



Indications, contraindications, warnings and precautions

A. Indications for Use

The STAN S31 Fetal Heart Monitor Fetal ECG Analysis System is indicated as an adjunct to fetal heart rate monitoring to determine whether obstetrical intervention is warranted when there is increased risk of developing metabolic acidosis. This device is intended for use in patients with:

- Planned vaginal delivery;
- >36 completed weeks gestation;
- Singleton fetus;
- Vertex presentation; and
- Ruptured amniotic membranes.

B. Contraindications

Use of the STAN S31 fetal ECG analysis function is contraindicated in the following situations:

- Non-reassuring, Grade 2 Fetal Heart Rate classification (as defined in the STAN S31 Training Materials). When fetal asphyxia has been severe and long lasting, the ST waveform returns towards normal, reflecting a markedly reduced ability by the fetus to respond. **A change over time can not be expected; therefore reliance on ST event signals in this situation may lead to serious adverse neonatal outcome.**
- In patients for whom use of a fetal scalp electrode is contraindicated such as:
 - HIV
 - Infectious hepatitis
 - Active herpes simplex virus
 - Known or suspected fetal coagulation disorder
- Patients with fetal bleeding disorders. Chronic fetal bleeding (e.g., due to partial placental abruption) leading to loss of fetal blood volume may result in a reduction in the margin of safety or time that the fetus can successfully respond to hypoxia.
- Monitoring initiated in the second stage of labor, since time may be insufficient to establish the baseline fetal ECG data required for automatic ST event signals.
- Patients experiencing precipitous labor, as rapid labor may preclude acquisition of necessary baseline fetal ECG data.
- Patients receiving Transcutaneous Electrical Nerve Stimulation (TENS) for analgesia during labor because TENS may interfere with acquisition of the fetal ECG signal.
- Patients requiring immediate delivery as in the following situations:
 - Conditions that preclude vaginal delivery such as documented or suspected placenta previa
 - Cord prolapse

Need for immediate delivery unrelated to fetal heart rate or fetal ECG, such as active maternal or fetal

C. Warnings

A warning alerts you to potentially serious outcomes (death, injury, or adverse events) to the user or the patients.

- **WARNING:** Intrapartum management of the fetus is a complex process that uses a variety of maternal and fetal considerations in the formulation of clinical decisions. The STAN Training Program and Guidelines are recommendations that are based on extensive clinical investigation and subsequent prospective clinical use. STAN Training Program and Guidelines are not a substitute for individualized clinical assessment and decision-making for each patient.
- **WARNING:** ST analysis is only an adjunct to fetal heart rate monitoring and should never be used exclusively to make patient management decisions. There are situations in which the fetus is experiencing hypoxia but an automatic ST event signal may not appear. These include the following:
 - Inadequate time to obtain baseline ECG
 - Poor signal quality
 - Pre-existing hypoxia

If there is reason to believe that any of the above applies, clinical decision making should not include ST analysis.

- **WARNING:** Centralized Monitoring Systems connected to STAN can display EFM tracings for FHR and uterine activity but may not support the display of Fetal ECG analysis information (ST analysis data). In this case ST information including events and signal quality information will not be available on the Centralized Monitoring System. Failure to regularly check the STAN monitor and Event Log for important ST information directly, especially during periods of non-reassuring fetal heart rate, may lead to important information being missed and injury to the patient.
- **WARNING:** Do not rely solely on the appearance of an ST event marker to signal the need for obstetrical intervention. If you suspect, on the basis of FHR-only and/or clinical data that the fetus is experiencing severe hypoxia, you should manage the patient accordingly despite the absence of an ST event marker.
- **WARNING:** If the fetal ECG analysis capability is lost, manual interpretation of ECG/ST data should not be attempted. Clinical management should be based on available data, e.g., FHR.
- **WARNING:** When fetal ECG analysis has not been available for ≥ 4 minutes and efforts to readjust the monitor fail to restore the signal, clinical management should be based on available data, e.g., FHR. No inferences regarding fetal status should be made on the basis of earlier fetal ECG analysis.
- **WARNING:** At the start of a recording, special attention should be paid to the log, and visual inspection of the FECCG signal. If a "Poor FECCG Signal Quality" event is active in the Event Log, adequate measures should be taken to improve the signal quality (by re-applying the electrodes if necessary).
- **WARNING:** Fetal ECG is similar to, but not the same as Adult ECG. Fetal heart pathology, such as hypoplastic left ventricle, can not be diagnosed from the fetal ECG signal. Even if the fetal ECG pattern appears normal, it can not be assumed that the fetal heart is normal. STAN S31 is not a substitute for a fetal echocardiography exam.
- **WARNING:** Before using STAN S31 output, verify that the ECG complex is of a normal appearance, by observing the raw ECG-signal in Signal Mode. In the event of a constant, non-fluctuating fetal heart rate, ensure that no other device is interfering with the STAN S31 signal.
- **WARNING:** The STAN S31 displays an inverted ECG waveform pattern (negative P waves) when the STAN S31 is applied on fetuses in breech presentation. If an inverted ECG is observed, fetal presentation and correct placement of the scalp electrode should be reassessed.
- **WARNING:** If insufficient monitoring time has accrued, STAN may be registering T/QRS signals but may not be ready to automatically signal ST events. In this situation, it may be possible to manually/visually detect a rise in T/QRS before an automatic ST event appears on the screen. For example, a prolonged bradycardia may occur with an accompanying rise in T/QRS before an ST event appears. In such situations, you should treat the observed T/QRS rise as a significant event in making patient management decisions.
- **WARNING:** Locate the monitor near the patient in a position that ensures it cannot accidentally fall on to the patient. Failure to do so could result in patient injury.
- **WARNING:** The STAN S31 fetal heart monitor is not shielded against electrocautery equipment or defibrillators and must not be used together with or in proximity to flammable substances, e.g., anaesthetic gases.
- **WARNING:** STAN S31 should be used only in rooms that are relatively free of dust, moisture, vibrations and extreme temperatures.
- **WARNING:** Neoventa Medical guarantees the functioning of the device only if it is used within the temperature range 50-104 degrees F.
- **WARNING:** Moisture - Ensure that the equipment and all its cables are dry when used. Condensation may occur if it is moved from one building to another. Should this be the case, dry the equipment thoroughly prior to mains connection.
- **WARNING:** The STAN S31 should not be used to 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.
- **WARNING:** Radio transmission equipment, mobile telephones, magnetic resonance imaging (MRI) machines, etc. may affect the functioning of the device and must not be used in its proximity. Particular care must be observed during the use of strong emission sources such as electrocautery, to prevent electrocautery cables, etc. being laid over or near the device.

