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Horizon scanning prioritising summary

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USCOM cardiac output monitor for ultrasonic cardiac output measurement in patients requiring haemodynamic monitoring.

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PRIORITISING SUMMARY

REGISTER ID: **000168**

NAME OF TECHNOLOGY: **USCOM CARDIAC OUTPUT MONITOR**

PURPOSE AND TARGET GROUP: **ULTRASONIC CARDIAC OUTPUT MEASUREMENT IN PATIENTS REQUIRING HAEMODYNAMIC 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	☐	No
ARTG number	81047	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia		✓	
Germany	✓		
Italy	✓		
India	✓		

IMPACT SUMMARY:

USCOM, an Australian company, provides the USCOM cardiac output monitor with the aim of diagnosing cardiac output in patients requiring haemodynamic monitoring. The USCOM monitor was approved by the Therapeutic Goods Administration (TGA) in November 2001 and was recently approved in the United States (February 2005).

BACKGROUND

Cardiac output is defined as the total volume of blood ejected by the heart ventricle per minute and is calculated as the product of the heart's stroke volume and the heart rate, expressed as ml/min or L/min. The normal range for people in the resting state is 4 to 8L/minute (Beers and Berkow 1999).

Cardiac output is a fundamental measure of the adequacy of myocardial function to meet the perfusion needs of tissue at any time. Decreases in cardiac output over time (when cardiac output is measured under similar conditions) may signal myocardial functional deterioration and the onset or progression of heart failure. On the other hand, improved cardiac output observed over a period of time may indicate a positive response to medical therapy (Demaria and Raisinghani, 2000).

The USCOM is a portable Continuous Wave Doppler device, which uses an ultrasonic transducer to measure blood flow transcutaneously. The transducer is placed over the patient's pulmonary or aortic valves to measure the stroke volume and cardiac output. Changes in blood flow patterns may indicate changes in cardiac function and continuous monitoring may be used for the early detection of disease. The USCOM allows beat-to-beat quantitative evaluation of cardiac haemodynamics and can be used to confirm normal cardiac function, detect and quantify abnormal function, and to evaluate the effectiveness of cardiovascular therapies (United States Food and Drug Administration 2005).

CLINICAL NEED AND BURDEN OF DISEASE

Monitoring cardiac output for both adult and paediatric patient groups is important in many medical situations where haemodynamic assessment is required, particularly during anaesthesia and in acute and coronary care situations.

A number of Medicare Benefits Schedule (MBS) item numbers relate to cardiac output measurements (13818, 22015, 38200, 38203, 38206). The Health Insurance Commission reported that a total of 7,074 procedures were performed under these MBS item numbers in a private hospital setting during the period from July 2003 to July 2004.

DIFFUSION

The USCOM was first installed in seven hospitals across Australia in 2003 for clinical use and assessment in a variety of specialist medical disciplines, including paediatrics, anaesthetics, cardiology and intensive care (USCOM 2005). To date, USCOM has sold approximately 50 devices in Australia, Europe and Asia (personal communication, USCOM).

It is likely that this device would receive rapid uptake in emergency medicine, intensive care and rural and remote areas as it is portable and may overcome the limitations of more invasive techniques.

COMPARATORS

There are several invasive and non-invasive methods for measuring cardiac output. The gold standard in measuring cardiac output is thermodilution. The thermodilution technique uses a special thermistor-tipped catheter (Swan-Ganz) which is inserted from a peripheral vein into the pulmonary artery. Cold saline of a known temperature and volume is injected into the right atrium from a proximal catheter port. The saline mixes with the blood as it passes through the ventricle and into the pulmonary artery, cooling the blood. The blood temperature is measured at the catheter tip lying within the pulmonary artery and a computer is used to acquire the thermodilution profile and compute the flow (Klabunde 2005). This technique takes repeated measures of mean cardiac output. Measuring cardiac output by thermodilution is rapid, although it can be expensive and may have risks associated with insertion or removal and maintenance of the catheter (Cholley 1998).

An alternative invasive catheterisation method is the Fick oxygen technique (Gola et al, 1996) Cardiac output is obtained by measuring the rate of oxygen consumption by the lungs, divided by the difference in oxygen content of arterial blood and mixed venous blood. Disadvantages of this technique include the need for right-sided heart catheterisation and obtaining expired gas measurements, which are invasive and complicated and in addition cannot give instantaneous results (Cholley 1998).

