SLOVENSKI STANDARD
SIST EN 60601-2-33:2003/A2:2008

01-maj-2008

Medicinska električna oprema - 2-33. del: Posebne varnostne zahteve za opremo za magnetno resonanco za medicinsko diagnostiko (IEC 60601-2-33:2002/A2:2007)

Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2002/A2:2007)

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit von Magnetresonanzgeräten für die medizinische Diagnostik (IEC 60601-2-33:2002/A2:2007)

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/A2:2007)

Ta slovenski standard je istoveten z: **EN 60601-2-33:2002/A2:2008**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-33:2003/A2:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-33/A2

March 2008

ICS 11.040.55

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/A2:2007)

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/A2:2007)

Medizinische elektrische Geräte -
Teil 2-33: Besondere Festlegungen für die Sicherheit von Magnetresonanzgeräten für die medizinische Diagnostik
(IEC 60601-2-33:2002/A2:2007)

This amendment A2 modifies the European Standard EN 60601-2-33:2002; it was approved by CENELEC on 2008-02-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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/A2:2008 E

Foreword

The text of document 62B/663/FDIS, future amendment 2 to IEC 60601-2-33:2002, 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 amendment A2 to EN 60601-2-33:2002 on 2008-02-01.

The following dates were fixed:

– latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2008-11-01
– latest date by which the national standards conflicting with the amendment have to be withdrawn	(dow)	2011-02-01

Endorsement notice

The text of amendment 2:2007 to the International Standard IEC 60601-2-33:2002 was approved by CENELEC as an amendment to the European Standard without any modification.

IEC 60601-2-33

Edition 2.0 2007-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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 utilisés pour le diagnostic médical

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX R

ICS 11.040.55

ISBN 2-8318-9358-5

FOREWORD

This amendment has been prepared by subcommittee 62B: Medical 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/663/FDIS	62B/675/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 maintenance result 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.

INTRODUCTION to Amendment 2

This second amendment to IEC 60601-2-33 addresses technical aspects of the medical diagnostic MR SYSTEM and the MR EQUIPMENT therein, related to the safety of PATIENTS examined with this system, the safety of the MR WORKER involved with its operation and the safety of the MR WORKER involved with the development, manufacturing, installation, and servicing of the MR SYSTEM. The new aspect introduced in this second amendment addresses the fact that in some countries electromagnetic field (EMF) exposure of workers is or will be limited by law.

Page 11

INTRODUCTION

Replace the second paragraph by the following:

This International Standard addresses technical aspects of the medical diagnostic MR SYSTEM and the MR EQUIPMENT therein, related to the safety of PATIENTS examined with this system, the safety of the MR WORKER involved with its operation and the safety of the MR WORKER involved with the development, manufacturing, installation, and servicing of the MR SYSTEM. Where limits of electromagnetic fields (EMF) exposure of PATIENTS and MR WORKER are stated, these limits do not imply that such levels of exposure can be assumed to be acceptable for workers in other professional settings and for the population at large. The limits provide a sensible balance between risks for the PATIENTS and MR WORKERS and benefits for the PATIENTS.

Add, after the second paragraph, the following new text:

The introduced EMF exposure limits required in this standard for an MR WORKER are equal to those allowed for PATIENTS. All exposure levels allowed for a PATIENT and for an MR WORKER protect them against negative instantaneous and long-term health effects.

Subjective short-term physiological and sensory effects are expected for the exposure to static magnetic fields only, these influence the well being of the MR WORKER marginally and only during or shortly after exposure.

For the exposure to GRADIENT OUTPUT and RF transmit fields, normally no short-term physiological and sensory effects are expected for MR WORKERS.

In addition no experimental or theoretical basis for cumulative biological effects in humans, resulting from exposure at the allowed levels has been generally accepted.

Add, to the list of examples of organisational aspects in the fourth paragraph, the following new item:

– rules to minimize and to limit the exposure of MR WORKERS.

