



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon Scanning Technology Prioritising Summary**

## **MRI compatible dual chamber pacemaker**

**November 2010**



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# PRIORITISING SUMMARY

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**REGISTER ID:** 000448

**NAME OF TECHNOLOGY:** MRI COMPATIBLE PACEMAKER

**PURPOSE AND TARGET GROUP:** FOR PATIENTS WITH THE STANDARD INDICATIONS FOR DUAL CHAMBER PACEMAKER IMPLANTATION WHO MAY REQUIRE AN MRI

**STAGE OF DEVELOPMENT (IN AUSTRALIA):**

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

**AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL**

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> Yes<br><br><input type="checkbox"/> No<br><input type="checkbox"/> Not applicable | ARTG number<br>Advisa DR MRI SureScan 164513 (22/08/2009)<br>EnRhythm MRI SureScan 162632 (22/06/2009)<br>CapSureFix MRI Pacemaker leads 165256 (15/09/2009) |
|---|--|

**INTERNATIONAL UTILISATION:**

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Italy	✓		
Czech Republic	✓		
Multi-centre trial – US, Canada, Europe and Middle East	✓		
Australia		✓	
New Zealand		✓	

**IMPACT SUMMARY:**

Medtronic Australasia Pty Ltd provides the Advisa DR MRI SureScan™, which superseded the EnRhythm™ MRI SureScan™, implantable dual chamber cardiac pacemaker, and the CapSureFix MRI™ pacemaker leads, all of which are magnetic

resonance imaging (MRI) compatible. The technology is available through cardiac specialists for patients who require cardiac pacing and may require clinical MRI scans throughout their life. BIOTRONIK SE & Co. KG (Germany) have recently gained [European approval](#) to market the ProMRI Pacing Systems that are MRI compatible under specific conditions and [St Jude Medical Inc](#) (USA) have indicated that clinical trials of an MRI compatible pacemaker system commenced in 2010.

## BACKGROUND

A pacemaker is a battery powered electrical device for stimulating or steadying the heartbeat or re-establishing the rhythm of an arrested heart. The intrinsic rhythm of the heart may be disrupted by a number of conditions including ischaemia or myocardial infarction. The pacemaker senses the rhythm of the patient's heart. If the rhythm becomes too slow the lead wires sense this and a signal is sent back to the pulse generator which then provides an electrical stimulus to contract the heart, re-establishing the correct rhythm (Figure 1).

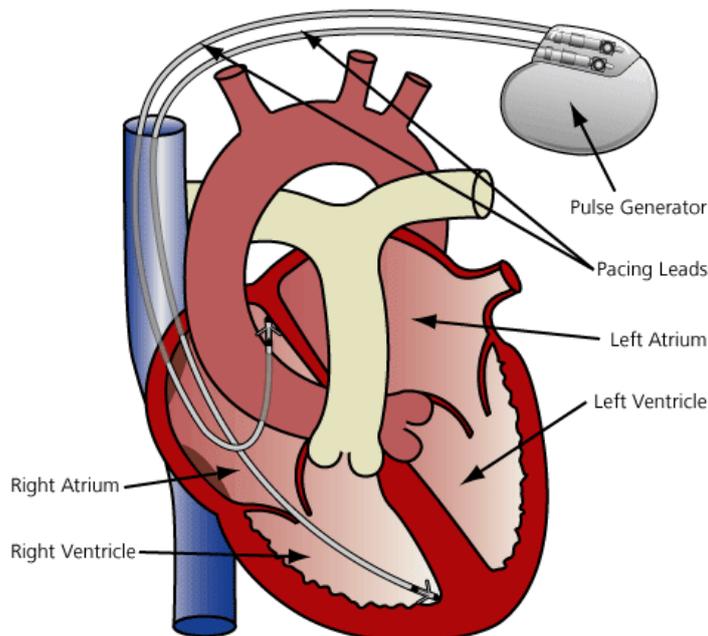


Figure 1 Schematic of a dual-chamber implanted pacemaker

Pacemakers can either have a single chamber, with a single lead going to the right ventricle or be dual chambered with two leads that pace the right atrium and the right ventricle in sequence (atrioventricular pacing). Dual chamber pacing adds 20-25 per cent to cardiac output which is reflected in an improvement in blood pressure. Pacemakers are inserted just below the collar bone with the pacing wires threaded through the right internal jugular or subclavian vein into the right atrium and ventricle. The lithium batteries that power pacemakers have a 6-10 year life span (Hammerschmidt 2008).

