertium, James086, Thljcl, Vaniac, Escarbot, Mentifisto, Ialsoagree, AntiVandalBot, Luna Santin, Seaphoto, Jfosorio, Rico402, Peter Harriman, Leuko, MER-C, Andonic, Ojchase, Kirrages, Beaumont, Mr. G. Williams, Acroterion, Magioladitis, Bongwarrior, VoABot II, BanRay, Voloshinov, Xanthym, Twsx, Colinsweet, JaffaCakeLover, PIrish, Cjemmott, Ciaccona, LtHija, Kf4yfd, MartinBot, STBot, Ultraviolet scissor flame, Pbroks13, Wolfpup2, J.delanoy, Mange01, Graeme.e.smith, Numbo3, Peter Chastain, Hans Dunkelberg, Uncle Dick, Ginsengbomb, Mamyles, BrokenSphere, McSly, Jeepday, JonMcLoone, Inomyabcs, Amcrawford, Pdcook, Earnhardt2010, CardinalDan, CSumit, Pleasantville, StrangerCaveDuck, Philip Trueman, TXiKiBoT, Teeteto~enwiki, JayC, Sigelhobit, Jackfork, Psyche825, BotKung, SQL, Falcon8765, Bartlev, Seresin, Thisismyrofl, Thehammer99, Monty845, Pjoef, Logan, SieBot, Yintan, Numenorean7, Flyer22 Reborn, Tiptoety, Radon210, Pratik mallya, Oda Mari, JSpung, Pob-pnuk, Oxymoron83, Antonio Lopez, Sjl0523, Chansonh, BenoniBot~enwiki, Omni-impotent, Kevinbcollins, MarkMLl, Jonmtkisco, Twinsday, ClueBot, Binksternet, The Thing That Should Not Be, LAgurl, Rafaelgarcia, DanielDeibler, CounterVandalismBot, Piledhigheranddeeper, Somno, DragonBot, Excirial, Ottre, Vanisheduser12345, Prietoquilmes, Tnxman307, Thingg, Honeyman1985, Aristoslayer, SoxBot III, XLinkBot, Rreagan007, WikHead, NellieBly, Marchije, Retoo, Addbot, Willking1979, Halosean, Kupolover, Yoenit, Jojhutton, Otisjimmy1, Jncraton, Ironholds, Aboctok, Download, UserDœ, Glane23, AnnaFrance, TStein, Tide rolls, Smartyepp, Beatsbox, Johncolton, Legobot, Luckas-bot, Yobot, 2D, Ptbotgourou, RHB100, THEN WHO WAS PHONE?, IW.HG, N1RK4UDSK714, Backslash Forwardslash, AnomieBOT, Safdarmarwat, Efa, Tucoxn, Etan J. Tal, Piano non troppo, AdjustShift, Yachtsman1, Blakefrigo, Manokarthikeyank, Materialscientist, RatOmeter2, Peavey00, Citation bot, Eumolpo, Bug 202, Xqbot, Blennow, NOrbeck, Pishawbaby, GrouchoBot, Jhbdel, SciberDoc, Prunesqualer, RibotBOT, Mathonius, Amaury, Doulos Christos, Ramshengale, Shadowjams, AbaCal, Joaquin008, Thehelpfulbot, Bajpeyee, Liquidluck, Lookang, TheKing2200, Pinethicket, Jivee Blau, גלבוא, Tom.Reding, Elevant, Wikitanvir, Magickallwiz, Noonz78, Tonymang, Jujutacular, Davidcon, Py4nf, FoxBot, TobeBot, Akshit Goyal, Reaper Eternal, Mean as custard, McSaks, RjwilmsiBot, Pizco2013, NerdyScienceDude, Newty23125, J36miles, EmausBot, Orphan Wiki, Moretim, Incognito-ErgoSum, RA0808, Finicky croc, Editorperson741, Wikipelli, K6ka, Erpert, Thecheesykid, Hhhippo, Hunters33, Jamesreidan911, Hdmicable, Axxonnfire, Donner60, Biegelsen, Llightex, DASHBotAV, ResearchRave, Gwen-chan, ClueBot NG, CocuBot, Chester Markel, Millermk, Upthetrail, Amos ben Avraham, Frietjes, Finniganawakens, Muon, Helpful Pixie Bot, Titodutta, Bibcode Bot, Sxybuksa, Bmusician, Furkhaocean, Hashem sfarim, Ladygaga1010, Tjbird9675, Jackjack9182, J991, Hero123213xdzero, Atyhwey, சஞ்சீ, Donreach, Pwnage22213, Vlasovad, Inkwon22, Matefkr, The Illusive Man, ChrisGualtieri, Thinks planes, Sae123, Harrbearharrbear, Dexbot, Webclient101, NopeJustAlex, Maxrightwing, Lugia2453, Frosty, Reatlas, KaeroDot, Greengreengreenred, Sonicbam3012, KidA 0083, Survival Observer, Sdaeun, Vipinvinu, Dustin V. S., DavidLeighEllis, Jamiebbbbb5, HiThere55, Chibqc, Mikael4u, QuantumMatt101, Jashgdjgakya, Poepkop, Jsharber, JPark234, LaurenGrace05, Bluesteelmagnum, Kellychau123, Tetra quark, UnWeave, Rodolfohidalgo0816, KasparBot, BKNS005 and Anonymous: 764

