

BS EN 60601-2-33:2010+A12:2016

Incorporating corrigenda October 2010, March 2012 and February 2016



BSI Standards Publication

Medical electrical equipment

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



National foreword

This British Standard is the UK implementation of EN 60601-2-33:2010+A12:2016, incorporating corrigendum October 2010. It is identical to IEC 60601-2-33:2010, incorporating amendment 1:2013, amendment 2:2015, corrigendum March 2012 and corrigendum February 2016. It supersedes BS EN 60601-2-33:2010+A2:2015, which will be withdrawn on 1 November 2019.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. For example, text altered by IEC corrigendum March 2012 is indicated in the text by AC1 AC1.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1.

BSI, as a member of CENELEC, is obliged to publish EN 60601-2-33 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval as a European Standard.

The UK Committee believes that the change in the instructions for use for scanning pregnant patients (in Subclause 201.7.9.2.101 u) should include the recommendation to limit rises in body temperature to less than 0,5°C, as is recommended in Annex AA.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2010.

Amendments/corrigenda issued since publication

Date	Text affected
31 March 2011	Implementation of CENELEC corrigendum October 2010; Annex ZZ revised
30 April 2012	Implementation of CENELEC amendment A11:2011; Annex ZZ revised.
31 July 2015	Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2015. Annex ZA updated
30 November 2015	Implementation of IEC amendment 2:2015 with CENELEC endorsement A2:2015. Annex ZA updated
31 May 2016	Implementation of IEC corrigenda March 2012 and February 2016
31 December 2016	Implementation of CENELEC amendment A12:2016; Annex ZA and Annex ZZ updated

**Medical electrical equipment -
Part 2-33: Particular requirements for the basic safety and essential
performance of magnetic resonance equipment for medical diagnosis
(IEC 60601-2-33:2010)**

Appareils électromédicaux -
Partie 2-33: Exigences particulières pour
la sécurité de base et les performances
essentielles des appareils à résonance
magnétique utilisés pour le diagnostic
médical
(CEI 60601-2-33:2010)

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

This European Standard was approved by CENELEC on 2010-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Foreword

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

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

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

The contents of the corrigendum of October 2010 have been included in this copy.

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

The following dates were fixed:

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

In this standard, the following print types are used:

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

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

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

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

Foreword to amendment A11

This document (EN 60601-2-33:2010/A11:2011) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2012-10-01
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2014-10-01

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Foreword to amendment A1

The text of document 62B/884/CDV, future IEC 60601-2-33:2010/A1, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-33:2010/A1:2015.

The following dates are fixed:

- latest date by which the document has to be (dop) 2016-01-14
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- latest date by which the national (dow) 2018-04-14
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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-33:2010/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-33:2010/A1:2013 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-33:2010, the following note has to be **added** for the standard indicated:

ISO 7010:2011 NOTE Harmonized as EN ISO 7010:2012 (not modified).

Foreword to amendment A2

The text of document 62B/977/FDIS, future IEC 60601-2-33:2010/A2 prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-33:2010/A2:2015.

The following dates are fixed:

- latest date by which the document has to be (dop) 2016-04-23
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2018-07-23
standards conflicting with the
document have to be withdrawn

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For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-33:2010/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-33:2010/A2:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-33:2010, the following note has to be **added** for the standard indicated:

IEC 62570:2014 NOTE Harmonized as EN 62570:2015 (not modified).

Foreword to amendment A12

This document (EN 60601-2-33:2010/A12:2016) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".

The following dates are fixed:

- latest date by which the document has to be implemented at (dop) 2017-11-01
national level by publication of an identical national
standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2019-11-01
the document have to be withdrawn

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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. However, for any use of this standard "within the meaning of Annex ZZ", the user must always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the IEC or ISO standard is referred to in the IEC text standard, this must be understood as a normative reference to the parallel EN standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE 1 The way in which referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD and IEC/ISO</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment	EN 60601-1	2006
+A1	2012	Part 1: General requirements for basic safety and essential performance	EN 60601-1/A1	2013
			EN 60601-1/A1/AC	2014
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	EN 60601-1-2	2015
IEC 60601-1-6	2010	Medical electrical equipment -	EN 60601-1-6	2010
+A1	2013	Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6/A1	2015
IEC 60601-1-8	2006	Medical electrical equipment -	EN 60601-1-8	2007
+A1	2012	Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8/AC	2010
			EN 60601-1-8/A1	2015
IEC 62570	2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	EN 62570	2015

Annex ZZ (informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of EU Directive 93/42/EEC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.

NOTE 3 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.

NOTE 4 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretionary choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

Table ZZ.1 – Relationship between Essential Requirements of Directive 93/42/EEC amended by 2007/47/EC, and Clauses and subclauses of this standard

No.	Essential Requirements	Coverage of EN 60601-2-33
I.	GENERAL REQUIREMENTS	
1.	General Guidance notes 1 - 6 shall be observed	
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER with regard to general¹⁾ X-ray radiation-related aspects of the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (refer to Clauses 4 to 13 of this collateral standard). This European Standard provides requirements to minimize risks of use error for the following aspects: 201.12.4.101 Operating modes 201.7.9.2.101 (Instructions for use) w) About function 201.7.9.3.101 (Technical Description) a) controlled access area Covered only with respect to 201.7.9.2.101 (Instructions for Use) p) Recommended training: Only to be used by professional and licensed users.
2.	General Guidance notes 1 - 6 shall be observed	
2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	1st paragraph covered under the condition that 2nd paragraph (including the following 3 bullets) is taken into account. 2nd paragraph, including the following 3 bullets, are covered for hazardous outputs inherent to MR equipment, under the condition that - the manufacturer implements state of the art risk controls as reflected in 201.4, to 201.17, 202 - and EN ISO 14971 (2012) including its Annex ZA.