Page 13

1 Scope and object

1.2 Object

Replace the first paragraph by the following:

This particular standard establishes requirements for the safety of MR EQUIPMENT to provide protection for the PATIENT and the MR WORKER.

NOTE This standard presumes that the MR WORKERS are properly screened medically, and properly trained and instructed in their duties.

Page 15

2 Terminology and definitions

2.12 Miscellaneous

Add, on page 21, the following new definition:

2.12.107
MR WORKER
person that because of his/her profession has to enter the CONTROLLED ACCESS AREA or equivalent of the MAGNETIC RESONANCE SYSTEM

NOTE Other persons like MR volunteers and PATIENT carers are not covered by this definition, however OPERATORS and staff are included in this definition (see rationale)

Page 27

6.8.2 INSTRUCTIONS FOR USE

aa) Pre-screening prior to an MR EXAMINATION

Replace the title of 6.8.2 aa) by:

aa) Pre-screening of the PATIENT and MR WORKER

Replace the first paragraph of 6.8.2 aa) as follows:

INSTRUCTIONS FOR USE shall provide clear recommendations to the USER regarding pre-screening of PATIENTS and MR WORKERS. This specifically applies to those PATIENTS and MR WORKERS who could be placed at risk due to their professional activity, past medical history, present medical state and/or the physical environment of the MR EQUIPMENT. These instructions shall indicate the need for a pre-screening program to identify such PATIENTS and MR WORKERS at risk, and shall provide recommendations to adequately safeguard these PATIENTS and MR WORKERS from injury. For the MR WORKER especially the risk due to the past professional activity, which may have caused accidental implantation of ferromagnetic materials, shall be considered.

dd) Excessive acoustic noise

Replace the title of 6.8.2 dd) by:

dd) Exposure of the PATIENT and MR WORKER to excessive acoustic noise

Replace the existing last dashed item by the following:

– shall draw attention to the fact that in some countries legislation may exist covering the exposure of MR WORKERS to noise.

Add a last dash to 6.8.2 dd):

– shall state that for tasks in the CONTROLLED ACCESS AREA during scanning, the MR WORKER shall wear adequate hearing protection to reach compliance with the rules for protection of workers to noise.

hh) Static magnetic field

Replace the title of item hh) by:

hh) Exposure of the PATIENT and MR WORKER to the static magnetic field

Replace the first bullet of 6.8.2 hh) by:

– explain the possible effects that PATIENTS and MR WORKERS may experience when the static magnetic field is above the level of NORMAL OPERATION MODE, paying particular attention to the effects that may be experienced if the PATIENT or MR WORKER'S head is moved rapidly while inside or close to the MR EQUIPMENT, including dizziness, vertigo, and a metallic taste in the mouth;

Add the following dashed items:

– explain that when the main static magnetic field is higher than 2 T and not exceeding 4 T, the MR SYSTEM is continuously operating in the FIRST LEVEL CONTROLLED OPERATION MODE and therefore ensure that MEDICAL SUPERVISION is provided for all PATIENTS

– explain that adequate training shall be given to MR WORKERS to minimise adverse health effects arising from the high static magnetic field. Explain the health effects related to the increased static magnetic fields and explain the possible changes in the MR compatibility of the tools and accessories used by the MR WORKER, as a function of the value of the static magnetic field.

