

## **Neoventa introduces unique fetal heart Monitor to the U.S. market**

**The U.S. Food and Drug Administration (FDA) has approved the STAN<sup>®</sup> S31 Fetal heart monitor Pre-Market Approval (PMA) application. STAN from Neoventa Medical is the first fetal monitor proven to reduce the risk of brain injury during labor.**

STAN provides a major breakthrough in Electronic Fetal Monitoring (EFM) by examining not only the fetal heart rate, but also detecting and analyzing changes in the shape of the fetal ECG waveform (ST analysis).

Changes in the ECG indicate that the fetus is suffering from a lack of oxygen. A randomized trial with 5,000 Swedish patients shows that use of STAN halves the number of infants suffering from injuries due to lack of oxygen and also lowers the emergency cesarean section rate. Recently, Neoventa sponsored a multi-center trial in the U.S. with 750 patients which showed very similar results to the Swedish study.

Dr Lawrence Devoe - Chairman of Obstetrics and Gynecology at the Medical College of Georgia and lead investigator of the STAN U.S. multi-center trial stated:

*“STAN will enable clinicians to make better judgments for intervention when needed and to avoid intervention when not needed. The STAN system has the potential to usher in a new era in EFM which could improve care for mothers and their infants.”*

Simon Grant, CEO of Neoventa:

*“We are very pleased with the FDA approval, and we are now looking forward to introducing a more advanced EFM with STAN to the U.S. market together with a partner. STAN is already used in 22 countries and in more than 50,000 deliveries every year.”*

The approval of the STAN<sup>®</sup> S31 Fetal heart monitor PMA application is a significant step towards an introduction of STAN on the U.S. market. Neoventa has engaged a consultant firm to help in implementing its strategy to seek a suitable partner to exploit the large untapped potential of the U.S. fetal heart monitoring market.

Currently, in the U.S. there are approximately 30,000 fetal monitoring devices in use that STAN could potentially replace. Neoventa will launch STAN in the U.S. during 2006.

## **Background information regarding STAN**

- STAN is used in 22 countries in more than 50,000 deliveries every year.
- The pivotal study illustrating the safety and efficacy of STAN was a multi-center randomized controlled trial of nearly 5,000 patients published in *The Lancet* in 2001<sup>1</sup> and in the *American Journal of Obstetrics and Gynecology* in 2003<sup>2</sup>. The study showed that STAN significantly reduced both the incidence of metabolic acidosis (-54%,  $p=0.02$ ) and operative interventions for fetal distress (-17%,  $p>0.05$ ).
- STAN is a unique methodology, originally developed in Sweden over 30 years and independently verified in a series of clinical trials, including more than 20,000 observations.

### **Neoventa Medical AB**

Neoventa is a privately held Swedish company situated in Mölndal, 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.

### **For further information please refer to:**

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<sup>1</sup> Amer-Wahlin et.al. *The Lancet*, Vol 358, 2001.

<sup>2</sup> Norén et al. *Am J Obstet Gynecol*. Vol 188, 2003.