IEC 60601-2-33

Edition 3.0 2013-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

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

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

CDV	Report on voting
62B/884/CDV	62B/904/RVC

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 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- withdrawn,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.

INTRODUCTION

This amendment has been published to adapt IEC 60601-2-33:2010 to the technical corrections introduced by Amendment 1 (2012) to IEC 60601-1:2005.

201.1 Scope, object and related standards

In the footnote, replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.1.1 Scope

Replace the existing fourth paragraph with the following:

The standard does not formulate specific requirements for MR EQUIPMENT or MR SYSTEMS used in INTERVENTIONAL MR EXAMINATIONS.

201.1.3 Collateral standards

Replace the second paragraph with the following:

IEC 60601-1-2:2007 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.2 Normative references

Replace the existing reference to IEC 60601-1:2005 by the following:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

Replace the existing reference to NEMA MS 4:2006 by the following:

NEMA MS 4:2010, *Acoustic noise measurement procedure for diagnostic magnetic resonance imaging (MRI) devices*

201.3 Terms and definitions

Replace the existing reference to IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

Table 201.101 – List of symbols

Delete the 14th row, containing the symbol t_{SAR}.

201.4.3 ESSENTIAL PERFORMANCE

Replace the existing Note 101 with the following:

NOTE 101 For the functions of the MR EQUIPMENT covered by this standard no specific ESSENTIAL PERFORMANCE requirements have been identified. Other functions of the MR EQUIPMENT may constitute ESSENTIAL PERFORMANCE. See the general standard for requirements to the RISK MANAGEMENT FILE of the MANUFACTURER to cover the analysis of ESSENTIAL PERFORMANCE of the MR EQUIPMENT.

201.5.7 Humidity preconditioning treatment

Replace the existing paragraph by the following:

For those MR SYSTEMS and MR EQUIPMENT that are to be used only in controlled environments, as to be specified in the technical description, no humidity preconditioning is required.

NOTE A controlled environment is not the same as CONTROLLED ACCESS AREA.

201.7 ME EQUIPMENT identification, marking and documents

Add the following subclause:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.13 Physiological effects (safety signs and warning statements)

Addition:

Applicable safety signs ISO 7010-W005 and ISO 7010-W006 shall be placed at the entrance of the CONTROLLED ACCESS AREA. The safety signs may be accompanied by text explaining that the magnetic field is always on, but that EMF emission is restricted to the situation when the MR EQUIPMENT is scanning.

For MR EQUIPMENT that does not require a CONTROLLED ACCESS AREA, the need for and location of the safety signs shall be described in the RISK MANAGEMENT FILE by the MANUFACTURER.

Information shall be provided in the instructions for use concerning specific physiological effects related to MR EQUIPMENT.

201.7.9.2 Instructions for use

Add the following new subclause:

201.7.9.2.17 ME EQUIPMENT emitting radiation

Addition:

NOTE The instructions for use in 201.7.9.2.101 and the compatibility technical specification sheet in the technical description in 201.7.9.3.101 provide detailed information concerning electromagnetic fields of the MR EQUIPMENT.

201.7.9.2.101 Instructions for use for MR EQUIPMENT

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

In the first dashed item of the second paragraph, replace NEMA MS 4:2005 *by* NEMA MS 4:2010.

Replace the existing text of Note 1 with the following:

NOTE 1 An applicable safety sign is ISO 7010-M003 (2011).

* u) Scanning of pregnant PATIENTS

Add the following new text at the end of the subclause:

Attention shall be drawn to the fact that the fetus is considered as part of the general public, and that it is especially sensitive to potential thermal events during the first trimester. The RESPONSIBLE ORGANIZATION should be advised to avoid scanning patients in the first trimester or with unknown pregnancy status.

NOTE Pregnancy status is part of the RIS information. It is recommended that feedback via the user interface be provided to the OPERATOR during examination setup to validate the pregnancy status. The MR EQUIPMENT may enforce scanning in NORMAL OPERATING MODE unless the pregnancy status is NO.

v) Scanning of PATIENTS with elevated body CORE TEMPERATURE.

Replace the existing text of the paragraph by the following:

The instructions for use shall describe that the MR EQUIPMENT provides the operating modes to enable the OPERATOR to limit the body CORE TEMPERATURE rise of the PATIENT to avoid undue heat stress and prevent local tissue damage in the body of the PATIENT. Applicable limit values can be found in Table 201.104.

201.7.9.3 Technical description

Add the following subclause:

201.7.9.3.1 General

Replacement of the eighth dashed item of the first paragraph and Note 2:

– information pertaining to any necessary recurrent BASIC SAFETY testing including details of the means, methods and recommended frequency.

201.7.9.3.101 Technical description of MR EQUIPMENT

b) Compatibility technical specification sheet

Replace, in the second bullet point of the second dashed item, the value 0,02 m *by* 0,05 m

*** 201.8.7.3 Allowable values**

Reletter additional item e) *as item* aa).

201.9.8.3.3 Dynamic forces due to loading from persons

Delete this subclause.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

201.12.4 Protection against hazardous output

Add the following new subclauses:

201.12.4.1 Intentional exceeding of safety limits

Addition:

NOTE The second level controlled operating mode covers all relevant requirements for MR EQUIPMENT.

201.12.4.2 Indication relevant to safety

Addition:

NOTE All relevant requirements for MR EQUIPMENT are covered in 201.12.4.101

Annex AA – Particular guidance and rational

AA.1 Rationale for particular clauses and subclauses

Add the following rationale:

Concerning 201.9.8.3.3 – Dynamic forces due to loading from persons (deleted)

Subclause 201.9.8.3.3 was introduced in the third edition of this standard. However the rational for this subclause in IEC 60601-1:2005 states that the requirement regarding the dynamic load test is only applicable for chairs and tables where dynamic load can be expected such as chairs for dental surgical procedures, X-ray tables, and many other similar types of ME EQUIPMENT. For patient tables used with MR or CT, it is not applicable, as the dynamic loading caused by a PATIENT is negligible.

Bibliography

Replace existing reference [166] with the following:

[166] ISO 7010:2011, *Graphical symbols – Safety colors and safety signs – Registered safety signs*