

Magnetic Resonance Imaging with MR Conditional Cardiac Pacemakers

Josef Vymazal, Aaron Rulseh, Miloš Táborský and Radovan Žáček
*Na Homolce Hospital, Prague
Czech Republic*

1. Introduction

1.0.0.1

The emergence and rapid development of Magnetic Resonance Imaging (MRI) in recent years has made MRI competitive with, and in many cases preferable to, many existing invasive and non-invasive imaging technologies. Primarily a neuroradiologic tool when introduced, MRI has quickly become the method of choice in many clinical fields, including cardiovascular imaging. In detecting the extent and precise location of myocardial ischemia, or in the diagnosis of arrhythmogenic right ventricular cardiomyopathy, MRI is the preferred investigative method. In general, MRI can currently be applied in the examination of almost all organs and systems, with the exception of those that have a low density of protons, such as the flat bones of the calvarium or the lungs. MRI is non-invasive, and since the electromagnetic energy applied in MRI is relatively weak, it carries no radiation burden. Furthermore, it is highly improbable that this energy is able to break chemical or biological bonds. Therefore, after almost thirty years of the clinical use, MRI is considered a safe technique.

1.0.0.2

There are approximately 60 million MRI scans performed worldwide every year (Sutton et al., 2008), and approximately two million Europeans currently have a cardiac pacemaker. It is estimated that between 50-75% of patients with a cardiac implant will be indicated for an MRI (Nazarian & Halperin, 2009), and every five seconds a patient is denied an MRI because of an implantable cardiac device (Medtronic, 2010). The increase in both indications for MRI and the prevalence of implanted cardiac pacemakers has necessitated the development of an MR conditional cardiac pacemaker system. As mentioned, MRI is preferable to other imaging methods in many cases, and the advent of MR conditional pacemaker systems allows the clinician to take advantage of this imaging modality (Figures 1, 2).

2. Magnetic resonance imaging

2.1 Basic principles

2.1.0.3

A thorough exposition of the principles governing magnetic resonance imaging is beyond the scope of this text, and we refer those interested readers to any of the excellent resources

available on this subject (McRobbie et al., 2007). It is however important to explain some of the basic principles of the modality as they relate to the safety of implanted cardiac pacemakers and related devices. An MR system unsurprisingly uses magnetic fields to induce and detect subtle changes in the imaging subject, transforming this information into images. The system is able to accomplish this feat using three cooperating fields: a static magnetic field, gradient magnetic fields, and radio frequency (RF) fields.

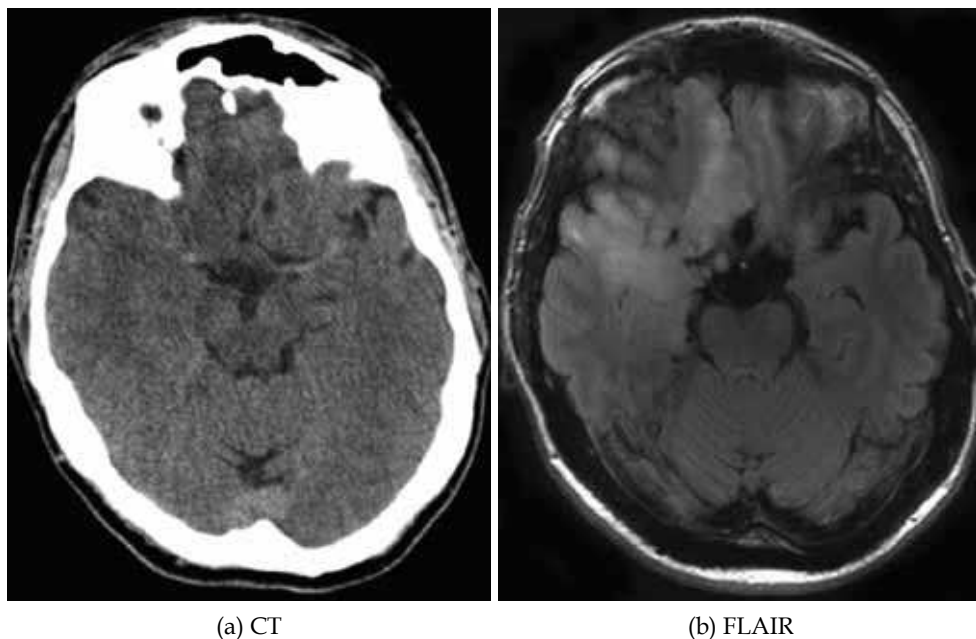


Fig. 1. Computerized tomography (CT) image and fluid-attenuated inversion recovery (FLAIR) MR image in the same patient with an EnRhythm MRI SureScan MR conditional pacemaker system. The images illustrate the advantages of MRI in some pathologies. In this patient, only slight hypodensity in the frontal region is visible in the CT image. The FLAIR image shows the extent and character of the pathology with greater precision – in this case, low grade astrocytoma.

2.1.0.4

The static magnetic field (B_0) of an MR system, as the name implies, remains constant and is present at all times, even when no examination is taking place. The magnetic flux density (magnitude) of this field is denoted in Tesla (T) ($1\text{T} = 10,000$ gauss), with most clinical scanners in use today being 1.5T or 3T. As a comparison, the magnetic flux density of the earth is approximately $50 \mu\text{T}$ (0.5 gauss). The source of this field is a coil, made of a specific alloy that when cooled to a temperature close to absolute zero loses nearly all electrical resistance. This condition is called superconductivity, and it enables the static magnetic field to remain on at all times, without the requirement of an external electric current to maintain the field. Another advantage of superconductive coils is their ability to provide a very homogeneous field, which is necessary for MR imaging.

