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STAN S21® Fetal Heart Monitor.

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PRIORITISING SUMMARY

REGISTER ID: **000151**

NAME OF TECHNOLOGY: **STAN S21® FETAL HEART MONITOR**

PURPOSE AND TARGET GROUP: **FETAL HEART MONITORING DURING LABOUR**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	☒	No
ARTG number		☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
The Netherlands	✓		
Sweden			✓
Italy	✓		
Norway	✓		

IMPACT SUMMARY:

Neoventa Medical, Inc. manufactures the STAN® S21 Fetal Heart Monitor system with the aim of monitoring fetal heart rate and ST segment during labour. The STAN® is approved for use in Europe and Food and Drug Administration clearance is expected in the United States during 2005.The manufacturer is currently investigating TGA approval and release in Australia (personal communication, Neoventa Medical Inc.).

BACKGROUND

Electronic fetal heart rate (FHR) monitoring, cardiotocography (CTG), is commonly used to assess fetal well-being during labour and to provide an early indication of fetal distress, which can lead to fetal hypoxia. Fetal heart rate monitoring may be performed externally or internally. External fetal heart rate monitoring involves the use of a device to listen to or record the fetal heartbeat through the mother's abdomen. A fetoscope (a type of stethoscope) is the most basic type of external monitor. Another type of monitor is a hand-held electronic Doppler ultrasound device. These methods are often used during antenatal visits to assess the fetal heart rate and also

occur at regular intervals during labour. FHR may be more accurately monitored internally by means of a fetal scalp electrode. This is attached to the fetal scalp cervical opening and is connected to the FHR monitor, and a print out of the FHR can be obtained for examination. Internal monitoring provides a more accurate and consistent transmission of the fetal heart rate than external monitoring because it is not affected by factors such as physical movement.

During labour the FHR may be monitored either intermittently or continuously depending on whether the birth is classified as low- or high-risk. When a birth is classified high-risk, the use of an internal continuous CTG is standard clinical practice. The continuous CTG consists of two transducers that are strapped to the mother's abdomen with elastic belts. The first of these is the cardiograph transducer that measures the baby's heart rate. The second transducer is the tokodynamometer that measures contractions of the uterus.

The use of electronic fetal heart rate monitoring is controversial as studies have shown variations in heart rates without any significant clinical impact on the fetus. The presence of abnormal fetal heart rate tracings has demonstrated low positive predictive value for fetal metabolic acidaemia and can result in unnecessary operative interventions without an improvement in perinatal outcomes (Dervaitis et al 2004).

The STAN® device (illustrated below) differs from standard CTG technology in that it is intended to provide midwives and doctors with more detailed information about the fetal hypoxic status during labour. It combines standard CTG technology with the addition of ST waveform analysis to provide a fetal ECG. The manufacturer states that the combination of CTG and ST waveform analysis enables precise identification of infants suffering from hypoxia, allowing for clinically necessary intervention. The fetal ECG is obtained via a fetal scalp electrode. The STAN® automatically identifies and analyses changes in the T wave and the ST segment of the fetal ECG. An increase in T wave amplitude, in relation to QRS amplitude, corresponds to the utilisation of glycogen stores (Neoventa Medical, Inc. 2005a). This represents myocardial anaerobic metabolism, which is an indication of fetal hypoxia.

Figure 1. The STAN® fetal monitor (Printed with permissionNeoventa Medical, Inc. 2005b)

CLINICAL NEED AND BURDEN OF DISEASE

It has been suggested that perinatal hypoxic-ischaemic encephalopathy affects approximately 1-4 out of 1,000 full-term infants, and nearly 60% of low birthweight infants (Gluckman 2004). While the presence of this syndrome has in the past been debated, studies demonstrate that a significant percentage of infants born with evidence of asphyxia proceed to develop an encephalopathy and later neurodevelopmental outcomes such as intellectual disability and cerebral palsy (Gluckman 2004).

In Australia, 255,095 babies born to 250,758 mothers were notified to perinatal data collections in the states and territories in 2002 (National Perinatal Statistics Unit, 2005). The number of public hospital separations in Australia for patients with pre-term delivery (AR-DRG number O60), in 2001- 02 was 5,665, approximately 2% of all births.

