

ELEKTRILISED MEDITSIINISEADMED. OSA 2-33:
ERINÕUDED MEDITSIINILISES DIAGNOSTIKAS
KASUTATAVA MAGNETRESONANTSSEADMETE
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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN IEC 60601-2-33:2024 sisaldab Euroopa standardi EN IEC 60601-2-33:2024 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.09.2024.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN IEC 60601-2-33:2024 consists of the English text of the European standard EN IEC 60601-2-33:2024.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 20.09.2024.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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EN IEC 60601-2-33

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2024

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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)

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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 (dop) 2025-03-20 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2027-09-20 document have to be withdrawn

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

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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 60601-1:2006¹, applies, except as follows:

Replace:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	-	-

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
essentielle des appareils à résonance magnétique utilisés pour le diagnostic
médical**



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INTERNATIONAL STANDARD

NORME INTERNATIONALE



**Medical electrical equipment –
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of magnetic resonance equipment for medical diagnosis**

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médical**

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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

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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:

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- "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,
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* INTRODUCTION

This International Standard addresses technical aspects of medical diagnostic MR EQUIPMENT and MR SYSTEMS, necessary to ensure the safety of PATIENTS, and to address electromagnetic field (EMF) exposure concerns for MR WORKERS involved with the operation, development, manufacturing, installation, and servicing of MR EQUIPMENT and MR SYSTEMS. Annex AA provides rationales for requirements and limit values including references to peer-reviewed publications used to establish the content of this document.

Exposure limits for PATIENTS and for MR WORKERS are selected to protect them from transient adverse health effects and from unacceptable RISK. In addition, scientific consensus today is that no experimental or theoretical basis exists to expect long-term adverse health effects in humans from (repeated) EMF exposures.

Organizational aspects related to safety of operating the MR EQUIPMENT are the task of the RESPONSIBLE ORGANIZATION. This task includes, but is not limited to:

- qualification of staff for decisions that are related to safety;
- adequate training of staff;
- definition of medical responsibility; including
 - rules for screening the PATIENT for contraindications or for conditions that can affect acceptable exposure;
 - rules for ROUTINE MONITORING, and for MEDICAL SUPERVISION of the PATIENT during the MR EXAMINATION;
 - rules for access to and oversight of the MR ENVIRONMENT, and for hearing protection;
- demarcating, maintaining and controlling access to the B_0 HAZARD AREA and the MR ENVIRONMENT, including
 - screening of any person entering this environment;
 - confirming that no materials or equipment entering this environment pose a HAZARD.
- emergency procedures for (rapid) removal of the PATIENT who is in the B_0 HAZARD AREA;
- emergency procedures related to a potential QUENCH of a superconductive magnet, when applicable;
- rules to minimize and to limit the exposure of MR workers to EMF;
- establishing and ensuring adequate preventive maintenance;
- evaluation and implementation of local regulations.

This fourth edition aligns with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and the associated updates of the collateral standards.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MAGNETIC RESONANCE (MR) EQUIPMENT and MAGNETIC RESONANCE (MR) SYSTEMS.

NOTE Where ME EQUIPMENT and ME SYSTEMS are used in the clause headings, this is to be understood to indicate MR EQUIPMENT and MR SYSTEMS.

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

If a clause or subclause is specifically intended to be applicable to MR EQUIPMENT only, or to MR 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 MR EQUIPMENT and to MR SYSTEMS, as relevant.

This document does not formulate additional specific requirements for MR EQUIPMENT or MR SYSTEMS used in INTERVENTIONAL MR EXAMINATIONS.

201.1.2 Object

Replacement:

The object of this document 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 document presumes that the MR WORKERS are screened, trained and instructed in their duties.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 applies as modified in Clause 202, IEC 60601-1-3 [1], IEC 60601-1-9 [2], IEC 60601-1-10 [3], IEC 60601-1-11 [4] and IEC 60601-1-12 [5] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.