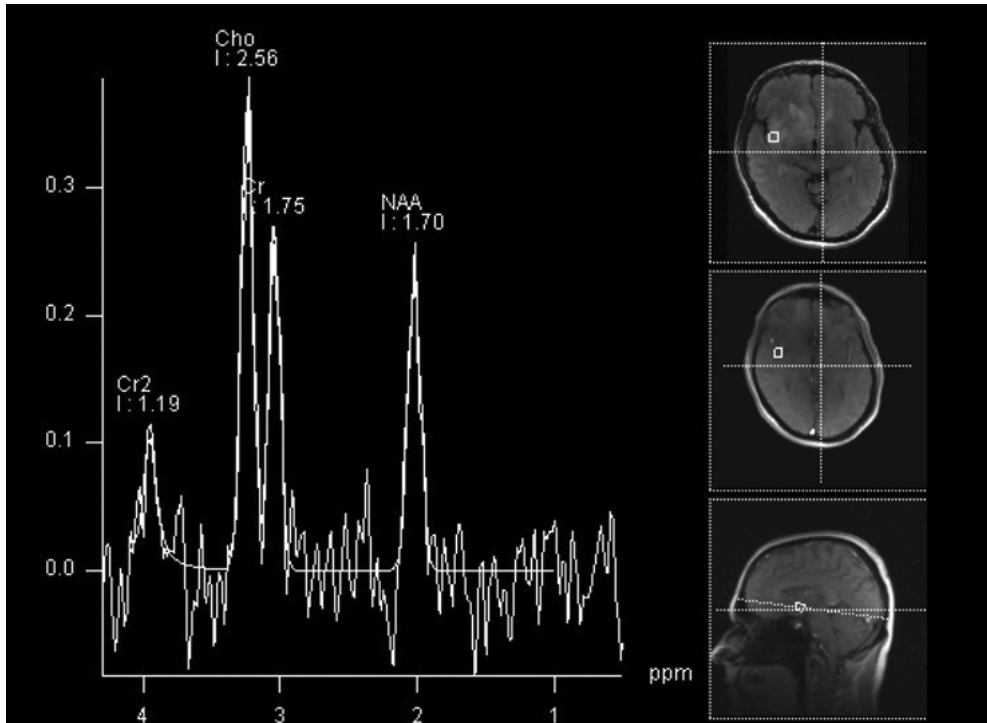


Fig. 2. MR conditional pacemaker systems also enable NMR spectroscopic studies of the brain, where individual brain metabolites are visualized. This spectroscopic examination was performed in the same patient as presented in Figure 1, and here an increased choline peak suggests the presence of brain tumor. This technique is especially sensitive to the homogeneity of the magnetic field, and the presence of the MR conditional cardiac pacemaker system did not negatively influence the results.

2.1.0.5

Clinical MRI is proton imaging, and only hydrogen nuclei in different local magnetic environments and conditions are imaged. Protons have a property called spin, which is the total angular momentum of its constituent parts (in fact many MR-related texts use spins synonymously with protons), as well as a magnetic dipole moment. When the subject is placed in the B_0 field, the protons tend to align with the B_0 field, and their magnetic dipole moments begin to precess. The usual analogy given to help visualize precession is the wobble of a spinning top. Precession results from torque when a magnetic dipole is placed in an external field. This is termed Larmor precession, and the frequency of precession is proportional to the magnetic field magnitude as stated by the Larmor equation (see Equation 1, where ω is precessional frequency, γ is gyromagnetic ratio (a constant for a given nucleus), and B_0 is the magnitude of the magnetic field). This alignment of protons in the B_0 field is the first step in creating MR images.

$$\omega = \gamma B_0 \quad (1)$$

2.1.0.6

Magnet field gradients are provided by the three paired orthogonal gradient coils, being superimposed on the static (B_0) field. The gradients are applied in short pulses and vary in amplitude, time and direction, allowing slice selection, frequency encoding, and phase encoding. To state this more simply, the linear gradients produced by the gradient coils allow spatial encoding of the imaging data (the gradient coils also serve an important role in many pulse sequences). Two critical properties of gradient coils that affect image quality and have important safety implications are the gradient strength and the gradient slew rate. Gradient strength (amplitude) is the change in field strength per unit distance, and is given in mT/m. The gradient slew rate is the rate of ascent or descent of a gradient from zero to its maximum amplitude, and is given in mT/m/msec, or more often in T/m/s.

2.1.0.7

Radio frequency pulses, in the most simplistic sense, are used to excite the protons so that meaningful data can be captured and used for image reconstruction. An RF pulse is a magnetic field oscillating at the Larmor frequency. When these pulses are applied for specific short durations, they are able to transfer energy to protons, or more accurately to change the spin state of protons, which are precessing at the same frequency. This is termed nuclear magnetic resonance, and is the process after which this modality is named. The result of the process is a change in energy state in the same direction as the B_0 field (a decrease in longitudinal magnetization), and the development of precessional phase coherence (development of transversal magnetization). Transversal magnetization is an essential process for MRI (Figure 3). Precessional phase coherence results in a vector of magnetization transverse to the B_0 field that, in the absence of phase coherence, is canceled out. Since this vector is not in the same plane as the B_0 field, it is not obscured by the B_0 field and can be detected. The protons quickly return to a lower energy state after cessation of the RF pulse in a process called relaxation. Longitudinal relaxation results in the transfer of thermal energy to the surrounding environment (spin-lattice relaxation), and is the basis for an important safety consideration, the specific absorption rate (SAR), which will be discussed shortly.

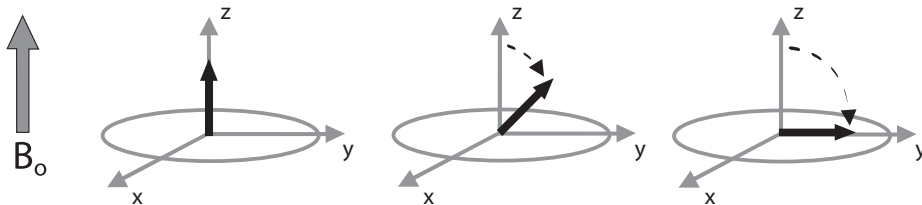


Fig. 3. The development of transversal magnetization.

