According to the National Vital Statistics Reports data for 2001, electronic fetal monitoring (EFM) is utilized in more than 84% of all births in the United States. The purpose of this device is to screen for early signs of fetal distress and allow for timely clinical intervention. This is accomplished through ongoing assessment of the continuously recorded fetal heart rate (FHR) and by comparison of this data to the trend of uterine activity. Clinicians who are properly educated in and accustomed to interpreting FHR data are able to recognize patterns and changes in the recorded FHR. These observations may reassure the care providers of fetal well-being, alert them to take further measures to assess fetal status, or prompt them to expedite delivery of the fetus.

Technical Aspects of Design and Function

The basic parameters of a state-of-the-art fetal monitor generally include:

- Multiple ultrasound channels, which provides the option for monitoring a twin gestation. The ultrasound transducer is applied externally to the maternal abdomen.
- Ultrasound uses high frequency sound waves. The wavelengths are alternately compressed and stretched (Doppler shift) to detect movement of the fetal heart.
- Gating the transmitted ultrasound carrier on alternate channels prevents interference from one channel to the other.
- The ability to supplant one channel of ultrasound with one channel of direct fetal electrocardiogram (FECG) in an intrapartum setting. The FECG signal is acquired through use of a spiral electrode that is attached to the fetal scalp.
- A uterine activity channel
  - The uterine activity channel will usually accept input from an external sensor known as a tocodynamometer (relative pressure device that senses changes in myometrial tone), or an internal sensor known as an intrauterine pressure catheter (absolute pressure device).
  - Internal pressure devices generally take 2 forms:
    - Fluid-filled catheters that connect to externally fixed strain gauges
    - Electronic, solid-state catheters equipped with pressure sensors

Fetal monitors are equipped with parameters necessary for their intended use, depending upon whether they are to be used before labor (antepartum) or during labor (intrapartum). Antepartum monitors are usually not equipped to perform internal monitoring and are therefore most often utilized in settings such as doctor's offices, triage, and testing areas. If internal monitoring is not required, however, the care provider may choose to utilize an antepartum monitor during the intrapartum.

Intrapartum monitors are equipped to perform the functions necessary for fetal evaluation during labor and delivery. Most intrapartum monitors also offer a variety of maternal monitoring options. Many systems include
the ability to interface blood oxygen saturation and non-invasive blood pressure monitors to the fetal monitor by means of RS-232C serial port and configurable communications protocols. Such interfaces allow the maternal parameters from these external devices to be recorded on the same trend recording with the fetal parameter data. Even in the presence of interfaces to external monitors, manufacturers now include maternal monitoring parameters within the fetal monitor itself. These include integrated non-invasive blood pressure, blood oxygen saturation, and 3-lead maternal ECG.

Currently, all fetal monitors include some form of thermo-graphic trend recorder for documentation purposes, even if the recorder is only offered as an option. While the future of EFM is moving inevitably toward the electronic medical record, automatic recording and archiving of the fetal strip chart still remains in the realm of separate clinical information and archive systems. To support these systems, fetal monitors incorporate a variety of communication mechanisms, including various export protocols and baud rates for RS232C serial communication and both proprietary and non-proprietary networking schemes.

**Device Management**

Device management is determined by the nature of the device and how it is utilized. In some settings, fetal monitors are moved from room to room as clinical need arises. Most fetal monitors, however, are not considered portable and do not come equipped with a carry handle. Due to its size and weight, the fetal monitor is best mobilized using a cart with accommodating dimensions. Carts that would otherwise be considered stable may become top-heavy when the fetal monitor is installed at a height that is comfortable for working and viewing. Stability while in motion, and particularly while traversing seams in doorways or elevators is paramount. This usually requires larger diameter casters or wheels.

Cable management is also a concern in a mobile configuration. Where clinical or central information systems are used, connections must be made to wall plates to facilitate data communications. Strain-relief of data communications cables is a priority, as carts may be moved prior to the disconnection of cables. The communications cables may stay with the unit with strain-relief at the cart or the cable may stay in the room if the connect/disconnect is made at the monitor, in which case strain-relief at the wall plate is appropriate.

Management of the monitor’s transducers is also a concern in the mobile environment. Transducer hangers or built-in transducer storage should be utilized to prevent running over transducers and cables. As most transducers are interchangeable between monitors (within brand), strain relieving of transducers is often not an option.

If the fetal monitor is permanently installed in a credenza or cabinet at the bedside, utility and positioning are most important. Points to consider when the equipment is in service include:
- Can the monitor be used effectively?
- Is there adequate access to all control panels (front, side and rear)?
- Are the displays visible to the clinicians from the position they will be in when using the equipment?
- Can alerts/alarms be heard?
- Does the monitor need to slide out on moving shelf?
- Is there adequate ventilation?
- Will transducer cables draped from the unit to the patient become problematic (eg, trip hazard)?

