Information for Prescribers

MANUAL P/N 2004435-001 REV. A

GE Medical Systems
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Revision A: 02-01

⚠ **CAUTION:** In the United States of America, Federal Law restricts this device to sale by or on the order of a physician.

NOTICE: Purchase of a 120 Series Monitor confers no express or implied license under any Nellcor Puritan Bennett patent to use the 120 Series Monitor with any fetal oximetry sensor that is not manufactured or licensed by Nellcor Puritan Bennett. The Nellcor OxiFirst Fetal Oxygen Saturation Monitoring System is covered by one or more of the following U.S. Patents and foreign equivalents: 4,621,643; 4,700,708; 5,228,440; 5,247,932; 5,377,675; 5,421,329; 5,660,567; 5,782,237; 5,743,260; and Des. 384,643.

Contents

Chapter 1

Introduction and Background

The 120 F-Series system continuously monitors intrapartum fetal oxygen saturation ($FSpO_2$) and is indicated **as an adjunct** to fetal heart rate (FHR) monitoring in the presence of a non-reassuring fetal heart rate pattern. It should only be used after maternal membranes have ruptured and on a singleton fetus in vertex presentation with a gestation age greater than or equal to 36 weeks. Refer to "Chapter 4, Clinical Study" .

This chapter provides the following information:

Introduction

The Nellcor clinical study, which was used to demonstrate safe and effective use, was performed using the Nellcor N-400 Monitor, the Nellcor Fetal Patient Module, and Nellcor FS14 Fetal Oxygen Sensors. The clinical data provided in this document was taken from the Nellcor clinical study (September 1999, with permission from Mallinckrodt, Inc.). **The results of the Nellcor study apply to the $FSpO_2$ feature included in the 120 F-Series Monitor.**

System Components

The fetal oxygen saturation monitoring system comprises:

- Corometrics 120 F-Series Maternal/Fetal Monitor
  (with integrated Nellcor FM-401 module)
- Corometrics Fetal Patient Module
  (a modified Nellcor patient module to connect to the monitor)
- Nellcor OxiFirst Fetal Oxygen Sensor (Series FS14)

The Corometrics 120 F-Series Monitor is manufactured by:

GE Medical Systems *Information Technologies.*
Milwaukee, Wisconsin 53223

Device Description

The 120 F-Series Monitor includes an integrated fetal oxygen saturation monitoring system used during labor and delivery to measure fetal oxygen saturation ($FSpO_2$).

The sensor is inserted transcervically into the mother's uterus and is positioned against the cheek or temple of the fetus. Two light emitting diodes (LEDs) located within the sensor shine light into fetal tissue and back-scattered light is received by an adjacent photodetector.

Hardware and software within the monitor process the signal to determine the oxygen saturation of the fetus and assess the quality of the optical signals. The values of saturation and optical signal quality are displayed on the monitor's front panel (along with other indicators), are printed on the monitor's strip chart paper, and are communicated to optional external equipment via serial ports.

The fetal oxygen saturation monitoring system consists of three components:

- Corometrics 120 F-Series Maternal/Fetal Monitor
- Corometrics Fetal Patient Module
- Nellcor OxiFirst Fetal Oxygen Sensor (Series FS14)

A diagram of the fetal oxygen saturation monitoring system in context is shown in Figure 1-1.

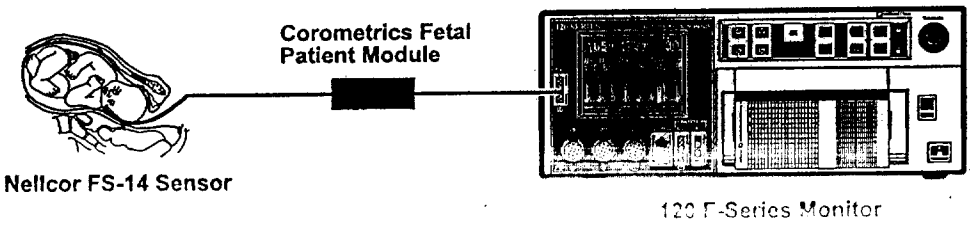

Figure 1-1. 120 F-Series Fetal Oxygen Saturation Monitoring System

The fetal sensor is inserted into the mother's uterus following spontaneous or artificial rupture of amniotic membranes. The sensor rests against the fetal face during monitoring and it does not penetrate the fetal skin. It is supplied sterile, packaged in a pouch for single use only. The sensor body is molded around the optical components and is made from a soft plastic with no sharp or abrasive surfaces.

The 120 F-Series Monitor automatically calibrates itself each time it is powered on, at periodic intervals thereafter, and whenever a new sensor is connected. The pulse indicator on the monitor display indicates the relative pulse amplitude of the photoplethysmogram.

