EMG Activity, Deflections Above Baseline: Potential Problems with Clinical Interpretation

• LabView may display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle contract. In the context of a pregnancy ≥36 completed weeks, clinical observation of maternal heart rate may lead to significant intervention, such as tocolytics, diagnostic procedures, and/or delivery earlier than 36 completed weeks.

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Indications for Use: The LabView System is a transabdominal electromyography and electro-cardiography intrapartum maternal-fetal sensor. It works non-invasively via surface electrodes on the maternal abdomen with appropriate monitoring of maternal and fetal heart rate (FHR), uterine activity and maternal heart rate (MHR). It is indicated for use on women who are ≥36 completed weeks in labor, with singleton pregnancies. It is intended for use by healthcare professionals in a clinical setting.

Contraindications, Warnings, and Precautions

• LabView is not indicated for use in multiparous-births. LabView has been tested in nulliparas and in multiparas at ≥36 completed weeks. LabView may display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle contract. In the context of a pregnancy ≥36 completed weeks, clinical observation of maternal heart rate may lead to significant intervention, such as tocolytics, diagnostic procedures, and/or delivery earlier than 36 completed weeks.

Clinical Use Warnings

• LabView is intended to be used in a clinical setting by clinical professionals who have been properly trained in the care of pregnant patients and in the use of monitor obstetric patients. Data from LabView must be evaluated in the context of other relevant information and the care provider’s knowledge of the patient’s medical condition. LabView is a diagnostic aid to the treating clinician and should not be made solely based on LabView-data.

• LabView has been shown to be effective in women who are ≥36 completed weeks in labor, with singleton pregnancies. LabView should not be used for antepartum monitoring, nor should it be used to monitor preterm labors.

• LabView measures electrical signals received through the electrode array that is placed on the mother’s abdomen. When the signal processing technology has determined that data may not be reliable, the LabView device may display non cardiac- component or accessory with that from a different manufacturer may result in lost-of-data and/or the failure of the LabView system. Only approved and qualified personnel should attempt any necessary internal servicing. Technical support may be contacted for assistance.
The LaborView Wireless Electrode System is suitable for use in all electromagnetic environments.

Checking the EMF:
- Connect the Electrode System to the fetal monitor.
- Confirm the monitor is receiving signals for both the contraction curve and heart rates.
- Assess how well the Electrode System wireless connection is working.
- If the Transmitter becomes disconnected from the Base Station, reconnect immediately and ensure all lights are appropriately illuminated.
- An amber Communications Indicator means that the wireless connection is not functioning. During subsequent use of the system, be prepared to use a wired connection if necessary.
- The Lab View device must be used at least 1.2 meters away from fixed RF transmitters.
- A single characteristic was suggested. Risks R-51 from the guided procedure have been evaluated and found to be acceptable. Risks R-51 from the use of the LaborView Wireless Electrode System should be reassessed as in the initial risk assessment.
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Technical Specifications:
- Guidance and manufacturer’s declaration – electromagnetic immunity:
  - IEC 61000-4-2: ±2 V for mains supply lines; ±1 kV for power supplies
  - IEC 61000-4-3: ±2 kV for mains supply lines; ±1 kV for power supplies
  - IEC 61000-4-4: ±8 kV air discharge, ±1 kV contact discharge
  - IEC 61000-4-5: ±2 kV line(s) to earth
  - IEC 61000-4-11: ±5 μA transient/burst discharge

Manufacturer:
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- Phone: 352-235-3897
- Fax: 352-337-6302

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