BS EN IEC 60601-2-33:2024

BSI Standards Publication

Medical electrical equipment

Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

bsi.

National foreword

This British Standard is the UK implementation of EN IEC 60601-2-33:2024. It is identical to IEC 60601-2-33:2022, incorporating corrigendum May 2023. It supersedes BS EN 60601-2-33:2010+A12:2016, which will be withdrawn on 20 September 2027.

BSI, as a member of CEN, is obliged to publish EN IEC 60601-2-33:2022 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval.

The previous edition of IEC 60601-2-33 defined a CONTROLLED ACCESS AREA to control exposure of individuals with medical implants. This included a magnetic field limit of 0.5 mT to provide an adequate safety margin for implants that still use a reed switch or Hall effect switch for control of patient therapy, referencing EN 45502-2-1, which requires cardiac pacemakers to be unaffected by static magnetic fields of flux density of up to 1 mT.

This version of IEC 60601-2-33 replaces the CONTROLLED ACCESS AREA with a new term, the B0 HAZARD AREA, with a relaxed magnetic field limit of 0.9 mT that more closely aligns with the limit in other medical device standards (especially that for pacemakers, ISO 14177).

The UK committee has concerns about the lack of evidence presented in the standard to demonstrate that a relaxation from 0.5 mT to 0.9 mT is appropriate for all medical implants, since the only international standards prescribing medical devices to be unaffected by static magnetic fields of flux density of up to 1 mT (± 0.1 mT) are for cardiac pacemakers and ICDs (e.g. ISO 14117).

The UK committee would also like to draw attention to the additional legal requirements in the UK for employers under The Health and Safety Statutory Instrument 2016 No. 588, which lays down legislative requirements regarding the control of electromagnetic fields at work regulations in Great Britain; similar legislation (Statutory Rule 2016 No. 266) covers Northern Ireland. These are part of the UK's implementation of Directive 2013/35/EU. This legislation includes an Action Level of 0.5 mT, above which employers in the UK are required to make a suitable and sufficient assessment of the risks to employees arising from their exposure to electromagnetic fields and subsequently eliminate or reduce to a minimum, so far as is reasonably practicable, the risks identified in the most recent risk assessment. This risk assessment must include consideration of Action Levels as well as multiple other factors, including other health and safety related information.

The UK participation in its preparation was entrusted to Technical Committee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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