2.1.0.8

An important point to note about the magnetic field produced by an MR system is that it extends beyond the bore of the magnet—this is called the fringe field. The fringe field produced by the superconductive coils of an MR system is analogous to the magnetic flux lines that can be visualized by placing iron shavings around a permanent magnet (Figure 4). The magnetic flux density of the fringe field decreases by the squared distance from the magnet, and this attenuation of magnitude is enhanced by the active magnetic shielding

present in all modern scanners. The “5 gauss line” is clearly marked around the scanner, generally being a line painted on the floor of the scanner room, which denotes the point at which the field is 5 gauss (0.5 mT). Five gauss is considered the maximum safe level of exposure for the general public, and access between this line and the bore of the magnet is strictly controlled.

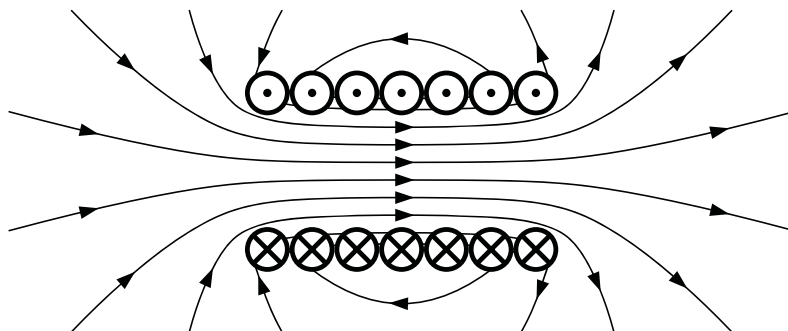


Fig. 4. Diagram illustrating the magnetic flux lines of a solenoid.

2.2 Safety

2.2.0.9

MRI is remarkable in that it can deliver images with superb soft tissue contrast while exposing the patient to very little risk. Nevertheless, there are important safety concerns that must be considered when performing an MR examination. In contrast to the stochastic effects of ionizing radiation used in many radiological modalities, e.g., X-ray or computerized tomography (CT) examinations, the effects of the magnetic fields used in MR systems on biological tissues follow a deterministic model. Therefore, the magnitude of the effect is dependent on parameters relating to exposure and can be predicted to a large extent, allowing the establishment of appropriate safety thresholds.

2.2.0.10

Several international organizations provide valuable safety recommendations for MRI. The International Electrotechnical Commission (IEC) and the International Commission on Non Ionizing Radiation Protection (ICNIRP) are two such organizations that provide guidance to manufacturers, regulatory bodies, and the public. As our discussion on MRI safety will primarily focus on implanted devices, we encourage readers interested in more detailed safety information to consult the documentation provided by the commissions mentioned above, or any of the excellent texts available on this subject (ICNIRP, 2009; IEC, 2010; Shellock, 2009).

2.2.0.11

The response of matter to an applied external field can be classified as diamagnetic, paramagnetic, or ferromagnetic (superparamagnetism, antiferromagnetism, and other types of magnetism may also be described, but are omitted here for the sake of simplicity). Diamagnetism is present in all materials and is the weakest property of the three. When para- and ferromagnetism are not present, diamagnetism is the dominant property and the

material is said to be diamagnetic. The electrons in these materials are covalently bound, balanced in magnetic moment, and tend to align in a way that opposes the applied external field. Most biological tissues are diamagnetic. In paramagnetic materials, the magnetic moments of electrons do not balance completely, and these materials exhibit a magnetization that is proportional to the applied external field. Paramagnetism is stronger than diamagnetism, and when present in a material it overpowers its inherent diamagnetic properties. Finally, ferromagnetic materials have domains in which the magnetic moments of unpaired electrons align parallel to each other. The domains are arranged in random orientations, but in the presence of an external field the domains become aligned and the material is said to be magnetized. Ferromagnetism is several orders of magnitude stronger than paramagnetism.

2.2.1 Magnetic field safety

2.2.1.1

The magnetic fields used in MRI can interact with implanted devices in several ways. Para- and ferromagnetic materials, provided they are not spherical in shape, will attempt to align themselves with the external B_0 and gradient fields to minimize free energy. This magnetomechanical interaction may exert force, torque or vibrational effects on the implanted device, which if significant could lead to tissue damage, lead displacement, or device malfunction. The B_0 field may intermittently affect reed switch activity, leading to asynchronous pacing or inhibition of pacing. Current may be induced in the leads by the gradient magnetic fields, this in turn may cause over- or under-sensing resulting in pacing inhibition or acceleration. Restrictions in the maximum gradient slew rate help to minimize induced current. RF fields may also induce current in the leads leading to inappropriate pacing. Furthermore, RF fields may cause significant heating of the leads due to induction, with lead temperatures increasing up to 20°C (Luechinger et al., 2005). Lead heating is an important safety consideration as it may lead to tissue necrosis. The SAR, the energy absorbed per unit of tissue mass and time, is restricted to minimize temperature gains. The SAR is calculated by the MR system, and more restrictive SAR limits must be observed when imaging patients with MR conditional pacing systems.

2.2.2 Device Safety

2.2.2.1

ASTM International (formally, the American Society for Testing and Materials) is a voluntary standards development organization responsible for the development of medical device safety standards in the MR environment recognized by the FDA (ASTM, 2008). The standard stipulates that device testing evaluate magnetically induced displacement force, magnetically induced torque, heating by RF fields, and MR image artifacts from passive implants. After testing, the device may be classified into one of three categories: MR safe, MR conditional, and MR unsafe.



Fig. 5. MR safe symbol

2.2.2.2

MR Safe – MR safe items pose no known hazards in all MR environments (Figure 5). Items in this category include diamagnetic materials known to be MR safe, or if determined to be MR safe from product testing, must include the highest static field strength that the item was tested in.



Fig. 6. MR conditional symbol

2.2.2.3

MR Conditional – MR conditional items have been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use (Figure 6). Field conditions that define the MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), radio frequency fields, and specific absorption rate. Additional conditions, including specific configurations of the item may be required. Conditions for safe operation must be defined and observed.



Fig. 7. MR unsafe symbol

2.2.2.4

MR Unsafe – MR unsafe items are known to pose hazards in all MR environments (Figure 7). The presence of an MR unsafe item is obviously a contraindication to MR examination. Implantable cardiac pacemakers usually belong to this category.

