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