$FSpO_2$ Display Area

If $FSpO_2$ is monitored while $MSpO_2$ is inactive, $FSpO_2$ displays underneath uterine activity. Refer to Figure 1-2. However, when dual SpO_2 monitoring occurs, $MSpO_2$ displays here while $FSpO_2$ information moves down next to the waveform directly below $MSpO_2$. Any waveform labels (speed, lead, scale) move to the left of the $FSpO_2$ area. Refer to Figure 1-3.

$FSpO_2$ Status Icons

A status icon may appear above the $\%FSpO_2$ value to provide additional information. Usually the message area will be blank; however, the icons representing **Sensor Unplugged**, **Sensor Lifted**, or **Searching for Fetal Pulse** can appear.

Sensor Unplugged

This icon appears whenever: the $FSpO_2$ sensor is disconnected from the fetal patient module cable; when the fetal patient module cable is disconnected from the monitor; or when an invalid $FSpO_2$ sensor is connected to the fetal patient module cable.

Sensor Lifted

This icon appears whenever the sensor is not making adequate contact at the sensor site on the fetus.

Pulse Search

This icon is displayed when the monitor is attempting to locate the fetal pulse. During successful monitoring, the message area is blank.

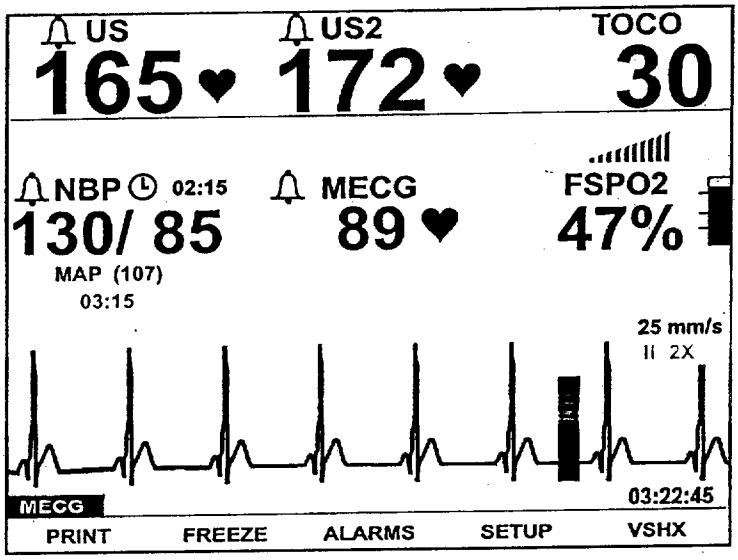

Figure 1-2. Display of Fetal Pulse Oximetry

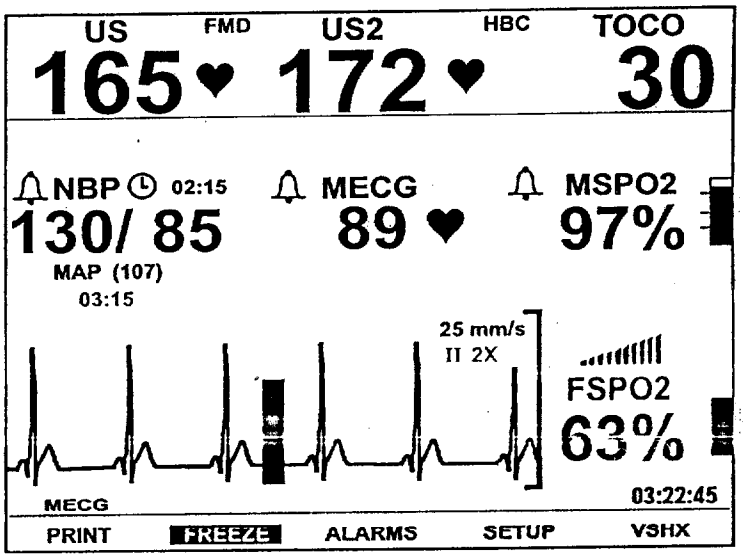

Figure 1-3. Simultaneous Display of Fetal and Maternal Pulse Oximetry

$FSpO_2$ Theory and Principles of Operation

The technology used in the 120 F-Series Monitor, like that of other pulse oximetry monitors, is based upon two principles. The first is that oxyhemoglobin (O_2Hb) and deoxyhemoglobin (HHb) differ in their ability to absorb light according to wavelength. The second is that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulsatile flow produced by each cardiac cycle.

For your notes

Chapter 2

Indications, Contraindications, Warnings, and Precautions

This chapter contains safety information related to $FSpO_2$ monitoring. For general equipment safety information on the 120 Series Monitor, refer to the "120 Series Operator's Manual".

This chapter provides the following information:

$FspO_2$ Intended Use/Indications

NOTE: For overall 120 Series Monitor indications for use, refer to "120 Series Operator's Manual".

