

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-33: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à résonance magnétique utilisés pour le diagnostic médical



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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

This fourth edition cancels and replaces the third edition published in 2010, Amendment 1:2013 and Amendment 2:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) aligned with IEC 60601-1:2005 and its two amendments IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;
- b) addition of safety requirements for the EMERGENCY FIELD SHUT DOWN UNIT;
- c) clarification of acoustic protection measures for the PATIENT and MR WORKER;
- d) addition of noise emission declaration for exposure inside the MR EXAMINATION ROOM, to support occupational health assessment by the RESPONSIBLE ORGANIZATION;

- e) addition of compliance methods for thermal safety of RF coils;
- f) addition of RF transmit definitions to match MR CONDITIONAL labelling requirements for MEDICAL DEVICES;
- g) clarification of requirements for MR CONDITIONAL labelling of ACCESSORIES;
- h) alignment of static magnetic field limit for B_0 HAZARD area to limits in other MEDICAL DEVICE standards (especially that for pacemakers, ISO 14117), the new limit value being 0,9 mT;
- i) improved description of the magnetic field related plots in the Compatibility Technical Specification Sheet (CTSS);
- j) provision of compatibility sequences (in the CTSS) to test auxiliary equipment by the MR manufacturer has become optional, and is expected to be eliminated in a future edition;
- k) a separate section with requirements for a site-planning document containing safety information;
- l) requirements for the alerting function (PATIENT to OPERATOR);
- m) introduction of MROC as mandatory functionality for 1,5 T and 3 T systems to facilitate scanning of PATIENTS with MEDICAL DEVICES labelled as MR CONDITIONAL, unless such scanning is explicitly contra-indicated by the MR MANUFACTURER;
- n) RF coil symbols in Table 201.A.102 have become mandatory, and the preferred and alternate signs have been swapped relative to the previous edition, with preferred now being the sign with color;
- o) determination of the B_1 stray field in 201.12.4.105.3.3 based on calculations only.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62B/1277/FDIS	62B/1284/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at http://www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the eighteen 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "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 and IEC 80601 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch/?ref=menu in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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* INTRODUCTION

This International Standard addresses technical aspects of medical diagnostic MR EQUIPMENT and MR SYSTEMS, necessary to ensure the safety of PATIENTS, and to address electromagnetic field (EMF) exposure concerns for MR WORKERS involved with the operation, development, manufacturing, installation, and servicing of MR EQUIPMENT and MR SYSTEMS. Annex AA provides rationales for requirements and limit values including references to peer-reviewed publications used to establish the content of this document.

Exposure limits for PATIENTS and for MR WORKERS are selected to protect them from transient adverse health effects and from unacceptable RISK. In addition, scientific consensus today is that no experimental or theoretical basis exists to expect long-term adverse health effects in humans from (repeated) EMF exposures.

Organizational aspects related to safety of operating the MR EQUIPMENT are the task of the RESPONSIBLE ORGANIZATION. This task includes, but is not limited to:

- qualification of staff for decisions that are related to safety;
- adequate training of staff;
- definition of medical responsibility; including
 - rules for screening the PATIENT for contraindications or for conditions that can affect acceptable exposure;
 - rules for ROUTINE MONITORING, and for MEDICAL SUPERVISION of the PATIENT during the MR EXAMINATION;
 - rules for access to and oversight of the MR ENVIRONMENT, and for hearing protection;
- demarcating, maintaining and controlling access to the B_0 HAZARD AREA and the MR ENVIRONMENT, including
 - screening of any person entering this environment;
 - confirming that no materials or equipment entering this environment pose a HAZARD.
- emergency procedures for (rapid) removal of the PATIENT who is in the B_0 HAZARD AREA;
- emergency procedures related to a potential QUENCH of a superconductive magnet, when applicable;
- rules to minimize and to limit the exposure of MR workers to EMF;
- establishing and ensuring adequate preventive maintenance;
- evaluation and implementation of local regulations.

This fourth edition aligns with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and the associated updates of the collateral standards.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MAGNETIC RESONANCE (MR) EQUIPMENT and MAGNETIC RESONANCE (MR) SYSTEMS.

NOTE Where ME EQUIPMENT and ME SYSTEMS are used in the clause headings, this is to be understood to indicate MR EQUIPMENT and MR SYSTEMS.

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

If a clause or subclause is specifically intended to be applicable to MR EQUIPMENT only, or to MR 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 MR EQUIPMENT and to MR SYSTEMS, as relevant.

This document does not formulate additional specific requirements for MR EQUIPMENT or MR SYSTEMS used in INTERVENTIONAL MR EXAMINATIONS.

201.1.2 Object

Replacement:

The object of this document 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 document presumes that the MR WORKERS are screened, trained and instructed in their duties.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 applies as modified in Clause 202. IEC 60601-1-3 [1], IEC 60601-1-9 [2], IEC 60601-1-10 [3], IEC 60601-1-11 [4] and IEC 60601-1-12 [5] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Addition:

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, viz. IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document 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 document addresses the content of Clause 4 of the 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the 60601-1-8 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 in this document.

"Addition" means that the text of this document 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 document.

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 3.154, additional definitions in this document 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 document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this document, 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 document.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 130.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60695-11-10:2013, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2:2013, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 62570:2014, *Standard practice for marking devices and other items for safety in the magnetic resonance environment*

ISO 3746:2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Part 1: Measurement at discrete points*

NEMA MS 4, *Acoustic noise measurement procedure for diagnostic magnetic resonance equipment*

NEMA MS 8, *Characterization of the Specific Absorption Rate (SAR) for magnetic resonance imaging systems*

NEMA MS 14, *Characterization of radiofrequency (RF) coil heating in 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, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

NOTE An index of defined terms is found beginning on page 142.

Addition:

*** 201.3.201**

AMBIENT TEMPERATURE

temperature of the air flowing through the PATIENT environment

201.3.202

B_0 HAZARD AREA

space around the MR EQUIPMENT where the static magnetic field can cause HARM

Note 1 to entry: The B_0 HAZARD AREA is not identical to the SPECIAL ENVIRONMENT as defined in IEC 60601-1-2.

Note 2 to entry: The B_0 HAZARD AREA is not identical to the MR ENVIRONMENT as defined in IEC 62570.

*** 201.3.203**

B_1^+

component of the RF magnetic field in the rotating frame that is effective for tilting of the nuclear magnetization

Note 1 to entry: B_1^+ is derived from the flip angle estimated from the MR signal as detected from an adjustment volume, which is typically represented by an axial slab passing through MR ISOCENTRE.

Note 2 to entry: The spatially-localized amplitude of total B_1 , especially in the off-centre position, can exceed the (spatially averaged and local) VALUE of B_1^+ by up to an order of magnitude.

201.3.204

B_1^+ PEAK

maximum VALUE of B_1^+

*** 201.3.205**

B_1^+ RMS

root mean square (RMS) of B_1^+ , which represents the highest average VALUE for any 10 s period, evaluated over the duration of the sequence:

$$B_1^+ \text{ RMS} = \sqrt{\frac{\int_0^{t_x} (B_1^+(t))^2 dt}{t_x}}$$

where t is time, and t_x is the integration time

Note 1 to entry: When a sequence is shorter than 10 s, the integration time equals the sequence duration, unless sliding window continuous integration across sequences is used.

*** 201.3.206**

$|dB/dt|$ PEAK

maximum time rate of change of the magnitude of the magnetic field generated by the combined outputs of the GRADIENT UNITS during the MR EXAMINATION, evaluated at the COMPLIANCE VOLUME

201.3.207

CIRCULARLY POLARIZED DRIVE

CP

RF excitation where the two principal electromagnetic modes of a birdcage VOLUME RF TRANSMIT COIL are driven with equal amplitude and 90° phase difference

Note 1 to entry: CIRCULARLY POLARIZED DRIVE is also commonly referred to as "quadrature drive" or "circularly polarized" and can be used interchangeably.

Note 2 to entry: CP into a loaded coil does not necessarily result in the lowest possible counter-rotating B_1^- component.

Note 3 to entry: A coil operating in CP can additionally use a single mode, linearly-polarized excitation if the exposure is infrequent, short, and does not exceed 50 % power drive for CP.

Note 4 to entry: Transverse electromagnetic (TEM) coils can be characterized as CP by using additional qualification and controls.

201.3.208

CIRCULARLY POLARIZED RF

time-varying B_1 field, where the field vector describes a circular trajectory in a plane orthogonal to the static magnetic field vector

Note 1 to entry: The polarity of the magnet determines the direction in which the generated B_1 field rotates to generate MR signals (that is, the B_1^+ component).

Note 2 to entry: A small B_1^- component (rotating in the opposite direction) is unavoidable in real-world implementations of VOLUME RF TRANSMIT COILS when using CIRCULARLY POLARIZED DRIVE. The consequence is that the generated time-varying B_1 field vector deviates slightly from the ideal circular trajectory.

201.3.209

COMPLIANCE VOLUME

space in which compliance of GRADIENT OUTPUT is inspected

Note 1 to entry: In CYLINDRICAL MR EQUIPMENT with a WHOLE BODY MAGNET, the COMPLIANCE VOLUME is a cylinder with its axis coinciding with the PATIENT's axis and with a radius of 0,20 m and with a length equal to the length of the gradient coil.

Note 2 to entry: 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 radius of 0,20 m or equal to half the distance between the poles of the magnet, whichever is less.

Note 3 to entry: In all other MR SYSTEMS, 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.

* 201.3.210

CORE TEMPERATURE

temperature of the internal organs in the body and the aortic blood

* 201.3.211

CUMULATIVE EQUIVALENT MINUTES AT 43 °C

CEM43

duration of exposure at a constant temperature of 43 °C required to produce the magnitude of a thermally induced bio-effect, i.e., an "iso-effect", as is produced by an exposure of duration t_{exam} at a different temperature T that can vary in time; defined mathematically as:

$$CEM43 = \int_0^{t_{\text{exam}}} R^{k(43-T(\tau))} d\tau$$

where

k = $(1\text{ °C})^{-1}$, a constant to render the exponent dimensionless;

$T(\tau)$ = temperature in °C during time course τ of an MR EXAMINATION;

τ = time (in min);

t_{exam} = duration (in min) of the MR EXAMINATION, including the time after the last RF exposure, during which the temperature returns to physiological baseline;

R = exponential constant: 0,25 for $T < 43\text{ °C}$ and 0,5 for $T \geq 43\text{ °C}$.

Note 1 to entry: This definition has been adapted from THERMALLY EQUIVALENT TIME, as defined in IEC 60601-2-62 [160].

Note 2 to entry: Temperature can vary throughout the body.

