MR safety risk assessment template to support a risk-benefit decision on an individual MRI request for a patient with an implanted/attached device/foreign body

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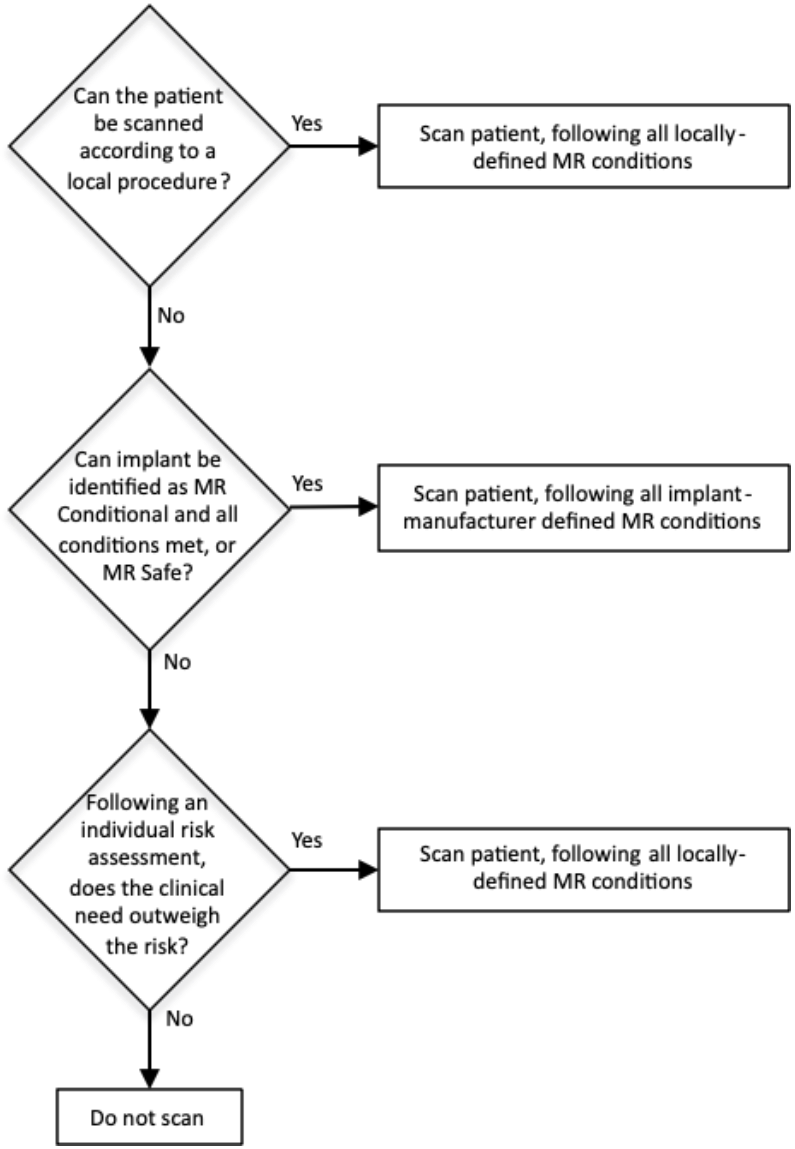
Introduction

The are multiple MR safety-related hazards associated with the MR scanning of a patient with an implanted/attached medical device/foreign body. Ideally, assurance of acceptable risk for a specific MR scan is provided by the manufacturer of the implanted/attached item via MR Safe or MR Conditional labelling. In the case of MR Conditional labelling, this assurance is only valid when all of the stated MR conditions are met. However, there are many scenarios where assurance of acceptable risk from the manufacturer of the implanted/attached item is not available. These include the following.

- The implanted/attached item cannot be identified
- The implanted/attached item is not labelled by the manufacturer as MR Safe or MR Conditional.
- The item is labelled as MR Conditional, but one or more conditions cannot be met.

In these cases, both the MHRA safety guidelines for MRI (2026) and the ACR manual on MR safety (2026) highlight that it is appropriate to consider a clinical need versus risk decision is required on how to proceed with an individual MR exam request. This is the third step in the example general workflow diagram (adapted from Ashmore *et al* (2025)) for managing MR requests of patients who have an implanted/attached device/foreign body.

This example MR risk assessment template aims to support sites looking to introduce/refine this workflow step. Additionally, this template aims to support evidencing that all MR safety related risks have been considered, as well as other appropriate considerations and recommendations from the MHRA guidelines for this workflow step.



Following completion of the risk assessment, if a decision is made that the clinical need outweighs the risk and the scan should proceed then it is expected that organisations will follow local procedures regarding patient consent. The intention for this risk assessment is that it is only valid for the specific MRI request. It may be updated if further information becomes available prior to the requested MRI scan, e.g. if additional information is provided by the implanted/attached device manufacturer. However, for any subsequent MRI request(s) it is expected that a fresh risk assessment will be performed since one or more aspects impacting the risk assessment may have changed. Information from previous risk assessments is recognised as being potentially relevant supporting material when utilised appropriately.

This template aims to utilise and cite appropriate reference material, as well as highlighting options for consideration into a local risk assessment template. Furthermore, two examples of completed risk assessments using this template are included in the appendix to demonstrate the use of this template for a basic case and a more complex example.

This template has been confirmed by the MHRA to be consistent with their safety guidelines for MRI.

Comments on this template are welcome and should be addressed to sigs@bir.org.uk.

