
**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.

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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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.

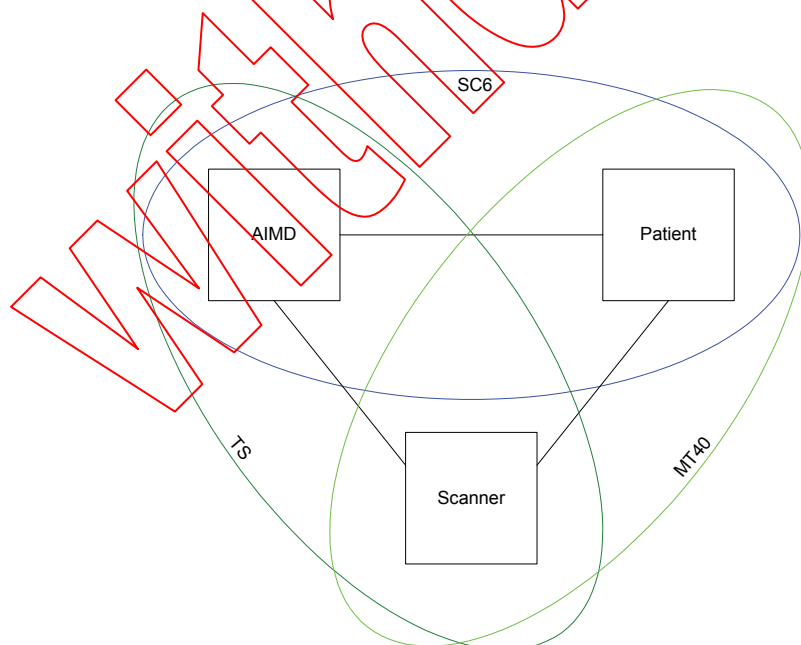


Figure 1 — Diagram showing the responsibilities of product committees and illustrating the extent of the scope of this Technical Specification in terms of the effects between AIMDs and MR scanners

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.

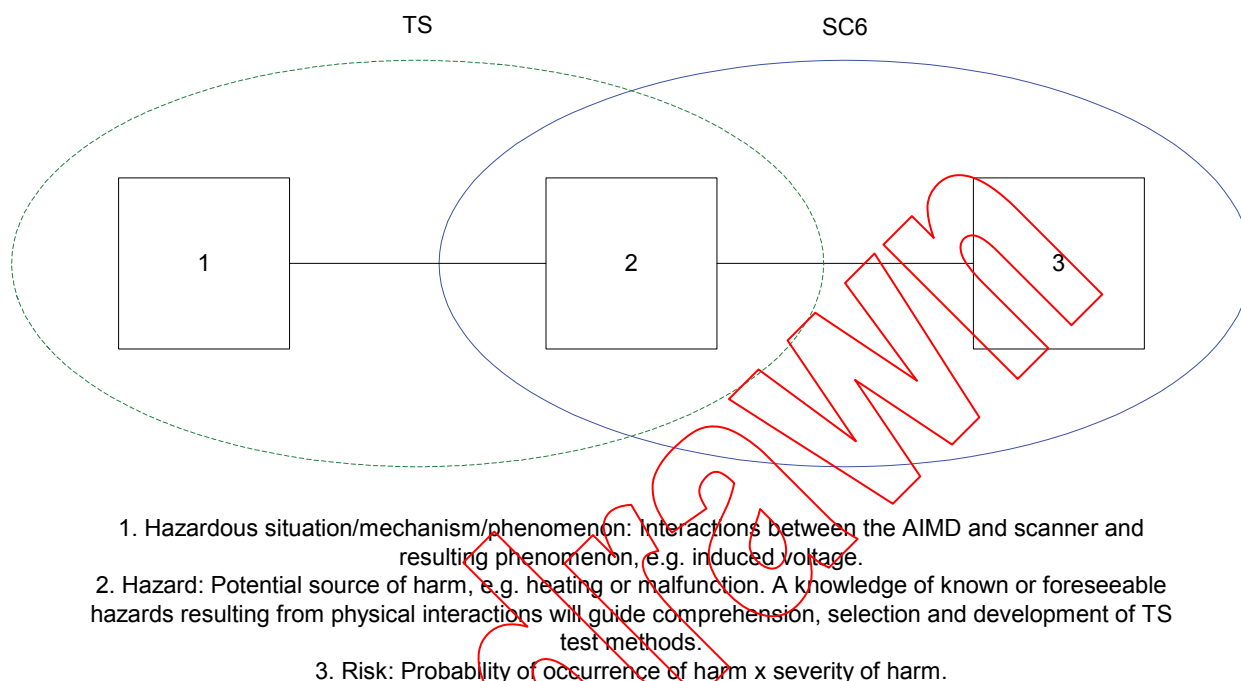


Figure 2 — Responsibilities of product committees illustrating the extent of the scope of this Technical Specification in terms of the delineation between hazards and harms

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.

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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*

3 Terms and definitions

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

3.1

AIMD

active implantable medical device

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

[ISO 13485:2003, definition 3.1]

NOTE For the purposes of this Technical Specification, an AIMD is a system consisting of a set of components (e.g. device and leads) and accessories which interact to achieve the performance intended by the manufacturer.

3.2

AIMD configuration

any unique combination or arrangement of AIMD system settings or components, particularly relative geometrical orientations or electrical connections between components (see Annex Q)

3.3

active medical device

medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

[ISO 13485:2003, definition 3.2]

3.4

B_0

static magnetic field of the MR scanner, taken as 1,5 T in this Technical Specification, unless otherwise stated

3.5

$B_{1\text{RMS}}$

root mean square (RMS) of B_1 , the radio frequency magnetic induction

$$B_{1\text{RMS}} = \sqrt{\frac{\int_0^{t_x} [B_1(t)]^2 dt}{t_x}}$$

where t is time, and t_x is the evaluation time, estimated at the RF transmit coil centre

[IEC 60601-2-33:2010, definition 201.3.201]

3.6

birdcage coil

radiator which generates the RF portion of the magnetic field

NOTE 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 In MR equipment with a cylindrical whole body magnet, the compliance volume is a cylinder whose axis coincides with the magnet axis, with a radius of 0,20 m and with a length equal to the gradient coil.

NOTE 2 Adapted from IEC 60601-2-33, definition 201.3.202.

3.8**cylindrical bore scanner reference coordinate system**

three dimensional Cartesian coordinate system in which the X axis lies in a horizontal plane, the Y axis in a vertical plane, the Z axis is coaxial with the magnet bore, and the origin of the reference coordinate system is located at isocentre

3.9**device**

that part of an AIMD that houses a power source and electronic circuit and which produces a stimulation voltage or current pulse

NOTE The complete AIMD includes the device and a means for conveying the output pulse to the stimulation site.

3.10**effective stimulus duration**

$t_{s,eff}$

duration of any period of the monotonic increasing or decreasing gradient, used to describe its limits for cardiac or peripheral nerve stimulation, defined as the ratio of the peak-to-peak field variation and the maximum value of the time derivative of the gradient in that period

[IEC 60601-2-33:2010, definition 201.3.205]

3.11**extrinsic electric potential**

unrectified voltage induced by fields external to the AIMD (i.e. not caused by the device)

3.12**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 Definition and validation of physiological stress is defined in the absence of additional sources that may cause or enhance stress factors (like AIMDs).

[IEC 60601-2-33:2010, definition 201.3.208]

3.13

G

magnetic field gradient in units of T/m

NOTE 1 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.

NOTE 2 Adapted from IEC 60601-2-33:2010, Table 201.101.

3.14**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

[IEC 60601-2-33:2010, definition 201.3.209]

3.15

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

[IEC 60601-2-33:2010, definition 201.3.210]

3.16

harm

physical injury or damage to health or property

NOTE Adapted from ISO/IEC Guide 51:1999, definition 3.3.

3.17

hazard

potential source of harm

NOTE Adapted from ISO/IEC Guide 51:1999, definition 3.5.

3.18

implant volume

patient-accessible space

NOTE In MR equipment with a cylindrical whole body magnet, the implant volume is a cylinder whose axis coincides with the magnet axis, with a radius of 0,25 m and with a length equal to the gradient coil

3.19

isocentre

in MR equipment, the null point of the spatially encoding gradients

NOTE 1 Typically, this also corresponds to the region of highest magnet homogeneity.

NOTE 2 Typically, this corresponds to the position in the system targeted for imaging.

[IEC 60601-2-33:2010, definition 201.3.214]

3.20

label

area bearing a marking, affixed to a device or package but not an integral part of the device or package

[ISO 14708-1:2000, definition 3.10]

3.21

lead

flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length

[ISO 14708-1:2000, definition 3.5]

3.22

MR equipment

magnetic resonance equipment

medical electrical equipment which is intended for *in vivo* magnetic resonance examination of a patient comprising all parts in hardware and software from the supply mains to the display monitor

[IEC 60601-2-33:2010, definition 201.3.218]

3.23**MR scanner****magnetic resonance scanner**

See 3.22

NOTE The term “scanner” is used throughout this Technical Specification in lieu of “equipment”.

3.24**malfunction**

device failure causing degradation of performance, loss of function, or unintentional responses

3.25**marking**

inscription on a device, package or label

[ISO 14708-1:2000, definition 3.9]

3.26**maximum gradient slew rate**

rate of change of the gradient obtained by switching the gradient unit between its maximum specified gradient strengths G_{+max} and G_{-max} in the shortest possible ramp time obtainable under normal scan conditions

[IEC 60601-2-33:2010, definition 201.3.222]

3.27**medical device**

article, used alone or in combination, with any accessories or software for its proper functioning, intended by the manufacturer to be used on human beings in the

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,
- investigation, replacement or modification of the anatomy or of a physiological process,
- support or sustenance of life

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means

NOTE Adapted from ISO 13485:2003, definition 3.7.

3.28**MR Conditional**

item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use

NOTE 1 Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

NOTE 2 Adapted from ASTM F2503, definition 3.1.9.

3.29**normal operating mode**

mode of operation of the MR equipment in which none of the outputs have a value that can cause physiological stress to patients

[IEC 60601-2-33:2010, definition 201.3.224]

3.30

rectification

voltage induced by fields external to the AIMD that is rectified by non-linear circuit elements within the AIMD

3.31

search coil

small diameter coil used in a compliance test to measure gradient output

[IEC 60601-2-33:2010, definition 201.3.230]

3.32

second level controlled operating mode

mode of operation of the MR equipment in which one or more outputs reach a value that can produce significant risk for patients, for which explicit ethical approval is required (i.e. a human studies protocol approved to local requirements)

[IEC 60601-2-33:2010, definition 201.3.231]

3.33

SAR

specific absorption rate

radio frequency power absorbed per unit of mass (W/kg)

[IEC 60601-2-33:2010, definition 201.3.233]

3.34

time rate of change of the magnetic field

dB/dt

rate of change of the magnetic flux density with time (T/s)

[IEC 60601-2-33:2010, definition 201.3.234]

3.35

transverse plane

x-y plane, normal to the axis of the bore of the scanner

3.36

volume RF transmit coil

RF transmit coil suitable for use in MR equipment that produces a homogeneous RF field over an extended volume encompassed by the coil

NOTE 1 The volume RF transmit coil can be a whole body RF transmit coil, a head RF transmit coil or an RF transmit coil designed for homogeneous exposure of a specific part of the body. A single-loop coil enclosing the body or a part of the body is considered to be a volume RF transmit coil (e.g. single-loop wrist coil).

NOTE 2 Adapted from IEC 60601-2-33:2010, definition 201.3.236.

3.37

whole body gradient system

gradient system suitable for use in whole body MR equipment

[IEC 60601-2-33:2010, definition 201.3.237]

3.38

whole body magnet

magnet suitable for use in whole body MR equipment

[IEC 60601-2-33:2010, definition 201.3.238]

3.39**whole body MR equipment****whole body magnetic resonance equipment**

MR equipment of sufficient size to allow whole body MR examination and partial body MR examination of adult patients

NOTE 1 It can be equipped with volume RF transmit coils, local RF transmit coils and with a special purpose gradient system.

NOTE 2 Adapted from IEC 60601-2-33:2010, definition 201.3.239.

3.40**whole body RF transmit coil**

volume RF transmit coil of sufficient size for whole body examinations of adult patients

[IEC 60601-2-33, definition 201.3.240]

3.41**whole body SAR**

SAR averaged over the total mass of the body and over a specified time

[IEC 60601-2-33:2010, definition 201.3.241]

4 Symbols and abbreviated terms

TEM	transverse electromagnetic
RF	radio frequency
SAR	specific absorption rate
ΔT	temperature difference
AIMD	active implantable medical device
GTEM	gigahertz transverse electromagnetic
MR	magnetic resonance
MRI	magnetic resonance imaging

5 General requirements for non-implantable parts

Requirements for non-implantable parts of an AIMD are outside the scope of this Technical Specification. They might be specified in a future edition.

