

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 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			
Scanning patients in MRI with MRI conditional pacemakers with no cardiologist present			
Hazards (Describe the harmful agent(s) and the adverse consequences they could cause)			
Historically cardiac pacemakers were considered an absolute contraindication to MRI. Tens of patients have been killed as a result of having had a pacemaker and been allowed to enter the MRI magnet room and been scanned. That being said, several companies (Medtronic, St Jude's, Boston Scientific etc) have now designed devices from the ground up to be safe in the MRI environment provided the conditions for safe scanning are adhered to. These devices have been through clinical trials and are CE marked. Since the introduction of these devices, no patient with an MRI conditional pacemaker has been reported to have been injured or died as a result of being in the MRI environment.			

Description of Risk

It should be clear here that we are not considering the risk of scanning patients with these devices, this has been considered elsewhere. As the company provide guidance on the conditions for safe scanning, provided these are adhered to, then the risk of scanning these patients in MRI is considered to be low.

What we are considering here are any additional risks associated with not having a cardiologist present during the scan. It is very difficult in practice, particularly in the in-patient circumstance to co-ordinate and organise a cardiologist to attend to a patient in Radiology, particularly one who is familiar with the patient history. We shall review here what conditions for safe scanning require input from the cardiologist and what the implications of not having the cardiologist present during scanning would be.

As part of the cardiology conditions for safe scanning, the integrity and settings of the device must be interrogated and then be placed in a safe operating mode for MRI. In NHS GGC this is typically done by a Cardiac Physiologist who are expert users of these devices.

Within the MR safe operating mode for a given device, there are a range of choices for which pacing mode the device should be operating in during the MRI scan. This decision should be made by a *Cardiologist or equivalent competency for patient care*. However, in practice, the decision could be made by a cardiologist (*or equivalent*) prior to the patient attending if a suitable protocol was in place.

The cardiac physiologist present can assist radiology staff in setting up the ECG of the patient. The patient ECG is further monitored during MRI scanning, while the cardiologist can monitor this, the cardiac physiologist is also competent to review and assess the ECG.

In the event of the patient having a serious cardiac event while in the MRI environment, the crash team would be summoned immediately to Radiology (telephone: 2222). In the interim, the patient would be removed from the MRI magnet room and attended to by the cardiac physiologist. CPR could be administered by them and a defibrillator is present and could be used if need be.

To date, no incidences or adverse events have been reported as a result of patient with an MRI conditional pacemaker being scanned in MRI. Thus the likelihood of such an incident, when the conditions for safe scanning are adhered to appears to be very low (rare). This is something we would rapidly review in view of any such incidences occurring.

Existing Precautions

Establish from a Cardiologist prior to the patient attending, which mode the pacing device should be operating during the MRI scan.

Ensure conditions for safe scanning for the device are satisfied, this can be done by the Cardiac Physiologist and Radiology staff, typically a combination of (MR authorised operator, Radiologist and MRI safety expert).

The cardiac physiologist will monitor the patient ECG throughout the MRI scan.

A defibrillator is present in Radiology/ MRI in case of a cardiac arrest and can be used if need be

A procedure is already in place to summon the crash team to Radiology / MRI in the event of a cardiac emergency

Describe how they might fail to prevent adverse outcomes.

If the appropriate protocol to prepare for the scan is not followed.

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	<u>Low</u>	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	By Whom	Start date	Action due date
List the actions required. If action by others is required, you must send them a copy			

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 Q-Pulse record

Next review date: As per Q-Pulse record