Note 3 to entry: CEM43 has been used in hyperthermia treatments to predict cell death as the thermally-induced bio-effect, it is not a proven metric for thermal protection.

201.3.212

CYLINDRICAL MR EQUIPMENT

MR EQUIPMENT with a substantially cylindrical PATIENT aperture, and a static magnetic field aligned with the long axis of the cylinder

Note 1 to entry: This is inclusive of elliptical PATIENT aperture equipment.

201.3.213

DETACHABLE

term qualifying an ACCESSORY fastened or otherwise secured at a specific location, and/or requiring a FUNCTIONAL CONNECTION to ME EQUIPMENT during NORMAL USE, and which can be installed and removed by the OPERATOR without the use of a TOOL

EXAMPLE 1 A VOLUME RF TRANSMIT COIL can be FIXED (integrated in the system) or a DETACHABLE ACCESSORY.

EXAMPLE 2 The squeeze bulb which is part of the PATIENT alerting function is often a DETACHABLE ACCESSORY.

EXAMPLE 3 Sensors for cardiac or respiratory triggering involve either a wired or wireless interface, which can both qualify such devices as DETACHABLE ACCESSORIES.

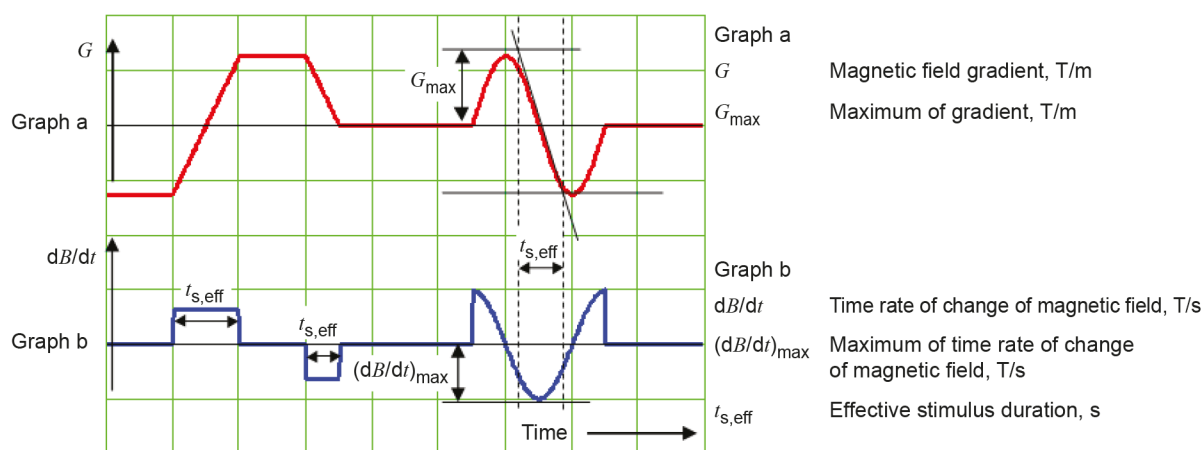
EXAMPLE 4 ACCESSORIES of other types of interfaces can qualify as DETACHABLE.

201.3.214

EFFECTIVE STIMULUS DURATION

$t_{s,eff}$

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



IEC

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

201.3.215

EMERGENCY FIELD SHUT DOWN UNIT

subsystem enabling fast removal of the magnetic field of a superconducting or resistive magnet in case of an emergency situation

201.3.216

FIRST LEVEL CONTROLLED OPERATING MODE

mode of operation of MR EQUIPMENT where MEDICAL SUPERVISION mitigates RISKS associated with biophysical effects induced by exposure to electromagnetic fields

Note 1 to entry: The electromagnetic fields essential to the operation of MR EQUIPMENT are the main magnetic field, the spatial encoding gradients, and RF. The operating mode for each field is independently assessed and reported.

Note 2 to entry: Indirect effects like displacement forces, acoustic noise, or interference with other MEDICAL DEVICES are not considered when identifying threshold exposure values.

201.3.217

GRADIENT OUTPUT

parameter characterizing the gradient performance 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

201.3.218

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

201.3.219

HEAD SAR

SAR averaged over the mass of the head

Note 1 to entry: The lower extent of the head is generally considered to be a line drawn from the foramen magnum anteriorly along the inferior border of the body of the mandible in closed mouth position.

*** 201.3.220**

INTERVENTIONAL MR EXAMINATION

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

201.3.221

LOCAL RF TRANSMIT COIL

RF transmit coil other than a VOLUME RF TRANSMIT COIL

201.3.222

LOCAL SAR

SAR averaged over any 10 g of tissue of the body

*** 201.3.223**

MAGNETIC RESONANCE

MR

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

201.3.224

MAGNETIC RESONANCE ENVIRONMENT

MR ENVIRONMENT

three-dimensional volume surrounding the MR magnet that contains both the SPECIAL ENVIRONMENT (Faraday shielded volume) and the B_0 HAZARD AREA

Note 1 to entry: This volume is the region in which an item might pose a HAZARD from exposure to the electromagnetic fields produced by the MR EQUIPMENT and ACCESSORIES, and for which access control is part of the RISK mitigation

Note 2 to entry: The entrance to the MR ENVIRONMENT is controlled by the RESPONSIBLE ORGANIZATION.

Note 3 to entry: The area to which entry is controlled is sometimes referred to as the MR controlled access area.

[SOURCE: IEC 62570:2014, 3.1.10, modified — Replacement of “0,50 mT field contour (5 gauss (G) line)” with “ B_0 HAZARD AREA”, and modification of the structure of the definition.]

201.3.225**MAGNETIC RESONANCE EQUIPMENT****MR EQUIPMENT**

MEDICAL ELECTRICAL EQUIPMENT for the MAGNETIC RESONANCE EXAMINATION of a PATIENT

Note 1 to entry: The MR EQUIPMENT is a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS).

201.3.226**MAGNETIC RESONANCE EXAMINATION****MR EXAMINATION**

PROCESS of acquiring data by MAGNETIC RESONANCE from a PATIENT

201.3.227**MAGNETIC RESONANCE EXAMINATION ROOM**

MR EXAMINATION ROOM

room where PATIENT undergoes an MR EXAMINATION

201.3.228**MAGNETIC RESONANCE ISOCENTRE**

MR ISOCENTRE

null point of the spatially encoding gradients

Note 1 to entry: Typically this also corresponds to the region of highest magnet homogeneity.

Note 2 to entry: Typically this corresponds with the position in the system targeted for imaging.

[SOURCE: IEC 62464-1:2018, 3.1.11, modified — Addition of “MAGNETIC RESONANCE” to the main term, and New Note 2 to entry.]

201.3.229**MAGNETIC RESONANCE SYSTEM**

MR SYSTEM

combination, as specified by the MR MANUFACTURER, of items of equipment, at least one of which is MR EQUIPMENT, to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

*** 201.3.230****MAGNETIC RESONANCE WORKER**

MR WORKER

person that because of their profession is trained concerning RISKS which can occur when entering the MR ENVIRONMENT

Note 1 to entry: MR volunteers and PATIENT's social companions are not covered by this definition.

201.3.231**MAXIMUM GRADIENT SLEW RATE**

rate of change of the gradient magnetic field by switching one GRADIENT UNIT between its maximum specified gradient strengths G_{+max} and G_{-max} in the shortest possible ramp time

*** 201.3.232****MEDICAL SUPERVISION**

ROUTINE MONITORING supplemented with medical management of PATIENTS who can be at elevated RISK from exposure to the MR EQUIPMENT

201.3.233

MR EQUIPMENT OUTPUT CONDITIONING

MROC

functionality allowing the OPERATOR to specify conditions to particular outputs for the MR EXAMINATION

Note 1 to entry: Such limits include those commonly specified in MR CONDITIONAL labelling.

201.3.234

MULTI CHANNEL-*N* DRIVE

MC-*N*

RF excitation where *N* independent waveforms are fed into a birdcage VOLUME RF TRANSMIT COIL with $N \geq 2$

Note 1 to entry: "*N*" to be replaced by the appropriate number, e.g. 2, 3, 4 etc.

Note 2 to entry: Transverse electromagnetic (TEM) coils can be characterized as MC-*N* by using additional qualification and controls.

Note 3 to entry: A VOLUME RF TRANSMIT COIL can have *M* additional feeds that derive their amplitudes and/or phases from the *N* independent waveforms. (*M* + *N* total feeds).

Note 4 to entry: A coil operating in MC-*N* can additionally provide CIRCULARLY POLARIZED RF and/or linearly polarized RF fields.

Note 5 to entry: Waveforms are classified as dependent if their amplitudes are identical and their phase difference is equal to the physical angular separation of the feed points. Independent waveforms can have an amplitude and phase relationship that varies with time during any RF pulse.

201.3.235

NORMAL OPERATING MODE

mode of operation of MR EQUIPMENT where the biophysical effect induced by a specific electromagnetic field typically presents negligible RISK

Note 1 to entry: The electromagnetic fields essential to the operation of MR EQUIPMENT are the main magnetic field, the spatial encoding gradients, and RF. The operating mode for each field is independently assessed and reported.

Note 2 to entry: Indirect effects like displacement forces, acoustic noise, or interference with other MEDICAL DEVICES are not considered when identifying threshold exposure values.

201.3.236

OTHER POLARIZATION

OP

RF excitation that does not qualify as either CP, or MC-*N*

Note 1 to entry: Operations using any RF transmit coil are OP unless they meet CP or MC-*N* compliance requirements, since this document connects CP and MC-*N* explicitly to birdcage VOLUME RF TRANSMIT COILS.

*** 201.3.237**

PARTIAL BODY SAR

SAR averaged over the region of the body that receives 95 % of the deposited RF power

201.3.238

PERIPHERAL NERVE STIMULATION THRESHOLD LEVEL

PNS THRESHOLD LEVEL

VALUE of the GRADIENT OUTPUT related to the onset of PNS sensation for the PATIENT

*** 201.3.239**

QUENCH

decay of the magnetic field resulting from the loss of super-conductivity, the associated rapid conversion of fluid cryogen to cryogenic gas and possible escape of gas into the environment

201.3.240**ROUTINE MONITORING**

monitoring the PATIENT during the MR EXAMINATION by qualified staff using visual and audio techniques

201.3.241**SEARCH COIL**

small diameter coil used in a compliance test to measure B_1^+ or GRADIENT OUTPUT

201.3.242**SECOND LEVEL CONTROLLED OPERATING MODE**

mode of operation of the MR EQUIPMENT for which the RESPONSIBLE ORGANIZATION defines RISK acceptability as part of a human studies protocol, and where MEDICAL SUPERVISION is implemented to mitigate such RISKS

Note 1 to entry: The operating mode controls the thresholds for RISKS associated with electromagnetic fields essential to the operation of MR EQUIPMENT, viz. the main magnetic field, the spatial encoding gradients, and RF. The operating mode for each field is independently assessed and reported.

