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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Международная Электротехническая Комиссия

PRICE CODE XC

For price, see current catalogue

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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.
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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 –

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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*.