# MR Safety Advice 2023

## Interpreting current MR Conditional labelling

Following on from **Advice sheet 4 2023 Update on MR safety standards** that highlighted introduction into the latest version of ASTM F2503 examples of proposed wording for MR Conditional labelling that will help for medical devices released in the **future**, here we are discussing some of the issues around examples of wording found in **current** MR Conditional labelling.

Not meeting all the MR conditions for an MR Conditional implant means that an examination is "off-label". However, this can be appropriate if the clinical needs outweigh the risks and is permissible under the MHRA guidelines (1). One of the aims of this info sheet is to help MR users to better understand some of the MR safety risks in these situations so they are better informed to make an appropriate decision. While device manufacturers cannot condone off-label use, they may be able to advise on device specific hazards which could inform a local risk-benefit analysis.

**Spatial field gradient limit**

The spatial field gradient (SFG) is a predictor of the translational force on a device. Implants are commonly labelled with an SFG limit. Prior to the 2015 revision of the ASTM F2052 standard for testing of translational force, results were typically reported at the tested field strength and SFG, without any indication of the safety margin. Essentially, the results were prone to highlight the limits of safety testing, not the limits of MR safety per se. Many devices are labelled with an SFG limit of 720 G/cm (7.2 T/m) which corresponds to achieving a pass when tested on a particular MRI system which was used for numerous tests. The introduction of an extrapolated SFG since 2015 avoids this limitation and provides a more helpful indicator of MR safety. Cylindrical MRI equipment typically has its maximum SFG located significantly "off-axis" and therefore it would be unusual for an implant to be exposed to a scanner's maximum SFG.

**SAR and $B1^{+}_{rms}$**

The risk of overheating the body or a body part due to RF energy is well recognised. The specific absorption rate (SAR) therefore became an important safety limit to prevent hyperthermia. SAR is often reported as a time-average over 6 minutes which is adequate for estimation of slow temperature rises. SAR estimates also contain significant uncertainties, due to the difficulty in calculating or measuring SAR directly.
Around conductive objects, high local SAR levels may cause rapid temperature rises. For example, if a tissue around an electrode can heat significantly in 15 seconds, but the only RF measure available is a 6-minute average, then a very large safety margin is required.
$B1^{+}_{rms}$ is a measure of the RF amplitude applied by the scanner, which can be measured precisely, and is reported with a short time (10 second) average, which makes it more suitable for estimating the heating risk related to implanted devices. The lower uncertainty associated with the $B1^{+}_{rms}$ limit avoids the need for very large safety margins which may otherwise be excessively restrictive.

**Scan duration**

The continued application of RF energy will result in a continued rise in temperature. Implant labelling often specifies a 15- or 30-minute duration limit, to ensure that temperatures do not rise above what has been tested in experiments or simulations.

There is potentially large uncertainty associated with longer scan durations. However, methods of mitigating heating include interleaving high and low SAR sequences, or adding pauses between sequences.

1. MHRA - Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, Feb 2021



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