SLOVENSKI STANDARD
SIST EN 60601-2-33:2010/A2:2015

01-december-2015

Medicinska električna oprema - 2-33. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za magnetno resonanco za medicinsko diagnostiko - Dopolnilo A2

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

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit von Magnetresonanzgeräten für die medizinische Diagnostik

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

Ta slovenski standard je istoveten z: **EN 60601-2-33:2010/A2:2015**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-33:2010/A2:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-33:2010/A2

September 2015

ICS 11.040.55

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/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 medical (IEC 60601-2-33:2010/A2:2015)

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Magnetresonanzgeräten für die medizinische Diagnostik (IEC 60601-2-33:2010/A2:2015)

This amendment A2 modifies the European Standard EN 60601-2-33:2010; it was approved by CENELEC on 2015-07-23. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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, 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

European 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).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When 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.cenelec.eu

Annex ZA of EN 60601-2-33:2010 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace the existing reference to IEC 60601-1-2:2007 by the following:				
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
Addition:				
IEC 60601-1-6 +A1	2010 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6 +A1	2010 2015
IEC 60601-1-8 +A1	2006 2012	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	EN 60601-1-8 + corr. March +A1 +A1/AC	2007 2010 2013 2014

IEC 60601-2-33

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

AMENDMENT 2
AMENDEMENT 2

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

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62B/977/FDIS	62B/987/RVD

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

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.

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 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.

201.1.3 Collateral standards

Replace, in the first sentence of the second paragraph, the reference to "IEC 60601-1-2:2007" *with* "IEC 60601-1-2:2014".

201.2 Normative references

*Replace, under "Replacement", the reference to "*IEC 60601-1-2:2007" *with* the following:

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*

Add, under "Replacement", the following new references:

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

201.3 Terms and definitions

*** 201.3.201**
B_{1+}rms

Delete, in the first line of the definition, "the MR relevant radiofrequency magnetic induction".

Replace, in the last line of the definition "evaluation time" *with* "integration time".

Replace, in the last line of the definition ", and is estimated at the RF transmit coil centre" *with* ", which shall be any 10 s period over the duration of the entire sequence"

Add the following new note to entry:

Note 1 to entry: B_{1+} 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.

201.3.203
CONTROLLED ACCESS AREA

Replace the existing text of the definition with the following:

area around the MR SYSTEM, to which access is controlled to prevent HARM from the magnetic field

Note 1 to entry: The CONTROLLED ACCESS AREA is not identical to the SPECIAL ENVIRONMENT or SPECIAL LOCATION as defined in IEC 60601-1-2:2014.

201.3.234
TIME RATE OF CHANGE OF THE MAGNETIC FIELD
d*B*/d*t*

Add, at the end of the definition, the following note to entry:

Note 1 to entry: The time rate of change of the magnetic field dB/dt is assumed to be evaluated in a suitably low frequency range (e.g. < 5 kHz) to disregard effects of switching amplifier ripple.

Add the following new terms:

201.3.242
FIXED PARAMETER OPTION
FPO
option within existing modes (i.e. NORMAL OPERATING MODE or FIRST LEVEL CONTROLLED OPERATING MODE), which specifies a set of operational limit values for the allowable RF field and GRADIENT OUTPUT and the specified B_0 of the MR EQUIPMENT in a MR EXAMINATION

201.3.243
FIXED PARAMETER OPTION:BASIC
FPO:B
"basic" denotes a specific implementation of FPO, exclusively for 1,5 T MR SYSTEMS

Note 1 to entry: The note to entry in French concerning the source of the abbreviation "FPO:B" concerns the French text only.