Note 2 to entry: Significant RISK in this mode can also relate to indirect effects like displacement forces, acoustic noise, heating of RF coil surfaces and cables, or interference with other MEDICAL DEVICES.

*** 201.3.243****SPATIAL FIELD GRADIENT**

SFG

spatial rate of change of the main magnetic field $\left| \nabla |\vec{B}_0| \right|$

Note 1 to entry: Attractive magnetic forces on magnetisable or saturated ferromagnetic objects scale linearly with SFG.

201.3.244**SPECIFIC ABSORPTION**

SA

RADIO-FREQUENCY energy absorbed per unit of mass, calculated from WHOLE BODY SAR.

Note 1 to entry: SA is also known as SED (specific energy dose) or SAE (specific absorbed energy). Transition to the exclusive use of SA is recommended.

Note 2 to entry: Use of SA associated with other SAR types as used in Table 201.104 is not recommended.

Note 3 to entry: The use of the units [W·min/kg] and [kJ/kg] is acceptable. Providing the conversion factor and/or the quantities in both units can be appropriate.

*** 201.3.245****SPECIFIC ABSORPTION RATE**

SAR

RADIO-FREQUENCY power absorbed per unit of mass

201.3.246**TIME RATE OF CHANGE OF THE MAGNETIC FIELD**

dB/dt

time rate of change of the magnitude of the magnetic field

Note 1 to entry: The dB/dt generated by the GRADIENT UNITS is assumed to be evaluated in a suitably low frequency range (e.g. < 5 kHz) to disregard effects of switching amplifier ripple.

Note 2 to entry: Motion in the static magnetic field also causes dB/dt .

201.3.247**TRANSVERSE FIELD MAGNET**

magnet for which the static magnetic field is at right angles to the long axis of the PATIENT's anatomy being imaged

*** 201.3.248**

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 1 to entry: A VOLUME RF TRANSMIT COIL is typically a WHOLE BODY RF TRANSMIT COIL, or an RF TRANSMIT COIL designed for homogeneous exposure of a specific part of the body.

201.3.249

WHOLE BODY GRADIENT SYSTEM

gradient system of sufficient size to perform an MR EXAMINATION on the torso of adult PATIENTS

201.3.250

WHOLE BODY MAGNET

magnet of sufficient size to perform an MR EXAMINATION on the torso of adult PATIENTS

201.3.251

WHOLE BODY RF TRANSMIT COIL

VOLUME RF TRANSMIT COIL of sufficient size to perform an MR EXAMINATION on the torso of adult PATIENTS

201.3.252

WHOLE BODY SAR

SAR averaged over the total mass of the body

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

NOTE For the functions of the MR EQUIPMENT covered by this document, no specific ESSENTIAL PERFORMANCE requirements have been identified. Other functions of the MR EQUIPMENT can constitute ESSENTIAL PERFORMANCE. See IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 for requirements to the RISK MANAGEMENT FILE of the MANUFACTURER to cover the analysis of ESSENTIAL PERFORMANCE of the MR EQUIPMENT.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.5.7 Humidity preconditioning treatment

Replacement of the first paragraph:

MR EQUIPMENT for which the MR MANUFACTURER does not specify environmental control conditions shall be subjected to a humidity preconditioning treatment prior to the tests of 8.7.4 and 8.8.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

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

201.7.2.2 Identification

Addition:

The USER INTERFACE shall provide an "About function" for the MR EQUIPMENT.

The "About function" shall display

- model name of the MR EQUIPMENT,
- NOMINAL B_0 VALUE, and
- software version.

The "About function" shall also display, or provide direct access to the specific location containing, the following information:

- maximum SFG of the static magnetic field [T/m] outside the FIXED magnet covers;
NOTE 1 Historical labelling practice for MR CONDITIONAL items uses G/cm where 1 T/m is equivalent to 100 G/cm. Providing the conversion factor and/or the quantities in both units can be appropriate.
- maximum spatial encoding gradient amplitude [mT/m] and MAXIMUM GRADIENT SLEW RATE [T/m/s], clarifying to the OPERATOR that this is specified on a per axis basis;
- NOMINAL frequency range per nuclei;
- maximum GRADIENT OUTPUT as unweighted combination of all GRADIENT UNITS, in the COMPLIANCE VOLUME.

NOTE 2 A direct link or reference to the CTSS can be provided in the "About function".

201.7.2.4 ACCESSORIES

Addition:

ACCESSORIES provided by the MANUFACTURER of MR EQUIPMENT for use inside the MR ENVIRONMENT shall be marked in accordance with IEC 62570, except for those ACCESSORIES designed with an exclusive mating connection to the MR EQUIPMENT.

NOTE 1 An exclusive mating connection is generally used for RF coils with any of the following: mechanical keying, analog or digital identification. Additional devices such as a PATIENT alerting device, physiology sensing devices, or a communication headset, often also implement such exclusive interfaces.

NOTE 2 Marking ACCESSORIES such as PATIENT positioning aids in accordance with IEC 62570 can help to prevent use of non-marked widely-available commercial equivalents which can actually be MR UNSAFE e.g. cushions with internal ferromagnetic springs.

DETACHABLE RF coils shall be marked with (NOMINAL) B_0 field strength.

DETACHABLE RF coils shall be marked with symbols provided in Table 201.A.102.

201.7.2.13 Physiological effects (SAFETY SIGNS and warning statements)

Addition:

SAFETY SIGN ISO 7010-W005 (2011-05) (see Table 201.A.101, SAFETY SIGN 1) shall be placed at the entrance of the SPECIAL ENVIRONMENT, if such environment is implemented to comply with IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020.

For MR EQUIPMENT that generates a stray field exceeding 0,9 mT outside its FIXED magnet cover, SAFETY SIGN ISO 7010-W006 (2011-05) (see Table 201.A.101, SAFETY SIGN 2) shall be placed at the entrance of the MR ENVIRONMENT.

For MR EQUIPMENT that requires hearing protection for PATIENTS or MR WORKERS, SAFETY SIGN ISO 7010-M003 (2011-05) (see Table 201.A.101, SAFETY SIGN 7) shall be placed at the entrance of the MR EXAMINATION ROOM.

For MR EQUIPMENT that requires cryogen refill, SAFETY SIGNS ISO 7010-M004 (2011-05) (see Table 201.A.101, SAFETY SIGN 8) and ISO 7010-M009 (2011-05) (see Table 201.A.101, SAFETY SIGN 9) should be placed near the location where the cryogen refill is performed.

The SAFETY SIGNS may be accompanied by text explaining that the static magnetic field is always on, but that EMF and acoustic noise emission is restricted to the situation when the MR EQUIPMENT is scanning.

For MR EQUIPMENT that does not require the implementation of a designated MR ENVIRONMENT, the need for and location of the SAFETY SIGNS shall be described in the RISK MANAGEMENT FILE by the MANUFACTURER.

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

* 201.7.4.3 Units of measurement

Addition:

Table 201.101 provides additional quantities and non-SI units that are acceptable for use on MR EQUIPMENT.

Table 201.101 – Units outside the SI units system that may be used on MR EQUIPMENT

Base quantity	Unit	
	Name	Symbol
SPECIFIC ABSORPTION (SA)	Watt minutes per kilogram NOTE 1 1 Wmin/kg corresponds to 0,060 kJ/kg	W·min/kg
SPATIAL FIELD GRADIENT (SFG)	gauss per centimetre NOTE 2 1 G/cm corresponds to 0,01 T/m	G/cm
thermal iso-effect on tissue	CUMULATIVE EQUIVALENT MINUTES AT 43 °C	CEM43

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.

The ACCOMPANYING DOCUMENTS shall recommend that training covers as appropriate the following special skills and knowledge for the intended OPERATOR:

- Emergency procedures as established by the RESPONSIBLE ORGANIZATION, see 201.7.9.2.101 c);
- Understanding RISKS related to the operation of MR EQUIPMENT, and consider as appropriate
 - attractive forces and torque;
 - use of cryogens;
 - heating and burns;
 - peripheral nerve stimulation;
 - acoustic noise;
 - interactions with other items used in the MR EXAMINATION ROOM.

201.7.9.2 Instructions for use

201.7.9.2.6 Installation

Addition:

Advance guidance for installation and site construction should be provided by the MR MANUFACTURER. See 201.7.101.

NOTE The instructions for use for PERMANENTLY INSTALLED MR EQUIPMENT do not need to reference this information.

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.

NOTE 1 These lists can be identified in groups.

The list shall include an explanation of safety-related messages including important causes, and possible action(s) by the OPERATOR, if any, that are available to resolve the situation indicated by the message.

NOTE 2 Requirements and guidelines for messages generated by an ALARM SYSTEM can be found in IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2005/AMD2:2020.

201.7.9.2.11 Shutdown procedure

Addition:

EMERGENCY FIELD SHUT DOWN

The instructions for use shall describe a method to resolve potential entrapment of subjects or equipment due to magnetic attraction. For superconductive and resistive magnets, the layout and method of operation of the EMERGENCY FIELD SHUT DOWN UNIT shall be described, including an explanation when and how it should be operated in the event of an emergency. Examples of situations which would require EMERGENCY FIELD SHUT DOWN shall be provided, and reference to the consequence of a QUENCH event shall be made, if applicable.

NOTE The magnetic field of permanent magnets cannot be removed in case of emergency.

201.7.9.2.13 * Maintenance

Addition:

The instructions for use for MR EQUIPMENT with a QUENCH pipe shall:

- explain that the RESPONSIBLE ORGANIZATION is responsible for periodic preventive maintenance and inspection;
- state the need for preventive maintenance and inspection to include the magnet's liquid cryogen level, and the adequacy of the venting system, inside and outside the MR EXAMINATION ROOM, and room over-pressure release measures;
- specify the recommended maintenance and inspection after the occurrence of a QUENCH.

The instructions for use for MR EQUIPMENT shall specify the recommended maintenance and inspection after events that would impact the physical or electrical integrity of the MR EQUIPMENT.

NOTE Examples of such events are earthquake, tornado, fire, flooding.

201.7.9.2.17 ME EQUIPMENT emitting radiation

Addition:

NOTE 1 The instructions for use in 201.7.9.2.101 and the technical description in 201.7.9.3.101 provide detailed information concerning electromagnetic fields of the MR EQUIPMENT.