Indications for the implantation of a permanent dual chamber cardiac pacemaker include symptomatic paroxysmal or permanent second- or third-degree atrioventricular (AV) block, symptomatic bilateral bundle branch block, symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders and bradycardia-tachycardia syndrome<sup>1</sup> to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmia. Dual chamber modes are specifically indicated for the treatment of conduction disorders that require restoration of both rate and AV synchrony, including various degrees of AV block to maintain the atrial contribution to cardiac output and intolerance to ventricular pacing (VVI or pacemaker syndrome) in the presence of persistent sinus rhythm (Medtronic).

It has been estimated that 75 per cent of patients implanted with a permanent pacemaker may require, over the course of their lifetime, a MRI scan (Mitka 2009) and that 17 per cent of these patients would require an MRI within the first year of implantation (Forleo et al 2010). MRI has advantages over other imaging modalities such as computed tomography or X-ray for the imaging of soft tissue and is radiation free. MRI scans are currently contraindicated for patients who have implanted pacemakers due to concerns that the electromagnetic field generated by an MRI scanner may interfere with the operation of the pacemaker and may damage system components (Roguin 2009). The potential hazards associated with patients with an implanted pacemaker who undergo an MRI are outlined in Table 1.

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<sup>1</sup> Bradycardia = slow heart rate, tachycardia = rapid heart rate. Bradycardia-tachycardia syndrome= sick sinus syndrome characterised by alternating periods of bradycardia and tachycardia.

Table 1 A summary of the potential hazards and results of a patient with an implanted pacemaker undergoing an MRI scan (Medtronic)

Potential hazard	MRI field interaction	Mechanism and source of hazard	Clinical impact
Lead heating	Radiofrequency	The pacing lead is conductive and acts as an antenna, picking up the radiofrequency energy. A portion of this energy is dissipated as heat in the cardiac tissue.	Cardiac tissue near the pacing lead may experience thermal damage and pacing therapy may be affected.
Unintended cardiac stimulation	Gradient Radiofrequency	The gradient and radiofrequency fields induce voltages in the pacemaker leads that will then be applied to the pacing lead electrodes. Direct stimulation of the heart may occur if the voltage pulses are large enough.	Cardiac stimulation may lead to a single or intermittent stimulation or a sustained tachycardia
Device interactions	Static Gradient Radiofrequency	These fields may affect the electrical operation of the pacemaker.	The pacemaker may malfunction and affect pacing therapy.
Pacemaker case heating	Gradient Radiofrequency	Electrical currents on the conductive surface of the pacemaker case are dissipated as heat.	May cause thermal damage to the tissue surrounding the pacemaker.
Force and torque	Static	This acts on ferromagnetic material in the pacemaker which may result in the movement of the device or leads.	Movement of the pacemaker or leads may affect pacing therapy and may cause discomfort.
Vibration	Static Gradient	The gradient magnetic field induces an electrical current which interacts with the conductive surface of the pacemaker. These currents interact with the static magnetic field causing vibration of the device.	May affect pacing therapy.

In the past, patients with implanted pacemakers have experienced serious adverse events or even death as a result of undergoing an MRI scan. However, recently pacemakers have become smaller and have less magnetic components. Several studies have been conducted where patients with an implanted pacemaker have undergone an MRI scan under close clinical supervision. These conditions include complete device interrogation and programming prior to the MRI scan and interrogation and re-programming of the device after the scan is completed. Although MRI scans are thought to be feasible under these conditions, it is still not a recommended clinical practice and patients should be selected on a case-by-case basis (Halshtok et al 2010).

Devices may be certified as either MR-safe, that is, it has or causes no known hazards in *all* MRI environments, or MR-conditional, meaning that it poses no hazards in a *specified* MRI environment used under *specified* conditions (Roguin 2009). The Medtronic EnRhythm™ MRI SureScan™ is the only implantable MRI-compatible dual chamber cardiac pacemaker on the market (Figure 2), and is used in conjunction with the MRI-compatible CapSureFix MRI™ pacemaker leads. The SureScan Pacing System is conditionally approved for use in 1.5 Tesla MRI scanners (personal communication Medtronic Australia).