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Operation and Use of Fetal Doppler

2.9 Fetal Monitor and Fetal Doppler

2.9.1 Clinical Use and Principles of Operation

Fetal monitors document two major functions: 1) the heart rate of the fetus, and 2) the contractions of the mother. A normal fetal heart rate is between 110 to 160 beats a minute. The sound of the beat is usually strong and regular. It is normal to have some changes in the fetal heart rate during labor, but drastic changes in heart rate before or after a contraction may indicate that the fetus is in distress. A fetus with large changes in heart rate may need to be removed from the womb immediately, by Caesarean section.

Fetal monitoring during labor, when it is most commonly applied, has been controversial since its inception. Some claim that fetal monitoring offers a monitoring tool that can reduce fetal mortality and morbidity. Others blame the technology for the large increases in Caesarean sections and the attendant maternal morbidity.

Currently, there are three widely used methods of monitoring the fetal heart rate: Doppler, Surface Electrodes, and a Scalp Electrode.

Surface electrodes are applied directly to the mother's body, typically with adhesive silver-silver chloride electrodes. The surface electrode technique operates identically to a typical electrocardiogram, but with much more complex signal processing to reduce the probability of mistaking a maternal heart beat for a fetal heart beat. The surface electrode approach to measuring the fetal heart rate has the advantages of being not invasive, being applicable at any time during pregnancy, and are very low cost. However, they are subject to artifacts from the maternal heart beat, don't work well with certain fetal positions and can't resolve multiple fetal pregnancies.

For the Doppler technique, a doctor, nurse, or technician applies ultrasound gel to the end of a flat transducer and moves it across the abdomen until a good reflection is found from the heart. The Doppler technique is the most common as it is less prone to artifacts than the surface electrodes and it is equally easy to apply. However, the transducer and accompanying electronics are expensive, may require repositioning during labor, and don't resolve multiple fetal pregnancies well.

The fetal Doppler probe is also used by itself to detect the fetal heart beat. As a hand-held device it can be used from about the end of the first trimester to delivery. The probe produces ultrasonic pressure waves at about 2.5 MHz and hand-held unit produces a sound with heart beat. A typically hand held device has no display or chart. The doctor must time or count the heart beats to determine the fetal heart rate.

The principle of operation of the Doppler probe is the Doppler Effect. If waves of a given frequency are transmitted to a stationary reflector, the reflected waves are of the same frequency as those transmitted. If the reflector is moving towards the transmitter-receiver, the reflected frequency will be higher than the transmitted frequency. In this case, the waves are bounced off the fetal heart. The occurrence of a frequency shift is taken as the presence of a heart beat by the machine.

Scalp electrodes are applied directly on the fetus' head and operate in a manner identical to a standard electrocardiogram. This approach is used only with high-risk patients, if labor is going

Malkin, Robert. "Fetal Monitor and Fetal Doppler: Use and Operation." From the publication: Medical Instrumentation in the Developing World. Engineering World Health, 2006.

very slowly or if the external fetal monitor is not detecting the fetal heart rate. The amniotic sac must be broken to apply the electrode. The scalp electrode gives accurate fetal electrocardiograms. However, it is invasive, opens the amniotic sac for infection, and cannot be easily applied to multiple fetal pregnancies.