3. MR conditional cardiac pacemaker systems

3.1 Introduction

3.1.0.5

The same need to perform MRI examinations in some patients with implanted cardiac pacemakers that spurred the development of MR conditional devices, also led some clinicians and researchers to attempt MRI examinations in non-pacemaker dependent patients with nonapproved devices. In each instance, the benefit of performing the examination was determined to out-weigh any associated risks. There have been some publications detailing the results of such endeavors, and in general they report satisfactory results (Luechinger et al., 2005; Nazarian et al., 2006; Sommer et al., 2006). However, one cannot generalize from these studies that all non-dependent patients with nonapproved

cardiac pacemakers can safely undergo an MRI examination, even when implementing stringent safety precautions, as these studies are limited by small sample sizes and the variety of implanted pacemakers, leads, and combinations thereof that were investigated. At least ten deaths have been attributed to MRI procedures in patients with cardiac pacemakers (Kanal et al., 2007; Martin et al., 2004). In light of these documented events, the clinician must be aware of potentially fatal outcomes when a standard implanted cardiac pacemaker is exposed to the strong magnetic fields of an MR system. These studies can however provide valuable guidance in those situations when a patient would benefit greatly from an MRI but has an MR unsafe device.

3.1.0.6

One response to the limited sample size in the studies mentioned previously has been the creation of the MagnaSafe Registry (MagnaSafe, 2010). The MagnaSafe Registry is a prospective multi-center study designed to determine the risk of non-thoracic 1.5T MRI scanning for patients with implanted cardiac devices, and aims to collect data from 1500 MRI examinations (1000 cardiac pacemakers, 500 implantable cardioverter-defibrillators). The data collected should help to refine safe scanning protocols and allow relatively better informed consent in those instances when an MRI is warranted and the patient does not enjoy the benefit of an MR conditional device. Some critics however have voiced concern over the utility of the registry, correctly pointing out that the study will likely lack the necessary power to establish the safety of any one device/lead combination.

3.1.0.7

With the vast number of cardiac pacemakers on the market, a great number of leads, and an overwhelming number of component combinations, device manufacturers have turned their attention to developing cardiac pacemaker systems designed specifically to minimize the safety concerns relevant to MRI examinations. MR conditional pacemaker systems are specific pacemaker/lead combinations that have undergone rigorous testing to establish their safety.

3.2 General principles shared by MR conditional pacemaker systems

3.2.0.8

Two manufacturers have been awarded CE approval to market their MR conditional pacemaker systems in the European Economic Area (EEA). Medtronic currently has CE approval for three systems: the EnRhythm, Advisa, and Ensura MRI SureScan pacing systems. Biotronik currently has CE approval for two systems: the Evia and the Entovis ProMRI MR conditional pacing systems.

3.2.0.9

These devices differ in some aspects from standard cardiac pacemakers. First, the amount of ferromagnetic parts is minimized, therefore the static magnetic field does not induce significant torque or vibration. Second, the leads of the pacemaker are isolated, therefore increases in temperature are also minimized. Third, the gradient and RF fields do not interfere with the pacing regime of the device on the condition that an MR conditional mode is activated. These features enable MR scanning in closed bore 1.5 Tesla systems.

3.2.0.10

MR scanners at 1.5 Tesla currently represent the gold standard of clinical MR imaging. A common sense rule that usually applies in MR imaging is that if a metallic implant is safe at a field strength of 1.5 Tesla, it is automatically safe for lower external fields. In the case of MR conditional cardiac pacemakers, this common sense rule does not apply. These devices have been constructed to be safe at a resonance frequency of approximately 64 MHz that corresponds to the external field of 1.5 Tesla. Different resonance frequencies, lower or higher, may interfere with the pacemaker system and thus be dangerous.

3.2.0.11

Our institution has practical experience with MRI in patients with MR conditional cardiac pacemakers as part of routine clinical practice, and also as participants in the EnRhythm SureScan clinical study (Vymazal et al., 2009). Over thirty patients with this device have been scanned at 1.5 Tesla in our hospital, and we have experienced no adverse events to date.

3.3 MRI in patients with MR conditional pacemaker systems

3.3.0.12

In a certain sense, the emergence of these medical devices complicates what has been, until now, a relatively straightforward situation. While until recently the presence of any implanted cardiac pacemaker was an absolute contraindication to MRI, now a radiological technician or radiologist has to ensure that several pre-MRI scanning conditions are met. First, it is important to ascertain that the patient does not have any other implanted devices, and that there are no abandoned, broken or intermittent leads, lead extensions or lead adapters present. This should be verified by chest X-ray, which also serves to identify the system as MR conditional. A standard chest X-ray reveals radiopaque markers on the device, unique for the specific type of pacemaker (Figure 8). Specific radiopaque markers are also present in the leads of Medtronic systems (Figure 9). The pacing system must be implanted for at least six weeks, and must in the left/right pectoral region. The six week period after the system has been implanted is an arbitrary period that also applies for most stents, metallic prosthesis, and other implants. The patient must also bring printed confirmation that specific MR pacing parameters have been activated. This includes activation of the MR conditional mode, and selection of an MRI pacing mode and rate. The printed confirmation is generated by a programming device and should be signed by the cardiologist or cardiovascular technician (Figure 10). Finally, suitable equipment for the MRI environment must be used for patient monitoring during the scanning procedure. An external defibrillator must also be available. Pre-MRI requirements are given in Table 1.

