

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis**

FOREWORD

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International standard IEC 60601-2-33 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2002, its Amendment 1 (2005) and Amendment 2 (2007) and constitutes a technical revision. This third edition of IEC 60601-2-33 is based on the second amendment to Edition 2. It has also been adapted to the third edition of IEC 60601-1 (2005), with technical modifications being introduced where appropriate.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62B/777/FDIS	62B/782/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website.

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.

The contents of the corrigenda 1 (March 2012) and 2 (February 2016) have been included in this copy.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

* 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 WORKERS 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.

Organizational aspects of safety are the task of the RESPONSIBLE ORGANIZATION. 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 organizational aspects are:

- operation in FIRST LEVEL CONTROLLED OPERATING 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 to EMF.

Extensive rationale is provided in Annex AA 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 and the collateral standards is explained in subclauses 201.1.3 and 201.1.4.

The introduced EMF exposure limits required in this standard for an MR WORKER will never exceed those allowed for PATIENTS. All exposure limits allowed for a PATIENT and for an MR WORKER are expected to protect them against negative health effects and unacceptable RISKS.

For the exposure to static magnetic fields, subjective short-term physiological and sensory effects are expected. 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.

The requirements for acoustic noise exposure are different for PATIENTS and MR WORKERS.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MR EQUIPMENT and MR SYSTEMS, hereafter referred to also as ME EQUIPMENT.

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

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

The standard does not formulate ESSENTIAL PERFORMANCE requirements related to INTERVENTIONAL MR EXAMINATIONS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MR EQUIPMENT to provide protection for the PATIENT and the MR WORKER.

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

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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

201.1.4 Particular standards

Replacement:

¹⁾ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 96.

Clause 2 of the general standard applies except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

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

NEMA MS 4:2006, *Acoustic noise measurements procedure for diagnostic magnetic resonance imaging devices*

NEMA MS 8:2008, *Characterization of the specific absorption rate (SAR) for magnetic resonance imaging systems*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and the following apply:

NOTE An index of defined terms is found beginning on page 104. A list of symbols used in the document is provided in Table 201.101.

Addition:

* 201.3.201

B_{1+} RMS

root mean square (rms) of B_{1+} , the MR relevant radiofrequency magnetic induction

$$B_{1+}\text{RMS} = \sqrt{\frac{\int_0^{t_x} (B_{1+}(t))^2 dt}{t_x}} .$$

where t is time, and t_x is the evaluation time, and is estimated at the RF transmit coil centre.

201.3.202

COMPLIANCE VOLUME

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. and with a length equal to the gradient coil

In MR EQUIPMENT with a TRANSVERSE FIELD MAGNET and a WHOLE BODY GRADIENT SYSTEM, the COMPLIANCE VOLUME is a cylinder aligned with the patient's axis, of length equal to the gradient coil diameter, and a diameter of 0,40 m or equal to the distance between the poles of the magnet, 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.

201.3.203

CONTROLLED ACCESS AREA

area to which access is controlled for safety reasons

201.3.204

CORE TEMPERATURE

mean temperature of the body core

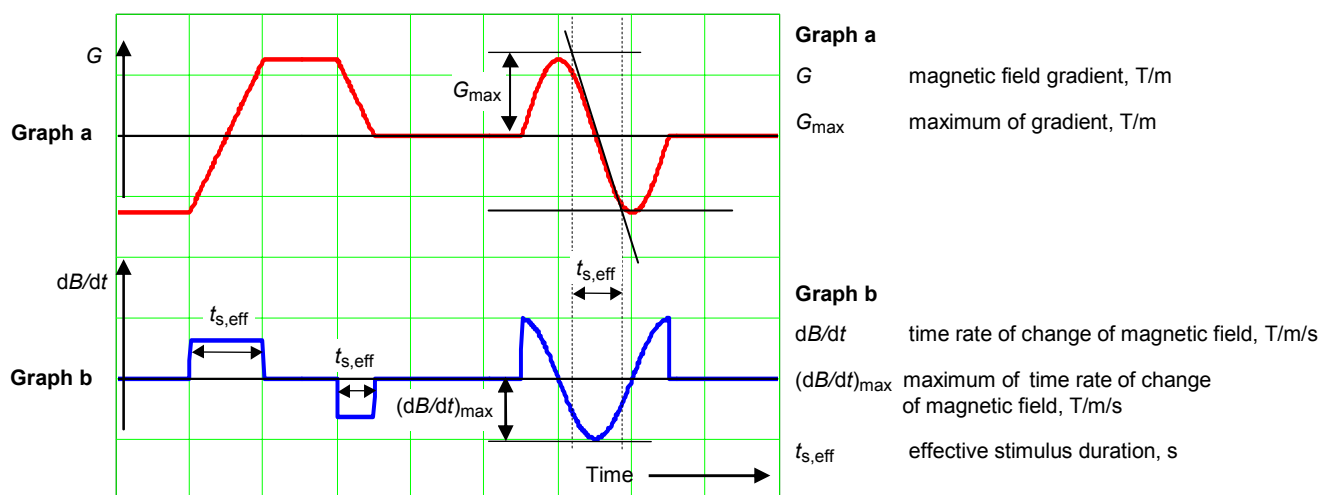
NOTE Typically equal to the rectal, sublingual, or tympanic temperature. More reliable representations of CORE TEMPERATURE are oesophageal or arterial blood temperature. Brain temperatures are CORE TEMPERATURES.

201.3.205

EFFECTIVE STIMULUS DURATION

$t_{s,eff}$

duration of any period of the monotonic increasing or decreasing gradient, used to describe its limits for cardiac or peripheral nerve stimulation, defined as the ratio of the peak-to-peak field variation and the maximum value of the time derivative of the gradient in that period (see Figure 201.101)



IEC 402/10

Three periods of monotonic change of the gradient G are shown in graph a. The corresponding GRADIENT OUTPUT dB/dt is shown in graph b and the EFFECTIVE STIMULUS DURATION $t_{s,eff}$ is indicated.

Figure 201.101 – Gradient waveform and EFFECTIVE STIMULUS DURATION

201.3.206

EMERGENCY FIELD SHUT DOWN UNIT

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

* 201.3.207

ENVIRONMENTAL TEMPERATURE

temperature [°C] of a uniform (isothermal) “black” enclosure in which an occupant would exchange the same amount of heat by radiation and convection as in the actual non-uniform environment

NOTE For the calculation of the ENVIRONMENTAL TEMPERATURE see rationale in Annex AA.

201.3.208

FIRST LEVEL CONTROLLED OPERATING MODE

mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that can cause physiological stress to PATIENTS which needs to be controlled by MEDICAL SUPERVISION

201.3.209

GRADIENT OUTPUT

parameter characterizing the gradient performance such as rate of change of the magnitude of the magnetic field, or electric field induced by one or more GRADIENT UNITS under specified conditions and at a specified position

201.3.210

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

201.3.211

HEAD RF TRANSMIT COIL

VOLUME RF TRANSMIT COIL suitable for use in MR EQUIPMENT for a MR EXAMINATION of the PATIENT's head

201.3.212

HEAD SAR

SAR averaged over the mass of the head and over a specified time

*** 201.3.213**

INTERVENTIONAL MR EXAMINATION

MR EXAMINATION applied to guide a medical (including invasive) procedure e.g. biopsy or the treatment of a lesion

201.3.214

ISOCENTRE

in MR EQUIPMENT null point of the spatially encoding gradients

NOTE 1 Typically this also corresponds to the region of highest magnet homogeneity

[IEC 62464-1:2007, definition 3.1.15]

NOTE 2 Typically this corresponds with the position in the system targeted for imaging.

201.3.215

LOCAL RF TRANSMIT COIL

RF transmit coil other than a VOLUME RF TRANSMIT COIL

201.3.216

LOCAL SAR

SAR averaged over any 10 g of tissue of the body and over a specified time

*** 201.3.217**

MAGNETIC RESONANCE

MR

resonant absorption of electromagnetic energy by an ensemble of atomic nuclei situated in a magnetic field

201.3.218

MAGNETIC RESONANCE EQUIPMENT

MR EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT which is intended for in vivo MAGNETIC RESONANCE EXAMINATION of a PATIENT comprising all parts in hardware and software from the SUPPLY MAINS to the display monitor

NOTE The MR EQUIPMENT is a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS).

201.3.219

MAGNETIC RESONANCE EXAMINATION

MR EXAMINATION

process of acquiring data by MAGNETIC RESONANCE from a PATIENT

201.3.220**MAGNETIC RESONANCE SYSTEM**

MR SYSTEM

ensemble of MR EQUIPMENT, ACCESSORIES including means for display, control, energy supplies, and the CONTROLLED ACCESS AREA, where provided

*** 201.3.221****MAGNETIC RESONANCE WORKER**

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, such as MR volunteers and PATIENT carers, are not covered by this definition. However, OPERATORS and staff are included in this definition (see rationale).

201.3.222**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

*** 201.3.223****MEDICAL SUPERVISION**

adequate medical management of PATIENTS who can 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

201.3.224**NORMAL OPERATING MODE**

mode of operation of the MR EQUIPMENT in which none of the outputs have a value that can cause physiological stress to PATIENTS

201.3.225**PARTIAL BODY SAR**

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

201.3.226**PNS OUTPUT**

value which estimates the level of peripheral nerve stimulation (PNS) for the PATIENT

201.3.227**PNS THRESHOLD LEVEL**

value of the PNS OUTPUT related to the onset of PNS sensation for the PATIENT

201.3.228**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

201.3.229**ROUTINE MONITORING**

routine PATIENT monitoring, carried out by responsible personnel 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

201.3.230

SEARCH COIL

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

201.3.231

SECOND LEVEL CONTROLLED OPERATING MODE

mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that can produce significant RISK for PATIENTS, for which explicit ethical approval is required (i.e. a human studies protocol approved to local requirements)

201.3.232

SPECIAL PURPOSE GRADIENT SYSTEM

gradient system suitable for use in MR EQUIPMENT for a special purpose

NOTE 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.

*** 201.3.233**

SPECIFIC ABSORPTION RATE

SAR

radio frequency power absorbed per unit of mass (W/kg)

201.3.234

TIME RATE OF CHANGE OF THE MAGNETIC FIELD

dB/dt

rate of change of the magnetic flux density with time (T/s)

201.3.235

TRANSVERSE FIELD MAGNET

magnet for which the field is at right angles to the axial direction of the PATIENT

201.3.236

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

NOTE 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).

201.3.237

WHOLE BODY GRADIENT SYSTEM

gradient system suitable for use in WHOLE BODY MR EQUIPMENT

201.3.238

WHOLE BODY MAGNET

magnet suitable for use in WHOLE BODY MR EQUIPMENT

201.3.239

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 can be equipped with VOLUME RF TRANSMIT COILS, LOCAL RF TRANSMIT COILS and with a SPECIAL PURPOSE GRADIENT SYSTEM

201.3.240

WHOLE BODY RF TRANSMIT COIL

VOLUME RF TRANSMIT COIL of sufficient size for whole body examinations of adult PATIENTS

201.3.241**WHOLE BODY SAR**

SAR averaged over the total mass of the body and over a specified time

Table 201.101 – List of symbols

Symbol	SI-Unit	Definition
B_0	T	Static magnetic field
B_{1+}	T	Magnetic induction of the radio frequency magnetic field
B_{1+RMS}	T	Root mean square of B_{1+}
dB/dt	T/s	TIME RATE OF CHANGE OF THE MAGNETIC FIELD (dB/dt)
E	V/m	Electric field induced by gradient switching
G	T/m	Magnetic field gradient
$L01$	V/m or T/s	Limit of the GRADIENT OUTPUT for the NORMAL OPERATING MODE
$L12$	V/m or T/s	Limit of the GRADIENT OUTPUT for the FIRST LEVEL CONTROLLED OPERATING MODE
O	depending on context	PNS OUTPUT
O_i	depending on context	PNS OUTPUT per GRADIENT UNIT
rb	V/m or T/s	Rheobase
SAR	W/kg	SPECIFIC ABSORPTION RATE (SAR)
$t_{s,eff}$	ms	EFFECTIVE STIMULUS DURATION
t_{SAR}	min	Averaging time for the determination of SAR
T	°C	Temperature
W_i	none	Weight factor per GRADIENT UNIT relating the GRADIENT OUTPUT of that unit to the limit

201.4 General requirements

Clause 4 of the general standard applies. except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

NOTE 101 No ESSENTIAL PERFORMANCE requirements have been identified for the MR EQUIPMENT within the scope of the standard.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies except as follows:

201.5.7 Humidity preconditioning treatment

Addition:

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies except as follows:

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS should provide sufficient information to the RESPONSIBLE ORGANIZATION to enable it to comply with the local regulations and requirements for exposure limits appropriate to the PATIENT and MR WORKER.

