NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-214

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	Eirin Beese John McLean	**Post Held:**	Trainee Clinical Scientist MR Safety Expert
Department:	**Imaging**	**Date (Initial Review):**	**01/04/2025**

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

Off-label MRI scanning of patients with Abbott FreeStyle Libre continuous glucose monitor (CGM) sensors, under US MRI conditions for 1.5T and 3T.

This risk assessment is applicable to Abbott FreeStyle Libre CGM sensors; **Libre 2, Libre 2 Plus, Libre 3, and Libre 3 Plus** (referred to as Libre Sensors from here onwards). Please see risk assessment (DR-GGC-RISK-077) for all other glucose monitors.

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

Patients rely on their CGM sensors to manage their diabetes. CGM sensors are an active implant that pierces the skin and are replaced periodically by patients or healthcare professionals. The Libre Sensors regularly record glucose levels and alarm in real time (via the Libre app) on patients' mobile phones, if blood sugar levels are above or below a set threshold. The Libre Sensors are also able to digitally connect with automated insulin dosing systems (infusion pumps). This risk assessment concerns Abbott Libre Sensors only, infusions pumps and mobile phones are MR Unsafe and must not be brought into the MR Scanner Room; please see risk assessment DR-GGC-RISK-078 for further information on insulin pumps.

Libre Sensors are labelled as MR Unsafe in the UK. However, Abbott Diabetes Care carried out extensive MR safety testing in 2022, resulting in the US Food and Drug Administration (FDA) clearing the MRI contraindication and Abbott achieving MR Conditional labelling for their Libre Sensors in the US [1, 2]. When approached, a representative from Abbott said they 'cannot comment around timelines or if the current labelling around MRI and the use of Freestyle Libre Sensors will change (in the UK)'.

There is risk of malfunction when introducing Libre Sensors to the MR Scanner's static magnetic field. An additional hazard is the dislodgement of the Libre Sensors from induced displacement or torque from the static magnetic field. There is also a risk of thermal heating and burns from the radiofrequency (RF) field. However, if following the US MR conditions, the risks to the patient and the risk of sensor malfunction can be mitigated and the patient can be safely scanned.

[1] Matievich, W., Kiaie, N., & Dunn, T. C. (2023). Safety and Functional Integrity of Continuous Glucose Monitoring Sensors When Used During Radiologic Procedures Under High Exposure Conditions. Journal of diabetes science and technology, 17(6), 1634–1643. https://doi.org/10.1177/19322968221106206

[2] Abbott. (2024, October 30th). *Abbott's FreeStyle Libre® 2 and 3: First Continuous Glucose Monitoring Systems Approved for Use During Medical Imaging* [Press release]. https://abbott.mediaroom.com/press-releases?item=124675

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.

Under specific MR conditions, Abbott have provided a guarantee of patient safety in the US for Libre Sensors. It is therefore considered safe to scan patients elsewhere, following the US MRI conditions for use, because the Libre Sensors remain the same, regardless of country. However, because MR labelling of the Libre Sensors has not been updated in the UK and remains MR Unsafe, MR scanning would be considered off-label and the risk is transferred to the health board rather than having the manufacturer's guarantee of safety when following the MR conditions.

Patients wearing their Libre Sensors are still at an increased risk of having a diabetic event because the sensor may produce inaccurate glucose readings when exposed to the MR Environment. However, normal function is expected to return up to one hour after leaving the MR Environment, with no lasting

effect on the sensors. As a result, patients should be advised to rely on manual glucose readings for one hour after leaving the MR Scanner Room to safely manage their diabetes.

Abbott reported that in phantom-based testing at 3T, the image artefact caused by the Libre 3 sensor extends radially approximately 5.8 cm from the sensor, and 6.9 cm from other Libre Sensors. The patient should therefore not be scanned with their Libre sensor on if the artefact will significantly impact the clinical benefit of the scan.

Detailed US MRI Scanning Conditions can be found at https://www.freestyle.abbott/us-en/safety-information.html, with a summary below:

- Magnetic Field Strength: 1.5T and 3T
- Operating Mode: Normal Operating Mode
- RF Excitation: Circularly Polarised
- RF Transmit Coil Type: Integrated Whole Body Transmit Coil
- Scan Duration
  - 1.5T, all locations
    - Up to 1 hour of continuous scanning without cooling period.
  - 3T, between the pelvis and the sternum
    - Up to 12 minutes of scanning with a cooling period of 2 minutes between scans.
  - 3T, above sternum and below pelvis
    - Up to 1 hour of continuous scanning without cooling period.

Existing Precautions	**Describe how they might fail to prevent adverse outcomes.**
MRI Referrers must declare any implants during the referral. Patients are taken through an extensive MRI Safety Checklist to identify any implants they may have. Abbott Diabetes Care have confirmed that all Abbott Libre Sensors that are available, or soon to be available, in the UK (Libre 2, Libre 2 Plus, Libre 3, and Libre 3 Plus) are MR Conditional in the US. Patients will be provided with an MRI information sheet regarding their Libre sensor and consented before their MR scan proceeds. The US MRI conditions for scanning will be followed.	Referrer and Patient may both fail to disclose that patient has a CGM sensor. Referrer and/or Patient may provide inaccurate information regarding the manufacturer and model of the CGM sensor. Patients with a CGM not covered by this risk assessment could receive an MRI scan due to a misunderstanding of the CGMs included in this risk assessment.

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