1) This standard is intended to provide a set of general specifications to be complemented by existing particular/device specific standards, or by other means, such as risk management.

No.	Essential Requirements	Coverage of EN 60601-2-33
	- eliminate or reduce risks as far as possible (inherently safe design and construction),	
	- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	
	- inform users of the residual risks due to any shortcomings of the protection measures adopted.	
3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	MR equipment following the design rules set out by this European Standard is intended for medical diagnosis, as called out in Article 1 (2) (a).
4	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	Covered in respect to Quality Assurance and Planned Maintenance, see 201.7.9.2.101 Instructions for Use q) quality assurance r) maintenance
5.	General Guidance notes 1 - 6 shall be observed	
5	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	No specific requirements in this standard.
6.	General Guidance notes 1 - 6 shall be observed	
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	Covered for hazardous outputs inherent to MR equipment, see a) for physiologic effects due to electromagnetic field exposures: 201.12.4 Protection against hazardous output b) for acoustic noise: 201.9.6.2.1 Audible acoustic energy 201.7.9.2.101 d) Exposure to excessive acoustic noise
II.	REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION	
General Guidance notes 1 - 6 shall be observed		
7	Chemical, physical and biological properties	
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I (3) on the 'General requirements'. Particular attention must be paid to:	Covered for the certain particular device characteristics of MR Equipment (see below)

No.	Essential Requirements	Coverage of EN 60601-2-33
	- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	No specific requirements in this standard.
	- the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,	Not applicable for MR Equipment (per its intended use)
	- where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand.	Not applicable for MR Equipment
7.2	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of the exposure.	No specific requirements in this standard.
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures;	No specific requirements in this standard.
	if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	Not applicable for MR Equipment
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.	Not applicable for MR Equipment
	For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.	Not applicable for MR Equipment

No.	Essential Requirements	Coverage of EN 60601-2-33
	Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.	
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.	Covered with respect to accidental Helium losses: 201.7.9.3.101 (Technical Description) c) safety provisions in the event of a quench, and 201.7.9.2.101 (Instructions for Use) f) Liquid and gaseous cryogenics
	Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances.	Not applicable for MR Equipment

No.	Essential Requirements	Coverage of EN 60601-2-33
	If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.	Not applicable for MR Equipment
	If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	Not applicable for MR Equipment
7.6	Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	No specific requirements in this standard.
8	Infection and microbial contamination	General Guidance note 2 and 3 shall be observed
8.1	The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	No specific requirements in this standard.
8.2	Tissues of animal origin must originate from animals that have been subject to veterinary controls and surveillance adapted to the intended use of the tissues.	Not applicable for MR Equipment
	Notified Bodies shall retain information on the geographical origin of the animals.	Not applicable for MR Equipment
	Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other <i>transmissible</i> agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	Not applicable for MR Equipment
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	Not applicable for MR Equipment

No.	Essential Requirements	Coverage of EN 60601-2-33
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	Not applicable for MR Equipment
8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	Not applicable for MR Equipment
8.6	Packaging system for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination;	Not applicable for MR Equipment
	the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Not applicable for MR Equipment
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Not applicable for MR Equipment
9	Construction and environmental properties	
General Guidance notes 1 - 6 shall be observed		
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices.	Covered in respect to aspects contained in 201.7.9.2.101 l) auxiliary equipment 201.7.9.3.101 b) compatibility technical specification sheet
	Any restrictions on use must be indicated on the label or in the instructions for use.	Covered by 201.7.9.2.101 Instructions for use. Patient conditions, contraindications, Operating modes
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:	
	- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	Covered for hazardous outputs inherent to MR equipment, see a) for physiologic effects due to electromagnetic field exposures: 201.12.4 Protection against hazardous output b) for acoustic noise: 201.9.6.2.1 Audible acoustic energy 201.7.9.2.101 d) Exposure to excessive acoustic noise and for the pressure vessel containing the magnetic field generating unit: 201.9.7.101 Helium vessels

No.	Essential Requirements	Coverage of EN 60601-2-33
	- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration;	Covered with respect to: 201.7.9.3.101 a) controlled access area (Faraday cage) and 202.5.1 definition of the Special Environment for MR equipment 202.5.2.2.2 a) maintaining RF shielding effectiveness
	- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	Covered with respect to: 202.6.101 Electromagnetic compatibility of MR equipment 201.7.9.2.101 l) auxiliary equipment t) implants
	- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	Covered in respect to Quality Assurance and Maintenance requirements: 201.7.9.2.101 (Instructions for Use) q) quality assurance r) maintenance
9.3	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition.	Covered in respect to: 201.7.9.2.101(Instructions for use) m) emergency field shutdown unit n) fire precautions 201.9.7.101 Helium vessel
	Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	Covered in respect to: 201.7.9.2.101 (Instructions of Use) m) emergency field shutdown unit n) fire precautions 201.9.7.101 Helium vessel 201.7.9.3.101 c)safety provisions in the event of a quench
10	Devices with a measuring function	
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device.	Not applicable to MRI equipment
	The limits of accuracy must be indicated by the manufacturer.	Not applicable to MRI equipment
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	Not applicable to MRI equipment

No.	Essential Requirements	Coverage of EN 60601-2-33
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	Not applicable to MRI equipment
11	Protection against radiation	
General Guidance notes 1 - 6 shall be observed		
11.1	General	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Covered for hazardous outputs inherent to MR equipment, i.e. non-ionizing radiation in respect to: 201.12.4 Protection against hazardous output And in particular 201.12.4.101 Operating modes 201.12.4.102 (protection from gradient output) 201.12.4.103 (protection from RF energy) 201.12.4.104 (protection from static magnetic fields)
11.2	Intended radiation	
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	Covered for electromagnetic fields generated by the MR equipment, i.e. non-ionizing radiation in respect to: 201.12.4 Protection against hazardous output And in particular 201.12.4.101 Operating modes 201.12.4.102 (protection from gradient output) 201.12.4.103 (protection from RF energy) 201.12.4.104 (protection from static magnetic fields)
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	Covered for electromagnetic fields generated by the MR equipment, i.e. non-ionizing radiation in 201.12.4.101 Operating modes
11.3	Unintended radiation	
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	Not applicable, MR Equipment does not generate ionizing radiation

