SLOVENSKI STANDARD
SIST EN IEC 60601-2-33:2024

01-november-2024

Medicinska električna oprema - 2-33. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za magnetno resonanco za medicinsko diagnostiko (IEC 60601-2-33:2022)

Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2022)

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit von Magnetresonanzgeräten für die medizinische Diagnostik (IEC 60601-2-33:2022)

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 60601-2-33:2022)

Ta slovenski standard je istoveten z: **EN IEC 60601-2-33:2024**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN IEC 60601-2-33:2024 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-33

September 2024

ICS 11.040.55

Supersedes EN 60601-2-33:2010/corrigendum Oct. 2010; EN 60601-2-33:2010; EN 60601-2-33:2010/A11:2011; EN 60601-2-33:2010/A1:2015; EN 60601-2-33:2010/A2:2015; EN 60601-2-33:2010/A12:2016; EN 60601-2-33:2010/AC:2016-03

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 60601-2-33:2022)

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 60601-2-33:2022)

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit von Magnetresonanzgeräten für die medizinische Diagnostik (IEC 60601-2-33:2022)

This European Standard was approved by CENELEC on 2022-09-08. 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 exists 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62B/1277/FDIS, future edition 4 of IEC 60601-2-33, prepared by SC 62B "Medical imaging equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-33:2024.

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) 2025-03-20
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-09-20

This document supersedes EN 60601-2-33:2010 and all of its amendments and corrigenda (if any).

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-2-33:2022 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-1-3	NOTE	Approved as EN 60601-1-3
IEC 60601-1-9	NOTE	Approved as EN 60601-1-9
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
IEC 60601-1-11	NOTE	Approved as EN 60601-1-11
IEC 60601-1-12	NOTE	Approved as EN 60601-1-12
IEC 62464-1	NOTE	Approved as EN IEC 62464-1
IEC 60364-7-710	NOTE	Approved as HD 60364-7-710
IEC 60601-2-62:2013	NOTE	Approved as EN 60601-2-62:2015 (not modified)
ISO 14630:2012	NOTE	Approved as EN ISO 14630:2012 (not modified)
ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) +A11:2021
IEC 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Annex ZA of EN 60601-1:2006[1], applies, except as follows:

Replace:

Publication	Year	Title	EN/HD	Year
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	EN 60601-1-2	2015
+ A1	2020		+ A1	2021

Add:

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
IEC 60695-11-10	2013	Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods	EN 60695-11-10	2013

[1] As impacted by EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024.

Publication	Year	Title	EN/HD	Year
IEC 61672-1	2013	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	2013
IEC 61672-2	2013	Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests	EN 61672-2	2013
IEC 62570	2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	EN 62570	2015
ISO 3746	2010	Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane	EN ISO 3746	2010
ISO 9614-1	-	Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points	EN ISO 9614-1	-
NEMA MS 4	-	Acoustic noise measurement procedure for diagnostic Magnetic Resonance Imaging (MRI) devices	-	-
NEMA MS 8	-	Characterization of the specific absorption rate (SAR) for magnetic resonance imaging systems	-	-
NEMA MS 14	-	Characterization of radiofrequency (RF) coil heating in magnetic resonance imaging systems	-	-

IEC 60601-2-33

Edition 4.0 2022-08

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ICS 11.040.55

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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IEC 60601-2-33
Edition 4.0 2022-08

MEDICAL ELECTRICAL EQUIPMENT –

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

INTERPRETATION SHEET 1

This interpretation sheet has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this interpretation sheet is based on the following documents:

DISH	Report on voting
62B/1315/DISH	62B/1319/RVDISH

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

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Definition 201.3.214 (EFFECTIVE STIMULUS DURATION $t_{s,eff}$)

The definition is clarified by the following:

a) It is important to consider that the magnetic field gradient displayed in Figure 201.101 can be realized by simultaneous activation of multiple GRADIENT UNITS.

b) The concept of $t_{s,eff}$ applies both to cardiac stimulation and peripheral nerve stimulation.

c) The appropriate timescale for evaluating the duration of monotonic increase or decrease of the GRADIENT OUTPUT is in the order of the chronaxie. When a discrete time-segment based approach is used for numerical evaluation, one or more discrete time segments deviating from monotonic increase or decrease will likely not reset $t_{s,eff}$ nor modify the likelihood of stimulation. Application of a filter as suggested in Annex AA (Formula AA.22) can prevent unintentional misinterpretation of monotonicity.

IEC 60601-2-33:2022-08/ISH1:2023-05(en)

ICS 11.040.55

Definition 201.3.219 (HEAD SAR)

Note 1 to entry is clarified as follows:

Extent of the head as provided in the note to entry represents a common understanding of medical professionals. Variation in assessment volume for HEAD SAR is acceptable for use by the MR MANUFACTURER when implementing IEC 60601-2-33. For example, these volumes could be (tilted) axial demarcations of cervical vertebrae C3, C5, or C7.

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

This fourth edition cancels and replaces the third edition published in 2010, Amendment 1:2013 and Amendment 2:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) aligned with IEC 60601-1:2005 and its two amendments IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;
b) addition of safety requirements for the EMERGENCY FIELD SHUT DOWN UNIT;
c) clarification of acoustic protection measures for the PATIENT and MR WORKER;
d) addition of noise emission declaration for exposure inside the MR EXAMINATION ROOM, to support occupational health assessment by the RESPONSIBLE ORGANIZATION;

e) addition of compliance methods for thermal safety of RF coils;

f) addition of RF transmit definitions to match MR CONDITIONAL labelling requirements for MEDICAL DEVICES;

g) clarification of requirements for MR CONDITIONAL labelling of ACCESSORIES;

h) alignment of static magnetic field limit for B_0 HAZARD area to limits in other MEDICAL DEVICE standards (especially that for pacemakers, ISO 14117), the new limit value being 0,9 mT;

i) improved description of the magnetic field related plots in the Compatibility Technical Specification Sheet (CTSS);

j) provision of compatibility sequences (in the CTSS) to test auxiliary equipment by the MR manufacturer has become optional, and is expected to be eliminated in a future edition;

k) a separate section with requirements for a site-planning document containing safety information;

l) requirements for the alerting function (PATIENT to OPERATOR);

m) introduction of MROC as mandatory functionality for 1,5 T and 3 T systems to facilitate scanning of PATIENTs with MEDICAL DEVICES labelled as MR CONDITIONAL, unless such scanning is explicitly contra-indicated by the MR MANUFACTURER;

n) RF coil symbols in Table 201.A.102 have become mandatory, and the preferred and alternate signs have been swapped relative to the previous edition, with preferred now being the sign with color;

o) determination of the B_1 stray field in 201.12.4.105.3.3 based on calculations only.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62B/1277/FDIS	62B/1284/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at http://www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the eighteen 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 and IEC 80601 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch/?ref=menu in the data related to the specific document. At this date, the document will be

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

The contents of the Interpretation Sheet 1 of May 2023 have been included in this copy.

IMPORTANT – The "colour inside" logo on the cover page of this document 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.