	Medtronic	Biotronik
Time since implantation	>6 weeks	>6 weeks
Radiopaque marker	PVX/PTA	SF
IPG position	L/R pectoral	Chest area
Activate MR Mode	✓	✓
Capture threshold <2.0 V at 0.4 ms	✓	✓
Lead impedance 200-1500 Ω	✓	✓

Table 1. Pre-MRI requirements for patients with MR conditional cardiac pacemaker systems. IPG, implantable pulse generator

3.3.0.13

After the pre-MRI scanning conditions have been met, the patient may undergo an MRI at 1.5 Tesla. Specific rules and limitations for imaging in patients with MR conditional systems are quite similar between systems and manufacturers, and are summarized in Table 2. Of note, the lateral decubitus position is contraindicated, and Biotronik further restricts patient position to only dorsal. Transmit coils cannot be used with Biotronik systems, only receive-only coils may be used. Biotronik systems also have a scan exclusion zone which must be observed (Figure 11). No coils, including receive-only coils, may be positioned within the scan exclusion zone. The result of this limitation is that no imaging data may be collected for this zone. The total scan time is also restricted to thirty minutes in Biotronik systems.

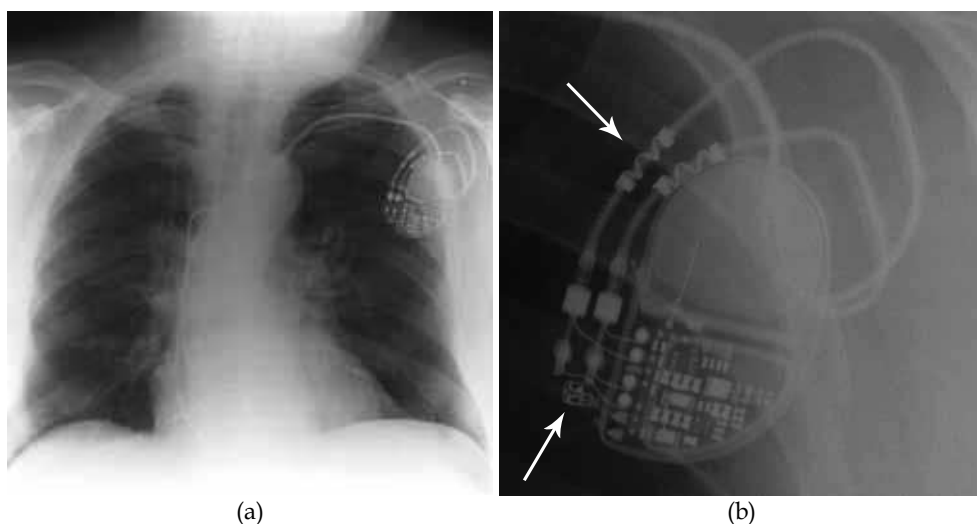


Fig. 8. Plain film chest X-ray allows visual confirmation of lead placement and integrity, implantable pulse generator (IPG) position, and MR conditional radiopaque markers (arrows).

	Medtronic	Biotronik
B_0 field	1.5T	1.5T
GSR	≤ 200 T/m/s	≤ 200 T/m/s
SAR – head	≤ 2 W/kg	≤ 2 W/kg
SAR – body	< 3.2 W/kg	< 3.2 W/kg
Patient position	No lateral decubitus	only dorsal
Patient monitoring	ECG/PO/BP	ECG+PO/ECG+BP
Scanning	Whole body	Scan exclusion zone
Coils	Transmit/receive	Only receive
Min. patient height	–	1.4 m

Table 2. Specific rules and limitations for MR scanning in patients with MR conditional cardiac pacemaker systems. SAR, specific absorption rate; GSR, gradient slew rate; ECG, electrocardiogram; PO, pulse oximetry; BP, blood pressure

3.3.0.14

After the MR examination is finished, the integrity of the pacemaker system should be evaluated by the programming machine, and it should be returned to normal operating mode.

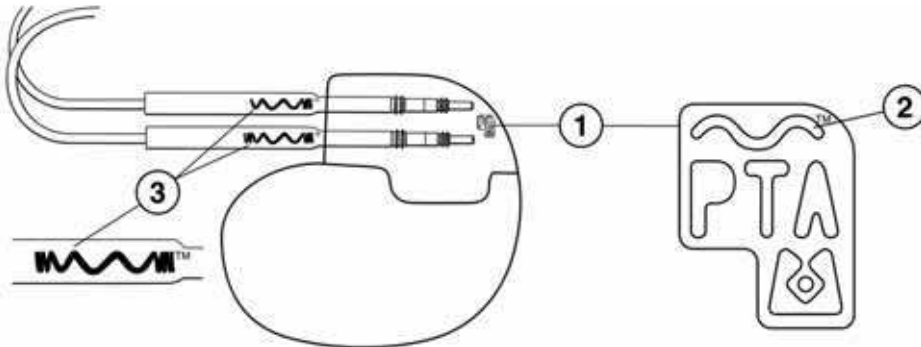


Fig. 9. Radiopaque symbols on the Medtronic EnRhythm MRI SureScan system. ① – Location of the device radiopaque symbol, ② – Device radiopaque symbol, ③ – Lead radiopaque symbol.

Device: EnRhythm MRI SMC001 Serial Number: #F6801885	Date of Visit: 23-Jul-2019 09:01:34 SW95 Software Version 7.1 Copyright © Medtronic, Inc. 2009	Device: EnRhythm MRI SMC001 Serial Number: #F6801885	Date of Visit: 23-Jul-2019 09:01:34 SW95 Software Version 7.1 Copyright © Medtronic, Inc. 2009
MRI SureScan Parameters Page 1 MRI SureScan Settings MRI SureScan: On Mode: ACD Lower Rate: 60 bpm A. Amplitude: 5 V A. Pulse Width: 1.0 ms During MRI SureScan operation: - No measurements or diagnostics are collected - Detection and therapies are off After the MRI scan: - Set MRI SureScan to Off to restore permanent device parameters		MRI SureScan Parameters Page 2 MRI SureScan Checklist The following device clinic information has been confirmed: System has been implanted for more than 6 weeks Device was implanted in the pectoral region No additional active implantable devices are present Leads are Medtronic MRI labeled Leads are electrically intact Absorbed or additional leads in vivo are not present No lead extenders or adapters are present Capture thresholds do not exceed 2.00 V at 0.40 ms Radiology considerations for MRI scan: MRI scanner is 1.5-Tesla only Continuous monitoring of the patient during MRI scan is required Observe the restrictions on landmark, SAR, and the use of local coils as described in the manual Note: See manual for detailed information	
Device Information Device: Medtronic EnRhythm MRI SMC #F6801885			

Fig. 10. Example pre-MRI report documenting activation of the MR conditional mode, and selection of an MRI pacing mode and rate.

