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RATIFICACIÓN DE DOCUMENTOS EUROPEOS FEBRERO 2011

HOJA DE ANUNCIO

En cumplimiento del punto 11.2.6.4 de las Reglas Internas de CEN/CENELEC Parte 2, se ha otorgado el rango de norma española al Documento Europeo siguiente:

Documento Europeo	Título	Fecha de Disponibilidad
EN 60601-2-33:2010	Equipos electromédicos. Parte 2-33: Requisitos particulares para la seguridad básica y características de funcionamiento esencial de los equipos de resonancia magnética para diagnóstico médico. (Ratificada por AENOR en febrero de 2011.)	2010-10-15

Este anuncio causará efecto a partir del primer día del mes siguiente al de su publicación en la revista UNE. La correspondiente versión oficial de este documento se encuentra disponible en la sede de AENOR, Calle Génova 6, 28004 MADRID.

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN 60601-2-33

October 2010

Supersedes EN 60601-2-33:2002 + A1:2005 + A2:2008

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)

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 (CEI 60601-2-33:2010) Medizinische elektrische Geräte -Teil 2-33: Besondere Festlegungen für die Sicherheit von Magnetresonanzgeräten für die medizinische Diagnostik (IEC 60601-2-33:2010)

This European Standard was approved by CENELEC on 2010-10-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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CENELEC

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

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Ref. No. EN 60601-2-33:2010 E

Foreword

The text of document 62B/777/FDIS, future edition 3 of IEC 60601-2-33, 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 was approved by CENELEC as EN 60601-2-33 on 2010-10-01.

This European Standard supersedes EN 60601-2-33:2002 + A1:2005 + A2:2008.

This EN 60601-2-33:2010 is based on the second amendment to EN 60601-2-33:2002. It has also been adapted to EN 60601-1:2006, with technical modifications being introduced where appropriate.

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

The following dates were fixed:

-	latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-07-01
-	latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-10-01

In this standard, 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- "clause" means one of the seventeen 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 standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- "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.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

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Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-33:2010 was approved by CENELEC as a European Standard without any modification.

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Clause 2 of the general standard applies except as follows:

Publication	<u>Year</u>	Title	<u>EN/HD</u>	<u>Year</u>
Replacement:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
Addition:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
NEMA MS 4	2006	Acoustic noise measurement procedure for diagnostic magnetic resonance imaging (MRI) devices	-	-
NEMA MS 8	2008	Characterization of the specific absorption rate (SAR) for magnetic resonance imaging systems	-	-

Annex ZZ

(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC with the exception of ERs 3, 4, 7.1 and 12.1.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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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

- 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 for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-33 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2002, its Amendment 1 (2005) and Amendment 2 (2007) and constitutes a technical revision. This third edition of IEC 60601-2-33 is based on the second amendment to Edition 2. It has also been adapted to the third edition of IEC 60601-1 (2005), with technical modifications being introduced where appropriate.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62B/777/FDIS	62B/782/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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A list of all parts of the IEC 60601 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 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.

The contents of the corrigendum of March 2012 have been included in this copy.

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