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Australia and New Zealand Horizon Scanning Network

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# **National Horizon Scanning Unit**

## **Horizon scanning prioritising summary**

### **Volume 5, Number 7:**

**Enpulse™ Pacing System: Implantable heart pacemaker that automatically adjusts electrical impulses for patients with cardiac arrhythmia.**

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The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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# PRIORITISING SUMMARY

**REGISTER ID:** 000098

**NAME OF TECHNOLOGY:** ENPULSE™ PACING SYSTEM

**PURPOSE AND TARGET GROUP:** IMPLANTABLE HEART PACEMAKER THAT AUTOMATICALLY ADJUSTS ELECTRICAL IMPULSES FOR PATIENTS WITH CARDIAC ARRHYTHMIA

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |  |   |
|--|---|
| <input type="checkbox"/> Yes           | ARTG number                             |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not applicable |

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Germany	✓		
Austria	✓		
Sweden	✓		
Yugoslavia	✓		

## IMPACT SUMMARY:

Medtronic has developed the EnPulse™ pacing system for patients with cardiac arrhythmia.

## BACKGROUND

A pacemaker is used to regulate the heartbeat of patients with a slow or irregular heartbeat (cardiac arrhythmia). An implanted generator produces electrical impulses that are conducted through leads to stimulate the heart muscle.

The EnPulse™ pacing system automatically monitors and adjusts the level of electrical impulses at regular intervals, unlike pacemakers that require manual adjustments by a physician. The American Food and Drug Administration approved the use of this pacemaker with an Internet-based remote monitoring network for cardiac devices, which is operated by the manufacturer. The network allows patients to transmit information from their pacemaker while at home or travelling, rather than making a trip to the doctor's office. Doctors can then review the

information and make any necessary adjustments to the patient's course of treatment (Medscape Medical News 2004a).

The new Medtronic EnPulse™ system is the first pacemaker capable of performing a complete set of diagnostic tests without human intervention. A previous Enpulse™ was approved in the United States in December, 2003 (Medtronic 2004). Pre-market approval for EnPulse™ Implantable Pulse Generator and Model 9991 Application Software was granted in March 2004. EnPulse™ pacemakers are indicated for use in patients who are experiencing conditions that warrant chronic cardiac pacing, including:

- 1) Symptomatic paroxysmal or permanent second or third-degree atrioventricular block.
- 2) Symptomatic bilateral bundle branch block.
- 3) Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated atrioventricular conduction disorders.
- 4) Bradycardia-tachycardia syndrome.
- 5) Vasovagal syndromes or hypersensitive carotid sinus syndromes (FDA 2004)

EnPulse™ pacemakers are also indicated for use in patients who may benefit from rate responsive pacing to support cardiac output during varying levels of activity.

### **CLINICAL NEED AND BURDEN OF DISEASE**

The number of hospital separations for 'Cardiac Pacemaker Implantation' in code F12Z in 2001-2 was 8,186 (AIHW 2004). The Australian National Hospital Morbidity Database listed 1,928 and 1,157 hospital separations for principal diagnoses I49.8 'Other specified cardiac arrhythmias' and I49.9 'Cardiac arrhythmia', unspecified respectively in the year 2001-2. There were also 691 and 2,538 hospital separations for 'Atrioventricular block, second and third (complete) degree (principal diagnoses, I44.1 and I44.2). The number of hospital separations for supraventricular tachycardia, ventricular tachycardia, and paroxysmal tachycardia in 2001-2 was 9,408 (principal diagnoses I47.1, I47.2, I47.9).

### **DIFFUSION**

Given that the total number of cardiac pacemaker implantation procedures is high, it is likely that there will be a rapid uptake of the EnPulse™.

### **COMPARATORS**

Conventional pacemakers count and store the number of 'events' (changes in electrical activity) occurring in the atrium and/or ventricle over a specified period of time (Pollak et al, 2003). The limitation of this technology is that it reflects the pacemaker's interpretation of events that it records. For example, it may over-sense appropriate activity or under-sense inappropriate activity that leads to paroxysmal atrial fibrillation. Follow-up manual threshold testing is necessary to objectively evaluate optimal pacemaker function. Automatic sensing may improve the detection of arrhythmias and the mechanisms that trigger the onset of arrhythmias.

### **COST IMPACT**

Current MBS item fees for single implantation of chamber permanent transvenous electrode, permanent cardiac pacemaker, and dual chamber permanent transvenous electrode (MBS item numbers 38278, 38281, 38284) are \$530.80, \$212.30, and \$695.90.

A comparison between the cost of the EnPulse™ and previous pacemaker models is currently not available from Medtronic Australia.

## **EFFECTIVENESS AND SAFETY ISSUES**

The manufacturer has just begun trialling the EnPulse™ in 25 medical institutions worldwide (Medtronic 2004b). To date Medtronic Australia has not provided information regarding trial methodology.

The trials will evaluate:

**Atrial Capture Management** whereby the system automatically adjusts impulses to optimally stimulate the right atrium. A previous Medtronic model (Kappa) has a similar function for stimulation of the right ventricle. The EnPulse™ is the only pacemaker designed to automatically deliver adaptive threshold management in both chambers of the heart.

**Search AV +:** The EnPulse™ system uses an automatic and expanded search method intended to sense the patient's natural heartbeats before delivering pacing therapy, which could reduce unnecessary stimulation impulses to the ventricle. Recent clinical studies have suggested that reducing this pacing stimulation may reduce the patient's risk of developing heart failure and extending the longevity of the device (Medtronic 2004b).

**Quick Look II screen:** This new user-interface with the device will allow clinicians to look at one programmer screen during a patient's device check appointment and instantly access complete information about the patient and device. In addition, the manufacturer will evaluate whether new trend monitoring capabilities reduce the amount of time needed to gather key information and shorten patient office visits.

## **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

## **CONCLUSION:**

There is currently limited evidence available on the safety and effectiveness of the EnPulse™. However, there is the potential for a rapid uptake of this technology in the Australian health system.

## **HEALTHPACT ACTION:**

Therefore it is recommended that this technology be monitored.

## **SOURCES OF FURTHER INFORMATION:**

AIHW 2004 'Interactive national hospital morbidity database'[Internet] Available from: <http://www.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/AHS/drg97-02> [Accessed May 24, 2004]

American Food and Drug Administration, 2004 [Internet] Available from: <http://www.fda.gov/cdrh/pma/pmafeb04.html> [Accessed May 13, 2004].

Medscape Medical News 2004 [Internet] Available from: <http://www.medscape.com/viewarticle/472069?src=search> [Accessed May 24, 2004].

Medtronic 2004a [Internet] Available from: [http://www.medtronic.com/newsroom/news\\_20040315a.html](http://www.medtronic.com/newsroom/news_20040315a.html) [Accessed May 13, 2004].

Medtronic 2004b [Internet] Available from: [http://www.medtronic.com/CH/downloadablefiles/EnPulse\\_1st\\_switzerland.pdf](http://www.medtronic.com/CH/downloadablefiles/EnPulse_1st_switzerland.pdf) [Accessed May 13, 2004].

Pollak, W. M, Simmons J. D, Interian A., Castellanos A., Myerburg R. J, Mitrani R. D., P 2003 'Pacemaker Diagnostics: A Critical Appraisal of Current Technology' *PACE*, 26(1):76-98

**SEARCH CRITERIA TO BE USED:**

Arrhythmia/diagnosis

Atrial Fibrillation/complications/ diagnosis/ therapy

Atrial Fibrillation/diagnosis/therapy

Cardiac Pacing, Artificial/methods

Pacemaker, Artificial

Tachycardia/diagnosis