No.	Essential Requirements	Coverage of EN 60601-2-33
11.4	Instructions	
11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Covered with respect to non-ionizing radiation (MR specific EMF) in 201.7.9.2.101 Instructions for use for mr equipment 201.7.9.3.101 b) Compatibility technical specification sheet
11.5	Ionizing radiation	
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	Not applicable for MR Equipment
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	Not applicable for MR Equipment
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	Not applicable for MR Equipment
12	Requirements for medical devices connected to or equipped with an energy source	
General Guidance notes 1 - 6 shall be observed		
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	Covered by normative reference to EN 60601-1, Clause 14
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	No specific requirements in this standard.
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	Not applicable for MR Equipment
12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	Not applicable for MR Equipment

No.	Essential Requirements	Coverage of EN 60601-2-33
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	Not applicable for MR Equipment
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	Covered with respect to: 201.7.9.3.101 a) controlled access area (Faraday cage) and 202.5.1 definition of the Special Environment for MR equipment 202.5.2.2.2 a) maintaining RF shielding effectiveness
12.6	Protection against electrical risks	
12.6.1	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	Covered with respect to leakage currents in 201.8.7.3 Allowable Values
12.7	Protection against mechanical and thermal risks	
12.7.1	Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	Covered by normative reference to EN 60601-1
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	No specific requirements in this standard.
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	Covered with respect to: 201.9.6.2.1 Audible acoustic energy
12.7.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	Covered by normative reference to EN 60601-1
12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	No specific requirements in this standard.

No.	Essential Requirements	Coverage of EN 60601-2-33
12.8	Protection against the risks posed to the patient by energy supplies or substances	
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	Not applicable for MR Equipment
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.	Not applicable for MR Equipment
	Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	Covered for hazardous outputs inherent to MR equipment: 201.12.4.101.2 All operating modes
12.9	The function of the controls and indicators must be clearly specified on the devices	Covered for hazardous outputs inherent to MR equipment: 201.12.4.101 Operating modes
	Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	No specific requirements in this standard.
13	Information supplied by the manufacturer	
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use.	Covered in respect to: 201.7.9.2.101 (Instructions for Use) 201.7.9.3.101 (Technical Description)
	As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.	Covered in respect of the following: 201.7.9.2.101 (Instructions for Use) e) Controlled Access Area 201.7.9.3.101 (Technical Description) a) Controlled Access Area demarcation and labelling with warning signs
	Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	Covered by normative reference to EN 60601-1
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colors must be described in the documentation supplied with the device.	Covered 201.7.9.3.101 a Controlled Access Area demarcation and labelling with warning signs

No.	Essential Requirements	Coverage of EN 60601-2-33
13.3	The label must bear the following particulars: (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community; (b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (c) where appropriate, the word 'STERILE'; (d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number; (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; (g) if the device is custom-made, the words 'custom-made device'; (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'; (i) any special storage and/or handling conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number; (m) where applicable, method of sterilization;	Covered by normative reference to EN 60601-1
	(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	Not applicable for MR Equipment
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Covered: 201.7.9.2.101 (Instructions for Use) 201.7.9.3.101 (Technical Description) a Controlled Access Area demarcation and labelling with warning signs
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Covered by normative reference to EN 60601-1

No.	Essential Requirements	Coverage of EN 60601-2-33
13.6	Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; (e) where appropriate, information to avoid certain risks in connection with implantation of the device; (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization;	Covered by normative reference to EN 60601-1, and 201.7.9.2.101 (Instructions for Use) 13.6b) Covered by implementation of prescribed Quality Assurance and Planned Maintenance, see 201.7.9.2.101 Instructions for Use q) quality assurance r) maintenance 13.6c) Not applicable for MR Equipment
	(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I; If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; (i) details of any further treatment or handling needed before the device can be used (for example sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	Covered by normative reference to EN 60601-1

No.	Essential Requirements	Coverage of EN 60601-2-33
	The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: (k) precautions to be taken in the event of changes in the performance of the device; (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; (n) precautions to be taken against any special, unusual risks related to the disposal of the device; (o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; (p) degree of accuracy claimed for devices with a measuring function; (q) date of issue or the latest revision of the instructions for use.	Covered by normative reference to EN 60601-1, and 201.7.9.2.101 (Instructions for Use) (m), (o) and (p) are not applicable for MR Equipment

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* INTRODUCTION

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

This International Standard addresses technical aspects of the medical diagnostic MR SYSTEM and the MR EQUIPMENT therein related to the safety of PATIENTS examined with this system, the safety of the MR WORKER involved with its operation and the safety of the MR WORKER involved with the development, manufacturing, installation, and servicing of the MR SYSTEM. Where limits of electromagnetic fields (EMF) exposure of PATIENTS and MR WORKERS are stated, these limits do not imply that such levels of exposure can be assumed to be acceptable for workers in other professional settings and for the population at large. The limits provide a sensible balance between RISKS for the PATIENTS and MR WORKERS and benefits for the PATIENTS.

Organizational aspects of safety are the task of the RESPONSIBLE ORGANIZATION. This task includes adequate training of staff, rules of access to the MR SYSTEM, qualification of staff for decisions that are related to safety, definition of medical responsibility and specific requirements for personnel following from that responsibility when the PATIENT is in or near the MR SYSTEM.

Examples of such organizational aspects are:

- operation in FIRST LEVEL CONTROLLED OPERATING MODE;
- emergency procedures for resuscitation of the PATIENT who is in the MR SYSTEM;
- emergency procedures after a QUENCH of the superconductive magnet when present;
- set-up and maintenance of a protocol for screening the PATIENT for contraindications or for conditions that may affect acceptable exposure;
- rules for ROUTINE MONITORING and for MEDICAL SUPERVISION of the PATIENT during the exam.
- rules to minimize and to limit the exposure of MR WORKERS to EMF.

Extensive rationale is provided in Annex AA for some of the definitions and requirements in order to provide the user of this standard with a reasonably complete access to the source material that was used in support of the considerations during drafting.

The relationship of this particular standard with IEC 60601-1 and the collateral standards is explained in subclauses 201.1.3 and 201.1.4.

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

For the exposure to static magnetic fields, subjective short-term physiological and sensory effects are expected. These influence the well being of the MR WORKER marginally and only during or shortly after exposure.

For the exposure to GRADIENT OUTPUT and RF transmit fields, normally no short-term physiological and sensory effects are expected for MR WORKERS.

In addition no experimental or theoretical basis for cumulative biological effects in humans, resulting from exposure at the allowed levels has been generally accepted.

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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

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

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

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

A1 The standard does not formulate specific requirements for MR EQUIPMENT or MR SYSTEMS used in INTERVENTIONAL MR EXAMINATIONS. **A1**

201.1.2 Object

Replacement:

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

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

201.1.3 Collateral standards

Addition:

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

A1 **A2** IEC 60601-1-2:2014 **A2** applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published. **A1**

201.1.4 Particular standards

Replacement:

¹⁾ The general standard is **A1** IEC 60601-1:2005+A1:2012 **A1**, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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

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

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

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

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

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

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

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

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

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

201.2 Normative references

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

Clause 2 of the general standard applies except as follows:

Replacement:

A2 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* **A2**

A2 IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012 **A2**

Addition:

A1 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

NEMA MS 4:2010, *Acoustic noise measurement procedure for diagnostic magnetic resonance imaging (MRI) devices* **A1**

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in **A1** IEC 60601-1:2005 +A1:2012 **A1** and the following apply:

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

Addition:

* 201.3.201

AC1 **B_{1+RMS}** **AC1**
root mean square (rms) of **AC1** B₁₊ the MR relevant radiofrequency magnetic induction **AC1**,

$$\mathbf{AC1} \ B_{1+RMS} = \sqrt{\frac{\int_0^{t_x} (B_{1+}(t))^2 dt}{t_x}} \cdot \mathbf{AC1}$$

where *t* is time, and *t_x* is the **A2** integration time, which shall be any 10 s period over the duration of the entire sequence **A2**

A2 Note 1 to entry: B₁₊ is derived from the flip angle averaged over an adjustment volume, which is typically represented by the axial central slab wherein MR signal is generated. **A2**

201.3.202

COMPLIANCE VOLUME

PATIENT accessible space in which compliance of GRADIENT OUTPUT is inspected

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

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

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

201.3.203

CONTROLLED ACCESS AREA

A_2 area around the MR SYSTEM, to which access is controlled to prevent HARM from the magnetic field

Note 1 to entry: The CONTROLLED ACCESS AREA is not identical to the SPECIAL ENVIRONMENT or SPECIAL LOCATION as defined in IEC 60601-1-2:2014. A_2

201.3.204

CORE TEMPERATURE

mean temperature of the body core

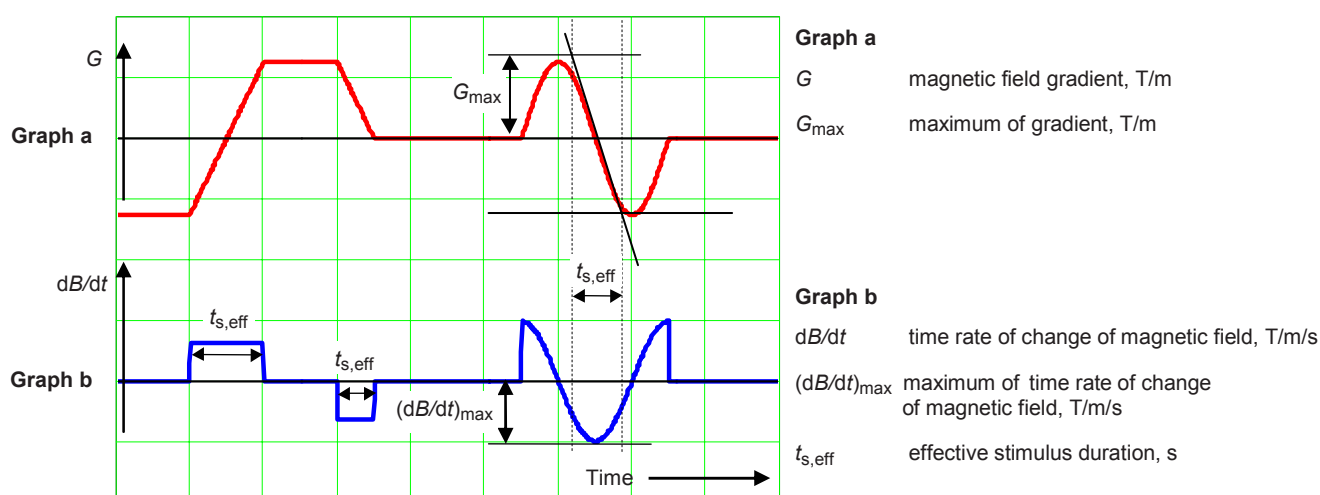
NOTE Typically equal to the rectal, sublingual, or tympanic temperature. More reliable representations of CORE TEMPERATURE are oesophageal or arterial blood temperature. Brain temperatures are CORE TEMPERATURES.