The contractions are measured with a strain gage transducer (usually called TOCO) either mounted externally or with a belt around the abdomen.

The fetal heart rate is displayed digitally on many units and in graphic form on a chart. Typical fetal heart rates are in the range of 110 to 160 beats per minute. During contractions the heart rate will decrease and revert to previous levels after the end of the contraction. If there is a delay in the heart rate returning to its previous level it can indicate that there is fetal distress.

2.9.2 Common Problems

User errors are common with fetal monitoring. Incorrect connections of the transducers and incorrect loading of the paper, or the loading of the wrong paper are the most common of these problems. Power supply problems, typically dead batteries, are common with the hand held fetal Doppler devices. Be sure that gel is being used between the ultrasonic transducer and the patient.

The Doppler probe is the most sensitive part of both the handheld and bedside devices. When it breaks no output is heard, even when a stethoscope or fetoscope indicate the presence of a fetal heart beat. You can quickly check the probe operation by gently tapping the probe surface about once per second. If this is not detected, there is certainly a probe problem.

The probe consists of the transducer assembly, the cable, and a multi-pin fixable connector. The cable contains between 5 and 80 separate conductors. The most frequent malfunction occurs as a result of a break in one or more of the cable conductors. Such malfunctions are usually the result of mishandling of the cable or of soaking it with gel. The probe is expensive and typically cannot be replaced in the developing world.

Fortunately, the cable can often be mended. The face of the probe is usually an acoustic lens. It must be handled with care. Do not drop the probe, and avoid scratching the face with sharp objects. Keep the probe assembly clean of oil and gel. Always clean the probe and cable with a tissue or damp cloth, after finishing work.

The surface electrode problems are similar or identical to those discussed in the chapter on electrocardiograms. Poor electrode function will result in no fetal heart beat being reported. Check that the patient electrode connections are clean and in good condition. Check that the leads to the patient are in good condition, that the conductor is not broken, and that there is not a short circuit to the shielding that surrounds the other connectors.

The last most common problem is with the paper. The paper is often installed wrong or the wrong paper is used with the device. Check that the digital heart beat and the paper trace are giving the same reading when you tap the transducer, or apply the electrodes to yourself. The chart recorders themselves are identical to those used for electrocardiograms. Check that chapter for ideas on what could be wrong with a chart recorder.

2.9.3 Suggested Minimal Testing

All of the transducers designed to measure the fetal heart rate can be used to measure your own heart rate. For surface electrodes, you may have to attach one set of electrodes to yourself (as the mother) and one set of electrodes to a friend (as the fetus) in order to satisfy any alarm conditions before operating the machine. The Doppler probe should work when placed on your chest, with the proper gel, near your heart. Check for the accuracy of both the digital display and the paper trace by comparing their output with a measure of your own heart rate from a watch. The two should be within 1 or 2 beats per minute of the correct rate.

For the contraction monitor, stretch the belt, or very gently press on the transducer at a rate of about one gentle push every minute. Use a watch to verify the time between applications. The monitor should reflect your application pressure (approximately) and rate (accurately – about 10%).

If both contraction rate and fetal heart rate are reported accurately, then the device is ready to release to the floor.

Malkin, Robert. "Fetal Monitor and Fetal Doppler: Use and Operation." From the publication: Medical Instrumentation in the Developing World. Engineering World Health, 2006.

6. Diagrams and Schematics of Fetal Doppler

Featured in this Section:

Jezewski, L. et.al. "A Novel Technique for Fetal heart Rate Estimation for Doppler Ultrasound Signal." *BioMedical Engineering OnLine,* Vol. 10, No. 92 (2011). Retrieved from: http://www.biomedical-engineering-online.com/content/10/1/92