The 120 F-Series system continuously monitors intrapartum fetal oxygen saturation ($FSpO_2$) and is indicated **as an adjunct** to fetal heart rate (FHR) monitoring in the presence of a non-reassuring fetal heart rate pattern. It should only be used after maternal membranes have ruptured and on a singleton fetus in vertex presentation with a gestational age greater than or equal to 36 weeks.

$FSpO_2$ Contraindications

CONTRAINDICATION

PATIENT CONDITIONS—Use of the $FSpO_2$ feature is contraindicated in patients with any of the following conditions:

- Documented or suspected placenta previa
- Ominous FHR pattern requiring immediate intervention
- Need for immediate delivery (unrelated to FHR pattern), such as active uterine bleeding.

$FSpO_2$ Warnings

WARNINGS

INDICATIONS FOR USE—The 120 F-Series System continuously monitors intrapartum fetal oxygen saturation ($FSpO_2$) and is indicated as an adjunct to fetal heart rate(FHR) monitoring in the presence of a non-reassuring heart rate pattern. It should only be used after maternal membranes have ruptured on a singleton fetus in vertex presentation with a gestational age greater than or equal to 36 weeks.

ELECTROSURGICAL EQUIPMENT—Do not use the $FSpO_2$ feature while using an Electrosurgical Unit (ESU). Remove the fetal oxygen sensor from the mother and fetus before using an ESU. An improperly grounded ESU can cause surface skin burns on the fetus if both the monitor and an ESU are used together.

EXPLOSION HAZARD—Do not use the monitor in the presence of flammable anesthetics or inside an oxygen tent. Such use may constitute a fire or explosion hazard.

WATER BIRTHS—Do not use the monitor to directly monitor patients during water births, in whirlpool or submersion water baths, during showers, or in any other situation where the mother is immersed in water. Doing so may result in electrical shock hazard.

INTERFACING OTHER EQUIPMENT—Monitoring equipment must be interfaced with other types of medical equipment by qualified biomedical engineering personnel. Be certain to consult manufacturer's specifications to maintain safe operation.

MATERNAL INFECTIONS—Do not use the $FSpO_2$ feature in women with active genital herpes or other infection precluding internal monitoring. Insertion of the fetal oxygen sensor in these women may result in transmission of pathogens to the fetus.

MATERNAL HIV—Do not use the $FSpO_2$ feature in women who are seropositive for human immunodeficiency virus (HIV). Insertion of the fetal oxygen sensor in these patients may result in fetal exposure to the virus.

MATERNAL HEPATITIS—Do not use the $FSpO_2$ feature in women who are seropositive for Hepatitis B and/or Hepatitis E. Insertion of the fetal oxygen sensor in these patients may result in fetal exposure to these antigens.

$FSpO_2$ Precautions

Clinical Use Precautions

PRECAUTIONS

TRAINING—Physicians and other licensed practitioners who use the $FSpO_2$ feature should have demonstrated expertise in determining fetal presentation and head position, and should be proficient in fetal scalp electrode and intrauterine pressure catheter placement.

DILATION AND ROM—Do not attempt to insert the sensor if the patient is dilated less than 2 cm or if amniotic membranes have not ruptured. Doing so may result in erroneous $FSpO_2$ measurements and/or patient injury. Do not attempt to rupture amniotic membranes with the sensor. Doing so may result in patient injury and/or sensor malfunction.

OPERATIVE/ASSISTED DELIVERY—Do not leave the fetal oxygen sensor in place during vacuum extraction, forceps delivery, or Cesarean delivery. Doing so may result in patient injury. Remove the fetal sensor before commencing any form of operative delivery.

STYLET USE—Never attempt to reinsert a stylet into the sensor cable chamber once it has been completely removed during sensor placement. Doing so may tear the stylet channel and expose the stylet which might result in serious patient injury. Sensor adjustments can be accomplished without the stylet.

SENSOR ACCURACY—Suboptimal sensor placement, excessive vernix, fetal hair, or motion artifact (due to uterine contractions or maternal position changes), may result in no $FSpO_2$ values being displayed, or erroneous $FSpO_2$ values.

FETAL BRADYCARDIA—If the fetal heart rate slows during vaginal exam or sensor insertion, stop the procedure. Do not proceed with sensor placement as this can cause a reflex bradycardia stimulus. Wait for the fetal heart rate to return to the previous range before proceeding.

DEFIBRILLATION—Do not leave the fetal oxygen sensor in place during defibrillation. Even though the sensor **manufacturer's package labeling indicates that the sensor may be left in place during defibrillation, the sensor should be removed when used with a Corometrics monitor.**

MRI EQUIPMENT—Do not use a monitor or fetal oxygen sensor during MRI scanning. Strong magnetic fields may affect the device causing erroneous $FSpO_2$ measurements.

Technical Precautions

PRECAUTIONS

SENSOR TYPE—Do not attempt to use any sensor other than sterile, single-use Nellcor Fetal Oxygen Sensors (FS14 Series) with a Corometrics Monitor. Use of any other Nellcor oximetry sensor or any sensor from another manufacturer may result in system malfunction, erroneous $FSpO_2$ measurements, and/or patient injury.