Definitions

Term	Definition	Reference/comment
Harm	Injury or damage to the health of people, or damage to property or the environment	ISO 14971
Hazard	Potential source of harm	ISO 14971
MR safety	Aspects of safety that are directly associated with an MR examination	Associated specifically with exposure to the MR scanner output fields (static magnetic field, RF and gradient fields). The hazards associated with these output fields are identified in ISO/TS 10974.
MR Safe	Posing no known hazards resulting from exposure to any MR Environment.	ASTM F2503-26
MR Conditional	Having demonstrated safety in the MR Environment within defined conditions.	ASTM F2503-26
MR Unsafe	Posing unacceptable risk within the MR Environment.	ASTM F2503-26
MR Environment	The three-dimensional volume surrounding the MR magnet that contains both the Special Environment (Faraday shielded volume) and the B0 Hazard Area	IEC 60601-2-33 (2022)
B0 Hazard area	The space around the MR equipment where the static magnetic field can cause harm.	IEC 60601-2-33 (2022)
Residual risk	Risk remaining after risk control measures have been implemented.	ISO 14971
Risk	Combination of the probability of occurrence of harm and the severity of that harm.	ISO 14971

Responsibilities

Individuals and their responsibilities as defined in the MHRA guidelines.

Individual	Responsibilities
Referrer	Clarifying the clinical need for the MRI scan Flagging potential MRI contraindications as part of the MRI request
MR Safety Expert	Provision of scientific advice on aspects of MR safety. Contributing to risk assessment
MR Responsible Person	Ensuring procedure for risk assessment in place.
MR Clinician, e.g. consultant radiologist	Making a risk-benefit decision on the MRI request based upon the local risk assessment
MR radiographer	May contribute to risk assessment as well as being responsible for the health and safety of the patient throughout the MRI scan.[1]
Relevant specialist clinician	It may be appropriate to also include a relevant specialist clinician (e.g. a cardiologist for advice regarding a CIED, neurosurgeon for advice regarding a neurostimulator)

Vetting

Since the amount of work involved in performing a risk assessment can be significant, sites may wish to precede this with a vetting step to confirm that the risk assessment is justified. Examples of specific questions to consider as part of such a vetting step include the following.

- Is the MR request appropriate for the clinical question?
- Are there any other available diagnostic tests that would be appropriate to address the clinical question?
- Is the MR scan expected to impact patient management?

[1] More general guidance on the responsibilities of the scanning radiographer in the UK are provided by the Society of Radiographers, https://www.sor.org/learning-advice/professional-body-guidance-and-publications/documents-and-publications/policy-guidance-document-library/safety-in-magnetic-resonance-imaging

Risk assessment

Examples are included as greyed out text. It is expected that these will be updated/removed as required.
Mitigation selection should also consider the risks associated with the mitigation, e.g. the benefits of a more localised RF transmission with a transmit-receive head RF coil may be outweighed by the negative impact on image quality from a lack of parallel imaging functionality.

Patient name	
Date of birth	
Hospital number	
Known details about the implanted/attached device/foreign body	e.g. type of device, manufacturer, model, date of implantation, implant location, institution where device was implanted
Details of MRI request & clinical question	
Urgency for the risk assessment	e.g. Routine, patient has attended, patient is on a 2 week wait pathway, Emergency (Scan required within 4 hours of request)[2]

[2] Sites are encouraged to consider how to manage cases where there may be an urgent need for a risk-benefit decision on how to manage the MRI request.

Reason for lack of assurance of acceptable risk from manufacturer of implanted/attached device/foreign body	e.g. unknown device manufacturer/model MR Unlabelled MR Conditional, but unmet MR condition(s)
Other information	e.g. risks associated with the patient not having the MRI scan (including availability and appropriateness of other diagnostic or treatment options) comment on any options to remove implanted/attached device/foreign body previous imaging (e.g. MRI, CT)

Risk assessment author(s)	
Date	
Summary of risks	
Highest risk score[3]	
Expectations regarding image artefact arising from the device/foreign body impacting on the ability to answer the clinical question.	

[3] The intention here is to highlight the highest risk score for the individual making the clinical need versus risk decision.

Risk scores are based the residual risk, where all mitigations are in place. See appendix for guidance on likelihood and severity scores. The risk scores are labelled with the associated hazard to allow them to be used in a risk matrix.

General hazard[4]	Description[5]	Mitigations[6]	Likelihood score	Severity score	Risk score[7]
Heat May arise from • RF field-induced heating of the device • Gradient field-induced device heating	Considerations include: • Where is the device/foreign body in relation to the transmit RF field? • Is the size of the device/foreign body less than 2 cm? • What is the size of the device/foreign body in relation to the RF wavelength? • Is the surface area of the device/foreign body particularly large?	Potential options include: • Reduced B1+rms or SAR • Static magnetic field strength that avoids RF half wavelength in tissue matching dimensions of object • use of transmit-receive coil to reduce exposure of device/foreign body to RF [incorporating a consideration of potential impact of a lack of parallel imaging techniques on diagnostic quality] • Gaps between sequences to allow cooling			R_{heat}
Vibration	Considerations include:	Potential options include:			$R_{vibration}$

[4] General hazards listed here are taken from table 1 in ISO/TS 10974 to ensure a comprehensive initial list. It is recognised in many cases some of these hazards may not be applicable, e.g. if the item is a passive device.
[5] Some questions for consideration are included for each hazard to support drafting a general text description for the likelihood and consequence of each hazard in the context of the specific MRI request.
[6] Potential mitigation options are included for consideration. It is expected that these will be selected/edited as required.
[7] Risk score = [likelihood score] x [severity score].

