

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 <i>Revised by Eirin Beese and Reviewed by Blair Johnston</i>	Post Held:	MR Safety Expert <i>Trainee Clinical Scientist MR Safety Expert</i>
Department:	Imaging	Date (Initial Review):	17/3/2015
Subject of Assessment: E.g.: hazard, task, equipment, location, people			
Scanning patients with MRI where cables or wires from physiological monitoring or gating equipment is connected to the patient. This includes patients with cardiac implantable electronic devices (CIEDs), using either MR Conditional patient monitoring equipment or the MRI scanner's inbuilt cardiac gating equipment. This risk assessment does not cover the risks of scanning patients with CIEDs (covered in DR-GGC-RISK-021 and supplemented by DR-GGC-RISK-043) but rather the risk of the use of monitoring equipment with patients.			
Hazards (Describe the harmful agent(s) and the adverse consequences they could cause)			
The radiofrequency (RF) power the MRI scanner uses to acquire images can couple with conductive material and induce currents, which can lead to heating. If the conductive material (such as metal wires or cables) are in contact with the patient, this can lead to a burn occurring. MR Conditional external monitoring equipment has been specifically designed for the monitoring of patients within the MR Environment (i.e. for the monitoring of patients under anaesthesia during their MRI scan). However, the use of this equipment to monitor patients with CIEDs is considered off-label, and there is currently no patient monitoring equipment available that can perform this function 'on-label'. Philips, Probo Medical (on behalf of iRadimed), and Wardray Premise (on behalf of Mammendorfer) representatives were contacted regarding the MR400, 3880, and Tesla M3 respectively, and confirmed that the contraindication for monitoring patients with CIEDs is either historical or from the theoretical increased risk of radiofrequency (RF) heating. Siemens, GE, Philips, and United Imaging's MRI inbuilt cardiac gating equipment and, if applicable, peripheral pulse gating equipment is MR Conditional but is designed for sequence triggering/gating and is not approved for patient monitoring.			
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.			
All patients undergoing MRI scans with monitoring equipment are at risk. Patients undergoing MRI scans while under anaesthesia are particularly vulnerable, due to their inability to communicate if any heating does occur during the scan. A condition of MR Conditional CIEDs is that patients must be monitored during their MRI scan. The exact requirements vary between CIED manufacturers, but pulse oximetry and/or ECG monitoring is usually required. Placing cables and electrocardiography (ECG) electrodes over implants with conductive material may form a conductive loop, which may increase the risk of heating to the patient and result in a burn. However, there is a large volume of empirical evidence that MR Conditional patient monitoring equipment can be used safely for monitoring patients with CIEDs during their MRI scan. Additionally, the alternative of not monitoring these patients would be of considerably higher risk. Based on the above and with the knowledge that the equipment undergoes rigorous testing to achieve its MR labelling, the risk to patients and their CIEDs is considered to be low.			

The use of an MRI scanner's inbuilt cardiac gating equipment for patient monitoring (of any patient) is not approved by the manufacturer. However, after conducting an evaluation of the equipment, MRI sites have gone on to use it for patient monitoring with no reported incidents: this is also supported by the 2024 consensus statement for MR imaging of patients with CIEDs [1]. The MRI safety risk from using inbuilt monitoring equipment is comparable to using external equipment, however, please defer to your local Cardiology team's opinion on its suitability for cardiac monitoring as it is not intended for this purpose.

[1] Bhuvva A, Charles-Edwards G, Ashmore J, et al. Joint British Society consensus recommendations for magnetic resonance imaging for patients with cardiac implantable electronic devices. *Heart*. 2024;110(4);e3. Available from: <https://doi.org/10.1136/heartjnl-2022-320810>

Existing Precautions	Describe how they might fail to prevent adverse outcomes.
All monitoring equipment suitable for use within the MR Environment must be labelled as either MR Safe or MR Conditional. Conditions of use are marked on individual pieces of equipment as necessary. Only MR Safe or MR Conditional ECG electrodes, pulse oximeter devices, and connecting cables shall be used. ECG leads will be positioned to be led out centrally from the bore and not near the bore periphery. During an MRI scan, the patient's physiological measurements will be monitored by an appropriately trained member of staff. Training of MRI Staff to set up and operate monitoring/gating equipment; including having knowledge of the safety concerns and appropriate mitigations to minimise current induction (such as using appropriate padding and ensuring no cable loops or 'cross points'). The patient shall be instructed to inform staff immediately if they feel any pain or heating sensation during their MRI scan. Patients are asked to press buzzer if they require to communicate with staff during the MRI scan. Annual training of MRI Staff and anaesthetic staff working in MRI to remind staff of the dangers involved with the cables and wires from external monitoring equipment. Any equipment planned for use in the monitoring of patients with CIEDs will be evaluated in agreement with Cardiology and locally tested (covering a range of different body parts and sequences) before being used clinically. During evaluation, cardiac monitoring/gating equipment will be tested one at a time to minimise heating risk to patients/volunteers.	Most often, burns to patients which have occurred as a result of cables or wires in the MRI scanner are caused by those cables or wires not being MR Safe or MR Conditional. A member of staff could inadvertently bring an MR Unsafe piece of equipment into the MRI Environment which may subsequently be used.

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

<u>Likelihood</u>	<u>Impact/Consequences</u>				
	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	<u>Low</u>	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