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Technical Information Report



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AAMI/ISO TIR10974:2018

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

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

Advancing Safety in Health Technology

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Approved 13 October 2017 by
AAMI

Registered 26 November 2017 with
American National Standards Institute

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Abstract: Applies 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.

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.

Keywords: MRI, active implant, pacemaker, implantable defibrillator, neurostimulator, cochlear implant, artificial heart, implantable infusion pump



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Published by

AAMI
4301 N. Fairfax Dr., Suite 301
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Printed in the United States of America

ISBN 978-1-57020-699-3

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Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

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All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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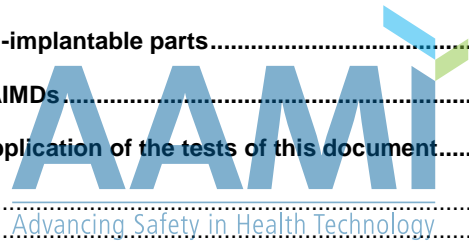
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Publication of this Technical Report that has been registered with ANSI has been approved by the Accredited Standards Developer (AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633). This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature.

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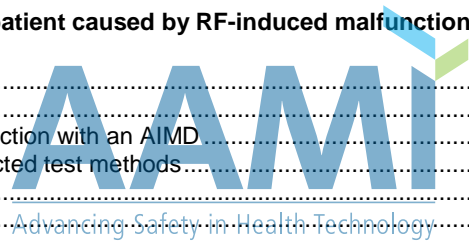
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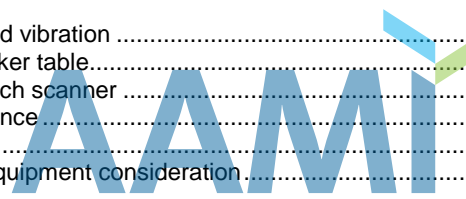


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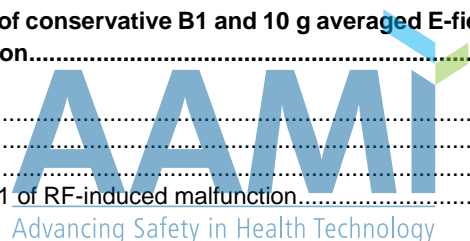
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Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

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Committee representation

Association for the Advancement of Medical Instrumentation

U.S. Technical Advisory Group (TAG) to ISO/TC 150/SC 6, Active implants

The adoption of ISO TS 10974 as an American National Standard was initiated by the AAMI U.S. Technical Advisory Group (TAG) to ISO/TC 150/SC 6, Active implants. This group functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI U.S. Technical Advisory Group (TAG) to ISO/TC 150/SC 6, Active implants played an active part in developing the ISO technical specification.

At the time this document was published, the **AAMI U.S. Technical Advisory Group (TAG) to ISO/TC 150/SC 6, Active implants** had the following members:

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Dave Thompson, LivaNova PLC
Java Von Arx, Micro Systems Engineering Inc

NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Background of the AAMI adoption of ISO TS 10974:2018

As indicated in the foreword to the main body of this document (page xiii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150, *Implants for surgery*, Subcommittee (SC) 6, *Active implants*, to provide guidance on tests to be carried out on active implantable device samples in order to characterize their interaction with magnetic and electromagnetic fields associated with an MR scanner. This revision reflects the experience gained since the first edition was published in 2013 and advances the understanding of relevant issues and concerns of the most common MR scanning field strength of 1,5 T.

U.S. participation in ISO/TC 150/SC 6 is organized through the U.S. Technical Advisory Group to ISO/TC 150/SC 6, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI/ISO TIR10974 was registered by the American National Standards Institute (ANSI) on 26 November 2017.

AAMI procedures require that technical information reports be reviewed every three years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

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As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

“May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

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NOTE Users of this technical information report are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N Fairfax Drive, Suite 301, Arlington, VA 22203.

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.

This is a preview edition of an AAMI guidance document and is not intended for use as a standard. It is intended for use as a reference only and should not be used as a basis for the purchase of the document before making a purchasing decision.

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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.