D. Precautions

A caution alerts you to exercise care necessary for the safe and effective use of the STAN S31 system.

- CAUTION: Signal quality must be continuously evaluated in order to use the fetal ECG as an adjunct to fetal heart rate in clinical management. Signal quality problems should be suspected in the following situations:
 - Signal information window reads "ST disabled"
 - Event log reads "Poor FECG signal quality"
 - Difficult to see QRS complex
 - Signal bar shows level 2 or less

In the event of signal quality problems, the following corrective action should be taken:

- Check skin electrode
- Check scalp electrode
- Check legplate cable

See section below for further information regarding signal quality.

- CAUTION: The safety and effectiveness of the STAN S31 System has not been systematically evaluated in the following situations:
 - Immature fetus (less than 36 gestational weeks)
 - Twin gestation
 - Breech presentation

However STAN S31 is capable of monitoring breech and twin gestations, so if you do choose to use the device in this/these situations you should take note of the following:

- Breech Presentation: attachment of a spiral fetal scalp electrode to breech will result in an inverted fetal ECG pattern. The STAN monitor is equipped with a "breech mode" function that should be initiated in the event that there is a clear indication for attempted vaginal breech delivery by a clinician with requisite skills.
- Twin Gestation: in the case of twins, the spiral electrode can only be applied to Twin A, thus fetal ECG data will only be available for that twin. Twin B can be monitored exclusively with external Doppler transducer using the STAN system. The STAN Clinical Guidelines, which are based on fetal heart rate plus ST data analysis, can only be applied to Twin A in the case of twins. Clinical management decisions regarding Twin B can not be based on STAN Guidelines because ECG analysis is not available.

- CAUTION: The STAN S31 ECG analysis feature is only an adjunct to conventional fetal heart monitoring, and should not be used as a substitute for clinical interpretation of FHR.
- CAUTION: All Instructions for Use, Contraindications, Warnings and Precautions for the use of the fetal scalp electrode should be observed.
- CAUTION: The STAN S31 should not be used if amniotic membranes have not fully receded away from where the scalp electrode has been applied. Contact between the electrode and membrane fragments could result in erroneous fetal ECG measurements.
- CAUTION: Do not attempt to rupture amniotic membranes with the scalp electrode. Doing so may result in erroneous fetal ECG measurements.
- CAUTION: Take care that the cables of the STAN S31 are not damaged during use or storage. Transducers and other connectors may be damaged if stepped on. When connecting cables and transducers, make sure there is no risk of anyone stumbling or tripping over the cables, since the patient and fetus may be injured if the scalp electrode or skin electrodes are pulled off. Connect only the mains cable to the mains supply.
- CAUTION: Do not use STAN S31 if the outside monitor cover appears to be damaged. Doing so may result in patient injury and instrument malfunction.
- CAUTION: Do not remove the outside monitor cover. Doing so may result in electrical shock hazard. There are no user-serviceable parts inside.

E. Electrical safety precautions

- CAUTION: Avoid contact between the scalp electrode, skin electrode or legplate contacts and earth or any electrically conductive object.
- CAUTION: Power source - The STAN S31 fetal heart monitor must be used only with a power source of 100-120V/60 Hz. The mains cable has three conductors for connection to an earthed wall socket. The system must be connected to an outlet with proper protective earth wiring.
- CAUTION: Incorrect mains connection - Check that the equipment is not connected to the mains by any component other than mains cable or approved trolley.
- CAUTION: Earth connection - The STAN S31 fetal heart monitor must have a protective earth connection. All forms of earth leakage represent a potential safety risk that may seriously injure patient and operator.
- CAUTION: System combinations - The electrical devices that may be connected to STAN S31 (Maternal Vital Signs Monitor, Thermal Recorder, network interface adapter and Central Monitoring Systems through the serial port isolation adapter) are described in the STAN S31 User Manual. If other medical electrical devices are connected to the patient, these devices should be powered from separate power outlets, and not from multiple socket outlets, to ensure the highest level of electrical safety. Contact a qualified technician or the supplier for more information.