NHS Greater Glasgow and Clyde

ID:

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 (of initial review):**	**6/6/2023**

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

Staff member with insulin pump working near the Hyperfine Swoop scanner

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

All (tethered or patch) insulin pumps are deemed MR Unsafe and manufacturers state that they must be removed prior to entering the MR Environment. If the pump requires an infusion set, this may be investigated to check if it is entirely plastic (MR Safe) or contains a steel needle (MR Unsafe) but if there is any doubt, this must also be removed.

The Hyperfine Swoop portable MRI system is a head-only ultra-low field scanner. This system is intended for use in the MIRACLES research project that will recruit patients that have had a clinically suspected stroke or transient ischaemic attack (TIA) or confirmed clinical diagnosis of stroke or TIA. As the Swoop scanner is ultra-low field, the MR Environment is much smaller than a typical MRI scanner.

A staff member working on the MIRACLES research project has an insulin pump. This risk assessment is intending to assess whether it is safe for this staff member to work near the Hyperfine Swoop system

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 model of the insulin pump is the Medtronic MiniMed 670G. The User Guide states:

- *Do not expose your pump to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the devices to malfunction, and result in serious injury. If your pump is exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance. Magnetic fields, and direct contact with magnets, may affect the accurate functioning of your system, which may lead to health risks such as hypoglycaemia or hyperglycemia.*
- *Do not expose your transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your transmitter is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.*
- *Do not expose your sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields as the performance of the sensor has not been evaluated under those conditions and may be unsafe. If your sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.*
- *Always remove your pump, sensor, transmitter, and meter before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. The magnetic fields and radiation in*

the immediate vicinity of this equipment can make your devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over delivery and severe hypoglycemia.

Medtronic were contacted to ask for more information, particularly if they could determine at what magnetic field strength it would be safe up to. Medtronic referred to the user guide but also added:

- *Medtronic MiniMed is not able to test for compatibility or adverse effect with every type of device, equipment, or environment. Our insulin pumps can be damaged by exposure to magnetic flux density (Gauss) above 600 gauss and Magnetic Fields (A/m) above 4000 A/m. Therefore, we recommend removing the pump under these conditions, exposure can affect the delivery of Insulin and as such is not recommended. Another option is to speak with their health care provider see if they have any advice.*

The Hyperfine Swoop is a 0.064 T (640 Gauss) scanner with a peak magnetic field strength (flux density) of 0.2 T (2000 Gauss) at the internal lip of the magnets (Figure 1).

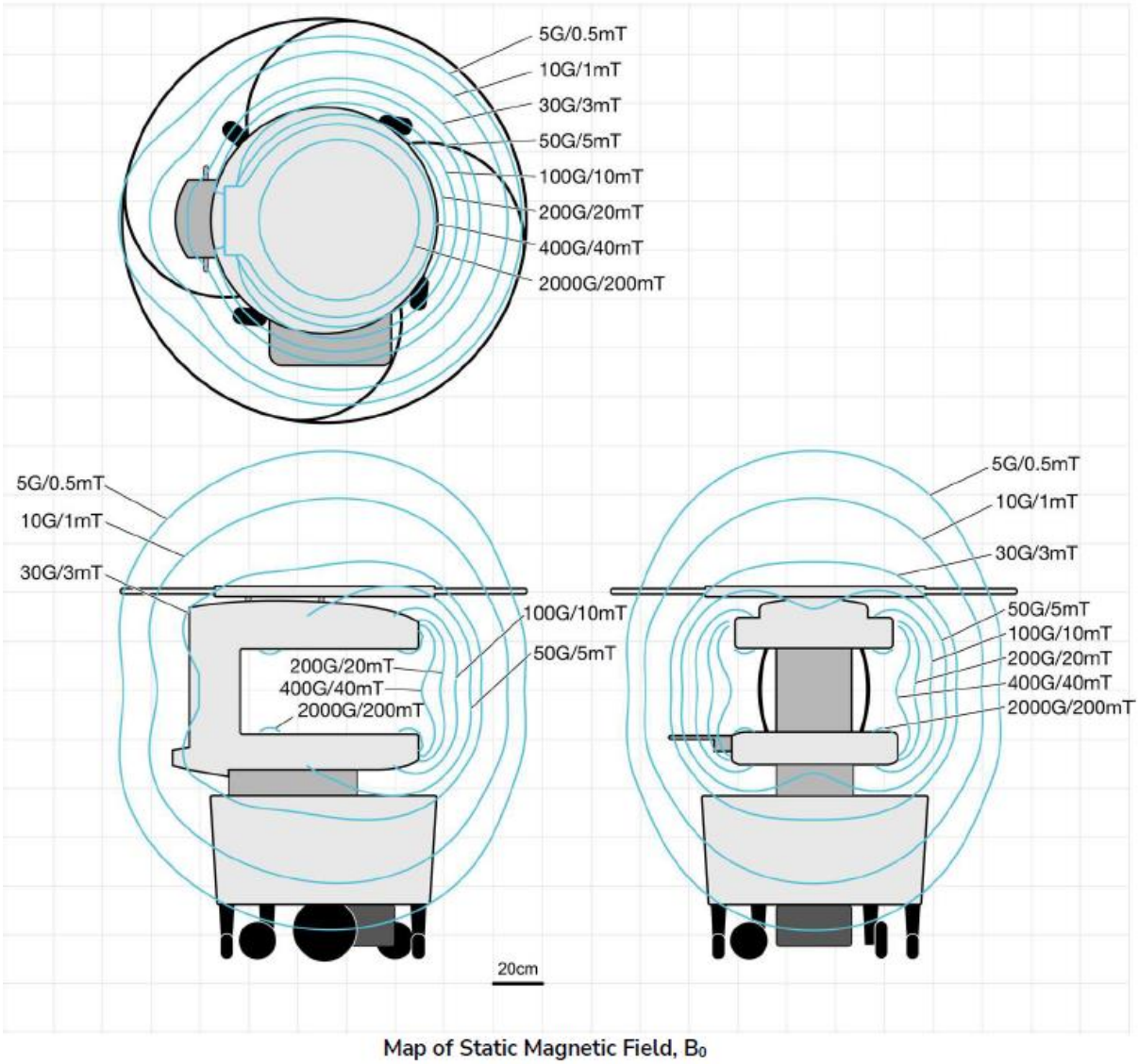

Figure 1: This information is reproduced from the Hyperfine Summary Specifications Sheet V10 Part No. 850-11001-06.

Even adding a safety margin of 400 Gauss/40 mT, a staff member working around the scanner would need their implant to effectively enter the scanner for it to exceed the 600 Gauss value quoted by Medtronic.

Existing Precautions	Describe how they might fail to prevent adverse outcomes.
No part of the insulin pump should be allowed to go within approx. 20cm of the bore. To further minimise the risk, we recommend that the staff member keeps their device as far from the Swoop scanner as practical and moves slowly whilst undertaking their duties in the MR Environment. The staff member will be asked to monitor the performance of their insulin pump carefully after they are required to enter the MR Environment If the staff member changes the insulin pump model they are using then they must not enter the MR Environment until MRI Physics have updated the risk assessment The staff member will be asked to read this risk assessment and invited to ask any questions to ensure they are fully aware of the potential risks and the precautions they will be asked to take. There is no obligation for this staff member to work around the MR Environment.	

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 23/11/23 **Date of next review** 23/11/25