NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-070

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:	John McLean	**Post Held:**	MR Safety Expert
Department:	**Imaging**	**Date (Initial Review):**	**04/09/2019**

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

Scanning patients with Vagal Nerve Stimulator (VNS) Devices with MRI under General Anaesthetic (GS)

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

Some patients have Vagal Nerve Stimulator (VNS) devices. These are a form of Active Implanted Medical Device (AIMD). The RF power, static magnetic field and imaging gradients of the MRI system may all pose a risk to devices of this type. There have been incidences where patients with VNS devices have been injured as a result of being scanned in MRI though this is typically where the conditions for safe scanning have not been adhered to.

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 Hazard described above may lead to the patient being burned or potentially to the malfunction of the device, the outcome or consequence of which, is difficult to predict. Typically one of the conditions of safe scanning of the VNS devices is that the patient must be able to respond to any heating or unusual sensation. Thus, strictly speaking scanning under GA implies an **off-licence** scenario. However on the basis of **significant clinical need** an MRI scan may be performed in the GA setting scanning if the existing precautions below are strictly adhered to.

Existing Precautions	**Describe how they might fail to prevent adverse outcomes.**
Referring clinicians should flag up the presence of a VNS device at the time the referral is made Patient information sheets sent out to patients requests that they contact the Imaging department if they have any implants or medical devices On attending for their appointment patients are further taken through an extensive MRI safety checklist to detect any implants, including VNS devices, the patient may have On establishing that a patient has a VNS device, the next step is to confirm the make and model of the device The conditions for safe scanning of the particular VNS device must be obtained and these conditions must be followed. Conditions will typically relate to the preparation for scanning, hardware selection, acquisition of images and post scanning care Radiographers involved in scanning have been made aware of the conditions for safe scanning of VNS	One of the conditions for safe scanning that is typical for VNS devices is to ensure that only local transmit / receive coils are used and that these are not placed over the position of the VNS itself. Radiographer may fail to be aware of these conditions or forget during scanning and inadvertently run the scanner using body transmit coil functionality. The inability of the patient to respond to any unusual sensations or heating is an added concern under this scenario.

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