IEC 60601-2-33

Edition 3.1 2013-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

IEC 60601-2-33:2010+A1:2013

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.55

ISBN 978-2-8322-0783-3

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of IEC 60601-2-33 consists of the third edition (2010) [documents 62B/777/FDIS and 62B/782/RVD], its corrigenda 1 (March 2012) and 2 (February 2016), and its amendment 1 (2013) [documents 62B/884/CDV and 62B/904/RVC]. It bears the edition number 3.1.

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

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 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.

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 the base publication and its amendment 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

* 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.

INTRODUCTION TO AMENDMENT 1

This amendment has been published to adapt IEC 60601-2-33:2010 to the technical corrections introduced by Amendment 1 (2012) to IEC 60601-1:2005.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard [1] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MR EQUIPMENT and MR SYSTEMS, hereafter referred to also as ME EQUIPMENT.

This standard does not cover the application of MR EQUIPMENT beyond the INTENDED USE.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

The standard does not formulate ~~ESSENTIAL PERFORMANCE requirements related to~~ specific requirements for MR EQUIPMENT or ~~MR~~ SYSTEMS used in INTERVENTIONAL MR EXAMINATIONS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MR EQUIPMENT to provide protection for the PATIENT and the MR WORKER.

NOTE This standard presumes that the MR WORKERS are properly medically screened, and properly trained and instructed in their duties.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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[1] The general standard is IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 98.

Clause 2 of the general standard applies except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

NEMA MS 4:~~2006~~2010, *Acoustic noise measurement procedure for diagnostic magnetic resonance imaging (MRI) devices*

NEMA MS 8:2008, *Characterization of the specific absorption rate (SAR) for magnetic resonance imaging systems*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 +A1:2012 and the following apply:

NOTE An index of defined terms is found beginning on page 106. A list of symbols used in the document is provided in Table 201.101.

Addition:

*** 201.3.201**
B_{1+}RMS
root mean square (rms) of B_{1+}, the MR relevant radiofrequency magnetic induction

$$B_{1+\mathrm{RMS}} = \sqrt{\frac{\int_0^{t_x} (B_{1+}(t))^2 \, \mathrm{d}t}{t_x}}.$$

where t is time, and t_x is the evaluation time, and is estimated at the RF transmit coil centre.

201.3.202
COMPLIANCE VOLUME
PATIENT accessible space in which compliance of GRADIENT OUTPUT is inspected

In MR EQUIPMENT with a cylindrical WHOLE BODY MAGNET, the COMPLIANCE VOLUME is a cylinder with its axis coinciding with the magnet axis and with a radius of 0,20 m. and with a length equal to the gradient coil

In MR EQUIPMENT with a TRANSVERSE FIELD MAGNET and a WHOLE BODY GRADIENT SYSTEM, the COMPLIANCE VOLUME is a cylinder aligned with the patient's axis, of length equal to the gradient coil diameter, and a diameter of 0,40 m or equal to the distance between the poles of the magnet, whichever is less.

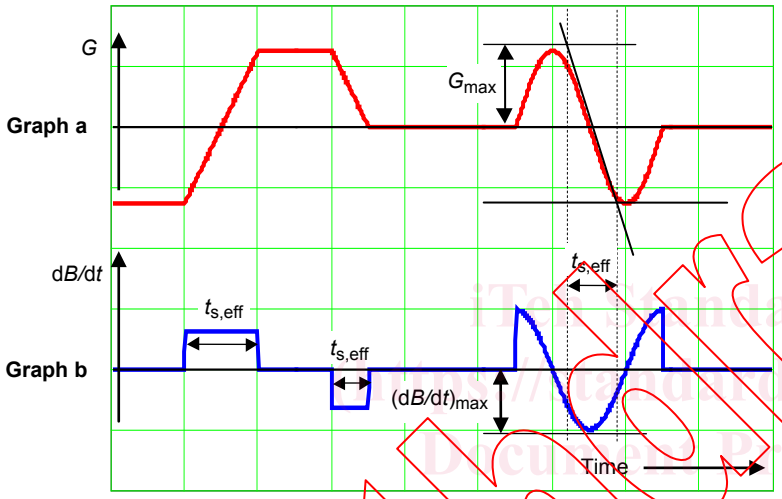
In all other MR EQUIPMENT the COMPLIANCE VOLUME is the volume where any part of a PATIENT body can be properly located according to the INTENDED USE of the MR EQUIPMENT.

201.3.203
CONTROLLED ACCESS AREA
area to which access is controlled for safety reasons

201.3.204
CORE TEMPERATURE
mean temperature of the body core

NOTE Typically equal to the rectal, sublingual, or tympanic temperature. More reliable representations of CORE TEMPERATURE are oesophageal or arterial blood temperature. Brain temperatures are CORE TEMPERATURES.

201.3.205
EFFECTIVE STIMULUS DURATION
$t_{s,eff}$
duration of any period of the monotonic increasing or decreasing gradient, used to describe its limits for cardiac or peripheral nerve stimulation, defined as the ratio of the peak-to-peak field variation and the maximum value of the time derivative of the gradient in that period (see Figure 201.101)



Graph a
G magnetic field gradient, T/m
G_{max} maximum of gradient, T/m

Graph b
dB/dt time rate of change of magnetic field, T/m/s
$(dB/dt)_{max}$ maximum of time rate of change of magnetic field, T/m/s
$t_{s,eff}$ effective stimulus duration, s

IEC 402/10

Three periods of monotonic change of the gradient G are shown in graph a. The corresponding GRADIENT OUTPUT dB/dt is shown in graph b and the EFFECTIVE STIMULUS DURATION $t_{s,eff}$ is indicated.

Figure 201.101 – Gradient waveform and EFFECTIVE STIMULUS DURATION

201.3.206
EMERGENCY FIELD SHUT DOWN UNIT
device for de-energizing a superconducting or resistive magnet in case of an emergency situation

*** 201.3.207**
ENVIRONMENTAL TEMPERATURE
temperature [°C] of a uniform (isothermal) “black” enclosure in which an occupant would exchange the same amount of heat by radiation and convection as in the actual non-uniform environment

NOTE For the calculation of the ENVIRONMENTAL TEMPERATURE see rationale in Annex AA.

201.3.208
FIRST LEVEL CONTROLLED OPERATING MODE
mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that can cause physiological stress to PATIENTS which needs to be controlled by MEDICAL SUPERVISION