May arise from gradient field-induced vibration while in a strong static magnetic field	• What will be the position of the device/foreign body during the MRI scan in relation to the maximum dB/dt?	• lower static magnetic field strength • lower gradient output			
Force May arise from B0-induced force	Considerations include: • What spatial field gradient will the device/foreign body be exposed to as the patient is moved in/out of the bore?	Potential options include: • lower static magnetic field strength • lower spatial field gradients • Immobilisation, e.g. pressure bandage			R_{force}
Torque May arise from B0-induced torque	Considerations include: • How symmetrical is the shape of the device/foreign body? • What static magnet fields will the device/foreign body be exposed to, including when the patient is moved in/out of the bore?	Potential options include: • lower static magnetic field strength • Immobilisation, e.g. pressure bandage			R_{torque}
Unintended stimulation May arise from • gradient field-induced lead voltage • RF field-induced rectified lead voltage	Considerations include: • Potential result of unintended cardiac stimulation is tachyarrythmia/ asystole	Potential options include: • Patient monitoring during the MRI scan • Reduced gradient slew rate • Plan for what to do in the event of induced arrhythmia • Appropriate device programming			$R_{stimulation}$

Malfunction May arise from exposure of implanted/attached device to • B0 field • RF field • Gradient field • Combination of fields	Considerations include: • What is are the potential results of device malfunction? • Is the function of the device intended to be programmed by an external magnet? • Where is the device/foreign body in relation to the transmit RF field?	Potential options include: • Appropriate device programming • Patient positioning • Reduced limit for B1+rms/SAR • Reduced gradient slew rate • Use of transmit-receive coil to reduce the RF exposure of the device • Appropriate patient monitoring • Post MRI scan device check • Availability of personnel to support emergency access.			$R_{malfunction}$

Have the following items listed in the MHRA guidelines been considered as part of risk assessment?	Tick to confirm
MRI scanner with a lower static and/or gradient fields	
Advice from implant manufacturer	
Professional body recommendations	
Published evidence of scanning the device	
Available data about the device	
MRI device parameters	
Appropriate programming of the device	
Suitable monitoring (e.g., SAR level, physiological signals) during the scan	
SAR exposure including consideration of methods to reduce, e.g., reduced flip angles, longer TRs, use of localised transmit-receive coils.	
Provision of procedures to ensure that a suitable clinician is available and in the dept at the time of the scan, e.g., for cardiac devices, a cardiologist or cardiac physiologist	
Procedures for post-scan evaluation of the patient	

Summary of mitigations, i.e. locally defined MR conditions[8]

[8] A list of all locally defined conditions for the scanning radiographer to utilise.

References

ACR manual on MR safety (2026), https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/radiology-safety/mr-safety

Ashmore et al. A framework for developing generic implant safety procedures for scanning patients with medical implants and devices in MRI. Br J Radiol 2025 Mar 1;98(1167):336-344. doi:10.1093/bjr/tqae232.

MHRA safety guidelines for MRI (2026), https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use

ASTM F2503-26 (2026) Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

IEC 60601-2-33 (2022). Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

ISO/TS 10974 (2018). Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

ISO 14971 (2019), Medical devices – Application of risk management to medical devices

Appendix

Copy of relevant section from MHRA guidelines

5.5.3 Managing Patients with Devices of Unknown MR Safety Status and Off-Label Scenarios

There may be a need to perform an MRI examination in the following scenarios:

- the patient has an MR CONDITIONAL device, but one or more MR Conditions cannot be met
- the patient is implanted with a device labelled as MR UNSAFE
- the patient has a device whose MR safety status is unknown, e.g., because the make and model of the device is unknown.
- the patient has an MR UNLABELLED implanted device.

If the benefit to the patient of this off-label procedure outweighs the potential risk, then scanning can be undertaken. Sites should develop local processes for scanning in these situations [192]. The following should be documented and available before the scan:

A multidisciplinary team (MDT) should undertake a risk assessment. As a minimum this should involve an MR RADIOGRAPHER, an MR SAFETY EXPERT and the MR CLINICIAN. It may be appropriate to also include a relevant specialist clinician (e.g. a cardiologist for advice regarding a CIED). The referring clinician is required to provide sufficient information to allow the MDT to perform the risk assessment. The following should be considered:

- Whether the scan has the potential to change patient management.
- Alternative imaging modalities/other diagnostic tests.
- The risks regarding onwards clinical management if a decision is made not to perform the MRI.
- Scanning on an MR system with lower static and/or gradient fields, which may require referral to other centres if not available locally.
- Advice from the implant manufacturer.
- Available Professional Body recommendations.
- Published evidence of scanning the device.
- Assessment of possible artefacts, and the impact they will have on diagnostic performance.

- Identification and implementation of precautions to minimise the risk. The following should be considered:
  - Appropriate programming of the device.
  - Suitable monitoring (e.g. SAR/$B_1{}^+{}_{RMS}$ levels, physiological signals) during the scan. Physiological monitoring may require additional suitably trained personnel to operate and/or interpret the results.
  - SAR/$B_1{}^+{}_{RMS}$ exposure including consideration of methods to reduce it, e.g. reduced flip angles, longer TRs, use of transmit/receive coils.
  - Patient positioning in the system.
  - The need to move the patient slowly into the bore of the magnet. This allows the patient to communicate whether they can feel any pain or discomfort.
- Provision of procedures to ensure that a suitable clinician is available and in the department at the time of the scan, e.g. for CIEDs, a cardiologist or cardiac physiologist.
- Post scan evaluation of the patient and where relevant, evaluation of the implanted device.