6 Requirements for particular AIMDs

Requirements for particular AIMDs are not specified in this Technical Specification. They might be specified in a future edition or in particular product standards.

7 Protection of patients from potential hazards caused by interactions of the AIMD and MR scanners

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

Table 1 – Potential patient hazards and corresponding test requirements

General hazards to the patient	Test requirement	Clause
Heat	RF field-induced heating of the AIMD	10
	Gradient field-induced device heating	11
Vibration	Gradient field-induced vibration	12
Force	B_0 -induced force	13
Torque	B_0 -induced torque	14
Extrinsic electric potential	Gradient field-induced lead voltage	16
Rectification	RF field-induced rectified lead voltage	17
Malfunction	B_0 field-induced device malfunction	18
	RF field-induced device malfunction	19
	Gradient field-induced device malfunction ^a	20
^a Device malfunction due to eddy current heating of internal components is covered in Clause 11. Device malfunction due to vibration of internal components is covered in Clause 12.		

RF-induced heating of tissue surrounding an AIMD is caused by elevated local SAR that arises from induced current.

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 applied to a device results from 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 non-linear circuit elements to conduct, for example, an input protection diode. Rectification might result in voltage pulses occurring on the lead and at a distal electrode. The resulting rectified voltage is an unintended consequence of physical interactions between the MR scanner and medical device 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 Technical Specification.

NOTE 1 Requirements regarding device-specific malfunctions might be specified in particular product standards.

Evaluation of the AIMD for these hazards involves some combination of testing and modelling. 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.

Device immunity to the B_0 , RF and gradient fields may be evaluated separately. For devices containing components affected by magnetic fields (e.g. saturable ferrite), a B_0 (static) field shall be simultaneously applied during testing unless it can be shown that the magnetic effects of these components will not affect device performance.

In addition to the tests listed in Table 1, this Technical Specification contains recommendations for image artifact evaluation (see Clause 15), combined field testing (see Clause 21) and requirements for markings and accompanying documentation (see Clause 22).

8 Test signals

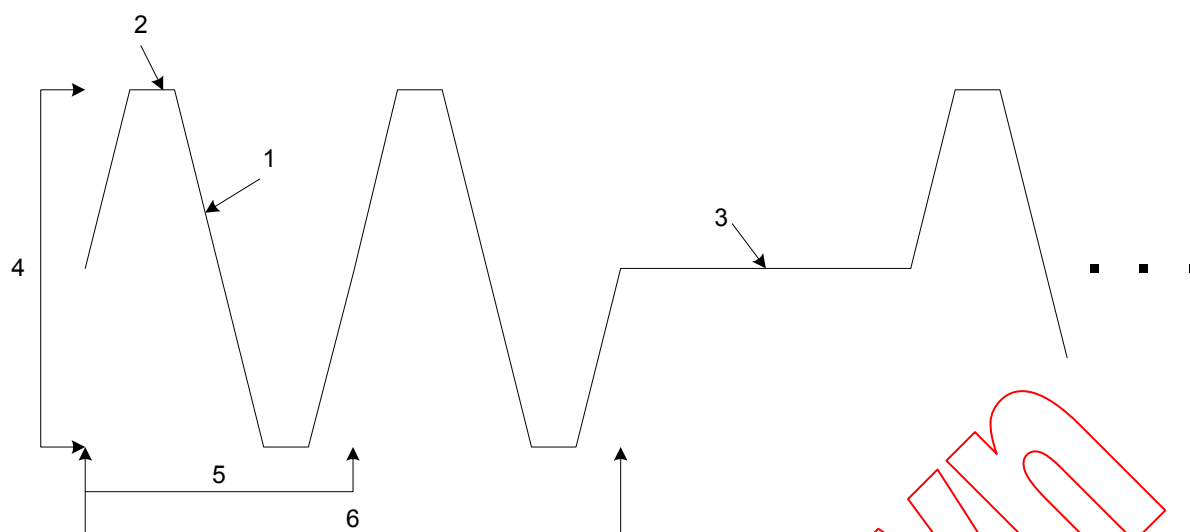
8.1 Gradient sequence of sequences

The trapezoidal waveform used to simulate the gradient field is shown in Figure 3. It is defined by three variable parameters: peak-to-peak amplitude, peak-to-peak rise/fall time, and dwell-time. Figure 3 presents an example of a test signal consisting of a burst of two waveform cycles followed by the "off-time" before the next burst. The combination of waveform parameters plus burst length and off-time defines a single sequence. Each sequence shall be run for a minimum of 15 s, or longer if necessary, to observe device response time.

The complete sequence of sequences consists of all combinations of the five variable parameters. Table 2 lists the range of required parameter values. Typically, all combinations in Table 2 are required; however some sequences may be omitted with appropriate rationale and documentation by the manufacturer. For circumstances in which this is allowed, refer to the individual test clauses.

The test signal shown in Figure 3 is appropriate for radiated testing. For injected voltage testing, the time derivative of Figure 3 is required as is shown in Figure 4. Table 3 lists the range of injected voltage test signal parameters, where amplitude values used for testing are determined according to the test method (radiated and injected) and tier (described in each test section).

NOTE 1 The test signals and parameters described in 8.1 are intended for bench-top testing only. Attempting to use them on clinical scanners is not encouraged or recommended and might result in scanner damage.



Key

- 1 TSLEW (p-p rise/fall time in ms)
- 2 TDWELL
- 3 TOFF (time between bursts)
- 4 B_G (gradient field strength, p-p amplitude in mT)
- 5 One cycle
- 6 Burst length (two cycles in this example)

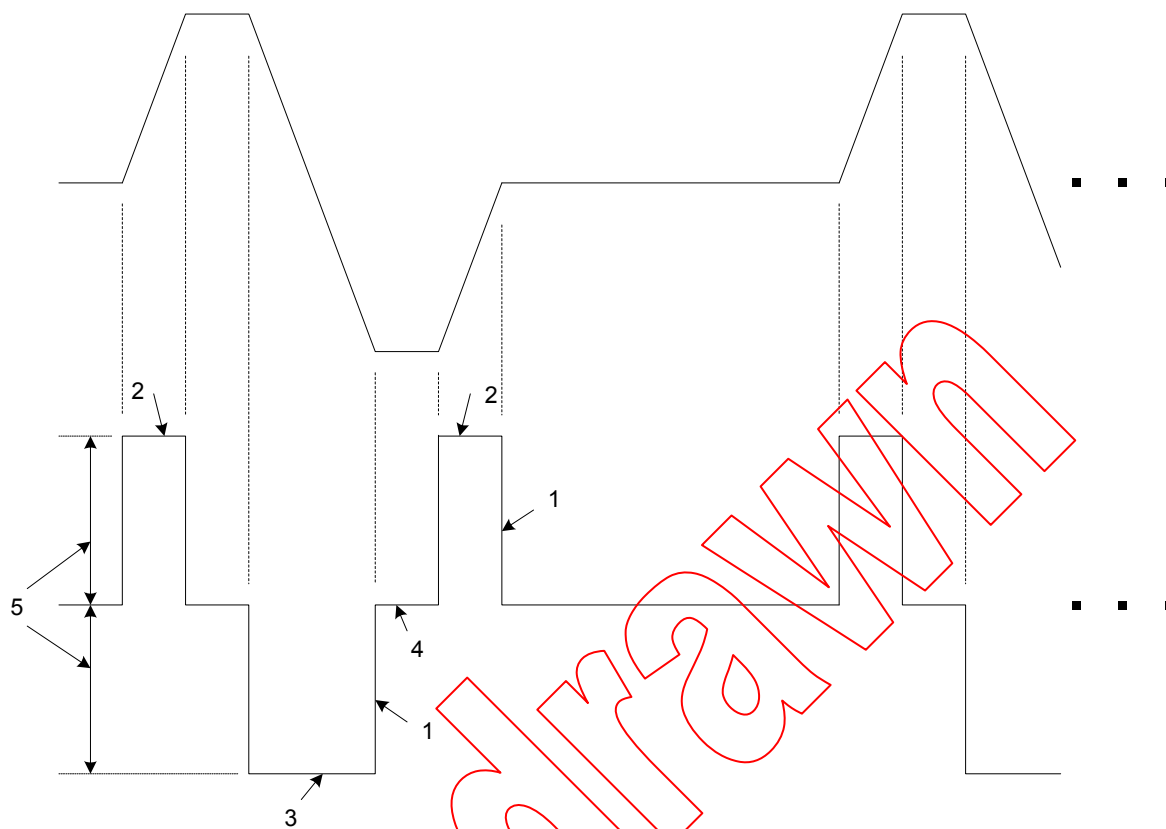
Figure 3 – Gradient test signal

Table 2 — Range of gradient test signal parameters

Parameter	Values													
B_G (mT)	1	2	5	10	20	30	40	–	–	–	–	–	–	–
TSLEW (ms)	0,2	0,4	1,0	2,0	–	–	–	–	–	–	–	–	–	–
Number of cycles (burst length)	1	2	5	10	20	–	–	–	–	–	–	–	–	–
TOFF (ms)	0,2	0,5	1,0	2,0	5,0	10	20	50	100	200	500	1 000	2 000	–
TDWELL (ms)	0,0	0,5	5,0	20	–	–	–	–	–	–	–	–	–	–
Exposure time per sequence	15 s minimum or characteristic response time of the device, if greater than 15 s													

NOTE 2 The parameter B_G as used in this Technical Specification, is not to be confused with the parameter G as used in IEC 60601-2-33. B_G is used to denote the peak-to-peak amplitude (in mT) of the simulated test signal whereas G is used to denote the amplitude (in mT/m) of the magnetic field gradient of the actual scanner. For example, along the Z axis of a scanner, the field strength of G_Z at a given spatial location is given by the distance from isocentre. This relationship was used to determine the test values for B_G in Table 2.

NOTE 3 It is understood that gradient amplifiers have a limited bandwidth and therefore gradient profiles are not strictly trapezoidal or triangular, depending on the particular selection of parameters in Table 2. A 10 kHz gradient amplifier bandwidth represents a lower (worst case) value (with respect to the gradient amplifier).



Key

- 1 TEDGE (maximum 10 % to 90 % rise or fall time in μs)
- 2 TAPW (Pulse A – positive pulse width)
- 3 TBPW (Pulse B – negative pulse width)
- 4 Equal to TDWELL
- 5 IVAMP (Pulse A and B amplitude in volts)

Figure 4 — Injected voltage test signal

Table 3 — Range of injected voltage test signal parameters

Parameter	Values			
IVAMP (volts)	See 20.2			
TAPW/TBPW (ms)	0,1/0,2	0,2/0,4	0,5/1,0	1,0/2,0
TEDGE (μs)	1 (maximum)			

8.2 RF sequence of sequences

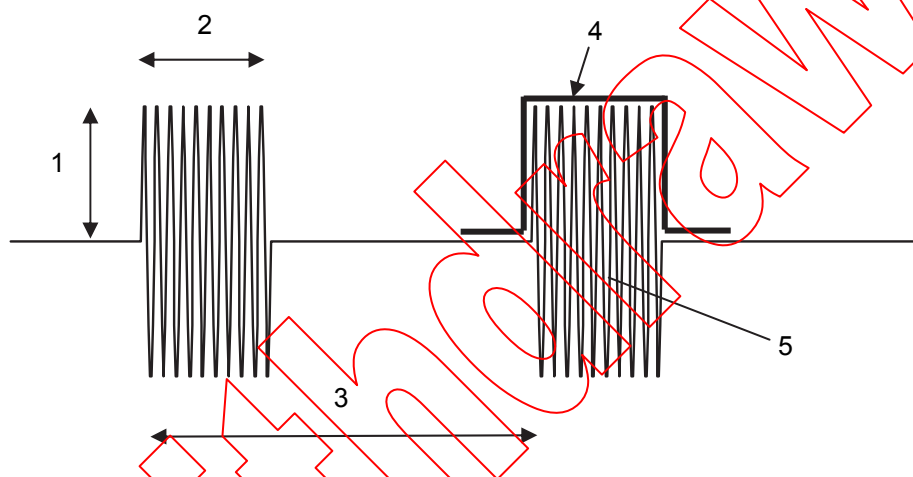
The test signal used to simulate the RF field is shown in Figure 5. It is defined by three variable parameters: B_1 peak amplitude at the isocentre, pulse width, and pulse period. One set of parameter values constitutes a

single sequence (e.g. $B_1 = 1 \mu\text{T}$, pulse width = $50 \mu\text{s}$, and pulse period = 1 ms constitutes a single sequence). Each sequence shall be run for a minimum of 15 s , or longer if necessary to observe device response time.