3.4 Currently approved MR conditional pacemaker systems

3.4.0.15 EnRhythm MRI™ SureScan™ pacing system

Medtronic's EnRhythm MRI SureScan pacing system received CE approval in November, 2008, and was the first MR conditional pacing system commercially available. The EnRhythm MRI SureScan pacing system consists of the EnRhythm MRI SureScan implantable pulse generator (IPG) and the CapSureFix MRI SureScan pacing leads. When the EnRhythm MRI SureScan pacing system was introduced, an isocenter landmark exclusion zone was stipulated between the superior surface of C1 and the inferior surface of T12, with respect to the position of the patient within the scanner bore, relative to the isocenter landmark of the bore. Recently this restriction has been lifted, and the EnRhythm MRI SureScan pacing system is now approved for full body imaging (Burrows, 2010).

3.4.0.16

The EnRhythm MRI SureScan pacing system can be identified on chest X-ray by specific radiopaque markers (Figure 12). The device radiopaque marker found on the IPG features the Medtronic company symbol, with a tilde (~) symbol above designating the device as MR conditional. Between these two symbols three letters are visible, in this case "PTA", which identifies this as a first generation SureScan device. Radiopaque markers on the leads are seen as a set of wavy lines close to the lead/IPG junction. This identifies the leads as MR conditional SureScan pacing leads.

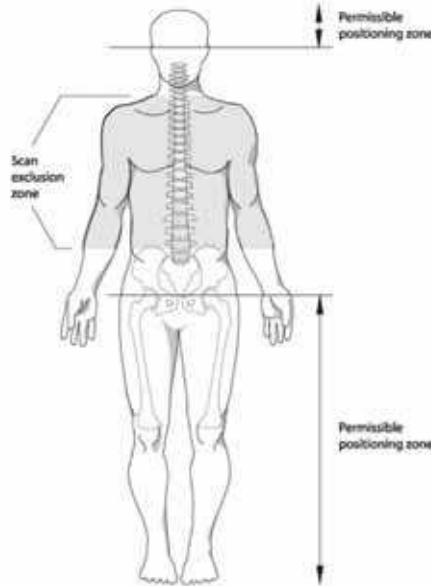


Fig. 11. Permissible positioning zone and scan exclusion zone for Biotronik Evia and Entovis ProMRI pacemaker systems. Starting from the foot end, the maximum allowed positioning mark for the isocenter is at the hip bone level. Starting from the top of the skull, the maximum allowed positioning mark for the isocenter is at the level of the eyes.

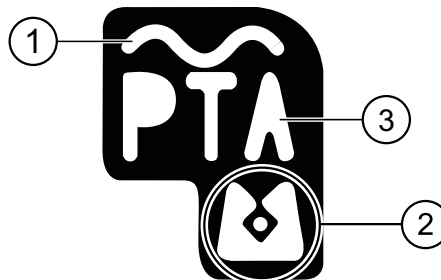


Fig. 12. Figure demonstrating the EnRhythm radiopaque device marker. ① – Marker identifying the device as MR conditional, ② – Medtronic identifier, ③ – Specific device identifier.

3.4.0.17

The EnRhythm MRI SureScan pacing system is no longer commercially available, having been supplanted by the company's next generation MR conditional pacing systems.

3.4.0.18 Advisa DR MRI™ SureScan™ pacing system

The Advisa DR MRI SureScan pacing system received CE approval in June, 2009, and is one of Medtronic's second generation MR conditional pacing systems. The Advisa DR MRI SureScan pacing system consists of the Advisa MRI SureScan IPG and the MRI SureScan leads.

3.4.0.19

The Advisa DR MRI SureScan pacing system can also be identified on chest X-ray by specific radiopaque markers (Figure 13). The device radiopaque marker found on the IPG features the Medtronic company symbol, with a tilde (~) symbol above designating the device as MR conditional. Between these two symbols three letters are visible, in this case "PVX", which identifies this as a second generation SureScan device. Radiopaque markers on the leads are seen as a set of wavy lines close to the lead/IPG junction. This identifies the leads as MR conditional SureScan pacing leads.

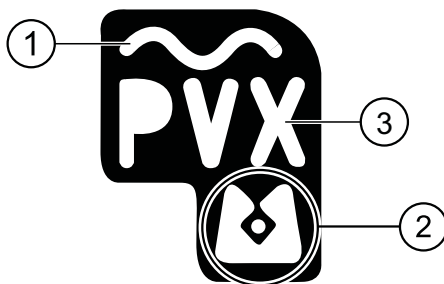


Fig. 13. Figure demonstrating the Advisa/Ensura radiopaque device marker. ① – Marker identifying the device as MR conditional, ② – Medtronic identifier, ③ – Specific device identifier.

3.4.0.20 Ensura MRI™ SureScan™ pacing system

The Ensura MRI SureScan pacing system was awarded CE approval in June, 2010, and is also a second generation MR conditional pacing system produced by Medtronic. The Ensura MRI SureScan pacing system is closely related to the Advisa MRI SureScan pacing system, and from the perspective of MRI safety they are the same. The Ensura system does differ in the pacing options available, being essentially a less featured and more affordable version of Advisa.

3.4.0.21

The radiopaque markers of the Ensura MRI SureScan pacing system are identical to the Advisa system described above (Figure 13).

3.4.0.22 Evia ProMRI® MR conditional pacing system

Biotronik received CE approval for the Evia ProMRI MR Conditional Pacing System in April, 2010. The Evia ProMRI system consists of the Evia SR/DR ProMRI IPG and Safio MR

conditional leads. A “-T” following the IPG model designation indicates that the device is equipped for Home Monitoring® service. Specific limitations with respect to MRI are summarized in Table 2, of note, a scan exclusion zone and permissible positioning zones within the MRI bore must be observed for safe operation (Figure 11).

