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

IEC 60601-2-33:2022-08(en-fr)

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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.

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.

* 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.

201.1.4 Particular standards

Addition:

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, viz. IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document 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 document addresses the content of Clause 4 of the 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the 60601-1-8 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 in this document.

"*Addition*" means that the text of this document 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 document.

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 3.154, additional definitions in this document 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 document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this document, 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 document.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 130.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

Replacement:

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*
IEC 60601-1-2:2014/AMD1:2020

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60695-11-10:2013, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2:2013, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 62570:2014, *Standard practice for marking devices and other items for safety in the magnetic resonance environment*

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*

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Part 1: Measurement at discrete points*

NEMA MS 4, *Acoustic noise measurement procedure for diagnostic magnetic resonance equipment*

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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 142.

Addition:

*** 201.3.201**
AMBIENT TEMPERATURE
temperature of the air flowing through the PATIENT environment

201.3.202
B_0 HAZARD AREA
space around the MR EQUIPMENT where the static magnetic field can cause HARM

Note 1 to entry: The B_0 HAZARD AREA is not identical to the SPECIAL ENVIRONMENT as defined in IEC 60601-1-2.

Note 2 to entry: The B_0 HAZARD AREA is not identical to the MR ENVIRONMENT as defined in IEC 62570.

*** 201.3.203**
B_1^+
component of the RF magnetic field in the rotating frame that is effective for tilting of the nuclear magnetization

Note 1 to entry: B_1^+ is derived from the flip angle estimated from the MR signal as detected from an adjustment volume, which is typically represented by an axial slab passing through MR ISOCENTRE.

Note 2 to entry: The spatially-localized amplitude of total B_1, especially in the off-centre position, can exceed the (spatially averaged and local) VALUE of B_1^+ by up to an order of magnitude.

201.3.204
B_1^+PEAK
maximum VALUE of B_1^+

*** 201.3.205**
B_1^+RMS
root mean square (RMS) of B_1^+, which represents the highest average VALUE for any 10 s period, evaluated over the duration of the sequence:

$$B_1^{+}\mathrm{RMS} = \sqrt{\frac{\int_0^{t_x} (B_1^{+}(t))^2 \, \mathrm{d}t}{t_x}}$$

where t is time, and t_x is the integration time

Note 1 to entry: When a sequence is shorter than 10 s, the integration time equals the sequence duration, unless sliding window continuous integration across sequences is used.

*** 201.3.206**
|dB/dt| PEAK
maximum time rate of change of the magnitude of the magnetic field generated by the combined outputs of the GRADIENT UNITS during the MR EXAMINATION, evaluated at the COMPLIANCE VOLUME

201.3.207
CIRCULARLY POLARIZED DRIVE
CP
RF excitation where the two principal electromagnetic modes of a birdcage VOLUME RF TRANSMIT COIL are driven with equal amplitude and 90° phase difference

Note 1 to entry: CIRCULARLY POLARIZED DRIVE is also commonly referred to as "quadrature drive" or "circularly polarized" and can be used interchangeably.

Note 2 to entry: CP into a loaded coil does not necessarily result in the lowest possible counter-rotating B_1^- component.

Note 3 to entry: A coil operating in CP can additionally use a single mode, linearly-polarized excitation if the exposure is infrequent, short, and does not exceed 50 % power drive for CP.

Note 4 to entry: Transverse electromagnetic (TEM) coils can be characterized as CP by using additional qualification and controls.

201.3.208
CIRCULARLY POLARIZED RF
time-varying B_1 field, where the field vector describes a circular trajectory in a plane orthogonal to the static magnetic field vector

Note 1 to entry: The polarity of the magnet determines the direction in which the generated B_1 field rotates to generate MR signals (that is, the B_1^+ component).

Note 2 to entry: A small B_1^- component (rotating in the opposite direction) is unavoidable in real-world implementations of VOLUME RF TRANSMIT COILS when using CIRCULARLY POLARIZED DRIVE. The consequence is that the generated time-varying B_1 field vector deviates slightly from the ideal circular trajectory.

201.3.209
COMPLIANCE VOLUME
space in which compliance of GRADIENT OUTPUT is inspected

Note 1 to entry: In CYLINDRICAL MR EQUIPMENT with a WHOLE BODY MAGNET, the COMPLIANCE VOLUME is a cylinder with its axis coinciding with the PATIENT's axis and with a radius of 0,20 m and with a length equal to the length of the gradient coil.

Note 2 to entry: 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 radius of 0,20 m or equal to half the distance between the poles of the magnet, whichever is less.

Note 3 to entry: In all other MR SYSTEMS, 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.

