NHS Greater Glasgow and Clyde

**ID:** DR-GGC-RISK-203

# 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) | **8/3/2023** |

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

Scanning patients in MRI with temporary epicardial pacing wires with no external component

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

Temporary pacemakers may be used during open-heart surgery if the patient has the potential for transient bradycardia as a result of their underlying pathology or the procedure to be undertaken is likely to produce transient or permanent bradycardia [1]. These temporary pacemakers are typically removed once they are no longer required or after being replaced by a permanent pacemaker but, in some cases, the temporary epicardial pacing wires may remain in situ and are cut at the skin leaving a short length of wire implanted. There are no epicardial pacing wires that are labelled MR Conditional.

Please note the distinction between temporary epicardial pacing wires and permanent epicardial pacing leads. Temporary epicardial pacing wires are implanted during cardiac surgery whereas permanent epicardial pacing leads are implanted as part of a permanent CIED system. Permanent epicardial leads are deemed a higher risk scenario. If a wire has been cut at the skin then it is unlikely to be a permanent epicardial pacing lead.

As with any abandoned lead, the main risks when undergoing an MRI scan are heating and induced currents.

**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.

A number of wires can be used for various pacing scenarios in the heart. Many of these are outlined here [2]. This article, similar to other guidelines and consensus statements, suggests that retained temporary epicardial pacing wires without an external component which were used to temporarily perform pacing during cardiac surgery should not be considered a contraindication to MRI scanning [3,4,5], as per the quotations below.

*"Patients with retained temporary epicardial pacing wires are believed to be able to safely undergo MR procedures, and patients do not need to be routinely screened for the presence of such wires before scanning" [3] (2007)*

*"Regarding performing whole body MRI in patients with confirmed retained temporary epicardial pacing wires cut at the skin, MRI can be performed at 1.5T or 3T." [4] (2019)*

The Heart Rhythm Society Consensus Guidelines, highlight the paucity of data surrounding ***permanent*** epicardial pacing leads and the in-vitro evidence highlighting the potential for heating [4]. They highlight:

*"At the present time, however, there are insufficient data to comment on the safety of MRI*

*performance with abandoned, epicardial, or fractured leads" [4]*

However they subsequently state:

*"Postsurgical temporary epicardial leads that have been partially removed are not considered to be abandoned pacing leads"* [4]

But do not comment further on such leads.

Most consensus guidelines refer to the article by Hartnell (1997) surrounding the safety of scanning patients with retained temporary epicardial pacing wires [6]. Here 51 patients were scanned without incident. However, in a subsequent commentary by Kanal it was highlighted that any generalisation from this study that retained epicardial pacing wires were safe should be cautioned [7]. In particular Kanal cautioned that higher gradient fields and selection of imaging site could lead to cardiac stimulation from an epicardial lead.

The length of the retained wire can be of variable length and it is challenging to visualise these wires to accurately measure the length of wire(s) in situ. Whilst many of the consensus papers justify proceeding with MRI scanning of temporary epicardial pacing wires based on an assumed, short length of retained wire when cut at the skin, clinical experience has shown that the length of wire left in situ can exceed ~17-18 cm in length. If a significant length of wire (> 10 cm) is identified on a chest x-ray then we recommend a radiologist reviews the benefit of the MRI against the theoretical risk.

The majority of the literature report no adverse events from scanning patients with retained temporary epicardial pacing wires but one reported a "mild sensory event" during a cardiac MR scan [8]. This patient "described a sensory event near the subcutaneous end of the retained lead" during their second cardiac MR scan. The effect stopped when the sequence was stopped but returned as soon as it was restarted but "No arrhythmic event or signs of skin irritation were observed" [8].

To-date, no adverse incident has been published of a case where any patient with a temporary epicardial wire has come to harm as a result of entering or being scanned in the MR Environment. Thus, there is no evidence to suggest scanning a patient with temporary epicardial wires presents a risk of injury to the patient. However, this situation continues to be monitored and it seems prudent to assess the risk-benefit ratio for individual cases when the wires are particularly long or there is another implant in close proximity to the temporary epicardial wires.

Patients with temporary epicardial wires may have other cardiac implants such as CIEDs. The Heart Rhythm Society Consensus Guidelines, quoted below, recommend that these cases should be treated on a case-by-case risk-benefit assessment.

"*Patients with MR conditional systems who also have abandoned PM or ICD leads (capped or not), extenders or adaptors, lead remnants, fractured lead(s), or surgically implanted epicardial leads, should be evaluated for scanning as if they have an MR nonconditional system.*" [4]

Image quality has been reported to not be impaired by the presence of pacing wires, even for cardiac MR [8].

<u>References</u>

[1] Gammage, Michael D. "Temporary cardiac pacing." Heart 83.6 (2000): 715-720.

[2] https://www.ismrm.org/smrt/E-Signals/2017-1/eSig_6_1_info_3.htm (accessed Mar 2023)

[3] https://www.ismrm.org/safety/2020/20_0301_Maralani_Safety_jmri_26909.pdf (accessed Mar 23)

[4] Julia H Indik. HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices, Heart Rhythm, 2017 Jul;14(7):e97-e153.

[5] Bhuva, Anish, et al. "Joint British Society consensus recommendations for magnetic resonance imaging for patients with cardiac implantable electronic devices." *Heart* (2022).

[6] Hartnell GG, et al. Safety of MR imaging in patients who have retained metallic materials after cardiac surgery. Am J Roentgenol 1997;168:1157–1159.

[7] Kanal E. Safety of MR imaging in patients with retained epicardial pacer wires. Am J Roentgenol 1998;170:213-4.

[8] Gatterer, Constantin, et al. "Safety and image quality of cardiovascular magnetic resonance imaging in patients with retained epicardial pacing wires after heart transplantation." *Journal of Cardiovascular Magnetic Resonance* 23.1 (2021): 1-8.

| **Existing Precautions** | **Describe how they might fail to prevent adverse outcomes.** |
|---|---|
| Clinicians referring patients for MRI scans must provide a clinical history including whether or not the patient has had any previous operations.<br><br>Patients who receive a letter regarding the details of their MRI investigation will be further asked if they have had any previous operations.<br><br>On attending for their MRI examination patients are taken through an extensive MRI safety checklist to identify any implants that they may have. If a patient has had previous heart surgery then we recommend viewing a previous chest x-ray for any implants.<br><br>If a patient is known to have particularly long retained epicardial leads, we recommend a radiologist weighs up the benefit of the MRI scan (and the risk of not getting the scan) against the theoretical risk of heating and induced currents. However, given the evidence in the literature then it is likely this risk is low as there are no reported incidents and there are recommendations that these wires do not need to be included in MRI screening forms. Therefore we cannot justify asking radiologists to review the imaging of each patient that has had previous cardiac surgery for the presence of retained pacing wires. | There is potential for these temporary epicardial wires to be confused with permanent epicardial leads, which are deemed a higher risk in MRI. As mentioned earlier, permanent epicardial leads are highly unlikely to have been cut to skin and they are much thicker than the temporary epicardial wires and so appear differently on x-rays.<br><br>The patient may fail to declare an implant that they have. However, given the multiple instances on which patients will be asked about their medical history the risk of not detecting the presence of previous cardiac surgery is negligible. |

| | |
|---|---|
| Patients with retained epicardial pacing wires and a CIED or abandoned CIED lead in situ will require a risk benefit decision from a Radiologist.<br><br>A National Generic Implant Safety Procedure (GISP) is currently being drafted for these implants that will include a detailed review of the literature. | |

**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**<br>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 |