IEC 60601-2-33

Edition 3.0 2015-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

AMENDMENT 2
AMENDEMENT 2

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

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

IEC 60601-2-33:2010-03/AMD2:2015-06(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62B/977/FDIS	62B/987/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

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

INTRODUCTION TO AMENDMENT 2

This Amendment 2 has been developed to increase the FIRST LEVEL CONTROLLED OPERATING MODE limit for the static field from 4 T to 8 T taking into account FDA, ICNIRP and other peer reviewed scientific literature. In addition, a non-compulsory option, FIXED PARAMETER OPTION:BASIC (FPO:B), is introduced to limit RF and gradient field outputs (peak and RMS) for scanning PATIENTS with MR conditional implants. Consequently, text is proposed for the Instructions for use to guide users in scanning PATIENTS with MR conditional implants.

Furthermore, references to newly published collateral standards have been updated.

201.1.3 Collateral standards

Replace, in the first sentence of the second paragraph, the reference to "IEC 60601-1-2:2007" *with* "IEC 60601-1-2:2014".

201.2 Normative references

*Replace, under "Replacement", the reference to "*IEC 60601-1-2:2007" *with* the following:

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*

Add, under "Replacement", the following new references:

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

201.3 Terms and definitions

*** 201.3.201**
B_{1+}rms

Delete, in the first line of the definition, "the MR relevant radiofrequency magnetic induction".

Replace, in the last line of the definition "evaluation time" *with* "integration time".

Replace, in the last line of the definition ", and is estimated at the RF transmit coil centre" *with* ", which shall be any 10 s period over the duration of the entire sequence"

Add the following new note to entry:

Note 1 to entry: B_{1+} 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.

201.3.203
CONTROLLED ACCESS AREA

Replace the existing text of the definition with the following:

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.

201.3.234
TIME RATE OF CHANGE OF THE MAGNETIC FIELD
d*B*/d*t*

Add, at the end of the definition, the following note to entry:

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.

Add the following new terms:

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**
(|d*B*/d*t*| *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**
(|d*B*/d*t*| *RMS*)$_{FPO}$
root mean square (rms) of the magnitude of the time rate of change of the magnetic field for FPO

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

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

*** 201.3.250**
SPATIAL FIELD GRADIENT
SFG
spatial rate of change of the main magnetic field $\left|\nabla\left|\vec{B}\right|\right|$, 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.

Table 201.101 – List of symbols

Replace the existing title with the following:

Table 201.101 – List of symbols and abbreviations

201.7 ME EQUIPMENT identification, marking and documents

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)

*Replace, in the first sentence of the first paragraph, "*ISO 7010-W005 and ISO 7010-W006*" with "*ISO 7010-W005 (see Table 201.D.101, safety sign 1) and ISO 7010-W006 (see Table 201.D.101, safety sign 2)"

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

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

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

Add, at the end of the only sentence in Note 1, "(see Table 201.D.101, safety sign 6)"

* f) Liquid and gaseous cryogens

Add, between the first and second bullet points under the last dash, the following new note:

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.

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

Replace, in the 4th dash, "4 T" with "8 T".

Replace, in the 8th dash, "4 T" with "8 T".

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

Replace the entire text of this item with the following:

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

w) About function

Replace the existing text of the second dash by the following:

– Maximum SPATIAL FIELD GRADIENT of the static magnetic field [T/m] outside the FIXED magnet covers

NOTE Historical labeling practice for MR conditional devices uses G/cm where 1 T/m is equivalent to 100 G/cm. Providing the conversion factor and/or the quantities in both units may be appropriate.