The complete sequence of sequences consists of all combinations of the three variable parameters. Table 4 lists the range of required parameter values. Typically, all combinations are required; however some sequences may be omitted with appropriate rationale and documentation by the manufacturer. For circumstances in which this is allowed, refer to the individual test clauses.

Parameter combinations for testing should be chosen taking into consideration those combinations that represent acute conditions for the specific device being tested. For example, parameter combinations which fall into known passbands should be selected for testing (see 8.2, Test 2). The selection of test parameter combinations shall be justified and documented. The amplitude values shall be adjusted accordingly, depending on the test method used (described in each test section). This test signal waveform is used for both radiated and injected methods.

NOTE The test signals and parameters described in 8.2 are intended for bench-top testing only. To attempt to use them on clinical scanners is not encouraged or recommended and might result in scanner damage.



Key

- 1 B_1 (RF field strength, peak amplitude in μT)
- 2 pulse width
- 3 pulse period
- 4 pulse shape (square)
- 5 frequency

Figure 5 — RF test signal

Table 4 – Range of RF test signal parameters

Parameter	Values
B_1 (μ T) peak at the isocentre	1, 2, 5, 10, 20, 30
Pulse width	See Table 5
Pulse period	See Table 5
Pulse shape	Square
Frequency (MHz)	$63,8 \pm 0,5$
Polarisation	Circular
Rise/fall time of pulse shape (ns)	500 (maximum)
Exposure time per sequence	15 s minimum or characteristic response time of the device, if greater than 15 s

Table 5 — Pulse width and pulse period matrix of RF sequence of sequences

Pulse period	Pulse width							
	50 μ s	100 μ s	200 μ s	500 μ s	1ms	2ms	5ms	10ms
1 ms	test	test	test	---	---	---	---	---
2 ms	test	test	test	---	---	---	---	---
5 ms	test	test	test	test	test	---	---	---
10 ms	test	test	test	test	test	test	---	---
20 ms	test	test	test	test	test	test	---	---
50 ms	test	test	test	test	test	test	test	test
100 ms	test	test	test	test	test	test	test	test
200 ms	test	test	test	test	test	test	test	test
500 ms	test	test	test	test	test	test	test	test
1 s	test	test	test	test	test	test	test	test

Test 1: Test all combinations of pulse width and pulse periods labelled "test" in Table 5 at the highest amplitude given in Table 4 for a minimum duration of 15 s per exposure, in order to assess device performance and behaviour. The AIMD manufacturer may reduce the above test combinations by providing rationale.

Test 2: Test at a minimum of one device-dependent susceptible modulation scheme(s), considering both pulse period and pulse width, using all amplitudes in the table, incrementally increasing the amplitude of the test signal from zero to maximum, in order to assess "windowing" effects. Wait for a minimum of 15 s at each amplitude step. If no device-dependent modulation schemes can be identified (e.g. a device that does not sense), a rationale shall be provided for waiving this test.

EXAMPLE A pulse period of 50 ms and a pulse width of 2 ms would fall in the sensing passband of a cardiac pacemaker, at which point it is expected to be the most susceptible.

Test 3: Test the maximum pulse width and the minimum pulse period labelled "test" in Table 5 at the maximum amplitude given in Table 4 for an exposure time of 30 min, in order to assess device damage from internal component heating. Consider performing this test before Test 1 and Test 2.

9 General considerations for application of the requirements of this Technical Specification

9.1 Compliance criteria

During each test, the device shall operate as intended according to its MR Conditional labelling (see 22.7 and 22.8).

After each test, the device shall operate as intended (including any special MR modes used only for scanning) with no loss of function, have no degradation of performance, and conform to all device specifications. All functionality (i.e. normal modes and MR modes) shall be checked after testing. Specific compliance criteria and the determination of risk resulting from device behavioural response during these tests are outside the scope of this Technical Specification (see 22.3).

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

NOTE 2 For devices that contain special MR modes used only for scanning, the AIMD manufacturers are encouraged to perform additional evaluation testing to assess hazards if labelling is not followed.

9.2 Monitoring equipment

For tests that require the AIMD to be monitored for proper performance and behaviour, the manufacturer shall use a monitoring method and/or device that do not cause any interference to the systems and devices under test. Removing any active components, modules or functionalities of the AIMD for arranging monitoring is not permitted.

9.3 Validation of models and test equipment

Test methods and tools used in implementing the requirements of this Technical Specification require validation, for example, the development of electromagnetic computational models, the measurement of test field strengths and injected voltage levels and phantom materials, and the monitoring method of AIMD performance and behaviour. See individual test clauses for specific requirements.

9.4 Uncertainty assessment

All tests require an analysis of the uncertainty of results. The requirements in Annex R shall apply. The analysis shall be included in test reports.

9.5 Test reports

Every test requires a report of the results. In general, each report shall include the information in this subclause. See individual test clauses for any additional requirements.

System components description:

- name and location of test facility and date(s) of testing;
- device model number(s) and product description of the configuration tested (include all system components, e.g. devices, leads;
- photograph or drawing of all system components;
- construction materials including magnetic (e.g. ferromagnetic) components;
- photograph or drawing of implant geometry showing key morphological features and dimensions;

- electrical description of AIMD describing the input circuitry at the device (including EMI capacitors) and the lead system.

Test methods:

- complete description of all tests performed;
- description and photographs or diagrams of each test set-up, including all test and measuring equipment, configuration and placement of AIMD components, and phantom placement within coils or MR scanner relative to isocentre;
- phantom dimensions and composition of tissue simulating material and electrical properties;
- simulators and auxiliary equipment, if any;
- AIMD settings and mode(s) of operation;
- justification for the injected and radiated exposure levels used, if applicable;
- evidence for the validation of test equipment and measuring apparatus;
- evidence for the validation of electromagnetic models and computation;
- detailed description of each pulse sequence used in the tests;
- manufacturer, model number and software version, if the test system is an MR scanner.

Test results and conclusions:

- evidence that the system operated in accordance with its MR Conditional labelling;
- test data that support the compliance determination for each test performed;
- effects on the AIMD observed during or after each test;
- deviations from the test methods;
- analysis used to interpret the measurement results;
- analysis demonstrating that the uncertainty of test results is within acceptable limits;
- any other relevant information needed for interpretation and reproduction of the tests (it is important that enough information be provided so that an experienced investigator could reliably reproduce the test results);
- conclusions.

10 Protection from harm to the patient caused by RF-induced heating

10.1 General

Determining the rise in local tissue temperature due to interaction of an AIMD with the RF field of an MRI scanner is a complicated process, and depends on AIMD design, MRI scanner technology (RF coil and pulse sequence design), patient size, anatomy, position, AIMD location and tissue properties. Depending on the specific conditions, variation of *in vivo* temperatures may span several orders of magnitude. For example, a small compact device implanted in an anatomical region that receives minimal RF exposure may pose

relatively little RF heating risk, whereas an elongated metallic device, such as a neurostimulator or pacemaker lead, may present an elevated risk.

The following subclauses outline the first step in the assessment; namely the methods for determining a conservative estimate of energy deposition, including the uncertainty, in a controlled *in vitro* test system. A four-tier testing approach is described in order to accommodate the diversity of AIMD configurations and specific applications. The second step assesses the maximum *in vivo* temperature rise using the assessed energy deposition of the first step, as described in Annex F. This Technical Specification does not provide tissue-specific thermogenic damage threshold values or guidance on how to determine application-specific risk factors for the determined temperature rise, which would constitute the third and final step in a complete assessment.

10.2 Outline of the four-tier approach

Tiers 1 and 2 follow an identical step-by-step measurement procedure but differ in the magnitude of the specified electric test field. Tiers 1 and 2 are only applicable if the AIMD does not include any concentrated filters (lumped elements) in the lead system of the AIMD such that the AIMD cannot be modelled using continuous properties per unit length. Tier 1 is the most conservative and computationally simple and it requires no additional electromagnetic modelling. Tiers 2 and 3 provide successively less overestimation of test field magnitudes, justified by electromagnetic computational analysis. Tier 4 provides the least overestimation of test fields, and requires the most stringent electromagnetic computational analysis.

10.2.1 Tier 1

Step 1: Determine the incident field for testing the AIMD in accordance with Table 6. The values in the tables have been computed using human models representing the human population, from children to adults, at the specified MRI operating mode (Normal or First Level control) (see Annex P). If the AIMD spans multiple body regions (head, trunk, extremities) the highest regional electric field (*E*-field) is used.

Step 2: Immerse the AIMD in a homogeneous simulated tissue medium and expose to a uniform (magnitude and phase) electric test field (see 10.5) at the amplitude equal to the value determined in Step 1. Testing at lower or higher field strengths with appropriate scaling is acceptable if linearity can be demonstrated. Testing at lower field strength and scaling up is only applicable if the signal-to-noise ratio is better than 10. If the AIMD is predominantly embedded in high conductivity tissues, the test is conducted in high conductivity medium (HCM) (see 10.5). If the AIMD is predominantly embedded in low conductivity tissues, the test is performed in low conductivity medium (LCM) (see 10.5).

Step 3: The maximum energy deposited by the AIMD is determined using SAR measurements or derived from temperature measurements in accordance with 10.7

Step 4: In case HCM has been applied in Step 2 and Step 3 and the AIMD can be embedded over the total length of more than 100 mm in low conductive tissues, Step 2 and Step 3 shall be repeated in LCM, or vice versa.

Step 5: For electrode leads longer than 100 mm, the resonant length shall be determined by measuring the energy deposition for lengths between 100 mm and the largest commercially available lead length. The resonant length is the length that produces maximum energy deposition at the analysed electrode pole. The worst-case energy deposition of any length measured in Step 3 shall be multiplied with the resonant length weighting factor of Table 8 to account for the worst-case phase condition. Alternatively, the phase factors can be determined for the investigated structure (see Annex K).

Step 6: A comprehensive uncertainty budget shall be determined in accordance with 10.8.

Step 7: The maximum energy deposition assessed in Step 1 to Step 6 is used to estimate the maximum *in vivo* temperature rise using Annex F.

Table 6 – Overall worst-case RMS E -field values (10 g average)

Body part	Maximum induced field normalized to B_1	Normal mode (2W/kg whole-body SAR)	First level mode (4W/kg whole-body SAR)
		$E_{RMSmax, in vivo}$	$E_{RMSmax, in vivo}$
Head	90 V/m/uT	420 V/m	420 V/m
Trunk	140 V/m/uT	500 V/m	700 V/m
Extremities	170 V/m/uT	600 V/m	850 V/m

NOTE 1 Evaluations are in accordance with 10.3 for all tissues and the entire population.

NOTE 2 The electric field values for the normal mode and first level control mode shown in this table are 10 g average values. E_{RMS} values for the head are normalized to whole head average SAR values of 3,2 W/kg for both normal mode and first level mode. E_{RMS} values for the trunk and extremities are normalized to whole body average SAR values of 2 W/kg for normal mode and 4 W/kg for first level mode. They represent the highest values calculated from a large set of numerical simulations using four different anatomical models with a mass ranging from 50 kg to 120 kg and a height ranging from 1,60 m to 1,78 m in a large number of representative positions in a generic 1,5 T birdcage coil (Annex J). The maximum E -field normalized to B_1 is not necessarily at the same location as the maximum E -field normalized to SAR. The maximum E -fields normalized to SAR were normalized to the whole body SAR maximum as occurred at the respective location of the body model in the coil where head and body SAR limits were considered separately. The resulting field values may not be obtainable in actual MRI systems and are subject to change when parameters and methods become more narrowly defined.

Table 7 – Conservative incident $B_{1RMS in vivo}$ field values for testing in accordance with Tier 1

Body part	Normal mode	First level mode
Head	7,0 μ T	7,0 μ T
Trunk	7,0 μ T	7,0 μ T
Extremities	7,0 μ T	7,0 μ T
NOTE As the maximum B_{1RMS} is not limited by the SAR limits but by the limitations of the commercial scanners, the B_{1RMS} to be used for magnetic coupling is set to 7 μ T. For details and rationale, see Annex P.		