201.7.9.2 Instructions for use

201.7.9.2.10 Messages

Replacement:

The instructions for use shall list all system messages, error messages, and fault messages that are generated related to safety concerns unless these messages are self-explanatory.

Addition:

*** 201.7.9.2.101 Instructions for use for MR EQUIPMENT**

*** a) Pre-screening of the PATIENT and the MR WORKER**

Instructions for use shall provide clear recommendations to the RESPONSIBLE ORGANIZATION 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 programme 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 and the PATIENT especially the RISK due to the past professional activity, which could have caused accidental implantation of ferromagnetic materials, shall be considered.

The following specific classes of PATIENTS shall be mentioned:

- classes of PATIENTS for whom MR EXAMINATIONS are considered to be contraindicated;
- classes of PATIENTS having higher than normal likelihood of needing emergency medical treatment, independent of the physical environment of the MR EQUIPMENT;
- classes of PATIENTS having a higher than normal likelihood of needing emergency medical treatment due to the elevated values of the applied fields, when the MR EQUIPMENT is capable of operating within the FIRST LEVEL CONTROLLED OPERATING MODE as described in subclause 201.12.4.101.

*** b) MEDICAL SUPERVISION OF PATIENTS**

Instructions for use shall provide clear recommendations to the RESPONSIBLE ORGANIZATION to establish a programme for the supervision appropriate to the classes of PATIENTS described in 201.7.9.2.101 a) and to the controlled modes of operation of the MR EQUIPMENT as defined in 201.3.208, 201.3.231 and 201.3.244.

Instructions for use shall:

- include the recommendation that all PATIENTS should receive at least ROUTINE MONITORING;
- if the MR EQUIPMENT is capable of operating within the FIRST LEVEL CONTROLLED OPERATING MODE: give recommendation that procedures should be established to ensure that MEDICAL SUPERVISION is provided when entering the FIRST LEVEL CONTROLLED OPERATING MODE;
- if the MR EQUIPMENT is provided with a SECOND LEVEL CONTROLLED OPERATING MODE: include notification that operation in the SECOND LEVEL CONTROLLED OPERATING MODE requires approval of investigational human studies protocol according to local requirements (e.g. ethics committee, investigational review board, etc.). In addition it shall be stated that the local approval should specifically state limits for GRADIENT OUTPUT, SAR and static field strength.

* c) Emergency medical procedures

Instructions for use shall give clear recommendation to the RESPONSIBLE ORGANIZATION to define and implement specific emergency medical procedures that apply to the PATIENT and that take into account the presence of the magnetic field, so that if during MR EXAMINATION the PATIENT feels ill or is injured by external causes, medical treatment can be given as soon as possible.

These instructions shall include recommendations to establish a procedure for removing PATIENTS rapidly from the magnet's influence, if necessary, by using the EMERGENCY FIELD SHUT DOWN UNIT.

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

The instructions for use:

- shall draw attention to the possibility that anaesthetised PATIENTS can have less than normal protection against high sound pressure, so that ear protection for these PATIENTS should not be omitted even at moderate sound levels;
- shall draw attention to the fact that in some countries legislation may exist covering the exposure of personnel to noise;
- 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 personnel to noise;
- shall draw attention to the RISK of temporary or permanent hearing impairment if adequate hearing protection is not used.

For MR EQUIPMENT that is capable of producing more than an A-weighted r.m.s. sound pressure level ($L_{Aeq, 1h}$) of 99 dB(A), the instructions for use:

- shall state that the A-weighted r.m.s. sound pressure level is measured according to NEMA MS 4:2005;
- shall state that hearing protection shall be used for the safety of the PATIENT and that this hearing protection shall be sufficient to reduce the A-weighted r.m.s. sound pressure level below 99 dB(A);
- shall state that special attention and special training for the OPERATOR is required for proper positioning of the hearing protection, especially when standard ear muffs cannot be applied, or no protection at all can be applied, as for neonates and premature infants;
- shall draw attention to a warning that due to increased anxiety, accepted sound pressure levels can still be of concern to pregnant women and the foetus, to new-borns, infants and young children and to the elderly;

NOTE 1 A suitable warning sign is specified in ISO 7010:2003, Amendment 3 (2007).

* e) CONTROLLED ACCESS AREA

When the installation of a CONTROLLED ACCESS AREA is required for the MR EQUIPMENT (see 201.7.9.3.101 a) and 202), the instructions for use

- shall state, that it is the responsibility of the RESPONSIBLE ORGANIZATION to follow local statutory requirements with respect to access to the CONTROLLED ACCESS AREA;
- shall specify, preferably accompanied by a scaled diagram, the size and shape of the CONTROLLED ACCESS AREA;
- shall indicate the need to establish adequate rules for controlling access to the CONTROLLED ACCESS AREA in terms of the potential RISK to PATIENTS and MR WORKERS within the CONTROLLED ACCESS AREA from the attraction of objects containing iron or other magnetically active materials or from torque on such metallic materials and the potential RISK to persons inadvertently entering the area who can be affected by the possible dysfunction of their medical implants such as pacemakers;

NOTE 2 For magnetic field strengths less than 0,5 mT no administrative controls are required.

- shall list EQUIPMENT and tools specified or recommended by the MANUFACTURER for use in the CONTROLLED ACCESS AREA. For all EQUIPMENT, ACCESSORIES or tools listed, a description should be given of special measures that are needed, if any, for their installation as well as special precautions, if any, for their use;
- shall state that peripheral equipment, including PATIENT monitoring, life supporting devices and emergency care equipment, which is not specified or recommended for use in the CONTROLLED ACCESS AREA, can be disturbed by the radio frequency field, the switched gradients or the magnetic fringe field of the MR EQUIPMENT and that this peripheral equipment can also disturb the proper functioning of the MR EQUIPMENT;
- shall explain the meaning of device labelling for MR safe, MR conditional and MR unsafe.

* f) Liquid and gaseous cryogenics

For MR EQUIPMENT equipped with superconducting magnets, instructions for use shall, in order to prevent accidents and QUENCH:

- require adequate provisions for supply of liquid cryogen;
- recommend that cryogen refilling be performed by trained and experienced personnel only;
- provide information on maintenance and inspection of the magnet including the liquid cryogen level(s);
- provide information on the minimum cryogen level(s) required for normal operation;
- require that frequent checks of cryogen level(s) be carried out by the RESPONSIBLE ORGANIZATION;
- give clear information on potential HAZARDS of the use of liquid cryogen as well as information on proper handling of these liquids. This shall include information concerning:
 - the wearing of protective clothing to prevent frostbite;
 - procedures to be performed after gas release;
 - precautions against lack of oxygen;
 - the use of non-magnetic containers for the cryogen that are being supplied;
 - procedures to be followed if flammable materials are found near the cryogen container.

NOTE 3 Liquid oxygen can accumulate, or the gaseous oxygen concentration can become high in the vicinity of the cryogen.

* g) Operating modes

Instructions for use shall provide information concerning the meaning and background of each mode of operation: NORMAL OPERATING MODE, FIRST LEVEL CONTROLLED OPERATING MODE, and SECOND LEVEL CONTROLLED OPERATING MODE, as they are defined in 201.12.4.101. The instructions for use shall also give the explanation that the static magnetic field, GRADIENT OUTPUT and SAR levels for PATIENTS are based on current scientific literature related to safety, and that the level of exposure, the decision of leaving the NORMAL OPERATING MODE and the possible need for physiological monitoring of the PATIENTS shall be a medical judgement as to the PATIENTS' potential RISK versus benefit.

Instructions for use shall explain the requirements of each operating mode:

- For MR EQUIPMENT operating within the NORMAL OPERATING MODE, no specific indication or measure is required to be displayed.
- For MR EQUIPMENT capable of operation in FIRST LEVEL CONTROLLED OPERATING MODE, the properties of the MR EQUIPMENT with respect to displayed indication before entering this mode and to deliberate action when entering this mode, as required in 201.12.4.101.4 shall be described. Also, MEDICAL SUPERVISION shall be recommended as required in 201.7.9.2.101 b).
- For MR EQUIPMENT capable of operating within the SECOND LEVEL CONTROLLED OPERATING MODE, specific security measures shall be provided as required in 201.12.4.101.5 to prevent unauthorised operation in the SECOND LEVEL CONTROLLED OPERATING MODE. Operation in the SECOND LEVEL CONTROLLED OPERATING MODE is only permitted under a human studies protocol approved according to local requirements as required in 201.7.9.2.101 b).

Instructions for use shall recommend that attention should be paid to the safety of PATIENTS in terms of the deliberate action and MEDICAL SUPERVISION which is required for entering the FIRST LEVEL CONTROLLED OPERATING MODE, or in terms of the specific security measures and approval of investigational human studies protocol according to local requirements required for entering the SECOND LEVEL CONTROLLED OPERATING MODE.

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

For MR EQUIPMENT that is capable of operation in the FIRST LEVEL CONTROLLED OPERATING MODE or the SECOND LEVEL CONTROLLED OPERATING MODE for static magnetic field, the instructions for use shall:

- explain the possible effects that PATIENTS and MR WORKERS can experience when the main static magnetic field is above the level of the NORMAL OPERATING MODE, paying particular attention to the effects that can be experienced if the PATIENT'S or the MR WORKER'S head is moved rapidly while inside or close to the MR EQUIPMENT, including vertigo, nausea and a metallic taste in the mouth;
- recommend that the PATIENT remains still while in the region of high static magnetic field;
- provide information on the values of B_0 which the MR EQUIPMENT is capable of;
- explain that when the main static magnetic field is higher than 3 T and not exceeding 4 T, the MR SYSTEM is continuously operating in the FIRST LEVEL CONTROLLED OPERATING 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 field;
- 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 OPERATING 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 special authorization.

i) Exposure of the PATIENT to time varying magnetic fields

For MR EQUIPMENT that is capable of operation at levels of GRADIENT OUTPUT above the NORMAL OPERATING MODE the instructions for use shall:

- explain the possible effects on the PATIENTS of the level of GRADIENT OUTPUT in each of the operating modes with which the MR EQUIPMENT is provided, paying particular attention to possible effects on the peripheral nervous system and on the heart;
- provide information on the GRADIENT OUTPUT of which the MR EQUIPMENT is capable in each operating mode;
- explain that the MR EQUIPMENT will display an indication of the appropriate operating mode when the value of GRADIENT OUTPUT exceeds the limits of the NORMAL OPERATING MODE;
- describe the gradient system as either a WHOLE BODY GRADIENT SYSTEM or as a SPECIAL PURPOSE GRADIENT SYSTEM and describe the volume in which the GRADIENT OUTPUT is in compliance.

j) Exposure of the PATIENT to radio frequency magnetic fields

The instructions for use shall draw attention to RISK factors, which can increase the potential for local excessive RF heating of the PATIENT and they shall describe ways for the OPERATOR to mitigate these RISK factors. These factors include:

- the presence of conductive (metallic) objects or implants within the sensitivity region of the RF transmit coil. All clothing containing metallic thread or components and all other metallic objects such as watches, coins, etc. shall be removed from the PATIENT;
- the use of medicinal products in transdermal patches which can cause burns to the underlying skin;
- the fact that skin-to-skin contact can form a conductive loop through part of the body, e.g., inner thigh-to-thigh, calf-to-calf, hand-to-hand, hand-to-body, ankle-to-ankle contact;
- the presence of damp clothing;
- the placement of the body or extremities against the RF transmit coil surface;
- the contact between PATIENT and RF receive coil cable and the routing of the RF coil cable in proximity to RF transmit coil;
- the formation of loops with RF receive coil cables and ECG leads;
- the use of MR conditional ECG electrodes and leads. Inform the OPERATOR to read and carefully follow the instructions for use. Inform the OPERATOR to always use electrodes that have not passed their expiration date.
- the scanning of sedated or unconscious PATIENTS, or PATIENTS with loss of feeling in any body part, e.g., paralysis of arms or legs, and who would therefore not be able to alert the OPERATOR as to excessive heating and associated tissue damage;
- the presence of unconnected receive coils or electric cables that remain in the RF transmit coil during the examination.

For MR EQUIPMENT that is capable of operation at SAR levels above the NORMAL OPERATING MODE, the instructions for use shall:

- explain the possible effects of elevated values of the different types of SAR that are limited by the MR EQUIPMENT as required in 201.12.4.103;

- explain the possible effects of the SAR on the PATIENTS in each of the operating modes provided by the MR EQUIPMENT, paying particular attention to the safety of PATIENTS who can have reduced thermal regulatory capabilities and increased sensitivity to raised body temperature (e.g. febrile and cardiac decompensated PATIENTS, those with compromised ability to perspire, and pregnant women). In addition, information describing the importance of environmental controls and the effect of ENVIRONMENTAL TEMPERATURE ON PATIENT CORE TEMPERATURE rise shall be provided, along with recommendations for environmental conditions for the PATIENT;
- provide information on the values of each type of SAR the MR EQUIPMENT is capable of;
- explain that the limits for the operating modes for WHOLE BODY SAR given in 201.12.4.103 assume that the ENVIRONMENTAL TEMPERATURE is not more than 25 °C. In addition, the instructions for use shall explain how the SAR is controlled outside these environmental specifications. This explanation shall
 - specify that the MR EQUIPMENT shall not be used when the ENVIRONMENTAL TEMPERATURE is greater than 25 °C, or
 - explain that the limit of the FIRST LEVEL CONTROLLED OPERATING MODE for SAR shall be reduced according to 201.12.4.103.2 (only for MR EQUIPMENT that has the capability to measure the ENVIRONMENTAL TEMPERATURE);
- draw attention to means to reduce the RISK from high SAR scanning, such as the need for breaks for the PATIENT to cool down, light clothing for the PATIENT and adequate ventilation of the PATIENT space;
- explain that the value of the B_{1+RMS} displayed on the CONTROL PANEL for each sequence is an indication of the RF magnetic field intensity. It can be of use to determine the RISK of scanning a patient with an active or passive implant.

* k) Occupational exposure to EMF

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. It shall provide sufficient information relating to the RISKS from these exposures to enable safe working procedures for the MR WORKER. The relevant requirements of 201.7.9.2.101 i) and j) 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;
- information on the maximum levels of the exposure in areas accessible to the MR WORKER, expressed in proper units for the static magnetic field (see subclause 201.7.9.2.101 h) and 201.12.4.104), the GRADIENT OUTPUT (see subclause 201.7.9.2.101.i) and 201.12.4.102) and the RF transmit field (see subclause 201.7.9.2.101 j) and 201.12.4.103) 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) can be induced in the PATIENT and MR WORKER when exposed to the gradients in the FIRST LEVEL CONTROLLED OPERATING 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 possible physiological effect of exposure to RF radiation is heating. Exposure to RF radiation can be minimized 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. Especially MR WORKERS performing INTERVENTIONAL MR EXAMINATIONS, shall be informed and trained that, although peripheral nerve stimulation is not expected, the SAFETY of PATIENTS shall not be compromised during interventional procedures due to peripheral nerve stimulation. Exposure to GRADIENT OUTPUT can be minimized by keeping sufficient distance away from the gradient coils during scanning.
- the possible physiological effects of exposure to 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 minimized 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.

NOTE 4 Local regulations might apply.

The instructions for use shall state that the limits for MR WORKERS may not be applicable when an MR WORKER is pregnant. It might be required in some countries that the 'member of the public' limit be applied to the foetus, which implies that the pregnant MR WORKER is not allowed to be present in the examination room during scanning.

The instructions for use shall state that in some countries legislation might exist covering occupational limits for exposure to EMF, that are lower than the limits for MR WORKER given in this standard.

* l) Auxiliary EQUIPMENT

The RESPONSIBLE ORGANIZATION shall be made aware that any application of physiological monitoring and sensing devices to the PATIENT should be made under the RESPONSIBLE ORGANIZATION'S direction and is the RESPONSIBLE ORGANIZATION'S responsibility.

The instructions for use shall warn the RESPONSIBLE ORGANIZATION and the OPERATOR that the use of auxiliary equipment, such as physiological monitoring and gating equipment and RF transmit coils, which has not been specifically tested and approved for use in the environment of the MR EQUIPMENT might result in burns or other injuries to the PATIENT. Instructions for use shall further warn the RESPONSIBLE ORGANIZATION and the OPERATOR that even auxiliary devices labelled as MR safe or MR conditional with MR EQUIPMENT or MR SYSTEMS might be capable of causing injury if the MANUFACTURERS instructions, especially with respect to electrically conducting lead positioning, are not followed.

m) EMERGENCY FIELD SHUT DOWN UNIT

The instructions for use shall indicate when and how the EMERGENCY FIELD SHUT DOWN UNIT should be operated in the event of an emergency. Examples of situations which would require emergency field shut down shall be provided.

NOTE 5 Permanent magnets cannot be de-energized in case of emergency.

n) Fire precautions

The instructions for use shall recommend to the RESPONSIBLE ORGANIZATION that fire precautions should be discussed with the local fire department, that emergency procedures

should be established and that it is the RESPONSIBLE ORGANIZATION's responsibility to take the necessary initiatives.

o) Artefacts

The instructions for use shall alert the OPERATOR to the fact that image artefacts can occur as a result of technological and physiological factors (e.g. magnet homogeneity, gradient linearity, truncation, aliasing, motion, flow, chemical shift, susceptibility variations, etc.). The effects of these factors (e.g. image non-uniformity, geometric distortion, ghosts, wraparound etc.) on the image shall be described. Methods of correcting or mitigating such effects (e.g. changing bandwidth, gradient moment nulling, pre-saturation, etc.) shall also be discussed.

p) Recommended training

The instructions for use shall recommend that training is needed for the MR WORKER to operate the MR EQUIPMENT safely and effectively. This training shall include emergency procedures, including those for the issues described in this subclause under

- c) Emergency medical procedures
- e) CONTROLLED ACCESS AREA
- m) EMERGENCY FIELD SHUT DOWN UNIT
- n) Fire precautions
- s) Emergency actions in the event of a QUENCH.

q) Quality assurance

The instructions for use shall describe the quality assurance procedures recommended for the RESPONSIBLE ORGANIZATION, including a description of all of the phantoms to be used.

r) Maintenance

The instructions for use shall include the recommended maintenance schedules for the MR EQUIPMENT. Items that should be performed by service personnel shall be identified.

* s) Emergency actions in case of a QUENCH

The instructions for use shall include instructions on how to identify a QUENCH and how to act in the event of a QUENCH, especially when the venting system of the superconducting magnet system fails.

* t) Scanning of PATIENTS with active or passive implants.

The instructions for use shall describe the significant RISK associated with the scanning of patients with active or passive implants containing conductive materials. The electromagnetic fields might exert strong forces on the metallic implants, or might interfere with the operation of active devices. They might cause significant artefacts in the MR image, and might cause adverse health effects such as internal heating that result in tissue damage, loss of physiologic function and serious injury.

When the implant device is labelled as MR safe or MR conditional, the OPERATOR is then informed via the instructions for use of the implant about the safety and possible conditions to be taken into account during scanning. The instructions for use shall explain that further information is described in the ACCOMPANYING DOCUMENTS of the implant MANUFACTURER.

* u) Scanning of pregnant PATIENTS.

The instructions for use shall describe that scanning of pregnant PATIENTS with the WHOLE BODY RF TRANSMIT COIL should be limited to the NORMAL OPERATING MODE with respect to the SAR level.

v) Scanning of PATIENTS with elevated body CORE TEMPERATURE.

The instructions for use shall describe that the MR EQUIPMENT shall limit the body CORE TEMPERATURE rise to avoid undue heat stress and prevent local tissue damage in the body of the PATIENT to values given in Table 201.104. The practical consequence of this limitation is that PATIENTS with a CORE TEMPERATURE higher than 39,5 °C cannot be scanned and PATIENTS with a CORE TEMPERATURE higher than 39,0 °C can only be scanned in NORMAL OPERATING MODE.

w) About function

The instructions for use shall specify where in the user interface the about function of the scanner can be found. The about function shall specify the hardware and software specification of the system, which together with the data given in the ACCOMPANYING DOCUMENTS can be used to determine the specification of the static magnetic field, the gradients and the RF. More specifically the following information shall be given:

- Nominal B_0 value
- Maximum gradient of the static magnetic field in T/m
- Nominal frequency range per nuclei
- Maximum GRADIENT OUTPUT on a cylinder with a diameter of 0,2 m, 0,4 m and bore-diameter minus 0,1 m

NOTE 6 For TRANSVERSE FIELD MAGNET types the cylinder axis (i.e. PATIENT axis) is perpendicular to the magnet axis. The term PATIENT bore is to be replaced by magnet gap between pole shoes: the term magnet length is to be replaced by pole shoe diameter.

201.7.9.3 Technical description

Addition:

201.7.9.3.101 Technical description of MR EQUIPMENT

a) CONTROLLED ACCESS AREA

For MR EQUIPMENT that generates a stray field exceeding 0,5 mT outside its permanently attached cover, and/or an electromagnetic interference level that does not comply with IEC 60601-1-2, the technical description

- shall indicate the necessity to define and permanently install a CONTROLLED ACCESS AREA around the MR EQUIPMENT such that outside this area
 - 1) the magnetic fringe field strength shall not exceed 0,5 mT, and
 - 2) the electromagnetic interference level complies with IEC 60601-1-2:2007;
- shall give clear recommendations as to how this CONTROLLED ACCESS AREA shall be delimited, e.g. by markings on the floor, barriers and/or other means to allow the RESPONSIBLE ORGANIZATION to adequately control access to this area by unauthorised persons;
- shall state that the CONTROLLED ACCESS AREA should be labelled at all entries by appropriate warning signs, including an indication of the presence of magnetic fields and their attractive force or the torque on ferromagnetic materials (see Annex AA for examples of warning signs and prohibitive signs).

When the MR EQUIPMENT is designed for installation in a room in which audiovisual contact with the PATIENT is likely to be limited, the technical description shall specify provisions in the design of the room and in the EQUIPMENT to enable audio and visual contact with the PATIENT during the MR EXAMINATION. The audio visual contact shall be sufficient to allow ROUTINE MONITORING and MEDICAL SUPERVISION of the PATIENT.

* b) Compatibility technical specification sheet

In addition to the instructions for use for MR EQUIPMENT a compatibility technical specification sheet shall be provided with sufficient information to enable testing the proper operation of peripheral equipment and to provide information to the RESPONSIBLE ORGANIZATION. The compatibility technical specification sheet (product data sheet) shall describe a number of parameters which characterise the MR EQUIPMENT. The parameter list includes:

- Magnet: type, field strength, bore dimension, cryogen types and boil-off rates, spatial distribution of surrounding field in plots relating to a typical installation of the MR EQUIPMENT:
 - The plots shall represent three suitable orthogonal planes through the magnet centre to illustrate maximum spatial extent of iso-magnetic contours.
 - Each plot shall contain at least the iso-magnetic contours with values of 0,5 mT, 1 mT, 3 mT, 5 mT, 10 mT, 20 mT, 40 mT, and 200 mT as well as a distance scale and a superimposed outline of the magnet.
 - The position where the spatial gradient of the main magnetic field is a maximum, and the values of B_0 and the spatial gradient of B_0 at that location. At this location the force on a saturated ferromagnetic object resulting from the spatial gradient of the main magnetic field is maximum.
 - The position where the product of the magnitude of the magnetic field B_0 and the spatial gradient of B_0 is a maximum and the value of B_0 and the spatial gradient of B_0 at that location. At this location, the force on a diamagnetic or paramagnetic object, or a ferromagnetic material below its magnetic saturation point, is a maximum.
 - A plot representing the 0,5 T, 1 T, 1,5 T, 2 T, 3 T and the 4 T iso-magnetic contours of the static magnetic field at positions accessible to and relevant for the MR WORKER shall be provided. Only the contour lines the magnet can produce are required.
 - Gradient system: type, maximum amplitude, fastest rise time, maximum slew rate and spatial distribution of the maximum magnitude values of the vector sum of the field components generated by each of the three GRADIENT UNITS:
 - Spatial distribution of the maximum magnitude values of the vector sum of the field components generated by each of the three GRADIENT UNITS simultaneously at the positions accessible to and relevant for the MR WORKER during scanning as described in subclause 201.12.4.105.2.3.
 - Spatial distribution of the maximum magnitude values of the vector sum of the field components generated by each of the three GRADIENT UNITS simultaneously at positions on virtual cylinders coaxial with the patient axis with diameters of 0,2 m, 0,4 m and 0,1 m less than the narrowest aperture of the PATIENT accessible space. The virtual cylinders have the same length as the gradient coil. In the cylinder axis direction the points shall have a separation of not more than 0,02 m. Detailed calculation shall be performed in a fashion equivalent to the description given in subclause 201.12.4.105.2.3.
- NOTE 1 These requirements are for PATIENT safety and consequently differ from the requirements for the MR WORKERS as defined in subclause 201.12.4.105.2.3.
- RF system, types of RF transmit coils, amplifier peak power, applied maximum RF transmit field bandwidth, the maximum specified B_{1+RMS} for each volume transmit coil, and
 - the spatial distribution of the maximum RF transmit field for the unloaded coil at the positions accessible to and relevant for the MR WORKER during scanning as described in subclause 201.12.4.105.3.3.

- the maximum RF transmit field at the ISOCENTRE of the system when the unloaded coil is positioned for imaging at the ISOCENTRE, and the distances from the ISOCENTRE on the coil axis (i.e. normally the z-direction) at which the RF transmit field is reduced by 3 dB and 10 dB from the maximum field at the ISOCENTRE

NOTE 2 These requirements are for PATIENT safety and consequently differ from the requirements for the MR WORKERS as defined in subclause 201.12.4.105.3.3.

– Compatibility protocols:

The MANUFACTURER of MR EQUIPMENT shall suggest protocols, which can be run routinely on the MR EQUIPMENT, to enable the MANUFACTURER of peripheral equipment to test the functionality of the peripheral equipment in the fields produced by the MR EQUIPMENT. The protocols are designed to run the MR EQUIPMENT with high transmit RF field or high gradient slew rates and amplitudes so that the MANUFACTURER of peripheral equipment can investigate the influence of the MR EQUIPMENT on its peripheral equipment. The tests are not intended for estimation of the possible effect of the peripheral equipment on the resulting image quality of the MR EQUIPMENT and are no guarantee that the peripheral equipment will function properly.

- PATIENT space: size, ventilation, communication, and lighting.
- PATIENT SUPPORT: dimensions, positioning, accuracy and maximum load.

* c) Safety provisions in the event of a QUENCH

For MR EQUIPMENT equipped with superconducting magnets, the ACCOMPANYING DOCUMENTS shall

- state the requirements for a venting system for the superconducting magnet which connects the cryostat of the magnet to the outside atmosphere and which is designed to withstand a QUENCH and to protect nearby persons in the event of a QUENCH;
- provide guidelines for the construction (dimensions, position, assembly and material to be applied) of the venting system for the superconducting magnet inside and outside the examination room;
- recommend a preventive maintenance program, which states that regular checks of the adequateness of the function of the venting system for the superconducting magnet are to be made;
- state requirements for the design of the examination room to ensure safety of the PATIENT and other persons inside and outside the examination room in the event of failure of the venting system during a QUENCH. The suggested design shall address the issues of reducing pressure build-up, temperature decrease and oxygen depletion during a QUENCH. A number of acceptable solutions for such provisions, demonstrated to be effective by simulation or test, shall be listed, so that even when the venting system of the superconducting magnet fails to work adequately, the chance of a HAZARD for the PATIENT or other persons inside as well as outside the examination room, as caused by pressure build-up, temperatures decrease or oxygen depletion during the QUENCH, is reduced considerably;
- state the need for the RESPONSIBLE ORGANIZATION to establish an emergency plan for a QUENCH, including a situation in which the venting system for the superconducting magnet fails to function adequately;
- state the need for possible extra control measures for the PATIENT ventilation system in order not to expose the PATIENT to additional helium transported to the PATIENT via the PATIENT ventilation system. The PATIENT ventilation system should have its inlet opening in a safe place (such as at a low level in the examination room or directly connected to the air-conditioning of the examination room), or be connected to a QUENCH detector, so that the PATIENT ventilation system can be automatically controlled when a QUENCH occurs and will not transport helium to the PATIENT inside the scanner.

NOTE 3 The venting system for the superconducting magnet is considered to be the cryogenic vent pipe and all the extra components necessary to safely accommodate a QUENCH.

NOTE 4 Examination room configurations demonstrated by simulation or test that are acceptable include:

- configurations in which the RF door opens outwards or is a sliding RF door;
- configurations in which the RF door opens inwards, if these include extra precautions to prevent PRESSURE build up. This can be realized by one of the following
 - an emergency examination room air extraction system, which can be switched on (possibly automatically via a hardwired oxygen monitor in the ceiling of the examination room to detect the escape of helium gas) to maximum in the event of a QUENCH; or
 - an opening in the wall or ceiling of the examination room, venting towards an open area; or
 - a possibility of opening the observation window in the examination room outward or by sliding; or
 - a second independent venting system for the superconducting magnet that remains operational in case the regular venting system for the superconducting magnet is obstructed; or
 - equivalent methods demonstrated to be effective by simulation or test.

d) Decay characteristics of magnetic field

For MR EQUIPMENT with superconducting magnets or resistive magnets, the technical description shall provide decay characteristics of the magnet in case of a QUENCH or of an emergency field shut down to enable the RESPONSIBLE ORGANIZATION to implement adequate life supporting and other safety procedures. These characteristics shall indicate the time from activation of the EMERGENCY FIELD SHUT DOWN UNIT to the moment at which the field strength in the centre of the magnet has fallen to 20 mT.

In the technical description, guidance shall be given regarding where and how to install the actuator of the EMERGENCY FIELD SHUT DOWN UNIT.

e) Type of gradient system

The gradient system shall be labelled in the technical description by the MANUFACTURER either as a WHOLE BODY GRADIENT SYSTEM or as a SPECIAL PURPOSE GRADIENT SYSTEM.

f) Safety site readiness check list

Recommend the usage of a 'safety site readiness check list', which should list all the safety related aspects for the installation and should be acknowledged by the relevant parties involved in the installation of the MR SYSTEM before operation of the system starts.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies except as follows:

* 201.8.7.3 Allowable values

Replacement:

- d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION. For permanently installed MR EQUIPMENT the EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 20 mA.

NOTE Local regulation can establish limits for protective earth currents of the installation. See also IEC 60364-7-710 [165] ²⁾.

Addition:

- e) Limits for PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under normal and single fault condition do not apply for frequencies above 1 MHz. Hazards arising from high frequency currents are addressed in 201.12.4.103.2.

²⁾ Figures in square brackets refer to the Bibliography.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies except as follows:

201.9.6 Acoustic energy (including infra- and ultrasound) and vibration

Replacement:

*** 201.9.6.2.1 Audible acoustic energy**

The MR EQUIPMENT shall not produce noise having an unweighted peak sound pressure level (L_P) higher than 140 dB referenced to 20 μ Pa in any accessible area.

Compliance is checked by applying NEMA MS 4.

201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure

Addition:

201.9.7.101 Helium vessels of MR EQUIPMENT

If the helium vessel is designed as a pressure vessel, then it shall be in compliance with subclause 9.7 of the general standard, or with national regulations.

201.9.8 HAZARDS associated with support systems

Replacement:

201.9.8.3.3 Dynamic forces due to loading from persons

Addition:

NOTE 1 The mass is accelerated for 150 mm, and then decelerates during compression of the 60 mm of foam, resulting in a force equivalent from 2 to 3 times the SAFE WORKING LOAD.

Where mechanical analysis proves that the following static load test is more severe than the dynamic load test specified in the general standard, it is possible to waive the dynamic load test based on RISK management.

Prior to performing this test, a PATIENT SUPPORT/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE where PATIENT LOADING and unloading takes place.

A mass which results in a force calculated to be greater than the dynamic load shall be placed on the PATIENT SUPPORT. The contact area of this mass is equivalent to that defined in Figure 33 of the general standard and is applied for at least one minute. Any loss of function or structural damage that could result in unacceptable RISK constitutes a failure.

NOTE 2 The foam described in Figure 33 is not used in this test.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies except as follows.

*** 201.12.4 Protection against hazardous output**

Addition:

201.12.4.101 Operating modes

201.12.4.101.1 General

When during its operation one or more of the outputs of the MR EQUIPMENT reach a level that might cause undue physiological stress to the PATIENT, the OPERATOR shall decide whether or not this operation is in the interest of the PATIENT. In this subclause, requirements on the design of the MR EQUIPMENT are given that can help the OPERATOR to make that decision. The requirements in this subclause describe three levels of operation of MR EQUIPMENT that are specified with respect to the user interface and information given to the OPERATOR (201.12.4.101) and with respect to the values of output permitted (201.12.4.102 – 201.12.4.104).

The requirements of this subclause shall apply separately for the operating modes regarding the GRADIENT OUTPUT, the SPECIFIC ABSORPTION RATES (SAR) and the static magnetic field.

Demonstration of compliance with the requirements of this subclause relating to operating modes, (i.e. the means for control, the deliberate action required and the information and indications provided) shall be checked by inspection. The methods of measurement to demonstrate compliance with the operating mode limits contained in 201.12.4.102 and 201.12.4.103 are described in 201.12.4.105.

201.12.4.101.2 All operating modes

MR EQUIPMENT shall comply with the following requirements:

- a) Means (control) shall be provided in order to ensure, that the limit(s) of the (selected) operating mode cannot be exceeded. This control shall be independent of OPERATOR input (as to PATIENT size, mass or position) or shall be checked by the MR EQUIPMENT in order to detect any OPERATOR input error.
- b) A reset to the NORMAL OPERATING MODE with respect to SAR and dB/dt shall be performed automatically with change of the PATIENT.
- c) The MR EQUIPMENT shall display on the CONTROL PANEL upon request the predicted value for the SAR. The MR EQUIPMENT shall display on the CONTROL PANEL upon request the predicted value for the B_{1+RMS} averaged over any 10 s period of the scan. The B_{1+RMS} value shall only be displayed when a volume RF transmit coil is applied.

NOTE It is assumed that the maximum GRADIENT OUTPUT the system can deliver is known and available in the technical description.

201.12.4.101.3 NORMAL OPERATING MODE

For MR EQUIPMENT that is not capable of operation at levels above the NORMAL OPERATING MODE as specified in 201.12.4.102 and 201.12.4.103, no specific indication of the operating mode is required to be displayed at the CONTROL PANEL.

201.12.4.101.4 FIRST LEVEL CONTROLLED OPERATING MODE

MR EQUIPMENT that allows the operation in the FIRST LEVEL CONTROLLED OPERATING MODE as specified in 201.12.4.102 and 201.12.4.103 shall comply with the following requirements:

- a) Before the start of each scan, an indication of the operating mode defined by the predicted value of the GRADIENT OUTPUT and SAR, to be applied during the scan shall be displayed at the CONTROL PANEL.
- b) If the value of the GRADIENT OUTPUT or SAR that controls the scan is such as to enter the FIRST LEVEL CONTROLLED OPERATING MODE, the attention of the OPERATOR shall be drawn to this condition by a clear indication on the CONTROL PANEL. A record of the operating mode or equivalent data shall be an integral part of the image data.
- c) A deliberate action of the OPERATOR shall be necessary in order to enter the FIRST LEVEL CONTROLLED OPERATING MODE.

201.12.4.101.5 SECOND LEVEL CONTROLLED OPERATING MODE

MR EQUIPMENT, which allows the operation in the SECOND LEVEL CONTROLLED OPERATING MODE for values of the GRADIENT OUTPUT or SAR as specified in 201.12.4.102 and 201.12.4.103, shall comply with the following requirements:

- a) A specific security measure that prevents access to the SECOND LEVEL CONTROLLED OPERATING MODE shall be deactivated before entering the SECOND LEVEL CONTROLLED OPERATING MODE. The specific security measure shall be designed so that the SECOND LEVEL CONTROLLED OPERATING MODE can be accessed only under the authorisation of the medically responsible person acting under the authority of a human studies protocol approved according to local requirements. The specific security measure shall involve a key-lock, a combination lock, a software password, or other protective device.
- b) Before the start of each scan, an indication of the operating mode defined by the maximum GRADIENT OUTPUT and SAR value for the scan, and a statement of the SAR and the GRADIENT OUTPUT value to be applied during the scan shall be displayed at the CONTROL PANEL.
- c) A record of the GRADIENT OUTPUT or SAR that controls the scan values and the equivalent data shall be an integral part of the image data.
- d) An indication to the OPERATOR shall be included that the operating conditions are potentially hazardous and that these conditions should not be applied for normal clinical use.
- e) The MR EQUIPMENT shall provide means to set adjustable limits (in the SECOND LEVEL CONTROLLED OPERATING MODE) of GRADIENT OUTPUT or different types of SAR which cannot be adjusted by the OPERATOR, unless authorized.

*** 201.12.4.102 Protection against excessive low frequency field variations produced by the gradient system**

201.12.4.102.1 General

In this standard, low frequency field variations produced by the gradient system are the variations which might produce cardiac or peripheral nerve stimulation (PNS) (i.e. the EFFECTIVE STIMULUS DURATION >20 μ s and thus no tissue heating is considered).

201.12.4.102.2 Objectives for limitation of PNS OUTPUT

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

NOTE MR EQUIPMENT that meets the requirements given in the following subclauses are considered to satisfy these objectives when balanced against their diagnostic efficacy.

For this particular standard it is understood that

- PNS is the sensation of an activation of the nervous system due to gradient switching;

- the onset of sensation is the PNS THRESHOLD LEVEL (see 201.3.227);
- uncomfortable PNS is the level tolerable to the PATIENT and the MR WORKER when properly informed and motivated;
- intolerable PNS is the level at which the PATIENT will ask the scan procedure to be terminated immediately;
- cardiac stimulation is the induction of an ectopic beat or other cardiac arrhythmia.

The MR EQUIPMENT shall minimize the occurrence of uncomfortable PNS in the NORMAL OPERATING MODE.

201.12.4.102.3 Limits for PNS OUTPUT

201.12.4.102.3.1 General

In this subclause, limits for the PATIENT and the MR WORKER are expressed as a maximum value for the PNS OUTPUT, either as the

- electric field E induced in the PATIENT or the MR WORKER by the changing magnetic field of the gradients, or
- dB/dt , the TIME RATE OF CHANGE OF THE MAGNETIC FIELD of the gradients.

The limits are a function of the EFFECTIVE STIMULUS DURATION $t_{s,eff}$. The EFFECTIVE STIMULUS DURATION is illustrated in Figure 201.101 for some waveforms.

Test conditions used to demonstrate compliance to these limits are defined in 201.12.4.105.2.

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

201.12.4.102.3.2 Limits related to prevention of cardiac stimulation

To protect against cardiac stimulation in each operating mode, the GRADIENT OUTPUT of all GRADIENT UNITS shall satisfy:

$$E < \frac{2}{\left\{ 1 - \exp\left(-\frac{t_{s,eff}}{3}\right) \right\}}$$

where

$t_{s,eff}$ (ms) is the EFFECTIVE STIMULUS DURATION ;

E (V/m) is the electric field induced by GRADIENT SWITCHING.

For MR EQUIPMENT provided with WHOLE BODY GRADIENT SYSTEMS, this limit may be replaced by:

$$dB / dt < \frac{20}{\left\{ 1 - \exp\left(-\frac{t_{s,eff}}{3}\right) \right\}}$$

where

dB/dt (T/s) is the rate of change of the magnetic field during GRADIENT switching;

$t_{s,eff}$ (ms) is the EFFECTIVE STIMULUS DURATION.

201.12.4.102.3.3 Limits related to peripheral nerve stimulation (PNS)

Limits of PNS OUTPUT either shall be based on the results of an experimental study of human subjects as described in section a) of this subclause or shall have values as stated in section b) of this subclause.

a) Directly determined limits

Limits related to minimising PNS for any given type of gradient system may be based on direct determination from a study on human volunteers and are as follows:

- for operation in the NORMAL OPERATING MODE, the gradient system shall operate at a level that does not exceed 80 % of the directly determined mean PNS THRESHOLD LEVEL, and
- for operation in the FIRST LEVEL CONTROLLED OPERATING MODE, the gradient system shall operate at a level that does not exceed 100 % of the directly determined mean PNS THRESHOLD LEVEL.

In addition the study may be used to derive weight factors for each GRADIENT UNIT, suitable for use in the control of the GRADIENT OUTPUT (see 201.12.4.102.2)

The manner in which the direct determined PNS THRESHOLD LEVEL and weight factors are obtained from the human volunteer study shall comply with the conditions stated in 201.12.4.105.1.

These limits and weight factors shall not be applied to other types of gradient systems, unless such types are shown to be of sufficiently similar design.

b) Default values

When no direct determination of limits is obtained, the GRADIENT OUTPUT limits for the NORMAL OPERATING MODE (L_{01}) and the FIRST LEVEL CONTROLLED OPERATING MODE (L_{12}) shall, depending on the label (as defined in 201.7.9.3.101 e) not be larger than the values stated below:

$$L_{12} = 1,0 \, rb(1 + 0,36 / t_{s,eff}), \quad (t_{s,eff} \text{ in ms})$$

$$L_{01} = 0,8 \, rb(1 + 0,36 / t_{s,eff}), \quad (t_{s,eff} \text{ in ms})$$

where

$t_{s,eff}$ (ms) is the EFFECTIVE STIMULUS DURATION and

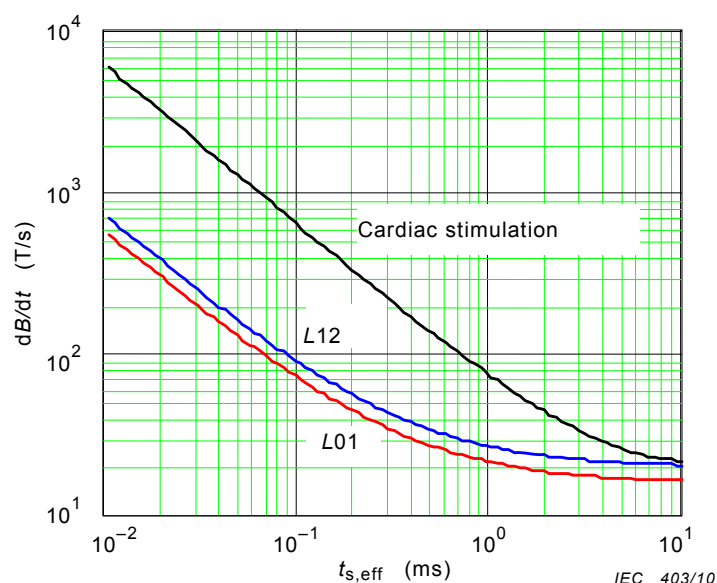
rb (here in T/s) is the rheobase given in Table 201.102.

L_{01} and L_{12} as well as rb shall either be expressed as the electric field E (V/m) induced or as the TIME RATE OF CHANGE OF THE MAGNETIC FIELD dB/dt (T/s).

Table 201.102 – Rheobase values per type of gradient system

Type of gradient system	rb expressed as E (V/m)	rb expressed as dB/dt (T/s)
WHOLE BODY GRADIENT SYSTEM	2,2	20
SPECIAL PURPOSE GRADIENT SYSTEM	2,2	Not applicable

Figure 201.102 gives a graphical presentation of the limits for GRADIENT OUTPUT for a WHOLE BODY GRADIENT SYSTEM related to cardiac stimulation and peripheral nerve stimulation, expressed in dB/dt , as a function of the EFFECTIVE STIMULUS DURATION.



Limits for peripheral nerve stimulation of GRADIENT OUTPUT for the NORMAL OPERATING MODE (L01) and the FIRST LEVEL CONTROLLED OPERATING MODE (L12) in WHOLE BODY GRADIENTS, expressed as dB/dt (T/s) versus t_s (ms). The limit of 201.12.4.102.3.2 for cardiac stimulation is shown for comparison.

Figure 201.102 – Limits for cardiac and peripheral nerve stimulation

201.12.4.102.3.4 Control of PNS OUTPUT

The MR EQUIPMENT shall control the PNS OUTPUT O of the gradient system so that it does not exceed the limits for peripheral nerve stimulation. O shall either be obtained by weighted quadratic addition from O_i , the maximum PNS OUTPUT of each GRADIENT UNIT i , or by properly validated alternative summation rules.

The equation expressing weighted quadratic addition shall be:

$$O = \sqrt{\sum (w_i O_i)^2}$$

where w_i is the weight factor per GRADIENT UNIT.

Weight factors for E -fields are always equal to one, weight factors for dB/dt are stated in Table 201.103. Values of weight factors derived by direct determination or other properly validated means may be used.

Table 201.103 – Weight factors for summation of the maximum output O_i per GRADIENT UNIT

Type of gradient system		Weight factors		
		W_{AP}^a	W_{LR}^a	W_{HF}^a
WHOLE BODY GRADIENT SYSTEM	Default values	1,0	1,0	1,0
	Cylinder magnets	1,0	0,8	0,7
	Empirical determination	1,0	b	b
SPECIAL PURPOSE GRADIENT SYSTEM	Default values	1,0	1,0	1,0
	Empirical determination	1,0	b	b
NOTE Weight factors for the E field are always equal to one.				
^a W_{AP}, W_{LR}, W_{HF}: Weighting factors allowed per GRADIENT UNIT, depending on the orientation of the direction of the GRADIENT UNITS with respect to the PATIENT coordinate system with axes AP (anterior-posterior), LR (left to right) and HF (head to feet). ^b Values of weight factors derived by direct determination or other properly validated means may be used.				

*** 201.12.4.103 Protection against excessive radio frequency energy**

*** 201.12.4.103.1 Limits for temperature**

To avoid undue heat stress and prevent local tissue damage in the body the MR EQUIPMENT shall limit the tissue temperature rise of the PATIENT to values given in Table 201.104 by limiting pulse sequence parameters and by limiting radio frequency power. 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 201.104 for the NORMAL OPERATING MODE and the FIRST LEVEL CONTROLLED OPERATING MODE.

Table 201.104 – Temperature limits

Operating mode ↓	Maximum CORE TEMPERATURE	Maximum Local tissue temperature	Rise of CORE TEMPERATURE °C
NORMAL	39	39	0,5
FIRST LEVEL CONTROLLED	40	40	1
SECOND LEVEL CONTROLLED	>40	>40	>1

Compliance to the limits to temperature rise may be reached by limiting the SPECIFIC ABSORPTION RATE (SAR) as specified in 201.12.4.103.2. These SAR values limits are derived such that the spatially localized temperatures are expected not to result in tissue damage.

The values of Tables 201.104 and 201.106 are conservative. Higher temperatures and higher LOCAL SAR values may be accepted for specific tissues if no unacceptable RISK for the PATIENT occurs.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

NOTE 1 Ongoing studies on tissue heating models, e.g. CEM43, might be incorporated in the future updates of this standard.

NOTE 2 Since the stray field of the RF transmit coil drops off rapidly outside the coil and by geometrical considerations, whole body exposure of the MR WORKER is not possible. It therefore can be assumed that the exposure for the MR WORKER is most likely to be at the level of NORMAL OPERATING MODE when the system is operating in FIRST LEVEL CONTROLLED OPERATING MODE

NOTE 3 The requirements regarding protection against radio frequency power assume that the MANUFACTURER'S recommendations regarding the control of ENVIRONMENTAL TEMPERATURE and other conditions are met.

NOTE 4 For ACCESSIBLE SURFACES the temperature limits of the general standard apply. For estimation, see rationale.

* 201.12.4.103.2 Limits for SAR

The methods of measurements to demonstrate compliance with these requirements are described in 201.12.4.105.3.

In Table 201.105, allowed ranges of values of WHOLE BODY SAR, PARTIAL BODY SAR AND HEAD SAR are given for NORMAL OPERATING MODE and FIRST LEVEL CONTROLLED OPERATING MODE. For the SECOND LEVEL CONTROLLED OPERATING MODE, no limits are given. These limits are considered the responsibility of the local investigational review board that has authorized its use.

The mass used to determine the WHOLE BODY SAR is given by the PATIENT mass. The mass to determine the PARTIAL BODY SAR is called exposed PATIENT mass. It is given by the PATIENT mass within the effective volume of the RF transmit coil. The effective volume of the RF transmit coil shall be that volume in which no more than 95 % of the total absorbed RF power is deposited inside a homogeneous material which fills the volume normally accessible by the PATIENT.

The mass to determine the HEAD SAR shall be the mass of the head approximated by a suitable model. The mass to determine the LOCAL SAR shall be 10 g.

Table 201.105 – SAR limits for volume transmit coils

Averaging time	6 min		
	WHOLE BODY SAR	PARTIAL BODY SAR	HEAD SAR
Body region →	Whole body	Exposed body part	Head
Operating mode ↓	(W/kg)	(W/kg)	(W/kg)
NORMAL	2	2 – 10 ^a	3,2
FIRST LEVEL CONTROLLED	4	4 – 10 ^a	3,2
SECOND LEVEL CONTROLLED	>4	>(4 –10) ^a	>3,2
Long MR EXAMINATION specific absorbed energy	The maximum allowed specific absorbed energy is 14,4 kJ/kg (= 240 W·min/kg) per MR EXAMINATION provided that the limits of this standard are still met		
Short duration SAR	The SAR limits over any 10 s period shall not exceed two times the stated values.		
^a The limit scales dynamically with the ratio "exposed PATIENT mass / PATIENT mass": NORMAL OPERATING MODE : PARTIAL BODY SAR = 10 W/kg - (8 W/kg * exposed PATIENT mass / PATIENT mass) FIRST LEVEL CONTROLLED OPERATING MODE : PARTIAL BODY SAR = 10 W/kg - (6 W/kg * exposed PATIENT mass / PATIENT mass)			

NOTE 1 MR WORKER exposure limits are the same as the maximally allowed limits for the PATIENTS. Compliance with the SAR limits for PATIENTS therefore in practice implies compliance for the MR WORKER.

NOTE 2 The ratio between the whole body SAR and the local SAR is discussed in the rationale

NOTE 3 The long MR EXAMINATION specific absorbed energy limit has been introduced because very long duration PATIENT studies have become more common. This limit is an initial simple model to consider the rate of power deposition versus the thermoregulatory capability of a human body. It limits either the MR examination duration or the SAR level of the individual scans of this MR examination and is applicable to all SAR limits and all operating

modes. If there are multiple, separate studies on a given day where the PATIENT has been given a reasonable rest, each study is considered to be independent from a long MR EXAMINATION specific absorbed energy perspective.

NOTE 4 Following the definition of a VOLUME RF TRANSMIT COIL, a transmit coil designed for exposure of the e.g. the knee or the wrist is considered to be a VOLUME RF TRANSMIT COIL. Since for these types of coils the exposed PATIENT mass is considerably reduced, the PARTIAL BODY SAR limits are applied.

Table 201.106 – SAR limits for local transmit coils

Averaging time	6 min		
	LOCAL SAR		
Body region →	Head	Trunk	Extremities
Operating mode ↓	(W/kg)	(W/kg)	(W/kg)
NORMAL	10 ^a	10	20
FIRST LEVEL CONTROLLED	20 ^a	20	40
SECOND LEVEL CONTROLLED	>20 ^a	>20	>40
Short duration SAR	The SAR limits over any 10 s period shall not exceed two times the stated values		
^a	NOTE In cases where the orbit is in the field of a small LOCAL RF TRANSMIT COIL, care should be taken to ensure that the temperature rise is limited to 1 °C.		

In Table 201.106 allowed ranges of values of LOCAL SAR are given for NORMAL OPERATING MODE and FIRST LEVEL CONTROLLED OPERATING MODE. For the SECOND LEVEL CONTROLLED OPERATING MODE, no limits are given. These limits are considered the responsibility of the local investigational review board that has authorized its use.

Voltages will be induced on the conductors placed in a time-varying magnetic field with time-varying components normal to at least some of the various loops. Electric fields between the conductors depend on spacing and can be arbitrarily large, but are typically localized. At radio frequencies, these localized electric fields can result in high LOCAL SAR levels. The issues can be avoided in a variety of ways (suppressing currents with baluns, using spacers to keep PATIENTS away from high field regions). It is imperative that localized SAR from transmission lines is controlled by the LOCAL SAR limits given in Table 201.106. It is the RESPONSIBLE ORGANIZATION's responsibility to follow the instructions given by the MR MANUFACTURER in the instructions for use.

When applicable the MANUFACTURER shall address in the RISK MANAGEMENT FILE the RISK associated with unwanted RF interaction.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

For WHOLE-BODY SAR, the values in Table 201.105 are valid at ENVIRONMENTAL TEMPERATURES below 25 °C. At higher temperatures, these values shall be reduced depending on actual ENVIRONMENTAL TEMPERATURE. The reduction of SAR limits for ENVIRONMENTAL TEMPERATURE starts at the derating temperature of 25 °C.

For ENVIRONMENTAL TEMPERATURE that exceeds the SAR-derating temperature, the WHOLE-BODY SAR limit shall be reduced by 0,25 W/kg per degree until the SAR is 2 W/kg for FIRST LEVEL CONTROLLED OPERATING MODE. Figure 201.103 is a graphical representation of the requirement in this subclause.

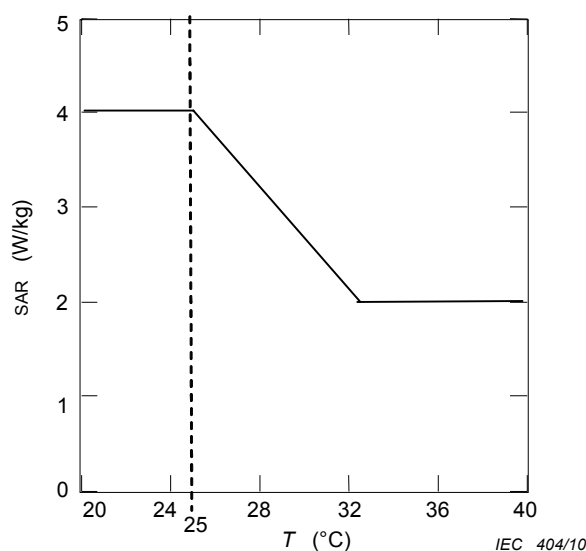


Figure 201.103 – Reduction of WHOLE BODY SAR limits at high temperatures

The curve displays WHOLE BODY SAR limits versus ENVIRONMENTAL TEMPERATURE for the FIRST LEVEL CONTROLLED OPERATING MODE.

201.12.4.103.3 Control of SAR

For exposure with a VOLUME RF TRANSMIT COIL, the MR EQUIPMENT shall control the HEAD SAR, the PARTIAL BODY SAR and the WHOLE BODY SAR,.

For exposure with a LOCAL RF TRANSMIT COIL, the MR EQUIPMENT shall control the LOCAL SAR and the WHOLE BODY SAR,.

NOTE 1 Depending on the actual given exposure situation - defined by the dimensions of the RF transmit coil and of the PATIENT and his position relative to the coil - one of the SAR aspects will be the limiting factor and hence will determine the maximum RF power allowed to transmit.

NOTE 2 Requirements on the display of SAR are given in 201.12.4.101.

NOTE 3 Multi channel transmit coils have attributes of both LOCAL and VOLUME RF TRANSMIT COILS. The appropriate control of SAR depends on the use of the coil.

*** 201.12.4.104 Protection against exposure to static magnetic fields**

The static magnetic field of the MR EQUIPMENT is the operating magnetic field strength.

For the static magnetic field, the following operating mode limits as defined in 201.12.4.101 apply:

- The NORMAL OPERATING MODE comprises values of the static magnetic field equal or lower than 3 T.
- The FIRST LEVEL CONTROLLED OPERATING MODE comprises values of the static magnetic field higher than 3 T and equal or lower than 4 T.

In view of the permanent character of the value of the static magnetic field, the concept of a deliberate action of the OPERATOR in order to enter the FIRST LEVEL CONTROLLED OPERATING MODE is not required.

- The SECOND LEVEL CONTROLLED OPERATING MODE comprises values of the static magnetic field higher than 4 T.

Physiological effects, such as vertigo and nausea, due to the movement in the static magnetic field for both the PATIENT and the MR WORKER shall be minimised. This means that the value of dB/dt , which the human body is exposed to when moving in the static magnetic stray field, shall be limited. The maximum allowed dB/dt values are the result of the speed of movement and the spatial field inhomogeneity (spatial gradient of the static magnetic field).

The allowed speed of motion for the transport of the PATIENT into the bore of the system through the gradient field of the static magnetic field shall be limited such that the maximum dB/dt value the PATIENT is exposed to shall be no more than 3 T/s. This limit is independent of the PATIENT's condition and therefore not related to a specific operating mode on the MR EQUIPMENT.

The instructions for use (see 201.7.9.2.101 k) shall explain the need to limit the speed of motion for the MR WORKER and the need for training.

201.12.4.105 Methods to demonstrate compliance with the requirements

201.12.4.105.1 Direct determination of the limits of the PNS OUTPUT

When limits of PNS OUTPUT are based on a direct determination study, the conduct of the study and the derivation of the threshold shall comply with this subclause.

The study shall be a human volunteer study. The observed parameter shall be the PNS THRESHOLD LEVEL.

The study shall have a defined protocol, including a period of training of the human subjects and a test for repeatability of the experience. Sample size shall be at least 11. Representative samples shall be obtained by including normal healthy adult subjects of both sexes.

To cover all PATIENT positions, a worst case position shall be determined for one EFFECTIVE STIMULUS DURATION and one volunteer, by stepwise displacement of the volunteer in the gradient system.

To cover all waveforms, three options are allowed:

- a) the threshold shall be recorded for all representative waveforms,
- b) the threshold shall be recorded for sinusoid or trapezoid waveforms and the dependence of threshold on waveform for other waveforms shall be inferred from a suitably validated model, or
- c) for all waveforms the threshold shall assumed to be equal to that recorded for trapezoid or sinusoid waveforms.

To cover the whole range of EFFECTIVE STIMULUS DURATIONS allowed by the gradient system, at least three values per decade shall be tested up to the maximum clinically relevant range. Interpolation between results may be used. All GRADIENT UNITS shall be tested individually, and when no stimulation is reached at maximum GRADIENT OUTPUT, combinations of two or three GRADIENT UNITS shall be tested in which at least one unit is driven at maximum output.