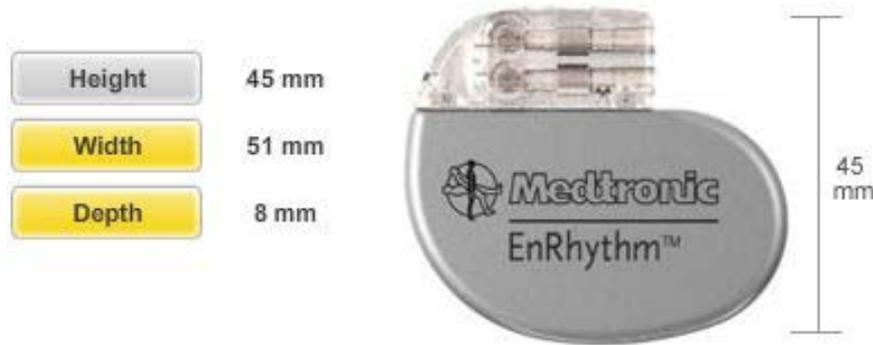


Figure 2 The EnRhythm™ MRI SureScan pacemaker (Medtronic 2009)

The EnRhythm™ MRI-compatible pacemaker differs from conventional pacemakers in a number of ways. In particular the pacemaker leads are thicker than conventional leads due to being insulated with silicon, reducing the degree of lead tip heating (Forleo et al 2010). Other changes to the device include reducing the amount of ferromagnetic material in the device, improvements to internal circuit protection to prevent disruption of the internal power supply and changes to the internal circuitry to reduce the possibility of cardiac stimulation. In addition, changes to the programming of the device enabled a choice between asynchronous and non-stimulation modes, an increase of pacing output to 5.0 volts/1.0 ms during an MRI scan and a 10 point system integrity check which if failed prevents the device from entering MRI program mode and restores the device to the pre-scan program (Wilkoff et al 2010).

Before undertaking an MRI examination in a patient with a pacemaker *in situ*, guidelines recommend that equipment and trained staff capable of performing CPR and defibrillation be present in the MRI suite. In addition, a cardiac electrophysiologist should be present to enable prompt re-programming of the pacemaker device if required. Pacemaker function should be checked before the patient leaves the MRI suite after the MRI scan, with further follow up at 1 – 6 weeks (personal communication Medtronic Australia). Although clinical advice suggested that patients with an MRI-compatible pacemaker should avoid MRI scans of the torso (personal communication Victorian Department of Health), Medtronic have indicated that this restriction has now been removed.

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

A comprehensive survey of the number of pacemakers and implantable cardioverter defibrillators was undertaken in Australia and New Zealand for the year 2005. Data were obtained via a survey of all companies that sold and registered pacemakers throughout Australia and via individual hospitals in New Zealand. During 2005 there were 123 Australian and seven New Zealand centres routinely performing the implantation of pacemaker devices. A total of 12,990 pacemakers were sold in Australia during 2005, of which 11,850 were new implants and 1,140 (8.8%) were

replacement devices. This figure represents a 17.7 per cent increase in the number of devices implanted in the year 2001 (11,034) and equates to a rate of 590 implanted pacemakers per million of population (Figure 2). A small fraction of these devices were biventricular pacemakers (461, 3.5%) used for cardiac resynchronisation therapy. No information was available as to the clinical indications for implantation in Australia (Mond & Whitlock 2008).

