

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**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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## CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards .....	8
201.2 Normative references.....	9
201.3 Terms and definitions.....	10
201.4 General requirements .....	15
201.5 General requirements for testing of ME EQUIPMENT .....	15
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	15
201.7 ME EQUIPMENT identification, marking and documents .....	16
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	27
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	28
201.10 Protection against unwanted and excessive radiation HAZARDS.....	28
201.11 Protection against excessive temperatures and other HAZARDS.....	28
201.12 Accuracy of controls and instruments and protection against hazardous outputs .....	29
201.13 HAZARDOUS SITUATIONS and fault conditions .....	47
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS).....	47
201.15 Construction of ME EQUIPMENT.....	47
201.16 ME SYSTEMS .....	47
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....	47
202 Electromagnetic compatibility – Requirements and tests .....	48
Annexes .....	48
Annex D (informative) Symbols on marking.....	49
Annex AA (informative) Particular guidance and rationale.....	51
Bibliography.....	96
Index of defined terms used in this particular standard.....	104
Figure 201.101 – Gradient waveform and EFFECTIVE STIMULUS DURATION .....	11
Figure 201.102 – Limits for cardiac and peripheral nerve stimulation .....	33
Figure 201.103 – Reduction of WHOLE BODY SAR limits at high temperatures.....	37
Figure 201.104 – Volume for determining the spatial maximum of gradient output .....	43
Figure 201.105 – Volume for determining the $B_1$ stray field .....	46
Figure 201.D.101 – Signs indicating a transmit only RF coil, transmit / receive RF coil and a receive only RF coil.....	50
Figure AA.1 – Static magnetic fields: flow potentials and retardation.....	68
Figure AA.2 – Experimental data on PNS threshold of human volunteers in WHOLE BODY MR EQUIPMENT.....	83
Figure AA.3 – Double logarithmic plot of experimental threshold values for peripheral nerve stimulation .....	84
Figure AA.4 – Response value $R(t)$ generated by convolution of a rectangular stimulus $dB/dt$ and a nerve impulse response function $n(t-\theta)$ .....	88
Figure AA.5 – Gradient waveform $G$ , stimulus waveform $dB/dt$ and response value $R$ , for a trapezoid EPI waveform starting at $t = 0$ .....	89

Figure AA.6 – Threshold values $dB/dt$ for two gradient waveforms, plotted against EFFECTIVE STIMULUS DURATION .....	89
Figure AA.7 – Threshold value of $dB/dt$ for a sinusoid gradient waveform, as function of the number of half periods in the waveform.....	90
Figure AA.8 – SAR limits for the exposed mass of a PATIENT.....	93
Table 201.101 – List of symbols.....	15
Table 201.102 – Rheobase values per type of gradient system.....	32
Table 201.103 – Weight factors for summation of the maximum output $O_j$ per GRADIENT UNIT .....	34
Table 201.104 – Temperature limits.....	34
Table 201.105 – SAR limits for volume transmit coils .....	35
Table 201.106 – SAR limits for local transmit coils .....	36
Table 201.D.101 – Examples of warning signs and prohibitive signs).....	49
Table AA.1 – Static field occupational standards.....	67

Withdrawing

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International standard IEC 60601-2-33 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2002, its Amendment 1 (2005) and Amendment 2 (2007) and constitutes a technical revision. This third edition of IEC 60601-2-33 is based on the second amendment to Edition 2. It has also been adapted to the third edition of IEC 60601-1 (2005), with technical modifications being introduced where appropriate.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62B/777/FDIS	62B/782/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references, in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website.

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.

The contents of the corrigenda 1 (March 2012) and 2 (February 2016) have been included in this copy.

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Withdrawn

## \* INTRODUCTION

This particular standard is written at a moment in which the technical evolution of MR EQUIPMENT is in rapid progress and the scientific foundation of its safe use is still expanding.

This International Standard addresses technical aspects of the medical diagnostic MR SYSTEM and the MR EQUIPMENT therein related to the safety of PATIENTS examined with this system, the safety of the MR WORKER involved with its operation and the safety of the MR WORKER involved with the development, manufacturing, installation, and servicing of the MR SYSTEM. Where limits of electromagnetic fields (EMF) exposure of PATIENTS and MR WORKERS are stated, these limits do not imply that such levels of exposure can be assumed to be acceptable for workers in other professional settings and for the population at large. The limits provide a sensible balance between RISKS for the PATIENTS and MR WORKERS and benefits for the PATIENTS.

Organizational aspects of safety are the task of the RESPONSIBLE ORGANIZATION. This task includes adequate training of staff, rules of access to the MR SYSTEM, qualification of staff for decisions that are related to safety, definition of medical responsibility and specific requirements for personnel following from that responsibility when the PATIENT is in or near the MR SYSTEM.

Examples of such organizational aspects are:

- operation in FIRST LEVEL CONTROLLED OPERATING MODE;
- emergency procedures for resuscitation of the PATIENT who is in the MR SYSTEM;
- emergency procedures after a QUENCH of the superconductive magnet when present;
- set-up and maintenance of a protocol for screening the PATIENT for contraindications or for conditions that may affect acceptable exposure;
- rules for ROUTINE MONITORING and for MEDICAL SUPERVISION of the PATIENT during the exam.
- rules to minimize and to limit the exposure of MR WORKERS to EMF.

Extensive rationale is provided in Annex AA for some of the definitions and requirements in order to provide the user of this standard with a reasonably complete access to the source material that was used in support of the considerations during drafting.

The relationship of this particular standard with IEC 60601-1 and the collateral standards is explained in subclauses 201.1.3 and 201.1.4.

The introduced EMF exposure limits required in this standard for an MR WORKER will never exceed those allowed for PATIENTS. All exposure limits allowed for a PATIENT and for an MR WORKER are expected to protect them against negative health effects and unacceptable RISKS.

For the exposure to static magnetic fields, subjective short-term physiological and sensory effects are expected. These influence the well being of the MR WORKER marginally and only during or shortly after exposure.

For the exposure to GRADIENT OUTPUT and RF transmit fields, normally no short-term physiological and sensory effects are expected for MR WORKERS.

In addition no experimental or theoretical basis for cumulative biological effects in humans, resulting from exposure at the allowed levels has been generally accepted.

The requirements for acoustic noise exposure are different for PATIENTS and MR WORKERS.