N O R M A I T A L I A N A C E I

Norma Italiana *Data Pubblicazione*

CEI EN 60601-2-33 **2011-11**

La seguente Norma è identica a: EN 60601-2-33:2010-10; EN 60601-2-33/EC:2010-10.

Titolo

Apparecchi elettromedicali
Parte 2: Prescrizioni particolari relative alla sicurezza fondamentale e alle prestazioni essenziali di apparecchi a risonanza magnetica per diagnostica medica

Title

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

Sommario

La presente Norma stabilisce particolari requisiti relativi alla sicurezza fondamentale e alle prestazioni essenziali per le apparecchiature per la risonanza magnetica con lo scopo di fornire una protezione per il paziente e il lavoratore addetto alla risonanza magnetica. La presente Norma sostituisce la Norma CEI EN 60601-2-33:2004-02 che rimane applicabile fino al 01-10-2013 e costituisce una revisione tecnica che è stata anche adattata alla terza edizione della IEC 60601-1.
La presente Norma soddisfa i requisiti essenziali della direttiva 93/42/CE.
Questa Norma viene pubblicata dal CEI nella sola lingua inglese in quanto particolarmente mirata a settori specialistici.
La presente Norma recepisce il testo originale inglese della Pubblicazione IEC.

DATI IDENTIFICATIVI CEI

Norma italiana	CEI EN 60601-2-33
Classificazione	CEI 62-77
Edizione	

COLLEGAMENTI/RELAZIONI TRA DOCUMENTI

Nazionali	
Europei	(IDT) EN 60601-2-33:2010-10; EN 60601-2-33/EC:2010-10;
Internazionali	(IDT) IEC 60601-2-33:2010-03;
Legislativi	
Legenda	*(IDT) - La Norma in oggetto è identica alle Norme indicate dopo il riferimento (IDT)*

INFORMAZIONI EDITORIALI

Pubblicazione	Norma Tecnica
Stato Edizione	In vigore
Data validità	01-12-2011
Ambito validità	Internazionale
Fascicolo	11606 E
Ed. Prec. Fasc.	7193:2004-02 che rimane applicabile fino al 01-10-2013
Comitato Tecnico	CT 62-Apparecchiature elettriche per uso medico

Approvata da	Presidente del CEI	*In data*	04-10-2011
	CENELEC	*In data*	01-10-2010
Sottoposta a	Inchiesta pubblica come Documento originale	*Chiusura in data*	05-02-2010

ICS	11.040.55;

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-33

October 2010

ICS 11.040.55

Supersedes EN 60601-2-33:2002 + A1:2005 + A2:2008

English version

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

(IEC 60601-2-33:2010)

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
(CEI 60601-2-33:2010)

Medizinische elektrische Geräte - Teil 2-33: Besondere Festlegungen für die Sicherheit von Magnetresonanzgeräten für die medizinische Diagnostik
(IEC 60601-2-33:2010)

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-33:2010 E

Foreword

The text of document 62B/777/FDIS, future edition 3 of IEC 60601-2-33, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-33 on 2010-10-01.

This European Standard supersedes EN 60601-2-33:2002 + A1:2005 + A2:2008.

This EN 60601-2-33:2010 is based on the second amendment to EN 60601-2-33:2002. It has also been adapted to EN 60601-1:2006, with technical modifications being introduced where appropriate.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-10-01

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.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-33:2010 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Clause 2 of the general standard applies except as follows:

Publication	Year	Title	EN/HD	Year
Replacement:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
Addition:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
NEMA MS 4	2006	Acoustic noise measurement procedure for diagnostic magnetic resonance imaging (MRI) devices	-	-
NEMA MS 8	2008	Characterization of the specific absorption rate (SAR) for magnetic resonance imaging systems	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC with the exception of ERs 3, 4, 7.1 and 12.1.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

Corrigendum to EN 60601-2-33:2010

English version

_____

Annex ZZ, 1st paragraph

Delete “with the exception of ERs 3, 4, 7.1 and 12.1”.

_____

October 2010

IEC 60601-2-33

Edition 3.0 2010-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE XE
CODE PRIX

ICS 11.040.55

ISBN 978-2-88910-221-1

CONTENTS

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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

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 standard [1)] 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 radio frequency magnetic induction

$$B_{1\mathrm{RMS}} = \sqrt{\frac{\int_0^{t_x} (B_1(t))^2 \, \mathrm{d}t}{t_x}} \, .$$

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.

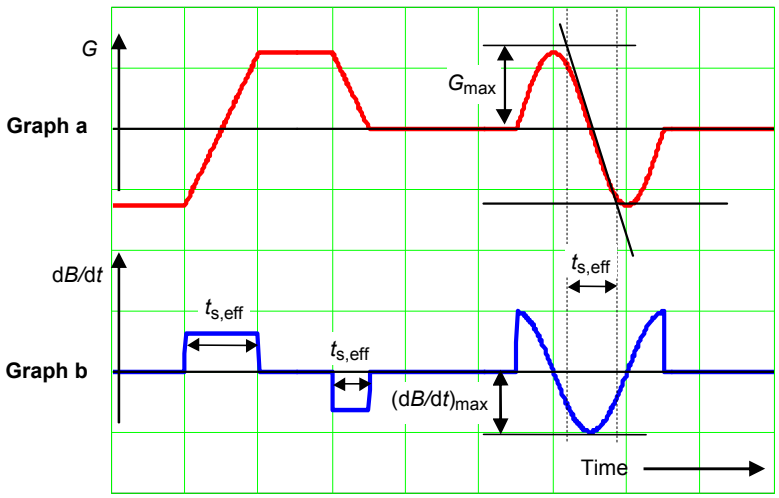
In all other MR EQUIPMENT the COMPLIANCE VOLUME is the volume where any part of a PATIENT body can be properly located according to the INTENDED USE of the MR EQUIPMENT.

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)



Graph a

G	magnetic field gradient, T/m
G_{max}	maximum of gradient, T/m

Graph b

dB/dt	time rate of change of magnetic field, T/m/s
$(dB/dt)_{max}$	maximum of time rate of change of magnetic field, T/m/s
$t_{s,eff}$	effective stimulus duration, s

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
d*B*/d*t*
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_1RMS	T	Root mean square of B_1
d*B*/d*t*	T/s	TIME RATE OF CHANGE OF THE MAGNETIC FIELD (d*B*/d*t*)
E	V/m	Electric field induced by gradient switching
G	T/m	Magnetic field gradient
*L*01	V/m or T/s	Limit of the GRADIENT OUTPUT for the NORMAL OPERATING MODE
*L*12	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 ($L_{Aeq,\ 1\ h}$) 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 cryogens

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_1RMS 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_1RMS 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 μPa 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_1RMS averaged over any 10 s period of the scan. The B_1RMS 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 μs 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:

$$\mathrm{d}B / \mathrm{d}t < \frac{20}{\left\{1 - \exp\left(-\frac{t_{s,eff}}{3}\right)\right\}}$$

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 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 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 ($L01$) and the FIRST LEVEL CONTROLLED OPERATING MODE ($L12$) shall, depending on the label (as defined in 201.7.9.3.101 e) not be larger than the values stated below:

$$L12 = 1{,}0\ rb(1 + 0{,}36/\ t_{s,eff}),\ \ (t_{s,eff} \text{ in ms})$$

$$L01 = 0{,}8\ rb(1 + 0{,}36/\ t_{s,eff}),\ \ (t_{s,eff} \text{ in ms})$$

where

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

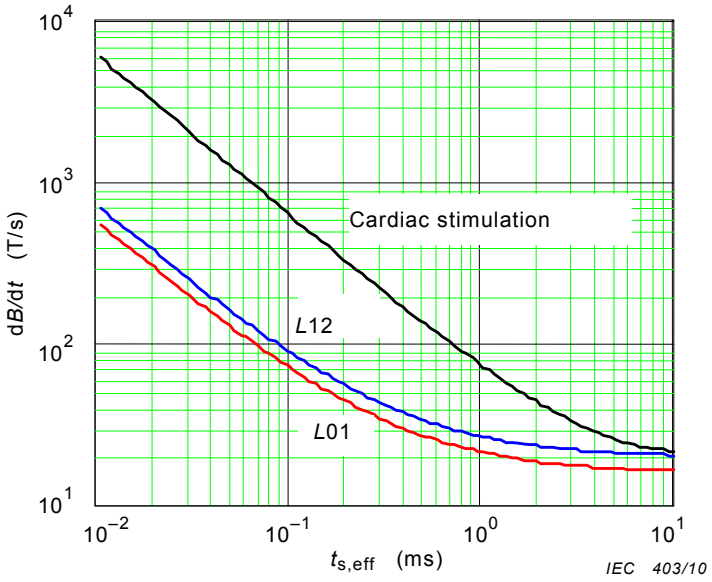
rb (here in T/s) is the rheobase given in Table 201.102.

$L01$ and $L12$ 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 d*B*/d*t* (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 (*L*01) and the FIRST LEVEL CONTROLLED OPERATING MODE (*L*12) in WHOLE BODY GRADIENTS, expressed as d*B*/d*t* (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 d*B*/d*t* 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.

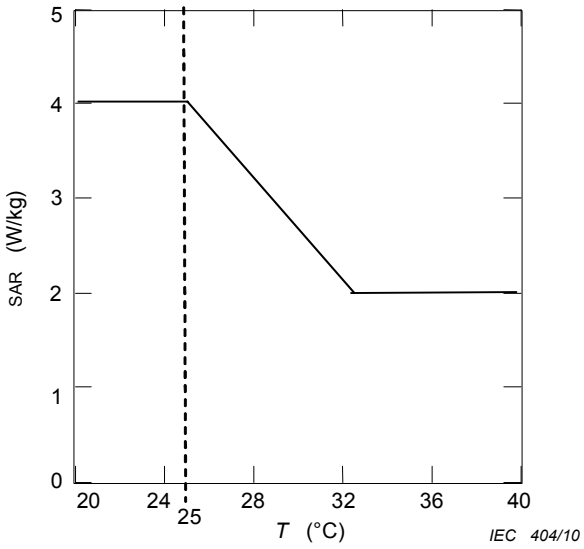


Figure 201.103 – Reduction of WHOLE BODY SAR limits at high temperatures

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:

a) The NORMAL OPERATING MODE comprises values of the static magnetic field equal or lower than 3 T.

b) 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.

c) 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 d*B*/d*t*, which the human body is exposed to when moving in the static magnetic stray field, shall be limited. The maximum allowed d*B*/d*t* 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 d*B*/d*t* 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:*

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

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:*

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

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) S*EARCH 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.

a) Turn off or maximally attenuate the radio frequency (RF) transmitter to prevent interference.

b) Turn off all GRADIENT UNITS other then the GRADIENT UNIT under test.

c) Drive the GRADIENT UNIT at the MAXIMUM GRADIENT SLEW RATE with a repetitive waveform.

d) Move the SEARCH COIL within the COMPLIANCE VOLUME to the location where its voltage is maximal.

e) Measure the peak value V_{out} of the SEARCH COIL voltage at this location.

f) 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

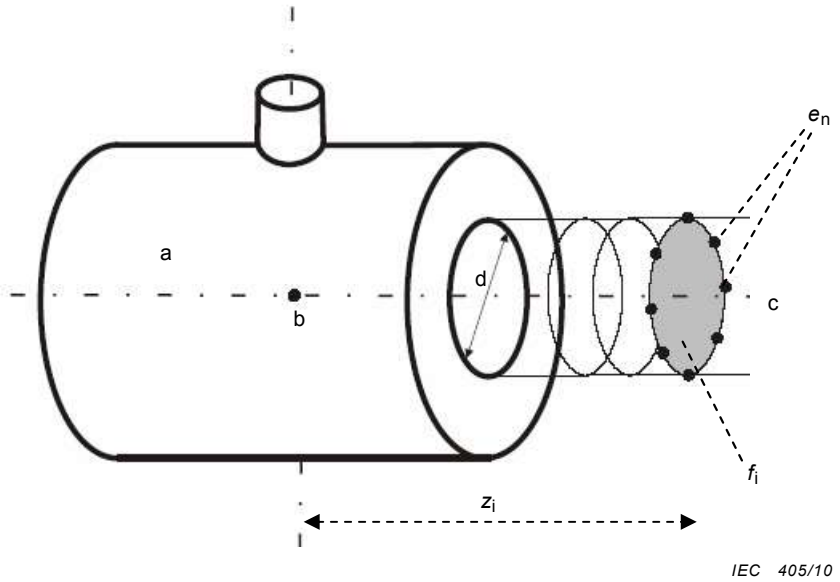


Figure 201.104a – Cylindrical magnet

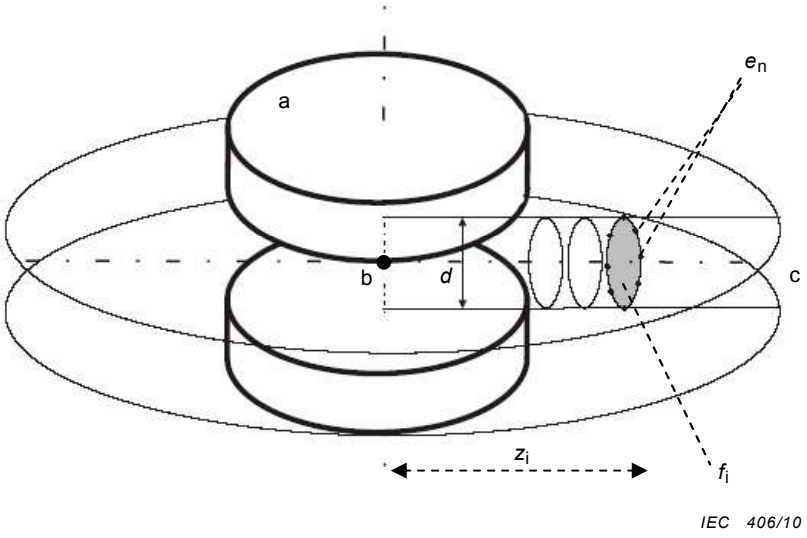


Figure 201.104b – TRANSVERSE FIELD MAGNET

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

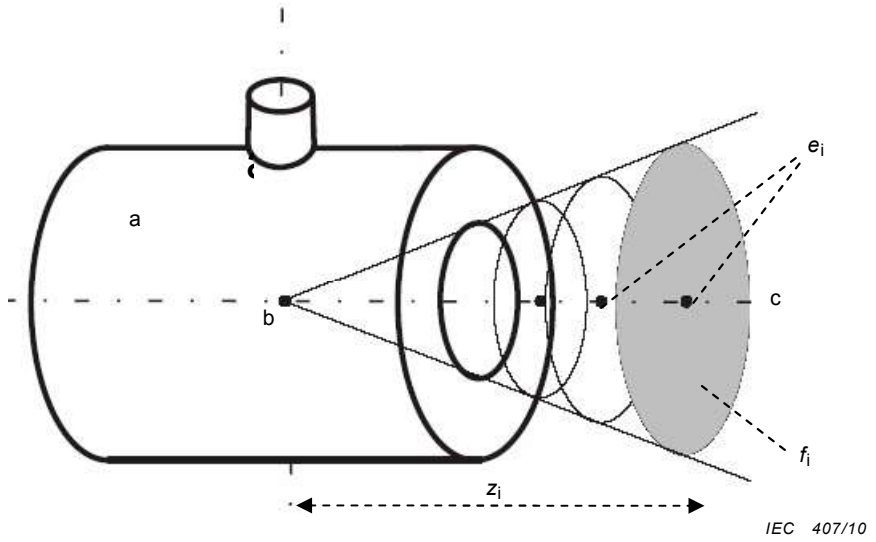


Figure 201.105a – Cylindrical magnet

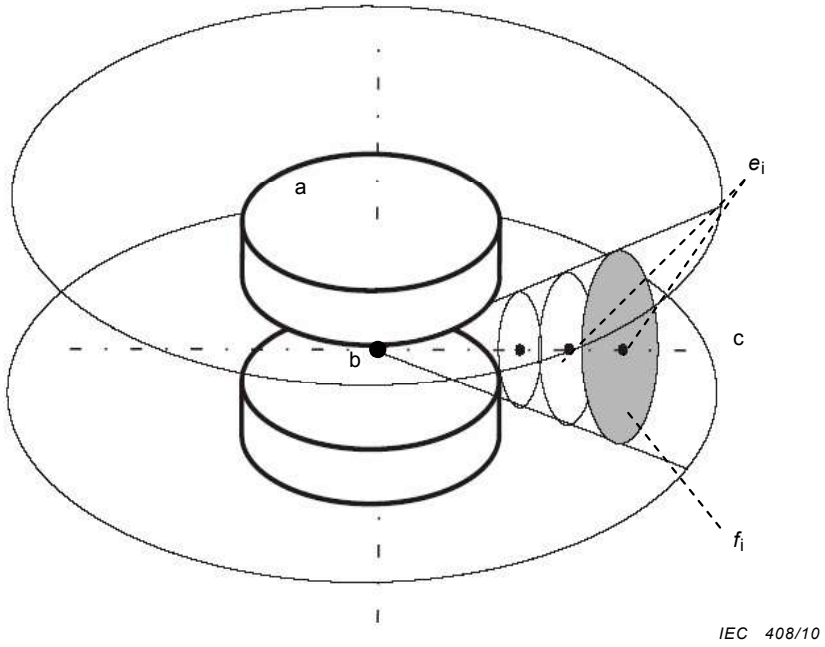


Figure 201.105b – TRANSVERSE FIELD MAGNET

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:

Annex D
(informative)

Symbols on marking

Annex D of the general standard applies, except as follows:

Addition:

Table 201.D.101 – Examples of warning signs and prohibitive signs [3]:

	**Warning sign** Warning, RISK of strong magnetic field
	**Warning sign** Warning, RISK of non-ionizing radiation
	**Prohibition sign** No access for person with pacemaker
	**Prohibition sign** No access for person with metal implants

3) The colour and basic form of these warnings and prohibitive signs have been taken from ISO 3864-1.

Prohibition sign

No access with metallic pieces or watches

Extra examples for the marking introduced for medical devices and other items for safety in the MR environment are introduced in the ASTM standard F2503-05. This relates specifically to markings for MR Safe, MR Conditional and MR Unsafe devices.

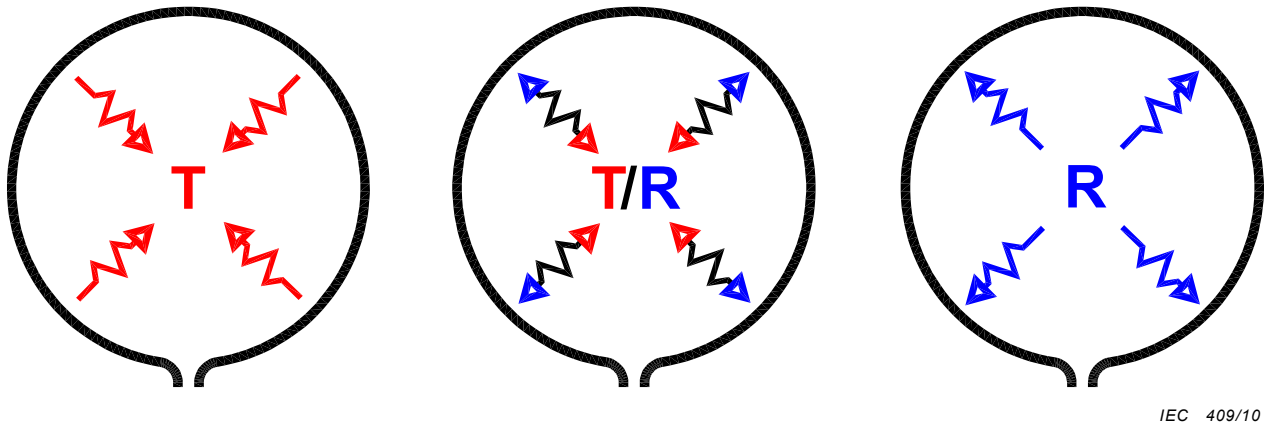


Figure 201.D.101 – Signs indicating a transmit only RF coil, transmit / receive RF coil and a receive only RF coil

Annex AA
(informative)

Particular guidance and rationale

AA.1 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Concerning the Introduction

In the recent years before the realization of the 3rd edition of this standard, a number of publications of general interest to the safety of MR scanners became available. For general guidance reference is given to these publications, see [150, 151, 152, 153][4]. Independent of the specific electromagnetic fields generated in and around an MR scanner, committees as IEEE [154] and ICNIRP [131, 162] have defined exposure limits for the static and time-varying electric, magnetic and electromagnetic field exposure for workers in controlled environments. Shortly after the acceptance of the 2nd edition of this standard ICNIRP published a so-called 'statement' specifically addressing the safety of MR patients [132].

An important new aspect introduced in the 2nd amendment to the 2nd edition of this standard is the fact that the employer of the MR WORKER is now encouraged to define rules and formulate requirements for the MR WORKERS because the EMF produced by the MR EQUIPMENT can result in exposure of workers, which is or will be limited by law. In the 2nd amendment exposure limits for MR WORKERS were introduced, which are equal to those allowed for PATIENTS. All exposure levels allowed for a PATIENT and for an MR WORKER protect them against negative health effects. While exposure for workers may be physically different because of the orientation of the workers as compared to the orientation of PATIENTs the same exposure limits apply. The fact that some exposure limits for PATIENTS are modified in this 3rd edition of the standard does not invalidate this statement. Therefore also in the 3rd edition of the standard the exposure limits for MR WORKERS are equal to those allowed for PATIENTS. The rationale for this choice given in the 2nd amendment is still valid and can be found in the rationale of subclauses 201.7.9.2.101 h) and 201.7.9.2.101 k) of this 3rd edition of the standard.

Concerning 201.3.201 – B_1RMS

B_1RMS is displayed on the CONTROL PANEL to provide a supplemental metric to SAR of the RF power deposition. The B_1RMS value might, for example, be used as a control on allowable RF power deposition in the implant manufacturer labelling for patients with implants.

B_1RMS on the CONTROL PANEL represents the maximal value when averaged over any 10 s period of the sequence, and is estimated at the RF transmit coil centre. The value of B_1 in the calculation is based on both polarization senses in the rotating frame [155].

$$B_1(t) = \sqrt{|B_1^+(t)|^2 + |B_1^-(t)|^2}$$

where B_1^+ is the component of the RF field in the rotating frame that is useful for tilting of the nuclear magnetization and B_1^- is the RF component that rotates counter to the rotation of the nuclear magnetization.

---

4) Figures in brackets refer to the Bibliography.

Note that for pure circular polarization $|B_1^-(t)|=0$ and for linear polarization $|B_1^-(t)|=|B_1^+(t)|$.

For a rectangular pulse with duration τ and amplitude $|B_1^+|$ in the positively rotating frame, the tilt angle θ is

$$\theta=\gamma|B_1^+|\tau$$

where γ is the nuclear gyromagnetic constant.

Concerning 201.3.207 – ENVIRONMENTAL TEMPERATURE

For this standard the ENVIRONMENTAL TEMPERATURE will be calculated as follows. Let scan room temperature (in °C) = *Tr*. Let scanner PATIENT bore wall temperature (in °C) = *Tb*. Let magnet bore length = *L*. Assume typical PATIENT height *h* = 1,76 m. Assume the coefficient of convection is *hc* = 9,5 W/(m^2 °C). Assume the coefficient of radiation is *hr* = 8,0 W/(m^2 °C). Then the ENVIRONMENTAL TEMPERATURE, *Te*, can be computed as follows.

Let PATIENT skin temperature (in °C) = *Ts* and assume that over the entire surface area, *A*, of the PATIENT energy is dissipated by convection, *C*, to air at room temperature:

$$C=A\,hc\,(Tr-Ts)\ .$$

NOTE Negative energy implies energy dissipated by the PATIENT. A rather conservative assumption is that PATIENT energy is dissipated by radiation to the bore wall over the entire surface area of the PATIENT.

$$R=A\,hr\,(Tb-Ts)\ .$$

The total heat lost is equivalent to that lost to a uniform ENVIRONMENTAL TEMPERATURE, *Te*:

$$A(hc+hr)(Te-Ts)=R+C=A\,hc\,(Tr-Ts)+A\,hr\,(Tb-Ts)\ .$$

Solving for *Te* results in the expression:

$$Te=\frac{hc\,Tr+hr\,Tb}{(hc+hr)}\ .$$

Concerning 201.3.213 – INTERVENTIONAL MR EXAMINATION

Examples: aspiration cytology, core biopsy, breast biopsy, wires localization, depth electrode placement in the brain for EEG of pallidotomies, chemo ablation, cryosurgery and thermal ablation using laser, focused ultrasound and radiofrequency energy. Can be used in the operating room to guide brain tumour resection after craniotomy. Can be coupled with endoscope procedures providing external and internal localization or visualization.

Equipment example: Open architecture magnets and fast imaging sequences (fluoroscopy). In-room console.

Special sequences examples: Temperature monitoring, keyhole imaging-

Non-invasive visualization and localization. Problem with geometric distortion due to non-linear gradients and susceptibility artefact.

