2024

ASMIRT

Position Paper

MRI scanning and MR Conditional Pacemakers

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There are a number of protected titles for medical radiation practice. They include:

Medical Radiation Practitioner (MRP)

Diagnostic Radiographer (DR)

Medical Imaging Technologist (MIT)

Radiographer

Nuclear Medicine Scientist (NMS)

Nuclear Medicine Technologist (NMT)

Radiation Therapist (RT).

For the purposes of our documentation we use the broad descriptor Medical Radiation Practitioner (MRP) recognising that it covers a range of areas of practice.

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ASMIRT Position Statement – MRI scanning and MR Conditional Pacemakers

The purpose of this document is to respond to the request that MR radiographers are to interrogate and program cardiac implantable electronic devices prior to an MR scan.

This document details information relating to the context and current environment with suggestions for maintenance of contemporary practice.

Background

MRI scanning is a diagnostic tool used to produce images to assess the structure and function of the body. Difficulties arise for patients who have defibrillators or cardiac pacemakers inserted, and who require an MRI scan. These devices are collectively known as cardiac implantable electronic devices or CIEDs.[1] Device manufacturers have identified the need to ensure that their products are MR Conditional* to ensure patient safety when performing MRI scans.

It is incumbent upon medical radiation practitioners to ensure that they have a robust understanding of the challenges including safety considerations of MRI when undertaking examinations of patients with CIEDs which may or may not be MR Conditional.

Definition

*MR Conditional – This term covers a wider range of implants and devices that are deemed safe for use in the MRI environment provided certain strict conditions are followed.[2] Whilst CIEDs may still contain magnetic, metallic, conductive, or RF-reactive components, testing has demonstrated safety in the MR environment within defined conditions.

MR Scanning

With approximately 200,000 pacemakers and defibrillators implanted in Australians, there is a high probability that at least half of these people will require some form of imaging in their lifetime including MRI scans.[3]

Patients who have an MRI-Conditional CIED and who attend for an MRI scan will require appropriate safety protocols to be followed. This includes checking the type of CIED (make, model, design) to ensure it is MRI Conditional. Following this, to perform an MRI scan on patients with MR-Conditional CIEDs, their devices require interrogation and programming into an MRI Mode prior to their scan. Interrogation of the device ensures that all components are functioning normally. Programming into MRI Mode allows the device to function adequately during the MRI scan and prevents the MRI scanner from interfering with the operation of the device. After the MRI scan is complete, the MRI Mode is deactivated so the device can return to its' normal operation.

The UK, like Australia, have a similar situation with around 500,000 implanted devices and patients requiring MR scans.[1] Literature from Bhuva et al, suggests that a solution to providing better services to these patients is to provide a sustainable, streamlined service that removes logistical barriers.[1] This "one stop" service incorporates reprogramming of devices and scan acquisition at a single location on a single visit.

Device interrogation and programming

To ensure that MR Conditional CIEDs are suitable for scanning, current practice consists of a healthcare team responsible for programming the CIED, which includes trained personnel such as a cardiac device physiologist, electrophysiologist, or cardiologist who have met the appropriate training and education requirements.[4] It is acknowledged by the Cardiac Society of Australia and New Zealand (CSANZ) Imaging Council that physicians, cardiac device physiologists, nurses, and vendors' cardiac technologists are also able to facilitate optimal programming of the CIED, however only after appropriate training and education (See table 1).[5]

Table 1: Training requirements

Physicians	Advanced training in cardiology or cardiothoracic surgery	Competency in pacing requirements
Cardiac Physiologists	Bachelor of Science (BSc) degree and employment as a cardiac physiologist Post Graduate Diploma in CIED management Allied Professionals Certified Cardiac Device Specialist (CCDS) Exam	Workplace training and industry-based education.
Nurses Cardiac Nurse specialist/nurse practitioner	Training in electrogram interpretation and device function	Completion of The International Board of Heart Rhythm Examiners (IBHRE) certification or equivalent plus ongoing CPD and appropriate registration
Vendors Cardiac Technologists		Provision of technical support and advice.

Device interrogation and programming includes switching the system into 'MRI Mode' and back to normal pacing mode. 'MRI Mode' minimises the risk of inappropriate CIED activation or inhibition of pacing.[4, 6-8]

Specific information relating to the CIEDs can be obtained via the manufacturer's manuals.

Emerging Changes to CIED Interrogation and Programming

With the progression of technology and to streamline the scan experience for the patient, manufacturers are developing new methods for MR-Conditional CIEDs to enter MRI Mode for scanning purposes and return it back to correct operations on scan completion. These methods may negate the presence of a vendor's technician or cardiac physiologist.

ASMIRT understand that certain vendors are changing how they offer services for patients with an MRI-Conditional CIED, when they require an MRI scan.

Biotronik have recently announced that they are developing technology where a CIED will automatically program itself into MRI Mode when the patient is placed within an MRI scanner. When the device is implanted, an appropriate MRI Mode for that patient is programmed into the device by their cardiologist. The program lasts for 12 months - which means that when the patient is reviewed by their cardiologist every 12 months, the MRI Mode is reviewed, and changed to a more appropriate program if required.

When the patient has an MRI, the MRI Mode program becomes active when the CIED is exposed to the MRI's magnetic field - meaning a cardiac technician does not have to be present. However, there is still a requirement for someone adequately trained to monitor the patient during the MRI scan. Without the presence of a cardiologist or cardiac physiologist/technician at the time of scanning, there would be no-one present who has adequate training to recognise whether the changes made by the program would be appropriate for the patient.

