
**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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Contents

Page

Foreword	vii
Introduction	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Symbols and abbreviated terms	7
5 General requirements for non-implantable parts	7
6 Requirements for particular AIMDs	7
7 Protection of patients from potential hazards caused by interactions of the AIMD and MR scanners	8
8 Test signals	9
8.1 Gradient sequence of sequences	9
8.2 RF sequence of sequences	11
9 General considerations for application of the requirements of this Technical Specification	14
9.1 Compliance criteria	14
9.2 Monitoring equipment	14
9.3 Validation of models and test equipment	14
9.4 Uncertainty assessment	14
9.5 Test reports	14
10 Protection from harm to the patient caused by RF-induced heating	15
10.1 General	15
10.2 Outline of the four-tier approach	16
10.2.1 Tier 1	16
10.2.2 Tier 2	18
10.2.3 Tier 3	18
10.2.4 Tier 4	19
10.3 Determination of the induced electric and magnetic fields	20
10.3.1 Electromagnetic simulation	20
10.3.2 Relevant parameters	20
10.3.3 Assessment procedure	20
10.3.4 Uncertainty budget of incident field assessment	20
10.4 Validation of electromagnetic AIMD models	21
10.4.1 Validation procedure	21
10.4.2 Validation criteria	21
10.5 Generation of incident fields for Tier 1 to Tier 3 and minimal medium requirements	21
10.6 Measurement system requirements	22
10.6.1 Probe specification	22
10.6.2 Validation and characterization of the measurement system	22
10.7 Procedures and protocols for determination of the distribution and magnitude of the absorbed energy in the tissue equivalent material by SAR and ΔT measurements	23
10.7.1 Determination of 3D relative distribution of local energy deposition	23
10.7.2 Measurement protocol for determination of maximum amplitude	24
10.8 Uncertainty assessment of energy deposition using SAR or temperature probes	27
10.9 Compliance criteria	28
10.10 Test report	28

11	Protection from harm to the patient caused by gradient-induced device heating	28
11.1	General.....	28
11.2	Testing considerations.....	29
11.2.1	General.....	29
11.2.2	Determination of clinical dB/dt exposure limits	29
11.2.3	Test duration	30
11.2.4	Data collection	30
11.3	Test requirements.....	31
11.3.1	General.....	31
11.3.2	In vitro, phantom or other suitable container.....	31
11.3.3	Gelled solution.....	31
11.3.4	Optical temperature probes.....	31
11.3.5	Temperature survey to determine worst-case orientation and hot spots	32
11.3.6	Minimum temperature instrumentation	32
11.3.7	Temperature data collection.....	32
11.3.8	Monitor applied dB/dt	32
11.3.9	Gradient field vector orientation relative to device.....	32
11.3.10	Monitoring AIMD for heating and malfunction	32
11.4	Lab testing using simulated MRI gradient field.....	33
11.4.1	Simulated field requirements	33
11.4.2	Pulse waveform RMS value	33
11.4.3	Gradient sequence of sequences	33
11.5	MR scanner testing.....	33
11.6	Analysis of gradient heating test	34
11.7	Uncertainty assessment	34
11.8	Test report	34
12	Protection from harm to the patient caused by gradient-induced vibration	35
12.1	General.....	35
12.2	General test considerations	36
12.2.1	Equipment	36
12.2.2	Determination of clinical dB/dt and B_0 exposure limits	39
12.2.3	Test signals	39
12.3	Test method for the evaluation of AIMD functionality during exposure to gradient-induced vibration.....	39
12.3.1	General requirements.....	39
12.3.2	Conducting functional testing using a research scanner	40
12.3.3	Conducting functional testing using simulated fields.....	40
12.3.4	Conducting functional testing using a clinical scanner.....	40
12.3.5	Conducting functional testing using a shaker table or other vibration test equipment.....	40
12.4	Test method for the evaluation of patient discomfort during exposure to gradient-induced vibration.....	41
12.4.1	General requirements.....	41
12.4.2	Conducting patient discomfort testing using a research scanner.....	42
12.4.3	Conducting patient discomfort testing using simulated fields.....	42
12.4.4	Conducting patient discomfort testing using a clinical scanner.....	42
12.4.5	Conducting patient discomfort testing using a shaker table or other vibration test equipment.....	43
12.5	Test method for the evaluation of risk of tissue injury during exposure to gradient-induced vibration	43
12.5.1	General requirements.....	43
12.5.2	Conducting testing for the evaluation of risk of tissue injury using a research scanner.....	46
12.5.3	Conducting testing for the evaluation of risk of tissue injury using simulated fields	46
12.5.4	Conducting testing for the evaluation of risk of tissue injury using a clinical scanner	46
12.5.5	Conducting testing for the evaluation of risk of tissue injury using a shaker table or other vibration test equipment	46
12.6	Uncertainty assessment	47
12.7	Test report	47
13	Protection from harm to the patient caused by B_0 -induced force	47

