TECHNICAL SPECIFICATION

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Second edition
2018-04

Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

Évaluation de la sécurité de l'imagerie par résonance magnétique pour les patients avec un dispositif médical implantable actif

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*, and Technical Committee IEC TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62B, *Diagnostic imaging equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition cancels and replaces the first edition (ISO/TS 10974:2012) which has been technically revised.

Introduction

The first edition (2012) of this document came about following a joint meeting between ISO/TC 150, *Implants for surgery*, and IEC/SC 62B/MT 40, *Magnetic resonance equipment for medical diagnosis*, in Vienna, Austria, in September 2006. An agreement was reached to coordinate efforts on the development of a new Technical Specification for the safety of patients with active implantable medical devices (AIMD) undergoing an MRI exam and related further development of IEC 60601-2-33.

This second edition represents experience gained from the first edition of its use in practice and the current understanding of relevant issues and concerns at 1,5 T, the most common MR field strength. The Joint Working Group (JWG) responsible for this document (ISO/TC 150/SC 6/JWG 2 and IEC/SC 62B/JWG 1) releases this edition to promote further developments in this area. The JWG anticipates the possibility that an International Standard might result from this work.

IEC 60601-2-33 provides supporting information. By mutual agreement between the JWG and MT 40, any and all MR scanner-related requirements will be considered by IEC/SC 62B/MT 40 and will be released through future amendments and editions of IEC 60601-2-33.

No requirements contained within this document, including the use of clinical scanners, construe or imply any obligation for compliance on the part of MR scanner manufacturers. Any statement to the contrary is strictly unintentional.

The relationship between product committees is shown in Figure 1. Straight lines represent the relationship and not necessarily a physical connection. Ellipses represent scope, i.e. the effects between patient and scanner, patient and AIMD, and AIMD and scanner.

The JWG is concerned with effects on the AIMD caused by the scanner. ISO/TC 150/SC 6 is concerned with resulting potential hazards to the patient caused by the AIMD. IEC 62B/MT40 is concerned with potential hazards to the patient caused by the MR scanner.

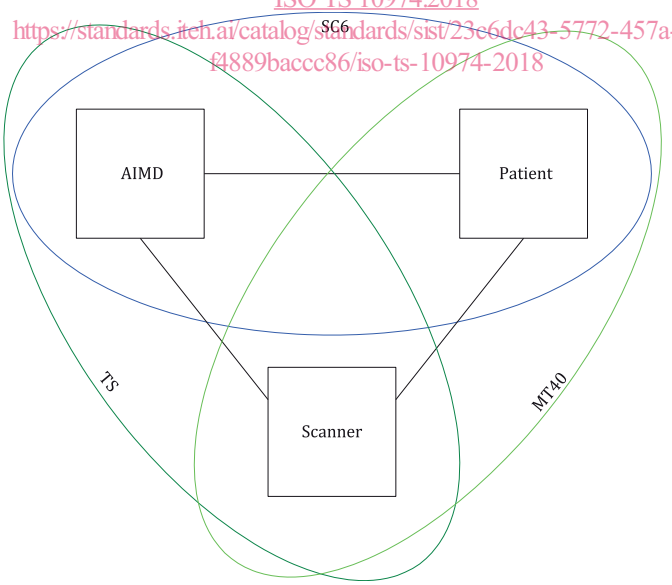

Figure 1 — Responsibilities of product committees illustrating the extent of the scope of this document in terms of the effects between AIMDs and MR scanners

The test methods contained in this document for evaluating device operation against several hazards are applicable to a broad class of AIMDs. Tests for particular device types are not included. Specific

compliance criteria and the determination of risk resulting from device behavioural responses during these tests are outside the scope of this document.

NOTE The device manufacturer, regulatory agencies and particular product committees, are responsible for setting specific compliance criteria and the determination of risk. For example, ISO/TC 150/SC 6 might turn the general provisions of this document into product-specific requirements.

The test methods in this document were derived from six known or foreseeable potential hazards to patients with an AIMD undergoing an MR scan. These general hazards give rise to specific test methods as shown in Table 1.

