

MR safety risk assessment for an individual MR request for a patient with an implanted/attached medical device or foreign body

There are multiple MR safety-related hazards associated with the MR scanning of a patient with an implanted/attached medical device/foreign body. In the case of medical devices, the manufacturer typically provides assurance of zero or acceptable risk from scanning, by providing labelling as either MR Safe or MR Conditional. In the case of MR Conditional labelling, this assurance is only valid when all stated MR conditions are met. However, there are many scenarios where establishing this assurance is not possible. These include the following.

- The implanted/attached item cannot be identified
- The implanted/attached item is not labelled by the manufacturer as MR Safe or MR Conditional.
- The item is labelled MR Conditional, but one or more conditions cannot be met.

In these cases, both the [MHRA safety guidelines for MRI](#) and the [ACR MRI Safety Manual](#) in these scenarios advise that it is appropriate for a clinical need versus risk decision to be made on how to proceed with the individual MR request.

A risk assessment is appropriate to support such a decision. To simplify the process, the BIR MR safety working group have developed an example template for such a risk assessment. This is due for publication on the [MRI risk-assessments page](#) of the BIR website. Individual organisations are free to use/adapt this for their own use.

Key aims of this template include the following.

- Incorporate information from relevant international standards as well as current and anticipated guidance, to help demonstrate content is appropriate.
- Provide examples of potential mitigations to reduce specific risks associated with named hazards.
- Include two examples of completed risk assessments to demonstrate utility of this risk assessment template across the broad range of scenarios where it might be applicable. The two examples include a relatively simple case and a relatively complex case.
- This template also covers the aspect of clinical risk associated with lack of access to MRI. Although not strictly part of the risk assessment, this is relevant as it informs the clinical risk-benefit decision.