Table 8 – Worst-case phase weighting factors for a single conductive lead (not including helical structures and structures with lumped elements)

Length as function of electrical resonant length ($l/l_{\text{resonance}}$)	Worst-case phase weighting factor (c_{phase})
0,2	1,0
0,4	1,0
0,6	1,0
0,8	1,0
1,0	1,0
1,2	1,1
1,4	1,2
1,6	1,3
1,8	1,4
2,0	1,5
2,2	1,6
2,4	1,7
2,6	1,8
2,8	1,9
3,0	2,0

NOTE The weighting factors were determined comparing the SAR increase at the lead tip under worst-case phase conditions to the SAR at resonance for insulated straight leads of different lead radii (0,4 mm to 1,2 mm), different insulation thicknesses (0,4 mm to 1,2 mm), and different insulation permittivities ($\epsilon_r = 1$ to 10). Lead lengths greater than 1 500 mm and phase gradients from 0 rad/m to 40 rad/m were considered for both HCM and LCM at 64MHz (see Annex K).

10.2.2 Tier 2

Step 1: Determine the incident field for testing the AIMD in accordance with 10.3 for any averaged 10 g tissue for the anatomically relevant implant locations. Determine the uncertainty of the determined incident test field.

Step 2 to Step 7: Conduct Step 2 to Step 7 of Tier 1.

10.2.3 Tier 3

Step 1: Determine the maximum incident field in accordance with 10.3 for the tangential E -field (magnitude and phase) and the magnetic field averaged over any 20 mm of anatomically relevant elongated AIMD path (this only applies for structures with a length-to-diameter ratio greater than 10) for the anatomically relevant implant locations. Determine the uncertainty of the determined incident test field.

Step 2 to Step 4: Conduct Step 2 to Step 4 of Tier 1 for constant phase of the incident E -field.

Step 5: For electrode leads longer than 100 mm, the resonant length shall be determined by measuring the energy deposition for lengths between 100 mm and the largest commercially available lead length. The resonant length is determined as the length of maximum energy deposition at the tip. The worst-case energy deposition of any length measured in Step 3 shall be multiplied with the worst-case phase multiplication factor, determined as follows.

- Option 1: Use the worst-case phase multiplication factor as provided in Table 8.
- Option 2: Assess the enhancement factor experimentally.

- Option 3: Develop a numerical electromagnetic model of the AIMD and validate this model in accordance with 10.4. Numerically or experimentally determine the worst-case enhancement factor compared to Step 2 to Step 5 of Tier 1 by varying a linear phase excitation at uniform magnitude over the phase range determined in Step 1.

Step 6 and Step 7: Conduct Steps 6 and 7 of Tier 1.

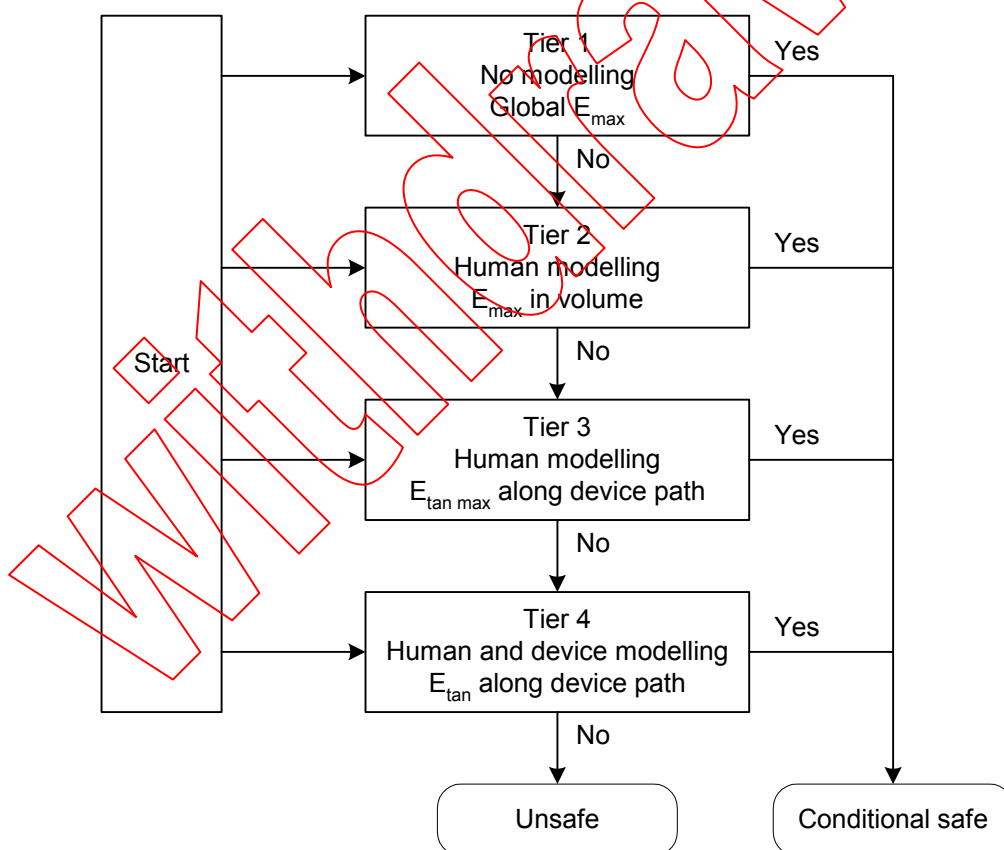
10.2.4 Tier 4

Step 1: Develop and validate an electromagnetic model (full-wave or lumped element) of the AIMD that is being evaluated. The AIMD model is validated by demonstrating the equivalence of the model and experimental results with the methodology defined in 10.4.

Step 2: Compute the energy deposition normalized to the appropriate incident field, e.g. $B_{1\text{RMS}}$, normal mode, using the validated numerical AIMD model for the defined patient population, considering all relevant parameters of 10.3.

Step 3: Determine the uncertainty budget of the evaluation. This will include measurement, computational and patient population coverage uncertainty.

Step 4: Compute the maximum tissue temperature rise for the energy deposition determined using Annex F.



NOTE Failure at an earlier stage leads to more complex methods in the following stages.

Figure 6 — Analysis flow diagram of the proposed tier approach

10.3 Determination of the induced electric and magnetic fields

10.3.1 Electromagnetic simulation

Tiers 2 to 4 require electromagnetic simulation results using numerical human body models to identify the electric and magnetic field magnitudes used in the *in vitro* phantom test procedure. This subclause provides a general overview of the requirements for determining the distribution of the excitation or of the field induced in the body that induces currents on the AIMD under test. From this distribution, the excitation will be derived for experimental assessment of the maximum local power deposition caused by the AIMD.

10.3.2 Relevant parameters

The RF excitation of the AIMD is proportional to B_1 and strongly dependent on the following parameters:

- RF frequency;
- body habitus or external anatomy;
- internal anatomy;
- location of the implant;
- transmitting RF coil design and polarization;
- position in the birdcage with respect to the isocentre;
- body posture in the coil.

NOTE The resulting field distribution may not be directly correlated to the distribution of these parameters; this necessitates careful evaluation of the transformation of the B_1 field to the induced fields.

10.3.3 Assessment procedure

Electromagnetic simulations will be performed to identify conservative *in vitro* test conditions. The conservative incident fields are determined by the following steps using validated electromagnetic simulation packages and human models.

- Identify the patient population and subdivide into subgroups with respect to anatomical properties such as length, BMI, age, etc., choosing the 95th percentile of the patient population for each relevant property.
- Compute the incident field distributions as defined in the applied tier and determine the 95th percentile incident field value for each subgroup in any of the clinically relevant postures and positions with respect to the isocentre for the specified relevant RF-transmitting coil designs.
- Determine the largest 95th percentile incident field of all subgroups and coil designs for use as the incident field amplitude.

10.3.4 Uncertainty budget of incident field assessment

An uncertainty budget for the distribution of the excitation is required. All of the above parameters shall be considered and shall include at least the following:

- transmitting RF coil design (including variations, e.g. polarization);
- inner and outer anatomy (BMI, size, tissue distribution, dielectric and thermal tissue parameters);

- position and posture in the birdcage (position in the birdcage with respect to the isocentre, body posture in the coil);
- AIMD paths in anatomy (geometrical distribution of AIMD location inside the body).

NOTE 1 These parameters can be evaluated separately if they are deemed to be sufficiently independent.

NOTE 2 The exact procedure depends on the tier that is applied.

NOTE 3 Table R.11 can be applied for the uncertainty assessment.

10.4 Validation of electromagnetic AIMD models

10.4.1 Validation procedure

Tier 4 and the third option in Tier 3 require modelling the response of the AIMD to an incident electromagnetic field. This clause outlines an *in vitro* approach that may be used to validate the AIMD model.

Step 1: Create a numerical model (e.g. a full model or lumped element model) of the AIMD configuration to be tested that represents all of its relevant RF characteristics and conduct a comprehensive uncertainty analysis for the AIMD model by robustness analysis, e.g. by Monte Carlo analysis.

Step 2: Evaluate multiple conditions including HCM and LCM (if applicable) that provide differences in the maximum energy depositions larger than the relative uncertainty of the assessment techniques and that represent the AIMD major electromagnetic properties. The test conditions shall be sufficiently large to validate the model prediction over the range of *in vivo* field conditions, one of which shall be the resonant length. If no differences are larger than the uncertainty of the assessment techniques, then choose the worst cases with respect to performance.

Step 3: Experimentally test the AIMD in accordance with 10.7.2 for all of the above test conditions.

Step 4: Determine the relative differences of experimental and numerical assessments for each test condition.

10.4.2 Validation criteria

If the relative differences between simulations and measurements for each of the test cases are within the combined relative uncertainties of measurement and simulation, the AIMD model can be considered validated, and the combined relative uncertainties should be considered as the uncertainty of the AIMD model.

10.5 Generation of incident fields for Tier 1 to Tier 3 and minimal medium requirements

Testing shall be performed using a known and measured electromagnetic field. Depending on the particular approach used, the test field may be uniform (in magnitude and phase) or spatially varying. The objective of the test system is to obtain the smallest uncertainty with respect to test results. Important test conditions are constant *E*-field amplitude and phase of Table 9. These conditions can be obtained with various RF sources (coil systems) and different phantoms. An example of a coil system that meets these requirements is given in Annex J. Examples of phantoms are provided in Annex M.

The dielectric properties of acceptable phantom materials for averaged high and low conductivity tissue parameters are defined in Table 10, for which an example of the recipe is provided in Annex L. If the energy deposition is determined by temperature measurements, the thermal properties of material shall be assessed with a precision of better than $\pm 20\%$, with viscosity larger than 0,1Pa·s.

Table 9 – Minimal requirements for the incident field for 1,5T test setups

Larmor frequency	64 MHz $\pm$ 5 %
$B_{1\text{RMS}}$	$> 2 \mu\text{T}$
Deviation from Uniform Etan-field over the entire AIMD path	$< \pm 1 \text{ dB}$ (Phase $< \pm 20$ degrees)
Drift of Etan-field during assessment	$< 0,25 \text{ dB}$

Table 10 – Dielectric properties of the liquid and gel materials to be used in the phantom

B_0 (T)	Tissue simulating medium	Relative permittivity, ϵ'_r	Conductivity, σ (S/m)
1,5	High conductivity medium (HCM)	78	0,47
1,5	Low conductivity medium (LCM)	11,5	0,045
NOTE Maximal acceptable tolerance ± 20 %.			

10.6 Measurement system requirements

10.6.1 Probe specification

The B_1 of the RF birdcage shall be monitored by a calibrated magnetic field probe that allows the monitoring of the field strength and the deviation from targeted polarization. Alternative methods based on transfer units can be used if equivalent. The suggested specifications of the measurement system probes are provided in Table 11.

Table 11 – Suggested specifications of the probes of the measurement system

	B-field probe	SAR probes	Temperature probe
Frequency range	64 $\pm$ 5 MHz	64 $\pm$ 5 MHz	—
Dynamic range	$< 0,1$ to $> 20 \mu\text{T}$	$< 0,01$ to 100 W/kg	< 10 to $> 40 ^\circ\text{C}$
Deviation from linearity	$< \pm 0,2 \text{ dB}$	$< \pm 0,2 \text{ dB}$	$< \pm 0,2 \text{ K}$
Noise (avg. $< 10 \text{ s}$)	$< 0,1 \mu\text{T}$	$< 0,01 \text{ W/kg}$	$< 0,1 \text{ K}$
Spherical isotropy directivity	$< 0,4 \text{ dB}$	$< 0,4 \text{ dB}$	—
Spatial resolution	$< 5 \text{ mm}$	$< 3 \text{ mm}$	$< 1 \text{ mm}$
NOTE If probes of lower specifications are used, additional uncertainty analysis is required.			