For aesthetic purposes, it is often desired that the cabinet doors remain closed when the device is not in use, which begs the following considerations:
- Will the doors close properly if the transducers are left plugged in?
- Is there adequate access to remove and replace the device should the need arise?
- Is there adequate access to all connector panels (front, side and rear)?
Is there adequate transducer storage?

Is there adequate storage for consumables?

Transducers and communications cables are often not treated with necessary care and should, therefore, be inspected regularly for cracks or failures in the integrity of their housings, strain and bend reliefs, and cables. The exterior of the monitor and transducer housings should be cleaned regularly in accordance with the manufacturer’s instructions. Note that many manufacturers explicitly specify and/or exclude many common cleaning agents. The manufacturer’s service or operator’s manual should be consulted.

Most monitors do not consume sufficient electrical power to require extraordinary measures in regard to thermal dissipation. However, where cooling fans are integrated into the device, exterior clearance should be maintained at installation to allow adequate airflow to the fan. Compressed air may be used to remove accumulations of dust during regular preventive maintenance.

The thermal print heads used in the data recorders collect dust and debris from the air and from the monitor paper. Should printing become spotty or dim, clean the print head in accordance with the manufacturer’s recommendations. Thermal print heads require thermally sensitive paper. Most manufacturers dictate minimum storage requirements for such consumables. This includes temperature (to prevent degradation of the thermal properties of the paper) and humidity (to prevent warping or skewing of the standard paper pack, which can lead to paper-jam or misalignment). These same requirements become extremely important when storing fetal data recordings for long-term record management. Improperly stored records may fade or darken over time, rendering them unreadable.

**Regulations**

Most fetal monitors are considered to be Class II Devices by the FDA’s Center for Devices and Radiological Health (CDRH). Class II medical devices are subject to the same general controls as Class I devices and also to Special Controls. Special Controls required by Class II devices grant the FDA more regulation to assure their safety and effectiveness. Special controls may include particular labeling requirements, mandatory performance standards, and post-market surveillance.

Most Class II devices, including fetal monitors, require Pre-market Notification 510(k) clearance before they can be marketed in the United States. In general, fetal monitors are manufactured to comply with the most rigorous medical device regulatory standards in the countries where they are marketed. Most bear the CE mark. In addition, most are listed with independent and standardized testing agencies such as Underwriters Laboratories (UL).

**Risk Management**

Fetal monitors require no extraordinary measures for their safe and effective use. However, it is necessary that clinicians who use the equipment be properly trained in their operation. The presence of a fetal monitor in the room does not replace the skill of a clinician. The data yielded by this device becomes useful information when incorporated into the entire clinical picture by a care provider who is educated in and familiar with EFM.

Risks can be minimized through a comprehensive program of:

- Ongoing education for all clinicians
- Regular service training for biomedical personnel
- Proper installation and cable management
- Proper and timely preventive maintenance
- Regular device and transducer inspection
- Safety testing (patient leakage, unit leakage, HIPOT) per institution biomedical department protocol, and whenever the unit is opened for service
- Proper cleaning and disinfection after each use

**Common Issues and Solutions**

EFM has certain known technologic limitations. While most basic EFM courses attended by clinicians address this issue, the information is often received at a time in their professional education when clinicians are more focused on learning the basics of FHR pattern interpretation than details of equipment operation. It is often not until these limitations affect interpretation of the data that clinicians seek greater knowledge of the workings of their monitor.

Some limitations of EFM are commonly encountered and recognized in the clinical arena. For example, in order to monitor in a manner that is non-invasive to both the patient and the fetus, external sensors (ultrasound transducer and tocodynamometer) are applied to
“Factors such as maternal positioning, movement, and abdominal size and shape; fetal position and activity...can affect transducer placement and the frequency of readjustment required.”

Other common issues relate to the mode of monitoring utilized. External monitoring has some inherent limitations. In processing the signal from the ultrasound transducer, the monitor must convert information about movement of the fetal heart into a FHR. The waveforms created by the Doppler shift are filtered and then put through a process of autocorrelation (successive comparison to identify similarities) to form a template against which all incoming waveform data is compared. It is from these correlations that the FHR is subsequently calculated. The determined FHR is continuously averaged with preceding and following data before being plotted on the fetal strip.

Clinicians are often concerned with assessing "short-term variability." This is a clinical term that refers to fluctuations in the FHR that occur from one beat to the next and are representative of normal sinus rhythm. When the FHR is monitored externally, this information cannot be assessed from the fetal strip chart. As explained above, the trend of the FHR has been processed and average and, therefore, does not represent information about individual intervals between beats of the fetal heart. If clinically indicated, this data can be obtained through use of a spiral electrode (internal monitoring).

External monitoring is also limited by range. When the FHR reaches the upper or lower limits of the monitor’s capability or changes abruptly, the FHR may be recorded on the fetal strip chart at either half or double the actual rate. This is known as "half-counting" and "double-counting." It is important to know that the audible signal from the monitor will continue to provide the actual FHR data. Half-counting and double-counting do not occur when internal monitoring is utilized.