* a) Operating modes and MROC

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 disclose the operating mode with respect to the static magnetic field strength.

The instructions for use shall explain that the GRADIENT OUTPUT and SAR limits for PATIENTS are based on current scientific literature related to safety, and that medical assessment as to the PATIENT's potential RISK versus benefit provides the basis for the decision to operate above the NORMAL OPERATING MODE and to provide MEDICAL SUPERVISION.

Instructions for use shall explain the requirements related to operating modes both for SAR and GRADIENT OUTPUT:

- For MR EQUIPMENT operating within the NORMAL OPERATING MODE, the use of this mode is displayed, see 201.12.4.101.2 d).

- For MR EQUIPMENT capable of operation in FIRST LEVEL CONTROLLED OPERATING MODE, a deliberate action is necessary in order to enter this mode, as required in 201.12.4.101.4, and the use of this mode is displayed for SAR and GRADIENT OUTPUT.
- For MR EQUIPMENT capable of operating within the SECOND LEVEL CONTROLLED OPERATING MODE, a description shall be provided of the dedicated security measures 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 shall only be permitted under a human or animal 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, which includes in-person evaluation of the PATIENT, 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.

The instructions for use shall also explain that the GRADIENT OUTPUT and SAR may be additionally constrained by MROC, as defined in 201.12.4.106, independent of the operating mode.

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

For MR EQUIPMENT that is capable of operation above NORMAL OPERATING MODE for static magnetic field, the instructions for use shall:

- explain the possible effects that PATIENTS and MR WORKERS can experience, paying particular attention to the effects that can be experienced when moving the PATIENT's or the MR WORKER'S head while inside or close to the MR EQUIPMENT. These effects include vertigo, nausea and a metallic taste in the mouth;
- recommend that the PATIENT remains still while in the region of high static magnetic field;
- explain that when the NOMINAL static magnetic field is higher than 3 T and not exceeding 8 T, the MR EQUIPMENT is continuously operating in the FIRST LEVEL CONTROLLED OPERATING MODE;
- explain that adequate training shall be given to MR WORKERS to minimise adverse health effects arising from the high static magnetic field, which includes advice to limit the speed of motion;
- explain that when the NOMINAL static magnetic field is higher than 8 T, the MR EQUIPMENT is continuously operating in the SECOND LEVEL CONTROLLED OPERATING MODE. See 201.7.9.2.101 b) for related requirements.

NOTE 2 NOMINAL is to be understood as the VALUE at MR ISOCENTRE, see also 201.7.9.3.101 b).

c) Exposure of the PATIENT to GRADIENT OUTPUT

The instructions for use shall:

- explain the possible effects on the PATIENTS of the level of GRADIENT OUTPUT, paying particular attention to possible effects on the peripheral nervous system;
- explain that the MR EQUIPMENT will display an indication of the operating mode for GRADIENT OUTPUT;
- describe the MR EQUIPMENT as equipped with a WHOLE BODY GRADIENT SYSTEM and/or as using other gradient coils.

d) Exposure of the PATIENT to RADIO FREQUENCY fields

The instructions for use shall draw attention to RISK factors, which can increase the potential for local excessive RF heating of the PATIENT.

The instructions for use shall provide guidance to mitigate these RISK factors.

Such guidance should include sketches for PATIENT and ACCESSORY positioning scenarios and should consider the relative location of PATIENT and RF transmit coil.

The RISK factors shall include as appropriate the following:

- the presence of electrically-conductive (such as metallic or carbon-fiber based) objects or MEDICAL DEVICES within the sensitivity region of the RF transmit coil. All electrically-conductive objects such as watches, coins, etc. and any clothing containing electrically-conductive thread or components shall be removed from the PATIENT and substituted with gowns and other protective equipment confirmed free of electrically-conductive material;
- the use of medicinal products in (electrically-conductive) transdermal patches which can cause burns to the underlying skin;
- the presence of damp clothing, towels or blankets;
- 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, both inside and outside the RF transmit coil;

NOTE 3 Such contacts can (also) occur outside the RF coil, e.g. as clasped hands in prone breast imaging positioning or touching calves for L-spine imaging, and can be prevented by appropriate use of padding.

- the placement of the body or limbs against or in close proximity to the RF transmit coil surface along the length of the coil;

NOTE 4 Such placement can be prevented by appropriate use of padding.

NOTE 5 The length of a FIXED VOLUME RF TRANSMIT COIL can be found in the CTSS.

- the contact between PATIENT and an RF coil cable, and the routing of the RF coil cable in proximity to the RF transmit coil;

NOTE 6 Such contacts can be prevented by appropriate use of padding.

- the formation of loops with RF coil cables and non-high impedance cables for detection of ECG, pulse oximetry, or other monitoring equipment;
- the use of MR CONDITIONAL ECG electrodes and leads, for which the OPERATOR shall be instructed to read and carefully follow the instructions for use and 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 RF coils.

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, paying particular attention to the safety of PATIENTS who can have reduced thermoregulatory capabilities and increased sensitivity to raised body temperature (e.g. febrile and cardiac decompensated PATIENTS, those with compromised ability to perspire, and pregnant women);
- provide information describing the importance of environmental controls and the effect of AMBIENT TEMPERATURE on PATIENT CORE TEMPERATURE rise, along with recommendations for environmental conditions for the PATIENT;
- explain that the limits for WHOLE BODY SAR given in 201.12.4.103.2 assume that the MR EQUIPMENT is operated in the temperature range for the MR EXAMINATION ROOM as specified by the MR MANUFACTURER;
- 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 MR EQUIPMENT will display an indication of the operating mode for SAR.

- provide information on SA to enable the OPERATOR to manage additional heat stress to the PATIENT or potential PATIENT thermal injury;
- explain that the VALUE of the B_1^+ RMS displayed on the CONTROL PANEL for each sequence is an indication of the RF magnetic field intensity, representing the highest average VALUE for any 10 s period of the sequence. It can be of use to determine the RISK of scanning a PATIENT with an active or passive MEDICAL DEVICE.

e) Scanning of febrile PATIENTS

The instructions for use shall explain that FIRST LEVEL CONTROLLED OPERATING MODE with respect to WHOLE BODY SAR should not be used for febrile PATIENTS, and total SA should be limited.

The instructions for use shall recommend to provide MEDICAL SUPERVISION for febrile PATIENTS.

* f) Occupational exposure to EMF

The instructions for use shall draw attention to the fact that MR WORKERS, when operating the MR EQUIPMENT according to its INTENDED USE, can be exposed to the electromagnetic fields (EMF) emitted by the MR EQUIPMENT, and that requirements of 201.7.9.2.17 c) and d) can also be relevant to protect the MR WORKER.

The instructions for use shall draw attention to the following RISK factors for the MR WORKER:

- possible physiological effects of exposure to RF is heating. Exposure to RF can be minimized by keeping sufficient distance away from the transmit RF coil or by reducing time of exposure during scanning;
- possible physiological effects of exposure to the GRADIENT OUTPUT is PNS. Especially MR WORKERS performing their duties near or inside the magnet, shall be informed and trained that occurrence of PNS is unlikely. If PNS is experienced by the MR WORKER, exposure to GRADIENT OUTPUT can be minimized by keeping sufficient distance away from the gradient coils during scanning. The SAFETY of PATIENTS shall not be compromised due to PNS of the MR WORKER;
- possible physiological effects of exposure to static magnetic field are dizziness, vertigo, and a metallic taste in the mouth. These acute symptoms quickly stop away from the magnet and can be less when avoiding rapid movements of the head while in the static magnetic field.

The instructions for use shall provide sufficient information relating to the RISKS from EMF exposures to enable safe working procedures for the MR WORKER:

- 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 201.7.9.2.17 b), and 201.12.4.104), the GRADIENT OUTPUT (see subclause 201.7.9.2.17 c), and 201.12.4.102) and the RF transmit field (see subclause 201.7.9.2.17 d), 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 MR WORKER when exposed to the gradients when operated above NORMAL OPERATING MODE;
- the fact that implants, and wearable or external devices and items, such as insulin pumps, physiology monitoring rings, watches, etc., can increase RISK.

The instructions for use can 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, for the pregnant MR WORKER,

- while no currently available epidemiological evidence demonstrates negative health effects to the foetus from occupational exposure within the MR ENVIRONMENT, extra precaution is recommended to avoid exposure to GRADIENT OUTPUT and RADIO FREQUENCY electromagnetic fields and acoustic noise levels during scanning;
- local regulations and guidance can impose stricter limits;
- the RESPONSIBLE ORGANIZATION shall be instructed to establish compliance with local regulations and guidance, which might include that 'member of the public' limits apply to the foetus. This can imply that the pregnant MR WORKER is not allowed to be present in the MR EXAMINATION ROOM during scanning.

The instructions for use shall state that in some countries, legislation can impose occupational limits for exposure to EMF, that are lower than the limits for MR WORKER given in this document.

Additional subclause:

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

*** a) Screening of individuals entering the MR ENVIRONMENT**

Instructions for use shall provide clear recommendations to the RESPONSIBLE ORGANIZATION regarding screening of PATIENTS, MR volunteers, social companions, MR WORKERS, and anyone entering the MR ENVIRONMENT. This specifically applies to anyone who could be placed at RISK due to their (past) 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 screening programme to identify anyone at RISK and shall provide recommendations to adequately protect such individuals from injury.

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 201.3.216, 201.3.235 and 201.3.242.

Instructions for use shall state that:

- all PATIENTS shall receive at least ROUTINE MONITORING;
- if the MR EQUIPMENT is capable of operating within the FIRST LEVEL CONTROLLED OPERATING MODE, procedures shall be established by the RESPONSIBLE ORGANIZATION 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:
 - clarify the notification required by 201.12.4.101.5 d) as follows:
MEDICAL SUPERVISION and approval of investigational human studies protocol according to local requirements (e.g. ethics committee, investigational review board, oversight by the RESPONSIBLE ORGANIZATION, etc.) is required for such operation, where the local approval shall also specifically state study-specific limits for GRADIENT OUTPUT, SAR, static magnetic field strength, acoustic exposure, and thermal exposure.
 - clarify that the RESPONSIBLE ORGANIZATION is solely responsible to perform all testing (e.g. thermal and acoustic) necessary to ensure safety for the use of the MR EQUIPMENT, including RF coils and other ACCESSORIES, at higher duty cycles and thresholds for RF and gradients enabled by SECOND LEVEL CONTROLLED OPERATING MODE.

* c) Emergency medical procedures

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

These instructions shall include recommendations to establish a procedure and free pathway for removing PATIENTS rapidly from the MR EXAMINATION ROOM or, if necessary, by using the EMERGENCY FIELD SHUT DOWN UNIT.

