Horizon Scanning Technology

Prioritising Summary

Masimo non-invasive pulse carbon monoxide oximeter

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PRIORITISING SUMMARY

REGISTER ID: **000413 (REFERRAL)**

NAME OF TECHNOLOGY: **NON-INVASIVE PULSE CARBON MONOXIDE OXIMETRY**

PURPOSE AND TARGET GROUP: **FOR CARBOXYHAEMOGLOBIN 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   138871
                                                 138873
                                                 153897

☐   No

☐   Not applicable

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY:

Masimo Australia Pty Ltd manufactures the Rainbow SET oximeter with the aim of providing continuous, non-invasive monitoring and measurement of blood constituents (oxygen, oxyhaemoglobin, haemoglobin, carboxyhaemoglobin and methemoglobin). The technology would be made available through emergency departments in major public or private hospitals for early detection and treatment of potentially life-threatening conditions such as carbon monoxide poisoning in adult, paediatric and neonatal patients, or for poorly perfused patients (FDA 2008). This technology may also be of use in emergency situations in rural and remote areas.

BACKGROUND

The Masimo Rainbow SET® oximeter provides a non-invasive means of monitoring arterial oxygen saturation (%SpO_2), pulse rate, carboxyhaemoglobin saturation

(%SpCO), methemoglobin[1] saturation (%SpMet) and perfusion index (PI). The device consists of a light weight, portable display unit which is connected to a sensor placed on the patient's fingertip if an adult, or hand or foot if a neonate (Figure 1). The sensor continuously collects data and sends it to the instrument, which displays the calculated data as a percentage.

Figure 1   The Rainbow SET oximeter (Masimo 2007)

Oxy-, deoxy-, carboxy-haemoglobin and methemoglobin all differ in their absorption of visible and infrared light and the Masimo oximeter uses a multi-wavelength sensor to differentiate between these components. Visible and infrared light ranging between 400-1000nm is passed through a capillary bed (ie the fingertip) and the change in light absorption is then measured (FDA 2008).

Although the Masimo oximeter can measure a number of haemoglobin parameters, most published papers in the peer review literature describe its use for the diagnosis and monitoring of *carboxyhaemoglobin* after exposure to carbon monoxide (CO). Levels of blood CO may be high due to the chronic exposure of individuals to cigarette smoke, or from acute episodes such as exposure to combustion heaters, inadequate ventilation of natural gas, fire or suicide attempt. The signs and symptoms of CO poisoning are non-specific and therefore may go undiagnosed. Symptoms may mimic those of a viral illness, including tiredness, shortness of breath, mild headaches and nausea (Chee et al 2008; Hampson et al 2006; Masimo 2007). Severe symptoms include dizziness, severe headaches, weakness, sleepiness, nausea and vomiting. As CO is an odourless, colourless gas many patients are unaware of their exposure. CO poisoning may result in long-term neurological damage, cardiovascular complications or even death (Chee et al 2008). An elevated blood COHb greater than two and nine

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[1] Methemoglobin is blood with an oxidised haemoglobin content

per cent for non-smokers and smokers, respectively, indicates an exposure to exogenous CO (Hampson et al 2006).

CLINICAL NEED AND BURDEN OF DISEASE

In Australia during the period 2006-07, there were 365 public hospital separations for the toxic effects of carbon monoxide poisoning (ICD-10 code T58), resulting in an average length of stay of 2.3 days (AIHW 2008). The 2007 AIHW report on poisoning in Australia, reported that during the period 2003-04, 11 per cent of hospital cases were from accidental poisoning by, and exposure to, gases including 79 cases of carbon monoxide poisoning. In addition, the majority of self harm cases of poisoning with gases were with carbon monoxide (n=325), with the number of males more than double the number of females (Berry & Harrison 2007). In New Zealand, data for public hospital separations were only presented as the entire ICD-10 toxicity category (T51-T65), representing 1,087[2] separations during the period 2002-03[3].

No publications could be identified which reported the number of accidental deaths by carbon monoxide poisoning in Australia or New Zealand, however deaths have occurred in recent years in Western Australia, New South Wales, Victoria and New Zealand. In the majority of cases the symptoms of carbon monoxide poisoning were not recognised upon presentation to emergency departments or general practitioners. In Victoria alone, six deaths in recent years were caused by defective gas appliances and flues in the home (Fenton 2004).

The Masimo oximeter is capable of measuring a number of parameters that are useful in the monitoring of patients with poor perfusion, such as those experiencing acute myocardial infarction (AMI). In New Zealand, the number of public hospital separations for patients with AMI, in 2003-2004 was 12,127. Provisional 2002 data reported 3,252 deaths with an underlying cause of AMI.[2] In Australia, the annual age-standardised rate of AMI public hospital admissions has been steadily decreasing since the early 1990s, corresponding to a decline in the incidence of AMI. However, the absolute number of admissions has remained steady or increased due to the increasing average age and overall growth of the population. In Australia, AMI occurs predominantly amongst those aged 40 years and over (97%), with almost two-thirds occurring among people aged 65-90 years of age. Men are twice as likely to be admitted as women (Mathur 2002).

DIFFUSION

The company was contacted on numerous occasions by the evaluators however no information on the diffusion of this device was forthcoming.