For each gradient waveform tested, for each GRADIENT UNIT and each EFFECTIVE STIMULUS DURATION, the mean PNS THRESHOLD LEVEL shall be derived from threshold value observed per volunteer in the worst case position.

Differences in threshold for the same waveform per GRADIENT UNIT observed in the study may be used as the basis for weight factors.

A report of the study of human subjects shall be made available for inspection upon request to any test facility that is documenting compliance with this standard. Upon request, the report

shall also be made available to any national regulatory authority in which the MR EQUIPMENT is commercially distributed.

This report shall state at minimum:

- waveform(s) and effective stimulus durations used;
- parameter used to describe the PNS OUTPUT;
- worst case position of volunteers in the MR EQUIPMENT;
- relevant demographic characteristics of the volunteers;
- number of volunteers;
- study protocol;
- PNS THRESHOLD LEVEL observed;
- directly determined PNS THRESHOLD LEVEL claimed;
- description of the model used to infer thresholds for waveforms that are not tested (if any);
- weighting factors claimed.

201.12.4.105.2 Determination of maximum GRADIENT OUTPUT

201.12.4.105.2.1 General requirement for the determination of the maximum GRADIENT OUTPUT

For each GRADIENT UNIT the spatial maximum of the GRADIENT OUTPUT in the COMPLIANCE VOLUME shall be determined at MAXIMUM GRADIENT SLEW RATE, using either the waveform that is provided by the MR EQUIPMENT for clinical use, or a trapezoid or sinusoid waveform.

201.12.4.105.2.2 Determination of the maximum GRADIENT OUTPUT for the PATIENT

This determination shall be either by calculation a) or by test b), as follows.

a) Compliance determination by calculation

When the GRADIENT OUTPUT is expressed in dB/dt, the calculation may be based on the geometry of the current windings of the gradient coils, using Biot-Savart's law.

When the GRADIENT OUTPUT is expressed in E, the calculation may be based on the geometry of the current windings of the gradient coils, using the magnetostatic expression for the magnetic vector potential A. The induced electric field E is the negative of the time derivative of A minus the gradient of the electrostatic potential due to electric charges. Gradient-induced rheobase electric field values listed in Table 201.102 are used to calculate L12 and L01. L12 and L01 are the highest magnitude electric field values found in or on a homogeneous (conductivity = 0,2 S/m) simple geometry PATIENT model, for example a 0,2 m radius cylinder for a whole body cylindrical bore or an ellipsoid for a head coil. The electric field is to be calculated using the formula

$$E = -\partial A / \partial t - \nabla \Phi$$

where

A is the magnetic vector potential due to currents in the gradient coils and

Φ is the electrostatic potential due to electric charges (as further described in section 15 of the rationale).

Other suitable models (such as inhomogeneous models) may produce different electric field threshold values and may be used as alternatives if justified by the MANUFACTURER.

The magnetic vector potential for straight line segments may be calculated in closed form and then summed (as vector components).

Report of results:

- dimensions of the COMPLIANCE VOLUME and coordinates of its boundaries.



Data is to be reported for each individual GRADIENT UNIT:

- maximum gradient strength $G_{+,max}$; $G_{-,max}$;
- value of the MAXIMUM GRADIENT SLEW RATE;
- value of the ramp time occurring when switching the GRADIENT UNIT between its maximum specified gradient strengths at MAXIMUM GRADIENT SLEW RATE (ms);
- value of the GRADIENT OUTPUT (dB/dt or E);
- coordinates of the location of maximum GRADIENT OUTPUT;
- details of the model for the inhomogeneous conductivity of the PATIENT, when used.

b) Compliance determination of the GRADIENT OUTPUT by test

Test hardware:

1) SEARCH COIL design

SEARCH COILS shall be constructed so that three orthogonal components (Cartesian or cylindrical) of the GRADIENT OUTPUT can be measured. For example, three independent orthogonal SEARCH COIL elements may be constructed about a common centre. This SEARCH COIL design allows measurement of each independent component of the GRADIENT OUTPUT without requiring repositioning during the measurement procedure.

Each SEARCH COIL element shall be circular and shall be small with respect to the GRADIENT UNIT under test to ensure accuracy. The SEARCH COIL element consists of n turns of wire with a radius of r . The axial length of the coil shall be less than 20 % of its diameter. The SEARCH COIL elements shall be no more than 50 mm in diameter. The response of the SEARCH COIL element shall be determined by calculation or measurement. The instantaneous magnitude of the component of dB/dt coaxial with the SEARCH COIL element shall be determined from the peak voltage, V_{coil} , induced in the coil by the time varying magnetic flux:

$$|dB/dt| = |V_{coil} / (n\pi \cdot r^2)|$$

For example a typical SEARCH COIL element would consist of 15 turns of copper wire of 0,6 mm diameter on a form of 50 mm diameter ($r = 25$ mm) resulting in a circular coil approximately 9 mm long. An induced voltage of 200 mV would then result in a dB/dt = 6,79 T/s coaxial with the SEARCH COIL.

The individual SEARCH COIL elements shall each be provided with an attenuator unit that shall be calibrated to provide the same sensitivity for each of the SEARCH COIL elements or the sensitivity of each element shall be known from calculation or measurement. The signals of the individual SEARCH COIL elements shall be fed in parallel to a unit of which the output is the square root of the sum of the square of each input. This unit shall present its output as a voltage, the SEARCH COIL voltage. Alternately, the individual element dB/dt values may be calculated based on the measured voltages and element sensitivity, as determined from calculation or measurement. The individual element dB/dt values may then be squared, summed, and the square root of this sum taken to obtain the dB/dt value for the GRADIENT UNIT under test. The sensitivity factor relates the SEARCH COIL voltage V_{out} to dB/dt (T/s) as:

$$V_{out} = S \text{ dB/dt}$$

The minimum sensitivity of 0,01 V/T/s is recommended to measure signal amplitudes in regions of small dB/dt (in the range of 1 T/s).

2) SEARCH COIL calibration

A calibration of the SEARCH COIL is needed to measure its sensitivity factor, S .

3) Voltage measurement device

The device used to measure voltage induced in the SEARCH COIL shall have a high input impedance and sufficient bandwidth to prevent signal attenuation, e.g. a storage oscilloscope.

The voltage-measuring device (storage oscilloscope) shall be placed at a location where it is accurate and not affected by magnetic fields.

The SEARCH COIL voltage shall be connected to the voltage measurement device by means of a high impedance cable; e.g. a twisted pair to avoid ringing on the waveform that might be experienced with coaxial cables. SEARCH COIL outputs can be connected to the oscilloscope by means of an analog filtering device, to maximally attenuate switching frequency components, for gradient amplifiers utilizing switching power supplies.

4) Positioning device

A means shall be provided for positioning and aligning the SEARCH COIL in the magnet in a stable and reproducible manner. The device shall permit positioning of the SEARCH COIL throughout the COMPLIANCE VOLUME.

Measurements:

Measurements are made within the COMPLIANCE VOLUME for each single GRADIENT UNIT, using either the waveform that is provided by the MR EQUIPMENT for clinical use or sinusoid or trapezoid gradient waveforms.

- Turn off or maximally attenuate the radio frequency (RF) transmitter to prevent interference.
- Turn off all GRADIENT UNITS other than the GRADIENT UNIT under test.
- Drive the GRADIENT UNIT at the MAXIMUM GRADIENT SLEW RATE with a repetitive waveform.
- Move the SEARCH COIL within the COMPLIANCE VOLUME to the location where its voltage is maximal.
- Measure the peak value V_{out} of the SEARCH COIL voltage at this location.
- The magnitude of the GRADIENT OUTPUT shall be determined as $dB/dt = V_{out}/S$.

Report of results

Parameter, general:	Unit
– dimensions of the COMPLIANCE VOLUME and coordinates of its boundaries	m
– value of the MAXIMUM GRADIENT SLEW RATE per GRADIENT UNIT	mT/m/ms
Data reported for each individual GRADIENT UNIT:	
– maximum gradient strength $G_{+,max}$, $G_{-,max}$	mT/m
– value of the ramp time occurring when switching the GRADIENT UNIT between its maximum specified gradient strengths at MAXIMUM GRADIENT SLEW RATE	ms
– coordinates of the location of maximum GRADIENT OUTPUT	m
– value of the GRADIENT OUTPUT dB/dt	T/s

201.12.4.105.2.3 Determination of the GRADIENT OUTPUT stray field as required for reporting in 201.7.9.3.101 b

To be able to estimate the exposure for MR WORKERS for each GRADIENT UNIT, the spatial maximum of the GRADIENT OUTPUT shall be determined in a volume, see Figures 201.104a and 201.104b. The specific point pattern shall represent worst-case locations where the MR WORKER has access to and can be maximally exposed by the GRADIENT UNIT.

NOTE 1 For TRANSVERSE FIELD MAGNET types, the cylinder axis (i.e. PATIENT axis) is perpendicular to the magnet axis. The term PATIENT bore is to be replaced by magnet gap between pole shoes: the term magnet length is to be replaced by pole shoe diameter.

- The specific point pattern shall be located on a virtual cylinder surrounding the PATIENT axis with a diameter equal to the narrowest aperture of the accessible PATIENT bore.
- The cylinder starts at the ISOCENTRE and exceeds the PATIENT bore opening (half the magnet length) by at least 1 m and preferably along the full length of the system PATIENT couch past the bore opening.
- In the cylinder axis direction the points shall have a separation of not more than 0,05 m.

- For each cylinder axis position at least 16 points shall be equidistantly spaced on the cylinder surface (i.e. on a circle). The points shall include those located half way between the x and y gradient axis (i.e. $n \times 45$ degrees, $n = 1, 3, 5, 7$).
- The magnetic field vector for each GRADIENT UNIT shall be calculated using the law of Biot Savart or measured for each point on the cylinder.
- For each point the three field vectors shall be summed and then the field magnitude shall be determined.
- The maximum magnitude values shall be plotted along the cylinder axis position. The axial position of the PATIENT bore opening shall be marked.

NOTE 2 The pattern is also considered to be relevant for estimating possible PNS for the MR WORKER and illustrates the relative field distribution outside the space accessible for the PATIENT.

Report of results:

- Distance of points along cylinder axis
- No. of points azimuthally;
- Graph of maximum magnitude values along the cylinder axis