Table 1 — Potential patient hazards and corresponding test methods

General hazard	Test method	Clause
Heat	RF field-induced heating of the AIMD	8
	Gradient field-induced device heating	9
Vibration	Gradient field-induced vibration	10
Force	B_0-induced force	11
Torque	B_0-induced torque	12
Unintended stimulation	Gradient field-induced lead voltage (extrinsic electric potential)	13
	RF field-induced rectified lead voltage	15
Malfunction	B_0 field-induced device malfunction	14
	RF field-induced device malfunction	15
	Gradient field-induced device malfunction	16
	Combined fields test	17

Figure 2 depicts the relationship between the three output fields of an MR scanner (RF, gradient, and B_0) and the hazards considered by this document. In the figure, extrinsic electric potential and RF rectification are represented as Unintended Stimulation and heat is shown as occurring from two sources, Electrode Heating and Device Heating. Numbers in parentheses indicate clause numbers. For example, RF field-induced heating of electrodes is evaluated according to the test method in Clause 8.

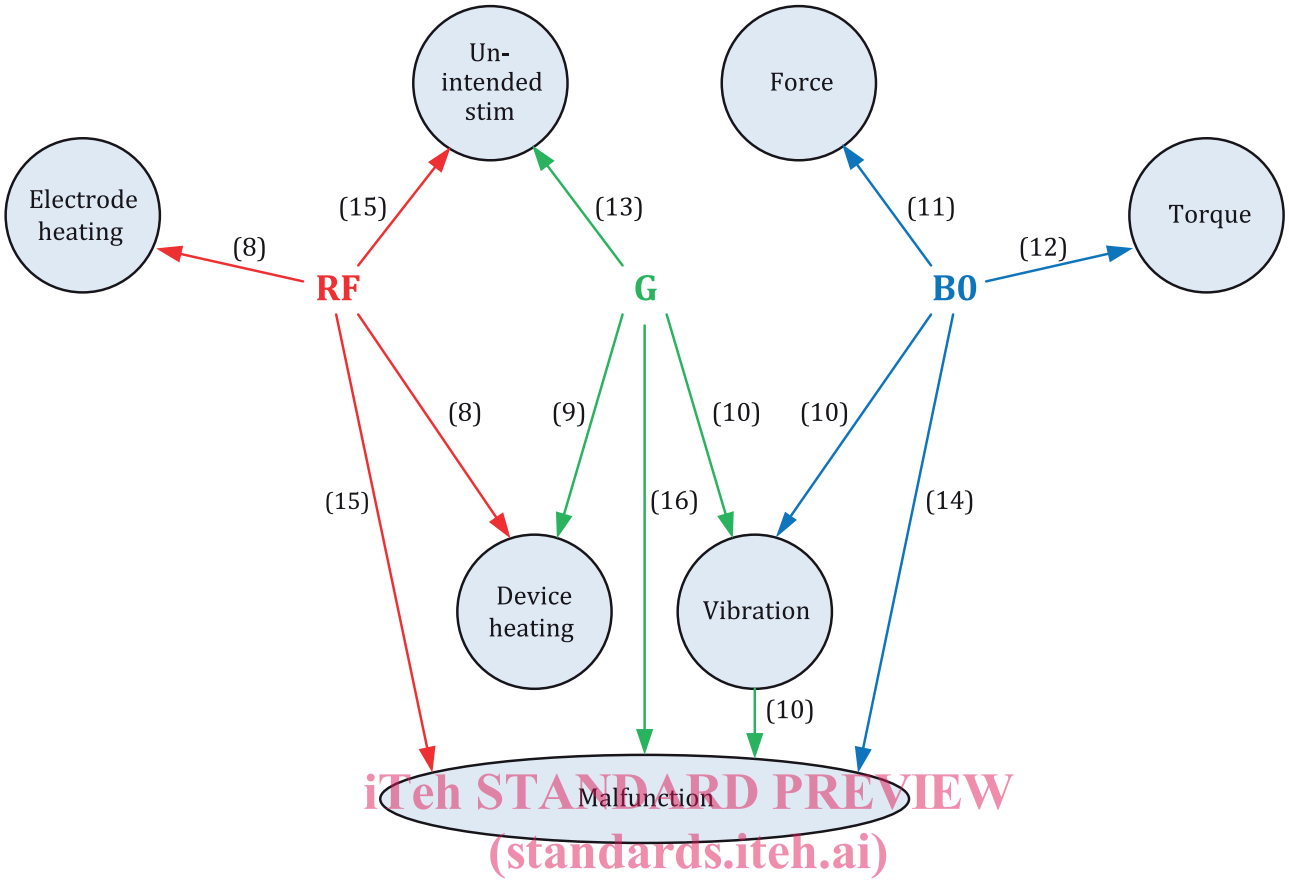

Figure 2 — Relationship between MR scanner output fields (RF, gradient, B_0) and hazards (test method clause numbers in parentheses)

Evaluation of the AIMD for these hazards involves some combination of testing and modelling. Tests in Clauses 8 through 16 may use bench-top testing, modelling, MR scanners, or a combination of these approaches. The test in Clause 17 uses an MR scanner. Devices are subjected to radiated fields or injected voltages in order to witness behavioural responses. Modelling may be employed to determine appropriate test signal voltage levels or to estimate tissue heating, for example. Within this document device immunity to the B_0, RF, and gradient fields is evaluated separately, except for Clause 17.

In addition to the tests listed in Table 1, this document contains requirements for markings and accompanying documentation (Clause 18).

RF-induced heating of tissues surrounding an AIMD is caused by elevated local SAR and associated component heating that arises from induced currents.

Gradient-induced device heating is caused by eddy currents.

Device vibration is due to the combined effect of the B_0 (static) and gradient fields.

Force and torque is caused by B_0 (static) interaction with magnetic materials.

Extrinsic electric potential is meant to imply that the induced voltage comes from outside the device as in the case of gradient-induced stimulation or modification of output pulses due to superposition. The result involves voltages not caused by a device malfunction.

