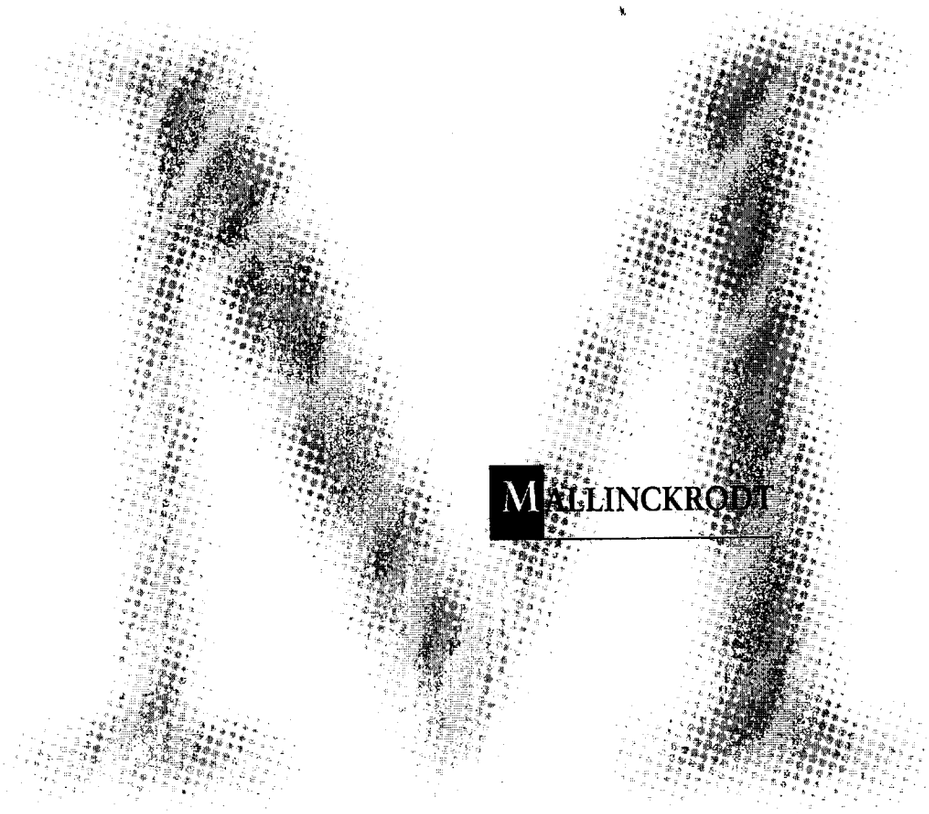
NELLCOR

Information for Prescribers

OxiFirst™ Fetal Oxygen Saturation Monitoring System



Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a properly licensed practitioner.

To contact Mallinckrodt's representative: In the United States, call 1.800.635.5267.

049225A-0500

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To obtain information about a warranty, if any, for this product, contact Mallinckrodt Technical Services or your local Mallinckrodt representative.

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SYSTEM COMPONENTS

The OxiFirst™ Fetal Oxygen Saturation Monitoring System comprises:

- Nellcor® Fetal Oxygen Saturation Monitor, Model N-400
- Nellcor Fetal Patient Module, Model FSpO2-PM
- OxiFirst Fetal Oxygen Sensor, Series FS14

The OxiFirst Fetal Oxygen Saturation Monitoring System is manufactured by:

Nellcor Puritan Bennett, Inc.
Pleasanton, CA 94588

DEVICE DESCRIPTION

The OxiFirst Fetal Oxygen Saturation Monitoring System (OxiFirst System) is a pulse oximetry system used during labor and delivery to measure fetal oxygen saturation (FSpO2).

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.

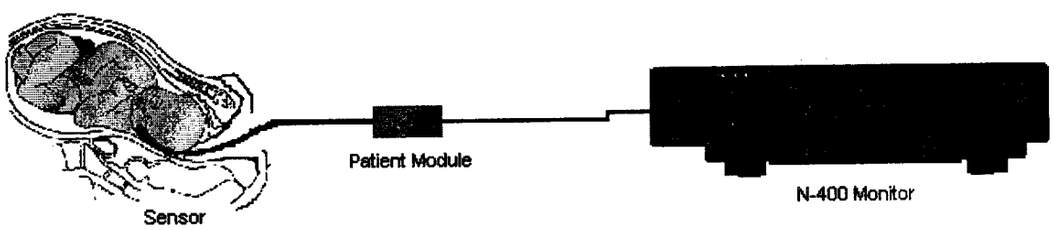
Hardware and software within the monitor process this signal to determine the oxygen saturation and pulse rate of the fetus and assess the quality of the optical signals. The values of saturation and optical pulse rate are displayed on the monitor's front panel (along with other indicators) and are communicated to external equipment via serial and/or analog ports.

The system consists of three components:

- FS14 Fetal Sensor
- Fetal Patient Module
- Fetal Oxygen Saturation Monitor, Model N-400

A diagram of the OxiFirst System in context is shown in Figure 1.

Figure 1: OxiFirst 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 N-400 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 oximeter front panel indicates the relative pulse amplitude of the photoplethysmogram.

THEORY AND PRINCIPLES OF OPERATION

The technology used in the OxiFirst Fetal Oxygen Saturation Monitoring System, like that of other pulse oximetry monitors, is based upon two basic 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, the light absorption by that blood) changes during the pulsatile flow produced by each cardiac cycle.

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INTENDED USE, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

INTENDED USE / INDICATIONS

The OxiFirst Fetal Oxygen Saturation Monitoring System continuously monitors intrapartum fetal oxygen saturation ($FSpO_2$). Use of the OxiFirst System is indicated **as an adjunct** to fetal heart rate monitoring in the presence of a nonreassuring 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.

CONTRAINDICATIONS

Use of the OxiFirst Fetal Oxygen Saturation Monitoring System is contraindicated in patients with 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.

WARNINGS AND PRECAUTIONS

Warnings

- The OxiFirst System is intended **as an adjunct** to fetal heart rate monitoring in fetuses with a nonreassuring heart rate pattern. It must be used in conjunction with clinical signs and symptoms.
- The N-400 System should not be used 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 N-400 monitor and an ESU are used together.
- The N-400 System should not be used in the presence of flammable anesthetics. Such use may constitute a fire or explosion hazard.
- The N-400 System should not be used to monitor patients during water births, in whirlpool or submersion water baths, during showers, or in any other situation where mother is immersed in water. Doing so may result in electrical shock hazard.
- The OxiFirst System should not be used 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.

- The OxiFirst System should not be used 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.

- Intrauterine insertion of the fetal oxygen sensor in women who are seropositive for Hepatitis B and/or Hepatitis E antigens may result in fetal exposure to these antigens.

PRECAUTIONS

Clinical Use Precautions

- Physicians and other licensed practitioners who use the OxiFirst System should have demonstrated expertise in determining fetal presentation and head position, and should be proficient in fetal scalp electrode and intrauterine pressure catheter placement.

- Do not attempt to insert the sensor if patient is dilated less than 2 cm or if amniotic membranes have not ruptured. Doing so may result in erroneous FSpO2 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.

- 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.

- Do not reinsert a stylet into the sensor cable chamber once it has been completely removed during sensor placement. Doing so may result in maternal injury. Sensor adjustments can be accomplished without the stylet being inserted into the sensor.

- Suboptimal sensor placement, excessive vernix, fetal hair or motion artifact (due to uterine contractions or maternal position changes) may result in no FSpO2 values being displayed, or erroneous FSpO2 values.

- 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.

- The fetal oxygen sensor may be left in place during defibrillation but FSpO2 readings may be inaccurate for a short time.

- Do not use the N-400 or fetal oxygen sensor during MRI scanning. Strong magnetic fields may affect the device causing erroneous FSpO2 measurements.

Technical Precautions

- Do not attempt to use any sensor other than sterile, single-use Nellcor® Fetal Oxygen Sensors (FS-14 Series) with the N-400 System. Use of any other Nellcor oximetry sensor or any sensor from another manufacturer may result in system malfunction, erroneous FSpO2 readings, and/or patient injury.

- Do not use a damaged sensor. Doing so may result in patient injury, sensor malfunction, and/or erroneous FSpO2 measurements.

- Never attempt to clean, reprocess or resterilize fetal oxygen sensors. Doing so may result in sensor malfunction, erroneous FSpO2 measurements, and/or infection or potential tissue injury to mother and/or fetus. Each fetal oxygen sensor is supplied as a sterile, single-use, disposable device.

- Do not attempt to remove the outside monitor cover. Doing so may result in electrical shock hazard. There are no user-serviceable parts inside.

- Replace fuses only with those of the same type and rating to protect against fire hazard.

- Do not immerse the sensor completely in liquid (the connector is not waterproof). Immersion of the sensor plug in liquid may result in sensor malfunction and/or erroneous FSpO2 measurements.

- 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 FSpO2 measurements.

- Do not connect Nellcor extension cables EC-4 or EC-8 to the OxiFirst System. Unreliable readings may result due to excessive electrical interference.

- Do not use any accessory equipment with the N-400 monitor unless it is recommended in this manual or other Mallinckrodt literature.

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ADVERSE EVENTS

Neonatal Deaths

Adverse Events Observed in Maternal and Fetal/Neonatal Patients

Potential Adverse Events

Medical Device Reporting Reminder

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

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 (3) neonatal deaths were in the FHR + FSpO2 group. The causes of death included two congenital cardiac anomalies and one cerebral infarction. Two (2) 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 event(s) in the FHR + FSpO2 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 the study was similar in both groups, with 46% of those in the FHR + FSpO2 group receiving antibiotics 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 event was reported in 70% of the FHR + FSpO2 group and 64% in the FHR-Alone group. The most frequently reported adverse event 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 + FSpO2 group ($p = 0.029$).

