Risk Assessment Form

Use this form for any detailed risk assessment unless a specific form is provided. Refer to your Summary of Hazards/Risks and complete forms as required, including those that are adequately controlled but could be serious in the absence of active management. The Action Plan and reply section is to help you pursue those requiring action.

Name of Initial Assessor /Reviewer:	Blair Johnston	**Post Held:**	Clinical Scientist
Department:	**Imaging**	**Date (of initial review):**	**6/6/2023**

Subject of Assessment: E.g.: hazard, task, equipment, location, people

MRI scanning of patients with MR Conditional passive implants on low and ultra-low field scanners (i.e. less than 1T)

For clarification purposes: this policy covers only passive implants i.e. the implant has no electronic, magnetic or programmable components.

Hazards (Describe the harmful agent(s) and the adverse consequences they could cause)

The static magnetic field of the MRI scanner has the potential to exert force on ferromagnetic objects. Furthermore, there is a risk of heating to all metal objects within the volume of the MRI transmission coil as a result of the RF power being transmitted. This is typically the length of the body coil, though it could be another, more focal, volume if a local transmit and receive coil is being used.

The majority of implants are tested only at 1.5T and 3T. This means that if they undergo MRI scanning on a low or ultra-low field system (i.e. less than 1T) then it would be considered an 'off-label' scan. The subject of this risk assessment is to assess the risk to patients with passive implants when exposed to the static magnetic field and the RF power of a low or ultra-low field MRI scanner compared with 1.5T scanner

Description of Risk

Describe the work that causes exposure to the hazard, and the relevant circumstances. Who is at risk? Highlight significant factors: what makes the risk more or less serious – e.g.: the time taken, how often the work is done, who does it, the work environment, anything else relevant.

Lower static magnetic fields and spatial field gradients produce less attractive forces, torque and Lenz-related forces. This suggests that the forces from the static magnetic field on implants in low field systems will be lower than those on 1.5T. Furthermore, the overwhelming majority of passive implants are non-ferrous or only mildly ferromagnetic. However, some low-field systems have a vertical field rather than horizontal field so the forces experienced may be different for ferromagnetic implants depending on their orientation.

Regarding the risks of the RF power of the MRI scanner, the resonant frequency of low-field systems is reduced meaning longer resonant wavelengths and lower energy deposition. This means that the SAR reduces with reducing field strength (SAR scales with B_0^2, Marques et al. 2019). With the increase in wavelength, the risk of resonant heating is reduced. It is considered unlikely that there is a large implant that is safe to scan at 1.5T but is unsafe at a lower field strength due to resonant heating.

One study measured RF induced heating of sixteen MR Unsafe nitinol guidewires and stainless-steel braided catheters for MRI–guided catheterisation at conditions known to generate maximal heating (Campbell-Washburn et al., 2019). The authors reported that heating was reduced at low-field, with nine devices producing a net temperature rise under 1°C in the 0.55T scanner. At 1.5T, a sequence that generated a temperature rise of 7.7°C in one guidewire was found to generate a temperature rise of 0.8°C at 0.55T (Campbell-Washburn et al., 2019). Whilst these are outside the scope of this risk assessment as they are classed as

MR Unsafe at 1.5T, they demonstrate the reduction in heating produced by lower-field MRI scanners.

If the low-field system has a change in the static field direction, then there will also be a change to the direction of the transmitted RF energy. This may present an increased risk in implants with leads (Gilk and Kanal, 2023) but it is not expected to present a significantly increased risk for passive implants.

Gilk and Kanal, 2023, report no significant safety concerns relating to the time-varying gradients of low-field MR systems.

It is worth noting that the susceptibility artefact around implants will be reduced in low-field MRI.

Prabhat and colleagues (2001) reported their methodology for their low field portable MRI (pMRI) system was to adhere to the 1.5T guidelines. Their exclusion criteria included "*the presence of an MRI contraindication such as: pacemaker, defibrillator, implanted medication pump, vagus nerve stimulator, deep-brain stimulator, or programmable shunt; MRI-incompatible surgical hardware such as metal staples, screws, clips, etc.; suspected metal in eye; presence of spinal fractures. Patients who were pregnant during the time of hospital stay or <18 years old were also excluded*." The authors go on to state that "*The pMRI device is safe for use with biomedical devices that have been cleared for magnets of field strength 1.5T and below*." Whilst the exclusion criteria didn't state this specifically, it appears that all patients with active implants and items deemed MR Unsafe were excluded from entering the scanner. The exclusion criteria also includes patients with suspected metal in their eye. Therefore, the authors effectively are stating that any MR Conditional passive implants can undergo low-field pMRI.