10.6.2 Validation and characterization of the measurement system

The test system, instrumentation and measurement procedures need to be validated using one of the generic AIMD as described in Annex I. Specific protocols shall be developed and available, together with a documented uncertainty budget to ensure that the same conditions with known uncertainty are obtained during the tests as during the validation, e.g. the same position of the phantom with respect to B_1 , magnitude of B_1 field or magnitude of the induced E -field.

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

10.7.1 Determination of 3D relative distribution of local energy deposition

The local temperature rise inside the tissue is the result of the absorbed energy deposition. In the first approximation, the distribution of the locally absorbed energy is a function of the local geometric properties of the AIMD and the magnitude is a function of the capability of the AIMD to collect RF energy. In the first step the relative energy distribution is determined. This can be based on numerical simulation of the local energy deposition, the uncertainty of which is validated by experimental SAR or temperature measurements or by the full 3D experimental SAR measurements. When this is established, the full assessment of AIMD performance for each required configuration can be conducted by absolute measurements of one or only a few points. One of the four following recommended procedures to determine the 3D distribution of energy depositions shall be used.

NOTE Procedure 3 and procedure 4 result in larger uncertainties.

Procedure 1: Numerical assessment with thermal validation

- Step 1: conduct quasi-static or full-wave electromagnetic (EM) modelling of the AIMD local geometry resulting in the highest energy deposition for the experimental medium.
- Step 2: conduct uncertainty assessment of the EM modelling, u_{EM} .
- Step 3: conduct thermal modelling of the energy deposition of Step 1 into a temperature distribution in the experimental medium.
- Step 4: conduct uncertainty assessment of the thermal modelling, $u_{thermal}$.
- Step 5: based on the distribution, determine the most suitable points for validating the distribution, i.e. the points resulting in the smallest uncertainty for validating the energy distribution.
- Step 6: measure ΔT at the selected points to verify the distribution using the procedure defined in 10.7.2.
- Step 7: conduct uncertainty assessment of the thermal measurement for the single point measurement, u_{meas} .
- Step 8: perform pattern matching and determination of the matching uncertainty ($u_{pattern\ matching}$).
- Step 9: if the deviation is less than the combined uncertainty, the model has been successfully validated and the uncertainty is equal to the combined uncertainty.

Procedure 2: Numerical assessment with SAR validation

- Step 1: conduct quasi-static or full-wave EM modelling of the AIMD local geometry, resulting in the highest energy deposition for the experimental medium.
- Step 2: conduct uncertainty assessment of the EM modelling, u_{EM} .
- Step 3: based on the SAR distribution, determine of the most suitable points for validating the distribution, i.e. the points resulting in the smallest uncertainty for validating the energy distribution.
- Step 4: measure SAR at the selected points to verify the distribution using the procedure defined in 10.7.2.
- Step 5: conduct uncertainty assessment of the SAR measurement, u_{meas} .
- Step 6: perform pattern matching and determination of the matching uncertainty, $u_{pattern\ matching}$.

- Step 7: if the deviation is less than the combined uncertainty, the model has been successfully validated and the uncertainty is equal to the combined uncertainty.

Procedure 3: Full 3D SAR measurements

- Step 1: conduct the full 3D SAR evaluation and determine the 3D distribution by interpolation and extrapolation.
- Step 2: determine the uncertainty of the 3D evaluation.

Procedure 4: Full 3D ΔT measurements

- Step 1: measure 3D ΔT using temperature probes following the protocol of 10.7.2.
- Step 2: determine the SAR distribution using the appropriate Green's functions.
- Step 3: conduct uncertainty assessment of the energy deposition.

10.7.2 Measurement protocol for determination of maximum amplitude

- Step 1: Preparation for the evaluation.

The systems for RF heating evaluation should fulfil the requirements of 10.5 and 10.6. The full validation should have been conducted according to Annex I.

Prior to testing, measures should be defined to ensure the intended conditions with the specified uncertainty are met (measurement of the induced E -field, monitoring the incident B_1 field, position of the phantom, etc.).

NOTE 1 The induced E -fields can be measured with dosimetric E -field probes or temperature probes, and the direction of the field can be determined by E -field probes or by correlations to computed field distributions. The phase information can be determined by time-domain sensors or computational techniques.

Measurement or validation of liquid/media parameters should be performed to ensure that the dielectric properties remain within the specified tolerance. The test shall be conducted within a defined interval of the liquid measurements to ensure the intended dielectric parameters during the tests.

NOTE 2 The dielectric parameters and the thermal properties of the media change when water evaporates. The dielectric parameters are also a function of temperature. If the dielectric parameters are within the requirements of Table 10, reproducible measurements can be obtained.

- Step 2: Mounting of AIMD and phantom preparation for SAR evaluation.

The mounting of the AIMD depends on the configuration being tested.

In the case of E -field coupling evaluations according to Tier 1, Tier 2 and Tier 3, the AIMD should be mounted along a path of constant magnitude (± 1 dB) and constant phase with known precision (± 10 degrees), as described in Annex M.

In the case of experimental E -field coupling evaluations according to Tier 3, not using the worst-case phase factor of Table 8, the AIMD should be mounted along a path of constant E -field magnitude (± 1 dB) and linear in phase with known precision (± 10 degrees).

In the case of Tier 3 and Tier 4 based on AIMD modelling, the AIMD should be mounted along paths providing suitable conditions (magnitude and phase) with known precision for validating the numerical AIMD model, one of which may correspond to a path of constant amplitude (± 1 dB) and constant phase.

For H -field coupling evaluations, the AIMD is moved to the central region of the phantom and oriented so that there is minimal tangential E -field coupling. Loops or similar structures are oriented to produce maximal coupling with the B_1 field.

Configuration for H -field coupling shall only be tested if the AIMD or any extension can form one or more loops or nearly closed loops when implanted, i.e. two parts (e.g. leads) that are not electrically short-circuited (RF) come close (within 20 mm) to each other. Otherwise testing for H -field coupling may be omitted.

— Step 3: AIMD configurations to be tested.

The AIMD configurations defined in Clause 3 and Annex R, and test conditions defined by the applied tiers (see 10.2), shall be tested. For devices smaller than 100 mm, only the longest configuration needs to be tested if the other configurations do not significantly change the electromagnetic properties of the device. For configurations larger than 100 mm, all configurations that result in a geometrical change larger than 20 % or by more than 50 mm, or that produce any significant change in the electromagnetic properties, shall be evaluated. For AIMDs with extensions that can vary in length (e.g. leads) and which are longer than 50 mm, successive reduction of the length by 50 mm until the total AIMD length (e.g. lead plus device) is 100 mm or less is required.

— Step 4: Scan of entire AIMD area for high energy deposition.

For each configuration of Step 3, switch on the power to a well-defined B_1 RMS and determine all locations of maximum energy deposition that are within -6 dB of the largest one. This can be determined by either:

- applying an array of temperature sensors at well-defined distances, or
- scanning with a SAR probe along the surface at well-defined distances.

The distance from the surface of the AIMD for sampling shall be less than 2 mm with a variation of less than 0,25 mm. The sampling separation along the AIMD should be less than 5 mm. It is not necessary to conduct the scan for all lengths if it can be demonstrated that the high energy deposition always occurs at the same location, independent of the length.

— Step 5: Evaluation of data — Define configurations for 3-D energy deposition assessment.

Determine the energy deposition at all surface areas of all configurations defined in Step 3 that are larger than $-(3 \text{ dB} + u)$. u is the uncertainty of the measurements of the scan to determine the location of maximal energy depositions as given in Step 2 to Step 4.

— Step 6: Repositioning of the device for the configurations selected in Step 5.

Mount the AIMD in the configurations according to Step 2 for those selected in Step 5.

— Step 7: Determination of the local 3D distribution of the energy deposition.

The distribution of the local 3D distribution of the energy deposition should be assessed for the defined configurations and locations in Step 5 according to one of the procedures defined in 10.7.1. In general, the accuracy of the probe position shall be better than 0,25 mm for SAR assessment and better than 0,5 mm for temperature evaluations.

— Step 8: Determination of the magnitude of local 3D distribution of the energy deposition.

The magnitude of the energy deposition is determined by one or more measurements in selected configurations and locations for all areas selected in Step 5.

NOTE 3 For ΔT measurements, it is recommended that a reference probe at a location that provides equivalent or consistent SAR distributions be monitored.

NOTE 4 SAR can be determined with isotropic dosimetric probes or with temperature probes. For ΔT measurements, it is recommended that a reference probe at a location that provides equivalent or consistent SAR distributions be monitored.

NOTE 5 SAR or ΔT are the induced SAR or induced temperature increases by the AIMD only beyond the background SAR and ΔT .

NOTE 6 Precise probe positioning with respect to the surface is necessary for the uncertainty budget, in particular for SAR probe evaluations.

— Step 9: Evaluation of results to determine maximum 3-D energy deposition and uncertainty budget.

The results of the configurations and locations selected in Step 5 shall be evaluated with respect to the total energy deposited whereby the values for the energy depositions of the E - and H -field coupling shall be added. The uncertainty budgets shall be determined for each location. All values that are within ± 3 dB of the largest values plus the uncertainty ($k=2$) shall be evaluated according to Annex F for maximum heating.

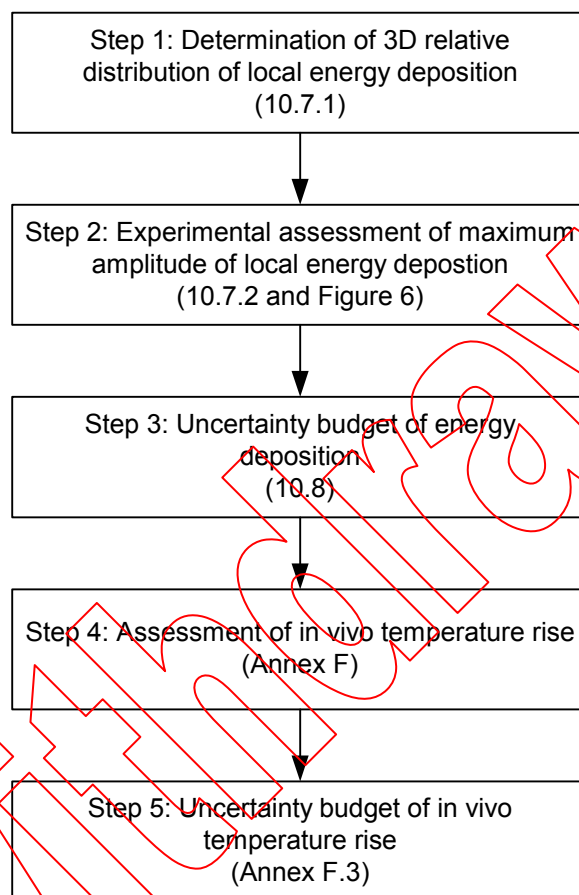


Figure 7 — Block diagram of the steps for the assessment of the maximum temperature rise *in vivo*