All serious adverse events in the FHR + FSpO2 group are listed in Table 1 (Maternal) and Table 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.

Table 1: Incidence of Maternal Serious Adverse Events

OxiFirst Fetal Oxygen Saturation Monitoring System Pilot Study + Randomized Controlled Trial		
Body System Adverse event N (%)	**FHR** **N=552**	**FHR + $FSpO_2$** **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)

The incidence of maternal serious adverse events in the FHR + FSpO2 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 event was endometrial disorder, postpartum hemorrhage, and fever (Table 1).

The most frequently reported fetal/neonatal serious adverse event was dyspnea, sepsis, hypoglycemia, and perinatal disorder (Table 2).

Table 2: Incidence of Neonatal Serious Adverse Events

OxiFirst Fetal Oxygen Saturation Monitoring System Pilot Study + Randomized Controlled Trial		
Body System Adverse event N (%)	**FHR** **N=552**	**FHR + $FSpO_2$** **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)
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)

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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.

CLINICAL STUDY

PURPOSE OF THE STUDY

The objectives of the study were:

- To assess whether the addition of the OxiFirst Fetal Oxygen Saturation Monitoring System 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 nonreassuring fetal status.
- To assess whether using the OxiFirst System, as an adjunct to FHR monitoring permits the safe continuation of labor during periods of nonreassuring fetal status. Use of the system is intended to continue labor during periods of nonreassuring FHR when the FSpO2 is ≥ 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 nonreassuring fetal status, 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 OxiFirst System 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 nonreassuring 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 FSpO2 monitoring with the OxiFirst System. Phase 1 was a Baseline observational study, without the use of FSpO2 monitoring or a clinical management protocol. Phase 2 was a Pilot Study to familiarize investigators with the randomization system, placement and use of the OxiFirst Fetal Oxygen System, and the clinical management protocol. Phase 3 was the multi-center Randomized Controlled Trial. In Phase 3, eligible patients were randomized to Test or Control groups, monitored by FSpO2 + 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 nonreassuring 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 with nonreassuring 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 the OxiFirst System.

During labor, the fetal heart rate tracing was classified as outlined in Table 3.

Table 3: Fetal Heart Rate Classification

FHR Classification	FHR Criteria
I	**Reassuring Group:** Any FHR pattern that did not meet criteria for Groups II or III.
II	**Nonreassuring Group:** Any one of the following for > 15 minutes: 1. Persistent late decelerations (> 50% of contractions) 2. Sinusoidal pattern [1] 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 seconds [2] • Persistent slow return to baseline • Long term variability < 5 bpm [3] • 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) [3]
III	**Ominous Group:** Prolonged deceleration to < 70 bpm for > 7 minutes

[1] Sinusoidal pattern were 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.

[2] Variable decelerations were to be timed from the beginning of the deceleration to the end of the deceleration (i.e., > 60 sec. in duration).

[3] Decreased variability not otherwise explained by the clinical situation (i.e., narcotic administration)

Table 3: Fetal heart rate classification: 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.

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 study groups of the study are described in Table 4 below.

Table 4: Clinical Management Protocol (Matrix)

FHR-Alone	FHR PATTERN GROUP	FHR and Oximeter	
		FSpO2 Not Reassuring [1]	FSpO2 Reassuring [2]
Continue labor unless otherwise indicated [3]	**Class I – Reassuring FHR**	Continue labor unless otherwise indicated [3]	Continue labor unless otherwise indicated [3]
Evaluate and manage nonreassuring FHR	**Class II - Nonreassuring FHR**		
Deliver for fetal distress	**Class III - Ominous FHR**	Deliver for fetal distress	Deliver for fetal distress

[1] FSpO2 Not Reassuring = FSpO2 remains < 30% between contractions, or no value available despite sensor adjustment.

[2] FSpO2 Reassuring = FSpO2 returns to a value of ≥ 30% between contractions.

[3] All corrective non-operative measures are allowed as in protocol text.

Table 4. Clinical management protocol for control and test groups of randomized controlled clinical trial phase 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 and oxygen saturation (FSpO2) monitoring is given in the right hand two columns according to the intersection of the FHR tracing (row), and the FSpO2 condition (column). See text for details on actions to be taken when the decision procedure calls for Evaluate and Manage Nonreassuring FHR or Deliver for Fetal Distress.

During the RCT, when the action called for in Table 4 was "Evaluate and manage nonreassuring FHR," the clinician was instructed to 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

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In addition, if the fetus was being monitored with the OxiFirst System and no FSpO2 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 Nonreassuring FHR", the clinician used the evaluation protocol described in Figure 2 to obtain additional information regarding fetal well-being.

Figure 2: Fetal Evaluation Protocol

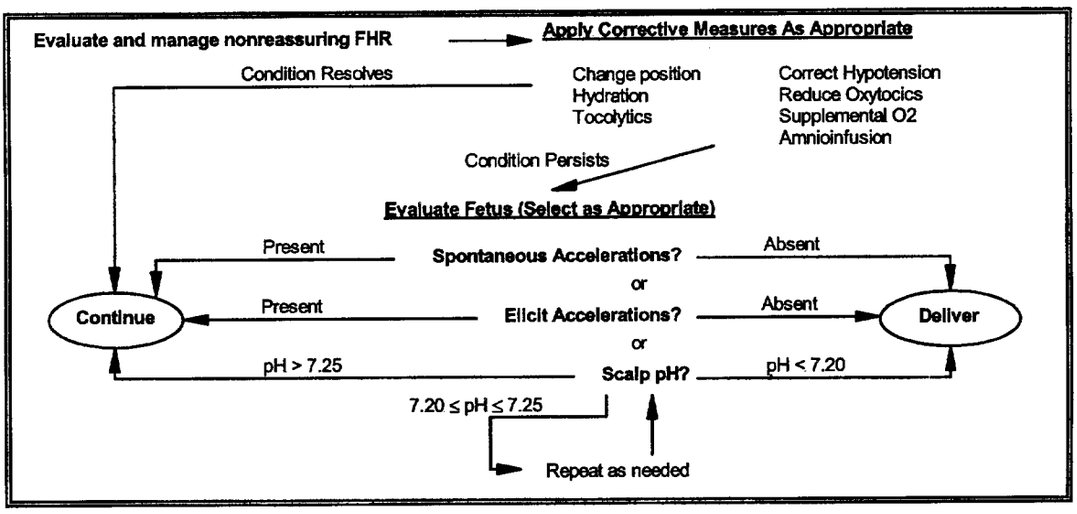

Figure 2. Fetal Evaluation Protocol. Protocol for evaluating the state of fetal well being.

RESULTS

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

- The study showed no change in overall Cesarean rates. Cesareans for NRFS were reduced by 50% in the group monitored with FHR+FSpO2 while Cesareans for dystocia increased (for reasons not explained by the available data).
- The continuation of labor during periods of nonreassuring fetal heart rate patterns permitted by the use of OxiFirst FSpO2 monitoring does not result in any adverse impact on the neonate.
- The placement, presence, and removal of the Fetal Oxygen Sensor does not alter the safety profile of labor and delivery when compared to the use of the FHR alone.

Compared with the Baseline phase, the Cesarean rate for all indications was significantly higher in both groups of the RCT (20% in the Baseline versus 26% in the FHR group and 29% in the FHR+FSpO2 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+FSpO2).

The overall incidence of assisted vaginal delivery in the RCT was not different between groups (23% FHR and 24% FHR+FSpO2) neither was the incidence of NRFS as the indication for AVD (11.3% FHR and 10.8% FHR+FSpO2).

DEVICE PERFORMANCE

A FSpO2 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 FSpO2 display, the signal was restored in 88% of cases. The median time between the adjustment and re-display was three (3) minutes.

In 39 cases (8%), a FSpO2 sensor was not placed in women assigned to the FHR+FSpO2 group. Reasons for non-placement of sensors are given in Table 5.

Table 5: Summary of reasons device placement not attempted

OxiFirst Fetal Oxygen Saturation Monitoring System Randomized Controlled Trial	
Reasons device placement not attempted [1]	**FHR+FSpO2 Group N=508**
Imminent delivery	15
Decision to C/S 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

[1] 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%) (Table 6).

Table 6: Summary of reasons for unsuccessful sensor placement

OxiFirst Fetal Oxygen Saturation Monitoring System Pilot Study +Randomized Controlled Trial	
Reasons for unsuccessful sensor placement	**FHR+FSpO2 Group N=508**
Difficult / other	10
Imminent delivery	5
Advanced Dilation	4
Bradycardia	1
High station / not eligible	1
Vernix	1
Decision to Cesarean delivery prior to sensor readings available	1

FSpO2 values at a single point in time may not provide an exact measure of fetal arterial oxygen saturation. When the FSpO2 value is observed over time, the system more accurately reflects the true oxygenation status of the fetus (-0.6 percentage difference between SaO2 and SpO2 when tested in animal models). See *Perinatal Reference Note #1* * for more information.

POST HOC OBSERVATIONS OF CLINICAL BEHAVIOR SURROUNDING PERIODS OF FSpO2 < 30%.

In this analysis, the entire monitoring period was divided into sequential epochs; each defined as the time that the FSpO2 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 FSpO2 state between contractions changed. Results and observations are from the 223 fetuses with at least one period of Low FSpO2.