14	Protection from harm to the patient caused by B_0 -induced torque	47
15	Protection from harm to the patient caused by image artefact	48
16	Protection from harm to the patient caused by gradient-induced extrinsic electric potential	48
16.1	General	48
16.2	Test procedure	48
16.3	Uncertainty assessment	49
16.4	Test report	49
17	Protection from harm to the patient caused by RF rectification	49
17.1	General	49
17.2	Test procedure	49
17.3	Uncertainty assessment	50
17.4	Test report	50
18	Protection from harm to the patient caused by B_0 -induced malfunction	50
18.1	General	50
18.2	Test procedure	50
18.3	Test equipment	50
18.3.1	Generating the B_0 field	50
18.3.2	Phantom and tissue simulation medium	51
18.4	Uncertainty assessment	51
18.5	Test report	51
19	Protection from harm to the patient caused by RF-induced malfunction	51
19.1	Introduction of tiered approach	51
19.2	Injected immunity test	53
19.2.1	Using the tiers	53
19.2.2	Test procedure	55
19.2.3	Test equipment	55
19.2.4	Uncertainty assessment	55
19.2.5	Test report	55
19.3	Radiated immunity test	56
19.3.1	Using the tiers	56
19.3.2	Test procedure	56
19.3.3	Test equipment	56
19.3.4	Uncertainty assessment	57
19.4	Test report	57
20	Protection from harm to the patient caused by gradient-induced malfunction	57
20.1	Introduction of tiered approach	57
20.2	Injected immunity test	58
20.2.1	Tier 1	58
20.2.2	Tier 2	62
20.2.3	Tier 3	65
20.2.4	Test procedure	67
20.2.5	Test equipment	67
20.2.6	Uncertainty assessment	67
20.2.7	Test report	67
20.3	Radiated immunity test	67
20.3.1	Applicability	67
20.3.2	Tier 1	67
20.3.3	Tier 2	68
20.3.4	Test procedure	69
20.3.5	Test equipment	69
20.3.6	Uncertainty assessment	69
20.3.7	Test report	69
21	Combined fields test	69
22	Markings and accompanying documentation	70

Annex A (informative) Gradient vibration patent declaration form	72
Annex B (informative) Derivation of lead length factor for injected voltage test levels for gradient-induced malfunction	74
Annex C (informative) Basic MR physics	78
Annex D (informative) Gradient injection network	80
Annex E (informative) RF injection network	82
Annex F (informative) Estimation of the temperature rise <i>in vivo</i> from determined energy deposition	85
Annex G (informative) Methods of assessment of the temperature rise <i>in vivo</i>	88
Annex H (informative) Assessment of dielectric and thermal parameters	91
Annex I (normative) Measurement system validation	94
Annex J (informative) Example of coil systems	107
Annex K (informative) Current distribution on the AIMD as a function of the phase distribution of the incident field	108
Annex L (informative) Recipe and rationale for tissue simulating materials	111
Annex M (informative) Generation of incident fields	113
Annex N (informative) Dielectric parameters	117
Annex O (informative) Thermal and electrical properties of scar tissues	119
Annex P (informative) Estimation of conservative B_1 and 10g averaged E-field values for Tier 1 for RF-induced heating and malfunction	120
Annex Q (informative) AIMD configurations	126
Annex R (normative) Uncertainty evaluation	127
Annex S (informative) Guidance on gradient field interactions and test methods for pacemakers	145
Annex T (informative) Characterization of lead port interface impedance for evaluating gradient-induced extrinsic electric potential effects	169
Annex U (informative) Method for <i>in vitro</i> measurement of gradient-induced E-field	173
Annex V (informative) Basic physics and interactions of gradient magnetic fields with AIMDs	184
Bibliography	197