DAMAGED EQUIPMENT—Do not use a damaged sensor. Doing so may result in patient injury, sensor malfunction, and/or erroneous $FSpO_2$ measurements.

CLEANING/STERILIZATION—Never attempt to clean, reprocess, or resterilize fetal oxygen sensors. Doing so may result in sensor malfunction, erroneous $FSpO_2$ measurements, and/or infection or potential tissue injury to mother and/or fetus. Each fetal oxygen sensor is supplied (by Mallinckrodt, Inc.) as a sterile, single-use, disposable device.

SERVICING—Do not remove the monitor cover or attempt to service this monitor yourself. Only qualified service personnel should attempt servicing this equipment. Refer servicing to an *Information Technologies* Service Representative.

SENSOR IMMERSION—Do not immerse the sensor completely in liquid (the plug is not waterproof). Immersion of the sensor plug in liquid may result in sensor malfunction and/or erroneous $FSpO_2$ measurements.

PATIENT MODULE IMMERSION—Do not immerse the fetal patient module completely in liquid— the unit is not waterproof. Fluid damage to the module may result in malfunction and/or erroneous $FSpO_2$ measurements.

Chapter 3

Adverse Events

Reports of any adverse events were collected from all mothers and babies enrolled in the Pilot (179) and Randomized Phases (1011) of the Nellcor N-400 Fetal Oxygen Saturation System trial (N=1190).

This chapter provides the following information:

Neonatal Deaths

No neonatal deaths occurred within 24 hours of birth in the Pilot Study or the Randomized Controlled Clinical Trial. There were five neonatal deaths at later times following birth. Three neonatal deaths were in the FHR + $FSpO_2$ group. The causes of death included two congenital cardiac anomalies and one cerebral infarction. Two neonatal deaths occurred in the FHR-Alone group; both babies had congenital cardiac anomalies. There were no maternal deaths.

Adverse Events Observed in Maternal and Fetal/ Neonatal Patients

Thirty-three percent (33%) of the maternal population experienced one or more adverse events in the FHR + $FSpO_2$ group, versus 30% in the FHR-Alone group. The most frequently reported adverse events in the mothers were fever, mucus membrane disorder, and urinary retention. The category of "mucus membrane disorder" included the adverse events of amnionitis, chorionitis, endometritis and chorioamnionitis. The number of laboring patients placed on antibiotics during this study was similar in both groups, with 46% if those in the FHR + $FSpO_2$ group receiving antiobiotics, compared with 41% in the FHR-Alone group (NS). There were no statistically significant differences in the occurrence of any specific adverse event reported across treatment groups for either maternal or fetal/neonatal patients.

In the fetal/neonatal patients, one or more adverse events were reported in 70% of the FHR + $FSpO_2$ group, compared with 64% in the FHR-Alone group. The most frequently reported adverse events in the neonatal population included ecchymosis, accidental injury, perinatal disorder, jaundice, and dyspnea. Included in the category of "perinatal disorder" was temperature instability and symptoms of respiratory distress. The number of infants in the FHR-Alone group who experienced no adverse event was 180 (36%) compared with 152 (30%) in the FHR + $FSpO_2$ group ($p=0.029$).

All serious adverse events in the FHR + $FSpO_2$ group are listed in Table 3-1 (maternal) and Table 3-2 (fetal/neonatal) along with the corresponding information for the FHR-Alone group.

In the study, a serious adverse event was defined as an adverse event that required major medical or surgical treatment outside the realm of routine obstetrical/neonatal care, such as: excessive hemorrhage, uterine perforation, or other serious injury to mother, fetus, or neonate.

The incidence of maternal serious adverse events in the FHR + $FSpO_2$ group was 15 (2.4%) mothers with 92 (14.4%) of fetuses/neonates experiencing one or more serious adverse events. The most frequently reported maternal serious adverse events were endometrial disorder, postpartum hemorrhage, and fever (Table 3-1).

Table 3-1. Incidence of Maternal Serious Adverse Events[a]		
Body System Adverse event N (%)	**FHR Alone Group** **N=552**	**FHR and $FSpO_2$ Group** **N=638**
Body as a Whole		
Fever	1 (0.2)	3 (0.5)
Cellulitis	1 (0.2)	1 (0.2)
Headache	1 (0.2)	1 (0.2)
Mucus Membrane Disorder	0	1 (0.2)
Cardiovascular System		
Thrombophlebitis	1 (0.2)	1 (0.2)
Metabolic/Nutritional		
Healing Abnormal	0	2 (0.3)
Respiratory System		
Pneumonia	0	1 (0.2)
Urogenital System		
Endometrial Disorder	6 (1.1)	5 (0.8)
Postpartum Hemorrhage	3 (0.6)	3 (0.5)
Hemorrhage of Pregnancy	0	1 (0.2)
Ruptured Uterus	2 (0.4)	1 (0.2)