Most fetuses had relatively few epochs of low FSpO2. The typical number of Low FSpO2 epochs was one or two per fetus. The typical (median) duration of Low FSpO2 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 FSpO2 epochs was longer at 21 minutes. Thus, most of the time, the FSpO2 is above 30% (reassuring) with relatively short signal absences. The majority of the Low FSpO2 epochs (69%) recovered to a High FSpO2 state, 27% were ended by a loss of signal, and 3% were followed by delivery of the fetus.

FHR patterns were not coupled to FSpO2 status. Class 1 Reassuring FHR patterns and the various types of Class 2 Nonreassuring FHR patterns were distributed across the Absent, High, and Low FSpO2 epochs in roughly the same proportion as the number of Absent, High, and Low FSpO2 epochs themselves. This indicates that the two measurements are independent. This is to be expected since FHR and FSpO2 measure different aspects of fetal physiology.

During the second stage of labor there were a significant number of Low FSpO2 epochs as well as an increased number of intermittent signal dropouts.

In fetuses exhibiting the presence of one or more epochs containing both Low FSpO2 and nonreassuring 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 nonreassuring FHR tracings described in the management protocol. In these patients the pivotal study demonstrated that the continuation of labor is safe during periods of nonreassuring FHR when the FSpO2 is ≥ 30% between contractions. The system is not intended to determine when to interrupt labor.

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* Perinatal Reference Note #1 (00032-0500): OxiFirst Fetal Oxygen Saturation Monitoring System – The Technology

HOW SUPPLIED

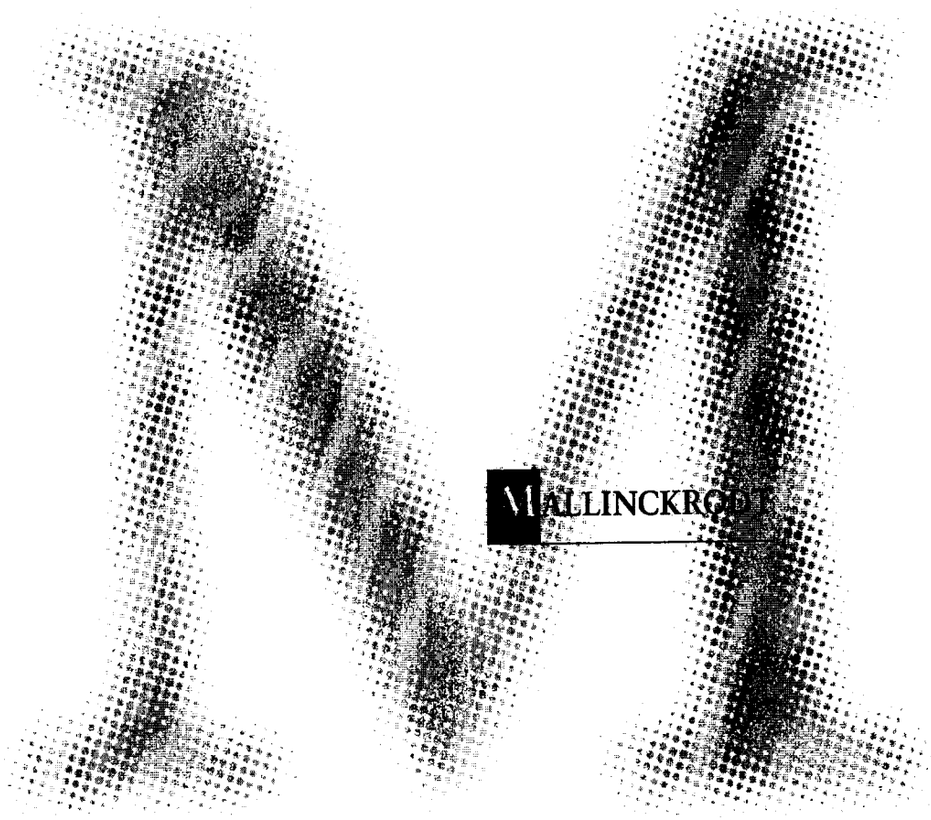
The N-400 monitor is supplied boxed with an electrical cable, fetal patient module, *N-400 Operator's Manual*, *Information for Prescribers* document, and the *Clinical Use Guide*.

Sensors are supplied sterile, for single use only, in boxes of six each.

NELLCOR

Clinical Use Guide

OxiFirst™ Fetal Oxygen Saturation Monitoring System



Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a properly licensed practitioner.

To contact Mallinckrodt's representative: In the United States, call 1.800.995.1329.

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INDICATIONS FOR USE, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

SAFETY DEFINITIONS

Term	Purpose
WARNING:	Alert the reader to hazards or potential serious outcomes to patient or users that may result from OxiFirst System misuse.
Caution:	Alert the reader to exercise special care necessary for the safe and effective use of the OxiFirst System. May also alert the reader to adverse effects on the N-400 monitor of use or misuse and the care necessary to avoid such effects.
PRECAUTIONS	Indicates that a grouping of two or more cautions follows.
Note:	Hints or tips for the reader that may make the OxiFirst System easier to use in specific situations.

INDICATIONS FOR USE

The OxiFirst Fetal Oxygen Saturation Monitoring System continuously monitors intrapartum fetal oxygen saturation (FSpO2). Use of the OxiFirst System is indicated **as an adjunct** to fetal heart rate monitoring in the presence of a nonreassuring 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.

CONTRAINDICATIONS

Use of the OxiFirst Fetal Oxygen Saturation Monitoring System is contraindicated in patients with 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.

WARNINGS AND PRECAUTIONS

Warnings

- The OxiFirst System is intended **as an adjunct** to fetal heart rate monitoring in fetuses with a nonreassuring heart rate pattern. It must be used in conjunction with clinical signs and symptoms.

- The N-400 System should not be used 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 N-400 monitor and an ESU are used together.

- The N-400 System should not be used in the presence of flammable anesthetics. Such use may constitute a fire or explosion hazard.

- The N-400 System should not be used to monitor fetuses during water births, in whirlpool or submersion water baths, during showers, or in any other situation where mother is immersed in water. Doing so may result in electrical shock hazard.

- The OxiFirst System should not be used 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.

- The OxiFirst System should not be used 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.

- Intrauterine insertion of the fetal oxygen sensor in women who are seropositive for Hepatitis B and/or Hepatitis E antigens may result in fetal exposure to these antigens.

PRECAUTIONS

Clinical Use Precautions

- Physicians and other licensed practitioners who use the OxiFirst System should have demonstrated expertise in determining fetal presentation and head position, and should be proficient in fetal scalp electrode and intrauterine pressure catheter placement.

- Do not attempt to insert the sensor if patient is dilated less than 2 cm or if amniotic membranes have not ruptured. Doing so may result in erroneous FSpO2 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.

- 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.

- Do not reinsert a stylet into the sensor cable chamber once it has been completely removed during sensor placement. Doing so may result in maternal injury. Sensor adjustments can be accomplished without the stylet being inserted into the sensor.

- Suboptimal sensor placement, excessive vernix, fetal hair or motion artifact (due to uterine contractions or maternal position changes) may result in no FSpO2 values being displayed, or erroneous FSpO2 values.

- 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.

- The fetal oxygen sensor may be left in place during defibrillation but FSpO2 readings may be inaccurate for a short time.

- Do not use the N-400 or fetal oxygen sensor during MRI scanning. Strong magnetic fields may affect the device causing erroneous FSpO2 measurements.

Technical Precautions

- Do not attempt to use any sensor other than sterile, single-use Nellcor Fetal Oxygen Sensors (FS-14 Series) with the N-400 System. Use of any other Nellcor oximetry sensor or any sensor from another manufacturer may result in system malfunction, erroneous FSpO2 readings, and/or patient injury.

- Do not use a damaged sensor. Doing so may result in patient injury, sensor malfunction, and/or erroneous FSpO2 measurements.

- Never attempt to clean, reprocess or resterilize fetal oxygen sensors. Doing so may result in sensor malfunction, erroneous FSpO2 measurements, and/or infection or potential tissue injury to mother and/or fetus. Each fetal oxygen sensor is supplied as a sterile, single-use, disposable device.

- Do not attempt to remove the outside monitor cover. Doing so may result in electrical shock hazard. There are no user-serviceable parts inside.

- Replace fuses only with those of the same type and rating to protect against fire hazard.

- Do not immerse the sensor completely in liquid (the connector is not waterproof). Immersion of the sensor plug in liquid may result in sensor malfunction and/or erroneous FSpO2 measurements.

- 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 FSpO2 measurements.

- Do not connect Nellcor extension cables EC-4 or EC-8 to the OxiFirst Oximetry System. Unreliable readings may result due to excessive electrical interference.

- Do not use any accessory equipment with the N-400 monitor unless it is recommended in this manual or other Mallinckrodt literature.

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PLACEMENT CRITERIA AND PATIENT MANAGEMENT

Sensor Placement Criteria

Patient Management

The *Clinical Use Guide* is intended to serve as a guide in the Labor and Delivery department for the use of the OxiFirst System. The guide is intended to introduce the user to the proper method of preparing the system, inserting the sensor, interpreting the front panel symbols on the N-400 monitor, the criteria for placing the sensor and the management of patients who have the sensor in place.

In addition, this guide provides suggestions for troubleshooting various problems that may be encountered in the use of this device. This guide is accompanied by the *Information for Prescribers* which describes the randomized clinical trial performed to support the use of this device during labor and delivery. The guidelines listed below for when to place a sensor and how to manage a patient once the sensor is placed are the guidelines used in the randomized controlled clinical trial.