201.3.244
$\boldsymbol{B_{1+}}$
component of the RF field in the rotating frame that is effective for tilting of the nuclear magnetization

201.3.245
$\boldsymbol{B_{1+}PEAK}$
peak amplitude of B_{1+}

*** 201.3.246**
(|d*B*/d*t*| *PEAK*)$_{FPO}$
maximum time rate of change of the magnitude of the magnetic field during the MR EXAMINATION, evaluated at the location defined for FPO, i.e. a surface providing 5 cm clearance to the outline of the PATIENT accessible volume

*** 201.3.247**
(|d*B*/d*t*| *RMS*)$_{FPO}$
root mean square (rms) of the magnitude of the time rate of change of the magnetic field for FPO

$$(|\frac{dB}{dt}|RMS)_{FPO} = \sqrt{\frac{\int_0^{t_x}\left(|\frac{dB_{FPO}}{dt}|\right)^2 d\tau}{t_x}}$$

Where t is time, and t_x is the integration time. dB_{FPO}/dt is a conservative model estimate of the magnetic field associated with the switching gradients

201.3.248
SLEW PERCENTAGE
fraction of time that any gradient is slewing at any rate

201.3.249
CIRCULARLY POLARIZED RF
RF excitation where the two principal electromagnetic modes of the VOLUME RF TRANSMIT COIL are driven with equal amplitude and 90° phase difference

Note 1 to entry: This drive operation is denoted as "CP" on user interfaces and in ACCOMPANYING DOCUMENTS.

Note 2 to entry: Circularly polarized RF is also commonly referred to as quadrature drive

*** 201.3.250**
SPATIAL FIELD GRADIENT
SFG
spatial rate of change of the main magnetic field $\left|\nabla\left|\vec{B}\right|\right|$, expressed in [T/m]

Note 1 to entry: Attractive magnetic forces on magnetisable or saturated ferromagnetic objects scale linearly with SFG.

Note 2 to entry: The note to entry in French concerning the source of the abbreviation "SFG" concerns the French text only.

Table 201.101 – List of symbols

Replace the existing title with the following:

Table 201.101 – List of symbols and abbreviations

201.7 ME EQUIPMENT identification, marking and documents

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.13 Physiological effects (safety signs and warning statements)

*Replace, in the first sentence of the first paragraph, "*ISO 7010-W005 and ISO 7010-W006*" with "*ISO 7010-W005 (see Table 201.D.101, safety sign 1) and ISO 7010-W006 (see Table 201.D.101, safety sign 2)"

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

*** 201.7.9.2.101 Instructions for use for MR EQUIPMENT**

* d) Exposure of the PATIENT and MR WORKER to excessive acoustic noise

Add, at the end of the only sentence in Note 1, "(see Table 201.D.101, safety sign 6)"

* f) Liquid and gaseous cryogens

Add, between the first and second bullet points under the last dash, the following new note:

NOTE Applicable safety signs ISO 7010-M004 (see Table 201.D.101, safety sign 7) and ISO 7010-M009 (see Table 201.D.101, safety sign 8) are appropriate for placement near the location where the cryogen refill is performed.

* h) Exposure of the PATIENT and MR WORKER to the static magnetic field

Replace, in the 4th dash, "4 T" with "8 T".

Replace, in the 8th dash, "4 T" with "8 T".

* t) Scanning of PATIENTs with active or passive implants.

Replace the entire text of this item with the following:

The instructions for use shall declare that MR scanning is contra-indicated for PATIENTS with implants, the exception being PATIENTS with known MR safe or MR conditional implants that can be scanned according to the conditions specified in the implant labelling. The instructions for use shall describe the following RISKS associated with the scanning of PATIENTS with active or passive implants containing metal or other magnetic and/or electrically conductive materials:

– the electromagnetic fields might exert strong forces on such implants;
– the electromagnetic fields might interfere with the operation of active devices;
– the implants might cause significant artefacts in the MR image;

– MR scanning when an implant is present might cause HARM such as internal heating that results in tissue damage, loss of physiologic function and serious injury.