[a] *Fetal Oxygen Saturation Monitoring System—Pilot Study and Randomized Controlled Trial.*

The most frequently reported fetal/neonatal serious adverse events were dyspnea, sepsis, hypoglycemia, and perinatal disorder (Table 3-2)

Table 3-2. Incidence of Neonatal Serious Adverse Events[a]

Body System Adverse event N (%)	**FHR Alone Group** N=552	**FHR and $FSpO_2$ Group** N=638
Body as a Whole		
Sepsis	15 (2.7)	19 (3.0)
Perinatal Disorder	5 (0.9)	9 (1.4)
Fever	1 (0.2)	3 (0.5)
Accidental Injury	0	1 (0.2)
Withdrawal Syndrome	0	1 (0.2)
Congenital Anomaly	0	1 (0.2)
Cardiovascular System		
Heart Malformation	1 (0.2)	3 (0.5)
Bradycardia	1 (0.2)	2 (0.3)
Cardiovascular Disorder	3 (0.6)	2 (0.3)
Hemorrhage	1 (0.2)	1 (0.2)
Aortic Stenosis	1 (0.2)	1 (0.2)
Tetralogy of Fallot	0	1 (0.2)
Pallor	2 (0.4)	1 (0.2)
Digestive System		
Jaundice	0	1 (0.2)
Gastrointestinal Disorder	0	1 (0.2)
Hemic/Lymphatic		
Hypovolemia	2 (0.4)	3 (0.5)
Polycythemia	0	2 (0.3)
Thrombocytopenia	0	1 (0.2)
Anemia	2 (0.4)	1 (0.2)
Metabolic/Nutritional		
Hypoglycemia	9 (1.8)	8 (1.3)
Cyanosis	1 (0.2)	3 (0.5)
Bilirubinemia	2 (0.4)	2 (0.3)
Acidosis	2 (0.4)	1 (0.2)
Musculoskeletal		
Myopathy	0	1 (0.2)

continued . . .

Table 3-2. Incidence of Neonatal Serious Adverse Events[a] (Continued)

Body System Adverse event N (%)	FHR Alone Group N=552	FHR and $FSpO_2$ Group N=638
Nervous System		
Meningitis	0	2 (0.3)
Hypotonia	3 (0.5)	1 (0.2)
Facial Paralysis	0	1 (0.2)
Respiratory System		
Dyspnea	21 (3.8)	26 (4.1)
Hyperventilation	0	6 (0.9)
Respiratory Disorder	7 (1.3)	5 (0.8)
Pneumothorax	2 (0.4)	4 (0.6)
Apnea	3 (0.5)	1 (0.2)
Bronchitis	0	1 (0.2)
Hypoventilation	3 (0.5)	1 (0.2)
Pneumonia	3 (0.5)	1 (0.2)
Skin		
Skin Disorder	0	1 (0.2)

[a] *Fetal Oxygen Saturation Monitoring System—Pilot Study and Randomized Controlled Trial.*

Potential Adverse Events

Possible risks or potential adverse events, not observed during the study include: maternal discomfort from sensor placement, umbilical cord damage, perforated uterus, and damage to the placenta.

Medical Device Reporting Reminder

Medical device manufacturers and users are required by law and regulation to report serious injury and death. See the "120 Series Operator's Manual" for more information.

Chapter 4

Clinical Study

This chapter describes the objectives of the clinical study and the methods used to obtain data. The chapter also discusses the results of the study.

This chapter provides the following information:

Purpose of the Study

The objectives of the study were:

- To assess whether the addition of $FSpO_2$ monitoring to standard fetal heart rate (FHR) monitoring, within a defined treatment protocol, results in a clinically meaningful and statistically significant reduction of the rate of Cesarean deliveries performed for the indication of non-reassuring fetal status.
- To assess whether using $FSpO_2$ monitoring, as an adjunct to FHR monitoring, permits the safe continuation of labor during periods of non-reassuring fetal status. Use of the $FSpO_2$ feature is intended to continue labor during periods of non-reassuring FHR when the $FSpO_2$ is greater than or equal to 30% between contractions. The use of the system is not intended to determine when to interrupt labor.
- To assess the safety of placement, presence, and removal of the fetal oxygen sensor.

The above objectives focused on reducing Cesarean deliveries performed for the indication of non-reassuring fetal status (NRFS), as a surrogate for the specificity of diagnosis for NRFS, without causing injury to mother or baby. The study was not designed to determine the sensitivity of the $FSpO_2$ monitoring at detecting fetal acidosis, or to examine other indications and modes of delivery such as assisted vaginal or Cesarean deliveries performed for reasons other than non-reassuring fetal status. In particular, there is no physiologic reason to believe that better intrapartum diagnosis of fetal oxygenation would have any impact on Cesarean delivery for dystocia or other reasons, unrelated to fetal oxygenation.

