

## **FDA Advisory Panel Unanimously Recommends Approval of the STAN Fetal heart monitor from Neoventa Medical**

**Gaithersburg, Maryland, June 23 2005**

**The U.S. Food and Drug Administration's (FDA) Obstetrics and Gynecology Advisory Panel voted Thursday to recommend approval of the STAN® S31 Fetal heart monitor Pre-Market Approval (PMA) application. STAN helps clinicians identify babies at risk due to oxygen deficiency during labor. It also reduces the number of unnecessary operative interventions.**

Though Electronic Fetal Monitoring (EFM) during labor is routine, problems due to fetal oxygen deficiency still occur regularly. Perinatal mortality for those babies monitored with EFM is still approximately 4 per 1000 births. In addition rates of operative intervention such as Cesarean section continue to rise.

The STAN monitor represents a major development in fetal monitoring by examining not only the fetal heart rate, but also the shape of the fetal ECG waveform. Changes in ST interval of the fetal ECG are an indication that the fetus is suffering from a lack of oxygen. The STAN fetal monitor automatically detects and analyzes these ECG changes using ST analysis. In a number of large European studies STAN and ST analysis were shown to help clinicians better decide when intervention was appropriate, thus resulting in more normal deliveries and healthier babies than with EFM.

Recently, Neoventa sponsored a multi-center trial in the U.S. which showed very similar results to the European studies. The results from this U.S. trial were presented at the FDA Advisory Panel meeting. Dr Lawrence Devoe - Chairman of Obstetrics and Gynecology at the Medical College of Georgia and lead investigator in the study commented:

*'ST segment analysis allows us to clarify EFM strips which are problematic. It will enable clinicians to make better judgments for intervention when needed and for avoiding intervention when not needed. I believe that the panelists realize that this system has the potential to usher in a new era in EFM which could improve care for mothers and their infants.'*

Dr Michael Ross of UCLA - Harbor, another investigator from the study also commented:

*The unanimous approval of STAN by the FDA panel indicates both the need, and now the opportunity, to improve the diagnostic capability of fetal heart rate monitoring. The panel was convinced that STAN monitoring has been shown to reduce the incidence of unnecessary operative interventions, while also reducing the incidence of infants at risk of injury due to lack of oxygen.*

*STAN represents the first major advancement in the assessment of the fetus during labor since the development of the fetal heart rate monitor.*

The recommendation of the FDA Advisory Panel is a significant step towards the US market introduction of STAN. The panel proposed four conditions to help ensure an effective introduction; their conditions focusing on clinician education and follow-up of results. Neoventa will work closely with the FDA to finalize the approval over the coming months.

Background information regarding STAN:

- STAN is used in 17 countries in more than 50.000 deliveries every year.

- In 2002 when the FDA Obstetrics and Gynecology Advisory panel considered STAN the Panel decided that US studies were needed to show that the method could be successfully applied in the US. The results of these studies were the focus of the recent panel meeting.
- The pivotal study illustrating the safety and efficacy of STAN was a multi-center randomized controlled trial of nearly 5000 patients published in The Lancet in 2001. The study showed that STAN significantly reduced the incidence of both metabolic acidosis and operative interventions for fetal distress. (Amer-Wahlin et.al. The Lancet, Vol 358, 2001)
- STAN is a unique product, originally developed in Sweden.

### **Neoventa Medical**

Neoventa Medical AB is a privately held Swedish company situated in Moelndal, Gothenburg. Neoventa develops and markets monitoring and management tools for improved perinatal healthcare. Neoventa has combined unique medical expertise with the latest technology to establish ST analysis as one of the most exciting advances within the field of perinatal medicine. STAN<sup>®</sup> S31 is the latest in a series of products for this purpose.

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