The instructions for use shall also address the following related to MR scanning of PATIENTS with MR conditional implants:

– the MR scan should only be conducted based on the result of a risk versus benefit assessment by the RESPONSIBLE ORGANIZATION;

– the MR OPERATOR shall adhere to the conditions of use defined in the MR conditional implant labelling as described in the ACCOMPANYING DOCUMENTS of the implant MANUFACTURER;

– the instructions for use shall include a statement to explain the roles and responsibilities of the MR MANUFACTURER, the implant MANUFACTURER and the MR OPERATOR in scanning of PATIENTS with MR conditional implants.

NOTE 8 Sample text is provided in Annex AA

w) About function

Replace the existing text of the second dash by the following:

– Maximum SPATIAL FIELD GRADIENT of the static magnetic field [T/m] outside the FIXED magnet covers

NOTE Historical labeling practice for MR conditional devices uses G/cm where 1 T/m is equivalent to 100 G/cm. Providing the conversion factor and/or the quantities in both units may be appropriate.

Add, after the second dash, the following new dash:

– Maximum spatial encoding gradient amplitude [mT/m] and maximum slew rate [T/m/s], both specified on a per axis basis

Replace the final dash with the following:

– Maximum combined GRADIENT OUTPUT [T/s] on a cylinder with a diameter of 0,2 m, 0,4 m and bore-diameter minus 0,1 m

Add, at the end of subclause 201.7.9.2.101, the following new item:

x) FPO (FIXED PARAMETER OPTION)

If the system has FPO capabilities, the following information shall be given:

– a statement that FPO limits the gradient and RF output in terms of dB/dt and B_{1+};

– a statement that FPO requires OPERATOR activation;

– instructions on how to activate FPO;

– a statement that FPO limits may be part of MR conditional medical device labelling and that other scanning limits and/or PATIENT preparation may be required in addition to FPO to fully comply with the implant device MR conditional labelling;

– a statement that FPO does not alter previously established operating modes, i.e. FPO can work in NORMAL OPERATING MODE and FIRST LEVEL CONTROLLED OPERATING MODE;

– a statement indicating that FPO is for use with devices that have MR conditional labelling that specifies FPO and the use of FPO when scanning PATIENTS with medical devices that do not have FPO labelling is potentially hazardous and may cause serious injury or death.

201.7.9.3 Technical description

201.7.9.3.101 Technical description of MR EQUIPMENT

a) CONTROLLED ACCESS AREA

Replace this subtitle as follows:

a) CONTROLLED ACCESS AREA and SPECIAL ENVIRONMENT

Replace, in the first paragraph, "permanently attached" *with* "FIXED magnet".

Delete, *in the same paragraph,* "and/or an electromagnetic interference level that does not comply with IEC 60601-1-2, ".

Add, at the end of the first dash, " the static magnetic fringe field strength shall not exceed 0,5 mT;"

Delete existing items 1) and 2).

*Add, in the third dash, before the words "*magnetic fields*", the word* "static".

Add, after the third dash, the following new paragraph:

For those parts of the MR EQUIPMENT that require installation in a SPECIAL ENVIRONMENT, to ensure compliance with IEC 60601-1-2:2014, the technical description shall describe the need for adequate RF shielding, including the presence of an RF door switch and interlock mechanism preventing undue RF emissions and immunity.

Add, after the new paragraph, the following new note:

NOTE 5 See also 202.5.2.2.2

* b) Compatibility technical specification sheet

Replace, in the third bullet under the first dash, the existing text of the first sentence with the following:

"The position in locations outside the FIXED magnet covers where SPATIAL FIELD GRADIENT (SFG) is maximum, and the values of B_0 and the SFG at that location."

Replace, in the fourth bullet under the first dash, the existing text of the first sentence with the following:

"The position in locations outside the FIXED magnet covers where the product of the magnitude of the static magnetic field B_0 and the SFG is maximum and the value of B_0 and SFG at that location."

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

201.9.8 HAZARDS associated with support systems

Replace the existing title of this subclause with the following:

201.9.8 MECHANICAL HAZARDS associated with support systems

Add the following new subclause:

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.3 Dynamic forces due to loading from persons

Addition:

Where it is determined that the dynamic loading test of the general standard applies, the following provides an alternative means of compliance.