Barts Health NHS
NHS Trust

STANDARD OPERATING PROCEDURE (SOP)

MRI Scanning for Patients with Cardiac Implantable Electronic Devices (Pacemakers and Implantable Cardiac Defibrillators)

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Related Trust policies (to be read in conjunction with)	
Document owner	Patricia Feuchter, BHC Head of Radiography

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Section 1: Executive summary

The presence of a cardiac pacemaker or defibrillator has traditionally been regarded as an absolute contraindication to MR scanning. 'MRI conditional' pacemakers now exist however (i.e. safe under certain conditions) which are significantly more resistant to MRI. Similarly there is increasing data suggesting that the risk of scanning non-MRI conditional 'legacy' pacemakers is minimal provided specific safety protocols are followed. There are also international guidelines published by British Heart Rhythm Society, European Society of Cardiology and Heart Rhythm Society outlining protocols and best practice for MRI scanning in patients with cardiac implantable electronic devices (CIEDs). This protocol incorporates these recommendations to enable the safe scanning of patients with both MRI conditional and non-MRI conditional cardiac devices using MRI. At Barts Heart Centre Cardiac Imaging, we perform approximately 300 scans per annum on patients with CIEDs. This SOP is to protect both staff and patients performing the scans.

Section 2: Revision chronology

Revision chronology			
SOP reference[1]	Effective date[2]	Reason for change[3]	Author[4]
V1.0 (Draft)		First Draft	Patricia Feuchter

Section 3: Purpose and scope

The purpose of this Standard Operating Procedure (SOP) is to specify the processes used to ensure the safe scanning of patients with cardiac devices to be scanned in Cardiac MRI.

Section 4: Background

Magnetic resonance imaging (MRI) is used increasingly to image patients for diagnostic purposes, and to assess responses to treatment. Formerly, MRI scanning of patients with implantable cardiac devices (loop recorders, pacemakers and implantable cardiac

defibrillators) was felt to be contra-indicated because of the risk of harm to the patient or device. However, the recognition that around 75% of device patients will have a lifetime indication for an MRI scan (17% in the 12 months following device implantation), has led to the development of MRI 'conditional' cardiac devices, to allow these patients to undergo MRI scanning. In addition, selected patients with non-MRI conditional devices have undergone MRI scanning safely, without deleterious effects on device function. This has been confirmed in recent clinical studies, and highlighted by inclusion of recommendations for scanning these patients in the 2017 Heart Rhythm Society Guidelines.

Section 5. Guidance

5.1 General guidance for doctors referring patients with implantable cardiac devices for MRI scans.

Prior to referral for an MRI scan, information should be obtained from the pacing clinic concerning details of the patient's implantable cardiac device (both generator and lead(s) where appropriate). *Bookings for MRI will not be accepted until this information has been received.*

The safety of most medical devices within an MRI scanner can be verified on www.mrisafety.com or via the device manufacturer websites. Currently, the following general principles apply:

For a device to be considered MRI conditional, all product labelling must be adhered to:

- Device and all leads to be labelled as MRI conditional and from the same manufacturer, to form an 'MRI conditional system'. Check on manufacturers' webites, or with the Devices Clinic.
- Pacing / ICD system implanted in either the right or left pectoral region
- Implanted device in place for more than 6 weeks (there are some exclusions to this).
- No other implantable devices (including old pacemakers or abandoned leads). If there is doubt then a CXR needs to be performed prior to MRI.
- Absence of broken leads, lead extenders or adaptors
- Patient should **not** be required to be positioned on their side within the scanner.

For non-MRI conditional devices (i.e. that do not fulfil the above criteria) additional information is required in writing from the referring consultant. Referrals all need to be discussed with the Lead Physician for Device MRI, Dr. Charlotte Manisty (charlotte.manisty@bartshealth.nhs.uk), and we reserve the right to refuse scans if indications or risk are deemed unacceptable. Referrals will not be accepted until this has step has been followed with the correct information provided.

- Confirmation that the clinical information cannot be obtained any other way (eg by another imaging modality)
- Confirmation that the clinical information is likely to influence clinical management

- Confirmation that the patient is aware that this is an 'off-label' indication, and that they will be asked to sign a consent form making them aware that there is a potential theoretical risk of device malfunction.

5.2 Equipment Requirements

MRI scanner

Scans currently should only be performed on hydrogen proton magnetic resonance imaging equipment and according to the CIED device conditions for scanning.

This is generally

- static magnetic field of no greater than **1.5T (Tesla)** with RF excitation frequency of 64 MHz.
- horizontal **closed-bore** scanner
- maximum gradient slew rate of **200 T/m/s per axis**
- Whole body SAR **≤ 2.0 W/kg** and **head SAR ≤ 3.2 W/kg**
- Scans should be acquired with **Normal operating mode** (only some devices allow first level controlled operating mode).

There are however some newer CIEDs that are conditional at 3T, and therefore device manufacturer guidance should be followed.

Monitoring

All patients should be monitored throughout the duration of the MRI scan with pulse oximetry waveform and ECG monitoring.

Safety equipment

The Resuscitation Trolley must be available in the department and must have an external defibrillator with the potential for transcutaneous pacing (non AECD). Resuscitation drugs must be available. These should be checked regularly and recorded. All resuscitation attempts should be performed only after moving the patient outside of Zone 4 in the MRI department.