In 2001-02 and 2002-03 there were 524 and 375 hospital separations in Australian hospitals for intrauterine hypoxia (AIHW 2005). There were also 7,510 and 7,166 hospital separations for principal diagnosis P22 Respiratory distress of newborn in years 2001-02 and 2002-03 respectively (AIHW 2005a). The number of internal fetal monitoring procedures increased from 8,481 in 2000-01 to 11,249 in 2001-02 (AIHW 2005b).

DIFFUSION

There are several maternal indications that require continuous fetal monitoring during labour including the following: diabetes, hypertension (pregnancy-induced or pregnancy associated), chemical dependence, renal disease, thrombophilia, cardiac disease, poor obstetric history, abnormal admission CTG, preterm labour, antepartum haemorrhage, multiple pregnancy, prolonged pregnancy, epidural, meconium, malpresentation, infection, intrapartum haemorrhage or prolonged labour. Given the trial evidence does not support EFM, it is debatable whether it is clinically useful.

The use of CTG +ST waveform analysis fetal monitoring is not available in Australia despite the number of years it has been trialled overseas. It is highly likely that a new diagnostic tool that adds more meaningful information to the clinical picture during high-risk birth would receive a rapid uptake.

COMPARATORS

Cardiotocography alone is considered the “gold standard” for the monitoring of fetal well-being during labour. In addition, intermittent fetal blood scalp sampling to measure pH and fetal oxygen saturation may be used to assess fetal status during labour.

EFFECTIVENESS AND SAFETY ISSUES

A Cochrane review (level I interventional evidence) on fetal ECG for fetal monitoring during labour (2003) included two trials of the STAN® out of a total of three trials. The review reported that the use of ST waveform analysis (2 trials, 7,400 women) during labour was associated with 56% relatively fewer babies with severe metabolic acidosis at birth than those babies monitored with CTG alone (cord pH less than 7.05 and base deficit greater than 12 mmol/L) (relative risk (RR) 0.44, [95% CI 0.26 to 0.75], data from 6,672 babies). In addition, the use of fetal ECG resulted in comparatively fewer fetal blood scalp samples during labour (RR 0.86, [95% CI 0.76 to 0.98]) and fewer operative deliveries (RR 0.89, [95% CI 0.82 to 0.97]). This review concluded

that the use of fetal ST waveform analysis was warranted when a decision had been made to undertake continuous electronic fetal heart rate monitoring.

The two trials (level II interventional evidence) included in this review were confined to births greater than 34 weeks (Westgate 1993) and term births (Amer-Wahlin 2001). These studies compared the use of CTG only versus CTG plus ST analysis using the STAN®. The main outcome variables assessed were metabolic acidosis at birth, and the rate of operative deliveries for fetal distress (caesarean sections, forceps or ventouse deliveries). In addition, Apgar scores at 1 and 5 minutes, and admissions to the neonatal intensive-care unit were assessed.

The Westgate trial of 2,434 high-risk labours found a 46% reduction ($p < 0.001$, odds ratio 1.85 [1.35-2.66]) in operative deliveries for fetal distress and trends to metabolic acidosis ($p = 0.09$, odds ratio 0.38 [0.13-1.07]) and fewer poor 5-minute Apgar scores ($p = 0.12$, odds ratio 0.62 [0.35-1.08]) in the ST waveform plus cardiotocogram (CTG) group (Westgate et al 1993). The study authors concluded that ST waveform analysis discriminates CTG changes during labour, and that the manufacturer's protocol for FHR and ST waveform interpretation was safe for practitioners to use.

The Amer-Wahlin et al study (2001) reported that CTG and ST waveform analysis resulted in significantly lower rates of umbilical-artery metabolic acidosis (15/2159 [0.7%]) than the cardiotocography only group (31/2,079 [2%], RR 0.47 , p=0.02) and a 17% relative reduction in operative fetal distress (193/2,519 (8%) vs 227/2,447 (9%), RR 0.83, p=0.047). No significant differences between the groups were found regarding Apgar scores, admissions to neonatal intensive care or neonatal encephalopathy. The rate of cord-artery metabolic acidosis was 1.5% in the CTG group and 0.7% in the CTG and ST group.