* d) Exposure to excessive acoustic energy (noise)

For MR EQUIPMENT that is capable of producing an A-weighted RMS sound pressure level ($L_{Aeq,1h}$) higher than 99 dB(A), the instructions for use shall explain that:

- MR scanning is usually associated with substantial acoustic noise emission;
- persons present in the MR EXAMINATION ROOM during MR scanning shall wear adequate hearing protection;

NOTE 1 See 201.9.6.2.1.101 to determine the appropriate level of hearing protection.

- the provided value for the minimum appropriate RATED hearing protection VALUE is required to reduce the A-weighted RMS sound pressure level $L_{Aeq,1h}$ to ≤ 99 dB(A);

NOTE 2 This specified RATED hearing protection VALUE can be used by the RESPONSIBLE ORGANIZATION to select appropriate means of hearing protection, and is usually specified as NRR, SNR or SLC80. The sum of the specified hearing protection VALUE and the 99 dB(A) limit will generally overestimate the actual emitted noise levels of the MR EQUIPMENT.

- there can be a RISK of temporary or permanent hearing impairment to any person present in the MR EXAMINATION ROOM during MR scanning if adequate hearing protection is not used;
- acceptable sound pressure levels for most individuals can be too high for sensitive individuals (e.g. those suffering from tinnitus, or under certain drug regimes, unconscious, newborns, young children and elderly), and additional hearing protection or other precautions can help reduce the sound pressure levels in such sensitive individuals;
- the RESPONSIBLE ORGANIZATION shall establish a hearing protection program to protect the MR WORKER in compliance with local regulations;
- the RESPONSIBLE ORGANIZATION shall establish dedicated training for the OPERATOR to ensure proper application of hearing protection on the PATIENT, especially when ear muffs cannot be applied, such as for neonates and premature infants or when there is a space restriction (e.g. head coil, stereotactic frame, radiation therapy immobilizers);

NOTE 3 Proper application includes but is not limited to proper fit and positioning, selection of size and shape of ear plugs, and consideration of ear canal size and shape.

- use of dual-hearing protection (e.g. in-ear and over-ear) can help mitigate damping loss in case of poor fit. Protection levels (as found on the label) for the two means of protection cannot be added. The second means of protection can account for an additional 5 dB(A) protection to the first and presumed superior primary means of protection.

NOTE 4 For example, if the earplugs are RATED at 25 dB and the earmuffs at 20 dB, the achieved level of protection is $25 + 5 = 30$ dB, assuming both protections are properly applied.

* e) Controlling access to the B_0 HAZARD AREA and MR ENVIRONMENT

When demarcation of a MR ENVIRONMENT is required for the MR EQUIPMENT (see 201.7.9.3.101 a) and Clause 202), the instructions for use shall:

- state that the RESPONSIBLE ORGANIZATION shall manage access to the MR ENVIRONMENT;
- indicate the need to establish adequate rules for controlling access to the B_0 HAZARD AREA in terms of the potential RISK to PATIENTS, MR WORKERS and other individuals from
 - attraction or torque of objects containing ferromagnetic materials;
 - potential dysfunction of MEDICAL DEVICES such as pacemakers due to interaction with the static magnetic field;

NOTE 5 For static magnetic field strengths less than 0,9 mT beyond the covers, no administrative or engineering controls are required.

- list equipment and TOOLS specified or recommended by the MANUFACTURER for use in the B_0 HAZARD 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. Possible changes in special measures and precautions as a function of the VALUE of the static magnetic field shall be explained;
- state that third-party equipment, including PATIENT monitoring, life supporting devices and emergency care equipment, which is not specified or recommended for use in the MR ENVIRONMENT, can be disturbed by the EMF associated with the use of the MR EQUIPMENT and that this third-party equipment can also disturb the proper functioning of the MR EQUIPMENT;
- explain the meaning of MR SAFE, MR CONDITIONAL and MR UNSAFE.

* f) Liquid and gaseous cryogens

For MR EQUIPMENT equipped with superconducting magnets for which cryogenic liquid refill is appropriate and cryogenic gas boil-off into the environment can occur, instructions for use shall, in order to mitigate accidents and a QUENCH event:

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

NOTE 6 Liquid oxygen can accumulate, or the gaseous oxygen concentration can become high in the vicinity of the cryogen.

* g) Emergency actions in case of a QUENCH

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

The instructions for use shall require the RESPONSIBLE ORGANIZATION to establish an adequate emergency plan.

h) 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 state that the RESPONSIBLE ORGANIZATION shall take appropriate initiatives.

* i) Third-party equipment and third-party ACCESSORIES

Instructions for use shall instruct the RESPONSIBLE ORGANIZATION and the OPERATOR to:

- establish that third-party equipment and third-party ACCESSORIES can be used safely in the MR ENVIRONMENT;

NOTE 7 This verdict can be based on a compatibility declaration from the MR MANUFACTURER or the third-party MANUFACTURER, or through consulting the MANUFACTURERS. Compatibility declarations cover both safety and performance, whereas declaration of MR CONDITIONAL is restricted to avoiding potential HAZARDS. 'Compatibility' relates to its definition in EU 2017/745 [7].

- consider the label and instructions for use of items and devices labelled as MR CONDITIONAL.

j) Artefacts

The instructions for use shall draw the OPERATOR'S attention to the fact that certain image artefacts can occur. Such 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, electromagnetic interference, magnetic susceptibility, or spurious proton signals from third-party equipment and third-party ACCESSORIES, etc.) on the image shall be described.

Methods of correcting or mitigating such effects on image quality (e.g. changing bandwidth, gradient moment nulling, pre-saturation, etc.) shall also be discussed.

* k) Scanning of PATIENTS with active or passive MEDICAL DEVICES

The instructions for use shall declare that MR scanning is contra-indicated for PATIENTS with active or passive MEDICAL DEVICES, the exception being PATIENTS with MEDICAL DEVICES declared as MR SAFE or MR CONDITIONAL, that can be scanned according to the conditions specified in the labelling of such MEDICAL DEVICES.

The instructions for use shall describe the significant RISKS associated with the scanning of PATIENTS with MEDICAL DEVICES that are not labelled MR SAFE or MR CONDITIONAL, or not adhering to the instructions on the label, in which cases:

- the electromagnetic fields can exert strong forces on such a MEDICAL DEVICE;
- the electromagnetic fields can interfere with the operation of an active MEDICAL DEVICE;
- such a MEDICAL DEVICE can cause significant artefacts in the MR image;
- MR scanning when a MEDICAL DEVICE is present can cause HARM such as internal heating that can result in tissue damage, loss of physiologic function and serious injury.

The instructions for use shall also address the following related to MR scanning of PATIENTS with MEDICAL DEVICES declared as MR CONDITIONAL:

- the MR scan should only be conducted based on the result of a RISK versus benefit assessment by the RESPONSIBLE ORGANIZATION;
- the OPERATOR shall adhere to the conditions of use defined in the MR CONDITIONAL labelling as described in the ACCOMPANYING DOCUMENTS supplied by the MANUFACTURER of such MEDICAL DEVICES.

The instructions for use shall include a statement to explain the roles and responsibilities of the MR MANUFACTURER, of the MANUFACTURER of MEDICAL DEVICES declared as MR SAFE or MR CONDITIONAL, and of the OPERATOR in scanning of PATIENTS with MEDICAL DEVICES declared as MR SAFE or MR CONDITIONAL.

NOTE 8 Sample text for such a statement is provided in Annex AA.

The instructions for use shall include a description of MROC functionality, as defined in 201.12.4.106, if implemented.

MROC description shall cover the following options, if implemented:

- other parameters to control system outputs;
- allowable range for controllable parameters, both mandatory (Table 201.107) and optional;
- optional functionality enabling control of multiple control-parameter configurations as a function of anatomical scanning position.

* l) Scanning of pregnant PATIENTS

The instructions for use shall describe that:

- scanning of pregnant PATIENTS should be limited to the NORMAL OPERATING MODE with respect to WHOLE BODY SAR;
- indications exist that the embryo is especially sensitive to potential thermal events during the first trimester.
- using pads can help isolating the woman and the fetus from vibrational coupling to the MR EQUIPMENT.

m) About function

The instructions for use shall specify where in the USER INTERFACE the "About function" of the MR EQUIPMENT can be found.

n) Physiology sensing functions

If the MR EQUIPMENT provides functionality to synchronize the imaging PROCESS to physiology (breathing and cardiac pulse), the ACCOMPANYING DOCUMENTS shall state that these signals are not intended for vital signs monitoring, unless otherwise indicated.

Particular attention shall be drawn to the fact that display of physiology signals is only intended as feedback on scan efficiency and does not provide information concerning PATIENT health.

NOTE 9 Requirements from particular standards concerning physiology signal detection and vital signs monitoring do not apply when physiology signals are only used for scan synchronization purposes.

NOTE 10 Loss of synchronization functionality does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

o) System used by the PATIENT to alert the OPERATOR

The instructions for use shall:

- inform the OPERATOR to check each PATIENT's ability to properly operate the system used by the PATIENT to alert the OPERATOR; and
- specify the method and frequency with which the OPERATOR shall check the proper functioning of the PATIENT alert system.

201.7.9.3 Technical description

201.7.9.3.1 General

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

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

Additional subclauses:

201.7.9.3.101 Technical description of MR EQUIPMENT

a) MR ENVIRONMENT, B_0 HAZARD AREA and SPECIAL ENVIRONMENT

For MR EQUIPMENT that generates a stray field exceeding 0,9 mT outside its FIXED magnet cover, the technical description shall indicate:

- the extent of the B_0 HAZARD AREA around the MR EQUIPMENT such that outside this area, the static magnetic fringe field strength shall not exceed 0,9 mT;
- how the B_0 HAZARD AREA may 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;
- that the MR ENVIRONMENT shall be labelled at all entries by appropriate warning signs, including an indication of the presence of static magnetic fields and their attractive force or the torque on ferromagnetic materials (see Annex A for examples of warning signs and prohibition signs).

For those parts of the MR EQUIPMENT that require installation in a SPECIAL ENVIRONMENT to ensure compliance with IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, the technical description shall describe the need for adequate RF shielding, including the presence of an RF door switch and interlock mechanism preventing undue RF emissions and ensuring RF IMMUNITY.

NOTE 1 See also 202.5.2.2.2.

* b) Compatibility technical specification sheet (CTSS)

In addition to the instructions for use for MR EQUIPMENT, a CTSS shall be provided to the RESPONSIBLE ORGANIZATION characterising the fully-installed MR EQUIPMENT, including potential variable operating conditions (e.g. B_0 strength). This information can be helpful when installing and/or evaluating the proper operation of MEDICAL DEVICES and third-party equipment, and to assess exposure to electromagnetic fields for the PATIENT and the MR WORKER.

