

## Risk Assessment Form

**ID: DR-GGC-RISK-042**

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.

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| **Name of initial Assessor/Reviewer** | John Foster | **Post Held:** | MR Safety Expert |
| **Department:** | **Imaging** | **Date (Initial Review):** | **15/01/2019** |
| 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 a coronary stent or stent(s) |
| 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 coronary stent or stents. 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 stent or stents when both are subject to the various components of the MRI i.e. static magnetic field, imaging gradients and RF power. ♦ see DR-GGC-RISK-021 |
| Description of RiskDescribe 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 coronary stent(s) 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 coronary stents. Similarly, the imaging gradients and RF power, while they may be present simultaneously over both the MR conditional pacemaker and stent 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 stent or stents. 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. 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.A crash team can be summoned in the event of a catastrophic event such as a cardiac arrest.General implant safety policies are in place for safe scanning of coronary stents during MRI. These are available at [www.mriphysics.scot.nhs.uk/implant-safety-policies/](http://www.mriphysics.scot.nhs.uk/implant-safety-policies/).  | Some unforeseen interaction between the MR conditional cardiac pacemaker and stent may occur. |

**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.**

With the existing precautions described above in place, if an interaction occurred the consequences for the patient have the potential to be minor. For example with heart rate and ECG monitoring throughout the scan, should the patient’s pacemaker stop working this would be detected instantaneously and the crash team could be summoned.

In conclusion, the level of this risk is LOW.

**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.**

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| **Date of last review:** | As per QPulse record | **Next review date:**  | As per QPulse record  |