Rectification of induced voltages can occur if the induced voltage is high enough to cause nonlinear circuit elements to conduct, for example, an input protection diode. Rectification might result in voltage pulses occurring at a distal electrode. The resulting rectified voltage is an unintended consequence of the reaction of the AIMD and is not considered a device failure or malfunction, per se.

Malfunction is meant to capture a wide range of performance issues, such as degradation of performance, loss of function, unintentional responses, etc., due to device failure caused by, for example, the improper operation of a circuit element or motor. Since malfunctions are highly device-specific, and unknown in a general sense for all AIMD types, they remain undefined in this document.

This document applies to AIMDs that are intended to be introduced into certain MR environments. It applies only to AIMDs that do not use sensing functions or to AIMDs that are programmed not to use sensing functions to affect therapy delivery during an MR scan.

The Combined Fields Test establishes an *in vitro* evaluation of the AIMD functioning under simultaneous exposure to the static, gradient, and RF magnetic field conditions. Unlike the maximal exposures required in the tests for Clauses 8 through 16, the Combined Fields Test exposes the AIMD to levels and temporal patterns of all three MR scanner magnetic field outputs simultaneously. The Combined Field Test alone does not constitute a comprehensive assessment of device performance and should be considered as one part of the overall assessment process.

Test methods described in this document are primarily designed and intended as bench-top tests using equipment and techniques producing effects (B_0 static, gradient, and RF) representative of those generated by MR 1,5 T scanners. The exception being Clause 17. Although, in a few cases, clinical scanner tests are implied, in all others, the AIMD manufacturer assumes the burden for development and validation of clinical scanner-based test methods. Furthermore, the test signals and parameters specifically described within this document for bench-top testing are not being encouraged or recommended for use on clinical scanners and to do so might result in scanner damage. No scanner operation beyond commercially released clinical performance is required from the MR Manufacturer.

The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) draw attention to the fact that it is claimed that compliance with this document may involve the use of a patent concerning gradient vibration given in Clause 10.

ISO and IEC take no position concerning the evidence, validity and scope of this patent right.