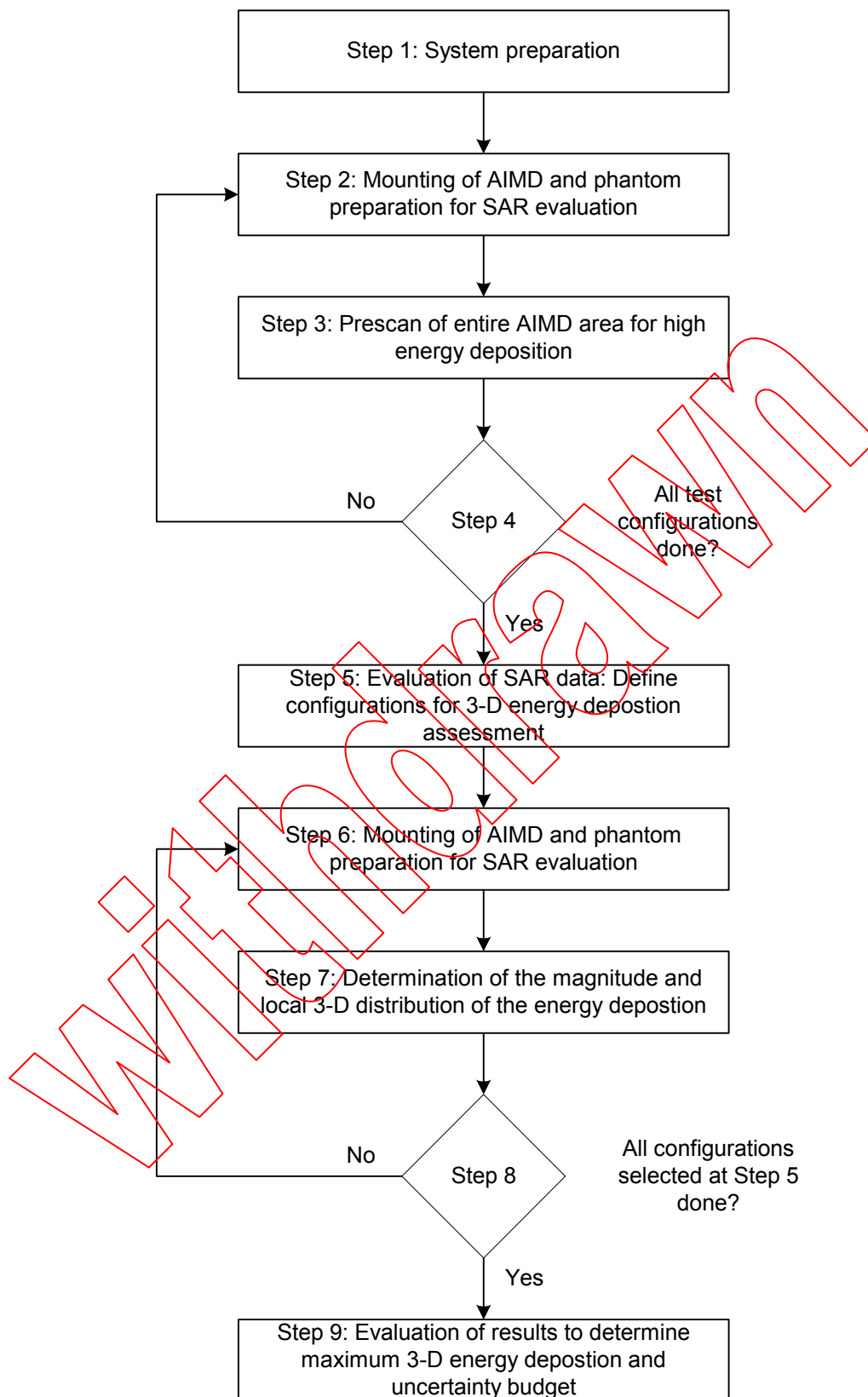


Figure 8 — Block diagram of the steps for experimentally determining the maximum amplitude

10.8 Uncertainty assessment of energy deposition using SAR or temperature probes

The requirements of R.2 shall apply.

10.9 Compliance criteria

Compliance shall be checked by examination of the manufacturer's records in accordance with the requirements in 9.1.

10.10 Test report

The following test report information is required in addition to the requirements of 9.5.

- a) *In vivo* justification of the *in vitro* incident field exposure level:
 - 1) description of the test approach used (Tier);
 - 2) summary of *in vivo* simulation results, if used;
 - 3) uncertainty analysis of the incident field assessment.
- b) Results of localized energy deposition assessment:
 - 1) description of the incident test fields and medium;
 - 2) description of the applied measurement technique for local energy deposition;
 - 3) uncertainty analysis of the maximum localized energy deposition measurement.
- c) Evaluation of the transformation from *in vitro* energy deposition to *in vivo* tissue temperature:
 - 1) description of the method used to transform energy deposition to tissue temperature;
 - 2) uncertainty analysis of the *in vivo* temperature transformation.
- d) Evaluation of the patient risk from localized *in vivo* temperature rise caused by RF-induced heating during an MRI scan.

11 Protection from harm to the patient caused by gradient-induced device heating

11.1 General

The pulsed gradient magnetic fields produced by 1,5 T MR scanners will induce eddy currents in any conductive material exposed to them (this clause does not address currents induced on implanted leads by gradient fields). A metallic implant will carry eddy currents induced by gradient field dB/dt in a conductive case and other conductive internal surfaces including AIMD internal circuit traces. The induced currents are a function of the electrical conductivity and dimensions of the surfaces. These currents have been shown to induce heating of an implant in bench testing. The instantaneous power deposited by eddy currents on a cylindrical disc is given by the follow equation:

$$P = \sigma T \pi \frac{R^4}{8} \left(\frac{dB}{dt} \cos \beta \right)^2$$

where

- P is instantaneous power deposited on a disc of radius R ;
- T is thickness;
- σ is conductivity;

$\frac{dB}{dt}$ is the time rate of change of the magnetic field incident at an angle of β to the normal to the disc.

When determining the average power deposited in the device and associated surrounding tissue, the mean value of the square of $\frac{dB}{dt}$ for the particular MRI sequence(s), as well as the integral of the exposure and incident angle across all conducting material of the device, shall be considered. The heating will be greatest for implants with a large surface area and high electrical conductivity (copper will heat more than titanium, for example).

NOTE Device heating caused by gradient field induced eddy currents is proportional to the mean value of the square of $\frac{dB}{dt}$ (or more precisely, $\frac{\partial B}{\partial t}$).

11.2 Testing considerations

11.2.1 General

The intensity and vector orientation of the pulsed gradient magnetic fields vary throughout the scanner bore. Device heating will be maximized when the device is located where gradient field $\frac{dB}{dt}$ is maximum. Typically, heating will be further maximized when the device is oriented such that the gradient field vector is orthogonal to the AIMD surface(s) with the largest conductive area. There may be exceptional situations, such as an unusual device case design or substantial power deposition in internal components, for which maximum heating will occur for some other device orientation. Evaluation of gradient-induced case heating shall be conducted under conditions sufficient to reflect all gradient system exposures allowed by the AIMD MR Conditional labelling provided for the AIMD.

The magnitude and orientation of gradient field $\frac{dB}{dt}$ varies as a function of location in and around the MR scanner. For the 1,5T cylindrical bore class of scanner, using whole body gradient coils, maximum levels of $\frac{dB}{dt}$ will be found near the inner wall of the bore and approximately 0,35 m along the z axis on either side of isocentre ($0,3 \text{ m} \leq |z| \leq 0,4 \text{ m}$). For scanners with atypically short bores, the region of maximum $\frac{dB}{dt}$ may be located closer to isocentre ($|z| < 0,3 \text{ m}$).

11.2.2 Determination of clinical $\frac{dB}{dt}$ exposure limits

11.2.2.1 Tier 1

The AIMD shall be exposed to a continuous triangular pulse radiated B field based on the definitions given in 8.1, gradient sequence of sequences, using the following parameter settings (see Figure 3):

TDWELL = 0 ms

TOFF = 0 ms

TSLEW = 0,2 ms

The B_G test value, which depends on the device location within the MRI bore, shall be the maximum shown in 20.3.2. The combination of maximum B_G test value and TSLEW = 0,2 ms triangle wave yields a 100 % slewing duty cycle $\frac{dB}{dt}$ which represents currently available MR scanner limits. Note that the mean square value of the resulting $\frac{dB}{dt}$ square wave function is theoretically equal to its peak value. Testing using this single gradient pulse sequence is sufficient as it will produce maximum device heating. In order to use these test signals and parameters, bench-top apparatus is required.

NOTE The test signals and parameters described in 8.1 are intended for bench-top testing only. To attempt to use them on clinical scanners is not encouraged or recommended and might result in scanner damage.

11.2.2.2 Tier 2

Use of Tier 1 test conditions may not be clinically realistic. Consequently, the AIMD manufacturer may make a determination of clinically relevant device maximum exposure conditions in terms of the mean square value of

dB/dt and vector orientation of the field relative to the device. If the Tier 1 test conditions are not used, the AIMD manufacturer shall provide a rationale for the dB/dt test conditions used to evaluate eddy current heating. The rationale shall indicate the source of gradient field dB/dt information, and indicate the spatial basis (i.e. single point, averaged over the area of a surface, or averaged over a volume) for the measurements or computations. If averaging is used, the surface or volume shall be equivalent to or smaller than the device under evaluation. Gradient field dB/dt information may come from measurement, from the MR equipment manufacturer's data sheet, or be obtained from and documented by the MR equipment manufacturer, etc.

NOTE Maximum (peak) gradient dB/dt data, at the surface of three cylinders of diameters 20 cm, 40 cm, and bore ID minus 10 cm, provided by MR vendors (see IEC 60601-2-33:2010, 201.7.9.3.101) can be helpful in determining clinically relevant test conditions for gradient-induced device heating.

If measurement is the method used to determine the clinical worst-case conditions, the 3-axis search coil and methods described in IEC 60601-2-33 may be used. Other search coils or E-M measurement probes may be used so long as the spatial averaging inherent in the coil or probe is consistent with the size of the AIMD device. If the mean square value of dB/dt is taken directly from measurement, care shall be taken that the pulse sequence used produces the clinically relevant maximum mean square value for gradient slewing.

Alternatively, the maximum mean square dB/dt may be calculated based on peak dB/dt and the clinically relevant maximum slewing duty ratio.

11.2.3 Test duration

11.2.3.1 Test duration determination

The test duration for temperature rise testing shall be determined by one of the following methods.

11.2.3.2 Test duration determined by temperature rise steady state

A gradient field, or simulated gradient field, with constant mean square dB/dt (when averaged over a time period of 1 min) shall be applied to the device under test until the temperature difference between the device and the gelled solution in which it is immersed (ΔT) stabilizes.

11.2.3.3 Test duration determined by clinical use condition

A profile of gradient field RMS dB/dt level and duration corresponding to worst-case clinical use shall be applied to the device under test.

NOTE Gradient field dB/dt can be quantified in terms of root mean square as well as mean square so long as the fact that device heating is proportional to the mean square is taken into account. That is, RMS values are squared when considering device heating proportionality.

11.2.3.4 Test duration determined by labelling constraints

If the AIMD MR Conditional labelling includes provisions that limit the duration of gradient field exposure, temperature testing shall be conducted in accordance with those provisions.

11.2.4 Data collection

The AIMD heating test requires simultaneous measurement of device temperature and gradient dB/dt exposure in a gelled solution, as defined in the test methods section.

11.3 Test requirements

11.3.1 General

Evaluation of device heating involves exposing the AIMD device to the specified gradient field dB/dt (mean square or RMS value and vector orientation) and measuring the resulting temperature rise. It may be necessary to immerse the device in a gelled solution using a suitable phantom to simulate transfer of heat away from the device provided by tissue when the device is implanted.

Use of a laboratory coil, amplifier and function generator that can simulate clinical gradient field exposure is preferred. This type of equipment has the benefit of being able to easily generate arbitrary pulse sequences that can be consistently reproduced. Because the volume of homogeneous field required for testing most AIMDs will be considerably smaller than that required in a scanner; the size, cost, cooling and power required by the laboratory equipment may also be considerably less. The use of this type of apparatus may be applied to Tier 1 and to Tier 2 (see 11.2.2).

Alternatively, testing may be conducted using a clinical MR scanner. If a scanner is used, care should be taken that the device location, device orientation and scanner set-up are well controlled. This is a difficult task and specialized knowledge is required in order to operate the MR equipment.

NOTE This statement does not construe or imply any burden or obligation on the part of MR equipment manufacturers.

It may not be necessary to expose the device to the clinical exposure limits of 11.2.2 during temperature testing to determine device heating. If the applied field generates a temperature rise large enough to be measured with sufficient accuracy, it may be possible to evaluate the device using linear temperature scaling and the RMS value of dB/dt , as shown below.

$$\Delta T_{\text{clinical exposure in-vitro}} = \Delta T_{\text{measured}} * \left[\frac{|dB/dt|_{\text{rms}} (\text{requirement})}{|dB/dt|_{\text{rms}} (\text{test})} \right]^2$$

If this method is used, a rationale shall be provided, including validation of the scaling factors.

11.3.2 In vitro, phantom or other suitable container

Position the instrumented device at the radial centre of a phantom filled with gelled solution. Position and orient the phantom and device as required in either laboratory test equipment capable of producing a simulated MR gradient field or a clinical MR scanner.

11.3.3 Gelled solution

For a device heating test, the phantom material is 9 g/l polyacrylic acid and 1,4 g/l saline.

NOTE This is the same material described in ASTM F2182, but a different mixture, and it may also be used for the induced voltage tests.

11.3.4 Optical temperature probes

Place at least two fibre-optic temperature probes on the surface of the device case (see Reference [18] or equivalent for more information). One probe should be near the centre of the largest surface of the device and the other should be near the outer edge of the device or, alternatively, at the hot spot identified during the initial temperature survey. Prior to applying any gradient sequences, record the initial temperature, T_0 . Since the device may have localized hot spots, the final location of temperature probes shall take this into account.