The CTSS shall include:

- Magnet:
 - Type, which shall be selected from the following terminology:
 - Static Magnetic Field (B_0) Orientation, one of the following defined expressions:
 - “Horizontal, cylindrical bore”;
 - “Perpendicular to PATIENT’S long axis”;
 - “Other”;

NOTE 2 Cylindrical bore magnet geometries can have an elliptical PATIENT aperture.

NOTE 3 Typical non-cylindrical magnet geometries (commonly referred to as open) are known in this document as TRANSVERSE FIELD MAGNET.

NOTE 4 Selection of terminology is based on existing/historical labelling practice.

- Permanent or Resistive or Superconducting;
- Actively Shielded, Passively Shielded, Unshielded;
- Field strength:
 - Constant or Variable Main Field;
 - NOMINAL B_0 VALUE at MR ISOCENTRE (in [T], to ± 5 % accuracy);
- cryogen types for MR EQUIPMENT equipped with superconducting magnets for which cryogenic liquid refill is appropriate and cryogenic gas boil-off into the environment can occur;
- B_0 : Two-dimensional isocontour plots of the main magnetic field B_0 outside the FIXED magnet covers, including the location and VALUE of the maximum B_0 VALUE (in [T]), for three orthogonal planes through the magnet centre.

No site-specific shielding provisions shall be considered for these plots, and building structural influences can be ignored.

Only the isocontour lines actually produced by the magnet shall be provided.

The caption of the plot shall read “Plot displaying static magnetic field B_0 drop-off which can be useful when interpreting MR CONDITIONAL labelling information”.

NOTE 5 Interpretation of the isocontour plots can be supported by including a schematic overview of the magnet covers and the PATIENT table as part of these plots.

NOTE 6 Magnets with adjustable configurations can best be represented by taking into account the worst extent of the isocontours relative to the floor of the MR EXAMINATION ROOM, for the superset of possible configurations. This will allow the RESPONSIBLE ORGANIZATION to display isocontours on the floor, and to define the extent of the B_0 HAZARD AREA in any direction.

Each isocontour line shall be labelled with its B_0 VALUE:

- A first set of plots shall contain the magnetic isocontours with values of 0,5 mT, 0,9 mT, 3 mT, 5 mT, 10 mT, 20 mT, 40 mT, 100 mT and 200 mT as well as a distance scale and a superimposed outline of the FIXED magnet covers;
- A second set of plots shall contain the magnetic isocontours with values of 0,5 T, 1 T, 1,5 T, 2 T, 3 T and any subsequent integer number up to and including the maximum field strength, at positions accessible to and relevant for the MR WORKER. Only the isocontour lines the magnet can produce outside the FIXED magnet covers, are required.
- SFG: Plots with isocontours to display the spatial distribution of the SFG outside the FIXED magnet covers for MR EQUIPMENT where SFG exceeds 0,1 T/m.
For MR EQUIPMENT where SFG does not reach 0,1 T/m, no isocontour plot is required and this fact shall be disclosed.

Each isocontour line shall be labelled with its SFG VALUE.

- Two-dimensional SFG isocontour plots for three orthogonal planes through the magnet centre. Each plot shall contain at least the isocontour lines actually produced by the magnet, and selected from the following list 0,1 T/m, 0,5 T/m, 1 T/m, 3 T/m, 5 T/m, 7 T/m, 10 T/m, 20 T/m, 30 T/m, 50 T/m. The plots shall also include an isocontour or a dot at the maximum SFG, with its VALUE (in [T/m]);

For magnets with adjustable configurations, the MR MANUFACTURER may select and describe additional configurations for which the isocontour plots are provided.

The caption of the plot shall read “Plot displaying SPATIAL FIELD GRADIENT (SFG) drop-off which can be useful when interpreting MR CONDITIONAL labelling information”.

NOTE 7 Interpretation of the isocontour plots can be supported by including a schematic overview of the magnet covers and the PATIENT table as part of these plots.

- Patient-centric SFG isocontour plot:
 - For CYLINDRICAL MR EQUIPMENT: A 2-dimensional plot displaying a set of multiple cylinders, perpendicular to B_0 , displaying maximum SFG values on the surface of each cylinder in units of mT/m, each cylinder co-aligned with the B_0 axis, and with their centre line passing through the MR ISOCENTRE. Cylinders shall be provided with diameter increments of 0,1 m, starting from 0,2 m diameter up to and including the bore diameter. An additional cylinder shall be provided as dashed line to indicate the location of maximum SFG;
 - For other types of MR EQUIPMENT: At least one 2-dimensional plot conforming to the PATIENT accessible space, with at least two isocontours and a spacing not to exceed 0,1 m. The view's perspective of the plot relative to the magnet geometry shall be explained or indicated.
- Gradient system:
 - type (WHOLE BODY GRADIENT SYSTEM and/or other);
 - maximum amplitude (in [mT/m]), fastest unipolar rise time (in [ms]), MAXIMUM GRADIENT SLEW RATE (in [T/m/s]), under NORMAL CONDITION and in NORMAL USE;
 - Spatial distribution of GRADIENT OUTPUT (in [T/s] or [V/m]) from simultaneous switching of each of all GRADIENT UNITS, as established using the procedure in 201.12.4.105.2.3.
- RF system:
 - for each RF transmit coil operating at ^1H frequency:
 - declaration of B_1 transmit polarization capability (e.g. CP, MC-2, MC-N);
 - classification of coil type as DETACHABLE or "integrated";

NOTE 8 Implant labelling uses "integrated" in customer-facing documentation to denote FIXED, used elsewhere in this document for coil classification. See also IEC 62570.

 - design center frequency and bandwidth;
 - maximum specified B_1^+ RMS under NORMAL CONDITION and in NORMAL USE;
 - the maximum B_1^+ PEAK that can occur for an approximate 75 kg to 100 kg adult PATIENT as derived from modelling, using the abdominal landmark for the integrated coil or a specified relevant landmark for other coils, under NORMAL CONDITION and in NORMAL USE;
 - for MR EQUIPMENT other than 1,5 T or 3 T, and for which MROC is provided: the maximum B_1^+ PEAK available for use during MROC operation, if different from the VALUE specified for the previous bullet.
 - spatial extent of the RF field for each unloaded VOLUME RF TRANSMIT COIL:
 - plot of distribution of the (total) B_1 transmit field for a single RF polarization, as described in 201.12.4.105.3.3, and together with a disclosure of the selected polarization, and an indication of the extent of the coil;

The caption of the plot shall read "Plot displaying drop-off of the B_1 transmit field along the centreline of the empty RF transmit coil, to support MR WORKER exposure assessment".

NOTE 9 The preferred disclosure is for CP; otherwise the MR MANUFACTURER can select and justify another drive condition.

 - electrical length of the FIXED VOLUME RF TRANSMIT COIL;

NOTE 10 This length represents approximately 95 % of the absorbed power for a typical load as defined in NEMA MS 8, also known as "effective length", and can help identify the extent of the RF transmit coil and can be part of sketches suggested in 201.7.9.2.17 d).

 - distances from the coil centre along the PATIENT axis at which the (total) B_1 transmit field is reduced by 3 dB and 10 dB from the maximum VALUE.

NOTE 11 This requirement is for PATIENT safety and consequently differ from the requirements for the MR WORKERS as defined in 201.12.4.105.3.3.

– Electromagnetic Exposure Level Threshold for MR WORKERS

A two-dimensional plot, parallel to the floor and passing through MR ISOCENTRE, shall be provided with (at least) a single isocontour of the (combined) worst case of the Exposure Level Values (ELVs) with respect to B_0 (2 T) and the internal electric field related to health effects ($1,1 \text{ Vm}^{-1}$) induced by the simultaneous switching of the GRADIENT UNITS.

NOTE 12 This plot represents an overview of the ELVs in the MR EXAMINATION ROOM for compliance with the EU physical agents Directive 2013/35/EU [22].

NOTE 13 Induced electric field assessment for MR WORKERS is based on the method described in 201.12.4.105.2.3.

– Compatibility sequences:

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

c) Acoustic energy (noise):

The technical description shall disclose the A-weighted RMS sound pressure level ($L_{Aeq,8h}$) at the MR WORKER position inside the MR EXAMINATION ROOM (see 201.9.6.2.1.101) as defined in NEMA MS 4.

The technical description shall state that measurements were performed in accordance with NEMA MS 4.

NOTE 14 The average sound pressure level corresponds to the VALUE specified for noise emission declarations per 2006/42/EC [8].

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 rounded to the nearest 5 second interval 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 approximately 20 mT.

e) Patient Handling system

– characteristics of PATIENT space:

- ventilation (forced flow yes/no);
- means of communication, as provided:
 - microphone;
 - visual contact such as a window or video monitoring system;
 - system enabling the PATIENT to alert the OPERATOR;

– information to help in PATIENT positioning:

- cross-sectional drawing including:
 - the tabletop and the magnet covers in the axial plane together with
 - MR ISOCENTRE to tabletop distance;
 - magnet cover to tabletop distance;

- width of tabletop;
- distance from MR ISOCENTRE to magnet outer cover (along the dash-dotted line of Figure 201.104);
- physical length of the PATIENT positioning space on the tabletop, and usable length of imaging coverage;
- information related to manoeuvring of a DETACHABLE PATIENT support:
 - maximum and minimum PATIENT table height;
 - bounding box for width and length;
 - mass of the assembly;
 - SAFE WORKING LOAD.
- f) EMERGENCY FIELD SHUT DOWN UNIT: for MR EQUIPMENT having an EMERGENCY FIELD SHUT DOWN UNIT not equipped with self-checking capabilities per 201.16.101 b) ii), the MANUFACTURER shall provide instructions how to check its function over the lifetime of the device.
- g) Operating range of MR EXAMINATION ROOM temperature as specified by the MR MANUFACTURER.

* 201.7.101 Site planning safety information for MR EQUIPMENT

Addition:

The MANUFACTURER shall include safety-relevant information in site-planning documentation for use by the RESPONSIBLE ORGANIZATION for construction and building provisions necessary for safe installation and operation of the MR EQUIPMENT.

NOTE 1 Such information can also be useful when setting up trailer-based MR EQUIPMENT.

The following topics shall be covered, as applicable,

- a) indicate the need to conform to applicable building codes and regulations;
- b) 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 EQUIPMENT before operation of the system starts.