The MR CLINICIAN ultimately takes responsibility for the decision of whether to proceed with the scan. Consideration should be given to what level of patient consent should be obtained for the procedure, and who is the most suitable person to consent the patient.

MRI unit staff should not feel pressured into adopting the above procedure if they do not have the skills, experience, staff and support available to them, e.g. mobile units. It may be appropriate for such units to refer a particular patient to another MRI unit with experience in either scanning the device/implant or in the general application of the above procedure. Sites that do not currently have expertise in scanning patients with complex implants are encouraged to work with an MR SAFETY EXPERT to develop local procedures to allow patients to access MRI.

Sites should develop local processes for scanning off-label and where the MR safety status of an implant is unknown. This should include a multidisciplinary team (MR RADIOGRAPHER, MR SAFETY EXPERT and MR CLINICIAN) risk assessment, risk minimisation strategies, support from relevant clinicians and post scan evaluation of the patient.

Copy of relevant section from ACR guidelines

APPENDIX 4:
Implanted Device MR Risk/Safety Assessment

In clinical practice, medically necessary MR examinations in the presence of implanted devices with potential safety concerns have become increasingly common [1]. MR Conditional implanted devices may require specific conditions for safe scanning that may be difficult to meet or limit the ability to acquire MR images of sufficient quality to address the specific clinical question. Similarly, implanted devices may lack documentation in the medical record (e.g., implanted at a different medical center or several years prior) and thus challenge the ability to determine the risk level. Moreover, a patient with the need for MR imaging may have an implanted device labeled as MR Unsafe, potentially precluding MR imaging.

Here, we provide a general approach to evaluating the potential risks of performing an MR examination when patients have implanted devices that, for example, may not meet all MR conditions for safe scanning. A similar discussion is included in the Medicines and Healthcare products Regulatory Agency document for reference [2]. It should be noted that itemizing the complex, multifactorial decision tree in all clinical scenarios is not only beyond the scope of this manual but also virtually impossible. Nevertheless, the guiding principle in this decision process should be to adequately address the risk versus benefit ratio of undergoing an MR examination for the patient. This often requires a discussion between the treating physician(s) and MR Personnel with expertise in MR safety (i.e., Level 2 MR Physician, MR Medical Director (MRMD), MR Safety Officer (MRSO), and/or MR Safety Expert (MRSE)). Alternative imaging modalities (e.g., computed tomography, ultrasound) and the medical risk of not receiving an MR examination should be considered. Lastly, research participants generally do not benefit from a research MR examination, and therefore, the threshold for accepting an unknown or higher-risk scenario should be much higher than that of a clinically indicated MR examination.

The following considerations, among potential others, should be addressed during the initial assessment, preparation, scanning, and post-examination follow-up phases of the MRI exam.

Initial assessment

1. Implanted device(s)
    a. Type of device(s).
    b. Manufacturer(s) and model(s).
    c. Anatomic location(s).
    d. Available information on MR conditions.
        i. Device eligibility for MR.
        ii. Vendor MR Conditional instructions for use (IFU).
            1. Exposure of object/device to
                a. static magnetic field
                b. time-varying gradient magnetic field
                c. radiofrequency (RF) magnetic field
        iii. Published recommendations from appropriate professional bodies.
        iv. Published evidence of scanning device under similar conditions.
    e. Current device status (operational, abandoned, damaged, implanted outside of vendor MR conditions, etc.).

    Note: addressing the above may require consulting the device manufacturer or local representative, a device specialist, relevant documentation, prior imaging, and/or operative reports and could lead to the need to acquire x-rays or CT prior to making a decision.

2. MR scanner
    a. Availability of a scanner to meet MR conditions.
        i. Field strength and orientation, spatial field gradient, gradient performance, RF coil (e.g., detachable transmit-receive coils).
        ii. Sequences and options for obtaining needed information within specific absorption rate (SAR)/B_{1^+rms} and/or dB/dt exposure limits with appropriate image quality.
        iii. MR Equipment Output Conditioning (MROC) options to manage RF and gradient outputs [3].
        iv. Availability of appropriate ancillary equipment, expert personnel, and emergent response team for monitoring and managing patient and device in the MR environment.
3. Patient
    a. Clinical question and/or requested examination.
        i. Patient positioning permitting compliance with MR conditions as well as consideration of location of implant(s) within the scanner to assess impact of static, RF, and gradient field conditions.
    b. Patient eligibility for MRI with device(s) via vendor IFU.
    c. Patient status (routine, emergency, under anesthesia, compromised thermoregulatory system, etc.).
    d. Potential impact of device artifacts and/or MR protocol and parameter limitations on examination image quality/diagnostic capacity.
    e. Further risk/benefit considerations.
        i. Potential injury to the patient.
        ii. Potential damage to the device and associated impact on the patient.
        iii. Clinical impact of performing a procedure to remove a device prior to examination.
        iv. Clinical impact of not performing or delaying the MR examination.
        v. Identification of alternative imaging approaches.
    f. Document risk versus benefit decision, and plan for managing risk during MR examination.