*** 201.3.210**
CORE TEMPERATURE
temperature of the internal organs in the body and the aortic blood

*** 201.3.211**
CUMULATIVE EQUIVALENT MINUTES AT 43 °C
CEM43
duration of exposure at a constant temperature of 43 °C required to produce the magnitude of a thermally induced bio-effect, i.e., an "iso-effect", as is produced by an exposure of duration t_{exam} at a different temperature T that can vary in time; defined mathematically as:

$$CEM\,43 = \int_0^{t_{\text{exam}}} R^{k(43-T(\tau))}\,\mathrm{d}\tau$$

where

k = (1 °C)$^{-1}$, a constant to render the exponent dimensionless;

$T(\tau)$ = temperature in °C during time course τ of an MR EXAMINATION;

τ = time (in min);

t_{exam} = duration (in min) of the MR EXAMINATION, including the time after the last RF exposure, during which the temperature returns to physiological baseline;

R = exponential constant: 0,25 for T < 43 °C and 0,5 for T ≥ 43 °C.

Note 1 to entry: This definition has been adapted from THERMALLY EQUIVALENT TIME, as defined in IEC 60601-2-62 [160].

Note 2 to entry: Temperature can vary throughout the body.

Note 3 to entry: CEM43 has been used in hyperthermia treatments to predict cell death as the thermally-induced bio-effect, it is not a proven metric for thermal protection.

201.3.212
CYLINDRICAL MR EQUIPMENT
MR EQUIPMENT with a substantially cylindrical PATIENT aperture, and a static magnetic field aligned with the long axis of the cylinder

Note 1 to entry: This is inclusive of elliptical PATIENT aperture equipment.

201.3.213
DETACHABLE
term qualifying an ACCESSORY fastened or otherwise secured at a specific location, and/or requiring a FUNCTIONAL CONNECTION to ME EQUIPMENT during NORMAL USE, and which can be installed and removed by the OPERATOR without the use of a TOOL

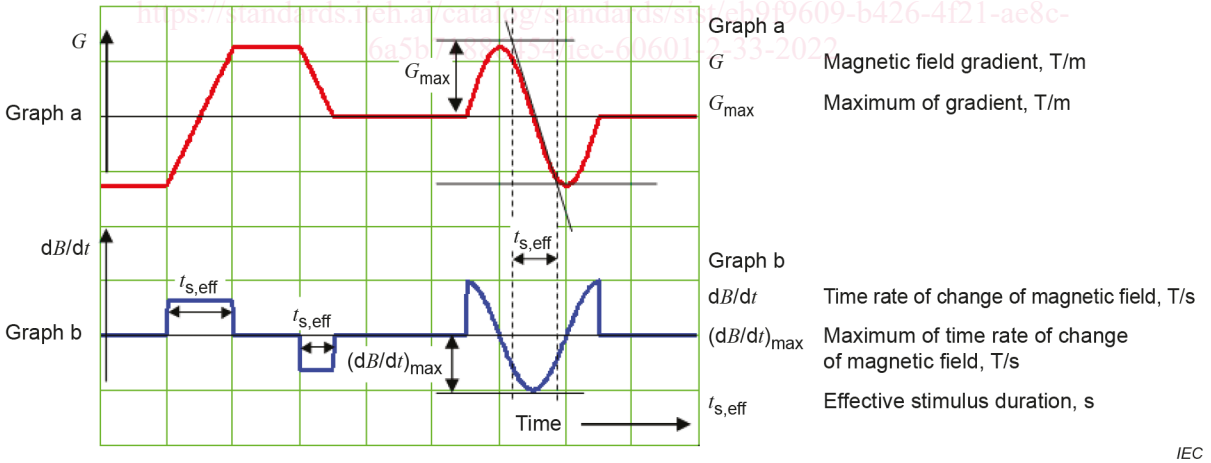
EXAMPLE 1 A VOLUME RF TRANSMIT COIL can be FIXED (integrated in the system) or a DETACHABLE ACCESSORY.

EXAMPLE 2 The squeeze bulb which is part of the PATIENT alerting function is often a DETACHABLE ACCESSORY.

EXAMPLE 3 Sensors for cardiac or respiratory triggering involve either a wired or wireless interface, which can both qualify such devices as DETACHABLE ACCESSORIES.

EXAMPLE 4 ACCESSORIES of other types of interfaces can qualify as DETACHABLE.

201.3.214
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)



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

201.3.215
EMERGENCY FIELD SHUT DOWN UNIT
subsystem enabling fast removal of the magnetic field of a superconducting or resistive magnet in case of an emergency situation