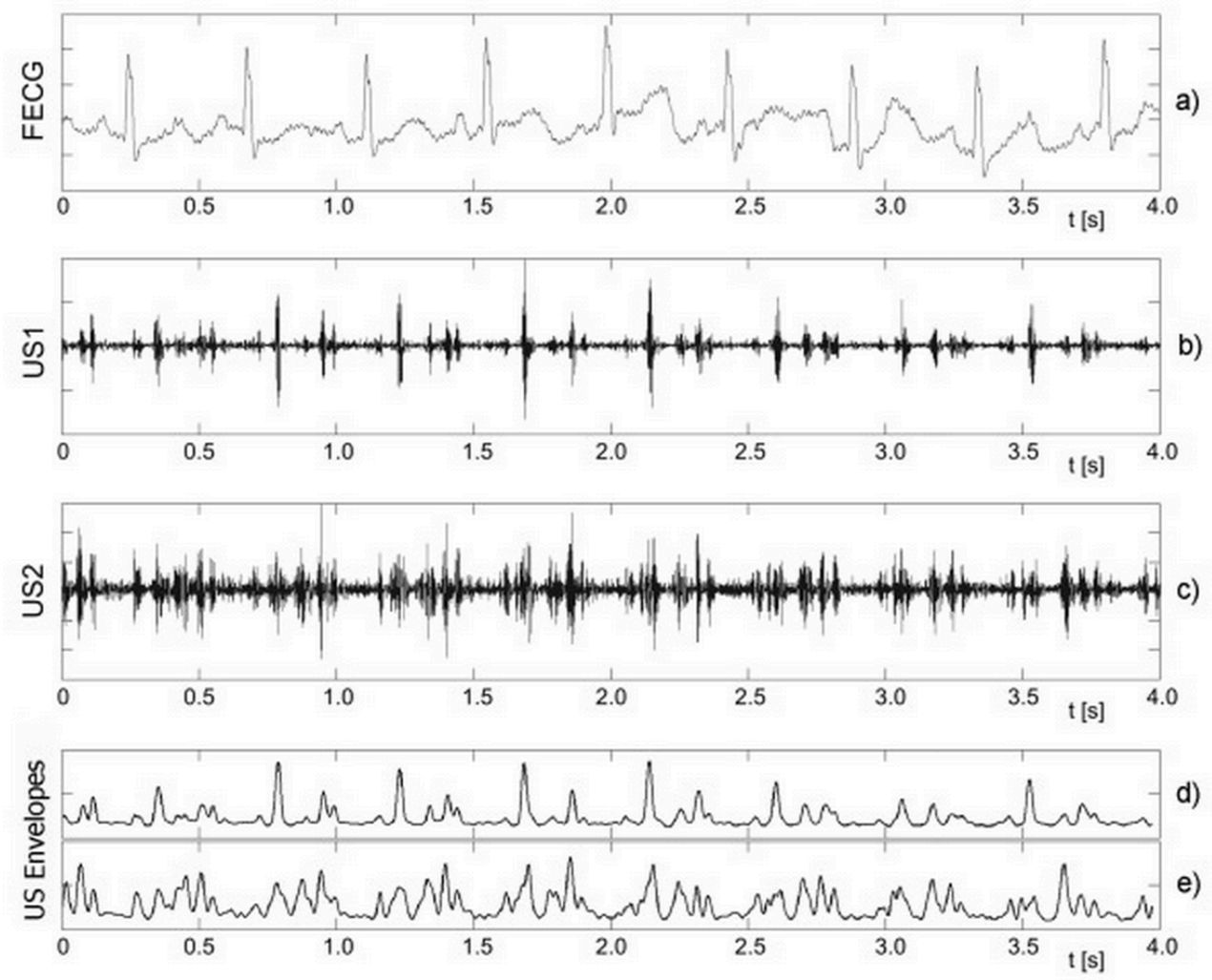
Openstax College. "28.17 Fetal Circulatory System." From the publication: *Biology*. Rice University: 2013, pgs. 1274.

WHO. "Foetal Cardiac Monitor." From the publication: "WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Figure 4: Fetal Heart Activity Signals

Figure 1.

Resolution: **standard** / high



Fetal heart activity signals. Four-second segments of the simultaneously acquired signals: a) direct electrocardiogram from an electrode placed on fetal head, b) and c) two Doppler ultrasound signals from two transducers placed separately but focused on the same fetus. Additionally, the envelopes of both Doppler signals are presented as d) and e). Both US signals differ significantly as for the number of cardiac cycle episodes being observed. The periodicity of Doppler signal is much easier to estimate in US1, but only the FECG signal enables explicit recognition of the timing of fetal cardiac events.