SENSOR PLACEMENT CRITERIA

The patient should be in active labor (dilation ≥ 2 cm, vertex -2 station or lower) with ruptured membranes. The placement of the Nellcor fetal oxygen sensor is appropriate if the fetal heart rate tracing shows evidence of one or more of the following nonreassuring FHR patterns.

- Baseline FHR between 100-110 with no accelerations > 15 bpm for more than 15 seconds
- Baseline FHR < 100 bpm with accelerations
- Increased variability > 25 bpm for > 30 minutes
- Mild or moderate variable decelerations for > 30 minutes
- Late decelerations (at least 1 per 30 minutes)
- Decreased variability < 5 bpm for > 30 minutes
- Persistent late decelerations (> 50% of contractions) for > 15 minutes
- Tachycardia > 160 bpm with long term variability < 5 bpm
- Sinusoidal pattern
- Variable decelerations with any of the following:
  - a relative drop of ≥ 70 bpm or an absolute drop to ≤ 70 bpm for 60 seconds
  - persistent slow return to baseline
  - long term variability < 5 bpm
  - tachycardia > 160 bpm
- Recurrent prolonged decelerations (2 or more below 70 bpm for > 90 seconds in 15 minutes)

PATIENT MANAGEMENT

To use the Management Matrix once a sensor has been placed, the fetal heart rate tracing is placed into the following three categories.

Table 1: Fetal Heart Rate Classification

FHR Classification	FHR Criteria
I	**Reassuring Group:** Any FHR pattern that did not meet criteria for Groups II or III.
II	**Nonreassuring Group:** Any one of the following for > 15 minutes: 1. Persistent late decelerations (> 50% of contractions) 2. Sinusoidal pattern [1] 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 seconds [2] • Persistent slow return to baseline • Long term variability < 5 bpm [3] • 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) [3]
III	**Ominous Group:** Prolonged deceleration to < 70 bpm for > 7 minutes

[1] Sinusoidal pattern are 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.

[2] Variable decelerations are to be timed from the beginning of the deceleration to the end of the deceleration (i.e., > 60 sec. in duration).

[3] Decreased variability not otherwise explained by the clinical situation (i.e., narcotic administration)

Table 1: FHR tracings are 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 is 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.

Patients are managed according to a clinical management protocol guided by the combination of FHR Classification and fetal oxygen saturation data. The clinical management protocol is described in Table 2 below.

Table 2: Clinical Management Protocol (Matrix)

FHR-Alone	FHR PATTERN GROUP	FHR and Oximeter	
		FSpO2 Not Reassuring [1]	FSpO2 Reassuring [2]
Continue labor unless otherwise indicated [3]	**Class I – Reassuring FHR**	Continue labor unless otherwise indicated [3]	Continue labor unless otherwise indicated [3]
Evaluate and manage nonreassuring FHR	**Class II - Nonreassuring FHR**	[illegible]	[illegible]
Deliver for fetal distress	**Class III - Ominous FHR**	Deliver for fetal distress	Deliver for fetal distress

[1] FSpO2 Not Reassuring = FSpO2 remains < 30% between contractions, or no value available despite sensor adjustment.

[2] FSpO2 Reassuring = FSpO2 returns to a value of ≥ 30% between contractions.

[3] All corrective non-operative measures are allowed as in protocol text.

Table 2: The clinical management procedure for patients using the combination of FHR and oxygen saturation (FSpO2) monitoring is given in the right hand two columns according to the intersection of the FHR tracing (row), and the FSpO2 condition (column). See text for details on actions to be taken when the decision calls for Evaluate and Manage Nonreassuring FHR or Deliver for Fetal Distress.

When the action called for in Table 2 is "Evaluate and manage nonreassuring FHR," the clinician should 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 include:

- 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 no FSpO2 value is being displayed, the clinician should adjust the sensor in an attempt to optimize placement.

If these maneuvers correct the indication for an intervention, the action listed corresponding to the corrected conditions determines the intervention level. Thus, if the protocol matrix (Table 2) indicates "Deliver for fetal distress", but the maneuvers taken by the bedside clinician correct the FHR and/or FSpO2 such that the indicated action changes to "Continue labor unless otherwise indicated", the appropriate action becomes "Continue labor unless otherwise indicated".

If the protocol matrix following the corrective maneuvers still indicates "Deliver for Fetal Distress", the fetus should be delivered as soon as practical by whatever means judged appropriate.

If the protocol matrix following the corrective maneuvers still indicates "Evaluate and manage nonreassuring FHR", the clinician uses the Evaluation protocol described in to obtain additional information regarding the fetal well-being. In addition, any of the above non-operative measures are allowed when the status is "Continue labor unless otherwise indicated."

Figure 1: Fetal Evaluation Protocol

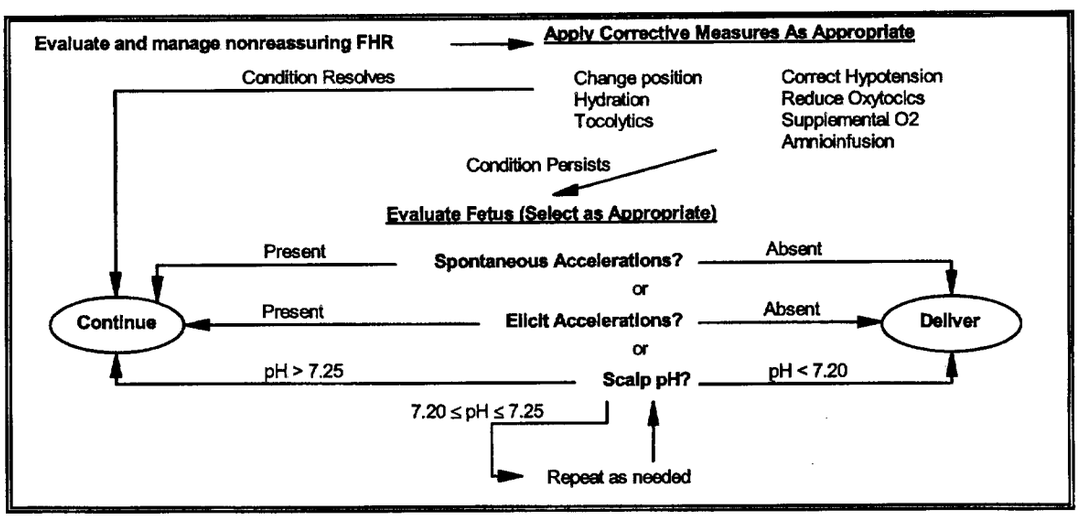
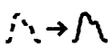


Figure 1. Fetal Evaluation Protocol. Protocol for evaluating the state of fetal well being in conditions indicating evaluate and manage nonreassuring FHR after steps taken to correct the condition.

SYMBOLS

Front Panel

	Searching for Fetal Pulse
	ECG Required
	Signal Quality
	Audio Alarm Off (indicator and button)
	Sensor Lifted
	Sensor Unplugged
	ECG Display (indicator and button)
2	Mode 2 Response Time
$FSpO_2\%$	Percent Oxygen Saturation Display
/min	Pulse Rate Display, measured in beats per minute (bpm) Or, ECG Rate when in ECG Display mode
SpO_2	Low Saturation Alarm Limit
	Response Time
⊙/○	ON/STANDBY
	Attention: See Instructions for Use or consult accompanying documents.

Rear Panel

I/O	Mains (AC) ON/OFF switch
	Increase (full-scale) Analog Output
	Fuse Replacement Symbol
	Decrease (zero) Analog Output
	RS-232 Interface
	Provides analog output of Plethysmograph waveform. The waveform is low resolution, autoscaled, and not intended for diagnostic purposes.
	Fetal SpO2 Analog Output
	Fetal High-level ECG Input
	Type BF (patient electrically isolated)
	Attention: See Instructions for Use or consult accompanying documents.
	Equipotential Ground
	Attention: Consult accompanying documents.

POWER UP AND SELF-TEST

Each time the ON/STANDBY switch is turned ON, the N-400 performs a self-test. If a problem occurs during the self-test, an error code will be displayed. See the *Troubleshooting* section for information regarding error codes and problem resolution.

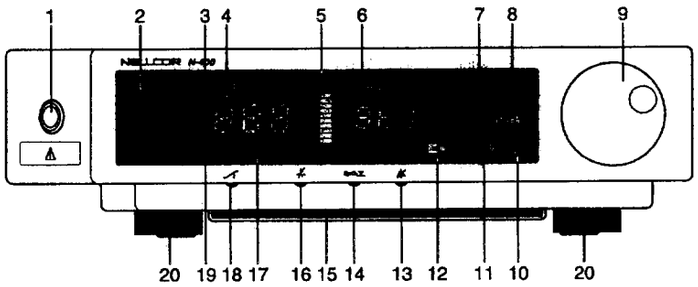
During the N-400 power up sequence:

- The display is initialized with dashes in the FSpO2 and pulse rate displays.
- The ***Audio Alarm Off*** indicator is on.
- The ***Sensor Lifted*** indicator is on if the sensor is plugged in; if not, the ***Sensor Unplugged*** indicator will be on.
- All other indicators are off.
- The ***Signal Quality*** indicator has a single bar lit at the far left.
- The ***Pulse Amplitude*** indicator has only the bottom bar illuminated.
- The FSpO2 analog output is at zero volts throughout the power-up sequence.

COMPONENTS

Figures 2 and 3 show the N-400 front and rear panels. Figure 4 shows the Fetal Patient Module and Figure 5 details the fetal oxygen sensor.

