ID: DR-GGC-RISK-089

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 / recent reviewer:	John McLean / n/a	**Post Held:**	MR Safety Expert
Department:	**Imaging**	**Date (of initial review):**	**28/8/2021**

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

Scanning patients with Patent Ductus Arteriosus (PDA), Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD) and Patent Foramen Ovale (PFO) or similar congenital cardiac conditions with clips or closure devices with 1.5T or 3T MRI

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

There are a range of hazards the MRI scanner presents. The static magnetic field may affect ferrous metallic objects. RF fields can lead to heating in wires and metallic objects. The imaging gradients may interact with active implanted medical devices.

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.

Patients with PFO, ASD, VSD and PFO clips or closure devices will be exposed to high static magnetic fields, RF power and imaging magnetic field gradients. This topic has been subjected to a detailed review. Clips and closure devices are not typically ferrous in nature, thus the static magnetic field is not a concern. The size of these devices is also typically too small to be a concern in regard to RF heating. Moreover, the passive nature of these devices mean the imaging gradients will not have any impact on these clips or devices.

Both from a review of the MR conditions for these devices and from the large empirical base. There is no substantive physical evidence to suggest scanning patient with these devices is a risk to patients at 1.5T and 3T.

Existing Precautions	**Describe how they might fail to prevent adverse outcomes.**
Patients are taken through an extensive MRI safety checklist to identify any implants that they may have A detailed review of MR safety for devices in this category has been done MRI physics staff monitor relevant mail forums and relevant social media channels for reports of adverse events in MRI with patient implants. MRI physics staff liaise with colleagues throughout the UK to cross check our knowledge on MRI safety for patient implants is up to date	A historical device in this category which is MR unsafe has not been considered A patient presents with a new device in this category which is MR unsafe and has not yet been considered Some unforeseen and previously unreported device and scanner interaction occurs to cause patient injury

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.

Assessment completed - date:	As per qpulse	**Review date:**	As per qpulse