NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-066

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	John McLean	**Post Held:**	MR Safety Expert
Department:	**Imaging**	**Date (Initial Review):**	**2/4/2019**

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

Off-label MRI scanning of patients with MRI conditional pacemakers due to the presence of an implantable cardiac loop recorder (e.g reveal device)

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

The hazards associated with safe scanning of MRI conditional pacemakers have been considered elsewhere. What we explicitly review here is any additional risk of MR scanning a patient with an MRI conditional pacing device and leads where the patient also has a cardiac loop recorder device such as a 'reveal' device.

This risk assessment is brought about as all of the manufacturers of MR conditional pacemakers typically cite something like 'no cardiac related implanted devices, components or accessories present other than the MR conditional pacing system ' as part of the conditions for safe scanning. However, taken in isolation, these devices would be considered MRI conditional. Thus, the vendors position is considered conservative based on, presumably, the likelihood of some speculative interaction between the MRI conditional pacing system and the cardiac loop recorder when both are subject to the various components of the MRI i.e. static magnetic field, imaging gradients and RF power.

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.

The risk under consideration here is the risk of an interaction between the MR conditional pacemaker and the cardiac loop recorded when both are subjected to the various fields of the MRI scanner.

The static magnetic field is not likely to facilitate any interaction between the MR conditional pacemaker and any cardiac loop recorder. Similarly, the imaging gradients and RF power, while they may be present simultaneously over both the MR conditional pacemaker and cardiac loop recorder are unlikely to facilitate any interaction between these devices. Therefore, in general the MR safety of these devices may be considered independently of one another and thus the likelihood of any interaction is considered to be low.

It is difficult to speculate over the potential impact of any speculative interaction between the MR, the MR conditional pacemaker and a cardiac loop recorder. This is because no such negative interaction has ever been recorded. While MR scanning of such instances may not be high in number, it is likely that similar scenarios have been played out safely.

Existing Precautions	**Describe how they might fail to prevent adverse outcomes.**
Clinicians referring patients for MRI scanner must state whether or not the patient has a cardiac pacemaker / defibrillator or not. The patient's heart rate and ECG will be monitored through the MR. The patient has a call button which they can press should the feel any unusual sensations or pain during the MR scan. On attending for their MRI examination patients are taken through an extensive MRI safety checklist to identify any implants that they may have.	Some unforeseen interaction between the MR conditional cardiac pacemaker and cardiac loop recorder may occur

A crash team can be summoned in the event of a catastrophic event such as a cardiac arrest Policies are in place for safe scanning of cardiac loop recorders during MRI	

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 **Next review date:** As per QPulse record