Add, after the second dash, the following new dash:

– Maximum spatial encoding gradient amplitude [mT/m] and maximum slew rate [T/m/s], both specified on a per axis basis

Replace the final dash with the following:

– Maximum combined GRADIENT OUTPUT [T/s] on a cylinder with a diameter of 0,2 m, 0,4 m and bore-diameter minus 0,1 m

Add, at the end of subclause 201.7.9.2.101, the following new item:

x) FPO (FIXED PARAMETER OPTION)

If the system has FPO capabilities, the following information shall be given:

– a statement that FPO limits the gradient and RF output in terms of dB/dt and B_{1+};
– a statement that FPO requires OPERATOR activation;
– instructions on how to activate FPO;
– a statement that FPO limits may be part of MR conditional medical device labelling and that other scanning limits and/or PATIENT preparation may be required in addition to FPO to fully comply with the implant device MR conditional labelling;
– a statement that FPO does not alter previously established operating modes, i.e. FPO can work in NORMAL OPERATING MODE and FIRST LEVEL CONTROLLED OPERATING MODE;
– a statement indicating that FPO is for use with devices that have MR conditional labelling that specifies FPO and the use of FPO when scanning PATIENTS with medical devices that do not have FPO labelling is potentially hazardous and may cause serious injury or death.

201.7.9.3 Technical description

201.7.9.3.101 Technical description of MR EQUIPMENT

a) CONTROLLED ACCESS AREA

Replace this subtitle as follows:

a) CONTROLLED ACCESS AREA and SPECIAL ENVIRONMENT

Replace, in the first paragraph, "permanently attached" *with* "FIXED magnet".

Delete, *in the same paragraph,* "and/or an electromagnetic interference level that does not comply with IEC 60601-1-2, ".

Add, at the end of the first dash, " the static magnetic fringe field strength shall not exceed 0,5 mT;"

Delete existing items 1) and 2).

*Add, in the third dash, before the words "*magnetic fields*", the word* "static".

Add, after the third dash, the following new paragraph:

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

Add, after the new paragraph, the following new note:

NOTE 5 See also 202.5.2.2.2

* b) Compatibility technical specification sheet

Replace, in the third bullet under the first dash, the existing text of the first sentence with the following:

"The position in locations outside the FIXED magnet covers where SPATIAL FIELD GRADIENT (SFG) is maximum, and the values of B_0 and the SFG at that location."

Replace, in the fourth bullet under the first dash, the existing text of the first sentence with the following:

"The position in locations outside the FIXED magnet covers where the product of the magnitude of the static magnetic field B_0 and the SFG is maximum and the value of B_0 and SFG at that location."

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

201.9.8 HAZARDS associated with support systems

Replace the existing title of this subclause with the following:

201.9.8 MECHANICAL HAZARDS associated with support systems

Add the following new subclause:

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.3 Dynamic forces due to loading from persons

Addition:

Where it is determined that the dynamic loading test of the general standard applies, the following provides an alternative means of compliance.

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

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

Compliance is checked by the following test:

Prior to performing this test, a PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL *USE WHERE PATIENT loading and unloading takes place.*

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

NOTE 2 The foam described in Figure 33 of the general standard is not required for this test.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

* 201.12.4 Protection against hazardous output

201.12.4.101 Operating modes

201.12.4.101.2 All operating modes

Add, at the end of this subclause:

d) The MR EQUIPMENT shall, on request, display "CP" on the CONTROL PANEL if CIRCULARLY POLARIZED RF is used for the scan. For systems capable of other types of driving the VOLUME RF TRANSMIT COIL, means shall be provided to the MR OPERATOR to select CIRCULARLY POLARIZED RF. If selected, CIRCULARLY POLARIZED RF shall be active over the entire examination.

* 201.12.4.103 Protection against excessive radio frequency energy

* 201.12.4.103.2 Limits for SAR

Table 201.105 – SAR limits for volume transmit coils

Replace, in the 8th row, 1st column "Long MR EXAMINATION specific absorbed energy" *with* "MR EXAMINATION specific absorbed energy"

Replace, in the 8th row, 2nd column, the entire text with:

"The max. energy dose (SAR × examination time) shall be limited, subject to the RISK MANAGEMENT."

Replace Note 3 with:

NOTE 3 The MR EXAMINATION specific absorbed energy limitation has been introduced because very long duration PATIENT studies have become more common. It limits either the MR EXAMINATION duration or the SAR level of the individual scans of this MR EXAMINATION and is applicable to all SAR limits and all operating modes. If there are multiple, separate studies on a given day where the PATIENT has been given a reasonable rest, each study is considered to be independent from a MR EXAMINATION specific absorbed energy perspective.

