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Vasotrac® continuous blood pressure monitoring.

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PRIORITISING SUMMARY

REGISTER ID: **000144**

NAME OF TECHNOLOGY: **VASOTRAC®**

PURPOSE AND TARGET GROUP: **CONTINUOUS BLOOD PRESSURE MONITORING**

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	ARTG number	
☒	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		

IMPACT SUMMARY:

Medvave, Inc. has developed Vasotrac® to continuously monitor blood pressure. Vasotrac® was first approved for use in the United States in 2001. It is not yet available in Australia.

BACKGROUND

Figure 1. Vasotrac® (Printed with permission: Medvave Inc)

The Vasotrac® unit consists of a nondisposable, fluid filled cushioned sensor that is placed over the radial artery in the wrist. The sensor is connected to a monitor with a display, a control panel and processing software using a cable. The Vasotrac® can monitor blood pressure (BP) and heart rate either intermittently or continuously. When in continuous mode, the device can generate a blood pressure and heart rate measurement every 25 heartbeats and an arterial pressure waveform is displayed on the monitor and the data stored. The device

could be particularly useful for paediatric and geriatric patients and in intensive care, where obtaining BP measurements can be problematic.

Other automated, continuous measurement devices exist such as the use of an arterial catheter or an oscillometer. These techniques are more invasive and may be difficult to use on problematic patients.

CLINICAL NEED AND BURDEN OF DISEASE

It is not possible to quantify the need for blood pressure monitoring in the Australian hospital setting as measurements are routinely checked for all types of patients.

DIFFUSION

It was not possible to access information on the uptake of the Vasotrac® from the manufacturer at the time of writing this summary.

COMPARATORS

The most common method to measure blood pressure is manually utililising a sphygmomanometer. This involves the application of a cuff to the upper arm cuff that is inflated and deflated over the brachial artery to yield a numeric display of systolic and diastolic blood pressure.

An alternative for continuous monitoring is the use of an arterial catheter for beat-to beat display of the pressure waveform and numeric display of BP. This technique is invasive and may difficult to apply in some patient groups. There are other automated devices that take continuous measurements using an oscillometric technique with a cuff placed on an upper or lower extremity, which is automatically inflated and deflated to obtain blood pressure measurements.

EFFECTIVENESS AND SAFETY ISSUES

See complete volume of Prioritising Summaries for definitions of Levels of Evidence.
The initial study (level III-3 diagnostic evidence) that assessed the effectiveness of the Vasotrac® compared it to radial artery catheterisation in four surgical centres (Belani et al 1999). Blood pressure measurements via the Vasotrac® and catheterisation of the radial artery were collected for a period of time ranging from 30 minutes to 6.2 hours, depending on the length of surgical procedure or intervention in the intensive care unit. A total of 17,468 measurements were available for analysis in 80 surgical and critically ill patients. The study reported that the Vasotrac® accurately measured BP and displayed a waveform and heart rate similar to BP measured intra-arterially. The Vasotrac® correlated highly with measurements obtained by a radial arterial catheter ($p<0.01$), systolic BP ($r^2=0.93$) and diastolic BP ($r^2=0.89$).

The authors reported no difficulty in measuring BP with the Vasotrac® using the radial artery, and that the device warranted further evaluation to assess performance during states of haemorrhage, hypotension, vasoconstriction and during longer periods of time than assessed in this study. The Vasotrac® was considered advantageous over the osillometric (cuff) method as it did not interfere with pulsed oximetry monitoring equipment or the flow of intravenous fluids.

In addition, the Vasotrac® has been tested (level III-3 diagnostic evidence) on 15 patients in an Emergency Department setting (Thomas et al, 2003). Mean arterial pressures (MAP) were assessed simultaneously by the Vasotrac®, an oscillometric brachial artery cuff and an arterial line in all patients. The diagnoses for this patient group were neurological (7/15, 47%), cardiac (2/15, 13%), and other medical (6/15, 40%). There was no difference between the MAP in each of the three study groups (ANOVA $p=0.98$). The study reported that the

Vasotrac® MAP assessments demonstrated a strong statistical correlation to arterial line MAPs and performed as well as the oscillometric cuff assessment.

Finally, the Vasotrac® was tested (level III-3 diagnostic evidence) for accuracy in 15 morbidly obese patients undergoing bariatric surgery and compared to both arterial line and upper arm oscillometric cuff pressure measurement (Hager et al 2004). In this study the Vasotrac® performed as well as the arterial line and was significantly more accurate than the cuff pressure monitoring. The correlation between the arterial line and the Vasotrac® was $r^2=0.81 \pm 0.04$ and significantly better than correlation between Vasotrac® and oscillometric cuff pressure measurement of $r^2=0.32 \pm 0.02$ ($p<0.001$).

The Vasotrac® was considered well suited to obese patients as the traditional cuff method of measuring blood pressure may be impossible to achieve or produce inaccurate measurements due to cuff size limitations.

COST IMPACT
The cost of the device in the United States is $3,850.00 (AUD$4,976). It was not possible to identify any information on likely cost impact of the Vasotrac® at the time of preparing this summary. Any cost impact would be the likely to occur in personnel time in placing arterial catheters, or conducting manual cuff measurements as part of regular patient observation.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS
No issues were identified/raised in the sources examined.

OTHER ISSUES
No issues were identified/raised in the sources examined.

CONCLUSION:
A non-invasive, accurate continuous blood pressure measurement device would be useful for certain patient groups and in certain medical settings. However, there is an absence of studies quantifying the impact of this technology on health or efficiency outcomes.

HEALTHPACT ACTION:
Technology will not impact significantly in terms of policy or cost burden on the Australian health system. Therefore it is recommended that this technology be archived.

SOURCES OF FURTHER INFORMATION:
Belani, K.,Ozaki, M.et al (1999a). 'A new noninvasive method to measure blood pressure: results of a multicenter trial', *Anesthesiology,* 91 (3), 686-692.

Belani, K. G.,Buckley, J. J. & Poliac, M. O. (1999b). 'Accuracy of radial artery blood pressure determination with the Vasotrac', *Can J Anaesth,* 46 (5 Pt 1), 488-496.

Belani, K., Komanduri, V. 2000 'Radial Artery Blood Pressure Monitoring in Children with the Vasotrac - A Preliminary Report' abstract 1278 presented American Society of Anesthesiologists Annual Meeting

Friedman, B. H.,Christie, I. C.et al (2004). 'Self-reported sensitivity to continuous noninvasive blood pressure monitoring via the radial artery', *J Psychosom Res,* 57 (2), 119-121.

Hager, H., Mandadi, G., Eagon, C., Pulley, D., Kurz, A. 2004 'Intraoperative Blood Pressure Measurement on the Wrist Is More Accurate Than on the Upper Arm in Morbidly Obese Patients'. Abstract 600 presented American Society of Anesthesiologists Annual Meeting

Thomas, S., Winsor, G.R., Pang, P.S., Driscoll, K.A., Parry, B.A. 2003 'Use of a radial artery compression device for non-invasive, near-continous blood pressure monitoring in the

emergency department.' Poster presentation, 2003 American College of Emergency Physicians Research Forum, October 12/13, Boston, MA

Medvave Inc (2004). *Blood Pressure Monitoring! Non-Invasive Direct Arterial BP Monitors by Medwave.* [Internet]. Medvave Inc. Available from: http://www.vasotrac.com/ [Accessed 31st January 2005].

SEARCH CRITERIA TO BE USED:

Blood Pressure
Blood Pressure Determination
Pulse
Radial Artery/physiology