This check list may cover the implementations related to items c) and g), and floor markings related to item f);

- c) statement that the MR EXAMINATION ROOM setup shall be designed to enable ROUTINE MONITORING of the PATIENT from the MR WORKER work positions;
- d) operating range of MR EXAMINATION ROOM temperature;
- e) NOMINAL B_0 VALUE (to within 5 % accuracy);
- f) B_0 and SFG isocontour plots for the MR EQUIPMENT, excluding site-specific shielding provisions and building structural influences, as specified in 201.7.9.3.101 b);
- g) guidance regarding where to install the actuator(s) of the EMERGENCY FIELD SHUT DOWN UNIT;
- h) safety provisions for cryogen venting under regular operation or in the event of a QUENCH:

For MR EQUIPMENT equipped with superconducting magnets for which cryogenic gas boil-off into the environment can occur as part of regular operation or in the event of a QUENCH:

- 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, outlet point and protective means such as a fenced space not accessible to the public, material to be applied, and appropriate lightning protection) of the venting system for the superconducting magnet inside and outside the MR EXAMINATION ROOM, including the provisions necessary for regular inspection;

NOTE 2 An appropriate warning sign near the outlet point is ISO 7010-W010 (2011-05) (see Table 201.A.101, SAFETY SIGN 3).

- state requirements for the design of the MR EXAMINATION ROOM to ensure safety of the PATIENT and other persons inside and outside the MR 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.

One or more 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 MR EXAMINATION ROOM, as caused by pressure build-up, temperatures decrease or oxygen depletion during the QUENCH, is reduced considerably;

- 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 MR EXAMINATION ROOM or directly connected to the air-conditioning of the MR 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. No venting system is necessary if the magnet's pressure vessel can retain all cryogenic gas.

NOTE 4 MR EXAMINATION ROOM configurations demonstrated by simulation or test that are acceptable when considering minimum performance criteria based on QUENCH flow rates and minimum room size, include one of the following:

- preferred option: an opening in the wall or ceiling of the MR EXAMINATION ROOM, venting towards an open area, for which the RESPONSIBLE ORGANIZATION has established that no RISK occurs when helium escapes; or
 - a manually-switchable MR EXAMINATION ROOM air extraction system, whose activation can be triggered automatically by an oxygen-depletion sensor; 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.
- i) describe the need to ensure that the MR EXAMINATION ROOM construction provides adequate suppression of acoustic noise, and to mitigate potential coupling of the building to structure-born vibrations (1 Hz to 4 kHz) actuated by the magnet feet, such that the acoustic exposure outside the MR EXAMINATION ROOM does not exceed limits derived from local regulations or from 201.9.6.2.1.102;
 - j) provide a reminder to ensure adequate space for manoeuvring MR CONDITIONAL MOBILE equipment to move the PATIENT within the MR ENVIRONMENT;
 - k) provide a reminder to establish that third-party equipment and third-party ACCESSORIES are selected as appropriate for SAFE use in the MR ENVIRONMENT;
 - l) provide a reminder to establish a communication plan for informing emergency responders concerning the HAZARDS related to the MR ENVIRONMENT;
 - m) all of the information specified in 201.7.9.3.101 b): CTSS, and 201.7.9.3.101 e): PATIENT handling system.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 [109].

Addition:

- aa) 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.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.9.6 Acoustic energy (including infra- and ultrasound) and vibration*Replacement:**** 201.9.6.2.1 Audible acoustic energy (noise)****201.9.6.2.1.101 Acoustic noise requirements inside the MR EXAMINATION ROOM**

In NORMAL USE, and inside the MR EXAMINATION ROOM, the PATIENT, MR WORKER and other persons shall not be exposed to acoustic energy from the MR EQUIPMENT, except sound from auditory ALARM SIGNALS, exceeding emission levels specified below:

- 140 dB(C) peak, sound pressure level for impulsive or impact acoustic energy (noise);
- the sum of 99 dB(A) for $L_{Aeq,1h}$, plus the RATED hearing protection VALUE per 201.7.9.2.101 d);

NOTE 1 For example, if the Noise Reduction Rating (NRR) or Single Number Rating (SNR) specified per 201.7.9.2.101 d) is 29 dB, the $L_{Aeq,1h}$ limit would be 128 dB(A). This VALUE provides the limiting compliance VALUE to which the VALUE reported per NEMA MS 4 is compared.

NOTE 2 Neonates and young children can benefit from lower exposure to acoustic energy.

Compliance is demonstrated by evaluating the $L_{Aeq,1h}$ VALUE obtained in accordance with NEMA MS 4 against the limits specified in this clause, and by inspection of the ACCOMPANYING DOCUMENTS.

201.9.6.2.1.102 Acoustic noise requirements outside the MR EXAMINATION ROOM

The noise emitted by the MR EQUIPMENT and its sub-assemblies, excluding the noise generated by the magnet-gradient coil sub-assembly during active gradient switching, and any auditory ALARM SIGNAL or alerting equipment, shall not exceed 85 dB(A) for $L_{Aeq,8h}$.

NOTE 1 This requirement ensures that sub-assemblies of MR EQUIPMENT satisfy the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Compliance is checked by measuring the maximum A-weighted sound pressure level at the minimum distances of a MR WORKER, SERVICE PERSONNEL or other persons from the source of acoustic energy in NORMAL USE, and if necessary, calculating the A-weighted sound pressure level produced by the MR EQUIPMENT in accordance with ISO 3746, ISO 9614-1 or IEC 61672-1, as explained by IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. The following conditions apply:

- a) *The MR EQUIPMENT is operated under worst-case NORMAL CONDITION, but excluding the noise generated as a result of imaging sequences.*
- b) *Any protective means provided with the MR EQUIPMENT, or called for in ACCOMPANYING DOCUMENTS (excluding means of hearing protection) are to be in place during sound measurement.*

NOTE 2 Protective means include, but are not limited to, cabinet doors/enclosures, sound isolation materials, etc

- c) *Sound level meters used in the measurement conform to IEC 61672-1 and IEC 61672-2.*
- d) *Sound measurements for large PERMANENTLY INSTALLED MR EQUIPMENT may be done in a representative installation setup.*
- e) *For non-PERMANENTLY INSTALLED MR EQUIPMENT, measurements shall take place in a location representative of its final installation and INTENDED USE, and with ambient noise no greater than 70 dB(A) to allow a valid measurement.*

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 9.7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and with national regulations.

201.9.8 MECHANICAL HAZARDS associated with support systems

Replacement:

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.3 Dynamic forces due to loading from persons

Addition:

Dynamic forces can be significant during PATIENT loading when the PATIENT support system is placed outside the magnet. Where it is determined that the dynamic loading test of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, the following provides an alternative means of compliance.

Where mechanical analysis proves that the following static load test is more severe than the dynamic load test specified in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, it is possible to waive the dynamic load test based on RISK MANAGEMENT.

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.

Replacement of the compliance section:

Compliance is checked by the following test:

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and is applied for at least 1 min. Any loss of function or structural damage that could result in unacceptable RISK constitutes a failure.

Addition:

NOTE 2 The foam described in Figure 33 of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 represents the human body, but the test can also be executed with a test fixture without foam.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.1.3 Measurements

Addition:

Compliance with the requirements of 11.1.1 and 11.1.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 is checked for RF coils, including housing and connecting cables, as follows:

- *for DETACHABLE RF coils: temperature measurements as specified in NEMA MS 14 for RF induced heating;*
- *for the FIXED RF transmit coil:*
 - *measurements per 11.1.3 in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, where operation of the MR EQUIPMENT involves RF transmission and gradient switching at a representative duty cycle as documented in the RISK MANAGEMENT FILE, or*
 - *measurements and analysis as described in NEMA MS 14 and documented in the RISK MANAGEMENT FILE;*
- *inspection of the instructions for use (section on operation of MR EQUIPMENT).*

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

* 201.12.4 Protection against hazardous output

201.12.4.1 Intentional exceeding of safety limits

Addition:

NOTE The SECOND LEVEL CONTROLLED OPERATING MODE covers all relevant requirements for MR EQUIPMENT.

201.12.4.2 Indication relevant to safety

Addition:

NOTE All relevant requirements for MR EQUIPMENT are covered in 201.12.4.101.

Additional subclauses:

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 to 201.12.4.104).

The requirements of this subclause shall apply separately for the operating modes regarding the spatial-encoding gradient and the RF outputs.

NOTE Disclosure of the operating mode with respect to static magnetic field is fully covered by the instructions for use.

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

The MR EQUIPMENT shall comply with the following requirements:

- a) The NORMAL OPERATING MODE regarding the spatial-encoding gradient and the RF outputs should be the default state of the MR EQUIPMENT when initiating an MR EXAMINATION;
- b) The MR EQUIPMENT shall monitor and control spatial-encoding gradient and RF outputs relative to the limits of the current operating mode;
- c) The control of spatial-encoding gradient and RF outputs shall be
 - 1) independent of OPERATOR input (as to PATIENT size, mass or position), or
 - 2) checked by the MR EQUIPMENT in order to detect any OPERATOR input error;
- d) The current operating mode for each of SAR and GRADIENT OUTPUT shall be displayed on the USER INTERFACE;
- e) The MR EQUIPMENT shall display, upon request or continuously, and at least for the next scan which is due to be operated, the estimated VALUE for the applicable SAR type (see Table 201.104), B_1^+ RMS, and fraction of PNS THRESHOLD LEVEL;

NOTE 1 This display function can be configured and initiated as needed by the OPERATOR

- f) For the scan actively depositing energy in the PATIENT, the MR EQUIPMENT shall display, upon request or continuously, the predicted VALUE for the applicable SAR type (see Table 201.104), B_1^+ RMS, and fraction of PNS THRESHOLD LEVEL;
- g) The B_1^+ RMS VALUE shall only be displayed when a VOLUME RF TRANSMIT COIL is applied;
- h) A record of the operating mode and related data for fraction of PNS THRESHOLD LEVEL, B_1^+ RMS and SAR shall be an integral part of the image data.

NOTE 2 This data can be recorded in MR DICOM tags (0018,9176) to (0018,9181), and (0018,1320).

201.12.4.101.3 NORMAL OPERATING MODE

No specific additional requirements apply to this mode.

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 require a deliberate action of the OPERATOR 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 modes (defined by the GRADIENT OUTPUT and SAR VALUE for the scan), and the SAR VALUE(s), and the GRADIENT OUTPUT VALUE (in the units of measurement selected by MR MANUFACTURER) to be applied during the scan shall be displayed at the CONTROL PANEL.
- c) A notification to the OPERATOR shall be included that the operating conditions are potentially hazardous.
- d) The MR EQUIPMENT shall provide means for authorized OPERATORS to configure and set adjustable limits (in the SECOND LEVEL CONTROLLED OPERATING MODE) of GRADIENT OUTPUT and/or different types of SAR, such that the set limits cannot be exceeded by the OPERATOR during scanning in SECOND LEVEL CONTROLLED OPERATING MODE.