The holder of this patent right has assured ISO and IEC that he or she is willing to negotiate licences under reasonable and non-discriminatory terms and conditions with applicants throughout the world. In this respect, the statement of the holder of this patent right is registered with ISO and IEC (an example of the patent declaration is shown in Annex G). Further information may be obtained from:

Medtronic, Inc.
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8200 Coral Sea St. NE, MVN43
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Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those identified above. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

1 Scope

This document is applicable to implantable parts of active implantable medical devices (AIMDs) intended to be used in patients who undergo a magnetic resonance scan in 1,5 T, cylindrical (circular or elliptical cross-section) bore, whole body MR scanners operating at approximately 64 MHz with whole body coil excitation.

NOTE 1 Requirements for non-implantable parts are outside the scope of this document.

The tests that are specified in this document are type tests that characterize interactions with the magnetic and electromagnetic fields associated with an MR scanner. The tests can be used to demonstrate device operation according to its MR Conditional labelling. The tests are not intended to be used for the routine testing of manufactured products.

NOTE 2 Modification of these tests for particular device types is left to particular product committees.

NOTE 3 Other interested parties, such as device manufacturers, regulatory agencies, and particular product committees, are responsible for setting specific compliance criteria and determining risk.

NOTE 4 Safety requirements for MR scanners can be found in IEC 60601-2-33.

NOTE 5 The scope is limited to AIMDs that do not use sensing functions or to AIMDs that are programmed not to use sensing functions to affect therapy delivery during an MR scan.

2 Normative references

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.

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

ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM F2213, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*

ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
active implantable medical device
AIMD
active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

Note 1 to entry: For the purposes of this document, an AIMD is a system consisting of a set of one or more implantable components (e.g. device and leads).

[SOURCE: ISO 14708-1:2014, 3.2]

3.2
B_0
static magnetic field of the MR scanner, taken as 1,5 T in this document, unless otherwise stated

3.3
$B_{1+\mathrm{rms}}$
root mean square (rms) of B_{1+}

$$B_{1+\mathrm{rms}} = \sqrt{\frac{\int_0^{t_x} \left[B_{1+}(t)\right]^2 dt}{t_x}}$$

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

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.

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.201]

3.4
B_{1+}
component of the RF field in the rotating frame that is effective for tilting of the nuclear magnetization

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.244]

3.5
$B_{1+\mathrm{peak}}$
peak amplitude of B_{1+}

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.245]

3.6
birdcage coil
radiator which generates the RF portion of the magnetic field

Note 1 to entry: This usually refers to a bench-top coil used to simulate the operation of a scanner's volume RF transmit coil.

3.7
compliance volume
patient-accessible space in which compliance of gradient output is inspected

Note 1 to entry: 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 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.

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.202]

3.8
|*dB/dt*| rms
root mean square (rms) of the magnitude of the time rate of change of the gradient magnetic field

$$\left|\frac{dB}{dt}\right|_{\mathrm{rms}} = \sqrt{\frac{\int_0^{t_x} \left|\frac{dB}{dt}\right|^2 dt}{t_x}}$$

where t is time, and t_x is the integration time.

3.9
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

Note 1 to entry: Definition and validation of physiological stress is defined in the absence of additional sources that can cause or enhance stress factors (like AIMDs).

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.208, modified — the term “may” in Note 1 to entry has been replaced to “can”.]

3.10
fixed parameter option
FPO
option within existing modes (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

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.242]

3.11
fixed parameter option:basic
FPO:B
“basic” denotes a specific implementation of FPO, exclusively for 1,5 T MR systems

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.243]

3.12
G
magnetic field gradient expressed in units of T/m

Note 1 to entry: G_x introduces a spatial gradient along the X-axis of the reference coordinate system, G_y introduces a gradient along the Y-axis, and G_z introduces a gradient along the Z-axis.

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, Table 201.101]

3.13
gradient output
parameter characterizing the gradient performance, such as rate of change of the magnitude of the magnetic field, or E-field induced by one or more gradient units, under specified conditions and at a specified position

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.209]

3.14
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

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.210]