Another instance during external monitoring when the limits of the monitor’s range may be challenged, or abrupt changes in the fetal heart rate may occur, is when a dysrhythmia is present. In this case, it is usually best to use an alternate method to assess the FHR (such as a fetoscope, stethoscope, or M-mode ultrasound). Depending on the type of dysrhythmia, internal monitoring may or may not provide a clinically useful signal.

Inadvertent acquisition of maternal heart rate can occur when external or internal monitoring is in use. If not positioned effectively, it is possible for the ultra-
sound transducer to sense pulsation of the maternal vessels rather than the intended FHR. The spiral electrode is also capable of acquiring a maternal signal. If this internal monitor is inadvertently applied to maternal tissue or to an expired fetus, the monitor may calculate the maternal ECG. These situations can be recognized quite readily by comparison of the palpated maternal pulse to the audible signal from the fetal monitor. Some monitors offer software that checks for this occurrence.

**Training and Service Equipment**

Most manufacturers offer some type of equipment training (in person, video, and/or computer-based) for clinical and biomedical personnel. Although fetal monitors have been in the marketplace for over 30 years, the nuances of operation, connection, and performance from one manufacturer to another and from one generation of monitors to the next make training a necessity. Operator manuals are mandated by most regulatory agencies. These should be maintained in proximity of the department where the device is used. Service manuals can be obtained from the manufacturer (sometimes at extra cost) and kept in the biomedical department.

No extraordinary test and service equipment is required to maintain fetal monitors. Standard electronic and biomedical safety test equipment and hand tools are usually adequate. Some manufacturers may provide, or offer for sale, simulators that will enhance or expedite functional testing. Most manufacturers also use proprietary input (transducer) connectors. Occasionally, manufacturers may utilize special fasteners in their design, indicating that there are no user-serviceable parts.

**Future Development of the Device**

One potential development that has been progressing in various forms over the years is an automated means for interpreting EFM data. Discrepancies in the terminology utilized for identification of FHR patterns and the subjective nature of pattern interpretation has been an ongoing issue in EFM. Computerized assessments have been integrated into some fetal monitors and may become more widely utilized in the future.

As mentioned previously, EFM functions well as a screening tool, but it is important to understand that the information it provides is not diagnostic. It is an indirect indicator of fetal oxygenation and acid-base status. A reassuring FHR tracing is indicative of a well-oxygenated fetus. A nonreassuring tracing, however, yields false positive results nearly 90% of the time (Low, Victory, Derrick, 1999). When a non-reassuring tracing is encountered, it is first necessary to determine whether emergent delivery is required. If not, then further investigation of fetal status is required to allow for appropriate intervention.

Until the mid ‘90s, fetal scalp blood sampling was commonly utilized as an adjunct method of fetal assessment during labor when a nonreassuring/nonemergent FHR pattern was present. A lancet was used to make a small incision in the fetal scalp and blood was collected into a capillary tube. The pH level of the sample determined whether the fetus was believed to be acidotic. As this method of assessment provided only a snapshot view of fetal status, the process often had to be repeated as labor continued. The performance of this procedure declined after studies (Clark, Gimovsky, Miller, 1984) demonstrated that, in many instances, clinically similar findings could be accomplished by manual stimulating the fetal head and observing for resulting changes in the FHR.

**For More Information...**

**Related Resources**


**Manufacturer Web Sites**

GE Medical, www.gemedicalsystems.com

Philips Medical Systems, www.medical.philips.com
In 2000, the FDA approved the use of fetal arterial oxygen saturation (FSpO2) monitoring. This is a direct, real-time method of assessing fetal oxygenation during labor when a nonreassuring/nonemergent FHR pattern is noted. FSpO2 data may be displayed on a stand-alone monitor or sent to the fetal monitor through a serial (RS-232C) interface. This technology is also offered as an optional feature in some fetal monitors designed for intrapartum use. When integrated into the fetal monitor, the FSpO2 value (expressed as a percentage) may be displayed on the strip chart recording and/or on the electronic display.

Fetal monitors equipped with FSpO2 are considered to be FDA PMA Class III devices. A PMA is a rigorous application process that includes the implementation of defined and qualified clinical studies and review by the FDA and an FDA Advisory Committee. Approval is based upon review of scientific evidence qualifying the device as safe and effective.

The future of this technology is yet unknown. In its Committee Opinion on Fetal Pulse Oximetry (2001), the American College of Obstetricians and Gynecologists (ACOG) stated that it “currently cannot endorse the adoption of this device in clinical practice” due to lack of sufficient evidence that it improves outcomes. More studies of this technology were thus initiated and it remains to be seen whether this technology will be more widely adopted into clinical practice. A potential benefit of the study of FSpO2 is improved correlation between fetal oxygenation and recognized FHR patterns. Better understanding of this relationship would improve EFM, whether or not FSpO2 is utilized.

References