Figure 2: N-400 Front Panel



Front Panel Components

1. **Patient module connector:** Fetal Patient Module connector.
2. **ON/STANDBY switch**: used to turn the N-400 ON and OFF.
3. ***Searching* indicator**: lights when the N-400 is attempting to locate the fetal pulse.
4. **FSpO2 display:** displays FSpO2 level calculated from qualified optical pulses.
5. ***Pulse Amplitude* indicator**: qualitative indicator of pulse amplitude at sensor site.
6. **Pulse rate display**: displays fetal pulse rate calculated from qualified optical pulses, or fetal heart rate when in ECG Display mode.

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7. **ECG Required indicator**: lights when a high level ECG signal from an EFM is not detected and the N-400 is in the ECG Display mode.

8. ***Signal Quality* indicator**: indicates average signal quality of pulses being detected at sensor site according to a software algorithm in the N-400.

9. **Control knob**: adjusts speaker volume when audible tones or alarms are selected, and is used in conjunction with push buttons to set various other limits and values.

10. **Audio alarm off indicator:** lights when the audio alarm has been silenced.

11. ***Sensor lifted* indicator**: lights when sensor is not making adequate contact at sensor site on fetus.

12. ***Sensor Unplugged* indicator**: lights when sensor is disconnected from patient module or patient module cable is disconnected from N-400.

13. **Audio alarm off button**: used to silence or enable the audio alarms.

14. **Low Saturation limit button**: used in conjunction with the control knob to set the low saturation alarm limit.

15. **Pull-out card slot**: contains three informational cards, one for the monitor, one for the sensor, and a sensor placement flowchart.

16. **ECG Display button**: used to override the default ECG Not Displayed mode of operation. In this mode, a high-level ECG signal from an EFM is required.

    To enable the ECG Display mode, push and hold the ECG Display button. As you hold this button, the fetal heart rate from the fetal heart rate monitor is continuously displayed. When you release this button, the N-400 returns to the optical pulse rate display.

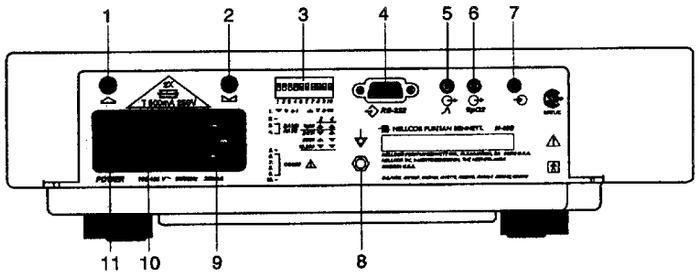
17. **ECG in Use indicator**: lights to indicate that the default ECG Not Displayed mode has been overridden. In this mode, a high-level ECG signal from an EFM is required.

18. **Response time button**: sets signal averaging time, changing from Mode 1 (default) to Mode 2 operation.

19. **Mode 2 indicator**: lights when Mode 2 response time is selected.

20. **Adjustable feet**: allows user to adjust the monitor to a different viewing angle.

Figure 3: N-400 Rear Panel



Rear Panel Components

1. **Increase (full-scale) button**: generates full-scale signal at analog outputs (voltage is dependent upon voltage scale switch setting).
2. **Decrease (zero) button**: generates zero-voltage signal at analog outputs.
3. DIP switches

   1: sets analog output voltage scale (DOWN = 0–1 V; UP = 0–10 V)

   2, 5, 9, 10: not used

   3, 4: sets baud rate for RS-232 output

   6, 7, 8: sets RS-232 communications format
4. **Serial communications connector:** provides RS-232 format digital interface via a standard 9-pin "D" connector pinout.
5. **Analog Output:** Provides analog output of Plethysmograph waveform. The waveform is low resolution, autoscaled, and not intended for diagnostic purposes.
6. **FSpO2 analog output jack** (3/32-inch subminiature): provides analog output of SpO2 data with a range of 0–100%.
7. **Fetal high-level ECG input jack** (3/32-inch subminiature): used for input of high-level ECG signal from EFM via ECG interface cable.
8. **Equipotential ground**: provides an earth ground connection for leakage testing.
9. **Mains (AC) power input:** connects N-400 to 110/120V~ via appropriate power cord and proper mains voltage selection.
10. **Mains (AC) voltage selector:** $115V_{AC}$.
11. **ON/OFF switch**: mains (AC) power switch.

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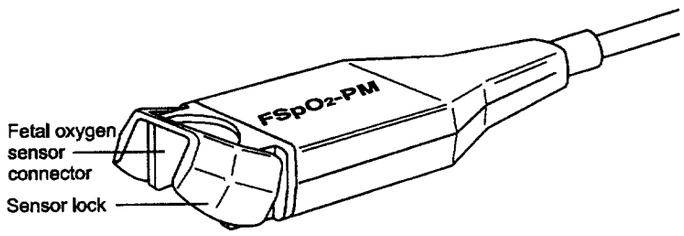
FETAL PATIENT MODULE

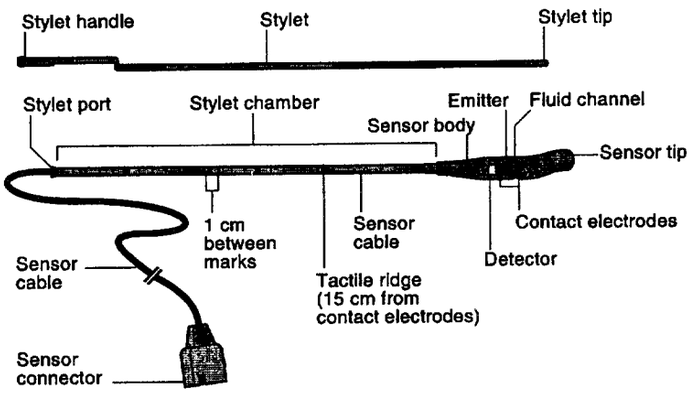
Figure 4: Fetal Patient Module



FS-14 FETAL OXYGEN SENSOR

Become familiar with the sensor before using it. Figure 5 shows the FS-14, along with descriptive labels.

Figure 5: FS-14 Fetal Oxygen Sensor



FETAL HEART RATE AND OPTICAL PULSE RATE DETERMINATION

The OxiFirst System determines optical fetal pulse in a very different way than an electronic fetal heart rate monitor measures fetal heart rate.

Fetal Heart Rate Measurement

Electronic fetal heart rate monitors determine fetal heart rate either by ultrasound or electrocardiography. An ultrasound transducer placed on the maternal abdomen directs an ultrasonic beam toward the fetal heart. This transducer detects the Doppler shifted frequency variations in the echoes created by moving cardiac structures. An autocorrelation process is used to resolve the time interval between successive cardiac cycles, producing the displayed fetal heart rate. When a spiral electrode is attached directly to the fetal presenting part, the fetal heart rate is computed based upon the interval between successive R-wave peaks of the fetal QRS complex.

Optical Pulse Rate Determination

By measuring the optical response of light that passes through arterial blood, the OxiFirst System identifies fetal pulses by finding the minimum and maximum amplitude of each pulse. Once two minimums are found, the distance between them is measured in time. From this time, the pulse rate in beats-per-minute is calculated. The optical pulse rate is displayed by the N-400 only when pulse quality is adequate to also calculate and display a fetal oxygen saturation value.

The OxiFirst System's optical pulse rate can be affected by uterine contractions, fetal perfusion and sensor placement, and therefore should not be used in patient management.

Optical pulse rate should not be used in place of fetal heart rate monitoring.

TYPICAL SETUP

Figure 6: Typical OxiFirst System Setup

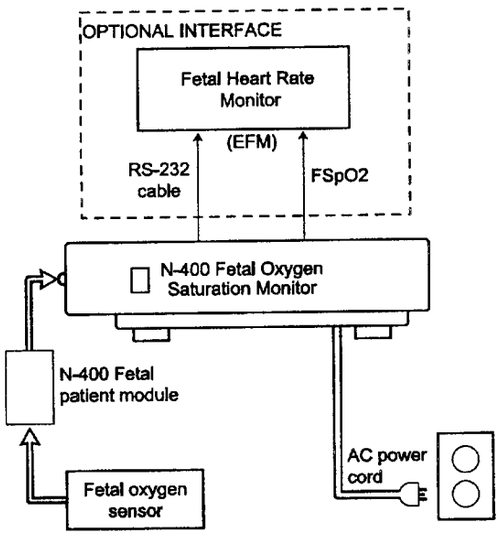


Figure 6 shows a typical OxiFirst System setup. The N-400 processes the optical signal seen by the fetal oxygen sensor, and displays calculated FSpO2 and pulse rate values derived from this signal. The N-400 is typically interfaced to an electronic fetal heart rate monitor (EFM) and the FSpO2 signals are recorded on the EFM strip chart.

BASIC OPERATION

The following procedure outlines the N-400 default mode of operation.

To turn the N-400 ON:

1. Ensure that the mains (AC) voltage selector on the back of the N-400 has been set for the appropriate mains (AC) voltage.

2. Connect the mains (AC) power cord to the N-400. Plug the other end of the cord into a hospital-grade outlet. Use only an outlet that has a grounding connection and use only the original hospital-grade mains (AC) power plug and cord, or an equivalent hospital-grade mains (AC) power plug and cord.

3. Verify that the front-panel ON/STANDBY switch is in the STANDBY position.

4. On the N-400 rear panel, turn the mains (AC) ON/OFF switch to ON.

5. On the N-400 front panel, turn the ON/STANDBY switch to ON.

Note: Some indicators will be lit and dashes (– –) will be displayed in the FSpO2 and pulse rate displays.

