NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-XXX

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	Pauline Hall Barrientos	**Post Held:**	Clinical Scientist
Department:	**Imaging**	**Date (Initial review):**	**19/10/2021**

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

Endoscopy/Colonoscopy Pill Cameras

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

Malfunction of PillCam in the presence of a magnetic field and potential moving due to presence of ferromagnetic components

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.

An endoscopy/colonoscopy capsule is a pill sized camera and it is designed for imaging the intestinal tract. Each capsule is typically equipped with a battery, a transmitter with antenna and LED. These components are enclosed in a biocompatible plastic casing.

After activation and ingestion the capsule passes through the gastrointestinal tract. During this process the video cameras acquire images and the transmitter sends them, via sensors, to the recorder; which is worn on a belt around the patient's waist. The capsule journey is typically 8 hours from the time of administration until it is excreted.

Currently in GGC Medtronic PillCam Colon 2 is being used.

The Medtronic documentation states the function of the PillCam capsule will be severely affected if in the presence of an MRI field. Additionally, the manufacture states: *Undergoing an MRI while the PillCam video capsule is inside the patient's body may result in serious damage to his/her intestinal tract or abdominal cavity*.

Existing Precautions	Describe how they might fail to prevent adverse outcomes.
<u>Pre scan</u> **There is a question in the MRI checklist asking if the patient has had this procedure within the last two weeks. If the answer is YES they must confirm they have excreted the pill. If they are unsure they should be sent for an x-ray to determine its presence.** **<u>During scan</u>** **The patient will be asked to press the buzzer if they feel any unusual/heating sensations during the scan. If the patient feels any discomfort the MR scan will be terminated.** **The PillCam should be in their intestinal tract for up to 8 hours. There are occasions where the PillCam could cause an obstruction, this would occur within two weeks, this is very rare. This is why we have a time limit of two weeks in the MRI safety checklist.**	**The patient answers YES in the checklist and confirmed the pill has been excreted but it hasn't.** **The patient answers NO but they have had the procedure recently and the PillCam is still in their intestinal tract**

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

<u>Likelihood</u>	**<u>Impact/Consequences</u>**				
	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.

The Risk for this service is Red (very high)

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