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

ISO/TS 10974 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

Introduction

This Technical Specification 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 Technical Specification represents a broad-based effort to capture 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 Technical Specification (ISO TC150/SC6/JWG2 and IEC SC62B/JWG1) recognizes its incomplete understanding and coverage of relevant details. The JWG releases this edition to promote developments in this area.

The JWG plans to refine this first edition with the intention of publishing a second edition in the time frame allowed by the ISO/IEC Directives and seeks input from interested parties. At this time, the JWG anticipates the possibility that eventually an International Standard might result from this work.

IEC 60601-2-33:2010 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.

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.

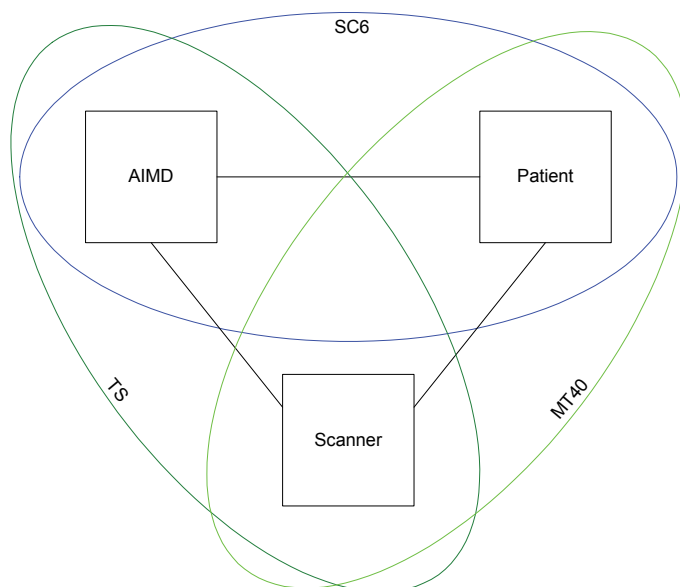


Figure 1 — Diagram showing the responsibilities of product committees and illustrating the extent of the scope of this Technical Specification in terms of the effects between AIMDs and MR scanners

This Technical Specification is concerned with interactions on the AIMD caused by the scanner. ISO/TC 150/SC 6 product committees are concerned with how those interactions affect patient safety.

This Technical Specification is general for all AIMD types, while ISO/TC 150/SC 6 product committees deal with specific types. ISO/TC 150/SC 6 will turn the general provisions of this Technical Specification into product-specific requirements, if necessary.

