SLOVENSKI STANDARD
SIST EN 60601-2-33:2003

01-april-2003

Nadomešča:
SIST EN 60601-2-33:1998
SIST EN 60601-2-33:1998/A11:1998

Medicinska električna oprema - 2-33. del: Posebne varnostne zahteve za opremo za magnetno resonanco za medicinsko diagnostiko (IEC 60601-2-33:2002)

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

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

Ta slovenski standard je istoveten z: **EN 60601-2-33:2002**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-33:2003 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-33

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

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 A1 A2	1979 1993 2000	Sound level meters	EN 60651 A1 A2	1994 1994 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

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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.
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.
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.

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

The committee has decided that the contents of this publication will remain unchanged until 2005-06. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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.

The standard addresses technical aspects of the medical diagnostic MR SYSTEM and the MR EQUIPMENT therein, related to safety of PATIENTS examined with this system and personnel involved with its operation. Where limits of exposure of PATIENTS and medical staff are stated, these limits do not imply that such levels of exposure can be assumed to be acceptable for the population at large. Rather the implication is that the limits provide for the PATIENT a sensible balance between risk and benefit and for the medical staff a balanced risk, given their responsibility for the wellbeing of the PATIENT.

Organisational aspects of safety are the task of the USER. This task includes adequate training of staff, rules of access to the MR SYSTEM, qualification of staff for decisions that are related to safety, definition of medical responsibility and specific requirements for personnel following from that responsibility when the PATIENT is in or near the MR SYSTEM.

Examples of such organisational aspects are:

– operation in first controlled mode;
– emergency procedures for resuscitation of the PATIENT who is in the MR SYSTEM,
– emergency procedures after a QUENCH of the superconductive magnet when present;
– set-up and maintenance of a protocol for screening the PATIENT for contraindications or for conditions that may affect acceptable exposure;
– rules for ROUTINE MONITORING and for MEDICAL SUPERVISION of the PATIENT during the exam.

Extensive rationale is provided in Annex BB 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 60601-1 (including its amendments) and the Collateral Standards is explained in 1.3.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-33: 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 and MAGNETIC RESONANCE SYSTEMS as defined in 2.2.102.

This Standard does not cover the application of MAGNETIC RESONANCE EQUIPMENT beyond the INTENDED USE.

1.2 Object

Replacement:

This Particular Standard establishes requirements for the safety of MAGNETIC RESONANCE EQUIPMENT to provide protection for the PATIENT.

It establishes requirements to provide information to 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 the "General Standard", consisting of

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, and its amendments 1 (1991) and 2 (1995),

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems*, and

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirement for safety – 4. Collateral Standard: Programmable electronic medical systems*.

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)", and IEC 60601-1-1 and IEC 60601-1-4 as "Collateral Standards".

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 Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses for which there is a rationale are marked with an asterisk *. These rationales can be found in informative annex BB. Annex BB does not form an integral 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 of a specified 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 a specified 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 (MR EQUIPMENT)
MEDICAL ELECTRICAL EQUIPMENT which is intended for in-vivo MAGNETIC RESONANCE EXAMINATION of a PATIENT. The MR EQUIPMENT comprises all parts in hardware and software from the SUPPLY MAINS to the display monitor. The MR EQUIPMENT is a Programmable Electrical Medical System (PEMS)

2.2.102
MAGNETIC RESONANCE SYSTEM (MR SYSTEM)
ensemble of MR EQUIPMENT, ACCESSORIES including means for display, control, energy supplies, and the CONTROLLED ACCESS AREA, where provided

2.2.103
WHOLE BODY MAGNETIC RESONANCE EQUIPMENT (WHOLE BODY MR EQUIPMENT)
MR EQUIPMENT of sufficient size to allow whole body MR-EXAMINATION and partial body MR-EXAMINATION of adult PATIENTS. It may be equipped with VOLUME RF TRANSMIT COILS, LOCAL RF TRANSMIT COILS and with a SPECIAL PURPOSE GRADIENT SYSTEM

2.2.104
WOLE BODY MAGNET
magnet suitable for use in WHOLE BODY MR EQUIPMENT

2.2.105
TRANSVERSE FIELD MAGNET
magnet for which the field is at right angles to the axial direction of the PATIENT

2.2.106
WHOLE BODY GRADIENT SYSTEM
a gradient system suitable for use in WHOLE BODY MR EQUIPMENT

2.2.107
SPECIAL PURPOSE GRADIENT SYSTEM
a gradient system suitable for use in MR EQUIPMENT for a special purpose.

An example of a SPECIAL PURPOSE GRADIENT SYSTEM is a gradient system that can be incorporated in MR EQUIPMENT to allow special examination of the head of the PATIENT

2.2.108
GRADIENT UNIT
all gradient coils and amplifiers that together generate a magnetic field gradient along one of the axes of the coordinate system of the MR EQUIPMENT

2.2.109
VOLUME RF TRANSMIT COIL
an RF transmit coil suitable for use in MR EQUIPMENT that produces a homogeneous RF field over an extended volume encompassed by the coil. The VOLUME RF TRANSMIT COIL can be a WHOLE BODY RF TRANSMIT COIL, a HEAD RF TRANSMIT COIL or a RF transmit coil designed for homogeneous exposure of a specific part of the body. A single loop coil enclosing the body or a part of the body is considered to be a VOLUME RF TRANSMIT COIL (example: single loop wrist coil)

2.2.110
WHOLE BODY RF TRANSMIT COIL
A VOLUME RF TRANSMIT COIL of sufficient size for whole body examinations of adult PATIENTS

2.2.111
HEAD RF TRANSMIT COIL
a VOLUME RF TRANSMIT COIL suitable for use in MR EQUIPMENT for a MAGNETIC RESONANCE EXAMINATION of the head of PATIENTS

2.2.112
LOCAL RF TRANSMIT COIL
an RF transmit coil other than a VOLUME RF TRANSMIT COIL. The LOCAL RF TRANSMIT COIL can be a coil for spectroscopy