SLOVENSKI STANDARD

SIST EN 60601-2-33:1998

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Medical electrical equipment - Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:1995)

ICS 11.040.50

Referenčna številka
SIST EN 60601-2-33:1998(en)

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN 60601-2-33

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Descriptors: Medical electrical equipment, magnetic resonance equipment, magnetic resonance examination, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
(IEC 601-2-33:1995)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité relatives aux appareils à résonance magnétique pour diagnostic médical
(CEI 601-2-33:1995)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von medizinischen diagnostischen Magnetresonanzgeräten
(IEC 601-2-33:1995)

This European Standard was approved by CENELEC on 1995-09-20. 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, 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

Foreword

The text of document 62B/240/DIS, future edition 1 of IEC 601-2-33, 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 1995-09-20.

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) 1996-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-07-01

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

Endorsement notice

The text of the International Standard IEC 601-2-33:1995 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
Addition to annex ZA of EN 60601-1:1990/A11:1993:				
IEC 601-1	1988	Medical electrical equipment	EN 60601-1	1990
A1	1991	Part 1: General requirements for safety	A1	1993
			A11	1993
			A12	1993
			+ corr. July	1994
A2	1995		A2[1]	1995
IEC 601-1-1	1992	1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 651	1979	Sound level meters	EN 60651	1994
IEC 788	1984	Medical radiology Terminology	HD 501 S1	1988
IEC 804	1985	Integrating-averaging sound level meters	EN 60804[2]	1994
ISO 1999	1990	Acoustics Determination of occupational noise exposure and evaluation of noise-induced hearing impairment	-	-

1) EN 60601-1:1990/A2 includes the corrigendum June 1995 to IEC 601:1988/A2.

2) EN 60804 includes A1:1989 to IEC 804.

Annex ZB (normative)

Normative references to international publications with their corresponding European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1980/A11:1993:				
IEC 950 (mod)	1991	Safety of information technology equipment, including electrical business equipment	EN 60950	1992
ISO 7731	1986	Danger signals for work places Auditory danger signals	-	-

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

Medical electrical equipment –

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

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SECTION TEN: CONSTRUCTIONAL REQUIREMENTS

Clause

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: 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 cooperation 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, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

International Standard IEC 601-2-33 has been prepared by sub-committee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

DIS	Report on voting
62B/240/DIS	62B/268/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.

Annex CC forms an integral part of this Particular Standard.

Annexes AA and BB are for information only.

In this Particular Standard, the following print types are used:

– Requirements, compliances with which can be tested and definitions: in roman type;

– Explanations, advice, introductions, general statements and references: in smaller type;

– *Test specifications: in italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN IEC 788 OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS (SEE ANNEX CC).

INTRODUCTION

This Particular Standard is written at a moment in which the technical evolution of MAGNETIC RESONANCE EQUIPMENT is in rapid progress and the scientific foundation of its safe use is still expanding.

Extensive rationale is provided for some of the definitions and requirements in order to provide the user of this standard with a reasonably complete access to the source material that was used in support of the considerations during drafting.

The relationship of this Particular Standard with IEC 601-1 (including the amendments) and the Collateral Standards is explained in 1.3.

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 *Scope*

Addition:

This Particular Standard applies to MAGNETIC RESONANCE EQUIPMENT as defined in 2.2.101.

This Standard does not cover MAGNETIC RESONANCE EQUIPMENT intended for use in medical research.

1.2 *Object*

Replacement:

This Particular Standard establishes requirements for the safety of MAGNETIC RESONANCE EQUIPMENT to provide protection for the PATIENT, the OPERATOR, staff associated with MAGNETIC RESONANCE EQUIPMENT and the general public. It also provides methods for demonstrating compliance with those requirements.

1.3 *Particular Standards*

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendments 1 and 2 and IEC 601-1-1: 1992, *Medical electrical equipment – Part 1: General requirements for safety, 1. Collateral Standard: Safety requirements for medical electrical systems.*

For brevity, IEC 601-1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)", and IEC 601-1-1 as the "Collateral Standard".

The term "this Standard" covers this Particular Standard, used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. 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 is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standards are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk *. These rationales can be found in an informative annex BB. Annex BB is not part of this Particular Standard and only gives additional information; it can never be the subject of testing.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or the Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or the Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or the Collateral Standard takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.2 *EQUIPMENT TYPES (classification)*

2.2.101 *MAGNETIC RESONANCE EQUIPMENT*

In medical diagnosis, MEDICAL ELECTRICAL EQUIPMENT which is intended for in-vivo MAGNETIC RESONANCE EXAMINATION.