Study Design

A three-phase multi-center clinical trial was designed to test for the clinical utility and safety of $FSpO_2$ monitoring. Phase 1 was a Baseline observational study, without the use of $FSpO_2$ monitoring or a clinical management protocol. Phase 2 was a Pilot Study to familiarize investigators with the randomization system, placement and use of the fetal oxygen monitoring system, and the clinical management protocol. Phase 3 was the multi-center Randomized Controlled Trial (RCT). In Phase 3, eligible patients were randomized to Test or Control groups, monitored by $FSpO_2$ + FHR (Test group) or FHR-Alone (Control group), managed during labor according to a defined patient care protocol in both groups, and observed for maternal and fetal outcome.

The major maternal outcome measures were the rate of Cesarean deliveries associated with non-reassuring fetal status and maternal safety measures. The major fetal outcome measures were neonatal status at birth and events of the immediate postpartum period.

Patients Studied

The study population was laboring women with ruptured membranes and non-reassuring fetal heart rate patterns.

Methods

Patients who met the inclusion/exclusion criteria were randomized into either the Test or Control group of the trial. Control patients were managed with conventional electronic FHR monitoring (FHR-Alone) and Test patients were managed with conventional FHR monitoring and $FSpO_2$ monitoring

During labor, the fetal heart rate tracing was classified as outlined in Table 4-1. FHR tracings were characterized according to the values of the baseline heart rate, the presence or absence of variability and accelerations, and the presence or absence of decelerations. Typically, the Classification I trace was characterized by a baseline between 110 and 160 BPM, with long term variability between 5 and 25 BPM, and either no decelerations or only early decelerations.

Table 4-1. Fetal Heart Rate Classification	
FHR Classification	**FHR Criteria**
I	**Reassuring Group** Any FHR pattern which did not meet criteria for groups II or III.
II	**Non-Reassuring Group** *Any one of the following for > 15 minutes:* 1. Persistent late decelerations (> 50% of contractions) 2. Sinusoidal pattern[a] 3. Variable decelerations with one or more of the following: • A relative drop of ≥ 70 BPM or an absolute drop to ≤ 70 BPM for > 60 sec.[b] • Persistent slow return to baseline • Long term variability < 5 BPM[c] • Tachycardia > 160 BPM 4. Recurrent prolonged decelerations (2 or more below 70 BPM for > 90 seconds) *Any one of the following for > 60 minutes:* 1. Tachycardia > 160 BPM with long term variability < 5 BPM 2. Persistent decreased variability (≤ 5 BPM for > 60 minutes)[c]
III	**Ominous Group** Prolonged deceleration to < 70 BPM for > 7 minutes

a *A sinusoidal pattern was defined as regular oscillations about the baseline, 5–15 BPM in magnitude, with 2 to 5 cycles per minute on an otherwise normal baseline with absent short-term variability.*

b *Variable decelerations were timed from the beginning of the deceleration to the end of the deceleration (i.e., > 60 seconds in duration).*

c *Decreased variability not otherwise explained by the clinical situation (i.e., narcotic administration).*

Patients were managed according to a clinical management protocol that was guided by the FHR Classification alone in the Control group and a combination of the FHR Classification and oxygen saturation data in the Test group. The clinical management protocols for both groups of the study are described in Table 4-2.

Table 4-2. Clinical Management Protocol Matrix

FHR Alone Group	FHR Pattern Group	FHR and $FSpO_2$ Group	
		SpO_2 Not Reassuring[a]	SpO_2 Reassuring[b]
Continue labor unless otherwise indicated [c]	**Class I: Reassuring FHR**	Continue labor unless otherwise indicated[c]	Continue labor unless otherwise indicated[c]
Evaluate and manage non-reassuring FHR	**Class II: Non-reassuring FHR**	Evaluate and manage non-reassuring FHR	Continue labor unless otherwise indicated[c]
Deliver for fetal distress	**Class III: Ominous FHR**	Deliver for fetal distress	Deliver for fetal distress

[a] *SpO_2 Not Reassuring = SpO_2 remains < 30% between contractions, or no value available despite sensor adjustment.*

[b] *SpO_2 Reassuring = SpO_2 returns to a value of 30% between contractions.*

[c] *All corrective non-operative measures are allowed as in protocol text in Figure 4-1.*

Table 4-2 provides the clinical management protocol used for the Control and Test groups in the Randomized Controlled Trial of the study. The management procedure for patients in the Control group is given by the column titled "FHR-Alone" and depends on the FHR classification (row). The management procedure for patients in the test group using the combination of FHR + $FSpO_2$ is given in the right hand two columns according to the intersection of the FHR tracing (row), and the SpO_2 condition (column). See text for details on actions to be taken when the decision procedure calls for Evaluate and Manage Non-Reassuring FHR or Deliver for Fetal Distress.

