

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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

**Appareils électromédicaux –
Partie 2-33: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils à résonance magnétique utilisés pour le diagnostic
médical**



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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62B/977/FDIS	62B/987/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION TO AMENDMENT 2

This Amendment 2 has been developed to increase the FIRST LEVEL CONTROLLED OPERATING MODE limit for the static field from 4 T to 8 T taking into account FDA, ICNIRP and other peer reviewed scientific literature. In addition, a non-compulsory option, FIXED PARAMETER OPTION: BASIC (FPO: B), is introduced to limit RF and gradient field outputs (peak and RMS) for scanning PATIENTS with MR conditional implants. Consequently, text is proposed for the Instructions for use to guide users in scanning PATIENTS with MR conditional implants.

Furthermore, references to newly published collateral standards have been updated.

201.1.3 Collateral standards

Replace, in the first sentence of the second paragraph, the reference to "IEC 60601-1-2:2007" with "IEC 60601-1-2:2014".

201.2 Normative references

Replace, under "Replacement", the reference to "IEC 60601-1-2:2007" with the following: