IEC 60601-2-33

Edition 2.2 2008-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

IEC 60601-2-33:2002+A1:2005+A2:2007

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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 International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. 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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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 consolidated version of IEC 60601-2-33 consists of the second edition (2002) [documents 62B/462/FDIS and 62B/467/RVD], its amendment 1 (2005) [documents 62B/573/FDIS and 62B/586/RVD] and its amendment 2 (2007) [documents 62B/663/FDIS and 62B/675/RVD].

The technical content is therefore identical to the base edition and its amendments and has been prepared for user convenience.

It bears the edition number 2.2.

A vertical line in the margin shows where the base publication has been modified by amendments 1 and 2.

The French version of this standard has not been voted upon.

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 the base publication and its amendments 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

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

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.

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.

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

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.

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.

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 MR EQUIPMENT as defined in 2.2.101 and MR SYSTEMS as defined in 2.2.102.

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

1.2 Object

Replacement:

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.

It establishes requirements to provide information to the OPERATOR, staff associated with MR 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
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
VOLUME RF TRANSMIT COIL of sufficient size for whole body examinations of adult PATIENTS

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

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

2.10 Operation of equipment

2.10.101
NORMAL OPERATING MODE
mode of operation of the MR EQUIPMENT in which none of the outputs have a value that may cause physiological stress to PATIENTS

2.10.102
FIRST LEVEL CONTROLLED OPERATING MODE
mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that may cause physiological stress to PATIENTS which needs to be controlled by MEDICAL SUPERVISION

2.10.103
SECOND LEVEL CONTROLLED OPERATING MODE
mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that may produce significant risk for PATIENTS, for which explicit ethical approval is required (i.e. a human studies protocol approved to local requirements)

*** 2.10.104**
MAGNETIC RESONANCE EXAMINATION (MR EXAMINATION)
process of acquiring data by MAGNETIC RESONANCE from a PATIENT

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
device for de-energizing a superconducting or resistive magnet in case of an emergency situation

2.11.103
QUENCH
transition of the electrical conductivity of a coil that is carrying a current from a super-conducting state to normal conductivity, resulting in rapid boil-off of fluid cryogen and decay of the magnetic field

2.12 Miscellaneous

*** 2.12.101**
MAGNETIC RESONANCE (MR)
resonant absorption of electromagnetic energy by an ensemble of atomic particles situated in a magnetic field

2.12.102
ROUTINE MONITORING
routine PATIENT monitoring which is carried out by responsible personal such as the OPERATOR and staff of the MR EQUIPMENT and consisting of audio and/or visual contact, as appropriate with the PATIENT during the MR EXAMINATION

*** 2.12.103**
MEDICAL SUPERVISION
adequate medical management of PATIENTS who may be at risk from some parameters of exposure to the MR EQUIPMENT, either because of the medical condition of the PATIENT, the levels of exposure or a combination

2.12.104
COMPLIANCE VOLUME
area of PATIENT accessible space in which compliance of GRADIENT OUTPUT is inspected

In MR EQUIPMENT with a cylindrical WHOLE BODY MAGNET, the COMPLIANCE VOLUME is a cylinder with its axis coinciding with the magnet axis and with a radius of 0,20 m.

In MR EQUIPMENT with a TRANSVERSE FIELD MAGNET and a WHOLE BODY GRADIENT SYSTEM, the COMPLIANCE VOLUME is a volume bound by planes parallel to the magnet poles and separated by a distance that is either the largest dimension of the accessible space between the poles of the magnet, or 0,40 m, whichever is less.

In all other MR EQUIPMENT the COMPLIANCE VOLUME is the volume where any part of a PATIENT body can be properly located according to the intended use of the MR EQUIPMENT.

2.12.105
MAXIMUM GRADIENT SLEW RATE
the rate of change of the gradient obtained by switching the GRADIENT UNIT between its maximum specified gradient strengths $G_{+\max}$ and $G_{-\max}$ in the shortest possible ramp time obtainable under normal scan conditions

2.12.106
SEARCH COIL
a small diameter coil used in a compliance test to measure GRADIENT OUTPUT

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)

2.101 Output

*** 2.101.1**
SPECIFIC ABSORBTION RATE
SAR
radio frequency power absorbed per unit of mass of an object (W/kg)

2.101.2
WHOLE BODY SAR
SAR averaged over the total mass of the PATIENTS body and over a specified time

2.101.3
PARTIAL BODY SAR
SAR averaged over the mass of the PATIENTS body that is exposed by the VOLUME RF TRANSMIT COIL and over a specified time

2.101.4
HEAD SAR
SAR averaged over the mass of the PATIENTS head and over a specified time