Consequences for MR WORKERs and PATIENT safety: Open architecture permits access to higher levels of all fields (static and time varying magnetic, RF).

Compatibility of instruments: The first step toward practical interventional MRI is development of instrumentation that can function satisfactorily and safely in the fields of clinical MR scanners. There is a potential for accidents caused by magnetically induced force on surgical instruments or monitoring equipment. Image artefacts may be caused by susceptibility differences. Artefacts also depend on pulse sequences (gradient echo gives more). Increase in artefact with field strength. Support instrumentation includes anaesthesia monitoring, lasers, RF generators and tracking systems. Gradients will induce voltage and current and may cause artefacts, therefore loops in cables should be avoided to prevent the danger of EMI between scanner and interventional electronics.

Compatibility of needles, catheters and other instruments developed for interventional purposes (composed of high-nickel stainless steel and other materials) reduce torque from the static field and minimize susceptibility artefacts.

Interventional procedures are increasingly being performed using MR SYSTEMs, so that measurements of bonding resistance and touch voltages should be performed on MR units, just as they are on conventional radiographic systems [146].

There will need to be some differences in procedure, because of the strong magnetic field within the scanning room, but the general principles will be the same.

Touch voltages should be measured using a conventional auto-ranging digital multimeter, equipped with a set of test leads long enough for the meter to be sited outside the scanning room. One lead should be attached to the earth reference bar (ERB), and the other lead, fitted with a sharp pointed probe used to check for touch voltages on any of the accessible conductive surfaces within the scanning room. The probe should be tested to ensure that it does not contain any significant amount of magnetic material by running a test magnet over it.

Measurements should also be made between the earth point on all mains sockets in the scanning room and the ERB. If any devices are plugged into sockets outside the scanning room and then used within the scanning room, these should be supplied from the same phase as any sockets within the scanning room, and the touch voltage on the earths of these sockets also measured. The touch voltage should be less than 10 mV, AC or DC. If a voltage greater than 10 mV is found, the measurement should be repeated using an IEC filter. If the touch voltage is still above 10 mV, the source of the voltage should be investigated. Once it has been established that there are no significant touch voltages present, the bonding resistance should be measured. A battery operated four-wire milliohmmeter should be used, in order that the meter can be kept at a safe distance from the midline of the field during the measurement. The meter should have a resolution better than 10 mΩ, and be capable of performing the measurement at a current greater than 100 mA.

The resistance between the ERB and all accessible conductive surfaces of installed equipment should be less than 100 milliohms. The resistance between the earth point of all mains sockets and the ERB should also be less than 100 mΩ.

Any portable devices should be plugged directly into a conveniently located hardwired socket. Extension mains leads should not be used within the scanning room.

Concerning 201.3.217 – MAGNETIC RESONANCE (MR)

The phenomenon of MR occurs when the frequency of electro-magnetic radiation equals the Larmor precession frequency of the nuclear or electron magnetic moments.

Concerning 201.3.221 – MAGNETIC RESONANCE WORKER (MR WORKER)

The concept of MR WORKERS is related to the level of exposure of this group of workers to the EMFs emitted by the MR SYSTEM. This level may be higher than what is allowed by legal regulations in some countries for workers in general, creating for the MR WORKER the need of special EMF exposure limits as defined in this standard. The EMF exposure limits stated in this document permit the unrestricted presence of the MR WORKER in CONTROLLED ACCESS AREA even during scanning. The level of these limits and the resulting RISKS to the MR WORKER are discussed elsewhere in this annex.

The term MR WORKERS includes all people working near the MR EQUIPMENT in the CONTROLLED ACCESS AREA or equivalent, either in the medical arena where the MR SYSTEM is installed and being operated and serviced or at the MANUFACTURER where the MR SYSTEM is being developed and manufactured. As such the MR WORKER includes but is not limited to the personnel maintaining the MR SYSTEM, the OPERATOR and the medical staff, or the MR WORKER can be the technical personnel at the MR MANUFACTURER, development and manufacturing engineers, installation and service personnel. Both groups of MR WORKERS are equally essential in maintaining the medical benefits for the PATIENTS.

Apart from the MR WORKER, two further groups of individuals exposed to the EMFs emitted by the MR SYSTEM can be discerned. These are MR volunteers and MR PATIENT carers.

An MR volunteer is an individual who has freely consented to an investigational MR procedure authorized by local regulations, and therefore is subject to the limits authorized by the ethics committee. An MR volunteer is therefore not considered to be an MR WORKER according to the definition in this standard.

An MR PATIENT carer is an individual, who supports the PATIENT during an examination and therefore may be exposed to the same level as for PATIENTS. MR PATIENT carers therefore can be informed and screened in the same way as the PATIENT. An MR PATIENT carer, who is not employed as an MR WORKER, is therefore not considered to be an MR WORKER according to the definition in this standard. An MR PATIENT carer who happens also to be an MR WORKER is to be seen as an MR WORKER.

Concerning 201.3.223 – MEDICAL SUPERVISION

MEDICAL SUPERVISION requires a positive assessment by a qualified medical practitioner of the RISK versus benefit for a particular scan, or a decision by a qualified surrogate of the practitioner that the PATIENT satisfies a set of objective criteria, formulated by a qualified medical practitioner, for the parameters of the scan and the condition of the PATIENT. MEDICAL SUPERVISION may entail physiological monitoring of the PATIENT by means of devices designed to measure or assess various physiological states (e.g. heart rate, ECG trace, blood pressure, pulse oximetry; but see cautions in 201.7.9.2.101 b)).

Concerning 201.3.233 – SPECIFIC ABSORPTION RATE (SAR)

The SAR is a function of the frequency (increasing approximately as the square of the frequency), the type and number of radio frequency pulses, the duration and repetition rate of pulses and the type of coil used for transmission. The important biological factors are: conductivity of tissue, specific gravity of the tissue, anatomical region examined, tissue type (e.g. the degree of perfusion) and mass of the PATIENT.

Concerning 201.7.9.2.101 – Instructions for use for MR EQUIPMENT

The instructions for use of MR EQUIPMENT complying with this standard play an important role in providing the necessary information to the RESPONSIBLE ORGANIZATION or OPERATOR.

Regarding the safety of PATIENTS, these documents should contain specific information on the content of programs for pre-screening of PATIENTS, MEDICAL SUPERVISION of PATIENTS in cases of use of the MR EQUIPMENT in controlled modes of operation and emergency procedures.

With regard to the safety of staff, the same documents should contain specific information on the handling of electronic equipment and/or metallic objects in the CONTROLLED ACCESS AREA and the use of cryogen in case a superconducting magnet is used.

Concerning 201.7.9.2.101 a) – Pre-screening of the PATIENT and MR WORKER

Pre-screening of the PATIENT and even the MR WORKER is important because an MR EXAMINATION or just being present near the MR EQUIPMENT can be considered to be a significant RISK [1] [2] for PATIENTS or MR WORKERS who have metallic implants or electrically, magnetically or mechanically activated implants (e.g. cardiac pacemakers) The origin of this RISK is related to the magnetic and electromagnetic fields produced by the MR EQUIPMENT, which may produce strong attraction and/or torque to the metallic implant or may interfere with the operation of active devices.

This applies also to PATIENTS and MR WORKERS who rely on electrically, magnetically or mechanically activated external life support systems.

Scanning PATIENTS with intracranial aneurysm clips is contra-indicated unless the physician is certain that the clip is not magnetically active.

Examination by MR EQUIPMENT, in terms of PATIENT pre-screening, requires particular caution in the following cases:

– PATIENTS with implanted surgical clips (haemostatic clips) or other ferromagnetic materials (which the magnetic field may dislodge);
– PATIENTS engaged in occupations or activities which may cause accidental implantation of ferromagnetic materials, or who may have imbedded metal fragments from military activities;
– PATIENTS with permanent (tattoo) eye-liner or with facial make-up (because severe eyelid irritation has been reported);
– PATIENTS with compromised thermoregulatory systems (e.g. neonates, low-birth-weight infants, certain cancer PATIENTS);
– PATIENTS with metal implants, because these may cause artefacts in diagnostic images due to magnetic field distortion;
– PATIENTS with implanted prosthetic heart valves;
– PATIENTS who are pregnant, because the safety of the MR EXAMINATION has not been completely established for embryos or foetuses. Qualified medical practitioners should determine (after considering alternatives) if the clinical value of the examination outweighs the RISKS.

Concerning 201.7.9.2.101 b) – MEDICAL SUPERVISION of PATIENTS

In terms of the potential need for MEDICAL SUPERVISION of the PATIENT, particular caution is required in performing MR EXAMINATIONS for the following cases:

– PATIENTS with a greater than normal potential for cardiac arrest;
– PATIENTS who are likely to develop seizures, or claustrophobic reactions;
– decompensated cardiac PATIENTS, febrile PATIENTS, and PATIENTS with impaired ability to perspire;
– PATIENTS who are unconscious, heavily sedated, or confused, and with whom no reliable communication can be maintained;

– babies and small infants who cannot be expected to use the audio communication channel provided with the MR EQUIPMENT;

– examinations which are carried out at ENVIRONMENTAL TEMPERATURE above 25 °C.

Concerning 201.7.9.2.101 c) – Emergency medical procedures

Attention should be paid to safety considerations related to the emergency procedures that could be necessary for particular PATIENT conditions. Though this is a subject that is the responsibility of the RESPONSIBLE ORGANIZATION, it may be helpful if the MANUFACTURER gives advice on this matter:

– a recommendation that there should be established a procedure for removing PATIENTS rapidly from the magnet's influence (if necessary, by shutting down the magnet) in case of an emergency;

– a recommendation to establish an appropriate plan for treating, outside the magnet's influence, a PATIENT who requires emergency assistance (because the safe and effective use of electronic or other metallic emergency equipment may be impossible near the magnet).

– a recommendation to establish a procedure for removing PATIENTS from the magnet's influence when an unexpected implant is found. In this case, using the EMERGENCY FIELD SHUT DOWN UNIT may not be appropriate in view of the relative rapid decay of the static magnetic field and a slow removal of the PATIENT from the magnet may be the most appropriate method.

Communication with the PATIENT or monitoring of an anaesthetised PATIENT should be assured throughout the MR EXAMINATION.

Certain PATIENTS may sustain claustrophobic reactions which should be discussed before a MR EXAMINATION is undertaken.

Concerning 201.7.9.2.101 d) – Exposure of the PATIENT and the MR WORKER to excessive acoustic noise

Standards to protect against hearing loss are based on the RISK for permanent noise-induced hearing loss caused by long term occupational exposure. The allowed exposure in the general standard is 80 dB(A) per 24 h. This limit can be increased with 3 dB per factor 2 less duration (i.e. 83 dB(A) per 12 h, 86 dB(A) per 6 hs, etc.). In addition it is ruled in some countries that at daily exposure levels above 85 dB(A) appropriate measures should be taken [3],[4]. This applies for workers.

For PATIENTS this standard requires that the instructions for use point to the need to apply hearing protection when the MR EQUIPMENT is capable of producing noise levels above 99 dB(A), which is derived from the limit of 80 dB(A) defined in subclause 9.6.2.1 of the general standard. This limit is increased by 14 dB, because the exposure duration is 1 h only. Another 5 dB are added because the exposure is given only once instead of daily, which can be derived from Kryter [5]. According to Kryter it is reasonable to assume that permanent shift of the acoustic threshold in occupationally exposed persons is proportional to the total noise energy present over the entire career. In total, the level above which hearing protection is required for the PATIENT is:

$$80 \text{ dB(A)} + 14 \text{ dB} + 5 \text{ dB} = 99 \text{ dB(A)}$$

The requirement is important because modern MR EQUIPMENT can produce noise levels to the PATIENT that are much higher than 99 dB(A). Mc Jury *et al.* [6] recently report levels up to 115 dB(A). The MR EQUIPMENT may produce a noise spectrum with a broad band centered around 1 kHz [7]. However, the design of strong GRADIENT UNITS in new MR EQUIPMENT may lead to higher noise levels as well as higher centre frequencies [8] (see also subclause 201.9.6.2.1). The noise attenuation from the use of properly applied hearing protection (ear muffs or earplugs) usually ranges from 25 dB – 30 dB at 2 kHz. Accidental sub-optimal use or

omission of hearing protection is not an acute safety problem for most PATIENTS [9]. Their typical exposure duration will be much below 1 h and the typical noise level in most scans is much (5 dB – 10 dB) below the maximum value of which the MR EQUIPMENT is capable. However this may not be true in MR EQUIPMENT that can produce very high noise levels. In addition, special care should be taken for the situation in which the PATIENT is given anaesthesia. In that case the aural reflex can be ineffective or much less effective than in conscious PATIENTS, because of the influence of the muscle relaxing drugs on the stapedius muscle in the middle ear [10]. The necessity of the careful use of ear protection especially in that situation has to be emphasized in the instructions for use.

Concerning 201.7.9.2.101 e) – CONTROLLED ACCESS AREA

The installation of a CONTROLLED ACCESS AREA and the appropriate use of warning signs and markings is necessary to control exposure of individuals with medical implants to high magnetic fields, and to prevent the entry of ferromagnetic objects into the CONTROLLED ACCESS AREA (see also rationale to 201.7.9.2.101 j) and 201.7.9.3.101 b)).

(1) Attraction and torque on ferromagnetic materials

NOTE This item refers to areas inside the CONTROLLED ACCESS AREA.

All magnets are surrounded by magnetic fringe fields. The major safety consideration is the development of administrative and physical barriers to prohibit the accidental introduction of ferromagnetic objects into the examination area.

In addition, the field distortions generated by small magnetic objects either in the PATIENT or accidentally introduced and clinging to the inside of the magnet can result in image artefacts. For these reasons, the examination area should be secured against unauthorised entry at all times.

Various HAZARDOUS SITUATIONS, which may be caused by interaction between ferromagnetic materials and the field, are as follows:

– ferromagnetic aneurysm clips or ferromagnetic fragments being displaced inside the body of the PATIENT, damaging surrounding tissue;
– loose ferromagnetic materials, attracted into the magnet, injuring the PATIENT externally; and
– a heavy ferromagnetic object, attracted to the surface of the magnet, trapping a person between it and the magnet.

The attractive force and/or torque exerted by a magnet upon an object composed of ferromagnetic materials is due to the interaction of the magnetic field and the induced magnetisation in the object. This force will therefore depend on the value and on the rate of variation in space of the magnetic field, on the specific magnetic properties of the object's materials as well as on the object's mass and shape.

Similarly, the torque exerted by the magnet on an object depends on the same quantities. It may also be present in the absence of any attractive force in a situation in which the field is perfectly uniform. An object will always experience a torque unless it is perfectly aligned with the field, whereas an attractive force will be exerted only in the presence of a non-uniform field.

Notwithstanding the fact that the force on an object depends on its magnetic nature and on the spatial rate of change of the field, it is more practicable to state the necessary precautions in terms of a field limit value, since measurements of the static field can be performed more easily. The attraction effects usually come into effect when the magnetic fringe field is stronger than 3 mT.

An alternative approach to control the attraction on ferromagnetic materials is described in the ACR Guidance Document for safe MR practices [142]. In stead of just defining field limit values which constitutes the CONTROLLED ACCESS AREA, the MR site is conceptually divided into four zones.

– Zone I, is the region which includes all areas that are freely accessible to the general public.

- Zone II, is the area which constitutes the interface between the uncontrolled Zone I and the strictly controlled Zones III and IV. Typically PATIENTs are greeted in Zone II.
- Zone III, is the region in which free access by untrained persons may result in serious accidents. Zone III is strictly under control by MR personnel and should be physically restricted from general public access by for example key locks. Non-MR personnel are not to be provided with independent Zone III access until such time as they undergo the proper education and training to become MR personnel themselves. Zone III, or at the very least the area within it wherein the static magnetic field's strength exceeds 0,5 mT, should be demarcated and clearly marked as being potentially hazardous.
- Zone IV, is the area which is synonymous with the MR scanner magnet room itself. It is by definition always located within Zone III. Zone IV should always be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields.

Other publications are available describing possible instructions for the design and realization of MR suites. Examples are the MRI Design guide as published by the Department of Veterans Affairs. [156].

Magnets can be classified roughly into the following general types:

– superconducting magnets,

– resistive magnets and

– permanent magnets.

Self-shielded magnets differ significantly from their non self-shielded counterparts with respect to the distribution of the magnetic fringe field. Non-self-shielded superconducting magnets and resistive magnets with an air core solenoid tend to have the same distribution of the magnetic fringe field, except that the intensity of the field differs.

The various types of magnets can be classified in terms of the attraction of ferromagnetic materials as follows:

– Non-self-shielded type magnets

  This type of magnet has the most extensive magnetic fringe field region and, therefore, produces the widest hazardous zone. Since the rate of change of the field is low, the expected forces are less severe. Due to their lower magnetic field, the resistive magnets have a proportionally smaller hazardous region than superconducting magnets.

– Self-shielded type magnets

  The magnetic fringe fields are restricted and therefore the hazardous zone is limited. Nevertheless, due to the significant field gradient, the maximum attractive force exerted by this type is greater than that of the non-self-shielded type.

– Permanent magnets

  The magnetic fringe field region is the most limited, with the smallest hazardous zone as a result. However the field gradient is more significant. Consequently there is a danger that ferromagnetic materials could be attracted even in the zone where the magnetic fringe field intensity is small. In addition, permanent magnets cannot in practice be de-magnetised in cases of emergency, whereas other types of magnet can be de-energised.

2) Effect of the static field on other devices

  The use of warning signs and the definition of a CONTROLLED ACCESS AREA are necessary to control exposure of individuals with medical implants. Generally, areas below 0,5 mT have not been shown to be a potential source of interference, e.g. to cardiac pace-makers [11]. The European Standard EN 45502-2-1 [12] reflects this fact by defining a threshold of 1 mT.

  The controlled access area is set to 0,5 mT in order to provide an adequate safety margin for implants that still use a reed switch or Hall effect switch for control of patient therapy. Typical switches are specified for operation at or above 1,0 mT but

margin is provided for switch tolerances, manufacturing variabilities, and other factors (e.g. component ageing, flux density variations).

Numerous electronic equipment found in a hospital department (e.g. X-RAY TUBES, cathode ray tubes, scintillation cameras, and X-RAY IMAGE INTENSIFIERS) may be affected by magnetic fields above a value of the order of 0,1 mT to 5 mT. Siting a MR EQUIPMENT in an area in which its magnetic fringe field impacts on this equipment may require shielding. Such shielding can also simplify the problems of control of access for safety reasons. It is worth noting that equipment such as television systems and video display terminals are particularly important in this respect because they are becoming more and more common in a medical facility. Computer electronics are generally not affected by the lowest fields. To erase magnetic information, such as that on credit cards requires a relatively low static field. Thresholds as low as 20 mT have been reported.

Since the output of a photo-multiplier tube is affected by the magnitude and orientation of magnetic fields, equipment whose operation is extremely sensitive to the gain of a photo-multiplier tube (e.g. belonging to a scintillation camera or a COMPUTED TOMOGRAPHY system) can be among those affected by the lowest magnetic fields. The entire equipment or individual photo-multiplier tubes can be magnetically shielded, but the large aperture of a scintillation camera will make magnetic shielding difficult in most cases.

Electroencephalographs and electrocardiographs may be used in areas near the MR EQUIPMENT sites, the former being extremely sensitive to time varying magnetic fields and the latter being relatively insensitive. However, quantitative data should be provided by the MANUFACTURER of the electroencephalograph or electrocardiograph equipment.

Concerning 201.7.9.2.101 f) – Liquid and gaseous cryogens

1) Handling of liquid cryogen: helium and nitrogen

   a) Properties of the cryogen

      – detrimental to health (see also item 2);
      – odourless;
      – non-flammable;
      – non-toxic;
      – helium is lighter than air;
      – when evaporating, they produce cold fogs which will spread.

      Nitrogen fog will sink quickly to the floor.

      At ENVIRONMENTAL TEMPERATURE (20 °C), 1 l of liquid helium will produce approximately 810 l of helium gas, and 1 l of liquid nitrogen will produce approximately 700 l of nitrogen gas.

   b) Dangers associated with cryogen

      Incorrect handling of helium and nitrogen can result in:

      – danger of cold injuries;
      – danger of suffocation;
      – danger of oxygen condensation.

      • Cold injuries

      When handling liquid nitrogen/helium, any contact with the skin should be avoided, because of the danger of cold injuries. Splashes on the skin cause skin damage similar to burns. The eyes are particularly vulnerable.

      • Danger of suffocation

      Leaking helium or nitrogen gas will displace the oxygen. An ambient air oxygen concentration of less than 17 % to 18 % is not sufficient for human respiration. The limit of the air oxygen concentration should meet national laws or regulations.

If a cloud of helium or nitrogen escapes into the examination room, it is advisable to immediately evacuate the room and to re-enter this room only after the oxygen content has been verified to be sufficiently high.

- Condensation of oxygen

The surface temperature of containers of nitrogen and helium may be sufficiently low to condense oxygen or oxygen-enriched air, which would add to a fire HAZARD.

If grease, oil or other combustible material is present in the vicinity of containers, the escape of cryogenic gases can lead to the formation of a potentially combustible liquid due to liquefaction of air and concentration of oxygen.

c) Protective clothing

The wearing of protective clothing is essential during all work in conjunction with liquefied cryogen.

Such clothing consists of:

– safety gloves;
– work gloves;
– face shield;
– laboratory coat/overalls (cotton or linen);
– non-magnetic safety shoes.

2) QUENCH

A QUENCH is due to excessive heating of the wires of the magnet immersed in liquid helium (e.g. induced by loss of vacuum, mechanical perturbations, excess external forces, etc).

Superconducting magnets can vent up to several hundred litres of cryogenic gases per hour during normal operation. During the QUENCH, approximately 10 m^3 to 10^3 m^3 of gas at atmospheric PRESSURE can be vented within a few minutes.

Usually, a QUENCH occurs when the quantity of liquid helium becomes insufficient to cool the superconducting coil. Due to the increase in the temperature of the coil, the superconducting wire exhibits normal conductivity, and an excessive boil-off starts.

If proper venting is not used, three effects can occur during rapid boil-off at a QUENCH:

– excessively cooled gases will freeze water molecules in the area adjacent to the magnet, causing a dense white fog;
– air in the room will be displaced by helium, making it difficult, if not impossible, to breathe;
– the helium gas that escapes during a QUENCH is extremely cold and might even freeze objects in its way.

3) Filling of cryogen

In some types of MR EQUIPMENT periodic refill of cryogen is necessary to keep the helium above the safety level to prevent the QUENCH. During the refill, excessive boil-off of cryogenic gas occurs which could cause the same condition as mentioned above. About 10 % to 30 % of liquid helium will be converted to gas during normal refilling.

Concerning 201.7.9.2.101 g) – Operating modes

See rationale concerning 201.12.4.103.

Concerning 201.7.9.2.101 h) – Exposure of the PATIENT and MR WORKER to static magnetic field

Static magnetic fields used in commercial MR EQUIPMENT range in strength from about 0,02 T to 3,0 T. Experimental units now range in field strength up to 10 T. While permanent magnets

and resistive magnets are utilized in some MR EQUIPMENT, most commercial MR EQUIPMENT use superconducting magnets.

In superconducting magnets, the static field is typically parallel to the long axis of the body. In some MR EQUIPMENT, supplied with a TRANSVERSE FIELD MAGNET, the static magnetic field is normal to the long axis of the PATIENT.

The magnetic field experienced by the PATIENT typically is limited to the operating field strength of the magnet. From the technical specification sheet, as provided by the MANUFACTURER following 201.7.9.3.101 b), it can be seen that for some magnets the stray field outside the bore of the magnet may even be higher then the operating field strength of the magnet.

Except in some cases of interventional work the MR WORKER can normally be assumed to be exposed only to the static magnetic field of the MR EQUIPMENT, in particular to its static magnetic fringe field.

It should be realized that the European Directive 2004/40/EC ([130] referred to in the rationale for 201.7.9.2.101 k) does not currently include exposure limit values for workers for the static magnetic field. Exposure limit values are given in Table 1 of the European Directive. The lowest frequency range is ‘up to 1 Hz’ and thus does not include the 0 Hz of the static magnetic field. Values for exposure to the static magnetic fields may be introduced in the EU directive which is under review (see the amending European Directive 2008/46/EC which delays the implementation at least until 30 April 2012). An updated guideline for the exposure limit values is introduced by ICNIRP (see rationale 201.7.9.2.101.k) in 2009 [162] (see also Table AA1 on static field occupational standards).

Exposure to the static magnetic field for the MR WORKER is allowed up to 4 T in this standard. This value is proposed because known physiological and sensory effects of the exposure to static magnetic fields up to 4 T are limited to subjective observations like dizziness and vertigo. These observations by the person involved can be dependent on the head movement of the person during exposure and vary a lot between individuals and are not considered to be a negative health effect for the MR WORKER apart from his/her general well being during exposure. However, together with possible effects on eye-hand coordination, the optimal performance of workers executing delicate procedures (e.g. surgeons) could be reduced, along with a concomitant reduction in safety [143].