11.3.5 Temperature survey to determine worst-case orientation and hot spots

Device heating will depend upon orientation of the device relative to the vector of the applied field. A survey shall be conducted to determine the orientation that produces the largest heating. The heating shall be measured with the device oriented in each of three orthogonal orientations relative to the applied gradient field (testing in MR scanner) or simulated gradient field (lab testing). One orientation shall place the largest surface of the case orthogonal to the applied field. Note that repeating testing with the device in each of the three orientations described above is an acceptable alternative to conducting the orientation survey. Whether or not the device orientation survey is helpful will depend upon the number of tests being conducted.

The device may have localized hot spots due to the case shape or heating contributed by power dissipated in internal components. Prior to testing, the device should also be surveyed for hot spots due to gradient-induced heating. The hot spot survey shall be conducted using the device orientation that produced maximum heating when the orientation survey was conducted.

11.3.6 Minimum temperature instrumentation

Temperature data collection shall be consistent with the intended use. A minimum of two temperature probes shall be used to measure device temperature, with at least one probe at the highest temperature spot found in the temperature survey. A minimum of two additional temperature probes shall be used to measure the temperature of the surrounding gelled electrolyte solution.

11.3.7 Temperature data collection

Data recording shall commence one minute prior to application of the actual or simulated gradient field. Data recording shall continue for the full duration of gradient field or simulated gradient field exposure. Following cessation of the field exposure, recording of temperature data shall continue for a minimum of 2 min. Temperature data shall be recorded at a rate sufficiently high to allow calculation of the AIMD thermal response time constant(s); the minimum temperature sampling rate shall be one sample per second.

11.3.8 Monitor applied dB/dt

Place a search coil in the region of the homogeneous field. Orient the probe to be orthogonal to the vector of the applied field and not more than one centimetre from the device. Record the applied dB/dt waveform used for the heating test. The recorded waveform shall have a sampling rate sufficient to capture the details of the dB/dt waveform and prevent aliasing of the signal. The recorded waveform shall have sufficient length to allow determination of mean values. If mean square or RMS dB/dt is not directly recorded, the gradient field exposure recording shall be such that it can be post-processed to calculate mean square or RMS dB/dt . A synchronization reference shall be provided to allow time correlation of dB/dt and temperature data recordings.

11.3.9 Gradient field vector orientation relative to device

The device temperature rise shall be measured in three orthogonal device orientations. One orientation shall place the largest surface of the device orthogonal to the applied field vector. Alternatively, the result of the orientation survey or other rationale may be used to justify using a single orientation (see 11.3.5).

11.3.10 Monitoring AIMD for heating and malfunction

Device performance and behaviour shall be monitored during testing for heating and for malfunction. Compliance shall be checked by examination of the manufacturer's records in accordance with the requirements in 9.1.

11.4 Lab testing using simulated MRI gradient field

11.4.1 Simulated field requirements

Case heating in the bench-top test is measured using the procedure described in 11.3. The device is placed in the gelled phantom with temperature probes attached and placed in a laboratory coil that applies the time-varying magnetic field. The preferred method is to apply the required RMS dB/dt determined in accordance with 11.2.2.

An alternative method is to test at a RMS dB/dt that is greater than or equal to 50 % of the RMS requirement from 11.2.2 (25 % of the mean square dB/dt requirement). If testing is conducted in this way and the resulting temperature rise is large enough to be measured accurately, then the result shall be scaled as described in 11.6 to find the temperature rise at the required RMS dB/dt exposure. If temperature rise measurements are scaled in this manner, the effect of measurement errors shall be carefully considered and taken into account.

11.4.2 Pulse waveform RMS value

The simulated gradient field pulse waveform may be adjusted to obtain the required RMS value of dB/dt by adjusting the amplitude and/or pulse sequence duty cycle.

The spectral content of the test waveform shall be similar to that produced by clinical scanners. If the gradient field excitation waveform is significantly different from clinical pulse sequence waveforms (e.g. a sinusoid rather than a series of trapezoidal pulses) a demonstration of equivalence shall be provided. Eddy current heating may be a function of spectral content due to the effective inductance experienced by the eddy currents.

11.4.3 Gradient sequence of sequences

A pulsed gradient magnetic field sequence of sequences (SOS) is defined in 8.1. The gradient SOS may be used as a guideline when defining the gradient field waveform used to test and evaluate AIMD device heating. The gradient SOS may not provide the RMS dB/dt value needed for temperature rise testing. The AIMD manufacturer shall provide a rationale relating the gradient field RMS dB/dt used for testing to the expected worst-case clinical exposure. It is not necessary to perform the device heating test using all of the pulse sequences identified in the gradient field sequence of sequences.

11.5 MR scanner testing

Most of the discussion regarding laboratory testing could be adapted to testing conducted using a clinical scanner. If a clinical scanner is used, adequate fixturing will be needed to locate and orient the phantom and device under test. Selecting, controlling and repeating the scanner clinical pulse sequence used for testing is also important.

The gradient output used for this test shall be consistent with intended AIMD labelling, taking into consideration variables between scanners and sequences. Pulse sequence characteristics and the magnitude of dB/dt are both important parameters to be considered because device heating will be proportional to the mean square (averaged over time) of gradient field dB/dt . An SOS is defined in 8.1. It may not be practical to apply the Tier 1 gradient field exposure requirements defined in 11.2.2 when testing is conducted using a clinical MR scanner.

The gradient SOS may be useful as a guide when selecting clinically relevant sequences used to test and evaluate AIMD device heating using Tier 2 test conditions in accordance with 11.2.2 of this Technical Specification. The AIMD manufacturer shall provide a rationale relating the gradient field mean square or RMS dB/dt used for testing to the expected worst-case clinical exposure.

As a minimum, gradient heating should be tested and evaluated using gradient intense compatibility protocol information provided by MR equipment manufacturers (see IEC 60601-2-33:2010, 201.7.9.3.101).

NOTE 1 The test signals and parameters described in 8.1 are intended for bench-top testing only. To attempt to use them on clinical scanners is not encouraged or recommended and might result in scanner damage.

NOTE 2 Generation of worst-case mean square dB/dt may require that the MR scanner is operated in its research mode. This mode of operation requires specialized knowledge that might not be readily available. This statement does not construe or imply any burden or obligation on the part of MR equipment manufacturers.

11.6 Analysis of gradient heating test

From the recorded dB/dt waveform taken from the search coil, determine the mean square value of dB/dt orthogonal to the plane of the search coil (and AIMD surface).

$$dB/dt(MS) = \frac{1}{\tau} \int_0^{\tau} \left(\frac{dB_y}{dt} \right)^2 dt$$

where

τ is a suitable averaging time for the dB/dt pulse sequence;

$dB/dt(MS)$ is the mean (averaged over time) of dB/dt squared.

The heating constant γ_{grad} is defined as

$$\Delta T = \gamma_{grad} \frac{dB}{dt}(MS)$$

NOTE 1 γ_{grad} can be used to predict the heating for any pulse sequence.

In general, *in vivo* heating will differ from that measured in this testing and will depend on factors such as the implant location and the type(s) of tissue in contact with the AIMD and surrounding the implant site, blood perfusion, etc. Analysis that takes these differences into account will be needed to evaluate the results of this testing.

The maximum tissue temperature determined from testing and analysis along with the temperature versus time exposure shall be used to evaluate the risk of harm.

NOTE 2 Determining a suitable averaging time should take into consideration the nature of the pulse sequence and the thermal time constant of the device under test.

11.7 Uncertainty assessment

The requirements of R.3 shall apply.

11.8 Test report

The following test report information is required in addition to the requirements of 9.5.

- Plots of data from the test, including recording of the maximum temperature rise after the steady state is reached.
- Record of gradient waveforms from the search coils.
- If MRI scanner-based testing is employed, a detailed description of each pulse sequence used in the testing. This will include the following description of the scan sequence and the parameters affecting the gradient pulse sequence and test conditions:

- type of pulse sequences(s) used in the testing (e.g. spin echo, fast spin echo, turbo spin echo, gradient echo, echo planar);
 - slice thickness, resolution in the phase and frequency axis;
 - slice orientation;
 - gradient amplitude (units of mT/m) for each axis (G_x , G_y , and G_z);
 - a theoretical or empirical rationale justifying the location and orientation of the device during testing.
- d) Any analysis needed to interpret the measurement results, such as scaling temperature rise measurements.

12 Protection from harm to the patient caused by gradient-induced vibration

12.1 General

Vibratory forces are caused by interaction between the gradient-induced eddy current magnetic moments of the AIMD and the MR scanner static magnetic field (B_0). Force and torque are generated if the eddy current magnetic moment and static magnetic field are misaligned. The magnitudes of the forces are proportional to the vector product of gradient field dB/dt and B_0 field. The MR gradient vibration forces are different from those the AIMD is subjected to during the handling and transportation vibration testing to which they are typically subjected, in the following ways:

- the forces act directly on electrically conductive parts rather than on the AIMD case in the manner of forces due to transportation, handling, and patient physical activity;
- the power spectral density level and frequency of the accelerations associated with gradient-induced AIMD vibration extend higher in frequency than those encountered in traditional shipping and handling tests;
- the forces are acting upon a device implanted in a patient.

Three harms have been identified as potentially resulting from gradient-induced vibratory force hazards:

- a) harm from AIMD malfunction (12.3);
- b) patient discomfort (12.4);
- c) injury to tissue surrounding the implant (12.5).

Because of the unique nature of the forces produced by the interaction of MR gradient field-induced eddy currents and the MR static field, some amount of testing will need to be conducted in a suitable MR scanner or in a laboratory using test equipment capable of generating magnetic fields that simulate those produced by clinical scanners.

The gradient-induced eddy currents developing within the AIMD conductive enclosure and internal component surfaces depend on the magnitude and orientation of the pulsed gradient dB/dt , size, and shape of the conductive materials, and conductivity. The induced eddy current and associated AIMD magnetic moment are maximized when the incident dB/dt is perpendicular to AIMD conductive surface(s).

The force and torque exerted on the AIMD are proportional to the cross product of the transient AIMD-induced magnetic moment and the B_0 field and, therefore, maximized when the AIMD conductive surface(s) are oriented tangent to the B_0 field vector. The torque axis is defined by the cross-product right hand rule convention. Figure 9 illustrates the situation for a simple conductive disk.

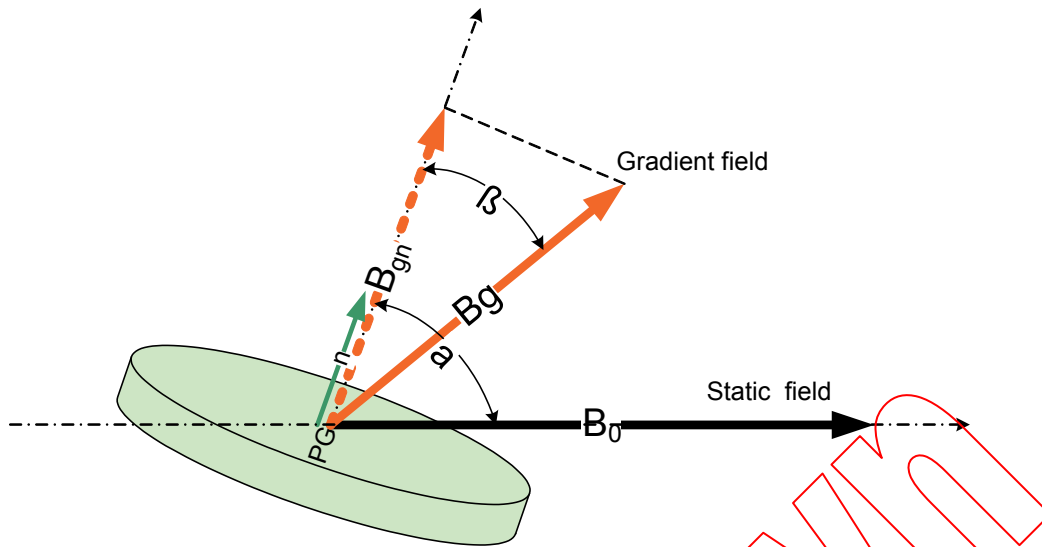


Figure 9 – Torque due to gradient-induced eddy current and static B_0 field

$$|Torque| = \frac{1}{8} \sigma \tau \pi R^4 B_0 \frac{dB_g}{dt} \sin(a) \cos(\beta)$$

where

R is the radius (m);

τ is the thickness (m);

σ is the conductivity (S/m);

β is the angle between the normal to conductive surface and the incident pulsed gradient field;

a is the angle between the eddy current-induced magnetic moment B_{gn} and the static B_0 field.