201.3.205

EFFECTIVE STIMULUS DURATION

$t_{s,eff}$

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



IEC 402/10

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

Figure 201.101 – Gradient waveform and EFFECTIVE STIMULUS DURATION

201.3.206

EMERGENCY FIELD SHUT DOWN UNIT

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

* 201.3.207

ENVIRONMENTAL TEMPERATURE

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

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

201.3.208

FIRST LEVEL CONTROLLED OPERATING MODE

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

201.3.209

GRADIENT OUTPUT

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

201.3.210

GRADIENT UNIT

all gradient coils and amplifiers that together generate a magnetic field gradient along one of the axes of the coordinate system of the MR EQUIPMENT

201.3.211

HEAD RF TRANSMIT COIL

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

201.3.212

HEAD SAR

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

*** 201.3.213**

INTERVENTIONAL MR EXAMINATION

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

201.3.214

ISOCENTRE

in MR EQUIPMENT null point of the spatially encoding gradients

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

[IEC 62464-1:2007, definition 3.1.15]

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

201.3.215

LOCAL RF TRANSMIT COIL

RF transmit coil other than a VOLUME RF TRANSMIT COIL

201.3.216

LOCAL SAR

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

*** 201.3.217**

MAGNETIC RESONANCE

MR

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

201.3.218

MAGNETIC RESONANCE EQUIPMENT

MR EQUIPMENT

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

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

201.3.219

MAGNETIC RESONANCE EXAMINATION

MR EXAMINATION

process of acquiring data by MAGNETIC RESONANCE from a PATIENT

201.3.220

MAGNETIC RESONANCE SYSTEM

MR SYSTEM

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

*** 201.3.221**

MAGNETIC RESONANCE WORKER

MR WORKER

person that because of his/her profession has to enter the CONTROLLED ACCESS AREA or equivalent of the MAGNETIC RESONANCE SYSTEM

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

201.3.222

MAXIMUM GRADIENT SLEW RATE

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

*** 201.3.223**

MEDICAL SUPERVISION

adequate medical management of PATIENTS who can be at RISK from some parameters of exposure to the MR EQUIPMENT, either because of the medical condition of the PATIENT, the levels of exposure or a combination

201.3.224

NORMAL OPERATING MODE

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

201.3.225

PARTIAL BODY SAR

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

201.3.226

PNS OUTPUT

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

201.3.227

PNS THRESHOLD LEVEL

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

201.3.228

QUENCH

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

201.3.229

ROUTINE MONITORING

routine PATIENT monitoring, carried out by responsible personnel such as the OPERATOR and staff of the MR EQUIPMENT and consisting of audio and/or visual contact, as appropriate with the PATIENT during the MR EXAMINATION

201.3.230

SEARCH COIL

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

201.3.231

SECOND LEVEL CONTROLLED OPERATING MODE

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

201.3.232

SPECIAL PURPOSE GRADIENT SYSTEM

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

NOTE An example of a SPECIAL PURPOSE GRADIENT SYSTEM is a gradient system that can be incorporated in MR EQUIPMENT to allow special examination of the head of the PATIENT.

*** 201.3.233**

SPECIFIC ABSORPTION RATE

SAR

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

201.3.234

TIME RATE OF CHANGE OF THE MAGNETIC FIELD

dB/dt

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

 Note 1 to entry: The time rate of change of the magnetic field dB/dt is assumed to be evaluated in a suitably low frequency range (e.g. < 5 kHz) to disregard effects of switching amplifier ripple. 

201.3.235

TRANSVERSE FIELD MAGNET

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

201.3.236

VOLUME RF TRANSMIT COIL

RF transmit coil suitable for use in MR EQUIPMENT that produces a homogeneous RF field over an extended volume encompassed by the coil

NOTE The VOLUME RF TRANSMIT COIL can be a WHOLE BODY RF TRANSMIT COIL, a HEAD RF TRANSMIT COIL or a RF TRANSMIT COIL designed for homogeneous exposure of a specific part of the body. A single loop coil enclosing the body or a part of the body is considered to be a VOLUME RF TRANSMIT COIL (example: single loop wrist coil).

201.3.237

WHOLE BODY GRADIENT SYSTEM

gradient system suitable for use in WHOLE BODY MR EQUIPMENT

201.3.238

WHOLE BODY MAGNET

magnet suitable for use in WHOLE BODY MR EQUIPMENT

201.3.239

WHOLE BODY MAGNETIC RESONANCE EQUIPMENT

WHOLE BODY MR EQUIPMENT

MR EQUIPMENT of sufficient size to allow whole body MR EXAMINATION and partial body MR EXAMINATION of adult PATIENTS. It can be equipped with VOLUME RF TRANSMIT COILS, LOCAL RF TRANSMIT COILS and with a SPECIAL PURPOSE GRADIENT SYSTEM

201.3.240

WHOLE BODY RF TRANSMIT COIL

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

201.3.241

WHOLE BODY SAR

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

201.3.242

FIXED PARAMETER OPTION

FPO

option within existing modes (i.e. NORMAL OPERATING MODE or FIRST LEVEL CONTROLLED OPERATING MODE), which specifies a set of operational limit values for the allowable RF field and GRADIENT OUTPUT and the specified B_0 of the MR EQUIPMENT in a MR EXAMINATION

201.3.243

FIXED PARAMETER OPTION: BASIC

FPO:B

“basic” denotes a specific implementation of FPO, exclusively for 1,5 T MR SYSTEMS

Note 1 to entry: The note to entry in French concerning the source of the abbreviation “FPO:B” concerns the French text only.