2.2.102 *MAGNETIC RESONANCE SYSTEM*

Ensemble of MAGNETIC RESONANCE EQUIPMENT, ACCESSORIES, energy supplies, and installation facilities.

2.10 *Operation of* EQUIPMENT

2.10.101 *NORMAL OPERATING MODE*

Mode of operation of MAGNETIC RESONANCE EQUIPMENT, in which all operating parameters are within recommended limits for protection against SAFETY HAZARDS during a MAGNETIC RESONANCE EXAMINATION, and in which performance requires only ROUTINE MONITORING to prevent SAFETY HAZARDS to the PATIENT.

2.10.102 *FIRST LEVEL CONTROLLED OPERATING MODE*

Mode of operation of MAGNETIC RESONANCE EQUIPMENT in which some operating parameters reach values that may cause undue physiological stress to PATIENTS.

2.10.103 *SECOND LEVEL CONTROLLED OPERATING MODE*

Mode of operation of MAGNETIC RESONANCE EQUIPMENT in which some operating parameters reach values that may produce significant risk for PATIENTS.

* 2.10.104 *SCAN DURATION*

Period of time from the beginning to the end of acquisition of data by the MAGNETIC RESONANCE EQUIPMENT, without OPERATOR intervention.

* 2.10.105 *MAGNETIC RESONANCE EXAMINATION*

Process of acquiring MAGNETIC RESONANCE data from a PATIENT during one session when the PATIENT is within the magnet's bore.

2.11 *Mechanical safety*

2.11.101 *CONTROLLED ACCESS AREA*

Area to which access is controlled for safety reasons.

2.11.102 *EMERGENCY FIELD SHUT-DOWN UNIT*

MAGNETIC RESONANCE EQUIPMENT equipped with resistive or superconducting magnets, device for de-energization of the magnet in case of an emergency.

2.12 *Miscellaneous*

* 2.12.101 *MAGNETIC RESONANCE*

Resonant absorption of electromagnetic energy by an ensemble of atomic nuclei situated in a magnetic field.

2.12.102 *QUENCH*

Uncontrolled transition of the electrical conductivity from a superconducting state to normal conductivity of a superconductive coil that is carrying a current, resulting in rapid boil-off of fluid cryogen.

* 2.12.103 *SPECIFIC ABSORPTION RATE (SAR)*

Radio frequency power absorbed per unit of mass of an object (W/kg).

2.12.104 *SPECIFIC ABSORBED ENERGY (SAE)*

Radio frequency energy absorbed per unit of mass of an object (J/kg).

* 2.12.105 *TIME RATE OF CHANGE OF MAGNETIC FIELD (dB/dt)*

Rate of change of the magnetic flux density with time (T/s).

2.12.106 *ROUTINE MONITORING*

Routine PATIENT monitoring which is carried out by the OPERATOR and staff of the MAGNETIC RESONANCE EQUIPMENT and consisting of audio and/or visual contact, as appropriate with the PATIENT during the MAGNETIC RESONANCE EXAMINATION.

* 2.12.107 *MEDICAL SUPERVISION*

Management of PATIENTS who may be at risk from some parameters of exposure to the MAGNETIC RESONANCE EQUIPMENT, either because of the medical condition of the PATIENT, the levels of exposure or a combination.

3 General requirements

This clause of the General Standard applies except as follows:

3.1 *Addition:*

A MAGNETIC RESONANCE EQUIPMENT shall not cause a SAFETY HAZARD to the PATIENT, the OPERATOR, staff and the general public.

Compliance is considered to be fulfilled, if the MAGNETIC RESONANCE EQUIPMENT meets the relevant requirements of this Standard.

General safety aspects of MEDICAL ELECTRICAL SYSTEMS are covered by IEC 601-1-1.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

* 6.8 *ACCOMPANYING DOCUMENTS*

6.8.1 *General*

Addition:

The ACCOMPANYING DOCUMENTS should provide sufficient information to the USER to enable him to comply with the local regulations and requirements for exposure limits appropriate to the OPERATOR, staff associated with the MAGNETIC RESONANCE EQUIPMENT, and the general public.