MR Safety advice 2022

The fourth edition of the International Electrotechnical Commission (IEC) standard 60601-2-33:2022

This year will see the publication of the fourth edition of the International Electrotechnical Commission (IEC) standard 60601-2-33:2022, replacing the third edition published in 2010 and updated in 2013 and 2015. The IEC 60601 standard has become a requirement for the commercialisation of electrical medical equipment in many countries. Part 2-33 is the *"Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.* There are numerous changes between the third and fourth editions and a few of the major differences are described here[1]:

1. MR Equipment Output Conditioning (MROC) is introduced as mandatory functionality at 1.5 T and 3 T which allows the MR operator to specify certain output limits of the MR system, e.g., RF transmit coil type, RF polarisation, maximum B_{1+RMS} and maximum gradient slew rate (per axis), in line with the MR-Conditional labelling of many implants[2].
2. The Specific Absorbed Energy (SAE) limit is eliminated. The SAE defined an arbitrary hard limit, i.e., an automatic system stop, of 4 W/kg for 60 minutes = 240 W min/kg. Due to the use of interventional MRI a hard limit was strongly discouraged by the US FDA. MR manufacturers will still post a warning when a chosen Specific Absorption (SA), now calculated from the whole -body SAR, is reached, but it will no longer stop the system.
3. The MR system 'About function' has been upgraded. It displays the MR system model name, the B_0 field strength and the software version. In addition, it should also display or provide access to a location containing the maximum spatial field gradient (T/m) outside the fixed covers of the magnet, the maximum gradient amplitude achievable (mT/m) and the maximum gradient slew rate (T/m/s) for each gradient axis.
4. The extent of the B_0 Hazard Area (MR Environment) around the magnet is now defined to be 0.9 mT rather than the 0.5 mT in the previous editions. However, the MHRA's limit of 0.5 mT is enshrined in the Control of Electromagnetic Fields at Work (CEMFAW) Regulations 2016, that cites the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines on the limits of exposure to static magnetic fields 2009 that recommends a 0.5 mT limit for the protection of medical devices. Therefore, there will have to be a change in the ICNIRP guidelines or a change in the CEMFAW legislation for the UK to adopt 0.9 mT rather than 0.5 mT for the extent of the MR Environment.
5. The manufacturers will expand their Compatibility Technical Specification Sheet (CTSS) to include more information characterising the MR system that may be useful when evaluating third party devices and to assess the exposure to electromagnetic field for both patients and workers. Examples include adding B_0 isocontour and spatial field gradient contour plots, as well as the spatial distribution of the gradient system and RF B_1 field outputs.

Note that once published, the regulators typically allow a 2–3-year window before the changes in the standard are typically implemented.

[1] With the kind assistance of Dr Michael Steckner, Canon Medical Research USA

[2] Some people may remember the Fixed Parameter Option:Basic (FPO:B) concept published in 2015, for 1.5 T. However, this was only adopted by a few implant vendors and no MR manufacturer. MROC is based upon the principles developed for FPO:B.

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