MR Safety Advice 2026

Update to the MR safety labelling standard

ASTM F2503[1] is the international standard for the labelling of medical devices and other items for safety in the MR Environment. It defines the terms MR Safe, MR Conditional and MR Unsafe. An updated version of this standard, ASTM F2503-26, was published earlier this year. This includes some small changes to improve the wording of the definitions, although the intentions behind each of these remain unchanged. This update provides an opportunity to reflect on the terms and to highlight some background aspects to help understand their definitions in the broader context of medical device risk management. The updated definitions are as follows.

MR Conditional—having demonstrated safety in the MR Environment within defined conditions.

MR Safe—posing no known hazards resulting from exposure to any MR Environment.

MR Unsafe—posing unacceptable risk within the MR Environment.

The MR Environment is the volume around the MR scanner where a hazard may arise from an item being exposed to the electromagnetic fields generated by the MR equipment. Hence, the MR Environment is a combination of the B0 Hazard Area (defined by the 0.9 mT fringe field, also known as the 9 gauss line) and the Faraday shielded volume (defined by the Faraday cage, also known as the RF cabin or RF cage).

An important backdrop to these MR safety labelling definitions is ISO 14971, the international standard for the application of risk management to medical devices. This defines safety as “freedom from unacceptable risk” which feeds into the definition of MR Unsafe. The general process of ISO 14971 is that risks are unacceptable until they are assessed, potentially mitigated and determined to meet acceptability criteria. Medical device manufacturers reduce risks in the design process to specified levels, after which they become known as residual risks. Subsequently, through MR safety testing, manufacturers gather evidence to demonstrate acceptable residual risks within certain conditions to regulatory bodies, i.e. to demonstrate safety. This feeds into the definition of MR Conditional.

A key aspect of MR Conditional is that the statement of demonstrated safety only applies when all of the stated MR conditions are met. Consequently, identifying an item is labelled as MR Conditional is only the initial step. The second step is to establish what all the conditions are. The third step is to establish whether all the conditions can be met. Typically, these conditions include limitations on the static magnetic field, the time-varying gradient magnetic fields and the RF fields, but various other limitations or requirements may also be specified.

MR Safe labelling is only valid for those items that are composed entirely of electrically nonconductive, nonmetallic, and nonmagnetic materials, since these materials do not present any hazard when exposed to the electromagnetic fields generated by any MR equipment. MR Safe items may still potentially cause MR image artifacts, e.g. an alcohol wipe.

Finally, an important aspect of ISO 14971 is that its scope is limited to device manufacturers performing a population-based risk assessment. It explicitly excludes decisions about the use of an individual medical device in the context of a specific clinical procedure, highlighting that some of these decisions can be made only by a qualified medical practitioner with knowledge of the patient’s health status, balancing the residual risks against the anticipated benefits of the procedure. Guidelines from the MHRA[2] and ACR[3] provide recommendations on how to develop a local procedure where such a clinical risk-benefit decision is required.

[1] https://store.astm.org/f2503-26.html, [2] https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use [3] https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/radiology-safety/mr-safety

The British Institute of Radiology
Audrey House, 16–20 Ely Place,
London, EC1N 6SN

T: +44 (0)20 3668 2220
E: admin@bir.org.uk
www.bir.org.uk