Although for specific types of MR WORKER the frequency of exposure to static magnetic fields >3 T may be relative high, there is no generally accepted known HARM to these MR WORKERS as a result of the sensory effects. In addition, the probability of HARM to the PATIENT as a result of these effects on the MR WORKER (resulting possibly in loss of concentration or unstable hand control) is estimated to be very low. It is subject to separate work place and function specific guidelines and regulations on working practice. Consequently, the RISK associated with both HAZARDS is estimated to be acceptable even at static magnetic fields up to 4 T. For both the PATIENT and the MR WORKER exposure to higher values than 4 T requires approval following local regulations.

An important point for consideration is the fact that many published reports indicate that it is not the exposure to the static magnetic field, but the movement in the static magnetic field (including the stray field of the magnets of the MR EQUIPMENT), that results in the observed physiological and sensory effects. It is claimed that just being exposed to the static magnetic field (e.g. standing next to the magnet or laying still on the PATIENT support in the field) does not create any sensory effect. This suggests exposure limits should be expressed in T/s rather than T. A recent publication by Glover [148] however suggests direct sensory effects caused by exposure to the static magnetic field. He reports postural sway and “falling” sensation next to a 7 T magnet observed by a volunteer standing still next to the magnet.

Movement in the inhomogeneous stray magnetic field of the magnet induces electric currents in the human tissue, which may call for an exposure limit value. Recent publications [145]

have illustrated that the current densities induced can exceed the values set by the ICNIRP guidelines [131] or the IEEE guidelines [154] in the frequency range of a few Hz, which can be seen as the frequency range relevant for the movement of an MR WORKER in the stray field of the magnet. Movement through static fields will induce currents above the relevant exposure limit values for time-varying EMF sources as given in the annex of the European Directive [130] and this will conflict with current practice with almost all high field MR SYSTEMs in the hospitals. At the time of definition of the third edition of this standard, the interpretation of the European Directive is subject to discussion. Specifically the question whether movement in the inhomogeneous stray field of the static magnetic field just outside the magnet is included and is required to be subject to the limits given for exposure to low frequency EMF is not answered at this moment.

The exposure limit proposed for PATIENT movement into the scanner is taken from the publication by Glover and is believed to set a conservative value for this movement exposure also taking into account the years of experience of patient movement into scanners, the related exposure to the changes in the static magnetic field and the fact that in routine practice PATIENTS hardly ever complain about the observed affects. The proposed limit is therefore also independent of the operating mode of the scanner. For MR WORKERS no concrete exposure limit is give for this type of exposure because in practice it will be impossible to monitor this field. Sensor devices are currently being developed [149] but are not available for routine use in the hospital.

In 2006 the World Health Organization published a report entitled: Environmental Health Criteria 232, Static fields [143]. This report is the result of an extensive review of all peer-reviewed literature on the health effects of electric and magnetic static fields. More than 500 references to literature are given and discussed. It reports on the possible interaction mechanisms with the human body, includes in vitro studies, animal studies, laboratory studies on humans, epidemiological studies, health RISK ASSESSMENT and recommendations for further studies. This report was the major source of input for the update of ICNIRP guidelines for human exposure to static magnetic fields [162]. It is however noted that the conclusion of this extensive report specifically for the health effects related to static magnetic fields is still formulated as: “Nonetheless, the severe lack of information has meant that it is not been possible to properly characterise the RISKS from static field exposure.”

- **Potential mechanisms for bioeffects**

Forces, torque, and permeability

The least glamorous and perhaps most significant mechanism for MR bioeffects is the missile HAZARD. Ferromagnetic objects will experience translational forces which will attract them towards high magnetic field regions in the magnet [15]. This force depends on the product of static magnetic field strength and the spatial gradient of the magnetic field strength. Low-field shielded magnets may, at certain spatial locations, produce larger magnetic gradients than even high-field, unshielded magnet [16]. The result is that such shielded low-field magnets may exert greater forces on ferromagnetic objects than even unshielded high-field magnets at certain locations [16]. The missile HAZARD necessitates training of personnel.

Diamagnetic objects will experience translational forces attracting them to low magnetic field regions away from the magnet [15], [17], [18]. Water is weakly diamagnetic. Ueno and Iwasaka [17], [18], showed that in an 8 T, small-bore magnet, water can experience a force up to 30 % the force of gravity. This force causes the water to separate in the uniform field region of the magnet. To a first approximation, superconducting, solenoidal magnets used in MR EQUIPMENT may be approximated as Helmholtz pairs. Assume a Helmholtz pair has a radius, R, and that the static magnetic field in the centre of the coil pair is B_0. Consider an object whose susceptibility is χ and whose density is ρ. Let the acceleration of gravity be g, let the permeability of free space be μ_0, and let z be the axis of the Helmholtz pair. The maximum acceleration, a, (normalized to the acceleration of gravity) this object should experience in the magnetic field of a Helmholtz pair of radius, R, may be expressed as:

$$a = \frac{\chi B}{\mu_0 \rho g}\left(\frac{\partial B}{\partial z}\right) \approx \frac{\chi}{\mu_0 \rho g}\left(\frac{-0{,}569 B_0{}^2}{R}\right) . \qquad \text{(AA.1)}$$

It can be shown that the peak force from a Helmholtz coil occurs at z/R = 0,787 (assuming the pair centre corresponds to z = 0). Ueno reported the maximum force product ($B\,\partial B/\partial z$) of his small bore system to be 400 T^2/m at z = 75 mm. Assuming a Helmholtz model applies, the radius of the Helmholtz pair $R = z$ /0,787 = 0,075 /0,787 = 0,095 and the maximum force product is $B\,\partial B/\partial z = 0{,}569\ B_0{}^2/R = 381$ T^2/m (less than a 4,7 % discrepancy).

Ueno's "Moses" effect was observed in a small (0,05 m) bore, 8 T magnet. Equation (AA.1) shows that water, which is diamagnetic ($\chi = -9{,}05 \times 10^{-6}$ and density = 1 000 kg/m^3) will experience an acceleration of about 30 % of the acceleration of gravity. When a tray is placed horizontally in the magnet and filled with water, the water is separated, leaving the tray in the magnet center dry. Ueno also found other subtle biological effects [19] related to the force product of the magnet. Equation (AA.1) predicts that force (and presumably biological effects) from magnets similar to Helmholtz magnets (such as solenoidal magnets) depends on the square of magnetic field strength and inversely on the radius of the effective Helmholtz pair. Assuming WHOLE BODY MAGNETS have a Helmholtz-equivalent radius of 1 m, then the force product for a WHOLE BODY MAGNET with 4 T is only 4 % of that of Ueno's magnet. So, in a WHOLE BODY MAGNET with 4 T water should experience an acceleration only about 1 % that of gravity.

A very indirect, but serious, bioeffect mechanism related to ferromagnetic objects involves pacemakers, brain stimulators and other active implantable medical devices. These devices. may have ferromagnetic reed relay switches which are actuated by magnetic fields of a few gauss [16]. Certain prostheses, shunts, screws, and other implants may experience forces in a static magnetic field. Proper care is to be exercised to ensure that the safety of such PATIENTS is not compromised.

Before leaving the subject of ferromagnetic objects, another indirect, potential HAZARD mechanism is to be identified. This potential HAZARD mechanism involves the tendency of magnetic cores in transformers and some conductors to saturate in the presence of high static fields. Equipment containing such magnetic cores may be damaged and cease to function. If such equipment serves monitoring or life support functions, then saturation of magnetic cores may pose significant potential RISKS to the PATIENT.

Electrically conductive objects, including those with relative permeability close to unity, may be susceptible to mechanical damping forces. These forces will occur if the motion of the objects cuts across magnetic lines of force. Currents generated in conductive objects will, by Lenz's law [20], produce magnetic fields which oppose the static magnetic field and damp the motion.

Nerve conduction velocity

Charges moving orthogonal to the static magnetic field will experience Lorentz forces in directions orthogonal to both the static field and the velocity vectors. This mechanism, the Hall effect, might influence nerve conduction [21]. Static magnetic fields may influence action potential propagation time down nerve fibres by altering conduction paths and nerve resistivities [21]. The type of alteration would depend on the relative orientation of the nerve fibre with respect to the static magnetic field and the strength of the magnetic field. Even a 10 % change from no-field nerve properties would require a static magnetic field strength of 24 T [21].

Induced electric fields

Charge carriers, such as flowing blood, moving in static magnetic fields induce transverse voltages [22]. The voltages, V, induced by the magneto-hydrodynamic effect, may be derived by considering the Lorentz force, F. This force, when divided by the elementary charge q,

expresses the transverse electric field. If the diameter of the blood vessel is *D*, the velocity of the blood flow is μ, and θ is the angle between the velocity vector and the static field, then from the Lorentz force law, we have (see Figure AA.1):

$$V = \frac{FD}{q} = \mu \cdot BD \cdot \sin(\Theta) \qquad \text{(AA.2)}$$

Faraday's law of induction, relates induced voltage to the rate of change of flux through an area, *A*. Flux is the integral of the dot product of magnetic field strength *B*, over the area. In static magnetic fields, the normal to the area has to change with time, *t*, to result in an induced voltage *V*:

$$V = \frac{\mathrm{d}\int \overline{B} \cdot \mathrm{d}\overline{A}}{\mathrm{d}t} \qquad \text{(AA.3)}$$

Respiration, cardiac displacements, and flowing blood may induce voltages in the body. One manifestation of these induced voltages (Figure AA.1) is the elevation in the "T" wave portion of the electrocardiogram at high static field levels [23]. During systole, the moving heart and flowing blood induce a body voltage close to the amplitude and near the cardiac cycle time of the "T" wave [23]. Chest wall motion during respiration in static magnetic fields will induce small voltages in the body. Schenck [24] has related vertigo, experienced by personnel who work near high magnetic fields, to pressures generated in the semi-circular canals of the inner ear by motion-induced electric fields.

Power line bioeffects and MR

Whether low level static and dynamic magnetic fields associated with power lines play roles in producing cancer has attracted much recent publicity. Epidemiological studies on effects of residential exposure to power lines at 50 and 60 Hz on childhood cancer have indicated excess RISK for certain cancers [25], [26], [27], [28], [29], [30], [31]. However, the statistical significance of the findings were mixed. Approximately half the studies of adult residential exposure to power lines found effects. However, only one study showed statistical significance. The other studies showed no effects. Several studies of occupational exposure to 50 - 60 Hz fields have been done [25], [32], [33], [34], [35], [36]. Again, the results are mixed, as is the statistical significance of the results. These studies postulate that milligauss fields, lower than those naturally occurring, cause bioeffects. The counter-intuitive hypothesis and mixed experimental results recently led Bernhardt [37] to conclude that additional investigations are needed to clarify this matter.

There are important differences between power line exposures and exposures encountered in MR. One difference is that MR magnetic fields are static, unlike the 60 Hz power line fields. Another difference is the lack of an electric field component associated with the MR static magnetic field. A proposed mechanism for any extra low frequency (ELF) bioeffects involves cyclotron resonance of calcium ions [38]. Such a mechanism requires both a magnetic field (which may be dynamic) and an orthogonal electric field varying at the cyclotron resonance frequency probably of calcium. The cyclotron resonance frequency for calcium ions is 384 Hz/mT. The earth has a magnetic field strength of about 0,02 mT to 0,05 mT. A 60 Hz electric field would require an orthogonal magnetic field strength of 0,156 mT for the cyclotron resonance of calcium ions. Such a combination of electric and magnetic fields may occur near power lines. In a 1,5 T magnet, a 576 kHz orthogonal electric field is required for cyclotron resonance. The resonant frequency in the MR EQUIPMENT is more than two orders of magnitude higher than the cyclotron resonance frequency for calcium for the same magnet. There is no electric field near the cyclotron resonance frequency in MR EQUIPMENT, since electromagnetic shielding is used. These shields protect the environment from MR signals and prevent environmental signals from degrading MR images.

Other proposed mechanisms for static field bioeffects

Chemical reaction rates, equilibrium, and concentrations might be altered if some or all of the reactants or products had magnetic moments which significantly modified reaction thermodynamics [16], [17], [24], [39], [40], [41]. However, up to 4 T, thermodynamic considerations indicate that the effects should be nearly immeasurable [24].

Other possible mechanisms for static magnetic field bioeffects have been proposed. For example, proton tunnelling in DNA due to changes in potential height caused by the static magnetic field [40]. Other mechanisms have been discussed in excellent reviews [16], [24], [37], [40], [42], [43], [44], [45], [46].

- **Observed static field bioeffects**

Experimental studies

The T-wave enhancement, electrocardiogram artefact is the only non-mechanical static field bioeffect that is widely accepted. It is reported for PATIENTS placed in static fields of at least 0,3 T. This phenomenon is rather in the realm of biological cause than effect. Flowing blood results in the induced voltage that leads to the T-wave artefact. No adverse effects result; the PATIENT resumes producing normal EKG traces immediately upon leaving the magnetic field [16][23]. Note that Jehenson, *et al.* [71], also found a 17 % increase in cardiac cycle length after 10 min of exposure to a 2 T field. Cardiac cycle length returned to normal 10 min after exposure and remained normal 22 h later.

Static magnetic fields used in MR EXAMINATION do not result in increases in body temperature [47] as had been suggested [48]. There appear to be no mutagenic effects [16][42][49]. However, Narra, *et al.* [70] found that a mere 30 min exposure of mice to 1,5 T fields caused a 15 % reduction in testicular sperm on the 16^{th} and 26^{th} day after exposure. There are no effects on nerve conduction, and latency [50][51][52]. Nerve excitability is either unaffected [50] or significantly increased [51] by high static magnetic fields.

Many of the proposed mechanisms may apply at a very high field strength, but apparently do not contribute significantly at static magnetic field levels below 3,0 T. For example, Atkins [53] has shown that at normal body temperature, thermodynamic considerations require static fields of at least 10 T to produce significant alterations in enzyme conformation. Wikwso and Barach [20] have shown that fields as high as 24 T would influence nerve conduction only slightly. Recently, Kinouchi, Yamaguchi, and Tenforde [72] showed that static fields up to 10 T should not be of concern due to voltages induced in the aorta.

There are several largely unsubstantiated reports of static magnetic field bioeffects. Oxygen consumption was observed to be depressed somewhat in mouse embryo kidney and liver cells in fields as high as 0,7 T [54]. Another study, however, found no effects at 0,6 T [55]. Contradictory results are reported on the haematology of animals exposed for weeks to high static magnetic fields [56][57][58]. There are several review articles that explore these areas in more depth [16][24][37][40][42][43][44][45][46].

At very high values of the static magnetic field (>10 T) effects are reported on the third cleavage of the frog egg leading to developmental abnormalities as reported by Denegre [140].

Experimental work at static fields above 2 T has been non-decisive. Prasad, *et al.* [71] exposed leopard frog eggs to 0,15 T or 4,5 T, or no field and found no differences in the groups. From this he concluded that magnetic fields up to 4,5 T have no effect on early development. Schenck, *et al.*[67] found increases in vertigo probability at 4 T compared to 1,5 T for human volunteers moving their heads in a 4 T field. In addition, he found statistically significant increase in nausea, metallic taste, and magneto-phosphene production. Raylman, Clavo, and Wahl [68] exposed human tumor cells to a 7 T magnetic field for 64 h. They found that the static field reduced viable tumor cell numbers by 19 % for melanoma, 22 % for ovarian carcinoma, and 41 % for lymphoma. They also found no evidence for alterations in cell growth cycles or in gross fragmentation of DNA. In another study Kroeker, *et al.* [69]

found no differences in pineal or serum melatonine levels between rats exposed to 0,08 T fields and those exposed to 7 T fields.

A theoretical investigation is published by Keltner [79], showing that even at very high values of the static magnetic field (= 10 T), magneto hydrodynamic effects in the main blood vessels will still have an insignificant effect on vascular pressure see Equation AA.2.

Epidemiological studies of human exposure to high static magnetic fields have been done [59][60][61][62][63]. Data on Russian industrial workers who were exposed during their work to both static and low frequency magnetic fields up to 0,1 T contain many subjective observations (e.g., headaches, chest pains, dizziness) [62][63]. These studies also lacked adequate controls for complicating factors such as chemicals in the workplace.

In marked contrast, studies of American workers who work with high magnetic fields showed no hazardous effects in fields up to 0,5 T in one study [59] and as high as 2,0 T in another study [60]. In recent years more 3,0 T MRI SYSTEMS are installed and routinely used for PATIENT studies. In the 2nd edition of this standard it was decided to define the NORMAL OPERATING MODE scanning up till a level of 2,0 T. This was mainly introduced due to lack of data and the wish to provide MEDICAL SUPERVISION to all PATIENTs being scanned at levels higher than 2,0 T. Since then the number of 3,0 T scanners is increased considerably and much more information is available about PATIENT experiences at these field strengths. In fact no PATIENT data are published in the literature describing negative health effects which need MEDICAL SUPERVISION. While investigations into these areas should be continued, there is no evidence that exposures to static magnetic fields of 3,0 T and lower put the PATIENT at RISK. For this reason it is proposed to raise the level of concern in this edition of the standard to 3,0 T.

One area of concern is whether static magnetic fields are hazardous to the unborn children of exposed pregnant workers. While proving safety in an absolute sense requires an infinite number of experiments, there is no evidence in the literature to date that exposure to static magnetic fields is hazardous. An epidemiological survey [61] of MR technologists in the United States found no correlation between exposure to high static magnetic fields and spontaneous abortion rates, infertility, low birth weight, or premature delivery. Ueno studied embryonic development of frogs in 6,34 T fields and found that rapid cleavage, cell multiplication, and differentiation were unaffected [48]. Kay also investigated embryonic development of frogs in high static fields and found no adverse effects [64]. McRobbie studied pregnant mice in gradient magnetic fields and found no effects on litter number or growth rate [65].

- **Static fields: Occupational safety standards**

In Table AA.1 a list of static occupational field exposure standards is provided. These include standards [74][75][76][77] from the National Radiological Protection Board (NRPB) used in the United Kingdom, from the American Congress of Government Industrial Hygienists (ACGIH), from the Lawrence Livermore National Laboratory (LLNL), and from the Australian Radiation Laboratory (ARL). Note that all the standards require a static field “dose” limit of either 200 mT or 60 mT. Assuming these limits apply to an 8 h day, then at 0,5 T, only one hour per day could be spent in the field using the 60 mT level.

The scientific basis for such static magnetic field dose limits is missing. There is a reference [78] to keeping the induced root mean square (r.m.s.) voltages below 1 mV. Apparently concern that blood pressure might be significantly elevated in high static fields led to limits on the length of exposures to static magnetic fields. As will be discussed in the next section, this concern turned out to be unjustified [79]. However, dose-based occupational exposure standards persist. Future static field exposure standards may be updated with MR exposures in mind.

Table AA.1 – Static field occupational standards

Source	Whole-body time average (8 h)	Whole-body maximum	Extremities time average (8 h)	Extremities maximum
ICNIRP[a]	200 mT	2 T	–	5 T
NRPB[b]	200 mT	2 T	200 mT	5 T
ACGIH[c]	60 mT	2 T	600 mT	5 T
LLNL[d]	60 mT	2 T	600 mT	2 T
ARL[e]	60 mT	5 T	200 mT	10 T
ICNIRP[f]	No limit	2 T[g]	No limit	5 T
BGV_B11[h]	212 mT[i]	2 T[i]	No limit	5 T[j]

[a] International Commission on Non-Ionizing Radiation Protection; 1993, [78]

[b] National Radiological Protection Board (UK)

[c] American Congress of Government Industrial Hygienists

[d] Lawrence Livermore National Laboratory

[e] Australian Radiation Laboratory

[f] International Commission on Non-Ionizing Radiation Protection; 2009, [162]

[g] Limit value is increased to 8T for a controlled environment.

[h] BGV_B11: Accident Prevention Regulation Electromagnetic Fields June 2001

[i] Limit value for the head and trunk is increased to 4 T with a maximum of duration of 2 h per day in the field of science and research e.g. in the course of a medical treatment

[j] Limit value is increased to 10T in the field of science and research e.g. in the course of a medical treatment

- **Static fields: mechanisms for occupational concerns**

As discussed above, in the presence of static magnetic fields, ferromagnetic materials may experience translational forces towards regions of higher magnetic field strength [24]. Ferromagnetic objects may also experience torque tending to align their magnetic moments with the static magnetic field [24]. Moving, electrically conductive objects may experience forces and torque in static magnetic fields due to Lenz's law [24].

Flow potentials [22] may be induced in conductive fluids (such as blood) moving through static magnetic fields. Flow-induced potentials cause artefacts on electrocardiogram (EKG) recordings [23]. Rapid head motion may induce voltages in the semi-circular canals of the inner ear sufficient to exceed the vertigo perception threshold [24]. Theoretical predictions of flow-induced blood pressure elevation apparently influenced occupational safety standards. However, the magnitude of this effect turns out to be extremely small [79].

Flow potential-induced electric fields may produce elevated T-wave artefacts on electro-cardiograms. These electric fields E may be derived from Equation (AA.4) (see Figure AA.1):

$$V = \frac{F\,D}{q} = v\,B\,D\sin(\theta) \qquad \text{(AA.4)}$$

This electric field is orthogonal to the plane containing the flow velocity vector and the static magnetic field. The highest flow velocity coincides in time with the T-wave on an EKG. For example, assume that the peak blood velocity is 0,6 m/s [40], the flow and static field make an angle of 30°, and the artery diameter = 0,02 m, then the induced voltage is 9 mV for a static magnetic field of 1,5 T. Contrast this result with typical EKG "R" wave amplitudes which are on the order of 10 mV. The resulting "T-swells" disappear with the static magnetic field. T-swells appear to have no biological significance. Whether chronic induction of such voltages

is of concern is not certain. However, evidence to date, suggests there are no safety issues up to at least 7 T.

Note that in most high field MR EQUIPMENT, the PATIENTS are aligned parallel to the static magnetic field. Peak blood flow velocities occur in the aorta [80]. Assuming the aorta is nearly aligned with the static magnetic field, then for typical MR EQUIPMENT the induced electric field should be small. Next, consider a worker standing in the gap of a magnet. For this case, θ is approximately equal to 90°, and the induced electric field is larger. Reilly [81] has estimated that an electric field of 6,2 V/m is needed to produce cardiac stimulation in the most sensitive population percentile for gradient ramp times >>3 ms. For gradient ramp times of 600 μs (more typical of MR EQUIPMENT), cardiac stimulation in the most sensitive population percentile rises to about 31 V/m. Cardiac stimulation in the most sensitive population percentile requires static magnetic fields to be at least 10 T (ramp times >>3 ms), but more typically about 52 T (for ramp times of 600 μs). It would be prudent to conduct experimental cardiac safety studies before building open magnets for MR EQUIPMENT with extremely high fields.

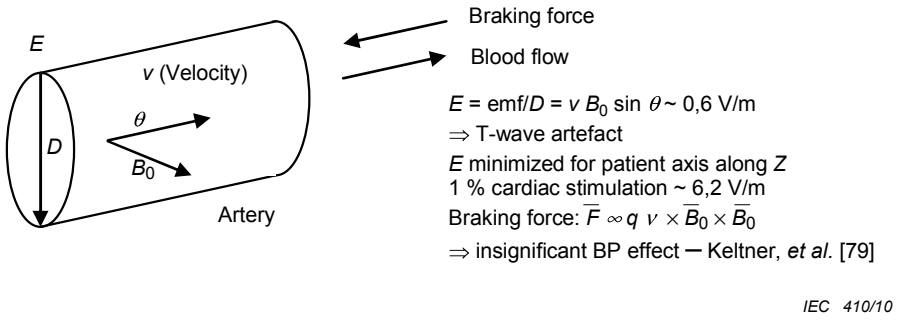


Figure AA.1 – Static magnetic fields: flow potentials and retardation

Blood flowing in a static magnetic field generates a flow potential proportional to the velocity, static magnetic field, and the sine of the angle between them. A braking force which opposes blood flow is also created, but its magnitude is physiologically insignificant up to at least 5 T.

The induced electric field will create a flow of charged particles along the electric field. These charged particles moving orthogonally to the magnetic field will experience a force which opposes blood flow [22] (see Figure AA.1). Apparently, this force was thought to be of concern since it might lead to an increase in blood pressure. However, Keltner, *et al.* [79] showed both theoretically and experimentally that this effect is of no concern.

Conclusions

There appears to be little or no evidence of HARMful effects from static magnetic field exposures (experimentally up to 7 T in this review). Theoretical concerns start as low as 10 T. A review of the effects of strong static magnetic fields has been published [82]. These and other data led the U.S. Food and Drug Administration to consider static fields below 4 T to be a non-significant RISK [74].