Jezewski *et al. BioMedical Engineering OnLine* 2011 **10**:92 doi:10.1186/1475-925X-10-92

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Jezewski, L. et.al. "A Novel Technique for Fetal heart Rate Estimation for Doppler Ultrasound Signal." BioMedical Engineering OnLine, Vol. 10, No. 92 (2011). Retrieved from: http://www.biomedical-engineering-online.com/content/10/1/92

Figure 5: The Fetal Circulatory System

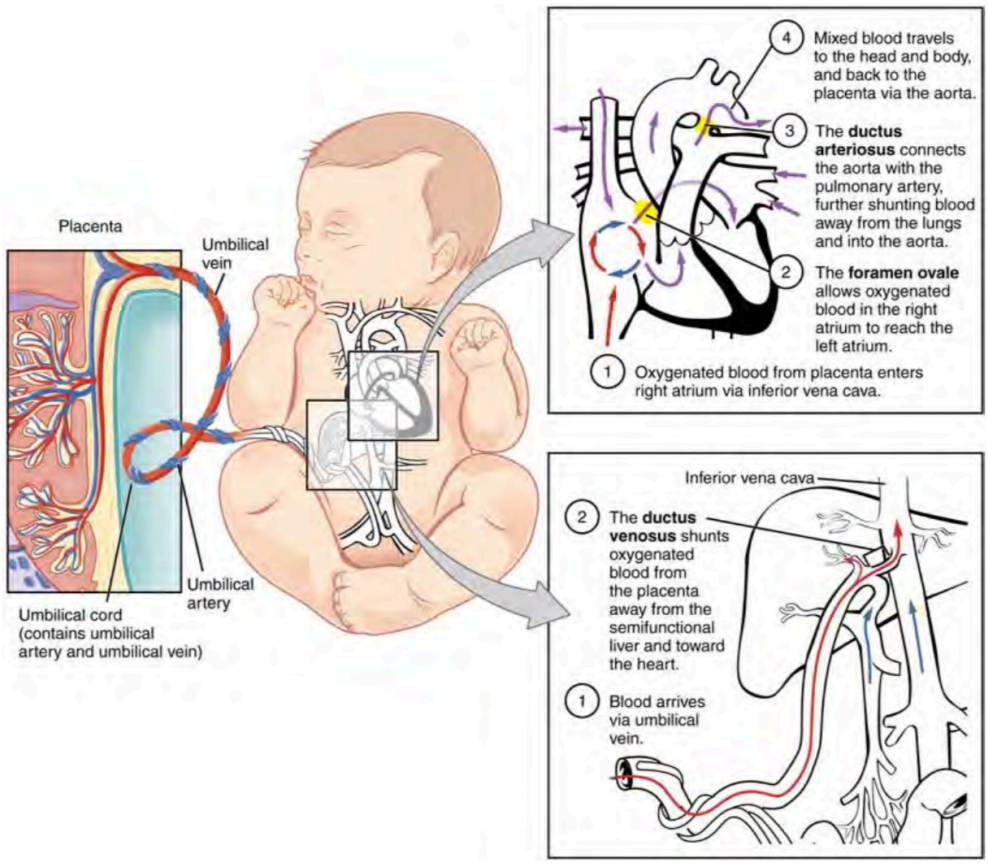

Figure 28.17 Fetal Circulatory System The fetal circulatory system includes three shunts to divert blood from undeveloped and partially functioning organs, as well as blood supply to and from the placenta.

Openstax College. "28.17 Fetal Circulatory System." From the publication: Biology. Rice University: 2013, p. 1274.