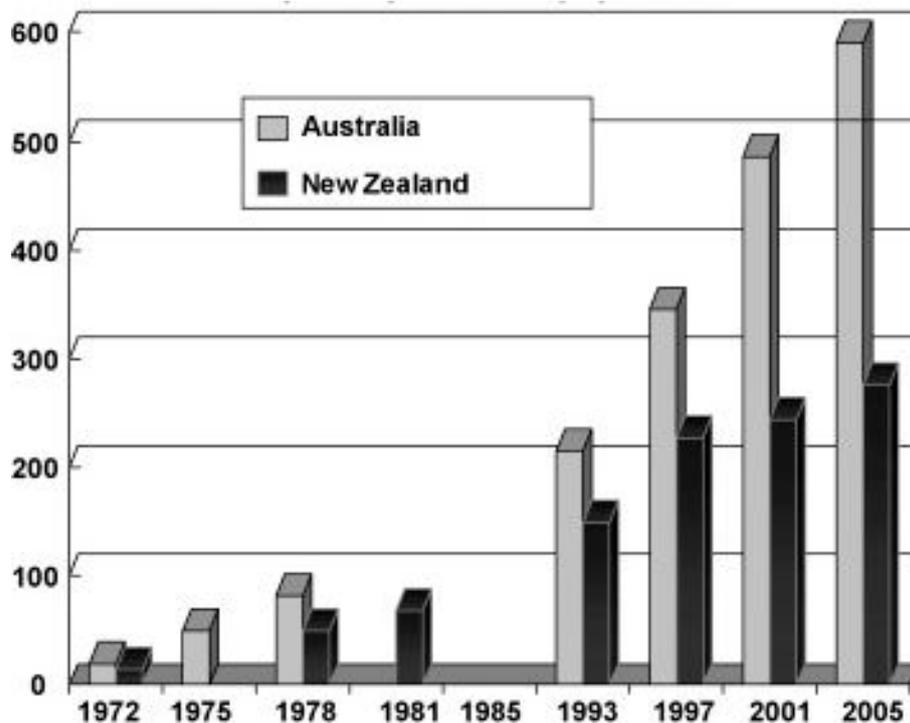


Figure 3 The number of pacemakers implanted per million population in Australia and New Zealand (Mond & Whitlock 2008)

In New Zealand for the same year, there were a total of 1,450 pacemakers implanted which was significant increase (30.7%) compared to the number implanted in 2001 (1,109). Of these, the majority were new implants (1,134) with 21.8 per cent (316) being replacement pacemakers. This number equates to a rate of 275 implanted pacemakers per million of population (Figure 3). Only 16 biventricular pacemakers were implanted. Clinical indications were collected for New Zealand with 49 per cent of pacemakers implanted for atrioventricular block, sinus node disease (28%), atrial fibrillation (18%), neurocardiogenic and carotid sinus syncope (2%) and all forms of cardiomyopathy (Mond & Whitlock 2008).

The prevalence of implanted pacemakers in the community is unclear in either Australia or New Zealand.

In Australia, the number of cardiac pacemaker implantations conducted in public hospitals has steadily increased from 5,648 in 1998-99 to 10,626 in 2007-08 (AR-DRG F12Z) (Figure 4). The average length of stay for the implantation procedure has remained steady over this period of time at 4.3 days. In addition, for the year 2007-08,

there were 4,151 public hospital separations for a cardiac pacemaker replacement (AR-DRG F17Z) and 747 separations for a pacemaker device revision, excluding replacement (AR-DRG F18Z) (AIHW 2010). According to the Medicare Australia Statistics web site a total of 134 pacemakers were implanted in the private sector, using the MBS item number 38353, for the calendar year 2009.

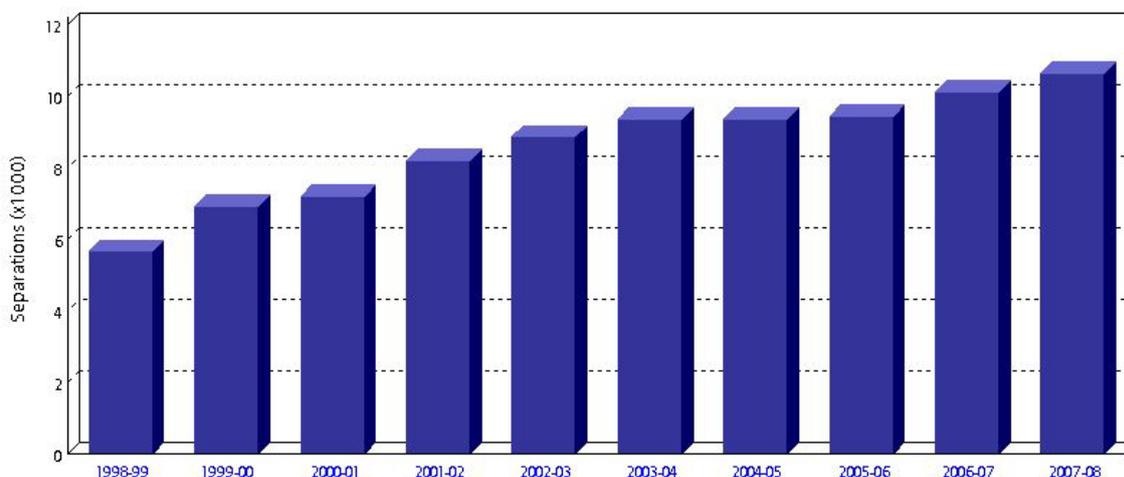


Figure 4 The number of Australian public hospital separations for the AR-DRG F12Z, cardiac pacemaker implantation (AIHW 2010)

## DIFFUSION

A small number (approx 40) of the first generation EnRhythm MRI pacemaker were sold in Australia during late 2009 and early 2010. Approximately 600 patients have been implanted with the new Advisa MRI SureScan pacing system since April 2010 (personal communication Medtronic Inc).