201.3.244

B_{1+}

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

201.3.245

B_{1+PEAK}

peak amplitude of B_{1+}

* 201.3.246

$(|dB/dt|_{PEAK})_{FPO}$

maximum time rate of change of the magnitude of the magnetic field during the MR EXAMINATION, evaluated at the location defined for FPO, i.e. a surface providing 5 cm clearance to the outline of the PATIENT accessible volume

* 201.3.247

$(|dB/dt|_{RMS})_{FPO}$

root mean square (rms) of the magnitude of the time rate of change of the magnetic field for FPO

$$\left(\left| \frac{dB}{dt} \right|_{RMS} \right)_{FPO} = \sqrt{\frac{\int_0^{t_x} \left(\left| \frac{dB_{FPO}}{dt} \right| \right)^2 d\tau}{t_x}}$$

Where t is time, and t_x is the integration time. dB_{FPO}/dt is a conservative model estimate of the magnetic field associated with the switching gradients

201.3.248

SLEW PERCENTAGE

fraction of time that any gradient is slewing at any rate

201.3.249

CIRCULARLY POLARIZED RF

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

Note 1 to entry: This drive operation is denoted as “CP” on user interfaces and in ACCOMPANYING DOCUMENTS.

Note 2 to entry: Circularly polarized RF is also commonly referred to as quadrature drive 

A2 * 201.3.250

**SPATIAL FIELD GRADIENT
SFG**

spatial rate of change of the main magnetic field $\left| \nabla \vec{B} \right|$, expressed in [T/m]

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

Note 2 to entry: The note to entry in French concerning the source of the abbreviation “SFG” concerns the French text only. **A2**

A2 Table 201.101 – List of symbols and abbreviations A2

Symbol	SI-Unit	Definition
B_0	T	Static magnetic field
AC1 B_{1+} AC1	T	Magnetic induction of the radio frequency magnetic field
AC1 B_{1+RMS} AC1	T	Root mean square of AC1 B_{1+} AC1
dB/dt	T/s	TIME RATE OF CHANGE OF THE MAGNETIC FIELD (dB/dt)
E	V/m	Electric field induced by gradient switching
G	T/m	Magnetic field gradient
$L01$	V/m or T/s	Limit of the GRADIENT OUTPUT for the NORMAL OPERATING MODE
$L12$	V/m or T/s	Limit of the GRADIENT OUTPUT for the FIRST LEVEL CONTROLLED OPERATING MODE
O	depending on context	PNS OUTPUT
O_i	depending on context	PNS OUTPUT per GRADIENT UNIT
rb	V/m or T/s	Rheobase
SAR	W/kg	SPECIFIC ABSORPTION RATE (SAR)
A1 Text deleted A1		
t_{SAR}	min	Averaging time for the determination of SAR
T	°C	Temperature
w_i	none	Weight factor per GRADIENT UNIT relating the GRADIENT OUTPUT of that unit to the limit

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

A1 NOTE 101 For the functions of the MR EQUIPMENT covered by this standard no specific ESSENTIAL PERFORMANCE requirements have been identified. Other functions of the MR EQUIPMENT may constitute ESSENTIAL PERFORMANCE.

See the general standard for requirements to the RISK MANAGEMENT FILE of the MANUFACTURER to cover the analysis of ESSENTIAL PERFORMANCE of the MR EQUIPMENT. **A1**

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies except as follows:

201.5.7 Humidity preconditioning treatment

Addition:

A1 For those MR SYSTEMS and MR EQUIPMENT that are to be used only in controlled environments, as to be specified in the technical description, no humidity preconditioning is required.

NOTE A controlled environment is not the same as CONTROLLED ACCESS AREA. **A1**

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies except as follows:

A1 201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.13 Physiological effects (safety signs and warning statements)

Addition:

Applicable safety signs **A2** ISO 7010-W005 (see Table 201.D.101, safety sign 1) and ISO 7010-W006 (see Table 201.D.101, safety sign 2) **A2** shall be placed at the entrance of the CONTROLLED ACCESS AREA. The safety signs may be accompanied by text explaining that the magnetic field is always on, but that EMF emission is restricted to the situation when the MR EQUIPMENT is scanning.

For MR EQUIPMENT that does not require a CONTROLLED ACCESS AREA, 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. **A1**

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

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

201.7.9.2 Instructions for use

201.7.9.2.10 Messages

Replacement:

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

A1 201.7.9.2.17 ME EQUIPMENT emitting radiation

Addition:

NOTE The instructions for use in 201.7.9.2.101 and the compatibility technical specification sheet in the technical description in 201.7.9.3.101 provide detailed information concerning electromagnetic fields of the MR EQUIPMENT. **A1**

Addition:

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

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

Instructions for use shall provide clear recommendations to the RESPONSIBLE ORGANIZATION regarding pre-screening of PATIENTS and MR WORKERS. This specifically applies to those PATIENTS and MR WORKERS who could be placed at RISK due to their professional activity, past medical history, present medical state and/or the physical environment of the MR EQUIPMENT. These instructions shall indicate the need for a pre-screening programme to identify such PATIENTS and MR WORKERS at RISK, and shall provide recommendations to adequately safeguard these PATIENTS and MR WORKERS from injury. For the MR WORKER and the PATIENT especially the RISK due to the past professional activity, which could have caused accidental implantation of ferromagnetic materials, shall be considered.

The following specific classes of PATIENTS shall be mentioned:

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

*** b) MEDICAL SUPERVISION OF PATIENTS**

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

Instructions for use shall:

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

*** c) Emergency medical procedures**

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

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

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

The instructions for use:

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

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

- shall state that the A-weighted r.m.s. sound pressure level is measured according to  NEMA MS 4:2010 .
- shall state that hearing protection shall be used for the safety of the PATIENT and that this hearing protection shall be sufficient to reduce the A-weighted r.m.s. sound pressure level below 99 dB(A);
- shall state that special attention and special training for the OPERATOR is required for proper positioning of the hearing protection, especially when standard ear muffs cannot be applied, or no protection at all can be applied, as for neonates and premature infants;
- shall draw attention to a warning that due to increased anxiety, accepted sound pressure levels can still be of concern to pregnant women and the foetus, to new-borns, infants and young children and to the elderly;

 NOTE 1 An applicable safety sign is ISO 7010-M003 (2011)  (see Table 201.D.101, safety sign 6) . 