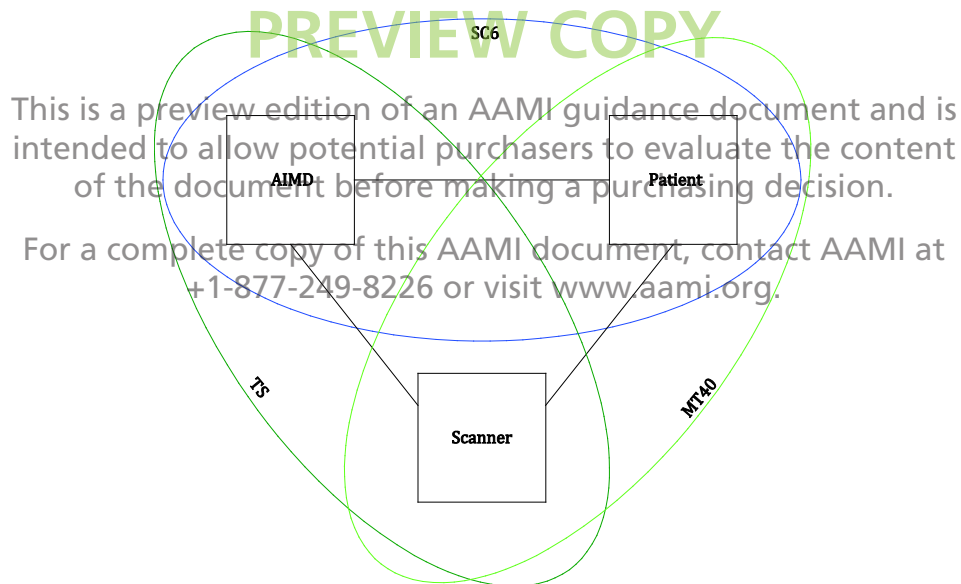


Figure 1 — Responsibilities of product committees illustrating the extent of the scope of this document in terms of the effects between AIMDs and MR scanners

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.

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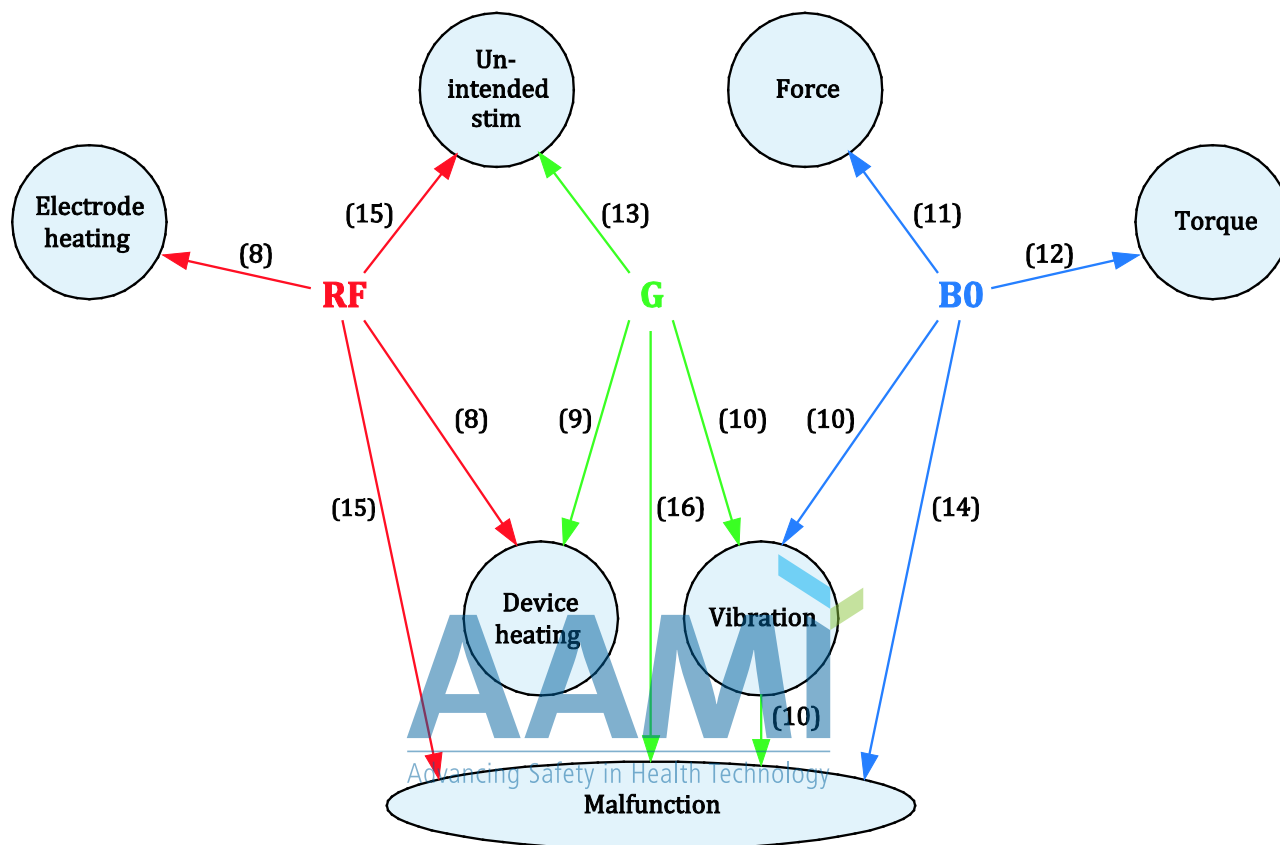


Figure 2 — Relationship between MR scanner output fields (RF, gradient, B_0) and hazards (test method clause numbers in parentheses)

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 17.1-877-249-8226 or visit www.aami.org.

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

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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.



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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*