## COMPARATORS

Patients implanted with conventional pacemakers should undergo clinical imaging with other modalities such as X-ray or CT. Patients with an implanted pacemaker may undergo an MRI in strictly supervised circumstances.

## SAFETY AND EFFECTIVENESS ISSUES

A large, multi-centre trial in the United States, Canada and Europe (Clinical Trials identifier [NCT00433654](#)) has recently been completed. This randomised controlled trial commenced in early 2007 and enrolled 464 patients who had a Class I or II indication<sup>2</sup> for dual chamber pacemaker implantation. All patients were implanted with the Medtronic EnRhythm MRI™ SureScan™ and the CapSureFix MRI™ leads and were then randomised in a 2:1 ratio to undergo MRI at 9-12 weeks post-implantation, or to receive no MRI scan (level II intervention evidence). MRI scans were conducted in a 1.5 Tesla (T) MRI and included 14 head and lumbar scan

<sup>2</sup> Class I and Class II indications according to the American College of Cardiology/American Heart Association (Gregoratos et al 1998)

sequences (Sutton et al 2008). Total MRI investigation time was 60 minutes (static magnetic field exposure) with an approximate 30 minute active MRI scanning time (gradient and radiofrequency field exposure). The specific absorption rate (SAR) for the whole body must not exceed 2.0 W/kg or 3.2 W/kg for the cranial region and the slew rate<sup>3</sup> should not exceed 200 T/m/s. Pulse oximetry monitored heart rate and blood oxygen saturation. Full interrogation of the device was conducted post-implantation, immediately prior and post MRI scans and at one week and one month after scanning. The primary outcome measures included the safety of the pacemaker during the MRI, that is the presence of any system-related complications including interference with pacemaker function by the magnetic field, unintended cardiac stimulation or electrical reset of the device. In addition, the performance of the pacemaker system in the top and bottom chambers of the heart following the MRI scans was assessed by the measurement of pacing threshold and sensing equivalence (Wilkoff et al 2010).

Wilkoff et al (2010) reported the final results of this study (mean follow-up  $11.2 \pm 5.2$  months, range 0.1 to 21.5 months). There was no difference in the characteristics between the two groups and the indications for pacemaker implantation included AV block (38.8%), sinus node dysfunction (45.5%) and other (15.7%). More patients in the MRI group had concomitant atrial fibrillation, atrial flutter or atrial tachycardia than those in the conventional group (50.4% vs 39.8%).

Of the 258 patients who were assigned to the MRI scan group, 226 patients had an MRI performed and completed the one month post-MRI follow-up but only 211 of these were per protocol. No MRI-related complications were reported for these patients, including those scanned outside of the protocol (partial scan n=6, SAR limit exceeded maximum n=8 and capture threshold exceeded n=1). In addition, one control group patient underwent scanning without incident. All of the 226 scans were performed safely with continuous pacemaker stimulation when programmed to asynchronous mode (n=158) or regular spontaneous intrinsic activation when programmed to no pacing mode (n=67). The status of one patient scanned was unknown. No pacemaker system disturbances were observed during or after the MRI in addition to no changes in heart rate, sustained ventricular arrhythmias or electrical resets of the pacemaker. Patients did report episodes of paraesthesia (n=3) and palpitations (n=1) which were associated with the MRI procedure rather than the interaction between the MRI and the pacemaker. Atrial fibrillation (n=1) and atrial flutter (n=1) was reported but was again considered not be to be associated with the pacemaker/ MRI scan interaction. Although 11 deaths did occur during the course of

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<sup>3</sup> Slew rate describes how fast the gradient coil reaches a particular amplitude ie the steepness of the curve. The time it takes to reach this amplitude is referred to as "rise time". At high slew rates the gradient switching is so fast that peripheral nerves may be stimulated, which is not dangerous but patients may feel their muscles contract.

the study, none were associated with the implantation procedure, the pacemaker or the MRI scan. At the one-month post-MRI follow-up assessment, 91.7 per cent of patients had not experienced any pacemaker related complications. A total of 37 patients did experience 43 complications that were deemed unrelated to the MRI scan including lead dislodgement (n=17), elevated capture thresholds<sup>4</sup> (n=9), pericardial effusion (n=3) and failure to capture (n=3). Complication rates for patients in the conventional pacemaker group were not reported.