3.4.0.23

The Evia ProMRI IPG can be identified by radiopaque markers on the device (Figure 14). The Biotronik logo is visible on the left, followed by two letters, in this case “SF”, which identify the device family. No radiopaque markers are present on the leads, necessitating that the investigating physician carefully review the patient documentation to ensure approved Safio leads are present.

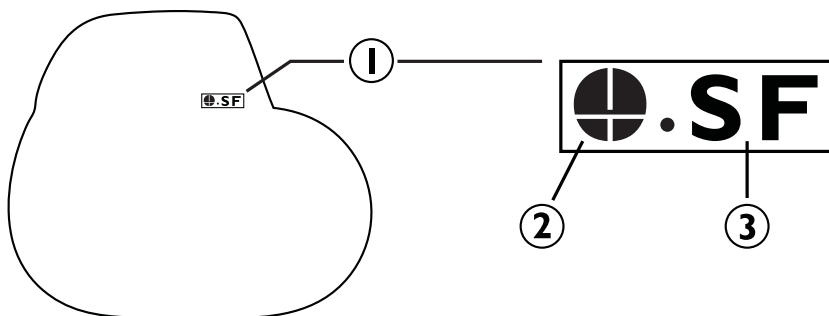


Fig. 14. Figure demonstrating the Biotronik radiopaque device marker. ① – Radiopaque device marker, ② – Biotronik identifier, ③ – Specific device identifier.

3.4.0.24 Entovis ProMRI® MR conditional pacing system

3.4.0.25

The Entovis ProMRI MR Conditional Pacing System produced by Biotronik also received CE approval in April, 2010. The Entovis ProMRI MR Conditional Pacing System consists of the Entovis DR/SR ProMRI IPG and Safio MR conditional leads. Like the Evia ProMRI IPG, a “-T” following the model designation indicates that the device is equipped for Home Monitoring® service. The Entovis ProMRI IPG is identical to the Evia ProMRI IPG from the perspective of MRI safety and radiopaque markers, as the two devices differ only in feature set and price point (Figures 11, 14).

4. Conclusion

4.0.0.26

MR conditional pacing systems are being actively developed, tested and refined by many cardiac pacemaker manufacturers. Currently, there are no FDA-approved MR conditional pacemaker systems, although several companies are actively pursuing this. The Revo MRI SureScan pacemaker system produced by Medtronic is expected to be the first system to gain FDA approval, after receiving unanimous recommendation from the FDA Circulatory System Devices Advisory Panel in March, 2010. The Revo MRI SureScan pacemaker system is a second generation Medtronic pacemaker system like the Advisa and Ensura. If approved, this system will have the same isocenter landmark exclusion zone that the

EnRhythm system launched with. No transmit coils may be used in this zone, but receive only coils are permitted, allowing off-center imaging of thoracic and abdominal organs (Figure 15). In other respects the Revo system is not expected to differ significantly from other second generation Medtronic systems.

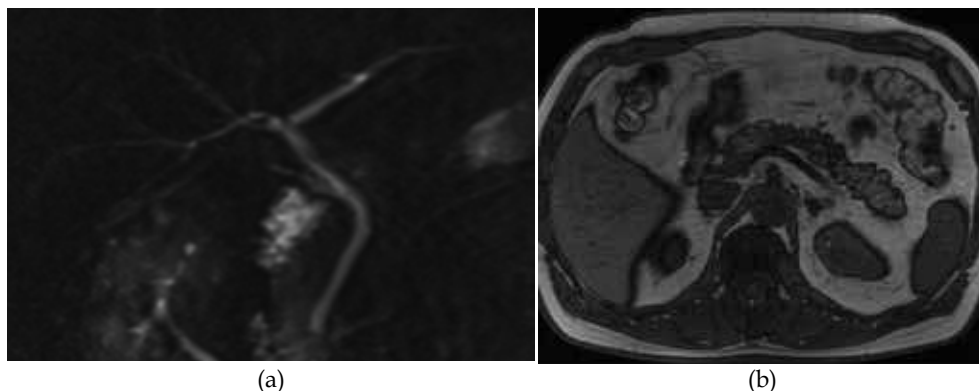


Fig. 15. (a) Magnetic resonance cholangiopancreatography (MRCP) examination in a patient with an EnRhythm MRI SureScan MR conditional pacemaker system using an off-center scanning approach. (b) True fast imaging with steady-state precession (TrueFISP) image of the abdomen in the same patient, also performed using an off-center scanning approach.

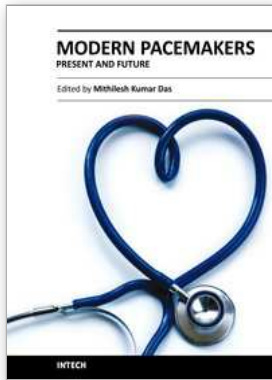
4.0.0.27

In the future we expect to see more of these devices gaining approval and appearing in our daily practice. As indications for MRI and the prevalence of implanted cardiac pacemakers increase, MR conditional cardiac pacemakers will do our patients a great service by giving them access to a powerful imaging modality while exposing them to a minimum of risk.

5. References

- ASTM (2008). ASTM f2503-08 (2008) standard practice for marking medical devices and other items for safety in the magnetic resonance environment, *Technical report*, American Society for Testing and Materials (ASTM) International. doi: 10.1520/F2503-08.
- Burrows, J. (2010). Updated information on enrhythm surescan pacemaker system. Personal communication.
- ICNIRP (2009). Guidelines on limits of exposure to static magnetic fields, *Health Physics* 96(4): 504–514. PMID: 19276710.
- IEC (2010). Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis. IEC 60601-2-33 (3rd edn.), *Technical report*, International Electrotechnical Commission (IEC).
- Kanal, E., Barkovich, A. J., Bell, C., Borgstede, J. P., Bradley, W. G., Froelich, J. W., Gilk, T., Gimbel, J. R., Gosbee, J., Kuhni-Kaminski, E., Lester, J. W., Nyenhuis, J., Parag, Y., Schaefer, D. J., Sebek-Scoumis, E. A., Weinreb, J., Zaremba, L. A., Wilcox, P., Lucey,