– explain that when the main static magnetic field is higher than 4 T, the MR system is continuously operating in the SECOND LEVEL CONTROLLED OPERATION MODE and therefore ensure that MEDICAL SUPERVISION is provided for all PATIENTS. Explain that in this situation MR WORKERS shall not be allowed to access the MR EQUIPMENT without local approval as required.

ii) Time varying magnetic fields

Replace the title of item ii) by the following:

ii) Exposure of the PATIENT to time varying magnetic fields

Replace the first paragraph by the following:

For MR EQUIPMENT that is capable of operation at levels of GRADIENT OUTPUT above the NORMAL OPERATING MODE, the INSTRUCTIONS FOR USE shall draw attention to risk factors, which may increase the potential for peripheral nerve stimulation for the PATIENT and they shall describe ways for the USER to mitigate these risk factors. The INSTRUCTIONS FOR USE shall:

jj) Radio frequency magnetic fields

Replace title of the item jj) by:

jj) Exposure of the PATIENT to radio frequency magnetic fields

Replace the first paragraph by the following:

The INSTRUCTIONS FOR USE shall draw attention to risk factors, which may increase the potential for local excessive RF heating of the PATIENT and they shall describe ways for the USER to mitigate these risk factors. These factors include:

kk) Occupational exposure

Replace the existing text of this item by the following new text:

The INSTRUCTIONS FOR USE shall draw attention to the fact that MR WORKERS can be exposed to the electromagnetic fields (EMF) emitted by the MR EQUIPMENT. They shall provide sufficient information relating to the risks from these exposures to enable safe working procedures for the MR WORKER. The relevant requirements of 6.8.2 ii) and jj) for the PATIENT shall also apply for the MR WORKER. This information shall also include

– specification of areas to which access by the MR WORKER is restricted, if any;
– the actual levels of the exposure in all areas accessible to the MR WORKER, expressed in proper units for the static magnetic field (see 6.8.2 hh) and 51.104), the GRADIENT OUTPUT (see 6.8.2.ii) and 51.102) and the RF transmit field (see 6.8.2 jj) and 51.103) generated by the MR EQUIPMENT;
– instructions that the MR WORKER shall be informed and trained sufficiently so that they can perform all their tasks safely in a way that minimizes their exposure to EMF emitted by the MR EQUIPMENT;
– a statement that there is a possibility that mild peripheral nerve stimulation (PNS) may be induced in the PATIENT and MR WORKER when exposed to the gradients in the FIRST LEVEL CONTROLLED OPERATION MODE;.

The risk factors associated with the expected exposure levels for the MR WORKER shall be explained. A description of ways for the MR WORKER to mitigate these risk factors shall be given.

Known factors to draw attention to are the following:

– The possible physiological effect of exposure to RF radiation is heating. Exposure to RF radiation can be minimised by keeping sufficient distance away from the transmit RF coil or by reducing time of exposure during scanning;
– The possible physiological effect of exposure to the GRADIENT OUTPUT is peripheral nerve stimulation for the person exposed. Exposure to GRADIENT OUTPUT can be minimised by keeping sufficient distance away from the gradient coils during scanning.
– The possible physiological effects of exposure to the static magnetic field are dizziness, vertigo, and a metallic taste in the mouth of the person exposed. Exposure to the static magnetic field can be minimised by staying away from the magnet (not just during

scanning but all the time) and by avoiding rapid movements of the head while in the static magnetic field.

The INSTRUCTIONS FOR USE may state that, it is generally accepted that no published evidence supporting the occurrence of cumulative and/or long-term effects after exposure to EMF emitted by the MR EQUIPMENT exists.

The INSTRUCTIONS FOR USE shall state that extra precaution is advisable for pregnant MR WORKERS, although there is no currently available epidemiological evidence for any negative health effects. Local regulations may apply.

The INSTRUCTIONS FOR USE shall state that the limits for MR WORKERS may not be applicable when an MR WORKER is pregnant. It may be required in some countries that the 'member of the public' limit be applied to the foetus.

The INSTRUCTIONS FOR USE shall state that in some countries legislation may exist covering occupational limits for exposure to EMF, that are lower than the limits for MR WORKER given in this standard.