Figure 7: WHO Heart Detector Specification

NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	Foetal heart detector
3	Specific type or variation (optional)	
4	GMDN name	Foetal heart detector, ultrasonic
5	GMDN code	35068
6	GMDN category	04 Electro mechanical medical devices 12 Diagnostic and therapeutic radiation devices
7	UMDNS name	Detectors, Fetal Heart, Ultrasonic
8	UMDNS code	11696
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Fetal heart detector, ultrasonic; Monitor, heart rate, fetal, ultrasonic; Monitor, heart sound, fetal, ultrasonic; Monitor, hemic sound, ultrasonic
11	Alternative code/s (optional)	S 11696; S 32624; S 39604; S 32622
12	Keywords (optional)	electrocardiograph (ECG), heart rate, fetal heart
13	GMDN/UMDNS definition (optional)	A device intended to enable audible detection of the foetal heart through the use of ultrasound.
PURPOSE OF USE		
14	Clinical or other purpose	Detect, measure, and display foetal heart activity. The primary purpose of the fetal heart detector is to provide quick reassurance of fetal well-being to both the mother and the healthcare worker. The fetal heartbeat cannot be heard with an obstetric stethoscope until 24 weeks after conception. Ultrasonic fetal heart detectors can easily detect fetal heart sounds throughout the pregnancy, starting as early as 8 weeks.
15	Level of use (if relevant)	Health centre, district hospital, provincial hospital, specialized hospital, General hospital
16	Clinical department/ward(if relevant)	Obstetrics and Gynecology, gynecology physician office
17	Overview of functional requirements	Fetal heart detectors are routinely used by physicians, obstetric nurses, and community midwives to record FHR values. Abnormal readings can quickly alert the healthcare worker to possible complications.
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	Microprocessor controlled equipment. LCD display with visualization of at least fetal heart rate. Integrated fetal heart processing software. Ultrasound working frequency in the range 2MHz -10% to 3MHz +10%. Sensitivity to detect fetal heart beats of at least a 10-12 weeks fetus. At least two high sensitivity equipment compatible probes provided: 2 and 3 MHz. Heart rate measurement range not smaller than 50-210 bpm with resolution not higher than 2 bpm. Audio output reproduction of the fetal heart rate with integrated speaker and with headphones. Audio volume control system integrated. At least 1 of system compatible headphones provided. At least one integrated serial port for PC connection and data transmission. Memory storage capacity of at least 4 hours of working data. Cable for data transmission. 1 pair of spare system compatible headphones. At least 1 bottle of gel for patient application. Carry case for easy transportation.
19	Displayed parameters	**FHR**
20	User adjustable settings	**Controls: volume, power on/off**
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	

WHO. “Foetal Cardiac Monitor.” From the publication: “WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

22	Mobility, portability(if relevant)	Bench top, **handheld models and small tabletop units**
23	Raw Materials(if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Batteries, rechargeable batteries should be considered to save on the cost of replacement batteries. Electrical source requirements: Amperage: _____; Voltage: _____. Compliance with _____ electrical standards and regulations.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Mandatory
26	Sterilization process for accessories (if relevant)	Mandatory
27	Consumables / reagents (if relevant)	
28	Spare parts (if relevant)	specific spare parts to consider in the maintenance of 2 year
29	Other components (if relevant)	
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	10 years
32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Normal conditions
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	None
36	Requirements for commissioning (if relevant)	
37	Training of user/s (if relevant)	user training is required
38	User care(if relevant)	Capable of easy sterilization with both alcohol and chlorine based agents Patient worn straps to be detachable and washable
WARRANTY AND MAINTENANCE		
39	Warranty	2 years full warranty
40	Maintenance tasks	preventive periodical warranty
41	Type of service contract	None
42	Spare parts availability post-warranty	for 8 years
43	Software / Hardware upgrade availability	
DOCUMENTATION		

44	Documentation requirements	service & operation manual
DECOMMISSIONING		
45	Estimated Life Span	10 years
SAFETY AND STANDARDS		
46	Risk Classification	Class B (GHTF Rule 10-1); Class II (USA); Class II (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	
48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 61266:1994 Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting
49	Reginal / Local Standards	JIS T 1506:2005 Ultrasonics -- Hand-held probe Doppler foetal heartbeat detectors -- Performance requirements and methods of measurement and reporting
50	Regulations	**US regulations** 21 CFR part 820 21 CFR section 884.2660 monitor, heart sound, fetal, ultrasonic **JP regulations** MHLW Ordinance No.169 35068000 Ultrasonic foetal heart detector

7. Resources for More Information about Fetal Monitors and Fetal Doppler

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