* 201.12.4.104 Protection against exposure to static magnetic fields

*Replace, in the first paragraph of item b), "*4 T" *with* "8 T".

Delete the second paragraph of item b).

Replace, in item c, “4 T” *with* “8 T”.

Replace, in the paragraph after item c) starting with “Physiological effects”, both instances of “shall” *with* “should”.

Add the following new subclause:

* 201.12.4.106 Fixed limits to physical outputs of MR EQUIPMENT

201.12.4.106.1 General

Scanning of a PATIENT with a device which is labelled MR conditional could require controlled outputs of the MR EQUIPMENT to less than the system capabilities. The MANUFACTURER of the MR EQUIPMENT may implement a FIXED PARAMETER OPTION (FPO) for this purpose. If implemented, FPO shall be designed to comply with all requirements of 201.12.4.106. FPO shall not interfere with proper application of the evaluation and reporting of the operating modes (see 201.12.4.101).

A system that has implemented FPO guarantees that the controlled outputs will not exceed the specified values. The safety of an MR conditional implant labelled for FPO cannot be assessed in a system running FPO.

201.12.4.106.2 Limit values

The following limits shall be applied to RF field and GRADIENT OUTPUT when the MR EQUIPMENT is operated in the FPO. The set of values provided in Table 201.107 shall be called FPO:B.

NOTE 1 B denotes “basic”. This reflects the possibility to add another FPO at a later point in time with other limit values than those defined in 201.107.

Table 201.107 – FPO limits applicable for cylindrical MR SYSTEMS

Physical Parameter	FPO:B
Nominal static magnetic field strength	1,5 T
Applicable coils	Birdcage WHOLE BODY RF TRANSMIT COIL Birdcage HEAD RF TRANSMIT COIL CIRCULARLY POLARIZED RF shall be applied.
B_{1+} *PEAK*	<= 30 μT
B_{1+} *RMS*	<= 3,2 μT
$(\lvert dB/dt\rvert\ PEAK)_{FPO}$	<= 100 T/s
$(\lvert dB/dt\rvert\ RMS)_{FPO}$	<= 56 T/s

NOTE 2 Cylindrical MR systems with elliptical PATIENT apertures can meet requirements for FPO:B.

201.12.4.106.3 User interface

The MR EQUIPMENT shall provide a means on the CONTROL PANEL to activate FPO during PATIENT registration. While active, the user interface shall indicate that FPO is enabled and give the FPO version (e.g. FPO:B). FPO:B will remain active for the remainder of the examination until the next PATIENT registration.

201.12.4.106.4 Implementation and demonstrating compliance for B_{1+} *PEAK

The MR EQUIPMENT shall control the value of B_{1+} *PEAK* for each RF pulse in every sequence, including adjustment sequences (prescan), not to exceed the values specified in Table 201.107.

Compliance is demonstrated by design review of the applied limits in the sequence pre-calculation software, or by evaluation of pre-calculated B_{1+} PEAK values for all RF pulses in sequences developed under FPO restrictions. Compliance shall be evaluated for all adjustment sequences intended to be used with FPO enabled. In addition, run-time hardware and/or software checks may be used in the MR EQUIPMENT to ensure that the actual B_{1+} PEAK never exceeds the B_{1+} PEAK values as specified in Table 201.107. A possible method to control B_{1+} PEAK is described in the rationale.

NOTE The spatially-localized amplitude of total B_1 vector, especially in the off-centre position, may exceed the nominal value of B_{1+} *PEAK* by up to an order of magnitude.

201.12.4.106.5 Implementation and demonstrating compliance for B_{1+} *RMS*

The MR EQUIPMENT shall control the value of B_{1+} *RMS* for every sequence, including adjustment sequences (e.g. prescan), not to exceed the values specified in Table 201.107.

Compliance shall be demonstrated by design review.

NOTE The spatially-localized amplitude of total B_1 *RMS* vector, especially in the off-centre position, may exceed the nominal value of B_{1+} *RMS* by up to an order of magnitude.