During the RCT, when the action called for in Table 4-2, was "Evaluate and Manage Non-Reassuring FHR" the clinician was instructed to first execute a series of escalating maneuvers intended to improve fetal oxygenation in an attempt to correct the condition(s) which triggered the abnormal state. The maneuvers included:

- Maternal repositioning to achieve uterine displacement
- Hydration
- Correct hypotension
- Tocolytic for hypertonic contractions
- Maternal oxygen
- Amnio-infusion
- Assessment and correction of oxytocin drug dose

In addition, if the fetus was being monitored with the $FSpO_2$ monitoring system and no $FSpO_2$ value was being displayed, the clinician adjusted the sensor in an attempt to optimize placement.

If the protocol matrix following the corrective maneuvers still indicated "Evaluate and Manage Non-Reassuring FHR", the clinician used the evaluation protocol described in Figure 4-1 to obtain additional information regarding fetal well-being.

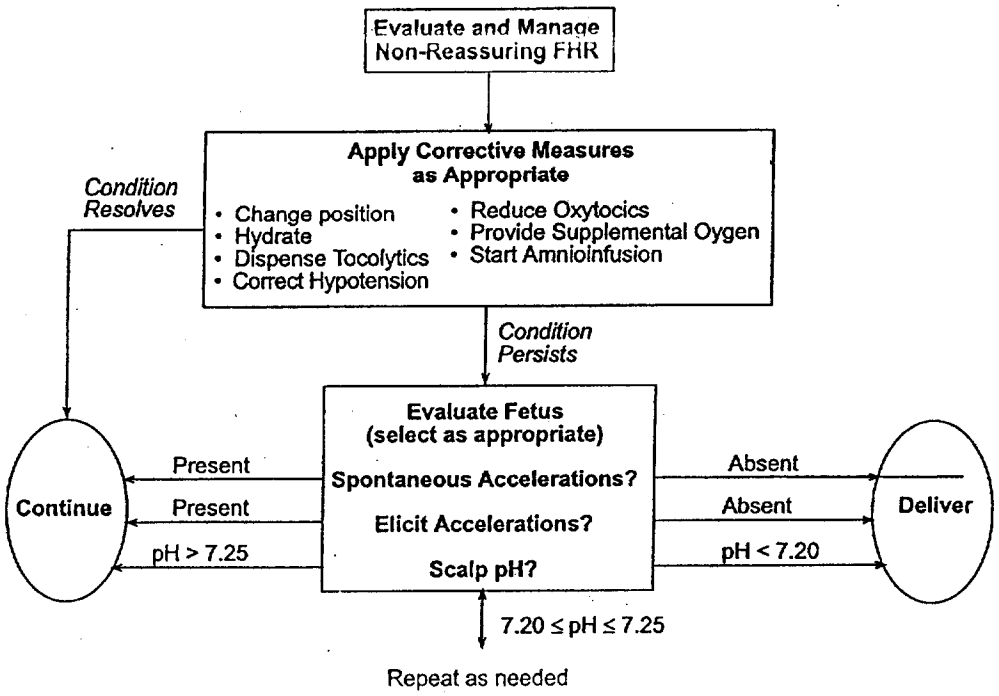

Figure 4-1. Fetal Evaluation Protocol

Results

The principal effectiveness and safety results demonstrated by the RCT are:

- In a randomized clinical trial, use of the $FSpO_2$ parameter (fetal oxygen saturation monitoring) as an adjunct to traditional FHR monitoring did not result in a reduction in the overall rate of deliveries by Cesarean-section. Cesarean deliveries for non-reassuring fetal status (NRFS) were *reduced* in the test group (FHR + $FSpO_2$).
- For reasons not explained by the study data, Cesarean deliveries for dystocia were *increased* in the test group to offset the reduction in Cesarean deliveries for NRFS.
- In this study of 1090 patients, the continuation of labor during periods of non-reassuring fetal heart rate patterns permitted by use of the $FSpO_2$ monitoring did not result in adverse impact on the neonate.
- The placement, presence, and removal of the fetal oxygen sensor does not appear to alter the safety profile of labor and delivery when compared to the use of the FHR alone.

Compared with the Baseline phase, the Cesarean delivery rate for all indications was significantly higher in both groups of the RCT (20% in the Baseline versus 26% in the FHR-Alone group and 29% in the FHR + $FSpO_2$ group). Cesarean deliveries for NRFS were also significantly higher in the FHR group of the RCT versus Baseline (5.3% Baseline: 10.2% FHR; 4.5% FHR + $FSpO_2$).

The overall incidence of assisted vaginal delivery in the RCT was not different between groups (23% FHR-Alone and 24% FHR + $FSpO_2$); neither was the incidence of NRFS as the indication for AVD (11.3% FHR-Alone and 10.8% FHR + $FSpO_2$).