Page 39

6.8.3 Technical description

bb) compatibility technical specification sheet

Add to the dashed item Magnet the following additional bullet:

- For MR equipment that is capable of operation in the FIRST LEVEL CONTROLLED OPERATION MODE or the SECOND LEVEL CONTROLLED OPERATION MODE for the static magnetic field, a plot representing the 0,5 T, 1 T, 1,5 T, 2 T, 3 T and the 4 T iso-magnetic contours at positions accessible to and relevant for the MR WORKER shall be included if the static magnetic field in the iso-centre exceeds any of these values.

Replace two existing dashed items as follows:

– Gradient system: type, amplitude, rise time, slew rate, and spatial distribution of the maximum magnitude values of the vector sum of all three GRADIENT OUTPUTS at the positions accessible to and relevant for the MR WORKER during scanning.

– RF system: types of RF transmit coil, amplifier peak r.m.s. power, applied maximum transmit RF magnetic field and bandwidth, spatial distribution of the maximum transmit RF magnetic field at the positions accessible to and relevant for the MR WORKER during scanning.

Page 51

51.101 Operating modes

51.101.1 All operating modes

Replace item: c) by:

c) The MR EQUIPMENT shall provide information upon request about the relevant SAR and relevant GRADIENT OUTPUT.

Page 53

51.101.3 FIRST LEVEL CONTROLLED OPERATING MODE

Replace item a) by:

a) Before the start of each scan, an indication of the operating mode defined by the value of the GRADIENT OUTPUT which will actually be applied during the scan and the value of the SAR which will actually be applied during the scan, and a prediction of these values (upon

request) shall be displayed at the CONTROL PANEL. The value for the GRADIENT OUTPUT shall be expressed as the percentage of the upper level of the FIRST LEVEL CONTROLLED OPERATION MODE (L12) for the scan applied.

51.101.4 SECOND LEVEL CONTROLLED OPERATING MODE

Replace item b) by:

b) Before the start of each scan, an indication of the operating mode defined by the value of the GRADIENT OUTPUT which will actually be applied during the scan and the value of the SAR which will actually be applied during the scan, and a prediction of these values (upon request) shall be displayed at the CONTROL PANEL. The value for the GRADIENT OUTPUT shall be expressed as the percentage of the upper level of the FIRST LEVEL CONTROLLED OPERATION MODE (L12) for the scan applied.

51.102 Protection against excessive low frequency field variations produced by the gradient system.

51.102.1 Objectives for limitation of GRADIENT OUTPUT

Replace, on page 55, the first two sentences of the existing text by the following

The MR EQUIPMENT shall be designed to automatically control the GRADIENT OUTPUT so that cardiac stimulation in the PATIENT and in the MR WORKER at any operating mode is prevented.

The MR EQUIPMENT shall be designed to automatically control the GRADIENT OUTPUT so that the occurrence of intolerable peripheral nerve stimulation (PNS) in the PATIENT and in the MR WORKER in any operating mode is minimised.

51.102.2 Limits for GRADIENT OUTPUT

Replace the existing first sentence by:

In this subclause, limits for the PATIENT and the MR WORKER are expressed either as the electric field E induced in the PATIENT or the MR WORKER by the changing magnetic field of the gradients, or by dB/dt, the time rate of change of that field.

Add the following note at the end of the subclause:

NOTE MR WORKER exposure limits are the same as for the PATIENTS. Compliance with the GRADIENT OUTPUT limits for PATIENTS therefore automatically implies compliance for the MR WORKERS.

Page 61

51.103 Protection against excessive radio frequency energy

51.103.1 Limits for temperature

Add to the existing first paragraph the following new text:

Allowed values for the temperature rise of the MR WORKER caused by the MR EQUIPMENT are equal to the values for the PATIENT as defined in Table 104 for the NORMAL OPERATING MODE and the FIRST LEVEL CONTROLLED OPERATING MODE.

Add the following note to Table 105:

NOTE MR WORKER exposure limits are the same as for the PATIENTS. Compliance with the SAR limits for PATIENTS therefore in practice implies compliance for the MR WORKERS.