To use the N-400:

6. Connect the fetal patient module to the N-400 front panel Patient Module connector. Align the red dots on the connector and push the patient module connector straight in. Do not twist the connector.

7. If desired, set the N-400 low saturation alarm limit (see *Use of Special Features* in *N-400 Operator's Manual*). The default low saturation alarm limit is zero.

8. Plug the fetal oxygen sensor into the sensor connector on the fetal patient module. The ***Sensor Unplugged*** indicator light should turn off and the ***Sensor Lifted*** indicator should turn on.

9. Place the sensor as described in the *Sensor Quick Guide* or *Sensor Pull-out Card* (mounted under the N-400 monitor), and the *Clincial Use Guide*.

10. After the sensor is appropriately positioned, the ***Sensor Lifted*** indicator turns off and the ***Searching*** indicator turns on.

11. The ***Pulse Amplitude*** indicator lights up with each pulse, with the number of bars lit dependent upon pulse strength.

12. The ***Signal Quality*** indicator lights up to display the quality of the signal used to calculate the FSpO2 value.

VARIABLE PULSE TONE FEATURE

When inserting or adjusting the FS-14 Fetal Oxygen Sensor, the Variable Pulse Tone feature may be of benefit in assessing the quality of the placement and the consistency of the fetal pulse signals being detected. This is the only feature that provides *instantaneous* feedback on the quality and reproducibility of fetal pulses detected by the sensor.

This feature is available on the N-400 monitor, but may not be available on fetal heart rate monitors using Nellcor FSpO2 technology.

To enable pulse tones, rotate the control knob on the N-400 front panel clockwise 3 to 5 full turns prior to putting on sterile gloves. This increases the volume so that beeps (pulse tones) can be heard as pulses are qualified during sensor placement.

When FSpO2 values are not displayed, each detected pulse of sufficient quality produces a beep tone. When the sensor is well positioned, these beeps sound in a rhythmic pattern matching the fetal heart rate.

If the beeps are intermittent or irregular, a slight adjustment may optimize the sensor placement, producing more continuous FSpO2 readings and improved monitoring quality.

When FSpO2 values are being displayed, each accepted fetal pulse produces an audible tone that varies in pitch, reflecting changes in fetal oxygen saturation. The tone pitch is higher as saturation rises and lower as saturation drops.

After using the variable pulse tone feature to assess and aid in an optimized sensor placement, the pulse tone volume may be lowered or silenced by rotating the control knob counterclockwise.

PREPARATION FOR PLACEMENT

1. Explain procedure to the patient, including possibility of discomfort with sensor placement.

2. Open the end of the sensor package that contains the sensor connector. Expose sensor connector only.

3. Leave the sterile sensor in the opened package until ready for insertion.

4. Attach the sensor connector to the fetal patient module.

5. Check to ensure that the emitter located within the sensor body lights up red. If it does not, use a new sensor.

6. Turn the control knob 2-3 turns clockwise to enable the audible pulse tone.

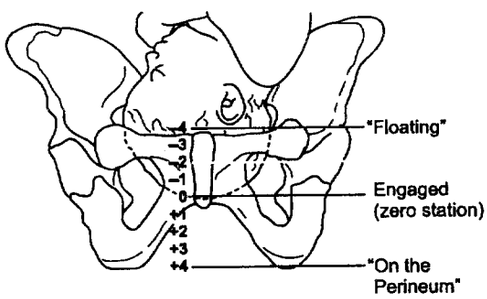
7. Palpate the patient's abdomen to determine the fetal position. This is most helpful if cervical dilatation is not sufficiently advanced to allow for identification of the fetal cranial landmarks.

Note: The fetal oxygen sensor is intended for use only on a singleton fetus in the vertex presentation.

8. Put on sterile gloves.

9. Perform a vaginal exam to determine dilatation, station, and fetal position to ascertain the optimal site for sensor introduction.

Figure 7: Pelvic Station Using Top of Presenting Part



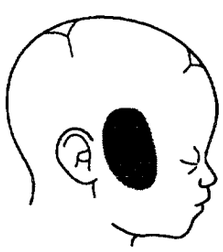
Note: If the head is too high (above –2 station), it is unlikely that a signal will be detected due to inadequate contact. With the head at –1 station or below, the ability to obtain contact and a signal is improved. See Figure 7.

10. Determine optimal sensor site relative to head position.

Note: The optimal sensor placement site is on the fetal cheek/temple, as shown in Figure 8. It is preferable to locate the sensor on the side of the fetal head facing the maternal spine (posterior cheek/temple area). This location can be determined by identifying the sagittal suture and one or, ideally, both of the fontanels.

Note: If the fetus is in the vertex presentation, but fetal head position cannot be precisely determined, assume the fetus is Occipito-Anterior (OA).

Figure 8: Ideal Sensor Placement Site



SENSOR PLACEMENT

1. Put on sterile gloves after enabling the ***Audible Pulse Tone*** feature.

2. Using sterile technique, remove the sensor from the package.

3. Determine that the fetus is in vertex presentation.

4. After identifying the sagittal suture and one or both of the fontanels, introduce the sensor at the optimum site relative to head position and depth. It is preferable to introduce the sensor on the side of the head facing the maternal spine (posterior cheek).

Caution: If 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.

5. Hold gloved fingers under sensor tip.

6. Introduce the sensor so that the tip of the sensor is at the midpoint of the sagittal suture. Ensure sensor optics are facing the fetus.

Note: Sensor placement should be attempted between contractions. If a contraction occurs during insertion of the sensor, stop the procedure. Wait for the contraction to end, then proceed with sensor placement. It is not necessary to remove the partially inserted sensor while waiting for the contraction to end.

Note: Some amniotic fluid may be lost during sensor insertion or during sensor repositioning. This may be observed more frequently when an intrauterine pressure catheter has been inserted.

7. Guide the sensor through the cervical os along the gloved examining fingers approximately perpendicular to the sagittal suture, but slightly towards the anterior fontanel (see Figures 9, 10, and 11). This should align the sensor with the fetal cheek.

Figure 9: Left Occipito-Anterior Position

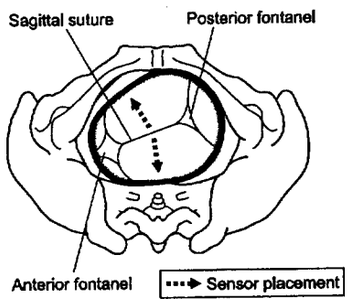


Figure 10: Right Occipito-Transverse Position

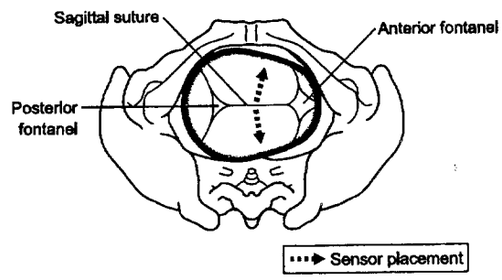
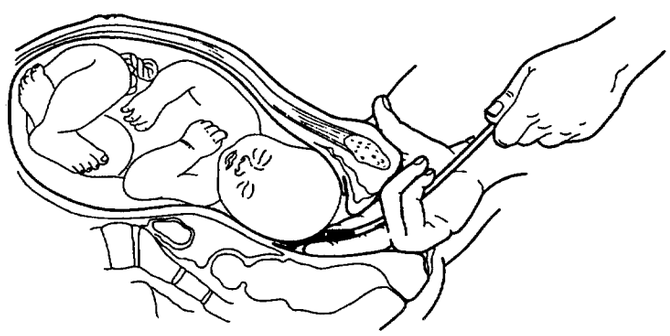


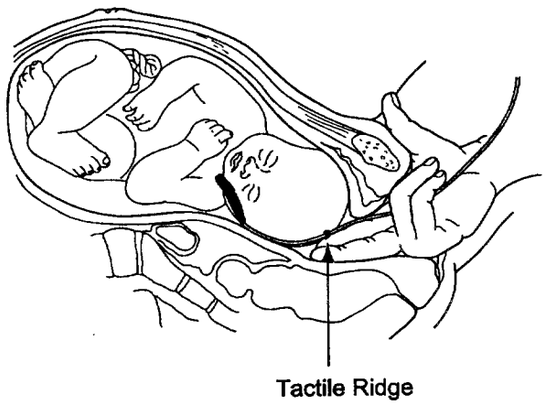
Figure 11: Introducing the Sensor



Note: If it is difficult to pass the sensor under the cervix, move the sensor to an easier entry location, insert about 3 cm, then, with the gloved examining fingers still in contact with the sensor, guide the sensor around to the desired location.

8. Insert the sensor until the 15-cm tactile ridge is felt at the midpoint of the presenting part. This corresponds to the tactile ridge crossing the tip of the examining fingers (Figure 12).

Figure 12: Insertion to the 15-cm Tactile Ridge



Caution: Do not force the sensor. If resistance is felt, guide the sensor to a more satisfactory site and continue with placement, if possible. An ear may be the source of resistance, indicating that the sensor placement should be slightly forward and away from the posterior fontanel.

Note: At dilatations of 7 cm or greater, resistance often indicates that the sensor is in the vagina rather than under the cervix.

9. Slowly advance the sensor another 3 or 4 cm to ensure that the LEDs and photodetector are positioned well beyond the fetal presenting part and hair.

