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Horizon Scanning Technology Prioritising Summary

Autopulse® automated compression device for CPR

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PRIORITISING SUMMARY

REGISTER ID: **000390**

NAME OF TECHNOLOGY: **AUTOPULSE®**

PURPOSE AND TARGET GROUP: **AUTOMATED, LOAD-DISTRIBUTING BAND FOR CHEST COMPRESSIONS ON PATIENTS REQUIRING CARDIAC RESUSCITATION**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☒ Yes — ARTG number **115714**
- ☐ No
- ☐ Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Germany		✓	
US		✓	

IMPACT SUMMARY:

Zoll Medical Australia Pty Ltd provides the Autopulse® Resuscitation System designed for performing automated chest compressions on patients requiring cardiac resuscitation. Cardiac arrest causes many deaths every year in Australia and correct use of cardiopulmonary resuscitation (CPR) can reduce the chance of death. However, CPR is often interrupted or applied using a substandard technique. The Autopulse® performs automated chest compressions on a patient allowing medical staff to perform other vital actions. In addition, the compressions performed by the Autopulse® may be of higher quality than those performed by medical staff.

BACKGROUND

Cardiac arrest is a common cause of death in Australia and may occur due to multiple causes. Rapid application of properly performed CPR can increase the survival of subjects having a cardiac arrest. Coronary perfusion pressure (CPP) is a critical

determinant of whether a return of spontaneous circulation (ROSC) will occur. It has been found that CPP of 15mmHg is a minimum required for ROSC to occur (Paradis et al 1990). The rate of compressions is also critical to the occurrence of ROSC, yet a study showed that even compressions applied in-hospital are often suboptimal (Abella et al 2005b). Interruptions to chest compressions due to fatigue, assisted respiration or patient transport, may negatively affect patient survival (Kellum et al 2006). The best survival rates in cardiac arrest are for those patients with ventricular fibrillation, also known as a shockable rhythm, which can be treated with defibrillation. In subjects having a cardiac arrest from non-fibrillation causes, chest compressions and advanced life support are recommended for the best outcome. However, both fibrillation and non-fibrillation cardiac arrest subjects will benefit from chest compressions (Kellum et al 2006).

The Autopulse® system is a portable, self powered device, which provides constant, high quality chest compressions to patients who have had a cardiac arrest. The Autopulse® device consists of a backboard containing a microprocessor controlled motorized rotating shaft, which automatically adjusts to the size and shape of each patient.

CLINICAL NEED AND BURDEN OF DISEASE

Cardiac arrest occurs for many different reasons including cardiovascular disease, electrophysiological abnormalities, toxins and shock. One Australian study showed that in out-of-hospital cardiac arrest patients the survival-to-hospital-discharge rate was 7.4 per cent in urban and 1.9 per cent in rural areas (Jennings et al 2006). A Victorian study found that out of 18, 827 out-of-hospital-cardiac arrests in 2002-2005, the survival rate was 3.8 per cent (Fridman et al 2007). An extrapolation to the Australian population (20.1 million at June 2004 (ABS 2006)) gives an estimated 18,000 deaths per year due to out-of-hospital cardiac arrest during the period of the study. One of the major causes of cardiac arrest is cardiovascular disease (CVD), which is a large burden on the Australian health care system both in terms of deaths and long term disability. It is estimated that CVD is responsible for 37.5 per cent of all deaths in Australia annually (Jennings et al 2006). Cardiac arrest is a major cause of CVD related deaths. There is a need for better treatments which may reduce death from cardiac arrest and its associated disability resulting from physical and neurological damage that occurs during hypoxia.

No data on the number of cardiac arrest events in New Zealand were identified. There were many studies published on measures to improve outcomes after cardiac arrest, however these studies combined data from Australian and New Zealand hospitals. In addition, published morbidity and mortality data from New Zealand combined ICD codes I30-I52, other forms of heart disease into one category.

DIFFUSION

Some diffusion of the Autopulse® device into Australia has occurred. Rural ambulance services in Victoria are using the device and sites in Gawler and Modbury, South Australia, are also trialling the device.

COMPARATORS

The gold standard for resuscitation of patients after cardiac arrest is manual CPR. Out-of-hospital cardiac arrest with resuscitation using manual CPR has a survival rate of approximately five per cent. The quality of compressions performed during CPR is often substandard and frequently interrupted, two factors known to decrease survival rates (Abella et al 2005a; Wik et al 2005). Correct chest compression rates and proper depth of chest compression without interruption correlate with higher survival rates (Abella et al 2005b).

SAFETY AND EFFECTIVENESS ISSUES

Several studies using the Autopulse® device have investigated the effect of the Autopulse on surrogate markers of survival and also its ability in real practice to improve CPR.

Initial human studies in terminally ill patients demonstrated that the Autopulse® system gave increased coronary perfusion pressure (CPP) when compared to manual chest compression. Terminally ill patients undergoing a cardiac arrest were given ten minutes of standard advanced life support as normally applied. If after this period no response was seen the patients were catheterised and randomised to first receive either conventional CPR or Autopulse® based CPR followed by the opposite treatment. CPP was determined from catheter readings. While conventional compressions were high quality, meeting standards of compression pressure and compression depth, the Autopulse® device, when compared to conventional compression, increased CPP (20 ± 12mmHg vs 15 ± 11mmHg, $p< 0.015$) (Timerman et al 2004). This study was a proof of concept study in humans designed to demonstrate the ability of the Autopulse® to significantly raise CPP a known survival factor and was not intended to provide resuscitation.

