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):**	**27/7/2023**

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

Use of MR Unsafe or MR Unlabelled patient monitoring equipment (i.e. ECG electrodes and leads, blood pressure monitors, pulse oximeters and syringe drivers) during Hyperfine Swoop head scanning where all components are outwith the head coil

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

The use of MR Unsafe or MR Unlabelled patient monitoring equipment in a standard (e.g. 1.5T or 3T) MRI scanner is strictly prohibited as it has the potential to cause RF heating and/or burns.

The Hyperfine Swoop portable MRI system is a head-only ultra-low field scanner. This system is intended for use in a 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. These patients need to be monitored before, during and after the scan. Whilst the preference would be for them to be monitored using MR Conditional patient monitoring equipment, this may not be possible and so this risk assessment is intending to assess the risk to patients if they undergo a head scan in the Hyperfine Swoop portable MRI scanner with MR Unsafe or MR Unlabelled patient monitoring equipment left in place.

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 FDA has not approved or cleared the Swoop system for use with ECG monitors, leads or electrodes within the 5 Gauss line. We assume the same can be said for blood pressure monitors and pulse oximeters and any other patient monitoring equipment. However, the patient group that are involved in this study will require monitoring during the scan.

The Swoop system includes a retractable ‘Gauss Guard’ ring that delineates the 0.5 mT (5 Gauss) line. If a device is entirely outside this Gauss Guard then there is no additional risk to the patient. However, if part or all of a device is required to enter the volume contained within the Gauss Guard then there is a risk from the static magnetic field. If these devices enter the bore of the scanner, then there is also a potential risk from the RF and time-varying gradients.

Hyperfine provided an evidence summary from the peer-reviewed literature of ECG lead usage with the Hyperfine Swoop system.

Sien and colleagues (1) scanned 14 neonates on a portable MRI system and stated “patient monitors, IV pumps and ECG leads were present during 100% of examinations” and “some equipment was within the 5-gauss line during imaging”. They highlighted that “Prior to scanning, the safety of and effects on image quality from support equipment present within the 5-gauss area of the pMRI system were assessed… The tested items included...monitoring leads (3M, Saint Paul, Minnesota, USA).” The authors reported that there were no MRI-related adverse events during the portable MRI examinations.

Mazurek and colleagues (2) reported scanning 104 patients and 38 healthy controls with the Hyperfine Swoop system. They reported that:

- “The scanning environment contained ferrous metal and standard intensive care unit equipment, including but not limited to the electrocardiogram and vital signs monitor, IV infusion pumps, ventilators, compressed gas tanks, and dialysis machines.”
- “The static magnetic field, gradient, and RF pulses of the pMRI scanner did not interfere with the operation of infusion pumps, mechanical ventilators, or hemodialysis machines.”
- “No adverse events occurred. Patients remained connected to all intravenous lines and ICU monitoring equipment during sequence acquisition.”
- “Patients and research staff did not experience any adverse events during pMRI deployment and could safely remain in the hospital room during scan acquisition

Similarly, Prabhat and colleagues (3) reported that they scanned over 35 patients with the Hyperfine Swoop system whilst they were connected to patient monitoring equipment. The authors concluded:

- “It does not require patients to be disconnected from their equipment and limits the potential risks associated with traveling with critically ill patients and the conventional MRI magnet. It can function in the presence of common hospital ferromagnetic devices, including ventilators, IV pumps, EKG monitors, dialysis machines, and compressed gas tanks, outside of the 5 Gauss line.”
- “Our preliminary findings demonstrate the safety and feasibility of obtaining point-of-care MR neuroimaging in a wide range of patients who present with neuropathology.”

Whilst acknowledging that it is the institutions responsibility to apply MR safety screening procedures, Hyperfine have stated:

“*we believe that any projectile risk or any risk to the patient related to RF-induced heating caused by ECG leads is minimal. Hyperfine is not aware of any adverse events related to the presence of ECG leads on any patients on which the Swoop system has been used. Additionally, the Swoop system has been used in several published studies on patients with ECG leads with no MR-related events.*”

Pulse oximeters and blood pressure monitors would not be expected to enter the bore of the scanner and so we only need to consider the static magnetic field. Given where these will be located on the patient, even if they enter the 0.5 mT volume, the risk of a projectile is low for this field strength.

Syringe drivers may also be connected to patients. These must be kept outwith the Gauss Guard. If, for any reason, they will be required to enter the Gauss Guard, the MRRP or MRSE should be contacted for advice.

The main risk from using MR Unsafe or MR Unlabelled patient monitoring equipment with the Hyperfine Swoop system is that the readings could be altered in the presence of the fringe magnetic fields so the performance any bit of equipment that could enter the Gauss Guard will be assessed when located in the highest static field that the equipment could feasibly be expected to enter. However, it is unlikely that the performance of this equipment will be affected as it has been tested at other centres and no adverse effects have been reported in the literature.

1. Sien, Maura E., et al. "Feasibility of and experience using a portable MRI scanner in the neonatal intensive care unit." *Archives of Disease in Childhood-Fetal and Neonatal Edition* 108.1 (2023): 45-50.
2. Mazurek, Mercy H., et al. "Portable, bedside, low-field magnetic resonance imaging for evaluation of intracerebral hemorrhage." *Nature communications* 12.1 (2021): 5119.

3. Prabhat, Anjali M., et al. "Methodology for low-field, portable magnetic resonance neuroimaging at the bedside." *Frontiers in Neurology* 12 (2021): 760321.

Existing Precautions	Describe how they might fail to prevent adverse outcomes.
If any part of the monitoring equipment is required to enter the head coil and cannot be moved outwith then staff must seek advice from an MRRP or MRSE. The performance of any bit of equipment that may feasibly enter the Gauss Guard will be assessed. Staff are instructed to keep all equipment outwith the Gauss Guard wherever possible. All patient monitors will be placed to the side of the Hyperfine Swoop system while in operation to reduce the risk of interference. All patient monitoring equipment must be MR Conditional when undergoing clinical MRI.	

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	**Date of next review**	As per Qpulse record