ICS 11.040.55 SLOVENSKÁ TECHNICKÁ NORMA Marec 2016

STN	**Zdravotnícke elektrické prístroje. Časť 2-33: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti prístrojov magnetickej rezonancie na zdravotnícku diagnostiku. Zmena A2**	**STN EN 60601-2-33/A2** 36 4800

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/16

STN EN 60601-2-33 z januára 2012 sa bez zmeny A2 môže používať do 23. 07. 2018.

Obsahuje: EN 60601-2-33:2010/A2:2015, IEC 60601-2-33:2010/AMD2:2015

122366

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

Edition 3.0 2015-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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

IEC 60601-2-33:2010-03/AMD2:2015-06(en-fr)

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IEC 60601-2-33

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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

ICS 11.040.55

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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.

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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