ELEKTRILISED MEDITSIINISEADMED. OSA 2-33: ERINÕUDED MEDITSIINILISES DIAGNOSTIKAS KASUTATAVA MAGNETRESONANTSSEADMESTIKU ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2010 + IEC 60601-2-33:2010/A1:2013 + IEC 60601-2-33:2010/A2:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-33:2010 +A11+A1+A2+A12:2016 sisaldab Euroopa standardi EN 60601-2-33:2010 ingliskeelset teksti ja selle muudatuste A11:2011, A1:2015, A2:2015 ja A12:2016 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-33 :2010+A11+A1+A2+A12:2016 consists of the English text of the European standard EN 60601-2-33:2010 and its amendments A11:2011, A1:2015, A2:2015 and A12:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.10.2010, muudatused A11 14.10.2011, A1 22.05.2015, A2 18.09.2015 ja A12 18.11.2016.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. Date of Availability of the European standard is 15.10.2010, for A11 14.10.2011, A1 22.05.2015, A2 18.09.2015 and A12 18.11.2016.
Muudatusega A11 lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega [A11] 〈A11〉. Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega [A1] 〈A1〉. Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega [A2] 〈A2〉. Muudatusega A12 lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega [A12] 〈A12〉. Standard on kättesaadav Eesti Standardi-keskusest.	The start and finish of text introduced or altered by amendment A11 is indicated in the text by symbols [A11] 〈A11〉. The start and finish of text introduced or altered by amendment A1 is indicated in the text by symbols [A1] 〈A1〉. The start and finish of text introduced or altered by amendment A2 is indicated in the text by symbols [A2] 〈A2〉. The start and finish of text introduced or altered by amendment A12 is indicated in the text by symbols [A12] 〈A12〉. The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.55

EUROOPA STANDARD

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-33 + A11 + A1 + A2 + A12

October 2010, October 2011, May 2015, September 2015, November 2016

ICS 11.040.55

Supersedes EN 60601-2-33:2002 + A1:2005 + A2:2008

English Version

Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2010+ IEC 60601-2-33:2010/A1:2013 + IEC 60601-2-33:2010/A2:2015)

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+ IEC 60601-2-33:2010/A1:2013 + IEC 60601-2-33:2010/A2:2015)

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit von Magnetresonanzgeräten für die medizinische Diagnostik (IEC 60601-2-33:2010+ IEC 60601-2-33:2010/A1:2013 + IEC 60601-2-33:2010/A2:2015)

This European Standard was approved by CENELEC on 2010-10-01, Amendment A11 was approved by CENELEC on 2011-10-01, Amendment A1 was approved by CENELEC on 2015-04-14, Amendment A2 was approved by CENELEC on 2015-07-23 and Amendment A12 was approved by CENELEC on 2016-11-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard and its Amendments A11, A1, A2 and A12 exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 60601-2-33:2010 E + EN 60601-2-33:2010/A11:2011 E
+ EN 60601-2-33:2010/A1:2015 E + EN 60601-2-33:2010/A2:2015 E + EN 60601-2-33:2010/A12:2016 E

Foreword

The text of document 62B/777/FDIS, future edition 3 of IEC 60601-2-33, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-33 on 2010-10-01.

This European Standard supersedes EN 60601-2-33:2002 + A1:2005 + A2:2008.

This EN 60601-2-33:2010 is based on the second amendment to EN 60601-2-33:2002. It has also been adapted to EN 60601-1:2006, with technical modifications being introduced where appropriate.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-10-01

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.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-2-33:2010 was approved by CENELEC as a European Standard without any modification.

⟨A11⟩ EN 60601-2-33:2010/A11:2011 foreword

This document (EN 60601-2-33:2010/A11:2011) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-10-01
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2014-10-01

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights. ⟨A11⟩

⟨A1⟩ EN 60601-2-33:2010/A1:2015 foreword

The text of document 62B/884/CDV, future IEC 60601-2-33:2010/A1, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-33:2010/A1:2015.
The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-14

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-33:2010/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-33:2010/A1:2013 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-33:2010, the following note has to be **added** for the standard indicated:

ISO 7010:2011	NOTE	Harmonized as EN ISO 7010:2012 (not modified). 〈A1〉

〈A2〉 EN 60601-2-33:2010/A2:2015 foreword

The text of document 62B/977/FDIS, future IEC 60601-2-33:2010/A2 prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-33:2010/A2:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-04-23
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-07-23

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-33:2010/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-33:2010/A2:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-33:2010, the following note has to be **added** for the standard indicated:

IEC 62570:2014	NOTE	Harmonized as EN 62570:2015 (not modified). 〈A2〉

⟨A12⟩ EN 60601-2-33:2010/A12:2016 foreword

This document (EN 60601-2-33:2010/A12:2016) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".
The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2017-11-01
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2019-11-01

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document. ⟨A12⟩

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

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.

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.

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.

▌A1⟩ The standard does not formulate specific requirements for MR EQUIPMENT or MR SYSTEMS used in INTERVENTIONAL MR EXAMINATIONS. ⟨A1▐

The standard does not formulate ESSENTIAL PERFORMANCE requirements related to.

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.

▌A1⟩ ▌A2⟩ IEC 60601-1-2:2014 ⟨A2▐ 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. ⟨A1▐

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

201.1.4 Particular standards

Replacement:

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 112.

Clause 2 of the general standard applies except as follows:

Replacement:

[A2] IEC 60601-1-2:2014*, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests* [A2]

[A2] IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012 [A2]

Addition:

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

[A1] NEMA MS 4: 2010, *Acoustic noise measurement procedure for diagnostic magnetic resonance imaging (MRI) devices* [A1]

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 [A1] IEC 60601-1:2005+A1:2012 [A1] and the following apply:

NOTE An index of defined terms is found beginning on page 139. 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+}, [A2] *deleted* [A2]

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

where t is time, and t_x is the [A2] integration time [A2], [A2] which shall be any 10 s period over the duration of the entire sequence [A2].

[A2] Note 1 to entry: B1+ is derived from the flip angle averaged over an adjustment volume, which is typically represented by the axial central slab wherein MR signal is generated. [A2]

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