Evaluation of gradient-induced vibration involves exposing the AIMD device to the specified worst-case (maximum) gradient field dB/dt , static field B_0 , and orientation. Testing can be conducted using combinations of dB/dt and B_0 different from those the AIMD will be exposed to during clinical MR exams so long as the vector product is greater than or equal to the requirement. For example, an AIMD with conditional labelling limiting MR use to 1,5 T scanners could be tested using a 3,0 T scanner to show a design margin of approximately 2:1.

When using a higher B_0 field, the potential for increased AIMD damping should be considered. The effect increases with increased device vibration displacement and when the plane of the device becomes more perpendicular to the plane of B_0 .

12.2 General test considerations

12.2.1 Equipment

There are four general equipment types and test methods [see a), b), c) and d)] applicable to the testing required to evaluate the three potential harms associated with AIMD vibration.

Gradient vibration testing can be performed using a variety of test equipment. The test method will depend on the type of equipment used. Use of a suitable research MR scanner, or simulated static and gradient fields produced by laboratory equipment, that allows the gradient waveform to be input from a function generator will provide the greatest flexibility and ease of use for vibration testing. Alternatively, once properly characterized

and validated, the use of a shaker table may offer a number of advantages for gradient vibration AIMD functional testing. Shaker table testing is not useful for testing related to patient discomfort or tissue injury.

a) Research MR scanner.

The research MR scanner as defined here does not refer to a clinical scanner operated in research or second level controlled operating mode. In this Technical Specification, a research MR scanner refers to non-clinical MR equipment used for research purposes. Conducting vibration testing using research MR scanner equipment that produces a combination of gradient and static magnetic fields can offer advantages. Using static field strengths and/or a gradient field dB/dt greater than the maximum allowed by AIMD labelling can provide a gradient field dB/dt and B_0 vector product greater than or equal to the maximum clinically relevant exposure. Research MR scanner equipment may also offer greater flexibility in tailoring gradient pulse sequences for the specific purpose of vibration testing.

NOTE 1 This statement does not construe or imply any burden or obligation on the part of MR equipment manufacturers.

b) Simulated B_0 and gradient magnetic fields.

Laboratory test equipment capable of producing suitable combined magnetic fields that simulate MR static and gradient magnetic fields may be used for vibration testing. Using static field strengths and/or gradient field dB/dt greater than the maximum allowed by AIMD labelling can provide a gradient field dB/dt and B_0 vector product greater than or equal to the maximum clinically relevant exposure. This type of equipment may offer greater flexibility in tailoring gradient pulse sequences for the specific purpose of vibration testing.

c) Clinical scanner.

A clinical MR scanner may be used for vibration testing. When a clinical MR scanner is used, the vector product of gradient field dB/dt and B_0 that the AIMD is exposed to shall be greater than or equal to the worst-case exposure allowed by the AIMD MR Conditional label instructions.

NOTE 2 This statement does not construe or imply any burden or obligation on the part of MR equipment manufacturers.

d) Shaker table

A shaker table or other vibration testing apparatus may be used for AIMD functional testing only. Testing for patient discomfort and tissue injury shall be conducted using equipment types a) to c) listed above. Use of a shaker table or other vibration testing apparatus will require development and validation of equivalency to MR scanner gradient and static magnetic field exposure. AIMD MR vibration characterization using at least one of equipment types a) to c) above will also be needed to develop and validate the equivalence of the test conditions when a shaker table or other vibration testing apparatus is used for AIMD functional testing.

The equipment types and applicability are provided in Table 12 and Table 13.

Table 10 – Description of gradient vibration test equipment types

Test equipment type	Test equipment key characteristics
a) Research scanner	- Vector product of B_0 and gradient field dB/dt are in excess of expected maximum clinical exposure. - Gradient waveform can be input from function generator or software sequence programming suitable pulse sequence.
b) Simulated B_0 and gradient field	- Vector product of B_0 and gradient field dB/dt are in excess of expected maximum clinical exposure. - Gradient waveform can be input from function generator.
c) Clinical scanner	- Vector product of B_0 and gradient field dB/dt are greater than or equal to the expected maximum clinical exposure. - If a shaker table is to be used to simulate MR gradient vibration, a clinical scanner shall be used with an instrumented AIMD to characterize the vibration profile that shaker table testing needs to simulate.
d) Shaker table	- Force applied to case only. It does not simulate force inputs on other electrically conductive components. - Requires characterization of internal assembly and component vibration forces, modes, resonances, etc., using instrumented AIMD in either an MR scanner or simulated gradient and static magnetic fields. - Requires development and validation of vibration profile(s) that are greater than or equal to the worst-case profile for a clinical MR scanner.

Table 13 – Comparison of relative testing effectiveness by test equipment type

Evaluation	Equipment type			
	a) Research scanner	b) Simulated B_0 and gradient field	c) Clinical scanner	d) Shaker table
Patient discomfort	Acceptable	Acceptable	Superior	N/A
Tissue injury	Acceptable	Acceptable	Acceptable	N/A
AIMD function	Superior	Superior	Acceptable	Acceptable ^a
^a Acceptable, provided that the shaker table can produce the necessary accelerations at frequencies in the kHz range and it has been shown that the shaker table spectral profile produces AIMD internal accelerations greater than or equal to those produced <i>in vivo</i> during clinical scanning.				

Testing shall preferably be conducted by exposing the AIMD to magnetic fields equivalent to both the MR static magnetic field (B_0) and the slewing MR gradient magnetic field (dB/dt). The most practical means of generating these fields may be to use an MR scanner for gradient vibration testing.

NOTE 3 Gradient-induced eddy currents can only develop in conductive parts. Therefore gradient-induced vibratory forces will be applied selectively to conductive AIMD parts. The frequency and amplitude of induced vibrations are affected by the gradient field and its orientation and also by the mechanical characteristics of the conductive parts themselves (including their vibratory modes and resonant frequencies). This can result in stresses being applied in different locations and with different magnitudes than might be achieved with typical means of vibration testing, e.g. a linear shaker table. For example, consider an AIMD with a non-conductive housing containing a circuit board to which a highly conductive but low mass shield enclosure is attached at a few points. Gradient eddy current-induced mechanical forces on the circuit board

may be greater than forces resulting from accelerating from the AIMD housing on a shaker table. Such forces could tend to be concentrated at the points of attachment.

If a shaker table is used to test AIMD operation during exposure to MR gradient vibration, the AIMD manufacturer shall demonstrate that the accelerations of affected components and their interconnections are equal to or greater than those experienced when the AIMD is used in an MR scanner in accordance with the AIMD MR Conditional labelling restrictions. This will require measurements in a scanner or the use of simulated B_0 and gradient fields to determine a vibration profile for use in development of testing using a shaker table.

If testing is conducted in a scanner or using simulated fields in a laboratory, the AIMD shall be tested at a point in space where dB/dt is perpendicular or nearly perpendicular to B_0 and where both dB/dt and B_0 are known. The vector product of dB/dt and B_0 used to conduct the test shall be consistent with MR Conditional labelling. The AIMD shall be tested with the normal to its greatest conductive cross section parallel to dB/dt , and again with the normal aligned along each of the two other mutually perpendicular axes (see Figure 10).

12.2.2 Determination of clinical dB/dt and B_0 exposure limits

General gradient field dB/dt exposure requirements are provided in 20.3.1 to 20.3.3. Tier 1 or Tier 2 requirements are applicable for gradient field-induced AIMD vibration testing. For some types of AIMD, the worst-case condition of maximum vector product of dB/dt and B_0 with the greatest conductive surface(s) of the AIMD device orthogonal to the gradient field vector may not be clinically relevant. When this is the case, the AIMD manufacturer may use Tier 2 to provide a rationale for evaluating gradient-induced vibration using a reduced exposure to the vector product of dB/dt and B_0 . The AIMD manufacturer shall make a determination of clinically relevant maximum exposure conditions in terms of the vector product of dB/dt and B_0 .

12.2.3 Test signals

MR gradient-induced AIMD vibration shall be evaluated in terms of the maximum acceleration the AIMD would experience in MR scanners with gradient output set in accordance with MR Conditional labelling. Pulse sequence characteristics and the magnitude of dB/dt are both important parameters to be considered. As a minimum, gradient vibration should be tested and evaluated using gradient intense compatibility protocol information provided by MR equipment manufacturers (see IEC 60601-2-33, 201.7.9.3.101) or equivalent gradient intense compatibility protocols. The gradient sequence of sequences defined elsewhere in this Technical Specification may not be suitable for vibration testing.

12.3 Test method for the evaluation of AIMD functionality during exposure to gradient-induced vibration

12.3.1 General requirements

12.3.1.1 The vector product of gradient field dB/dt and B_0 used to conduct AIMD functional testing shall be at least equal to the maximum vector product the AIMD will be exposed to during clinical MR examinations when the MR Conditional labelling conditions of use are observed. Gradient field dB/dt magnitude shall be determined in accordance with 12.2.2. An additional safety factor of 100 % (test exposure vector product of static field and gradient field dB/dt ($B_0 \times dB/dt$) = 2x maximum clinical exposure) is recommended. The gradient field pulse sequences shall be equivalent to the protocols specified in 12.2.3.

12.3.1.2 The AIMD shall be tested with the gradient field dB/dt vector orthogonal to the plane of the AIMD's greatest conductive surface, and again with the normal aligned along each of the two other mutually perpendicular axes (see Figure 10).

12.3.1.3 The AIMD shall be exposed to gradient field dB/dt and B_0 for a minimum of 1 h for each of the three AIMD orientations.

12.3.1.4 A single axis search coil or equivalent sensor shall be used to monitor and record the component of gradient field dB/dt orthogonal to the plane of the AIMD's greatest conductive surface. The distance between the search coil or other sensor shall be no greater than one centimetre. The recorded waveform shall

have a sampling rate sufficient to capture the details of the dB/dt waveform and prevent aliasing of the signal. The recorded waveform shall have sufficient length to fully characterize the pulse sequence.

12.3.1.5 Device performance and behaviour shall be monitored during the test. Compliance shall be checked by examination of the manufacturer's records in accordance with the requirements in 9.1.

12.3.2 Conducting functional testing using a research scanner

The requirements specified in 12.3.1 apply.

12.3.3 Conducting functional testing using simulated fields

The requirements specified in 12.3.1 apply.

12.3.4 Conducting functional testing using a clinical scanner

The requirements specified in 12.3.1 apply.

When a clinical scanner is used for AIMD functional testing, it may be possible to exceed the required clinical exposure vector product of dB/dt and B_0 by using one or more of the following techniques.

- Conducting the test using the clinical worst-case dB/dt and B_0 greater than clinical worst case. For example, if the MR Conditional labelling restricts MR scanning to 1.5 T scanners, testing in a 3 T scanner using clinical worst-case dB/dt will give a test margin of approximately 100 %.
- Testing in a location that is not clinically relevant for the AIMD but produces a larger vector product of dB/dt and B_0 (and consequently larger vibration forces). For example, testing the AIMD at a location very close to the inner wall of the scanner bore in a region of very high dB/dt that the AIMD would not be exposed to clinically may provide a useful test margin.
- Testing using an AIMD orientation that is not clinically relevant but produces a larger vector product of dB/dt and B_0 (and consequently larger vibration forces). AIMD vibration will typically be at a maximum when dB/dt is orthogonal to the largest conductive AIMD surfaces. This orientation may not be clinically relevant for some AIMDs.

12.3.5 Conducting functional testing using a shaker table or other vibration test equipment

The process for development and validation of a suitable method and test regimen using a shaker table or other vibration test equipment capable of simulating vibration caused by MR gradient and static magnetic fields might be very difficult. The following steps should be taken.

- a) Use an instrumented AIMD to measure a relative velocity between the components, a relative acceleration between the components, a relative displacement between the components and accelerations at the AIMD case surface.
- b) Measure the magnitude of the MR vibration response of the AIMD to dB/dt at various frequencies. These measurements shall be made using one of the equipment types a) through c) defined in 12.2.1. It is not necessary to use the worst-case vector product of gradient field dB/dt and static field B_0 as the test environment. The vibration response can be measured during exposure to a different (i.e. less than the clinical worst case) vector product of gradient field dB/dt and static field B_0 . The measurement results can then be scaled to the required gradient dB/dt and B_0 vector product greater than or equal to clinically relevant exposure.
- c) Use the measured MR vibration response from item b) above to develop equipment, vibration profile(s), and methods for mechanically producing a vibration response that is greater than or equal to the measured MR vibration response at all measurement points. The same instrumentation listed in item a) above shall be used to measure the AIMD vibration response on the shaker table or other vibration test equipment.