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 Original Assessor/ reviewer:	Rebecca Stace / John McLean	**Post Held:**	Clinical Scientist
Department:	**Imaging**	**Date of last review:**	**21/06/2023**

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

Scanning patients in MRI with non-programmable CSF shunts

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

Typically, non-programmable CSF shunt valves are non-metallic and do not contain magnetic active components like programmable CSF shunt valves. Those non-programmable shunt valves which are non-metallic do not pose an MRI safety risk. However, there are non-programmable shunt valves which contain metal components – stainless-steel being the material which poses an MRI safety risk. The safety concerns relating to these metallic non-programmable shunt valves include:

- Movement of the shunt valve/metallic components within the valve due to interaction with the static magnetic field.
- RF heating of the metallic components.
- Metal-induced artefact compromising diagnostic quality of image.

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.

Shunt valves are typically no more than 5cm in length, and stainless-steel has been used as the material of choice for springs, proximal ends of the valve and, in some cases, for the valve housing. The majority of all non-programmable shunt valves are silicone-based which is an MR Safe material. Studies conducted on metallic non-programmable shunt valves has shown either no measurable ferromagnetism or weak ferromagnetism. There have been no published cases of patients with non-programmable shunt valves having any adverse outcome or injury as a result of being scanned using MRI.

Upon referring a patient for an MRI scan the referrer is required to complete a safety checklist where they should declare any patient implants. The patient is also taken through an MRI safety checklist upon arrival to the MRI department. Due to the format of the safety questionnaires used, patients are typically asked about implants three times in different ways, therefore the risk of not identifying the presence of a shunt is negligible. In this patient group, there is the risk of unknowingly scanning a programmable CSF shunt if it is not identified correctly during the screening process where, instead, it is incorrectly thought the patient's shunt is non-programmable. All programmable CSF shunts are currently MR Conditional and thus there is potential for injury/adverse event if scanned out with the specified conditions. The greatest concern is MRI-induced alteration to the valve settings of these shunt type – if not rectified, over or under-drainage of CSF can result for which adverse events may include recurrent hydrocephalus and subdural haematoma.

It is also noted that the MR Conditional criteria for the Codman Hakim Precision Valve (non-programmable), as stated on mrisafety.com includes a limit on the spatial gradient of 720G/cm. This limit is to be increased for the scanning of non-programmable valves in a generic implant safety policy as the static magnetic field gradient is not a limit of safety, but rather a limit of testing in which it indicates the highest T/m of the scanner a particular device was tested on. MR technology has advanced considerably over the past decade in which scanners have increased static magnetic field gradients to enable their location within smaller sized rooms and to better contain the static magnetic field. The concern would be that the increased static magnetic field gradient would result in an increased torque/translational force exerted on the shunt valve – however, there are few non-programmable shunt valves, if any that would be ferromagnetic enough to be affected and the maximum spatial field gradient is not a value the patient and their implant would come into contact with considering it is typically located within the covers of the magnet. The associated increased risk is therefore considered negligible.

An important point to address is the statement made by Frank Shellock in the SMRT mailbase regarding the said existence of at least one MR Unsafe Holter type valve. Although there is this indication of an MR Unsafe Holter type valve, the empirical evidence suggests patients with Holter type valves have been scanned safely at 1.5T with no adverse events or injuries recorded. Whilst these devices have not been determined to be MR Safe or MR Conditional, our experiences suggest patients have been scanned safely at 1.5T and thus the risk of scanning patients with these shunt valves is considered low.

Internal accessories which include reservoirs/pumping chambers, anti-siphon devices/siphon control devices/gravitational units, connectors and filters are considered to be low risk. Although there is this indication of an MRI Unsafe unnamed right angle stainless steel ventricular shunt tube connector which exhibited "measurable" ferromagnetism at 0.147T and 1.44T, its ferromagnetic mass is poorly described and not quantified to suggest it would be adversely ferromagnetic. Likewise, the Cordis ventricular shunt tube connector with metal connector has been described as exhibiting "evident" ferromagnetism and "slight" image distortion. Whilst the prevalence of these internal accessories is unknown, there have been no reported incidents. This, together with the lack of evidence of hazard level suggests a low risk associated with scanning these shunt components.

Existing Precautions

Summarise current controls In place	Describe how they might fail to prevent adverse outcomes.
Patients are taken through an extensive MRI safety checklist to identify any implants that they may have. For patients where shunt type (non-programmable/ programmable) is unknown, an X-ray may be taken to aid identification. MRI scan should not proceed unless safety status of implant can be confirmed.	The patient may fail to declare an implant that they have. N/A

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