Note: The sensor cable mark should be approximately 25 - 27 cm at the introitus if the fetus is at –2 station.

10. Withdraw the sensor in 1 cm increments to bring it back on to the preferred monitoring area of the fetal cheek. Observe all indicators and displays on the front of the monitor with each 1 cm move to determine the progress towards positioning the sensor in an optimal location.

    When the ***Sensor Lifted*** indicator or message is not illuminated, remove the stylet with the opposite hand, while continuing to hold the sensor in position with gloved fingers.

WARNING: Never attempt to reinsert a stylet into the sensor cable chamber once it has been completely removed during sensor placement. Doing so may result in maternal injury.

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11. Continue to hold the sensor in position with gloved fingers while observing the monitor.

    a) If the ***Sensor Lifted*** indicator or message reappears on the monitor display, withdraw the sensor in 1 cm increments until contact is achieved. You should not have to withdraw the sensor more than 3 to 4 cm.

    If you have withdrawn it more than 4 cm and still do not have contact, the sensor may be over hair, or there may be vernix covering the contact reference electrode in the fluid channel.

    Reassess sensor placement relative to fetal head position, and reassess sensor depth relative to fetal station by noting the centimeter mark at the introitus.

    After reassessing fetal position and fetal station, withdraw the sensor head to the edge of the cervical lip and reinsert the sensor until the tactile ridge is at the midpoint of the presenting part. Slowly advance the sensor an additional 3 to 4 cm and begin again to slowly withdraw in 1 cm increments.

    b) If the ***Sensor Lifted*** indicator or message goes out, indicating that contact has been achieved, continue to hold the sensor in place with gloved fingers for about 15 seconds until the sensor seats itself.

Note: During sensor insertion and before the tactile ridge reaches the midpoint of the presenting part, the ***Sensor Lifted*** indicator or message may disappear from the display when the contact electrodes touch maternal tissue (vaginal or cervical). However, unless the tactile ridge has reached the midpoint of the presenting part, the fact that the indicator or message is not displayed does not necessarily indicate proper contact with the fetal skin.

    c) Note the cm mark on the stylet chamber relative to the introitus.

    d) If you are still not successful in achieving sensor contact and FSpO2 display after one to two attempts to reposition, remove sensor and inspect it for the presence of vernix.

    e) The appearance of heavy vernix on the sensor or in the fluid channel may indicate that the sensor was placed over hair rather than on the cheek or temple area. Vernix over the cheek or temple is unusual in the full term fetus, but, if present, may preclude FSpO2 monitoring for that specific fetus.

Special Note:
The following instructions refer to the ***Signal Quality*** indicator on the N-400 monitor. A fetal heart rate monitor containing Nellcor FSpO2 technology may function differently. Refer to the operator's manual available from the manufacturer of the FHR monitor for further information.

f) Watch for activity on the monitor ***Pulse Amplitude*** bar and ***Signal Quality*** indicators to provide feedback on the quality and relative strength of the fetal pulses that are being detected by the sensor.

The ***Signal Quality*** indicator should slowly climb from one segment on the display to five or more segments before an initial FSpO2 value and fetal pulse rate will be displayed on the front panel of the monitor.

g) If ***Signal Quality*** is two to three segments only, the sensor is not in a location that will continuously provide fetal pulses of sufficient quality for FSpO2 measurement.

Reassess sensor placement relative to fetal head position and reassess sensor depth relative to fetal station, then adjust, or reposition sensor for better pulse signal quality. Usually the sensor only needs to be advanced or withdrawn (adjustment) a centimeter or two.

However, it may be necessary to completely reposition the sensor by withdrawing the sensor head back to the cervical lip and reinserting, as described in step 11 a.

Note: Whenever it is necessary to reposition the sensor, do not withdraw the sensor completely. Withdraw the sensor body to the cervical lip. It can then be moved around easily to a new position with gloved examining fingers.

h) Try to achieve a stable signal quality of seven or more segments, which indicates optimal positioning on the fetal face or temple.

If signal quality remains below five bars for two to three minutes after the initial placement, it is unlikely that FSpO2 will be displayed, even if contact has been achieved. Reassess sensor placement relative to fetal head position and reassess sensor depth relative to fetal station, then attempt to reposition sensor for more consistent fetal pulses with better signal quality.

i) After the sensor has been optimally positioned, the monitor should display data within two to three minutes. Observe that FSpO2 and pulse rate are displayed. If data are displayed within two to three minutes, and signal quality is stable at five or more segments, leave the sensor positioned as is and remove examining fingers.

Note: Verify that the pulse rate displayed by the N-400 closely matches the fetal heart rate as determined by ausculation to ensure that the oxygen saturation is fetal in origin.

12. When the head rotates as it descends, the sensor may need to be adjusted or repositioned.

    a) Observe the monitor periodically throughout the course of labor to determine whether or not the sensor needs adjusting or repositioning.

    b) When the sensor is in optimal position on the fetus, between contractions, you should observe:

    - Nearly continuous display of FSpO2
    - Nearly continuous display of fetal pulse rate (on the N-400).
    - No illumination of the ***Sensor Lifted*** indicator or message
    - Signal quality stable at 7 or more segments (on the N-400)
    - Rhythmic ramping of the ***Pulse Amplitude*** bar

    c) Occasionally during uterine contractions, some or all of the parameters listed above may be momentarily lost from the display due to normal forces applied to the fetus and sensor. Always wait for a few seconds after a contraction subsides before attempting to adjust or reposition the sensor, as displayed values may return.

    d) If FSpO2 is no longer being continuously displayed between contractions, observe the monitor to determine status of Sensor Lifted, Pulse Amplitude, and ***Signal Quality*** indicators.

    e) If the Sensor Lifted indicator or message is illuminated, note cm mark at introitus to determine any change in relative depth of the sensor since it was last adjusted.

    Slowly withdraw or advance the sensor in 1-cm increments based on the status of labor progress and the cm mark at the introitus until contact is re-established with the fetus.

    f) Follow steps 11-f through 11-i related to signal quality to re-establish an optimal sensor placement following sensor adjustment/repositioning.

    g) If the Sensor Lifted indicator or message is not illuminated, and FSpO2 is no longer being continuously displayed between contractions, it is likely that signal quality has degraded and the ***Signal Quality*** indicator has dropped below 5 segments. Adjust the sensor slightly or withdraw/advance the sensor in 1-cm increments until a stable signal quality of 5 segments or more is re-established.

13. The sensor may be left in place during normal, unassisted vaginal delivery.

WARNING: Remove sensor prior to vacuum extraction, forceps delivery, or Cesarean delivery.

Caution: If a lubricant is to be used to aid in sensor placement, use only a sterile water-soluble obstetrical lubricant, such as K-Y® Jelly.

TROUBLESHOOTING GUIDE

1. **Displayed FSpO2 does not match with the SaO2 value calculated from a fetal scalp blood sample measurement on a blood gas analyzer.**

   - Close agreement requires simultaneous blood sampling and pulse oximeter measurements from the same blood supply. Blood samples exposed to air during the sampling process may not accurately reflect true blood values.
   - The SaO2 calculation may not have been correctly adjusted for the effects of pH, temperature, PaCO2, 2,3-DPG, or the presence of fetal hemoglobin. Check whether calculations have been corrected appropriately for relevant variables. (See the "Principles of Operation" section in the *N-400 Operator's Manual* for more information.) In general, calculated SaO2 values are not as reliable as direct CO-Oximeter or pulse oximeter measurements.
   - OxiFirst System accuracy can be affected by incorrect sensor application or use, significant levels of dysfunctional hemoglobins, excessive patient movement, venous pulsation, or nearby electrosurgical interference. Observe all instructions, warnings, and cautions in this manual and in the *N-400 Operator's Manual.*
   - Oxygen saturation greater than 85% and/or pulse rate less than 100 could indicate that the values are maternal in origin. Check sensor placement to ensure that it is properly positioned on the fetus.

2. **Displayed FSpO2 does not match with the SaO2 value calculated from a fetal scalp blood sample measurement on a laboratory CO-Oximeter.**

   - Close agreement requires simultaneous blood sampling and pulse oximeter measurements from the same blood supply. Blood samples exposed to air during the sampling process may not accurately reflect true blood values.
   - Fractional measurements may not have been converted to functional measurements before the comparison was made. The N-400, as well as other two-wavelength oximeters, measures functional saturation. Multi-wavelength oximeters measure fractional saturation.
     Fractional measurements must be converted to functional measurements for comparison. Refer to the equation for this conversion in the *Principles of Operation* section in the *N-400 Operator's Manual.*
   - Oxygen saturation greater than 85% and/or pulse rate less than 100 could indicate that the values are maternal in origin. Check sensor placement to ensure that it is properly positioned on the fetus.
   - Check whether or not co-oximeter values have been correctly adjusted for the presence of fetal hemoglobin.

3. **Displayed pulse rate does not agree with that of an electronic fetal heart rate monitor.**

   - Excessive maternal or fetal motion may be making it impossible for the N-400 to find a pulse pattern. If possible, keep the mother still.
   - Ensure that the sensor is properly positioned on the fetus.
   - Oxygen saturation greater than 85% and/or pulse rate less than 100 could indicate that the values are maternal in origin. Check sensor placement to ensure that it is properly positioned on the fetus.

4. **Fetal heart rate slows during, or immediately following, sensor placement.**

   - A fetal response to stimulation could cause a reflex bradycardia.

Caution: Stop the exam. Do not proceed with sensor placement. Wait for the fetal heart rate to return to the previous range before proceeding with sensor insertion.