Concerning 201.7.9.2.101 k) – Occupational exposure to EMF

Limits for the protection of workers for exposure to electromagnetic fields are introduced in the European Directive 2004/40/EC [130] which was adopted by the Council and the European parliament in April 2004. Since then, the directive has been amended and the implementation has been delayed (Directive 2008/46/EC of April 23, 2008) at least until 2012. The limits introduced, are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guideline for workers in general [3].

The limits for electromagnetic exposure for the MR WORKER, introduced in this standard are in excess of those permitted by the ICNIRP guideline [3] as the result of the following rationale:

- The devices are expected to be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of PATIENTs, or the safety and health of users or, where applicable, other persons, provided that any RISKS which may be associated with their use constitute acceptable RISKS when weighed against the benefits to the PATIENT and are compatible with a high level of protection of health and safety.
- It is the philosophy of ICNIRP to give exposure limits for the protection of workers in general. ICNIRP does not consider the need to balance associated health RISKS with social benefit (social and economical considerations are outside of the remit of ICNIRP) and therefore ICNIRP cannot consider the possible relaxation of its guidelines for special categories of workers based on social arguments. Thus, ICNIRP does not acknowledge the specific and unique situation of MR WORKERs and more specifically the RISK/benefit for the PATIENT and balancing this benefit with the RISK for the MR WORKER.
- ICNIRP guidelines for the safe exposure of MR PATIENTS are recently published [132]. Limits are identical to those in IEC 60601-2-33, 2nd edition (2002).
- This RISK MANAGEMENT approach is specifically applied for the exposure to static magnetic fields for the MR WORKER, see the addition to the rationale of 201.7.9.2.101 h)
- The limits in the range of a few Hz to about 100 kHz for the MR WORKER are based on thresholds for peripheral nerve and muscle stimulation and cardiac muscle stimulation and are low enough to avoid all such physiological effects. There are no peer-reviewed published reports of gradient-induced magneto-phosphenes.
- Since minimal peripheral nerve stimulation could be accepted for the MR WORKER under some circumstances, it may be required to give extra instructions to the MR WORKER to avoid an exposure to the GRADIENT OUTPUT. A prediction of the expected GRADIENT OUTPUT is displayed (on request) on the CONTROL PANEL and can be used to either avoid exposure by creating sufficient distance from the scanner during scanning or by reducing the value of the GRADIENT OUTPUT. Since the stray field of the gradient coil drops off rapidly outside the coil and by geometrical considerations, exposure of the MR WORKER can be assumed to be most likely at the level of NORMAL OPERATING MODE and peripheral nerve stimulation is not expected for the MR WORKER.

For pregnant MR WORKERS extra precaution is advisable. It is advisable for a pregnant MR WORKER not to stay in the scan room during scanning to avoid unnecessary exposure to gradient and radiofrequency electromagnetic fields and noise levels. Local regulations may apply.

Instructions for use are required to state that the limits for workers may not be applicable when a MR WORKER is pregnant. It may be required that the ‘member of the public’ limit may be applied to the foetus in some countries.

The RISK MANAGEMENT approach is also applied for the exposure to the GRADIENT OUTPUT EMF generated by MR SYSTEMS when balancing the probability of RISK of ionizing radiation versus MR [133]. The cumulative effect of exposure to ionizing radiation has been studied extensively.

Workers exposed to ionizing radiation with energy ≥ 12,4 eV (or (2×10^{-18}) J) are regulated by limits recommended by such groups as the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiation Protection (ICRP). To illustrate the difference between that type of radiation and the frequency range of the EMF in an MR SYSTEM (1 kHz – 1 GHz), the following: An MR scanner would need a magnetic field strength of $(7{,}04 \times 10^7)$ T (the resonant frequency for protons would be $(3{,}0 \times 10^{15})$ Hz) to reach this threshold level (five orders of magnitude above the field strengths of any current scanners). At 4 T the energy in any MR photons (assuming the system is capable of radiating) would be a factor of $(1{,}8 \times 10^7)$ below the 12,4 eV threshold. In fact, the energy of any 4 T photons would be a factor of $(3{,}4 \times 10^5)$ below the threshold energy needed to break hydrogen-hydrogen bonding in water (the weakest of all bonds) [135]. So, in MR biological

interactions similar to radiation damage by ionizing radiation from single photons are not possible. This reasoning suggests that it can be concluded that cumulative effects on the molecular level from EMF exposure from MR will be absent. To the working group's knowledge, there are no peer reviewed published studies up to the present day that show any of these cumulative effects.

In the United States the annual occupational exposure limit [137] for ionizing radiation (10 CFR 20 subpart C) is 0,05 Sv (5 rem), while the general public may not be exposed to more than 0,001 Sv (0,1 rem). The threshold for observable effects from ionizing radiation is about 0,05 Sv. A PATIENT receiving a head computed tomography (CT) scan is estimated to receive up to 0,03 Sv. The RISK of dying from cancer from an exposure to 0,01 Sv (1 rem) has been estimated at 0,0005. In contrast, there is no known RISK of dying from EMF exposures generated by MR EQUIPMENT provided OPERATORs comply with IEC 60601-2-33 (2002).

In conclusion, RISKS to MR WORKERS exposed to the possible EMF generated by MR SYSTEMS appear to be very low. Workers exposed to ionizing radiation appear to be at higher, but still acceptable RISK levels.

The probability of cardiac stimulation under the 2nd edition of the IEC 60601-2-33 limits is close to zero, as shown in the rationale of subclause 201.12.4.102 (4). Reilly [85] determined that cardiac fibrillation thresholds follow a lognormal distribution with the threshold for the most sensitive percentile about half the value for the median. In addition, Reilly estimated that for a given animal the median cardiac stimulation threshold is about 40% of the cardiac fibrillation level. Reilly estimated that the rate of change of the magnetic field, $(\mathrm{d}B/\mathrm{d}t)_{1\%\ \mathrm{cardiac}}$, which may stimulate hearts in the most sensitive percentile of the population, is related to the total gradient ramp duration, d, and to a time constant, τ, and may be expressed by the following equation:

$$\left(\frac{\mathrm{d}B}{\mathrm{d}t}\right)_{1\%\,cardiac} = \frac{60}{1-\exp\left(\frac{-d}{\tau}\right)} .$$

Reilly used a value of 3 ms for τ. Bourland et al [90] found that thresholds for canine cardiac stimulation when adjusted for the relative ratio between humans and dogs agreed well with Reilly's estimates extrapolated to the cardiac mean. In the IEC rationale it was shown that Reilly's estimates indicate the probability of cardiac excitation at the mean peripheral nerve stimulation limit is on the order of 10^{-9}. Schaefer [136] found similar estimates. So, cardiac stimulation is extremely unlikely at the IEC 60601-2-33, 2nd edition (2002) limits.

- **Peripheral nerve stimulation versus magneto phosphenes for the GRADIENT OUTPUT**

Specifically for the frequency range relevant for the GRADIENT OUTPUT, the 1 kHz to 10 kHz range, the ICNIRP limits are based on extrapolations of the effects related to evoked potentials in the retina, which can result in visual stimulations (visual phosphenes). There is no evidence that such visual stimulation constitutes an adverse effect or leads to any long-term HARM. These effects are observed at somewhat lower frequencies than relevant for MR. Since retinal tissue can be compared with brain tissue (the central nervous system), these effects are used by ICNIRP as a model for effects in the central nervous system and are extrapolated to the somewhat higher frequency range. In addition, these ICNIRP guidelines include a large safety margin and resulted in an exposure limit expressed as 10 mA/m^2. A recent review of this effect was organized by the NRPB in 2004 and confirmed the 10 mA/m^2 (including a factor 10 safety margin). At somewhat higher frequencies the electric current densities generated by the GRADIENT OUTPUT in the PATIENT is much higher and is known to generate Peripheral Nerve Stimulation at the frequencies and waveforms relevant for MR. The visual stimulations seem not to be the relevant physiologic effect for the somewhat higher frequencies and specific gradient waveforms applied for MR (and are never reported in relation to the GRADIENT OUTPUT of MR EQUIPMENT). For MR PATIENTS limits are based on Peripheral Nerve Stimulation effects. This observation is confirmed by the ICNIRP in a recent

publication [132], specifically addressing exposure limits for MR PATIENTS. The PNS limits have never been reported to result in unsafe situations in medical practice.

For the kHz frequency range, ICNIRP has formulated action values expressed as electric field strength of 610 V/m. This value is much higher than the values for the electric field generated in a human body by the GRADIENT OUTPUT. The exposure limits for the current densities are 10 mA/m^2 at 1 kHz and 10 A/m^2 at 1 MHz. Between 100 kHz and 1 MHz a body SAR limit of 0,4 W/kg has to be satisfied. The 610 V/m action value is derived from the electrical LF/RF current, which is driven from the electric field in an almost empty space. Inside the human body the *E*-field is much lower due to the electrical conductivity $\sigma \approx 1$ S/m. Assuming a large capacitor of length *L* and cross section *A* with a much thinner slice *LB* (human body) of a complex dielectric permittivity ε_r ($\varepsilon_r = \varepsilon' + i\varepsilon'' = \varepsilon' + i\sigma/\varepsilon_0\omega$) the overall capacitancy is given by

$$\frac{1}{C} = \frac{L - LB}{\varepsilon_0 A} + \frac{LB}{\varepsilon_r \varepsilon_0 A}$$

Since $|\varepsilon_r| >> 1$ (for the considered frequency range) and $LB << L$ the capacitancy *C* is not affected by the physical presence of the human body. Hence, the current *I* through the capacitor is given by

$$I = \frac{\omega \varepsilon_0 A}{L} U'$$

and the current density *J* is given by

$$J = \omega \varepsilon_0 E$$

(*I*, *J* are amplitudes only and *U* is the potential in Volts and *E* is the electric field in V/m)

At 1 kHz and *E* = 610 V/m one obtains a current density of 33 μA/m^2 and at 1 MHz a current density of 33 mA/m^2, respectively. These values are much lower than the exposure limits!

Let us consider SAR values. The SAR is given by

$SAR = \frac{1}{\sigma\rho} J^2$, where ρ is the tissue density..

For $\sigma \approx 1$S/m and $\rho = 10^3$ kg/m^3 one obtains a SAR of 10^{-7} W/kg at 1 kHz and 0,1 W/kg at 1 MHz assuming the exposure limits of 0,01 mA/m^2 at 1 kHz and 10 A/m^2 at 1 MHz, respectively.

Concerning 201.7.9.2.101 l) – Auxiliary EQUIPMENT

Care should be taken in the selection of monitoring/sensing devices to ensure that they are specifically intended for use with MR EQUIPMENT (e.g. high resistance ECG leads). Electrically conducting materials, except those which have to make electrical contact with the PATIENT (e.g. ECG electrodes), should be electrically insulated from the PATIENT. All conducting materials should be thermally insulated from the PATIENT. The MANUFACTURER'S instruction for arranging monitoring leads (e.g. to avoid closed loops) and other cables near the PATIENT are required to be followed. The purpose of all these measures is to minimise the likelihood of induced currents because of coupling to the RF transmit coil, with the concomitant RISK of burns to the PATIENT.

Concerning 201.7.9.2.101 s) – Emergency actions in case of a QUENCH

In addition to the information given in item cc) of 201.7.9.2.101 on emergency medical procedures and item f) of 201.7.9.2.101 on liquid and gaseous cryogens, this item provides information pertinent to emergencies present in the event that magnet helium gas escapes from the magnet into the examination room or other adjacent rooms during a QUENCH. This situation may be present when the venting system of the superconducting magnet fails either in part or fully during a magnet QUENCH. In this case, HAZARDs may be present for the personnel involved. The information provided here will be useful for the RESPONSIBLE ORGANIZATION in establishing an emergency plan adapted to local requirements.

While a QUENCH as such is a rare event, the additional failure of a venting system of the magnet is even more unlikely. Although thousands of MR SYSTEMS are in operation, there have been only a few reports to date regarding accidents or near accidents involving personal injuries in relationship to a QUENCH. Nevertheless, the MANUFACTURERS are required to point out the potential HAZARD of the combined event and to provide information pertinent to this type of emergency. Note that the information covers the highly unlikely, yet possibly serious event of a malfunctioning venting system at the time of a QUENCH of the superconducting magnet.

- **What is a QUENCH?**

During a QUENCH, the magnet loses its super-conductivity. The magnetic field ramps down in a matter of seconds – typically lasting approximately 20 s. The magnet begins to warm up. Liquid helium boils off at a rate of 500 l to 1 500 l within a few minutes and expands quickly. The exact boil-off rate amount depends on the fill level as well as the field strength of the magnet. A 3 T magnet may have a higher boil-off rate than a 1,5 T magnet. One litre of liquid helium translates into approximately 810 l of gaseous helium. During maximum conditions this means approximately 1 000 m^3 of gas. A manual QUENCH may be initiated by activating the EMERGENCY FIELD SHUT DOWN UNIT. Another source for QUENCHing is when the helium fill level decreases to a point where the magnet begins to warm up. In rare instances, a spontaneous QUENCH may be observed that cannot be explained by the presence of obvious causes.

Hissing or whistling noises caused by the quickly escaping stream of cold helium gas may accompany a QUENCH. Plumes of white fog sink to the floor mainly from the upper part of the magnet from the vicinity of the QUENCH line due to condensation of both water vapour and air. The stream of helium gas diminishes in a matter of minutes. Air near the non-insulated components of the magnet and the QUENCH line condenses into liquid air and drips to the floor.

- **RISKS associated with a failing venting system**

The purpose of the venting system of the superconducting magnet is to securely exhaust gaseous helium to the outside. The main element of this system is a conduit that is designed to transport the escaping helium gas to a safe open area. The possibility of a QUENCH should be taken into careful consideration during the design of both the magnet and the venting system of the superconducting magnet. As a result, a QUENCH should be completely harmless to personnel. Also, neither the magnet nor the MR installation as such should be subject to damage during a QUENCH.

An emergency situation will arise if a QUENCH venting system fails. Helium is lighter than air, and is non-poisonous and non-flammable. However, since it displaces oxygen, the RISK of suffocation exists. Cryogenic helium escaping into the ambient air leads to white clouds caused by condensation. These clouds will adversely affect visibility.

Persons may be rendered unconscious by the lack of oxygen entering their respiratory system. Depending on the helium concentration present in the air, a few breaths may suffice to result in unconsciousness.

In addition, escaping helium is extremely cold, possibly causing hypothermia and frostbite. The latter results in injuries resembling burns (cryogenic burns) after the skin is exposed to normal temperature levels. Skin contact with cold parts or liquid air may also lead to frostbite.

A variety of failures of the venting system of the superconducting magnet are conceivable. For instance, the following may occur.

– Small leaks: smaller amounts of helium gas are exhausted to the outside via the heating and air conditioning system and replaced by fresh air. This is not a critical situation as long as the heating and air conditioning system functions as required.
– These leakages are the result of constructional errors that need to be corrected.
– The venting system of the superconducting magnet fails in part: only part of the helium gas is exhausted to the outside via the integrated venting system. Larger amounts of helium are present in the examination room. The heating and air conditioning system cannot remove the helium due to its volume. Large clouds form, which adversely effects visibility. Additionally, the PRESSURE in the room increases. Depending on the size of the leakage, hazardous conditions may be present for the personnel involved.
– Total failure: the venting system of the superconducting magnet fails completely, e.g. through blockage or breaks in the line. The entire amount of gas is exhausted into the examination room. If the requirements and recommendations previously mentioned are not followed, there is an increased potential for loss of life in the case of a complete cryogen vent failure.
– Up to 1 000 m^3 of gas are blown into the room, which frequently has a volume of less than 100 m^3.

Concerning 201.7.9.2.101 t) – Scanning of PATIENTS with active or passive implants

Reference is given to the ASTM standard F2503-05 [144], which formulates the definitions of MR safe, MR conditional and MR unsafe devices and describes how these markings are to be interpreted and handled by both the implant MANUFACTURER and the OPERATOR planning to scan a PATIENT with a specific type of implant.

Concerning 201.7.9.2.101 u) – Scanning of pregnant PATIENTS

Pregnant women may be compromised in their ability to dissipate heat. In this context, it is worth noting that heat loss from the embryo and foetus across the placental barrier may be less efficient than heat dissipation in other well vascularised tissues. Elevated body temperature is known to be teratogenic to a number of mammalian species including primates, and has been implicated in central nervous system and facial defects in children whose mothers developed prolonged severe hyperthermia (>39 °C), especially during the first trimester of pregnancy [109][110]. In these cases it is desirable to limit rises in body temperature to less than 0,5 °C [106]. Furthermore, a detailed numerical study [141] of SPECIFIC ABSORPTION RATE and temperature increase calculations within pregnant woman models exposed to MAGNETIC RESONANCE imaging showed that in the FIRST LEVEL CONTROLLED OPERATING MODE foetus temperature exceeds or approaches 38 °C for frequencies, 64 MHz and 128 MHz. Based on the results of this study, local foetus heating should be minimised by using NORMAL OPERATING MODE sequences which minimize the whole body SPECIFIC ABSORPTION RATE in the mother.

Concerning 201.7.9.3.101 b) – Compatibility technical specification sheet

The summary specification sheet is often referred to as the product data sheet. Specific information on this sheet can help the RESPONSIBLE ORGANIZATION to assess the compatibility of peripheral equipment with the specific MR EQUIPMENT. The compatibility of peripheral equipment relates to both MANUFACTURERS, and only when both MANUFACTURERS issue a compatibility statement does the RESPONSIBLE ORGANIZATION have no further concern. In all other situations the RESPONSIBLE ORGANIZATION is required to ensure that both types of equipment do not disturb the proper functioning of the other.

It is very important to realise that the system configuration of the MR EQUIPMENT can affect the proper operation of peripheral equipment and vice versa. For instance the installation of stronger gradient systems on the MR EQUIPMENT may affect the functionality of peripheral equipment, like a physiological monitoring and sensing device applied near the magnet bore. Therefore in case of an upgrade of the MR EQUIPMENT the RESPONSIBLE ORGANIZATION should inform the MANUFACTURER of the peripheral equipment to assure the safety and performance of the equipment [83].

Concerning 201.7.9.3.101 c) – Safety provisions in the event of a QUENCH

- **Examination room configuration**

A number of examination room features are suggested in the standard. For the examination room features a clear distinction is made between the helium venting system for the superconducting magnet needed in case of a QUENCH and the PATIENT ventilation system needed for daily air refreshment for the PATIENTS. The examination room features try to maximise the time available to remove a PATIENT from the system in the event of a QUENCH associated with a failing venting system of the superconducting magnet. These features will help increase the time available to remove a PATIENT to an average time of a few minutes. In general the operation of the PATIENT ventilation system should be monitored carefully. Some PATIENT ventilation systems bring fresh conditioned air from the top of the examination room to the PATIENT. In the event of a QUENCH associated with a failing venting system of the superconducting magnet, this is very unfavourable for the PATIENT, and the operation of the PATIENT ventilation system should be stopped, preferably automatically via the detection of the QUENCH by a sensor. Also, an automated warning to the OPERATOR can be considered in all situations. The fitting of an oxygen monitor, wired to audible and visual alarms, in the ceiling of the examination room to give an early warning of the escape of helium gas is recommended. When remodelling of the examination room is performed, the integrity of the RF-shielding has to be tested again.

- **Door of the examination room opens inwards – constructional safety measures**

The most unfavourable situation for the examination room is when the door of the examination room opens inwards. In this situation, slight overpressure due to helium gas leakage may make opening of the door extremely difficult. Depending on the ventilation system for the room, overpressure may be present for a considerable length of time. Installation of a provision in the examination room to allow air breathing for persons present in the examination room during the QUENCH in this situation may help to increase the time available to allow for pressure equalization in the room.

To address this situation the following alternatives are available:

– The door is reconfigured so that it opens to the outside, and thus into the control room.

– The door is replaced with an RF-sealed sliding door. It should be ensured that the door closes in a way that allows it to move away from the frame in case of overpressure, that is, it facilitates opening the door.

– The fixed observation window is replaced by a window opening into the control room or by an RF-sealed sliding window.

– Panels are installed in the examination room wall, door or ceiling that can be unlocked and opened to the outside in case of emergency or allow for continual pressure equalization to interstitional space. These panels require an RF-sealed installation. After opening the panel, the outlet should measure at least (60×60) cm^2. When using rectangular panels, the shorter side should measure a minimum of 60 cm in length. Also, easy removal of the panel by a single person has to be ensured. In addition, a minimum distance of 1 meter to the next wall needs to be observed. The panel should be installed as far as possible toward the top of the room to allow escape of the low-density helium.

– The examination room MANUFACTURER can provide additional RF-sealed room openings (metal grids) that lead directly to the outside. However, these openings are also conduits for acoustic noise generated outside the examination room. Again, these openings should

be installed as far as possible toward the top to allow escape of the low-density helium. To maintain unobstructed flow through a pipe, the diameter of a long line has to be appropriate.

– An oxygen detector and alarm can be hardwired to an emergency air extraction system to turn on automatically to maximum air extraction power when in alarm mode due to a too low oxygen level.

For doors moved via auxiliary drives (e.g. electrical or pneumatic), manual operation has to be ensured as well.

If included in the installation, the observation window may be broken although this may be difficult to accomplish. The window usually includes wiring for the RF-shielding that needs to be worked through as well. However, the resulting glass splinters may injure rescue personnel. Depending on the construction and the thickness of the window, the OPERATOR has to provide suitable tools for breaking the window.

- **Maintenance**

A preventive maintenance program should include the following actions.

Checking the exhaust system and room venting.

The installation of the room venting system and the cryogen venting system for the superconducting magnet has to adhere to the requirements and should be checked by trained personnel. Both systems have to be visually inspected at regular intervals to determine inappropriate changes, in particular:

– design changes inside and outside the shielded examination room;

– inappropriate changes;

– damage to the thermal insulation of the exhaust line;

– damage to the exhaust line;

– obstructed exit, e.g. presence of bird nests (is the protective grid still intact?);

– damage to protective rain covers (these are regularly required for vertically exiting QUENCH lines. Depending on the design, they are also frequently in place for horizontal exits).

– Has the exhaust to the outside been changed after the system was handed over to the customer thus subjecting others to the exhausted gas? This may involve, for example, windows installed at a later date, exits and entrances put in place for heating and air conditioning systems, new buildings or temporarily installed containers and any other foreign debris or construction matter that could negatively influence the performance of the venting system.

– Has the heating and air conditioning system or venting system of the room been changed, e.g. by adding additional venting inlets or outlets in adjacent rooms?

– Were additional MR SYSTEMS installed?

– Is the same QUENCH line used for additional MR SYSTEMS?

Since each system is subject to either changes or remodelling of the building during its operating life, the OPERATOR needs to be thoroughly familiar with the importance of the QUENCH line and the venting system. For this reason, we recommend frequent visual inspections (e.g. with respect to constructional changes in the vicinity of the QUENCH line, severe weather-related changes such as ice, snow or sand). In case of questionable system functionality, the venting system installation contractor should be contacted.

- **Emergency plan**

The following recommendations are designed to help the OPERATOR in establishing an emergency plan that should include the following:

- layout of the MR-suite with respect to windows, escape routes both for personnel or for venting exhaust gas to the outside, emergency manual switches on the PATIENT support for fast PATIENT removal;
- availability of emergency personnel (e.g. ambulance personnel, on-site fire emergency response teams and on and off-site security);
- instructions and information provided to fire departments and police departments (to be provided before an actual emergency as described in the operating manual), including the need for an extra check whether the magnetic field is still present or not;
- rescue exercises performed with the respective personnel;
- operating personnel should be trained in overseeing the evacuation of the MR suite and adjacent rooms;
- Personnel should only return to the MR suite after the situation is back to normal, that is, noises have stopped and vision is no longer obstructed. For safety reasons, all rooms should be thoroughly aired; windows and doors to the outside should be open. Usually the air conditioning system will provide for effective air exchange.

If persons are present in the magnet room, consider the following.

- **Standard scenario:** the QUENCH line works as planned. The PATIENT can be easily removed. Contact with cryogenic parts is prohibited.
- **Small leaks:** these would lead to small clouds of fog that clearly remain above head level and are visibly removed by the heating and air conditioning system. White fog-like clouds may sink to the floor. These clouds consist of cold air and do not lead to oxygen depletion. In this case, overpressure is not present. There is no RISK of suffocation for either PATIENT or personnel. The PATIENT can be removed, either immediately or after a few minutes depending on the PATIENT'S reaction to the situation. Contact with cryogenic parts is prohibited.
- **Partial or complete failure of the QUENCH line:** large fog-like clouds are present that may impair visibility. PRESSURE in the examination room will increase. All persons inside the room or entering to help with rescue are in danger. During a complete failure of the venting system of the superconducting magnet inside the examination room, the examination room would be quickly filled with cryogenic helium gas.

As a rule, rescue personnel should not work alone, but rather in groups of two or more persons.

Usually, the strongest gas flow occurs within the first few minutes and will subsequently subside. However, the course of gas flow is not fully predictable, since at the time of occurrence the type of error in the QUENCH line is generally not fully known.