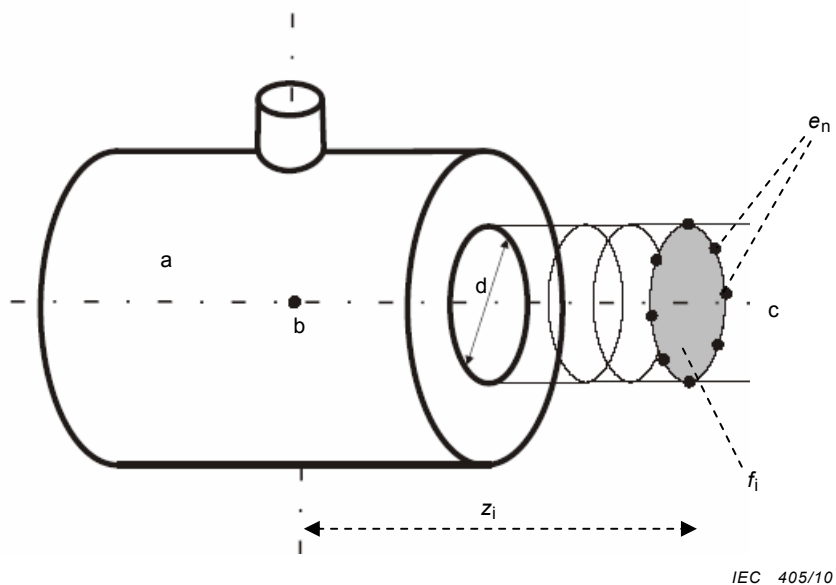


Figure 201.104a – Cylindrical magnet

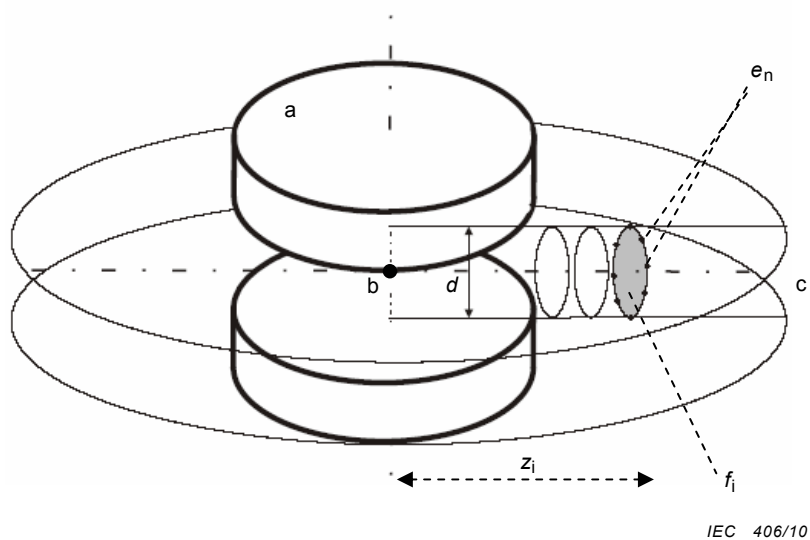


Figure 201.104b – TRANSVERSE FIELD MAGNET

- a magnet
- b ISOCENTRE
- c PATIENT axis and axis of a virtual cylinder
- d diameter of virtual cylinder representing the minimum accessible PATIENT bore;
- e_n points on the cylinder surface where the magnitude of all three magnetic field vectors shall be determined. The maximum magnetic field magnitude found on the cylinder surface at distance z_i from the ISOCENTRE (point b) in any of the points e_n represents the worst case field on the surface f_i .

Figure 201.104 – Volume for determining the spatial maximum of gradient output

201.12.4.105.3 Determination of radio frequency energy deposition

201.12.4.105.3.1 Temperature

The temperature limits specified in 201.12.4.103.1 may be used to derive equivalent limits for the operating parameters of the MR EQUIPMENT. This determination shall employ experimental data or numerical methods (e.g. finite element methods).

201.12.4.105.3.2 Determination of SAR

The WHOLE BODY SAR shall be determined by measurement of the absorbed RF power and the PATIENT mass based on OPERATOR input or other suitable means. The absorbed RF power determined by the MR EQUIPMENT shall be tested by measurement using one of the methods specified below or an equivalent.

The PARTIAL BODY SAR shall be determined from the WHOLE BODY SAR by applying properly validated and sufficiently robust theoretical or empirical models relating the PARTIAL BODY SAR to the dimension of the VOLUME RF TRANSMIT COIL, PATIENT mass and size and the PATIENT position. A suitable model to determine the exposed PATIENT mass for example is to simulate the PATIENT's body by a variety of homogeneous cylinders. The distribution of the LOCAL SAR may be determined by theoretical models or by experiment.

The applied model in case of PARTIAL BODY SAR and LOCAL SAR shall be validated by comparing values derived from the model with those figures directly accessible for measurement (for example: the temperature distribution in a phantom).

Compliance shall be determined by inspection of measurements that verify the SAR determination over the entire range of power levels the MR EQUIPMENT is capable of, assuring a safe operation given by the specified SAR limits.

Acceptable methods to determine the absorbed RF power employed are known as "pulse energy method" and "calorimetric method" according to NEMA MS 8.

*** 201.12.4.105.3.3 Determination of the B_1 stray field as required for reporting in 201.7.9.3.101 b)**

The maximum RF transmit field of the RF transmit coil shall be measured or calculated and reported at the positions accessible to and relevant for the MR WORKER.

$B_1(z)$ field shall be measured or calculated at points along the PATIENT axis (i.e. normally the z-direction) beginning in the ISOCENTRE.

NOTE 1 For cylindrical magnets the PATIENT axis is equivalent to the magnet axis; for TRANSVERSE FIELD MAGNET types the cylinder axis (i.e. PATIENT axis) is perpendicular to the magnet axis.

It is sufficient to measure/calculate the B_1 field along the PATIENT axis only because the B_1 field is assumed to be sufficiently homogenous in each transversal plane of the RF transmit coil.

- The distance between each successive point shall not exceed 0,1 m.
- The magnitude of the B_1 field shall be measured or calculated for each point.
NOTE For magnets with circular polarized RF transmit field it is sufficient to determine the radial component only.
- The measurement can be performed by using a suitable pick up coil and a network analyzer or by using an RF signal generator and a spectrum analyzer
- The ratio of $B_1^2(z)$ and $B_1^2(0)$ shall be calculated for each point.
- The calculated value for a single point at the distance z from the ISOCENTRE shall apply to all locations on a base area of a virtual cone to represent worst-case condition on this base area, see Figures 201.105a and 201.105b. The base area of the cone is the area

perpendicular to the straight line at distance z from the ISOCENTRE. The cone is defined by the opening angle given by the projection from the ISOCENTRE to the magnet aperture. The height of the cone is given by the distance z (see Figure 201.105a).

For TRANSVERSE FIELD MAGNET types the area is defined by the superposition of base areas by rotating the cone around the ISOCENTRE (see Figure 201.105b).

NOTE 2 See rationale for detailed explanation.

Report of results:

- Axial coordinates of the points where $B_1^2(z)$ is measured or calculated i.e. at the positions accessible to and relevant for the MR WORKER.
- Magnitude of the magnetic field $B_1^2(z)$ in the measured points relative to the magnitude $B_1^2(0)$ in the ISOCENTRE

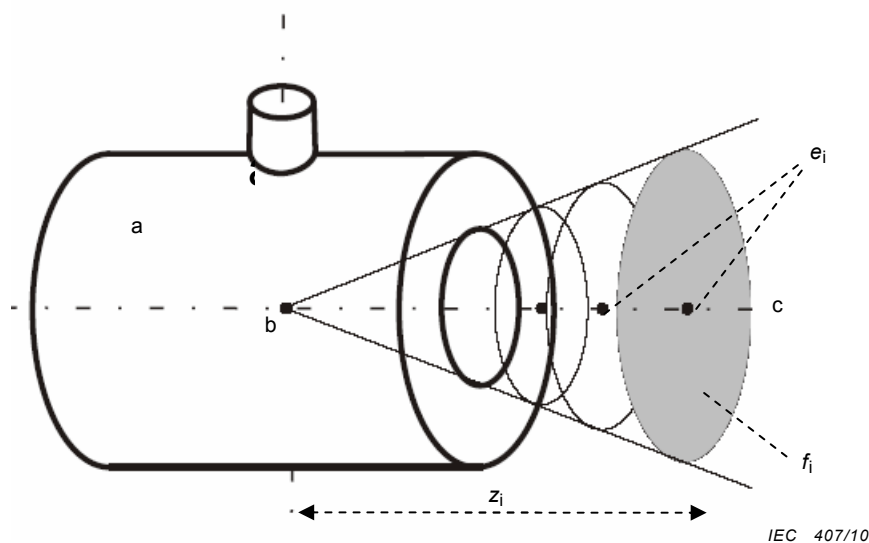


Figure 201.105a – Cylindrical magnet

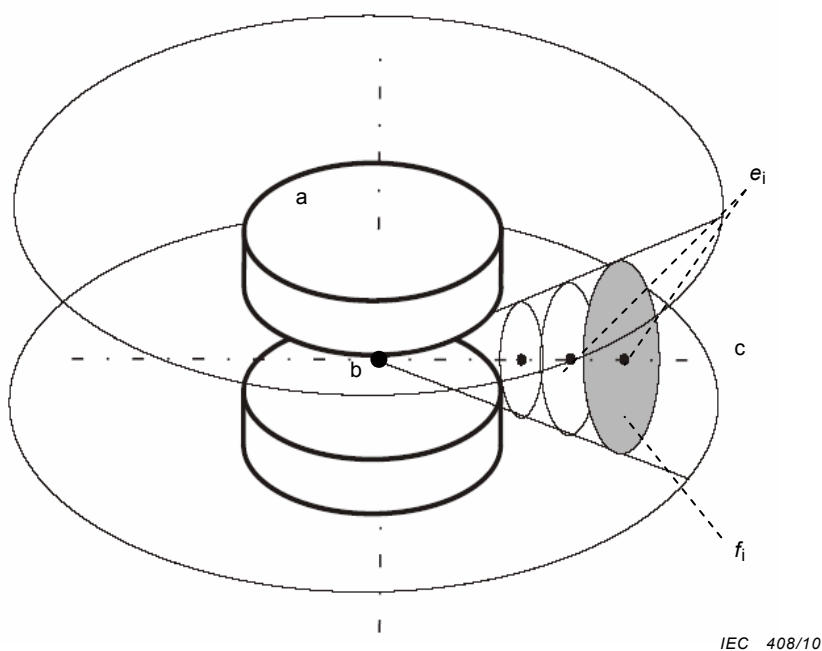


Figure 201.105b – TRANSVERSE FIELD MAGNET

- a magnet
- b ISOCENTRE
- c PATIENT axis
- z_i distance of point e_i from ISOCENTRE.

$B_1(z_i)$ shall be determined by measurement or calculation. The ratio $B_1^2(z_i)$ and $B_1^2(0)$ shall be calculated for each point e_i . The calculated value in point e_i shall apply for the corresponding grey area f_i . The value in point e_i always represents a worst case for any location within the area f_i .

Figure 201.105 – Volume for determining the B_1 stray field

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

Addition:

201.15.101 Liquid cryogen and cryogen gases

For MR EQUIPMENT that is equipped with a superconducting magnet, means shall be provided to monitor the cryogen level(s).

Requirements on the provision in the instructions for use of information concerning liquid cryogen and cryogenic gases are given in 201.7.9.2.101. f).

201.16 ME SYSTEMS

Clause 16 of the general standard applies, except as follows:

201.16.8 Interruption of the power supply to parts of an ME SYSTEM

Addition:

201.16.8.101 EMERGENCY FIELD SHUT DOWN UNIT

MR EQUIPMENT equipped with a superconducting magnet or resistive magnet shall be provided with an EMERGENCY FIELD SHUT DOWN UNIT.

NOTE 1 Such an emergency situation is, for example, the entrapment of persons in the magnetic field resulting from ferromagnetic objects.

NOTE 2 Requirements on the provision in the instructions for use of information concerning the EMERGENCY FIELD SHUT DOWN UNIT are given in 201.7.9.2.101 m).

NOTE 3 Information on the magnetic field decay characteristics during emergency field shut down are required in 201.7.9.3.101 d) for the ACCOMPANYING DOCUMENTS.

201.16.8.102 Scan interruption

A facility shall be provided to allow the OPERATOR to immediately stop the scan by interrupting the power to the gradient system and that to the RF transmit coil.

*** 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**

Clause 17 of the general standard applies.

NOTE In Clause 202 of this particular standard, additional requirements for electromagnetic compatibility are given.

*** 202 Electromagnetic compatibility – Requirements and tests**

IEC 60601-1-2:2007 applies except as follows:

202.6 ELECTROMAGNETIC COMPATIBILITY

Addition:

202.6.101 ELECTROMAGNETIC COMPATIBILITY of MR EQUIPMENT

Outside the CONTROLLED ACCESS AREA the magnetic stray field shall be smaller than 0,5 mT and the electromagnetic interference level shall comply with Collateral Standard IEC 60601-1-2.

Inside the CONTROLLED ACCESS AREA the requirements of IEC 60601-1-2 do not apply. The requirements stated in subclause 201.7.9.2.101 e) are applicable.

NOTE 1 For electromagnetic compatibility purposes the CONTROLLED ACCESS AREA, when installed, is considered to be part of the MR SYSTEM.

NOTE 2 Inside the CONTROLLED ACCESS AREA, special interface requirements may be set by the MANUFACTURER of the MR EQUIPMENT.

Annexes

The annexes of the general standard apply, except as follows: