Nederlandse

norm

NEN-EN-IEC 60601-2-33 (en; fr)

Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2002,IDT)

november 2002
ICS 11.040.55

Vervangt NEN 10601-2-33:1995; NEN 10601-2-33:1995/A11:1997

Als Nederlandse norm is aanvaard:
- EN 60602-2-33:2002,IDT
- IEC 60601-2-33:2002,IDT

Normcommissie 301 062 "Medische elektrische toestellen"

NEN

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Nederlands voorwoord

Voor de in deze norm vermelde normatieve verwijzingen bestaan in Nederland de volgende equivalenten:

vermelde norm	Nederlandse norm	titel
IEC 60601-1:1988	NEN 10601-1:1990	Veiligheid van medisch-elektrische toestellen - Deel 1: Algemene eisen (en,fr)
IEC 60601-1-1:2000	NEN-EN-IEC 60601-1-1:2001	Medische elektrische toestellen - Deel 1-1: Algemene veiligheidseisen - Secundaire norm: Veiligheidseisen voor medische elektrische systemen (en,fr)
IEC 60601-1-4:1996	NEN 10601-1-4:1996	Medische elektrische toestellen - Deel 1: Algemene veiligheidseisen - Sectie 4: Secundaire norm: Programmeerbare elektrische medische systemen (en)

EUROPEAN STANDARD **EN 60601-2-33**

NORME EUROPÉENNE

EUROPÄISCHE NORM October 2002

ICS 11.040.55 Supersedes EN 60601-2-33:1995 + A11:1997

English version

Medical electrical equipment
Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
(IEC 60601-2-33:2002)

Appareils électromédicaux
Partie 2-33: Règles particulières
de sécurité relatives aux appareils
à résonance magnétique
pour diagnostic médical
(CEI 60601-2-33:2002)

Medizinische elektrische Geräte
Teil 2-33: Besondere Festlegungen für die
Sicherheit von Magnetresonanzgeräten
für die medizinische Diagnostik
(IEC 60601-2-33:2002)

This European Standard was approved by CENELEC on 2002-07-01. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-2-33:2002 E

Foreword

The text of document 62B/462/FDIS, future edition 2 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 2002-07-01.

This European Standard supersedes EN 60601-2-33:1995 + A11:1997.

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)	2003-05-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2005-07-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA, BB and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

In this standard, the following print types are used:
– requirements, compliance with which can be tested, and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: smaller roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS STANDARD OR IN IEC 60788: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-33:2002 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Replacement in annex ZA of EN 60601-1:1990/A2:1995				
IEC 60601-1-2	2001	Medical electrical equipment Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001
Addition to annex ZA of EN 60601-1:1990/A2:1995				
IEC 60651	1979	Sound level meters	EN 60651	1994
A1	1993		A1	1994
A2	2000		A2	2001
IEC 60788	1984	Medical radiology - Terminology	-	-
IEC 60804	2000	Integrating-averaging sound level meters	EN 60804	2000
ISO 1999	1990	Acoustics - Determination of occupational noise exposure and estimation of noise-induced hearing impairment	-	-

Annex ZB
(normative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995				
ISO 3864	- [1)]	Safety colours and safety signs	-	-
ISO 7731 (mod.)	1986	Danger signals for work places - Auditory danger signals	EN 457 [2)]	1992

1) Undated reference.

2) The title of EN 457 reads “Safety of machinery – Auditory danger signals – General requirements, design and testing”

INTERNATIONAL STANDARD

IEC 60601-2-33

Second edition
2002-05

Medical electrical equipment –

Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

Appareils électromédicaux –

Partie 2-33: Règles particulières de sécurité relatives aux appareils à résonance magnétique pour diagnostic médical

Reference number
IEC 60601-2-33:2002(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-33 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1995 and constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62B/462/FDIS	62B/467/RVD

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

Annexes AA and BB are for information only.

NEN
CONNECT

ALTIJD DE ACTUELE NORM IN UW BEZIT HEBBEN?

Nooit meer zoeken in de systemen en uzelf de vraag stellen: ‘Is NEN-EN-IEC 60601-2-33:2002 en;fr de laatste versie?’

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