Prior to opening the door to the examination room, all available doors and windows should be opened to ensure sufficient ventilation. All personnel in the vicinity of the system who are not needed for rescue activities should leave prior to the rescue of the PATIENT in the examination room. When opening the door, possible overpressure in the room should be factored in as follows:

- If the door opens outward in the direction of the control room, the door may fly open due to overpressure. The OPERATOR should be aware of this possibility so injuries caused by the unexpected opening of the door can be avoided.
- If the door opens inward in the direction of the examination room, it may be impossible to open it due to the overpressure in the room. In this case, existing windows and emergency flaps should be opened. The overpressure may lead to windows or flaps swinging unexpectedly. If there are no emergency openings, the observation window may be smashed. However, the resulting glass splinters may injure rescue personnel. Depending on the construction and the thickness of the window, the RESPONSIBLE ORGANIZATION has to provide suitable tools for breaking the window.

After opening the door to the examination room, the helium gas may escape to adjacent rooms, endangering the safety of the rescue personnel. It is possible to check the oxygen levels in the air with an oxygen monitor. A gas mask does not protect against oxygen displacement by the helium gas. An air tank is necessary in order to remain in a facility subject to escaping helium. In addition to the RISK of suffocation there is also the additional RISK of hypothermia or frostbite.

Since the helium gas warms up quickly and spreads downward from the ceiling, a rescue worker standing upright is exposed to greater danger than a PATIENT lying on the PATIENT SUPPORT. There may be more air nearer to the floor. A rescue worker may gain time by going down on hands and knees to take breaths of air.

After the PATIENT has been removed from the examination room, no personnel should be present in the vicinity of the MR SYSTEM until the QUENCH has been stopped and ventilation has been ensured.

After a QUENCH, the service procedure as described in the ACCOMPANYING DOCUMENTS has to be performed. The maintenance personnel should be informed immediately to put the MR SYSTEM back into operation.

Concerning 201.8.7.3 – Allowable values

Application of leakage current test requirements from the general standard are to be clarified for surface coils. The allowable values for the leakage current as formulated in subclause 8.7.3 e) of the general standard cannot be measured for all situations. On the MR EQUIPMENT, PATIENT limits for leakage current and PATIENT auxiliary currents under NORMAL and SINGLE FAULT CONDITIONS do not apply for frequencies above 1 MHz. Regardless the waveform and frequency, the HAZARDS related to leakage currents are controlled via the requirements formulated for the local SAR as formulated in subclause 201.12.4.103.2 of this standard.

Concerning 201.9.6.2.1 – Audible acoustic energy

The high rates of change of current passing through the gradient coils in a static magnetic field produce vibrations in the audible frequency range. These are often manifested as loud "knocking" sounds.

Sudden hearing loss can be caused by short very loud noises, such as these knocks, in which the relevant safety parameter is the peak sound pressure level, measured in dB relative to 20 μPa.

The limit on peak sound pressure level of 140 dB has been taken from current internationally accepted values. It is difficult to predict under what circumstances the MR EQUIPMENT will produce the worst case situation with respect to acoustic noise production. It may very well happen that due to the frequency response characteristics of the MR EQUIPMENT the worst case acoustic noise situation is found for a clinical protocol (which by coincidence stimulates the MR EQUIPMENT at a mechanical resonance frequency and consequently produces more acoustic noise).

See also rationale 201.7.9.2.101 d).

Concerning 201.12.4 – Protection against hazardous output

The time varying (gradient) field, radio frequency field and static magnetic field generated by MR EQUIPMENT may influence physiological functions to an extent that safety measures are required. The recommendations given are based on current scientific knowledge and technical understanding. Existing guidelines have been considered in establishing these recommendations. When new evidence becomes available revisions may be necessary.

Diagnostic MR EXAMINATIONS usually can be completed within about one hour. Therefore considerations are concerned with effects of exposure of PATIENTS for periods of about one hour with emphasis on immediate (acute) adverse reactions.

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

(1) Overview

Time-varying magnetic fields induce an electric field *E* in accord with Faraday's law. The switching of gradient coils in the MR EQUIPMENT presents a time-varying magnetic field (d*B*/d*t* or $\dot{B}$), so that the body of the PATIENT is exposed to the induced electric field. This field can affect excitable tissue with thresholds that are frequency dependent. At frequencies above 10 kHz, higher fields are required for an effect [84]. The electric field in turn induces an electric current and this will cause heating according to Ohm's law. In practice, heating effects by GRADIENT OUTPUT are not of concern.

In the simple case of a uniform time-varying magnetic field and a cylindrical body of uniform conductivity with its axis parallel to the magnetic field *B*, the electric field *E* is directed along circular paths perpendicular to *B*. Therefore its magnitude is proportional to the radius of its path. As a consequence, the levels of concern depend on the size of the gradient system and the extent of the conducting medium. Tissue stimulation occurs more easily when the time varying gradient field is generated in large gradient systems.

(2) Safety concerns

The primary concern with respect to GRADIENT OUTPUT is cardiac fibrillation and stimulation of peripheral nerves. Cardiac fibrillation is the most serious event because it is an immediately life-threatening condition. Stimulation of nerves is of concern because strong stimuli may be experienced as intolerably painful. These phenomena of concern occur at supra-threshold levels of cardiac stimulation (CS) and peripheral nerve stimulation (PNS).

A secondary concern is heating of the PATIENT. Although heating by the induced electric currents presently is low, it is additive to that caused by the RF exposure in the MR EQUIPMENT and the concern relates to the combined effect of the two heating sources.

(3) Excitation models

The theoretical spatial extended non-linear node (SENN) nerve model of Reilly [85] predicts that threshold conditions for nerve stimulation can be well described by the local electrical field strength *E* at the end point of the nerve, parallel to its direction and by the duration of the stimulus t_s. At long stimulus duration, the threshold field asymptotically reaches its lowest level E_{min} and at short stimulus duration, the threshold is proportional to the product of E_{min} and 1/ t_s.

Reilly suggested that the threshold function of t_s can be approximated by an exponential form as

$$E_{TH} = E_{min} \Big/ 1 - \exp(-t_s / t_c) \qquad \text{(AA.5)}$$

From the model, the minimum value in humans of the threshold E_{min} for cardiac stimulation and PNS for monopolar rectangular electrical stimuli is estimated to be 6,2 V/m. The experimental values for the time constant t_c range between about 0,12 ms and 0,8 ms for PNS. For cardiac stimulation this range is 1 ms to 8 ms, and Reilly suggests 3 ms as a representative value.

An alternative to the exponential relation of Equation (AA.5) has been proposed that allows a more accurate description of experimental data [86][87]. This alternative function shows the threshold to have a hyperbolic dependence on stimulus duration, as:

$$E_{TH} = \textit{rheobase}\ (1+\textit{chronaxie} / t_s) \qquad \text{(AA.6)}$$

In this equation rheobase is the low frequency limit of the threshold stimulus and chronaxie is the characteristic reaction time of the nerves under consideration. As in Equation (AA.5), t_s is the duration of the stimulus. The equation holds for unipolar rectangular stimuli. As discussed below, recent experiments establish that PNS by gradient fields is accurately characterized by Equation (AA.6) using a chronaxie of 360 μs [89][90][91].

Schaefer [88] pointed out that in comparison to the exponential relation of Equation (AA.5), the hyperbolic expression of Equation (AA.6) is also better suited for a fit to the theoretical values of the threshold from Reilly's SENN model. Thus, Equation (AA.6) is used here to describe limits for peripheral nerve stimulation.

(4) Physiologic limits for cardiac and peripheral nerve stimulation and heating

Reilly [85] compared a variety of studies of electrical stimulation in animals. He observed that the cardiac fibrillation thresholds are log-normally distributed with the most sensitive percentile about factor two lower than the median. Moreover, he estimates that in a given animal the stimulation threshold (onset of ectopic beats) will be 40 % of the cardiac fibrillation level. By extrapolation to humans, he assumes the human stimulation threshold from his SENN model is 20 % of the human mean fibrillation level. Reilly estimated that a dB/dt of (71,3; 72,1; 50,8) T/s for switching of the (x, y, z) gradients is needed to achieve an electric field in the heart of 6,2 V/m, his estimate for the rheobase field for stimulation for the most sensitive 1-percentile.

Bourland *et al.* [90] reported a median cardiac stimulation threshold in the dog for switching of the HF gradient in excess of 2 700 T/s at a ramp duration of 530 μs. With a cardiac nerve time constant of 3 ms this corresponds to an asymptotic value of the stimulation level of 440 T/s. From calculations considering dog and human physiology, a unit of dB/dt along the length of the subject induces an electric field in the human heart 2,81 times greater than in the dog heart so that for humans an asymptotic stimulus level of 156 T/s is inferred and the 1-percentile level expected at 78 T/s, in reasonable agreement with Reilly's estimate.

The limit used in this standard to avoid cardiac stimulation incorporates a safety factor 3 below the 1-percentile threshold. It is based on the SENN model and the experimentally determined cardiac excitation threshold level. With the assumptions given, this limit would correspond to a likelihood for cardiac stimulation that is less than 2×10^{-9}. In addition, it turns out that the peripheral nerve stimulation limit given in this standard is below the cardiac stimulation limit for all stimulus durations of practical interest.

In the Purdue study of Bourland *et al.* [90] on 84 subjects the dB/dt needed for lowest percentile of uncomfortable stimulation is approximately equal to the median threshold for PNS for switching of the gradient in both the anterior-posterior (AP) and head-foot (HF) gradient directions. The lowest percentile for intolerable stimulation occurred at dB/dt about 20 % above the median PNS threshold. Painful stimulation is not only a source of serious discomfort; it is also associated with involuntary muscle contraction, so that cooperation of the PATIENT and efficacy of the examination is seriously compromised at this level. Intolerable stimulation clearly is the endpoint in that respect. In addition the reaction of the PATIENT in such a situation constitutes a further safety RISK. So, in this standard, the mean stimulation level is chosen as the limit for the FIRST LEVEL CONTROLLED OPERATING MODE and 80 % of this is selected as the limit for the NORMAL OPERATING MODE.

The allowed exposure level for MR WORKERS for the GRADIENT OUTPUT is set at a PATIENT level such that the occurrence of intolerable PNS is minimized. It is difficult to relate this level to

the mean threshold level for PNS for the PATIENTS because the MR WORKER may occupy positions in the scanner, which cannot or will not be reached by the PATIENT.

Caution should be exercised prior to any interventional MR to avoid unexpected PNS of the MR WORKER during his duties that can compromise the safety of the PATIENT.

(5) The relation between *E*-field and d*B*/d*t* in the MR EQUIPMENT

The translation of *E* field limits into d*B*/d*t* limits requires knowledge of the relation between these parameters in the typical geometry of the PATIENT and gradient system.

The electric field *E* induced by the gradient system in the body is related to the spatial distribution of d*B*/d*t* and to the body geometry. For any closed trajectory *l* that circumscribes a surface *S*, the basic physics equation is

$$\oint \overline{E} \cdot d\,\overline{l} = -\int \frac{\mathrm{d}\,\overline{B}}{\mathrm{d}\,t} \times d\,\overline{S} \qquad \text{(AA.7)}$$

It can be solved when the boundary conditions are specified. As an illustrative simplification, the PATIENT may be represented by a homogeneously conducting prolate rotational ellipsoid with semi-major axial length *a* and semi-minor axial length *b* and the space outside the PATIENT by an insulating medium. When a spatially homogeneous time varying magnetic field is applied perpendicular to the major axis of this ellipsoid, the maximum value of *E* occurs in the mid-plane of the ellipsoid, along its perimeter. It follows that this perimeter is the locus at which PNS is expected to occur first. Reilly [85] points out that at that position

$$|E| = \frac{a^2 b}{(a^2 + b^2)} \mathrm{d}B/\mathrm{d}t \qquad \text{(AA.8)}$$

When the ellipsoid has semi-axial lengths *a* = 0,4 m and *b* = 0,2 m, representing the cross-section of the PATIENT with a field in the AP direction, the resulting relation is

$$|E| = 0{,}16\ \mathrm{d}B/\mathrm{d}t \qquad \text{(AA.9)}$$

where

E is in V/m, and

d*B*/d*t* is in T/s.

When the time varying magnetic field is parallel to the major axis of the ellipsoid, a case that represents a field in the HF direction, the induced electric field is parallel to its circular cross-section with radius *b* = 0,2 m, in which case

$$|E| = 0{,}10\ \mathrm{d}B/\mathrm{d}t \qquad \text{(AA.10)}$$

where

E is in V/m, and

d*B*/d*t* is in T/s.

In reality, the field from the gradient system in the MR EQUIPMENT is inhomogeneous. Within the gradient system, the spatial maximum value of d*B*/d*t* at the periphery of the PATIENT is higher than the average of d*B*/d*t* over his body. Recent calculations with a morphologically realistic human model report that the factors in Equations (AA.9) and (AA.10) are 0,11 and 0,08, respectively, for d*B*/d*t* taken as the maximum value at a radius of 0,2 m. Similar values

were reported by Botwell and Bowley [92]. They calculated the currents induced in a conducting cylinder of radius 0,195 m within an imager. From results presented in their paper, values of $E/(\mathrm{d}B/\mathrm{d}t)$ ($\mathrm{d}B/\mathrm{d}t$ being the maximal value at r = 0,195 m) can be determined. For switching of the transverse gradient, the ratio is 0,121 and the ratio is 0,087 for switching of the longitudinal gradient. Note that the local maximal electric field will be perhaps greater by a factor of 2 if the model considers non-homogeneous conductivity, such as would arise from inclusion of bone.

The translation of Equation (AA.6) into an expression for the threshold value of $\mathrm{d}B/\mathrm{d}t$ is possible when its value is related to a specific representative location. A characteristic feature of the gradient waveform in an MR EQUIPMENT is its repetitive bipolar shape. For a trapezoid gradient waveform (see Figure 201.101 in subclause 201.3 of the standard), the induced E field will be a series of rectangular stimuli with alternating sign. The stimulus duration t_s of a bipolar ramp in a trapezoid gradient waveform with maximum amplitude G_{max} follows from

$$t_s = \frac{2G_{max}}{\dot{G}} \qquad \text{(AA.11)}$$

(6) Instrumentally defined limits for CS

In this standard, Equation (AA.6) is used to convert the physiological limit for cardiac stimulation as discussed in item (4). The cardiac time constant t_c is assumed to be 3 ms. Reilly's value of the one percentile threshold electric field is used as the cardiac stimulation electric field rheobase *rbc*. Equation (AA.10) is used to convert from electric field rheobase to $\mathrm{d}B/\mathrm{d}t$ rheobase. The safety factor 3 introduced in item (4) is used. The limit protecting against cardiac fibrillation becomes:

$$L = \frac{rbc}{3}\frac{1}{1-\exp(-t_s/t_c)} \qquad \text{(AA.12)}$$

where *rbc* = 6,2 V/m or 62 T/s

(7) Direct demonstration of GRADIENT OUTPUT limits for PNS in whole body MR EQUIPMENT

This standard describes a number of approaches to obtain MR EQUIPMENT specific values of threshold PNS. These are discussed in this and in the next items. In establishing limits for PNS, this standard allows experimental assessment of thresholds as a basis for determination of limits (direct determination). The direct determination requires experimental work with volunteers in a representative model of the GRADIENT UNIT. Based on the assumed validity of a hyperbolic relation between threshold and ramp time, a possible approach for the direct demonstration is to establish a rheobase and a chronaxie based on the test for a limited number of ramp times and generate recursion relations for each ramp time used. Further modelling may be used to limit the number of waveforms actually tested. One example of such modelling is given in item (16).

Limits derived from the experimental work with volunteers should obey the physiological requirements as listed in item (4). The workload from such a direct demonstration may be excessive, and for some important waveforms, the standard provides numerical limits as an alternative, discussed in items (8) to (14).

Gradient induced electric fields in homogeneous spheres depend on $\mathrm{d}B/\mathrm{d}t$, total gradient ramp time, and the radius of the sphere. Electric field stimulation thresholds are similar for both adults and children, though thresholds may be higher in children [160]. Therefore stimulation thresholds established for adults should be conservative for children and children can be excluded from the volunteer study.

(8) Numerically defined default limits for PNS

Direct demonstration of PNS limits is not always feasible. To offer an alternative in such cases, this standard provides numerically defined default limits for d*B*/d*t* and for *E*. These limits are based on three volunteer studies in which the MR EQUIPMENT was used to obtain PNS. The results of these studies are published by Ham *et al.* [89], Bourland *et al.* [90], and Hebrank *et al.* [91]. In each of these publications, threshold PNS was observed as a function of d*B*/d*t* and pulse duration in volunteers exposed to switching of the gradients in a WHOLE BODY GRADIENT SYSTEM in cylindrical WHOLE BODY MAGNETS. Although the d*B*/d*t* values used in these publications to express threshold PNS were not directly comparable and details of the gradient waveforms differed, comparison of the results of these authors could be obtained. The comparison makes use of some unpublished details collected for the purpose of establishing a basis for the PNS limits used in this standard. The comparison basis is summarized in item (9). GRADIENT OUTPUT limits for whole body MR EQUIPMENT on this basis are derived in item (10).

(9) Comparison basis for GRADIENT OUTPUT

The basis used to compare the experimental work [89][90][91] is the following: All d*B*/d*t* values were recalculated to d*B*/d*t,* the spatio-temporal maximum of the modulus value of d*B*/d*t*, occurring on the wall of a cylinder of 0,2 m, coaxial to the magnet. This volume was chosen to represent the volume normally accessible to the PATIENT. All gradient waveforms used were EPI waveforms with trapezoid shape. The direction of the switched gradient was anterior posterior (AP) in two of the three publications, and the result of all GRADIENT UNITS driven simultaneously in the third [89]. In this publication the thresholds for an AP direction of the switched gradient could be obtained by regression. The flat tops of the waveforms were 0,3 ms in Bourland [90], 0,4 ms in Ham [89] and 0,5 ms in Hebrank [91]. These differences in flat top duration were assumed to be of second order influence and were neglected. The width of the distributions of individual thresholds could be evaluated for two of the three studies [90][91], because in these studies a large number of volunteers participated. The observed standard deviations expressed as a fraction of the mean were found to be of similar size in both studies and a value of 0,24 was adopted to define the confidence regions of the mean thresholds.

When for a ramp time the threshold could not be reached for all subjects, because of technical limits of the gradient system, the trimmed mean was used as an estimator for the mean. In a case where *c* highest thresholds from *N* volunteers could not be observed, this statistic is defined as the average over the central fraction $N - 2c$ of the ordered thresholds.

(10) Experimental data on PNS threshold of human volunteers in whole body MR EQUIPMENT

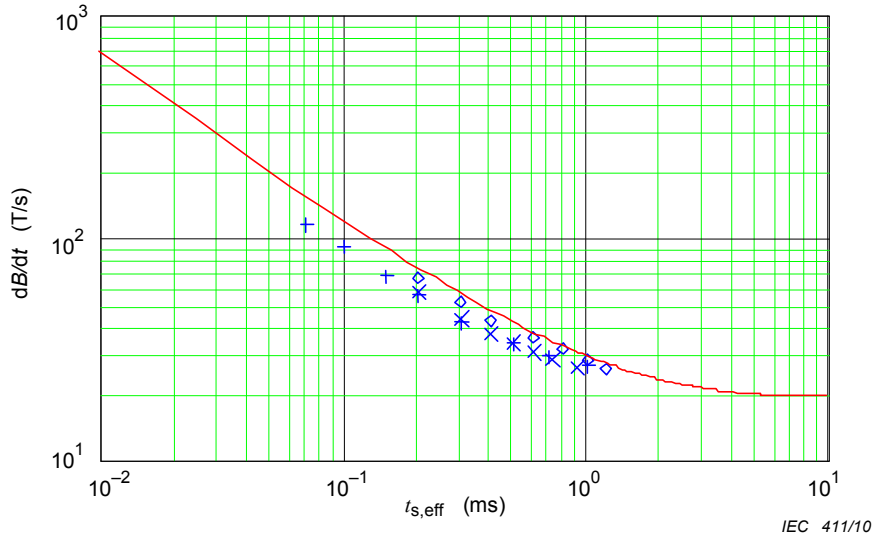
The results of the experimental values converted on the comparison basis as described in item (9) are given in Figure AA.2. The data are shown to be consistent, although the MR EQUIPMENT used were of different MANUFACTURERS so that differences in design of the gradient hardware were present. A single hyperbolic threshold stimulation function according to the following equation:

$$\mathrm{d}B/\mathrm{d}t = 1{,}0\ rb\ (1 + 0{,}36/\ t_{s,\mathrm{eff}})$$

is obtained by fitting to all data points, with statistical weight to each data point that takes into account the number of volunteers examined in each of the quoted reports. The obtained value of rheobase is

$$rb = 19{,}7 \pm 1\ \mathrm{T/s},$$

which is in this standard rounded to 20 T/s. The chronaxie is $t_c = 0{,}36$ ms.



Double logarithmic plot of experimental threshold values for peripheral nerve stimulation with trapezoid EPI waveforms, versus ramp time t_s (◊ Ham [89], + Bourland [90], x Hebrank [91]). In all experiments the data hold for the AP orientation of the direction of the switched gradient. The threshold values are expressed as d*B*/d*t*, the spatio-temporal maximum of the modulus of d*B*/d*t* on a cylindrical surface coaxial to the magnet, with a radius of 0,2 m. The solid line is the hyperbola fitted to all data points, with a statistical weight per point that reflects the number of volunteers tested in each of the quoted reports. The characteristic parameters of the hyperbola are the rheobase *rb* = 19,7 T/s and the chronaxie t_c = 0,36 ms (see equation above: d*B*/d*t* = 1,0 *rb* (1 + 0,36/ *t* s,eff)).

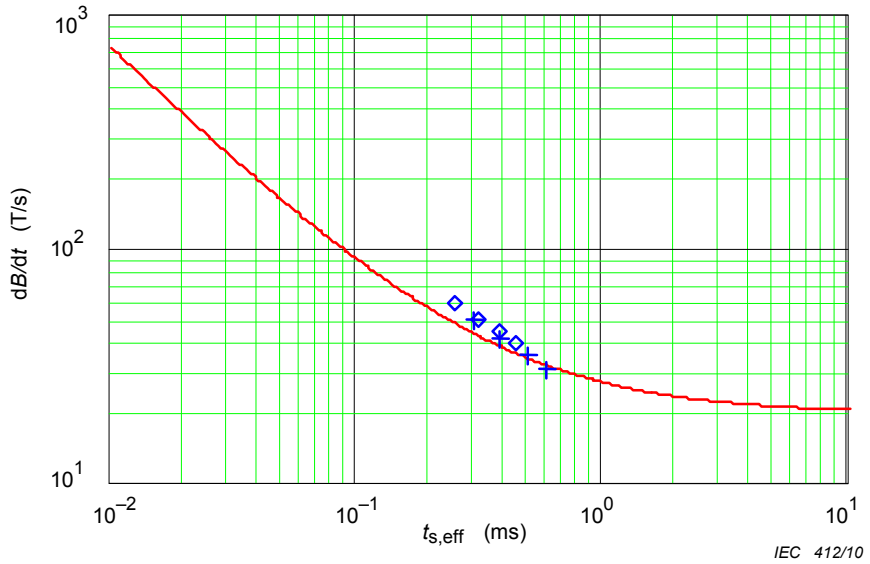
Figure AA.2 – Experimental data on PNS threshold of human volunteers in WHOLE BODY MR EQUIPMENT

(11) Experimental data on PNS threshold other than trapezoid waveforms

The threshold of d*B*/d*t* is seen to depend on the stimulus duration t_s. For gradient waveforms that are not trapezoidal, the stimulus duration has no unique definition. Harvey *et al.* [93] and Mansfield [94] showed that the thresholds for sinusoid waveforms become very nearly equal to those for trapezoids when in a sinusoid waveform $B(t) = B_{max} \sin(2\pi t / T)$ the EFFECTIVE STIMULUS DURATION is defined as the ratio of amplitude and maximum rate of change:

$$t_{s,eff} = 2B_{max} / \dot{B}(0) = T / \pi \qquad \text{(AA.13)}$$

Frese *et al.* [95] compared AP directed trapezoid and sinusoid waveforms in the same MR EQUIPMENT. Figure AA.3 illustrates the fit obtained when plotted as function of $t_{s,eff}$. The example demonstrates the validity of its use. In this standard, $t_{s,eff}$ will be used to describe EFFECTIVE STIMULUS DURATION.



The waveforms are trapezoid EPI (+) and sinusoid EPI waveforms (◊). They are displayed versus the EFFECTIVE STIMULUS DURATION $t_{s,eff}$. data from Frese [95]. The data hold for the AP orientation of the switched gradient. The threshold values are expressed as the spatial maximum of the modulus of dB/dt on a cylindrical surface coaxial to the magnet, with a radius of 0,2 m. The solid line is the hyperbola fitted to all data points, identical to the one shown in Figure AA.2.

Figure AA.3 – Double logarithmic plot of experimental threshold values for peripheral nerve stimulation

(12) Experimental data on PNS threshold values depending on the orientation of the body of the PATIENT with respect to the direction of the switched gradient

The value of rheobase as a function of the direction of the switched gradient was obtained experimentally in WHOLE BODY MR EQUIPMENT. For the HF-gradient coil, the Purdue study on 84 volunteers reports a rheobase of 29,5 T/s and chronaxie of 0,36 ms. Note that in those experiments, a single winding, which reproduces a magnetic field pattern at each end of an actual HF-gradient coil, was used to simulate the stimulating effects of switching the HF-radient. The subject was longitudinally positioned for lowest PNS threshold. This experiment shows that the PNS threshold for Head-Feet (HF) gradient directions in such MR EQUIPMENT is higher than for the AP direction, with a ratio for AP and HF gradient directions of 0,66. Between LR and AP gradients a similar difference in threshold exists. The data on 10 volunteers of Budinger [96], who inspected these thresholds by rotating the gradient coil with respect to the volunteers, show a ratio between the thresholds of AP and LR gradients of 0,8. In view of these results, this standard allows weight factors for calculation of the GRADIENT OUTPUT of HF and LR gradient that equal w_{HF} = 0,7 and w_{LR} = 0,8.

(13) Nerve stimulation in case of the combination of waveforms from more than one GRADIENT UNIT

The MR imaging sequence always contains a combination of gradient waveforms from all three GRADIENT UNITS.

The strongest stimulation will occur when all coils are driven simultaneously with identical waveforms at maximum GRADIENT OUTPUT. At each moment in the space around the magnetic isocentre the value of total rate of change $(dB/dt)_{total}$ will be the vector sum of the contributions $(dB/dt)_i$ from each GRADIENT UNIT i. Note that the induced electric field, which is believed to be the mechanism for stimulation, will similarly be due to the vector addition of the electric fields E_i arising from each switching gradient. The value of $(dB/dt)_{total}$ will be a function of space in a way that depends strongly on the octant as defined by the gradient co-ordinate system. The largest values will occur in the octants in which the direction of $(dB/dt)_{total}$ and that of each $(dB/dt)_i$ are at angles smaller than 90°. This condition will always

exist in two of the octants, and during a combination of complex waveforms in which the gradients change sign, this worst case condition will switch to other octants. Within a worst case octant, the spatial maximum value of $(dB/dt)_{total}$ is smaller than the sum of the spatial maxima of $(dB/dt)_i$, because these latter maxima do not occur at the same point. Moreover, even in such an octant the vector directions of $(dB/dt)_i$ at the position of maximum $(dB/dt)_{total}$ are not completely parallel.

Therefore, in the case considered, (all coils driven simultaneously with identical waveforms at maximum dB/dt) the joint effect on stimulation is less than the linear sum of the effects of the individual coils.

This standard assumes that the effect of simultaneous switched gradients can be represented by a weighted quadratic summation of the $(dB/dt)_i$ of the individual GRADIENT UNITS. Weighting factors are as given in item (12).

When the stimulus duration t_s of the three gradients at maximum drive are not the same, quadratic addition can still be meaningful, but the common limit has to be replaced by the individual limits for each stimulus duration t_s.

In MR EXAMINATION sequences with simultaneous waveforms at maximum amplitude of each gradient is a rare event, so the assumption of its occurrence is a conservative one. More realistic estimates of the threshold for partially simultaneous waveforms from different coils can be obtained by more exacting models that take into account the shape of each waveform. An example of such a model is described in item (16).

(14) Limits for PNS for WHOLE BODY GRADIENT SYSTEMS

As stated in item (4), the limit of the FIRST LEVEL CONTROLLED OPERATING MODE is that GRADIENT OUTPUT that gives threshold PNS. This physiological definition can be restated quantitatively: for WHOLE BODY GRADIENT SYSTEMS this limit is based on the threshold values found for switching of AP gradients in item (10).

It is a limit that holds for the maximum GRADIENT OUTPUT of a gradient system with a given waveform.

- The maximum GRADIENT OUTPUT of the MR EQUIPMENT is assumed to be caused by the simultaneous output of all GRADIENT UNITS, each at its maximum slew rate and at maximum gradient amplitude. It is measured as the spatial maximum modulus value of GRADIENT OUTPUT occurring in a COMPLIANCE VOLUME.
- The COMPLIANCE VOLUME is defined in the standard. Its dimensions are assumed to exclude the region where the large diameter body parts of the PATIENT are not normally present, and it may be smaller than the actual space accessible to the PATIENT.
- The dependence includes the stimulus duration correction for thresholds between sinusoids and trapezoids from item (11).
- The simultaneous output is derived from inspection of the GRADIENT OUTPUT of individual GRADIENT UNITS, using the orientation dependant threshold ratios w_i from item (12) and the quadratic summation rule of item (13).

This results in

$$\sqrt{\sum (w_i \mathrm{d}B/\mathrm{d}t_i)^2} \quad < \quad 20\times(1+0{,}36/t_s) \qquad \text{(AA.14)}$$

dB/dt values can be obtained by calculation or by testing. Calculation is possible from the coil geometry and current distribution by use of Biot-Savart's law:

$$\dot{\vec{B}}(r) = \int \frac{\mu \, \dot{I}(\vec{r}')d\vec{l}' \times (\vec{r} - \vec{r}')}{4\pi \left|\vec{r} - \vec{r}'\right|^3} \qquad \text{(AA.15)}$$

where *dl′* is an element of the coil windings at position *r′.*

(15) Limits for PNS based on *E* field calculation

For gradient systems that differ in size from WHOLE BODY GRADIENT SYSTEMS, the information from the experimental work relating GRADIENT OUTPUT to threshold PNS in WHOLE BODY GRADIENT SYSTEMS is not directly applicable. This is because this relation depends on the geometry of coil and PATIENT. If for instance a gradient system only exposed heads with a radius of 0,1 m, then the GRADIENT OUTPUT limits from item (8) may be too restrictive by a factor of about 2. For the wide variety of gradient systems in special purpose MR EQUIPMENT (e.g. special MR EQUIPMENT for breasts, extremities or head, or special gradient system designs for use in WHOLE BODY MR EQUIPMENT (such as gradient systems for microscopy, heart and head), this standard allows the use of limits for the electric field *E* induced by switching of the gradients. The rationale is that *E* is the quantity that directly relates to the physiological model described in item (3).

Although the value of *E* in a given coil and PATIENT geometry cannot easily be measured, its calculation is possible from the coil geometry and current distribution when the effects of currents induced in the PATIENT are neglected. The electric field in the PATIENT due to the switched gradients can then be expressed as

$$E = -\partial A / \partial t - \nabla \Phi \qquad \text{(AA.16)}$$

where *A* is the magnetic vector potential due to currents in gradient coils. The time derivative $\partial A / \partial t$ is calculated from

$$\vec{E}(r) = \dot{\vec{A}}(r) = \int \frac{\mu \cdot \dot{I}(\vec{r}')d\vec{l}'}{4\pi \left|\vec{r} - \vec{r}'\right|} \qquad \text{(AA.17)}$$

where

$\dot{I}$ is the rate of change of the coil current and

dl′ is an element of the coil windings at position *r′*.

The electrostatic potential Φ is due to electric charge at the interfaces between discontinuities in electrical conductivity (such as the air-PATIENT interface) and is a consequence of conservation of electric charge.

The electrostatic potential in general needs to be calculated with a computer technique. A noteworthy special case in which Φ is zero is for a cylindrically symmetric z-gradient applied along the axis of a conducting cylinder. In this case, $E = -\partial A / \partial t$. Equation (AA.17) is valid for a complex PATIENT model. A useful simplification is to approximate the body section of interest as a cylinder or spheroid of uniform conductivity.

In this standard the threshold for *E* is assumed to have the hyperbolic shape of the threshold function of Equation (AA.6), with chronaxie of 0,36 ms as discussed in item (10) and with a rheobase that is based on the orientation related values for d*B*/d*t* and the Purdue computational results for the ratio between *E* and d*B*/d*t* (see item (4)). It is emphasized that the electric field is calculated assuming a uniform conductivity throughout the PATIENT. The so obtained rheobase electric field is 2,16 V/m for switching of the AP gradient and 2,4 V/m for that of the HF gradient. The difference in these two values is not regarded to be significant and thus 2,2 V/m is felt to be a good estimate for the electric field rheobase for PNS by a trapezoidal pulse train for all gradient orientations. Parallel to the argument for limits of d*B*/d*t*,

the limit of E in the FIRST LEVEL CONTROLLED OPERATING MODE is equal to the threshold value of E. For the NORMAL OPERATING MODE the limit is reduced by the factor 0,8. The limit for E is valid for all types of MR EQUIPMENT. The value of E is the maximum occurring in a COMPLIANCE VOLUME for a given GRADIENT OUTPUT. The statements parallels that of item (14), but the simultaneous output of the GRADIENT UNITS may be derived by the quadratic summation rule of item (13), but orientation dependent weighting factors are not allowed. For instance, for EPI waveforms with a stimulus duration $t_{s,eff}$, this results in

$$\sqrt{\sum (E_t)^2} \quad < \quad 2{,}2 \times (1 + 0{,}36 / t_{s,eff}) \tag{AA.18}$$

(16) A model for threshold values of PNS for complex waveforms

A hyperbolic threshold function similar to Equation (AA.6) and with rheobase and chronaxie defined in item (10) is valid for repeated bipolar rectangular stimuli (and for sinusoids, with use of the EFFECTIVE STIMULUS DURATION defined in Equation (AA.14)). In order to deal with the complex gradient waveforms, such as often used in MR imaging, an extension may be desired, because for such a waveforms the threshold may be higher. A more general threshold function can be found by regarding stimulus $\dot{B}(t)$ which belongs to this waveform as a series of Dirac functions that cause the nerve response to build up so that it eventually reaches threshold [97]. From Equation (AA.6) one can express R_{rect}, the sub-threshold response for a single rectangular stimulus with duration t_s as

$$R_{rect} = \frac{\dot{B}}{\dot{B}_{TH}} = \frac{\dot{B}\, t_s}{rb\,(t_c + t_s)} \tag{AA.19}$$

R_{rect} can be considered as a function of t_s. Its derivative with respect to t_s is

$$\frac{d\dot{R}_{rect}(t_s)}{d(t_s)} = \frac{\dot{B}}{rb} \cdot \frac{t_c}{(t_c + t_s)^2} \tag{AA.20}$$

Equation (AA.20) describes a contribution to the response value at $t = t_s$ of a Dirac-shaped addition to the stimulus at $t = 0$ with value $\dot{B}$. For the more general case, the increase in the response value $\Delta R(t)$ at time t from a Dirac shaped stimulus at time θ with strength $\dot{B}(\theta)$ is

$$dR(t) = \frac{\dot{B}(\theta) d\theta}{rb} \frac{t_c}{(t_c + t - \theta)^2} \tag{AA.21}$$

The total value of the nerve response $R(t)$ at any time for any stimulus $\dot{B}(\theta)$ for $0 < \theta < T$ is obtained by convolution:

$$R(t) = \frac{1}{rb} \int_0^t \frac{\dot{B}(\theta)\, t_c}{(t_c + t - \theta)^2}\, d\theta \tag{AA.22}$$

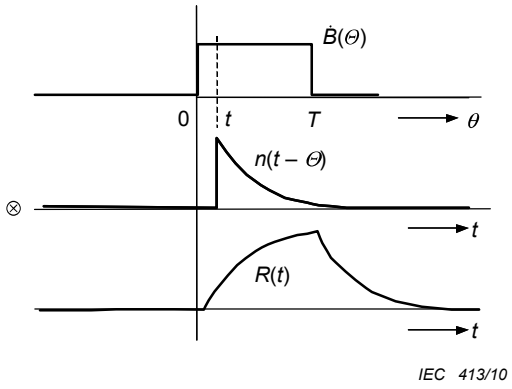
Figure AA.4 shows $R(t)$ for a simple rectangular stimulus. Excitation will occur when the amplitude dB/dt_{max} of the stimulus causes the maximum temporal value of $R(t)$ to be larger than 1.

As an example, for an Echo Planar Imaging (EPI) waveform the complex stimulus is a series of rectangular stimuli with alternating sign in which the first stimulus in the series has half the duration of the other ones. Flat tops of the gradient waveform correspond to time intervals between the stimuli. The result of integration of Equation (AA.21) for this case is shown

graphically for PNS in Figure AA.5. The maximum value of $R(t)$ is reached at the end of the first full duration stimulus. The figures suggest that the model can be used to derive threshold conditions for any waveform, given the threshold for a simple waveform.

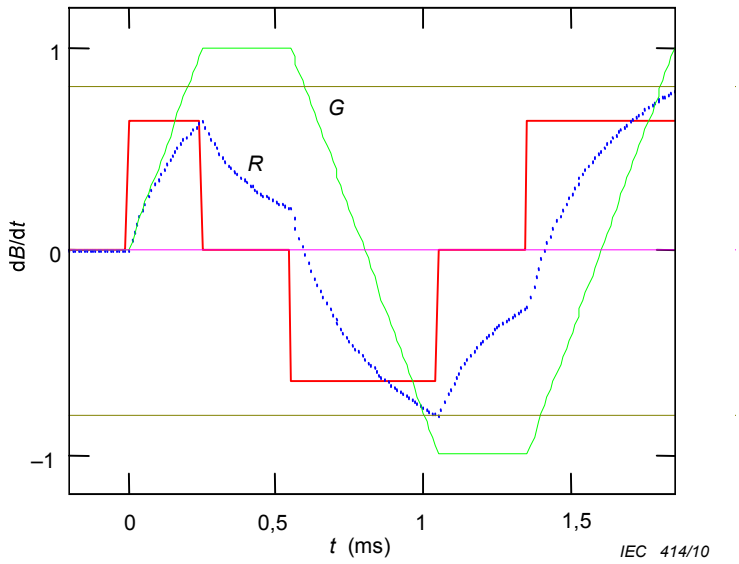
Predictions of the model are compared to the experiment in Figures AA.6 and AA.7. Figure AA.6 shows thresholds for trapezoid waveforms of the Purdue study (for details see item (10). Equation (AA.22) was used to find the threshold function by plugging in the experimental trapezoid waveform into $\dot{B}(\theta)$. Rheobase *rb* and chronaxie t_c (Equation (AA.22)) were adjusted for best fit. One can see that the obtained values are not equal to rheobase and chronaxie found for the same dataset in item (10). This is caused by the difference in their definition: in Equation (AA.22), *rb* and *tc* are defined for monopolar rectangular stimuli. In addition, Figure AA.6 shows the threshold function that would be obtained from Equation (AA.22) for the same rheobase and chronaxie, but for a sinusoid waveform, plotted against the EFFECTIVE STIMULUS DURATION as defined in Equation (AA.14). The model is shown to support the use of this definition reasonably well. The model predicts that for both waveforms the thresholds will be equal within 10 % over a large range of EFFECTIVE STIMULUS DURATION. Although the model predicts the strong drop in the experimental threshold between a single half period and a continuous sinusoid experiment, the more subtle changes found experimentally for sinusoids with a duration between 1 and 10 periods are not predicted. More extensive models are needed [91]. Their SAFE (stimulation approximation by filtering and evaluation) model applies three temporal filters to the gradient waveform and sums the output. The filters model the generation of action potentials within nerve cells and spread of the signal via synapses. While the model does not claim to describe the physiological behaviour, it does predict all dependencies of the stimulation threshold on stimulus duration, sinusoidal versus trapezoidal and number of gradient cycles.

Figure AA.7 shows the threshold as a function of the number of half periods of a sinusoid stimulus. The threshold was scaled to fit experimental data from Budinger [96].



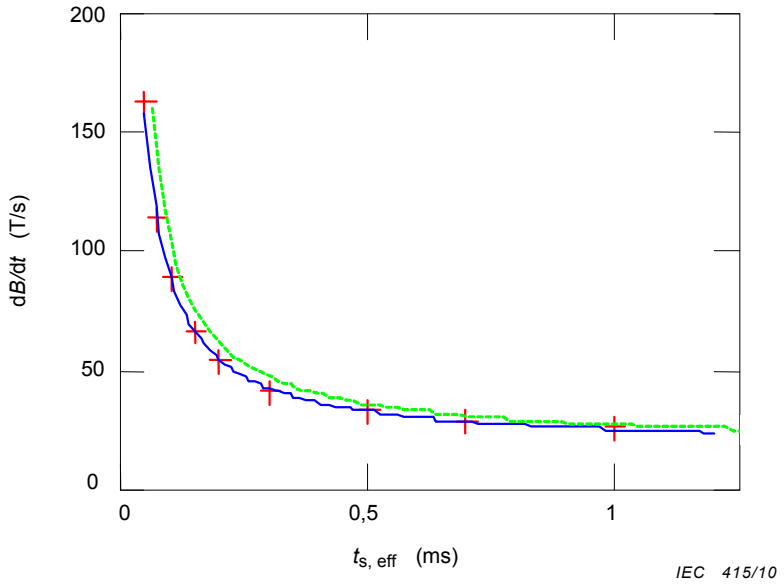
⊗ symbolizes convolution. $n(t) = t_c / rb\ (t_c + t)^2$

Figure AA.4 – Response value *R*(*t*) generated by convolution of a rectangular stimulus d*B*/d*t* and a nerve impulse response function *n*(*t*-*θ*)



Vertical axes have relative units. *R* is calculated from Equation (AA.19) with t_c = 0,36 ms. The hatched lines, at equal ordinate values, illustrate that the maximum nerve response is reached after the first negative ramp.

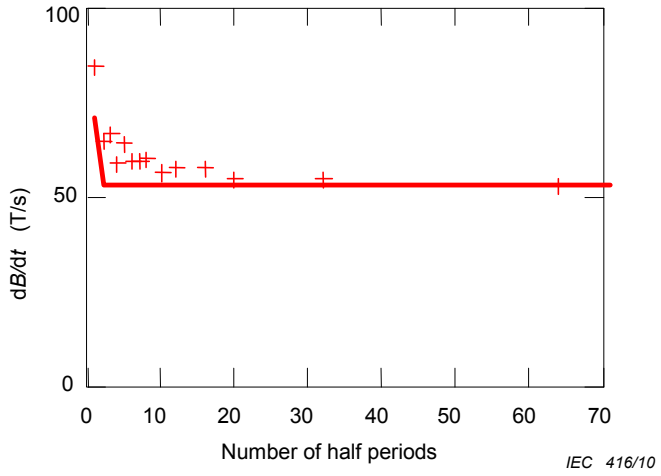
Figure AA.5 – Gradient waveform *G*, stimulus waveform d*B*/d*t* and response value *R*, for a trapezoid EPI waveform starting at *t* = 0



The lower curve is for trapezoid waveforms; it is obtained by fitting the experimental data (+) of Bourland [90] to Equation (AA.19). The obtained values of rheobase and chronaxie are 17,3 T/s and 0,3 ms.

The upper curve is for a sinusoid waveform, using the same values of rheobase and chronaxie.

Figure AA.6 – Threshold values d*B*/d*t* for two gradient waveforms, plotted against EFFECTIVE STIMULUS DURATION



NOTE Experimental data of Budinger [96] included; solid line: from Equation (AA.22), matched at N = 64.

Figure AA.7 – Threshold value of d*B*/d*t* for a sinusoid gradient waveform, as function of the number of half periods in the waveform

Concerning 201.12.4.103 – Protection against excessive radio frequency energy

Heating is a major consequence of exposure to the radio frequency frequencies used in MAGNETIC RESONANCE (usually greater than 1 MHz). Many of the biological effects of acute exposure to radio frequency are consistent with responses to induced heating resulting from rises in tissue or body temperature of about 1 °C or more, or with responses for minimising the total heat load [98].

The radio frequency induced heat load can be directly related to the SAR. Other important factors which influence PATIENT response to a given heat load include the air temperature, relative humidity, air flow rate and the degree of PATIENT insulation. While local and WHOLE-BODY SAR limits are sometimes useful for determining the level of concern, temperature rise is the primary criterion. For this reason the temperature rise criterion is included in this standard.

Localised regions of heating or "hot spots" may cause local temperature rises. It is important to screen PATIENTS for contra-indicated implants, tattoes, etc. which could result in increased localized heating [2]. Power absorption increases in proportion to the square of the radial distance from the centre of the body [99] and the electrical inhomogeneity of the body alters current flow and local energy absorption. Studies using spherical models predict that worst case "hot spots" would be produced by a sphere of low conductivity (bone or fat) located on the outer edge of a large conductive sphere (e.g. muscle); a "hot spot" can occur with an SAR of up to 2,5 times the local average value [100]. Calculations based on a heterogeneous mathematical model of the human body [101][102] suggest that localised tissue SAR within the body could be up to 5 or even 8 times greater over small volumes compared to the whole body average value [103]. However, these relative increases are reduced to a factor of about 2 to 4 when averaged over complete individual body organs [103][104]. The probability of high localised tissue SAR is reduced by quadrature excitation, and its effects are moderated by thermal diffusion and blood flow.

Thermal effects arise because of the temperature sensitivity of most biological processes. The primary concerns regarding radio frequency exposure are to avoid excessive physiological responses to a marked rise in body temperature and to avoid raising tissue temperature to a level which might incur some degree of HARM [1].

The most sensitive responses of humans to acute whole-body heating by radio frequency are probably those concerned with thermo-regulation and include increased cardiac output and skin blood flow coupled with a slight drop in arterial blood pressure [105]. These responses become maximal, even in subjects lying passively in ENVIRONMENTAL TEMPERATURES, as body temperatures rise by more than about 2 °C. Adverse health effects are not expected in people with unimpaired thermo-regulatory and cardiovascular functions if the increase in body temperature does not exceed 1 °C [106]; some specific exceptions are given below.

The whole-body thermo-regulatory response of humans exposed to MR EXAMINATION has been mathematically modelled. Adair and Berglund [111] calculated that the body temperature of a lightly clothed PATIENT whose thermo-regulatory ability was unimpaired would rise by up to 0,6 °C, depending on environmental conditions, during exposure at WHOLE-BODY SAR's of up to 4 W/kg. The results of these calculations are in reasonable agreement with studies of volunteers exposed to up to 4 W/kg for 20 min to 30 min [112][113][114][115]. In addition, there have been no reports of adverse health effects from excessive local or systematic heating in PATIENTS exposed at WHOLE-BODY SAR's of up to about 1,5 W/kg [116].

Limits on WHOLE BODY SAR are presented in 201.12.4.103. A limit of 2,0 W/kg for the NORMAL OPERATING MODE is recommended as the highest WHOLE BODY SAR which all persons, regardless of health status, should be able to tolerate. People with unimpaired thermo-regulatory and cardiovascular systems should tolerate higher WHOLE BODY SAR's; an upper limit of 4 W/kg for the FIRST LEVEL CONTROLLED OPERATING MODE is recommended. Individual tolerance to raised body temperature is highly variable, however; even in healthy people, therefore, MEDICAL SUPERVISION is required [117].

The limits above were developed assuming temperatures in the MR EXAMINATION room of less than 25 °C and minimal air flow; in addition, the PATIENT is assumed to be lightly clothed. Calculations by Adair and Berglund [118][119] can be used to derive correction factors for environments which restrict heat loss. It can be estimated that for each °C of ENVIRONMENTAL TEMPERATURE above 24 °C, restrictions on WHOLE BODY SAR should be lowered by 0,25 W/kg. Similarly, for each 10 % of relative humidity in excess of 60 %, the limits might be lowered by 0,1 W/kg. The temperature sensitivity is taken into account in this standard by a requirement for reducing the SAR limits at high temperature. Since the sensitivity for the humidity is relatively small and difficult to maintain, the sensitivity dependence for the SAR as function of the humidity is no longer included in the 3rd edition of this standard. Individual responses will, however, be variable; increased attention at the appropriate level of supervision should be observed when using these correction factors.

Some regions of the body, such as the head, may be particularly vulnerable to raised temperature. The developing embryo or foetus should be regarded as particularly sensitive to raised temperatures [147]; however, tissues in the trunk and limbs are considered less sensitive. It has been suggested by Czerski and Athey [120] that localised temperatures of about 38 °C in the head, 39 °C in the trunk and 40 °C in the extremities are unlikely to produce adverse effects. Simple calculation [121] relating localised heating in the eye to SAR in the head suggests that exposure resulting in 3 W/kg to the head is unlikely to raise the temperature of the eye by more than 1,6 °C; brain temperatures are unlikely to rise by more than 1 °C under these conditions. In experimental measurements on un-shorn sheep, [122], several animals were subjected to a 4 W/kg head scan for 60 min to 90 min while peripheral and deep tissue temperatures including cornea, vitreous humour, skin of head, tongue, jugular vein, and rectum were measured. In another experiment, similar temperatures were measured in six animals that were subjected to WHOLE BODY SAR's of 1,5, 2, or 4 W/kg. In the head scan experiments, skin and eye increased in temperature by approximately 1,5 °C. The temperature of the jugular vein (brain temperature) rose 0,46 °C ± 0,05 °C following 60 min to 90 min of scanning. In the whole body scans, rectal and jugular vein temperatures rose approximately 1°C above the pre-exposure value while skin temperature of the abdomen rose as much as 7 °C. Based on models and animal data, HEAD SAR levels (averaged over the head) up to 3,2 W/kg are considered below the level of concern. The 3,2 W/kg HEAD SAR limit, which is the value necessary to limit the temperature rise in the eye to 1 °C, has been used in the United States for over a decade without adverse reports. In addition, other LOCAL SAR limits have been made consistent with ICNIRP.

The rise in temperature in any object that occurs in response to the intermittent absorption of radio frequency energy from, e.g. a pulsed radio frequency source, can be equated with the SAR value averaged over the 50 % thermal equilibrium time, the time taken for the temperature increase at the centre of a heated region to rise by 50 % of the maximum value after the application of a heat source. The thermal equilibrium time for the body is not known accurately, but can be estimated as around 15 min to 30 min, whereas smaller masses of tissues, such as the eye, have a thermal equilibrium time of about 5 min [123]. This standard conservatively uses 6 min as the averaging period for determining SAR for all tissues and for the body.

The RF transmit coils can be separated into two classes: the VOLUME RF TRANSMIT COILS, and the LOCAL RF TRANSMIT COILS. Popular members of the class of VOLUME RF TRANSMIT COILS are the body resonator and the head coil. LOCAL RF TRANSMIT COILS are commonly used with respect to the spectroscopic application.

The separation into the two classes is introduced in order to enable simple, but – in view of safety – still sufficient rules with respect to the control of SAR.

With respect to the VOLUME RF TRANSMIT COILS it is sufficient to control the whole body and the PARTIAL BODY SAR (including the HEAD SAR) aspects alone, while for the LOCAL RF TRANSMIT COILS the control of the whole body and the LOCAL SAR aspect is adequate.

The simultaneous control of the WHOLE BODY SAR together with the PARTIAL BODY SAR, or with the LOCAL SAR is necessary, in order to meet the large variation of exposure situations as given by the variability of the coil-, and PATIENT dimensions and their relative positions. This requirement automatically adjusts the SAR supervision to the most critical SAR aspect. This is demonstrated in the following four examples:

Example 1: The examination of an adult with a HEAD RF TRANSMIT COIL clearly means a partial body exposure (the head in general). In this case the HEAD SAR will limit the amount of RF power transmission. However, the examination of an infant with the same HEAD RF TRANSMIT COIL, should be judged as a whole body exposure (if the infant fits completely inside the mentioned coil). In this case the WHOLE BODY SAR will be the limiting factor.

Example 2: The examination of the head of a child within a relative large sized body resonator may cause a more critical WHOLE BODY SAR value than the HEAD SAR value.

Example 3: The examination of a large-sized adult with a relative short body resonator means a partial body exposure more than a whole body exposure. In this case the SAR of the exposed partial body needs to be limited to a safe level.

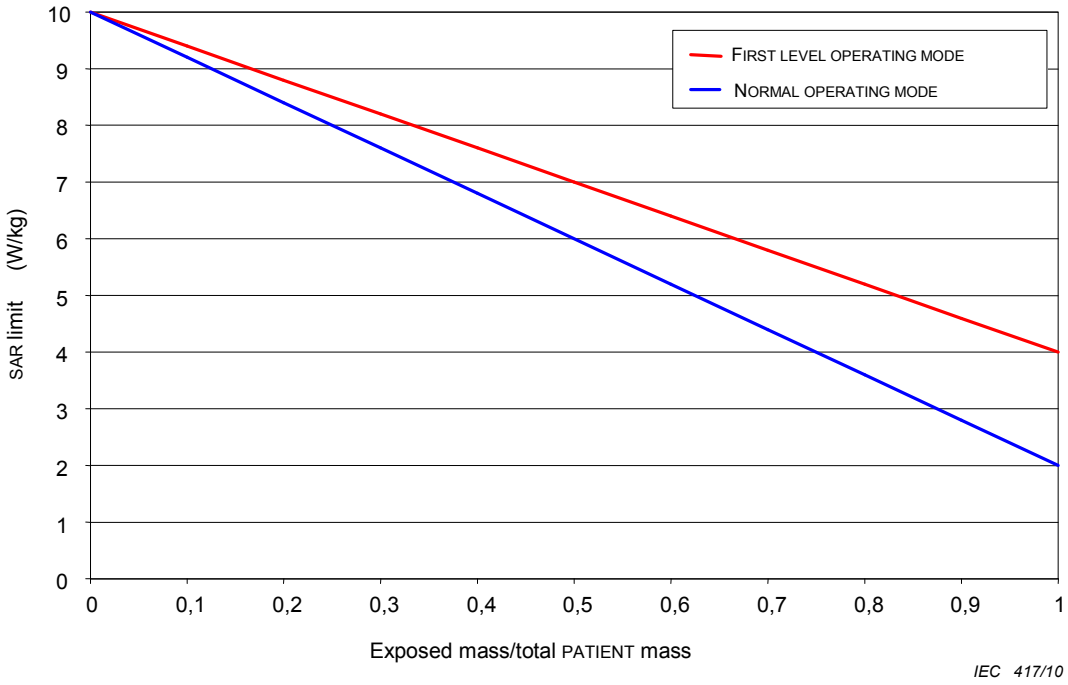
Example 4: The examination of an adult with a LOCAL RF TRANSMIT COIL obviously requires the control of the LOCAL SAR. However, in case of an infant and a relatively large LOCAL RF TRANSMIT COIL the WHOLE BODY SAR might become the most critical figure.

The HEAD SAR, the WHOLE BODY SAR and the LOCAL SAR limits have been justified by several sources of experimental data and theoretical modelling in the past. However the desired simplification of the SAR control with respect to the volume type of RF transmit coils makes it necessary to introduce a PARTIAL BODY SAR limit with respect to the exposed part of the body (see e.g. example 3). This limit has been chosen to vary with the ratio:

(*Mass of the exposed part of the body*) / (*total PATIENT mass*)

The following consideration leads to this prescription. If the PATIENT completely fits inside the RF TRANSMIT COIL, the exposed mass equals the total PATIENT mass, and hence the limit with respect to the partial body exposure should be identical to the WHOLE BODY SAR limit. On the other side, however, the limit may increase with decreasing coil length. For very short RF TRANSMIT COILS the PARTIAL BODY SAR limit equals the LOCAL SAR limit. A linear dependency on the above mentioned mass ratio seems to be justified to be applied for ratios above 0,3. For

lower ratios theoretically a more than linear increase of the SAR limit could be justified in view of the fact, that the LOCAL SAR is averaged over any 10 g of tissue. For this reason the LOCAL SAR limits as specified in Table 201.106 for local transmit coils are not applied for the PARTIAL BODY SAR, since it relates to larger masses. In Table 201.105 the 10 W/kg is therefore still kept as an upper limit for the PARTIAL BODY SAR. Figure AA.8 shows a graphical illustration of this.



NOTE To determine the distribution of the absorbed RF power and to determine the mass of the exposed part of the body the PATIENT shape has to be modelled based on the PATIENT registration data (e.g., by simple cylinders simulating head, torso and extremities). For this statistical data of normal measurements during growth anthropometric data sources might be applied, for example those published by the US National Centre for Health Statistics (NCHS).

Figure AA.8 – SAR limits for the exposed mass of a PATIENT

Concerning 201.12.4.103.1 – Limits for temperature

There have been several studies of thermoregulatory responses of volunteers exposed to RF in MR EQUIPMENT [119, 161]. In general, these have demonstrated that exposure for up to 30 min, under conditions in which the whole body SAR was less than 4 W/kg, caused an increase in the body core temperature of less than 1 °C. A maximum temperature rise of 1 °C is well accepted for PATIENTS. Following the ICNIRP guidelines [131], there is a safety factor of 10 between PATIENTS and occupational workers, which provides adequate protection for occupational RF exposure. The resulting 0,4 W/kg is estimated to result in a temperature rise of 0,1 °C. The natural daily variation of the body temperature exceeds 0,1 °C by an order of magnitude, even more during strenuous exercise. Therefore, the ICNIRP occupational exposure limit seems to be overly conservative. In practice, MR WORKERS are expected to work in positions at which their head and arms are closer to the isocentre than other parts of their body. Therefore the WHOLE BODY SAR of the MR WORKER can be assumed to be much lower than that of the PATIENT.

It can be estimated that when the system is operating in the FIRST LEVEL CONTROLLED OPERATING MODE in respect of the PATIENT positioned in the volume transmit RF coil, the WHOLE BODY SAR of an MR WORKER is most likely to be in a range defined by the NORMAL OPERATING MODE: The RF field B_1 at NORMAL OPERATING MODE is about 70 % of the FIRST LEVEL CONTROLLED OPERATING MODE. It can be assumed with sufficient accuracy that the B_1 field of an RF transmit coil has dropped already to less than 70 % when moving from the coil centre

to the physical end of the coil. Therefore the WHOLE BODY SAR of an MR WORKER is always in a range defined by the NORMAL OPERATING MODE when the MR WORKER is not intersecting the effective volume of the RF transmit coil (alternative “the volume encompassed by the RF coil”) even if the system is operating in the FIRST LEVEL CONTROLLED OPERATING MODE. Assuming the operating mode for the MR WORKERS is always equal to the operating mode for the PATIENT is clearly a conservative assumption.

IEC 60601-1, 3rd edition sets a surface temperature limit (T_{limit} = 43 °C) for objects which may come into contact with the human body. This limit is also made dependent of the time of contact and material applied, allowing even higher surface temperature limits for shorter times and materials other than metals and liquids.

The 2nd edition of this standard introduced spatially localized temperature limits, which were different for the head, torso and extremities, whereby no different temperatures were allowed for the NORMAL OPERATING MODE and the FIRST LEVEL CONTROLLED OPERATING MODE. Only for the SECOND LEVEL CONTROLLED OPERATING MODE higher (not limited) temperatures were allowed. This 3rd edition of the standard has modified the allowed temperature limits in an attempt to make these temperature limits more in line with the current practice and overall allowed body temperatures. As a result the maximum allowed temperature body CORE TEMPERATURE is raised in FIRST LEVEL CONTROLLED OPERATING MODE to 40 °C and maximum local tissue temperatures are introduced. It is however realized that for the local tissue temperatures no concrete methodology and uncertainty budget is added to demonstrate compliance with the temperature limits. Compliance to the limits to temperature and temperature rise is reached by limiting the SAR.

However, it would be useful to identify limits for surface heating of electronic circuitry (e.g. a RF receive coil). Skin temperature under normal (non-scanning) conditions is about 33 °C, but during MR EXAMINATIONS with high WHOLE BODY SAR, skin blood vessels dilate and skin temperature approaches core (about 37 °C).

Assuming the following values for the parameters :

– the ENVIRONMENTAL TEMPERATURE T_a is 21 °C (294 K);
– the skin temperature T_s is $T_a + \Delta T$;
– let SAR be the whole-body SPECIFIC ABSORPTION RATE;
– let MET be the basal metabolic (= 1,2 W/kg),
– let m be PATIENT mass (= 75 kg), and
– let σ be the Stefan - Boltzmann constant (5,67 x 10^{-8} W/(m^2 K^4)), and
– area A the PATIENT surface area (= 1,9 m^2).

The electronic circuitry under test is placed on an appropriate (thermally insulated) phantom and a 20 min scan protocol is used at the highest clinical WHOLE-BODY SAR for the MR EQUIPMENT.

Then, the heating of the electronic circuitry surface temperature rise might be limited to:

$$12{,}9\ °\mathrm{C} - 6{,}9\ \frac{°\mathrm{C}}{\mathrm{W/kg}}\ SAR \quad \text{or} \quad 4\ °\mathrm{C} \quad \text{(whichever is more).}$$

Concerning 201.12.4.103.2 – Limits for SAR

In the 2nd edition of this standard all SAR limits were given in one table. In the text of the clause on control of SAR, it was explained that for VOLUME RF TRANSMIT COILS only the whole body SAR, the partial body SAR or the head SAR are to be controlled, whereas the local SAR is to be controlled for LOCAL RF TRANSMIT COILS. In the 3rd edition of the standard the table is split into Tables 201.105 and 201.106 for clarity. The control conditions are not changed.

In addition for the FIRST LEVEL CONTROLLED OPERATING MODE for the local SAR values a higher value is introduced in the 3rd edition as compared to the 2nd edition of the standard. The justification for this higher value is found in literature whereby via simulations the local SAR value, related to scanning with a VOLUME RF TRANSMIT BODY COIL, is calculated. Numerous publications, see [157, 158, 159, 163, 164], have indicated that the local SAR values can actually be about a factor of 10 to 15 higher than the whole body SAR. Already at 1,5 T, whole-body electromagnetic field (EM) simulations indicate significant B_1 field non-uniformity and local SAR hotspots that can exceed the published guidelines even while the whole body SAR is within limits. In view of these publications, but still taking a conservative approach, because clearly more research is needed, the max value for the local SAR is doubled in Table 201.106.

Concerning 201.12.4.104 – Protection against exposure to static magnetic fields

The rationales for the choice of 3 T as the limit for the NORMAL OPERATING MODE and 4 T as the limit for the FIRST LEVEL CONTROLLED OPERATING MODE are described in the paragraphs concerning 201.7.9.2.101 h) of this annex.

Concerning 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 SAR for a PATIENT located in the RF transmit coil is controlled by the system. Both, the SAR of the PATIENT and the corresponding RF magnetic field B_1 in the centre of the RF transmit coil are known. The SAR expected for MR WORKERs at other places than the centre of the RF transmit coil is assessed as ratio of $B_1$² at the position of interest (i.e. $B_1^2(z)$) and the B_1^2 at the coil centre (i.e. B_1^2 (0)).

The ratio defines a worst case estimate for the SAR of a MR WORKER at the position of interest.

$$SAR_{worker} <= SAR_{patient} * (B_1^2 (z) / B_1^2(0))$$

The RF power is reduced to 50 %, when B_1 (z) has dropped by 3 dB (i.e. appr. 70 %). For a bird cage coil typically this is close to the physical end of the coil.

Since the MR WORKERS are expected to work in positions at which their head and arms are closer to the ISOCENTRE than other parts of their body, the SAR in arms and especially in the head will be more important than their WHOLE BODY SAR. The WHOLE BODY SAR of the MR WORKER can be assumed to be much lower than that of the PATIENT

Concerning 201.17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS and
concerning 202 – Electromagnetic compatibility – Requirements and tests

Within the CONTROLLED ACCESS AREA the MR SYSTEM will generally not comply with the current requirements for radio frequency emission. These requirements are primarily intended to protect radio communication and are laid down in International Standards such as CISPR 11. Permissible limits for radio frequency emission are in the range of 30 dBμV/m to 50 dBμV/m. It is proposed that in coming standard emission levels for MR EQUIPMENT, COMPUTED TOMOGRAPHY equipment and complex X-RAY EQUIPMENT be measured at the boundaries of the room or of the building.

IEC standards on EMC are in preparation, which deal with the immunity for radio frequency fields of medical equipment. It is expected that immunity will be required for the general case of fields up to 1 V/m or 3 V/m and for special cases, such as life sustaining and some PATIENT monitoring equipment, at fields up to 10 V/m or 100 V/m.

Actually, within the CONTROLLED ACCESS AREA around the MR EQUIPMENT, radio frequency field strengths may easily exceed these limits and can have values in excess of 100 V/m. It is clear that peripheral equipment used in the CONTROLLED ACCESS AREA might be disturbed by this field.

Bibliography

[1] SHELLOCK, FG. and KANAL, E. *Magnetic Resonance: Bioeffects, Safety, and Patient Management*. New York: Lippincott Raven Press, 1996.

[2] SHELLOCK, FG. *Pocket Guide to MR Procedures and Metallic Objects: Update 2000*. New York: Lippincott, Williams and Wilkins, 2000.

[3] Occupational Health and Safety Administration, USA. *Occupational noise exposure. Occupational health and safety standards*, 1970, Part 1910.95, 29 CFR, Ch XVII.

[4] European Community. Council directive 2003/10/EC on the minimum health and safety requirements regarding the exposure of of workers to the risks arising from physical agents (noise)

[5] KRYTER, KD. Interruption in days or years of exposure. In *The effects of noise on man*. 2nd edition. Acad. Press, 1985, p.274-275, ISBN 0-12-427460-9.

[6] MC JURY, M. and SHELLOCK, FG. Auditory noise associated with MRI procedures: a review. *J Mag Res Im*, 2000, 12:37-45.

[7] COUNTER, S. A., OLOFSSON, A., GRAHN, H., BORG, E. MRI acoustic noise: sound pressure and frequency analysis. *J Mag Res Im*, 1997, 7:606-611.

[8] FOSTER, JR., HALL, DA., SUMMERFIELD, AQ., BOWTELI, R. W. Sound level measurements and calculation of safe noise dosage at 3 T. *J Mag Res Im*, 2000, 12:157-164.

[9] BRUMMET, RE., TALBOTT, JM., CHARUHAS, P. Potential hearing loss resulting from MR imaging. *Radiology*, 1988, 169:539-540.

[10] MANGHAM, CA. The effect of drugs and systemic disease on the acoustic reflex. In SILMAN, S., ed. *The acoustic reflex, basic principles and clinical applications*. Acad. Press 1984, p.441-464, ISBN 0-12-64350-6.

[11] BARBARO, V, BARTOLINI, P., TARRICONE, L.. Evaluation of static magnetic field levels interfering with pacemakers. *Physica Medica*, VII, 1991, p.73-76.

[12] EN 45502-2-1:2003, *Safety of Implantable Cardiac Pacemakers*

[13] ATHEY, TW. Current FDA guidance for MR patient exposure and considerations for the Future. *Annals of the New York Academy of Sciences*, 1992, 649, p.242-257.

[14] FDA, 1988, (August 2), *Guidance for content and review of a magnetic resonance diagnostic device 510(k) application: safety parameter action levels*, Center for Devices and Radiological Health Report (Rockville, Maryland).

[15] STRATTON, JA. *Electromagnetic Theory*. New York: MacGraw Hill, 1941, p.153 156.

[16] KANAL, E. An overview of electromagnetic safety considerations associated with magnetic resonance imaging. *Annals of the New York Academy of Sciences*, 1992, 649, p.204-224.

[17] UENO, S. and IWASAKA, M. Properties of diamagnetic fluid in high gradient magnetic fields. *J. Appl. Phys*., 1994, 75, p.7177-7179.

[18] UENO, S. and IWASAKA, M. Parting of water by magnetic fields. *IEEE Trans. Magn*., 1994, 30, p.44698-4700.

[19] ICHIOKA, S., MINEGISHI, M., IWASAKA, M., SHIBATA, M., NAKATSUKA, T., HARII, K., KAMIYA, A., and UENO S. High-intensity static magnetic fields modulate skin microcirculation and temperature in vivo. *Bioelectromagnetics*, 2000, 21, p.183-188.

[20] HALLIDAY, D. and RESNICK, R. *Physics*. New York: John Wiley, 1966, p.873.

[21] WIKWSO, JP. Jr. and BARACH, JP. An Estimate of the Steady Magnetic Field Strength Required to Influence Nerve Conduction. *IEEE Trans. Biomed. Eng*., 1980, 27, p.722.

[22] KOLIN, A. Improved apparatus and technique for electromagnetic determination of blood flow. *Rev. Sci. Instrum*. 1952, 23, p.235-240.

[23] BEISCHER, DE., and KNEPTON, JC. Jr. Influence of strong magnetic fields on the electrocardiogram of squirrel monkeys, (Saimiri Sciureus). *Aerospace Med*., 1964, 35, p.939.

[24] SCHENCK, JF. Health and physiological effects of human exposure to whole-body four-Tesla magnetic fields during MRI. *Annals of the New York Academy of Sciences*, 1992, 649, p.285-301.

[25] COLEMAN, MP. and BERAL V. A Review of epidemiological studies of health effects of living near or working with electricity generation and transmission equipment. *Int. J. Epid*., 1988, 17, p.1-13.

[26] DENNIS, JA., MUIRHEAD, CR. and ENNIS, JR. Epidemiological studies of exposure to electromagnetic fields, II: cancer. *J. Radiol. Prot*., 1991, 11, p.13-25.

[27] KNAVE, GG. and TORNQUIST, SG. *Epidemiological studies on effects of exposure to ELF electromagnetic fields. A review of Biological Effects of Static and ELF Magnetic Fields*. Ed. JH. Bernhardt. Munich: mmV Medizin, 1986, p.143-153.

[28] SAVITZ, DA., WACHTEL, H., BARNES, FA., JOHN, EM. and TORDIK, JG. Case control study of childhood cancer and exposure to 60 Hz magnetic fields. *Am. J. Epidemiol*., 1988, 128, p.21-38.

[29] TOMENIUS, L., HALLSTROM, L. and ENANDER, B. *Electrical constructions and 50 Hz magnetic fields at the dwellings of tumor cases (0-18 years of age) in the country of Stockholm*. Proc. Int. Symp. Occup. Health and Safety in Mining and Tunneling, 1982.

[30] WERTHEIMER, N. and LEEPER, E. Electrical wiring configuration and childhood cancer. *Am. J. Epidemiol*. 1979, 109, p.273-284.

[31] WERTHEIMER, N. and LEEPER, E. Adult cancer related to electrical wires near the home. *Int. J. Epidemiol*. 1982, 11, p.345-355.

[32] CALLE, EE. and SAVITZ, DA. Leukemia in occupational groups with presumed exposure to electrical and magnetic fields. *New England J. Med*., 1985, 313, p.1476 1477.

[33] COLEMAN, M., BELL J., and SKEET R. Leukaemia incidence in electrical workers. *Lancet*, 1981, 1, p.982-983.

[34] LIN, R.S. et al. Occupational exposure to electromagnetic fields and the occurrence of brain tumors: an analysis of possible association. *J. Occup. Med*. 1985, 27, p.413-419.

[35] MCDOWALL, ME. Leukemia mortality in electrical workers in England and Wales. *Lancet*, 1983, 1, p.246.

[36] MILHAM, S. Jr. Mortality from leukemia in workers exposed to electrical and magnetic fields. *New Engl. J. Med*. 1982, 307, p.249.

[37] BERNHARDT, JH. Non-ionizing radiation safety: radio-frequency radiation, electric and magnetic fields. *Phys. Med. Biol*., 1992, 4, p.807-844.

[38] LYLE, BL., et al. Modulation of Calcium Uptake by concanavalin A and ouabain in normal and leukemic T-lymphocytes exposed to magnetic fields under calcium cyclotron resonance conditions. *Abstracts of the Twelfth Annual Meeting of the Bioelectromagnetics Society*, San Antonio, TX, 1990, p.51.

[39] HABERDITZL, W. Enzyme activity in high magnetic fields. *Nature*, 1967, 213, p. 72 73.

[40] MANSFIELD. P. and MORRIS, PG. NMR Imaging in Biomedicine. In WAUGH, JS., ed. *Advances in Magnetic Resonance*, Suppl. 2. New York: Academic Press, 1982.

[41] MCLAUCHLAN, KA. The effects of magnetic fields on chemical reactions. *Sci Prog*, 1981, 67, 509 529.

[42] WAUGH, J. Biomagnetic effects, In WAUGH, JS, ed. *Advances in Magnetic Resonance*, Suppl. 2. New York: Academic Press, 1982.

[43] PERSSON, BRR. and STAHLBERG, F. Potential health hazards and safety aspects of clinical NMR examinations. In BERTIL, BRR, ed. *Seminars on Biomedical Applications of Nuclear Magnetic Resonance.* Lund, Sweden: Radiation Physics Dept., Lasarettet.

[44] SAUNDERS, RD. and SMITH, H. Safety aspects of NMR clinical imaging. *British Medical Bulletin*, 1984, 40(2), p.148 154.

[45] SHELLOCK, FG. Biological effects and safety aspects of magnetic resonance imaging. *Magnetic Resonance Quarterly*, 1989, 5(4), p.243-261.

[46] TENFORDE, TS., and BUDINGER, TF. Biological effects and physical safety aspects of NMR imaging and in-vivo spectroscopy. In THOMAS, SR. and DIXON, RL., eds. *NMR in Medicine: Instrumentation and Clinical Applications*, Medical Monograph No.14, New York: Amer. Assoc. Phys. Med., 1986, p.493-548.

[47] SHELLOCK, FG., SCHAEFER, DJ, and GORDON CJ. Effect of a 1,5 T static magnetic field on body temperature of DJ man. *Magn. Reson. Med.*, 1986, 3, p.644-647.

[48] SPERBER, D., OLDENBOURG, R. and DRANSFIELD, DK. Magnetic field induced temperature change in mice. *Naturwissenschaften*, 1984, 71, p.101.

[49] UENO, S. Embryonic development of xenopus laevis under static magnetic fields up to 6,34 T. *J. Appl. Phys.*, 1990, 67, p.5841-5843.

[50] GAFFEY, CT. and TENFORDE, TS. Bioelectric properties of frog sciatic nerves during exposure to stationary magnetic fields. *Radiat. Environ. Biophys.*, 1983, 22, p.61-73.

[51] HONG, CZ. AND SHELLOCK, FG. Short-term exposure to a 1,5 Tesla static magnetic field does not affect somato-sensory-evoked potentials in man. *Magnetic Resonance Imaging*, 1990, 8, p.65-69.

[52] HONG, CZ., HARMON, D., and YU, J. Static magnetic field influence on rat tail nerve function. *Arch. Phys. Med. Rehabil.*, 1986, 67, p.746-749.

[53] ATKINS, PW. Magnetic field effects. *Chem Brit*, 1976, 12, p.214 218.

[54] COOK, ES., FARDON, JC. and NUTINI, LG. Effects of magnetic fields on cellular respiration. In BARNOTHY, M.F., ed. *Biological Effects of Magnetic Fields*, Vol. 2. New York: Plenum Press, 1969, p.67 78.

[55] FARDON, JC., POYDOK, SME. and BASULTO, G. Effect of magnetic fields on the respiration of malignant, embryonic, and adult tissue. *Nature*, 1966, 211, p.433.

[56] BARNOTHY, MF. Hematological changes in mice. In Barnothy, MF., ed. *Biological Effects of Magnetic Fields*, Vol. 1. New York: Plenum Press, 1964, p.109 126.

[57] EISELEIN, JE., BOUTELL, HM. and BIGGS, MW. Biological effects of magnetic fields negative results. *Aerospace Med*, 1961, 32, p.383 386.

[58] BATTOCLETTI, JH., SALLES CUNHA, S., HALBACH, RE. et al. Exposure of Rhesus Monkeys to 20,000 G Steady Magnetic Field: Effect on Blood Parameters. *Med Phys*, 1981, 8, p.115 118.

[59] BEISCHER, DE. Human tolerance to magnetic fields. *Astronautics* 1962, 7, p. 24.

[60] BUDINGER, TF., BRISTOL, KS., YEN, CK. et al. *Biological effects of static magnetic fields*. Abstracts, Third Annual meeting, Society of Magnetic Resonance in Medicine, New York, 1984, p.113.

[61] KANAL, E., SHELLOCK, FG. and SAVITZ, DA. *Survey of reproductive health among female MR OPERATORS*. Abstract presented at the Seventy-seventh Annual Meeting of the Radiological Society of North America, 1991.

[62] VYALOV, A.M. Magnetic fields as a factor in the industrial environment. *Vestn Akad Med Nauk SSSR*, 1967, 8, p.72 79.

[63] VYALOV, A.M. Clinico hygenic and experimental data on the effects of magnetic fields under industrial conditions. In KHOLODOV, Yu. A., ed. *Influence of Magnetic Fields on Biological Objects*, Joint Publ Res Service Rep No. 63038. Springfield, VA: National Technical Information Service, 1974, p.163-174.

[64] KAY, HH., HERFKENS, RJ., and KAY, BK. Effect of magnetic resonance imaging on Xenopus laevis embryogenesis. *Magn Reson Imaging* ,1988, 6, p.501-506.

[65] MCROBBIE D., FOSTER MA. Pulsed magnetic field exposure during pregnancy and implications for NMR foetal imaging: a study with mice. *Magn Reson Imaging*, 1985, 3, p.231-234.

[66] PRASAD, N., WRIGHT, DA., FORD, JJ., THORNBY, JI. Safety of 4-T MR imaging: study of effects on developing frog embryos. *Radiology*, 1990 Jan., 174(1), p.251-253.

[67] SCHENCK, JF., DUMOULIN, CL., REDINGTON, RW., KRESSEL, HY., ELLIOTT, RT., MCDOUGALL, IL. Human exposure to 4,0-Tesla magnetic fields in a whole-body scanner. *Med Phys*, 1992 July, 19(4), p.1089-1098.

[68] RAYLMAN, RR., CLAVO, AC., WAHL, RL. Exposure to strong static magnetic field slows the growth of human cancer cells in vitro. *Bioelectromagnetics*, 1996, 17(5), p.358-363.

[69] KROEKER, G., PARKINSON, D., VRIEND, J., PEELING, J. Neurochemical effects of static magnetic field exposure. *Surg Neurol*, 1996 Jan., 45(1), p.62-66.

[70] NARRA, VR., HOWELL, RW., GODDU, SM., RAO, DV. Effects of a 1,5-Tesla static magnetic field on spermatogenesis and embryogenesis in mice. *Invest Radiol*, 1996 Sep, 31(9), p.586-590.

[71] JEHENSON, P., DUBOC, D., LAVERGNE, T., GUIZE, L., GUERIN, F., DEGEORGES, M., SYROTA, A. Change in human cardiac rhythm induced by a 2-T static magnetic field. *Radiology*, 1988 Jan., 166(1 Pt 1), p.227-230.

[72] KINOUCHI, Y., YAMAGUCHI, H., TENFORDE, TS. Theoretical analysis of magnetic field interactions with aortic blood flow. *Bioelectromagnetics*, 1996, 17(1), p.21-32.

[73] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. *Guidance for Magnetic Resonance Diagnostic Devices – Criteria for Significant Risk Investigations*. 1997.

[74] National Radiological Protection Board (UK). *Guidance as to Restrictions on Exposures to Static (DC) Electric and Magnetic Fields*. Documents of the NRPB: Vol 15, No 2, 2004.

[75] American Conference of Governmental Industrial Hygienists (ACGIH), *Threshold Limit Values for Chemical Substances and Physical Agents*. 1993-1994.

[76] MILLER, G. Exposure Guidelines for Magnetic Fields. *Am Ind Hyg Assoc Jour*, 1987, 48, p.957-968.

[77] Australian Radiation Laboratory. *Safety Guidelines for Magnetic Resonance Diagnostic Facilities.* 1991.

[78] International Commission on Non-ionizing Radiation Protection (ICNIRP). Guidelines on Limits of Exposure to Static Magnetic Fields. *Health Physics*, 1994, 66(1), p.100-106.

[79] KELTNER, JR., ROOS, MS., BRAKEMAN, PR. and BUDINGER, TF. Magnetohydrodynamics of Blood Flow. *Magnetic Resonance in Medicine*, 1990, 16, p.139-149.

[80] GANONG, WF. *Review of Medical Physiology*, 6th Edition. Los Altos, CA: Lange Medical Publ, 1973.

[81] REILLY, JP. *Cardiac sensitivity to electrical stimulation*. U.S. Food and Drug Administration Report MT 89-101, 1989.

[82] SCHENCK, JF. Safety of Strong, Static Magnetic Fields. *J of Magn. Res. Imaging*, 2000, 12, 2-19.

[83] National Electrical Manufacturers Association, MR Section. Accessory equipment considerations with respect to magnetic resonance imaging compatibility. *J of Magn. Res. Imaging*, 1998.

[84] BERNHARDT, JH. The establishment of frequency dependent limits for electric and magnetic fields and evaluation of indirect effects. *Radiat. Environ. Biophys*, 1988, 27, p.1 27.

[85] REILLY, JP. Peripheral nerve and cardiac excitation by time-varying magnetic fields: A comparison of thresholds. *NY Acad. of Sci.*, 1992, 649, p.96-117.

[86] LAPICQUE, L.. Definition experimental de l'excitation. *Comptes Rendues Acad. Sci.*, 1909, 67, p.280-285.

[87] IRNICH W., SCHMITT F. Magnetostimulation in MRI. Mag. Res. Med., 1995, 33, p.619-623

[88] SCHAEFER, D.J. Safety Aspects of Radio Frequency Power Deposition. In *Magnetic Resonance*. E. Kanal, ed. MRI Clinics of North America, 1998, 6(4), p.775-789.

[89] HAM, CGL, ENGELS, JML., VAN DE WIEL, GT., MACHIELSEN, A. Peripheral nerve stimulation during MRI: effects of high gradient amplitudes and switching rates. *J. Mag. Res. Imaging*, 1997, 5, p.933-937.

[90] BOURLAND, JD., NYENHUIS, JA. and SCHAEFER, DJ. Physiologic Effects of Intense MRI Gradient Fields. *Neuroimaging Clinics of North America*, 1999, 9(2), p.363-377.

[91] HEBRANK, FX. and GEBHARDT M. SAFE Model – a new method for predicting peripheral nerve stimulations in MRI. *Soc. Mag. Res. Im*. Proceedings 2000 conference, 2000, p.2007.

[92] BOTWELL, R. and BOWLEY, L.M. Analytic calculations of the E-Fields Induced by Time-Varying Magnetic Fields Generated by Cylindrical Gradient Coils. *Mag. Res. Med*., 2000, 44, p.782-790.

[93] HARVEY, P.R. and MANSFIELD, P. Avoiding Peripheral Nerve Stimulation: Gradient Waveform Criteria For Optimum Resolution in EPI. *Mag. Res. Med*., 1994, 32, p.236-241.

[94] MANSFIELD, P. and HARVEY, PR. Limits to Neural Stimulation in EPI. *Mag. Res. Med*., 1993, 29, p.746-758.

[95] FRESE, G., HEBRANK, FX., RENZ, W., STORCH, T. Physikalische Parameter bei der Anwendung der MRT. *Radiologe*, 1998, 38, p.750-758.

[96] BUDINGER, TF., FISCHER, H., HENTSCHEL, D., REINFELDER, HE., SCHMITT, F. Physiological effects of fast oscillating magnetic field gradients. *Jour. Comp. Ass.Tech*, 1991, 15, p.909-914.

[97] DEN BOER, JA., BAKKER, R., HAM, CGL., SMINK, J. Generalization to complex stimulus shape of the nerve stimulation threshold based on existing knowledge of its relation to stimulus duration for rectangular stimuli. *Proceedings ISMRM,* 1999, p.108.

[98] SAUNDERS, RD., SIENKIEWICZ, ZJ. and KOWALCZUK, CI. Biological effects of electromagnetic fields and radiation. *J. Radiol. Prot*., 1991, 11, p.27-42.

[99] BOTTOMLEY, PA. and ANDREW, ER. RF magnetic field penetration, phase shift and power dissipation in biological tissue: Implications for NMR imaging. *Phys. Med. Biol*., 1978, 23, p.630-643.

[100] SCHENCK, JF. and HUSSAIN, MA. *Power deposition during magnetic resonance. The effects of local inhomogeneities and field exclusion*. General Electric Corporate Research and development Labs. NMR Project Memo No. 84-199, Oct 17, 1984.

[101] GANDHI, OP. and CHEN, JY. Absorption and Distribution Patterns of RF Fields. *Annals of the New York Academy of Sciences*, 1992, 649, p.131-143.

[102] GRANDOLFO, M., POLICHETTI, A., VECCHIA, P. and GANDHI, OP. Spatial Distribution of RF Power in Critical Organs during Magnetic resonance Imaging. *Annals of the New York Academy of Sciences*, 1992, 649, p.176-187.

[103] GABRIEL, C. *Localised SAR in people undergoing NMR imaging*. A report prepared for the National Radiological Protection Board, Chilton, Didcot, Oxon, UK. by University Microwave, London, 1989.

[104] GRANDOLFO, M., VECCHIA, P., GANDHI, OP. Magnetic resonance imaging: Calculation of rates of energy absorption by a human-torso model. *Bioelectromagnetics*, 1990, 11, p.117-128.

[105] ROWELL, LB. Cardiovascular aspects of human thermoregulation. *Circ. Res*., 1983, 52, p.367.

[106] International Radiation Protection Association (IRPA)/ International Non-Ionizing Radiation Committee (INRC). Protection of the patient undergoing a magnetic resonance examination. *Health Physics*, 1991, 61, p.923-928.

[107] KENNEY, WL. Physiological correlates of heat intolerance. *Sports Med*., 1985, 2, p.279-286.

[108] MINARD, D. Pre-employment and periodic medical examinations for workers on hot jobs. In DUKES-DUBOS, FN and HENSCHEL, A., eds., *Proceedings of a NIOSH Workshop on Recommended Heat Stress Standards*. Cincinnati, Ohio: U S Department of Health and Human Services, DHSS (NIOSH) 81-108, 1980, p.61-70.

[109] SMITH, DA., CLARREN, SK., HARVEY, MAS. Hyperthermia as a possible teratogenic agent. *Pediatrics*, 1978, 92, p.878-883.

[110] PLEET, H., GRAHAM JM. and SMITH, DW. Central nervous system and facial defects associated with maternal hyperthermia at four to 14 weeks' gestation. *Pediatrics*, 1981, 67, p.785-789.

[111] ADAIR, ER., and BERGLUND, LG. On the thermoregulatory consequences of NMR imaging. *Magn. Reson. Imaging*, 1986, 4, p.321-333.

[112] SCHAEFER, DJ., BARBER, BJ., GORDON, CJ., ZIELONKA, J., and HECKER, J. Thermal effects of magnetic resonance imaging (MRI). In *Abstracts: Society of Magnetic Resonance in Medicine.* Volume 2. Berkeley, California: Society of Magnetic Resonance in Medicine, 1985, p.925-926.

[113] KIDO, DK., MORRIS, TW., ERICKSON, JL., PLEWES, dB., and SIMON, JH. Physiologic changes during high field strength MR imaging. *Am J Neuroradiol*, 1987, 8, p.263-266.

[114] ABART, J., BRINKER, G., IRLBACHER, W., GREBMEIER, J. Temperature and heart rate changes in MRI at SAR levels of up to 3 W/kg. Abstract, *Society for Magnetic Resonance in Medicine*, 1989 August, p.998.

[115] SHELLOCK, FG., SCHAEFER, DJ., CRUES, JV. Alterations in body and skin temperatures caused by magnetic resonance imaging: is the recommended exposure for radio frequency radiation too conservative? *Brit. J. Radiol*., 1989, 62, p.902-909.

[116] SCHAEFER, DJ.,. Dosimetry and effects of MR exposure to RF and switched magnetic fields. In MAGIN, RI., LIBURDY, RP. and PERSSON, B., eds. *Biological Effects and Safety Aspects of Nuclear Magnetic Resonance Imaging and Spectroscopy*. The New York Academy of Sciences, 1991, 649, p.225-236.

[117] NIOSH, 1986. *Occupational exposure to hot environments*. Revised criteria, 1986. National Institute for Occupational Safety and Health, U.S. Dept. of Health and Human Services, DHHS (NIOSH), p.86-113.

[118] ADAIR, ER., and BERGLUND, LG., Thermoregulatory consequences of cardiovascular impairment during NMR imaging in warm/humid environments. *Magn. Reson. Imag*. 1989, 7, p.25-37.

[119] ADAIR, ER. and BERGLUND LG. Predicted thermophysiological responses of humans to MRI fields. In MAGIN, RI., LIBURDY, RP., and PERSSON, B., eds. *Biological Effects and Safety Aspects of Nuclear Magnetic Resonance Imaging and Spectroscopy*. Annals of the New York Academy of Sciences, 1992, 649, p.188-200.

[120] CZERSKI, P. and ATHEY, TW. *Safety of magnetic resonance in vivo diagnostic examinations: Theoretical and clinical considerations*. Rockville, Maryland: Centre for Devices and Radiological Health, 1987.

[121] ATHEY, TW. A model of the temperature rise in the head due to magnetic resonance imaging procedures. *Magn. Reson. Med*., 1989, 9, p.177-184.

[122] BARBER, BJ., SCHAEFER, DJ., GORDON, CJ., ZAWIEJA, DC. and HECKER, J. Thermal effects of MR imaging: worst-case studies on sheep. *American Journal of Roentgenology*, 1990, 155, p.1105-1110.

[123] SCOTT, JA. A finite element model of heat transport in the human eye. *Phys. Med. Biol*., 1988, 33, p.227-241.

[124] BOTTOMLEY, PA., and EDELSTEIN, WA. Power deposition in whole-body NMR imaging. *Med. Phys*., 1981, 8, p.510-512.

[125] SHELLOCK, FG. and KANAL, E. *Magnetic Resonance: Bioeffects, Safety and Patient Management*. New York: Lippincot Raven Press, 1996.

[126] SCHAEFER, DJ. Safety Aspects of Radio Frequency Power Deposition. In *Magnetic Resonance*., E. Kanal, ed. MRI Clinics of North America, 1998, 6(4), p.775-789.

[127] SHELLOCK, FG., *Pocket Guide to MR Procedures and Metallic Objects: Update 2000*. New York: Lippincott Williams and Wilkins, 2000.

[128] SCHAEFER, DJ. and BOURLAND, JD. Review of Patient Safety in Time-Varying Gradient Fields. *J of Magn. Res. Imaging*, 2000, 12(1), p.20-29.

[129] SHELLOCK, F.G., ed. *Magnetic Resonance Procedures: Health Effects and Safety*. CRC Press, 2001.

[130] *European Directive on EMF exposure for workers*, 2004/40/EC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:159:0001:0026:EN:PDF

[131] International Commission on Non-Ionizing Radiation Protection (ICNIRP), Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). *Health Physics*, April 1998, Volume 74, Number 4, pp 494–522.

[132] International Commission on Non-Ionizing Radiation Protection (ICNIRP), Medical magnetic resonance (MR) procedures: protection of patients. *Health Physics*, August 2004, Volume 87, Number 2, pp 197-216.

[133] International Commission on Non-Ionizing Radiation Protection (ICNIRP), *Use of the ICNIRP EMF guidelines.* (March 31, 1999), http://www.icnirp.de/documents/Use.htm. p.2.

[134] American Conference of Government and Industrial Hygienists, *Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices*, 1994, p. 89.

[135] LEHNINGER, A.L., *Biochemistry*, 1970, Worth, New York, pp 40-41.

[136] SCHAEFER, D.J. Safety Aspects of Switched Gradient Fields. *MRI Clinics of North America*, vol. 6, No. 4, November, 1998, p. 743.

[137] U.S. Nuclear Regulatory Commission, *10 CFR 20 subpart C*, at http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/.

[138] J.A. NYENHUIS, J.D. BOURLAND, A.V. KILDISHEV and D.J. SCHAEFER, "Health Effects and Safety of Intense MRI Gradient Fields", in *Magnetic Resonance Procedures: Health Effects and Safety*, edited by F.G. Shellock, CRC Press, 2001, pages 31-54.

[139] J.A. DEN BOER, J.D. BOURLAND, J.A. NYENHUIS, C.L.G. HAM, J.M.L. ENGELS, F.X. HEBRANK, G. FRESE, and D.J. SCHAEFER. Comparison of the Threshold for Peripheral Nerve Stimulation during Gradient Switching in Whole Body MR SYSTEMS. *J. Magn. Reson. Imaging*, Vol. 15, pp. 520-525, 2002.

[140] J.M. DENEGRE, JR. J. M. VALLES, K. LIN, W. B. JORDAN, K. L. MOWRY, Cleavage planes in frog eggs are altered by strong magnetic fields. *Proc Natl Acad Sci*, 95, 14729-32 1998

[141] WU, D. SHAMSI, S. CHEN, J. KAINZ, W. et al. Evaluations of Specific Absorption Rate and Temperature Increase Within Pregnant Female Models in Magnetic Resonance Imaging Birdcage Coils. *Microwave Theory and Techniques*, Volume: 54, Issue: 12, Part 2: 4472-4478, Dec. 2006

[142] ACR Guidance Document for safe MR practises, *Amer. Journal of Radiology*, June 2007, Vol 188, pages 1 -27, or http://www.acr.org/SecondaryMainMenuCategories/quality_safety/MRSafety/safe_mr07.aspx

[143] World Health Organization, *Environmental health Criteria 232, Static fields*, 2006

[144] ASTM standard F2503-05:2005, *Standard Practise for Marking Medical Devices and Other items for safety in the Magnetic Resonance Environment*

[145] CROZIER, S., LIU, F. Numerical evaluation of the fields induced by body motion in or near high-field MRI scanners. *Prog in Biophysics & Molecular Biology*, 2005, Vol 87, Nrs 2-3, pages 267-278

[146] Medical Electrical Installation Guidance, http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Technicalinformation/MEIGaN-MedicalElectricalInstallationGuidance/index.htm

[147] Gowland P. and De Wilde, J. Temperature increase in the fetus due to RF exposure during MR scanning. *Phys. Med. Biol*. 53, 2008, L15-L18

[148] Glover, P. M., Cavin, C., Qian, W., Bowtell, R. and Gowland P. Magnetic-Field induced Vertigo: A Theoretical and Experimental Investigation. *Bioelectromagnetics* 28: 349 – 361, 2007

[149] Fuentes, M. A., Trakic, A., Wilson, S. J. and Crozier, S. Analysis and Measurements of Magnetic Field Exposures for Healthcare Workers in Selected MR environments. IEEE *Transactions on Biomedical Engineering*, Vol. 55, No. 4, p 1355, 2008

[150] MR Safey special issue, *JMRI*, Vol 26, 2007

[151] Protection of Patients and Volunteers Undergoing MRI procedures, 2008, publication by the Health Protection Agency, ISBN 978-0-85951-623-5, http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1222673275443?p=1199451989432

[152] MHRA Device Bulletin, *Safety guidelines for MRI equipment in clinical use*, 2007

[153] EC study on 4 hospital sites: *An investigation into occupational exposure of electromagnetic fields for personnel with and around medical MRI equipment*, 2008

[154] IEEE C95.6: *Standard for Safety Levels with Respect to Human Exposure to Electromagnetic Fields (0–3 kHz)*. New York: IEEE, 2002.

[155] Hoult, D.I. The Principle of Reciprocity in Signal Strength Calculations – A Mathematical Guide, Concepts. In *Magnetic Resonance*, Part A, Wiley Periodicals, Vol. 12, pp. 173-187, 2000.

[156] MRI Design Guide as published by the Department of Veterans Affairs. http://www.va.gov/facmgt/standard/dguide/mri/mri01.pdf

[157] Collins, C.M., Mao, W. Liu, W. , and Smith, M. B. *Calculated Local and Average SAR in Comparison with Regulatory Limits*.14th Scientific Meeting and Exhibition held in Seattle, WA USA, 6-12 May 2006., p 2044

[158] den Boer J, Atalar E, Szimtenings M, Kleihorst R, Engels H., ISMRM Safety Workshop, 2005.

[159] Nadobny, J., Brinker G., Diehl D., Stetter E., Szimtenings M. and Wust P. Evaluation of MR-induced hot spots for different temporal SAR modes using a time-dependent finite difference method with explicit temperature gradient treatment. *IEEE Trans Biomed Eng* 54 (10) Oct 2007, p 1837-1850

[160] Ellis, R.R. and Ellingson, R.J. Responses to electrical stimulation of the median nerve in the human newborn. *Developmental Psychobiology*, Volume 6 Issue 3, Pages 235 – 244, Published Online: 13 Oct 2004

[161] Shellock, F. G., Crues, J. V. Temperature, heart rate and blood pressure changes associated with clinical imaging at 1./5T. *Radiology*, 163, 1987, p 259 – 262.

[162] International Commission on Non-Ionizing Radiation Protection (ICNIRP), Guidelines on limits of exposure to static magnetic fields. *Health Physics*, 2009, Vol 96, Nr 4, p 504

[163] Hand, JF., Li, Y., Thomas, EL., Rutherford, MA. and Hajnal, JV. Prediction of Specific Absorption Rate in mother and fetus associated with MRI examinations during pregnancy. *Magnetic resonance in Medicine*, 2006, 55, p 883

[164] Wang, Z., Lin, JC., Mao, W., Liu, W., Smith, MB. and Collins, CM. SA and temperature: Simulations and comparison of regulatory limits for MRI. *Journal of magnetic resonance*, 2007, 26, p 437

[165] IEC 60364-7-710, *Electrical installations of buildings – Part 7-710: Requirements for special installations or locations – Medical locations*

[166] ISO 7010:2003, *Graphical symbols – Safety colours and safety signs – Safety signs used in workplaces and public areas*
Amendment 3 (2007)

Index of defined terms used in this particular standard

La presente Norma è stata compilata dal Comitato Elettrotecnico Italiano e beneficia del riconoscimento di cui alla legge 1° Marzo 1968, n. 186.
Editore CEI, Comitato Elettrotecnico Italiano, Milano – Stampa in proprio
Autorizzazione del Tribunale di Milano N. 4093 del 24 Luglio 1956
Responsabile: Ing. R. Bacci

Comitato Tecnico Elaboratore
CT 62-Apparecchiature elettriche per uso medico

Altre Norme di possibile interesse sull'argomento

CEI EN 60601-1 (CEI 62-5)
Apparecchi elettromedicali - Parte 1: Norme generali per la sicurezza

CEI EN 60601-1 (CEI 62-5)
Apparecchi elettromedicali - Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali

CEI EN 60601-1-2 (CEI 62-50)
Apparecchi elettromedicali - Parte 1: Prescrizioni generali per la sicurezza fondamentale e prestazioni essenziali - Norma collaterale: Compatibilità elettromagnetica - Prescrizioni e prove

CEI EN 60601-1-1 (CEI 62-51)
Apparecchi elettromedicali - Parte 1: Norme generali per la sicurezza - Norma Collaterale: Prescrizioni di sicurezza per i sistemi elettromedicali