Two good quality studies reported conflicting results. The first study, investigating out-of-hospital cardiac arrest was prospective and cluster-randomised with five separate EMS sites involved in the US and Canada. The primary outcome was survival to four hours after emergency call was placed and secondary outcomes included hospital discharge and neurological performance. The trial included 1,071 patients across all sites, with 554 randomised to the Autopulse® group and 517 to the manual CPR group. Within each site half of the clusters were randomised to Autopulse® CPR and half to manual CPR. An independent review panel recommended an early termination to the study after a preliminary review found that there was no benefit to the patients with the Autopulse® device with regard to the

primary outcome of 4-hour survival (29.5% for Autopulse® vs 28.5% for manual CPR; *p* =0.74). Although not significant, there was a reduction in survival to hospital discharge with the Autopulse® treated patients (5.8% vs 9.9% for manual CPR; *p* =0.06). Good cerebral outcomes were significantly less likely to occur with Autopulse® treatment (3.1%) compared to manual CPR (7.5%; *p* =0.006) (Hallstrom et al 2006) (level II intervention evidence).

The second study used a historical control during the introduction of the Autopulse® into a single urban emergency service site. The patient population consisted of 783 patients who were treated out-of-hospital with either manual CPR (499 patients) or Autopulse® (284 patients). Of the patients included in the intention to treat Autopulse® phase, 210 were actually treated with the device. The manual CPR phase was conducted entirely before the Autopulse® phase of the trial. Primary outcome was ROSC with secondary outcomes including survival to hospital admission and discharge and neurological function at discharge. In contrast to the above study the Autopulse® was found to have an overall beneficial effect on patients who had suffered a cardiac arrest. Significantly more patients had a ROSC in the Autopulse® group (34.5% 95% CI [29.2-40.3]) compared to the manual CPR group (20.2% [95% CI [16.9-24.0]). Additionally both the rates of survival to hospital admission and discharge were also significantly higher in the Autopulse® group. The Autopulse® hospital admission rate was 20.9 per cent (95% CI [16.6, 26.1]) versus 11.1 per cent (95% CI [8.6, 14.2]). The survival to hospital discharge was 9.7 per cent (95% CI [6.7-13.8]) for Autopulse® compared to 2.9 per cent (95% CI [1.7, 4.8]) for manual CPR (Ong et al 2006) (level III-3 intervention evidence).

A non comparative study published in 2007 investigated usage and safety related issues resulting from the use of Autopulse®. Forty-six patients were resuscitated with the device and in 25 (54.3%) ROSC occurred and 10 (21.8%) patients survived to discharge. Mean set-up time for the Autopulse® device was 4.7 ± 5.9 minutes after arrival at the scene with 67 per cent of Autopulse® set-ups performed in less than three minutes. In the case of three patients the Autopulse® was deemed to not be sufficient for CPR and its use was discontinued in favour of using a cardiopump device. In two of these three cases this did not improve the patient's status. This study also reported no adverse safety events associated with the use of Autopulse® (Krep et al 2007) (level IV intervention evidence).

In summary, there is conflicting evidence about the efficacy of the Autopulse® device. There have been several speculative attempts to explain and reconcile the conflicting results from the largest studies published. These conclude that protocol design and implementation of the Autopulse® system and procedures are likely to impact on the effectiveness of the device. The highest level of evidence shows that the Autopulse® is not beneficial to patient outcome yet several other studies have contradicted this result.

COST IMPACT

Zoll Medical sells the Autopulse® kit for AUD$ 22,000. This includes the backboard, three batteries and charger, a disposable single-use lifeband, and an information DVD. Additional bands can be purchased for AUD$240, with three or more bands receiving a $100 discount from the total cost (personal communication Zoll Medical).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

The Autopulse® device has some enthusiastic backing from users. This may be due to the critical, difficult and tiring nature of providing correct manual CPR. The Autopulse® frees up at least one person during CPR. These issues, while important, should not influence the decision of whether the Autopulse® can provide better patient outcomes and it may be that, while difficult, manual CPR is best for the patient.

SUMMARY OF FINDINGS

There is a state of controversy over the effectiveness of the Autopulse® device with the highest level of evidence showing no benefit to patients and a possible negative effect. Despite this, other studies show positive outcome for patients and these conflicting results may be reconciled due to differing protocols and usage patterns of the device. Further studies are needed to clarify these issues. The device is beginning to diffuse into the Australian market, indicating that the contradictory efficacy results may not deter the uptake of the Autopulse®.

HEALTHPACT ACTION:

Autopulse® was considered to be the most established automated compression device on the current market. A trial of this device is currently underway in rural Victoria and is expected to report results in 12-months time. Therefore HealthPACT recommended that this technology be monitored for further information in 12-months time.

NUMBER OF INCLUDED STUDIES

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

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SEARCH CRITERIA TO BE USED:

Cardiopulmonary Resuscitation/ instrumentation

Emergency Medical Services

Heart Arrest/ therapy