The medical charts of a subgroup of 351 babies admitted to special care baby units from the above study group were analysed for signs of neonatal encephalopathy and other signs of intrapartum hypoxia. Twenty-nine babies were classified with adverse/complicated neonatal outcome: 19 in the CTG arm and 10 in the CTG and ST arm (Noren et al 2003). The number of live babies born with moderate or severe neonatal encephalopathy was significantly higher (0.33%, 8/2,447 babies) in the CTG-only group compared to the CTG and ST group (0.04%, 1/2,519 babies).

Two other trials with the STAN S21 (level IV interventional evidence) with a total of 1,210 births reported that CTG+ST analysis was more specific at detecting fetal acidaemia than CTG alone (Amer-Wahlin et al 2002 and Kwee et al 2004).

COST IMPACT

A company representative indicated that the cost of the STAN S21 is approximately 1.5 times to twice the cost of standard fetal monitors (personal communication Neoventa Medical Inc). Continuous fetal heart monitors for intrapartum fetal monitoring can cost approximately US $5,000.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

Given that the STAN S21 device has been found to be effective at reducing rates of cord artery metabolic acidosis, studies assessing its longer term impact would be useful.

The incorporation of this new technology and its use in fetal management during labour would require training of all health professionals involved in managing labour.

CONCLUSION:

There are a number of high quality studies reporting a demonstrated effect of reducing adverse outcomes during labour with the use of STAN S21®. However the use of Stan S21® will not have a significant impact on the public health system.

HEALTH PACT DECISION:

Archive

LIST OF STUDIES INCLUDED

Total number of studies	
Level I intervention evidence	1
Level II intervention evidence	2
Level IV intervention evidence	2

SOURCES OF FURTHER INFORMATION:

AIHW (2005a) *Interactive national hospital morbidity data. Principal diagnosis data cube.* [Internet]. Australian Institute of Health and Welfare. Available from: http://www.aihw.gov.au/cognos/cgi-in/ppdscgi.exe?DC=Q&E=/AHS/principaldiagnosis0203 [Accessed 10th January, 2005].

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Kwee, A., van der Hoorn-van den Beld, C. W. et al (2004). 'STAN S21 fetal heart monitor for fetal surveillance during labor: an observational study in 637 patients', *J Matern Fetal Neonatal Med*, 15 (6), 400-407.

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Neilson JP. Fetal electrocardiogram (ECG) for fetal monitoring during labour. *The Cochrane Database of Systematic Reviews* 2003, Issue 2. Art. No.: CD000116. DOI: 10.1002/14651858.CD000116.

Neoventa Inc. (2005a) *Neoventa Medical-Products.* [Internet] Available from: http://www.neoventa.se/Articles/Products/index.html [Accessed 10th January, 2005].

Neoventa Inc. (2005b) *ST Analysis STAN® Methodology* [Internet] Available from: http://www.neoventa.se/Articles/ST_Analysis/default.html [Accessed 10th January, 2005].

Noren, H., Amer-Wahlin, I. et al (2003). "Fetal electrocardiography in labor and neonatal outcome: data from the Swedish randomized controlled trial on intrapartum fetal monitoring". *Am J Obstet Gynecol, 188 (1) 183-192.*

Ross, M. G., Devoe, L. D. & Rosen, K. G. (2004). 'ST-segment analysis of the fetal electrocardiogram improves fetal heart rate tracing interpretation and clinical decision making', *J Matern Fetal Neonatal Med*, 15 (3), 181-185.

Westgate, J., Harris, M. et al (1993). 'Plymouth randomized trial of cardiotocogram only versus ST waveform plus cardiotocogram for intrapartum monitoring in 2400 cases', *Am J Obstet Gynecol*, 169 (5), 1151-1160.

SEARCH CRITERIA TO BE USED:

Acidosis/congenital/ etiology
Cardiotocography/instrumentation
Fetal Blood/chemistry
Fetal Distress/diagnosis
Fetal Monitoring/ instrumentation/ methods
Heart Rate, Fetal
Labor, Obstetric
Pregnancy
Pregnancy Outcome