
**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*

This document is a preview generated by ERS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	vii
Introduction.....	viii
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Symbols and abbreviated terms.....	6
5 General requirements for non-implantable parts.....	6
6 Requirements for particular AIMDs.....	6
7 General considerations for application of the tests of this document.....	6
7.1 Compliance criteria.....	6
7.2 Use of tiers.....	7
7.3 Test reports.....	7
7.3.1 General.....	7
7.3.2 Description of the AIMD under test.....	7
7.3.3 Test methods and results.....	7
8 Protection from harm to the patient caused by RF-induced heating.....	8
8.1 Introduction.....	8
8.2 Outline of the Stage 1 four-tier approach.....	8
8.3 Measurement system prerequisites for all tiers.....	10
8.3.1 RF field source.....	10
8.3.2 Tissue simulating phantom.....	10
8.3.3 Definition of power deposition.....	12
8.3.4 Measurement system validation.....	12
8.4 Determination of RF-induced power deposition in a tissue simulating medium.....	12
8.4.1 General.....	12
8.4.2 Determine location of hot spots around the AIMD.....	13
8.4.3 Determination of spatial (3D) distribution of power deposition for each hot spot.....	13
8.4.4 Determine the final power deposition.....	14
8.5 Proximity effect of electrodes from multiple leads.....	16
8.6 Modelling prerequisites for Tier 2, Tier 3, and Tier 4.....	17
8.7 Tier selection for RF-induced power deposition.....	17
8.7.1 General.....	17
8.7.2 Tier 1.....	17
8.7.3 Tier 2.....	18
8.7.4 Tier 3.....	19
8.7.5 Tier 4.....	20
8.8 <i>In vitro</i> model validation.....	21
8.9 Overall uncertainty analysis.....	23
8.10 <i>In vivo</i> analysis of power deposition.....	24
8.11 RF-induced heating assessment flow chart.....	24
9 Protection from harm to the patient caused by gradient-induced device heating.....	27
9.1 Introduction.....	27
9.2 Testing considerations.....	28
9.2.1 General.....	28
9.2.2 Determination of $ dB/dt $ rms exposure limits.....	29
9.2.3 Determination of test duration.....	29
9.3 Test requirements.....	29
9.3.1 General.....	29
9.3.2 <i>In vitro</i> test phantom or other suitable container.....	30
9.3.3 Gelled solution.....	30

9.3.4	Temperature survey to determine orientation and hot spots	30
9.3.5	Minimum temperature instrumentation	31
9.3.6	Definition of dB/dt test waveform	31
9.3.7	Characterization of applied dB/dt	32
9.4	Lab testing using simulated MR gradient field	32
9.5	MR scanner testing	32
9.6	Analysis of gradient heating test	33
10	Protection from harm to the patient caused by gradient-induced vibration	33
10.1	Introduction	33
10.2	Overview of tiers	34
10.3	MR environmental conditions	35
10.3.1	General	35
10.3.2	Determination of maximum clinical dB/dt	35
10.3.3	Determination of clinical B_0	35
10.3.4	Determination of clinical $dB/dt \times B_0$	35
10.3.5	Test frequencies	35
10.3.6	Test duration	36
10.3.7	Test temperature	37
10.4	General test procedure	37
10.4.1	Measurement of gradient field and determination of AIMD location	37
10.4.2	AIMD/test unit setup	37
10.5	Method 1 — MR scanner	38
10.6	Method 2 — Shaker table	39
10.6.1	General	39
10.6.2	Determine scanner input	39
10.6.3	AIMD vibration response	39
10.6.4	Determine shaker table amplitude (dB/dt scaling)	40
10.6.5	Perform vibration exposure using a shaker table	40
11	Protection from harm to the patient caused by B_0-induced force	41
12	Protection from harm to the patient caused by B_0-induced torque	41
13	Protection from harm to the patient caused by gradient-induced extrinsic electric potential	41
13.1	Introduction	41
13.2	General requirements	42
13.3	Gradient pulse leakage test	46
13.3.1	General	46
13.3.2	Test equipment	46
13.3.3	Test signal	46
13.3.4	Tier 1 — Combined gradient-induced charge measurement test procedure	48
13.3.5	Tier 2 — Separate transient gradient-induced charge and steady-state current measurement test procedure	51
13.4	Gradient rectification test	53
13.4.1	General	53
13.4.2	Test equipment	53
13.4.3	Test signal	53
13.4.4	Gradient-induced rectification measurement test procedure	54
13.5	Gradient pulse distortion of AIMD output test	56
13.5.1	General	56
13.5.2	Test equipment	56
13.5.3	Test signal	56
13.5.4	Gradient-induced AIMD output distortion test procedure	56
14	Protection from harm to the patient caused by B_0-induced malfunction	58
14.1	Introduction	58
14.2	Static field testing	59
14.2.1	B_0 general requirements for static field testing	59
14.2.2	B_0 field generation	60

14.2.3	Test conditions.....	60
14.3	Test procedures.....	60
14.3.1	General.....	60
14.3.2	Class 0 test procedure.....	60
14.3.3	Class 1 test procedure.....	60
14.3.4	Class 2 test procedure.....	61
15	Protection from harm to the patient caused by RF-induced malfunction and RF rectification.....	61
15.1	Introduction.....	61
15.2	General requirements.....	61
15.3	Mechanisms for RF interaction with an AIMD.....	61
15.4	Selecting radiated vs injected test methods.....	63
15.4.1	General.....	63
15.4.2	AIMD type designation for test method selection.....	63
15.4.3	RF antenna type designation for test method selection.....	65
15.4.4	RF EMC tier selection.....	65
15.4.5	RF test conditions.....	65
15.4.6	B_0 considerations.....	68
15.5	Injected immunity test.....	68
15.5.1	General.....	68
15.5.2	Determination of peak and rms injected levels for Tier 1 and Tier 2 — AIMD with short electrical length.....	69
15.5.3	Determination of peak and rms injected levels for Tier 3 and Tier 4.....	69
15.5.4	Injected immunity test procedure.....	71
15.5.5	RF phase test conditions.....	71
15.5.6	AIMD monitoring during the test.....	72
15.6	Radiated immunity test.....	72
15.6.1	General.....	72
15.6.2	Determining the RF radiated field level.....	72
15.6.3	Radiated test procedure.....	72
15.6.4	AIMD monitoring during the test.....	73
15.7	Test equipment.....	73
15.7.1	Generating the RF electric field for radiated testing (AIMD with short electrical length).....	73
15.7.2	Phantom and tissue simulating medium for radiated testing.....	73
15.7.3	AIMD monitoring apparatus.....	73
15.7.4	RF level measuring device.....	74
15.7.5	RF injection network.....	74
15.8	Determining the peak RF injected level using a radiated test.....	75
16	Protection from harm to the patient caused by gradient-induced malfunction.....	76
16.1	Introduction.....	76
16.2	General requirements.....	76
16.3	Selecting radiated and injected test methods.....	77
16.4	Radiated immunity test.....	78
16.4.1	General.....	78
16.4.2	Test equipment.....	78
16.4.3	Radiated test signal.....	79
16.4.4	Test procedure.....	81
16.5	Injected immunity test.....	82
16.5.1	General.....	82
16.5.2	Test equipment.....	82
16.5.3	Injected test signal.....	82
16.5.4	Test procedure.....	84
16.5.5	AIMD test configuration.....	86
17	Combined fields test.....	93
17.1	Introduction.....	93
17.2	Test setup.....	94

17.3	AIMD fixation.....	96
17.4	Test procedure.....	97
17.4.1	General.....	97
17.4.2	Before MR exposure.....	97
17.4.3	During MR exposure.....	97
17.4.4	After MR exposure.....	97
17.5	Test equipment.....	97
17.5.1	Field generation.....	97
17.5.2	Phantom and tissue simulating medium.....	97
17.5.3	AIMD monitoring apparatus.....	98
18	Markings and accompanying documentation.....	98
18.1	Definitions.....	98
18.2	Applicability of labelling requirements.....	98
18.3	Labelling requirements.....	98
Annex A	(normative) Pulsed gradient exposure for Clause 10, Clause 13, and Clause 16.....	100
Annex B	(informative) Derivation of lead length factor for injected voltage test levels for Clause 13 and Clause 16.....	112
Annex C	(informative) Tier 1 high tangential E-field trough line resonator.....	121
Annex D	(informative) Supporting information and rationale for gradient-induced device heating.....	128
Annex E	(informative) Example RF injection network.....	133
Annex F	(informative) Supporting information and rationale for MR-induced vibration.....	135
Annex G	(informative) Gradient vibration patent declaration form.....	139
Annex H	(informative) Assessment of dielectric and thermal parameters.....	141
Annex I	(informative) RF exposure system validation method.....	146
Annex J	(informative) MR scanner RF transmit coil.....	156
Annex K	(informative) Current distribution on the AIMD as a function of the phase distribution of the incident field.....	158
Annex L	(informative) Tissue simulating medium formulations.....	161
Annex M	(informative) Generation of incident fields.....	165
Annex N	(informative) Dielectric and thermal tissue properties.....	180
Annex O	(informative) Gradient field injected testing — AIMD electrode tissue impedance determination method.....	184
Annex P	(informative) Estimation of conservative B_1 and 10 g averaged E-field values for Tier 1 for RF-induced heating and RF malfunction.....	189
Annex Q	(informative) AIMD configuration.....	197
Annex R	(informative) Electrically excitable tissue stimulation, terms and definitions.....	198
Annex S	(informative) Combined fields test.....	200
Annex T	(informative) General methods for modelling dB/dt levels in MR gradient coils.....	206
Bibliography	212

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.

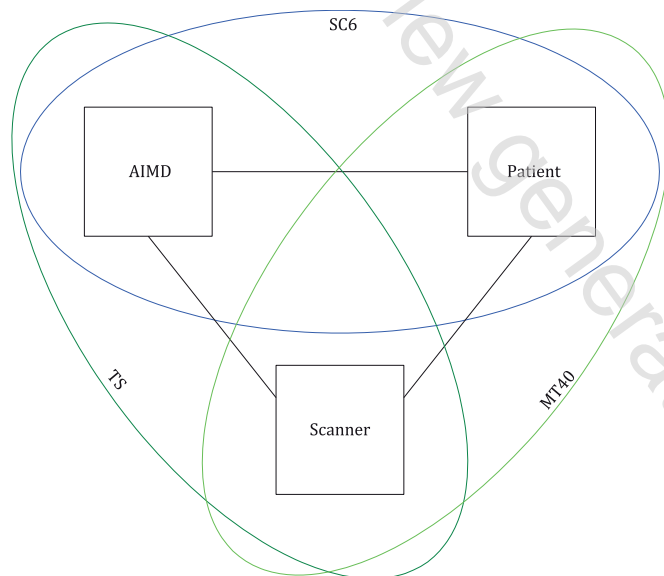


Figure 1 — Responsibilities of product committees illustrating the extent of the scope of this document in terms of the effects between AIMDs and MR scanners

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](#).

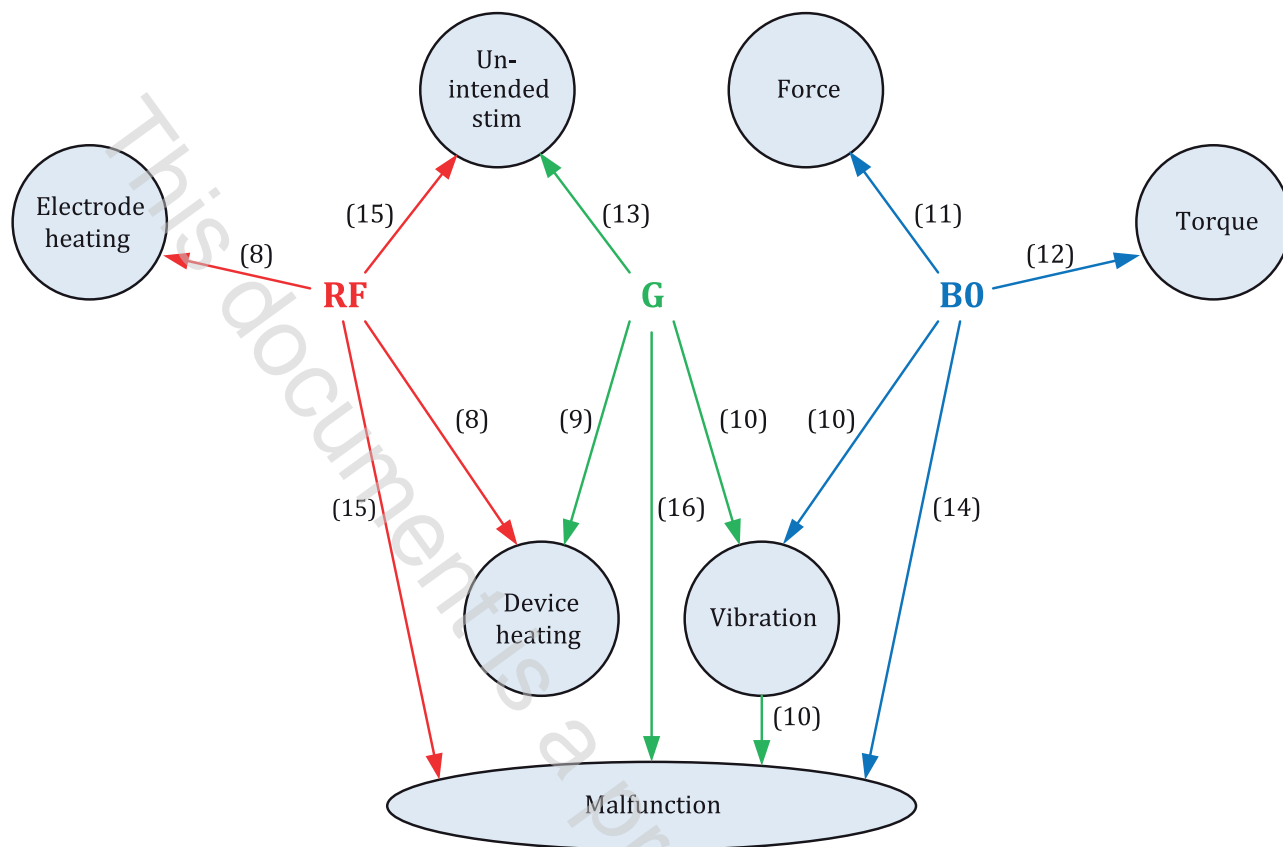


Figure 2 — Relationship between MR scanner output fields (RF, gradient, B_0) and hazards (test method clause numbers in parentheses)

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.
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

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.