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[2] Data supplied by Chris Lewis from the New Zealand Health Information Service. Total population of New Zealand for the year 2003 was 4,009,200.
[3] Equivalent Australian data for T51-T65 for 2006-07 was 6,527 separations, however a large proportion of these separations were from T63 – the toxic effect of contact with venomous animals (n=2,902) which is unlikely to be the case NZ

COMPARATORS

The most common means of measuring COHb is by processing either a venous or arterial blood sample using a laboratory based multi-wavelength CO-oximeter. Samples may be processed by these oximeters in 10 minutes, however not all hospitals will have one as standard equipment and samples may need to be processed in pathology laboratories, which would further delay diagnosis. Each additional reading will require an additional blood sample to be taken (Hampson et al 2006; Masimo 2007).

SAFETY AND EFFECTIVENESS ISSUES

A small study conducted by Barker et al (2006) compared the accuracy of the Masimo CO-oximeter to a conventional laboratory CO-oximeter for the measurement of COHb and methemoglobin (MetHb) levels (level III-2 diagnostic evidence). Ten volunteers inspired 500ppm carbon monoxide and 10 different volunteers received 300mg intravenous sodium nitrate to induce methemoglobin. All volunteers were cannulated for the regular sampling of 3mls each of venous and arterial blood, which were analysed on three calibrated laboratory CO-oximeters. At the same time, each volunteer had a Masimo CO-oximeter sensor attached to digits two, three and four of both hands, a total of six sensors. In the COHb group, all 10 subjects reached the maximum 15 per cent COHb level without experiencing any unpleasant symptoms. Levels of COHb decreased to 10 per cent within 1-hour after CO inspiration ceased. When all readings were pooled for the ten CO exposed subjects the correlation coefficient for the two methods was high at R=0.87. The Masimo CO-oximeter measured COHb with a precision of ± 2.19 per cent. When all readings were pooled for the 10 subjects who underwent MetHb induction the correlation coefficient was excellent at R=0.99. The Masimo CO-oximeter measured MetHb with a precision of ± 0.45 per cent (Barker et al 2006).

An abstract presented at the Society of Technology in Anaesthesia reported similar results in 19 surgical patients and 19 healthy volunteers who had their levels of haemoglobin measured using the Masimo and conventional laboratory based CO-oximeters. The correlation between the two methods with a total of 458 data pairs was good with R=0.898, with a precision of ± 1.09 per cent (Macknet et al 2007) (level III-2 diagnostic evidence).

A large case series conducted measured the COHb of all adults who were treated in an emergency department over the 3-month winter period with the non-invasive Masimo CO-oximeter (level IV diagnostic evidence). Nurses and technicians were trained in the use of the CO-oximeter and a smoking history was taken from all patients. Of the 14,438 patients who presented to the emergency department, 10,856 (75%) took part in the study. The mean SpCO was 5.17% ± 3.78% and 2.9% ± 2.76% amongst smokers and non-smokers, respectively. Screening continued for a further 6-month period and during the total nine month study, 28 cases of CO toxicity were identified,

11 of whom were occult and only identified by the measurement of SpCO. Confirmatory venous or arterial COHb measurements were then taken, which correlated with the SpCO readings with an R=0.72. There were 22 patients with a raised SpCO and the confirmatory venous CO-oximetry sample was negative (false positive). Although only a small number of patients had both the venous and the Masimo CO-oximetry (number not explicitly stated), the sensitivity and specificity of SpCO were 94 and 54 per cent, respectively. The authors concluded that the use of a non-invasive CO-oximeter in a busy emergency department was feasible (Suner et al 2008).

A similar case series to detect occult CO toxicity was conducted in an emergency department over a 13-month period (level IV diagnostic evidence). A total of 74,880 patients (72% of all patients presenting to the ED) underwent SpCO testing with the Masimo CO-oximeter. Patients with an elevated SpCO reading then underwent venous CO-oximetry. Twenty-eight patients were identified as having elevated SpCO levels. Of these, 19 patients had an obvious exposure to CO (smokers n=15, house fire n=3, suicide attempt n=1) and were therefore excluded. Two patients had slightly elevated SpCO levels, however review data on these patients were not available. Seven patients were considered to have occult CO toxicity. Follow-up data were available on only two of these cases. In both of cases an exogenous source of CO was identified in the home. The authors conclude that the Masimo CO-oximeter may be a useful triage tool in the emergency department (Chee et al 2008).

COST IMPACT

The company was contacted on numerous occasions by the evaluators however no information on the diffusion of this device was forthcoming.

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.

SUMMARY OF FINDINGS

Although the comparative studies included for assessment indicate that SpCO readings taken with the Masimo SET® CO-oximeter correlate highly with those obtained with conventional CO-oximetry, the small size of the studies is cause for concern. Larger scale studies need to be conducted. The two large case series indicate that the Masimo may be useful in an emergency department setting, requiring minimal training and is capable of detecting occult cases of carbon monoxide poisoning.

HEALTHPACT ACTION:

The non-invasive Masimo CO-oximeter may provide greater utility for the measurement of SpCO in an emergency department environment. It is likely that hospitals will make individual decisions on whether or not to purchase this device and diffusion of the device will occur naturally within the health care system. Therefore HealthPACT has recommended that further assessment of this technology is no longer warranted.

NUMBER OF INCLUDED STUDIES

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

REFERENCES:

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Suner, S., Partridge, R. et al (2008). 'Non-invasive pulse CO-oximetry screening in the emergency department identifies occult carbon monoxide toxicity', *J Emerg Med,* 34 (4), 441-450.

SEARCH CRITERIA TO BE USED:

Blood Chemical Analysis
Carboxyhemoglobin/*analysis
Methemoglobin/*analysis
Methemoglobinemia/blood/diagnosis
Oximetry
Biological Markers/blood
Carbon Monoxide Poisoning/*blood