* e) CONTROLLED ACCESS AREA

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

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

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

- shall list EQUIPMENT and tools specified or recommended by the MANUFACTURER for use in the CONTROLLED ACCESS AREA. For all EQUIPMENT, ACCESSORIES or tools listed, a description should be given of special measures that are needed, if any, for their installation as well as special precautions, if any, for their use;

- shall state that peripheral equipment, including PATIENT monitoring, life supporting devices and emergency care equipment, which is not specified or recommended for use in the CONTROLLED ACCESS AREA, can be disturbed by the radio frequency field, the switched gradients or the magnetic fringe field of the MR EQUIPMENT and that this peripheral equipment can also disturb the proper functioning of the MR EQUIPMENT;
- shall explain the meaning of device labelling for MR safe, MR conditional and MR unsafe.

* f) Liquid and gaseous cryogens

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

- require adequate provisions for supply of liquid cryogen;
- recommend that cryogen refilling be performed by trained and experienced personnel only;
- provide information on maintenance and inspection of the magnet including the liquid cryogen level(s);
- provide information on the minimum cryogen level(s) required for normal operation;
- require that frequent checks of cryogen level(s) be carried out by the RESPONSIBLE ORGANIZATION;
- give clear information on potential HAZARDS of the use of liquid cryogen as well as information on proper handling of these liquids. This shall include information concerning:

- the wearing of protective clothing to prevent frostbite;

 NOTE Applicable safety signs ISO 7010-M004 (see Table 201.D.101, safety sign 7) and ISO 7010-M009 (see Table 201.D.101, safety sign 8) are appropriate for placement near the location where the cryogen refill is performed. 

- procedures to be performed after gas release;
- precautions against lack of oxygen;
- the use of non-magnetic containers for the cryogen that are being supplied;
- procedures to be followed if flammable materials are found near the cryogen container.

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

* g) Operating modes

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

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

- For MR EQUIPMENT operating within the NORMAL OPERATING MODE, no specific indication or measure is required to be displayed.
- For MR EQUIPMENT capable of operation in FIRST LEVEL CONTROLLED OPERATING MODE, the properties of the MR EQUIPMENT with respect to displayed indication before entering this mode and to deliberate action when entering this mode, as required in 201.12.4.101.4 shall be described. Also, MEDICAL SUPERVISION shall be recommended as required in 201.7.9.2.101 b).

- For MR EQUIPMENT capable of operating within the SECOND LEVEL CONTROLLED OPERATING MODE, specific security measures shall be provided as required in 201.12.4.101.5 to prevent unauthorised operation in the SECOND LEVEL CONTROLLED OPERATING MODE. Operation in the SECOND LEVEL CONTROLLED OPERATING MODE is only permitted under a human studies protocol approved according to local requirements as required in 201.7.9.2.101 b).

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

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

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

- explain the possible effects that PATIENTS and MR WORKERS can experience when the main static magnetic field is above the level of the NORMAL OPERATING MODE, paying particular attention to the effects that can be experienced if the PATIENT'S or the MR WORKER'S head is moved rapidly while inside or close to the MR EQUIPMENT, including vertigo, nausea and a metallic taste in the mouth;
- recommend that the PATIENT remains still while in the region of high static magnetic field;
- provide information on the values of B_0 which the MR EQUIPMENT is capable of;
- explain that when the main static magnetic field is higher than 3 T and not exceeding $\boxed{A_2}$ 8 T $\boxed{A_2}$, the MR SYSTEM is continuously operating in the FIRST LEVEL CONTROLLED OPERATING MODE and therefore ensure that MEDICAL SUPERVISION is provided for all PATIENTS;
- explain that adequate training shall be given to MR WORKERS to minimise adverse health effects arising from the high static magnetic field;
- explain the health effects related to the increased static magnetic field;
- explain the possible changes in the MR compatibility of the tools and accessories used by the MR WORKER as a function of the value of the static magnetic field;
- explain that when the main static magnetic field is higher than $\boxed{A_2}$ 8 T $\boxed{A_2}$, the MR SYSTEM is continuously operating in the SECOND LEVEL CONTROLLED OPERATING MODE and therefore ensure that MEDICAL SUPERVISION is provided for all PATIENTS. Explain that in this situation MR WORKERS shall not be allowed to access the MR EQUIPMENT without special authorization.

i) Exposure of the PATIENT to time varying magnetic fields

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

- explain the possible effects on the PATIENTS of the level of GRADIENT OUTPUT in each of the operating modes with which the MR EQUIPMENT is provided, paying particular attention to possible effects on the peripheral nervous system and on the heart;
- provide information on the GRADIENT OUTPUT of which the MR EQUIPMENT is capable in each operating mode;
- explain that the MR EQUIPMENT will display an indication of the appropriate operating mode when the value of GRADIENT OUTPUT exceeds the limits of the NORMAL OPERATING MODE;

- describe the gradient system as either a WHOLE BODY GRADIENT SYSTEM or as a SPECIAL PURPOSE GRADIENT SYSTEM and describe the volume in which the GRADIENT OUTPUT is in compliance.

j) Exposure of the PATIENT to radio frequency magnetic fields

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

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

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

- explain the possible effects of elevated values of the different types of SAR that are limited by the MR EQUIPMENT as required in 201.12.4.103;
- explain the possible effects of the SAR on the PATIENTS in each of the operating modes provided by the MR EQUIPMENT, paying particular attention to the safety of PATIENTS who can have reduced thermal regulatory capabilities and increased sensitivity to raised body temperature (e.g. febrile and cardiac decompensated PATIENTS, those with compromised ability to perspire, and pregnant women). In addition, information describing the importance of environmental controls and the effect of ENVIRONMENTAL TEMPERATURE ON PATIENT CORE TEMPERATURE rise shall be provided, along with recommendations for environmental conditions for the PATIENT;
- provide information on the values of each type of SAR the MR EQUIPMENT is capable of;
- explain that the limits for the operating modes for WHOLE BODY SAR given in 201.12.4.103 assume that the ENVIRONMENTAL TEMPERATURE is not more than 25 °C. In addition, the instructions for use shall explain how the SAR is controlled outside these environmental specifications. This explanation shall
 - specify that the MR EQUIPMENT shall not be used when the ENVIRONMENTAL TEMPERATURE is greater than 25 °C, or