5. **FSpO2 or pulse rate change rapidly; *Pulse Amplitude* indicator is erratic.**

   - Check the fetus for other signs of distress.
   - Excessive maternal or fetal motion may be making it impossible for the N-400 to find a pulse pattern. If possible, keep the mother still.
   - Check whether the sensor is positioned properly, and reposition it if necessary.
   - Set the N-400 response time for Mode 1.
   - A nearby electrosurgical unit (ESU) may be interfering with performance.

WARNING: The OxiFirst System should not be used 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 OxiFirst System and an ESU are used together.

6. **FSpO2 readings >85%.**

   - The sensor may be facing the uterine wall and may be reading maternal saturation. Confirm that the sensor is positioned correctly against the fetus.
   - The sensor has white markings on both sides. The side with numbers at 1-cm intervals (30, 29, 28, 27...) should be facing toward the fetus. The side with numbers only at 17, 20, 25, 30 is the maternal side and should be facing away from the fetus.
   - Palpate the maternal pulse and compare it to the heart rate displayed on the fetal heart rate monitor and to the pulse rate displayed on the N-400 monitor. If the maternal pulse matches the N-400 displayed pulse rate, sensor is most likely monitoring maternal oxygen saturation. Reposition or adjust the sensor.
   - Normal sensor operation may be affected by maternal pulsations or vernix in the fluid channel. Withdraw the sensor in 1 cm increments to better position the sensor; hold in place for 15 seconds.
   - If still unsuccessful in correcting this condition, completely withdraw sensor and inspect for vernix in the fluid channel.

7. **No contact. *Sensor Lifted* indicator  or message remains lit even though appropriate adjustments have been made.**

   - Station of the head may be too high. Wait for the head to descend to –1 or 0 station.
   - Assess sensor depth relative to station of fetal head; advance or withdraw the sensor as needed.
   - As the head descends, the sensor should also descend. If the sensor has not descended, (as indicated by the centimeter mark at the introitus) withdraw the sensor in 1 cm increments until contact is again achieved, noting the cm mark on the stylet chamber relative to introitus.
   - Remove the sensor and check for vernix in the fluid channel. Apply a new sensor.
   - The sensor may be faulty. Remove the sensor and insert a new one.
   - Save faulty sensor and contact a qualified Technical Service representative to report the problem.

8. ***Sensor Unplugged*** **indicator is on.** 

   - Check connection between the sensor and the patient module.
   - Check connection between patient module cable and monitor.
   - If all connections are okay, try a new sensor.
   - If problem persists, try a new patient module.
   - If problem persists, contact a qualified service representative for further assistance.
   - N-400 does not turn on.
   - Check that the mains (AC) ON/OFF switch is set to ON.
   - Check mains (AC) connection. Check that N-400 is connected properly to mains (AC) supply.
   - Check mains (AC) fuses.

9. **Patient module cannot be connected.**

   - Use only a Nellcor Fetal Patient Module.
   - Connector pins may be bent; replace with another Fetal Patient Module.

10. ***Searching*** **indicator is on;** ***Pulse Amplitude*** **appears to indicate pulses, but there is no FSpO2 or pulse rate displayed.** 

    - Check the fetus.
    - The signal quality is below the acceptable threshold requirement necessary to post data on the display.
    - Excessive maternal or fetal patient motion may be interfering with signal quality. If possible, keep the patient still.
    - The sensor may be improperly positioned; assess sensor location and determine appropriate adjustment.
    - The fetus's perfusion may be too low for the N-400 to detect an acceptable pulse.
    - If ***Searching*** indicator continues to display after evaluations and adjustments:
      - The sensor may be damaged; replace it.
      - The patient module may be damaged; try another Fetal Patient Module.

11. **Signal lost, searching for fetal pulse. May be due to:**

    - Fetal movement. Wait for movement to stop.
    - Maternal movement. Wait for movement to stop.
    - Contraction. Wait for contraction to end.
    - Sensor ascent or descent independent of fetal head descent. Note centimeter mark on stylet chamber relative to the introitus. Adjust sensor by advancing or withdrawing it to regain signal.
    - Relative quality of signal may have degraded at the sensor site. Try repositioning sensor to a more optimal site.
    - On the N-400 monitor, enable the Variable Pulse Tone feature to assess quality of sensor placement and to aid in adjusting or repositioning the sensor to a more optimal site.

ALARMS

The default state of the audio alarms is OFF. If audio alarms are to be used, they must first be enabled. If audio alarms are enabled, do not set the alarm volume too low to be heard.

When the audio alarm off indicator is illuminated, no audio alarm sounds.

INACCURATE MEASUREMENTS AND LOSS OF PULSE SIGNAL

Inaccurate measurements may be caused by:

- incorrect application or use of a sensor;
- significant levels of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin;
- excessive fetal or maternal patient movement;
- venous pulsation.

Loss of pulse signal can occur:

- during uterine contractions;
- if the fetus experiences shock, hypotension, severe vasoconstriction, severe anemia, arterial occlusion proximal to the sensor, or cardiac arrest.

The user must independently verify that the N-400 pulse rate displayed is the actual fetal heart rate. This can be done by auscultation.

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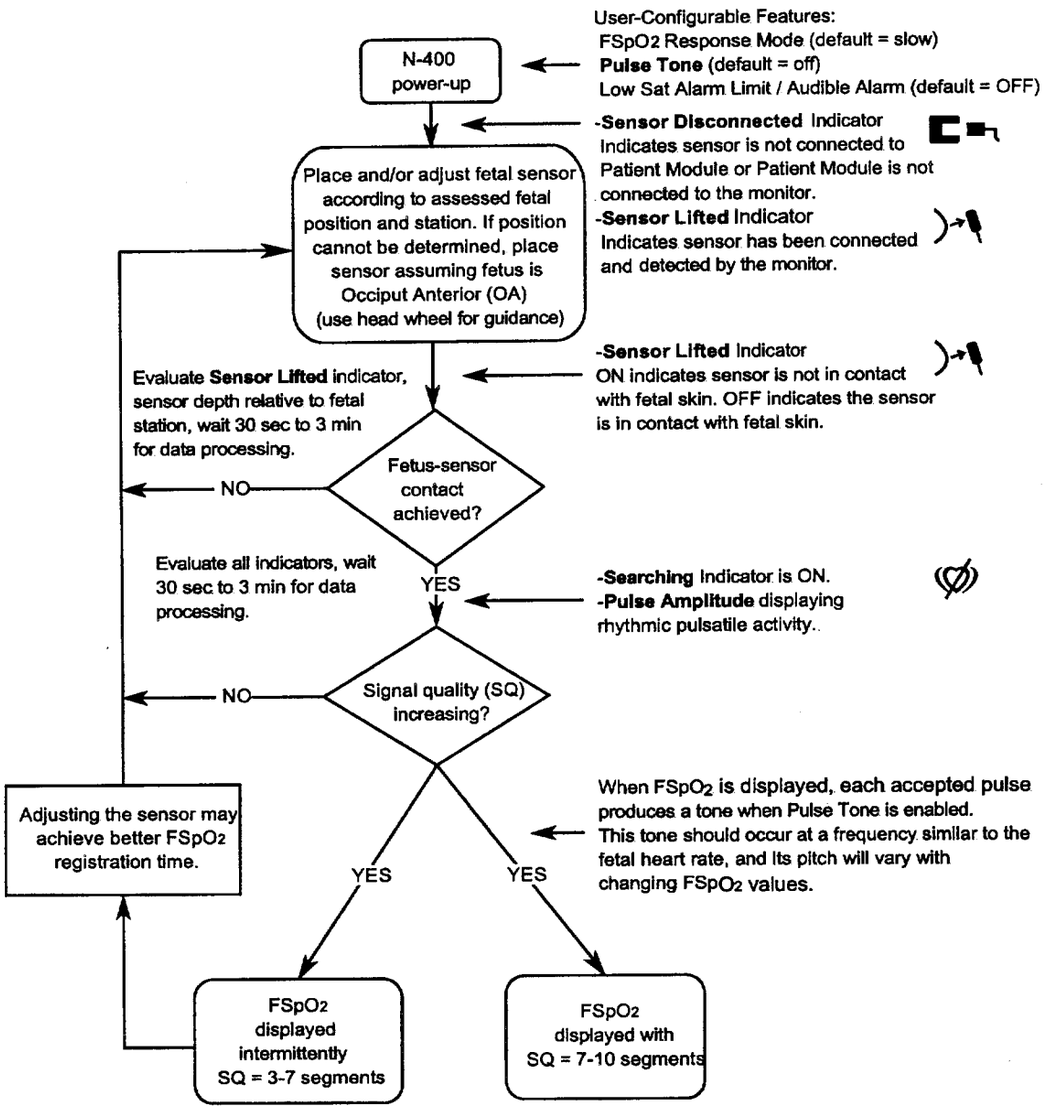
APPENDIX I: SENSOR PLACEMENT FLOWCHART



Non-Optimal Sensor Site
-Signal quality fluctuating from 3 to 7 segments.
-Nonrhythmic pulses seen on Pulse Amplitude indicator.
-Nonrhythmic tones heard when pulse tone is enabled.
-Sensor depth does not correlate with fetal station.
-Optical pulse rate of the N-400 does not correlate with FHR.

Optimal Sensor Site
-Sensor Lifted indicator is never ON.
-Signal quality is consistently above 7 segments.
-Rhythmic pulses seen on Pulse Amplitude indicator.
-Rhythmic tones heard when pulse tone is enabled.
-Optical pulse rate of the N-400 closely matches FHR.

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