Device Performance

A $FSpO_2$ signal was obtained in 95% of the test subjects where sensor placement was attempted. When a sensor adjustment or replacement was made during a period of no $FSpO_2$ display, the signal was restored in 88% of cases. The median time between the adjustment and re-display was three minutes.

In 39 cases (8%), a $FSpO_2$ sensor was not placed in women assigned to the FHR + $FSpO_2$ group. Reasons for non-placement of sensors are given in Table 4-3.

Table 4-3. Summary of Reasons Device Placement Not Attempted[a]

Reasons Device Placement Not Attempted[b]	FHR + $FSpO_2$ Group N = 508
Imminent delivery	15
Decision for Cesarean delivery made prior to placement	7
Patient withdrew	7
Not eligible (discovered after patient was enrolled)	4
Physician withdrew	3
Research nurse not available	2
Heart rate ominous	1
Equipment failure	1

a *Fetal Oxygen Saturation Monitoring System—Pilot Study and Randomized Controlled Trial.*
b *More than one reason was reported in two patients.*

In the 469 patients in whom an attempt was made to place the sensor, placement was successful in 446 (95%) and unsuccessful in 23 (5%). See Table 4-4.

Table 4-4. Summary of Reasons for Unsuccessful Sensor Placement[a]

Reasons for Unsuccessful Sensor Placement	FHR + $FSpO_2$ Group N = 508
Difficult/other	10
Imminent delivery	5
Advanced dilation	4
Bradycardia	1
High station / not eligible	1
Vernix	1
Decision for Cesarean delivery made prior to sensor readings available	1

[a] *Fetal Oxygen Saturation Monitoring System—Pilot Study and Randomized Controlled Trial.*

$FSpO_2$ values at a single point in time may not provide an exact measure of fetal arterial oxygen saturation. When the $FSpO_2$ value is observed over time, the system more accurately reflects the true oxygenation status of the fetus (–0.6 percentage difference between SaO_2 and SpO_2 when tested in animal models).

Post Hoc Observations of Clinical Behavior Surrounding Periods of $FSpO_2$ < 30%

In this analysis, the entire monitoring period was divided into sequential epochs; each defined as the time that the $FSpO_2$ value was either High (≥ 30%), Low (< 30%) or Absent (no signal displayed) between contractions. The start of the first epoch was when the signal was initially obtained, reading High or Low. Subsequent epochs (High, Low or Absent) began when the $FSpO_2$ state between contractions changed. Results and observations are from the 223 fetuses with at least one period of Low $FSpO_2$.

Most fetuses had relatively few epochs of low $FSpO_2$. The typical number of Low $FSpO_2$ epochs was one or two per fetus. The typical (median) duration of Low $FSpO_2$ epochs was short at 5 minutes. The typical (median) duration of absent signal was also short at 8 minutes. In contrast, the typical (median) duration of high $FSpO_2$ epochs was longer at 21 minutes. Thus, most of the time, the $FSpO_2$ is above 30% (reassuring) with relatively short signal absences. The majority of the Low $FSpO_2$ epochs (69%) recovered to a High $FSpO_2$ state, 27% were ended by a loss of signal, and 3% were followed by delivery of the fetus.

FHR patterns were not coupled to $FSpO_2$ status. Class 1 Reassuring FHR patterns and the various types of Class 2 Non-reassuring FHR patterns were distributed across the Absent, High, and Low $FSpO_2$ epochs in roughly the same proportion as the number of Absent, High, and Low $FSpO_2$ epochs themselves. This indicates that the two measurements are independent. This is to be expected since FHR and $FSpO_2$ measure different aspects of fetal physiology.

During the second stage of labor there were a significant number of Low $FSpO_2$ epochs as well as an increased number of intermittent signal dropouts.

In fetuses exhibiting the presence of one or more epochs containing both Low $FSpO_2$ and non-reassuring FHR patterns in the same epoch, there was a higher incidence of delivery by Cesarean (34% vs. 27%) and AVD (36% vs. 20%). For Cesarean deliveries there was a higher incidence of delivery for NRFS (24% vs. 12%) and FIL/DYS (29% vs. 14%). This suggests increased clinician concern for these fetuses.

Individualization of Treatment

Patients who would benefit from use of this device are those who exhibit the non-reassuring FHR tracings described in the management protocol. In these patients the pivotal study demonstrated that the continuation of labor is safe during periods of non-reassuring FHR when the $FSpO_2$ is 30% between contractions. The system is not intended to determine when to interrupt labor.

How Supplied

The Corometrics 120 F-Series Monitor is supplied with the following items to support $FSpO_2$ monitoring: fetal patient module, "Information for Prescribers Manual", "120 Series Operator's Manual","Maternal/Fetal Monitoring Clinical Application Operator's Manual", and "120 Series Quick Reference Guide". Contact information is listed on the Guarantee page in the front of this document.

You must order Nellcor FS14 Sensors and a "Sensor Placement Guide" directly from Mallinckrodt, Inc.

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