- explain that the limit of the FIRST LEVEL CONTROLLED OPERATING MODE for SAR shall be reduced according to 201.12.4.103.2 (only for MR EQUIPMENT that has the capability to measure the ENVIRONMENTAL TEMPERATURE);
- draw attention to means to reduce the RISK from high SAR scanning, such as the need for breaks for the PATIENT to cool down, light clothing for the PATIENT and adequate ventilation of the PATIENT space;
- explain that the value of the $\overline{B_{1+RMS}}$ displayed on the CONTROL PANEL for each sequence is an indication of the RF magnetic field intensity. It can be of use to determine the RISK of scanning a patient with an active or passive implant.

* k) Occupational exposure to EMF

The instructions for use shall draw attention to the fact that MR WORKERS can be exposed to the electromagnetic fields (EMF) emitted by the MR EQUIPMENT. It shall provide sufficient information relating to the RISKS from these exposures to enable safe working procedures for the MR WORKER. The relevant requirements of 201.7.9.2.101 i) and j) for the PATIENT shall also apply for the MR WORKER. This information shall also include

- specification of areas to which access by the MR WORKER is restricted, if any;
- information on the maximum levels of the exposure in areas accessible to the MR WORKER, expressed in proper units for the static magnetic field (see subclause 201.7.9.2.101 h) and 201.12.4.104), the GRADIENT OUTPUT (see subclause 201.7.9.2.101.i) and 201.12.4.102) and the RF transmit field (see subclause 201.7.9.2.101 j) and 201.12.4.103) generated by the MR EQUIPMENT;
- instructions that the MR WORKER shall be informed and trained sufficiently so that they can perform all their tasks safely in a way that minimizes their exposure to EMF emitted by the MR EQUIPMENT;
- a statement that there is a possibility that mild Peripheral Nerve Stimulation (PNS) can be induced in the PATIENT and MR WORKER when exposed to the gradients in the FIRST LEVEL CONTROLLED OPERATING MODE;

The RISK factors associated with the expected exposure levels for the MR WORKER shall be explained. A description of ways for the MR WORKER to mitigate these RISK factors shall be given.

Known factors to draw attention to are:

- the possible physiological effect of exposure to RF radiation is heating. Exposure to RF radiation can be minimized by keeping sufficient distance away from the transmit RF coil or by reducing time of exposure during scanning;
- the possible physiological effect of exposure to the GRADIENT OUTPUT is peripheral nerve stimulation for the person exposed. Especially MR WORKERS performing INTERVENTIONAL MR EXAMINATIONS, shall be informed and trained that, although peripheral nerve stimulation is not expected, the SAFETY of PATIENTS shall not be compromised during interventional procedures due to peripheral nerve stimulation. Exposure to GRADIENT OUTPUT can be minimized by keeping sufficient distance away from the gradient coils during scanning.
- the possible physiological effects of exposure to static magnetic field are dizziness, vertigo, and a metallic taste in the mouth of the person exposed. Exposure to the static magnetic field can be minimized by staying away from the magnet (not just during scanning but all the time) and by avoiding rapid movements of the head while in the static magnetic field.

The INSTRUCTIONS FOR USE may state that it is generally accepted that no published evidence supporting the occurrence of cumulative and/or long-term effects after exposure to EMF emitted by the MR EQUIPMENT exists.

The instructions for use shall state that extra precaution is advisable for pregnant MR WORKERS, although there is no currently available epidemiological evidence for any negative health effects.

NOTE 4 Local regulations might apply.

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

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

* l) Auxiliary EQUIPMENT

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

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

m) EMERGENCY FIELD SHUT DOWN UNIT

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

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

n) Fire precautions

The instructions for use shall recommend to the RESPONSIBLE ORGANIZATION that fire precautions should be discussed with the local fire department, that emergency procedures should be established and that it is the RESPONSIBLE ORGANIZATION's responsibility to take the necessary initiatives.

o) Artefacts

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

p) Recommended training

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

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

q) Quality assurance

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

r) Maintenance

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

* s) Emergency actions in case of a QUENCH

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

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

A₂ The instructions for use shall declare that MR scanning is contra-indicated for PATIENTS with implants, the exception being PATIENTS with known MR safe or MR conditional implants that can be scanned according to the conditions specified in the implant labelling. The instructions for use shall describe the following RISKS associated with the scanning of PATIENTS with active or passive implants containing metal or other magnetic and/or electrically conductive materials:

- the electromagnetic fields might exert strong forces on such implants;
- the electromagnetic fields might interfere with the operation of active devices;
- the implants might cause significant artefacts in the MR image;
- MR scanning when an implant is present might cause HARM such as internal heating that results 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 MR conditional implants:

- the MR scan should only be conducted based on the result of a risk versus benefit assessment by the RESPONSIBLE ORGANIZATION;
- the MR OPERATOR shall adhere to the conditions of use defined in the MR conditional implant labelling as described in the ACCOMPANYING DOCUMENTS of the implant MANUFACTURER;
- the instructions for use shall include a statement to explain the roles and responsibilities of the MR MANUFACTURER, the implant MANUFACTURER and the MR OPERATOR in scanning of PATIENTS with MR conditional implants.

NOTE 8 Sample text is provided in Annex AA. **A₂**