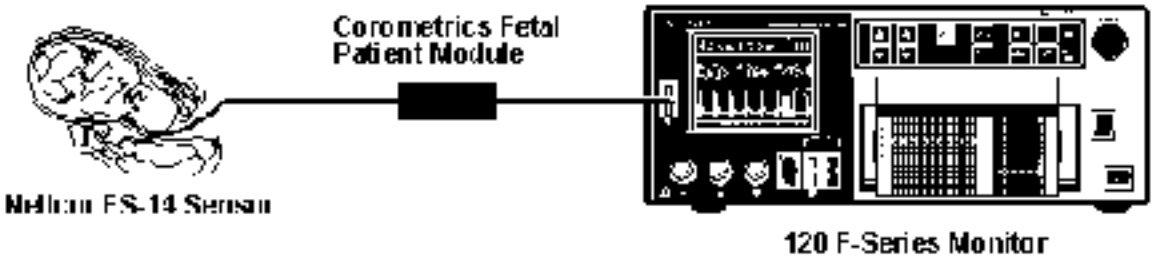
Corometrics 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen Saturation Monitoring - P000016



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Corometrics 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen Saturation Monitoring
Manufacturer: GE Medical Systems Information Technologies
Address: 61 Barnes Park Road North, Wallingford, CT
Approval Date: February 9, 2001
Approval Letter: **http://www.fda.gov/cdrh/pdf/p000016a.pdf**

What is it? This device is an electronic maternal/fetal monitor used during labor, with a new monitoring feature that continuously measures fetal oxygen saturation ("FSpO2"), the amount of oxygen in the blood of the fetus. The monitor also measures the fetus' heart rate and the contractions of the mother's uterus (womb). To make this new FSpO2 measurement, the Corometrics 120 F-Series monitor uses technology from Mallinckrodt's recently approved OxiFirst™Fetal Oxygen Saturation Monitoring System http://www.fda.gov/cdrh/mda/docs/p990053.html

How does it work? The OxiFirst™ sensor (Nellcor FS-14 sensor, in diagram above) is inserted through the mother's birth canal into the uterus (womb), where it rests against the cheek or temple of the fetus. Two light emitting diodes (LEDs) in the sensor shine light onto the skin of the fetus. The light reflects back to a photodetector (light-measuring device) in the sensor, and the photodetector signal is electronically processed to produce the FSpO2 measurement. The monitor can measure the oxygen saturation because blood rich in oxygen scatters back different-colored light than blood low in oxygen. The FSpO2 value is displayed continuously as a percentage on the monitor's front panel, along with other

measurements. The doctor removes the OxiFirst™sensor just before the baby is delivered.

When is it used? The OxiFirst™ sensor may be used with this monitor if the fetal heart rate pattern shows abnormalities that indicate the fetus may not be getting enough oxygen. It is intended for use only on single (not multiple) fetuses of at least 36 weeks of pregnancy, where the mother's water has broken, and the fetal head is in the normal, head-down, position for delivery. ;

What will it accomplish?

- Fetal heart rate (FHR) patterns are an indirect measure of how much oxygen is in the fetus' blood. For the past 30 years, clinicians have used FHR evaluation as the primary way to evaluate how the fetus is doing during the stresses of labor. Adding information about fetal oxygen levels with this new monitor may help the doctor to better understand the condition of the fetus during labor.
- In the pivotal clinical study that supported approval of the OxiFirst™ sensor, the overall rate of cesarean deliveries was unchanged whether or not the new monitor was used. However, use of the monitor did reduce cesarean deliveries for a subgroup of patients who were diagnosed with a non-reassuring fetal status. This indicates that clinical understanding of fetal condition during labor improved with the use of this new monitor. FDA has required the sponsor to conduct a post approval study to see how cesarean delivery rates are affected as the monitor is introduced into general clinical practice

When should it not be used? Use of the fetal oxygen saturation monitoring feature is not recommended in patients with any of the following conditions:

- Documented or suspected placenta previa, in which the membrane that nourishes the fetus has developed abnormally in the lower part of the uterus (womb) near the birth canal.
- Need for immediate action, such as changing the position of the fetus with forceps, or the need for immediate delivery.

Additional information:

- Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p000016.html
- The SSED and labeling for the Mallinckrodt PMA (P990053) for the OxiFirst™Fetal Oxygen Saturation Monitoring System may be viewed at the following website: http://www.fda.gov/cdrh/pdf/p990053.html
- FDA's Office of Women's Health web site : http://www.fda.gov/womens/default.htm

(Updated 7/11/01)