Medtronic have recently announced that their cardiac technologists now charge a fee for attendance for minimum numbers of patients, and additional fees for each additional patient. Medtronic have also released an app-based system for MRI departments to independently program CIEDs into MRI Mode, which is provided on a subscription basis. Operationally, when the app connects to the patient's device, the app automatically determines what device parameters are required for an MRI Mode. Aside from entering and exiting the MRI Mode, a safety feature of the app is that the device settings cannot be specifically altered. ASMIRT are also aware of other imaging centres who are using third party cardiac technicians when scanning MRI Conditional patients, rather than using this new app.

Implications for medical radiation practitioners

There are significant implications to be considered when utilising a device like this and altering a patient's CIED. At this present juncture, this is outside the scope of practice for a medical radiation practitioner.

Current process involves receiving an 'order' from the patient's treating cardiologist - this both makes them aware their patient is having an MRI and provides instructions on how their device is to be reprogrammed, based on their individual circumstances, for their MRI scan. In regard to Medtronic's CareLink SmartSync MRI Access app, whilst documentation from the manufacturer of the app indicates that there are built in fail safes for the app, there are still considerable risks to be assessed and analysed prior to adoption, with stakeholder consultation to ensure accurate detailed workflows are integrated properly into the relevant workplaces.

Changing a patient's prescribed therapy is outside the scope of practice of medical radiation practitioners. ASMIRT acknowledges the analogy with reprogramming a patient's spinal cord stimulator, where this is not in the remit of the medical radiation practitioner as this is a therapy that has been programmed and is administered by their treating doctor.

Other manufacturers of CIEDs have provided greater consideration for specific programming for specific patients, for regular consultation with their cardiologist, and no requirement for medical radiation practitioners to adjust their device.

CIED providers

CIED providers deliver services to their patients for devices they have implanted. As such, these organisations have a role to play in ensuring the continued care and safety of their clients/patients, remaining accountable for any upgrades etc.

Scanning considerations

Organisations which scan patients with MRI Conditional CIEDs are recommended to integrate appropriate workflows and must ensure appropriate safety checks are implemented.

This can include the following:

- Scanning is undertaken during normal operating hours where sufficient trained personnel are available to assist and respond to any adverse events if and when they occur.[4]
- Documentation from the patient's cardiologist detailing the location (positioning, for artefact location), stating mode, impedance etc. of the device and authorisation that they consent to the device being put in MRI mode. Selection of the appropriate scanning instructions for this patient is associated with their medical record.
- Consent from the patient is obtained and recorded for the scan.
- Protocols for documenting the interrogation and re-programming of the CIED prior to the scan.[4]

- The appropriate trained staff convert the device into MRI Mode as specified by the cardiologist, prior to the scan.
- A nurse with Advanced Life Support/cardiac training monitors the patient during and after the scan.
- The appropriately trained staff returns the device back into normal operational mode after the MRI scan is complete.
- Consider implications (cost and resources) when scanning patients in regional Australia with CIEDs.

Regulatory Authority Ahpra/MRPBA

As per Ahpra/MRPBA, Scope of Practice is the responsibility of the practitioner to develop. "Practitioners have a duty to make the care of patients or clients their first concern and to practise safely and effectively. In meeting this duty of care, practitioners have a responsibility to recognise and work within the limits of their competence and scope of practice….It important that practitioners ensure that they have the appropriate qualifications, contemporary skills and experience to provide safe and effective care."[9]

It is recommended that the practitioner consults with their workplace regarding education/training and credentialling requirements for undertaking this new scope of CIED Device interrogation and programming.

ASMIRT Recommendation / Professional Indemnity Insurance requirements

In the above context, including CIED programming for the purpose of MRI scanning may be considered within a medical radiation practitioner's scope of practice **ONLY** after the appropriate training/ education and credentialing has been provided to them.[10] The completion of an appropriate theoretical and practical component of learning is required (as per table 1). This can be via an externally credentialled program, or one that has been developed in-house. ASMIRT understand that with the purchase of the app-based system, there will be a significant reliance on vendor training.

In the situation where a medical imaging practice is willing to train the medical radiation practitioner in such a procedure, the medical radiation practitioner is in agreement, and all stakeholders (radiologists, cardiologists, nursing staff etc) have written (and signed) departmental policies outlining the organisation's specific processes, consent processes, and protocols, it may be possible.

ASMIRT's insurer advises the need for clear documentation detailing training and credentialling processes as well as detailed signed workplace policies.

ASMIRT recommends consulting whether the insurance policy of the various organisations will provide sufficient cover to determine whether this new change of scope will be covered.

Additional Recommendations/Future Direction

ASMIRT recognises that technology that can improve diagnostic accuracy in disease detection represents better quality outcomes for patients. However, the use of technology must be balanced against development/progression and day-to-day operations vs service continuity. Whilst this technology is relatively new, it is acknowledged that rapid changes will drive adoption and adaptation in the clinical environment. This document will be reviewed every three years, however updates will be provided, to remain reflective of contemporary practice.

Acknowledgements

ASMIRT thank the MRI Reference Group and the Professional Standards Committee for their expertise, input, and review of this document.

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Additional resources

Bhuva A., Charles-Edwards G., Ashmore J, et al. (2024) Joint British Society consensus recommendations for magnetic resonance imaging for patients with cardiac implantable electronic devices. Heart 2024;110:e3.