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

201.12.4.102.1 General

In this document, low frequency field variations produced by the gradient system are the variations which might produce cardiac or peripheral nerve stimulation (PNS), i.e. the EFFECTIVE STIMULUS DURATION > 20 μ s, and tissue heating is not considered for electrical stimulation protection limits.

201.12.4.102.2 Objectives for limitation of GRADIENT 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 peripheral nerve stimulation (PNS) in the PATIENT and in the MR WORKER in NORMAL OPERATING MODE and FIRST LEVEL CONTROLLED OPERATING MODE is minimized by controlling GRADIENT OUTPUT to permissible limits.

201.12.4.102.3 Limits for GRADIENT 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 GRADIENT 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 of the gradients.

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

NOTE 1 Methods to demonstrate compliance are found in 201.12.4.105.2.

NOTE 2 MR WORKER exposure limits are the same as the maximally allowed limits for the PATIENTS. Compliance with the GRADIENT 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 combined shall satisfy:

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

where

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

E is the electric field induced by GRADIENT SWITCHING, in V/m.

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

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

where

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

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

201.12.4.102.3.3 Limits related to peripheral nerve stimulation (PNS)

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

Limits and weight factors obtained from direct determination shall not be applied to alternative designs of gradient systems, unless such designs can be shown to be equivalent in terms of GRADIENT OUTPUT.

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

$t_{s,eff}$ is the EFFECTIVE STIMULUS DURATION, in ms; and

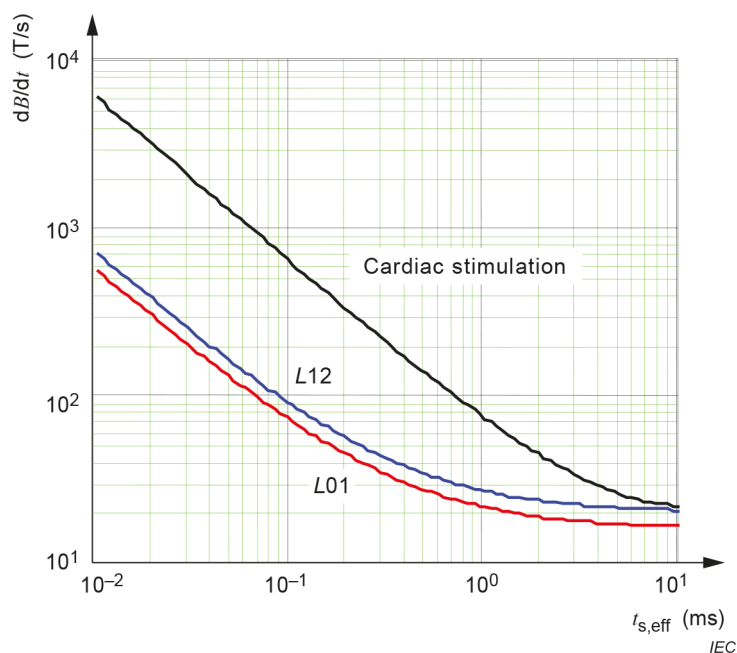
rb is the rheobase given in Table 201.102, here in T/s.

L01 and *L12* as well as rb shall either be expressed as the electric field E (V/m) induced or as the dB/dt (T/s).

Table 201.102 – Rheobase values per type of gradient system

Type of gradient system	rb expressed as E (V/m)	rb expressed as dB/dt (T/s)
WHOLE BODY GRADIENT SYSTEM in CYLINDRICAL MR EQUIPMENT	2,2	20
Other	2,2	not established

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



Limits for peripheral nerve stimulation of GRADIENT OUTPUT for the NORMAL OPERATING MODE (L01) and the FIRST LEVEL CONTROLLED OPERATING MODE (L12) in WHOLE BODY GRADIENTS, expressed as dB/dt versus $t_{s,eff}$. 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 GRADIENT OUTPUT

The MR EQUIPMENT shall control the GRADIENT OUTPUT O 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 GRADIENT 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.

Weighting factors for E -fields are always equal to one, weight factors for dB/dt are stated in Table 201.103.

Table 201.103 – Weighting factors for PNS evaluation per GRADIENT UNIT

Type of gradient system	Weighting options	Weight factors		
		w_{AP}^a	w_{LR}^a	w_{HF}^a
WHOLE BODY GRADIENT SYSTEM	Unweighted values	1,0	1,0	1,0
	Default cylindrical values	1,0	0,8	0,7
	Empirical determination	b	b	b
Other gradient designs	Unweighted values	1,0	1,0	1,0
	Empirical determination	b	b	b
^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 General

Exposure to RF energy can cause systemic and local temperature rise which can be a source of potential HARM to the PATIENT. Thermal stress is avoided in this document by limiting the SAR. SAR limits are derived such that the spatially localized temperatures are expected not to result in tissue damage.

NOTE 1 CEM43 is a method developed to assess treatment effects of severe hyperthermia. Its role in providing protective limits for mild RF exposure is a topic of active research.

NOTE 2 Skin temperatures can be elevated through contact to hot surfaces. For ACCESSIBLE SURFACES the temperature limits of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply, see also 201.11.1.3.

NOTE 3 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 substantially less than that for the PATIENT. Local exposure can be similar to that for the PATIENT.

* 201.12.4.103.2 Limits for SAR, and SA feedback

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

In Table 201.104, 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 shall be the PATIENT mass.

The mass to determine the PARTIAL BODY SAR shall be the 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.

The MR EQUIPMENT shall accumulate SA during the MR EXAMINATION and shall, upon request, display SA for the PATIENT.

The MR EQUIPMENT shall provide an indication to the OPERATOR when SA exceeds a VALUE of 120 [W·min/kg].

Indications related to SA shall not interrupt scanning.

Table 201.104 – SAR limits for VOLUME RF TRANSMIT COILS

Averaging time	6 min		
SAR type →	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 to 10 ^a	3,2
FIRST LEVEL CONTROLLED OPERATING MODE	4	4 to 10 ^a	3,2
SECOND LEVEL CONTROLLED OPERATING MODE	>4	>(4 to10) ^a	>3,2
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: $\text{PARTIAL BODY SAR} = 10 \text{ W/kg} - (8 \text{ W/kg} \times \text{exposed PATIENT mass} / \text{PATIENT mass})$ FIRST LEVEL CONTROLLED OPERATING MODE: $\text{PARTIAL BODY SAR} = 10 \text{ W/kg} - (6 \text{ W/kg} \times \text{exposed PATIENT mass} / \text{PATIENT mass})$			

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 Annex AA.

NOTE 3 SA feedback on the USER INTERFACE has been introduced because very long duration PATIENT studies have become more common. 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 with respect to SA.

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, in general the PARTIAL BODY SAR limits is limiting.

Table 201.105 – SAR limits for LOCAL RF 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 OPERATING MODE	20 ^a	20	40
SECOND LEVEL CONTROLLED OPERATING MODE	>20 ^a	>20	>40
Short duration SAR	The SAR limits over any 10 s period shall not exceed two times the stated values		
^a 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 201.105 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. Instead, limits shall be specified and agreed by the local investigational review board that authorizes 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 201.105. 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.

The FIRST LEVEL CONTROLLED OPERATING MODE limit for WHOLE BODY SAR in Table 201.104 is valid at AMBIENT TEMPERATURE up to 25 °C. For MR EQUIPMENT that supports operations above 25 °C, the MR EQUIPMENT shall

- revert to NORMAL OPERATING MODE (with respect to SAR) when the temperature exceeds 25 °C, or
- reduce the applicable WHOLE BODY SAR limit for FIRST LEVEL CONTROLLED OPERATING MODE by 0,25 W/kg per degree until the SAR is 2 W/kg, see Figure 201.103 for illustration.

NOTE 5 For the SECOND LEVEL CONTROLLED OPERATING MODE, no requirements related to AMBIENT TEMPERATURE derating are given. Derating relative to limits defined by the local investigational review board is considered the responsibility of the local investigational review board that has authorized its use.

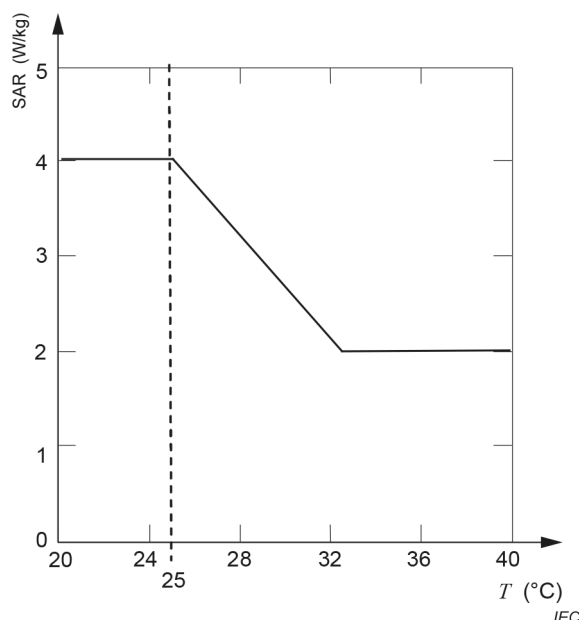


Figure 201.103 – Applicable WHOLE BODY SAR limit values in FIRST LEVEL CONTROLLED OPERATING MODE as function of AMBIENT TEMPERATURE

201.12.4.103.3 Control of SAR

For exposure with a VOLUME RF TRANSMIT COIL, the MR EQUIPMENT shall control conservative estimates of WHOLE BODY SAR, HEAD SAR, and at least one of the following: PARTIAL BODY SAR or LOCAL SAR.

For exposure with a LOCAL RF TRANSMIT COIL, the MR EQUIPMENT shall control conservative estimates of LOCAL SAR and 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 their 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 RF transmit coils with multiple channels can 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

For the (NOMINAL) static magnetic field B_0 , as disclosed in the CTSS, see 201.7.9.3.101 b), 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 8 T.
- c) The SECOND LEVEL CONTROLLED OPERATING MODE comprises values of the static magnetic field higher than 8 T.

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

NOTE MR WORKER concerns are dealt with in the instructions for use, 201.7.9.2.17 b).

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

201.12.4.105 Methods to demonstrate compliance with the requirements

201.12.4.105.1 Direct determination of the limits of the GRADIENT OUTPUT

When limits of GRADIENT 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.