None of the patients in the MRI group and only one of the control patients experienced an increase in pacing capture threshold. The success rate for atrial sensing amplitude was equivalent in both the MRI (94.7%) and control (92.8%) patients. Similar rates were observed for ventricular sensing amplitude (Wilkoff et al 2010).

A smaller comparative study reported on the implantation and efficacy of the EnRhythm™ device, although patients did *not* undergo an MRI. Of 107 consecutive patients, 50 were implanted with the EnRhythm™ device and 57 were implanted with a conventional dual chamber pacemaker (level III-2 intervention evidence). Indications for pacemaker implantation included symptomatic sinus node disease (34.6%) and second and/or third-degree AV block (65.4%). Postoperative follow-up was conducted at one, three, six (n=80) and 12-months (n=27) (Forleo et al 2010).

There was no difference in procedure time, fluoroscopy time or length of hospital stay for patients implanted with the EnRhythm™ or the conventional pacemaker. The insertion of both leads via the cephalic vein was possible in 60 and 68.4 per cent of patients in the EnRhythm™ and conventional group, respectively, with the remaining patients in both groups requiring a subclavian vein puncture to place at least one lead. The implantation success rate for both groups was 100 per cent. In the early post-implantation period one patient experienced a ventricular lead displacement from the right ventricular outflow tract to the right ventricular apex, which required reoperation. During the follow-up period (median 6.8 months, range 3-12 months) no cases of high pacing threshold, inadequate sensing, chronic lead displacement, lead conductor fracture, insulation defect or infection were noted in either group. Only one patient underwent an MRI (of the knee) during follow-up which occurred without incident or significant changes in sensing (Forleo et al 2010).

An earlier study was published by Vymazal et al (2009), however only the abstract of this study was available in English. The MRI-compatible cardiac pacemaker EnRhythm™ was implanted in 52 patients, 25 of whom were randomised for an MRI scan using a closed-bore 1.5 T MRI: The pacemaker was implanted at least six weeks prior to conducting the MRI scan. The pacemaker was switched into the MR

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<sup>4</sup> The electrical pulse emitted by the pacemaker has to be strong enough, and last long enough, to capture the myocardium. The capture threshold is the minimum amount of electrical pulse required to pace the heart.

compatible mode just prior to the patient undergoing the scan and was switched back to normal mode post-scan and interrogated. No adverse events were reported, however the authors recommended that the type of the pacemaker and electrodes should be ascertained prior to MRI scanning by chest x-ray.

It should be noted that that these results are only limited to MRI scans conducted in a 1.5T scanner and as such this technology is limited to *safe* use in older scanners.

#### **COST IMPACT**

The Advisa MRI pacemaker is listed on the private prosthesis list (code MC933) and is priced equivalent to the non-MRI version of the Advisa pacemaker (MC934) at A\$11,780 (personal communication Medtronic Inc).

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

No issues were identified/raised in the sources examined.

#### **OTHER ISSUES**

The majority of the study investigators involved in the Wilkoff et al (2010) study are consultants to Medtronic (Sutton et al 2008). In addition, Medtronic Inc provided funding for this study (Wilkoff et al 2010).

#### **SUMMARY OF FINDINGS**

Based on the studies included for assessment in this summary it would appear that the use of the EnRhythm™ MRI-compatible pacemaker is safe to use in patients who undergo scans in a 1.5 Tesla MRI and that the EnRhythm™ functions as effectively as conventional pacemakers. It should be noted that that these results are *only* limited to MRI scans conducted in a 1.5T scanner and as such this technology is limited to *safe* use in these scanners.

#### **HEALTHPACT ASSESSMENT:**

This device is currently diffusing in the Australian and New Zealand health systems and uptake of the technology is likely to increase. As many of the States are currently investing in 3.0 tesla MRIs there may be questions surrounding infrastructure requirements as these devices are currently only approved for use in 1.5 T MRIs. However, as the majority of MRIs (approximately 80%) in Australia are 1.5 T, patients implanted with an MRI-compatible pacemaker are assured continued access to an appropriate MRI scanner.

#### **NUMBER OF INCLUDED STUDIES**

Total number of studies	3
Level III-2 intervention evidence	2
Level II intervention evidence	1

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**SEARCH CRITERIA TO BE USED:**

Magnetic resonance imaging

Pacemaker, Artificial

Bradycardia

Arrhythmias, Cardiac

Heart Diseases

Cardiovascular Diseases