Frank Shellock posted a question in the UK and USA MRI Safety Groups on Facebook on 6/6/23 asking if anyone knows of "*any passive implant tested and labelled for 1.5- and/or 3-Tesla that would pose a risk to a patient undergoing an MRI exam on a scanner operating below 1.5-Tesla?*" This suggests that he is not aware of any and the responses to this post had not identified any at the time of writing. Kanal stated in response that "*Any device thermally tested at 1.5T or 3T is tested based on the assumption of resonant lengths particular to those fields as well as those RF excitation planes along the transverse human axis (i.e. axial to a human lying in the bore)*" and highlighted his paper on this topic which has been referenced in this risk assessment.

- Campbell-Washburn, Adrienne E., et al. "Opportunities in interventional and diagnostic imaging by using high-performance low-field-strength MRI." *Radiology* 293.2 (2019): 384-393.
- Gilk, Tobias, and Emanuel Kanal. "MRI safety considerations associated with low-field MRI: mostly good news." *Magnetic Resonance Materials in Physics, Biology and Medicine* (2023): 1-2.
- Marques, José P., Frank FJ Simonis, and Andrew G. Webb. "Low-field MRI: An MR physics perspective." *Journal of magnetic resonance imaging* 49.6 (2019): 1528-1542.
- Prabhat, Anjali M., et al. "Methodology for low-field, portable magnetic resonance neuroimaging at the bedside." *Frontiers in Neurology* 12 (2021): 760321.

Existing Precautions	**Describe how they might fail to prevent adverse outcomes.**
Patients are taken through an MRI safety checklist prior to entering the MR scanner to identify any implants or contraindications. If a patient is identified as having a passive implant, do not assume it is safe to undergo low or ultra-low field MRI. You must follow the safety guidance as if they were undergoing a 1.5T scan. For example, if a patient has an	There is a theoretical risk that the change in field orientation could present an increased risk to patients compared with 1.5T. The risk of this is deemed low. There is a risk that an active implant will be assumed to be passive.

aneurysm clip, documented proof of the make and model of the clip must be found, and it must be MR Conditional at 1.5T MRI for the scan to go ahead on a low or ultra-low field MRI system. If uncertain if a patient's implant is passive, do not proceed to scan, seek advice from MRI Physics. If a patient has an active implant or any other safety concern (e.g. metal in the eye or shrapnel), do not proceed to scan, seek advice from MRI Physics.	

Level of Risk - Is the control of this risk adequate?
Give more than one risk level if the assessment covers a range of circumstances. You can use the 'matrix' to show how 'likelihood' and 'consequences' combine to give a conclusion. Also, be critical of existing measures: if you can think how they might fail, or how they could be improved, these are indications of a red or orange risk.

Risk Matrix

Likelihood	**Impact/Consequences**				
	Negligible	**Minor**	**Moderate**	**Major**	**Extreme**
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	**Low**	Low	Low	Medium	Medium

Very High **High** **Medium** **Low**

Current risk level

Given the current precautions, and how effective and reliable they are, what is the current level of risk? **Green** is the target – you have thought it through critically and you have no serious worries. Devise ways of making the risk green wherever you can. **Yellow** is acceptable but with some reservations. You can achieve these levels by reducing the inherent risk and or by effective and reliable precautions.
High (Orange) or Very High (Red) risks are unacceptable and must be acted on: use the Action Plan section to summarise and communicate the problems and actions required.

Action Plan (if risk level is **High (Orange) or Very High (Red)**

Use this part of the form for risks that require action. Use it to communicate, with your Line Manager or Risk Coordinator or others if required. If using a copy of this form to notify others, they should reply on the form and return to you. Check that you do receive replies.

Describe the measures required to make the work safe. Include hardware – engineering controls, and procedures. Say what you intend to change. If proposed actions are out with your remit, identify them on the plan below but do not say who or by when; leave this to the manager with the authority to decide this and allocate the resources required.

Proposed actions to control the problem List the actions required. If action by others is required, you must send them a copy	**By Whom**	**Start date**	**Action due date**

Action by Others Required - Complete as appropriate: (please tick or enter YES, name and date where appropriate)

Report up management chain for action	
Report to Estates for action	
Contact advisers/specialists	
Alert your staff to problem, new working practice, interim solutions, etc	

Reply

If you receive this form as a manager from someone in your department, you must decide how the risk is to be managed. Update the action plan and reply with a copy to others who need to know. If appropriate, you should note additions to the Directorate / Service Risk Register.

If you receive this as an adviser or other specialist, reply to the sender and investigate further as required.

Date of last review	As per Qpulse record	**Date of next review**	As per Qpulse record