Preparation and scanning

1. Implanted device(s) (as appropriate).
    a. Appropriate device expert, including MRSE and/or clinician present if needed.
    b. Device battery level.
    c. Patient/clinician implanted device programmer electrically charged and available

        i. Interrogate device to establish/verify eligibility (i.e., impedance check/lead damage).
        ii. Record/save settings (i.e., cardiac implantable devices, deep brain stimulator, vagal nerve stimulator, programmable shunt).
        iii. Program device for MR environment (e.g., MR Conditional mode).
    d. Secure and immobilize on patient (i.e., cochlear magnet, tissue expander with magnetic port).
    e. Plan for device damage or inability to recover normal function.
2. MR scanner and environment.
    a. Patient scheduled to appropriate MR resource at an appropriate time.
    b. MR safety screening and training of team members possibly to include non-MR Personnel that may need to be present during examination.
    c. Consultation or direct supervision (MRMD, MRSO, or MRSE) as needed/required
    d. Modified MR protocol available to meet planned conditions.
    e. Scanner in appropriate operating mode or MROC setting for SAR/$B_1^+{}_{rms}$ and dB/dt.
        i. Active monitoring of scanner output and timing during examination by appropriately trained personnel to meet MR conditions.
3. Patient
    a. Verification of patient eligibility for MR.
    b. Informed consent when appropriate.
    c. Educated on device preparation for examination.
    d. Proper positioning of patient and device within bore and RF coil.
        i. Management of external leads or cables.
        ii. Distancing device from bore wall.
        iii. Placement of sealed ice packs for external object cooling.
    e. Communication plan (with the team and with the patient).
        i. Audible, visual, and squeeze ball.
        ii. Clear instructions to patient (and team) on what sensations to expect and when/how to stop examination or communicate with the team.
    f. Patient monitoring and management plan.
        i. Appropriate physiological monitoring.
        ii. Sedation or anesthesia.
        iii. Planned periods of nonscanning for cooling off if necessary.

Post-examination follow-up

1. Patient: assess for pain or injury.
2. Device: assess and/or reprogram device to normal function.

Sites are encouraged to objectively assess their capability of safely performing an MR examination under challenging/unusual conditions. Thoughtful consideration of referring the patient to an alternate imaging facility with the necessary expertise is encouraged when appropriate.

References

1. Shellock FG. Chapter 18: MRI issues for implants and devices. In: Shellock FG, Crues JV III, eds. *MRI Biological Effects, Safety, and Patient Management*. Biomedical Research Publishing Group; 2022:462-497.
2. Medicines and Healthcare products Regulatory Agency. Safety guidelines for magnetic resonance imaging equipment in clinical use. Published November 7, 2014. Accessed April 22, 2024. https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use#full-publication-update-history
3. International Electrotechnical Commission. Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. 4th ed. Published August 4, 2022. Accessed April 22, 2024. https://webstore.iec.ch/publication/67211

Risk scoring matrix

The following risk scoring and risk matrix and are examples only. It is recommended to substitute these with local templates.

Likelihood scores. These are based on estimated probability of occurrence of harm.

Likelihood score	Description	Approximate estimated probability
1	Very unlikely	1 in 100,000
2	Unlikely	1 in 10,000
3	Possible	1 in 1,000
4	Likely	1 in 100
5	Very likely	1 in 10

Severity scores. These are based on the severity of the potential harm.

Severity score	Description
1	**Negligible**. No obvious harm or minimal patient harm requiring no / minimal intervention or treatment.
2	**Minor**. Minor harm or illness, requiring minor intervention. Increase in length of stay by 1-3 days
3	**Moderate**. Moderate harm requiring professional intervention or impacts on a small number of persons. Increase in length of hospital stay by 4 - 14 days.
4	**Major**. Major harm leading to long term incapacity / disability which is directly linked to mismanagement of patient care or other organisational failures. Increase in length of hospital stay >14 days
5	**Extreme**. Considerable harm or death / multiple injuries or irreversible health effects

It may be helpful to populate a risk matrix with the various risk scores. Further classification of different areas within the risk matrix (e.g. via colour coding) may be beneficial, e.g. to identify additional local requirements.

Risk Rating = Likelihood x Severity		Severity (S)				
		Negligible 1	Minor 2	Moderate 3	Major 4	Extreme 5
Likelihood (L)	Almost Certain 5					
	Likely 4					
	Possible 3					
	Unlikely 2					
	Rare 1					

Examples of reported adverse incidents arising from hazards

The aim here is to highlight examples of the potential severity of individual hazards to support severity scoring.

Hazard	Examples of severity associated with hazard for particular implanted/attached devices
Heat May arise from • RF field-induced heating of the device • Gradient field-induced device heating	**Permanent neurological deficit**. Henderson et al. Permanent neurological deficit related to magnetic resonance imaging in a patient with implanted deep brain stimulation electrodes for Parkinson's disease: case report. Neurosurgery. 2005 Nov;57(5):E1063. doi: 10.1227/01.neu.0000180810.16964.3e.
Vibration May arise from gradient field-induced vibration while in a strong static magnetic field	
Force May arise from B0-induced force	It is difficult to determine in these cases whether the main contribution arose from force or torque, so examples here are assigned to both hazards together. **Death**. Klucznik et al. Placement of a ferromagnetic intracerebral aneurysm clip in a magnetic field with a fatal outcome. Radiology. 1993 Jun;187(3):855-6. doi: 10.1148/radiology.187.3.8497645. **Blindness**. Kelly et al. Ferromagnetism of intraocular foreign body causes unilateral blindness after magnetic resonance study. Am. J. Neuroradiol.1986; 7: 243–5.
Torque May arise from B0-induced torque	
Unintended stimulation May arise from • gradient field-induced lead voltage	**Pain or discomfort.** Ragukonis T. Off-Label Magnetic Resonance Imaging (MRI) in Patients with Persistent Pain with Spinal Cord Stimulators: A Case Series. J Pain Res. 2022 Nov 22;15:3625-3638. doi: 10.2147/JPR.S357416

