NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-021

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)	**23/3/2015**

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

Scanning patients in MRI with MRI conditional pacemakers

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

The MRI scanner can present a number of hazards to active implant medical device (AIMD's) such as cardiac pacemakers. Given the role pacemakers play, clearly any adverse impact on the devices function, or causing the device to malfunction may have devastating consequences for the patient. There have been a number of deaths as a result of patients with cardiac pacemakers having been brought into the MRI environment and scanned.

In recent years, a number of companies of developed MRI conditional pacemaker devices. These are devices specifically designed from the ground up to be safe in the MRI environment provided a range of conditions can be satisfied.

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 MRI conditional pacemakers. While patients with non-conditional MRI pacemakers remain an absolute contraindication to MRI. The patients of concern here are those patients with MRI conditional pacemaker devices. To-date, no adverse incident has been published of a case where any patient with an MRI conditional pacemaker device has come to hard as a result of entering or being scanned in the MRI environment. This situation continues to be monitored. Thus, there is no evidence to suggest scanning a patient with a conditional pacemaker presents a risk of injury to the patient.

Not following the conditions of safe scanning may lead to an increased likelihood of device malfunction or patient injury.

Patients are increasingly being implanted with these devices to ensure patients have access to MRI as a healthcare technology in the future. It is likely that in the near future the scanning such devices will be required to be a routine event.

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. Patients who receive a letter regarding the details of their MRI investigation will be further asked if they have a cardiac pacemaker / defibrillator or not On attending for their MRI examination patients are taken through an extensive MRI safety checklist to identify any implants that they may have. Patients with MRI conditional pacemakers will only be scanned if documented proof is available of the make and model of the device is available. Given the implications of making a mistake, word of mouth information is not good enough to confirm the make and model of an MRI conditional pacemaker. Scanning staff must be familiar with the MRI conditional criteria for the particular device that is to be scanned.	**The patient may fail to declare an implant that they have. However, given the multiple instances on which patients will be asked about their medical history the risk of not detecting the presence of a pacemaker/defibrillator is negligible.** **Outpatients are increasingly being appointed for scanning slots without letters from the MRI department i.e. they are typically being appointed by telephone. This removes one of the layers of safety which was previously in place. One can envisage a situation in future where other technologies (text messages) are being routinely used to appoint patients for MRI examinations. Managers establishing these systems must be aware of the safety risks presented by MRI and ensure appropriate measures continue to be implemented as booking systems evolve.**

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