Another means to estimate cardiac output is the transesophageal echocardiographic approach. By visualising the heart blood flow velocity directly, the echocardiographic approach overcomes several limitations of the above methods, but is strongly operator-dependent and

may not always be readily available. Heavy sedation or anaesthesia of the patient is necessary and the equipment required to perform this technique is expensive (Demaria and Raisinghani, 2000).

There are several non-invasive cardiac output devices currently available. One uses the reverse Fick principle utilising expired oxygen. The patient re-breathes into a measuring system through a mask and the concentration of oxygen is calculated. Changes in electrical impedence in the thorax are measured by a bioimpedance device and used to calculate fluid volumes (personal communication, cardiologist).

EFFECTIVENESS AND SAFETY ISSUES

The USCOM was compared to the thermodilution technique (level III-1 diagnostic evidence) in a group of intensive care patients (n=22), after cardiac surgery (Tan et al 2005). All patients received both standard thermodilution cardiac output measurement using a pulmonary artery catheter as well as USCOM measurements of cardiac output. Three to five thermodilution readings were recorded for all patients and the mean value was recorded as the $CO_{PAC.}$ USCOM measurements were performed by a single operator who was blinded to the CO_{PAC} readings (level III-I diagnostic evidence). Forty sets of paired measurements were obtained. Some variation in the pulmonary flow profiles were recorded from the second to the fourth intercostal spaces (second intercostal space, n=11; third intercostal space n=25; fourth intercostal space; n=4).

Tan et al (2005) reported no adverse events or complications with the use of the USCOM device during this study. Comparison of the two techniques showed a mean difference in cardiac output measurements of ±0.82 L/min (95% CI -0.09, 0.44) and the limits of agreement (Bland-Altman) were -1.43 (-1.88 to -0.98) and 1.78 (1.33 to 2.23).

O'Driscoll et al (2005) presented preliminary results of a similar study at the 2nd Asian Pacific Congress of Heart Failure (APCHF), Singapore (unpublished, level III-2 diagnostic evidence). Cardiac output was measured in 15 patients with both the USCOM and a thermodilution catheter. A correlation of $r^2 = 71.4\%$ was obtained between the diagnostic techniques, and the Bland Altman analysis of cardiac outputs of < 5L/min had a bias of 0.12 and limits of agreement of -1.21 to 1.45 L/min. (O'Driscoll et al 2005). The USCOM tended to underestimate cardiac output when it was greater than 5L/min, when compared to thermodilution.

There are several abstracts of unpublished studies with similar levels of evidence of the USCOM listed on the company website in different clinical situations, including emergency departments, air rescue, intensive care and patients undergoing right heart catheterisation (USCOM 2005). There have been approximately 20 conference/meeting presentations on the validation of the USCOM. Five of these studies directly compared the USCOM to thermodilution using Swan Ganz catheters (personal communication, USCOM). To date, in addition to the study by Tan et al (2005) there has been only one other published, peer-reviewed paper which described a study conducted on dogs.

COST IMPACT

The manufacturer claims that the use of the USCOM would result in cost saving, as it is not as expensive to use as the invasive cardiac output monitoring methods. It is reasonable to expect a reduction in the costs associated with surgical catheterisation, anaesthesia and personnel time. It is also claimed that the USCOM is more cost-effective when compared to other non-invasive methods. However, at the time of writing this summary there are no published studies that examine the cost impact of the USCOM compared to any of the current methods available for determining cardiac output.

The cost of the USCOM is A$42,000. The current fee for the MBS item numbers for measuring cardiac output range from $96.50 (item number 13818) to $545.25 (item number 38206).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

The chairman of USCOM co-authored several of the abstracts presented on the company website.

CONCLUSION:

The use USCOM is a rapid, non-invasive diagnosis and monitoring tool that may have application in the measurement of cardiac output in patient groups or situations where the gold standard is difficult to perform. Although the USCOM appears to have diffused into several Australian hospitals, there is insufficient empirical data on its impact. There are few published studies available to demonstrate the accuracy of the device and safety compared to other methods.