For the duration of a patient's scan with a non-MRI conditional device, the device manufacturer's programmer must be present in the department.

Equipment	Quantity
Cardiac enabled MRI scanner with ECG and pulse oximetry sensors	1
Device Programmer – different manufacturers	3
Emergency Resuscitation Trolley (standard) including a manual defibrillator with the capability to deliver external transcutaneous pacing	1
MRI Compatible Evacuation Trolley	1
MRI compatible Cardiac Monitor	1

Image archive and Reporting System • CVI42 • Report42 • Sectra RIS/PACS	1
Trust PC • Datix • Imaging Database • Intranet (Trust Policies)	1

5.3 Personnel Requirements for Scanning

For patients with an **MRI conditional system**, there should be

- A member of staff present nominated the responsible physician
- Personnel available with the patient for the duration of the scan with the skill to perform advanced cardiac life support, including expertise in the performance of CPR, arrhythmia recognition, defibrillation and transcutaneous pacing.
- A cardiac device physiologist or cardiologist training in cardiac devices should be present to re-program the device pre and post scan. They need not be in attendance for the duration of the scan but must remain on site.

For patients with a **non-MRI conditional system**

- The cardiac device physiologist should remain in attendance in the MRI department for the duration of the scan (with the appropriate programmer).

5.4 Written Consent for Scanning patients with Non-MRI conditional CIEDs

All patients with Non-MRI conditional CIEDs should sign a written consent form on the day of scanning, following a detailed discussion with a cardiology doctor regarding the potential theoretical risks and benefits of scanning.

Patients unable to given informed written consent should have a Form 4 signed as per Trust protocol by two doctors.

5.5 Pacemaker re-programming for MRI

This should be performed by appropriately trained personnel (cardiac device physiologist, cardiologist or electrophysiology fellow, or specialist device technician.

Patients with MRI-conditional CIEDs

- All patients should have their devices interrogated immediately prior to scanning, and a record of the battery life (voltage), pacing thresholds, P and R wave amplitudes and lead impedances noted.
- CIEDs should be re-programmed into 'MRI-Safe' mode as per manufacturer guidance.
- Post scan, a repeat device interrogation should be performed, and lead and generator parameters recorded as per above.
- Any significant changes should be noted (lead threshold change >1.0V, P/R wave amplitude reduction of >50%, impedance change of >50ohms) and the patient offered a follow up appointment in the Device Clinic within two weeks.

Patients with Non MRI-conditional CIEDs

- All patients should have their devices interrogated immediately prior to scanning as above.
- If pacing dependent or high rate of ventricular pacing, program to asynchronous pacing (VOO/ DOO) at a rate higher than their intrinsic rate to avoid competitive pacing
- If little requirement for pacing, program pacing off (OVO/ ODO) or VVI/ DDI.
- Deactivate all tachycardia detection and therapies, and switch off advanced magnet mode and noise/ rate response features.
- Post scan, a repeat device interrogation should be performed, and lead and generator parameters recorded as per above.
- Any significant changes should be noted (lead threshold change >1.0V, P/R wave amplitude reduction of >50%, impedance change of >50ohms) and the patient offered a follow up appointment in the Device Clinic within two weeks.

Section 6 – Personnel involved with SOP

6.1 Staff groups SOP applies to

This SOP applies to all staff working in the Barts Heart Centre Cardiac Imaging Department, including:

- Imaging Clinical Director and Consultants (within Radiology and Cardiology)
- Imaging Fellows and Trainees
- Cardiac Physiologists

- Cardiac MRI Radiographers
- MRI Physicists

6.2- Key operational relationships

Inter-department relationships

- Radiologists
- Cardiac Physiologists
- MRI Physicists

Other departments

- Cardiology
- Safeguarding Team
- Resus Team
- Barts Site DoN/ Deputy DoN

External stakeholders

- Clinicians caring for these patients

6.3 Responsible personnel

- Clinical Director (Cardiac Imaging)
- Cardiac Physiologists
- Operational Lead Radiographer, Cross Sectional
- General Manager (Specialised, Imaging, Pharmacy, OPD & Network)
- Cardiac Imaging MDT (all)

Section 7: SOP review and monitoring compliance/audit requirements

7.1 SOP Review

This policy will be reviewed in 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents, unless changing circumstances necessitate an earlier review.

7.2 Audit requirements

Annual compliance audit (Cardiac Imaging Governance Lead)

- Monitor compliance in protocolling criteria and documentation
- Non-compliance to be reported and investigated via DATIX

Section 8: SOP dissemination and training

8.1 Dissemination

- New Staff – At local induction and competency assessment
- Existing Staff - New versions to be disseminated via email for existing staff

8.2 Training

There is no mandatory training associated with this policy. Ad hoc training based on an individual's training needs will be defined within their annual appraisal or job plan

Read and confirm (Appendix I)

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APPENDIX I – Individual Statement of Compliance

This statement is to be scanned and returned to the stored electronically in your individual HR folder. The original need not be retained. The departmental competency dashboard must be updated.

SOP Title ……..

Version Number ……..

"I have read and understand my duties described in this standard operating procedure"

Signed …… **Date** ……

Name ……..