• RF field-induced rectified lead voltage	
Malfunction May arise from • B0 field • RF field • Gradient field • Combination of fields	**Cardiac asystole**. Gimbel RJ. Unexpected asystole during 3T magnetic resonance imaging of a pacemaker-dependent patient with a 'modern' pacemaker. Europace, 2009, Vol.11(9), p.1241-1242. doi:10.1093/europace/eup162 **Death**. Safety Concerns with Implantable Infusion Pumps in the Magnetic Resonance (MR) Environment: FDA Safety Communication, https://wayback.archive-it.org/7993/20201224130324/https://www.fda.gov/medical-devices/safety-communications/safety-concerns-implantable-infusion-pumps-magnetic-resonance-mr-environment-fda-safety

Example risk assessments

The aim here is to present examples of a risk assessment using this template. Two examples are provided with the aim of demonstrating utility of this template for both a relatively basic scenario and a much more complex case. In both examples, the proposed mitigation options are given as examples of what might be appropriate for the MRI request at a particular institution. They may not be appropriate for similar MRI requests at other institutions.

Example 1: Small metal fragment

Patient name	xxxx
Date of birth	xxxx
Hospital number	xxxx
Known details about the implanted/attached device/foreign body	Small metal fragment of unknown origin visible near kidneys on CT image Superficial location. Patient unaware of its existence.
Details of MRI request & clinical question	Prostate MRI
Urgency for the risk assessment	Patient is on a 2 week wait pathway
Reason for lack of assurance of acceptable risk from manufacturer of implanted/attached device/foreign body	Unknown device manufacturer/model

Other information	Metal object viewable on previous CT (date = xxxx)

Risk assessment author(s)	xxxx
Date	xxxx
Summary of risks	Assuming object is ferromagnetic, it will experience ferromagnetic attraction and torque, potentially leading to tissue damage. The small size means it is not expected to present a risk of significant localised heating.
Highest risk score[9]	10
Expectations regarding image artefact arising from the device/foreign body impacting on the ability to answer the clinical question.	Image artefact expected in the region of the object, but this is expected to be outside the imaging FoV.

[9] The intention here is to highlight the highest risk score for the individual making the clinical need versus risk decision.

General hazard[10]	Description[11]	Mitigations[12]	Likelihood score	Severity score	Risk score[13]
Heat May arise from • RF field-induced heating of the device • Gradient field-induced device heating	The size of the fragment is smaller than the 2 cm threshold that is quoted in ASTM F2182 standard for assessing the RF heating on a passive device. Gradient field-induced heating will be negligible for item of this size	Not applicable	1	3	3
Vibration May arise from gradient field-induced vibration while in a strong static magnetic field	Location of object during MRI scan will be close to maximum dB/dt along the z-direction. No known incidents where vibration identified as the specific source of harm.	Make the patient aware they may sense vibration at the location of the object when they can hear the MRI machine scanning. Check with patient after localiser.	3	1	3

[10] General hazards listed here are taken from table 1 in ISO/TS 10974 to ensure a comprehensive initial list. It is recognised in some cases some of these hazards may not be applicable, e.g. if the item is a passive device.
[11] Some questions for consideration are included for each hazard to support drafting a general text description for the likelihood and consequence of each hazard in the context of the specific MRI request.
[12] Potential mitigation options are included for consideration. It is expected that these will be selected/edited as required.
[13] Risk score = [likelihood score] x [severity score].

Force May arise from B0-induced force	Assuming object is ferromagnetic it will experience an attractive force. Location of object is not expected to approach the position of maximum spatial field gradient at the edges of the bore entrance. The object is not embedded within bone, but surrounding tissue is expected to provide some anchoring. Radiologist has confirmed the object is not immediately adjacent to critical structures.	Utilise MRI scanner 1 which will result in object being exposed to lower spatial field gradients in comparison to MRI scanner 2. Prior to the scan, use a strong handheld magnet to provide an indication to the patient of attractive force/torque they may experience. Make patient aware they may sense a small pull as they approach the MRI scanner and as they move into the bore. Approach the MRI scanner slowly. Move patient into the MRI scanner bore slowly.	5	2	10
Torque May arise from B0-induced torque	Shape of object is relatively symmetrical, so torque experienced is expected to be very small and significantly less force than the attractive force.	Utilise MRI system with lowest static magnetic field. Prior to the scan, use a strong handheld magnet to provide an indication to the patient of attractive force/torque they may experience.	3	2	6
Unintended stimulation May arise from	Not applicable	Not applicable	NA	NA	NA

• gradient field-induced lead voltage • RF field-induced rectified lead voltage					
Malfunction May arise from • B0 field • RF field • Gradient field • Combination of fields	Not applicable as not an active device	Not applicable	NA	NA	NA