HEALTH PACT ACTION:

Monitor

LIST OF STUDIES INCLUDED

Total number of studies	
Level III-1 diagnostic evidence	1
Level III-2 diagnostic evidence	1

SOURCES OF FURTHER INFORMATION:

Beers, M.H., Berwkow, R. (1999) The Merck Manual of Diagnosis and Therapy. Merck Research Laboratories.

Bein, B., Worthmann, F. et al (2004). 'Comparison of esophageal Doppler, pulse contour analysis, and real-time pulmonary artery thermodilution for the continuous measurement of cardiac output', *J Cardiothorac Vasc Anesth*, 18 (2), 185-189.

Cholley, B.P. (1998) 'Benefits, risks and alternatives of pulmonary artery catheterization' *Curr Opin Anaesthesiol*, 11(6), 645-650

De Maria, A. N. & Raisinghani, A. (2000). 'Comparative overview of cardiac output measurement methods: has impedance cardiography come of age?' *Congest Heart Fail*, 6 (2), 60-73.

Engoren, M. & Barbee, D. (2005). 'Comparison of cardiac output determined by bioimpedance, thermodilution, and the Fick method', *Am J Crit Care*, 14 (1), 40-45.

Gola, A., Pozzoli, M. et al (1996). 'Comparison of Doppler echocardiography with thermodilution for assessing cardiac output in advanced congestive heart failure', *Am J Cardiol*, 78 (6), 708-712.

Katz, W. E., Gasior, T. A. et al (1993). 'Transgastric continuous-wave Doppler to determine cardiac output', *Am J Cardiol*, 71 (10), 853-857.

Klabunde, R. E. (2005). *Cardiovascular Physiology Concepts* [Internet] Available from: http://www.cvphysiology.com/textbook.htm [Accessed April 13, 2005].

Looyenga, D. S., Liebson, P. R. et al (1989). 'Determination of cardiac output in critically ill patients by dual beam Doppler echocardiography', *J Am Coll Cardiol*, 13 (2), 340-347.

Moxon, D., Pinder, M. et al (2003). 'Clinical evaluation of the HemoSonic monitor in cardiac surgical patients in the ICU', *Anaesth Intensive Care*, 31 (4), 408-411.

Nishimura, R. A., Callahan, M. J. et al (1984). 'Noninvasive measurement of cardiac output by continuous-wave Doppler echocardiography: initial experience and review of the literature', *Mayo Clin Proc*, 59 (7), 484-489.

O'Driscoll, G., Wright, J.J., Wright, I.W., Green, D.J., Phillips, R.A., (2005.) "Cardiac Output Measurement with the USCOM Ultrasonic Cardiac Output Monitor" Abstract presented at the 2nd Asian Pacific Congress of Heart Failure (APCHF), Singapore, January 12, 2005

Royse, C. F., Royse, A. G. et al (1999). 'Measurement of cardiac output by transoesophageal echocardiography: a comparison of two Doppler methods with thermodilution', *Anaesth Intensive Care*, 27 (6), 586-590.

Tan, H. L., Pinder, M. et al (2005). 'Clinical evaluation of USCOM ultrasonic cardiac output monitor in cardiac surgical patients in intensive care unit', *Br J Anaesth*, 94 (3), 287-291.

United States Food and Drug Administration (2005) *K043139 510 (K) Summary*[Internet] Available from: http://www.fda.gov/cdrh/pdf4/K043139.pdf [Accessed 30th March, 2005].

USCOM (2005). *USCOM NEWS* [Internet] Available from: http://www.uscom.com.au/USCOM%20news/news12_05_03.htm [Accessed 30th March, 2005].

Vandenbogaerde, J. F., Scheldewaert, R. G. et al (1986). 'Comparison between ultrasonic and thermodilution cardiac output measurements in intensive care patients', *Crit Care Med*, 14 (4), 294-297.

SEARCH CRITERIA TO BE USED:

Cardiac Output
Cardiac Surgical Procedures
Heart Failure, Congestive/ diagnosis/ physiopathology/ultrasonography
Hemodynamic Processes
Intensive Care/ methods
Monitoring, Physiologic/instrumentation/methods
Thermodilution