ID: DR-GGC-RISK-077



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	Blair Johnston	Post Held:	Clinical Scientist
Department:	Imaging	Date (Initial Review):	21/4/2020

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

MRI safety status of patients with glucose monitors

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

With the exception of the Eversense and Eversense XL sensors, all glucose monitors are classified as MR Unsafe. The sensor is an active implant that pierces the skin and is replaced periodically by the patient or a healthcare professional. The hazards for one such device, Abbott's Freestyle Libre which has a small battery within the sensor, are the risk of malfunction or heating and burns when placed within the MRI scanner (Wright and Perkins, 2018). However, there may also be a displacement or projectile risk for this and other monitors.

Wright, D., and V. Perkins. "Magnetic resonance safety of the Freestyle Libre glucose monitoring system." *Anaesthesia* 73.11 (2018): 1446-1447.

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 Eversense transmitter is MR Unsafe and must be removed prior to entering the MR Environment but the sensor is MR Conditional and can be scanned safety at 1.5T and 3T, as per the conditions stated in the policy.

For all other CGMs, it is necessary for the patient to remove their glucose monitor prior to entering the MR Environment for the MRI to proceed safely. However, some patients may be unwilling to remove the monitor. Whilst it is important to ensure care is not withheld unnecessarily or delayed, if a patient is unwilling to remove the monitor, the scan must be rescheduled to a time when the patient no longer has the monitor or is able to remove it.

Existing Precautions	Describe how they might fail to prevent adverse outcomes.
With the exception of the Eversense CGM system, all glucose monitors are classed as MR Unsafe. Therefore, the monitor must be removed before the patient can enter the MR Environment to undergo their scan.	Patients may fail to disclose that they have a glucose monitor during the MRI safety checklist procedure.

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	<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