201.12.4.106.6 Implementation and demonstrating compliance for (|d*B*/d*t*| *PEAK*)$_{FPO}$

The MR EQUIPMENT shall control the value of (|d*B*/d*t*| *PEAK*)$_{FPO}$ whenever the gradient is slewing, in every sequence, including adjustment sequences, not to exceed the values specified in Table 201.107.

The values for (|d*B*/d*t*| *PEAK*)$_{FPO}$ shall be controlled at a surface providing 5 cm clearance to the outline of the PATIENT accessible volume.

The (|d*B*/d*t*| *PEAK*)$_{FPO}$ value shall be calculated per sequence.

Compliance is demonstrated by application of calculation methods specified in 201.12.4.105.2.2 at the surface providing 5 cm clearance to the outline of the PATIENT accessible volume. Based on symmetries, calculation in one octant of the gradient coil may be sufficient to demonstrate compliance. Software validation for representative sequences shall prove that calculated values do not exceed the value defined in Table 201.107. This can be a measurement with a pick up coil at representative locations.

201.12.4.106.7 Implementation and demonstrating compliance for (|dB/dt| RMS)$_{FPO}$

The MR EQUIPMENT shall control the value of (|d*B*/d*t*| *RMS*)$_{FPO}$ for every sequence, including adjustment sequences, not to exceed the values specified in Table 201.107.The MANUFACTURER shall select one of the following five tiers based on numerical evaluation of the GRADIENT OUTPUT to implement control of (|d*B*/d*t*| *RMS*)$_{FPO}$.

a) Calculate maximum allowed SLEW PERCENTAGE using (|d*B*/d*t*| *RMS*)$_{FPO}$ and (|d*B*/d*t*| *PEAK*)$_{FPO}$ from Table 201.107 where the relationship is (|d*B*/d*t*| *RMS*)$_{FPO}$ = (|d*B*/d*t*| *PEAK*)$_{FPO}$ *SQRT(SLEW PERCENTAGE). The MR EQUIPMENT shall ensure by evaluation of the gradient waveforms that the actual SLEW PERCENTAGE in the sequence will not exceed the maximum allowed SLEW PERCENTAGE.

b) Calculate peak |d*B*/d*t*| for each gradient slew using the method of 201.12.4.106.6, determine the global maximum (|d*B*/d*t*| *PEAK*)$_{FPO}$ of all gradient slews in the sequence, and use that maximum to calculate (|d*B*/d*t*| *RMS*)$_{FPO}$ = (|d*B*/d*t*| *PEAK*)$_{FPO}$ *SQRT(SLEW

PERCENTAGE), where the actual SLEW PERCENTAGE in the sequence is derived using numerical evaluation of the sequence gradient waveform. The MR EQUIPMENT shall ensure that $(|dB/dt|\ RMS)_{FPO}$ does not exceed that value from Table 201.107.

c) Calculate peak $|dB/dt|$ for each gradient slew using the method of 201.12.4.106.6. $(|dB/dt|\ RMS)_{FPO}$ shall be derived from a full integration of the values of peak $|dB/dt|$ for the individual slews, over the duration of the sequence. The MR EQUIPMENT shall ensure that $(|dB/dt|\ RMS)_{FPO}$ does not exceed that value from Table 201.107.

d) Calculate peak $|dB/dt|$ for each gradient slew in all octants of the gradient coil. $|dB/dt|\ RMS$ shall be evaluated in each octant by full integration over the duration of the sequence of peak $|dB/dt|$ of every gradient slew. $(|dB/dt|\ RMS)_{FPO}$ is the maximum of $|dB/dt|\ RMS$ as calculated in the individual octants. The MR EQUIPMENT shall ensure that $(|dB/dt|\ RMS)_{FPO}$ does not exceed that value from Table 201.107.

e) Calculate peak $|dB/dt|$ between every gradient waveform control point in all octants of the gradient coil. $|dB/dt|\ RMS$ shall be evaluated in each octant by full integration over the duration of the sequence. $(|dB/dt|\ RMS)_{FPO}$ is the maximum of $|dB/dt|\ RMS$ as calculated in the individual octants. The MR EQUIPMENT shall ensure that $(|dB/dt|\ RMS)_{FPO}$ does not exceed that value from Table 201.107.

NOTE Each tier offers progressively more accuracy and sequence performance.

The $(|dB/dt|\ RMS)_{FPO}$ evaluation interval shall not exceed 6 min. If the sequence exceeds 6 min, report the worst 6 min segment. If the sequence is less than 6 min, the $(|dB/dt|\ RMS)_{FPO}$ evaluation interval can be averaged over several sequences, but not to exceed 6 min.

Compliance is demonstrated by simulation of representative sequences.

* 202 Electromagnetic compatibility – Requirements and tests

Replace the entire existing text of the clause with the following:

IEC 60601-1-2:2014 applies except as follows:

202.2 Normative references

Amendment:

Delete the following normative references: IEC 60601-1-11:2010, IEC 60601-1-12, IEC 60601-2-2:2009, IEC 60601-2-3:2012.

202.5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents

202.5.1 Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT

Replacement:

The SPECIAL ENVIRONMENT for the MR SYSTEM is defined as the room equipped with RF shielding provisions containing the magnet, including the access door, penetration panels for power and control cables, and an optional window. The RF shielding effectiveness of this room shall be specified in the ACCOMPANYING DOCUMENTS.

202.5.2 ACCOMPANYING DOCUMENTS

202.5.2.1 Instructions for use

Amendment:

This subclause does not apply to the instructions for use but to the technical description of the MR SYSTEM.

202.5.2.1.1 * General

Amendment:

Delete items c) and f).

202.5.2.2 Technical description

202.5.2.2.2 Requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT

Amendment:

Delete item d).

Addition:

aa) recommended practices to help maintain the RF shielding effectiveness and integrity of the RF shielded room for the EXPECTED SERVICE LIFE of the MR SYSTEM.

NOTE Examples of recommended practices include but are not limited to the following:

– periodic cleaning and inspection of the RF access door(s). RF shielding performance of access door(s) is compromised if damaged or if dirt and debris is accumulated on the door perimeter;

– disallow any unauthorised electrical cables to enter the RF shielded room;

– disallow any unauthorised modifications to the RF shielded room.

202.7 ELECTROMAGNETIC EMISSIONS REQUIREMENTS FOR ME EQUIPMENT AND ME SYSTEMS

Addition:

202.7.101 ELECTROMAGNETIC EMISSIONS for MR EQUIPMENT

The MR EQUIPMENT outside the SPECIAL ENVIRONMENT shall comply with Clause 7 of IEC 60601-1-2:2014.

Inside the SPECIAL ENVIRONMENT, Clause 7 of IEC 60601-1-2:2014 does not apply. The requirements stated in 201.7.9.2.101 e) are applicable.

202.8 Electromagnetic IMMUNITY requirements FOR MR EQUIPMENT

Addition:

202.8.101 Electromagnetic IMMUNITY for MR EQUIPMENT

The MR EQUIPMENT outside the SPECIAL ENVIRONMENT shall comply with Clause 8 of IEC 60601-1-2:2014.

All OPERATOR and PATIENT ACCESSIBLE PARTS of the MR EQUIPMENT in the SPECIAL ENVIRONMENT shall comply with the ESD requirements in clause 8.1 of IEC 60601-1-2:2014.

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall determine if components of the MR EQUIPMENT used inside the SPECIAL ENVIRONMENT should comply with requirements of Clause 8 in order to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE When selecting the immunity requirements inside the special environment, the manufacturer takes into account the electromagnetic disturbances related to electromagnetic phenomena that could interfere with provisions to ensure basic safety and essential performance.

Annex D Symbols on marking

Replace the entire existing text of the annex with the following:

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

Addition:

Additional safety signs and symbols that may be used for marking on or with MR SYSTEMS and MR EQUIPMENT are found in Tables 201.D.101, 201.D.102 and 201.D.103.

Table 201.D.101 – MR safety signs

No.	Safety sign	Reference	Title
1		ISO 7010-W005	Warning; Non-ionizing radiation
2		ISO 7010- W006	Warning; Magnetic field
3		ISO 7010-P007	No access for people with active implanted cardiac devices
4		ISO 7010-P014	No access for people with metallic implants
5		ISO 7010-P008	No metallic articles or watches