- L., Sass, N. & the ACR Blue Ribbon Panel on MR Safety (2007). ACR guidance document for safe MR practices: 2007, *Am. J. Roentgenol.* 188(6): 1447-1474.
- Luechinger, R., Zeijlemaker, V. A., Pedersen, E. M., Mortensen, P., Falk, E., Duru, F., Candinas, R. & Boesiger, P. (2005). In vivo heating of pacemaker leads during magnetic resonance imaging, *European Heart Journal* 26(4): 376-383.
- MagnaSafe (2010). The MagnaSafe registry, web. URL: <http://www.magnasafe.org>
- Martin, E. T., Coman, J. A., Shellock, F. G., Pulling, C. C., Fair, R. & Jenkins, K. (2004). Magnetic resonance imaging and cardiac pacemaker safety at 1.5-Tesla, *Journal of the American College of Cardiology* 43(7): 1315-1324. PMID: 15063447.
- McRobbie, D. W., Moore, E. A., Graves, M. J. & Prince, M. R. (2007). *MRI from Picture to Proton*, 2 edn, Cambridge University Press.
- Medtronic (2010). MRI safety must be proven for cardiac devices, web. URL: <http://www.medtronic.com>
- Nazarian, S. & Halperin, H. R. (2009). How to perform magnetic resonance imaging on patients with implantable cardiac arrhythmia devices, *Heart Rhythm: The Official Journal of the Heart Rhythm Society* 6(1): 138-143. PMID: 19121814.
- Nazarian, S., Roguin, A., Zviman, M. M., Lardo, A. C., Dickfeld, T. L., Calkins, H., Weiss, R. G., Berger, R. D., Bluemke, D. A. & Halperin, H. R. (2006). Clinical utility and safety of a protocol for noncardiac and cardiac magnetic resonance imaging of patients with permanent pacemakers and Implantable-Cardioverter defibrillators at 1.5 tesla, *Circulation* 114(12): 1277-1284.
- Shellock, F. G. (2009). *The Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2009 Edition*, 1 edn, Biomedical Research Publishing Company.
- Sommer, T., Naehle, C. P., Yang, A., Zeijlemaker, V., Hackenbroch, M., Schmiedel, A., Meyer, C., Strach, K., Skowasch, D., Vahlhaus, C., Litt, H. & Schild, H. (2006). Strategy for safe performance of extrathoracic magnetic resonance imaging at 1.5 tesla in the presence of cardiac pacemakers in Non-Pacemaker-Dependent patients: A prospective study with 115 examinations, *Circulation* 114(12): 1285-1292.
- Sutton, R., Kanal, E., Wilkoff, B. L., Bello, D., Luechinger, R., Jenniskens, I., Hull, M. & Sommer, T. (2008). Safety of magnetic resonance imaging of patients with a new Medtronic EnRhythm MRI SureScan pacing system: clinical study design, *Trials* 2(9): 68-68.
- Vymazal, J., Taborsky, M. & Zacek, R. (2009). Magnetic resonance imaging with implanted cardiac pacemaker enrhythm MRI surescan with MR compatible electrodes capsurefix MRI - first experience, *Ces Radiol* 63(1): 9-12.



Modern Pacemakers - Present and Future

Edited by Prof. Mithilesh R Das

ISBN 978-953-307-214-2

Hard cover, 610 pages

Publisher InTech

Published online 14, February, 2011

Published in print edition February, 2011

The book focuses upon clinical as well as engineering aspects of modern cardiac pacemakers. Modern pacemaker functions, implant techniques, various complications related to implant and complications during follow-up are covered. The issue of interaction between magnetic resonance imaging and pacemakers are well discussed. Chapters are also included discussing the role of pacemakers in congenital and acquired conduction disease. Apart from pacing for bradycardia, the role of pacemakers in cardiac resynchronization therapy has been an important aspect of management of advanced heart failure. The book provides an excellent overview of implantation techniques as well as benefits and limitations of cardiac resynchronization therapy. Pacemaker follow-up with remote monitoring is getting more and more acceptance in clinical practice; therefore, chapters related to various aspects of remote monitoring are also incorporated in the book. The current aspect of cardiac pacemaker physiology and role of cardiac ion channels, as well as the present and future of biopacemakers are included to glimpse into the future management of conduction system diseases. We have also included chapters regarding gut pacemakers as well as pacemaker mechanisms of neural networks. Therefore, the book covers the entire spectrum of modern pacemaker therapy including implant techniques, device related complications, interactions, limitations, and benefits (including the role of pacing role in heart failure), as well as future prospects of cardiac pacing.

How to reference

In order to correctly reference this scholarly work, feel free to copy and paste the following:

Josef Vymazal, Aaron Rulseh, Miloš Táborský and Radovan Žáček (2011). Magnetic Resonance Imaging with MR Conditional Cardiac Pacemakers, *Modern Pacemakers - Present and Future*, Prof. Mithilesh R Das (Ed.), ISBN: 978-953-307-214-2, InTech, Available from: <http://www.intechopen.com/books/modern-pacemakers-present-and-future/magnetic-resonance-imaging-with-mr-conditional-cardiac-pacemakers>

INTECH
open science | open minds

InTech Europe

University Campus STeP Ri
Slavka Krautzeka 83/A
51000 Rijeka, Croatia
Phone: +385 (51) 770 447
Fax: +385 (51) 686 166

InTech China

Unit 405, Office Block, Hotel Equatorial Shanghai
No.65, Yan An Road (West), Shanghai, 200040, China
中国上海市延安西路65号上海国际贵都大饭店办公楼405单元
Phone: +86-21-62489820
Fax: +86-21-62489821

© 2011 The Author(s). Licensee IntechOpen. This chapter is distributed under the terms of the [Creative Commons Attribution-NonCommercial-ShareAlike-3.0 License](#), which permits use, distribution and reproduction for non-commercial purposes, provided the original is properly cited and derivative works building on this content are distributed under the same license.