Risk Rating = Likelihood x Severity		Severity (S)				
		Negligible 1	Minor 2	Moderate 3	Major 4	Extreme 5
Likelihood (L)	Almost Certain 5		R_{force}			
	Likely 4					
	Possible 3	$R_{vibration}$	R_{torque}			
	Unlikely 2					
	Rare 1			R_{heat}		

Have the following items listed in the MHRA guidelines been considered as part of risk assessment?	Tick to confirm
MRI scanner with a lower static and/or gradient fields	✓
Advice from implant manufacturer	NA
Professional body recommendations	✓
Published evidence of scanning the device	NA
Available data about the device	NA
MRI device parameters	NA
Appropriate programming of the device	NA
Suitable monitoring (e.g., SAR level, physiological signals) during the scan	✓
SAR exposure including consideration of methods to reduce, e.g., reduced flip angles, longer TRs, use of localised transmit-receive coils.	✓
Provision of procedures to ensure that a suitable clinician is available and in the dept at the time of the scan, e.g., for cardiac devices, a cardiologist or cardiac physiologist	✓
Procedures for post-scan evaluation of the patient	✓

Summary of mitigations, i.e. locally defined MR conditions[14]

Utilise MRI system with lowest static magnetic field and lowest spatial field gradients along the z-axis.

Prior to the scan, use a strong handheld magnet to provide an indication to the patient of the attractive force/torque that they may experience.

Make the patient aware they may sense a small pull as they approach the MRI scanner and as they move into the bore. Approach the MRI scanner slowly. Move patient into the MRI scanner bore slowly.

Make the patient aware they may sense vibration at the location of the object when they can hear the MRI machine scanning. Check with patient after localiser.

[14] A list of all locally defined conditions for the scanning radiographer to utilise.

Example 2: MR Unlabelled cardiac pacemaker

Patient name	xxxx
Date of birth	xxxx
Hospital number	xxxx
Known details about the implanted/attached device/foreign body	MR Unlabelled cardiac pacemaker Device implanted 2015
Details of MRI request & clinical question	Brain MRI
Urgency for the risk assessment	MRI required for stereotactic radiotherapy planning Patient is on a 2 week wait pathway Patient has attended. Device was not mentioned on the MRI request
Reason for lack of assurance of acceptable risk from manufacturer of implanted/attached device/foreign body	MR Unlabelled
Other information	Significant risks associated with extraction of leads Patient is not pacing dependent

Risk assessment author(s)	xxxx, MRSE xxxx, consultant cardiologist
Date	xxxx
Summary of risks	Since the device is not labelled by the manufacturer as MR Conditional, the full range of MR safety related risks are relevant. Although there is growing clinical evidence from several 1000s of patients with MR Unlabelled cardiac devices undergoing MRI scanning without adverse incident, these numbers are still small compared to the numbers of scenarios tested by formal MR safety testing.
Highest risk score[15]	5
Expectations regarding image artefact arising from the device/foreign body impacting on the ability to answer the clinical question.	Image artefact expected in the region of the object, but this is expected to be outside the imaging FoV.

[15] The intention here is to highlight the highest risk score for the individual making the clinical need versus risk decision.

General hazard[16]	Description[17]	Mitigations[18]	Likelihood score	Severity score	Risk score[19]
Heat May arise from • RF field-induced heating of the device • Gradient field-induced device heating	A review (Rahsepar et al 2020) of 2028 MRI examinations performed in 1464 study participants with 2755 device leads found there was no evidence of an association between radiofrequency energy deposition, dB/dt, or scan duration and changes in device or lead parameters. Anatomical regions with the highest SAR values were cardiac, lumbar spine and thoracic spine, with mean peak whole-body SAR values of 2.2 +/- 0.9, 2.5 +/-0.7 and 3.1 +/- 0.6 W/kg. A separate review (Mollerus et al 2010) of 127 MRI examinations performed in 103	Use transmit-receive head coil to reduce exposure of device to RF [incorporating a consideration of potential impact of a lack of parallel imaging techniques on diagnostic quality].	1	3	3

[16] General hazards listed here are taken from table 1 in ISO/TS 10974 to ensure a comprehensive initial list. It is recognised in some cases some of these hazards may not be applicable, e.g. if the item is a passive device.
[17] Some questions for consideration are included for each hazard to support drafting a general text description for the likelihood and consequence of each hazard in the context of the specific MRI request.
[18] Potential mitigation options are included for consideration. It is expected that these will be selected/edited as required.
[19] Risk score = [likelihood score] x [severity score].

	patients with cardiac pacemaker of ICD undergoing MRI at 1.5T without any SAR restrictions found no differences between SAR level groups in terms of pacing, sensing, or impedance changes when the leads were analysed by lead location. When the leads were analysed as an aggregate, the changes in pacing thresholds were greater in the low-SAR group than in the high-SAR group.				
Vibration May arise from gradient field-induced vibration while in a strong static magnetic field	Not aware of any incidents that have been linked specifically to vibration.	None	1	3	3
Force May arise from B0-induced force	Joint British Society consensus guidelines (Bhuva et al (2024)) highlight even for MR Unlabelled pacemakers with market release before 2002, the attractive force and torque experienced due to the magnetic fields associated with a 1.5 T MRI scanner were shown	Book for available 1.5T scanner with the lowest spatial field gradients along the z-axis.	1	2	2