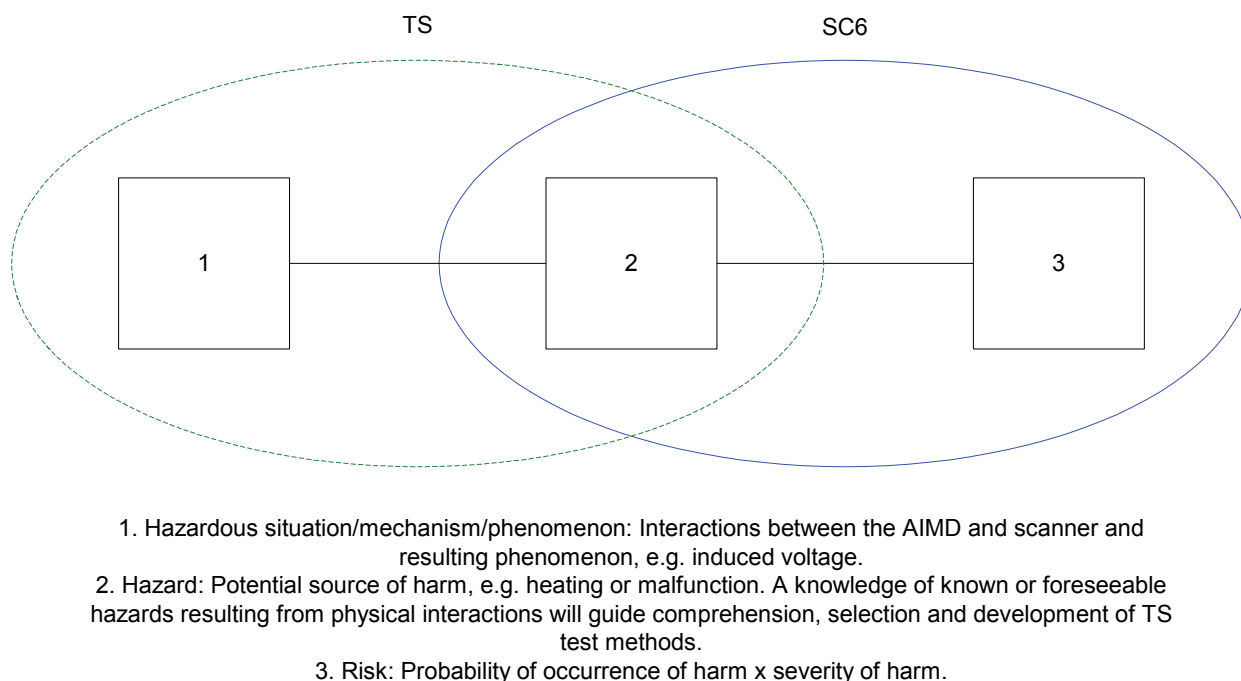


Figure 2 — Responsibilities of product committees illustrating the extent of the scope of this Technical Specification in terms of the delineation between hazards and harms

Test methods described in this Technical Specification are primarily designed and intended as bench-top tests using equipment and techniques to simulate the fields (B_0 static, gradient, and RF) found in MR 1,5 T scanners. 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 Technical Specification for bench-top testing (e.g. Clause 8) are not being encouraged or recommended for use on clinical scanners and to do so might result in scanner damage.

No requirements contained within this Technical Specification, including the use of clinical scanners, construe or imply any burden or obligation on the part of MR equipment manufacturers. Any statement to the contrary is strictly unintentional.

The requirements contained within this Technical Specification are based on specific potential hazards that have been identified as applicable to a general class of AIMDs (see Clause 7). Risks associated with these specific hazards, and any additional hazards and risks that might occur for any specific AIMD type (e.g. implantable neurostimulators), are outside the scope of this Technical Specification.

NOTE 1 Other interested parties, such as device manufacturers, regulatory agencies and particular product committees, are responsible for setting specific compliance criteria and determining risk.

NOTE 2 The discussion of risk and, in some cases, test methods in some of the informative annexes (e.g. Annex S, Annex T and Annex V) serves to provide additional information and a rationale that might assist readers in their comprehension of this material. The information provided in these annexes is supplementary and subordinate to the normative requirements in this Technical Specification.

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 Technical Specification may involve the use of a patent concerning gradient vibration given in Clause 12.

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 (a copy of the patent declaration is shown in Annex A). Further information may be obtained from:

Medtronic, Inc.
Open Innovation and Intellectual Property
8200 Coral Sea St. NE, MVN43
Mounds View, MN 55112
USA

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

IMPORTANT — The electronic file of this document contains colours which are considered to be useful for the correct understanding of the document. Users should therefore consider printing this document using a colour printer.

1 Scope

This Technical Specification 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 bore, whole body MR scanners for imaging the hydrogen nucleus.

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

The tests that are specified in this Technical Specification are type tests intended to be carried out on samples of a device to characterize interactions with the magnetic and electromagnetic fields associated with an MR scanner. They 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.

This Technical Specification contains test methods that are applicable to a broad class of AIMDs for the purpose of evaluating device operation against several hazards (see Clause 7). Tests for particular device types are not included. Specific compliance criteria and the determination of risk resulting from device behavioural response during these tests are outside the scope of this Technical Specification.

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 All safety requirements for MRI scanners can be found in IEC 60601-2-33.

2 Normative references

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

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

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

ANSI/AAMI PC69:2007, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*

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 F2503-08, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*