	to be lower than the confining forces of surrounding tissue and hence low enough to present no safety risk.				
Torque May arise from B0-induced torque	Joint British Society consensus guidelines (Bhuva et al (2024)) highlight even for MR Unlabelled pacemakers with market release before 2002, the torque experienced due to the magnetic fields associated with a 1.5 T MRI scanner were shown to be lower than the confining forces of surrounding tissue and hence low enough to present no safety risk.	None	1	2	2
Unintended stimulation May arise from • gradient field-induced lead voltage • RF field-induced rectified lead voltage	A systematic review (Shah et al 2018) of publications from 1990-2017 found 70 studies that performed MR scanning of patients with MR Unlabelled pacemakers and ICDs, involving 5099 patients who underwent a total of 5908 MRI examinations. These studies included 3692 patients with MR Unlabelled pacemakers.	Cardiac physiologist to monitor the patient throughout their time in the MR Environment.	1	3	3

	From all these studies, only a small number of minor adverse events were reported, all of which were described as having no clinical significance. Those relating to unintended stimulation included 0.2% cases (n=11) of unexpected pacing behaviour. There were no incidents of malfunction for devices released to market after 2005 when patients undergo MR scanning under conditions similar to those required for MR Conditional devices.				
Malfunction May arise from • B0 field • RF field • Gradient field • Combination of fields	A systematic review (Shah et al 2018) of publications from 1990-2017 found 70 studies that performed MR scanning of patients with MR Unlabelled pacemakers and ICDs, involving 5099 patients who underwent a total of 5908 MRI examinations. These studies included 3692 patients with MR Unlabelled pacemakers.	Reprogram the device into asynchronous mode prior to MRI scan and reprogramme after MRI scan. Cardiac physiologist to monitor the patient throughout their time in the MR Environment. Use transmit-receive head coil to reduce RF exposure to the device.	1	5	5

	From all these studies, only a small number of minor adverse events were reported, all of which were described as having no clinical significance. The rate of safety events reported from these group of studies (in order, with highest rate first) was 1. Power on reset: 1.6% (n=94), although no events were observed in patients with devices released to market after 2005 2. Patient symptoms: 0.3% (n=17) 3. Unexpected pacing behaviour: 0.2% (n=11) 4. Lead failure: 0.1% (n=3) 5. ICD shock/anti-tachycardia pacing: 0.02% (n=1) There were no incidents of malfunction for devices released to market after 2005 when patients undergo MR scanning under conditions	Arrange MRI scan for site with cardiology department for better support in the unlikely event of a device failure.			

	similar to those required for MR Conditional devices. A case report (Gimbel (2009)) of a patient with an MR Unlabelled pacemaker undergoing a brain MRI at 3T reported where asystole occurred when MRI scan commenced. The scan was stopped seconds later and effective pacing resumed. The pacemaker, described as manufactured after 2000, was put into an asynchronous mode prior to the MRI scan.				

References

Bhuva et al. Joint British Society consensus recommendations for magnetic resonance imaging for patients with cardiac implantable electronic devices. Heart. 110.4 (2024): e3-e3.

Gimbel RJ. Unexpected asystole during 3T magnetic resonance imaging of a pacemaker-dependent patient with a ‘modern’ pacemaker. Europace , 2009, Vol.11(9), p.1241-1242. doi:10.1093/europace/eup162

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Rahsepar et al. The relationship between MRI radiofrequency energy and function of nonconditional implanted cardiac devices: a prospective evaluation. Radiology 295.2 (2020): 307-313.

Shah et al. Magnetic resonance imaging safety in nonconditional pacemaker and defibrillator recipients: A meta-analysis and systematic review. Heart Rhythm 15.7 (2018): 1001-1008.

Risk Rating = Likelihood x Severity		Severity (S)				
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Likelihood (L)	Almost Certain 5					
	Likely 4					
	Possible 3					
	Unlikely 2					
	Rare 1		R_{force}, R_{torque}	$R_{heat}, R_{vibration}, R_{stimulation}$		$R_{malfunction}$

Have the following items listed in the MHRA guidelines been considered as part of risk assessment?	Tick to confirm
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MRI device parameters	✓
Appropriate programming of the device	✓
Suitable monitoring (e.g. SAR level, physiological signals) during the scan	✓
SAR exposure including consideration of methods to reduce, e.g., reduced flip angles, longer TRs, use of localised transmit-receive coils.	✓
Provision of procedures to ensure that a suitable clinician is available and in the dept at the time of the scan, e.g., for cardiac devices, a cardiologist or cardiac physiologist	✓
Procedures for post-scan evaluation of the patient	✓

Summary of mitigations, i.e. locally defined MR conditions[20]

- Explain to patient that the MRI scan needs to be rearranged for a different day when it will be possible to organise attendance of other clinical colleagues who are required to reprogramme the pacemaker before and after the MRI scan, and to help monitor the patient during the MRI scan.
- Rebook patient for a slot when a cardiac physiologist is able to attend for the entirety of the MRI scan.
- Rebook for site where there is on-site emergency cardiac support.
- Book for scanner with lowest static magnetic field strength that is clinically appropriate.
- Cardiac physiologist to reprogram device into an appropriate mode (e.g. asynchronous) prior to MRI scan
- Cardiac physiologist to perform cardiac monitoring during the time period that the patient is in the MR exam room.
- Cardiac physiologist to restore the original device programming after the MRI scan.

[20] A list of all locally defined conditions for the scanning radiographer to utilise.